AD-A268 124

IMENTATION PAGE

Form Approved
OMB No 0704 0188

...estimating the time for reviewing instructions, searching existing data sources, gathering and maintaining the collection of information. Send comments regarding this burden estimate or any other aspect of this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 ... to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.

2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
1993	THESIS/DISSERTATION

4. TITLE AND SUBTITLE
Ventricular Assist Devices: Physiology Meets Technology

5. FUNDING NUMBERS

6. AUTHOR(S)
Cynthia K. Hilsher

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
AFIT Student Attending: Univ of Maryland

8. PERFORMING ORGANIZATION REPORT NUMBER
AFIT/CI/CIA- 93-06

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)
DEPARTMENT OF THE AIR FORCE
AFIT/CI
2950 P STREET
WRIGHT-PATTERSON AFB OH 45433-7765

10. SPONSORING/MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION/AVAILABILITY STATEMENT
Approved for Public Release IAW 190-1
Distribution Unlimited
MICHAEL M. BRICKER, SMSgt, USAF
Chief Administration

12b. DISTRIBUTION CODE

13. ABSTRACT *(Maximum 200 words)*

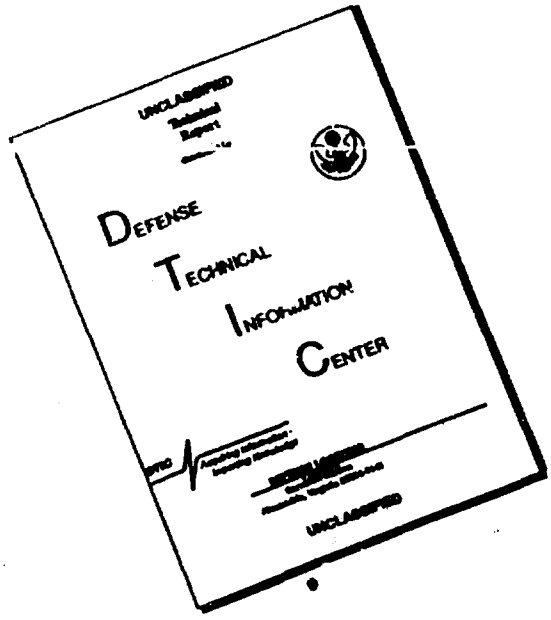
DTIC
ELECTE
AUG 13 1993
S B D

93-18728

14. SUBJECT TERMS	15. NUMBER OF PAGES 71
	16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT

DISCLAIMER NOTICE



THIS DOCUMENT IS BEST QUALITY AVAILABLE. THE COPY FURNISHED TO DTIC CONTAINED A SIGNIFICANT NUMBER OF PAGES WHICH DO NOT REPRODUCE LEGIBLY.

Ventricular Assist Devices: Physiology Meets Technology

Cynthia K. Hilsher

University of Maryland at Baltimore

Graduate School of Nursing

Seminar paper submitted to the Faculty of the
Graduate School of the University of Maryland
in partial fulfillment of the requirements
for the degree of Master of Science
1993

Running head: VADs

Approval Sheet

Title of Scholarly Paper: Ventricular Assist Devices: Physiology Meets Technology

Name of Candidate: Cynthia Kay Hilsher

Scholarly Paper approved by:

Patricia Gonce Morton

Patricia Morton, PhD, RN

Assistant Professor

Graduate Program, Trauma/Critical Care Nursing

University of Maryland

Marguerite Littleton Kearney

Marguerite Littleton Kearney, DNSc, RN

Associate Professor

Graduate Program, Trauma/Critical Care Nursing

University of Maryland

DTIC QUALITY INSPECTED 3

Accession For	
NTIS GRA&I	☑
DTIC TAB	☐
Unannounced	☐
Justification	
By	
Distribution/	
Availability Codes	
Dist	Avail and/or Special
A-1	

Table of Contents

Abstract

Ventricular assist devices (VADs) offer a vital option to severely compromised cardiac patients. By maintaining perfusion throughout the body, VADs allow necessary time for recovery or retrieval of a donor heart. Patient selection is imperative for positive patient outcomes and cost containment. The three designs of VADs include the roller pump, centrifugal pump, and pneumatic pump. The pneumatic pump offers the most hope in the development of a permanent device. Evaluation of both the patient and the device determines the effectiveness of treatment and ultimately patient outcome. Advanced nursing practice incorporates the five roles of the clinical nurse specialist to provide optimal and holistic care for the unique VAD patient population.

CHAPTER 1

Overview

Historical Perspective

Providing temporary circulatory support in severely compromised cardiac patients can mean the differences between life and death. Ventricular assist devices are a dramatic change from days when treatment for heart failure was bedrest and digitalis (Quaal, 1991). Rapid development in circulatory support took place after the discovery of heparin by Howel in 1916. Heparin is essential to minimize the risk of blood clot formation during extracorporeal circulation. The first successful human application of a mechanical circulatory device was in 1954 by John Gibbon (Rutan, 1991; Pennington, 1990). Partial support technology appeared in 1962 with the introduction of the intra-aortic balloon pump (IABP). The IABP is today the most predominantly used method of mechanical support. Statistics indicate it is used in four to five percent in the postcardiotomy patients (Pennington et al., 1989). The IABP augments the cardiac output up to fifteen percent over normal flow rate. The problem is when partial support is not enough to maintain adequate circulation for the patient to survive. A more complete form of circulatory assistance is provided with a Ventricular Assist Device (VAD). Clinical trials for VADs started in 1975. Ventricular assist devices offer a necessary, more comprehensive alternative treatment to the management of cardiac failure refractory to pharmacological support and intra-aortic balloon pulsations.

Need for VAD Technology

Heart disease continues to be the leading the cause of death in the United

States (National Center for Health Statistics, personal communication, February 12, 1993). Approximately 1.5 million Americans suffer a myocardial infarction (MI) each year. Of the 1.5 million, approximately 540,000 people die (Woods & Underhill, 1989). TheCenter for Disease Control reports in 1986, twenty-eight percent of total deaths in the United States were due to coronary heart disease (CDC, 1989).

Two complications commonly associated with MIs and coronary artery disease are cardiogenic shock and congestive heart failure. Ten to twenty percent of people who suffer a MI develop cardiogenic shock. The mortality rate associated with cardiogenic shock remains over eighty percent (Loveys, 1989). Another common complication is the risk of developing heart failure. Thirty to sixty percent of MI patients suffer heart failure (Laurent - Bo, 1989). There are four classes of heart failure, according to the New York Association Cardiac Status and Prognosis Classification system. Each class identifies the cardiac status with the associated prognosis. Class one is a person with an uncompromised cardiac status having a good prognosis. The prognosis is worse with each subsequent class. Class four is the group of patients who rely on the possibility of a future heart transplant in order to live.

A limiting factor to the transplant option is the significant shortage of donor organs for transplantation (Kriett & Kaye, 1990). The need for donor hearts far outreaches the supply available. Estimated need for cardiac transplants in the United States alone is currently between fifteen to thirty thousand, while only two to three thousand potential donor hearts are available (Simpson, 1990). An average waiting period for a donor heart is three to six months (Simpson, 1990;

Ruzevich et al., 1989). Many patients die during the long waiting period or suffer irreversible injury to vital organs which makes them no longer eligible for transplantation (Reedy et al., 1989).

The lack of available donor hearts identifies the need for an alternative treatment option. Ventricular assist devices can provide patients total circulatory support during the wait for a cardiac transplant. VADs not only maintain adequate circulation in the interim but restore an optimal level of health to patients who's health has slowly deteriorated due to living with a poor or marginal cardiac function. Ventricular assist devices offer a temporary means of support to give valuable time for a donor heart to be found. Acknowledging the severe donor shortage with the high need for cardiac transplantation supports the research priority of seeking a permanent artificial device as the solution to the lack of donor hearts.

Another justification for using VADs and the goal of developing a permanent artificial heart relates to the cost of caring for patients with cardiovascular disease. Heart disease is one of the two leading causes of hospital admissions in 1990 (CDC, 1992). This results in one hundred and fifteen days of care per 1000 required for heart disease alone. Looking at men over age 65, the number of required hospitalized days increases to 639 per 1000 (Rutan, 1991). Heart disease consumes a large portion of the nation's medical resources. An estimated eleven percent of the Gross National Product is presently spent on health expenditures (CDC, 1992). Reducing the number of hospital days, decreasing the amount of resources consumed plus improving the quality of life for end-stage heart disease is a worthwhile goal. Ventricular assist devices are

the stepping stones to finding that solution.

Physiology Alteration Necessitating VAD Support

Theoretically, the VAD gives the heart time to rest and potentially recover while maintaining adequate circulation for all vital organs. Impaired cellular perfusion results in anaerobic metabolism and triggers the release of mediators causing further injury to the cell. If the cycle of injury is not interrupted, multiple system organ failure (MSOF) results. The mortality for a single organ dysfunction is thirty percent. Mortality rises as more organ systems fail. With failure of four organ system, the mortality rate is one hundred percent (Ayres, Schlichtig, & Sterling, 1988). These mortality statistics illustrate the importance of restoring adequate circulation to all organ systems before the damage is irreversible. Ventricular assist devices restore adequate circulation and break the deadly cycle.

The VAD performs two physiological functions: 1) to augment the systemic blood flow, and to 2) unload the ventricle. The device functions by pumping the blood, augmenting total blood flow. By the VAD performing the ventricular work of systole, the energy demand placed on the injured ventricle is reduced. The second function is to "unload" the ventricle. This term refers to decreasing the volume of blood returning to the injured ventricle. Fifty to seventy-five percent of the blood flow is diverting through the VAD, reducing the amount of blood pumped by the impaired ventricle. Again, less blood being pumped by the impaired ventricle equates with less energy and oxygen requirements. The reduction in energy requirements allows the injured heart to potentially recover from the insult. By increasing the oxygen supply and/or reducing the myocardial

oxygen demands, more oxygen is provided to the injured cells thus reducing the magnitude of myocardial injury (Pennock, Pae, Pierce, & Waldhausen, 1979). Farrar (1985) reported findings to support Pennock's work. Farrar noted a reduction in damage from myocardial infarction and ischemic tissue damage reversed with the use of a ventricular assist device.

Cardiac output is determined by the stroke volume times the heart rate. Preload, afterload, and contractility influence stroke volume. The ventricular assist device optimizes preload and afterload by adjusting the flow to maintain the left atrial pressure between 4 and 12 mmHg (Litwik et al., 1978). Contractility is performed or augmented by the assist device. The ventricles function interdependent of each other by both hemodynamic and mechanical interaction (Elbeery et al., 1990; Farrar et al., 1985). The hemodynamic aspect reflects the in-series nature of circulation. Output of one ventricle becomes the input of the other. A balance needs to be preserved when using assist devices between the assisted ventricular output and the unassisted ventricular output. Output of the assist device can never exceed the natural heart's unassisted ventricle. The mechanical interaction involves the coupling between the ventricles. Both ventricles share the interventricular septum and the common muscle fibers that connect the free wall of the right ventricle to the left ventricle. Changes in the pressure-volume relationship can alter the compliance in the contralateral ventricle (Farrar, 1985).

The principle behind VAD support is flow assistance. A VAD can assist, augment or totally replace the work of an impaired heart. This is different from the intra-aortic balloon pump (IABP) which uses the principle of pressure

assistance to augment the cardiac output. Pressure assistance aids the work of systole for the native heart, but the native heart still must generate systole (Ruzevich et al., 1988). To compare the IABP to the VAD, the IABP can augment the cardiac output a maximum of 15 percent while the VAD can completely support circulation even during episodes of ventricular tachycardia or ventricular fibrillation (McKay et al., 1991). A study showed the VAD to be superior to the IABP in preserving myocardial structure and function (Mickleborough et al., 1987). The VAD demonstrated the ability to preserve structural integrity (a smaller percentage of myocardial necrosis) in only three hours of support as compared to IABP support. Both groups exhibited stable hemodynamic parameters. The reduction in myocardial necrosis from VAD support as compared to IABP support could mean the difference between life or death.

Goals of VAD Support

The goal of any circulatory assist device is to arrest deterioration and to stabilize the hemodynamic condition of the person. Ventricular assist devices are a temporary method to support circulation until the heart recovers or the logistics of cardiac transplantation can be arranged. Presently, a permanent device is not available. Patients who are not candidate for cardiac transplantation should not be placed on VAD support.

Indications

The patient population benefiting from VAD support fall into three broad categories. The first group of patients are those post cardiotomy that cannot be weaned off cardiopulmonary bypass (CPB) or deteriorate after being weaned off

CPB. This comprises 1 to 4 % of all patients who have open heart surgery. The second group of patients are those in cardiogenic shock following an acute myocardial infarction. The third group are patients suffering from severe cardiomyopathy. In this case, the VAD is used in transition until the patient can receive a cardiac transplantation. Patients using the VAD as in transition or a bridge are referred to as Bridge to Transplant patients.

Patient Selection

Cost continues to be a consideration in these tough economic times of cost containment. The high cost of VAD technology limits the use of VADs only to the patients who have a reasonable chance for a positive outcome. Selection of patients who would potentially benefit from those who would not benefit from a ventricular assist device is necessary to prevent costly, ineffective utilization of limited resources (Golding et al., 1992; Gaines et al., 1985). The ability to predict probable positive outcomes allows a more retrievable and ethically acceptable group of patients to support with VAD technology. A classic study by Norman (1977) guides selection of patients most likely to survive with VAD support. Certain chronic illnesses limit the success of VAD support. Examples of illness that exclude using a VAD for support are chronic renal failure, permanent central nervous system disease, cancer with metastasis, severe hepatic disease, significant blood dyscrasia, severe pulmonary disease, sepsis, or multiple system organ failure. If the patient had open heart surgery, the original surgical procedure must be technically satisfactory to consider using VAD technology.

Other considerations in using VADs is the size and the age of the patient. Patients who have a body surface area less than 1.0 m2 pose a problem with the

fit of the device. Smaller devices are on the horizon, but are yet still unavailable at most institutions. Age has been discussed as an exclusion criterion for using this device. Generally no one over the age of 70 is considered a suitable candidate for a VAD. The rationale for the age restriction stems from the increased mortality rate of older patients with VADs. After age 70, the overall survival rate falls to 10.2 percent compared to the survival rate of 34.4 percent if under the age of 60 (Miller, Pae, & Pierce, 1990). The final decision is negotiable if the physiological age is much younger than the chronological age (Pennington, 1990).

Inclusion criteria revolves primarily around the hemodynamic status of the patient. Ventricular failure warrants the insertion of a VAD. Indications are the patient's mean arterial pressure is less than 60 mmHg, cardiac index less that 2 liters/min/m2; atrial pressure greater than 20 mmHg; systemic vascular resistance greater than 2100 dynes/sec/cm3, and urine output less than 20 ml/hr. All other therapeutic interventions, such as maximum pharmacological therapy, optimal fluid status, adequate heart rate (pacing if needed) and use of a intra-aortic balloon pump (if appropriate) are unsuccessful at maintaining adequate perfusion under the above conditions. Early VAD intervention is credited potentially to improve the survival rate (Mickleborough et al., 1987; Zumbro et al., 1987; Schoen et al., 1986; Norman et al., 1977). Through a retrospective need analysis for mechanical circulatory support, only one percent of patients post cardiotomy receive VAD (McGee et al., 1980). This study postulated the need is actually closer to three percent, indicating VAD technology is not being used to it's full potential.

Mortality & Morbidity Rates

Survival rate associated with VADs range from thirty to forty percent for postcardiotomy patients (Pennington, 1990). If used as a bridge to transplant, the survival rate increases to a range of eighty to eighty-five percent (Pennington, 1990). A poor prognosis is given to a VAD patient if the hemodynamic status does not improve within 48 to 72 hours after initiating support (Litwik, 1985). Other negative indicators for survival include biventricular failure, acute renal failure, and peri-operative infarction (Miller, Pae, & Pierce, 1990; Pennington et al., 1989; Zumbro et al., 1987). Biventricular failure is a result of a pre-existing condition in the unassisted ventricle unveiled by VAD support. Renal dysfunction is the most significant prognostic negative indicator of survival during VAD support (Golding et al, 1992). Peri-operative infarction is thought to be directly related to the severe global myocardial ischemia during cardiopulmonary bypass which when the oxygenated flow is restored results in reperfusion injury (Schoen et al., 1986). Frequent causes of death with VAD patients are myocardial necrosis, hemorrhage, or infection (Golding et al, 1992; Pierce et al., 1989; Griffith et al., 1988; McBride et al., 1987; & Schoen et al., 1986).

Summary

In summary, heart disease affects millions of people each year. It costs society billions of dollars. Ventricular assist devices provide flow assistance to support the circulation and prevent organ system failure. Necessary time is given by a VAD for the native myocardium to regain function or for a donor heart to be found. The need for a permanent artificial device is apparent, especially in light

of the current donor heart shortage. Ventricular assist devices are in the clinical trial phase. Research is descriptive in nature, listing the complications and patient outcomes. The use of registries and multi-centered studies help establish standards of care and protocols for VAD patients by increasing the sample population. As the device is used more frequently and for extended periods of time, more detailed studies will be obtained. Presently, indications for patient selection guides VAD utilization.

CHAPTER 2

Designs of VADs

General description

Ventricular assist devices consist of three components: 1) the blood pump and cannulas; 2) the energy source; and 3) the console to monitor the system. Ventricular assist devices can be divided into external verses internal designs in regards to where the device is placed. Examples of external VADs are the roller pump, the centrifugal pump, and the pneumatic pump. The pump remains outside with the cannulas entering the body. Internal VADs are primarily pneumatic in design but the pump and cannulas are located within the body. The primary advantage to internal VADs is a reduced risk for infection. A brief description of each type of ventricular assist system with the advantages and disadvantages is given.

Roller Pump System

A roller pump functions according to the principle of positive displacement (English, 1989). Blood is pushed forward by compressing the tubing with a roller at a continuous, non-pulsatile rate. Low volumes of blood are moved by high pressures. Cardiac output or flow rates are controlled by the pump's rotation speed, increasing the rotation to increase the flow rate. The maximum flow rate is 6 L/min, the average rate ranging between 2 and 4 L/min. If the flow rate is set too high, the atrium can collapse due to a vacuum effect from the device. Inadequate filling of the ventricles will result in a decreased cardiac output. If the flow rate is set too low, thrombus formation is likely to occur. An example of a roller pump design is the standard cardiopulmonary bypass machine.

Advantages to the roller system is the simple design, the most inexpensive system to use and widespread availability. Disadvantages include hemolysis of the red blood cells due to the high pressures, potential for air emboli and a dangerous build-up of outflow pressures. Heparinization is required with this design to prevent thrombus formation. This system is best suitable for short-term application. Hemolysis and coagulopathies become a significant problem with long-term use of a roller system.

Litwik (1985), designer of the roller pump, added a unique feature to this system. Now the pump can be discontinued without re-entry into the chest. Litwik feels this is a major advantage in reducing the stress a second operative procedure causes. Obturators are placed inside biocompatible cannulas to permanently occlude the cannulas. Documentation supports the use of biocompatible obturated cannulas remaining in the body for ten years of clinical follow-up (Litwik, 1985). The roller pump is the only system to offer this feature.

Centrifugal Pump System

The centrifugal pump uses the principle of kinetic energy to push the blood forward in a non-pulsatile flow. Kinetic energy is created by the rotation of two magnetic cones that create a vortex or tornado-like effect (Mulford, 1987). The speed of the pump regulates the centrifugal force exerted to maintain blood flow. The greater the speed, the greater the force which results in a greater output from the pump (Shinn, 1989).

The centrifugal pump is demand-responsive adjusting the energy to the pressure and volume within the system. It is designed to move large volumes of blood but at low pressures. An increase in pressure results in an automatic

decrease in the flow rate. A demand-responsive system eliminates the detrimental effect of high pressures on red blood cells. In response to volume, flow adjusts to the amount of blood returning to the system. Essentially, the centrifugal pump maintains a constant pressure over a wide range of flow rates (Ruzevich, 1991). Flow rates range from 3.5 to 4 L/min with the centrifugal system.

Advantages of the centrifugal pump design are a decreased risk for air emboli or pressure build-up due to the demand-responsive design of the system. The demand-responsive design also decreases hemolysis. It is a simple design with widespread availability. Centrifugal pumps are relatively inexpensive, costing $11,000 for the monitoring console and $150 per each disposable pump head (Smith & Cleavinger, 1991). Pump heads are changed every 24 to 48 hours. Another advantage to the centrifugal system is that there is no size limitations for patient selection. A 50 ml or an 80 ml pump head allows for either adult or pediatric patients. Biventricular support can be accomplished by using two centrifugal pump systems. The final advantage is the benefit of leaving the native heart in place. This benefit allows a possibility for the native heart to regain some degree of function if the patient becomes ineligible for transplantation. If the native heart is surgically removed and the patient becomes ineligible for a cardiac transplant, the patient has no chance for survival (Zumbro et al., 1987).

The major disadvantage of the centrifugal system is the non-pulsatile flow which requires the use of an intra-aortic balloon pump to create physiologic pulsation. Benefits of a pulsatile flow has been shown to improve kidney perfusion, decrease peripheral vascular resistance, and increase systemic circulation (Marchette et al., 1988). Non-pulsatile flow results in

microcirculatory shunting and edema formation (Ruzevich, 1991). By using the IABP with the centrifugal pump, problems resulting from a non-pulsatile VAD are minimal. Non-pulsative flow resurfaces as a problem if the IABP cannot be inserted due to severe perpherial vascular disease (Litwik et al., 1985). Another disadvantage to the centrifugal system is the restricted mobility due to the inability to close the sternum post-insertion of the cannulas.

Heparinization is not required with the centrifugal system if the flow rates are greater than 2 L/min (Magovern et al., 1985). High flow rates result in hemolysis of red blood cells with the centrifugal pump. The goal is to maintain flow rate within an ideal range to optimize the benefits of the centrifugal pump. Centrifugal pumps are used as a short-term assist device, providing a better flow rate than the roller system with fewer complications. Examples of centrifugal devices are the Bio-medicus pump, Centrimed, or the Medtronic. (See figure 1)

Pneumatic Pump System

Pneumatic assist devices are a pulsatile, air-driven pump. The sac-like chamber uses a diaphragm to separate the blood from the compressed air. The diaphragm expands or compresses with the movement of pressurized air. Positive air pressure compresses the sac, causing the blood to be ejected into the systemic circulation. Negative pressure can be added during diastole to expand the space in the chamber helping to fill more easily. The flow of the blood is directed by the mechanical valves in the device. Maximum flow rate is 6.5 L/min. Two energy sources are needed to run the pneumatic system. One energy source is compressed air needed to collapse and expand the diaphragm. The other energy source is electrical power to operate the console.

Figure 1: Centrifugal Pump

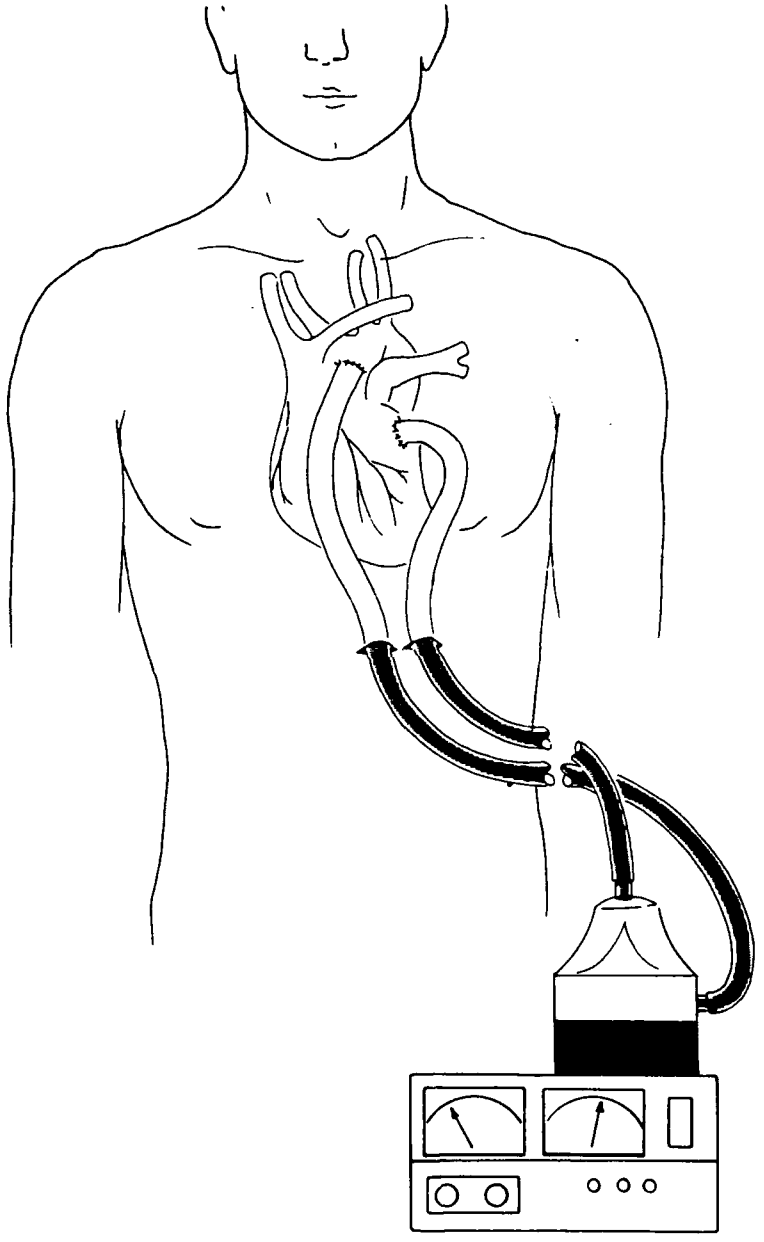


Figure 1: Reprinted from "Preventing Complications of Ventricular Assist Devices" by M. A. English, 1989, Dimensions of Critical Care Nursing, 8(6), p. 332.

Modes of operating the pneumatic pump are: 1) a fixed-rate mode, 2) a fill-to-empty mode, and 3) the ECG synchronization mode. The fixed-rate mode is asynchronous with the intrinsic rhythm of the heart. This mode is used when initiating the ventricular support or during the weaning phase. The fill-to-empty mode maintains the same stroke volume for the patient despite changes in heart rate. This method is the mode of choice for managing VAD patients clinically since the VAD rate and output automatically adjust to the varying venous return (Ley, 1991). The third method is the ECG synchronization mode, using the R wave of the QRS complex to signal the pump. With this mode, the rate of ventricular assistance can be adjusted much like the intra-aortic balloon pump to every second, third or fourth beat. The ECG mode is another method to wean patients from the VAD.

A major advantage of the pneumatic pump system is the pulsatile flow which allows for long term support. It provides superior flow rates over the roller system or the centrifugal system. The pneumatic system does not require anticoagulants, but is recommended during the weaning process if flow rates are less than 2.5 L/min (Barden & Lee, 1990). The pneumatic pump can provide biventricular support with the use of two pump heads. External pneumatic VADs leave the heart in place to allow an alternate treatment plan if needed.

Disadvantages with the pneumatic system include the complex nature of the system design, the need for an investigational device evaluation (IDE), considerable expense, and the limited availability. An investigational device evaluation is required to be submitted to the Food and Drug Administration to ensure appropriate use of the device. Devices which existed before 1976, such as

the roller and the centrifugal pump system, do not require an IDE application (Smith & Cleavinger, 1991; Cleavinger et al., 1989). The need for an application limits the number of centers eligible for using the pneumatic assist device technology. The cost of a external pneumatic assist device is more expensive than either the roller or the centrifugal system, estimated at $40,000 to $70,000 for the monitoring console, and $11,000 to $13,000 per device (Smith & Cleavinger, 1991). External pneumatic assist devices also carry an increased risk for infection due to the blood circulating outside the body. To minimize the risk of infection, the cannulas are tunneled through the chest wall using Dacron skin buttons before connecting to the external pump. The skin buttons promote tissue growth at the exit sites to serve as a barrier against infection (Stetich, Empey, & Sasmor, 1986). Skin buttons also are used with the internal systems to protect against infection around the energy source drive lines.

The pneumatic ventricular assist device can be used safely for longer periods of time than either the roller or the centrifugal system. Patients have been supported greater than 80 days without complications (Ruzevich, 1991). Examples of external pneumatic ventricular assist devices are the Pierce-Donachy (Thoratec), Symbion, and Thermedics. A biventricular pneumatic system is the ABIOMED 5000. (See Figure 2)

Internal pneumatic ventricular assist systems also are available. Presently two systems are on the market, the Heartmate and the Novacor. Both systems are only left-ventricular assist devices and are implanted in the abdominal cavity. The major benefit is the decrease risk of infection. Price for an implantable pneumatic system is higher, listed as $65,000 for the console and an additional $24,000 for

Figure 2: Pneumatic Pump

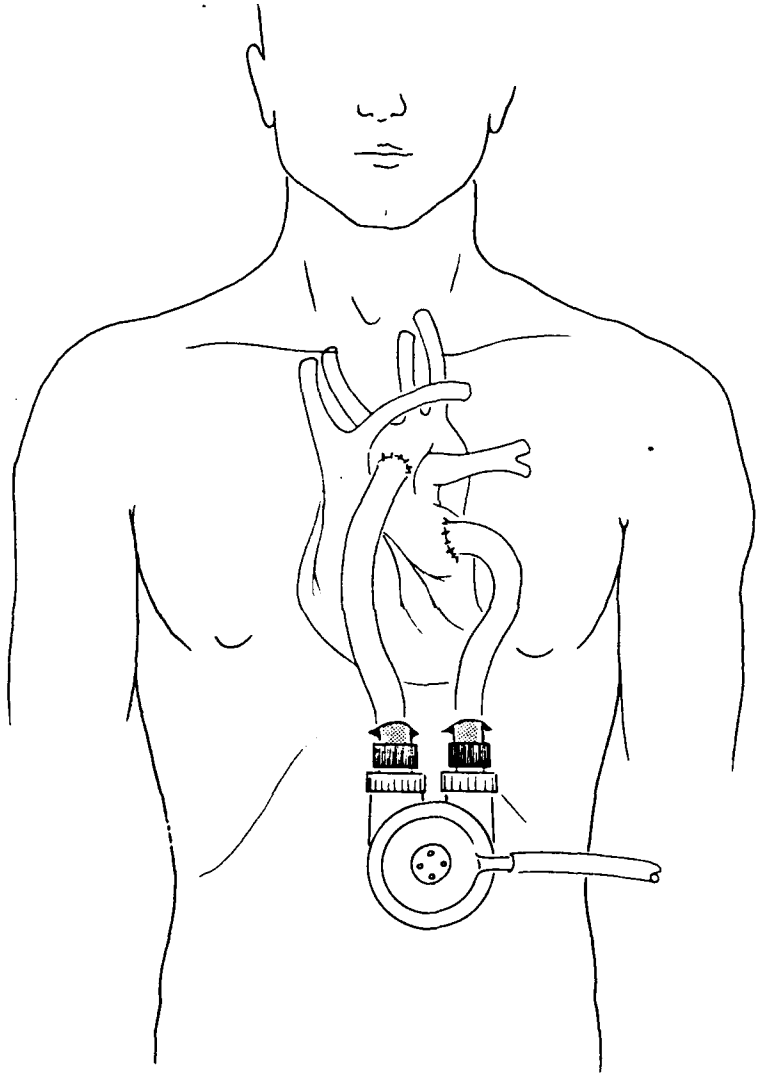


Figure 2: Reprinted from "Preventing Complications of Ventricular Assist Devices" by M. A. English, 1989, Dimensions of Critical Care Nursing, 8(6), p. 333.

the pump (Smith & Cleavinger, 1991). Even though the implantable pneumatic system allows the native heart to remain in place, it is considered as only a bridge to transplant. Ventricular cannulation required by the device impairs the remaining ventricular function.

Total Artificial Heart (TAH)

The Artificial Heart Program founded in 1964 by the National Heart, Lung, and Blood Institute (NHLBI) continues to struggle with designing a permanent artificial heart. The key contender is the pneumatic pump design. Presently two pneumatic artificial hearts are available for clinical study. They are the Jarvik-7 and the Utah-100. A smaller version of the Jarvik 7, called the Jarvik 7-70 is available for smaller patients. With the TAH, the native heart is excised and the TAH is placed inside the chest cavity.

An advantage of the total artificial heart is complete control of the cardiovascular system. This allows the device to provide whatever cardiac output is needed by the patient, up to 10 L/min. Other devices are restricted to the amount or flow by the unassisted ventricle's function. Mobility is crucial to the psychological and physical well-being of the patient due to the time length involved with TAH. Mobility is increased by using a semiportable unit called a circulatory support system (CSS) to supply the air source for the pneumatic system while ambulating. The Heimes Portable Heart Driver, contained in a shoulder bag, is another system designed for patient ambulation (Mays et al., 1986). The major problem with the pneumatic system as a permanent device is the need to be tied to the energy source. Other disadvantages of the TAH are the need for a IDE application, complications with fit inside the chest cavity, the need

for anticoagulants, and the expense. The console for an TAH is $70,000 and $22,000 for the pump (Smith & Cleavinger, 1991). Another major disadvantage is excising the heart, leaving cardiac transplantation as the only treatment option.

Device Selection

With the numerous designs of VADs available, selection of the appropriate device for each individual patient is imperative to maximizes the benefits and minimizes the risks. Factors to consider when choosing a design are: 1) the location of the collapse, 2) the type of ventricular failure, 3) the estimated time length of use, and 4) the availability of the device at a specific institution (Ruzevich, 1991). The location of the ventricular collapse, whether it is right or left-sided failure and the expected outcome indicates the most appropriate device. Certain devices are only used with left ventricular failure. Estimating the length of time the device will be needed is another important consideration. Some devices have a limited time benefit, while others can be safely used for a longer time period. The final consideration rests with the availability of the device in the specific institution. Ventricular assist devices are still under investigation and are restricted to certain institutions.

Cannulation

Device selection and the cannulation are inter-related. Certain devices require specific methods of cannulation. Cannulation for the roller pump uses the femoral vein as the outflow, positioning the cannula at the superior vena cava and right atrium. The inflow is returned through the ascending aorta arch. The centrifugal system cannulates the right or left atrium, returning the blood flow through the pulmonary artery or aorta respectively. The pneumatic system offers

a choice of cannulation. The decision for either atrial or ventricular cannulation rests with the expected patient outcome. A patient who is expected to recover function of the native heart ideally should be atrially cannulated, sparing further damage to the ventricles. Ventricular cannulation is beneficial to patients requiring VAD support as a bridge to cardiac transplant when damage to the ventricle is unimportant. The advantage to ventricular cannulation is better unloading of the ventricle which decreases the oxygen requirements of the myocardium. This allows more oxygen to be available for other organ systems and saves the left atrium as a donor site for cardiac transplantation.

Comparison between VADs Designs

The various designs of VADs cover a diverse need for this technology. Using the most cost-effective method to adequately support the patient seems logical. The roller pump system is the most inexpensive method of circulatory support, but research has shown that remaining on a roller pump system longer than seven hours has a negative impact on survival (Pennington et al., 1989). Statistics comparing VAD designs to associated patient outcomes are given in the Combined Registry for the Clinical Use of Mechanical Ventricular Assist Devices for post-cardiotomy patients (Miller, Pae, & Pierce, 1990). Centrifugal systems are the most frequently used device, used one and a half times more often than the pneumatic system. Patient outcomes for both systems are comparable. The availability of the centrifugal system due to not needing an IDE application could be contributing factors to this finding.

Comparing the location of support, right verses left ventricular support, with the associated outcome also is analyzed. The majority of the patients require left

ventricular support. Outcomes associated with the different location of support are as follows: Left VAD (LVAD) - total of 239 patients, 46.4 percent weaned from device, 25.5 percent of the patients weaned were discharged home; Bi ventricular assist device (BVAD) - total of 152 patients, 42.1 percent weaned from device, 19.1 percent of the patients weaned were discharged home; and Right VAD (RVAD) - total of 60 patients, 46.7 percent weaned form the device, 28.3 percent of the patients weaned were discharged home. These statistics support the negative impact biventricular failure has on survival rate (Zumbro et al., 1987). Assessing the potential for right ventricular failure intraoperatively while inserting a left VAD proves difficult due to the right ventricle dysfunction possibly occurring hours after insertion.

Gender and age considerations are identified in the registry, listing men as the primary recipient for VADs four to one. Patient age averages 54 for men and 51 for women. Discharge rate is inversely associated with age. The older the patient, the lower the discharge rate. Under age 59, sixty-seven percent of VAD patients are discharged. A gradual decrease is seen until ages over 70 having a discharge rate of only twenty-nine percent. This confirms age as an indicator for patient selection.

Summary

The different designs of VADs allow the device to meet a wide diversity of patient needs. Short term support is offered by the roller pump if less than seven hours or centrifugal system if less than two weeks. The pneumatic system may be used for a much longer time period with the implantable devices offering the greatest time length due to the decreased risk of infection. Selection of the

appropriate device rests on several patient factors including the location of failure, the type and length of support needed, and the availability of specific devices. The centrifugal design has similar patient outcomes as the pneumatic design but is presently used more frequently due to the availability. The pneumatic pump offers the most hope in a future artificial heart.

CHAPTER 3

Management of the VAD patient

Interaction between the man and device.

Patients requiring circulatory support are unique in the dynamic interaction between the device and the human host. Nurses need to recognize the complex, multisystem interaction when they assess the VAD patient. The cardiovascular system is the delivery mechanism for oxygen and nutrients to the rest of the human body. Ventricular assist devices help maintain this vital link of delivery. Every system in the body requires the delivery of oxygen and nutrients to maintain proper function. Assessment of each system identifies not only the efficiency of the VAD but the patient's chance for survival.

Currently, the VAD is used in approximately 1000 patients a year in the United States or one percent of patients experiencing cardiogenic shock following surgery, myocardial infarction or cardiac transplant (Swartz et al., 1989; Zumbro et al., 1987). This small percentage limits the experience of health care providers with the device. A multidisciplinary approach is recommended as the most effective method to manage these unique patients (Cleavinger et al., 1989; Swartz et al., 1989). Efforts from all disciplines, such as biomedical engineers, hematologist, infectious-disease specialists, immunologists, physiologists, cardiologists, perfusionists, surgeons and nurses are essential to ensure an acceptable outcome (Swartz et al., 1989). By combining expertise from the different specialties not only helps identify current patient needs but assists in improving the technology for future devices.

Role of the Nurse

The nurse's primary responsibility focuses on the patient. Expert clinical skills plus a thorough understanding of the physiology behind VADs are necessary for a nurse to achieve total quality patient care. The technical aspects of the device are primarily handled by the engineering support staff or the perfusionist but the bedside nurse must be able to interpret proper functioning of the device and troubleshoot in cases of emergencies.

Assessment of VAD

Functioning of the VAD is detected by clinical assessment of the patient and by monitoring the information given on the VAD console. The design of the VAD alters the various parameters used to program the device. With the roller or the centrifugal system, the important parameters are flow rate and the pump speed. Pressure is measured in the centrifugal system. Monitoring the system's flow rate guides the speed selection for the system. The pneumatic system offers other selections to optimize the patient status. A more detailed description is given.

Pneumatic VAD Parameters

Four parameters indicated on the console regulate VAD function. They are heart rate, percent systole, and two drive line pressure gauges. Heart rate for the device has a maximum rate of 199 bpm. It is normally set between 75 and 100 bpm. Consideration needs to be given if the device is supporting one ventricle or both. If only one ventricle, the unassisted ventricle's function is paramount in determining the VAD parameters.

Percent systole reflects the pre-set time interval given for the device to complete ejection. Percent systole indirectly determines filling time or diastole.

In a normal cardiac cycle, systole takes one third of the total cardiac cycle. Sufficient time is necessary for adequate filling of the device during diastole and for complete ejection during systole. The percent systole reflects this balance. It is typically set greater than 300 msec or forty to fifty percent of the cardiac cycle (Ley, 1991). A longer percent systole permits lower drive pressures needed to pump the blood from the device. An internal vacuum can be applied to facilitate filling during the shorter diastolic phase. A negative pressure between 0 to 150 mmHg on the exhausted air maximizes filling (Mays et al, 1986).

The drive line pressure is the amount of force required to propel the blood from the VAD. An adequate drive line pressure is 75 mmHg above the patient's systolic blood pressure. High pressures cause hemolysis and may indicate increased afterload. Treatment for high drive line pressures includes giving vasodilators such as Nipride to reduce afterload and/or increasing the percent systole to distribute the pressure over a greater period of time.

VAD Waveforms

Waveform analysis allows interpretation of the device's performance as well as the hemodynamic condition of the patient. Cardiac output is calculated by measuring the amount of air that leaves the ventricle during diastole. This amount of air is proportional to the VAD's stroke volume (Robinson et al., 1989). The computer in the console calculates the cardiac output by heart rate times the stroke volume.

A horizontal axis on the waveform indicates complete filling of the device. With complete filling, the blood flow temporarily stops while waiting for ejection. The VAD ideally uses partial filling to keep the blood flow moving. This reduces

the risk of thrombus formation due to blood stasis (Henker et al. , 1988).

A small spike at the end of the ejection phase is the signal of complete ejection. The spike indicates the membrane is completely stretched, ejecting all the blood within the device. The spike on ejection also shows extra reserve within the device to accommodate more preload or to pump against a higher afterload if the patient's condition changes within a certain range. The goal for VAD drive line pressure via waveform analysis is to maintain partial filling during diastole with full ejection each cycle (Henker et al. , 1988). (See figure 3) Over driving the VAD system is seen when the device is programmed to accommodate a larger workload. The over drive waveform is characterized by a plateau at the end of the ejection phase. (See figure 4) Hypovolemia causes the device to overdrive. Under driving the VAD system is seen when the device is programmed to handle a smaller workload. The device is overextended and unable to accommodate extra volume or pressure. The under drive waveform is characterized by a square shape. (See figure 5) Underdriving occurs with a hypertensive crisis or exercise. Assessing VAD waveforms aids in achieving optimal filling, ejection and output from the device.

VAD Emergencies

Emergency conditions require immediate intervention by the bedside nurse. Delays while notifying the perfusionist or the physician can be lethal. An example of a life threatening emergency is the disconnection of the tubing. The nurse must intervene immediately or the patient will exsanguinate. Quickly clamping the tubing as close to the patient as possible is imperative (Mulford, 1987). Other emergent situations the bedside nurse needs to know are categorized

Figure 3: VAD Waveforms

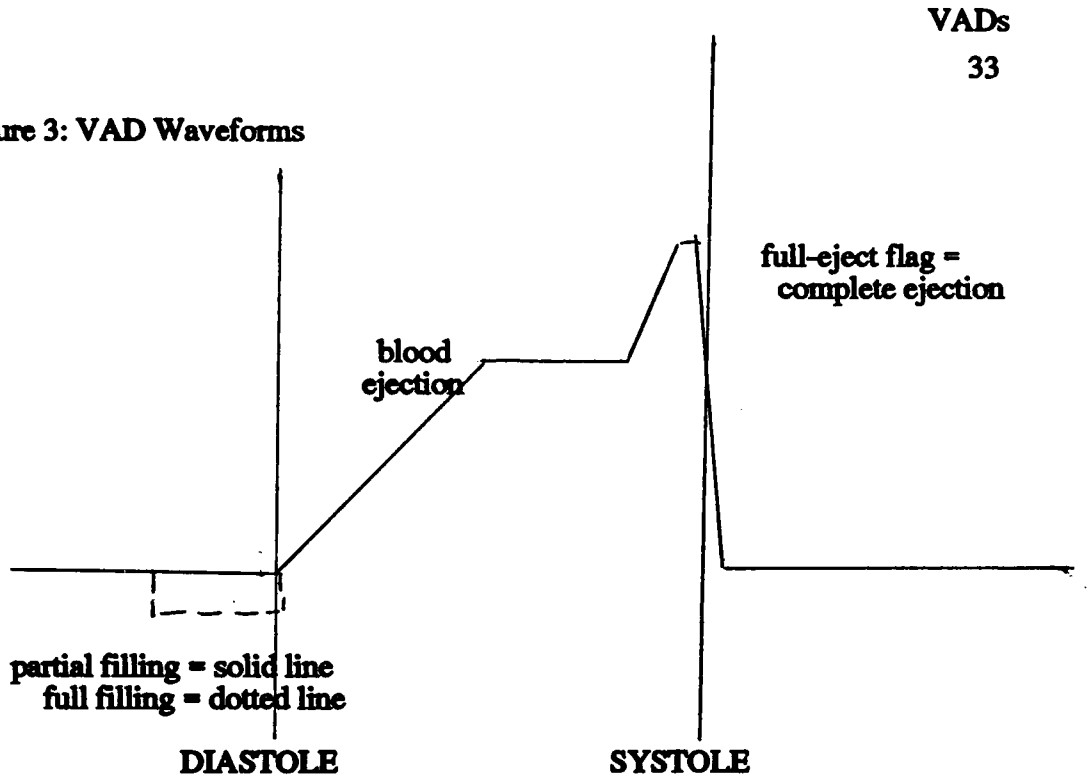


Figure 3: The ideal waveform with partial filling and complete ejection.

Figure 4: Over drive waveform

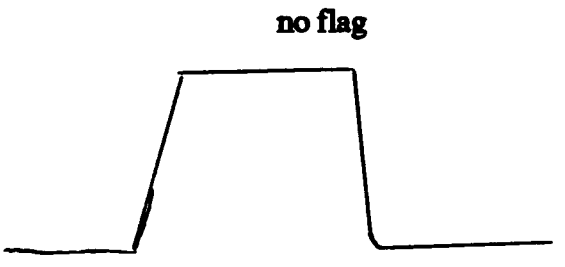


Figure 5: Under drive wave form

by an alarm system built into the console. Red lights infer potentially life-threatening situations, requiring immediate attention. Examples are low drive pressures, low cardiac output, or an extreme right to left imbalance. Flashing orange and yellow lights indicate a less urgent situation. An example is the activation of the back-up or reserve tanks of pressurized air to run the pneumatic system. The nurse must know which energy source is being used to prevent the loss of a power source in the future. A periodic tone also indicates the use of battery power to run the electrical system (Mays et al., 1986). Accurate assessment of the situation determines the appropriate intervention. Nurses must be able to evaluate the patient and the VAD to act quickly and appropriately.

A final mechanical emergency a nurse must recognize is pump failure. A second back-up unit should always be in the room, preset to substitute with the primary system if the need arises. VAD failure is suspected when the number of revolutions per minute is progressively higher to achieve the same flow rate. This indicates an increase in resistance somewhere within the system. Thrombus formation or a kink in the tubing could cause increased resistance. Another potential cause is the malfunction of the valves in the pump. Through hourly documentation, changes in the number of revolutions without an increase in flow rate are detected. Assessment with appropriate notification or intervention prevents a no flow crisis.

Clinical emergencies may also be patient-related. Cardiac arrest or ventricular fibrillation are handled similarly to the usual procedure except no external cardiac massage is performed (Mondejar, 1979). The flow rate for the device is increased to maintain perfusion. Hypertensive episodes cause underdriving of the

VAD system due to the increased systemic pressure. Drive line pressures may need to be temporarily increased to overcome the higher resistance. The main efforts are to reduce the blood pressure.

Patient Assessment

A systems approach for patient assessment is applied to organize the variation in assessment due to the VAD and potential complications associated for each system. Vigilant surveillance of the VAD patient is essential for optimal care and patient outcome. Sound clinical skills plus a thorough understanding of the VAD technology aids the nurse in providing quality patient care.

Neurological System

Assessment of the neurological system in the VAD patient presents two different clinical pictures. Some patients are alert and oriented while others are heavily sedated and paralyzed. Either patient requires frequent neurologic exams. Neurologic evaluations are done to assess the perfusion of the brain and are a good index of systemic blood flow (Mondejar, 1979). Neurological evaluation commonly include the Glascow Coma Scale to assess neurologic status through level of consciousness, pupil response, and motor function (Miller & Pitz, 1989). Complications associated with general VAD support frequently are detected much earlier in the neurological system. Examples are bleeding, emboli and / or hypoxia. Detection by routine neurological exam can decrease the severity or limit the extent of damage to the patient. Nursing care is discussed in regards to the specific diagnoses relating to the neurological system.

Potential for injury due to bleeding. The focus for nursing care of VAD patients is to prevent coagulopathies. Bleeding is a problem in the immediate

post-operative period and should be controlled within twelve to twenty-four hours (Abou-Awdi, 1991). Recommendations for coagulation studies are every four hours. Maintaining a normal range of values for coagulation prevents bleeding disorders.

Interventions center on identifying a potential for bleeding before the injury occurs. Chest tube drainage is measured hourly and should be less than 100 ml/hr during the first four hours. A gradual decrease of drainage is noted over the next eight to twelve hours. Any deviation is reported to the physician. Bleeding is also assessed in endotracheal secretions, nasogastric drainage, and urinary output. Other interventions include administering blood products and crystalloids to maintain adequate blood volume. Fresh frozen plasma is given if the prothrombin or partial prothrombin times are prolonged. Platelets are given for a low platelet count. Platelets are frequently needed due to the cell lysis from the cardiopulmonary bypass machine.

Neurologic assessments are crucial to prevent or minimize deficits. Changes in pupillary reaction, motor deficit or changes in the level of consciousness may indicate cerebral hemorrhage (Mulford, 1987). Sedation and paralytic drugs affect patient's responses to neurologic exams and must be considered.

Potential for injury due to thrombus formation After controlling post-operative bleeding, the next challenge with the VAD patient is to prevent thrombus formation. Heparin drips are determined by the design of the system or if the blood flow through the device is less than 2 L/min. The partial prothrombin time for anticoagulation ranges between 150 and 200 secs. Patients using the VAD as a bridge to transplant are placed on a anticoagulation protocol

immediately. This protocol initially anticoagulates the VAD patients with a heparin drip but converts the patient to oral medication for long-term use. Other considerations to prevent thrombosis formation is to purge the system at regular intervals to prevent stasis of blood. With the centrifugal system, pump heads are changed every 24 to 48 hours to prevent clot formation.

Alteration in tissue perfusion (hypoxia) related to low cardiac output. The primary goal of VAD support is to maintain adequate circulation to all organ systems. Inadequate cerebral perfusion is detected much earlier than other organ systems by subtle changes in the patient's sensorium. Adjusting the VAD flow rates or ventilatory setting improves systemic oxygenation / perfusion. Early detection is the key to injury prevention.

Alteration in comfort related to postoperative pain, presence of invasive lines and immobility. Adequate pain control as determined by the patient is another goal of nursing care. Pain assessment should reflect type, degree, location, and duration of the discomfort. Offer the patient back care and repositioning as well as analgesics to relieve discomfort. Evaluate effects of analgesics. Reassure the patient that steps will be taken to relieve the pain.

Potential for sensory overload / sensory deprivation related to environmental influences. An overall concern of nursing care is to promote patient physiological and psychological well-being. The critical care environment itself can negatively influence the patient's psychological well-being. Noise and the lighting cause physiological and behavioral changes. Physiological responses to noise may be an increase in heart rate, blood pressure, sodium and water retention, and a rise in cortisol and cholesterol levels (Riegel, 1989). Sources of

noise in the critical care environment are found everywhere. Mechanical equipment, alarms, movement of people and objects all create noise. In addition there is noise from people talking, coughing or patients' moaning. Behavioral responses are seen by the patient's inability to problem solve, restlessness, nervousness, and/or a disturbed sleep pattern (Riegel, 1989). The artificial lighting influences the patient's circadian rhythm and may cause sleep deprivation. A higher incidence of depression is reported with patients not exposed to natural sunlight (Riegel, 1989). Research is looking at a special fluorescent light which mimics natural sunlight as a potential treatment. The noise and vibration from the VAD also initially contribute to sleep deprivation (Shinn, 1991). Over time the VAD noise is a comfort to the patient, confirming everything is working.

Accurate assessment of the patient's perception is necessary to plan the appropriate intervention. Some patients experience sensory overload from the same environmental stimuli that others paradoxically experience as sensory deprivation (Riegel, 1989). Patients who have sensory overload report noise being irritating to them. Stimuli should be limited, providing a more quiet environment. Methods to control the noise level are to use curtains or private rooms to separate the patient from the noise, cover the equipment with a towel to absorb some noise, or face the patient away from the noise source reducing the stimuli. It is recommended to screen the number of non-family visitors while allowing the family to have quiet time alone with the patient.

Patients experiencing sensory deprivation while in the critical care environment report feeling bored. These patients need more stimuli for their

psychological well-being. Encourage family visits. Personalize the patient's room with cards and pictures. Support diversional activities through the occupational therapy department.

Other efforts for both sensory overload and deprivation center around maintaining the patient's circadian rhythm to promote normal sleeping patterns. Structure nursing care together for minimal disruption to sleep cycles. Sleep cycles average 90 minutes to 2 hours (Droppert & Kilian, 1992). Allow the patient a complete cycle. Another method to promote adequate sleep is to maintain a day/ night orientation by turning off lights during normal sleep periods.

Another factor in the patient's perception of the critical care environment is the level or degree of pain and anxiety experienced by the patient. Pain and anxiety inhibit restful sleep which increases sleep deprivation and ultimately distorts the patient's perception of environmental stimuli (English, 1989). An intervention is to explain to the patient and family what to expect while in the critical care setting, decreasing the level of anxiety. Pain relief is another essential component to help the patient tolerate the critical care environment.

Cardiovascular System

Assessment of the cardiovascular system focuses primarily on the patient's hemodynamic parameters and cardiac rhythm. Auscultation of the heart sounds is difficult due to the clicking noise from the VAD. Proper functioning of the VAD is primarily dependent on adequate filling. The VAD can only deliver what volume it receives. Central venous pressure, pulmonary artery pressure, or left atrial pressure lines directly measure the filling pressures. To ensure adequate

VAD output, optimal fluid status and cardiac rhythm are needed.

Monitoring cardiac output in the VAD patients is the most integral aspect of patient care. Every system in the body is dependent on the heart's ability to deliver oxygen and nutrients. Cardiac output measures the delivery of blood to the cells and organ systems. The original problem of inadequate delivery or blood flow is compensated by the VAD. The nurse's responsibility is to ensure adequate delivery is maintained throughout the hospitalization. Cardiac output is dependent on heart rate, preload (fluid status) and afterload. Contractility is augmented by the VAD. Determining cardiac output poses a dilemma in the VAD patient. Patients supported by a left VAD use the typical thermodilution method to calculate cardiac output. But, patients supported by a right VAD need to use the Fick equation to determine cardiac output since the VAD alters the flow (Ley, 1991). Description of potential problems with each determinant of cardiac output facilitates the assessment of cardiac output as the final nursing diagnosis.

Potential alteration in tissue perfusion related to dysrhythmias. Heart rate is one determinant of cardiac output. Alterations in heart rate negatively affect cardiac output. Dysrhythmias reduce stroke volume and increase myocardial oxygen consumption. Even though the pneumatic VADs can provide sufficient output during dysrhythmias, it is beneficial to normalize the heart rate. Ideally, heart rate ranges between 60 and 100 bpm. Pacing is indicated to augment a slower rhythm or to convert a supraventricular tachycardia to a normal rhythm. Antiarrhythmic drugs are also indicated for ventricular irritability. Manual compressions during cardiopulmonary resuscitation is not recommended due to the risk of dislodging the cannulas but cardioversion or defibrillation may be

attempted after medication efforts fail.

Potential for fluid volume deficit related to hypovolemia or bleeding. Hypovolemia is a common problem with VAD patients. It is recognized by low atrial pressures with a low cardiac output. Treatment is to stabilize the vital signs and filling pressures with adequate fluid therapy. Colloid products are preferred over crystalloids because they provide a greater intravascular expansion and decrease fluid requirements (Ley, 1991). Blood products are administered according to the patient's hematocrit and platelet count. The fluid therapy's goal is to maintain the filling pressure of the right atrium or central venous pressure at 5 to 15 mmHg and the left atrium pressure at 10 to 15 mmHg (Ley, 1991). Adequate filling pressures optimize preload for the VAD which ultimately improves cardiac output and organ perfusion.

Alteration in cardiac output related to decreased myocardial contractility. Low cardiac output or a low flow state negatively affects every organ system. Therefore, the primary rationale for using a VAD is to augment circulation. Afterload is another determinant of cardiac output. Systemic vascular resistance represents the afterload the VAD must overcome to pump the blood out to the systemic circulation. Systemic vascular resistance should range between 800 and 1000 dynes/sec/m2. Vasodilators, such as nitrates, are used to reduce afterload . Contractility is the last determinant of cardiac output and is augmented as needed by the device.

A common complication of VAD support is failure of the unassisted ventricle. Low cardiac output associated with an elevated atrial pressure in the unsupported ventricle and a low atrial pressure in the supported ventricle indicates failure of

the unsupported ventricle. Ventricular assist devices commonly unmask ventricular dysfunction of the unsupported ventricle. Research shows that fifty percent of the patients using a left VAD demonstrate right heart failure (Pierce et al., 1989). Treatment for right heart failure is to support the failing ventricle with inotropes and fluid therapy. Isoproterenol is the drug of choice for right heart failure due to the positive inotropic effect plus it reduces pulmonary vascular resistance or right ventricular afterload. Right VAD may be indicated with severe failure.

In review, potential problems associated with a low cardiac output can be divided into bilateral or unilateral problems. Bilateral problems of high atrial pressures associated with a low cardiac output indicate pump failure or a surgical emergency such as cardiac tamponade. Bilateral low atrial pressures with a low cardiac output indicate hypovolemia. Unilateral problems with one atrial pressure elevated and the other atrial pressure low or normal indicate failure of the unsupported ventricle or a kink in the cannula.

Pulmonary System

Assessment of the pulmonary system by auscultation is limited due to the noise from the VAD. Other indicators are used to assess the patient's pulmonary status. Monitoring the patient's oxygen saturation, arterial blood gas results, and respiratory rate are clues for the nurse. Daily chest X-rays also help identify pulmonary pathology. A goal for VAD patients is early extubation within twenty-four to forty-eight hours post VAD insertion (Ley, 1991). Complications associated with the pulmonary system largely stem from prolonged intubation. As soon as the hemodynamic parameters are stable and the effects of anesthesia

subside, the patient is extubated.

Impaired gas exchange related to atelectasis / sedation / immobility. Maintaining adequate oxygenation and early detection of pulmonary complication are the essential elements of nursing care with the pulmonary system. Patient's color of skin, mucous membranes, and nail beds indirectly assess the level of oxygenation. Oxygen saturation and arterial blood gas results directly reflect the lungs ability to oxygenate the blood. Adjusting the ventilator settings may be necessary to provide adequate oxygen levels to the patient. Oxygen therapy aims at maintaining the pO2 greater than 75 mmHg, the pCO2 less than 45 mmHg, and the oxygen saturation greater than 95 percent (Ley, 1991). Hypoxemia initially may be due to pulmonary edema or a mild form of adult respiratory distress syndrome (ARDS) from the aggressive fluid resuscitation. Severe hypoxemia or shock lung may result from multiple transfusions (usually greater than 30 units of RBCs) due to post-operative bleeding. Severe hypoxemia associated with an elevated central venous pressure and a normal chest X-ray may indicate a patent foramen ovale with right to left shunting (Ley, 1991). Pierce (1989) identified a patent foramen ovale as a problem with the VAD unmasking an otherwise asymptomatic pathology. Another important aspect to improve gas exchange is to maintain a patent airway. Suctioning the patient's airway as needed is a vital nursing responsibility .

Potential for infection related to invasive lines and the depressed immune response of VAD patients. Infections occur in VAD patients as often as sixty-one percent. Survival rate for VAD patients with infections drops significantly. Pneumonia is the leading cause of septic complications in VAD patients (Ley,

1991; Pierce et al., 1989; McBride et al., 1987). Research directly related septic complications to the duration of mechanical support (McBride et al., 1987; Termuhlen et al., 1987). Infectious complications are due to nosocomial organisms not opportunistic pathogens (Griffith et al., 1988; McBride et al., 1987). Nosocomial infections indicate the need for the health care providers to practice good handwashing and prevent the spread of organisms. One study did report a possible link with VAD insertion and a profound t-cell lymphopenia (McBride et al., 1987). This link could be a contributing factor with VAD patients developing nosocomial infections.

Nurses must use aseptic technique in order to prevent unnecessary exposure to pathogens. Information from monitoring patient's temperature, white blood cell counts, and changes in secretions will identify and allow earlier interventions in treatment of infections. Certain institutions have developed antibiotic protocols to reduce the risk for infections (Ley, 1991; Pierce et al., 1989; Reedy et al., 1989). Other methods to reduce the risk of infections are early extubation and patient mobilization. Patients who are using the VAD as a bridge to cardiac transplant have all unnecessary invasive lines removed by post-op day four to minimize risk (Abou-Adwi, 1991). Adequate nutrition also has been identified as a key to preventing infections (Pierce et al., 1989).

Alteration in mobility related to VAD insertion. Complications associated with immobility such as pneumonia and skin breakdown need to be avoided. Protocols for activity levels are used to guide the VAD patient's rehabilitation process to prevent these complications. Early ambulation is especially important for the VAD patients awaiting cardiac transplant who needs to improve their

physical condition for a better post-transplant outcome. Patients who remain sedated and paralyzed present the greatest challenge to the nurse. For these patients, proper body alignment and frequent repositioning are critical. Air mattresses or specialty beds offer another alternative. Physical therapy starts within twenty-four hours after VAD insertion to prevent musculoskeletal breakdown. Passive range of motion is the initial intervention. As the patient's condition permits, the patient is encouraged to get out of bed, increasing activity level as tolerated. Within two weeks, the patient ambulates in the room. By week three, the patient ambulates in the hall and rides a stationary bicycle in the room (Ley, 1991; Reedy et al., 1989).

Gastrointestinal System

Assessing the gastrointestinal system by auscultation again is complicated by the noise of the VAD. Other indicators are used to assess the gastrointestinal function such as daily weights, laboratory values, nasogastric tube residuals, and presence of flatus or stool. The importance of adequate nutrition cannot be stressed enough to prevent complications.

Potential for nutritional deficit related to limited intake and an increase metabolic demand. The goal for VAD patients is to achieve a positive nitrogen balance. This balance is evident by stable daily weights and normal laboratory values, such as electrolytes and protein levels. Tube feedings should start as soon as normal function returns to the bowel. Ideally, tube feedings start within forty-eight hours after VAD insertion (Ley, 1991). Tube feedings provide a source of nutrition and protect the mucosal lining of the gastrointestinal tract. Parental nutrition can supplement enteral feedings if the patient is unable to tolerate the

full daily requirements. Recommended daily intake should exceed 3,000 cal/day (Ley, 1991; Reedy et al., 1989). In addition to tube feedings providing nutritional support, tube feedings protect against bacterial translocation through the gastrointestinal tract. Bacterial translocation is thought to occur during low flow states and ultimately to lead to MSOF (Fink, 1991).

Genitourinary System

The method of assessment for the genitourinary system for VAD patients is essentially unchanged. The important point is the significance renal failure has in regards to VAD patient survivability. Renal failure is the greatest negative indicator for survival with VADs (Golding et al., 1992; Pennington et al., 1989; Termuhlen et al., 1989; Bernhard et al., 1985). These findings supports the significance of monitoring renal function and to minimize potential renal complications.

Potential for alteration in tissue perfusion: renal failure related to low cardiac output. Acute tubular necrosis from prolonged hypotension or a low flow state is thought to cause postoperative renal failure (Swartz, 1992; Ruzevich, 1991). Renal function is measured by monitoring fluid intake and output in addition to laboratory values. Urine output should remain greater that 0.5 to 1 cc/kg/hr indicating adequate perfusion to the kidneys. Laboratory studies give a more detailed indication of renal function, focusing on electrolyte, BUN and creatinine values. Another contributing factor to renal pathology is hemoglobinemia. Hemolysis occurs from the cardiopulmonary bypass machine and is cleared through the kidneys within the first twenty-four hours. Persistent hemolysis, lasting longer than twenty-four hours, indicates a current problem. Plasma

hemoglobin levels determine the amount of hemolysis occurring (Henker et al., 1991). Adjusting the VAD parameters decreases hemolysis. Therapies to correct renal failure imbalances include ultrafiltration, peritoneal dialysis, or hemodialysis (Barden & Lee, 1990).

Psychosocial System

The heart represents more to society than just a muscle that pumps blood (Henker, 1991, p. 604). A person's emotions are linked to the heart. Recognizing the significance of the heart to the patient and family enables the nurse to better understand what this illness means. Ventricular assist devices are used as a last ditch effort to save someone's life, indicating the use of VADs represents a family crisis of immense proportions. Crisis management and continual psychological support for both the patient and the family are imperative (Barden & Lee, 1990; Hravnak & George, 1989).

Alteration in Body Image related to heart failure, VAD insertion. With the heart having such emotional significance attached to it, patients may feel they are losing a very special part of themselves. Inform the patient and family what is involved with the day-to-day living with a VAD as a life-line. Discuss potential implications for life changes. Encourage verbalization of the patient's and family's fears, concerns and anger associated with the need for a VAD. In cases where the patient is intubated or heavily sedated, provide an appropriate method to facilitate communication. Convey empathy and understanding to the patient and family and offer other support networks to help the patient grieve the change in lifestyle (Stetich, Empey, & Sassmor, 1986). The patient's psychological outlook influences the chance for recovery (Ruzevich, 1991).

Potential alteration in individual and family coping related to life threatening illness. Achievement of the goal to help patients and family members cope more effectively during a crisis situation relies on decreasing the level of fear and anxiety associated with the illness. The patient and family are grieving the loss of a lifestyle, hopes or dreams. Nursing needs to support the patient and family through the stages of grief at a pace that allows an adequate level of functioning (Baas & Johantgen, 1988; Henker et al., 1988) Anger is a normal phase in the grieving process but can be minimized through a better understanding of the situation. Developing a trusting relationship between the primary nurse and the patient / family is essential in order to offer effective support throughout the hospitalization. Open communication and active listening are keys to establishing a trusting relationship. All questions must be answered honestly at the appropriate level of understanding with a realistic atmosphere of hope. Remain calm and reassuring to the family at all times. Initially, daily conferences between the primary nurse, physician and the family offer the family a direct line of information when they desperately need answers. Prepare the patient and family for any procedures or tests to decrease the level of anxiety of something new.

Another method to increase the level of functioning within the family is to facilitate family visiting. Individualize visiting hours to accommodate the family's needs and allow for privacy. The patient and family need time to work through this stressful experience. Family roles are temporarily or permanently altered. The patient may become depressed with the feeling of dependency to others and the VAD for support. By giving the patient choices in the daily

schedule, the patient's sense of independence may increase. Encourage the patient to maintain his /her identity as much as possible in the hospital setting.

Weaning

The decision to wean the patient off the VAD support is based on criteria relating to the recovery of the native ventricles. Patients who required the VAD support due to cardiomyopathy do not wean. The VAD is a bridge to transplant until a donor heart can be found (Whitman, 1990). The importance of predicting when a patient can wean from the VAD stems from the positive correlation between the length of time on VAD support and the rate of complications. Indication of ventricular recovery is determined by the native heart contribution to the total cardiac output. Subtracting the VAD flow rate from the total systemic blood flow gives the native heart's output (Teplitz, 1990). Weaning trials are not attempted until after the VAD is in place for more than twenty-four hours. This time frame was established from research findings reporting poor patient outcomes if weaned earlier than twenty-four hours (Termuhlen et al., 1987). If there is no potential for weaning within the first week, it is recommended to place the patient on the list for transplantation.

Weaning protocols vary from institution to institution. The method of weaning depends on the type of device inserted. Assessing the patient's readiness to wean from the VAD is tested daily by an on-off approach. Turning off the VAD for 15 seconds allows the nurse to assess the ability of the native ventricle to accommodate an increased amount of blood flow. Left arterial pressure guides the weaning process by determining the heart's readiness to assume the full work load. If the left atrial pressure rises to greater than 30 mmHg, the patient is not

ready to wean. If the left atrial pressure remains between 20 and 25 mmHg for 60 seconds plus maintains a systolic pressure greater than 100 mmHg, a cardiac output is measured. The cardiac index must be at least 2.0 L/m/m2 to continue the weaning process (Teplitz, 1990; Ruzevich et al., 1988; Gaines et al., 1985). Clamping the cannulas during the on-off periods causes an increased risk for thrombus formation (Pennington et al., 1989). If the patient is ready to wean, the VAD flow rate is reduced by fifty percent.

Another method to predict the ability to wean is by gradually reducing the VAD flow rates by 200 to 400 ml/min. This method of weaning allows the native ventricle to assume the workload more gradual. Constant assessment is necessary to determine if the native ventricle is capable of weaning. If the patient tolerates the increased flow rates for four to six hours, the VAD is reduced by another fifty percent. Heparinization is recommended at this point of the weaning process to prevent thrombosis formation unless the device already required heparin administration (Reedy et al., 1989).

Pneumatic VAD systems offer a variation to flow weaning. Weaning can be done similar to the IABP by adjusting the frequency of support. Using the fixed mode, VAD support can be titrated to every second or third heart beat. Minimal VAD rate is 40 bpm. The roller and centrifugal system only wean by flow adjustment. The key to weaning is total awareness of the patient's hemodynamic status and the tolerance to the weaning process.

Removal of the VAD occurs after the patient is maintained on a low flow rate of 400 to 600 ml/min for approximately eight to twelve hours (Teplitz, 1990). The goal of weaning is to remove the VAD with minimal vasoactive drug support.

Biventricular support may warrant two weaning processes due to the ventricles recovering at different rates (Whitman, 1990).

Ethical Considerations

The goal of circulatory assist devices and the artificial heart is to improve quality of life as well as to save lives according to the Cardiology Advisory Committee of the National Heart Lung Blood Institute (NHLBI). The Cardiology Advisory Committee's philosophy is if there are a substantial number of people whom a device would benefit, is cost effective, and the device is not inherently dangerous or dehumanizing, it is appropriate to proceed with the development of a permanent device (Cardiology Advisory Committee, 1977). Society must face the difficult decision concerning the allocation of resources . Estimated total cost for a permanent artificial device is $150,000 in 1983 dollars (Van Citters et al., 1985). This figure includes the implantation and maintenance costs for the projected four and one-half years of survival expected with a permanent device. The cost for a VAD is comparable to other high cost therapies such as heart transplantation, renal dialysis or bone marrow transplantation. But widespread use of high cost technology displaces funds that might be invested more wisely. For example, family planning, prenatal care programs, well-baby clinics, dental and visual screening have been discontinued or drastically cut due to lack of funds (Krekeler, 1988). Society expects availability and success with all medical technology without accepting the costs. The ethical dilemma facing society is distributive justice, how to fairly distribute the limited available resources. Ventricular assist device technology provides a needed treatment modality. The question is not whether VAD technology should be pursued but how all high-cost

technology is going to be dispersed.

Summary

Management of the VAD patient is crucial to improve survivability. Thorough assessment and evaluation of the patient and the device ensure adequate perfusion necessary to achieve positive patient outcomes. Early detection of problems decreases the extent and severity of complications. Early weaning is crucial to prevent complications frequently associated with VAD support. Ethical concerns deal with the use of high cost technology, not unique to VAD technology. Society needs to face difficult choices concerning all high cost technology.

CHAPTER 4

Implications for Advanced Nursing Practice

The interaction between human physiology and VAD technology creates a dynamic, multi-system situation. To ensure positive patient outcomes, both the proper device functioning and adequate patient perfusion need consideration. The American Association of Critical Care Nurses (AACN) believes the critical care clinical nurse specialist (CNS) is essential to the management of complex, systems-related patient problems (AACN, 1989). Optimal patient outcomes necessitate integrating the five roles of the CNS to effectively and efficiently manage VAD patients. Expert clinical skills and in-depth knowledge enables the CNS to anticipate and to evaluate the unique needs of the VAD patient and the family.

Advanced Practitioner

The CNS masters cognitive and psychomotor skills necessary for diagnosis, treatment, and evaluation of the human response to actual or potential life-threatening problems (AACN, 1989). Ventricular assist device technology affects every system in the human body. Evaluating the human response to the VAD is imperative to manage care for this unique patient population. The CNS has the necessary skills to evaluate VAD effectiveness in relationship to the human body. Early interventions eliminate potential life-threatening emergencies and promote positive patient outcomes.

The CNS also is responsible and accountable for developing standards of care and protocols for nursing practice. Protocols and standards of care incorporate research findings into practice to promote quality patient care. Protocols designed

for VAD patients target potential complications associated with the device. The rationale for instituting interventions before a problem develops is to reduce the incidence of complications. For example, VAD protocols focus on activity rehabilitation, antibiotic therapy, and anticoagulant therapy to help the staff address potential problems before common complications associated with VAD technology occur. Evaluation of these protocols determines the effectiveness of the specific intervention. Nursing research lacks in evaluating effectiveness of nursing interventions. The CNS is crucial to actively participate in not only the development and institution of research-based protocols, but also must evaluate organizational policies and standards to promote quality patient care.

By virtue of the clinical expertise and in-depth knowledge of a particular clinical population, CNSs are expert coaches to the patients while role modeling for the staff (Koetters, 1989). The technological-dependency of VAD patients places the patient and family in an unfamiliar environment. The staff also is typically unfamiliar with VAD technology due to the infrequency of VAD utilization. The CNS is instrumental in not only guiding the patient and family through a life-threatening crisis but fosters learning with the staff on the workings of the VAD.

Role modeling is another benefit of direct patient care by the CNS. The CNS serves as a guide of excellence, demonstrating timely, quality , cost-effective expert nursing care (Menard, 1987). This encourages the staff to strive for the same level of excellence as the CNS. But CNS's role modeling goes beyond bedside nursing to promote all aspects of professional nursing. The combination of advanced education , expert clinical practice, inter professional relationships,

and involvement in professional activities colors the staff 's perception of the CNS role and nursing. The positive, professional image the CNS provides while caring for VAD patients encourages others to provide the same high quality care. By documenting specific experiences with VAD patients, CNSs can aid other professions and institutions to learn valuable lessons and ultimately to improve care for future VAD patients.

A final contribution of the advanced practitioner is as a clinical resource. The CNS must be a skilled decision maker (Menard 1987). If unsure of an answer, the CNS must strive to find an answer in a timely manner. The CNS must be reliable and dependable when asked to help the staff or the patient for an answer to a question. Dependability maintains the confidence of the staff and the patient, facilitating the effectiveness of the CNS.

Ethical and legal concerns also challenge the staff and CNS when caring for VAD patients. The CNS uses collaborative efforts with other health care professionals and the institution's bioethics committee to give direction and support to the staff on specific patient situations. The advanced practitioner role overlaps frequently with the other CNS's roles of educator, consultant, researcher, and manager. The CNS must assume the role most beneficial to accomplish the task at hand. The ultimate responsibility of the CNS is the patient's welfare. If at any time the patient's welfare is severely compromised, the CNS must step in and act as a clinical expert to ensure patient safety.

Educator

Education of patients, families, and staff hinges on the CNS 's ability to anticipate patient and staff needs. Assessment of patient and staff needs directs

the CNS to plan appropriate interventions. Staff first must assess the patient's perception of the illness and the patient's readiness to learn before beginning to teach a patient. The perception of the illness is crucial to the patient's psychological outlook and willingness to learn which directly influences patient outcome. Evaluation of the patient's perception is critical to caring for VAD patients. The connection between the heart and people's emotions may cause an added fear to the hospitalization for VAD patients. How the VAD patient views the illness and it's impact on the future lifestyle may warrant additional time to process the implications associated with the need for VAD technology. The CNS is instrumental in implementing appropriate support services to help the VAD patient and family adjust to the various changes. Coordination between the CNS and other disciplines such as dietary, physical therapy, and occupational therapy helps prevent information overload for the patient and family.

The goal for the CNS is to provide effective learning for each individual patient throughout the hospitalization (Priest, 1989). Evaluation is an integral part of the learning process and must be incorporated into the learning strategy to ensure effective learning. A study on IABP instruction to patients and family members documented patients and families prefer individual instruction over audiovisual methods (Goran, 1989). Time restraints limit the use of individual instruction. The benefit of written instructions and video tapes is the option for the family to refer back to information when they are mentally and emotionally ready to receive more explicit information.

The CNS educates the staff by acting as a role model in actual patient care activities and by organizing formal inservice programs. Ongoing inservice

programs or workshops are suggested to keep the staff familiar with the VAD system (Cleavinger et al., 1989; Swartz et al., 1989). The infrequency of VAD patients in the critical care setting illustrates the important role the CNS occupies to maintain quality care with the VAD patient. The CNS can serve as a resource person to help staff identify potential and/or actual patient problems. Another component of the CNS's educational role with VAD patients is to publish articles on VAD technology and personal experience caring for VAD patients. Dissemination of information concerning the care of VAD patients among health care professionals is essential to improve patient outcomes.

Consultant

As the CNS becomes more proficient in the role, the focus of practice changes from direct patient care to more scholarly activities and consultation. Consultation is a process of communication between professionals. It is a collaborative relationship. The goal of consultation is acquisition of problem solving skills. The CNS, as a consultant, openly discusses which responsibilities are to be shared, divided, or assumed by each health care professional (Barron, 1989). Through negotiation of roles, the CNS clarifies the responsibilities associated with this complex, multi-discipline clinical problem of providing VAD support.

Consultation can be a formal process initiated by a written contract or an informal process of assessing and giving recommendation to a specific problem. Formal consultations may come from outside the critical care area or institution. Informal consultation can occur during patient rounds. Managing the VAD patient requires the CNS to use consultation to coordinate with other related

disciplines the plan to provide optimal care for this complex patient group. The CNS maintains communication with the Transplant Program, Infectious Disease Department, Hematology Department, Biomedical Engineers, and others essential departments to effectively plan the care for VAD patients.

Researcher

The CNS is in an ideal position to bridge the gap between research and clinical practice. The CNS needs to expand the scientific knowledge that current nursing practice is based on by utilizing, facilitating, and conducting nursing research in the critical care setting (AACN, 1987). Research findings improve patient care only if the findings are disseminated and utilized by the bedside nurse. The CNS is responsible to incorporate research findings into protocols and standards of care to establish unit-based expectations of patient care. The CNS also may need to act as a change agent to facilitate implementation of new standards. Actual research endeavors may not be a practical option in all environments. The CNS must assess the institution's readiness for and commitment to research before starting a research project.

Other opportunities to participate in research besides conducting actual studies include roundtable discussions on current research findings, collaboration in other studies, or quality assurance investigations (McGuire & Harwood, 1989). A basic research expectation of a CNS is to evaluate, communicate, and incorporate research findings applicable into clinical practice. Identifying potential research questions from clinical problems is another expectation from the American Nurses' Association Guidelines for the Investigative Functions of Nurses (1981).

Nursing research with VAD technology is limited. The majority of studies are

descriptive studies, listing patient complications and outcomes associated with VAD support. Henker, Smith, & Murdaugh (1988) looked at the effects of nursing interventions on cardiac output in patients with a total artificial heart (TAH). A major limitation of the study was the small sample size (N = 6). Obtaining a large enough sample size for generalization continues to present a problem in conducting research on new technology such as VAD support. Another reason the findings of Henker, Smith, & Murdaugh study cannot be generalized to all VAD patients is due to the difference between partial support with the native heart contributing to the total cardiac output and total hemodynamic control seen with the TAH. Suggested areas of future research include:

1) the effect of positioning on hemodynamic parameters
2) the effects of nursing interventions on partial VAD support
3) the difference in the amount of blood products used between the pneumatic system and the centrifugal system.
4) the difference between left VAD cardiac output measurements as compared to a pulmonary artery catheter readings (computer accuracy vs. the standard thermodilution method)
5) the effectiveness of the various VAD protocols (i.e. antibiotic protocol and infection rates)
6) the effectiveness of family teaching in regards to anxiety levels
7) the patient's perception on the quality of life with VAD support
8) the impact of the CNS has on patient and family satisfaction
9) the rate of complications in units with a designated CNS and

without a CNS

On the VAD support team, a research person is assigned to collect and evaluate date. Another role of the research person is to coordinate regulatory affairs and multicentered studies (Swartz et al., 1989). The CNS is identified as a key person to collaborate with the research person or actually be the research person for the VAD team.

Manager

Caring for VAD patients is both a multi-system and a multi-discipline problem. This dynamic interaction creates a challenge to coordinate effectively all aspects of care necessary to achieve positive patient outcomes. The CNS combines management and leadership skills to positively influence the delivery of patient care (Gournic, 1989). Management focuses on the organizational goals. A manager sets objectives, organizes, motivates, and communicates these objectives, measures performance and most importantly develops the potential of the people (Gournic, 1989). A leader influences positive change by communication and moral building. Both personal and professional goals are important with a leader.

Clinical nurse specialists may have a line position, giving legitimate power to implement change. But a line position potentially can cause the CNS to trade-off staff's openness and comradery with the legitimate authority to enforce necessary change. Whether in a line or staff position, the CNS as a manager is responsible to evaluate staff performance and the quality of patient care. Evaluating the staff and patient care influences the planning of future educational programs and research activities. Again, combining all the roles of the CNS to provide quality

care.

Cost containment is another reality of today's economic environment. The CNS is instrumental to the organization by implementing cost saving strategies. Patient selection and preventative measures against complications reduce ineffective utilization of VAD technology. The CNS must take an integral part in assessing factors to decrease morbidity and mortality associated with VAD support. Product evaluation of items used with VAD patients is another area CNSs can actively participate in analyzing and saving the organization money. Marketing the CNS 's expertise with VAD technology can generate revenue for the organization by offering programs and consultation services to other institutions. As a manager, the CNS is keenly aware of the organization's goals and financial viability.

Summary

The CNS blends the roles of advanced practitioner, educator, consultant, researcher, and manager to enhance the quality of patient care. Advanced nursing practice promotes the orderly transfer of technology from the laboratory to clinical practice in VAD patients. The CNS facilitates collaboration between health care professions culminating in a synergistic process of achieving optimal patient outcomes. Effective inter- and intra-discipline work promotes safe, effective, holistic quality care for VAD patients and their family.

References

Abou-Awdi, N. L. (1991). Thermo cardiosystems left ventricular assist device as a bridge to cardiac transplant. AACN Clinical Issues in Critical Care Nursing, 2 (3), 545-551.

American Association of Critical-Care Nurses (1989). AACN's competence statements for differtiated nursing practice in critical care. Newport Beach, CA: Aurthor.

Ayres, S., Schlichtig, R., & Sterling, M. (1988). Care of the Critically Ill (3rd ed.). Chicago: Yearbook Medical Publishers, Inc.

Baas, L., & Johantgen, M. (1988). Heart transplantation: a case study. Journal of Cardiovascular Nursing, 2 (2), 68-72.

Barden, C., & Lee, R. (1990). Update on ventricular assist devices. AACN Clinical Issues in Critical Care Nursing, 1 (1), 13-30.

Barron, A. (1989). The CNS as consultant. In A. B. Hamric & J. A. Spross (Eds.), The Clinical Nurse Specialist in Theory and Practice (pp. 125-146). Philadelphia: W. B. Saunders.

Bernhard, W. F., Clay, W., Gernes, D., Hougen, T., Sherman, C., Burke, D., Schoen, F. J., & Poirier, V. L. (1985). Temporary and permanent left ventricular bypass: laboratory and clinical observations. World Journal of Surgery, 9 (1), 54-64.

Brannon, P. H., & Towner, S. B. (1986). Ventricular failure: new therapy using the mechanical assist device. Critical Care Nurse, 6 (2), 70-84.

Cardiology Advisory Committee. (1977). Mechanically assisted circulation: the status of the NHLBI program and recommendations for the future.

Washington, DC: U. S. Government Printing Office.

Centers for Disease Control. (1989) Chronic disease reports: coronary heart disease mortality, United States, 1986. Mortality & Morbidity Weekly Report, 38, 285-288.

Centers for Disease Control. (1992). National hospital discharge survey: annual summary, 1990. Vital and Health Statistics, 13 (112), 1-20.

Cleavinger, M. R. , Smith, R. G. , Loffing, D. H. , Nelson, R. J. , & Sato, D. J. (1989). The circulatory assist device program at University Medical Center. Critical Care Nursing Clinics of North America, 1 (3), 515-525.

Droppert, B. M. , & Kilian, K. (1992). Psychological impact of critical care. In M. Vazquez, S. E. Lazear & E. Larson (Eds.), Critical Care Nursing (pp. 116-121). Philadelphia: W. B. Saunders.

Elbeery, J. R. , Owen, C. H. , Savitt, M. A. , Davis, W. , Feneley, M. P. , Rankin, J. S. , & VanTrigt, P. (1990). Effects of the left ventricular assist device on right ventricular function. The Journal of Thoracic and Cardiovascular Surgery, 99, 809-816.

English, M. A. (1989). Preventing complications of ventricular assist devices. Dimensions of Critical Care Nursing, 8 (6), 330-336.

Farrar, D. J. , Compton, P. G. , Hershon, J. J. , Fonger, J. D. , & Hill, J. D. (1985). Right heart interaction with the mechanically assisted left heart. World Journal of Surgery, 9 (1), 89-102.

Fink, M. P. (1991). Gastrointestinal mucosal injury in experimental models of shock, trauma, & sepsis. Critical Care Medicine, 19 (5), 627-638.

Gaines, W. E.. , Pierce, W. S. , Donachy, J. H. , Rosenberg, G. , Landis, D. L. ,

Richenbacher, W. E., & Waldhausen, J. A. (1985). The Pennsylvania State University paracorporeal ventricular assist pump: optimal methods of use. World Journal of Surgery, 9 (1), 47-53.

Golding, L. A., Crouch, R. D., Stewart, R. W., Novoa, R., Lytle, B. W., McCarthy, P. M., Taylor, P. C., Loop, F. D., & Cosgrove, D. M. (1992). Postcardiotomy centrifugal mechanical ventricular support, Annuals of Thoracic Surgery, 54, 1059-1064.

Goran, S. F. (1989). Family perceptions of the intra-aortic balloon pumping experience. Critical Care Clinics of North America, 1 (3), 475-477.

Gournic, J. L. (1989). Clinical leadership, management and the CNS. In A. B. Hamric & J. A. Spross (Eds.), The Clinical Nurse Specialist in Theory and Practice (pp. 227-250).
Philadelphia: W. B. Saunders.

Griffith, B. P., Kormos, R. L., Hardesty, R. L., Armitage, J. M., & Dummer, J. S. (1988). The artificial heart: infection-related morbidity and its effect on transplantation. Annuals of Thoracic Surgery, 45 (4), 409-414.

Henker, R. (1991). Cardiac assist devices as a bridge to cardiac transplant. AACN Clinical Issues in Critical Care Nursing, 2 (3),598-605.

Henker, R., Smith, R. G., & Murdaugh, C. (1988). Effects of nursing interventions on cardiac output in the patient with a total artificial heart. Journal of Cardiovascular Nursing, 2 (2), 56-67.

Hravnak, M., & George, E. (1989). Nursing considerations for the patient with a total artificial heart. Critical Care Nursing Clinics of North America, 1 (3), 495-513.

Koetters, T. L. (1989). Clinical practice and direct patient care. In A. B. Hamric & J. A. Spross (Eds.), The Clinical Nurse Specialist in Theory and Practice (pp. 107-124). Philadelphia: W. B. Saunders.

Krekeler, K. (1988). Dividing health resources ethically: organ transplants for a few versus comprehensive care for many. In B. S. Heater & B. AuBuchon (Eds.), Controversies in Critical Care Nursing (pp. 115-123). Rockville, MD: An Aspen Publication.

Kriett, J. M. , & Kaye, M. P. (1990). The registry of the International Society for Heart Transplantation: seventh official report, 1990. Journal of Heart Transplantation, 9 (4), 323-330..

Laurent-Bopp, D. (1989). Heart failure. In S. L. Underhill, S. L. Woods, E. Froelicher, & C. J. Halpenny (Eds.), Cardiac Nursing (pp. 561-570). Philadelphia: J. B. Lippincott.

Ley, S. J. (1991). The Thoratec ventricular assist device: nursing guidelines. AACN Clinical Issues in Critical Care Nursing, 2 (3), 529-544.

Litwak, R. S. , Koffsky, R. M. , Jurado, R. A. , Lukban, S. B. , Saha, C. K. , Vrandecic, M. , Mindich, B. , Mitchell, B. , King, P. , & Kaminsky, L. (1978). Support of severely impaired cardiac performance with left-heart assist device following intracardiac operation. Heart & Lung, 7 (4), 622-627.

Litwak, R. S. , Koffsky, R. M. , Jurado, R. A. , Mitchell, B. A. , & King, P. (1985). A decade of experience with a left heart assist device in patients undergoing open intracardiac operation. World Journal of Surgery, 9 (1), 18-24.

Loveys, B. J. (1989). Complications of acute myocardial infarctions. In S. L.

Underhill, S. L. Woods, E. Froelicher, & C. J. Halpenny (Eds.), Cardiac Nursing (pp. 517-526). Philadelphia: J. B. Lippincott.

Magovern, G. J. , Park, S. B. , & Maher, T. D. (1985). Use of a centrifugal pump without anticoagulants for postoperative left ventricular assist. World Journal of Surgery, 9 (1), 25-36.

McGuire, D. B. & Harwood, K. V. (1989). The CNS as researcher. In A. B. Hamric & J. A. Spross (Eds.), The Clinical Nurse Specialist in Theory and Practice (pp. 169-204). Philadelphia: W. B. Saunders.

Marchetta, S. , & Stennis, E. (1988). Ventricular assist devices: applications for critical care. Journal of Cardiovascular Nursing, 2 (2), 39-55.

Mays, J. B. , Williams, M. A. , Barker, L. E. , Hastings, L. , & DeVries, W. C. (1986). Diagnostic monitoring and drive system management of patients with total artificial heart. Heart & Lung, 15 (5), 466-475.

McBride, L. R. , Ruzevich, S. A. , Pennington, D. G. , Kennedy, D. J. , Kanter, K. R. , Miller, L. W. , Swartz, M. T. , & Termuhlen, D. F. (1987). Infectious complications associated with ventricular assist device support. Transactions of American Society of Artificial Organs, 33, 201-202.

McGee, M. G. , Zillgitt, S. L. , Trono, R. , Turner, S. A. , Davis, G. L. , Fuqua, J. M. , Edelman, S. K. , & Norman, J. C. (1980). Retrospective analysis of the need for mechanical circulatory support (intraaortic balloon pump / abdominal left ventricular assist device or partial artificial heart) after cardiopulmonary bypass. The American Journal of Cardiology, 48, 135-142.

McKay, R. G. . , Penny, W. F. , Wyman, R. M. , Clay, W., Carr, J. G. , Bernhard, W. F. , & Grossman, W. (1991). Hemodynamic evaluation of a chronically

implanted, electrically powered left ventricular assist system: responses to acute circulatory stress. Journal of the American College of Cardiology, 18 (7), 1779-1786.

Menard, S. W. (1987). The CNS as practitioner. In S. W. Menard (Ed.), The Clinical Nurse Specialist: Perspectives on Practice (pp. 81-100). New York: John Wiley & Sons.

Mickleborough, L. L. , Rebeyka, I. , Wilson, G. J. , Gray, G. , & Desrosiers, A. (1987). Comparison of left ventricular assist and intra-aortic balloon counterpulsation during early reperfusion after ischemic arrest of the heart. The Journal of Thoracic and Cardiovascular Surgery, 93, 597-608.

Miller, K. , & Pitz, K. (1989). Symbion acute ventricular assist device: nursing challenge. Dimensions of Critical Care Nursing, 8 (3), 43-55.

Miller, C. A. , Pae, W. E. , & Pierce, W. S. (1990). Combined Registry for the clinical use of mechanical ventricular assist devices: postcardiotomy cardiogenic shock. Asaio Transactions, 36 (1), 43-46.

Mondejar, E. (1979). The patient with left heart assist device: nursing management. Heart & Lung, 8 (2), 296-301.

Mulford, E. (1987). Nursing perspectives for the patient receiving postoperative ventricular assistance in the critical care unit. Heart & Lung, 16 (3), 246-255.

National Centers for Health Statistics. (personal communications, February 12, 1993).

Norman, J. C. , Cooley, D. A... , Igo, S. R. , Hibbs, C. W. , Johnson, M. D. , Bennett, J. G. , Fuqua, J. M. , Trono, R. , & Edmonds, C. H. (1977). Prognostic indices for survival during postcardiotomy intra-aortic balloon

pumping: methods of scoring and classification with implications for left ventricular assist device utilization. The Journal of Thoracic and Cardiovascular Surgery, 74,(5), 709-720.

Pennington, D. G. (1990). Circulatory support at the turn of the decade: a clinician's view. Asaio Transactions, 36 (3), 126-131.

Pennington, D. G. , Joyce, L. D. , Pae, W. E. , Burkholder, J. A. (1989). Patient selection: panel discussion. Annuals of Thorac Surgery, 47, 77-81.

Pennington, D. G.. , McBride, L. R. , Swartz, M. T. , Kanter, K. R. , Kaiser, G. C., Barner, H. B. , Miller, L. W. , Naunheim, K. S. , Fiore, A. C. , & Willman, V. L. (1989). Use of the Pierce-Donachy VAD in patients with cardiogenic shock after cardiac operations. Annuals of Thoracic Surgery, 47, 130-135.

Pennock, J. L , Pae, W. E. , Pierce, W. S. , & Waldhausen, J. A. (1979). Reduction of myocardial infarct size: comparison between left atrial and left ventricular bypass. Circulation, 59 (2), 275-279.

Pierce, W. S. (1984). The implantable ventricular assist pump. The Journal of Thoracic and Cardiovascular Surgery, 87, 811-813.

Pierce, W. S. , Gray, L. A. , McBride, L. R. , & Frazier, O. H. (1989). Other postoperative complications. Annuals of Thoracic Surgery, 47, 96-101.

Priest, A. (1989). The CNS as educator. In A. B. Hamric & J. A. Spross (Eds.), The Clinical Nurse Specialist in Theory and Practice (pp. 147-168). Philadelphia: W. B. Saunders.

Quaal, S. (1991). Cardiac assist devices: Preface. AACN Clinical Issues in Critical Care Nursing, 2 (3), 475-476.

Reedy, J. E. , Ruzevich, S. A. , Swartz, M. T. , Termuhlen, D. F. , & Pennington,

D. G. (1989). Nursing care of a patient requiring prolonged mechanical circulatory support. Progress in Cardiovascular Nursing, 4 (1), 1-9.

Riegel, B. (1989). Stressors of critically ill patients. In B. Riegel & D. Ehrenreich (Eds.), Psychological Aspects of Critical Care Nursing (pp. 17-30). Rockville, MD: An Aspen Publication.

Robison, P. D. , Pantalos, G. M. , & Olsen, D. B. (1989). Pneumatically powered blood pumps used as a bridge to cardiac transplantation: characteristics and development. Critical Care Clinics of North America, 1 (3), 485-494.

Rutan, P. M. (1991). Mechanical support beyond the intra-aortic balloon pump. AACN Clinical Issues in Critical Care Nursing, 2 (3), 477-487.

Ruzevich, S. (1991). Heart assist devices: state of the art. Critical Care Nursing Clinics of North America, 3 (4), 723-732.

Ruzevich S. A. , Swartz, M. T. , Reedy, J. E. , Termuhlen, D. F. , McBride, L. R. , Frese, S. M. , & Pennington, D. G. (1989). Retrospective analysis of the psychologic effects of mechanical circulatory support. Journal of Heart Transplant, 9, 202-212.

Ruzevich, S. A. , Swartz, M. T. , & Pennington, D. G. (1988). Nursing care of the patient with a pneumatic ventricular assist device. Heart & Lung, 17 (4), 399-405.

Schoen, F. J. , Palmer, D. C. , Bernhard, W. F. , Pennington, D. G. , Haudenschild, C. C. , Rattiff, N. B. , Berger, R. L. , Golding, L. R. , & Watson, J. T. (1986). Clinical temporary ventricular assist. Journal of Thoracic and Cardiovascular Surgery, 92, 1071-1081.

Shinn, J. A. (1989). Circulatory assist devices. In S. L. Underhill, S. L. Woods,

E. Froelicher, & C. J. Halpenny (Eds.), Cardiac Nursing (pp. 571-584). Philadelphia: J. B. Lippincott.

Shinn, J. A. (1991). Novacor left ventricular assist system. AACN Clinical Issues in Critical Care Nursing, 2 (3), 575-586.

Simpson, M. , Luquire, R. , & Dewitt, L. (1990). TCI left ventricular assist device: nursing implications. Dimensions of Critical Care Nursing, 9 (6), 318-326.

Smith, R. G. , & Cleavinger, M. (1991). Current perspectives on the use of circulatory assist devices. AACN Clinical Issues in Critical Care Nursing, 2 (3), 488-499.

Spross, J. A. (1989). The CNS as collaborator. In A. B. Hamric & J. A. Spross (Eds.), The Clinical Nurse Specialist in Theory and Practice (pp. 205-226). Philadelphia: W. B. Saunders.

Stetich, J. , Empey, D. , & Sasmor, M. (1986). The initial surgical intensive care unit nursing experience with the permanent total artificial heart. Heart & Lung, 15 (5), 475-487.

Swartz, M. T. , Ruzevich, S. A. , Reedy, J. E. , Termuhlen, D. F. , & Pennington, D. G. (1989). Team approach to circulatory support. Critical Care Nursing Clinics of North America, 1 (3), 479-484.

Teplitz, L. (1990). An algorithm for ventricular assist devices. Dimensions of Critical Care Nursing, 9 (5), 256-265.

Teplitz, L. (1990). Patients with ventricular assist devices: nursing diagnoses. Dimensions of Critical Care Nursing, 9 (2), 82-87.

Termuhlen, D. F. , Swartz, M. T. , Pennington, D. G. , Samuels, L. D. , McBride,

L. R. , Kanter, K. R. , & Ruzevich, S. A. (1987). Predictors for weaning patients from ventricular assist devices. Transactions of American Society of Artificial Internal Organs, 33, 683-688.

Van Citters, R. L. , Bauer, C. B. , Christropherson, L. K. , Eberhart, R. C. , Eddy, D. M. , Frye, R. L. , Jonsen, A. R. , Keller, K. H. , Levine, R. J. , McGoon, D. C. , Pauker, S. G. , Rackley, C. E. , Willman, V. L. , & Frommer, P. L. (1985). Artificial heart and assist devices: directions, needs, costs, societal and ethical issues. Artificial Organs, 9 (4), 375-415.

Whitman, G. R. (1992). Mechanical assistance for the patient with a failing heart. In B. M. Dossey, C. E. Guzzetta, & C. V. Kenner (Eds.), Critical Care Nursing: Body, Mind, Spirit (pp. 261-288). Philadelphia: J. B. Lippincott.

Woods, S. L. & Underhill, S. L. (1989). Myocardial ischemia and infarction. In S. L. Underhill, S. L. Woods, E. Froelicher, & C. J. Halpenny (Eds.), Cardiac Nursing (pp. 488-508). Philadelphia: J. B. Lippincott.

Zumbro, G. L. , Kitchens, W. R. , Shearer, G. , Harville, G. , Bailey, L. , & Galloway, R. F. (1987). Mechanical assistance for cardiogenic shock following cardiac surgery, myocardial infarction, and cardiac transplantation. Annuals of Thoracic Surgery, 44, 11-13.