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Very little is known about the incidence, onset, time course, and symptomatology of premature menopause induced by breast cancer therapy. No prospective study has been reported. Accrual in the present study was begun on January 1, 1998, but has not reached target numbers. Additional funding has been obtained to continue to follow this cohort of young women and to recruit an additional 200 participants. (DOD Behavioral Center of Excellence in Breast Cancer: Quality of Life and Functional Status across the Life Course, BC004060, DAMD 17-01-1-0447.) Preliminary analyses of the 611 current participants have been done.

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INTRODUCTION

MENSTRUAL CYCLE MAINTENANCE AND QUALITY OF LIFE: A PROSPECTIVE STUDY

INTRODUCTION

The frequent morbidity associated with most cancers and their treatments make the measurement of health-related quality of life a critical mechanism for determining the toll of the entire disease. Young breast cancer patients may face treatment-induced menopause and with it may experience hot flashes, mood changes, sleep disturbances, vaginal dryness, and the cascading effect of anxiety and depression. In the United States, Wake Forest University has particular expertise in quality of life with naturally occurring menopause. Wake Forest is the coordinating center for behavioral quality of life issues for the Women's Health Initiative, funded by the National Institute of Health, which has accrued more than 100,000 study subjects.

Very little is known about the incidence, onset, time course, and symptomatology of premature menopause induced by breast cancer therapy. No prospective study exists. The purpose of the present study is to identify determinants of treatment-related amenorrhea and its effect on quality of life in a cohort of young breast cancer patients.

BODY

STATEMENT OF WORK

Task 1. Months 1-2 - COMPLETED

a) Focus groups for final questionnaire wording

Focus groups were held at Wake Forest University, the clinical coordinating center. As well as the wording for the baseline data questionnaires, the proposed procedural sequences were decided with attention to the women's preferences for baseline and follow-up procedures.

See work output in the revised annual report 1998 and 1999. This Manual of Procedures contains more than 200 pages and consists of chapters on organizational structure; protocol; recruitment prescreening and eligibility; consenting process; baseline data collection visits; collecting participant information; chart review forms; study data forms and questionnaires; instructions for menstrual diaries; follow up contacts; data management; and quality control. This assures that the research study procedure is conducted absolutely identically in accruing women throughout the country and over the duration of the study.

Done as first reported in the revised annual report 1998.

b) Pilot calendar and questionnaires in Texas and New York City population

The questionnaires and menstrual bleeding calendars were tested on non-protocol patients in Texas and New York City and were found to be satisfactory. This included follow up forms for baseline data and questionnaires, for six-month follow-up and for one-year follow-up attached in the revised annual report 1998.

Done as first reported in the revised annual report 1998.

c) Hire personnel.

Personnel were hired on schedule and within the budgeted salary amount.

Done as first reported in the revised annual report 1998.

d) Keep lists of potential patients.

Patients were identified from registrations of various services within each of the hospitals: Surgery, Radiation Therapy, Medical Oncology, Psychiatry, Nutrition and General Medicine.

Done as first reported in the revised annual report 1998.

Patients continue to be accrued through lists maintained in the various services within Memorial Sloan-Kettering Cancer Center.

Task 2. Months 2-24

a) Identify and Enroll patients – Time Line Amended

As noted, by September of 1998, 185 patients had been enrolled. This was considerably less than half of the targeted accrual by Month 9 after accrual began and steps were taken to increase the self-referral patients, as noted in the body of the revised annual report 1998.

Task 2: Time Extended

By September 1999, 456 patients had been enrolled in the study. This was less than the original targeted accrual numbers. Lt. Col. J. Pearson of the Office of Regulatory Affairs granted an extension for continued accrual. (attached in 1999 report)

By September 2000, 559 participants were enrolled in the study. To date, recruitment has gone smoothly, although we have encountered a higher than expected ineligibility rate across the participating centers. In our original proposal, we had anticipated 30% ineligibility in women aged 18-45 years due to a hysterectomy, irregular periods, or metastatic disease at diagnosis. In reality, however, our ineligibility rate has been approximately 45-48% across all centers. The primary exclusion criterion has been a prior hysterectomy, which has occurred in approximately 40% of the ineligible potential participants in this age group, particularly among the Southern population. As a result, although we have had a low overall refusal rate of 5-10% among all eligible women, our pool of eligible women has been lower than anticipated. Thus, we have fallen short of our original recruitment goal of 800 participants. In order to continue to recruit and follow prospectively a cohort of 800 young women, an application has been submitted for additional funding. (Breast Cancer Center for Excellence Proposal: Quality of Life and Functional Status across the Life Course).

By September 2001, 611 participants were enrolled in the study. In order to continue to recruit and follow prospectively a cohort of 800 women, an application was submitted for additional funding by Wake Forest University. An additional \$1,200,178 was awarded for the continuation of this study in the Breast Cancer Center for Excellence Proposal: Quality of Life and Functional Status across the Life Course. (BC004060; DAMD17-01-1-0447).

Participant Accrual

Memorial Sloan-Kettering – 433 participants
Wake Forest – 49 participants
MD Anderson/Texas – 129 participants

Current recruitment ended at Wake Forest University and MD Anderson on December 31, 1999,

which was the end of their contractual obligations for recruitment. An additional \$1,200,178 was awarded recently for the continuation of this study through a DOD funded Breast Cancer Behavioral Center of Excellence: Quality of Life and Functional Status across the Life Course (BC004060; DAMD17-01-1-0447) Under this new award, Memorial Sloan-Kettering will continue to recruit through tumor registries, physician referrals, and self-referrals. The University of Texas-Southwestern will be added as a new clinical center to recruit study participants. Wake Forest and MD Anderson will finish follow up for existing patients but will not recruit additional patients.

One or more of the following strategies will continue to be utilized in recruiting new participants into the study at Memorial Sloan-Kettering and M.D. Anderson:

1. Patient Identification through Tumor and Surgical Registries.
Once women with stage 1-3 breast cancer have been identified, the patients' oncologists/surgeons are contacted by clinic staff to obtain approval to approach the patient. If the physician approves, the patient is approached at the clinic site, or the patient is sent a letter describing the purpose of the study, which will be followed by a telephone call. Approval was obtained from the IRB for permission to make follow up calls to these patients. The clinic staff person will screen the person to ensure she meets the eligibility criteria, and then will ask the patient to participate in the study if she is eligible.
2. Referral through Physicians.
The clinical center's participating investigators, oncologists, surgeons, and radiologists also identify participants. In most instances, these physicians will have already explained the study to the participant, and the clinic staff contacts the patient to invite her to participate in the study. The patient is screened to ensure that she meets all eligibility criteria.
3. Self-Referral
Women may hear about the study through the many strategies that have been implemented to recruit participants nationally. They are screened for study eligibility, and asked to join the study if the eligibility criteria are met. The patients will sign the informed consent, a medical record release, and will complete all baseline study questionnaires.

The Clinical Coordinating Center at the Wake Forest School of Medicine continues to monitor recruitment and issues monthly recruitment reports to each participating institution.

Task 3. Months 8-45

- a) Mail out and receive back study calendars and other data instruments.

Questionnaires and menstrual calendars have been received on schedule for 6, 12, 18, 24, 30, and 36-month follow up.

See the next section for current follow-up figures and retention rates.

b) Enter data in ongoing fashion.

Data monitoring and tracking

The Coordinating Center performs editing procedures to ensure the quality of the data collected by the Clinical Centers. These are as follows: 1) initial screening of the data, using logic and range checks that are built into the data entry system and 2) edits which assess the serial integrity of the data.

Much of the data collected from study subjects comes from regularly scheduled mailings. Time windows have been defined for these scheduled mailings. A tracking system is in place to facilitate on-time collection of data.

c) Crosscheck data and clean.

Adherence and retention rates

Recruitment to this study began January 1, 1998. As of September 2001, 611 participants have been enrolled. To date, 82 participants have been dropped from the protocol (13.4%). This includes 17 participant deaths. Of the surviving 65 patients, reasons for dropping include: metastatic disease, too busy, lost interest in the study, could not be reached after repeated attempts, lack of time, overwhelmed by treatment and/or family responsibilities, and miscellaneous reasons (eg. husband asked her to stop participating). Of the 529 active participants, adherence to completing study follow-up forms and bleeding calendars has averaged to 89% and 90% respectively, up through the 18 months assessment point. We attribute these high adherence rates to a detailed tracking system for the receipt of the study forms, and an incentive program to keep people interested in the program. Our tracking system alerts our study project managers when forms are not received by 21 days past their expected return date. This triggers a protocol where patients receive a postcard or telephone call, depending on their adherence history, to remind them of their overdue forms. Our data collector works with the patients to get the forms returned, and to address any concerns patients might have about the protocol and study requirements. Patients are also given the option of completing their calendars or forms on the telephone, if they prefer. Most patients complete follow-up forms by mail, however.

We have also instituted several adherence and retention and incentive strategies to keep women interested in the study. These have included sending all participants birthday cards, and holiday cards in December. A quarterly newsletter is also sent all to all participants, the most recent spring 2001. (Appendix A). This provides participants with information about literature related to breast cancer, information about the staff at the participating medical centers, recipes and information shared by our participants. We have also mailed all participants reminder tokens, such as books, key chains, kitchen magnets, and post-it boards.

In addition, to the above mechanisms, we also have a toll free 800 number for women to call and

ask questions about their forms or the study. Participants are also provided with the e-mail addresses our program managers. Adherence rates have increased with the implementation of all these adherence strategies, and we will continue to find ways to retain the study cohort over the course of the follow-up period.

d) Write annual report.

October 1998 Annual Report complete.

October 1998 Annual Report revised.

October 1999 Annual Report complete.

October 2000 Annual Report complete.

October 2001 Final Report in progress.

KEY RESEARCH ACCOMPLISHMENTS

In order to continue recruitment for greater numbers of patients and to extend follow-up, this project has just received additional funding almost equal to the original funding. (DOD Behavioral Center of Excellence in Breast Cancer: Quality of Life and Functional Status across the Life Course, BC004060, DAMD 17-01-1-0447).

Therefore the final conclusions to the research questions await reaching the projected sample size with adequate follow-up.

- Longitudinal data on the quality of life of young patients following treatment from breast cancer.
- Chemotherapeutic agents and other factors predicting premature menopause.
- Specific influence of premature menopause on quality of life of the young breast cancer survivor.

PRELIMINARY RESEARCH ACCOMPLISHMENTS

- Analyses have been initiated to examine amenorrhea at 12 months after enrollment. Sixty-one percent of all of the study subjects have had menstrual cycles in months 9-12.
- Approximately half of the patients reported menopause-related symptoms, primarily hot flashes (43%) and vaginal dryness (56%), by the 12-month questionnaire assessment.
- Rates of self-reported arm and hand swelling are high and seem to be increasing. (24% at 6 months and 30% at 12 months).
- Twenty-one participants have reported pregnancies, which has resulted in 11 live births. All infants and mothers had good birth outcomes. No cancer recurrences or new primary breast cancers have been reported in these 21 women.
- From baseline through 30 months, patients had fewer depressive symptoms if they had high levels of social support. Scoring on questionnaires indicated an increase in quality of life in participants over time, with the biggest gains occurring at approximately 1 year past diagnosis.

REPORTABLE OUTCOMES

Ongoing results of the study were reported at the Era of Hope; Department of Defense Breast Cancer Research Meeting in Atlanta, Georgia held in June 2000. The study was chosen as one of the platform presentations. In addition a poster was presented with statistics similar to those in the previous section. Abstract was submitted in the 2000 annual report.

The study was presented at the American Society of Clinical Oncology Annual meeting in New Orleans, Louisiana held in May 2000. Abstract was submitted in the 2000 annual report.

Paskett ED, Naughton MJ, Robertson J, Petrek J. Lymphedema in Young Breast Cancer Survivors. Poster presented at the 7th Annual Multidisciplinary Symposium on Breast Disease, February 27, 2001, Amelia Island, Florida. This poster, completing using the swelling data collected on these patients, won 1st place for best poster presentation and paper at this symposium. (Appendix B)

Additional funding has been obtained to continue to follow prospectively this cohort of young breast cancer patients. (DOD Behavioral Center of Excellence in Breast Cancer: Quality of Life and Functional Status across the Life Course, BC004060, DAMD 17-01-1-0447).

CONCLUSIONS

In order to continue recruitment for greater patients and to extend follow-up, this project has just received additional funding almost equal to the original funding. (DOD Behavioral Center of Excellence in Breast Cancer: Quality of Life and Functional Status across the Life Course, BC004060, DAMD 17-01-1-0447).

Therefore the final conclusions to the research questions await reaching the projected sample size with adequate follow-up.

Preliminary Data

As of September 2001, 611 have been recruited to the study. The average age of our current participants was 39 years at the time of enrollment. Approximately 87% are Caucasian, 5% are African –American, 4% are Hispanic, 3% are Asian-Pacific Islander, and 1% are Native American. Although only 13% are minorities, this is in line with other national studies. Targeted efforts have been made to recruit minority women, such as media attention in Spanish language and ethnic newspapers (See appendices of 1999 annual report).

The women are well educated, with 65% having received at least a four-year college degree. The majority of our participants are married (70%), or living in a marriage-like relationship (5%). Approximately 9% are divorced or separated and 1% are widowed. Sixteen percent of the patients have never been married. Approximately 55% were working full-time at the time of diagnosis, and 14% were working part-time. Only 17% were full-time homemakers, disabled (6%), students (1%), or unemployed (3%). Approximately 70% have children under the age of 18.

Stage of cancer at diagnosis was Stage I: 42%, Stage II: 38%, and Stage III: 10%. Only 1% of patients had tumors located in both breasts. Seventy-one percent had no family history of breast cancer among their primary family relatives. Approximately 93% had axillary node dissection. The type of surgery completed was 49% total mastectomy, and the rest had their breast spared. Sixty percent of all those who underwent total mastectomy had immediate breast reconstruction. Chemotherapy of various agents and duration was received by 86% of the study subjects.

At 12 months post-baseline, (for the women who have reached that follow-up time point), 3.5% of the patients have indicated a recurrence in the treated breast or axilla, and an additional 1.4% had reported a diagnosis of a new primary cancer other than breast.

For the majority of patients, improvements in well being, particularly physical and functional well being are being observed between baseline, and 6 and 12 months. However, the patients are reporting menopause-related symptoms, primarily hot flashes (43%) and vaginal dryness (56%), by the 12-month assessment. Rates of self-reported arm and hand swelling are also increasing over time (24% at 6 months and 30% at 12 months).

At 12 months post-baseline questionnaire at enrollment, 61% of the patients have had menstrual cycles in months 9-12.

In examining continued menstrual cycling in relation to potential future pregnancy, approximately 31% of the patients had indicated they had wanted a first child, or additional children, 6 months prior to their diagnosis, and an additional 11% of the women were undecided.

As of September 2001, 21 participants have reported pregnancies, which has resulted in 11 live births. All infants and mothers had good birth outcomes. Based on the rate of pregnancy that was desired among the cohort at baseline, we estimate, conservatively, that approximately 10 – 15% (n=100) of our sample will attempt to become pregnant as they progress further post-treatment.

Please see the attached Appendix B which contains more detailed information on some of the preliminary analyses that have been performed on these data.

References:

None



Menstrual Cycle Maintenance and Quality of Life
in Young Women with Breast Cancer Study
Newsletter -March 2001

**Message from
the Coordinating Center**

Things are going well here at the Coordinating Center. We hope all of you are enjoying this new year. **Doris Clark** has been promoted to Assistant Project Manager. We are very proud of her and the work she does with our participants.

We now have 580 women enrolled in the Menstrual Cycle Maintenance and Quality of Life after Breast Cancer Study. For those of you receiving the newsletter for the first time, we have four clinical centers that have enrolled participants: Memorial Sloan-Kettering in New York; M.D. Anderson and Presbyterian Hospital in Texas; and Wake Forest University Baptist Medical Center in North Carolina.

Age of Participants

The current ages of our participants are:

- .5% are age 21-25
- 2.5% are age 26-30
- 32% are age 31-39
- 48% are age 40-45
- 17% are 46 years old and older

Educational Status

- 10% are high school graduates or less
- 37% have some college/business or professional school
- 27% are college graduates
- 20% have a master's degree
- 6% have a doctoral degree

Racial Status

- 87% are Caucasian
- 6% are African American
- 4% are Hispanic

3% are Asian

Employment Status

- 17% work full time as homemakers
- 55% are employed full time
- 13% are employed part time
- 6% are on disability and not working at this time
- 1% are students
- .5% are retired

Marital Status

- 75% are married or have a live-in relationship
- 15% have never been married
- 10% are separated, divorced or widowed

**Congratulations to the lucky winners
of our third rewards drawings!**

Gift cards drawn in November, 2000 from calendar and questionnaire entries:
Diane C. Burch, Mountain Lakes, NJ
Monica A. McNamara, Yonkers, NY
Roni A. Strassman, Chicago, IL
Susan D. Wiley, Tequesta, FL
Cynthia L. Debock, Houston, TX
Laura Lyons, Winston-Salem, NC
Lisa M. Castillo, Grapevine, TX

Just a reminder that, in **April**, in addition to our regular quarterly drawing, we will be **drawing for two round trip airfare tickets to anywhere in the Continental USA on USAirways**. So be sure to return your calendars and questionnaire booklets by their due dates in order to be eligible for these prizes.

Websites

The National Women's Health Information Center provides information on health-related topics of interest to women, their families, and friends. NWHIC's goals are to deliver fast, reliable and accessible health information to women everywhere. Their Website address is www.4woman.gov
Toll Free number 1-800-994-WOMAN or
TDD: 1-888-220-5446.



Recommended Reading

See the enclosed pamphlet on Lymphedema, published by the American Cancer Society.

Tom Batiuk, creator of Funky Winkerbean, has written and illustrated *Lisa's Story*, a creative, entertaining, and educational book about breast cancer. Lisa finds a lump, encounters her diagnosis, goes through chemotherapy, loses her hair, tackles billing problems, and much more. Batiuk comments that "Although there is no cure for life, interesting, humorous, and useful descriptions of our struggles can, and I think do, make a difference." Andrea Martin, herself a breast cancer survivor and founder and executive director of the Breast Cancer Fund writes, "Batiuk has brought breast cancer into the unique venue of the comic strip with sensitivity, realism, and wit - attributes essential to the breast cancer experience." We highly recommend this book to you. This book is published by Penguin Putnam Inc, (ISBN-0-399-52666-8).



A New Recipe

The American Institute for Cancer Research publishes recipes for healthier living on their web site - www.aicr.org. Once there, click on "The New American Plate."

In the Fall newsletter, we featured a Main Dish from this site. This month, we feature one of their Salads, which is printed just for

you with *special permission from the American Institute for Cancer Research.*

Garden Pasta Salad and Basil Dressing

Pasta salads are wonderful all year round. Use any vegetables you have on hand. For special occasions, add artichokes, shrimp and capers. For a main course salad, add cooked fish, shrimp, pine nuts or low-fat cheeses.

Salad

3/4 cup chopped green beans
1/2 lb. pasta (bow tie, corkscrew or penne)
2 cups thinly sliced yellow or green zucchini
2 medium carrots, diagonal sliced
Half sweet red pepper, cut in thin strips
1 large tomato, chopped
1/4 cup finely chopped scallions or chives
1/4 cup black olives
2 tbsp. minced fresh basil or 1 tsp. dried

Basil dressing

3 tbsp. wine or cider vinegar
2 tbsp. olive oil
2 tbsp. water
2 tbsp. chopped fresh basil or 1/2 tsp. dried
1 tsp. Dijon mustard
1 tsp. minced garlic
1/8 tsp crushed red pepper flakes

In a pot of boiling water, blanch beans for 3 minutes; drain and cool under cold water. In large pot of boiling water, cook pasta until tender but firm; drain and rinse well under cold water. Drain again and place in large salad bowl. Add beans, zucchini, carrots, red pepper, tomato, scallions or chives, olives and basil.

Dressing: In a small bowl, whisk together vinegar, oil, water, basil, mustard, garlic and hot pepper flakes until well mixed. Pour over salad and toss to mix.

Makes 10 servings, about 1 cup each. About 135 calories, 4 grams of fat per serving.

Participant Stories

Many of you have commented on how much you have enjoyed and been inspired by some of our participants' personal stories. Three more participants have been kind enough to share their stories this month. Each has had a unique and interesting experience.

The first story is from **Sallie Black** of Hickory, North Carolina, who has found comfort along the way by listening to Reba McEntire's music. The second is from **Evelyn Ronga** of Hopatcong, New Jersey, who teaches breast cancer awareness. The third is from **Liz Bailey** of Ventura, California, a pioneer in the field of television and film camera operation.

Thank you, **Sallie, Evelyn,** and **Liz** for taking the time to write to us. We hope you enjoy their stories.

Comfort in Reba's Music

by Sallie Black

Breast cancer and country music are two topics that are usually not associated with each other. However, in my battle against cancer, the two go hand in hand.

On April 19, 1999, my world was shattered with a diagnosis of breast cancer. My breast would need to be removed immediately, and I would need extensive chemotherapy to kill any remaining cancer in my body. I was devastated. How could this be happening to me? I was only 42 years old. Cancer was only supposed to happen to other people, older people. I had so many unanswered questions and so many unanswered why's. I was diagnosed in the fall during the last six weeks of school. In my 19 years of teaching, I have missed very little school. What would I do without my friends and colleagues at work, and the special times we shared daily?

The depression I felt was overwhelming; visiting doctor after doctor only made things worse. The drive to the appointments seemed to take hours. In the beginning, as I traveled back and forth between doctors' offices, I would often hear Reba McEntire and Randy Travis songs back to back. This always lifted my spirits immediately. My mother, who had passed away six years earlier, loved Randy Travis, while Reba was my favorite. How often do you hear these two singers back to back on today's country music stations? I felt Mom was letting me know that she was with me during those trips. This was only the beginning of how Reba's music helped me deal with my pain. The many commutes to appointments, chemotherapy treatments, and follow-up visits made me feel as if my life was being played out either in my car on the way to a doctor's office or in the doctor's office itself. But, during each trip, I would hear at least one Reba song. Her music would relax and comfort me, making me feel at ease.

My chemotherapy treatments began on May 17, 1999, and were to conclude on July 19, 1999. I wanted very much to attend the Reba McEntire concert on July 11 in Charlotte, North Carolina, for which I had already purchased tickets. Even though there are times during the chemotherapy treatments that you should not be around people, much less big crowds, I was determined to see Reba during this time in my life. As it turned out, a friend of mine had entered my name in a contest to meet Reba while she was in Raleigh, North Carolina on July 10. My friend wrote about what I was going through and about the kind of person I was. I did not win the contest to meet Reba, but I did receive two free tickets to her concert in Raleigh. This was even better than my original goal; I was going to see back-to-back Reba concerts. It was a dream come true, especially as I would be going for my fourth and final treatment that following week. It was a great weekend of celebration.

Later, the time arrived for my yearly mammogram. I was so nervous. What if the cancer had returned? But as I turned on the car radio, a Reba McEntire song started playing. Almost immediately, I felt more relaxed, and later received great news that the cancer had not returned.

On April 28, 2000, I had reconstructive surgery, and when my friend picked me up at the hospital, a Reba song was blasting on the car radio. After my reconstructive surgery, I began to think about getting my story to Reba. In early September 2000, I heard that she would be performing in Charlotte, North Carolina, on October 7. I immediately purchased tickets to her concert and decided to send a copy of my story to the radio station that was sponsoring Reba's visit to Charlotte. I mailed my story to the only female deejay at the station. Terry received my story, and on September 26, at 6:45am, I received a call from the radio station saying they loved my story and wanted to do a live interview with me. Terry actually read some of my story to the listeners; and while we were on the air, she surprised me with backstage passes to meet Reba.

On October 7, I met Reba backstage and was able to tell her how much her music helped me during my battle with breast cancer. She talked with me about how I was doing, and then signed one copy of my story for me to frame and kept a copy to read. We shared a warm hug and parted. The next day, October 8, was my birthday. It is safe to say that this was the best birthday I have ever had.

Reba songs helped me deal with the many up and downs that I experienced during my battle and helped me maintain a positive attitude throughout this struggle. Reba's newest single, entitled "I'll Be" truly describes what her music has meant to me:

"When troubles come around, I will come to you. I'll be your shoulder when you need

someone to lean on When you need someone to see you through, I'll be there to carry you. I'll be there." Thank you, Reba.



A Family's History and Hope

by Evelyn Ronga

I am a volunteer for the American Cancer Society, and also a recent volunteer for the Susan G. Komen Foundation. I decided to become a volunteer after I was diagnosed with breast cancer in October of 1998, at the age of 33. But, unfortunately, cancer had already entered my life at an even earlier age. I was 22 years old when my mother was diagnosed with breast cancer, and I was 28 years old when my father was diagnosed with colon and liver cancer. Three years ago, I was diagnosed with malignant melanoma. With all this in mind, you can imagine how "aware" I am of cancer.

That awareness may have saved my life. While doing a self breast exam, I noticed a lump. Everything happened so quickly after my diagnosis. I had a lumpectomy and a fairly new procedure called "sentinel node biopsy." This was followed by a lymph node dissection because one node was positive. I went through chemotherapy and radiation. I had port-a-caths (because my veins were weak). I experienced many of the side effects: nausea, weight loss, tiredness, achiness, and hair loss.

My husband, who is also my best friend, even shaved his head of thick Italian hair so I wouldn't feel so uncomfortable. To this day, he still shaves it; go figure. I joined support groups where I met some extraordinary people. Some of them are

even long time survivors. I made new friends along the way and, unfortunately, became distant with some old friends. I also have my own support system at home with some very good friends who I call family. I am able to still work full time, and I exercise a little too.

I kept my faith through it all, which helped me a great deal. And in the end, after I have climbed so hard and reached the top of the mountain, I feel stronger than ever before. I attribute my strength to my parents, may they rest in peace.

As you all know, dealing with cancer is not easy. Given a choice, I would have just as soon skipped it, as I'm sure all of you would have. But in a way, it gave me a better understanding and appreciation for life. No longer do I take things for granted. I appreciate the people I have around me. I am more aware of the colors in a butterfly or in a bright, brisk fall day. I take more notice in a smile on an innocent child's face. I appreciate the sun, the moon, the clouds and even the rain. Through all of my experiences, I have found strength, determination and a desire and commitment to move forward with my life, as I hope all of you will too. There are so many things that cancer cannot do to you. It cannot cripple love, can it? Nor can it kill friendship, silence courage, or conquer our spirits. And it most certainly cannot shatter hope. Courage has brought me to where I am today, and hope has given me the confidence that there will be a cure for cancer one day. . .one day soon.



Priorities in Focus

by Liz Bailey

Raised in Louisiana by a jazz clarinetist father and classical pianist mother, I was set for a musical career. Involved in gifted arts, ballet and dramatics programs, I participated in 36 plays before the age of 12. While attending Louisiana State University, I was given Nikon camera and asked to tell a story "without words" for a visual communications class. I fell in love with photography and went on to study at the Polytechnic of London and the Royal Photographic Society in the United Kingdom.

Upon returning to the states, I graduated with a Bachelor of Fine Arts in Design and was hired by New Orleans CBS affiliate WWL, becoming the first professional camerawoman in my native state. During that time, I filmed many Louisiana personalities such as The Neville Brothers Band, child prodigy Harry Connick, Jr. and the late Zydeco King, Clifton Chenier. My documentaries covered everything from Mardi Gras to swamp tours, from oil rigs and hurricane catastrophes to civil rights turmoil and Louisiana's ever colorful politics. Another highlight was pulling 5Gs in a Phantom F-16 jet with the Louisiana's Air National Guard and, as a result, I was awarded honorary membership in their "Coonass (Cajun) Militia."

In 1980, I relocating to Los Angeles, and made my first movie with Francis Ford Coppola, "One From the Heart" and later worked on Oscar award-winner "The Right Stuff." Recent credits include "Independence Day" and "Fearless." TV credits include: Star Trek, Murphy Brown, Judge Judy, Home Improvement, Port Charles and Entertainment Tonight. My music production include work with Carlos Santana, Will Smith, Sarah McLachlan, Michael Bolton, Whitney Houston, Stevie Wonder, Paula Cole and The Rolling Stones, as well as many shows for MTV and the House of Blues.com.

I was diagnosed with breast cancer in March 1999, and treated at UCLA's Revlon Breast Center. There, three years before, I had shot a documentary with Dr. Susan Love, M.D. With zero family history of cancer, I never dreamed that at age 43, I would return to UCLA as a patient for three lumpectomies, four rounds of chemo, and seven weeks of radiation. I was really concerned about upper body strength, so I insisted on the sentinnel node dissection and followed up with a couple of months of physical therapy to "get my beans back." I am now one year out of treatment and taking tamoxifin.

I feel like I've been at "Cancer University" for the last couple of years, completely changing my view of nutrition and adapting a lot of my cajun dishes, plus learning to cook with tofu and soy products. I take a supplement of 17 fruits & veggies, first recommended to me by my friend Bea Weitz, a remarkable breast cancer survivor/mentor from a Wellness Community cancer support group.

A few years ago, my 23-year marriage ended in divorce. I was totally heart-broken. But I recently married my high school sweetheart, Paul, and we love to sail around the Ventura Harbor island where we live with 12-year old son, David. I remain vigilant in my survivorship, and participating in the *Menstrual Cycle Maintenance and Quality of Life Breast Cancer Study* is a part of the healing process. Also, I am much more in touch with my spirituality now, and we're attending church regularly. Life is just too precious to take for granted. I was recently certified in Reiki, the Japanese "healing touch" therapy, and I donate and receive services at the Ventura Cancer Center with other cancer patients. I received so much support during this crisis, now that I feel better, I want to give back to those who are hurting.

What's on the horizon? Well, I just turned down a Grammy concert because it conflicted with a family ski trip. I love my work, but that "drive" is not my number one priority anymore. It's my family that reminds me why I love my life.



Our next newsletter in May will feature a very special participant profile and give you some exciting news about the study.

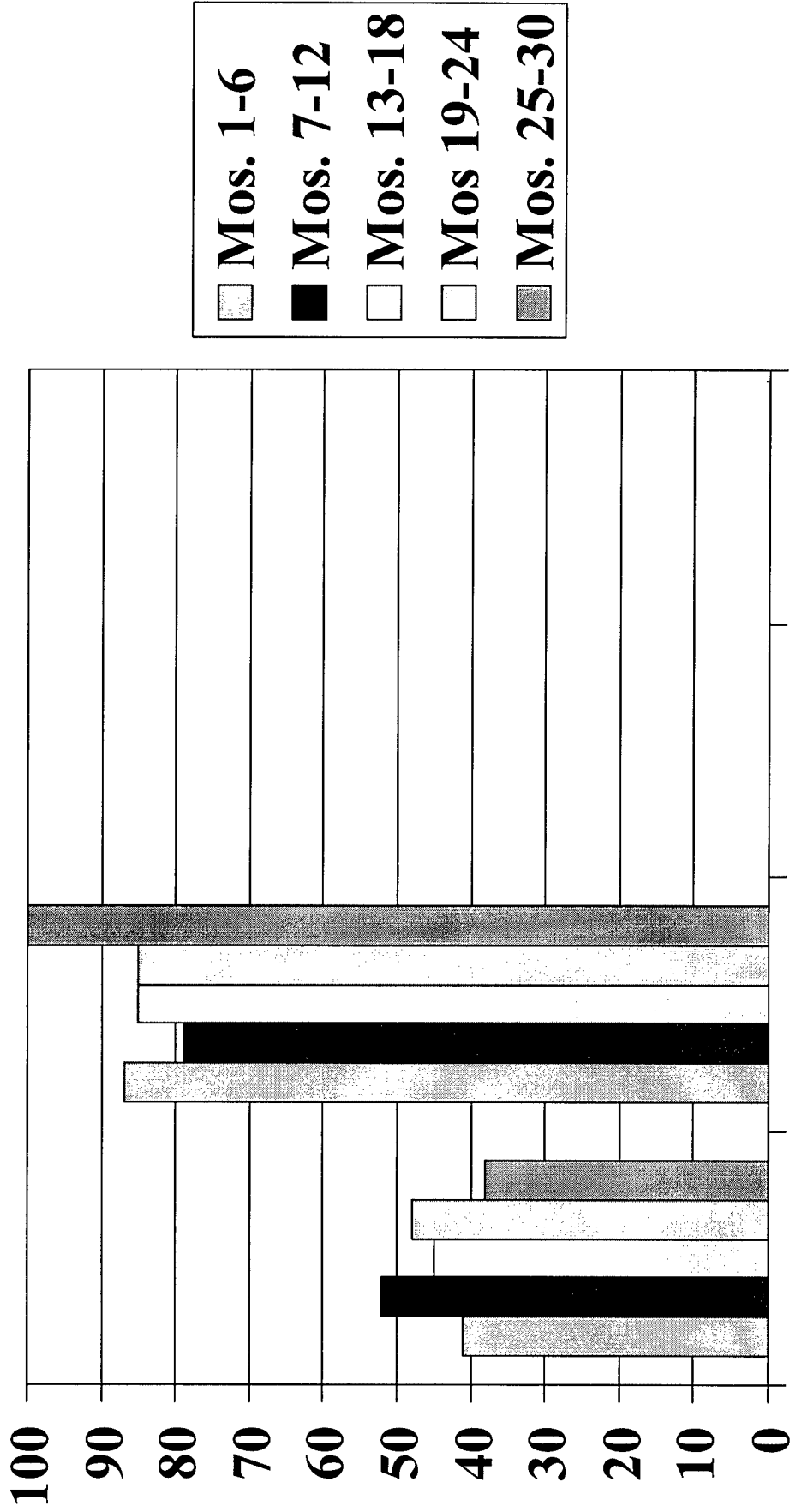
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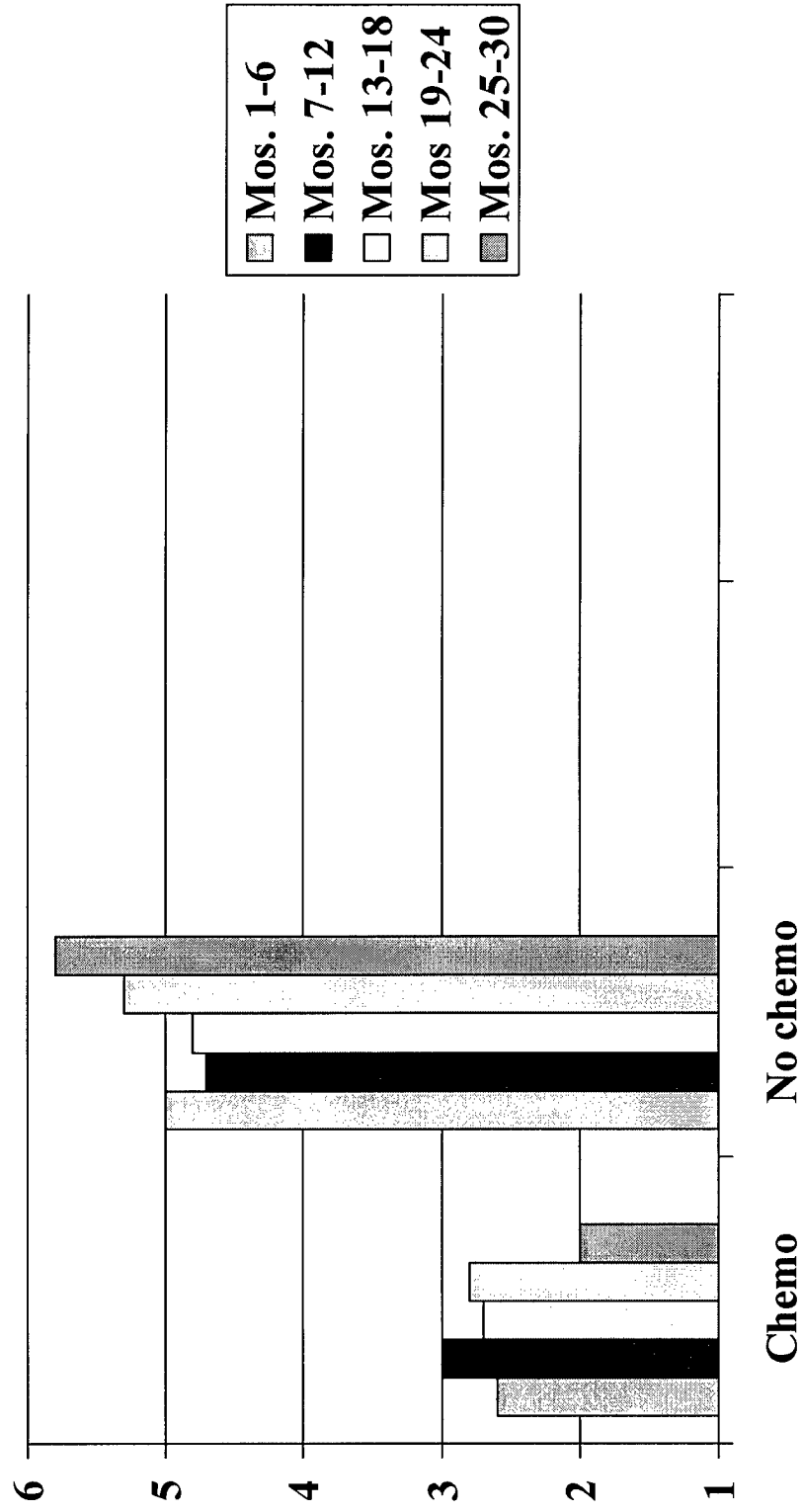
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Percentage of Patients Having Monthly Bleeding



Chemo No chemo

Average Number of Days of Bleeding for Patients With Monthly Bleeding



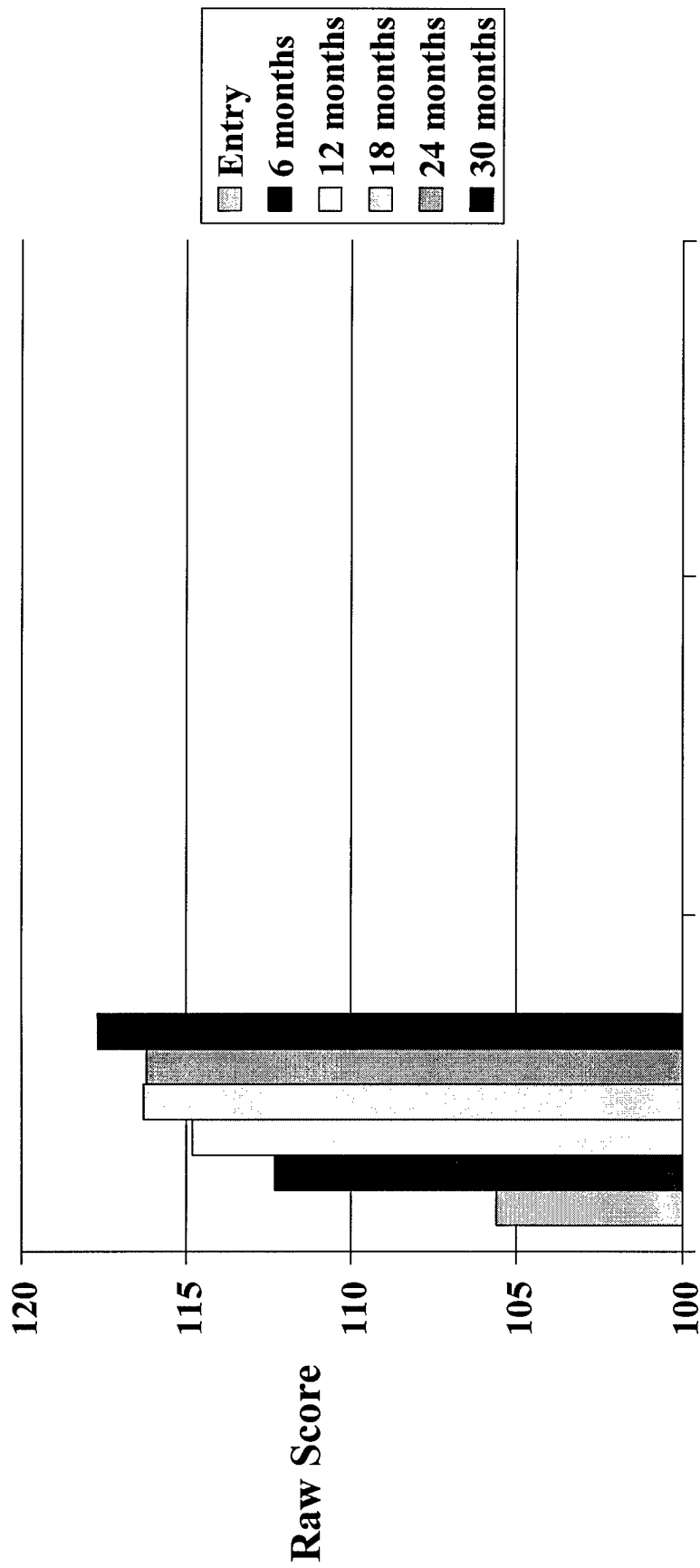
Percentage of Study Subjects Reporting These Symptoms

	<u>Entry%</u>	<u>6 mo.%</u>	<u>12 mo.%</u>
• Low Energy:	80	80	77
• Restless Sleep:	79	68	68
• Feeling Depressed:	67	59	54
• Mood Changes:	66	64	63
• Vaginal Dryness:	40	41	43
• Night Sweats:	37	45	46
• Hot Flashes:	36	55	56

Quality of Life Questionnaire (Raw Score)

	<u>Entry</u>	<u>6 mo.</u>	<u>12mo.</u>	<u>18mo.</u>	<u>24mo.</u>	<u>30mo.</u>
• <u>FACT-B:</u>	105.7	112.3	114.8	116.3	116.2	117.7
• <u>SF-12 P:</u>	44.3	47.8	50.3	50.5	51.0	51.4
• <u>SF-12 M:</u>	43.0	43.5	43.1	43.6	44.0	44.4
• <u>Beck Dep:</u>	9.9	8.5	8.2	7.9	7.6	6.9

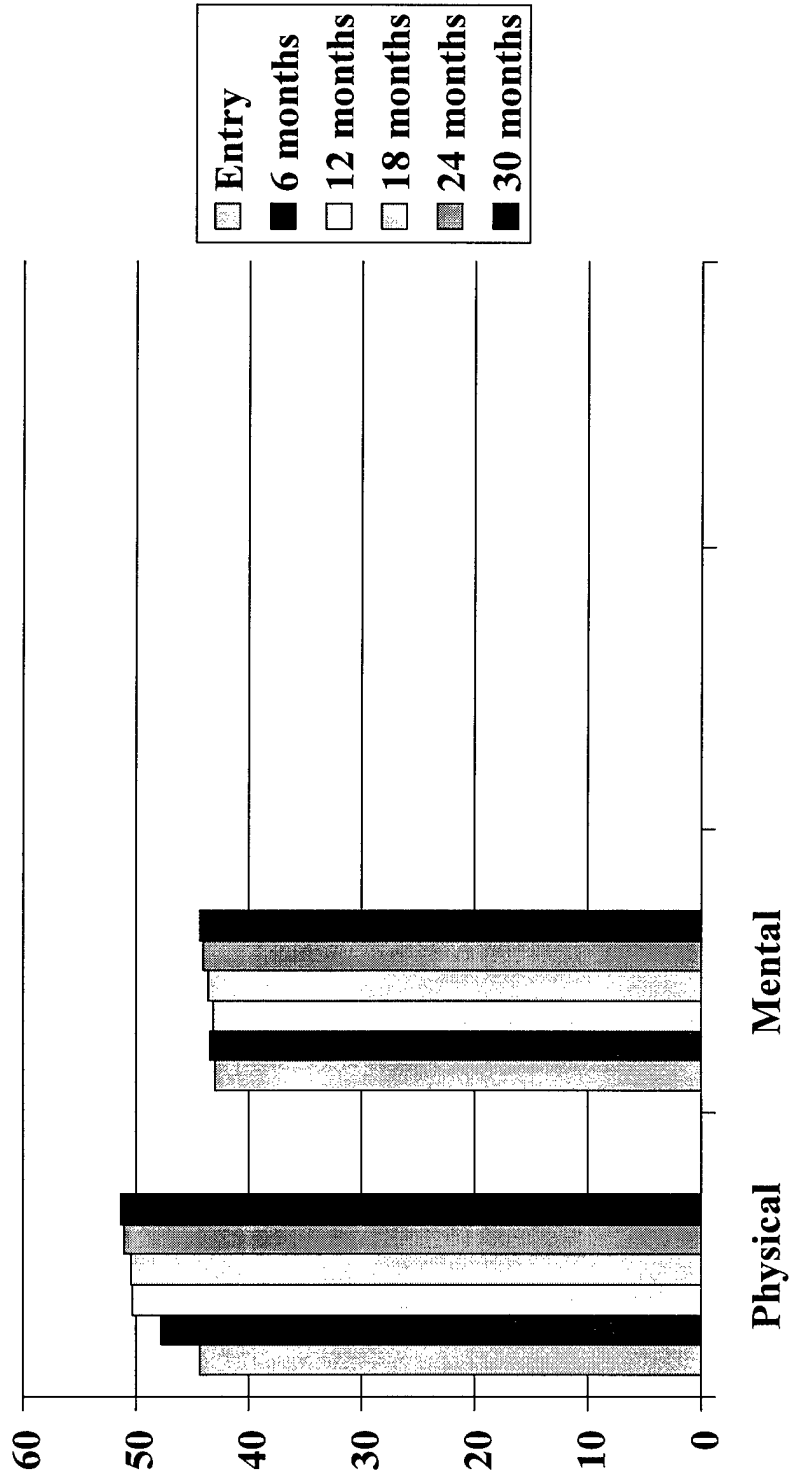
Functional Assessment of Cancer Therapy - Breast (FACT-B)



FACT-Breast Total Score

- Race: lower reported quality of life scores for non-whites than whites at entry, 12, 18, and 30 months.
- Ever Smoked: lower quality of life score at 12, 18, and 24 months
- Treatment: lower quality of life score at entry for patients receiving chemotherapy, and at entry and 6 months for those receiving radiation therapy
- Social Support: higher quality of life score with higher scores in level of social support

SF-12 Subscales



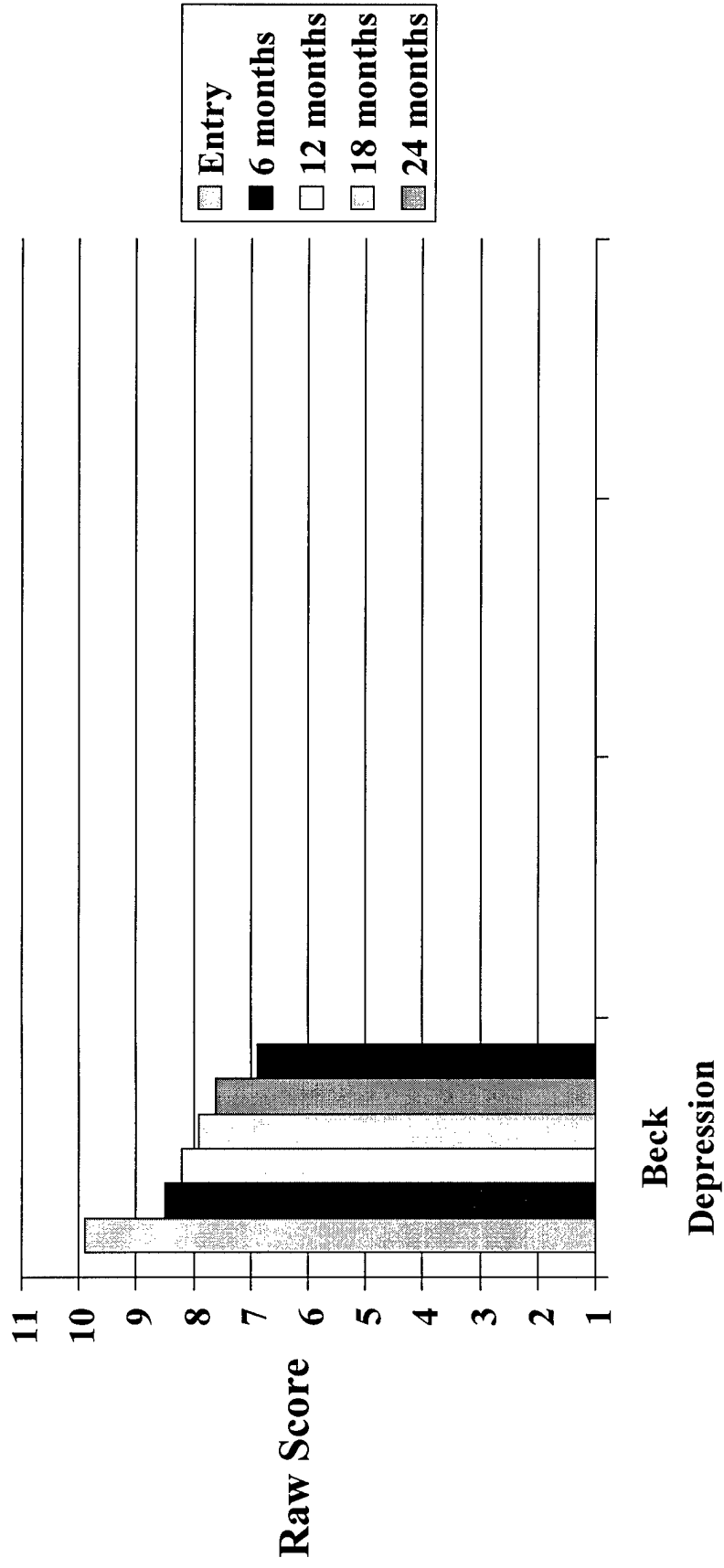
SF-12 Physical Summary Scale

- Lesser Axillary Surgery: was associated with higher physical functioning at 6 and 12 months
- Social Support: higher scores on the social support scale was associated with better physical functioning at baseline, 6 and 12 months.

SF-12 Mental Health Summary

- Nodes: Fewer lymph nodes with metastatic cancer was associated with better mental status
- Ever Smoking: Ever smoking status was negatively associated with mental health status at 6, 18, and 24 months.
- Social Support: Higher scores of social support was associated with higher mental health status at baseline, 6, 12, 18, 24, and 30 months.

Beck Depression Inventory



Beck Depression Inventory (BDI)

- From baseline through 30 months, patients had fewer depressive symptoms if they had *high levels of social support*.
- At entry only: more depressive scores were associated with a lower age at diagnosis and receiving *chemotherapy*.
- More depressive scores at 6, 12, and 18 months for those who had ever *smoked*.