DEPARTMENT OF CLINICAL INVESTIGATION

# ANNUAL RESEARCH PROGRESS REPORT

## FISCAL YEAR 1988
## VOLUME I

BROOKE ARMY MEDICAL CENTER FORT SAM HOUSTON, TEXAS 78234

SECURITY CLASSIFICATION OF THIS PAGE (When Data Entered)

ADA204221

| REPORT DOCUMENTATION PAGE | | READ INSTRUCTIONS BEFORE COMPLETING FORM |
|---|---|---|
| 1. REPORT NUMBER<br>RCS MED-300 | 2. GOVT ACCESSION NO. | 3. RECIPIENT'S CATALOG NUMBER |
| 4. TITLE (and Subtitle)<br>ANNUAL RESEARCH PROGRESS REPORT | | 5. TYPE OF REPORT & PERIOD COVERED<br>ANNUAL - FY 88<br>6. PERFORMING ORG. REPORT NUMBER |
| 7. AUTHOR(s)<br>RICKY D. LATHAM<br>Major, MC | | 8. CONTRACT OR GRANT NUMBER(s) |
| 9. PERFORMING ORGANIZATION NAME AND ADDRESS<br>Department of Clinical Investigation<br>Brooke Army Medical Center<br>Fort Sam Houston, TX 78234-6200 | | 10. PROGRAM ELEMENT, PROJECT, TASK AREA & WORK UNIT NUMBERS |
| 11. CONTROLLING OFFICE NAME AND ADDRESS<br>Commander<br>Brooke Army Medical Center<br>Fort Sam Houston, TX 78234-6200 | | 12. REPORT DATE<br>1 October 1988<br>13. NUMBER OF PAGES<br>594 |
| 14. MONITORING AGENCY NAME & ADDRESS(if different from Controlling Office)<br>Office of The Surgeon General<br>Department of the Army<br>Washington, D.C. 20314 | | 15. SECURITY CLASS. (of this report)<br>Unclassified<br>15a. DECLASSIFICATION/DOWNGRADING SCHEDULE |

16. DISTRIBUTION STATEMENT (of this Report)

APPROVED FOR PUBLIC RELEASE: DISTRIBUTION UNLIMITED

17. DISTRIBUTION STATEMENT (of the abstract entered in Block 20, if different from Report)

n/a

18. SUPPLEMENTARY NOTES

The findings in this report are not to be construed as an official Department of the Army position unless so designated by other authorized documents.

19. KEY WORDS (Continue on reverse side if necessary and identify by block number)

Clinical Investigations, all medical specialties
Publications, presentations
Detail Summary Sheets (Study Objective; Technical Approach; Progress; Status)

20. ABSTRACT (Continue on reverse side if necessary and identify by block number)

Subject report identifies the research activities conducted by Brooke Army Medical Center investigators through protocols approved by the Clinical Investigation Committee, the Institutional Review Board, and the Animal Care Committee and registered with the Department of Clinical Investigation during FY 1988. Report also includes known presentations and publications by the Brooke Army Medical Center staff. The research protocols described were

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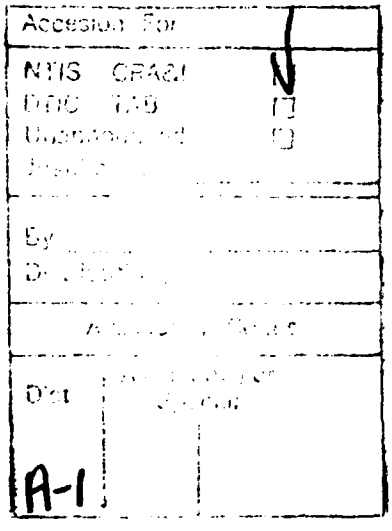
Block 20. Abstract

conducted under the provisions of AR 40-38, Clinical Investigation Program; AR 40-7, Use of Investigational Drugs in Humans; USAMRDC 70-25, Use of Volunteers as Subjects of Research; HSC Reg 40-23, Management of Clinical Investigation Protocols and Reports; and BAMC Memo 40-98, Department of Clinical Investigation, to insure the medical well-being, preservation of rights and dignity of human subjects who participated in these investigational studies. Research studies involving the use of laboratory animals were conducted under the provisions of AR 70-18, Laboratory Animals, Procurement, Transportation, Use, Care, and Public Affairs.



# FOREWORD

The Department of Clinical Investigation at Brooke Army Medical Center has completed another outstanding year. The number of protocols, as well as the general quality of work, has continued to improve year by year. This work could not be accomplished without the continued superior expertise and support of the assigned personnel, both technical and administrative.

The significant effort of our department in the past year, as the previous, has been the integration of our resources and efforts into the Joint Military Medical Command, San Antonio. Having reviewed the protocol approval process from both institutions, we have successfully negotiated to maintain the traditional approval process here at BAMC which is both efficient and timely. This approach provides the most expeditious mechanism for the investigator to initiate his protocol with the protocol approval authority resting with the Commander, Brooke Army Medical Center, and with administrative oversight resting with Health Services Command. We have made some internal changes, however, in this approval process, borrowing a concept from the Air Force. We have instituted a joint meeting of the IRB and the Clinical Investigation Committee under the designation of an Institutional Review Committee. The result is that an investigator only has to present before one committee to explain and defend his protocol. This not only expedites protocol approval but minimizes the time away from patient care activities which a physician must manage in order to present his research proposal. We have also instituted within each department peer review panels to work with individual investigators in helping them to prepare their protocols not only for scientific merit but also for proper format. This mechanism is also more conducive to an instructional basis for the development and preparation of a research proposal.

This academic year we have instituted a department Core Curriculum Lecture Series to provide seminars on research related topics covering a broad range of subjects necessary to understanding and conducting clinical research. We have chosen topics which may not be covered in a standard medical specialty GME program. It was also our desire to provide exposure of the hospital staff to established and recognized authorities in various areas of biomedical research to learn from the perspectives which can be shared by these experts.

We continue to increase our graphics illustration support and our slide production capabilities have become one of the more popular resource activities converged upon by staff and housestaff.

We welcome the addition of LTC Bob Whiddon, Microbiologist, to our staff who is providing significant new direction and support to the bone marrow rescue program, as well as initiating a number of clinical and basic microbiology protocols. Additionally, Dr. John Ward, a cardiovascular physiologist from Incarnate Word University, joined the DCI staff of investigators. Dr. Ward not only brings his expertise in physiology to the department but also has

significant experience as a software engineer. Drs. Whiddon and Ward have already become valuable assets to the department and have become vitally integrated in a number of clinical protocols with various departments. Wforward to their continued outstanding contributions, along with the other established DCI staff.

The Commander's Award continues to be an incentive to young investigators. The winners this year were: 1st Place - MAJ Gregg T. Anders and MAJ James E. Johnson, Department of Medicine - "Exercise Dysfunction in Patients Seropositive for the Human Immunodeficiency Virus; 2nd Place - MAJ Robert G. Knight, Department of Surgery - "Hemodynamic Effects of Anesthetic Induction with Ketamine or Etomidate in Swine; and 3rd Place - MAJ Christopher Barrilleaux, Department of Medicine - "Influence of Campylobacter pylori Associated Nonulcer Gastritis on Solid-Phase Gastric Emptying."

Other BAMC investigators receiving national awards were: MAJ Carey D. Chisholm, Department of Emergency Medicine, CPC Competition, awarded "Best Discussant," Southern Medical Society; MAJ Howard S. Heiman, Department of Pediatrics, Ogden Braton Award for his presentation, "Maternal Antibody to Group B Streptococcus Type III Protects Suckling Rats from Hematogenous and Enteral GBS Infection;" CPT David K. Hayes, Deptmarnt of Surgery, First Place Resident Paper Competition, "Viability of Skin Flaps Subjected to Chemical Peel;" and CPT Howard Burris, Department of Medicine, John L. Carpenter Outstanding Resident Paper, "Variation in Erythrocyte Sedimentation Rate (ESR) in End-Stage Renal Disease (ESRD) and Chronic Renal Failure (CRF)."

The clouds on the horizon with regard to budgetary and personnel constraints requiring some "belt-tightening" have certainly become a reality. A critical shortage of professional and support personnel exists for all departments at BAMC and the Department of Clinical Investigation is no exception. I believe that some innovative and creative measures will need to be or pursued to continue bolstering the research machine at Brooke Army Medical Center. We are strongly supporting a search for extramural funds and are beginning to have some success in this area. We will seek to help investigators to apply to federal funding agencies and/or military granting institutions in an effort to provide extramural monetary support to continue research required by some large scaled projects. The doors are beginning to open to us via the U.S. Army Medical Research and Development Command as well as the Henry M. Jackson Foundation.

I wish to congratulate all the members of this department who have provided excellent service over the past year as well as the professional staff of BAMC who have worked long and hard on their research ideas and clinical projects. I am looking forward to 1989 being an even more successful year as BAMC assumes even more of a leading role as a research institute of excellence in the San Antonio biotech community and the Army military medical community as well.

RICKY D. LATHAM
Major, MC
Chief, Dept of Clinical Investigation

## UNIT SUMMARY - FISCAL YEAR 1988

### A. Objectives

The objectives of the Department of Clinical Investigation are as follows:

1. To achieve continuous improvement in the quality of patient care.

2. To assist in the professional growth and development of the house staff by providing guidance and support in clinical research.

3. To provide a milieu conducive to retention of competent staff personnel and recruitment of new personnel.

4. To provide a review body for research proposals by investigators currently assigned to MEDDAC Units in an effort to promote an interest in Army medicine and retention in the Army Medical Corps.

5. To maintain an atmosphere of inquiry consistent with the dynamic nature of the health sciences.

6. To maintain a high professional standard and accreditation of advanced health programs.

7. To assure the highest level of professional standards in the conduct of human research and animal research.

### B. Technical Approach

All research, investigational and training activities within the Department of Clinical Investigation are conducted under the guidance of AR 40-7, AR 40-38, AR 70-25, AR 70-18, and HSC Reg 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with the applicable regulations.

### C. Staffing

| Name | Rank | MOS | Title |
|---|---|---|---|
| Goldner, Fred H.** | COL | 60G | Chief, Gastroenterologist |
| Latham, Ricky D.* | MAJ | 61F | Chief, Cardiologist |
| Peace, Theopolis | COL | 64B | Veterinary Lab Animal Officer |
| Whiddon, Robert G., Jr.* | LTC | 68A | Microbiologist |
| Danley, David L. | MAJ | 68E | Immunologist |
| Gelston, Hugh M., Jr.** | MAJ | 68A | Microbiologist |
| Diaz, Noel | SSG | 92B2 | NCOIC |
| Hinds, Johnny W. | SSG | 92B2 | Med Lab Specialist |
| Jones, Sheila | SSG | 92B2 | Med Lab Specialist |

* Assigned 1 May 88; 7 Jul 88
** Reassigned 1 May 87; 19 Jul 88

C. Staffing (continued)

| Name | Rank | MOS | Title |
|---|---|---|---|
| Jalaluddin, Muhammed* | SSG | 92B2 | Med Lab Specialist |
| Elysee, Victor* | SGT | 92B2 | Med Lab Specialist |
| Gaines, Marlene | SGT | 91T | Animal Care Specialist |
| Park, Chung* | SP4 | 91T | Animal Care Specialist |
| Merrill, Gerald A. | GS11 | 00401 | Research Immunologist |
| Avala, Eleanor | GS11 | 00644 | Medical Technologist |
| Grassel, Janice | GS11 | 00404 | Biological Laboratory Technician |
| Posch, John*** | GS11 | 00644 | Medical Technologist |
| Arrington, Mary* | GS10 | 00610 | Research Nurse |
| Reeb, Barbara | GS9 | 00644 | Medical Technologist |
| Chapa, Isidoro | GS7 | 00645 | Medical Technician |
| Rios, Roberto | GS9 | 01020 | Medical Scientific Illustrator |
| Bratten, Dodie | GS9 | 00301 | Clin Research Protocol Coord |
| Smith, Helen J. | GS6 | 01087 | Editorial Assistant |

* Assigned 6 May 88; 8 Feb 88; 1 Oct 87; 28 Sep 87
** Reassigned 17 Dec 86, 19 Sep 86
*** Resigned 30 Jul 88

D. Funding

| Type | Fiscal Year 87 | Fiscal Year 88 |
|---|---|---|
| Civilian personnel to include benefits | 439,225.00 | Not available |
| Consumable supplies | 121,000.00 | 111,415.00 |
| Civilian contracts to include consultants | 50,124.00 | 10,200.00 |
| TDY | 2,865.00 | 2,690.00 |
| Publications | 13,653.00 | 13,392.00 |
| Noninvestment equipment (Minor MEDCASE) | -------- | -------- |
| Other OMA | | |
| OMA Total | 645,252.00 | 137,697.00 |
| MEDCASE | 63,815.70 | 172,600.00 |
| Other | | |
| Military | 546,511.00 | Not available |
| TOTAL | 1,255,578.70 | 310,297.00 |

## Protocol Disposition FY 88

| | Terminated | Transferred | Completed | Ongoing to FY 89 |
|---|---|---|---|---|
| FY 77 | - | | 0 | 1 |
| FY 78 | 0 | | 0 | 1 |
| FY 82 | 0 | | 0 | 1* |
| FY 83 | 0 | | 0 | 2 |
| FY 84 | 3 | | 1 | 3 |
| FY 85 | 4 | | 4 | 4 |
| FY 86 | 11 | | 21 | 16 |
| FY 87 | 12 | | 29 | 46* |
| FY 88 | 4 | | 15 | 81 |
| | 34 | | 71 | 155 |

*Protocol C-13-82 inadvertently reported as closed.
*87 protocols were ongoing to FY 88 instead of 88.

## Training Protocols

| | Terminated | Completed | Ongoing to FY 88 |
|---|---|---|---|
| FY 82 | | | 2 |
| FY 85 | | | 1 |
| FY 86 | 0 | 0 | 9 |
| FY 87 | 0 | 0 | 7 |
| FY 88 | 0 | 0 | 1 |
| | 0 | 0 | 20 |

## Group Protocol Disposition FY 87*

| | Terminated | Completed | Ongoing to FY 88 |
|---|---|---|---|
| SWOG | 0 | 26 | 82 |
| GOG | 28 | 0 | 0* |
| POG | 0 | 8 | 43 |
| | 2 | 47 | 125 |

*GOG 85 ongoing as SWOG 8695

The decrease in number of protocols can be explained as follows:

a. Decrease in number of POG protocols and in animal and training protocols.

b. Inactivation of GOG.

TABLE OF CONTENTS

Code: C - Completed P - Published

O - Ongoing PR - Presentation

T - Terminated

DEPARTMENT OF THE ARMY
Brooke Army Medical Center
Fort Sam Houston, Texas 78234-6200
DEPARTMENT OF CLINICAL INVESTIGATION

# PUBLICATIONS

## DEPARTMENT OF CLINICAL INVESTIGATION

Gunn, B.A., Davis, C.E. Staphylococcus haemolyticus urinary tract infection. J. Clin. Microbiol., 26(5):1055-1057, May 1988. (C)

Merrill, G.A., Horowitz, P., Bauman, S., et al. Detection of time dependent and oxidatively induced antigens of bovine liver rhodanese with monoclonal antibodies. J. Biol. Chem., (in press). (C)

Merrill, G.A., et al. The effect of streptococcus pneumoniae infection on the binding of insulin to plasma membranes isolated from rat liver. J. Clin. Invest., (in press). (C)

Latham, R.D., et a. Ventricular/vascular coupling and regional arterial dynamics. Circulation, (in press). (C)

Latham, R.D., Rubal, B.J., Westerhof, N., Sipkema, P. Aortic input impedance during the Mueller maneuver. J. Appl. Physiol., (in press). (C)

Wiswell, T.E., Gelston, H.M., Jones, S., et al. Effect of circumcision status on periurethral bacterial flora during the first year of life. J. Pediat., 113:442-446, Sep 88. (C)

## Department of Emergency Medicine

Coleridge, S.T. Rural medicine. The D.O., 28:10, Oct 87.

Larsen, M.A. MeSH. REM, 2:#5, Nov 87.

Morgan, J. Scalp laceration repair without prior hair removal. Am. J. Emerg. Med., 6(1):7-10, Jan 88. (C)

Coleridge, S.T., York, R.C. Cardiopulmonary arrest following intravenous phenytoin loading. Am. J. Emerg. Med., 6(3):225-259, May 88.

Berman, D., Norris, R. Inhaled bronchodilators in the young pediatric asthmatic: A method of delivery. Am. J. Emerg. Med., 6(6):206, May 88.

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Wagner, M.L. Gonorrhea. In "The Clinical Practice of Emergency Medicine." Harwood-Nuss, A.L. (Ed.). Philadelphia, J.B. Lippincott Co., (in press).

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## Department of Medicine

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Cushner, H.M., Mulrow, J.P., Copley, J.B., et al. Atrial natriuretic peptide response to physiologic maneuvers in cardiac transplant patients. Kidney Int., 33:259, 1988. (C)

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Kroenke, K., Wood, D.R., Mangelsdorff, A.D., et al. Chronic fatigue in primary care. J.A.M.A., 1988. (C)

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Gastroenterology Service

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Mego, D., Omori, D., Hanley, J. Transdermal scopolamine as a cause of transient psychosis in two elderly patients. So. Med. J., 81(3):394-395, Mar 88.

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Hematology Oncology Service

Brown, T.D., et al. Phase II trial of Bisantrene in hepatocellular carcinoma: A Southwest Oncology Group study. Cancer Treat. Rep., 71:1101-1102, Nov 87. (C)

Lillis, P.K., Brown, T.D., et al. Phase II trial of recombinant Beta Interferon in advanced colorectal cancer. Cancer Treat. Rep., 71:965-967, Oct 87. (C)

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O'Rourke, T.J., Brown, T.D., Friess, G., Beougher, K.L. A phase I clinical trial of combination Alpha-2 Interferon (AIFN) in advanced cancer. Proceed. A.S.C.O., Vol 7, #656, Mar 88. (C)

Harvey W. Triple lumen catheters (TLC) in autologous bone marrow transplant (ABMT) patients. Proceed. A.S.C.O., Vol 7, #182, Mar 88. (C)

Levey, T.L. Angioimmunoblastic lymphadenopahty: Comprehensive review. Cancer Invest., 5(6):633-647, 1987.

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Nephrology Service

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Pulmonary Disease Service

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## Department of Pathology and Area Laboratory Services

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## Department of Pediatrics

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## Department of Surgery

### Anesthesia and Operative Service

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Orthopaedic Surgery Service

Silver, S.M. Tank turret injuries. Milit. Med., Nov 87.

Otolaryngology Service

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Urology Service

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Thompson, I.M., Peek, M. Improvement in survival of patients with renal cell carcinoma - the role of the serendipitously detected tumor. J. Urol., 140:487-490, Sep 88.

Thompson, I.M. Changing incidence of carcinoma of the prostate associated with annual urologic screening. So. Med. J., (in press). (C)

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Truwitt, C., Thompson, I.M. Idiopathic macroorchidism. J. Clin. Ultrasound, (in press).

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## Physical Medicine and Rehabilitation Service

Jansen, R.D. Perceived Competencies of Army Occupational Therapists in the Role of Upper Extremity Musculoskeletal Screeners. Mary Lipscomb Hamrick Research Pamphlet.

## Preventive Medicine Service

Longfield, R.N., Hawkes, C., Longfield, J.N., et al. The prospective evaluation of asymptomatic patients seropositive for the human immunodeficiency virus. Clin. Resch, 36(1):21A, Jan 88.

## Nutritional Care Division

Saxton, L. Fat chance: hidden fats contain visible dangers. Newsleader HealthLine, 11 Mar 88.

Finley, M.C. Too much sgar may sour a diet. Newsleader HealthLine, 25 Mar 88.

Aguilar, A. Fast food low in fiber, high in calories. Newsleader HealthLine, 25 Mar 88.

DEPARTMENT OF THE ARMY
Brooke Army Medical Center
Fort Sam Houston, Texas 78234-6200
DEPARTMENT OF CLINICAL INVESTIGATION

## PRESENTATIONS

### DEPARTMENT OF CLINICAL INVESTIGATION

Arrington, M.E. CVA Patient Falls: Intrinsic Risk Factors Profile. Second Annual Research Conference, University of Texas School of Nursing, San Antonio, TX, 22 Sep 88. (C)

Danley, D.L. Development of a Clinical Investigation Program in Support of the Joint Military Medical Program, San Antonio. The Society of Armed Forces Medical Laboratory Scientists, Reno, NV, 19-24 Mar 88.

Danley, D.L. Development of a Clinical Investigation Program in Support of the Joint Military Medical Command, San Antonio. Second annual Clinical Investigation Program Workshop, Keesler AFB, Miss., 16-18 Mar 88.

Goldner, F.H. Clinical Investigation Program at BAMC. MRDC Commander's Conference, Fort Detrick, MD, 8-9 Feb 88.

Latham, R.D. The Laboratory of Aerospace Cardiopulmonary Research. Military Medical Pulmonary Research Review and Analysis, Fitzsimons Army Medical Center, Aurora, CO, 21 Sep 88. (C)

Merrill, G.A. An Immunological Study of Thodanese Conformation. Department of Biochemistry Faculty Research Seminar, University of Texas Health Science Center, San Antonio, TX, Oct 87. (C)

Wiswell, T.E., Gelston, H.M., Jones, S.K., et al. Prepuce Presence Portends Persistence of Potentially Perilous Periurethral Pathogens. Nov 87. (C)

### DEPARTMENT OF EMERGENCY MEDICINE

Chisholm, C.D. CPC Competition (Awarded "Best Discussant"). Southern Medical Society, Emergency Medicine Section, San Francisco, CA, 1 Nov 87.

Chisholm, C.D. CO Poisoning and MAST. Darnall Army Community Hospital, Fort Hood, TX, 9 Oct 87.

Norris, R.L. Venomous Snakebite. Brady/Green Community Health Center, San Antonio, TX, 10 Oct 87. (C)

Norris, R.L. Field Management of Venomous Snakebite. Trinity University, San Antonio, TX, 24 Oct 87. (C)

Coleridge, S.T. Emergency Medicine Board Preparation Course Examiner. American College of Emergency Physicians, Dallas, TX, Jan 88.

Coleridge, S.T. Moderator: Admiral Eske Research Seminar. 6th National Conference, AMOPS, Kissimmee, FL, Mar 88.

Berman, D. Computerized Algorithm Directed Triage in the Emergency Department. 6th National Conference, AMOPS, Kissimmee, FL, Mar 88

Chisholm, C.D. Toxicology Ground Rounds. University of Pittsburg, Pittsburg, PA, [illegible] 88.

Norris, R.L. Instructor in Emergency Medicine Oral Board Preparation Course. Texas Chapter, American College Emergency Physicians, Dallas, TX, Jan 88.

Norris, R.L. First Aid for Venomous Snakebite. Security Police, Brooks AFB, San Antonio, TX, Mar 88. (C)

Norris, R.L. First Aid for Venomous Snakebite. Security Police, Brooks AFB, San Antonio, TX, Mar 88. (C)

Cowesky, B. Pneumatic Antishock Garment. Wright Patterson AFB, Dayton, OH, Jan 88. (C)

Coleridge, S.T. Moderator Abstract Session. 8th Annual Tri-Service Symposium in Emergency Medicine (EM), San Antonio, TX, Apr 88.

Coleridge, S.T. Emergency Department Triage. 8th Annual Tri-Service Symposium in EM, San Antonio, TX, Apr 88.

Berman, D. Poison Control Centers: How Do They Interact with the Emergency Department. 8th Annual Tri-Service Symposium in EM, San Antonio, TX, 6 Apr 88.

Chisholm, C.D. Program Director of Government Services Chapter of ACEP. Tri-Service Symposium in EM, San Antonio, TX, Apr 88.

Chisholm, C.D. Oral Board Preparation Course Faculty. Tri-Service Symposium in EM, San Antonio, TX, Apr 88.

Cowesky, B. Effects of PASG on Systemic pH and Lactic Acidosis. Association of Emergen Physicians, Cincinnati, OH, May 88. (C)

Chisholm, C.D. The Training of the EMS Physician; Consensus Paper. National Assocation of EMS Physicians, Washington, D.C., Jun 88.

Chisholm, C.D. The Prehospital Management of Multiple Casualties. Texas Tech University EMS Update/South Plains EMS, Lubbock, TX, Sep 88.

Chisholm, C.D. Hazardous Materials - Prehospital Management. Texas Tech University EMS Update/South Plains EMS, Lubbock, TX, Sep 88.

Chisholm, C.D. Panel Discussion: Disaster Management - A Multiacquisitional Approach. Texas Tech University EMS Update/South Plains EMS, Lubbock TX, Sep 88.

Chisholm, C.D. Carbon Monoxide Poisoning. Madigan Emergency Medicine Grand Rounds, Tacoma, WA, 4th Qtr, 88.

Chisholm, C.D. Narcotic Overdose. Madigan Emergency Medicine Grand Rounds, Tacoma, WA, 4th Qtr, 88.

Chisholm, C.D. Toxicology Case Studies. Madigan Emergency Medicine Grand Rounds, Tacoma, WA, 4th Qtr, 88.

Olinger, M.L. Botulism and Tetanus: Clostridial Neurotoxic Diseases. Darnall Army Community Hospital Grand Rounds, Fort Hood, TX, Sep 88.

## DEPARTMENT OF MEDICINE

### Office of the Chief

Copley, J.B. Evaluation of the Renal Mass. Department of Medicine Grand Rounds, Madigan Army Medical Center, Tacoma, WA, Jan 88.

Copley, J.B. Prevention of Postoperative Peritoneal Dialysis Catheter-Related Infections. 8th National Symposium CAPD, Kansas City, MO, Feb 88.

Copley, J.B. Calcium Citrate: A Nonaluminum Containing Phosphate Binder for the Treatment of CRF. 7th Annual S.T.A.R.T. Meeting, Austin, TX, Mar 88. (C)

### Cardiology Service

Pasipoularides, A. Are Ejection Phase Doppler/Echo Indices Sensitive Markers of Contractile Dysfunction in Cardiomyopathy? Role of Afterload Mismatch. 60th Annual Scientific Sessions, American Heart Association, Anaheim, CA, Nov 87. (C)

Stoughton, T.L. Relationship of Peak Instantaneous, Peak-to-Peak and Mean Pressure Gradients in Aortic Stenosis. ACP Regional Army Meeting, San Francisco, CA, Oct 87. (C)

Stoughton, T.L. Relationship of Peak Instantaneous, Peak-to-Peak and Mean Pressure Gradients in Aortic Stenosis. 60th Annual Scientific Sessions, American Heart Association, Anaheim, CA, Nov 87. (C)

Stoughton, T.L. Hemodynamic Validationof Proposed Noninvasive Indices of Aortic Stenosis. Poster Session. 60th Annual Scientific Sessions, American Heart Association, Anaheim, CA, Nov 87. (C)

Latham, R.D. New Onset Idiopathic Dilated Cardiomyopathy: Incidence of Myocarditis and the Efficacy of Prednisone Therapy. ACP Regional Army Meeting, San Francisco, CA, Oct 87. (C)

Latham, R.D. Systemic Arterial Compliance at Rest and Exercise in Normal Man. ACP Regional Army Meeting, San Francisco, CA, Oct 87. (C)

Bailey, S.R. Angiographic Predictors of Success in PTCA of Coronary Artery Bypass Grafts. ACP Regional Army Meeting, San Francisco, CA, Oct 87.

Johns, J.P. Pre-Systolic Flow in the LVOT by Doppler, ACP Regional Army Meeting, San Francisco, CA, Oct 87. (C)

Kono, A. Mannitol Prophylaxis Against Acute Renal Failure Following Coronary Angiography in High Risk Patients. Society of Air Force Physicians Annual Meeting, San Antonio, TX, Mar 88. (C)

Johns J.P. Transient Pressure-Flow Correlates of Isovolumic Contraction: Simultaneous Doppler-Micromanometry in Man. Society of Air Force Physicians Annual Meeting, San Antonio, TX, Mar 88. (C)

Latham, R.D. Incidence of Myocarditis and Efficacy of Therapy in New Onset Idiopathic Dilated Cardiomyopathy. Society of Air Force Physicians Annual Meeting, San Antonio, TX, Mar 88. (C)

Whitney, E.J. Combination Drug Therapy for Hypercholesterolemia. Society of Air Force Physicians Annual Meeting, San Antonio, TX, Mar 88. (C)

Bailey, S.R. Systolic Dynamics and Afterload Mismatch in Dilated Cardiomyopathy. Society of Air Force Physicians Annual Meeting, San Antonio, TX, Mar 88. (C)

Cawthon, M.A., Latham, R.D. Myocardial gallium uptake correlation with endomyocardial biopsy in patients with dilated cardiomyopathy. Southwestern Chapter, Society of Nuclear Medicine, Mar 88. (C)

Rogan, K. Predictors of Cardiac Death in Patients with Coronary Artery Anomalies. American College of Cardiology, Atlanta, GA, 27-31 Mar 88.

Latham, R.D. Ventricular/Vascular Coupling Dynamics in a Chronically Hypertensive Baboon Model. American College of Cardiology, Atlanta, GA, 27-31 Mar 88. (C)

Latham, R.D. Regional Arterial Compliance in vivo in Man and Nonhuman Primates. American College of Cardiology, Atlanta, GA, 27-31 Mar 88. (C)

Slife, D. Model Estimation of Pulmonary Compliance. Pulmonary Research Review and Analysis. Fitzsimons Army Medical Center, Aurora, CO, 20 Sep 88. (C)

Dermatology Service

Salasche, S. Delayed Application of Tie-Over Dressing in Full Thickness Skin Grafts. Annual Scientific Session of the American College of Mohs Micrographic Surgery and Cutaneous Oncology, Monterey, CA, Apr 88.

Salasche, S. Interpreting Mohs Frozen Sections: Mohs Surgeons vs. Pathologists. Annual Scientific Session of the American College of Mohs Micrographic Surgery and Cutaneous Oncology, Monterey, CA, Apr 88.

Salasche, S. Training a Surgical Assistant. Annual Clinical and Scientific Meeting of the American Society for Dermatologic Surgery, Monterey, CA, Apr 88.

Salasche, S. Visualized Basting Sutures in the Application of Full-Thickness Skin Grafts. Annual Clinical and Scientific Meeting of the American Society for Dermatologic Surgery, Monterey, CA, Apr 88.

Radentz, W. Opportunistic Phaeohyphomycotic Infection in an Immunocompromised Host. Texas Society of Dermatology Spring Meeting, May 88.

Lewis, C.W. Chairman, Clinical Session on Dermatology. Texas Medical Association Meeting, San Antonio, TX, 14 May 88.

Lewis, C.W. Program Chairman, Annual Uniformed Services Dermatology Seminar. San Antonio, TX, 1-6 May 88.

Salasche, S.J. Anatomy and Surgery of the Nail. Supericial Anatomy and Cutaneous Surgery Course, San Diego, CA, 15 Jul 88.

Salasche, S.J. Biology of Basal Cell Carcinoma. Johns Hopkins Medical Institute, Baltimore, MD, 25 Aug 88.

Salasche, S.J. Second Intention Wound Healing. 9th International Congress of Dermatologic Surgery, Edinburgh, Scotland, 27 Sep 88.

Salasche, S.J. Reconstruction of the Nose. 9th International Congress of Dermatologic Surgery, Edinburgh, Scotland, 27 Sep 88.

Endocrinology Service

Thomason, A.M. Evaluation of a High Sensitivity Thyrotropin Assay. 4th Annual Army Regional American College of Physicians Meeting, San Francisco, CA, 23 Oct 87.

Gastroenterology Service

Angueira, C. The Tilt Test: The Effect of Diabetes Mellitus and Antihypertensive Medication on Normal Values. 16th Annual William Beaumont Gastroenterology Symposium, San Francisco, CA, 23-26 Oct 87. (C)

Peluso, F.E. Follow-up of Hot Biopsy Forceps Treatment of Diminutive Colon Polyps. 16th Annual William Beaumont Gastroenterology Symposium, San Francisco, CA, 23-26 Oct 87. (C)

Miller, R. Effect of Hyperbaric Oxygen on Acetaminophen Induced Hepatotoxicity in Mice. 16 Annual William Beaumont Gastroenterology Symposium, San Francisco, CA, 23-26 Oct 87. (C)

Peluso, F.E. Follow-up of Hot Biopsy Forceps Treatment of Diminutive Colon Polyps. Society of Air Force Physicians, San Antonio, TX, Feb 88. (C)

Peluso, F.E. Follow-up of Hot Biopsy Forceps Treatment of Diminutive Colon Polyps. American Gastroenterology Association Meeting, New Orleans, LA, May 88. (C)

General Medicine Service

Simmons, J. Blood Pressure and the Rolled-up Army Sleeve. Army ACP Meeting, San Francisco, CA, Oct 87. (C)

Omori, D. Do Decongestants Raise Blood Pressure. Army ACP Meeting, San Francisco, CA, Oct 87.

Simmons, J. Attending Rounds. Army ACP Meeting, San Francisco, CA, Oct 87.

Omori, D. Does Phenylpropanolamine Affect Blood Pressure in Mildly Hypertensive Patients? Southern Region Meeting at the SGIM Meeting, New Orleans, LA, Feb 88. (C)

Omori, D. Does Phenylpropanolamine Affect Blood Pressure in Mildly Hypertensive Patients? Air Force Physicians Annual Meeting, San Antonio, TX, Mar 88. (C)

Simmons, J. Blood Pressure and the Rolled-up Armsleeve. Southern Region Meeting at the SGIM Meeting, New Orleans, New Orleans, LA, Feb 88. (C)

Simmons, J. Blood Pressure and the Rolled-up Armsleeve. National SGIM Meeting, Crystal City, VA, Apr 88. (C)

Omori, D. Does Phenylpropanolamine Affect Blood Pressure in Mildly Hypertensive Patients: National SGIM Meeting, Crystal City, VA, Apr 88. (C)

Simmons, J., Kroenke, K., O'Connell, M. Workshop: Attending Rounds. National SGIM Meeting, Crystal City, VA, Apr 88.

Infectious Disease

Longfield, R.N. The Prospective Evaluation of Asymptomatic Patients Seropositive for the Human Immunodeficiency Virus. American Federation for Clinical Research, New Orleans, LA, 3-5 Feb 88. (C)

Nephrology Service

Tapp, D.C. The Effect of Caloric Restriction on the Progression of Chronic Renal Failure. Present Concepts in Internal Medicine, Army Regional ACP Meeting, San Francisco, CA, 23 Oct 87.

Salmond, R.C. The Effects of 5/6 Renal Ablation on Tubuloglomerular Feedback Activity. Present Concepts in Internal Medicine, Army Regional ACP Meeting, San Francisco, CA, 23 Oct 87.

Travis, P. Mechanisms of Hypercalcemia in Patients with Malignancy. Present Concepts in Internal Medicine, Army Regional ACP Meeting, San Francisco, CA, 23 Oct 87.

Lindberg, J.S. Use of Lysine Vasopressin in the Treatment of Refractory Hemodialysis Associated Hypotension. Present Concepts in Internal Medicine, Army Regional ACP Meeting, San Francisco, CA, 23 Oct 87. (C)

Salmond, R. Tubuloglomerular Feedback in Diabetic Rats. American Society of Nephrology, Washington, DC, Dec 87.

Tapp, D.C. Calorie Restriction Retards the Progression of Chronic Renal Failure in Rats. American Society of Nephrology, Washington, DC, Dec 87.

Lindberg, J.S. et al. Lysine Vasopressin in the Treatment of Refractory Hemodialysis Induced Hypotension. American Society of Nephrology, Washington, DC, Dec 87. (C)

Wortham, W.G. The Utility of a Human Immunodeficiency Virus Staging System in ESRD Patients. American Society of Nephrology, Washington, DC, Dec 87. (C)

Cushner, H. Atrial Natriuretic Peptide Response to Physiologic Maneuvers in Cardiac Transplant Patients. American Society of Nephrology, Washington, DC, Dec 87. (C)

Copley, J.B. Calcium Citrate, A Non-Aluminum Containing $PO_4$ Binder in CRF. South Texas Association for Renal Therapy (START), Austin, TX, 26 Mar 88. (C)

Neurology Service

Halliday, A.W. Unusual White Matter Diseases. Neurology Grand Rounds, University of Texas Health Science Center, San Antonio, TX, 10 Mar 88.

Atkinson, S.W. Neurofibromatosis. Neurology Grand Rounds, University of Texas Health Science Center, San Antonio, TX, 26 May 88.

Pulmonary Disease Service

Crosland, W.A. Flow Cytometry in the Cytologic Analysis of Bronchial Washings in Lung Cancer. U.S. Army Regional American College of Physicians Meeting, San Francisco, CA, 22-25 Oct 87. (C)

Anders, G.T. Transbronchial Biopsy without Fluoroscopy: A Seven Year Perspective. U.S. Army Regional American College of Physicians Meeting, San Francisco, CA, 22-25 Oct 87. (C)

Anders, G.T. Nd-YAG Laser Endobronchial Photoresection and Endobronchial Brachytherapy: The BAMC Experience. U.S. Army Regional American College of Physicians Meeting, San Francisco, CA, 22-25 Oct 87.

Johnson, J.E. Improvement in Pulmonary Function Patients with COPD During a Comprehensive Pulmonary Rehabilitation Program. U.S. Army Regional American College of Physicians Meeting, San Francisco, CA, 22-25 Oct 87. (C)

Anders, G.T. Exercise Testing in Patients with Dyspnea and Normal Spirometry. Southern Medical Association, San Antonio, TX, 1 Nov 87.

Anders, G.T. Nd-YAG Laser Endobronchial Photoresection and Endobronchial Brachytherapy: The BAMC Experience. San Antonio Lung Club, San Antonio, TX, 4 Nov 87.

Anders, G.T. Nd-YAG Laser Endobronchial Photoresection and Endobronchial Brachy-Btherapy: The BAMC Experience. Society of Air Force Physicians/Air Force Regional Meeting of the American College of Physicians, San Antonio, TX, 29 Feb 88.

Anders, G.T. Nd-YAG Laser Endobronchial Photoresection and Endobronchial Brachytherapy: The BAMC Experience. Association of Military Osteopathic Physicians and Surgeons, Orlando, FL, 30 Mar 88.

Anders, G.T. Exercise Dysfunction in HIV-Infected Patients. Annual Meeting of the American Thoracic Society, Las Vegas, NV, 11 May 88. (C)

Johnson, J.E. Bronchoalveolar Lavage Findings in Patients Seropositive for Human Immunodeficiency Virus (HIV). Annual Meeting of the American Thoracic Society, Las Vegas, NV, 11 May 88. (C)

Blanton, H.M. Diagnostic and Therapeutic Consideations in Patients with Atypical Mycobacteria. 1988 Statewide Physician Conference on Tuberculosis. Austin, TX, 9-10 Jun 88.

Rheumatology Service

Melton, G.B. Takayasu's Arteritis and Coronary Disease. Army Regional American College of Physicians Meeting, San Francisco, CA, 26 Oct 87.

## DEPARTMENT OF NURSING

Anderson, F. Relationship of Total Blood Cholesterol to High Density Lipoprotein in Patients Undergoing Artery Bypass Graft. American Heart Association, Cardiovascular Research Seminar, San Antonio, TX, 20 Feb 88.

Wehner, R.J. Principles of Trauma Management: Management of the Traumatized Airway. AANA National Meeting, Seattle, WA, 15 Aug 88.

Yoder, L. Cancer Biology and Therapy. University of Texas Health Science Center School of Nursing, San Antonio, TX, 26 Sep 88.

Yoder, L. Role Components of the Clinical Nurse Specialist. Poster Session, University of Iowa Conference for Clinical Nurse Specialists, Amana, Iowa, 21 Sep 88.

## DEPARTMENT OF OBSTETRICS AND GYNECOLOGY

Burke, T.W. Screening for Gynecologic Cancer. Tumor Conference, University of Southern California, Los Angeles, CA, 87.

Burke, T.W. Treatment Failure in Endometrial Carcinoma. Gynecology Conference, Sloan-Kettering Cancer Center, New York, NY, 87.

Burke, T.W. Continuous Thoracic Epidural Analgesia for the Control of Pain Associated with Pleural Sclerosis. 26th Annual Meeting of the Armed Forces District of ACOG, Denver, CO, Oct 87.

Burke, T.W. Treatment Failure in Endometrial Carcinoma. 26t Annual Meeting of the Armed Forces District of ACOG, Denver, CO, Oct 87.

Burke, T.W. Radical Hysterectomy with Ovarian Conservation. 26th Annual Meeting of the Armed Forces District of ACOG, Denver, CO, Oct 87.

Burke, T.W. Retroperitoneal Nerve Sheath Tumors Presenting as a Pelvic Mass. Poster Presentation at the 26th Annual Meeting of the Armed Forces District of ACOG, Denver, CO, Oct 87.

Burke, T.W. Methotrexate Induced Erythema Multiforme. 26th Annual Meeting of the Armed Forces District of ACOG, Denver, CO, Oct 87.

Hayslip, C.C. Characteristics of Patients with Complications of Elective Termination of Pregnancy Procedures. Armed Forces District Meeting of ACOG, Denver, CO, Oct 87.

Hayslip, C.C. Perinatal Parameters in Women with Antithyroid Autoantibodies. Armed Forces District Meeting of ACOG, Denver, CO, Oct 87.

Hayslip, C.C. Correlation of Postpartum Serum Antithyroid Antibody Titers with Postpartum Thyroid Dysfunction. Armed Forces District Meeting of ACOG, Denver, CO, Oct 87.

Hayslip, C.C. Effect of Lactation on Bone Mineral Density in Healthy Postpartum Women. American College of OB-GYN, Boston, MA, May 88.

## DEPARTMENT OF PATHOLOGY

Beckius, M.L. Cutaneous Phaeohyphomycosis in a Heart Transplant Recipient Caused by a Pycnidial-Forming Fungus. American Society of Microbiologists Meeting, Miami Beach, FL, May 88.

Jackson, M.E. Body Cavity Fluids Cytology. Eighth Annual Cytopathology Refresher Course, Wilford Hall USAF Medical Center, San Antonio, TX, Apr 88.

Day, P.L. Aspiration Cytology of Prostate. Eighth Annual Cytopathology Refresher Course, Wilford Hall USAF Medical Center, San Antonio, TX, 15 Apr 88.

Berkland, M.E., et al. Interesting Case Presentations Review. San Antonio Society of Pathology, San Antonio, TX, 6 Sep 88.

Westermeier, T.G. Hematologic Malignancies and the Laboratory. National West Florida Laboratory Association, Pensacola, FL, 16 Sep 88.

Beckius, M.L. Phaeohyphomycotic cutaneous disease caused by Pleurophoma in a Cardiac Transplant Patient. American Society of Microbiology, Miami, FL, May 88.

## DEPARTMENT OF PEDIATRICS

Heiman, H.S. Maternal Antibody to Group B Streptococcus Type III Protects Suckling Rats from Hematogenous and Enteral GBS Infection. 23rd Annual Tri-Service Pediatric Seminar, San Diego, CA, Mar 88. (Recipient of Ogden Braton Award)

Juster, C. RSV Pleural Effusion. Pediatric Grand Rounds, University of Texas Health Science Center, San Antonio, TX, Mar 88.

Lee, T. Strokes in Children. Pediatric Grand Rounds, University of Texas Health Science Center, San Antonio, TX, Mar 88.

Tiwary, C. Neonatal Screening of Metatolic and Endocrine Diseases. 6th National Neonatal Screening Symposium, Portland, OR, May 88. (C)

Carter, J. High Frequency Oscillatory Ventilation (HFOV) and Extracorporeal Membrane Oxygenation (ECMO) in the Treatment of Term Infants Failing Conventional Ventilation. Society for Pediatric Research, Washington, DC, May 88.

Takao, R.T. Conversion Reactions in Adolescents. Department of Pediatrics Grand Rounds, Creighton University Medical Center, Omaha, NE, 7 Sep 88.

Takao, R.T. Housestaff Stress. Department of Pediatrics Grand Rounds, Creighton University Medical Center, Omaha, NE, 7 Sep 88.

## DEPARTMENT OF RADIOLOGY

Hartshorne, M.F. Radiation Accident Management. Decontamination Workshop, University of New Mexico, Albuquerque, NM, 2 Oct 87.

Hartshorne, M.F. Board Preparation Cases. Department of Radiology, Fitzsimons Army Medical Center, Aurora, CO, 2 Nov 87.

Hartshorne, M.F. Bone I. Nuclear Medicine Residents/Fellows, University of Texas Health Science Center, San Antonio, TX, 13 Nov 87.

Hartshorne, M.F. Bone II. Nuclear Medicine Residents/Fellows, University of Texas Health Science Center, San Antonio, TX, 20 Nov 87.

Hartshorne, M.F. Nuclear Hazards Trainign Course. University of New Mexico, Albuquerque, NM, 5 Jan 88.

Hartshorne, M.F. Tl-201 Basic Lecture. Public Health Service Hospital Staff, Albuquerque, NM, 17 Feb 88.

Hartshorne, M.F. Tl-201 Exercise Testing. American College of Nuclear Physicians Scientific Session, Scottsdale, AZ, 20 Feb 88.

Hartshorne, M.F. Tl-201 Exercise Testing. Physicians in Nuclear Fall Meeting. Scottsdale, AZ, Feb 88.

Hartshorne, M.F. Sensitivity of Ga-67 Chest SPECT. Southwestern Chapter Society of Nuclear Medicine, 33rd Annual Meeting, San Antonio, TX, 18 Mar 88.

Cawthon, M.A. Myocardial Gallium Uptake Correlation with Endomyocardial Biopsy in Patients with Dilated Cardiomyopathy. Southwester Chapter Society of Nuclear Medicine, 33rd Annual Meeting, San Antonio, TX, 19 Mar 88.

Truwit, C.L. Scintigraphy of the Charcot Foot: Infected or Not? Southwestern Chapter Society of Nuclear Medicine, 33rd Annual Meeting, San Antonio, TX, 19 Mar 88.

Hartshorne, M.F. Board Review Radiology/Nuclear Medicine. University of Texas Health Science Center, San Antonio, TX, 19 Apr 88.

Hartshorne, M.F. Nuclear Radiology Board Review. Walter Reed Army Medical Center, Washington, DC, 28 Apr 88.

Hartshorne, M.F. Benign Bone Scans. Washington, DC Chapter American College of Radiology, 28 Apr 88.

Hartshorne, M.F. Nuclear Radiology Board Review. Bethesda Nuclear Medicine Fellows/Radiology Residents, Bethesda, MD, 29 Apr 88.

Hartshorne, M.F. Radiation Accident Management. Nuclear Medicine Grand Rounds Stanford Medical Center, Palo Alto, CA, 4 May 88.

Hartshorne, M.F. Board Review, Nuclear Radiology. Letterman Army Medical Center Radiology Residents, Presidio of San Francisco, CA, 4 May 88.

Hartshorne, M.F. Nuclear Medicine Review. David Grant USAF Medical Center, Travis AFB, CA, 5 May 88.

Hartshorne, M.F. Nuclear Medicine Review. David Grant USAF Medical Center, Travis AFB/Radiology Residents, Sacramento, CA, 6 May 88.

## DEPARTMENT OF SURGERY

### Office of the Chief

Rosenthal, D. The History of Hernias. American College of Osteopathic Surgeons, 29-31 Jan 88.

Rosenthal, D. Management of Recurrent Hernias. American College of Osteopathic Surgeons, 29-31 Jan 88.

Rosenthal, D. Management of Parastomal Hernias. American College of Osteopathic Surgeons, 29-31 Jan 88.

Rosenthal, D. Functional Anatomy of Anorectal Sphincters. Annual Sansum Clinic Course in Colorectal Surgery, 9-11 Mar 88.

Rosenthal, D. Indications and Techniques of Repair of Parastomal Hernias. Annual Sansum Clinic Course in Colorectal Surgery, 9-11 Mar 88.

Rosenthal, D. De Clysteribus. Annual Sansum Clinic Course in Colorectal Surgery, 9-11 Mar 88.

Rosenthal, D. Fistula-in-Ano. Society of Air Force Clinical Surgery, Oakland, CA, Apr 88.

Rosenthal, D. Colorectal Trauma. USAREUR Annual Meeting, Garmish, France, 6 May 88.

Rosenthal, D. Management of Ano-Rectal Sepsis. USAREUR Annual Meeting, Garmish, France, 6 May 88.

Rosenthal, D. Management and Prevention of Stoma Complication. Fairview General Hospital, Oakland, CA, Jun 88.

Rosenthal, D. Penetrating Colon Trauma. ACOS, Boston, MA, Jun 88.

Rosenthal, D. Reoperation for Fistula-In-Ano. ACOS, Boston, MA, Jun 88.

### Anesthesia and Operative Service

Middaugh, R.E. Reversal of Respiratory Depression. Northwest Anesthesia Associates, New Orleans, LA, 18-23 Oct 87.

Middaugh, T.E. Reglan, Robinol, Ranitidine. Northwest Anesthesia ASsociates, New Orleans, LA, 18-23 Oct 88.

Middaugh, R.E. Premedicaiotn - Use It or Not? Northwest Anesthesia Associates, New Orleans, LA, 18-23 Oct 87.

Middaugh, R.E. Pediatric Pharmacokineties. Northwest Anesthesia Associates, New Orleans, LA, 18-23 Oct 87.

Middaugh, R.E. Crystalloids - Are They Drugs? Northwest Anesthesia Associates, New Orleans, LA, 18-23 Oct 87.

Middaugh, R.E. Update in Pharmacology. Northwest Anesthesia Associates, New Orleans, LA, 18-23 Oct 87.

Menk, E.J. Frontiers in Chronic Pain Management. Department of Anesthesiology, University of Texas Health Science Center, San Antonio, TX, 13 Jan 88.

Dougherty, T.B. Burn Anesthesia. Department of Anesthesiology, University of Texas Health Science Center, San Antonio, TX, 20 Jan 88.

Middaugh, R.E. ACLS in Retrospective. Reserve Forces, Ponce, Puerto Rico, 20-21 Feb 88.

Middaugh, R.E. ACLS in Perspective. Reserve Forces, Ponce, Puerto Rico, 20-21 Feb 88.

Menk, E.J. Resuscitation in Infants and Children. Reserve Forces, Ponce, Puerto Rico, 20-21 Feb 88.

Menk, E.J. Fundamentals of Airway Management. Reserve Forces, Ponce, Puerto Rico, 20-21 Feb 88.

Middaugh, R.E. Fundamentals of Airway Management. Reserve Forces, Ponce, Puerto Rico, 20-21 Feb 88.

Menk, E.J. Medical Legal Aspects of ACLS. Reserve Forces, Ponce, Puerto Rico, 20-21 Feb 88.

Middaugh, R.E. Acid-Base Interpretation. Reserve Forces, Ponce, Puerto Rico, 20-21 Feb 88.

Menk, E.J. The Mega Code Scenario. Reserve Forces, Ponce, Puerto Rico, 20-21 Feb 88.

Menk, E.J. Topical Capsaicin for the Treatment of Post-Herpetic Neuralgia - A Pilot Study. Poster Presentation at American Society of Regional Anesthesia, San Francisco, CA, 17-20 Mar 88. (C)

Middaugh, R.E. Neonatal Anesthesia. Santa Rosa Neonatal Conference, San Antonio, TX, 18 Mar 88.

Middaugh, R.E. Neonatal Analgesia. Santa Rosa Neonatal Conference, San Antonio, TX, 18 Mar 88.

Fox, B.J. Anesthesia and ECT. Department of Anesthesiology, University of Texas Health Science Center, San Antonio, TX, 28 Apr 88.

Middaugh, R.E. Verbal Instruction Techniques for Pediatric Patients - Tall Tales for Tiny Tots. Department of Anesthesiology, University of Texas Health Science Center, San Antonio, TX, 5 May 88.

Middaugh, R.E. Anesthesia and Laser Safety. Northwest Anesthesia Associates Anesthesia Seminars, Cancun, MX, 23-27 May 88.

Middaugh, R.E. Update in Anesthesia. Northwest Anesthesia Associates Anesthesia Seminars, Cancun, MX, 23-27 May 88.

Middaugh, R.E. Capnography. Northwest Anesthesia Associates Anesthesia Seminars, Cancun, MX, 23-27 May 88.

Middaugh, R.E. Pulse Oximetry. Northwest Anesthesia Associates Anesthesia Seminars, Cancun, MX, 23-27 May 88.

Middaugh, R.E. Anesthesia for Geriatrics. Northwest Anesthesia Associates Anesthesia Seminars, Cancun, MX, 23-27 May 88.

Middaugh, R.E. Update ACLS. Northwest Anesthesia Associates Anesthesia Seminars, Cancun, MX, 23-27 May 88.

Middaugh, R.E. Update BLS. Northwest Anesthesia Associates Anesthesia Seminars, Cancun, MX, 23-27 May 88.

Middaugh, R.E. Preparation of Pediatric Patients. Northwest Anesthesia Associates Anesthesia Seminars, Cancun, MX, 23-27 May 88.

Kingsley, C.P. Evaluation of Cricothyroidotomy Device for Emergency Airway Management. Pulmonary Research Review and Analysis, Fitzsimons Army Medical Center, Aurora, CO, 22 Sep 88.

Kingsley, C.P. Preliminary Evaluation of Drawover Vaporizer Anesthesia in Animals and Humans. Pulmonary Research Review and Analysis, Fitzsimons Army Medical Center, Aurora, CO, 22 Sep 88. (C)

Olson, K. Clinical Evaluation of Field Blood Gas Analyzer. Pulmonary Research Review and Analysis, Fitzsimons Army Medical Center, Aurora, CO, 22 Sep 88. (C)

Cardiothoracic Surgery Service

Helsel, R.A. Mitral Regurgitation - Tricuspid Regurgitation. COBE Summit Seminar. Keystone, CO, 5-8 Mar 88.

General Surgery Service

Cook, R.D. Diagnostic Peritoneal Lavage. Kilimanjaro Christian Medical Center Trauma Conference, Moshi, Tanzania, Africa, Oct 87.

Cook, R.D. Initial Burn Management. Kilimanjaro Christian Medical Center Trauma Conference, Moshi, Tanzania, Africa, Oct 87.

Cook, R.D. Trauma Scales and Triage of the Multiple Injured Patient. Kilimanjaro Christian Medical Center Trauma Conference, Moshi, Tanzania, Africa, Oct 87. (C)

Solenberger, R.I. Experience Using Triple Lumen Catheters in Children. Pediatric Oncology Group, New Orleans, LA, Nov 87.

Mozingo, D.W. Ocular Manifestations of Carotid Artery Disease. 15th Annual Vascular Surgery Seminar, Society for Military Vascular Surgeons, Bethesda, MD, Dec 87.

Solenberger, R.I. Surgeons Role in Short Gut and Malabsorption Problems. South Central Texas Society of Gastrointestinal Assistants, San Antonio, TX, 4-6 Mar 88.

Khoury, D.A. Prophylactic Peritoneal Windows in Renal Allograft Transplants. Residents Symposium, Fort Sam Houston, TX, 26 Mar 88.

Robert, J.P. Annual Mammography - Who Needs It? Residents Symposium, Fort Sam Houston, TX, 26 Mar 88.

Cook, R.D. Trauma Score - A Prospective Study of Application. Residents Symposium, Fort Sam Houston, TX, 26 Mar 88. (C)

Alcover, B. Patterns of Recurrence in Colorectal Cancer. Residents Symposium, Fort Sam Houston, TX, 26 Mar 88.

Black, C.P. Fine Needle Aspiration Cytology in the Diagnosis of Solid Breast Masses. Residents Symposium, Fort Sam Houston, TX, 26 Mar 88.

Walker, L.C. Inflammatory Breast Cancer. Residents Symposium, Fort Sam Houston, TX, 26 Mar 88.

Jackson, M.R. Results of Cholecystectomy for Symptomatic Cholelithiasis. Residents Symposium, Fort Sam Houston, TX, 26 Mar 88.

Olsen, S.B. Appendicitis in the Over 50 Population. Residents Symposium, Fort Sam Houston, TX, 26 Mar 88.

Robertson, F.M. Pelvic Fractures. Residents Symposium, Fort Sam Houston, TX, 26 Mar 88.

Bradshaw, W. H. Gastrointestinal Melanoma. Residents Symposium, Fort Sam Houston, TX, 26 Mar 88.

Harrison, D.L. Malignant Fibrohistiocytoma. Residents Symposium, Fort Sam Houston, TX, 26 Mar 88.

Mo[illegible], L.W. [illegible] of Carotid Artery Disease. Residents Symposium, [illegible], TX, 26 Mar 88.

[illegible], T.L. [illegible] Lymphomatosum - An Increasing Incidence? [illegible], TX, 26 Mar 88.

Br[illegible] [illegible] the Head and Neck - Depth of Invasion Subsite Analysis. [illegible] Houston, TX, 26 mar 88.

[illegible] Hematuria in Blunt Trauma. Residents [illegible]

[illegible] Temporal Hemangioma. Gary P. Wratten Symposium, 29 Mar [illegible]

[illegible]

[illegible] Cell and Squamous Cell Carcinoma with Orbital Invasion. [illegible] Society of Ophthalmic Plastic and Reconstructive Surgery, Nov 87.

[illegible] Plastics Symposium, University of Texas Health Science Center, San Antonio, TX, Nov 87.

Hollsten, D.A. Plastics and Reconstructive Surgery. American Society of Ophthalmic Plastic and Reconstructive Surgery, Nov 87.

Hollsten, D.A. Oculoplastics. Plastics Symposium, University of Texas Health Science Center, San Antonio, TX, Nov 87.

Mazzoli, R.A. Director. Ocular Trauma Course. Fort Sam Houston, TX, 22-26 Feb 88.

Glover, A.T. Corneal Trauma. Ocular Trauma Course, Brooke Army Medical Center, Fort Sam Houston, TX, 22-26 Feb 88.

Mazzoli, R.A. Ocular Trauma/Vitrectomy Techniques. Ocular Trauma Course, Brooke Army Medical Center, Fort Sam Houston, TX, 22-26 Feb 88.

Mazzoli, R.A. Intraocular Foreign Bodies. Ocular Trauma Course, Brooke Army Medical Center, Fort Sam Houston, TX, 22-26 Feb 88.

Glover, A.T. [illegible] Oculoplastic Symposium, University of Texas Health [illegible], TX, 11 Mar 88.

[illegible], A.T. [illegible], Alamo City Ophthalmology Residents Conference. [illegible] Health Science Center, San Antonio, TX, 4-5 Mar 88.

[illegible], M., Lenses and Optics for the Olympic Shooter. Alamo City Ophthalmology Residents Conference, University of Texas Health Science Center, San Antonio, TX, 4-5 Mar 88.

Hansen, E.A. Sub-Tenon's Retrobulbar Anesthetic for Cataract Extraction. Alamo City Ophthalmology Residents Conference, University of Texas Health Science Center, San Antonio, TX, 4-5 Mar 88.

Dirks, M.S. Norfloxacin vs. Tobramycin in the Treatment of Acute Bacterial Infections of the External Eye. Alamo City Ophthalmology Residents Conference, University of Texas Health Science Center, San Antonio, TX, 4-5 Mar 88. (C)

Foster, M.S. Monofixation Syndrome. Alamo City Ophthalmology Residents Conference, University of Texas Health Science Center, San Antonio, TX, 4-5 Mar 88.

Farris, S.R. Contact Lens Contamination. Alamo City Ophthalmology Residents Conference, University of Texas Health Science Center, San Antonio, TX, 4-5 Mar 88.

Grimes, S.R. Preoperative Chemical Preparation of the Eye. Alamo City Ophthalmology Residents Conference, University of Texas Health Science Center, San Antonio, TX, 4-5 Mar 88.

White, W.L. Relative Tear Flow in Lacrimal Canaliculi as Assessed by Dacryoscintigraphy. Alamo City Opthalmology Residents Conference, University of Texas Health Science Center, San Antonio, TX, 4-5 Mar 88. (C)

Kietz, T.J. A Reviw of Intraocular Lens Power Calculation. Alamo City Ophthalmology Residents Conference, University of Texas Health Science Center, San Antonio, TX, 4-5 Mar 88.

Mazzoli, R.A. Care of the Burn Patient. Surgeon General's ISR Burn Symposium, Institute of Surgical Research, Brooke Army Medical Center, Fort Sam Houston, TX, 13 Jan 88.

Glover, A.T. Ptosis. University of Texas Health Science Center, San Antonio, TX, Jun 88.

Glover, A.T. Orbital Cellulitis. Retirement Symposium for COL John Shore, Wilford Hall USAF Medical Center, Lackland AFB, TX, Aug 88.

Orthopaedic Surgery Service

Compton, R. Resectional Arthroplasty for Comminuted Olecrenon Fractures. Society of Military Orthopaedic Surgeons, Nov 87.

Warren, H. Ipsilateral Fractures of the Femur and Tibia. Society of Military Orthopaedic Surgeons, Nov 87.

Christensen, K. The Use of an Intraoperatively Placed Epidural Catheter for Postoperative Pain Management in Spinal Instrumentation. Society of Military Orthopaedic Surgeons, Nov 87.

Emery, S. Arthrodiastasis [illegible] Comparison with Computerized Tomography. Society of Military Orthopaedic Surgeons, Nov 87.

Greenfield, G. [illegible] Calcaneocuboid Reflex - A Predictor? Society of Military Orthopaedic Surgeons, Nov 87.

Norwood, L. [illegible] Pain Examination for Psychogenic Low Back Pain. Society of Military Orthopaedic Surgeons, Nov 87.

Park, M. Stress Fracture Evaluation with Dual-Photon Absorptiometry. Society of Military Orthopaedic Surgeons, Nov 87. (C)

Phillips, E. [illegible] and Histological Effects of Continuous Passive Motion on Skin of Rabbits. Society of Military Orthopaedic Surgeons, Nov 87. (C)

Hank, M. The Clenched Fist Syndrome. Southern Orthopaedic Association, Nov 87.

Bucknell, A.L. Alternative Techniques in Uncemented Acetabular Arthroplasty. Department of Orthopaedic Surgery, University of Texas Health Science Center, San Antonio, TX, Dec 87. (C)

Bucknell, A.L. Clinical Experience with the Polysulfone Stem in THA. Course in Uncemented Total Hip Arthroplasty, San Antonio, TX, Dec 87. (C)

Bucknell, A.L. Clinical Experience with OPTI-FIX Titanium Stem. Course in Uncemented Total Hip Arthroplasty, San Antonio, TX, Dec 87. (C)

Silver, S. Analysis of 50 Patients with Threaded Metallic Acetabular Prosthesis. Course in Uncemented Hip Arthroplasty, San Antonio, TX, Dec 87.

Bucknell, A.L. Ultrasound Evaluation of Morton's Neuroma. American Orthopaedic Foot and Ankle Society, Atlanta, GA, Feb 88.

Bucknell, A.L. BAMC OptiFix Investigators Report. OptiFix Investigators Meeting, American Academy of Orthopaedic Surgeons, Atlanta GA, Feb 88. (C)

Bucknell, A.L. Orthopaedic Research in the Army. Association of Orthopaedic Surgeons, New Orleans, LA, Mar 88.

Warren, H.L. Prevention of Shoulder Injuries in Swimming and Triathalon. Endurance Sports Training Seminar, San Antonio, TX, May 88.

Compton, R. Resection Arthroplasty for Comminuted Olecrannon Fractures. Texas Orthopaedic Association, San Antonio, TX, May 88.

Hank, M. Evaluation of Stress Fractures Using Dual Phoon Absorptiometer. Texas Orthopaedic Association, San Antonio, TX, May 88. (C)

Bucknell, A.L. Concepts in Military Operational Orthopaedix. SOMED V, Fort Bragg, NC, [illegible] 88.

Bucknell, A.L. Design Principles and Research on the Spectron E.F. Total Hip System. Advanced Concepts and Future Possibilities in Hip Arthroplasty, Cincinnati, OH, Jun 88.

Bucknell, A.L. Design Principles and Clinical Experience with the Porous Polysulfone Ti-6A-4V Hip System. Advanced Concepts and Fugure Possibilities in Hip Arthroplasty, Cincinnati, OH, Jun 88. (C)

Bucknell, A.L. Advances in Reconstructive Surgery. Cincinnati, OH, 17 Sep 88.

Bucknell, A.L. Design Rationale for the Spectron E.F. Total Hip System. Cincinnati, OH, 17 Sep 88.

Bucknell, A.L. Princples and Techniques in Salvage (Revision) Total Hip Arthroplasty. Cincinnati, OH, 17 Sep 88.

Melendez, E. Common Hand Injuries. Orthopaedic Grand Rounds, Reynolds Army Hospital, Fort Sill, OK, Aug 88.

Melendez, E. Common Hand Injuries. Orthopaedic Grand Rounds, U.S. Army Community Hospital, Fort Polk, LA, Aug 88.

Sunshein, K. Nuclear Medicine Studies for the Diagnosis of Osteomyelitis of the Foot. U.S. Army Podiatry Conference, Fort Carson, CO, 5-7 Apr 88.

Otolaryngology Service

Moss, J. Director, 1987 Bronchoesophageal and CO2 Laser Endoscopy Course. Brooke Army Medical Center, Fort Sam Houston, TX, 29-30 Oct 87. (C)

Moss, J. Bronchoscopy and Esophagoscopy Laboratory Moderator. Bronchoesophageal and CO2 Laser Endoscopy Course, Fort Sam Houston, TX, 29-30 Oct 87.

Moss, J. Laser Excision of the Larynx. Bronchoesophageal and CO2 Laser Endoscopy Course, Brooke Army Medical Center, Fort Sam Houston, TX, 29-30 Oct 87.

Moss, J. Rhabdomyosarcoma of the Head and Neck: The BAMC Experience. Annual Scientific Association of the Southern Medical Association, San Antonio, TX, 2-5 Nov 87.

Fraker, J.T. Evaluation of the Neck Mass. Annual Scientific Association of the Southrn Medical Association, San Antonio, TX, 2-5 Nov 87.

Stambaugh, K.I. Augmentation Mentoplasty. Plastic and Reconstructive Surgery of the Face Course, Brooke Army Medical Center, Fort Sam Houston, TX, 11-12 Dec 87.

Moss, J. Chemical Peel. Plastic and Reconstructive Surgery of the Face Course, Brooke Army Medical Center, Fort Sam Houston, TX, 11-12 Dec 87.

Jarchow, R.C. Dermabrasion. Plastic and Reconstructive Surgery of the Face Course, Brooke Army Medical Center, Fort Sam Houston TX, 11-12 Dec 87.

Jarchow, R.C. Incisions for Myringotomy. Southern Region Scientific Program of the American Academy of Facial Plastic and Reconstructive Surgery, Birmingham, AL, Jan 88.

Jarchow, R.C. Moderator for the Southern Region Scientific Program. American Academy of Facial Plastic and Reconstructive Surgery, Birmingham, AL, Jan 88.

Jarchow, R.C. Nasal Discussant, Southern Region Scientific Program. American Academy of Facial Plastic and Reconstructive Surgery, Birmingham, AL, Jan 88.

Fraker, J.T. Management of Macroglossia in the Beckwith-Wiedeman Syndrome. American Academy of Otolaryngoly-Head and Neck Surgery Annual Meeting, Washington, DC, 25-29 Sep 88.

Fraker, J.T. Case Report of Angiosarcomas. American Academy of Otolaryngology-Head and Neck Surgery Annual Meeting, Washington, DC, 25-29 Sep 88.

Gibbons, D.E. Craniocervical Chordoma. American Academy of Otolaryngology-Head and Neck Surgery Annual Meeting, Washington, DC, 25-29 Sep 88.

Farrior, R.T. Surgical Principles and Techniques in Face-Lift. American Academy of Otolaryngology-Head and Neck Surgery Annual Meeting, Washington, DC, 25-29 Sep 88.

Hayes, D.K. Viability of Skin Flaps Subjected to Chemical Peel. Society of Military Otolaryngologists-Head and Neck Surgeons Annual Meeting, Washington, DC, 27 Sep 88. (First Plast Resident Paper Competition) (C)

Peripheral Vascular Surgery

Olson, D.W. Aortic Anastomotic Aneurysm. 15th Annual Vascular Surgical Symposium, Bethesda, MD, 5 Dec 87.

Ramirez, M.F. Upper Extremity Cavernous Hemangioma, A Case Report. 15th Annual Vascular Surgical Symposium, Bethesda, MD, 5 Dec 87.

Mozingo, D.W. Ocular Manifestations of Carotid Artery Disease. 15th Annual Vascular Surgical Symposium, Bethesda, MD, 5 Dec 87.

Ramirez, M.F. Management of Venous Hemagiomas. Gary P. Wratten Symposium, 30 Mar 88.

Plastic Surgery Service

Young, R.N. The Versatility of the Latissimus Dorsi Flap. South Texas Chaper of the American College of Surgeons' Annual Meeting, El Paso, TX, 30 Jan 88.

Young, R.N. Flaps for Acute Burns. Annual Military Plastic Surgery Symposium, Fitzsimons Army Medical Center, Aurora, CO, Apr 88.

Surgical Intensive Care Unit

Cook, R.D., Ducey, J.P. Prospective Comparison of Trauma Score and Crasms Scale - A Preliminary Report. Military Surgical Symposium, San Antonio, TX, 16 Mar 88. (C)

Reilly, J.R., Ducey, J.P. A Comparison of the Cerebral and Cardiovascular Effects of Complete Resuscitation with isotonic and Hypertonic Saline, Hetastarch and Whole Blood Following Hemorrhge. American College of Emergency Physicians Conference, New Orleans, LA, Sep 88.

Ducey, J.P. The Medical Graphics Respiratory Physiology. Pulmonary Research Review and Analysis, Fitzsimons Army Medical Center, Aurora, CO, 22 Sep 88

Urology Service

Rodriguez, F.R. Continent Urinary Diversion. Kimbrough Urological Seminar, Washington DC, 5 Nov 87.

Zeidman, E.J. Spurious Impotence After Hypospadias Repair. Kimbrough Urological Seminar, Washington, DC, 4 Nov 87.

Zeidman, E.J. Male Sling Operation for Neurogenic Incontinence. Kimbrough Urological Seminar, Washington, DC, 6 Nov 87.

Zeidman, E.J. Urodynamics - Basic Principles. William Beaumont Urology Conference, Fort Bliss, TX, 14 Dec 87.

Hansberry, K. Fine Needle Aspirate Comparison with Standard Biopsy. Kimbrough Urological Seminar, Washington, DC, 5 Nov 87.

Zeidman, E.J. Basic Principles of Urology. Department of Urology, University of Texas Health Science Center, San Antonio, TX, 7 Jan 88.

Zeidman, E.J. Pathophysiology of Micturition. Department of Urology, University of Texas Health Science Center, San Antonio, TX, 17 Mar 88.

Zeidman, E.J. Vaginal Surgery for Incontinence. McDonald Urological Seminar, Phoenix, AZ, 19 Mar 88.

Zeidman, E.J. Incontinence. McDonald Urological Seminar, Phoenix, AZ, 19 Mar 88.

Thompson, I.M. Screening and Early Detection of Carcinomas of the Prostate. West Point Medical Association Annual Meeting, West Point, NY, Sep 88. (C)

Zeidman, E.J. Genitourinary Trauma. West Point Medical Association Annual Meeting, West Point, NY, Sep 88.

Zeidman, E.J. Diagnosis and Treatment of Incontinence. Henry Ford Hospital, Detroit, MI, Sep 88.

## PHYSICAL MEDICINE AND REHABILITATION SERVICE

Jansen, R.D. Perceived Competencies of Army Occupational Therapists in the Role of Upper Extremity Musculoskeletal Screeners. AMSC Research Course, Leesburg, VA, 87.

Sund[illegible] Application of Ethics to the Practice of Occupational Therapy. Mary[illegible] State Occupational Therapy Conference, Timinion, MD, Jan 88.

Jansen R.D. The Role of Army Occupational Therapy as Upper Extremity Evaluators. Texas Occupational Therapy Association, San Antonio, TX, Jan 88.

Webb, A.J. Employment Opportunities in the Uniformed Services. American Physical Therapy Association Conference, Minority Affairs Commission, Las Vegas, NV, 14 Jun 88.

## PREVENTIVE MEDICINE SERVICE

Longfield, J.N. Gastroenteritis Outbreak Investigation in the Field Setting. U.S. Air Force Environmental Health Officers, San Antonio, TX, Feb 88.

## NUTRITIONAL CARE DIVISION

Hemingway, M.M. Wellness Program - General Nutrition. U.S. Army Health Services Command, Fort Sam Houston, TX, 12 Nov 87.

Hemingway, M.M. Wellness Program - Weight Control. U.S. Army Health Services Command, Fort Sam Houston, TX, 12 Nov 87.

Hemingway, M.M. Dietetics and Nutrition. Fort Sam Houston Retired Nurses Club, San Antonio, TX, 17 Nov 87.

Hemingway, M.M. Nutrition and Dental Health. Fort Sam Houston Elementary School, Fort Sam Houston, TX, 4 Feb 88.

Freese-Kepczyk, B. Cooking without Your Salt Shaker. Question and Answer Session, Foley's, North Star Mall, San Antonio, TX, 13 Feb 88.

Freese-Kepczyk, B. Low Cholesterol, Low Fat Cooking. Question and Answer Session, Foley's, North Star Mall, San Antonio, TX, 20 Feb 88.

Hemingway, M.M. Wellness Program - Nutrition. U.S. Army Health Services Command, Fort Sam Houston, TX, 22 Feb 88.

Hemingway, M.M. Wellness Program - Weight Control. U.S. Army Health Services Command, Fort Sam Houston, TX, 22 Feb 88.

Hemingway, M.M. Good Nutrition. Fort Sam Houston Elemenary School PTA, Fort Sam Houston, TX, 23 Feb 88.

Freese-Kepczyk, B. Heart Healthy Recipes for Kids. Foley's, North Star Mall, San Antonio, TX, 27 Feb 88.

Kline, D.M. After School Snacks. Fort Sam Houston, Elementary School, Fort Sam Houston, TX, 10 Mar 88.

Kline, D.M. Breakfast. Fort Sam Houston Elementary School, Fort Sam Houston, TX, 10 Mar 88.

Hemingway, M.M. Silver Servers. McArthur Church of Christ, San Antonio, TX, 2 Jun 88.

Hughes, J.W. Good Nutrition. Armed Forces Day, Kelly AFB, TX, 29 May 88.

Hemingway, M.M. General Nutrition. Business and Professional Women's Club, San Antonio, TX, 19 Apr 88.

Freese-Kepczyk, B. Nutrition and Exercise. San Antonio District Dietetic Association and Incarnate Word College, San Antonio, TX, 23 Apr 88.

Hemingway, M.M. Nutrition Jeopardy. Fort Sam Houston Elementary School Summer Camp, Fort Sam Houston, TX, 18-21 Jul 88

Hemingway, M.M. Nutrition in the Grocery Store. Question and Answer Session, HEB Store, San Antonio, TX, 24 Sep 88.

Freese-Kepczyk, B. Low Fat, Low Cholesterol: Guidelines for Finding Hidden Fat in the Grocery Store. HEB Food Festival, San Antonio, TX, 24 Sep 88.

Detail Summary Sheet

Date: 12 Oct 88 Proj No: C-46-85 Status: Ongoing

Title: Isolation and Characterization of the Chlorinating Moiety of *Aspergillus sp.* and *Penicillium sp.*

| | |
|---|---|
| Start Date 10 Jun 85 | Est Comp Date: |
| Principal Investigator<br>Gerald A. Merrill | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Clinical Investigation | Associate Investigators:<br>Victor Elysee, SGT<br>Paul M. Horowitz, Ph.D. |
| Key Words:<br>*Aspergillus sp.*<br>*Penicillium sp.* | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: $946.45 |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review n/a Results

Objective(s): 1) To isolate a haloperoxidase from a readily available source which has characteristics that would enable it to be utilized in a chemiluminescent immunoassay system currently being developed under protocol C-45-83.

2) To gain understanding of the mechanism of action of haloperoxidase, so insight into the physiological roles of this class of enzymes (i.e., the microbicidal action) in various cell types (granulocytes, plants, fungi, etc.) can be gained.

Technical Approach: Selected fungi (*Aspergillus sp.* and *Penicillium sp.*) would be cultured in Czapek Dox media and homogenized. Following centrifugation, both supernatant and pellet would be assayed for haloperoxidase activity at various chloride/HOOH ratios at a series of pH's using a standard assay for halogenating activity employing monochlorodimedon. If a significant halogenating activity is detected furthur purification of the responsible enzyme would be initiated. The methods employed for purification would depend on gross charcteristics of the enzyme such as pI, carbohydrate content, mclecular weight, etc. The purified enzyme would then be tested for optimum conditions for HOOH dependent halogenation and for its ability to catalyze the chemiluminogenic dioxygenation of cyclic hydrazides (luminol derivatives) at various pH's and halide/HOOH ratios in an attempt to achieve a practical enzyme for use in development of a chemiluminogenic enzyme linked immunoassay system. Proposal of an enzyme mechanism of action would involve use of methods designed to show conformational changes in substrates and enzyme during catalysis, to include fluorescent techniques.

Progress: Species of fungi which have previously been shown to have peroxidase activity were obtained from stock cultures isolated from patients and stored frozen at the mycology section of the University of Texas Health Science Center. These spcies are of two genera which have other species reported to produce

C-46-85 (continued)

chlorinated toxins in moderate amounts, and thus were likely to possess haloperoxidases which could effect toxin halogenation. The three fungi - Syncephaloblastum racemosium R683 and R693 and Trichoderma viride R613 - were grown in Czapek Dox media. The growth media were tested at 2 pHs (6.0 and 6.8) at each of 4 halide concentrations (0, 100, 400, and 1500 mEq/l) of both $Cl^-$ and $Br^-$ by a chemiluminogenic assay utilizing luminol as a specific peroxidase probe. No halide dependent peroxidase activity was noted. Fungal mycelia were centrifuged and washed free of growth media. Washed mycelia were homogenized in a tween 80 containing buffer and again centrifuged. The resultant supernatant was not associated with haloperoxidase activity. The tween extracted mycelium were further extracted in ethanol and following centrifugation, the supernatants were evaluated and shown not to be associated with haloperoxidase activity. It was concluded that although peroxidase activity was associated with these fungi, their peroxidases did not require halide as a cofactor.

Future attempts at isolation of haloperoxidase from fungi will be with fungi stains obtained commercially which have proven chlorenated toxins associated with them.

Detail Summary Sheet

Date: 28 Sep 88 Proj No: C-16-87 Status: Completed

Title: A Study on the Specificity of Phospholipase Associated with the Cell Wall of Candida albicans

| | |
|---|---|
| Start Date 29 Jan 87 | Est Comp Date: |
| Principal Investigator<br>David L. Danley, MAJ, MS | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Clinical Investigation | Associate Investigators:<br>Johnny W. Hinds, SSG |
| Key Words:<br>Candida albicans | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: 798.33 |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): 1) To determine the susceptibilities of various phospholipid substrates to degradation by phospholipoase(s) associated with the cell wall of C. albicans.

2) To isolate and purify a soluble form of the active enzyme(s) which can be tested for cytotoxicity against human monocytes.

Technical Approach: To determine the susceptibility of various phospholipids to degradation to fungal cell phospholipases, we incubated radiolabeled phospholipids with viable yeast cells, extracted total lipids with chloroform:methanol, and separated components by thin layer chromatography.

Progress: New studies were initiated to look at other enzymatic capabilities of C. albicans that would effect monocyte killing. Particular attention was paid to proteolytic enzymes. Assays used to detect proteases in supernatants of five day old cultures failed to detect significant activity in cultures of yeast cells incubated for one hour. However, in the process of using a particular reagent,4,4'-dithiodipyridine (DTDP), to test for enzymatic activity, we discovered that yeast cells have a tremendous capacity to reduce disulfide bonds. When yeast cells were treated with sulfhydral blockers, such as N-ethylmaleimide

C-16-87 (continued)

(NEM) or iodoacetate (IAA), they no longer reduced DTDP, and they were not cytotoxic for human monocytes. Treatment with either NEM or IAA did not kill the yeast cells, but they were no longer capable of germinating on cornmeal agar.

With these findings and those reported in C-30-87, it was decided to concentrate our efforts in a single protocol to investigate cell wall sulfhydral groups and the pathogenicity of C. albicans.

Detail Summary Sheet

Date: 31 Oct 88 Proj No: C-30-87 Status: Completed

Title: An Investigation on the Significance of Monocyte Lysis by Candida Albicans Yeast Cells

| | |
|---|---|
| Start Date 2 Mar 87 | Est Comp Date: |
| Principal Investigator<br>David L. Danley, MAJ, MS | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Clinical Investigation | Associate Investigators:<br>Johnny W. Hinds, SSG |
| Key Words:<br>Candida albicans | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: 533.45 |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): We have recently determined that human monocytes are uniquely susceptible to lysis by yeast cells of Candida albicans in vitro. The objective of this proposal is to dtermine whether or not this finding has any applicability to our understanding of host immunity to this opportunistic fungus and to determine if this finding can be integrated into an assay that will help clinicians define the patient at risk from infection by Candida albicans.

Technical Approach: Peripheral blood was drawn from volunteers, and the mononuclear leukocyte fraction was isolated by density gradient centrifugation. Afterwards, these cells were labeled with 51-chromium and incubated with yeast cells of C. albicans or soluble extracts from this fungus. Monocyte killing was measured by determining the amount of radioisotope released into the culture supernatant after one hour.

Progress: It is not clear how C. albicans yeast cells lyse monocytes. The fact that monocyte killing is inhibited by pretreatment of yeast cells with sulfhydral blocking agents suggests that the monocytes may be susceptible to the extreme reducing environment created by these sulfhydral groups; or they may be susceptible to cell wall enzymes that are activated, like B-glucanase, when disulfide bonds are reduced. This work will be continued in a single protocol to investigate cell wall sulfhydral groups and the pathogenicity of C. albicans.

Detail Summary Sheet

| | | |
|---|---|---|
| Date: 8 Nov 88 | Proj No: C-18-88 | Status: Ongoing |

Title: Development of an Indirect Chemiluminogenic Enzyme Linked Immunoassay (CELIA) for Demonstrating Conformational Changes in a Model Protein

| | |
|---|---|
| Start Date 16 Dec 88 | Est Comp Date: |
| Principal Investigator<br>Gerald A. Merrill | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Clinical Investigation | Associate Investigators:<br>Paul M. Horowitz, Ph.D., UTHSC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: 779.93 |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To develop monoclonal antibodies (MAB) to rhodanese, a well characterized model protein, and use thse antibodies in the development of an indirect soluble chemiluminescent enzyme linked assay system.

To assess the binding affinities of anti-rhodanese monoclonal antibodies for their epitopes and demonstrate conformational changes involving the rhodanese epitopes by monitoring changes in binding affinities.

Technical Approach: Monoclonal antibodies to rhodanese will be produced by fusion of SP2/0 myeloma cells and spleen cells (lymphocytes) of mice immunized with rhodanse and adjuncts. Monoclontal antibodies (MABs) will be used as probes for the existence and accessibility of epitopes. Loss or gain of epitope expression as the enzyme is manipulated and isolation in various stable states will be evidence of conformational changes. Subtle confomrational changes will be monitored by noting changes in binding affinities of MABs for respective epitopes. Binding affinities will be assessed by use of an indirect chemiluminogenic enzyme linked immunoassay (CELIA) which will be developed.

Progress: Three MABs to rhodanese have been produced. Although the epitopes recognized by these MABs have not yet been mapped, the three MABs have been shown to bind to different proteolytic fragments of rhodanese and are thus distinctly different MABs recognizing unique epitopes. None of the MABs recognizes rhodanese in its active substrate bound fomr (ES) if rhodanese is kept at 4°C. When ES is allowed to warm to room temperature for even brief periods, one mAB (MAB 4) is able to recognize its epitope. This epitope is expressed on the free enzyme

C-18-88 (continued)

(E) at both 24° and 4°C. Neither of the other MABs (MAB11 and R207) recognize their respective epitopes on active soluble rhodanese in either the E or ES form.

As rhodanese is termally inactivated at 37°C, E inactivates substantially faster than ES. Detectionof epitopes recognized by the MABs precedes inactivation. For all three MABs, the epitope is exprssed on E earlier than DN ES, suggesting ES is a more conformationally stable conformer. In both the E and ES forms of the enzyme, the MAB14 epitope is exprssed first followed by expression of the MAB11 epitope. The R207 epitope is expressed last in both cass. This is immunological evidence that rhodanese is thermally inactivated by a gradual unfolding of its native conformation.

Rhodanese is rapidly inactivated by oxidation with $H_2O_2$. However, evidence for conformational changes red shifted fluorescence emission spectra, increased binding of apoloir probes, and increased proteolytic sysceptibility are not observed until much later and only when $CN^-$ and peroxide remain in the presence of the inactivated en: yme. Rhodanese inactivated by peroxide oxidation wsa evaluated for epitope expression. MAB14 recognized its epitope on oxidized rhodanese whether or not $CN^-$ and peroxide were removed. The MAB11 epitope was expressed to only a slight degree when kept at 40°C whether or not $CN^-$ and peroxide were removed. At 24°C, the MAB11 epitope was substantially expressed but removal of $CN^-$ and peroxide reduced binding of MAB11. The epitope recognized by R207 was not expressed on oxidized rhodanese at 9°C but wax expressed at 27°C. Expression was reduced by $CN^-$ and peroxide removal. Oxidation of rhodanese at 37°C resulted in expressiion of all epitopes. Thus, expression of the epitope recognized by mAB14 appears to require the lest conformational change while the R207 requires significantly more denaturation. These results indicate conformational differences between E and ES not previously demonstrated. They also demonstrate the time dependent antigen expresison of thermally denatured enzyme suggesting a gradual unfolding of the enzyme. Results also indicate that ES is substantially more resistant to thermally induced conformational changes than E.

Detail Summary Sheet

Date: 8 Nov 88 Proj No: C-22-88 Status: Ongoing

Title: Comparison of PT and aPTT Values Obtained from Standard Venipuncture and Implanted Venous Access Device Methods

| | |
|---|---|
| Start Date 13 Jan 88 | Est Comp Date: |
| Principal Investigator<br>Mary E. Arrington, R.N., MSN | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Clinical Investigation | Associate Investigators:<br>Eleanor Ayala, M.T.<br>Steven Drennan, 1LT AN<br>Osburn Stone, CPT, AN<br>Patricia Potts, 1LT, AN<br>Michael E. Berkland, CPT, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To investigate the extent of variation in prothrombin time (PT) and activated partial thromboplastin time (aPTT) obtained from two blood sampling methods from implanted venous access devices as compared to standard peripheral venipunctures in Hematology/Oncology patients.

Technical Approach: One hundred sample sets will be studied, 50 in each group, from a convenience sample. Following a 20 ml normal saline preflush and a 5 cc discard, six serial blood volumes will be sampled from each subjects implanted venous access device (IVAD). Subjects will serve as their own controls via concurrent venipuncture. Two IVAD conditons will be studied - heparin locked IVAD's and IVAD's receiving non-heparinized infusates. Each serial volume will be tested using Pt and aPTT, as well as thrombin times as futher evidence of heparin contamination.

Progress: A pilot of four subject's samples (2 in each IVAD condition) was performed with one subject's (non-heparinized) serial samples approximating venous controls. It was determined by statistician that 7 subjects were needed for statistical significance for the heparin locked gorup alone. Seven subjects were then sampled without any misadventures encountered. The data are currently undergoing analysis.

Detail Summary Sheet

Date: 31 Oct 88 Proj No: C-25-88 Status: Ongoing

Title: Use of Fluorescence-Activated Flow Cytometry to Identify Bone Cells

| | |
|---|---|
| Start Date 14 Jan 88 | Est Comp Date: |
| Principal Investigator<br>David L. Danley, MAJ, MS | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Clinical Investigation | Associate Investigators:<br>Janice Grassel, M.T.<br>Barbara Reeb, M.T. |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: 929.65 |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To determine the feasibility of using FACS to identify bone cells and to study their metabolic activities.

Technical Approach: In our initial study, we propose to use human or animal cell lines with known charcteristics of osteoblasts: SAOS-2 (human), MT-3T3 (human, and ROS 17/2.8 (rats). They will be grown and passed under sterile conditions in the CI tissue culture facilities. To identify cell types and function, we will use a FACS 400.

Progress: Cell lines and media have been obtained. Study will start in near future.

Detail Summary Sheet

| Date: 8 Nov 88 | Proj No.: C-33-88 | Status: Ongoing |
|---|---|---|

Title: Health Beliefs and Glycemic Control of Type II Diabetics

| Start Date 17 Feb 88 | Est Comp Date: |
|---|---|
| Principal Investigator<br>Mary E. Arrington, R.N., MSN | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Clinical Investigation | Associate Investigators:<br>John Simmons, MAJ, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To describe health beliefs specific to a diabetic population and their relationship to the glycemic control attained.

Technical Approach: The health beliefs and glycemic control of 120 accessible adult, type II diabetic patients will be studied utilizing a descriptive survey research design. The Diabetes Health Belif Scale, a demographic questionnaire and a glycosylated hemoglbin will be used as the basis for data collection.

Progress: Due to the transfer of the principal investigator, the study has been turned over to MAJ John Simmons.

Detail Summary Sheet

| Date: 8 Nov 88 | Proj No: C-50-88 | Status: Ongoing |
|---|---|---|

Title: CVA Patient Falls: Intrinsic Risk Factors Profile

| Start Date 2 May 88 | Est Comp Date: |
|---|---|
| Principal Investigator<br>Mary E. Arrington, R.N., MSN | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of | Associate Investigators:<br>Vicki Byers, Ph.D., RN, CNRN |
| Key Words: | Kenn Finstuen, M.S., M.Ed., Ph.D. |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): 1) To identify the characteristics that are associated with CVA patients falling.

2) To explain the nature of the relationship among characteristics and falling.

3) To compare, within the patient profiles, the characteristics of CVA patients who fall with those CVA patients who do not.

Technical Approach: The procedure involved in this collaborative study was a retrospecitve in-patient chart audit as the method of data collection. Charts, laboratory reports, scan reports, and incident reports were reviewed and data collected using the Data Sheet-Fall Tool developed by the investigators. A 96% inter-rater reliability of the data collection tool was determined on 10 CVA fall patients prior to data collection. The independent variables include demographics, hemisphere of CVA, blood pressure, weight loss prior to fall, combination of neurological deficit, activity level at time of fall, mental status, medications, and laboratory values.

Progress: Data collection has been completed. The samples meeting the study criteria consisted of 220 CVA fallers and 110 CVA non-falling patients from three major medical centers in the San Antonio area to include over 5½ years of charts at Brooke Army Medical Center. Data analysis consisting of descriptive and multivariate parametric statistics are currently underway and twelve hypotheses will be tested to examine the strength on the relationships between the independent variables and falling.

Detail Summary Sheet

| | | |
|---|---|---|
| Date: 8 Nov 88 | Proj No: C-56-88 | Status: Completed |

Title: Patient Pain Perceptions and Coping Strategies Used in Early Convalescence from Coronary Bypass Surgery

| | |
|---|---|
| Start Date 3 Jun 88 | Est Comp Date: |
| Principal Investigator<br>Mary E. Arrington, R.N., MSN | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of | Associate Investigators:<br>Mary L. Heye, R.N., M.S.N. |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 15 BAMC

Total Number of Subjects Enrolled to Date: 15 BAMC, 29 from other hospitals

Date of Periodic Review _____ Results _____

Objective(s): To examine the patient's perception of pain, and the coping strategies patients use or develop to deal with pain during early convalescence from CB surgery.

Technical Approach: At BAMC 15 patients who had undergone coronary bypass surgery were interviewed during the first week postoperative. A second interview was conducted the thir postoperative week in the patient's home or if the patient lived out of town the instruments were mained to the patient. Patients were asked about locations of pain, actions used to relieve pain, and to complete two instruments related to the postoperative pain: The McGill Pain Questionnaire and the Jalowiec Coping Scale.

Progress: Patient interviews are completed. No adverse reactions or misadventures have been encountered or noted. The first tests run were alpha reliabilities on the subscales of the McGill Pain Questionnaire and thee Jalowiec Coping Scales. The results showed adequate reliability. On the pain questionnaire subscales, the salpha was .51, .84, and .79 for the first administrion, and .57, .64, and .80 for the second administration, respectively. On the coping scales the alpha was .88, .70, and .72 for the first administration, and .86, .78, and .81 for the second administration. Based on these analyses, specific items may be deleted to improve the reliabilities.

Detail Summary Sheet

Date: 12 Oct 88 Proj No: C-15-86 Status: Completed

Title: Penicillin and Erythromycin Levels after Oral Administration in the Preoperative Oral and Maxillofacial Surgery Patients.

| | |
|---|---|
| Start Date 6 Feb 86 | Est Comp Date: |
| Principal Investigator<br>Michael E. Lessin, COL, DC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Dentistry/Oral Surgery | Associate Investigators:<br>Hugh M. Gelston, Jr., MAJ, MS |
| Key Words: | Sheila Jones, SSG |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 23 Mar 88 Results Completed

Objective(s): To establish whether adequate serum levels of penicillin or erythromycin are obtained after oral administration following current American Heart Association guidelines for the prevention of SBE in the patient undergoing elective or emergency removal of impacted teeth or infected teeth with associated periapical abscess, pericoronitis and/or associated space abscesses.

Technical Approach: Subjects in the study will not ordinarily need penicillin or erythromycin prophylaxis for the prevention of SBE. Dosages will be administered orally in the Oral Surgery Clinic according to the schema outlined in the study protocol.

Progress: From this study we concluded that oral administration of phenoxymethyl penicillin (penicillin V) in a 2 gm dose, in patients instructed to fast prior to an intravenous sedation procedure for third molar removal, appears to deliver concentrations of the drug sufficient to meet the therapeutic requirements for the attempted prevention of bacteremias. This was found in post administration times ranging from 30 to 60 minutes prior to surgery. Variations in patient compliance to the fasting rule, the rate of gastric emptying and levels of anxiety and their effects on drug absorption appear to have no adverse effect.

C-15-86 (continued)

For those practitioners who choose to use oral preparations of penicillin rather than intravenous, it is recommended that the 2 gm recommeded oral dose for SBE prophylaxis be administered in the office under supervision to insure compliance

Detail Summary Sheet

Date: 1 Nov 88 Proj No: C-74-87 Status: Ongoing

Title: Short Term High Dose Steroids in Orthognathic Surgery

| | |
|---|---|
| Start Date 12 Aug 87 | Est Comp Date: |
| Principal Investigator<br>John McLaughlin, LTC, DC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Dentistry/Oral Surgery | Associate Investigators: |
| Key Words:<br>Steroids<br>Surgery, Orthognathic | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review n/a Results _____

Objective(s): To determine the effects of high dose steroids on serum cortisol levels in oral surgery patients.

Technical Approach: Fifteen patients undergoing orthognathic and preprosthetic surgery will receive 20 mg of Decadron at the beginning of surgery and then 20 mg every two hours while they are in surgery. Postoperatively they will receive 8 mg of Decadron every six hours for 24 hours and then two intramuscular injections of 80 mg of Depo-Medrol on the morning after surgery and the following morning. Serum cortisol levels will be checked at the time of admission, immediately postoperatively on the day of surgery, postoperative day three which would correspond to maximum suppression, postoperative day frou which is after the delayed release steroid, then on a weekly basis until serum cortisol level returns to baseline.

Progress: The study has been temporarily suspended. No data has been collected to date, nor have any patients been enrolled in the study. We plan to activate the study when a new resident can be assigned to it.

Detail Summary Sheet

| Date: 8 Nov 88 | Proj No: C-16-88 | Status: Ongoing |
|---|---|---|

Title: Effects of Chlorhexidine Gluconate Oral Rinse Versus Normal Saline and Cepacol on the Incidence of Local Osteitis in Mandibular Third Molar Surgery

| Start Date 2 Dec 87 | Est Comp Date: |
|---|---|
| Principal Investigator<br>James E. Berwick, MAJ, DC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Dentistry/Oral Surgery | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 80

Total Number of Subjects Enrolled to Date: 80

Date of Periodic Review _____ Results _____

Objective(s): To determine whether a chlorhexidine gluconate containing oral rinse (Peridex) used as a preoperative rinse and intraoperative lavage agent will reduce the incidence of local osteitis following mandibular third molar surgery, in comparison to similar procedures with normal saline and Cepacol and no rinse.

Technical Approach: Patients participating in the study will be oral surgery outpatients requiring extraction of both mandibular third molars. The patients will be randomly divided into four groups. The first group will be asked to rinse with 15 cc of Peridex for one minute. Following the removal of the mandibular third molars, each of the surgical sites wil be lavaged with normal saline followed by Peridex diluted in saline. The second group will be treated the same, but Cepacol substituted for Peridex. The third group will have normal saline only used, and the fourth group will not receive a preoperative rinse, but will receive the standard intraoperative lavage with normal saline.

Progress: The clinical trial is complete. The raw data are undergoing initial evaluation. There were no complications with the study.

Detail Summary Sheet

Date: 12 Oct 88 Proj No: C-51-86 Status: Terminated

Title: Puncture Wounds of the Foot: A Randomized Prospective Study of Superficial Cleansing vs Epidermal Debridement in the Treatment of Superficial Puncture Wounds.

| | |
|---|---|
| Start Date 9 Jun 86 | Est Comp Date: |
| Principal Investigator (vice Sugg)<br>John F. Schlesser, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Emergency Medicine | Associate Investigators:<br>Daniel J. Boyle, MAJ, MC<br>Vern Peters, D.P.M. |
| Key Words:<br>Wounds, puncture | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 16 Jun 88 Results Continue

Objective(s): To evaluate two methods of wound care for superficial puncture wounds of the foot and to determine if there is a difference between superficial cleansing and epidermal debridement in the treatment of these plantar injuries in a prospective, randomized study.

Technical Approach: Patients eligible for this study will be assigned to one of two treatment groups. Both groups will have an x-ray to insure no boney involvement and will receive tetanus prophylaxis if indicated. The first group will receive local anesthesia and have the wound cleansed. The second group will also receive anesthesia and debridement of the skin around the puncture wound. They will be re-evaluated in three days and again at the end of two weeks to see how well the wound is healing and to determine if there is any infection.

Progress: This study terminated due to the fact that too may patients would be required to complete an adequate study (very low incidence of complications in this disease process).

Detail Summary Sheet

Date: 27 Oct 88 Proj No: C-66-86 Status: Ongoing

Title: The Antimicrobial Spectrum of Fresh Water Contaminated Wounds and the Incidence of Wound Infections Associated with These Injuries

| | |
|---|---|
| Start Date 8 Jul 86 | Est Comp Date: |
| Principal Investigator (Singletary)<br>Carey Chisholm, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Emergency Medicine | Associate Investigators: |
| Key Words:<br>Wound, contaminated<br>Wound, infection | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 18

Total Number of Subjects Enrolled to Date: 18

Date of Periodic Review 9 Sep 88 Results Continue

Objective(s): 1) To identify common fresh waterborn human pathogens involved in wounds acquired in or around fresh water bodies within the state of Texas.

2) To determine the incidence of wound infectins in wounds contaminated by fresh water.

3) To make recommendations for initial choice of antibiotics for wound infections caused by fresh water bacteria.

Technical Approach: Patients presenting for care to the BAMC Emergency Department with an acutely acquired (less than 24 hours) or infected wound that had been contaminated by fresh water will be studied. All wounds will be swabbed and culture swab sent for culture and antibiotic sensitivities.

Progress: Eighteen subjects entered with data retrieved during this reporting period. Plan to get preliminary report together and continue to enroll subjects.

Detail Summary Sheet

Date: 28 Oct 88 Proj No: C-67-86 Status: Ongoing

Title: The Choice of Antibiotics for Marine Acquired Wound Infections

| | |
|---|---|
| Start Date 8 Jul 86 | Est Comp Date: |
| Principal Investigator (Singletary)<br>Carey Chisholm, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Emergency Medicine | Associate Investigators: |
| Key Words:<br>Infection, marine acquired | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 9 Sep 88 Results Continue

Objective(s): 1) To identify the organisms responsible for infections of salt water contaminated wounds from the Texas/Gulf Coast region.

2) To determine antibiotic sensitivities for the pathogens involved in salt water exposed wound infections.

3) To make recommendations for the initial choice of antimicrobials to be utilized in treating salt water contaminated wounds pending culture results.

Technical Approach: All patients with an acutely acquired or infected wound with a history of salt water contamination will be initially eligible to participate in the study. All wounds will be swabbed for culture and sent for culture and sensitivity. If clinically indicated, debridement and/or suturing will e performed. Tetanus prophylaxis will be administered if indicated.

Progress: No subjects were enrolled during the summer; however, we plan to keep the study open.

Detail Summary Sheet

Date: 28 Sep 88 Proj No: C-17-87 Status: Ongoing

Title: Comparison of Diphenhydramine, Promethazine, and Placebo in Patients with Abdominal Pain

| | |
|---|---|
| Start Date 10 Feb 87 | Est Comp Date: |
| Principal Investigator<br>Robert N. Norris, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Emergency Medicine | Associate Investigators: |
| Key Words:<br>Pain, abdominal | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of subjects Enrolled to Date:

Date of Periodic Review 23 Mar 88 Results Continue

Objective(s): 1) To evaluate the relief of abdominal pain using Diphenhydramine and Promethazine.

2) To compare the efficacy of Diphenhydramine versus Promethazine in the treatment of abdominal pain.

Technical Approach: This is a prospective randomized, double blind study of patients between the ages of 18 and 60 years who are diagnosed as having gastroenteritis. Following evaluation, the patient will be asked to rate the severity of abdominal pain using the numerical scale 1 through 5. Patients will be randomized by the coding sequence - A, B, C. Diphenhydramine, Promethazine, and normal saline will be placed in letter coded vials whose contents will be unknown to the evaluators. The evaluator will obtain 1 cc from the corresponding vial which correlates Diphenhydramine, 50 mg; Promethazine, 25 mg: or normal saline. The fluid will be administered intravenously over two minutes. The patient will be asked to evaluate the severity of the abdominal pain at 15 minutes and 30 minutes using the same numerical scale.

Progress: Data are being analyzed.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: C-63-87 Status: Ongoing

Title: Role of Routine Radiographs in the Evaluation of Acute Knee Complaints in the Emergency Department

| | |
|---|---|
| Start Date 25 Jun 87 | Est Comp Date: |
| Principal Investigator<br>CPT Robert L. Norris, Jr. | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Emergency Medicine | Associate Investigators:<br>Peter Curka, CPT, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review n/a Results

Objective(s): To develop a set of high-yield criteria based on a careful history and physical examination in patients with acute knee complaints that will guide Emergency Department physicians in the ordering of knee radiographs.

Technical Approach: All patients 15 years of age and older presenting to the Emergency Department with a chief complaint of acute knee pain or dysfunction will be included in the study. A thorough history and orthopedic examination as outlined in the study form will be performed. The examining physician will then document whether or not he/she expects to find an abnormality on radiographic examination and what he/she expects that abnormality to be. Then in a retrospective manner, each case will be reviewed, comparing the examining physician's expectations and findings to the findings from the official radiologic report to determine whether the x-rays made any difference in the patient's diagnosis or management.

Progress: Approximately 700 cases have been reviewed. We are preparing to begin analysis with computer data base program.

Detail Summary Sheet

| Date: 1 Nov 88 | Proj No: C-73-87 | Status: Ongoing |
|---|---|---|

Title: The availability of Antivenin (Crotilidae) Polyvalent and Antivenin (Micrurus fulvius) in Texas Hospitals Providing Emergency Medical Care

| Start Date 12 Aug 87 | Est Comp Date: |
|---|---|
| Principal Investigator<br>William W. Collier, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Emergency Medicine | Associate Investigators:<br>Robert L. Norris, CPT, MC |
| Key Words:<br>Antivenin | |
| Accumulative MEDCASE<br>Cost: | Est Accumulative<br>OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To attempt to determine the actual supply and availability of antivenins against the venomous snakes indigenous to texas in hospitals providing emergency medical care in the State.

Technical Approach: A questionnaire will be sent to all pharmacy directors of hospitals in the State of Texas. The pharmacy director will be asked to quantitate his/her faciliti's antivenin supply curently in stock. Simultaneously, a questionnaire will be mailed to all directors of Emergency Departments/Emergency Rooms of hospitals in the State. They will be asked several pertinent questions regarding their facility's approach to the management of snakebite victims.

Progress: Data have been collected and are being analyzed.

Detail Summary Sheet

Date: 26 Jul 88 Proj No: C-78-87 Status: Terminated

Title: Maximal Inspiratory Pressure and Serum CPK in the Evaluation of Obstructive Airway Disease.

| | |
|---|---|
| Start Date 13 Aug 87 | Est Comp Date: |
| Principal Investigator<br>Patrick Jordan, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Emergency Medicine | Associate Investigators:<br>Mark Larsen, COL, MC |
| Key Words:<br>Obstructive airway disease | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 20

Total Number of Subjects Enrolled to Date: 20

Date of Periodic Review 15 Jun 88 Results Terminated

Objective(s): To discover if the measurement of maximal inspiratory pressure (MIP) and serum CPK serve as prognostic factors in the evaluation of patients with obstructive airway disease (asthma and COPD).

Technical Approach: Twenty subjects presenting to the Emergency Department with an acute exacerbation of their asthma or COPD were included in the study. A MIP gauge reading was performed on each patient before and after treatment. A Wright's spirometer was utilized to obtain expiratory flow before and after treatment. Pulsus paradoxus was recorded at time of initial evaluation and post treatment.

Progress: Projected was delayed for a period of eight months because of equipment failure. Only 20 patients were enrolled; however, no conclusive results could be obtained on such a small number.

Both investigators have PCS'd; therefore, the study is terminated.

Detail Summary Sheet

Date: 27 Oct 88 Proj No: C-89-87 Status: Ongoing

Title: Prognostic Predictive Value of the Clinical/Hemodynamic Classification Schema of Left Ventricular Performance in Acute Myocardial Infarction Determined at the Time of Presentation and 72 Hours Post-Admission

| | |
|---|---|
| Start Date 21 Sep 87 | Est Comp Date: |
| Principal Investigator<br>Brenda A. Gowesky, CPT, USAF MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Emergency Medicine | Associate Investigators:<br>Ricky D. Latham, MAJ, MC |
| Key Words:<br>Infarction, myocardial | Lawrence Pupa, MAJ, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 9 Sep 88 Results Continue

Objective(s): 1) To determine the predictive value of the Killip classification in acute myocardial infarction for short term prognosis.

2) To correlate the Forrester classification documented by invasive measurements as well as noninvasive assessment of left ventricular function with the Killip classification and prognosis.

Technical Approach: Patients arriving in the Emergency Room at BAMC with a chief complaint of chest pain and/or shortness of breath will be entered into the study. It is the object of this study to correlate noninvasive Killip with the invasive monitoring of the Forrester classification and to correlate these with hospital mortality and prognosis. Residents will assess the patient and complete a questionnaire.

Progress: No progress has been made due to lack of assistance from the resident staff and the rigid rotation schedule of the principal investigator. It is anticipated that the study will be initiated and completed within the next six months.

Detail Summary Sheet

| Date: 27 Oct 88 | Proj No: C-92-87 | Status: Terminated |
|---|---|---|

Title: A 12 Year Retrospective Analysis of MICU Experience at BAMC

| Start Date 21 Sep 87 | Est Comp Date: |
|---|---|
| Principal Investigator<br>David L. Glendening, COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Emergency Medicine | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE<br>Cost: | Est Accumulative<br>OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): 1) To evaluate the impact of population aging on MICU Services at BAMC.

2) To compare demographic trends in sex, mean annual age of admissions, and death for the MICU population and all adult admissions to BAMC and Department of Medicine during the 12 year period 1974-1985.

Technical Approach: This is a retrospective chart review of admissions to MICU.

Progress: Study was terminated before review was completed.

Detail Summary Sheet

Date: 8 Noc 88 Proj No: C-13-82 Status: Ongoing

Title: Intracardiac Pressure and Flow Changes Following Amyl Nitrite Inhalation.

| | |
|---|---|
| Start Date 8 Jan 82 | Est Comp Date: |
| Principal Investigator<br>Steven Bailey, M.D., MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators:<br>Bernard J. Rubal, Ph.D., DAC |
| Key Words:<br>Intracardiac pressure | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 9

Date of Periodic Review 23 Mar 88 Results Completed

Objective(s): To better understand the hemodynamic events responsible for the auscultatory changes following amyl nitrite inhalation in normal man.

Technical Approach: Patients on no medical therapy who are felt to be probably normal are offered a chance to participate after a routine heart catheterization using a 3 sensor catheter in the right heart and a 2 sensor catheter in the left heart. They inhale amyl nitrite and the intracardiac pressure and flow response is recorded.

Progress: Even though this study has been completed, it remains open for data analysis.

Detail Summary Sheet

Date: 12 Sep 88 Proj No: C-51-83 Status: Ongoing

Title: Use of Isotretinoin in Prevention of Basal Cell Carcinoma.

| | |
|---|---|
| Start Date 16 Jun 83 | Est Comp Date: |
| Principal Investigator<br>Stuart J. Salasche, M.D., COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Dermatology | Associate Investigators:<br>Catherine Pollard, R.N. |
| Key Words:<br>Basal cell carcinoma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date: 168

Date of Periodic Review 11 Mar 88 Results Continue

Objective(s): To evaluate the effectiveness of low dosage levels of isotretinoin in reducing the incidence of basal cell carcinomas in a high risk population; to examine possible side effects associated with long term administration of low doses of isotretinoin.

Technical Approach: Patients having at least two basal cell carcinomas in the last five years are contacted. If interested in participation, they are screened according to protocol. If all inclusion factors are met, they are randomized and begun on medication or placebo. After beginning medication, follow-up will occur at two weeks, three months, six months and every six months thereafter for the duration of the study. Patients are on medication for three years and have follow-up for two years afterward. Physical exams are done yearly. History, laboratory data, total skin exam, and necessary biopsies are done at each visit. Lateral cervical and thoracic spine films are done at 0 and 36 months on each patient and at 6, 12, or 18 months depending on entry date.

Progress: Patient accrual is complete. One hundred sixty eight patients have been enrolled and patient compliance has been extremely high - in excess of 90%. Close monitoring of patients on study will continue for approximately three years.

Detail Summary Sheet

| Date: 12 Oct 88 | Proj No: C-18-84 | Status: Ongoing |
|---|---|---|

Title: Congestive Cardiomyopathy: Evaluation of Transvenous Myocardial Biopsy and Treatment with an Anti-Inflammatory Regimen.

| Start Date 16 Mar 84 | Est Comp Date: |
|---|---|
| Principal Investigator<br>Ricky D. Latham, M.D., MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators:<br>John P. Mulrow, MAJ, MC<br>Bernard J. Rubal, Ph.D.<br>Renu Virmani, MAj, MC, AFIP<br>Max Rabinowitz, M.D., AFIP<br>James Baker, M.D., WRAMC<br>Stephen Ramee, CPT, MC, LAMC |
| Key Words:<br>Cardiomyopathy, congestive | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: $3373.00 |

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 49

Date of Periodic Review 23 Mar 88 Results Continue

Objective(s): To assess the efficacy of using an endomyocardial biopsy technique in the diagnosis and management of congestive cardiomyopathy by identifying specific etiologies and/or those patients with an inflammatory cellular reaction.

Technical Approach: Patients undergo complete noninvasive assessment with laboratory echocardiogram, MUGA, and Gallium. Then, if eligible, endomyocardial biopsy is performed. NIH interprets the histology and Hahnemann University does immunological assessment. Patients must have cath proven normal coronary arteries. Patients should be randomized to Prednisone and noninvasive studies repeated in 6 months, 12 months, and 18 months.

Protocol has been amended to include left heart biopsy.

Progress: The following results are furnished: (a) Prednisone afforded no effect on survival; (b) 100% biopsies with myocarditis were normal in three months, and (c) increased RVEDP was associated with increased mortality.

Detail Summary Sheet

Date: 12 Oct 88 Proj No: C-19-84 Status: Ongoing

Title: Dypyridamole MUGA Studies Compared with Quantitative Tomographic Stress and Dypyridamole Infusion TL201 Scintigrams for Assessing Coronary Artery Disease.

| | |
|---|---|
| Start Date 16 Mar 84 | Est Comp Date: |
| Principal Investigator<br>Ricky D. Latham, M.D., MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators:<br>Michael Cawthon, M.D., MAJ, MC |
| Key Words:<br>Coronary artery disease | Michael F. Hartshorne, M.D., MAJ, MC<br>Joseph P. Murgo, M.D., COL, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 23 Mar 88 Results Continue

Objective(s): To assess the sensitivity of dypyridamole MUGA study as compared to dypyridamole infusion TL 201 studies to detect significant coronary artery disease.

Technical Approach: IV Persantine, 60 mg/kg, is given over 4 minutes. $TL^{201}$ is given 2 minutes after infusion. For MUGA, $TCM^{99}$ is given and rest study performed before infusion. Studies are then done at 3 minute intervals x 4. All patients are submitted to cardiac catheterization and results of anatomy are determined.

Phase II approach changed and approved by IRB to use ventriculography instead of DSA.

Progress: Results show dypyridamole MUGA has 63% sensitivity and >95% specificity. $TL^{201}$ false positive rate was 11%. No ventriculographic changes were seen.

Detail Summary Sheet

Date: 12 Sep 88 Proj No: C-32-84 Status: Terminated

Title: Effect of Discontinuance of Smoking on Gastroesophageal Reflux.

| | |
|---|---|
| Start Date 10 May 84 | Est Comp Date: |
| Principal Investigator<br>Fred Goldner, M.D., COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Gastroenterology | Associate Investigators: |
| Key Words:<br>Gastroesophageal reflux | |
| Accumulative MEDCASE<br>Cost: $9,920.00 | Est Accumulative<br>OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Jun 88 Results Terminated

Objective(s): To determine if discontinuance of cigarette smoking will decrease gastroesophageal reflux in a population of smokers with pyrosis.

Technical Approach: Ambulatory 24 hour pH monitoring technology will be applied to a group of smoking patients with pyrosis before and after discontinuance of smoking. A standard set of criteria will be applied to determine if the discontinuance of smoking has a significant effect on gastroesophageal reflux.

Progress: Study terminated due to other duty responsibilities of the principal investigator.

Detail Summary Sheet

Date: 8 Aug 88 Proj No: C-43-84 Status: Completed

Title: Assessment of Radiocontrast Induced Acute Renal Failure Following Coronary Angiography: An Evaluation of Intravenous Mannitol Infusion as a Preventive Measure.

| | |
|---|---|
| Start Date 17 Jul 84 | Est Comp Date: |
| Principal Investigator (vice Condos)<br>Alan Kono, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators:<br>Steven Bailey, MAJ, MC<br>J. Brian Copley, COL, MC |
| Key Words:<br>Angiography, Coronary<br>Renal failure | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date: 41

Date of Periodic Review 2 Nov 87 Results Completed

Objective(s): To determine the incidence of radiocontrast-induced acute renal failure in a high risk subgroup following selective cardiac angiography, to determine the effects of hemodynamic status on this incidence, and to compare the effect of intravenous mannitol infusion following angiography as compared to placebo on the incidence of development of acute renal failure.

Technical Approach: Forty-one patients with chronic renal insufficiency or diabetes mellitus undergoing diagnostic cardiac catheterization (Cath) were prospectively enrolled. Patients were randomized to receive Mannitol, 50 gm (n=21), or 125 cc saline at the end of the angiography (n=20). Serial BUN and creatinines were evaluated for 72 hrs. Renal failure was defined as a rise in creatinine by >25%.

Progress: The incidence of renal failure was the same in both groups. Cardiac output, LV end-diastolic pressure, and ejection fraction failed to predict patients at risk for renal failure. Renal failure predictors were older age ($65\pm10$ vs $56\pm8$ yrs; $p < 0.21$) and prior renal insufficiency (CR=$2.2\pm.9$ vs $1.3\pm.6$; $p < .01$).

We conclude that Mannitol is not effective in preventing renal failure in high risk patients and hemodynamic parameters do not predict renal failure.

Detail Summary Sheet

Date: 12 Sep 88 Proj No: C-50-84 Status: Terminated

Title: The Effect of Weight Loss on Gastroesophageal Reflux.

| | |
|---|---|
| Start Date 22 Aug 84 | Est Comp Date: |
| Principal Investigator<br>Fred Goldner, M.D., COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Gastroenterology | Associate Investigators: |
| Key Words:<br>Gastroesophageal reflux | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 9 Sep 88 Results Terminated

Objective(s): To determine if weight loss achieved through caloric restriction will improve gastroesophageal reflux of acid.

Technical Approach: 24-hour ambulatory pH testing will be performed on a group of obese subjects with pyrosis, before and after weight loss. A standard set of reflux criteria will be applied to determine if weight loss affects the degree of gastroesophageal reflux.

Progress: No patients were entered on the study. Study terminated due to other obligations of principal investigator.

Detail Summary Sheet

Date: 8 Nov 88 Proj No: C-73-84 Status: Ongoing

Title: Comparison of Micromanometer Tip Left Atrial Catheter Monitoring with Fluid Pulmonary Artery Pressure Monitoring in Postoperative Open Heart Surgery Patients, a Trend Analysis in the SICU.

| | |
|---|---|
| Start Date 25 Sep 84 | Est Comp Date: |
| Principal Investigator (vice Bailey)<br>John W. McClure, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators:<br>Ricky D. Latham, MAJ, MC<br>Bernard J. Rubal, Ph.D.<br>Steven R. Bailey, MAJ, MC |
| Key Words:<br>Catheter, left atrial | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 4

Total Number of Subjects Enrolled to Date: 4

Date of Periodic Review 9 Sep 88 Results

Objective(s): To compare the pressures obtained from a high fidelity, micromanometer transducer mounted on a left atrial catheter to those obtained from a flow-directed, balloon-tipped catheter in the pulmonary artery in patients recovering from open heart surgery.

Technical Approach: At the time of surgery, a micromanometer tip left atrial catheter will be inserted through the pulmonary vein into the atrium. A flow-directed, balloon-tipped catheter will be inserted into the pulmonary artery in the routine manner. Pressure and blood gas measurements will be recorded at two hour intervals or more often if indicated. Analysis will continue until the catheters are removed.

Progress: Four patients have been entered. No significant reportable data are available at this time.

Detail Summary Sheet

Date: 12 Sep 88 Proj No: C-38-85 Status: Terminated

Title: Carbohydrate Binding by Activated Charcoal In Vivo and In Vitro and Its Effect on the Production of Breath Hydrogen.

| | |
|---|---|
| Start Date 29 Apr 85 | Est Comp Date: |
| Principal Investigator<br>Bernard Feldman, M.D., CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine | Associate Investigators<br>Fred Goldner, M.D., COL, MC<br>Regina Marshall, R.N |
| Key Words:<br>Carbohydrate binding<br>Breath hydrogen | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Jun 88 Results Terminated

Objective(s): To assess the efficacy of activated charcoal in binding carbohydrates in the GI tract.

Technical Approach: A fasting breath hydrogen sample will be obtained. After ingesting the carbohydrate, subjects will blow a sample of their breath into special Mylar-coated foil bags and stored until analyzed. They will be asked to obtain samples hourly for eight hours and will be given a diary to record symptoms. Samples will be analyzed and a rise of greater than 20 parts per million of hydrogen gas over fasting concentration will be interpreted as carbohydrate malabsorption. Comparison will be made between the treated and placebo groups to determine if activated charcoal can bind carbohydrate and prevent fermentation and production of breath hydrogen.

Progress: Protocol terminated due to transfer of principal investigator.

Detail Summary Sheet

Date: 12 Sep 88 Proj No: C-49-85 Status: Ongoing

Title: Skin Test Responses to Wholebody Fireant Extracts: Allergic vs. Irritant Reactivity.

| | |
|---|---|
| Start Date 10 Jun 85 | Est Comp Date: |
| Principal Investigator<br>Ana A. Ortiz, M.D., COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Allergy | Associate Investigators:<br>Dane C. McBride, M.D., MAJ, MC |
| Key Words:<br>Fireant extrcts | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date: 20

Date of Periodic Review 16 Jun 88 Results Continue

Objective(s): To define a range of dilutions of imported fireant (IFA) whole-body extracts which will differentiate patients with immediate (Type I) hypersensitivity to imported fireants from those with negative or irritant responses to skin testing.

Technical Approach: Once participants have been classified into one of the three study groups, they will complete a questionnaite. They will then be skin tested by the prick method with commercially produced IFA wholebody extracts. Participants will also be skin tested by the intradermal method to IFA wholebody extracts.

Progress: No reportable data are available at this time.

Detail Summary Sheet

| Date: 12 Sep 88 | Proj No: C-9-86 | Status: Completed |
|---|---|---|

Title: Validation of Formula for QRS Prediction Utilizing QRS Duration and R-R Interval

| Start Date 19 Jun 87 Reopened | Est Comp Date: |
|---|---|
| Principal Investigator<br>James K. Gillman, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators:<br>John P. Mulrow, M.D. |
| Key Words:<br>Electrocardiography | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date: 180

Date of Periodic Review 23 Mar 88 Results Completed

Objective(s): To validate a new formula for Q-T prediction developed from the European Communities Project on Common Standards in Quantitative Electrocardiography (CSE) utilizing QRS Duration and R-R interval.

Technical Approach: ECG's will be performed using standard multichannel Marquette HC equipment. Computer determined values for QRS duration, R-R interval, and Q-T interval will be utilized in both the CSE formula and Bazett's formula for Q-T prediction. All ECG's will be measured blindly to verify T wave offset by one of the investigators.

Bazett's and the CSE formulae will be compared for the prediction of QT interval. Additionally, the CSE formula developed in Europe will be compared to the equation derived from the Sam Antonio study.

Progress: Review of data at time of presentation to the Association of American Cardiologists meeting in San Francisco indicated that there would be no benefit from enrolling additional subjects on this study.

Detail Summary Sheet

| Date: 12 Sep 88 | Proj No: C-12-86 | Status: Terminated |
|---|---|---|

Title: Dipyridamole Echocardiography for the Detection of Coronary Artery Disease.

| | |
|---|---|
| Start Date 16 Jan 86 | Est Comp Date: |
| Principal Investigator (vice Hoadley)<br>Ricky D. Latham, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators:<br>Michael Crawford, M.D.<br>John M. Bauman, MAJ, MC |
| Key Words:<br>Echocardiography | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: 166.00 |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review 23 Mar 88 Results Continue

Objective(s): To assess the sensitivity, specificity, and predictive value of echocardiography during dipyridamole infusion for the presence of coronary artery disease.

Technical Approach: Two-dimensional echocardiography (2DE) and TI-201 scintigraphy (TS) have been used successfully with intravenous dipyridamole (D) for detecting coronary artery disease (CAD), but no comparative data exists. Thus, we studied 47 patients (pts) with chest pain syndromes and no prior infarctions; 22 with and 25 without CAD by cardiac catheterization. Biapical 2DE and planar TS were obtained immediately after 0.9 mg/kg D and compared to appropriate control images in a blinded fashion.

Progress: Following transfer of principal investigator (MAJ Hoadley), it was impossible to complete the data acquisition and analysis. Therefore, the study is terminated.

Detail Summary Sheet

| Date: 12 Oct 88 | Proj No: C-23-86 | Status: Completed |
|---|---|---|

Title: The Role of Intravenous Immune Globulin in 10% Maltose-pH 4.25 in Reducing the Mortality and Morbidity of Infection in Cancer Patients at Risk for Severe Neutropenia.

| | |
|---|---|
| Start Date 26 Feb 86 | Est Comp Date: |
| Principal Investigator<br>Robert N. Longfield, LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Infectious Dis. | Associate Investigators: |
| Key Words:<br>Globulin, immune | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 2

Total Number of Subjects Enrolled to Date: 12

Date of Periodic Review 23 Mar 88 Results Continue

Objective(s): To determine if prophylactic administration of high-dose IG IV to patients undergoing intensive cancer chemotherapy reduces the morbidity and mortality from infectious complications.

Technical Approach: The clinical efficacy of high dose intravenous immunoglobulin in preventing or ameliorating infections in neutropenic patients is being evaluated in a double blind - placebo controlled - multicenter trial. Consenting patiens are given weekly infusions of study agent coinciding with the onset of chemotherapy and continuing until the absolute neutrophil count rises above $500/mm^3$. Antibiotic therapy, febrile episodes and proved infections are recorded for further analysis.

Progress: The multicenter trial has been completed and case report forms have been sent to Dr. Barry Kramer at the NCI-Navy Oncology Program at Bethesda Naval Hospital. No major side effects have been attributed to IVIG during the study. One BAMC patient who received IVIG (active agent) was severely neutropic for more than six months of intensive chemotherapy and has survived to present in complete remission.

Detail Summary Sheet

Date: 8 Nov 88 Proj No: C-30-86 Status: Ongoing

Title: Incidence and Significance of a Presystolic "A-Wave" as Determined by Doppler Echocardiography.

| | |
|---|---|
| Start Date 12 Mar 86 | Est Comp Date: |
| Principal Investigator<br>Joseph P. Johns, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators:<br>Stephen D. Hoadley, MAJ, MC |
| Key Words:<br>Echocardiography, Doppler | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: 1,190.16 |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date: 77

Date of Periodic Review 23 Mar 88 Results Completed

Objective(s): To assess the frequency and hemodynamic significance of a presystolic Doppler "A-wave", as observed in the left ventricular outflow tract.

Technical Approach: The presence of a presystolic wave has been shown in previous doppler studies of the pulmonary artery. To examine and the presence and significance of this wave in the LVOT, two approaches are being taken. (1) Noninvasive echo/doppler studies of normal patients are being compared to patients with HTN, LVH, or aortic stenosis. (2) Simultaneous doppler and left ventricular pressure measurements are being obtained in an attempt to define significance of this finding.

Progress: The pre-ejection wave appears nearly spontaneously with a pressure impulse in aortic root tracings. It is anticipated that two additional patients will need to be enrolled before preliminary inspection of data.

Even though at the time of annual review this study was reported as completed, it remains open for additional patient accrual.

Detail Summary Sheet

Date: 12 Sep 88 Proj No: C-34-86 Status: Completed

Title: A Trial Combination of Alpha-2 IFN and Gamma IFN in Advanced Malignant States.

| | |
|---|---|
| Start Date 4 Apr 86 | Est Comp Date: |
| Principal Investigator<br>Thomas D. Brown, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Oncology | Associate Investigators:<br>Timothy J. O'Rourke, LTC, MC<br>Kenneth Beougher, MAJ, MS |
| Key Words:<br>Interferon, Alpha-2<br>Interferon, Gamma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date: 21

Date of Periodic Review 16 Jun 88 Results Completed

Objective(s): 1) To determine the safety/toxicity of IFN gamma when given in combination with IFN Alpha-2 in patients with advanced malignant disease.

2) Although efficacy is not a primary objective, periodic evaluations for response will be made.

Technical Approach: This will be an open label study of approximately 18 patients with advanced malignancy for whom no known standard treatment exists. Patients will be entered sequentially to the first dose level. The next dose level should not be opened to potent entry until a safety and tolerance has been assessed at the previous level.

Progress: In this study, AIFN was given at a fixed dose of $2.0 \times 10^6$ SC every other day 3 days a week and GIFN was given at excalating doses by a 2-hour IV infusion daily for 5 days every other week. Dose excalation for individual patients was not allowed. Twenty-one patients received 40 evaluable 4 week courses at 6 dose levels. In addition, to routine clinical and laboratory monitoring, 18 patients had Holter monitoring for 5 days prior to therapy and during the first 5 days of therapy. Toxicities of WHO grade 3 included fever and flu-like symptoms (9 patients), nausea and vomiting (2 patients), leukopenia (4 patients and granulocytopenia (3 patients). Toxicities of WHO grad 1 or 2 included transient abnormal liver function tests and hypotension. These toxicities were not dose related.

C-34-86 (continued)

This study was closed prior to reaching a maximally tolerated dose at the request of the sponsor (Schering Corp.). They felt that the observed toxicity, along with the disappointing early results with alpha and gamma IFN in phase II studies, did not support further investigation of this schedule.

Detail Summary Sheet

| | | |
|---|---|---|
| Date: 8 Nov 88 | Proj No: C-55-86 | Status: Ongoing |

Title: Right Heart Flow Dynamics ("Flow Dynamics in the Right Ventricular Outflow Tract" previous title)

| | |
|---|---|
| Start Date 12 Jun 86 | Est Comp Date: |
| Principal Investigator (vice Hoadley)<br>Joseph Johns, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators:<br>Randy Condos, LTC, MC |
| Key Words:<br>Ultrasound, Doppler | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 6

Total Number of Subjects Enrolled to Date: 12

Date of Periodic Review 16 Jun 88 Results Continue

Objective(s): To use Doppler ultrasound combined with high fidelity pressure measurements in the right ventricular outflow tract and proximal pulmonary artery to determine the pressure-flow relationships in that region.

Technical Approach: A complete two-dimensional and M-mode echocardiographic examination will be performed with particular attention to discovering right heart valvular disease or intracardiac shunts. Right heart catheterization with a Millar high-fidelity triple tip catheter will be performed in the standard manner. The electromagnetic flow probe will be calibrated using simultaneous Fick and thermal dilution cardiac outpus. This will be used to correlate with the doppler flow probe. Doppler ultrasound will be calibrated in the usual manner, ensuring that each strip chart has a "menu" with a stop-frame 2-D echo.

A two-way split-plot ANOVA was performed on 12 patients to assess the effect of Index of hypertrophy (IH) and age on maximum pre-ejection flow (PE) velocity.

Progress: From preliminary evaluation of the data it was concluded that PE velocity is affected by age and does not represent a useful noninvasive index of LV contractile performance in hypertrophy.

Detail Summary Sheet

Date: 12 Sep 88 Proj No: C-56-86 Status: Terminated

Title: Splitting of the Second Heart Sound in Constrictive Pericarditis.

| | |
|---|---|
| Start Date 12 Jun 86 | Est Comp Date: |
| Principal Investigator<br>Lawrence E. Pupa, Jr., MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators:<br>Stephen R. Bailey, MAJ, MC |
| Key Words:<br>Pericarditis | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 8

Total Number of Subjects Enrolled to Date: 8

Date of Periodic Review _____ Results _____

Objective(s): To evaluate the respiratory variation of the aortic and pulmonary components of the second heart sound in patients with constrictive pericarditis.

Technical Approach: Retrosepctive analysis of cases of constrictive pericarditis will be performed from among the data already obtained over the past 10 years at BAMC. All data will be analyzed by comparing at least six resting respiratory cycles in each patient at peak inspiration and end-expiration, analyzing for changes in the time intervals as well as the total $Q\text{-}A_2$ and $Q\text{-}P_2$ intervals.

Progress: Study terminated due to lack of adequate data on retrospective analysis.

Detail Summary Sheet

Date: 12 Sep 88 Proj No: C-60-86 Status: Ongoing

Title: The Natural History of HTLV-III Infection and Disease in a United States Military Population.

| | |
|---|---|
| Start Date 25 Jun 86 | Est Comp Date: |
| Principal Investigator<br>C. Kenneth McAllister, COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Infectious Dis. | Associate Investigators: |
| Key Words:<br>HTLV-III | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): 1) To assess the impact of HTLV-III infection on fitness for duty (deployability, military readiness and retention) by systematically defining the natural disease progression in individuals with documented HTLV-III infections in the general military population (active duty, dependents and retirees).

2) To form an information basis and a study cohort upon which number other studies can be built (i.e., drug treatment of HTLV-III, etc.)

Technical Approach: Each HTLV-III infected individual will be staged according to the Walter Reed Staging Classification. The only additional requirements of individuals enrolled in this study are (1) additional information gathered from each individual as a consequence of this study will be centralized in a common data base; (2) serum and CSF will be stored at WRAIR for future testing.

Progress: Data continues to be collected and is to be analyzed by the Preventive Medicine Service at Walter Reed Army Institute of Research.

Detail Summary Sheet

Date: 28 Oct 88 Proj No: C-63-86 Status: Terminated

Title: A Descriptive Study of the Relationships Between Perceived Level of Social Support and Self-Reported Symptoms of Stress in Hemodialysis Patients and Their Spouses.

| | |
|---|---|
| Start Date 8 Jul 86 | Est Comp Date: |
| Principal Investigator<br>Cynthia Collins, RN | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Nephrology | Associate Investigators:<br>John B. Copley, LTC, MC |
| Key Words:<br>Hemodialysis<br>Stress | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 9 Sep 88 Results Terminate

Objective(s): To examine the relationships between perceived level of social support and self-reported symptoms of stress, as identified by both hemodialysis patients and their spouses.

Technical Approach: This study is directed towards the observation and analysis of three interrelated research problems:

1. How does an individual's perceived level of social support influence his/her self-reported symptoms of stress?

2. What relationship exists between a hemodialysis patient's self-reported stress symptoms and his/her spouse's perception of social support availability?

3. What is the relationship between the patient-spouse combined measures of perceived social support and the spouse's self-reported stress symptoms?

Progress: Principal investigator moved without leaving forwarding address. Therefore the study was terminated.

Detail Summary Sheet

Date: 12 Sep 88 Proj No: C-70-86 Status: Terminated

Title: The Use of Nebulized Cromolyn in Status Asthmaticus

| | |
|---|---|
| Start Date 12 Aug 86 | Est Comp Date: |
| Principal Investigator<br>Gabriel E. Gonzalez, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Allergy | Associate Investigators:<br>Ana A. Ortiz, LTC, MC |
| Key Words:<br>Asthma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 9 Sep 88 Results Terminated

Objective(s): To determine whether nebulized cromolyn can alter the immediate and the post-hospitalization period of status asthmaticus.

Technical Approach: Patients admitted from the ER or specialty clinics with the diagnosis of status asthmaticus will be entered into the study. All asthmatics will be treated according to established criteria. Patients will be randomly assigned to two study groups. Group I will receive 20 mg of nebulized cromolyn and Group II will be given nebulized saline.

Progress: Study terminated due to release from active duty of the principal investigator.

Detail Summary Sheet

| Date: 12 Sep 88 | Proj No: C-74-86 | Status: Ongoing |
|---|---|---|

Title: Intensive Chemotherapy, Delayed Local Irradiation, Total Body Irradiation and Autologous Bone Marrow Rescue in Treating High Risk Ewing's Sarcoma

| | |
|---|---|
| Start Date 12 Aug 86 | Est Comp Date: |
| Principal Investigator (vice Harvey)<br>Richard O. Giudice, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Oncology | Associate Investigators:<br>Timothy J. O'Rourke, LTC, MC<br>Paul J. Thomas, COL, MC<br>Barbara Reeb, GS-9<br>John J. Posch, Jr., GS-11 |
| Key Words:<br>Sarcoma, Ewing's | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 9 Sep 88 Results Continue

Objective(s): 1) To improve disease-free survival of patients with Ewing's sarcoma having a high risk of treatment failure.

2) To test the effectiveness of intensive induciton chemotherapy, delayed RT to the primary tumor and TBI with ABMR.

3) To test the toxicity of such a regimen.

4) To test the accuracy of currently available staging techniques and monitoring techniques in recognizing residual primary and metastatic tumor.

5) To test whether tumor size independently of other variables predicts long-term disease-free survival.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a collaborative study with the University of Florida, Gainesville, FL. Patient accrual has been extremely slow.

Detail Summary Sheet

Date: 9 Sep 88 Proj No: C-77-86 Status: Completed

Title: A Phase I Evaluation of DUP 785 in Cancer Patients on a Single Daily Intravenous Dosing Schedule Over a 5-Day Period

| | |
|---|---|
| Start Date 14 Aug 86 | Est Comp Date: |
| Principal Investigator (vice Brown)<br>Timothy J. O'Rourke, LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Oncology | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 11

Total Number of Subjects Enrolled to Date: 26

Date of Periodic Review 10 Sep 87 Results Completed

Objective(s): 1) To determine the maximally tolerated dose of DUP 785 in cancer patients following intravenous dose administration over a 5-day period, with repeats every four weeks.

2) To determine the qualitative and quantitative and reversibility of adverse reactions of DUP 785 administered in this fashion.

3) To determine the dose limiting toxicity of DUP 785.

4) To determine the pharmacokinetics of DUP 785.

5) To document any antitumor activity of DUP 785 in cancer patients.

Technical Approach: All patients with histologic proof of malignancy who are not candidates for known regimens or protocol treatments of higher efficacy or priority are eligible. Patients must have a life expectancy of at least eight weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was completed within the last year. Excellent tolerated dose of DUP 785 in daily x 5 intravenous schedule was 250mg/$M^2$ for good risk patients. The recommended phase II dose for good risk patients was 250mg/$M^2$ and for poor risk patients 135 mg/$M^2$. Dose limiting toxicities included thrombocytopenia, dermatitis, and mucositis. Other toxicities included nausea and vomiting, malaise, anorexia, diarrhea, phlebitis, possible transaminase elevation, anemia, granulocytopenia, and leukopenia. There were no drug related deaths.

Detail Summary Sheet

| Date: 27 Oct 88 | Proj No: C-85-86 | Status: Terminated |
|---|---|---|

Title: Evaluation of Right and Left Ventricular Performance During V.V.I. and D.V.I. Pacing

| Start Date 8 Sep 86 | Est Comp Date: |
|---|---|
| Principal Investigator<br>John P. Mulrow, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators:<br>A. Pasipoularides, M.D., Ph.C. |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 9 Sep 88 Results Terminated

Objective(s): To describe ejection and hemodynamic parameters for right and left ventricular function before and during cardiac pacing.

Technical Approach: Eligible patients will be divided into three groups as follows: Group A - Ten patients with normal ventricular function demonstrated by a normal EKG, chest x-ray, cardiopulmonary physical examination, and echocardiogram; Group B - ten patients with a history of single myocardial infarction documented by prior hospitalization or EKG; Group C - ten patients with global left ventricular dysfunction demonstrated by physical examination, chest x-ray, and EKG, who demonstrate no symptoms of ischemic heart disease and have normal coronary anatomy. Each group will undergo resting and left Millar triple-tip hemodynamics with flow and determination of cardiac output followed by atrioventricular pacing with decreased atrioventricular conduction time. Atrioventricular pacing will then be terminated and V.V.I. pacing will commence. Right and left Millar triple-tip hemodynamics with flow and thermal dilution during V.V.I. will be performed.

Progress: Study terminated due to release from active duty of principal investigator.

Detail Summary Sheet

Date: 28 Oct 88 Proj No: C-94-86 Status: Ongoing

Title: Human Pyloric Response to Intraduodenal Blood: A Manometric Study

| | |
|---|---|
| Start Date 29 Sep 86 | Est Comp Date: |
| Principal Investigator<br>Julian E. Armstrong, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Gastroenterology | Associate Investigators:<br>Fred Goldner, COL, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 5

Total Number of Subjects Enrolled to Date: 5

Date of Periodic Review 9 Sep 88 Results Continue

Objective(s): To determine the association between the presence of blood in the duodenum and pyloric manometric response.

Technical Approach: Forty patients will be studied; 20 would be controls (normal endoscopic exam of duodenum) and 20 patients would have duodenal ulcers. All patients would undergo endoscopi exam in the standard manner. At the completion of the diagnostic exam, pyloric sphincter measurements will be made.

Progress: Five patients have been studied to date without incident. Due to transfer of principal investigator, the project has been temporarily halted. However, request keeping the project open pending assignment of new principal investigator.

Detail Summary Sheet

| | | |
|---|---|---|
| Date: 8 Nov 88 | Proj No: C-2-87 | Status: Ongoing |

Title: Percutaneous Transluminal Valvuloplasty in Adult Mitral/Aortic Stenosis

| | |
|---|---|
| Start Date 19 Nov 87 | Est Completion Date: |
| Principal Investigator<br>Steven R. Bailey, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators:<br>Robert A. Helsel, COL, MC<br>Brent A. Grishkin, COL, MC |
| Key Words:<br>Stenosis, aortic<br>Stenosis, mitral | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 3

Total Number of Subjects Enrolled to Date: 3

Date of Periodic Review 8 Nov 88 Results Continue

Objective(s): To apply the technique of percutaneous balloon dilatation of valvular aortic/mitral stenosis to a patient population at high risk of morbidity and mortality from aortic/mitral valve replacement and/or chronic anticoagulation.

Technical Approach: All patients age 21 or older with hemodynamically proven symptomatic aortic stenosis of either calcific/degenerative or congenital etiologies or patients age 21 or older with hemodynamically proven, significant mitral valve stenosis will be eligible if they are clinically considered to be a high risk for surgical valve replacement or chronic anticoagulation. Cardiac catheterization and valvuloplasty will be performed as outlined in the study protocol.

Progress: Three patients have been enrolled - 2 mitral and 1 aortic . However, the one patient with aortic stensis did not have valvuloplasty since AV area was >.9 $cm^2$. One mitral valvuloplasty was successful; the second sustained a left ventricular performation with death in the operating room.

Detail Summary Sheet

Date: 31 Oct 88 Proj No: C-8-87 Status: Completed

Title: Effect of Fish Oil Supplementation on Essential Hypertension

| | |
|---|---|
| Start Date 15 Jan 87 | Est Comp Date: |
| Principal Investigator<br>Edwin J. Whitney, MAJ, USAF MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators:<br>Joe M. Moody, Jr., LTC, MC |
| Key Words:<br>Hypertension<br>Fish oil | Stacey Adams<br>Mary Dunn, MAJ, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 21

Total Number of Subjects Enrolled to Date: 100

Date of Periodic Review 23 Mar 88 Results Completed

Objective(s): To determine whether or not fish oil supplementation (eicosapentanoic acid [EPA] and docosahexanoid acid [DHA]) can lower blood pressures in patients with essential hypertension.

Technical Approach: Patients referred to the Cardiovascular Risk Clinic will be eligible for this study. The patients will attend the cardiovascular risk management program with at least three follow-up visits at six week intervals. Two hundred eligible patients will be block randomized in a double blind manner to the fish oil supplement (20 ml in gelatin capsules) or an identical appearing placebo (10 ml oilive oil in gelatin capsules). The patient will consume the fish oil supplement or the placebot for eight weeks.

Progress: Fish oil lowered blood pressure in about 40-60% of patients with diastolic blood pressures in excess of 90 and/or systolic blood pressures in excess of 140. However, olive oil supplementation lowered blood pressure in a much smaller percent of patients. Since neither the fish oil nor the olive oil had any significant impact on the blood pressure in normotensive individuals, there were not enough participants enrolled to show a statistically significant difference between the two. Since the olive oil appeared to affect the blood pressure of 20-25% of the hypertensive patients, it may not be a true placebo.

Detail Summary Sheet

| | | |
|---|---|---|
| Date: 31 Oct 88 | Proj No: C-9-87 | Status: Completed |

Title: Effect of a Commercially Available Fish Oil Preparation on Serum Lipids in a Group of Patients with Documented Coronary Artery Disease

| | |
|---|---|
| Start Date 15 Jan 87 | Est Comp Date: |
| Principal Investigator<br>Edwin J. Whitney, MAJ, USAF MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators:<br>Steven R. Bailey, MAJ, MC<br>Mary Dunn, MAJ, MC<br>Stacey Adams |
| Key Words:<br>Fish oil<br>Coronary artery disease<br>Hyperlipidemia | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 21

Total Number of Subjects Enrolled to Date: 100

Date of Periodic Review 23 Mar 88 Results Completed

Objective(s): To determine the effect of commerdially available fish oil preparations containing eicosapentanoic acid (EPA) and docosahexanoic acid (DHA) on serum lipids in a large group of patients with hyperlipidemia and documented coronary artery disease.

Technical Approach: Patients who have attended the cardiovascular factor modification risk clinic and who have demonstrated stable total cholesterol, triglycerides, HDL cholesterol and weight levels over a four month period will be eligible for this study. The patients will receive four hours of detailed instruction in risk factor modification in the Cardiovascular Risk Clinic. Serum lipids will be determined at six week intervals. After lipid and weight stabilization, the patients will be randomized in a double blind manner to fish oil or placebo. The fish oil supplementation will be to 3.6 gm per day of EPA and 2.4 gm of DHA. This amount of EPA and DHA is contained in roughly 20 ml of fish oil (which will be supplied in 325 mg capsules). The placebo will be identical appearing capsules containing olive oil. The supplements will be administered for 8 weeks. Serum lipids will be determined at 2 week intervals.

Progress: Cholesterol changes were noted at four to eight weeks. The remainder of the data is being analyzed.

Detail Summary Sheet

Date: 31 Oct 88 Proj No: C-10-87 Status: Ongoing

Title: Effect of Reducing the Total Cholesterol/HDL Cholesteral Ratio to Less than 3.0

| | |
|---|---|
| Start Date 15 Jan 87 | Est Comp Date: |
| Principal Investigator<br>Edwin J. Whitney, MAJ, USAF MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators:<br>Steven R. Bailey, MAJ, MC |
| Key Words:<br>Cholesterol, total<br>Cholesterol, HDL | Mary Dunn, MAJ, AN<br>Stacey Adams |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: 16.50 |

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 23 Mar 88 Results Continue

Objective(s): To determine the effect of reducing the TC/HDL cholesterol ratio to less than, or equal to 3.0 in patients with angiographically documented coronary artery disease.

Technical Approach: Patients who have received cardiac catheterizations within 3 months of entry and have measurable stenoses will be eligible. One hundred patients will be randomized to a control group or the active treatment group. The control group will receive the routine cardiac rehabilitation program. They will not receive lipid lowering medications. Patients in the active treatment group will receive detailed instructions in risk factor modification and followed serially every 6 weeks to ensure optimization of serum lipids. Primary intervention will consist of diet and lifestyle changes (exercise, stop smoking, diet, weight loss); however, medications will be used in those whose ratio of TC/HDL remains above 3.0. Standard lipid lowering agents will be used to optimize the TC/HDL cholesterol ratio and total cholesterol.

Progress: One patient enrolled. On repeat catheteriation there was objective evidence for regression of LAD lesion and diagonal lesion.

Detail Summary Sheet

Date: 28 Sep 88 Proj No: C-11-87 Status: Ongoing

Title: Atrial Natriuretic Peptide and Hemodynamics in Orthotopic Cardiac Transplantation.

| | |
|---|---|
| Start Date 15 Jan 87 | Est Comp Date: |
| Principal Investigator<br>Ricky D. Latham, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators:<br>John B. Copley, COL, MC<br>John P. Mulrow, M.D. |
| Key Words:<br>Transplantation, cardiac | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date: 4

Date of Periodic Review 23 Mar 88 Results Continue

Objective(s): To examine the relationship of cardiac pressures, atrial natriuretic peptide levels and catecholamine levels during rest and exercise in patients with orthotopic cardiac transplantation.

Technical Approach: To assess the responsiveness of atrial natriuretic factor (ANF) in orthotopic cardiac transplantation (TX), we obtained peripheral (P) and central (PA) ANF levels at rest (R) and exercise (E) in 4 patients (pts) on a high salt diet (200 mEq sodium [NA], 80 mEq potassium). There were 3 females, a 1 male, mean age 42±16 years who were 10±3.0 months post-TX, clinically stable and free from rejection on biopsy. Medications except for immunosuppressives were stopped before study. Daily 24 hour urine collections documented NA balance and serum creatinine was less than 1.5 mg/dl in all pts. ANF determinations (pg/ml) were performed on extracted plasma. Simultaneous right and left hi-fidelity hemodynamics were obtained with P and PA ANF levels at R and E.

Progress: While ANF levels increased from P to PA at R and E, only increases from PA R to PA E (178±69 to 452±260) were significant ($p<0.05$). A significant increase in RA from R to E occurred (6±1 to 16±2) but did not correlate with R and E changes in PA ANF levels. We conclude ANF can respond in the TX heart to a high salt diet and exercise. Mechanisms of release of ANF are not clear.

Detail Summary Sheet

| Date: 28 Sep 88 | Proj No: C-12-87 | Status: Ongoing |
|---|---|---|

Title: Clinical and Outpatient Follow-up of Cardiac Transplantation

| | |
|---|---|
| Start Date 15 Jan 87 | Est Comp Date: |
| Principal Investigator (vice Latham)<br>William R. Condos, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators:<br>Steven R. Bailey, MAJ, MC<br>Ricky D. Latham, MAJ, MC |
| Key Words:<br>Transplantation, cardiac | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date: 4

Date of Periodic Review 23 Mar 88 Results Continue

Objective(s): To describe the evolution and present state of the art for cardiac transplantation and to describe the clinical follow-up of patients at BAMC.

Technical Approach: Patients referred by BAMC for cardiac transplantation to institution(s) in San Antonio will return to Brooke following the immediate postoperative care at the surgical center. At each follow-up visit, the following will be obtained: ECG, urine analysis, creatinine clearance, chest x-ray, CBC, PA20, cyclosporin level and titers for cytomegalic herpes and varicella virus. Five-day ambulatory ECG monitoring, radionuclide assessment of diastolic, systolic function, and echo cardiography Doppler will be performed at appropriate intervals. Endomyocardial biopsies to detect rejection will be performed weekly for the first six weeks, monthly for the next six to seven months, and then every two to three months for life.

Progress: Data collection is in progress.

Detail Summary Sheet

| Date: 28 Sep 88 | Proj No: C-13-87 | Status: Ongoing |
|---|---|---|

Title: Evaluation of Biventricular Performance in the Deinnervated Heart

| | |
|---|---|
| Start Date 15 Jan 87 | Est Comp Date: |
| Principal Investigator<br>Ricky D. Latham, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators:<br>Steven R. Bailey, MAJ, MC<br>Ares Pasipoularides, M.D., Ph.D. |
| Key Words:<br>Heart, deinnervated | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date: 4

Date of Periodic Review 23 Mar 88 Results Continue

Objective(s): To examine the following biventricular parameters in the deinnervated heart at rest, volume expansion (leg raising) and submaximal dynamic exercise: (1) systolic ejection indices; (2) pressure volume loops; (3) diastolic indices of stress-strain; and (4) hemodynamic response to Valsalva and Mueller maneuvers.

Technical Approach: To evaluate the exercise (E) response in cardiac transplant (Tx) patients (pts) on cyclosporine, we performed right and left heart catheterization at rest (R) and supine bicycle (E) using multisensor high fidelity catheters. Four pts (3 females, 1 male) mean age 47±15 years, mean 10±months post transplant, who were clinically stable and free of rejection by biopsy were studied off cardiac medications.

High fidelity catheters were used to measure simultaneous aortic root pressure (Ao) and flow velocity and LV pressure at rest and during suppine bicycle exercise (Ex). Fourier analysis of Ao and flow signals was used to calculate characteristic input impedance ($Z_c$). Diastolic decay Ao was used to determine systemic compliance (C) by a monoexponential model (RC).

Progress: To assess similarities with essential hypertension, dynamics in our first four cardiac transpants (TP) with significant cyclosporine-related hypertension were studied during cardiac catheterization, compared to 10 hypertensive controls (aged 46±10 years; HC). Mean Ao in TP increased ($p<.01$) 2±5 mmHg with Ex vs 21±13 in HC. C increased in TP with EX (75±58%) vs a decrease in HC(-8.4±16%; $p<.05$). EX Z decreased in TP (-40±11%) consistent with an increased C and little increase or no change in aortic area. In TP, arterial dynamics during exercise differ vs HC, probably due to different vascular structural adaptation.

Detail Summary Sheet

Date: 31 Sep 88 Proj No: C-14-87 Status: Ongoing

Title: Prospective Randomized Clinical Trial of the Capillary Cloning System for Patients with Extensive Small Cell Lung Cancer

| | |
|---|---|
| Start Date 15 Jan 87 | Est Comp Date: |
| Principal Investigator<br>Arlene J. Zaloznik, LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Oncology | Associate Investigators: |
| Key Words:<br>Cancer, small cell lung | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 23 Mar 88 Results Continue

Objective(s): To perform a prospective randomized single agent clinical trial of the newly developed capillary cloning system.

Technical Approach: A portion of tumor will be removed and sent to the laboratory for capillary cloning to determine which drugs will or will not be effective in the treatment of small cell lung cancer.

Progress: SWOG is currently considering this for group protocol.

Detail Summary Sheet

| Date: 28 Sep 88 | Proj No: C-18-87 | Status: Completed |
|---|---|---|

Title: Use of Lysine Vasopressin in the Treatment of Hemodialysis Induced Hypotension

| Start Date 10 Feb 87 | Est Comp Date: |
|---|---|
| Principal Investigator<br>Jill S. Lindberg, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Nephrology | Associate Investigators:<br>John B. Copley, COL, MC |
| Key Words:<br>Hypotension<br>Hemodialysis | Kenneth Melton, MAJ, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 6

Total Number of Subjects Enrolled to Date: 6

Date of Periodic Review 23 Mar 88 Results Continue

Objective(s): To assess the serum levels of ADH, catecholamines and renins in patients with unknown dialysis induced hypotension.

Technical Approach: Six patients were studied who had refractory hemodialysis-induced hypotension (HIH). Intranasal lysine vasopressin (LV) and intranasal placebo were administered in a double-blind crossover fashion.

Progress: With LV, the mean number of hypotensive episodes was less ($0.9 \pm 0.8$ vs. $1.5 \pm 1$; $p<.05$), as was the total volume of intravenous fluid required ($155 \pm 57$ cc vs. $280 \pm 123$ cc; $p<.05$). Additionally, systolic, diastolic and MAP were significantly greater at 90 minutes treatment time. Epinephrine, norepinephrine, and antidiuretic hormone levels were elevated at baseline and fell with hypotension despite the use of LV, probably reflecting the underlying autonomic deficiency. LV may be useful in the therapy of refractory HIH.

Detail Summary Sheet

| Date: 21 Oct 88 | Proj No: C-20-87 | Status: Completed |
|---|---|---|

Title: Analysis of Frequency of HTLV-III Seropositivity in a Hemodialysis, Peritoneal Dialysis and Transplant Population and Its Implication Concerning Current Methods of Staging of HIV Associated Disease

| Start Date 10 Feb 87 | Est Comp Date: |
|---|---|
| Principal Investigator<br>William G. Wortham, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Nephrology | Associate Investigators:<br>John B. Copley, COL, MC |
| Key Words: | David G. Burleson, LTC, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Mar 88 Results Continue

Objective(s): 1) To demonstrate the overall T-cell count including T-cell subsets in our chronic hemo and peritoneal diaglysis population and renal transplant population.

2) To determine and compare delayed cutaneous hypersensitivity in both end stage renal disease patients and normal controls.

3) To compare the T-cell subsets and absolute lymphocyte counts in HIV+ and HIV- end stage renal disease patients.

4) To determine the frequency of HLA-D, Dr4 antibodies in the serum of end stage renal disease patients, false positive patients, and controls.

Technical Approach: The Walter Reed Staging System for HIV infection utilizes the response of patients to a standard anergy panel (delayed hypersensitivity) as well as the absolute number of $T_4$ (helper) cells per cubic millimeter of blood to assess HIV-related disease propagation. To determine whether this method of staging for HIV infection can be applied to the dialysis patient, we performed a prospective evaluation of this population based on the Walter Reed System. Thus, total T-cell subsets in HIV Elisa negative dialysis patients were compared to HIV Elisa negative controls. In addition, we assessed delayed hypersensitivity by application of a standard anergy panel to dialysis patients and healthy controls.

Progress: We found that total lymphocytes, total and percentages of $OKT_3$, $OKT_4$, $OKT_{11}$ and Leu-3-positive staining cells were significantly less in dialysis patients compared to controls. This did not appear to be a function of time on dialysis in months. Delayed hypersensitivity was severely depressed in dialysis patients and normal in controls.

C-20-87 (continued)

We conclude that the current method of staging HIV infections by the Walter Reed system cannot be applied to the chronic dialysis patient because of immunologic abnormalities inherent to end-stage renal disease.

Detail Summary Sheet

| Date: 31 Oct 88 | Proj No: C-23-87 | Status: Terminated |
|---|---|---|

Title: Open-Label Phase I Study to Evaluate the Safety of Recombinant Beta Interferon (Betaseron--IFN-$B_{ser}$) Given Intravenously in Combination with 5-Fluorouracil (5FU) in Patients with Advanced Cancer

| | |
|---|---|
| Start Date 17 Feb 87 | Est Comp Date: |
| Principal Investigator (vice Brown)<br>Timothy J. O'Rourke, LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Departmentof Medicine/Oncology | Associate Investigators: |
| Key Words:<br>Beta Interferon | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 23 Mar 88 Results Continue

Objective(s): 1) To determine maximal tolerated dose for Betaseron when given by intravenous injection in a dose of 45, 90, 180, 270, or 360 x $10^6$ IU, once a day, 3 days a week in combination with 5FU therapy.

2) To determine safety and tolerance of the stated combination regimen in these patients.

Technical Approach: Patients with histologically confirmed carcinoma of the lung, liver, biliary system, pancreas, stomach, esophagus, small intestine, colon, or rectum are eligible for this study. The malignancy must be surgically incurable and not treatable with any standard antineoplastic therapy known to be effective.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study. It is terminated as there are no plans to activate it.

Detail Summary Sheet

Date: 31 Oct 88 Proj No: C-24-87 Status: Terminated

Title: A Multicenter Open Label Phase II Study to Evaluate the Safety and Efficacy of Escalating Doses of IFN-$B_{ser}$ Given Intravenously in Patients with Advanced Renal Cell Carcinoma, Melanoma, or Non-Small Cell Lung Cancer

| | |
|---|---|
| Start Date 17 Feb 87 | Est Comp Date: |
| Principal Investigator (vice Brown)<br>Timothy J. O'Rourke, LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Oncology | Associate Investigators: |
| Key Words:<br>Beta Interferon | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review 23 Mar 88 Results Continue

Objective(s): 1) To determine maximum tolerated dose when IFN-$B_{ser}$ is given by intravenous injeciton in doses escalating from 90 to 540 x $10^6$ IU, on a once-a-day Monday, Wednesday, and Friday schedule for 12 weeks or longer in patients with measurable renal cell carcinoma, melanoma, or non-small cell lung cancer

2) To determine the safety, tolerance, and therapeutic effect of IFN-$_{ser}$ when given in the stated regimen.

Technical Approach: Patients with histologically confirmed renal cell carcinoma, melanoma, or non-small cell lung cancer, incurable by radiation or surgery are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study, and it should be closed as there are no current plans to activate it.

Detail Summary Sheet

Date: 28 Sep 88 Proj No: C-28-87 Status: Completed

Title: Free 1.25-dihydroxyvitamin $D_3$ Levels in Patients with Renal Failure and in Patients Who Have Received Successful Renal Transplants

| | |
|---|---|
| Start Date 2 Mar 87 | Est Comp Date: |
| Principal Investigator (vice Lindberg)<br>Karl Koenig, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Nephrology | Associate Investigators:<br>Greg Jaffers, LTC, USAF MC |
| Key Words:<br>Transplant, renal | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 26

Total Number of Subjects Enrolled to Date: 26

Date of Periodic Review 23 Mar 88 Results Continue

Objective(s): To determine the level of serum free 1.25-dihydroxy Vitamin $D_3$ ($1.15\text{-}(OH)_2D_3$) levels in patients with moderate chronic renal failure, end-stage renal disease, and those patients with renal failure who have received a successful renal transplant.

Technical Approach: 1.25-dihydroxy Vitamin $D_3$ levels will be drawn on patients prior to and 6-8 weeks post transplant.

Progress: Study completed. Awaiting preliminary report of the data collected which is still in process of being tabulated, organized, and analyzed. Since the principal investigator, MAJ Lindberg, is no longer assigned at BAMC, it is most unlikely that any results will become available.

Detail Summary Sheet

Date: 1 Jul 88 Proj No: C-29-87 Status: Completed

Title: Influence of Campylobacter pyloridis Associated Non-Ulcerative Gastritis on Gastric Emptying

| | |
|---|---|
| Start Date 2 Mar 87 | Est Comp Date: |
| Principal Investigator<br>Christophe N. Barrilleaux, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Gastroenterology | Associate Investigators:<br>Fred Goldner, COL, MC |
| Key Words:<br>Campylobacter pyloridis | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: 410.00 |

Number of Subjects Enrolled During Reporting Period: 22

Total Number of Subjects Enrolled to Date: 22

Date of Periodic Review 23 Mar 88 Results Continue

Objective(s): To evaluate the effect of histologically proven, Campylobacter pyloridis infection associated, non-ulcerative gastritis on solid-phase gastric emptying.

Technical Approach: Patients found to have symptoms suggestive of nonulcer gastritis and infected or colonized with C. pylori were treated with an appropriate antibiotic regimen (Bismuth sub-salicylate and Amoxicillin simultaneously for 14 days) in an attempt to eradicate the C. pylori. Presence or absence of C. pylori was documented by finding C. pylori on H and E stained histologic sections, in cytologic brushing samples, culture of C. pylori from biopsy specimens and positive urease reaction of gastric tissue.

Progress: Treatment of Campylobacter pylori-treated, nonulcer gastritis with a two week, simultaneous course of Amoxicillin and bismuth subsalicylate liquid (Pepto-Bismol) eradicated C. pylori from the gastric antra of 22 patients and healed "active" antritis in these patients. Although short term eradication of the organism was achieved, no statement can be made regarding long term prognosis based on this study. When nuclear solid-phase gastric emptying times were tested before and after eradication of the C. pylori and "active" antritis, there was a statistically significant improvement in the mean nuclear gastric

C-29-87 (continued)

solid-phase emptying times. Cytologic brushings of the gastric antru evaluated after resuspension, filtration, and Gram stain proved to be equal in effectiveness fo multiple hematoxylin and eosin stained endoscopic pinch biopsies, urease broth testing and CLOtest strips. CLOtest urease test strips were found to be significantly faster in the production of a positive result than CUB, but were no more sensitive.

Further weight must be given to the theory that C. pylori, already considered the etiologic factor for Type B gastritis, is either the cause of or one of the key etiologic factors of the antral hypomotility found in peptic ulcer disease. C. pylori is, therefore, very likely a key factor in the production of peptic ulcer disease itself.

Detail Summary Sheet

| Date: 26 Oct 88 | Proj No: C-37-87 | Status: Ongoing |
|---|---|---|

Title: Phase II Study of Carbetimer in Lung Carcinoma

| | |
|---|---|
| Start Date 18 Mar 87 | Est Comp Date: |
| Principal Investigator (vice Brown)<br>Arlene J. Zaloznik, LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Oncology | Associate Investigators: |
| Key Words:<br>Carbetimer | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 4

Date of Periodic Review 8 Apr 88 Results Continue

Objective(s): 1) To determine the response rate and response duration in subjects with advanced non-small cell carcinoma of the lung treated with carbetimer.

2) To define the qualitative and quantitative toxicities of carbetimer administered in a Phase II study.

Technical Approach: For inclusion in the study, all subjects must have a histologic diagnosis of recurrent or metastatic non-small cell cacner of the lung. Subjects with recurrent or metastatic non-small cell cancer of the lung must be previously untreated except for surgery and/or radiotherapy.

Therapy will follow the schema outlined in the study protocol.

Progress: It is anticipated that this study will soon be converted to a SWOG study.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: C-41-87 Status: Ongoing

Title: Shortening of Left Ventricular Isovolumic Contraction Time During Exercise in Normal Man

| | |
|---|---|
| Start Date 9 Apr 87 | Est Comp Date: |
| Principal Investigator<br>Joe M. Moody, LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators:<br>Joseph P. Johns, MAJ, MC |
| Key Words: | Ares Pasipoularides, M.D., Ph.D. |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 7

Total Number of Subjects Enrolled to Date: 7

Date of Periodic Review 16 Jun 88 Results Continue

Objective(s): To assess, using noninvasive tools, the relative timing of mitral valve closure and aortic valve opening at rest and during exercise in normal volunteers.

Technical Approach: Simultaneous M-mode echocardiography of aortic and mitral valves isperformed during upright bicycle exercise in normal volunteers. Recordings are obtained at increasing heart rates to assess changes in MC-AO interval.

Progress: The results are undergoing analysis but they already show a predictable and previously demonstrated decrease in diastolic filling period and less of a decrease in left ventricular ejection time. The new finding is that the interval from the mitral valve closure to the aortic valve opening decreases with progressively intense exercise, and in three of the seven patients at heart rates of 150-180, the mitral valve closure actually followed aortic valve opening. This unusual and interesting finding in a normal person with severe exercise is probably due to the inertial effect of the diastolic left ventricular

C-41-87 (continued)

filling which delays mitral valve closure to the point where left ventricular pressure has already risen above aortic diastolic pressure, causing aortic opening.

There have been no complications, misadventures, or adverse reactions involving the seven subjects who have participated. Their participation was viewed as a positive experience overall for them.

Detail Summary Sheet

| Date: 1 Nov 88 | Proj No: C-42-87 | Status: Ongoing |
|---|---|---|

Title: Total Systemic and Regional Aortic Compliance at Rest and with Exercise

| Start Date 9 Apr 87 | Est Comp Date: |
|---|---|
| Principal Investigator (vice Matthews)<br>David Slife, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 6

Total Number of Subjects Enrolled to Date: 6

Date of Periodic Review 16 Jun 88 Results Continue

Objective(s): 1) To compare compliance as determined by a three-element windkessel arterial model (using aortic input pressure and flow) at rest and with exercise, to compliance determined by the standard RC model in normal man.

2) To compare aortic compliance by each method in normal and hypertensive patients.

3) To evaluate the regional proximal aortic contribution to the total systemic capacitance.

Technical Approach: To evaluate the exercise response of systemic compliance (C) and arterial elastance ($E_a$), supine bicycle exercise was performed during cardiac catheterization in 10 hypertensive (H) patients and compared to 10 normotensive (H) controls. Steady state high fidelity LV and aortic root pressures and thermodilution cardiac outputs were measured at baseline and with exercise. Digitized Ao signals and systemic resistance (R) were used to calculate C from a monoexponential RC model. Estimates of $E_a$ were calculated from end-systolic pressure/stroke volume.

Progress: Three normals and three hypertensive patients have been enrolled. No reportable data are available at this time.

Detail Summary Sheet

Date: 28 Sep 88 Proj No: C-43-87 Status: Terminated

Title: Silent Myocardial Ischemia in Diabetic Patients with Cardiac Autonomic Dysfunction

| | |
|---|---|
| Start Date 9 Apr 87 | Est Comp Date: |
| Principal Investigator<br>David M. Slife, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To evaluate diabetic patients to determine if there is a correlation between autonomic dysfunction and silent cardiac ischemia.

Technical Approach: Each participant will undergo five separate tests in evaluation of autonomic neuropathy. In evaluation of silent myocardial ischemia, a holter monitor for 48 hours, exercise stress test with thallium, and exercise MUGA scan will be performed.

Progress: Principal investigator not interested in continuing the study.

Detail Summary Sheet

Date: 1 Nov 87 Proj No: C-44-87 Status: Completed

Title: Follow-up of Hot Biopsy Forceps Treatment of Diminutive Colon Polyps

| | |
|---|---|
| Start Date 9 Apr 87 | Est Comp Date: |
| Principal Investigator<br>Francis E. Peluso, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Gastroenterology | Associate Investigators:<br>Fred Goldner, COL, MC |
| Key Words:<br>Polyp<br>Hot biopsy forceps | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 39

Total Number of Subjects Enrolled to Date: 39

Date of Periodic Review 16 Jun 88 Results Continue

Objective(s): 1) To determine whether hot biopsy forceps technique destroys diminutive (< 5mm) polyps.

2) To determine the extent of surrounding tissue damage induced by this technique.

Technical Approach: Thirty-nine subjects undergoing routine colonoscopy requiring hot biopsy were entered into the study. Biopsy location, coagulation current setting, duration of current, and measurement of coagulum were noted. Patients then underwent flexible sigmoidoscopy at 1 and 2 weeks post-procedure. Biopsy sites were described and measured. Apparent polyp remnants were biopsied with pinch forceps.

Progress: There were no clinical complications. Sixty-two (62) biopsy sites were examined in 39 patients. Bland, shallow ulcers with smooth margins were typically seen. Twenty sites were healed. Eleven sites had polyp remnants which were histologically identical to the original biopsy (five adenomatous and six hyperplastic).

Conclusion: There was no significant tissude damage and no clinical sequelae. The hot biopsy forceps technique proved unreliable in the short term, with 17.4% resulting in incompletely treated polyps.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: C-45-87 Status: Ongoing

Title: Utility of Solubilized Calcium Citrate in the Management of Moderate and End-Stage Renal Failure

| | |
|---|---|
| Start Date 9 Apr 87 | Est Comp Date: |
| Principal Investigator (vice Lindberg)<br>Karl Koenig, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Nephrology | Associate Investigators:<br>J. Brian Copley, COL, MC<br>Howard M. Cushner, MAJ, MC<br>John M. Bauman, MAJ, MC |
| Key Words:<br>Renal failure, end-stage | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 50

Total Number of Subjects Enrolled to Date: 65

Date of Periodic Review 16 Jun 88 Results Continue

Objective(s): To assess the value of solubilized calcium citrate (Super-Citracal$^{tm}$) in the management of moderate and end-stage renal failure.

Technical Approach: Seventy-five to 150 adult patients of either sex with endogenous creatinine clearance ranging from 25-60 ml/min will participate in the study. Eligible participants will be randomly assigned into three groups. Patients in Group I will receive Super-Citracal 500 mg calcium three/day (with meals). Those in Group II will take calcium carbonate 500 mg calcium three/day (with meals). Patients in Group III will receive placebo medication three/day (with meals). The remainder of the study will be conducted as outlined in the study protocol.

Progress: End-stage renal disease (dialysis patients) portion of the study is complete. Early to moder renal failure portion to be completed by the end of November 1988. No data yet available.

Detail Summary Sheet

| | | |
|---|---|---|
| Date: 1 Nov 88 | Proj No: C-49-87 | Status: Ongoing |

Title: Phase II Study of Carbetimer in Advanced Breast Carcinoma

| | |
|---|---|
| Start Date 11 May 87 | Est Comp Date: |
| Principal Investigator<br>Arlene J. Zaloznik, LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Oncology | Associate Investigators: |
| Key Words:<br>Carcinoma, breast | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Jun 88 Results Continue

Objective(s): 1) To determine the response rate and response duration in subjects with advanced breast carcinoma treated with carbetimer.

2) To define the qualitative and quantitative toxicities of carbetimer administered in a Phase II study.

Technical Approach: To be eligible for this study, all subjects must have a histologic diagnosis of breast carcinoma. Subjects must have an estimated survival of at least 12 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Four patients registered by university under their supervision. One patient currently undergoing evaluation at BAMC for possible therapy.

Detail Summary Sheet

| Date: 1 Nov 88 | Proj No: C-52-87 | Status: Ongoing |
|---|---|---|

Title: Autologous Bone Marrow Rescue in Patients with Acute Leukemia and Lymphoma Using Ex-Vivo Marrow Treatment with 4-Hydroperoxycyclophosphamide (4-HC)

| Start Date 13 May 87 | Est Comp Date: |
|---|---|
| Principal Investigator<br>Richard O. Giudice, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Oncology | Associate Investigators:<br>Paul J. Thomas, COL, MC<br>Allen Potter, LTC, MC<br>Barbara Reeb, DAC<br>John J. Posch, Jr., DAC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: 900.00 |

Number of Subjects Enrolled During Reporting Period: 3

Total Number of Subjects Enrolled to Date: 6

Date of Periodic Review 16 Jun 88 Results Continue

Objective(s): 1) To evaluate autologous marrow rescue after intensive therapy in patients with acute leukemia and lymphoma in second remission or subsequent remission or in early relapse.

2) To study the effects of ex-vivo bone marrow purging utilizing 4-HC on malignant cells, marrow stem cells, and relationship to subsequent engraftment times.

3) To study the acute toxic effects of the preparative regimens.

Technical Approach: To be eligible for this study, all patients must have a diagnosis of acute leukemia or agressive histology lymphoma and have relapsed after therapy. Bone marrow should be harvested when the patient is in remission.

Therapy will follow the schema outlined in the study protocol.

Progress: One adult with non-Hodgkin's lymphoma and two children with acute myelogenous leukemia have been treated. All are alive and well.

Detail Summary Sheet

| Date: 26 Jul 88 | Proj No: C-53-87 | Status: Completed |
|---|---|---|

Title: An Evaluation of Flow Cytometry in the Cytologic Analysis of Bronchial Washings

| | |
|---|---|
| Start Date 13 May 87 | Est Comp Date: |
| Principal Investigator<br>William A. Crosland, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Pulmonary Dis. | Associate Investigators:<br>Michael Jackson, MAJ, MC<br>Harvey M. Richey, III, MAJ, MC<br>Janice Grassel |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 15

Total Number of Subjects Enrolled to Date: 15

Date of Periodic Review 15 Jun 88 Results Completed

Objective(s): To investigate whether the frequency of DNA distribution as determined by flow cytometry can increase the sensitivity and specificity of bronchial washings in the diagnosis of patients with lung cancer.

Technical Approach: Fifteen patients with abnormal chest roengenography and with lung cancer as a probable diagnosis underwent bronchoscopic studies. Patients undergoing diagnostic bronchoscopy had either a bronchial washing (BW) or bronchoalveolar lavage (BAL) performed prior to any biopsies f brushings. In those patients with a visible endobronchial lesion, a BW was done in the involved visible airway prior to any biopsies or brushings. If no abnormality was visible, a BAL was done in the subsegment corresponding to the radiographic abnormality. The bronchial washing or BAL specimen was then homogenizedand the sample equally divided. One-half of the sample was submitted for routine microscopic cytologic analysis and the remainder for DNA analysis. Histologic diagnosis was determined by biopsy obtained at bronchoscopy or at surgery. Tumor size was determined by radiographic imaging using a chest radiogram or cmputerized axial tomography supplemented by measurement of the surgical pathologic specimen if possible. Cytology and biopsy cytopathologic interpretations were made blinded and independently.

Progress: Fifteen patients had diagnostic bronchoscopy with 10 undergoing bronchial washing and 5 BAL. This sample population was predominantly male (13M/1F) and had a mean age of 62 years. Twelve of the tumors occurred centrally or within the visible airway and 3 peripherally. Histologically, 27% (4) were small cell undifferentiated, 40% (6) adenocarcinoma, 13% (2) non-typable non-small cell cacinoma and 20% (3) squamous cell carcinoma.

C-53-87 (continued)

Microscopic cytology diagnosed 4 of 15 malignancies for a sensitivity of 26%, In cases where an endobronchial biopsy was obtained, cytology was positive in 4 of 12 with a 28% sensitivity. If the endobronchial biopsy was positive, cytology was positive in 4 of 8 with a 50% sensitivity. Flow cytometry measured the DNA content in a mean number of 6832 cells per sample. A DNA index of a peak of >1.2 was felt consistant with aneuploidy. Flow cytometry detected aneuploidy in only 1 of 15 bronchial specimens and was associated with positive microscopic cytology and biopsy.

The resutls of this study indicate that flow cytometry alone is not an effective technique for identifying cancer in bronchial washings.

Detail Summary Sheet

| | | |
|---|---|---|
| Date: 8 Nov 88 | Proj No: C-54-87 | Status: Ongoing |

Title: Left Ventricular Systolic Dynamics in Coronary Arterial Disease at Rest and in Exercise

| | |
|---|---|
| Start Date 13 May 87 | Est Comp Date: |
| Principal Investigator<br>Steven R. Bailey, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators:<br>Ares Pasipoularides, M.D., Ph.D. |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 16 Jun 88 Results Continue

Objective(s): To develop indices for LV pumping efficiency and regional wall contractility in CAD. We will quantify intraventricular pressure distributions promoting the displacement of blood in the LV chamber towards the aortic valve in the course of systolic isovolumic contraction and ejection.

Technical Approach: Twenty patients with suspected CAD will be prospectively evaluated during routine diagnostic cardiac catheterization prior to retrograde left ventriculography. All patients will undergo standard retrograde arterial catheterization from the arm using an #8 high fidelity catheter with two laterally mounted micromanometrs and an electromagnetic flow sensor at the level of the proximal pressure sensor. The study will be carried out as outlined in the protocol.

Progress: None. Will begin enrolling patients in the near future.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: C-57-87 Status: Ongoing

Title: Phase I Trial of Intrapleurally Administered Intron-A®

| | |
|---|---|
| Start Date 29 May 87 | Est Comp Date: |
| Principal Investigator (Brown)<br>Timothy J. O'Rourke, LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Oncology | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 2

Total Number of Subjects Enrolled to Date: 2

Date of Periodic Review 16 Jun 88 Results

Objective(s): To determine the tolerance to and toxicity of intrapleural administration of Intron-A® in patients with malignant pleural effusions.

Technical Approach: To be eligible for this study the patient must have histologically proven diagnosis of cancer involving the pleura, as demonstrated by pleural fluid cytology or pleural biopsy positive for carcinoma or lymphoma, or histologically proven intrathoracic malignancy with a cytologically negative effusion, without other apparent etiology. The patient's malignant pleural effusion must be refractory to standard systemic therapy, or the patient's tumor must have no known effective standard therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: Two patients have been netered on this study at BAMC. Neither has experienced significant toxicity. The study continues at the 4 million unit/$M^2$ dose level.

Detail Summary Sheet

| | | |
|---|---|---|
| Date: 1 Nov 88 | Proj No: C-58-87 | Status: Ongoing |

Title: Phase I Study of LY186641 (Sulfonylurea)

| | |
|---|---|
| Start Date 29 May 87 | Est Comp Date: |
| Principal Investigator (vice Brown)<br>Timothy J. O'Rourke, LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Oncology | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 4

Total Number of Subjects Enrolled to Date: 8

Date of Periodic Review 16 Jun 88 Results Continue

Objective(s): To determine the maximum tolerated dose (which is both predictable and reversible) of LY186641 as a single dose given every 3 weeks.

Technical Approach: In order to be eligible for inclusion in this study, all patients must have microscopically confirmed diagnosis of advanced or metastatic cancer. All patients' tumors must be refractory to all known forms of effective therapy (surgery, radiotherapy, chemotherapy) as well as other investigational agents of higher potential efficacy. Patients must have a predicted life expectancy of at least 12 weeks and a performance status less than or equal to 2.

Therapy will follow the schema outlined in the study protocol.

Progress: Since this study opened, eight patients have been treated at BAMC. Mild methemoglobinemia (10%) has been seen and no other significant toxicity. Accrual of patients continues at the 1550 mg/$M^2$ dose level.

Detail Summary Sheet

| Date: 1 Nov 88 | Proj No: C-59-87 | Status: Ongoing |
|---|---|---|

Title: Phase I Study of LY188011 (Difluorodeoxycytidine)

| | |
|---|---|
| Start Date 29 May 87 | Est Comp Date: |
| Principal Investigator (vice Brown)<br>Timothy J. O'Rourke, LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Oncology | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 12

Total Number of Subjects Enrolled to Date: 15

Date of Periodic Review 16 Jun 88 Results Continue

Objective(s): To determine the maximum tolerated dose of LY188011 as a single dose given for 5 consecutive days with each cycle repeated every 21 days.

Technical Approach: Patients msut have a microscopically confirmed diagnosis of metastatic or advanced cancer. Patients' cancers must be refractory to effective therapy (surgery, radiotherapy, chemotherapy) as well as other investigational agents of higher potential efficacy. Patients must have a predicted life expectancy of at least 12 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Fifteen patients have been entered in this study. Significant fever and flu-like symptoms have been seen. In one patient at the 7 mg/$M^2$ dose level, this toxicity was life-threatening and was associated with hypertension and transient renal failure. Subsequent patients at 7 mg/$M^2$ and 9 mg/$M^2$ have had acceptable toxicity. One patient at 9 mg/$M^2$ had sudden death on day 13 thought related to coronary artery disease discovered at autopsy and not related to drug. The study continues at the 9 mg/$M^2$ dose level.

Detail Summary Sheet

| Date: 1 Nov 88 | Proj No: C-62-87 | Status: Ongoing |
|---|---|---|

Title: Development of an Autologous Bone Marrow Rescue Program (Master Protocol)

| | |
|---|---|
| Start Date 25 Jun 87 | Est Comp Date: |
| Principal Investigator<br>Richard O. Giudice, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Oncology | Associate Investigators:<br>Paul J. Thomas, COL, MC<br>Allen Potter, LTC, MC<br>John J. Posch, Jr., DAC<br>Barbara Reeb, DAC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: 11,595.00 |

Number of Subjects Enrolled During Reporting Period: 4

Total Number of Subjects Enrolled to Date: 10

Date of Periodic Review _____ Results _____

Objective(s): 1) To develop an autologous bone marrow rescue program at Brooke Army Medical Center.

2) To participate in research and clinical studies individually as well as part of the Southwest Oncology Group and Pediatric Oncology Group.

3) To establish a competent marrow rescue service for all eligible DOD patients for present clinical indications and future indications, i.e., radiation exposure.

Technical Approach: Bone marrow stem cells will be obtained by multiple bone marrow aspirations under general anesthesia. The marrow will be prepared by accepted methods and frozen for future reinfusion.

This is the master protocol for the autologous bone marrow transplant program.

Progress: Many bone marrows have been harvested and stored for possible future use. We have approximately 20 bone marrows stored in the freezer.

Detail Summary Sheet

| Date: 1 Nov 88 | Proj No: C-64-87 | Status: Ongoing |
|---|---|---|

Title: Evaluation of Patients with Human Immunodeficiency Virus (HIV) Seropositivity Detected by Screening for the Presence and Potential Etiology of Exercise Intolerance

| Start Date 2 Jul 87 | Est Comp Date: |
|---|---|
| Principal Investigator<br>James E. Johnson, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Pulmonary | Associate Investigators:<br>Gregg T. Anders, CPT, MC<br>Herman M. Blanton, MAJ, MC<br>Eleanor Ayala, DAC |
| Key Words: | |
| Accumulative MEDCAST Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 5

Total Number of Subjects Enrolled to Date: 38

Date of Periodic Review 9 Sep 88 Results Continue

Objective(s): Patients with HIV seropositivity have been noted to have exercise intolerance at an early stage when they are otherwise asymptomatic. The goals of this study are as follows: 1) To determine the prevalence of complaints of exercise intolerance and dyspnea in the study population. 2) To document whether abnormalities of exercise physiology exist in these patients complaining of exercise intolerance. 3) To evaluate these patients for potential causes of exercise intolerance such as early opportunistic pulmonary infection or lymphocytic interstitial pneumonitis (LIP).

Technical Approach: All active duty patients admitted to the HIV ward or referred to the HIV clinic for evauation will be considered eligible for the study. These patients will be given a questionnaire on the day of admission including questions regarding exercise tolerance and dyspnea as well as previous lung, heart and muscle diseases. The response to these questions will be used for further patient selection. All participants will undergo gallium scan of the lungs, pulmonary function testing to include lung volumes and a $D_LCO$, cycle ergometry pulmonary exercise testing and bronchoalveolar lavage (BAL). The BAL fluid will be divided and submitted for the following: 1) staining for routine cytological evaluation (for evidence of viral infection) as well as for AFB and GMS stains; 2) culture fo AFB, Fungi, CMV and HIV virus; 3) HIV antigen testing for comparison to peripheral blood titers; 4) quantitation of lymphocytes, PMN's, monocytes as well as lymphocyte subsets particiularly OKT4 and OKT8.

Progress: When compared to a similar group of 11 seronegative controls, the patients exercised to a significantly lower maximum oxygen consumpton ($VO_2$) [2.36 $\pm$ 0.56 vs. 3.08 $\pm$ .58 liters] and workload [172.7 $\pm$ 0.56 vs. 240.5 $\pm$ 331.1 watts]. The ventilatory anaerobic threshold (VAT) was significantly lower for the patients [1.41 0.42 vs. 2.49 $\pm$ 0.41 liters]. Twelve of the patients, but

C-64-87 (continued)

none of the controls, had VVAT/maximum predicted $VO_1$ values less than 40%, a finding consistent with limitation in oxygen delivery. BAL fluid analysis revealed no evidence of opportunistic infection. HIV was recovered from 18.8% of those fluids cultured. BAL lymphocyte subset analysis revealed a reduction in $T_4/T_8$ ratio which correlated poorly with peripheral blood $T_4$ lymphocyte numbers.

Detail Summary Sheet

Date: 26 Jul 88 Proj No: C-66-87 Status: Ongoing

Title: Immunosuppressive Therapy for Biopsy Proven Myocarditis (Collaborative Study with University of Utah Medical Center and Centers for Multicenter Trial)

| | |
|---|---|
| Start Date 2 Jul 87 | Est Comp Date: |
| Principal Investigator<br>Ricky D. Latham, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators:<br>William R. Condos, LTC, MC |
| Key Words:<br>Myocarditis | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 2

Date of Periodic Review 12 Aug 88 Results Continue

Objective(s): To test the hypothesis that immunosuppressive therapy is beneficial in myocarditis.

Technical Approach: This is a national muticenter trial including 23 patient enrollment centers. Therapy will follow the schema outlined in the study protocol.

Progress: Two patients have been entered on this study. One is doing fine in follow-up. One patient received a course of cyclosporine with no problems. Several months after completion of therapy, the patient expired due to progressive disease while waiting for a heart transplant.

Detail Summary Sheet

Date: 28 Oct 88 Proj No: C-67-87 Status: Terminated

Title: Laser Vaporization versus Dermabrasion for the Treatment of Hypertrophic Actinic Keratoses

| | |
|---|---|
| Start Date 17 Jul 87 | Est Comp Date: |
| Principal Investigator (vice Yevich)<br>Alfred J. Hockley, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Dermatology | Associate Investigators:<br>Stuart J. Salasche, COL, MC |
| Key Words:<br>Keratoses, actinic | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To compare two different treatment modalities of active keratoses, namely $CO_2$ laser vaporization versus dermabrasion.

Technical Approach: The study will be a paired comparison of the two modalities including a minimum of twenty outpatients. These persons will have have three to five hypertrophic actinic keratoses on the dorsum of their hand or foreamr. Each patient will service as his own control as actinic keratoses of one hand will be treated with $CO_2$ laser and the other will be treated with dermabrasion.

Progress: Study terminated at request of principal investigator.

Detail Summary Sheet

| Date: 1 Nov 88 | Proj No: C-70-87 | Status: Ongoing |
|---|---|---|

Title: High Dose Busulfan with Autologous Bone Marrow Rescue

| | |
|---|---|
| Start Date 17 Jul 87 | Est Comp Date: |
| Principal Investigator (vice Harvey)<br>Richard O. Giudice, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Oncology | Associate Investigators:<br>R. Foulke, MAJ, MC<br>Paul Thomas, COL, MC<br>Allen Potter, LTC, MC<br>Barbara Reeb. DAC<br>John J. Posch, DAC<br>E. Nash, MAJ, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: 6500.00 |

Number of Subjects Enrolled During Reporting Period: 2

Total Number of Subjects Enrolled to Date: 8

Date of Periodic Review 9 Sep 88 Results Continue

Objective(s): 1) To study the toxicities associated with the treatment of refractory malignancies, utilizing cyclophosphamide, busulfan and etoposide.

2) To evaluate the response rates and the response duration of patients treated with the above regimen.

Technical Approach: An IND for busulfan was obtained in March 1987. The protocol was amended in June to include the use of cycophosphamide and etoposide (VP-16). Inclusion/Exclusion criteria and therapy is as outlined in the study protocol.

Progress: Protocol was amended to change route of VP-16 administration from 22 hour continuous infusion to Bolus. Since the amendment, two patients have been treated. Both are alive, one in partial remission and one in complete remission.

Detail Summary Sheet

Date: 26 Sep 88 Proj No: C-71-87 Status: Ongoing

Title: Use of Clofazimine in Immunocompromised Patients for the Treatment of Infections Caused by Mycobacterium Avium-Intracellulare and Other Atypical Mycobacteria Resistant to Conventional Antituberculous Therapy.

| | |
|---|---|
| Start Date 17 Jul 87 | Est Comp Date: |
| Principal Investigator (Hawkes)<br>J. William Kelly, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Infectious Dis. | Associate Investigators:<br>C. Kenneth McAllister, COL, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 9 Sep 88 Results Continue

Objective(s): To use and determine the effectiveness of the investigaitonal drug clofazimine (Lamprene®) for the treatment of infections due to Mycobacterium avium-intracellulare and other atypical mycobacteria in immunocompromised patients.

Technical Approach: Selection of patients will be on the basis of medical history, physical examination and laboratory studies including an evaluation of immunological status. Attempts will be made to culture body fluids and or tissue specimens from patients to substantiate the presence of atypical mycobacterial infection. All mycobacterial isolates will be tested in vitro for sensitivity to clofazimine.

Progress: The study remains open for eligible patients.

Detail Summary Sheet

| | | |
|---|---|---|
| Date: 26 Sep 88 | Proj No: C-72-87 | Status: Ongoing |

Title: Rifabutin (Ansamycin LM 427) CDC Protocol

| | |
|---|---|
| Start Date 17 Jul 87 | Est Comp Date: |
| Principal Investigator (vice Hawkes)<br>J. William Kelly, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Infectious Dis. | Associate Investigators:<br>C. Kenneth McAllister, COL, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 9 Sep 88 Results Continue

Objective(s): To determine the effectiveness of Rifabutin in the treatment of patients with disseminated M. avium complex disease, localized M. avium complex disease unresponsive to standard therapy, selected patients with rifampin-resistant M.tuberculosis, and other selected patients with mycobacterial infections.

Technical Approach: Under the compassional release IND, Rifabutin is intended for immunocompromised patients with disseminated M. avium complex disease, patients with pulmonary MAC disease unresponsive to standard therapy, and patients with rifampin-resistant tuberculosis. Other patients with mycobacterial diseases which have not responded to standard therapy may also be eligible to receive Rifabutin. Therapy will follow the schema outlined in the study protocol.

Progress: The study remains open for eligible patients.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: C-76-87 Status: Ongoing

Title: A Study of Patterns of Ambulatory Oxygen Saturation in Patients with Chronic Obstructive Lung Disease

| | |
|---|---|
| Start Date 13 Aug 87 | Est Comp Date: |
| Principal Investigator<br>William A. Crosland, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Pulmonary Dis. | Associate Investigators: |
| Key Words:<br>Oxygen saturation | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 9 Sep 88 Results Continue

Objective(s): To determine by 24 hours ambulatory oxygen saturation monitoring if constant low flow oxygen therapy is an effective method of preventing oxygen desaturation and if oxygen desaturation occurs in patients without room air hypoxemia.

Technical Approach: Data to be collected on each patient meetig the inclusion criteria are the patient's age, sex, duration on oxygen therapy, pulmonary function, room air arterial blood gas, arterial blood gas on oxygen, hematocrit, EKG, and rate of oxygen flow. The patient will then wear an ambulatory pulse oximent and maintain a log of daily activities. Patients that show evidence of desaturation will have a second period of ambulatory oxygen saturation monitoring. During this second period, a 24 hour Holtor monitor will be performed. The 24 hour pulse oxymeter and Holtor monitor recordings will be examined to determine if periods of desaturation are associated with dysrhythmias.

Progress: No patients enrolled as of now - pending arrival of equipment.

Detail Summary Sheet

| | | |
|---|---|---|
| **Date: 1 Nov 88** | **Proj No: C-77-87** | **Status: Terminated** |

Title: The Efficacy of Lactaid vs Lactrase in the Treatment of Lactose Intolerance

| | |
|---|---|
| Start Date 13 Aug 87 | Est Comp Date: |
| Principal Investigator<br>Bernard M. Feldman, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicinte/Gastroenterol. | Associate Investigators:<br>Fred Goldner, COL, MC |
| Key Words:<br>Lactaid<br>Lactrase<br>Lactose | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To assess the efficacy of two forms of lactase therapy (Lactaid and Lactrase) in patients with lactase deficiency.

Technical Approach: Following a 12 hour fast, each patient will dring 25 grams of lactose dissolved in water. In a random fashion, all patients will initially receive Lactaid or Lactrase tablets at the manufacturers recommended dose with the lactose meal. Breath hydrogen samples will be collected immediately prior and every hour for eight yours following lactose ingestion.

Progress: Study terminated due to inability to obtain approval to accept donation of Lactaid and Lactrase from the drug company. However, eleven patients had been studied prior to receiving the HSC Memo, dated 7 Dec 87. From this small number it was concluded that administrationof Lactrase or Lactaid 10 minutes before a lactose meal was equally efficacious in decreasing the clinical symptoms of lactose intolerance and reducing excretion of breath oxygen.

Detail Summary Sheet

Date: 28 Oct 88 Proj No: C-85-87 Status: Terminated

Title: Assessment of Calcium Acetate as a Phosphate Binder and Calcium Supplement in Patients with Chronic Renal Failure

| | |
|---|---|
| Start Date 9 Spe 87 | Est Comp Date: |
| Principal Investigator<br>J. Brian Copley, COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine | Associate Investigators: |
| Key Words:<br>Renal failure, chronic | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 9 Sep 88 Results Terminate

Objective(s): To assess the usefulness of calcium acetate as a phosphate binder and calcium supplement in patients with end-stage renal disease.

Technical Approach: All patients who consent to enter the study will have their phosphate binding agents discontinued for one week. Only those patietns who have a serum phosphorus greater than 5.5 mg/dl will be continued on this study. Patients will be treated with either an aluminum containing phosphate binding agent or calcium acetate in a double blinded fashion. At the completion of two months on the study drug, the patients will be switched to the other phosphate binding agent. Every two weeks during the study a PA20 will be drawn mid-week predialysis. At four and eight weeks after beginning the study drug, a serum albumin and C terminal PTH will be drawn.

Progress: Study terminated due to release from active duty of principal investigator.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: C-88-87 Status: Ongoing

Title: A Survey of Intracolonic Combustible Gas Compositions with Various Endoscopic Preparations

| | |
|---|---|
| Start Date 10 Sep 87 | Est Comp Date: |
| Principal Investigator<br>Francis E. Peluso, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Gastroenterology | Associate Investigators:<br>Fred Goldner, COL, MC |
| Key Words:<br>Gas, intracolonic | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: 573.50 |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review n/a Results

Objective(s): 1) To determine whether phosphate enema is an adequate preparation for rectosigmoid electrocautery during sigmoidoscopy, with respect to concentrations of conbustible gases.

2) To determine how an oral polyethylene glycol preparation (Colyte, Edlaw Preparations) and phosphate enema (C.B. Fleet Co.) compare with respect to combustable gas concentrations in the rectum.

3) To determine how regional concentrations of combustible gases in the colon correlate with regional visual assessments of bowel preparation with polyethylene glycol.

Technical Approach: Thirty patients undergoing routine flexible sigmoidoscopy and thirty patients undergoing routine colonoscopy will be entered into the study. The standard bowel cleansing regimens for each procedure will be utilized. At colonoscopy, six gas samples will be obtained via a polyvinyl tube passed through the scope. The method of collecting gas samples during flexible sigmoidoscopy will be identical.

Progress: Study hsa not begun due to problems obtaining part of chromatograph apparatus from Fisher.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: C-91-87 Status: Ongoing

Title: Phase I Study of LY188011 (Difluorodeoxycytidine - Seven Day Continuous Intravenous Infusion)

| | |
|---|---|
| Start Date 21 Sep 87 | Est Comp Date: |
| Principal Investigator (vice Brown)<br>Timothy J. O'Rourke, LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Oncology | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 15

Total Number of Subjects Enrolled to Date: 15

Date of Periodic Review 9 Sep 88 Results Continue

Objective(s): To determine the maximum tolerated dose (which is both predictable and reversible) of LY188011 as a single dose given as a 7 day continuous infusion with each cycle repeated every 28 days.

Technical Approach. Patients must have a microscopically confirmed diagnosis of metastatic or advanced cancer. The cancers must be refractory to effective therapy (surgeyr, radiotherapy, chemotherapy) as well as other investigational agents of higher potential efficacy.

Therapy will follow the schema outlined in the study protocol.

Progress: Fifteen patients have been entered at Brooke and we are continuing to enter patients at the 9 mg/$M^2$ level. Toxicity to date has included fever and flu-like symptoms, nausea and vomiting, and hypotension, which in one patient resulted in transient renal dysfunction. We are continuing to enter patients on study with a maximum tolerated dose not yet determined.

Detail Summary Sheet

| Date: 8 Nov 88 | Proj No: C-6-88 | Status: Completed |
|---|---|---|

Title: Weight Changes in Treated Hypothyroidism.

| Start Date 17 Nov 87 | Est Comp Date: |
|---|---|
| Principal Investigator<br>Jeffrey Abrams, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/General Medicine | Associate Investigators:<br>Kurt Kroenke, LTC, MC<br>John Simmons, MAJ, MC |
| Key Words:<br>Hypothyroidism | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To evaluate weight changes after initiation of treatment for hypothyroidism.

Technical Approach: Twenty-seven patients with hypothyroidism and 27 controls were studied. Cases were selected from Nuclear Medicine Laboratory registers. Records were reviewed to find TSH and weights at time of abnormal laboratory studies and then two years later. The 27 controls were selected from Internal Medicine Clinic charts.

Progress: Cases and controls were similar with respect to mean age (55 vs. 61, $p=0.05$), sex (82% vs. 78% female, $p<0.10$), and mean initial weight (160 vs. 153 pounds, $p<0.10$).

After two years, cases tended to gain weight and controls tended to lose weight, though changes were not significant within groups. A subgroup of cases, who failed to normalize their TSH, demonstrated a significant increase in weight. Furthermore, the weight gain in these patients was significantly different from

controls ($p < 0.005$). The weight changes in subjects who normalized their TSH (0.33 =/1 2.59) was not significantly different from controls (-3.26 +/- 1/858, $p>.10$). The mean of the populations was different when analyzed by the F-test ($F=6.79$, $p=0.01$).

The commonly held belief that treatment of hypothyroidism will lead to weight loss is not supported by our data. Although other studies suggest an initial diuretic effect, long term weight loss is not demonstrable. Untreated hypothyroidism may lead to weight gain, however. This weight gain in the absence of therapy suggests that hormone replacement may correct some, but not all, of the metabolic effects of thyroid hormone deficiency. Screening for hypothyroidism in obese patients without other manifestations of hypothyroidism may not meet the expectations of physician and patient with respect to anticipated weight loss. Even with adequate treatment, long term weight loss may not occur. Further prospective study is indicated to clarify the prognosis of weight loss in treated hypothyroidism.

Detail Summary Sheet

| Date: 20 Apr 88 | Proj No: C-9-88 | Status: Terminated |
|---|---|---|

Title: Comparison of Two Totally Implantable Venous Access Systems: Port-a-Cath (Pharmacia) and Hickman Subcutaneous Port (Davol).

| Start Date 1 Dec 87 | Est Comp Date: |
|---|---|
| Principal Investigator<br>Margaret A. Vajdos, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/General Medicine | Associate Investigators:<br>Mary E. Arrington, R.N., MSN |
| Key Words:<br>Port-a-Cath<br>Hickman Port | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 2

Total Number of Subjects Enrolled to Date: 2

Date of Periodic Review _____ Results _____

Objective(s): To compare two totally implantable venous access systems in regards to advantages and disadvantages associated with (a) surgical insertion, (b) morbidity, (c) patient acceptability, and (d) function and maintenance.

Technical Approach: One hundred Hematology-Oncology patients, who have been determined to be candidates for central venous access, will be prospectively randomized to receive either the Port-a-Cath or Hickman Subcutaneous Port implanted venous access systems. Assessment of the implantation site will begin within three days postoperatively and continue at least weekly. Patient interviews will commence within three days postoperatively and continue approximately every four weeks until the termination of the study.

Progress: Only two patients entered. Unable to standardize the surgical procedure. Study terminated.

Detail Summary Sheet

Date: 28 Sep 88 Proj No: C-11-88 Status: Ongoing

Title: Effect of Thyroid Replacement on Lipid Profile - Differences Associated with Keeping the TSH in Low Normal as Compared to Upper Normal Euthyroid Range

| | |
|---|---|
| Start Date 2 Dec 87 | Est Comp Date: |
| Principal Investigator<br>Albert M. Thomason, COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Endocrinology | Associate Investigators: |
| Key Words:<br>Euthyroid | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 2

Total Number of Subjects Enrolled to Date: 2

Date of Periodic Review _____ Results _____

Objective(s): To demonstrate a difference of the lipid profile of euthyroid patients treated with higher or lower doses of thyroid replacement therapy.

Technical Approach: Patients being treated with thyroid replacement would be enlisted as volunteers. Individual patients would have their TSH levels adjusted by varying their thyroid replacement dose to above 3.5 mcIU or below 1.1 mcIU/ml depending on whether the initial value was above or below the mean euthyoid value of 2.3 mdIU/ml. The patient would be maintained at the lower or higher TSH value for 3 months as determined by monthly measurements. Then, the patient's serum lipid profile (cholesterol, triglyceride, and HDL cholesterol) would be determined after a 14 hour fast x 2. Subsequently, the patient would have his dosage of thyroid replacement adjusted to keep his TSH value in the opposite end of the euthyroid range from which it was initially. After three months of stabilization of the new value of TSH level, the plasma lipid profile would be repeated. Subsequently, the patient would once again have his TSH value adjusted to a relatively higher or lower value depending on where he started initially. After another 3 month period of stabilization, lipid profile would again be obtained.

Progress: Patients are still undergoing first phase of stabilization of their TSH value.

Detail Summa heet

Date: 20 Apr 88 Proj No: C 3-88 Status: Terminated

Title: Prophylactic Antihistamine Use in Prevention of Adverse Reactions to Radiographic Contrast.

| | |
|---|---|
| Start Date 2 Dec 87 | Est Comp Date: |
| Principal Investigator<br>Lawrence R. Ragard, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/General Medicine | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 5

Total Number of Subjects Enrolled to Date: 5

Date of Periodic Review _____ Results _____

Objective(s): 1) To re-examine the use of antihistamines in reducing adverse, both allergic and non-allergic, reactions to radiographic contrast.

2) To examine the benefit of using a H1 and an H2 antihistamine together and separately in prevention of adverse effects of radiographic contrast.

Technical Approach: Approximately 80-100 patients will be randomized to one of four groups. Two groups will receive Zantac and two will receive a placebo. Five minutes before the injection of the IVP dye each group will receive either dimetane or placebo. Participants will be asked to fill out a questionnaire regarding their symptoms prior to and after the IVP.

Progress: Terminated due to an insufficient number of patients to complete the study.

Detail Summary Sheet

| Date: 8 Nov 88 | Proj No: C-14-88 | Status: Ongoing |
|---|---|---|

Title: Atrial Fibrillatory Wave Size and Left Atrial Enlargement: An Echocardiographic Analysis.

| Start Date 2 Dec 87 | Est Comp Date: |
|---|---|
| Principal Investigator<br>Douglas G. Ebersole, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators:<br>J. Mark Moody, LTC, MC<br>James Gilman, MAJ, MC<br>Joseph Johns, MAJ, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 40

Total Number of Subjects Enrolled to Date: 40

Date of Periodic Review _____ Results _____

Objective(s): To determine if atrial fibrillatory wave size correlates with left atrial size by M-mode and 2-D echocardiographic assessment.

Technical Approach: New diagnoses of atrial fibrillation or sequential patients receiving EKG's found to be in atrial fibriallation are undergoing (1) 4 minute EKG's for fibriallatory wave analysis and (2) echocardiogram to assess left atrial size.

Progress: 80% of desired number of patients have been entered. Data collected on these patients but will not be reviewed until patient accrual is completed.

Detail Summary Sheet

Date: 28 Sep 88 Proj No: C-15-88 Status: Completed

Title: Common Ambulatory Complaints: Prevalence, Evaluation, Management and Outcome.

| | |
|---|---|
| Start Date 2 Dec 88 | Est Comp Date: |
| Principal Investigator<br>Kutr Kroenke, LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine | Associate Investigators:<br>Dr. A. Mangelsdorff, HSC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): This is a retrospective chart audit study of common complaints to determine their prevalence, the extent and the results of diagnostic evaluations, the therapy prescribed, and the outcome of such symptoms.

Technical Approach: One thousand records for the three year period August 1984 through August 1987 were reviewed. Data abstracted included patient age, race, sex, symptom, duration of symptom, diagnostic evaluation, therapy and outcome.

Progress: A total to 567 new complaints of chest pain, fatigue, dizziness, headache, edema, back pain, dyspnea, insomnia, abdominal pain, numbness, impotence, weight loss, cough, and constipation were noted, with 38% of the patients reporting at least one symptoma. Although diagnostic testing was performed in over two-thirds of the cases, an orgnaic etiology was demonstrated in only 16%. The cost of discovering an organic diagnosis was high, particularly for certain symptoms such as headache and back pain. Treatment was provided for only 55% of the symptoms and was often ineffective. Where outcome was documented, 164 (53%)

C-15-88 (continued)

of 307 symptoms improved. Three favorable prognostic factors were an organic etiology (p=0.006), a symptom duration of less than four months (p=0.009), and a history of two or fewer symptoms (p=0.001). In summary, the classification, evaluation and management of common symptoms needs to be refined. Diagnostic strategies emphasizing organic causes may be inadequate.

Detail Summary Sheet

| Date: 8 Nov 88 | Proj No: C-17-88 | Status: Ongoing |
|---|---|---|

Title: Evaluation of Immunocyte Populations in Mice Infected with *Coccidioides immitis* (fungus)

| | |
|---|---|
| Start Date 16 Dec 87 | Est Comp Date: |
| Principal Investigator<br>J. William Kelly, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Infectious Dis. | Associate Investigators:<br>David L. Danley, MAJ, MS<br>Rebecca Cox, Ph.D.<br>Janice M. Grassel, M.T. |
| Key Words:<br>*Coccidioides immitis* | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To evaluate, using flow cytometry, the immunocyte populations associated with Tissues infected with *C. immitis* from susceptible and resistant strains of mice.

Technical Approach: In this study we propose to identify and enumerate different immunocyte populations in the spleen and peripheral blood of DBA/2 and BALB/c mice infected intranasally with *C. immitis*, using a fluorescence-activated cell sorter (FACS). All animals will be maintained and infected by Dr. R. Cox and her associates at the San Antonio Chest Hospital. Animals will be infected with ten spores intranasally. At various times after infection, spleen cells, peripheral blood, and lung tissue will be recovered. A single cell suspension will be obtained from solid tissue by mincing the organs in balanced salt solution; whereas peripheral leukocytes will be assayed without separation from contaminating erythrocytes.

Progress: Technical difficulties involving the delivery of gamma-interferon and acquisition of a second FACS machine have delayed proress on this study. The first sets of mice have been inoculated.

Detail Summary Sheet

Date: 8 Nov 88 Proj No: C-19-88 Status: Ongoing

Title: Effect of Oral Agents vs Insulin Therapy on Lipid Profile

| | |
|---|---|
| Start Date 13 Jan 88 | Est Comp Date: |
| Principal Investigator<br>Albert M. Thomason, COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Endocrinology | Associate Investigators: |
| Key Words:<br>Insulin therapy | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To demonstrate whether low density lipoprotein cholesterol and total cholesterol-high density lipoprotein cholesterol ratios are worse in Type II diabetics treated with insulin as compared to oral agents.

Technical Approach: 30 patients being treated with oral hypoglycemic agents would be enlisted as volunteers. For the first 3 months, the patient would be followed on his/her usual oral hypoglycemic agent to determine average HGB A1C and lipid profile values. Subsequently the patient would be taken off the oral hypoglycemic agent and placed on human insulin therapy in such a dosage as to keep the Hgb A1C value as near as possible to the value the patient had while being treated with oral hypoglycemic agent. After 4 months on insulin therapy, the patient's lipid profiles for the previous 3 months would be averaged to compare the lipid profie while on oral hypoglycemic therapy. Subsequently, the patient would be taken off insulin and restarted on the same dose of hypoglycemic agent as previously taken. At the end of 4 months, the patient's lipid profile would be averaged as before.

Progress: None, due to lack of volunteers.

Detail Summary Sheet

| | | |
|---|---|---|
| Date: 8 Nov 88 | Proj No: C-23-88 | Status: Ongoing |

Title: Do Oral Iron Supplements Cause False Positive or True Positive Hemoccult Tests? Use of Hemoquant Assays for Hemoglobin Quantification.

| | |
|---|---|
| Start Date 13 Jan 88 | Est Comp Date: |
| Principal Investigator<br>Edward F. Coles, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Gastroenterology | Associate Investigators: |
| Key Words:<br>Hemoccult tests | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: 3960.00 |

Number of Subjects Enrolled During Reporting Period: 16

Total Number of Subjects Enrolled to Date: 16

Date of Periodic Review _____ Results _____

Objective(s): To determine if positive Hemoccult test frequently observed in patients taking various oral iron supplements is a true-positive or a false-positive reaction by simultaneous quantitation of gastrointestinal blood loss by the Hemaquant method.

Technical Approach: Healthy volunteers are enrolled in a 4-week protocol where they are asked to follow a standard diet for hemoccult testing. On weeks 1 and 3, they submit stools on days 3, 5, and 7 of the diet, and these serve as controls. On week 2, they take ferrous sulfate, 324 mg 1 t.i.d., and submit stools on days 3, 5, and 7. On week 4, they take ferrous gluconate, 324 mg 1 t.i.d., and submit stools on days 3, 5, and 7. All stools are tested for hemoccult and hemoquants.

Progress: Thus far the results indicate that neither iron sulfate nor iron gluconate cause GI bleeding manifested by all negative hemoccults and all normal hemoquants. Based on this we will be recommending that any positive hemoccults found in patients taking iron products be fully evaluated for GI pathology which is unrelated to taking iron products in usual therapeutic doses. Further, this study confirms prior observations that iron preparations do not interfere with hemoquant values.

Detail Summary Sheet

| Date: 10 Nov 88 | Proj No: C-34-88 | Status: Completed |
|---|---|---|

Title: Variation of Erythrocyte Sedimentation Rate (ESR) in End-Stage Renal Disease (ESRD) and Chronic Renal Failure (CRF)

| Start Date 4 Mar 88 | Est Comp Date: |
|---|---|
| Principal Investigator<br>Howard A. Burris, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/General Medicine | Associate Investigators:<br>John B. Copley, COL, MC<br>Ken Melton, MAJ, MC |
| Key Words:<br>End-Stage Renal Disease<br>Chronic Renal Failure<br>Erythrocyte Secimendation Rate | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 30

Total Number of Subjects Enrolled to Date: 30

Date of Periodic Review _____ Results _____

Objective(s): 1) To assess whether ESR determinations are useful in patients with ESRD and in patients with varying degrees of CRF.

2) To assess whether other acute phase reactants, specifically, serum fibrinogen and C-reactive protein (CRP) are of diagnostic utility and whether they correlate with the ESR.

3) To assess whether the level of ESR elevation is increased by the degree of renal function.

Technical Approach: Eighteen hemodialysis patients enrolled and underwent three montly blood draws for assessment of CBC, ESR, fibrinogen, CRP, and PA-20.

Twelve chronic renal failure patients were enrolled and underwent one blood draw for above noted lab and one 24 hour urine collection for total protein and creatinine.

Progress: While the vast majority of the patients in this study had normal or slightly above normal CRP values, the absolute number of 33% with some elevation precludes it from being useful as a screening test. Similarly, most fibrinogen levels were in the high normal range, with only 16% showing absolute elevations, but still not statistically adequate for use as a screening test. However, a full complement of patients, both dialysis and non-dialysis dependent, must be accumulated for full statistical analysis and correlation. Even if the final outcome were to clearly show acute phase reactants and ESR are not valid

screening tests in these patients secondary to nonspecific elevations, this finding would be beneficial in helping to prevent being "fooled" by a laboratory abnormality in this patient population. At present, it seems that clinical judgment cannot be aided by ESR, CRP, or fibrinogen determinations in patients with ESRD, either as a screening test or with the wide disparity of values obtained at present, as markers of disease remission or progression.

Detail Summary Sheet

Date: 8 Nov 88 Proj No: C-37-88 Status: Ongoing

Title: A Comparison of Cine and DSA Quantitative Coronary Angiography

| | |
|---|---|
| Start Date 7 Mar 88 | Est Comp Date: |
| Principal Investigator<br>Jeffrey Abrams, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/General Medicine | Associate Investigators:<br>Steven R. Bailey, MAJ, MC |
| Key Words: | Eleanor Ayala, M.T., MBA |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To compare the latest automated techniques for evaluation of coronary artery stenoses to planimetry of coronary artery casts.

Technical Approach: With the consent of family members, ten cadavers wer studied. Hearts were removed and arteries selectively injected with barium latex at 10 ATM for five minutes. Biplane cineangiographic films plus digitial images taken, coronary casts decalcifed and sectioned.

Progress: Specimens are currently in decalcification. Data analysis has not begun.

Detail Summary Sheet

Date: 30 Sep 88 Proj No: C-40-88 Status: Completed

Title: Aluminum Absorption with the Use of Aluminum Containing Compounds in Combination with Solubilized Calcium Citrate in Dialysis Patients

| | |
|---|---|
| Start Date 29 Mar 88 | Est Comp Date: |
| Principal Investigator<br>Karl G. Koenig, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Nephrology | Associate Investigators:<br>Jill Lindberg, MAJ, MC<br>John B. Copley, COL, MC<br>Howard M. Cushner, MAJ, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 16

Total Number of Subjects Enrolled to Date: 16

Date of Periodic Review _____ Results _____

Objective(s): To assess whether citrate in the form of solubilized calcium citrate increases aluminum absorption in dialysis patients.

Technical Approach: Sixteen hemodialysis patients had serum albumin levels drawn while on aluminum-containing phosphate binders compared to the levels when they took both aluminum phosphate buffers plus calcium citrate.

Progress: Preliminary results show no significant difference in aluminum levels.

Detail Summary Sheet

| Date: 30 Jun 88 | Proj No: C-41-88 | Status: Completed |
|---|---|---|

Title: Calcium Tolerance Study

| | |
|---|---|
| Start Date 29 Mar 88 | Est Comp Date: |
| Principal Investigator<br>Michael A. O'Connell, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 41

Total Number of Subjects Enrolled to Date: 41

Date of Periodic Review _____ Results _____

Objective(s): To determine GI tolerance of various currently available oral calcium products in both pre- and post-menopausal women in whom calcium supplementation is indicated for the prevention of osteoporosis.

Technical Approach: Forty-one healthy women underwent four phases of study using three commercially available oral calcium supplements and placebo (each for one week, with a three-day washout in between) in a double-blinded randomized fashion. At the end of each week, the subjects completed a standardized survey to assess the presence and severity of several common gastrointestinal complains sometimes associated with oral calcium supplement.

Progress: No statistically significant differences in gastrointestinal side effects were found between calcium supplements and placebo. However, there was a significantly greater difficult encountered with swallowing Posture when compared to Citrcal and Os-Cal. In summary, commercially available oral calcium supplements are well tolerated. Concern about gastrointestinal side effects should not be a limiting factor in the decision to initiate oral calcium supplementation.

Detail Summary Sheet

| Date: 8 Nov 88 | Proj No: C-44-88 | Status: Completed |
|---|---|---|

Title: Common Ambulatory Complaints: A Survey of Primary Care Outpatients

| Start Date 29 Mar 88 | Est Comp Date: |
|---|---|
| Principal Investigator<br>Kurt Kroenke, LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine | Associate Investigators:<br>Mary E. Arrington, R.N., MSN |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To determine the prevalence of common ambulatory complaints, the degree of patient concern, and the modalities patients have found helpful in dealing with such symptoms.

Technical Approach: Five hundred patients were surveyed in the Internal Medicine Clinic of which 410 (82%) completed the survey.

Progress: It was found that all 17 symptoms surveyed were common, present in 10% to 31% of all respondents. In three out of four instances, the patient had told a doctor of the symptom, but in nearly half of the cases, no effective therapy had been found. Symptoms are very common in outpatient medicine, but current management is inadequate.

Detail Summary Sheet

Date: 8 Nov 88 Proj No: C-47-88 Status: Ongoing

Title: Percutaneous Recanalization of Human Coronary Arteries with Balloon-Expandable Intracoronary Grafts (BEIG)

| | |
|---|---|
| Start Date 25 Apr 88 | Est Comp Date: |
| Principal Investigator<br>Steven R. Bailey, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 3

Total Number of Subjects Enrolled to Date: 3

Date of Periodic Review _____ Results _____

Objective(s): 1) To determine the safety of the stent by evaluating reported clinical complications associated with its placement.

2) To determine the effectiveness of the stent by evaluating patients for long-term patency rates. Patency will be compared with results reported in the literature for PTCA alone. In addition, results will be compared with follow-up of a concomitant group of control patients treated by PTCA.

Technical Approach: This study is designed as a prospective survey following placement of a Balloon Expandable Intracoronary Stent in a coronary artery. The stent will initially be implanted in patients with confirmed collateral blood flow to the distal portion of the stenotic coronary artery.

Progress: Three patients have been entered into the study. All are doing extremely well. One patient has been returned to full duty without limitations.

Detail Summary Sheet

| Date: 8 Nov 88 | Proj No: C-51-88 | Status: Ongoing |
|---|---|---|

Title: Bowel Preparation for 60 cm Flexible Sigmoidoscopy

| | |
|---|---|
| Start Date 9 May 88 | Est Comp Date: |
| Principal Investigator<br>Kevin L. Preston, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Gastroenterology | Associate Investigators:<br>Francis E. Peluso, MAJ, MC<br>Fred Goldner, COL, MC |
| Key Words:<br>Sigmoidoscopy | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To evaluate the efficacy of various enema administration schedules in achieving optimal bowel preparation for 60 cm flexible sigmoidoscopy.

Technical Approach: The study groups will consist of male and female patients over the age of 18 who are to undergo outpatient flexible sigmoidoscopy for routine indications. Three groups will be evaluated and will consist of 30 patients each. The groups will consist of the following phosphate enema regimens: Group 1 - a single enema 1 hour prior to the procedure; Group 2 - 2 enemas given in close succession, 1 hour prior to the procedure; and Group 3 - 1 enema given 3 hours and again at 1 hour prior to the procedure.

Progress: Patient accrual continues. It is too early to report any meaningful data.

Detail Summary Sheet

| Date: 8 Nov 88 | Proj No: C-55-88 | Status: Ongoing |
|---|---|---|

Title: Epidemiology and Clinical Data in Patients with AIDS and Mycobacterium Tuberculosis (MTb) Infection in Texas

| Start Date 9 May 88 | Est Comp Date: |
|---|---|
| Principal Investigator<br>Gregg T. Anders, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Pulmonary | Associate Investigators:<br>H. M. Blanton, MAJ, MC |
| Key Words: | |
| Accumulative MEDCASE<br>Cos | Est Accumulative<br>OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 14

Total Number of Subjects Enrolled to Date: 14

Date of Periodic Review _____ Results _____

Objective(s): To evaluate the occurrence of MTb infection in patients with HIV infection as well as full-blown AIDS and to assess clinical response to therapy and occurrence of drug resistance; to assess in vitro susceptibility patterns and to determine effectiveness of MTb chemoprophylaxis in HIV infected patients.

Technical Approach: Records review of inpatient and outpatient records at participating institutions.

Progress: There is apparently a sub-class of patients with MTb and AIDS who are presenting with signs of "classical" tuberculosis. Therapy may be necessary for the lifespan of the patient.

Detail Summary Sheet

| Date: 9 Nov 88 | Proj No: C-60-88 | Status: Ongoing |
|---|---|---|

Title: Hemodynamics of Aortic Stenosis

| | |
|---|---|
| Start Date 3 Jun 88 | Est Comp Date: |
| Principal Investigator<br>Roger Belbel, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): 1) To develop hemodynamic parameters obtained by invasive and noninvasive means which could be used to assess left ventricular adaptation to pressure overload.

2) To develop new indices for assessing severity of aortic stenosis.

Technical Approach: This study is a retrospective analysis of data obtained from archived analog hemodynamic measurements from nonconsecutive patients with documented aortic stenosis.

Progress: Retrospective review completed; data are being analyzed.

Detail Summary Sheet

| Date: 9 Nov 88 | Proj No: C-61-88 | Status: Ongoing |
|---|---|---|

Title: Non-invasive Estimation of Prosthetic Aortic Valve Area Using Doppler Ultrasound

| Start Date 3 Jun 88 | Est Comp Date: |
|---|---|
| Principal Investigator<br>Joseph P. Johns, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To determine if Doppler ultrasound, using the equation of continuity, can accurately estimate the effective area of prosthetic valves in the aortic area.

Technical Approach: A multicenter study will be performed involving patients at WRAMC, BAMC, and FAMC. It will be a two-armed study. There will be a retrospective evaluationof patients who have undergone aortic valve replacement within the past two years at these medical centers. There will be a prospective analysis of patients undergoing valve replacement. All patients will undergo 2-D and M-mode echocardiography as well as pulsed and continuous wave Doppler echocardiography of the aortic valve.

Progress: None. Study is being reviewed at WRAMC.

Detail Summary Sheet

| Date: 9 Nov 88 | Proj No: C-67-88 | Status: Ongoing |
|---|---|---|

Title: Evaluation of Patients with Human Immunodeficiency Virus (HIV) Seropositivity for the Presence of Cardiac Disease

| | |
|---|---|
| Start Date 14 Jul 88 | Est Comp Date: |
| Principal Investigator<br>James E. Johnson, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Pulmonary | Associate Investigators:<br>Greg A. Anders, MAJ, MC<br>Ricky D. Latham, MAJ, MC<br>C. Kenneth McAllister, COL, MC<br>J. William Kelly, MAJ, MC<br>David M. Slife, CPT, MC |
| Key Words:<br>HIV seropositivity | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 5

Total Number of Subjects Enrolled to Date: 5

Date of Periodic Review _____ Results _____

Objective(s): To measure directly the cardiac response to exercise in these patients in an effort to document whether or not there are abnormalities.

Technical Approach: Patients are undergoing right heart catheterization with maximum incremental exercise with expired gas analysis and mixed venous lactates.

Progress: Preliminary results of the first five patients indicate normal or mildly impaired cardiac responses but early output of lactate at low $O_2$ extraction.

Detail Summary Sheet

| Date: 30 Sep 88 | Proj No: C-69-88 | Status: |
|---|---|---|

Title: Colonic Lavage Solution (Colyte) as a Treatment for Chronic Constipation

| Start Date 14 Jul 88 | Est Comp Date: |
|---|---|
| Principal Investigator<br>Richard Andorsky, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Gastroenterology | Associate Investigators:<br>Fred Goldner, COL, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): 1) To determine if Colyte might be an effective therapy for the treatment of chronic refractory constipation.

2) To determine the appropriate dosing schedule when using Colyte as therapy for chronic constipation.

Technical Approach: Participants will be randomized to receive either Colyte or placebo one to two glasses per day for five days. They will stop for two days and then receive whichever solution they did not receive during the initial five days.

Progress: No progress has been made. The investigators are awaiting approval to accept the Colyte and placebo donated by the company (Reed & Carnick).

Detail Summary Sheet

Date: 9 Nov 88 Proj No: C-71-88 Status: Ongoing

Title: Evaluation of the Effects of Coronary Collateral Vessels on Exercise-Induced Wall Motion Abnormalities

| | |
|---|---|
| Start Date 5 Aug 88 | Est Comp Date: |
| Principal Investigator<br>Joseph P. Johns, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 2

Total Number of Subjects Enrolled to Date: 2

Date of Periodic Review _____ Results _____

Objective(s): To determine the role that the degree of coronary collateralization has on the induction of exercise-induced wall motion abnormalities during exercise echocardiography.

Technical Approach: Subjects will be recruited from patients at BAMC, and the Audie Murphy VA Hospital, who have recently undergone cardiac catheterization and selective coronary cineangiography for the investigation of known or suspected coronary artery disease. When possible, all antianginal medications will be discontinued three half-lives prior to exercise testing. Upright bicycle exercise which allows for continuous echocardiographic imaging throughout exercise and during recovery will be used. All exercise echocardiographic studies will be recorded on videotape for analysis.

Progress: Two patients studied thus far. Fewer subjects than expected have been encountered.

Detail Summary Sheet

Date: 9 Nov 88 Proj No: C-72-88 Status: Ongoing

Title: Long Term 5-Fluorouracil Infusion for Recurrent Head and Neck Cancer

| | |
|---|---|
| Start Date 5 Aug 88 | Est Comp Date: |
| Principal Investigator<br>Patrick W. Cobb, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Hem-Oncology | Associate Investigators:<br>Arlene J. Zaloznik, LTC, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To study the effect of a continuous infusion of 5-Fluorouracil (300 $mg/m^2/d$) on patients with recurrent head and neck cancer.

Technical Approach: Patients will receive 300 $mg/m^2/d$ of 5-FU in a continuous infusion via central venous catheter. All patients will be placed on vitamin B6, 150 mg/d orally, to prevent and/or ameliorate palmar-plantar erythrodysethesia. Patiens with recurrent squamous cell cancer of the head and neck who are not candidates for curative treatment with radiation therapy or surgery are eligible for the study.

Progress: At the present time no patients have been entered on this study. Three patients have been offered the protocol but all refused.

Detail Summary Sheet

| | | |
|---|---|---|
| Date: 9 Nov 88 | Proj No: C-74-88 | Status: Ongoing |

Title: A Prospective Analysis of Cardiac Changes Related to Radiation Therapy

| | |
|---|---|
| Start Date 5 Aug 88 | Est Comp Date: |
| Principal Investigator<br>William T. Wright, Jr., CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Cardiology | Associate Investigators:<br>J. Mark Moody, LTC, MC<br>Douglas Jackson, CPT, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____ Results_____

Objective(s): 1) To assess immediate (short term) effects of mediastinal irradiation on ventricular function.

2) To assess predictors of ventricular function before and after mediastinal irradiation.

3) To establish a baseline for evaluation of late cardiac changes, to include coronary artery occlusion related to radiation.

Technical Approach: Patients will be eligible for this study who are 18 years of age or older and who are to receive irradiation to the mediastinum including any portion of the heart in the field regardless of tumor type. Patients will be stratified to one of three groups according to the amount of heart included in the radiation field receiving a minimum of 1,000 rads. Groups in which less than or equal to one-third of total heart tissue, greater than one-third, but less than two-thirds of total heart tissue, and greater than two-thirds of total heart tissue will be identified. All patients will answer a symptom questionnaire prior to initiation of testing.

Progress: This is a new study.

Detail Summary Sheet

| Date: 9 Nov 88 | Proj No: C-78-88 | Status: Ongoing |
|---|---|---|

Title: Phase II Study of Patients with Primary Malignant Gliomas Treated with Intracranial Recombinant IL-2 and Autologous LAK Cells (Collaborative Study with Audie Murphy VA Hospital)

| Start Date 8 Sep 88 | Est Comp Date: |
|---|---|
| Principal Investigator<br>Timothy J. O'Rourke, LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Oncology | Associate Investigators:<br>Arlene J. Zaloznik, LTC, MC<br>Mark R. Keaton, CPT, MC<br>Thomas D. Brown, M.D. |
| Key Words:<br>Glioma<br>Recombinant IL-2 | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): 1) To determine the time of disease progression, and overall survival in patients with primary malignant gliomas treated with surgical resection and postoperative intracranial IL-2 and autologous LAK cells.

2) To detect preliminary evidence for objective response in those patients with measurable disease postoperatively.

3) To determine the toxicity of IL-2 and autologous LAK cells administered intracranially in this patient population.

4) To correlate in vitro biologic parameters of these patients' malignant gliomas with their clinical outcomes.

Technical Approach: Pending approval by NIH for submission to the FDA for IND.

Progress: None. The study will start upon receipt of IND.

Detail Summary Sheet

| Date: 9 Nov 88 | Proj No: C-87-88 | Status: Ongoing |
|---|---|---|

Title: Evaluation of Blood Flow in Full Thickness Skin Grafts Utilizing the Laser Doppler Velocimeter

| | |
|---|---|
| Start Date 12 Oct 88 | Est Comp Date: |
| Principal Investigator<br>Michael J. Mulvaney, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Dermatology | Associate Investigators:<br>Stuart J. Salasche, COL, MC |
| Key Words:<br>Laser Doppler Velocimeter | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____ Results_____

Objective(s): To measure cutaneous blood flow in full thickness skin grafts from the time of placement until stabilization of blood flow occurs and the graft "takes". To correlate blood flow data to observed clinical color and texctue changes, as well as known physiologic changes that have been documented in full thickness skin grafts.

Technical Approach: Patients requiring full thickness skin grafts following cancer removal will be asked to participate. The Laser Doppler Velociment (LDV) will be used to measure blood flow in the anticipated donor site, the contralateral donor site, and the forehead. A postoperative reading of the full thickness skin graft foreheads and the contralateral donor site. Daily radings will be obtained for two weeks as well as photographs.

Progress: This is a new study.

Detail Summary Sheet

Date: 29 Nov 88 Proj No: C-88-88 Status: Ongoing

Title: Phase I Study of LY186641 (Sulfonylurea) Given Over 21 Days Every Four Weeks

| | |
|---|---|
| Start Date 22 Nov 88 | Est Comp Date: |
| Principal Investigator<br>Timothy J. O'Rourke, LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Ongology | Associate Investigators:<br>Hematology-Oncology Staff |
| Key Words:<br>Sulfonylurea | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____ Results_____

Objective(s): To determine the maximum tolerated dose of LY186641 as single daily doses given in multiple courses of 21 consecutive days followed by a rest period of approximately 7 days.

Technical Approach: All patients must have a histopathologically confirmed diagnosis of advanced or metastatic cancer. Therapy will follow the schema outlined in the company protocol.

Progress: This is a continuation of previous studies of sulfonylurea. As the study has only recently been approved, no patients have been entered.

Detail Summary Sheet

Date: 29 Nov 88 Proj No: C-89-88 Status: Ongoing

Title: A Randomized, Double-Blind Efficacy, Safety and Pharmacokinetic Study of Two Doses BMY-25801 in Patients Receiving High-Dose Cisplatin, Phase II

| | |
|---|---|
| Start Date 22 Nov 88 | Est Comp Date: |
| Principal Investigator<br>Terry R. Jenkins, LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Oncology | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To compare the antiemetic efficacy, safety, and pharmacokinetics of two doses of BMY-25801 in 80 chemotherapy-naive cancer patients receiving cisplatin $\geq$100 mg/m$^2$ in combination with other chemotherapeutic agents.

Technical Approach: This is a randomized double-blinded parallel phase II trial comparing the antiemetic properties of two intravenous doses of BMY-25801, 1.2 mg/kg and 6.0 mg/kg in 80 chemotherapy-naive cancer patients treated with cisplatin or in combination with other chemotherapeutic agents. Patients will be randomly allocated to receive 3 intravenous doses of BMY-25801 at 1.2 mg/kg or 6.0 mg/kg. The study will be adminstered over 15 minutes; 0.5 hours before and 1.5 and 3.5 hours after the initiation of the cisplatin infusion.

Progress: This is a new study recently. No patients have been enrolled.

Detail Summary Sheet

Date: 29 Nov 88 Proj No: C-91-88 Status: Ongoing

Title: A Randomized Double-Blind Comparison of Three Dose Levels of Intravenous GR-C507/75 in the Prevention of Nausea and Vomiting Associated with Cisplatin

| | |
|---|---|
| Start Date 22 Nov 88 | Est Comp Date: |
| Principal Investigator<br>Timothy J. O'Rourke, LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Ongology | Associate Investigators:<br>Arlene J. Zaloznik, LTC, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To compare the antiemetic efficacy of three different doses of intravenous GR-C507/75 in patients receiving cisplatin for the first time; to further define the safety profile of intravenous GR-C507/75 when used as an antiemetic in patients with cancer receiving cisplatin for the first time.

Technical Approach: Male or nonpregnant females who are to receive cisplatin as a single dose of $\geq$100 mg/m$^2$ for the first time will be eligible. Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study which has only recently been approved by the Clinical Investigation Program Division, HSC. No patients have been enrolled.

Detail Summary Sheet

Date: 29 Nov 88 Proj No: C-92-88 Status: Ongoing

Title: Domperidone (R 33,812) Compassionate Clearance Single Patient Protocol

| | |
|---|---|
| Start Date 22 Nov 88 | Est Comp Date: |
| Principal Investigator<br>Eddie Starnes, COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Medicine/Gastroenterology | Associate Investigators:<br>Francis E. Peluso, MAJ, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 2

Total Number of Subjects Enrolled to Date: 2

Date of Periodic Review _____ Results _____

Objective(s): To treat patients with gastric stasis who have failed conventional forms of therapy.

Technical Approach: Only patients who have failed all other forms of therapy meeting the eligibility criteria may be entered on this study. Therapy will follow the schema outlined in the study protocol.

Progress: Two patients have been approved for entry on this study. Their therapeutic response to the investigational drug has been very dramatic without any significant side effects.

Detail Summary Sheet

Date: 8 Sep 88 Proj No: C-48-86 Status: Ongoing

Title: Animal Facilitated Therapy (AFT) in the Brooke Army Medical Center Pediatric Department.

| | |
|---|---|
| Start Date 4 Apr 86 | Est Comp Date: |
| Principal Investigator<br>Lynn J. Anderson, MAJ, VC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Ministry & Pastoral Care | Associate Investigators:<br>Carolyn Randle, LTC, MC |
| Key Words:<br>Therapy, animal facilitated | Robert VanIngen, MAJ, CH<br>Jesse DelaCruz, LTC, AN |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review n/a Results _____

Objective(s): 1) Determine patient and staff opinions of animal facilitated therapy before and after such therapy has been utilized.

2) Educate staff, subjects, and subjects' families of the potential values of AFT to them.

3) Evaluate specifically: (a) the distractive value of an animal to a child during a stressful exam or test, and (b) the value of an animal as a cotherapist in mental health counseling sessions.

4) Identify other potential studies for future evaluation.

Technical Approach: Subjects will be selected from children currently being treated by the BAMC Pediatric Department. They will be chosen on the basis of their desire to be involved in the program. We will evaluate the distractive value of an animal to a child during a stressful exam or procedure such as repeated withdrawal of blood samples from patients being evaluated for diabetes. It is hypothesized that the presence of an animal during those times would distract the patient from the procedure, thus making the procedure easier for the patient and also for the staff involved. The study has been explanded to include patients being seen in the Department of Psychiatry.

Progress: This study continues to report many success stories on the Pediatric Ward and in the Department of Psychiatry as manifested by the following case reports.

Case 1 - Polly was taken to visit a child recovering from open-heart surgery. The child eyed the dog and withdrew back against the wall. I rolled Polly over

to show where she'd been spayed and explained that she had had surgery too. The child then allowed Polly to peek at the incision and suddenly realized he wasn't all alone.

Case 2 - An eleven-year-old girl knew she was dying of leukemia. When Polly brushed by her, she thought of her own dog, who resembled Polly. After her dog had undergone a required veterinary exam, we were able to make an exception to policy wherein the dog was allowed to visit her. She died a few months later, but her hospital stay wasn't quite so harsh with part of her familiary world beside her.

Case 3 - A patient visiting the Psychiatry Clinic confined himself to a private room and got a little out of control. Polly walked in, and after five minutes he was hugging the dog and crying. Polly had done in a few minutes what could have taken hours.

Detail Summary Sheet

Date: 9 Nov 88 Proj No: C-2-86 Status: Completed

Title: Expectations and Experience Evaluation of Oncology Patients Participating in Phase II Clinical Trials

| | |
|---|---|
| Start Date 28 Oct 86 | Est Comp Date: |
| Principal Investigator (vice Tracy)<br>Linda Yoder, MAJ, AN | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Nursing/Oncology | Associate Investigators:<br>Pam Clement, Ph.D. |
| Key Words:<br>Patients, oncology | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 22 Jan 88 Results Continue

Objective(s): To describe the expectations of patients entering a phase I clinical trial and to describe their evaluations of their experience after their particpation.

Technical Approach: Participants will be interviewed before the drug study begins and again approximately two months later. They will be asked to complete the Millon Behavioral Health Inventory questionnaire after the first interview.

Progress: Data gathering has been completed; however, no reportable data are available since all of the information has been sent to the original principal investigator, MAJ Annette Etnyre, for manuscript preparation.

Detail Summary Sheet

Date: 8 Aug 88 Proj No: C-72-86 Status: Completed

Title: Development and Testing of an Expected Sensation Preoperative Teaching Tool Utilizing Sensation Descriptions of Postoperative Patients

| | |
|---|---|
| Start Date 12 Aug 86 | Est Comp Date: |
| Principal Investigator<br>Pamela J. Hildreth, MAJ, AN | Facility<br>Brooke Army Medical Center/UTHSC |
| Dept/Svc<br>Department of Nursing | Associate Investigators:<br>Reginald D. Williams, COL, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 10

Total Number of Subjects Enrolled to Date: 10

Date of Periodic Review 10 Sep 87 Results Continue

Objective(s): To develop and test a preoperative teaching tool which incorporates sensations surgical patients can expect to experience.

Technical Approach: In phase I, a postoperative interview schedule will be developed to assess the surgical sensation experiences of postoperative patients. The questions will relate to sensations encountered by the patient during the pre-operative, recovery room, and first 24-48 hours postoperative periods.

For Phase II, a second postoperative interview schedule will be developed to determine the effectiveness of the expected sensation preoperative teaching tool.

Progress: Phase I has been completed. Surgical patients were able to accurately recall and describe surgical sensations occurring during the preoperative, recovery and postoperative periods. A surgical teaching tool was developed for orthopedic patients based on these descriptions.

Due to time constraints on the principal investigator, Phase II will not be done.

Detail Summary Sheet

Date: 12 Sep 88 Proj No: C-75-86 Status: Completed

Title: Position Change for Electrocardiograms in Patients with Chronic Obstructive Pulmonary Disease

| | |
|---|---|
| Start Date 12 Aug 86 | Est Comp Date: |
| Principal Investigator<br>Sheila Westbrook, CPT, AN | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Nursing | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 56

Total Number of Subjects Enrolled to Date: 56

Date of Periodic Review 9 Sep 88 Results Completed

Objective(s): To determine if there is a difference in electrocardiograms recorded in a supine position compared to a position of rest in chronic obstructive airway patients.

Technical Approach: A two part study will be conducted to determine the effects of two positions (flat and 45° angle) on electrocardiograms measured by the 12 lead EKG on a group of 30 normal healthy volunteers and a group of 50 patients with chronic obstructive pulmonary disease. Two EKGs will be recorded - one in the supine position and one in the 45° position. The first reading will be in the 45° position and the second in the supine. A lead placement will be marked on the chest wall of all subjects to assure that no change in lead placement will take place with the change in body position.

Progress: A total of 30 normal healthy volunteers and 26 COPD patients completed the study. T-test analysis of the supine and 45 degree position electrocardiograms reflected no significant difference demonstrated in the Durations and Intervals. The only significant difference was in the amplitude which would be expected with the movement of the heart toward the chest wall.

Detail Summary Sheet

| Date: 1 Nov 88 | Proj No: C-61-87 | Status: Completed |
|---|---|---|

Title: The Cost Effectiveness and Treatment Efficacy of an Outpatient Self-Management Program for Patients with Respiratory Problems: Asthma, Chronic Bronchitis, or Emphysema

| Start Date 25 Jun 87 | Est Comp Date: |
|---|---|
| Principal Investigator<br>Laura Terriquez, CPT, AN | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Nursing/Emergency Room | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: 2620.00 |

Number of Subjects Enrolled During Reporting Period: 4

Total Number of Subjects Enrolled to Date: 26

Date of Periodic Review _____ Results _____

Objective(s): 1) To assist patients in coping and understanding their disease process by teaching them how to assume responsibility for their care and the techniques that will help them achieve self-management of their disease.

2) To organize the initial and follow-up care of the asthmatic patients to reduce the number of return visits to the emergency room and the number of admissions.

Technical Approach: In a group of patients with COPD/Asthma, the effect of an eight week outpatient program of self-management on hospitalizations, Emergency Room visits and clinic visits was examined. Twenty-six men and women diagnosed with COPD and/or asthma completed a comprehensive course of instruction using a multidisciplinary approach in the management of their disease. Hospitalizations, hospital days, Emergency Room visits and Pulmonary Clinic visits were measured six months prior to and six months after completion of the course. Pulmonary function tests were administered prior and upon completion of the course.

Progress: Significant differences were found ($p<.05$) when disease type was compared to the FEV1/FVC ratio as well as when the ratios calculated at the beginning and at the end of the course were compared ($p<.01$). A regression model demonstrated ($p<.05$) that the disease and drugs used by the patient were the greatest predictors of the FEV1/FVC ratio. There was a significant decrease in ER visits ($p<.001$) during the six months following completion of the course when compared to the six month period prior to taking the course. There were no significant differences in hospital days or Pulmonary Clinic visits.

C-61-87 (continued)

The data indicate that this program is valuable in reducing Emergency Room visits for COPD/Asthma patients. This course of instruction should be reduced to a four week program, and the study repeated to collect more refined data.

Detail Summary Sheet

Date: 26 Oct 88 Proj No: C-75-87 Status: Terminated

Title: Oxygenation During Suction in Neonates

| | |
|---|---|
| Start Date 13 Aug 87 | Est Comp Date: |
| Principal Investigator<br>Allison L. Mirakian, CPT, AN | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Nursing | Associate Investigators: |
| Key Words:<br>Neonates | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To provide three different levels of oxygen supplementation during suction and to describe the patient's response in terms of oxygen saturation and its relationship to oxygen content to determine if any of the three levels will consistently maintain the infant's oxygen saturation within the normoxemic range throughout the suction procedure.

Technical Approach: Criteria for admission to the study includes the requirement that the infant be less than 10 days of age, born after 26 weeks gestation and prior to 37 weeks gestation, have a diagnosis of respiratory distress syndrome, and have an oxygen requirement between 25 and 60%. Three different amounts of additioanl oxygen will be given during the suctioning procedure. Suctioning will be done once using 100% oxygen. The next time the infant is suctioned 10% more oxygen will be used and then 20% more the next time.

Progress: Study terminated due to failure to obtain loan of equipment.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: C-86-87 Status: Ongoing

Title: A Descriptive Study of the Effectiveness of Patient Controlled Analgesia (PCA): Morphine vs Meperidine (Demerol) in Postoperative Gynecological Patients

| | |
|---|---|
| Start Date 9 Sep 87 | Est Comp Date: |
| Principal Investigator<br>Lorraine Sneed, 1LT, AN | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Nursing | Associate Investigators: |
| Key Words:<br>Analgesia | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 16

Total Number of Subjects Enrolled to Date: 16

Date of Periodic Review 9 Sep 88 Results Continue

Objective(s): 1) To compare the effects of a patient controlled analgesia (morphine sulfate vs meperidine) on bowel and urinary function in postoperative gynecological patients.

2) To compare the effects of morphine vs meperidine via PCA in the incidence of nausea and vomiting in immediate postoperative gynecological patients.

3) To compare the effectiveness of morphine vs meperidine via PCA for postoperative pain management.

Technical Approach: Participants will be assigned to either the morphine or demerol group and instructed in the proper use of the PCA machine. Bedside assessments will be made of each patient every 2 hours for 12 hours and then every 4 hours for 12 hours, and then every 4 hours until completion of the study. Bedside assessments will include recording urinary output, bowel activity, incidence of nausea and vomiting and pain control.

Progress: Sixteen patients have been registered on this study. No reportable data are available at this time.

Detail Summary Sheet

| | | |
|---|---|---|
| Date: 1 Nov 88 | Proj No: C-95-87 | Status: Completed |

Title: A Comparison Study of Elderly Patient Utilization of Army Emergency and Outpatient Departments

| | |
|---|---|
| Start Date 29 Sep 87 | Est Comp Date: |
| Principal Investigator<br>Vicky M. Sheldon, MAJ, AN | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Nursing | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To identify specific factors associated with emergency and outpatient department use by patients over 65 years of age.

Technical Approach: Two hundred and fifty patients reporting to the emergency and outpatient departments were given a questionnaire to complete. They were asked what factors differentiate the use of a specific department (emergency or outpatient) when seeking health care.

Progress: Results indicated that there were no significant differences between the groups concerning the predisposing and enabling factors. Two need factors, duration of present condition and urgency of need of care, were significantly different, with those in the Emergency Department presenting with a more acute condition and with the perception of a more urgent need of care than those in the Outpatient Department. In differentiating use of a specific department when seeking health care, convenience of hours was a determining factor in use of the Emergency Department. Also, the perception of physician and nursing staff

C-95-87 (continued)

competency was higher for those using the Emergency Department. Using discriminant analysis, 15 variables were useful in correctly classifying 75% of the Emergency Department group and 85% of the Outpatient Department group.

Preparations need to be made now to meet the growing needs of the elderly patient utilizing military health care facilities. Administrators, educators, and staff must have a descriptive knowledge of the elderly patient and their utilization patterns in order to provide care in the most effective manner possible.

Detail Summary Sheet

| Date: 8 Nov 88 | Proj No: C-5-88 | Status: Ongoing |
|---|---|---|

Title: Determinants of Army Ambulatory Health Care Services Utilization by Retired Military and Their Spouses

| | |
|---|---|
| Principal Investigator<br>Richard G. Jensen, MAJ, AN | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Nursing | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): This study has been designed to answer the following research questions:

1) What is the retired military population's average annual Army ambulatory care utilization rate?

2) What individual, societal, health services system, and need for care factors are associated with the use of Army ambulatory care services?

3) What combination of determinants best profiles an individual who is at risk for being a higher than average user of Army ambulatory care services?

Technical Approach: Mailout survey sent to 496 Army retirees from list maintained by Retirement Services at Fort Sam Houston, TX. 262 surveys completed and returned.

Progress: Data has been collected but not analyzed.

Detail Summary Sheet

Date: 8 Nov 88 Proj No: C-32-88 Status: Ongoing

Title: The Effects of Progressive Relaxation for Stress Management Among Critical Care Nurses

| | |
|---|---|
| Start Date 17 Feb 88 | Est Comp Date: |
| Principal Investigator<br>Paulette L. Williams, LTC, AN | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Nursing | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: 69.50 |

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review _____ Results _____

Objective(s): To determin the effects of progressive relaxation as a stress management strategy for critical care nurses.

Technical Approach: Quasi experimental design.

Progress: Study in progress.

Detail Summary Sheet

| | | |
|---|---|---|
| Date: 8 Nov 88 | Proj No: C-36-88 | Status: Ongoing |

Title: Survey of Surgical and Surgeon Skin Preparation

| | |
|---|---|
| Start Date 7 Mar [illegible] | Est Comp Date: |
| Principal Investigator<br>Louise Cuthbertson, CPT, AN | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Nursing | Associate Investigators:<br>Gerald O. Greenfield, MAJ, MC |
| Key Words: | Michael H. Haak, CPT, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 60

Total Number of Subjects Enrolled to Date: 60

Date of Periodic Review _____ Results _____

Objective(s): Using a survey, the various methods of surgical and surgeon's preoperative skin preparation at Brooke Army Medical Center will be assessed. The reasoning and scientific basis will be measured by the survey; these may not correlate with the literature and published standards.

Technical Approach: An anonymous survey was made of physicians utilizing the operating rooms at BAMC. They were asked to answer a variety of questions regarding various skin preparation techniques, scientific basis of choices, and personal hand washing techniques.

Progress: Questionnaires completed, results being evaluated.

Detail Summary Sheet

| Date: 8 Nov 88 | Proj No: C-49-88 | Status: Terminated |
|---|---|---|

Title: The Efficacy of the Silver Impregnated Collagen Collar (VitaCuff) for Long-Term Venous Catheter Care in the Surgical Intensive Care Unit

| Start Date 9 May 88 | Est Comp Date: |
|---|---|
| Principal Investigator<br>Nancy Emma, SSG | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Nursing | Associate Investigators:<br>Mary E. Arrington, R.N., MSN<br>Joseph P. Ducey, MAJ, MC<br>Robert N. Longfield, LTC, MC<br>Ron Hilliard, MAJ, AN |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____ Results_____

Objective(s): To compare triple lumen catheters inserted with and without the VitaCuff for: (a) colonization rates of catheter tips and transcutaneous segments, (b) types of aerobes and fungi on catheter segments, (c) rates of catheter-related bacteremia, (d) complications of mechanical insertion, and (e) cost associated with use and morbidity of each catheter type.

Technical Approach: One hundred critically il patients requiring central venous access on Ward 13A (SICU) will be prospectively randomized into one of two groups. Fifty in Group I (control, standard) will undergo triple lumen catheter (TLC) replacement every 72 hours, and 50 in Group II (VitaCuff) will undergo TLC replacement upto 28 days. The subjects' clinical course, catheter site day changes, and data relevent to the study objectives will be monitored. Catheters and blood cultures from subjects' suspected of catheter related infection will be handled in the usual manner. Others will be removed at the appropriate interval, after two aerobic blood cultures have been obtained. Under aseptic conditions, the catheter will be immediately cut into three segments and cultured. A pilot study of a modified quantitative culture method will be conducted on five catheters not needed in the course of patient care, utilizing whole and split catheter segments.

Progress:No patients were entered into the study. Pilot cultures of intradermal and intravascuar segments (whole and split) were performed on two non-VitaCuff catheters. Each segment was subjected to serial, one minute vortex washing in stserile distilled water. The number of colony forming units (CFU) was determined by duplicate surface culture of 0.2 ml aliquots of each wash. Staphylococcus epidermidis was the common organism with the maximum number of CFU found at the third and fourth washes on the split segments. The same organism

C-49-88 (continued)

was found in both the whole and split segments; however, there was a hundred-fold increase in the number of CFU found in the split segments.

Due to the principal investigator being transferred from the study ward, the study was turned over to LTC Robert N. Longfield. However, LTC Longfield felt that major revisions in the protocol would be necessary of the study were to be completed. He has opted to terminate the study and resubmit at a later date.

Detail Summary Sheet

Date: 9 Nov 88 Proj No: C-59-88 Status: Ongoing

Title: Reliability and Validity of Instruments to Measure Stress in Parents and Temperament and Behavior in 4-5 Year Olds

| | |
|---|---|
| Start Date 3 Jun 88 | Est Comp Date: |
| Principal Investigator<br>Marianne W. Callich, MAJ, AN | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Nursing | Associate Investigators:<br>Jean M. Johnson, Ph.D., UTHSC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 30

Total Number of Subjects Enrolled to Date: 30

Date of Periodic Review _____ Results _____

Objective(s): 1) To obtain normative data for the following instruments: a) Behavioral Style Questionnaire, b) the Child Behavior Checklist, and c) the Hassles Scale.

2) To test the internal consistency of all three instruments.

3) To obtain test-retest reliability for the Behavioral Style Questionnaire and the Hassles Scale.

4) To determine the content validity of these instruments for use with families in the San Antonio area.

Technical Approach: As outlined in objectives. Testing correlation between instruments.

Progress: Patient accrual has been completed. Data are being analyzed.

Detail Summary Sheet

Date: 9 Nov 88 Proj No: C-80-88 Status: Ongoing

Title: The Impact of the Use of Active Imagery on Labor and Delivery

| | |
|---|---|
| Start Date 8 Sep 88 | Est Comp Date: |
| Principal Investigator<br>Cheryl Vaiani, MAJ, AN | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Nursing | Associate Investigators:<br>Penelope Ward, R.N., Ph.D. Candidate<br>(CDR, USNR) |
| Key Words: | |
| Accumulative MEDCASE<br>Cost: | Est Accumulative<br>OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To determine how the use of active imagery affects labor and delivery.

Technical Approach: This two part study will evaluate the psychological progressive of couples through pregnancy and compare the results of the use of active imagery both within group and between experimental and control groups.

Progress: Following approval of the minutes of the IRB by the Executive Committee, it was determined that this was in error. In accordance with AR 40-66, approval to access patient records must be obtained from The Surgeon General. Therefore, the study was put on hold pending receipt of TSGO approval.

Detail Summary Sheet

Date: 9 Nov 88 Proj No: C-60-87 Status: Completed

Title: Double-Blind Study to Compare Bleeding Patterns in Estrogen Replacement Therapy (Cooperative Study with UTSA Health Science Center)

| | |
|---|---|
| Start Date 24 Jun 87 | Est Comp Date: |
| Principal Investigator<br>Harry T. Hutchinson, LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Obstetrics and Gynecology | Associate Investigators: |
| Key Words:<br>Estrogen | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 16 Jun 88 Results Continue

Objective(s): To evaluate the efficacy and safety of continuous vs interrupted regimens of estropipate combined with norethindrone (NET), compared to estropipate alone, when administered for the treatment of estrogen deficiency.

Technical Approach: To be eligible for admission into the study, patients must be in good health, have an intact uterus, and be candidates for estrogen replacement therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual has been completed. Data are being analyzed by the university.

Detail Summary Sheet

Date: 9 Nov 88 Proj No: C-85-88 Status: Ongoing

Title: Hormonal and Sonographic Assessments of First Trimester Pregnancies Complicated by Vaginal Bleeding

| | |
|---|---|
| Start Date 8 Sep 88 | Est Comp Date: |
| Principal Investigator<br>Scott Allan Valento, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Obstetrics-Gynecology | Associate Investigators:<br>Clifford C. Hayslip, LTC, MC |
| Key Words:<br>Beta HCG levels | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To determine the value of serum progesterone, estradiol, and beta HCG levels in the assessment of complicated first trimester pregnancies, and to compare vaginal and abdominal ultrasound in the early diagnosis of abnormal pregnancies.

Technical Approach: Approximately 200 patients presenting to the GYN Clinic with vaginal bleeding and known or suspected pregnancy will be asked to participate in the study. Each patient will have serum beta HCG,, progesteron and estradiol levels drawn. The evaluating physician will perform a pelvic exam and both a vaginal and abdominal ultrasound. If an intrauterine pregnancy is confirmed by ultrasound, repeat hormonal levels and ultrasound will be repeated in 2-7 days. Patients with suspected ectopic pregnancy will also have an initial hormonal evaluation and ultrasounds performed. Those patients not undergoing immediate surgery will have repeat hormonal levels and ultrasound performed in 24-48 hours. Patients with threatened miscarriage will be followed in the same manner as described for ectopic pregnancies.

Progress: This is a new study.

Detail Summary Sheet

Date: 28 Oct 88 Proj No: C-65-86 Status: Ongoing

Title: Identifying Pathogenic Coryneform Bacteria

| | |
|---|---|
| Start Date 8 Jul 86 | Est Comp Date: |
| Principal Investigator<br>S. Vern Juchau, COL, MS | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Pathology/Microbiology | Associate Investigators:<br>Bruce A. Gunn, LTC, MS |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: 490.28 |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): 1) To investigate a means of identifying and separating coryneform bacteria that can be isolated from the human body.

2) To attempt to correlate identified groups with normal flora or pathogenic potential.

3) To provide clinical microbiologists and physicians with a tool to better interpret the significance of the isolation of a gram-positive, non-spore forming bacillus which does not fall into one of the groups of known primary pathogens.

Technical Approach: The major focu of this study will be to classify coryneform bacteria of human origin on the basis of cellular fatty acids with the aid of a gas-liquid chromatography. Profiles of ATCC strains of human coryneforms will be constructed to serve as a data base to which clinical isolates will be compared.

Progress: Biochemical profiles of several ATCC strains of coryneform bacteria have been achieved. These have not so far been very satisfactory for differentiating between species of coryneform bacteria.

Detail Summary Sheet

| | |
|---|---|
| Date: 28 Oct 88 Proj No: C-78-86 | Status: Completed |
| Title: The Effect of Ionizing Radiation upon Components of Normal Human Blood, Bacteria Contaminating Platelet Concentrates and Cytomegalovirus Naturally Occurring in Leukocytes Incidentally Present in Blood Components for Transfusion Therapy | |
| Start Date 8 Sep 86 | Est Comp Date: |
| Principal Investigator<br>David F. Jadwin, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Pathology | Associate Investigators:<br>Robert C. Allen, MAJ, MC |
| Key Words: | Janet Martinez, SSG |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: $4923.00 |
| Number of Subjects Enrolled During Reporting Period: | |
| Total Number of Subjects Enrolled to Date: | |
| Date of Periodic Review _____ Results _____ | |

Objective(s): To quantify the dose effect of extracorporeal ionizing radiation upon in vitro platelet function, as measured by platelet aggregation in response to collagen, to adenosine diphosphate, and to epinephrine stimuli. (Protocol 1)

Note: This project is composed of eight protocols. Objectives 2 thru 8 are as listed in the protocol.

Technical Approach: Protocol 1 - Platelet concentrates from approximately 100 different donors will be utilized. Platelet concentrates will be partitioned into experimental aliquots from which baseline platelet count and aggregometry will be performed. Leukocyte counting and limited differential counts will also be obtained. Following collection and processing, platelet concentrates will receive exponential doses of ionizing gamma radiation (between 10,000 and 200,000 rads from a Cesium 137 source); control aliquots of platelet concentrates will not be subjected to irradiation.

Progress: During the period of the study, the effects of ionizing radiation upon selected blood components were studied. Multiple units of fresh frozen plasma were subjected to ionizing radiation from a cesium-137 source for variable exposure periods. Effects upon coagulation studies (prothrombin time, partial thromboplastin time) were not measurably different from controls until the fresh frozen plasma had been exposed to 160,000 Rads.

C-78-86 (continued)

Attempts to measure the effect of ionizing radiation upon platelets was not satisfactory because only aging platelet concentrates were available for study. When platelet activity studies were performed on these concentrates (platelet aggregation), suitable baseline levels could not be achieved.

In order to determine the effect of ionizing radiation upon cytomegalovirus, urine from a CMV-infected patient was subjected to ionizing radiation from a cesium-137 source. Urine from CMV patients subjected to 200,000 Rads of ionizing radiation contained CMV particles capable of replication in cell culture media. This suggests that ionizing radiation in the dose range capable of altering structural and enzymatic proteins in serum is insufficient to inactivate CMV particles.

The effect of ionizing radiation upon Escherichia coli (E. coli) infected concentrates was studied. Although significant reductions in bacterial counts occurred following exposure to as much as 160,000 Rads occurred, consistent bacteriocidal effect by radiation could not be achieved at this level of exposure. Staphylococcus aureus was determined to be more sensitive to ionizing radiation, but required doses as high as 160,000 Rads for complete sterilization. From these studies, it is concluded that bacterial sterilization by ionizing radiation is not feasible.

Although sterilization of blood by ionizing radiation does not seem possible by this study, it documents, in part, the relative radio-resistance of the coagulation cascade to ionizing radiation.

Detail Summary Sheet

| Date: 8 Nov 88 | Proj No: C-31-88 | Status: Completed |
|---|---|---|

Title: Human Immunodeficiency Virus and Malnutrition

| | |
|---|---|
| Start Date 17 Feb 88 | Est Comp Date: |
| Principal Investigator<br>Joan C. Case, SSG | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Pathology | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 25

Total Number of Subjects Enrolled to Date: 25

Date of Periodic Review _____ Results _____

Objective(s): To examine patients in the different stages of HIV disease and see if it can be determined, by use of anthropometric data, biochemical data and informational data, at what distinct stage malnutrition begins.

Technical Approach: Twenty-five patients have been enrolled. Each patient had the following: weight (kg), height (cm), percent body fat, MAMC, albumin, serum creatinine, urine creatinine, transferrin, iron, iron binding capacity, BUN and percent lymphocytes. Each patient also completed a 24-hour diet recall, a food frequency questionnaire, and a diet history.

Progress: Significantly lower transferrin levels, total iron binding capacity, serum albumin and serum creatinine were found in the patients as compared to the normal ranges for these tests. The white blood count and the percent lymphocyte count showed below normal values.

After completion of the food questionnaire, diet history and twenty-four hour recall, it was very clear that nutrition education and nutrition assessment should be a regular part of the care they receive. They experience the same

C-31-88 (continued)

stresses and bad nutrition habits faced by most people on a regular basis. The research shows that the health of the immune system may have a direct bearing on when the patient contracts an opportunistic infection and the frequency of the infections. Nutrition assessment and counseling at the time of diagnosis and/or staging should be provided.

Detail Summary Sheet

Date: 8 Nov 88 Proj No: C-45-88 Status: Ongoing

Title: A Brief Analysis of the Role of Simultaneous DNA Flow Cytometry on Routine EndoPAP® Endometrial Sample

| | |
|---|---|
| Start Date 29 Mar 88 | Est Comp Date: |
| Principal Investigator<br>Donald H. Gale, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Pathology | Associate Investigators:<br>Hansa B. Raval, COL, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): 1) To assess a simple method of specimen collection that will enable simultaneous correlation between cytology and DNA analysis

2) To determine the role of DNA analysis in Cytologically difficult cases.

Technical Approach: Flow cytometric evaluation performed on many of the 47 original samples. Technical difficulties imited early samples usefulness and one computer problem (dumped data) eradicated additional findings. Currently, however, 15 samples are under evaluation for correlation and clinical utility.

Progress: Technically feasible concept has been proven, clinical utility still needs evaluation.

Detail Summary Sheet

| Date: 31 Oct 88 | Proj No: C-64-88 | Status: Ongoing |
|---|---|---|

Title: Rapid Laboratory Detection of Mycoplasmosis Using a Radiometric Device

| Start Date 14 Jul 88 | Est Comp Date: |
|---|---|
| Principal Investigator<br>William Nauschuetz, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Pathology | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): 1) To determine if Mycoplasma pneumoniae can be detected from clinical specimens using a system by which the pathogen is selected and detected by the evolution of $^{14}C$-labelled $CO_2$ from medium containing $^{14}C$-labelled glucose.

2) To determine if the amount of liberated $^{14}C$-labelled $CO_2$ allows sufficient sensitivity such that growth of the M. pneumoniae is detected significantly faster than allowed by conventional isolation techniques.

3) To mold this detection system into one which is compatible with the BACTEC Blood Culture Instrument, which is a common microbiology laboratory tool, found in a significant percentage of clinical laboratories.

Technical Approach: To develop a system by which SP4 medium will be made to include $^{14}C$-labelled glucose, as well as ampicillin, fungizone, crystal violet and thallium acetate to inhibit other bacterial, mycotic, and mycoplasmal species found in respiratory systems.

Progress: None due to the temporary assignment of the principal investigator to the Academy of Health Sciences. The study will resume when he returns in December.

Detail Summary Sheet

Date: 31 Oct 88 Proj No: C-34-85 Status: Ongoing

Title: Effect of Dietary Modifications on Weight Change in Obese Children with Different Insulin Responses to Glucose and Leucine Challenge.

| | |
|---|---|
| Start Date | Est Comp Date: |
| Principal Investigator<br>Chandra M. Tiwary, M.D., COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Pediatrics | Associate Investigators:<br>Regina Marshall, R.N. |
| Key Words:<br>Children, obese | Isidoro Chapa<br>Elizabeth A. Milner, 1LT, MS |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 16 Jun 88 Results Continue

Objective(s): 1) To determine if specific dietary modifications can result in improved weight reduction in certain categories of obese children.

2) To develop a profile for these children by identifying common characteristics according to their insulin responses to tolerance testing.

Technical Approach: Eligible patients will have a complete history, physical, CBC, SMAC-20, oral glucose tolerance test (1.75 gm/kg, max. 100 gms); and oral leucine tolerance test (150 mg/kg). Subjects will be classified into elevated and normal insulin goups in accordance with their insulin response to glucose and leucine challenges. All paritcipants will receive dietary instructions and will be provided with behavior modification instructions.

Progress: Due to nonavailability of dietary support personnel, there has been no progress on this phase of the study. Other investigations have continued. The measurement of Na/K ATPase has not been done due to malfunction of the instruments. We are saving the specimens for this measurement when this instrument is in working condition.

Detail Summary Sheet

Date: 12 Sep 88 Proj No: C-73-85 Status: Terminated

Title: Prospective Study of Chlamydia Infection in Neonates and Infants of Carrier Mothers Using Culture and EIA Techniques.

| | |
|---|---|
| Start Date 27 Sep 85 | Est Comp Date: |
| Principal Investigator<br>Carol Robertson, M.D., CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Pediatrics | Associate Investigators: |
| Key Words:<br>Chlamydia infection | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: $1610.00 |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 9 Sep 88 Results Terminated

Objective(s): 1) To determine Chlamydia trachomatis infection rate in BAMC Obstetric population.

2) To determine transmission rate of Chlamydia to neonates.

3) To evaluate morbidity of infants at risk for Chlamydia infections.

4) To compare Elisa technique to culture technique in nasopharynx, conjunctiva, and rectum for detection of Chlamydia trachomatis.

Technical Approach: At time of speculum examination upon admission to the labor suite, chlamydia culture and EIA will be obtained on the mother. Infants will have nasopharynx, rectum, and conjunctiva swabs for culture and EIA within 24 hours of birth while in nursery. Only infants of positive mothers or infants who are positive in the nursery will have follow-up cultures at 2 and 16 weeks or prn with the development of symtpoms.

Progress: We have cultured 250 infants (healthy) from newborn nursery. One culture was positive; 249 were negative. After reviewing our culture and chlamydiazyne techniques, my feeling is that our current rate of positive cervical cultures in mothers is approximately 1-2%. With an estimated transmission rate of 10-15%, we would estimate this study to take several years to obtain reliable numbers.

C-73-85 (continued)

An additional problem in our nursery has been the serious personnel problem. We have had considerable cutbacks in our unit. COL Woodall (Chief) in conjunction with the nursing staff felt we were not able to continue to support this study.

Detail Summary Sheet

Date: 12 Sep 88 Proj No: C-16-86 Status: Completed

Title: A Comparison of Periurethral Bacterial Flora in Circumcised and Uncircumcised Males Infants During the First Six Months of Life.

| | |
|---|---|
| Start Date 6 Feb 86 | Est Comp Date: |
| Principal Investigator (vice Wiswell)<br>Gea Miller, M.D. | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Pediatrics | Associate Investigators:<br>Hugh M. Gelston, Jr., MAJ, MS<br>Sheila Jones, SSG |
| Key Words:<br>Infections, urinary tract | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: 10,292.00 |

Number of Subjects Enrolled During Reporting Period: 300

Total Number of Subjects Enrolled to Date: 300

Date of Periodic Review 23 Mar 88 Results Completed

Objective(s): To assess the possible differences in periurethral bacterial flora and the role this may have in urinary tract infections in male infants.

Technical Approach: Specimens for bacterial culture will be obtained from six patient groups: newborn, 2 weeks, 2 months, 4 months, 6 months, and 1 year of age. Calgiswabs were used to obtain specimens from the urethra and the glans/foreskin area of 25 circumcised and 25 uncircumcised male infants from each group. The specimens were assayed to enumerate the aerobic species present and to determine the colony count for each species. The specimens were placed directly into a tube containing 2.0 ml of sterile saline. The tubes containing the swabs were vortexed at maximum speed for 20 seconds. Three ten-fold dilutions of the specimens were made and plated on enriched and selective media. The speciation was accomplished using conventional methods and colony counts determined for each species.

Progress: The results of the glans cultures were similar to those from the urethra. Uncircumciased boys had significantly higher total colony counts ($p<0.003$) at all ages except 12 months. Escherichia coli was present significantly more often ($p<0.01$) in the urethras of uncircumcised boys at 2 weeks, 2 months, 4 months, and 6 months. Gram-negative uropathogenic organisms (Klebsiella-enterobacter, Proteus mirabilis, and Pseudomonas aeruginosa) were cultured more frequently ($p<0.0005$) from the urethras of uncircumcised boys at

C-16-86 (continued)

2 months, 4 months and 6 months. The specific colony counts fo *E. coli* and the other uropathogenic organisms were significantly higher ($p<0.05$) at all ages except 12 months.

We conclude that during the first 6 months of life, the presence of a foreskin is associated with a greater quantity of periurethral bacteria and a greater likelihood for the presence of, as well as high concentrations of potentially uropathogenic organisms.

Detail Summary Sheet

Date: 31 Oct 88 Proj No: C-21-86 Status: Ongoing

Title: A Comparison of High Frequency Oscillatory Ventilation and Conventional Ventillation in the Management of Respiratory Distress Syndrome in Infants Less Than 1750 Grams. (Collaborative Study with Wilford Hall USAF Hospital)

| | |
|---|---|
| Start Date 19 Mar 86 | Est Comp Date: |
| Principal Investigator<br>Jan Carter, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Pediatrics | Associate Investigators:<br>Howard Heiman, MAJ, MC<br>John Woodall, COL, MC |
| Key Words:<br>Syndrome, respiratory distress | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: 470.00 |

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 12

Date of Periodic Review 23 Mar 88 Results Continue

Objective(s): To evaluate the efficacy of using high frequency oscillatory ventilation (HFOV) in the management of respiratory distress syndrome (RDS) in premature infants, as compared to using the conventional neonatal ventilation (CV) therapy of intermittent mandatory ventilation and continuous distending pressure.

Technical Approach: The study population will consist of premature infants less than 33 weeks gestational age, less than 1750 grams birth weight, and less than 24 hours of age who require mechanical ventilation for treatment of RDS. Patients will be separated into four categories by birth weight and then randomly assigned to one of three treatment groups: CV only, HFOV initially followed by CV, or HFOV only.

Progress: This project has been on hold until Dr's Woodall and Heiman have become certified in HFOV use. No new patients have been entered since May 1987

Detail Summary Sheet

Date: 31 Oct 88 Proj No: C-22-86 Status: Ongoing

Title: Prophylactic Intravenous Immunoglobulin in High Risk Neonates. (Collaborative Study with Walter Reed Army Medical Center)

| | |
|---|---|
| Start Date 26 Feb 86 | Est Comp Date: |
| Principal Investigator (vice Wiswell)<br>Jan Carter, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Pediatrics | Associate Investigators:<br>Leonard E. Weisman, LTC, MC |
| Key Words:<br>Neonate, high risk | John Woodall, COL, MC<br>Howrd Heiman, MAJ, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 15

Total Number of Subjects Enrolled to Date: 25

Date of Periodic Review 23 Mar 88 Results Continue

Objective(s): To evaluate, in a double blind manner, the effectiveness, compared to an albumin placebo, of IVIG in preventing infectious disease and/or reducing morbidity and mortality in the high risk neonate.

Technical Approach: Participants will be given one of two medications. One will contain antibody to Group B streptococci and the other will contain human albumin and sugar. One dose of the medication will be given by vein over a one hour period. 2 cc. of blood will be drawn before the medicine is given, immediately after it is given, and at one, two, and eight weeks later. Babies will be followed over an 8 weeks period for evidence of infection.

Progress: No complications. The project is going well.

Detail Summary Sheet

Date: 12 Sep 88 Proj No: C-59-86 Status: Terminated

Title: Chlamydia Urethral Colonization in Sexually Active Teenage Males.

| | |
|---|---|
| Start Date 25 Jun 86 | Est Comp Date: |
| Principal Investigator<br>John A. Baker, LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Pediatrics | Associate Investigators:<br>Richard Takao, COL, MC |
| Key Words:<br>Chlamydia | Thomas Perez, GS12 |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 16 Jun 88 Results Terminated

Objective(s): To determine the presence of Chlamydia trachomatis colonization in the urethra of teenage males who are or have been sexually active.

Technical Approach: Teenage males who enter the BAMC Adolescent Clinic will be given a questionnaire pertaining to the chlamydia study. They will be interviewed by one of the physicians in the adoescent clinic for the purpose of explaining the study. If they agree to participate in the study, urethral smears will be obtained and sent to the laboratory for chlamydia culture and Chlamydiazyme assays.

Progress: This project was terminated due to the unrealistic limitations imposed by the JAG and Institutional Review Board requiring parental notification regarding nature of questionnaire. Several studies have been published indicating the presence of chlamydia colonization in the male urethra of 10-15%. Information is pointing to the need for this test to be considered as a routine test in sexually active males to help contain the increasing prevalence of chlamydia.

Detail Summary Sheet

Date: 12 Sep 88 Proj No: C-71-86 Status: Terminated

Title: Prospective Analysis of HTLV-III Infection in Children and Its Effect on Childhood Immunization

| | |
|---|---|
| Start Date 12 Aug 86 | Est Comp Date: |
| Principal Investigator<br>James H. Brien, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Pediatrics | Associate Investigators: |
| Key Words:<br>Infection, HTLV-III | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 9 Sep 88 Results Terminated

Objective(s): The clinical and immunologic assessment and follow-up of HTLV-III infected (and *high risk) children will be performed. The objectives of this protocol will be to collect, organize, and analyze this data prospectively so that changes in each patient's status can be detected quickly and so that changes in the gorup as a whole can be identified and responded to with minimum delay.

Technical Approach: Information is obtained and entered into a computerized data base. Blood studies concerning AIDS will be analyzed at Walter Reed Army Medical Center.

Progress: This study was never started.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: C-40-87 Status: Ongoing

Title: Surfactant Production by Bacteria

| | |
|---|---|
| Start Date 8 Apr 87 | Est Comp Date: |
| Principal Investigator<br>Chandra M. Tiwary, COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Pediatrics | Associate Investigators:<br>Hugh M. Gelston, Jr., MAJ, MS |
| Key Words: | Sheila Jones, SSG |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: $481.30 |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review n/a Results

Objective(s): To measure the surface tension lowering activity of pathogenic, non-motile bacteria and compare the same with that of motile pathogenic bacteria.

Technical Approach: Several different species will be assayed for surfactant production. The bacteria will be obtained from the collection of control organisms that are maintained by the DCI bacteriology laboratory. An overnight trypticase soy broth (TSB) culture will be used for the determination of the colony count and for surfactant production by each species of bacteria. A chloroform-methanol extraction will be made from each culture using the following: 1) cell free TSB, 2) the overnight culture, and 3) sonicated bacteria from the overnight culture. The surfactant production will be measured by the reduction of the surface tension of water produced by the addition of aliquots from the three different chloroform-methanol extractions from each culture. The reduction in surface tension/$10^7$ bacteria will be determined for each species of bacteria. The data will be analyzed to determine if there is a difference in surfactant production between pathogenic and nonpathogenic bacteria.

Progress: The study is about 90% complete. We measured the surface tension (ST) of the cocci and bacilli and found significant differences among them. Some bacteria secrete surface active material while others do not. We are trying to correlate the change in ST with the motility, virulence or other properties of the bacteria.

Detail Summary Sheet

Date: 28 Sep 88 Proj No: C-56-87 Status: Completed

Title: Carbamazepine Therapy for Aggressive Behavior in Children

| | |
|---|---|
| Start Date 13 May 87 | Est Comp Date: |
| Principal Investigator<br>Cindy Juster, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Pediatrics | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 11

Total Number of Subjects Enrolled to Date: 11

Date of Periodic Review 16 Jun 88 Results Completed

Objective(s): To establish through a double blind evaluation the effectiveness of Carbamazepine in controlling aggressive behavior in childhood.

Technical Approach: A double blind crossover protocol will be used with each patient serving as his her own control. Using a table of random numbers, the patient will be randomized to initially receive either carbamazepine or a placebo daily for one month. Following a two week washout period, the patient will receive the other form of therapy. Carbamazepine will be initiated in a dose of 6-10 mg/kg/day in all age groups.

Progress: Overall, Carbamazepine proved to be effective in approximately 50% of the cases.

Detail Summary Sheet

| Date: 1 Nov 88 | Proj No: C-79-87 | Status: Ongoing |
|---|---|---|

Title: Appetite and Pectin

| Start Date 9 Sep 87 | Est Comp Date: |
|---|---|
| Principal Investigator<br>Chandra M. Tiwary, COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Pediatrics | Associate Investigators: |
| Key Words:<br>Appetite<br>Obesity | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: 650.00 |

Number of Subjects Enrolled During Reporting Period: 28

Total Number of Subjects Enrolled to Date: 28

Date of Periodic Review 9 Sep 88 Results Continue

Objective(s): To assess the role of pectin in suppression of hunger in obese children.

Technical Approach: Subjects will be obese children (ages 6-18) attending the pediatric clinic. All subjects will be studied twice at least 3 days apart. Subjects will be given either orange juice or orange juice with pectin. The child will be asked to describe the degree of hunger on a scale of 1 to 20, giving a rating of 1 if most full and 20 if very hungry. The same scale will be used to rate hunger every hour for four hours. At the end of four hours, the child will be given ice cream and again asked to rate hunger. Saliva production will be measured on three times - before drinking the juice, 4 hours after drinking the juice, and 1/2 hour after eating the ice cream.

Progress: The effect of pectin on appetite, although showing a trend towards decreasing it, is variable. The appetite of the same child varies from day-to-day. The effect of pectin on saliva weight has not been analyzed. Enrollment of more patients and analysis of the data may give statistically meaningful results.

Detail Summary Sheet

Date: 22 Oct 88 Proj No: C-80-87 Status: Completed

Title: Efficacy of Sedation with Chloral Hydrate in Children

| | |
|---|---|
| Start Date 9 Sep 87 | Est Comp Date: |
| Principal Investigator<br>Peter D. Rumm, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Pediatrics | Associate Investigators:<br>Richard Takao, COL, MC |
| Key Words:<br>Chloral hydrate | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 44

Total Number of Subjects Enrolled to Date: 50

Date of Periodic Review 9 Sep 88 Results Completed

Objective(s): 1) Determination of the expected duration of sedation with dosages of chloral hydrate.

2) Determination of the rate of failure on the first attempt of sedation with chloral hydrate and analysis of the factors that may have contributed to the initial failure.

Technical Approach: Fifty patients ages 2 months to 15 years were sedated for 25 CT scans, 10 MRI's, 6 electroencephalograms, and 9 miscellaneous tests. Initial dose was at the discretion of the ordering physician, with a mean of 58 mg/kg and a range of 25-81 mg/kg. The drug was administered one-half hour before the test, unless the patient was on stand-by for the test, in which case the drug was given when the ward was notified. A sedation score was recorded at the start of the test, at completion, and one-half hour later. Use of other drugs or additional dosages of chloral hydrate were also recorded. Effective sedation was defined as effective completion of the diagnostic test with a sedation score of at least 3 out of the 4-point scale at completion of the test.

Progress: Of the 50 patients given chloral hydrate, 43 were sedated effectively with completion of the test and a sedation score of at least 3/4 at the end of the diagnostic test, for an 86% success rate. 23/43 patients had a score of 4/4 after their procedure, with the same number having a sedation score of 4/4 one-half hour later. There were no complications or side effects in any of the patients.

Detail Summary Sheet

| Date: 1 Nov 88 | Proj No: C-87-87 | Status: Completed |
|---|---|---|

Title: Evaluation of Blood Pressure Measurement in Children (Collaborative Study with University of Texas Health Science Center)

| | |
|---|---|
| Start Date 9 Sep 87 | Est Comp Date: |
| Principal Investigator<br>Richard Takao, COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Pediatrics | Associate Investigators:<br>Myung Park, M.D., UTHSCSA |
| Key Words:<br>Blood Pressure | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 300-400

Total Number of Subjects Enrolled to Date: 300-400

Date of Periodic Review 9 Sep 88 Results Completed

Objective(s): To obtain normative data on blood pressure measurements in children.

Technical Approach: We measured blood pressure (BP) and heart rate in 1554 healthy infants and children aged 2 weeks to 5 years using the Dinamap Monitor, an oscillometric device, in order to establish normative values in this age group. BP cuff width was selected to be 40-50% of the circumberence of the upper arm. Three BP measurements and heart rate were obtained in the waiting room of pediatricians' offices before the patients were examined by the doctor or nurse. Triplicate BP measurements were obtained in 87% of infants less than 3 years of age, and in all children 3 years or older.

Progress: The average value of BP [systolic/diastolic (mean)] increased rapidly from the 2-3 week value of 78/47(59) to the 1-5 month value of 95/60(74). No significant increase in BP occurred until 2 years of age [96/56(71)] when systolic and mean pressures started to increase at an annual rate of 2 mm Hg for systolic and 1 mm Hg for mean pressures until reaching the 5 year value of 104/58(75). Diastolic pressure did not increase from 1 month to 5 years of age. Heart rate decreased with increasing age from the 2-3 week value of 153 to the 5 year value of 97 per minute. There was no difference in BP and heart rate values between male and female or among different ethnic groups in the age range studied.

Detail Summary Sheet

| | | |
|---|---|---|
| Date: 8 Nov 88 | Proj No: C-24-88 | Status: Ongoing |

Title: Ceftriaxone for Outpatient Management of Suspected Occult Bacteremia

| | |
|---|---|
| Start Date 13 Jan 88 | Est Comp Date: |
| Principal Investigator<br>James H. Brien, LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Pediatrics | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 18

Total Number of Subjects Enrolled to Date: 18

Date of Periodic Review _____ Results _____

Objective(s): To determine the effectiveness of Ceftriaxone in the outpatient management of children three to thirty-six months of age with suspected occult bacteremia.

Technical Approach: Children are randomized to either receive Ceftriaxone IM or Augmentin PO with ongoing follow-up until fever and illness is resolved.

Progress: Eighteen patients have been enrolled and all have done well. Three patients were proven to be bacteremic and responded to therapy.

Detail Summary Sheet

Date: 8 Nov 88 Proj No: C-43-88 Status: Ongoing

Title: An Analysis of Adoescent Suicide Gesture Patients at Brooke Army Medical Center

| | |
|---|---|
| Start Date 29 Mar 88 | Est Comp Date: |
| Principal Investigator<br>Carla Iavarone, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Pediatrics | Associate Investigators:<br>Richard Takao, COL, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 6

Total Number of Subjects Enrolled to Date: 6

Date of Periodic Review _____ Results _____

Objective(s): To gather information that may subsequently be helpful in formulating an intervention plan in order to reduce the frequency of adolescent suicide gestures.

Technical Approach: Persons 18 years of age and younger who have been admitted to BAMC Pediatrics for having committed a suicide gesture during the course of the study or within the previous five years will be eligible for the study. Objective data will be collected by review of the inpatient chart and if necessary by phone or personal interview. The cases will be carefully scrutinized to determine if any identifiable pattern or similarities exist.

Progress: Patient accrual continues. No reportable data are available at this time.

Detail Summary Sheet

Date: 29 Nov 88 Proj No: C-90-88 Status: Ongoing

Title: Phase I Study of Piritrexim in Children with Advanced Leukemia and Solid Tumors (A Multicenter Study under the Direction of Dr. Thomas E. Williams, Santa Rosa Childrens Hospital)

| | |
|---|---|
| Start Date 22 Nov 88 | Est Comp Date: |
| Principal Investigator<br>Paul J. Thomas, COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Pediatrics | Associate Investigators:<br>Allen R. Potter, LTC, MC |
| Key Words:<br>Leukemia | Timothy J. O'Rourke, LTC, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To define the maximum tolerated dose and the dose limiting toxicity when Piritrexim capsules are administered orally to children in a daily x 5 schedule repeated every three weeks.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 12 Sep 88 Proj No: C-12-77 Status: Ongoing

Title: Intravenous Administration of $I^{131}$ (NP 59) for Adrenal Evaluation of Imaging.

| | |
|---|---|
| Start Date 15 Nov 76 | Est Comp Date: |
| Principal Investigator(vice Hartshorne)<br>James D. Hieronimus, LTC, USAF MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department Radiology/Nuclear Medicine | Associate Investigators:<br>James H. Timmons, CPT, MC |
| Key Words:<br>Adrenal scan | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 6

Total Number of Subjects Enrolled to Date: 11

Date of Periodic Review 22 Jan 88 Results Continue

Objective(s): Clinical evaluation of NP 59 as a diagnostic agent for the detection of adrenal-cortical disorders and as a potential scanning agent for detecting structural abnormalities of the adrenal medulla.

Technical Approach: This study will be performed on 50 patients after complete evaluation by the Endocrinology Service. The radiopharmaceutical will be administered by slow IV injection with a dose of 1mCi in adults and 15mCi/kg in children. Lugol's solution, 5 drops twice daily starting one day before injection and continuing for two weeks, will be used to block thyroid uptake of radioiodine. Images will be obtained on th 4th, 7th, and 11th day following injection using scintillation camera.

Progress: In spite of a limited number of patients entered into this study, it remains open for diagnostic purposes.

Detail Summary Sheet

| Date: 28 Oct 88 | Proj No: C-90-86 | Status: Completed |
|---|---|---|

Title: Investigation of I-123 Iofetamine HCl in Brain Scanning

| | |
|---|---|
| Start Date 11 Dec 86 | Est Comp Date: |
| Principal Investigator<br>Michael F. Hartshorne, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Radiology/Nuclear Med. | Associate Investigators: |
| Key Words:<br>Iofetamine | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 13

Total Number of Subjects Enrolled to Date: 40

Date of Periodic Review 9 Sep 88 Results Completed

Objective(s): 1) To evaluate the clinical utility of I-123 Iofetamine.

2) To allow clinicians at this facility to have access to a more physiologic brain imaging agent thereby improving the quality of patient care.

Technical Approach: Patients will be selected and referred to the Nuclear Medicine Service primarily by Neurology and/or Neurosurgery Service. Both in-patients and outpatients will be accepted.

Progress: Iofetamine is presently available for general use. It's usefulness as a functional agent has been demonstrated in several disease states, most notably, partial complex seizures, dementia, and evaluation of soft neurologic signs.

Detail Summary Sheet

Date: 12 Sep 88 Proj No: C-21-78 Status: Ongoing

Title: Clinical Study of Intraocular Lenses.

| | |
|---|---|
| Start Date February 1978 | Est Comp Date: |
| Principal Investigator (vice Walker)<br>Calvin E. Mein, LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Ophthalmology | Associate Investigators:<br>Arthur T. Glover, MAJ, MC<br>Donald A. Gagliano, MAJ, MC<br>John D. Walker, COL, MC |
| Key Words:<br>Intraocular lens<br>Cataract extraction | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 296

Total Number of Subjects Enrolled to Date: 2131

Date of Periodic Review 23 Mar 88 Results Continue

Objective(s): To establish the safety and effectiveness of this device for use in human subjects according to guidelines recommended by the Food and Drug Administration ophthalmic advisory panel.

Technical Approach: Intraocular lenses are implanted according to the company protocol.

Progress: Lens implant results have been excellent.

Detail Summary Sheet

Date: 12 Sep 88 Proj No: C-12-83 Status: Ongoing

Title: Is Routine Intraoperative Cholangiography (IOC) a Useful Adjunct to Cholecystectomy?

| | |
|---|---|
| Start Date 6 Jan 83 | Est Comp Date: |
| Principal Investigator<br>Daniel Rosenthal, M.D., COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/General Surgery | Associate Investigators: |
| Key Words:<br>Intraoperative cholangiography | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review n/a Results

Objective(s): To determine if routine IOC significantly alters the management of patients with cholecystolithiasis by demonstrating at operation the presence of unsuspected stones in the biliary tree.

Technical Approach: All medical centers using routine IOC will be asked to participate. On a quarterly basis, they will be asked to report the number of IOCs performed, number of normals, what was done, and the number of minutes added to the procedure.

Progress: Data collection continues.

Detail Summary Sheet

Date: 8 Nov 88 Proj No: C-72-84 Status: Terminated

Title: Outpatient Intra-Arterial Digital Subtraction Angiography in the Evaluation of Patients with Atherosclerotic Peripheral Vascular Disease.

| | |
|---|---|
| Start Date 25 Sep 84 | Est Comp Date: |
| Principal Investigator<br>David W. Olson, M.D., LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Vascular Surgery | Associate Investigators:<br>Manuel Ramirez, M.D., MAJ, MC |
| Key Words:<br>Angiography, digital subtraction | Harrell Cox, M.D., MAJ, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 54

Date of Periodic Review 9 Sep 88 Results Terminated

Objective(s): To determine the safety, feasibility, and accuracy of outpatient intra-arterial angiography using digital subtraction angiographic technology in patients with known atherosclerotic peripheral vascular disease who otherwise would undergo conventional angiography.

Technical Approach: Patients who would routinely be scheduled for elective admission for conventional angiography will be offered outpatient intra-arterial digital subtraction angiography. Routine x-ray and blood studies will be obtained prior to the date of the scheduled arteriogram. Arteriography will be performed in the Digital Subtraction Angiography Suite utilizing the standard Seldinger technique. Upon completion of the angiogram, the patient will be observed in the Recovery Room for two hours. If there are no complications, the patient will be discharged.

Progress: The principal investigator requested termination of this study due to paucity of patients meeting the criteria for outpatient subtraction angiography.

Detail Summary Sheet

Date: 27 Oct 87 Proj No: C-5-85 Status: Completed

Title: Localization of the Distribution of Regional Anesthetics.

| | |
|---|---|
| Start Date 15 Jan 85 | Est Comp Date: |
| Principal Investigator<br>Emil J. Menk, M.D., MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Anesthesiology | Associate Investigators:<br>John M. Bauman, M.D., CPT, MC<br>Robert E. Middaugh, M.D., CPT, MC<br>Curtis L. Baysinger, M.D., MAJ, MC<br>Michael A. Cawthon, D.O., MAJ, MC<br>William J. Reynolds, M.D., LTC, MC<br>Michael F. Hartshorne, M.D., MAJ, MC |
| Key Words:<br>Anesthetic, regional | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 32

Date of Periodic Review 23 Mar 88 Results Completed

Objective(s): To define the area and extent of flow of anesthetics during regional blockades.

Technical Approach: Approximately 10 patients will be evaluated utilizing the following techniques: axillary, interscalene, stellate ganglion, intercostal nerve, and epidural blockade. Patients will be brought to the Nuclear Medicine clinic for injection and imaging whenever possible. Standard doses and volumes of the local anesthetics routinely used will be employed, as well as strict aseptic technique. Each group of 10 patients will receive the anesthetic as a single bolus injection, and the other will receive 10 cc boluses with serial imaging after each bolus.

When bone scanning is felt to be indicated to better define the anatomy of flow, injection of the MDP will take place approximately 3-4 hours prior to imaging and injection of the anesthetic agent/DTPA mixture.

Progress: The paravertebral blocks have shown us that the flow pattern of this block is easily reproducible with reliable results as to flow pattern (i.e., dermatomes blocker per cc of local anesthetic injected) and analgesia produced. The continuous intercostal block, however, is extremely variable with at least four distinct flow patterns.

Detail Summary Sheet

Date: 12 Sep 88 Proj No: C-22-85 Status: Terminated

Title: Systematic Evaluation of Recurrent Nephrolithiasis.

| | |
|---|---|
| Start Date 5 Feb 85 | Est Comp Date: |
| Principal Investigator (vice Thompson)<br>Kurt L. Hansberry, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Urology | Associate Investigators: |
| Key Words:<br>Nephrolithiasis | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 23 Mar 88 Results Terminated

Objective(s): To determine if a systematic evaluation of nephrolithiasis with tailored therapeutic techniques can reduce incidence of stone disease.

Technical Approach: This is a two-part analysis of the importance of metabolic evaluation for nephrolithiasis. One part will compare the incidence of stone recurrence within a population of stone formers who did not undergo metabolic evaluation. The second part of the study will perform calcium-loading tests on stone formers in an attempt to categorize those with hypercalciuria. They will then be treated appropriately and compared with the historical controls.

Progress: Terminated due to lack of personnel to conduct study.

Detail Summary Sheet

Date: 12 Sep 88 Proj No: C-41-85 Status: Terminated

Title: Evaluation of Various Techniques of Septoplasty and Total Nasal Septal Reconstructive Surgical Procedures Utilizing Rhinometric Studies.

| | |
|---|---|
| Start Date 29 Apr 85 | Est Comp Date: |
| Principal Investigator (vice LePore)<br>Jesse Moss, Jr., LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Otolaryngology | Associate Investigators:<br>Robert C. Jarchow, LTC, MC |
| Key Words:<br>Rhinomanometry | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Jun 88 Results Terminated

Objective(s): 1) To utilize anterior rhinometric principles in the preoperative assessment of patients prior to nasal surgery.

2) To utilize anterior rhinometric principles in the postoperative evaluation of patients who have had either septoplasty surgery and/or total nasal septal reconstructive surgery.

3) Compare the rhinometric results with the surgical techniques to gain more information which may help us elucidate the intranasal deformities most likely to be improved by intranasal surgery, and which technique may be used in similar circumstances to achieve the best results.

Technical Approach: All patients who undergo nasal surgery will have anterior rhinomanometry performed according to presently accepted methods. Patients will have intranasal photography performed to help in the evaluation. Photography will be performed prior to use of local intranasal decongestants (¼% neosynephrine) and after its use as is performed in rhiinometric studies. All patients will have their visible anatomic deformities mapped out preoperatively and intraoperatively. Six weeks after surgery, anterior rhinomanometry will again be performed to ascertain objectively the results of the surgical procedure. The patient's subjective impression concerning the result will be noted. Six months after surgery and one and two years after, the patient will be asked to return for another rhinomanometric examination.

Progress: Study terminated due to malfunction of equipment.

Detail Summary Sheet

Date: 12 Sep 88 Proj No: C-59-85 Status: Completed

Title: Multicenter Trial of Cryotherapy for Retinopathy of Prematurity.

| | |
|---|---|
| Start Date 10 Jul 87 Reopened | Est Comp Date: |
| Principal Investigator<br>Calvin E. Mein, LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Ophthalmology | Associate Investigators: |
| Key Words:<br>Cryotherapy | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 4

Total Number of Subjects Enrolled to Date: 9 (BAMC)

Date of Periodic Review 9 Sep 88 Results Completed

Objective(s): To determine the safety and efficacy of cryotherapy of the peripheral retina in severe retinopathy of prematurity (ROP) to prevent progression of the acute disease to severe grades of cicatricial retrolental fibroplasia.

Technical Approach: Prospective data will be accumulated from infants who are at risk for developing stage 3+ ROP. Those who reach that stage will be eligible for randomization in the cryotherapy study.

Progress: There has been a positive response in the patients entered on this study. Patients on the study will continue to be followed.

Detail Summary Sheet

Date: 12 Oct 88 Proj No: C-70-85 Status: Ongoing

Title: High Frequency Hearing Levels in Otherwise Healthy Children Exposed to Three or More In Utero Diagnostic Ultrasounds

| | |
|---|---|
| Start Date 27 Sep 85 | Est Comp Date: |
| Principal Investigator (vice Lepore)<br>Kenneth B. Aspinall, COL, MS | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Otolaryngology | Associate Investigators:<br>Leonard W. Brown, MAJ, MC |
| Key Words:<br>High frequency hearing levels | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 9 Sep 88 Results Continue

Objective(s): 1) To establish a normal value for high frequency hearing thresholds in children.

2) To compare a control group of healthy children with "normal" hearing threshold to a group of healthy children exposed to three or more in utero ultrasounds.

Technical Approach: This study is a continuation of study C-41-81.

A minimum of 50 otherwise healthy children between 3-6 years of age for each of two groups will be examined for high frequency hearing thresholds. The first group will consist of children exposed to three or more in utero ultrasounds, and the second group will consist of children without a history of ultrasound exposure. The primary frequencies to be studied are between 10-20,000 Hz.

Progress: Despite the identification of possible subjects for the research, there has been a major set back in terms of instrumentation. It has taken a considerable amount of time to obtain the necessary equipment for the protocol. The equipment was in place but malfunctions began to occur. The audiometer has been sent back to the manufacturer twice in the past three months for repairs and calibration. Several clinic members have since been tested on the equipment; however, threshold results are highly inconsistent. This situation suggests that the validity and/or reliability of the current audiometer is

C-70-85 (continued)

questionable at best. Attempts are under way to obtain on-site assistance from the manufacturer to insure proper functioning of the equipment, or to explore the possibility of a replacement audiometer for the research project.

Detail Summary Sheet

Date: 12 Sep 88 Proj No: C-71-85 Status: Completed

Title: The Effects of a Constant Infusion of Etomidate and Sufentanil on Somatosensory Evoked Potentials in Neurosurgical Patients.

| | |
|---|---|
| Start Date 27 Sep 85 | Est Comp Date: |
| Principal Investigator (vice Zablocki)<br>Jerry Epps, M.D., CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Anesthesiology | Associate Investigators:<br>Lloyd Youngblood, M.D., COL, MC |
| Key Words:<br>Somatosensory potentials | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 5

Total Number of Subjects Enrolled to Date: 5

Date of Periodic Review 9 Sep 88 Results Completed

Objective(s): To determine the effects of a total intravenous anesthetic technique utilizing a constant infusion of etomidate and sufentanil on the intraoperative monitoring of somatosensory evoked potentials during neurosurgical procedures.

Technical Approach: Twenty adult patients undergoing elective intracranial or spine operations will be asked to participate. Induction of anesthesia will be accomplished in the standard fashion. Somatosensory evoked potentials will be monitored with the Nicolet* CA-1000 multichannel signal averager. Sites for recording electrodes for both modalities will be measured using the International 10-20 System. A set of baseline measurements will be obtained prior to induction of anesthesia. A second set will be obtained 10 minutes ost-induction and a third set 30 minutes post-induction. Each measurement will be reproduced at least once and superimposed to eliminate artifact.

Progress: Data collection has been completed. Preliminary evidence shows minimal changes in EP measurement.

Detail Summary Sheet

Date: 12 Oct 88 Proj No: C-1-86 Status: Ongoing

Title: Continuous Intra-Arterial Chemotherapy for Advanced Refractory Pelvic Malignancies Employing an Implantable Infusion System

| | |
|---|---|
| Start Date 28 Oct 85 | Est Comp Date: |
| Principal Investigator(vice Rodriguez)<br>Ian M. Thompson, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Urology | Associate Investigators:<br>Francisco Rodriguez, COL, MC<br>Richard O. Giudice, MAJ, MC<br>Michael Hartshorne, MAJ, MC<br>Marvin Walker, MAJ, MC |
| Key Words:<br>Infusion System, implantable | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review 22 Jan 88 Results Continue

Objective(s): To determine the efficacy of continuous infusion of intraarterial chemotherapeutic agents for pelvic malignancies utilizing an implantable infusion system (Porta-Cath)®.

Technical Approach: Patients with advanced pelvic malignancies are eligible. After analysis of feeding tumor vessels from the digital subraction angiography, a decision will be made as to which hypogastric vessel supplies the majority of the tumor. An oblique, lower quadrant incision will be made on the approriate side and the hypogastric artery and its proximal branches will be dissected extraperitoneally. The lumen will be dilated and and the catheter directed into the hypogastric artery. The tip of the catheter will be placed immediately above the highest vessel off which tumor vessels arise.

Progress: One patient was initially placed on study but Porta-Cath could not be implanted. The study is being kept open for future patients who qualify.

Detail Summary Sheet

Date: 12 Mar 88 Proj No: C-5-86 Status: Completed

Title: Ketamine Infusion: An Alternative Anesthetic Technique in the Morbidly Obese Patient.

| | |
|---|---|
| Start Date 16 Jan 86 | Est Comp Date: |
| Principal Investigator<br>William E. Strong, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Anesthesiology | Associate Investigators:<br>Alexander Rubin, CPT, MC |
| Key Words:<br>Obese | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 24

Total Number of Subjects Enrolled to Date: 24

Date of Periodic Review 23 Mar 88 Results Continue

Objective(s): To assess the feasibility of ketamine infusion as an anesthetic technique in the morbidly obese.

Technical Approach: Morbidly obese patients (male or female) without major cardiovascular disease undergoing vertical banding gastroplasty are eligible for the study. All patients entering the study will receive ketamine anesthesia.

Progress: Ketamine by continuous infusion with nitrous oxide and atracurium was used as the primary anesthetic in 24 patients undergoing vertical bonding gastroplasty. Four patients required supplementation with other agents to control sympathetic responses. No cardiopulmonary complications were noted postoperatively but one patient complained of dysphoria. This anesthetic technique is a safe alternative with potential benefits in this unique patient population at risk for cardiopulmonary dysfunction.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: C-18-86 Status: Completed

Title: Cephalometric Evaluation of the Sleep Apnea Patient.

| | |
|---|---|
| Start Date 6 Feb 86 | Est Comp Date: |
| Principal Investigator<br>Jesse Moss, Jr., LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Otolaryngology | Associate Investigators:<br>Donna Gibbons, CPT, MC |
| Key Words:<br>Sleep apnea | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 23 Mar 88 Results Continue

Objective(s): 1) To establish the value of a cephalogram in predicting sleep apnea.

2) To establish the value of a cephalogram in predicting the success of uvulopalatopharyngoplasty.

Technical Approach: Thirty patients will be assigned to each of four groups - 30 controls, 30 with normal cephalograms and abnormal sleep studies, 30 with abnormal cephalograms and normal sleep studies, and 30 with abnormal cephalograms and abnormal sleep studies. Based on results of cephalometry, surgical correction may or may not be recommended. Cephalogram and other pertinent data will be collected and x-ray findings will be correlated with success/failure rate of surgery.

Progress: The data showed a relationship between the distance from the hyoid bone to base of tongue and the length of the uvula to be a significant correlation. The combined correlation of the two distances appear to be a 70% positive sleep apnea study. Theoretically this could eliminate an expensive sleep study.

Detail Summary Sheet

| Date: 27 Oct 87 | Proj No: C-39-86 | Status: Completed |
|---|---|---|

Title: Sympathetic Blockade and Oral Prednisone Therapy in the Treatment of Herpes Zoster and Post Herpetic Neuralgia.

| | |
|---|---|
| Start Date 4 Apr 86 | Est Comp Date: |
| Principal Investigator (vice Feldman)<br>Emil Menk, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Anesthesiology | Associate Investigators:<br>Ava Feldman, CPT, MC |
| Key Words:<br>Herpes zoster | J. Henneberger, CPT, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 4

Total Number of Subjects Enrolled to Date: 12

Date of Periodic Review 16 Jun 88 Results Completed

Objective(s): To determine if sympathetic blockade will reduce the incidence of post herpetic neuralgia in patients with herpes zoster treated with oral prednisone.

Technical Approach: Patients will be randomized into two groups; one will receive nerve blocks with local anesthetic and the other injections with saline. The blocks and injections will be made appropriate to the distribution of the acute herpetic outbreak. All patients will receive oral prednisone according to the current protocol of the Dermatology Service. The following dta will be recorded: age, weight, distribution of the outbreak, onset of pain, onset of cutaneous eruption, when blocks were started, when oral prednisone was started, start of oral pain medicines, and the amount of oral pain medicine used during the herpetic eruption. Patients will be asked to fill out a short questionnaire to assess adequacy of pain relief and improvement in function.

Progress: Seven patients have been entered into the block group and five into the control group. No patients in the block group developed post-herpetic neuralgia. One of the five patients in the control group developed post-herpetic neuralgia.

Detail Summary Sheet

Date: 12 Oct 88 Proj No: C-52-86 Status: Ongoing

Title: Correlation of Sperm ATP-dependent Bioluminescence and Sperm Motility.

| | |
|---|---|
| Start Date 12 May 86 | Est Comp Date: |
| Principal Investigator<br>Ian M. Thompson, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Urology | Associate Investigators:<br>Gerald Merrill, GS11 |
| Key Words:<br>Sperm motility | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: $400.00 |

Number of Subjects Enrolled During Reporting Period: 25

Total Number of Subjects Enrolled to Date: 25

Date of Periodic Review _____ Results _____

Objective(s): To establish an association between sperm ATP concentrations as determined by bioluminescence and sperm motility.

Technical Approach: This protocol will utilize the discarded semen for bioluminescence analysis.

Progress: Data are being analyzed.

Detail Summary Sheet

Date: 12 Sep 88 Proj No: C-57-86 Status: Completed

Title: Porous Polysulfone Coated Titanium Alloy (Ti-6Al-4V) Hip Prosthesis.

| | |
|---|---|
| Start Date 10 Jun 86 | Est Comp Date: |
| Principal Investigator<br>Allan L. Bucknell, COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Orthopaedics | Associate Investigators: |
| Key Words:<br>Hip prosthesis | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 11

Total Number of Subjects Enrolled to Date: 43

Date of Periodic Review 16 Jun 88 Results Continue

Objective(s): To prove safety and efficacy of the use of porous surfaces (with stability afforded by biological fixation instead of bone cement) by statistical comparison to similar patient populations of like cemented components and other published data.

Technical Approach: The Porous Polysulfone Coated Titanium Alloy Hip Prosthesis is intended to serve as the femoral component of a two component system used in total hip arthroplasty. This femoral component will differ from other femoral components in that it does not rely on polymethylmethacrylate (PMMA) bone cement for stabilization within the femoral canal. The criteria used in this evaluation to determine safety will be removal rate. The type and incidence of all complications will be tabulated for analysis along with the removal rate. The criteria for determining efficacy will be pain relief, range of motion and the ability to walk.

Progress: No adverse side effects and no major complications have been encountered. Further implantation have been stopped. However, patients previously implanted will continue to be followed clinically and radiographically.

Detail Summary Sheet

Date: 12 Sep 88 Proj No: C-62-86 Status: Completed

Title: Efficacy of Endotracheal Tube Cuff Palpation in Distinguishing Endotracheal from Esophageal Intubation.

| | |
|---|---|
| Start Date 8 Jul 86 | Est Comp Date: |
| Principal Investigator<br>Robert G. Knight, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Anesthesiology | Associate Investigators: |
| Key Words:<br>Intubation, endotracheal | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 15

Total Number of Subjects Enrolled to Date: 15

Date of Periodic Review 16 Jun 88 Results Completed

Objective(s): To determine if palpation of the endotracheal tube cuff in the sternal notch is a sensitive and specific means of quickly assessing correct placement of the endotracheal tube.

Technical Approach: Fifteen ASA I and II adults scheduled for elective surgery were randomly assigned to one of two groups. Routine monitoring ws used on all patients including mass spectrometry and pulse oximeter. Group one patients were endotracheally intubated following preoxygenation, curare 3 mg, succinylcholine 1.5 mg/kg, and pentathol 4 mg/kg. Group two patients were similarly anesthetized. After being evaluated with direct laryngoscopy as having an easily visualized airway, they had endotracheal tubes placed to the same depths in the esophagus. In both groups the pilot balloon was inflated to a pressure of 20 mm/Hg. A blinded fellow or staff anesthesiologist had ten seconds to evaluate tube placement. Position was evaluated initially by pressing above the suprasternal notch while palpating the pilot balloon. Next a single breath was given and the endotracheal tube observed for condensation during exhalation.

Progress: Eight patients were randomized and placed in group one. The endotracheal tube cuff was palpated eight of eight times. Group two consisted of seven patients. The endotracheal tube cuff was palpated six of seven times ($P \leq .467$).

Presence of humidity in the tracheal placed endotracheal tubes occurred eight of eight times versus two of seven times in the endotracheal tubes placed in the esophagus ($P \leq .007$).

C-62-86 (continued)

The present study underscores the potential for catastrophe whenever cuff palpation or the presence of water condensation are used to discriminate between esophageal and endotracheal tube placement. Esophageal tube cuffs were commonly palpated as endotracheal by blinded, trained observers. The presence of condensation, although statistically less likely, can and does occur. That it did occur 28% of the time in the present study should strongly discourage its presence from being interpreted as a "reliable" indication of a successful outcome. The rsuls of this evaluation should reempohasize the need for careful assessment of multiple signs and symptoms as well as the use of advanced tehcnology whenever feasible.

Detail Summary Sheet

Date: 28 Sep 88 Proj No: C-73-86 Status: Ongoing

Title: Comparison of External Pneumatic Compression Boots and Embolex in Prophylaxis Against Deep Vein Thrombosis

| | |
|---|---|
| Start Date 12 August 1986 | Est Comp Date: |
| Principal Investigator (vice Hansberry)<br>Ian M. Thompson, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Oncology | Associate Investigators:<br>John M. Bauman, MAJ, MC<br>Francisco Rodriguez, COL, MC |
| Key Words:<br>Thrombosis, deep vein | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 76

Total Number of Subjects Enrolled to Date: 76

Date of Periodic Review 9 Sep 88 Results Continue

Objective(s): To compare the efficacy and complication rates of external pneumatic compression (EPC) boots and the drug Embolex in preventing lower extremity venous thrombosis in patients undergoing open urologic procedures.

Technical Approach: Adult male patients 40 years of age and older scheduled for open urologic procedures are eligible. Patients will be assigned to one of three treatment groups according to a table of random numbers. Group I will receive Embolex 2 hours before and every 12 hours during the post-operative period. Group II will have external pneumatic compression of the calves achieved by inflatable boots. EPC will be applied during induction of anesthesia and continued until the patient is ambulatory at least three times a day. Controls will wear Ted hose pre- and post-operatively.

Progress: Initial results of this study suggest Embolex to be the most effective method of deep venous thrombosis prophylaxis.

Detail Summary Sheet

Date: 27 Oct 88 Proj No: C-76-86 Status: Completed

Title: Incidence of Spinal Headache After SAB as Related to Needle Bevel Relationship to Dural Fibers, and Position of Patient During SAB.

| | |
|---|---|
| Start Date 12 Aug 86 | Est Comp Date: |
| Principal Investigator<br>Robert D. Culling, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Anesthesiology | Associate Investigators:<br>J. Culclasure, CPT, MC<br>Jerry Epps, CPT, MC |
| Key Words:<br>Headache, spinal | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date: 520

Date of Periodic Review 9 Sep 88 Results Completed

Objective(s): To determine if the incidence of spinal headache is increased in patients when the bevel of the spinal needle is inserted perpendicular to the dural fibers versus parallel insertion of the needle.

Technical Approach: Patients were divided randomly into four groups: I) seated with bevel inserted perpendicular to dural fibers, II) seated with bevel inserted parallel to dural fibers, III) lateral decubitus with bevel inserted perpendicular to dural fibers, and IV) lateral decubitus with bevel inserted parallel to dural fibers. Patients were followed for 72 hours post-op.

Progress: Data are currently being analyzed. Preliminary results indicate no difference in the incidence of spinal headache between any groups.

Detail Summary Sheet

Date: 20 Apr 88 Proj No: C-79-86 Status: Terminated

Title: Tissue Vitamin A Levels in the Oral Mucosa of Head and Neck Cancer Patients

| | |
|---|---|
| Start Date 8 Sep 86 | Est Comp Date: |
| Principal Investigator<br>Roger J. Simpson, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Otolaryngology | Associate Investigators:<br>Michael Peek, GS-9<br>Otolaryngology Staff |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 16 Jun 88 Results Terminated

Objective(s): 1) To compare the tissue level of retinol in the oral mucosa of head and neck cancer patients with a control population.

2) To determine if there is a correlation between the tissue retinol level of the cancer patient and the degree of differentiation of the tumor.

Technical Approach: The study group will include head and neck cancer patients admitted with a diagnosis of epithelial carcinoma of the head and neck. All patients and controls will be biopsied with cupped biopsy forceps. The left retromolar trigone will be biopsied except those involved with tumor in which case the opposite side or another oral site will be used. The control and patient groups will be analyzed by the difference in mean tests; and the correlation between the degree of differentiation of tumor and the level of vitamin A will be examined.

Progress: Study terminated due to inability to obtain control subjects.

Detail Summary Sheet

Date: 28 Oct 88 Proj No: C-87-86 Status: Ongoing

Title: LCSG 853 - A Clinical Trial in Patients with Stage II and III Completely Resected Non-Small Cell Lung Cancer Comparing Chemotherapy (CAT) versus No Therapy Following Surgery...

| | |
|---|---|
| Start Date 8 Sep 86 | Est Comp Date: |
| Principal Investigator<br>Brent A. Grishkin, COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Cardiothoracic | Associate Investigators: |
| Key Words:<br>Cancer, non-small cell lung | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 9 Sep 88 Results Continue

Objective(s): 1) To compare combination chemotherapy (CAP given at 4-week intervals for 4 cycles) as an adjuvant to surgery to prolong disease-free interval and survival with no immediate adjuvant treatment following complete resection of stage II and III non-small cell cancer of the lung.

2) To compare combination chemotherapy (CAP) administered immediately postoperatively in prolonging survival in these patients with delayed combination chemotherapy administered at the time of systemic recurrence in the no-treatment control group.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Patients with completely resected stage II/III disease are offered enrollment in this protocol as their staging becomes known.

Detail Summary Sheet

Date: 8 Aug 88 Proj No: C-89-86 Status: Completed

Title: Kennedy Ligament Augmentation Device in Reconstruction of the Unstable Knee for Anterior Cruciate Instability

| | |
|---|---|
| Start Date 12 Sep 86 | Est Comp Date: |
| Principal Investigator<br>Allan L. Bucknell, COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Orthopaedic | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 9 Sep 88 Results Completed

Objective(s): To demonstrate the effectiveness of the Kennedy LAD as a perioperative facilitator and as an augmentation device for repair or reconstruction of the anterior cruciate ligament.

Technical Approach: As outlined in the 3M Company protocol.

Progress: This study is completed as the device is now approved by the FDA.

Detail Summary Sheet

| Date: 27 Oct 88 | Proj No: C-93-86 | Status: Completed |
|---|---|---|

Title: Sphenopalatine Ganglion Blocks for Treatment of Nicotine Addiction

| Start Date 29 Sep 86 | Est Comp Date: |
|---|---|
| Principal Investigator<br>Emil J. Menk, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Anesthesiology | Associate Investigators: |
| Key Words:<br>Addiction, nicotine | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 17

Total Number of Subjects Enrolled to Date: 17

Date of Periodic Review _____ Results _____

Objective(s): Treatment of the nicotine abstinance withdrawal syndrome associated with acute cessation of tobacco with sphenopalatine ganglion blocks.

Technical Approach: Subjects were randomly assigned to one of three study groups. The 1st group received topical 4% cocaine, a 2nd group received .75% Bupivicaine with 1:100,000 epinephrine, and a 3rd group received saline. Subjects werecigarette smokers who demonstrated a desire to quit smoking. All subjects completed a "tolerance questionnaire" which measured the degree of physical dependence.

Progress: Seventeen patients completed the treatment course involving daily intra-nasal application of local anesthetic (bupivacaine or cocaine) or saline over the sphenopalatine ganglion. The data demonstrated a significantly lower associaiton of physical symptoms with patients undergoing sphenopalatine ganalion block. There were significantly fewer symptoms of withdrawal ($p < .05$) in patients receiving the longer acting local anesthetic bupivacaine as compared to cocaine. Patients in the nonplacebo groups demonstrated a lower relapse rate at 30 days ($p < .05$) to smoking than patients in the placebo groups.

Detail Summary Sheet

| Date: 27 Oct 88 | Proj No: C-95-86 | Status: Completed |
|---|---|---|

Title: Capnometry During the Administration of Supplemental Oxygen

| Start Date 29 Sep 86 | Est Comp Date: |
|---|---|
| Principal Investigator<br>Emil J. Menk, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Anesthesiology | Associate Investigators:<br>Robert E. Middaugh, MAJ, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date: 38

Date of Periodic Review Results

Objective(s): To evaluate noninvasive methods of capnometry while administering supplemental oxygen to patients during surgery.

Technical Approach: Thirty-eight patients were given oxygen and monitored using nasal cannula, venti mask, and a semi-closed anesthesia circuit. Three sets of end tidal $CO_2$ values were recorded for each oxygen apparatus.

Progress: System Three (nasal cannula) recorded the highest average value of $36.7 \pm 3.9$ followed by System One (semiclosed circuit) at $34.8 \pm 3.9$ and System Two (nonbreathing mask) at $25.3 \pm 6.5$ Comparison of the average end tidal carbon dioxide values with a one way analysis of variance demonstrated a statistically significant difference between the three groups.

Detail Summary Sheet

Date: 27 Sep 88 | Proj No: C-1-87 | Status: Completed

Title: The Effect of External Electrical Stimulation on Spine Fusions (Lumbar)

| | |
|---|---|
| Start Date 19 Nov 86 | Est Comp Date: |
| Principal Investigator<br>Gerald Q. Greenfield, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Orthopaedics | Associate Investigators:<br>Allen L. Bucknell, COL, MC<br>Michael Haak, CPT, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review 22 Jan 88 Results Continue

Objective(s): To determine whether the Spinal Stim-System will increase the success rate and decrease the healing time in patients having undergone a lumbar fusion.

Technical Approach: The study group at BAMC will become part of a large multi-center project. Patients will be assigned to groups in a randomized double blind fashion as each patient will have a "stimulator" applied, but activity of each determined by a code at the company. Patients will be followed by clinical evaluation as well as serial radiographs. Since current data incidates that fusion takes four to six months, all patients will use the external stimulator for a minimum of eight hours daily over three to nine months.

Progress: Study closed by central controlled. Study results showed that external stimulation enhances interbody spine fusion compared to non-stimulated group. Effect is seen at 4-6 months postoperative.

Detail Summary Sheet

| Date: 31 Oct 88 | Proj No: C-3-87 | Status: Ongoing |
|---|---|---|

Title: Radical Retropubic Prostatectomy and Orchiectomy for Stage C Carcinoma of the Prostate

| | |
|---|---|
| Start Date 19 Nov 87 | Est Comp Date: |
| Principal Investigator<br>John Brizzolara, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Urology | Associate Investigators:<br>Ian M. Thompson, MAJ, MC |
| Key Words:<br>Prostate<br>Carcinoma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date: 1

Date of Periodic Review _____ Results _____

Objective(s): To determine the efficacy of combined hormonal and surgical therapy for carcinoma of the prostate.

Technical Approach: Patients eligible for entry into the study will either be placed on Leupron theapy, one injection per day for two months, or undergo bilateral simple orchiectomy. Eight weeks following orchiectomy, radical prostatectomy will be performed.

After post-hormonal manipulation studies are obtained, patients will undergo staging pelvic lymphadenectomy. Postoperative treatment shall be in accordance with standard procedures.

Progress: One patient has been entered into the study. Despite excellent response to Lupron, negative node dissection, and uneventful prostatectomy, he now has manifestd metastatic disease.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: C-32-87 Status: Ongoing

Title: LCSG 821 - A Randomized Comparative Trial of Lobectomy versus Limited Resection for Patients with Cancer of the Lung

| | |
|---|---|
| Start Date 2 Mar 87 | Est Comp Date: |
| Principal Investigator<br>Brent A. Grishkin, COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Cardiothoracic | Associate Investigators: |
| Key Words:<br>Lobectomy | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 6

Date of Periodic Review 23 Mar 88 Results Continue

Objective(s): 1) To determine if limited pulmonary resection (wedge resection or segmental resection) for peripheral $T_1N_0M_0$ non-small cell lung cancer is as effective as lobection in preventing recurrence of disease.

2) To compare morbidity and mortality of imited resection with that of standard lobectomy.

3) To compare postoperative pulmonary funciton with regard to type of procedure employed.

Technical Approach: Eligible patients must have a presumed diagnosis of non-small cell carcinoma of the lung (squamous cell, adenocarcinoma or large cell). The patient must be a candidate for lobectomy.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient originally enrolled May 87 has died of 2nd primary.

May 88 LCSG review shows no difference in perioperative morbidity between the randomized groups.

Detail Summary Sheet

| Date: 1 Nov 88 | Proj No: C-33-87 | Status: Completed |
|---|---|---|

Title: Morbidity Associated with Pelvic Lymphadenectomy

| | |
|---|---|
| Start Date 2 Mar 87 | Est Comp Date: |
| Principal Investigator (vice Rodriguez)<br>Ian M. Thompson, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Urology | Associate Investigators:<br>Francisco Rodriguez, COL, MC |
| Key Words:<br>Lymphadenectomy, pelvic | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To determine the morbidity associated with pelvic lymphadenectomy.

Technical Approach: The inpatient records of all patients undergoing pelvic lymphadenectomy during the period 1978 to 1986 will be reviewed. In addition, outpatient records will be reviewed for any evidence of long term sequelae of the operation.

Progress: All cases within this time frame have been identified. Complications have been tolerated.

Detail Summary Sheet

| Date: 1 Nov 88 | Proj No: C-34-87 | Status: Terminated |
|---|---|---|

Title: Bowel Obstruction Secondary to Carcinoma of the Prostate

| Start Date 2 Mar 87 | Est Comp Date: |
|---|---|
| Principal Investigator (vice Rodriguez)<br>Ian M. Thompson, MAJ, MD | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Urology | Associate Investigators:<br>Francisco R. Rodriguez, COL, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To discern the natural history of patients developing rectal obstrction secondaryt o carcinoma of the prostate. To further determine the effect of treatments given to patients with this extensive disease.

Technical Approach: All cases of bowel obstruction secondary to carcinoma of the prostate will be retrieved from records of the Urology Oncology data registry at BAMC.

Progress: Three cases of this clinical circumstance have been identified at BAMC. However, letters to all other military medical centers failed to yield any responses. For that reason, the study is terminated.

Detail Summary Sheet

| Date: 1 Nov 88 | Proj No: C-46-87 | Status: Ongoing |
|---|---|---|

Title: LCSG 862 - Immunohistochemical Analysis of Lung Cancer

| | |
|---|---|
| Start Date 9 Apr 87 | Est Comp Date: |
| Principal Investigator<br>Brent A. Grishkin, COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Cardiothoracic | Associate Investigators:<br>Robert A. Helsel, COL, MC |
| Key Words: | Lida A. Crooks, MAJ, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 2

Date of Periodic Review 16 Jun 88 Results Continue

Objective(s): 1) To ascertain the predictive value of a series of immunohistochemical markers for response and survival in a previously studied patient population on whom data on routine prognostic factors, response, survival and toxicity is known.

2) To ascertain whether patterns of disease prsentation are correlated with specific markers for cell surface and cytoskeletal proteins.

3) To ascertain if thepattern of loss of markers used to define the small cell "variant" cell lines and specimens is predictive of improved response in non-small cell patients.

Technical Approach: Data collection and registration are as outlined in the study protocol.

Progress: Study applicable only to patients also on LCSG 853 protocol (C-87-86).

Detail Summary Sheet

| Date: 1 Nov 88 | Proj No: C-50-87 | Status: Ongoing |
|---|---|---|

Title: Chromosomal Analysis of Genitourinary Neoplasms

| | |
|---|---|
| Start Date 11 May 87 | Est Comp Date: |
| Principal Investigator<br>Ian M. Thompson, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Urology | Associate Investigators:<br>Eric J. Zeidman, MAJ, MC |
| Key Words:<br>Karyotype | Kurt L. Hansberry, CPT, MC<br>Isidoro Chapa, GS-7 |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: 5215.28 |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To correlate tumor karyotypes with patient data, tumor stage and grade, and clinical course of the disease.

Technical Approach: At the time of removal of a genitourinary tumor, a small piece of tumor tissue will be sent for karyotyping. The technique for karyotyping will employ the coverslip method. Chromosomal banding will include standard techniques for G-banding, Q-banding (fluorescence), and C-banding. Photographs will include intact banded metaphase plates. Karyotyping will be performed by cutting individual chromosomes from photographs and identifying according to standard nomenclature.

Progress: This study is progressing quite nicely. With technical improvements, karyotype results are currently much more interpretable. Initial results suggest essentially normal karyotypes for renal and prostatic tumors but quite bizarre karyotypes (isochromosomes, deletion, tetraploidy) for many bladder tumors.

Detail Summary Sheet

| Date: 1 Nov 88 | Proj No: C-55-87 | Status: Terminated |
|---|---|---|

Title: The Effect of Combined Low Dose Dopamine and Furosemide on Urine Production and Renal Function in Acute Oliguric Renal Failure

| Start Date 13 May 87 | Est Comp Date: |
|---|---|
| Principal Investigator (vice Cushner)<br>Joseph P. Ducey, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Intensivist | Associate Investigators: |
| Key Words:<br>Renal failure<br>Dopamine | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review 16 Jun 88 Results Continue

Objective(s): To determine the effectiveness of furosemide and low dose dopamine in patients with established acute renal failure (ARF) in order to see if these agents favorably alter the patient's course.

Technical Approach: Patients meeting the criteria for inclusion will be assigned to one of the trial groups via a random numbers table. Group I will receive low dose dopamine plus furosemide by continuous infusion. Patients in Group II will receive saline-placebo as substitution for both continuous dopamine and intermittent furosemide infusion. Therapy and data collection will follow the schema outlined in the study protocol.

Progress: Co-investigators from the Nephrology Service and Nuclear Medicine have been transferred, making completion of this protocol impossible. No patients have been entered.

Detail Summary Sheet

| Date: 27 Oct 88 | Proj No: C-65-87 | Status: Ongoing |
|---|---|---|

Title: Trauma Score

| | |
|---|---|
| Start Date 2 Jul 87 | Est Comp Date: |
| Principal Investigator<br>R. Duane Cook, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/General Surgery | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review n/a Results _____

Objective(s): This study will compare the TRAUMA SCORE and CRAMS (Circulation, Respiration, Abdomen, Motor, Speech) SCALE as predictors of outcome and triage instruments in major trauma, and will also serve to document the present state of trauma care at BAMC.

Technical Approach: The study population will be comprised of all patients brought to the BAMC Emergency Department because of major trauma who are either admitted, transferred to another hospital, or die prior to admission. After stabilization of the patient, a checklist will be completed by a physician involved in the resuscitation to record information regarding teh patient's pre-hospital and emergency department condition and care. Each patient will be scored according to both the TRAUMA SCORE and the CRAMS SCALE. Following disposition, the final diagnoses, procedures, complications and ultimate outcome will be obtained to complete each patient's file.

Progress: The study was designed to extend over a two year period, with the first six months serving as a pilot study. During the pilot study phase, 130 patients were seen in the Emergency Department. One hundred-thirteen (87%) were males, with only 17 females. The average age of the entire group was 28.8 years. The most frequent dispositions from the ER were the operating room (30%), and to Beach Pavilion for CT scanning (30%). Twelve percent were

admitted directly to one of the two surgical intensive care units. Eleven percent were transferred to another hospital, and twelve patients (9%) died before leaving the Emergency Department.

In addition to 14 patients transferred directly from the ER, 8 other patients were either transferred later or left against medical advice for a total of 22. Of the 108 patients in whom ultimate outcome could be determined, there were 85 survivors and 23 deaths, for a total mortality of 21.3%.

When categorized by the Trauma Score, 62 patients (57%) had scores of 15 or 16 with no deaths. There was an incremental increase in mortality in patients with scores of 14 to 10, and no survivors in the 14 patients with scores of 9 or less. The CRAMS score distirubtion varied somewhat in that there were not as many patients at the high end of the scale. There were no deaths in the 36 patients (33%) with scores of 9 or 20. Again, an incremental increase in mortality was present from scores 8 to 5, with no survivors in the group with scores of 4 or less.

This preliminary report supports the findings of other published series that demonstrate a correlation between both the Trauma Score and CRAMS Scale with survival.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: C-90-87 Status: Ongoing

Title: Opti-Fix[tm] Hip Prosthesis (Multicenter Study)

| | |
|---|---|
| Start Date 21 Sep 87 | Est Comp Date: |
| Principal Investigator<br>Allen L. Bucknell, COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Orthopaedics | Associate Investigators: |
| Key Words:<br>Prosthesis, hip | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 7

Total Number of Subjects Enrolled to Date: 7

Date of Periodic Review 9 Sep 88 Results Continue

Objective(s): To prove safety and efficacy of the use of porous surfaces (with stability afforded by biologic fixation instead of bone cement) by statistical comparison to similar patient populations of like cemented components and other published data.

Technical Approach: Patients requiring total hip replacement will be asked to participate in this study. If they agree, the Opti-Fix[tm] will be implanted as outlined in the study protocol.

Progress: Early results equivalent or better than cemented total hip replacement, based upon Harris hip scale.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: C-93-87 Status: Completed

Title: The Relative Roles of the Lacrimal Canaliculi in Tear Drainage

| | |
|---|---|
| Start Date 28 Sep 87 | Est Comp Date: |
| Principal Investigator<br>William L. White, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Ophthalmology | Associate Investigators: |
| Key Words:<br>Tear drainage | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 11

Total Number of Subjects Enrolled to Date: 11

Date of Periodic Review 9 Sep 88 Results Completed

Objective(s): To determine the rate at which the superior and inferior canaliculi transport tears relative to each other.

Technical Approach: In order to evaluate the relative tear flow in the canaliculi quantitatively by a physiologic method, we studied 22 eyes in 11 patients utilizing dacryoscintigraphy and selective canalicular obstruction with absorbable collagen plugs.

Progress: We found no statistical difference in tear flow between the upper and lower canalicular systems. Results suggest that repair of isolated canalicular lacerations be considered without regard as to which specific canaliculus is injured.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: C-94-87 Status: Terminated

Title: Correlation of the Bacterial Colonization of the Adenoidal Tissue and Middle Ear Effusion

| | |
|---|---|
| Start Date 28 Sep 87 | Est Comp Date: |
| Principal Investigator<br>John T. Fraker, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Otolaryngology | Associate Investigators:<br>Jesse Moss, Jr., LTC, MC<br>Hugh M. Gelston, Jr., MAJ, MS<br>Sheila Jones, SSG |
| Key Words:<br>Adenoidectomy | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review 9 Sep 88 Results Terminated

Objective(s): To compare the bacterial content of the adenoid tissue and middle ear effusion in children.

Technical Approach: All patients ages 2 to 18 undergoing adenoidectomy and myringotomy with PE tube placement will be asked to participate. At the time of surgical removal of the adenoids, a small portion of the tissue will be taken and sent for anaerobic culture and identification. At the same time, using an anaerobic transport swab, culture will be taken of the middle ear effusion for identification of the organisms present.

Progress: Unable to proceed with study as a result of loss of personnel in Clinical Investigations.

Detail Summary Sheet

Date: 8 Nov 88 Proj No: C-1-88 Status: Ongoing

Title: Fully Coated Porous Polysulfone Titanium Alloy (TI-6AL-4V) Hip Prosthesis

| | |
|---|---|
| Start Date 13 Nov 87 | Est Comp Date: |
| Principal Investigator<br>Allan L. Bucknell, COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Orthopaedic | Associate Investigators: |
| Key Words:<br>Hip prosthesis | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 10

Total Number of Subjects Enrolled to Date: 10

Date of Periodic Review _____ Results _____

Objective(s): To determine (1) whether the prostehses may be stabilized by biological fixation into the porous surface material of the femoral component without the use of bone cement; and (2) whether the stability of the prostheses will occur and whether it will be equal to or superior to the stability afforded by methods currently used with other hip prostheses.

Technical Approach: As outlined in the company protocol.

Progress: The prostheses are all in place. The early results show no loosening or implant failure. Follow-up continues and the results will be tabulated with the nationwide results.

Detail Summary Sheet

Date: 28 Sep 88 Proj No: C-2-88 Status: Ongoing

Title: Bone Conduction Implantable Device

| | |
|---|---|
| Start Date 17 Nov 87 | Est Comp Date: |
| Jesse Moss, LTC, MC | Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Otolaryngology | Associate Investigators:<br>John Ribera, CPT, MS |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To determine the feasibility of implanting bone conduction devices in patients with mild to moderate conductive hearing loss in comparison to benefits from conventional hearing prostheses.

Technical Approach: This will be a single blind study available to 30 patients with conductive hearing losses which cannot be ameliorated through existing surgical procedures or conventional hearing aids.

the XOMED Audiant device will be implanted into the mastoid bone. After the incision is healed, the sound transmitter with the external coil will be applied over the magnet.

Progress: This study has not been started because of nonavailability of funds to purchase the device.

Detail Summary Sheet

Date: 8 Nov 88 Proj No: C-3-88 Status: Ongoing

Title: Comparison of Trigger Point Injections Using a Local Anesthetic with and without a Steroid in the Treatment of Myofascial Pain Syndrome.

| | |
|---|---|
| Start Date 17 Nov 87 | Est Comp Date: |
| Principal Investigator<br>William E. Strong, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Anesthesiology | Associate Investigators:<br>Emil J. Menk, MAJ, MC |
| Key Words:<br>Syndrome, myofascial pain<br>Trigger point | Timothy Hansen, CPT, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 3

Total Number of Subjects Enrolled to Date: 3

Date of Periodic Review 20 Apr 88 Results Continue

Objective(s): 1) Compare the therapeutic effects of injecting a trigger point with Marcaine alone or Marcaine with Kenalog.

2) Compare the duration of effect when injecting a trigger point with Marcaine alone or Marcaine with Kenalog.

3) Compare pain of injection of a trigger point using Marcaine alone and Marcaine with Kenalog.

Technical Approach: Patients with diagnosis of myofascial pain syndrome who are referred to the Pain Clinic will be recruited for the study. After information sheet is completed, subjects will be randomly assigned to one of two treatment groups. Patients will be placed in the supine position on the examination table, and dolormeter will be used to monitor the amount of pressure on trigger point required to reproduce maximal discomfort. Group I will receive 10 cc, 0.5% Marcaine, and Group II 10 cc, 0.5% Marcaine with 20 mg Kenalog. Patients will be asked to mark a Visual Analog Scale (VAS) and a pressure reading will be taken at various times during the investigaiton.

Progress: Study was temporarily on hold because PI was out of pain clinic for six months. The study will resume in the near future.

Detail Summary Sheet

| Date: 8 Nov 88 | Proj No: C-4-88 | Status: Completed |
|---|---|---|

Title: Comparison of Bretylium and Lidocaine in the Prevention of Ventricular Fibrillation after Aorta Cross-Clamping.

| | |
|---|---|
| Start Date 17 Nov 87 | Est Comp Date: |
| Principal Investigator<br>Jeffery J. Kirlangitis, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Anesthesiology | Associate Investigators:<br>Robert Helsel, COL, MC<br>Brent A. Grishkin, COL, MC<br>Robert Middaugh, MAJ, MC<br>Robert Knight, MAJ, MC<br>William Goglin, CPT, MC |
| Key Words:<br>Ventricular fibrillation | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:_____

Total Number of Subjects Enrolled to Date:_____

Date of Periodic Review_____ Results_____

Objective(s): To compare the benefits of intravenous bretylium and lidocaine in reducing the incidence and severity of ventricular fibrillation after aortic cross-clamping during myocardial revascularization.

Technical Approach: Twenty-three patients undergoing coronary artery bypass surgery were randomly assigned in a double blind fashion to a bretylium, lidocaine, or saline groups. Open heart surgery was conducted using standard cardiopulmonary bypass procedures.

Progress: There was no significant difference between groups with respect to age, sex, preoperative medications, past medical history, ejection fraction, average number of bypasses, cross-clamp time, or temperature during bypass.

The incidence of ventricular fibrillation after aortic cross-clamp release was: saline 91%, lidocaine 64% ($p < .01$), and bretylium 35% ($p < .01$). The number of coutershocks required to defibrillate while lower in the bretylium group did not rech statistical significance.

C-4-88 (continued)

The results of this study indicate that bretylium is more effective than lidocaine in reducing the incidenceof reperfusion ventricular fibrillation after aortic cross-clamp release during elective myocardial revascularization. The requirement for defibrillation with DC coutnershocks was also reduced in the bretylium group. No adverse effects were noted. Bretylium warrants further study in this setting and may prove a valuable adjunct to reducing patinet morbidity.

Detail Summary Sheet

Date: 8 Nov 88 Proj No: C-7-88 Status: Ongoing

Title: The Time Principle in the Induction of Anesthesia.

| | |
|---|---|
| Start Date 1 Dec 87 | Est Comp Date: |
| Principal Investigator<br>Douglas Culling, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Anesthesiology | Associate Investigators:<br>Emil J. Menk, MAJ, MC |
| Key Words:<br>Timing principle | Robert E. Middaugh, MAJ, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 34

Total Number of Subjects Enrolled to Date: 34

Date of Periodic Review _____ Results _____

Objective(s): To determine if a single large bolus of a nondepolarizing neuromuscular blocking drug, if given using the timing principle, will produce reliable relaxation for intubation within 60 seconds after the induction of anesthesia.

Technical Approach: Patients were randomly assigned to one of three groups. Groups differed only in the vecuronium dose administered during induction with group A receiving .1 mg/kg, group B ,15 mg/kg, and group C .2 mg/kg. All groups received reglan and ranitidine preoperatively. Routine monitoring included pulse oximetry and mass spectrometry. The degree of neuromuscular blockade was visually estimated via train of four using a Digi Stim II nerve stimulator after the patient lost consciousness. After pre-oxygenation, all patients were given midazolam IV. One minute later level of consciousness was assessed, and the appropriate bolus of vecuonium was given. At the onset of clinical weakness, as judged by hand grip or decreased ventilatory effort, patients were asked to cough and then received sodium pentothal. Six seconds later patients were intubated and clinical conditions during intubation graded.

Progress: All groups were similar in terms of age, weight, and sex. Intubation scores were uniformly excellent. There was also no significant difference between onset time of clinical weakness. However, there was a significant difference between groups for the time required for the return of twitch. Additionally, this was found to correlate with increasing age. Commonly patients exhibited a hemodynamic response to intubations with elevations of both heart rate and blood pressure.

C-7-88 (continued)

In the present study, timing the administration of a single moderate sized volus of vecuronium to the onset of clinical weakness provided consistently excellent intubating conditons at 60 seconds. From a pharmacodynamic standpoint this method of administration seems logical. The "timing principle" may provide the optimal method of administration of current nondepolarizing muscle relaxants for rapid sequence intubations.

Detail Summary Sheet

Date: 31 Oct 88 Proj No: C-8-88 Status: Completed

Title: Prevention of Contamination of the Concha® Water Humidifier.

| | |
|---|---|
| Start Date 1 Dec 88 | Est Comp Date: |
| Principal Investigator<br>Timothy E. Hansen, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Anesthesiology | Associate Investigators:<br>Robert E. Middaugh, MAJ, MC<br>Emil J. Menk, MAJ, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative<br>OMA Cost: 641.52 |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To assess the effectiveness of eliminating bacterial contamination from patient to humifier system by a simple alteration in the inspiratory limb of the circle anesthetic circuit.

Technical Approach: Prior to induction of anesthesia, the inspiratory limb of the disposable anesthetic circle circuit was bisected and a disposable water trap was interposed. During the surgical procedure the water trap was allowed to assume a dependent position along the circuit and excess condensation was drained via this trap. At the end of the surgical procedure, samples were btained with sterile cotton tipped swabs at three locations: 1) trachea from the tip of a sterile suction catheter, 2) inside the water trap reservoir, and 3) inside the distal inspiratory limb attached to the humidifier. These samples were cultured using routine microbiological methods.

Progress: Thirty-seven of fifty-five patients studied had a positive tracheobronchial culture. There were seven (12.7%) positive cultures from the water trap reservoir which correlated 100% with the culture taken from the trachea of the patient. There were no positive cultures obtained from the circuit distal to the trap. When patients were assessed as to length of procedure, the circuit (water trap) became progressively colonized. Two samples collected during the 6-9 hour interval however, had no growth from their tracheobroncial samples.

Detail Summary Sheet

Date: 8 Nov 88 Proj No: C-10-88 Status: Ongoing

Title: C-Reactive Protein, Erythrocyte Sedimentation Rate, and White Blood Count in Aseptic Loosening of Total Joint Components

| | |
|---|---|
| Start Date 2 Dec 87 | Est Comp Date: |
| Principal Investigator<br>Henry G. Chambers, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Orthopaedics | Associate Investigators:<br>Allan L. Bucknell, COL, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: 391.00 |

Number of Subjects Enrolled During Reporting Period: 50

Total Number of Subjects Enrolled to Date: 50

Date of Periodic Review _____ Results _____

Objective(s): To prospectively evaluate the efficacy of these blood tests in the evaluation of pre- and postoperative revision total joint patients.

Technical Approach: All patients who enter the hospital for a revision total joint arthroplasty will have a CRP, ESR, and WBC level drawn at the time of initial routine preoperative evaluation. These will be repeated immediately postoperatively, on postoperative days 1 thru 5, at 6 weeks, at 3 months and at 6 months. Should an infection be suspected clinically, a CRP level will be drawn at that time as well.

Progress: The initial laboratory results have been compiled but the statistics and code have not been broken.

Detail Summary Sheet

Date: 8 Nov 88 Proj No: C-12-88 Status: Ongoing

Title: The Effect of Bone Allograft in Total Joint Replacement on C-Reactive Protein, Erythrocyte Sedimentation Rate, and White Blood Cell Count.

| | |
|---|---|
| Start Date 2 Dec 87 | Est Comp Date: |
| Principal Investigator<br>Henry G. Chambers, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Orthopaedics | Associate Investigators:<br>Allan L. Bucknell, COL, MC |
| Key Words:<br>Bone allograft | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: 135.00 |

Number of Subjects Enrolled During Reporting Period: 50

Total Number of Subjects Enrolled to Date: 50

Date of Periodic Review _____ Results _____

Objective(s): To prospectively evaluate the efficacy of these blood tests in the evaluation of patients undergoing total joint replacement with bone allograft.

Technical Approach: All patients who enter the hospital for a total joint arthoplasty in whom an allograft is planned will have a CRP, ESR, and WBC level drawn at the time of initial routine preoperative evaluation. These will be repeated immediately postoperatively, on postoperative days 1 thru 5, at 6 weeks, at 3 months and at 6 months. Should an infection be suspected clinically, a CRP level will be drawn at that time as well.

Progress: Each patients laboratory results have been charted but the statistics and the code have not been broken.

Detail Summary Sheet

| Date: 8 Nov 88 | Proj No: C-20-88 | Status: Ongoing |
|---|---|---|

Title: LCSG 871 - Centralized Non-Small Cell Lung Cancer Specimen Repository and DNA/RNA Bank

| | |
|---|---|
| Start Date 13 Jan 88 | Est Comp Date: |
| Principal Investigator<br>Brent A. Grishkin, COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Cardiothoracic | Associate Investigators:<br>Michael Jackson, MAJ, MC<br>Robert A. Helsel, COL, MC |
| Key Words:<br>Non-small cell lung cancer | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 2

Total Number of Subjects Enrolled to Date: 3

Date of Periodic Review _____ Results _____

Objective(s): To provide the LCSG tissue repository with specimens of non-small cell lung cancer and adjacent normal tisue from previously untreated patients who are undergoing resection of lung cancer.

TECHNICAL APPROACH: Patients with non-small cell lung cancer, who have not received prior treatment, who undergo resectional therapy, will be invited to participate. At the time of operation, if sufficient tissue is available, portions of the primary tumor and adjacent normal lung tissue will be processed as outlined in the study protocol.

Progress: Tissue analysis being conducted at UCLA. BAMC specimens are being hel in -70°C storage until sufficient number have been collected to ship to UCLA as a group.

Detail Summary Sheet

| | | |
|---|---|---|
| Date: 8 Nov 88 | Proj No: C-21-88 | Status: Ongoing |

Title: Evaluation of Stress Fractures with Dual Photon Absorptiometry

| | |
|---|---|
| Start Date 13 Jan 88 | Est Comp Date: |
| Principal Investigator<br>Michael H. Haak, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Orthopaedic | Associate Investigators: |
| Key Words:<br>Fractures, stress | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 20

Total Number of Subjects Enrolled to Date: 20

Date of Periodic Review _____ Results _____

Objective(s): To evaluate dual photo absorptiometry, a relatively new diagnostic technique for quantiative evaluation of bone mineral content, in patients with stress fracture injury.

Technical Approach: Utilizing bone densitometry - evaluate stress fracture sites and compare to uninjured side, also evaluate systemic bone mineral density by checking L5 spine.

Progress: No difference noted in comparing site of stress fracture to uninjured side ($p<.05$). Significant ($p<.05$) change in systemic bone mineral density from spine data.

Detail Summary Sheet

| Date: 8 Nov 88 | Proj No: C-26-88 | Status: Ongoing |
|---|---|---|

Title: Physio-Stim™ Pulsed Electromagnetic Field Therapy System

| | |
|---|---|
| Start Date 17 Feb 88 | Est Comp Date: |
| Principal Investigator<br>Allan L. Bucknell, COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Orthopaedic | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 1

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To determine the effectiveness and safety of the Physio-Stim™ Electromagnetic Field Therapy System in the treatment of ununited fractures of long and short bones and failed arthrodeses.

Technical Approach: Patients meeting the criteria for inclusion in this study will be randomly assigned to receive either daily treatment using the Physio-Stim™ Therapy System or standard therapy. Patients assigned to the Physio-Stim™ Therapy System group will be asked to apply it over the fracture area 8 hours a day for six months. Patients in the standard therapy group will continue treatment program of non-weight bearing, elevation, and physical therapy.

Progress: We have enrolled one patient, and he opted to exit the study after four months because he preferred the operative treatment of this delayed union.

Detail Summary Sheet

| Date: 30 Sep 88 | Proj No: C-27-88 | Status: Ongoing |
|---|---|---|

Title: Evaluation of Continuous Positive Airway Pressure (CPAP) as an Adjunct to Respiratory Therapy After Spinal Surgery

| | |
|---|---|
| Start Date 17 Feb 88 | Est Comp Date: |
| Principal Investigator<br>Michael H. Haak, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Orthopaedic | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To test the benefits of CPAP following spine surgery and correlate its use with respiratory funciton and postoperative complications.

Technical Approach: Use continuous positive airway pressure as an adjunct to respiratory therapy in patients undergoing spine fusion.

Progress: Final selection of respiratory parameters to be monitored will be made. Waiting while computer data storage by ICU to facilitate collection is being installed.

Detail Summary Sheet

| Date: 8 Nov 88 | Proj No: C-28-88 | Status: Ongoing |
|---|---|---|

Title: In vivo Monitoring of Reconstructed Hip Joints During Walking

| Start Date 17 Feb 88 | Est Comp Date: |
|---|---|
| Principal Investigator<br>Allan L. Bucknell, COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Orthopaedic | Associate Investigators:<br>James A. Davidson, M.S. |
| Key Words:<br>Reconstructed hip joint | Henry G. Chambers, MAJ, MC<br>Michael H. Haak, CPT, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To determine the activity the activity associated change in temperature in vivo for total hip replacement arthroplasty.

Technical Approach: A thermocouple will be placed in the hip joints of patients who have received a total hip arthroplasty with either a cobalt-chrome hip or a ceramic head to evaluate if there is any change in hip temperature.

Progress: The original thermocouple sent to us was too brittle and when placed in a cadaveric hip bent and broke. A new thermocouple is here for evaluation. We are awaiting permission to place it in a cadaver.

Detail Summary Sheet

Date: 8 Nov 88 Proj No: C-29-88 Status: Ongoing

Title: Evaluation of Arthroplasty-Associated Bone Density Changse with Dual Photon Absorptiometry.

| | |
|---|---|
| Start Date 17 Feb 88 | Est Comp Date: |
| Principal Investigator<br>Michael H. Haak, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Orthopaedic | Associate Investigators:<br>Allan L. Bucknell, COL, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To evaluate the bone mineral density and associated strength of bone in patients undergoing total hip replacement arthroplasty.

Technical Approach: Evaluate by sequential bone densitometry patients undergoing uncemented hip arthroplasty and evaluate bone density associated with certain prosthesis designs.

Progress: Testing shows that in a significant number of subjects, variability up to 10% was occurring because of lack of rigid positioning.

Detail Summary Sheet

| Date: 8 Nov 88 | Proj No: C-30-88 | Status: Ongoing |
|---|---|---|

Title: Functional Evaluation of Morbidity with Upper Extremity Arterial Catheterization

| Start Date 17 Feb 88 | Est Comp Date: |
|---|---|
| Principal Investigator<br>Michael H. Haak, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Orthopaedic | Associate Investigators:<br>Richard Jansen, CPT, MS<br>William Wright, CPT, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: 277.55 |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To evaluate the morbidity associated upper extremity arterial catheterization with prospective subjective and objective functional upper extremity evaluation of patients receiving elective cardiac catheterization.

Technical Approach: Patients undergoing catheterization will have pre-cath and interval evaluation of upper extremity function.

Progress: Once initial training in upper extremity catheterization for new cardiology fellows is completed, patient enrollment will start.

Detail Summary Sheet

| Date: 8 Nov 88 | Proj No: C-35-88 | Status: Ongoing |
|---|---|---|

Title: Evaluation of Luque Interpeduncular Segmental Fixation in Spinal Injury

| | |
|---|---|
| Start Date 7 Mar 88 | Est Comp Date: |
| Principal Investigator<br>Gerald O. Greenfield, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Orthopaedic | Associate Investigators:<br>Michael H. Haak, CPT, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 10

Total Number of Subjects Enrolled to Date: 10

Date of Periodic Review _____ Results _____

Objective(s): To review the BAMC experience with the Luque Interpeduncular Segmental Fixation System by assessment of pre- and postoperative radiologic evaluations and interim/long term results.

Technical Approach: Review operative reports, narrative summary and final radiographs utilizing Luque Interpeduncular Segmental Fixation System.

Progress: All reviewed patients now achieved. Progressing to bony fusion of posterolateral/interbody fusion.

Detail Summary Sheet

Date: 8 Nov 88 Proj No: C-38-88 Status: Ongoing

Title: Bone Density Changes with Compression Plating of Fractures

| | |
|---|---|
| Start Date 7 Mar 88 | Est Comp Date: |
| Principal Investigator<br>Rick D. Compton, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Orthopaedic | Associate Investigators:<br>Michael H. Haak, CPT, MC |
| Key Words: | Edwin Melendez, COL, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 4

Total Number of Subjects Enrolled to Date: 4

Date of Periodic Review _____ Results _____

Objective(s): Patients undergoing removal of compression plates after treatment of fractures will undergo bone densitometry of involved and uninvolved sites. Bone density changes will be plotted versus time since plating for various bones to quantify plate associated bone density loss.

Technical Approach: Dual photon absorptiometry will be utilized after plate removal to determine if bone density can be associated with plating of fractures as compared to the uninjured side.

Progress: Four patients scanned to date. No comparison can be made at this time.

Detail Summary Sheet

| Date: 8 Nov 88 | Proj No: C-39-88 | Status: Ongoing |
|---|---|---|

Title: EValuation of Constituents in the Synovial Fluid of Reconstructed Hips

| | |
|---|---|
| Start Date 29 Mar 88 | Est Comp Date: |
| Principal Investigator<br>Henry G. Chambers, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Orthopaedic | Associate Investigators:<br>Allan L. Bucknell, COL, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 5

Total Number of Subjects Enrolled to Date: 5

Date of Periodic Review_____ Results_____

Objective(s): Evaluation of constituents in the synovial fluid of reconstructed hips.

Technical Approcah: Twenty patients with reconstructed hips will have samples of synovial fluid collected. Each sample will be evaluated for hyaluronic acid, cholesterol, and glucose concentration.

Progress: The fluid is being evaluated in Memphis, Tennessee and the results are not available at this time.

Detail Summary Sheet

| Date: 8 Nov 88 | Proj No: C-48-88 | Status: Completed |
|---|---|---|

Title: The Significance of the Cross-Table Lateral X-ray of the Hip - A Cadaveric and Retrospective Study

| Start Date 19 Apr 88 | Est Comp Date: |
|---|---|
| Principal Investigator<br>George D. Harrington, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Orthopaedic | Associate Investigators:<br>Henry G. Chambers, MAJ, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To correlate the x-rays of the cadaveric specimen with x-rays of patients pending total hip revision.

Technical Approach: Cross table lateral radiographs were taken of a cadaveric pelvis and right hip in various orientations. A retrospective study was undertaken evaluating 53 patient's radiographs who had revision arthroplasty, endoprosthetic hemi-arthroplasty or total hip arthrobplasty (a total of 250 cross table lateral radiographs).

Progress: Anatomic and radiographic evaluation demonstrated a constant orientation of the posterior acetabulum about a reference line drawn along the anterior cortex of the ischial tuberosity. Examination of the anatomic specimen demonstrated that a significant portion of the posterior acetabular column is oriented inferior to the reference line.

In the retrospective study it was found that the magnitude of protrusion of the acetabular component beneath the reference could be used to estimate posterior

C-48-88 (continued)

acetabular deficiency. A high correlation with the cadaveric x-ray findings was noted, and one could predict posterior acetabular deficiency.

The cross table lateral is an important additional means to evaluate the posterior acetabular column prior to revision hip arthroplasty in the non-dysplastic hip.

Detail Summary Sheet

| Date: 8 Nov 88 | Proj No: C-52-88 | Status: Ongoing |
|---|---|---|

Title: Multiclinic Trial of Fibrillar Collagen/Calcium Phosphate Ceramic (COLHAP)

| Start Date 9 MaY 88 | Est Comp Date: |
|---|---|
| Principal Investigator<br>Allan L. Bucknell, COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Orthopaedic | Associate Investigators:<br>Henry G. Chambers, MAJ, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To determine the efficacy (functional and roentgenographic rsults) and benefits of COLHAP bone marrow when used for grafting procedures of long bones; to determine the safety of COLHAP (the incidence of significant device-related reactions); and to compare the efficacy and safety of COLHAP with standard autografting procedures.

Technical Approach: As outlined in the company protocol.

Progress: Although many bone grafting procedures have been cone, none of the patients were candidates for this study. We are still enrolled in the study and will continue to search for patients.

Detail Summary Sheet

Date: 8 Nov 88 Proj No: C-53-88 Status: Ongoing

Title: Is the Sodium Pentothal Test Valid?

| | |
|---|---|
| Start Date 9 May 88 | Est Comp Date: |
| Principal Investigator (vice Hansen)<br>Roger L. Wesley, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Anesthesiology | Associate Investigators:<br>Richard E. Emery, CPT, MC |
| Key Words: | Emil J. Menk, MAJ, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 10

Total Number of Subjects Enrolled to Date: 10

Date of Periodic Review _____ Results _____

Objective(s): To assess the effectiveness of the sodium pentothal test in differentiating somatic from psychogenic pain.

Technical Approach: Healthy (ASA I or II) patients with known neurologic compromise and with reproducible clinical findings (i.e., radiculopathy with pain and positive straight leg raise test) are tested in the operating room as they are being induced with sodium pentothal. They are given a painful stimuli - an achilles pinch, and a straight leg raise, and the response to both recorded. The patients are induced with incremental doses of IV sodium pentothal until a response to voice command and a lid lash reflex is lost. The patients are then given the same painful stimulus, and agian, a straight leg raise test is performed with responses recorded.

Progress: Thus far, nine of ten patients have responded with negative pentothal pain tests, preliminarily indicating a 90% validity of the test.

Detail Summary Sheet

| Date: 8 Nov 88 | Proj No: C-54-88 | Status: Ongoing |
|---|---|---|

Title: Clinical Usage of Atracurium

| | |
|---|---|
| Start Date 9 May 88 | Est Comp Date: |
| Principal Investigator<br>Charles P. Kingsley, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Anesthesiology | Associate Investigators:<br>Richard Peterson, CPT, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To contribute the clinical experience of the usage of the muscle relaxant Atracurium at BAMC to a nationwide data base.

Technical Approach: In an effort to assemble a large data base on the clinical usage of the drug, Atracurium, Burroughs-Wellcome has asked 200 institutions to collect data on initial dosages, total dosage, and reversal requirements for 50 patients. This data will be pooled and analyzed using appropriate statistical tests.

Progress: Data has been recovered from 50 patient records and submitted to Burroughs Wellcome for analysis with the pooled data.

Detail Summary Sheet

| Date: 8 Nov 88 | Proj No: C-57-88 | Status: Ongoing |
|---|---|---|

Title: VitaPatch Pin Protection Device, Phase I and II

| | |
|---|---|
| Start Date 3 Jun 88 | Est Comp Date: |
| Principal Investigator<br>George Harrington, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Orthopaedic | Associate Investigators:<br>Gerard Pennington, CPT, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): Phase I - To evaluate Vitapatch™, a new skin dressing which contains antibiotics.

Phase II - To evaluate the safety and effectiveness of a new protection device, called VitaPatch. The effectiveness will be evaluated in terms of differences in the rate of bacterial colonization/infection, site appearance, convenience of use, and patient comfort as compared with established protocol.

Technical Approach: Phase I - After obtaining culture samples of the skin, patches (6 with antibiotic, 6 without) are placed on the abdomen. At the end of 24 hours, 48 hours, and 5 days two patches will be removed from each side of the abdomen and a culture taken.

Phase II - Patients requiring pin placement to assist healing of a fracture will be asked to participate. At the time of pin placement half of them will be covered with VitaPatch and half will receive standard treatment. The patches will remain in place for 72 hours, unless drainage requires prior removal. At the time of removal, all pin sites will be cultured for bacterial contamination and checked for signs of infection.

Progress: Because of changes in investigators, no reportable data are available at this time. The principal investigator at this time is CPT Jeffrey J. Behrens.

Detail Summary Sheet

| Date: 9 Nov 88 | Proj No: C-62-88 | Status: Ongoing |
|---|---|---|

Title: Short Term Evaluation of the Safety and Efficacy of Topically Applied Capsaicin in Pain Associated with Postherpetic Neuralgia

| Start Date 13 Jun 88 | Est Comp Date: |
|---|---|
| Principal Investigator<br>Emil J. Menk, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Anesthesiology | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 13

Total Number of Subjects Enrolled to Date: 13

Date of Periodic Review _____ Results _____

Objective(s): This is a six-week, double-blind, vehicle controlled multi-center clinical trial to evaluate the clinical safety and efficacy of topically applied 0.075% capsaicin cream for the relief of the pain of chronic postherpetic neuralgia.

Technical Approach: Patients who have had the pain of postherpetic neuralgia for greater than six months are invited to participate in this double-blind study to evaluate the efficacy of topically applied 0.075% capsaicin cream.

Progress: Three out of thirteen patients dropped out of the study due to inability to tolerate the burning of the cream upon application. One patient of the 13 had complete relief of pain and has not been entered into the long term evaluation. One patient is still participating in the study and the other nine have been entered into the long-term evaluation. The code (blinded) for the cream has not been broken.

Detail Summary Sheet

| Date: 9 Nov 88 | Proj No: C-63-88 | Status: Ongoing |
|---|---|---|

Title: Long Term Evaluation of the Safety and Efficacy of Topically Applied Capsaicin in Pain Associated with Postherpetic Neuralgia

| Start Date 13 Jun 88 | Est Comp Date: |
|---|---|
| Principal Investigator<br>Emil J. Menk, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Anesthesiology | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 9

Total Number of Subjects Enrolled to Date: 9

Date of Periodic Review _____ Results _____

Objective(s): This is a long term (up to 12 months), open-label, multi-center clinical trial to evaluate the clinical afety and efficacy of topically applied 0.075% capsaicin cream for the relief of the pain of postherpetic neuralgia.

Technical Approach: For those patients that do not gain relief from the blinded short term evaluation, they are invited to participate in the long term, open-label study to evaluate the efficacy of topically applied 0.075% capsaicin cream.

Progress: One out of nine patients entered into the study dropped out due to the inability to tolerate the burning of the cream upon application. It is too early to draw any conclusions regarding the effectiveness of this treatment program.

Detail Summary Sheet

| Date: 9 Nov 88 | Proj No: C-65-88 | Status: Ongoing |
|---|---|---|

Title: Local Anesthesia for Retinal Detachment Surgery

| | |
|---|---|
| Start Date 14 Jul 88 | Est Comp Date: |
| Principal Investigator<br>Calvin E. Mein, LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Ophthalmology | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To determine the safety and effectiveness of local anesthesia for retinal detachment surgery.

Technical Approach: Patients 18 years of age and older scheduled to undergo retinal detachment surgery will be eligible for the study. Rather than blindly penetrate the retrobulbar space with a sharp needls as is present accepted practice, the proposed technique utilizes a direct subtenon approach with a blunt irrigation needle.

Progress: No patients have been entered as we plan to revise the protocol.

Detail Summary Sheet

| Date: 9 Nov 88 | Proj No: C-66-88 | Status: Ongoing |
|---|---|---|

Title: Lacrimal Pump Quantification

| Start Date 14 Jul 88 | Est Comp Date: |
|---|---|
| Principal Investigator<br>William L. White, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Ophthalmology | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 0

Date of Periodic Review _____ Results _____

Objective(s): To utilize dacryoscintigraphy to quantitate the rate that passage of tears through the lacrimal drainage system is influenced by blinking.

Technical Approach: Eleven patients have been studied - 10 males and 1 female. One drop of 0.5% proparacaine was placed in each eye. A punctum in each eye was randomly selected, and a cotton tipped applicator soaked in 0.5% proparacaine was applied to the chosen puncta for approximately one minute. The puncta were then dilated and an absorbable temporary intracanalicular collagen implant was inserted into each puncta. The implant was then pushed further into the cnaaliculus with a punctal dilator. Dacryoscintigraphy was performed within the next three hours. Imaging was done with a 3 mm pinhole collimator for 7 to 15 minutes at an 8 cm subject distance. After waiting a minimum of 7 days, the process was repeated in the opposite punctum in each eye. The complete scan was reviewed in a series of summed images after each individual session to data colleciton to ensure that patient movement was minimal.

Progress: This is a new study. No patients have been entered to date.

Detail Summary Sheet

| | | |
|---|---|---|
| Date: 9 Nov 88 | Proj No: C-68-88 | Status: Ongoing |

Title: Non-Thermal Pulsed High Peak Power Electromagnetic Energy (Diapulse™ ) in the Treatment of Ankle Sprains

| | |
|---|---|
| Start Date 14 Jul 88 | Est Comp Date: |
| Principal Investigator<br>Henry G. Chambers, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Orthopaedic | Associate Investigators:<br>Gerard Pennington, CPT, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 2

Total Number of Subjects Enrolled to Date: 2

Date of Periodic Review _____ Results _____

Objective(s): To assess the effects of Diapulse™ on the edema and rehabilitation time after ankle sprains.

Technical Approach: Patients will receive treatment in a blinded manner to determine efficacy of Diapulse in the rehabilitation of ankle sprains.

Progress: No significance has been determined at this time.

Detail Summary Sheet

Date: 9 Nov 88 Proj No: C-70-88 Status: Ongoing

Title: The Ideal Test Dose for Detection of Subarachnoid Injection in Spinal Anesthesia

| | |
|---|---|
| Start Date 5 Aug 88 | Est Comp Date: |
| Principal Investigator<br>Gary S. Baxter, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Anesthesiology | Associate Investigators:<br>Douglas Culling, MAJ, MC |
| Key Words:<br>Test dose<br>Continuous spinal anesthesia | Emil Menk, MAJ, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 120

Total Number of Subjects Enrolled to Date: 120

Date of Periodic Review _____ Results _____

Objective(s): To determine the minimum concentration of local anesthetic required to detect evidence of subarachnoid injection in a reasonable amount of time during attempted epidural anesthesia, yet in a small enough dosage not to produce a high or total spinal in a parturient.

Technical Approach: Patients will have a continuous spinal catheter inserted in the L3-L4 or L4-L5 interspace which freely aspirates CSF. 2 ml of one of the four study drugs to which has been added 15 mcg of epinephrine will be injected. Study drugs are 1.5% lidocaine isobaric and hyperbaric; and 0.5% marcaine isobaric and hyperbaric. Data is then collected over a 10 minute period to include heart rate, blood pressure, sensory loss to pinprick and cold at the S2 and catheter dermatomal level. The study is then concluded and additional anesthetic is administered as required for surgery.

Progress: The code indicating which local anesthetic each patient received has not yet been revealed. No conclusions can be made at this time. There has been no intraoperative complication or excessive delay in beginning surgery as a result of this study. Sevearl patients developed post-dural headaches which were easily treated with a epidural blood patch. This is a recognized complication of spinal anesthesia.

Detail Summary Sheet

Date: 9 Nov 88 Proj No: C-73-88 Status: Onging

Title: Marital Enrichment Aural Rehabilitation Program for the Hearing Impaired

| | |
|---|---|
| Start Date 5 Aug 88 | Est Comp Date: |
| Principal Investigator (vice Aspinall)<br>John E. Ribera, CPT, MS | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Otolaryngology | Associate Investigators:<br>Kenneth Aspinall, COL, MS |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): 1) To investigate marital discord as a significant factor in the noncompliant use of hearing aids.

2) To introduce communication strategies to current traditional aural rehabilitation programs.

3) To create a screeing program to be used by audiologists in identifying and referring those hearing impaired couples needing marital counseling.

Technical Approach: Subjects 50 years of age and older with a history of noise exposure and beilateral high frequency hearing loss will be eligible for the study. Subjects will be randomly assigned to experimental and control groups. A four week, 2½ hour per week, aural rehabilitation program and marital enrichment program will be given to the experimetnal group. The control group will receive a traditional aural rehabilitation program during the same time span. A three month follow-up will be conducted for both the experimental and control group to identify the extent to which the hearing aid has been utilized and the extent to which ommunication skills have been maintained.

Progress: This is a new study.

Detail Summary Sheet

Date: 9 Nov 88 Proj No: C-75-88 Status: Ongoing

Title: A Closed-Jaw Method of Orotracheal Intubation using the "Lightwand" Transillumination Technique

| | |
|---|---|
| Start Date 5 Aug 88 | Est Comp Date: |
| Principal Investigator<br>Timothy Castro, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Anesthesiology | Associate Investigators:<br>Michael Matson, CPT, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 23

Total Number of Subjects Enrolled to Date: 23

Date of Periodic Review _____ Results _____

Objective(s): 1) To assess the success rate of lightwand guided orotracheal intubation in patients whose mandibles are maintained in a closed position.

2) To determine the time required for lightwand guided intubation using the closed-jaw technique.

3) To compare the results of this study to prior studies that utilized lightwand guided orotracheal intubaiton with initial jaw positioning and tongue grasp.

Technical Approach: ASA I patients undergoing general endotracheal anesthesia are being orally intubated with their mouth closed using the light wand.

Progress: All intubations have been successful. No complications.

Detail Summary Sheet

Date: 9 Nov 88 Proj No: C-76-88 Status: Ongoing

Title: Double-Blind, Multicenter, Placebo Controlled Clinical Trial to Evaluate the Efficacy and safety of Ha-1A Human Monoclonal Antibody in Patients with Severe Gram-Negative Sepsis/Gram-Negative Septic Shock

| | |
|---|---|
| Start Date 29 Aug 88 | Est Comp Date: |
| Principal Investigator<br>Joseph P. Ducey, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/SICU | Associate Investigators:<br>Michael Lamiel, LTC, MC<br>David L. Danley, MAJ, MS |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To determine the efficacy of Ha-1A monoclonal antibody in reducing the mortality and/or direct morbidity of gram-negative sepsis as compared to a placebo group; to determine the impact that Ha-1A has on patient benefit; to determine the impact that HA-1A has on laboratory parameters/ clinical signs associated with sepsis; and to determine the safety and potential for immunogenicity of Ha-1A monoclonal antibody administration in patients presenting with the clinical syndrome of gram negative sepsis.

Technical Approach: Eligible patients will be randomized to receive either the HA-1A or placebo (human albumin). Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No reportable data are available at this time.

Detail Summary Sheet

Date: 9 Nov 88 Proj No: C-77-88 Status: Ongoing

Title: Storz Intraocular Lens Clinical Trial

| | |
|---|---|
| Start Date 29 Aug 88 | Est Comp Date: |
| Principal Investigator<br>Calvin E. Mein, LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Ophthalmology | Associate Investigators:<br>Donald A. Hollsten, LTC, MC |
| Key Words:<br>Intraocular lens | Arthur Glover, MAJ, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To determine postoperative visual acuity of patients receiving an intraocular lens; to measure the occurrence and time course of postoperative ocular complications and adverse reactions for intraocular lens implan subjects; to measure the occurrence of postoperative lens related complications for the intraocular lens implan group; and to measure subgroups within the implant study population that are at "high risk" for the development of particulr complications, as compared to the historical control group.

Technical Approach: As outlined in the company protocol.

Progress: This is a new study.

Detail Summary Sheet

Date: 9 Nov 88 Proj No: C-79-88 Status: Ongoing

Title: Collaborative Ocular Melanoma Study

| | |
|---|---|
| Start Date 8 Sep 88 | Est Comp Date: |
| Principal Investigator<br>Donald A. Hollsten, LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Ophthalmology | Associate Investigators: |
| Key Words:<br>Melanoma | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): 1. To determine the efficacy of enucleation versus placque irradiation in the treatment of medium size ocular melanomas.

2) To determine the efficacy of enucleation without pre-operative external radiation versus enucleation combined with pre-operative external radiation in the teatment of large ocular melanomas.

3) To determine the clinical course and community treatment standards i the treatment of small ocular melanomas.

Technical Approach: As outlined in the Collaborative Group protocol. The principal investigator will serve as the enucleating surgeon on this study.

Progress: None.

Detail Summary Sheet

Date: 9 Nov 88 Proj No: C-86-88 Status: Ongoing

Title: Comparison of the Effectiveness of Lidocaine 1.5 mg/kg, 2.25 mg/kg, and 3 mg/kg in the prevention of Ventricular Fibrillation After Aortic Cross-Clamping.

| | |
|---|---|
| Start Date 12 Oct 88 | Est Comp Date: |
| Principal Investigator<br>Kay Karasek, CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Department of Surgery/Anesthesiology | Associate Investigators:<br>William Goglin, MAJ, MC<br>Charles J. Kingsley, MAJ, MC<br>Kevin Olson, CPT, MC |
| Key Words:<br>Lidocaine | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To study the dose of lidocaine most beneficial in reducing the incidence and severity of ventricular fibrillation after aortic cross-clamping during surgery for myocardial revascularization.

Technical Approach: Thirty adult patients undergoing coronary artery bypass surgery will be randomized to one of three groups. Group I will receive 1.5 mg/kg lidocaine, Group II will receive 2.25 mg/kg lidocaine, and Group III will receive 3 mg/kg lidocaine approximately five minutes prior to the release of the aortic cross clamp. At 15 minutes, 30 minutes and one hour post release of the aortic cross-clamp, blood for lidocaine assays will be drawn.

Progress: This is a new study.

Detail Summary Sheet

Date: 9 Nov 88 Proj No: C-58-88 Status: Ongoing

Title: Joint Mobilization Plus Active Range of Motion Exercises versus HOme Active Range of Motion Exercises in the Treatment of Adhesive Capsulitis

| | |
|---|---|
| Start Date 3 Jun 88 | Est Comp Date: |
| Principal Investigator<br>Carol J. Johnson, 1LT, SP | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Physical Medicine & Rehabilitation Svc | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 4

Total Number of Subjects Enrolled to Date: 4

Date of Periodic Review _____ Results _____

Objective(s): To compare the effectiveness of joint mobilization plus active range of motion (AROM) exercises versus a home AROM exercise program.

Technical Approach: Male and female patients, 40-70 years of age, with a diagnosis of frozen shoulder are randomly assigned to one of two treatment groups. Group A receives joint mobilization three times a week as well as a daily home exercise program. Group B is on a home exercise program only (wand, pendulum, towel stretch, wall climbing, etc.). Subjects will discontinue joint mobilization when functional AROM is restored (150° flexion, 130° abduction, 60° internal and external rotation). Shoulder AROM measurements are being taken initially, at 2 weeks, 1 month, 2 months and 3 months.

Progress: Progress has been slow due to lack of patients. Otherwise, there are no problems.

Detail Summary Sheet

Date: 8 Nov 88 Proj No: C-46-88 Status: Terminated

Title: Sensitivity of Clinical Tests in Diagnosis of Stress Fractures

| | |
|---|---|
| Start Date 29 Mar 88 | Est Comp Date: |
| Principal Investigator<br>Steven D. Hunte, CPT, SP | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Physical Therapy Service | Associate Investigators:<br>Gerry Dybel, 1LT, SP<br>Ron Shippee, MAJ, MS<br>Michael Haak, CPT, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To retrospectively determine the best clinical tests for stress fractures of the lower extremity confirmed by routine technetium scintigrams.

Technical Approach: Study was not started.

Progress: Study terminated due to transfer of principal investigator.

Detail Summary Sheet

| Date: 8 Nov 88 | Proj No: C-42-88 | Status: Ongoing |
|---|---|---|

Title: Evaluation of Routine Human Immunodeficiency Virus (HIV) Screening Program in Hospitalized Patients.

| Start Date 29 Mar 88 | Est Comp Date: |
|---|---|
| Principal Investigator<br>Jenice N. Longfield, MAJ, MC | Facility<br>Brooke Army Medical Center |
| Dept/Svc<br>Preventive Medicine Service | Associate Investigators: |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 1205

Total Number of Subjects Enrolled to Date: 1205

Date of Periodic Review _____ Results _____

Objective(s): To assess the impact of implementing a routine HIV screening program in hospital admissions in a tertiary care hospital in an area of low prevalence for the HIV infection.

Technical Approach: Evaluate implementation of routine screeningof hospital admission on selected medicine and surgery wards via a questionnaire requiring data from chart review. Subsequent correlation with laboratory test results and laboratory statistics. Outcome variables include acceptance rate for screening by nonactive duty patients, rate of positive test results, hospital day when results become available, etc. Outcome variables will be categorized by ward, service, and demographic characteristics.

Progress: Data collection completed. Data entry into computer completed; analysis will begin in the near future.

Detail Summary Sheet

| Date: 9 Nov 88 | Proj No: C-15-87 | Status: Completed |
|---|---|---|

Title: Electroanalgesia as it relates to electrically induced quariceps femoris muscle contraction.

| | |
|---|---|
| Start Date 15 Jan 87 | Est Comp Date: |
| Principal Investigator<br>Frank B. Underwood, CPT, SP | Facility<br>Academy of Health Sciences |
| Dept/Svc<br>Physical Therapy Section | Associate Investigators:<br>LCDR Gary L. Kremser, MS, USN |
| Key Words: | LTC David G. Greathouse, SP |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 0

Total Number of Subjects Enrolled to Date: 19

Date of Periodic Review 23 Mar 88 Results Continue

Objective(s): To investigate the effect of a 20 minute application of high frequency, low-amplitude electrical current on involuntary torque production by the quadriceps femoris muscle group.

Technical Approach: Maximum voluntary isometric torque production of the quadriceps femoris muscle group is determined via the Cybex dynamometer. One of the two muscle groups (left or right) receives low-amplitude current from the Electrostim 180-2 electrical stimulator, followed by a maximal tolerated current to produce torque. The opposite muscle group receives the maximal tolerated current without the preceding low-amplitude current. The mean of the torque production and the maximal tolerable current will then be compared using the t-test.

Progress: Nineteen subjects have been studied. Preliminary data analysis indicates a significant relationship between current and torque and a significant difference between the treatment conditions.

Detail Summary Sheet

| Date: 1 Nov 88 | Proj No: C-81-87 | Status: Completed |
|---|---|---|

Title: A Comparison of Actual and Apparent Lumbar Lordosis and the Validity of the Flexible Rod as a Noninvasive Measure of Lordosis in Black vs White Females

| | |
|---|---|
| Start Date 9 Sep 87 | Est Comp Date: |
| Principal Investigator<br>Eileen Mosner, 2LT, SP | Facility<br>Academy of Health Sciences |
| Dept/Svc<br>Physical Therapy Section | Associate Investigators:<br>Jean M. Bryan, MSJ, SP |
| Key Words:<br>Lordosis | Margaret A. Stull, MAJ, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 56

Total Number of Subjects Enrolled to Date: 56

Date of Periodic Review 9 Sep 88 Results Completed

Objective(s): To study the effects of racial group of origin upon the dependent variables of actual and apparent measures of lumbar lordosis. This study will also investigate the validity of the flexible rod as a noninvasive measure of lumbar lordosis in both black and white adult females.

Technical Approach: Subjects were assigned to one of two groups. Group I consisted of 27 black females, and Group II consisted of 29 white females. Height and weight of volunteers was measured using a standard height/weight scale, and the subject's weight complied with AR 600-9 standards. A lateral lumbosacral roentgenograph was taken of each subject, and an actual (skeletal) lumbosacral (ALS) lordosis angle was calculated from the roentgenograph. A flexible ruller was then molded to the contour of the subject's lumbosacral spine, and the previously marked L2 and PSIS intersection bony landmarks were measured on the flexible ruler. The flexible ruer lordosis angle (FRA) was then calculated and correlated to the subject's ALS.

Progress: The validity of the flexible ruler as a measure of actual lumbosacral lordosis was poor (Pearson's Correlation Coefficient = 0.23, p - 0.10, N=53). The flexible ruller was an invalid measure of the actual lumbosacral angle and is therefore of little clinical value in assessment of lumbar lordosis.

Detail Summary Sheet

Date: 1 Nov 88 Proj No: C-82-87 Status: Completed

Title: The Effects of Transcutaneous Electrical Nerve Stimulation (TENS) on Neural Conduction of the Superficial Radial Nerve

| | |
|---|---|
| Start Date 9 Sep 87 | Est Comp Date: |
| Principal Investigator<br>Steven H. Bullock, 2LT, SP | Facility<br>Academy of Health Sciences |
| Dept/Svc<br>Physical Therapy Section | Associate Investigators:<br>Stephen P. Layman, 2LT, SP<br>Rebecca D. Nowlin, 2LT, SP |
| Key Words:<br>TENS | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 12

Total Number of Subjects Enrolled to Date: 12

Date of Periodic Review 9 Sep 88 Results Completed

Objective(s): To investigate the effect of various intensities of TENS upon the dependent variable of neural conduction of the superficial radial nerve in normal subjects.

Technical Approach: Twelve healthy active duty Army subjects between 21 and 35 years were randomly assigned to one of the treatment groups; control (n=4), low intensity TENS (n=4), and High intensity TENS (n=4). Antidromic sensory nerve conduction amplitude and latency as wekk as skin temperature were measured in conjunction with the application of treatment to the suprficial radial nerve of each subject's right forearm. An analysis of variance with repeated measures was used to examine the data.

Progress: No significant change was noted in distal sensory latency of the evoked sensory potential in either experimental or control groups as a result of the application of TENS. However, an overall F-test revealed a significant difference in the amplitudes between the control group and the two TENS groups (LIT and HIT) but not between LIT and HIT treatment groups. This study demonstrates that an application of TENS, regardless of intensity, does not significantly alter the conduction of the superficial radial nerve.

Detail Summary Sheet

| Date: 1 Nov 87 | Proj No: C-83-87 | Status: Completed |
|---|---|---|

Title: An Operational Definition of Lower Limb Dominance

| | |
|---|---|
| Start Date 9 Sep 87 | Est Comp Date: |
| Principal Investigator<br>Garn T. Loveland, 2LT, SP | Facility<br>Academy of Health Scineces |
| Dept/Svc<br>Physical Therapy Section | Associate Investigators:<br>Robert L. Matekel, 2LT, SP<br>William G. Sumsion, 2LT, SP |
| Key Words:<br>Dominance, lower limb | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 54

Total Number of Subjects Enrolled to Date: 54

Date of Periodic Review 9 Sep 88 Results Completed

Objective(s): To establish a consistent and reliable procedure for determining lower limb dominance.

Technical Approach: Fifty-four subjects (29 males, 25 females) were evaluated for lower extremity strength dominance based on isokinetic peak torque values for knee flexion and extension at 60 and 180°/sec. Each subject was also assessed according to four possible predictors of lower extremity dominance: preferred kicking leg, handedness, circumferential thigh girth, and subjective opinion.

Progress: Student t-test ($p < 0.001$) showed a significant difference in peak torque output between the dominand and nondominant lower extremities of the subjects tested. Chi-square analysis ($p < 0.01$) revealed lower extremity dominance not dependent on kicking leg, handedness, or subjective opinion; however, dependence was shown between knee flexion peak torque values and circumferential thigh girth. These results indicate a significant strength difference between the lower extremities of a normal subject, and that a determination of the stronger lower extremity cannot be made except by isokinetic testing, and possibly by circumferential thigh girth measurement.

Detail Summary Sheet

Date: 1 Nov 87 Proj No: C-84-87 Status: Completed

Title: Effects of Gender and Handedness on Neural Conduction in Human Subjects

| | |
|---|---|
| Start Date 9 Sep 87 | Est Comp Date: |
| Principal Investigator<br>Gerald Harkins, 2LT SP | Facility<br>Academy of Health Sciences |
| Dept/Svc<br>Physical Therapy Section | Associate Investigators:<br>Daniel Jayne, 2LT, SP |
| Key Words:<br>Conduction, neural | Lawrence Masullo, 2LT, SP<br>Kelly Norton, 2LT, SP |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: 20

Total Number of Subjects Enrolled to Date: 20

Date of Periodic Review 9 Sep 88 Results Completed

Objective(s): To investigate the effects of gender and handedness upon the dependent variable of neural conduction (NC).

Technical Approach: Twenty subjects will be used for this study and grouped according to their gender and handedness. Distal motor latencies, distal sensory latencies, amplitudes of the motor and sensory evoked responses, as well as motor conduction velocities were determined for each nerve. Skin temperature was maintained above 32°C and was monitored with a telethermometer. Room temperature was maintained at a constant 28°C.

Progress: The results showed no effect of gender or handedness on the neural conductor latencies, amplitudes and velocities for the nerves tested. All statistical analyses were performed at the 0.05 level of significance.

This study indicates that the standardized charts prsently used in electrophysiology labs are a valid reference for neural conduction studies regardless of gender or handedness of the patient.

Detail Summary Sheet

Date: 9 Nov 88 Proj No: C-81-88 Status: Ongoing

Title: A Measurement of Lumbar Intervertebral Distraction Produced During Portable Static Pelvic Traction

| | |
|---|---|
| Start Date 8 Sep 88 | Est Comp Date: |
| Principal Investigator<br>Thomas F. Hartz, 2LT, SP | Facility<br>Academy of Health Sciences |
| Dept/Svc<br>Physical Therapy Section | Associate Investigators:<br>David P. Klauber, 2LT, SP<br>Michael G Ryder, 2LT, SP<br>Monte S. Wilson, 2LT, SP<br>Charles L. Truwit, MAJ, MC |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period: _____

Total Number of Subjects Enrolled to Date: _____

Date of Periodic Review _____ Results _____

Objective(s): To determine the efectiveness of the Granburg E-Z Tract in the productior of lumbar intervertebral distraction and the potential value of this device in a home environment.

Technical Approach: Subjects will be assigned to one of two groups, an experimental or a control group. All participants will undergo back examination and back x-ray. Next the E-Z Tract traction device will be applied. After 10 minutes in the traction device, Group I will have the second x-ray taken. AFter placement in the E-Z Tract, Group II will have traction applied and at the end of 10 minutes will have their second x-ray taken.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 9 Nov 88 Proj No: C-82-88 Status: Ongoing

Title: The Effect of Verbal vs. Recorded Positive Motivational Messages on Quadriceps Femoris Peak Torque Values.

| | |
|---|---|
| Start Date 8 Sep 88 | Est Comp Date: |
| Principal Investigator<br>Melanie R. Carlone, ENS, SP | Facility<br>Academy of Health Sciences |
| Dept/Svc<br>Physical Therapy Section | Associate Investigators:<br>Laurie J. George, 2LT, SP<br>Lori S. Ryan, 1LT, SP |
| Key Words:<br>Isokinetic exercise | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To investigate the effect of direct verbal versus recorded positive motivational messages on the dependent variable of peak torque produced by the quadriceps femoris muscle group using isokinetic exercise.

Technical Approach: All participants will be tested on the Cybex II isokinetic machine on two separate occasions. During one test they will be given one set of instructions and during the other test a different set of instructions. Peak torque values will be assessed during each test period.

Progress: This is a new study. No reportable data are available.

Detail Summary Sheet

Date: 9 Nov 88 Proj No: C-83-88 Status: Ongoing

Title: A Comparison of Orthodromic and Antidromic Sensory Nerve Conduction Latencies and Amplitudes for the Median and Ulnar Nerves

| | |
|---|---|
| Start Date 8 Sep 88 | Est Comp Date: |
| Principal Investigator<br>Kelly Ayote, 2LT, SP | Facility<br>Academy of Health Sciences |
| Dept/Svc<br>Physical Therapy Section | Associate Investigators:<br>Andrew Priest, 2LT, SP |
| Key Words:<br>Sensory nerve conduction | Don Hansen, 2LT, SP<br>Lanny Boswell, ENS, SP |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To compare the effects of different neural conduction measurement techniques (i.e. orthodromic and antidromic) upon the dependent variables of nerve conduction latency and amplitude values in the median and ulnar nerves.

Technical Approach: Twenty subjects grouped according to gender and handedness will be included in the study. Prior to testing, each subject will undergo a brief physical examination to screen for neurological deficits. Neural conduction latencies and amplitudes will be measured using a Caldwll 5200A electromyograph and stimulator. A supramaximal stimulus intensity will be used to produce each evoked sensory response.

Progress: This is a new study.

Detail Summary Sheet

Date: 9 Nov 88 Proj No: C-84-88 Status: Ongoing

Title: Effects of Ice and Recovery Time on Maximal Involuntary Torque Production Using the Electrostim 180

| | |
|---|---|
| Start Date 8 Sep 88 | Est Comp Date: |
| Principal Investigator<br>Jan W. Durst, 2LT, SP | Facility<br>Academy of Health Sciences |
| Dept/Svc<br>Physical Therapy Section | Associate Investigators:<br>David Gohdes, 2LT, SP<br>Wendy Ward, 2LT, SP<br>Kevin Workman, 2LT, SP |
| Key Words: | |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: |

Number of Subjects Enrolled During Reporting Period:

Total Number of Subjects Enrolled to Date:

Date of Periodic Review Results

Objective(s): To investigate the effects of ice application and recovery time upon the dependent variable of involuntary peak torque production of the quadriceps femoris.

Technical Approach: Twenty subjects will be asked to participate in this study. Both of the subject's legs will be used, one in the control condition and one in the experimental condition. Each subject will be given a briefing concerning subjective response to electrostimulation therapy. Surface electrodes will be placed on both thighs and the electrical stimulation machine will induce a current which will cause the thigh muscles to controct. The force produced by the muscles as well as the amount of current produced by the machine will be reocrded. Ice will be applied to one thigh for 30 minutes. Both thighs will be stimulated again immediately following the ice treatment and repeated at 30 and 90 minutes post treatment.

Progress: This is a new study.

## AUTHOR INDEX

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