

Mechanical Assist Devices for Heart Failure Education

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Abstract

An educational deficit has been noted among Certified Registered Nurse Anesthetists (CRNAs) of varying backgrounds at a prominent hospital in Central Florida. This is also compounded by a minimal number of available research studies and educational text book materials. The educational lecture provided addressed the need for additional knowledge available to fourth semester Student Registered Nurse Anesthetists (SRNAs). This lecture is also available for utilization by current CRNAs at the previously noted hospital.

A convenience sample of 21 SRNAs was utilized. Informed consent and anonymity within the education evaluation process was of paramount concern. No personal data was collected. A pretest and a posttest were provided on a voluntary basis and evaluated for the difference between the two test scores. After completion of the lecture and evaluation, a paired t test was used to compare the results for statistical significance. A p value of < 0.05 was observed, establishing statistical significance. Results obtained concluded that in almost all cases the mean test score significantly increased from the pretest to the posttest. The lecture was made available for future review. The hope is that with increased knowledge, patient safety may be enhanced.

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Problem

Certified Registered Nurse Anesthetists have limited education toward an understanding of mechanical assist devices that help patients suffering from heart failure. A prominent CRNA text book by Barash et al. (2013), dedicates less than 0.0012% of the text toward the understanding of these devices. This text is widely considered to be significant source for the nurse anesthetist's education. This educational deficit and limited understanding requires improvement as CRNAs and SRNAs continue to see this patient populace throughout their educational program and careers.

Recent discussions at a heart transplant hospital with CRNAs revealed apprehension and self-stated lack of understanding concerning the function and utilization of mechanical assist devices (MAD). This stated problem may hinder the appropriate level of care that can be provided to heart failure patients as the mechanical assist device programs across the country continue to grow.

The American Association of Nurse Anesthetists (AANA) is also involved by providing an educational module with examination for continuing education credits. This module provides an update for nurse anesthetists caring for patients with ventricular assist devices (VAD). However, this module addresses the use of VADs only in the non-cardiac setting. This fuels the debate that SRNAs would benefit considerably by improving the education in schools concerning the use of mechanical assist devices. With organizations such as the AANA having built this into the education modules available for current CRNAs reinforces a rise in the importance of strong education in this area.

Review of Literature

The Joint Commission is responsible for accreditation for hospitals across the country. This accreditation body considers ventricular assist devices as part of an advanced practice model. The use of advanced practice techniques before heart transplant has seen a rise from 22 percent in 2007 to greater than 35 percent utilization in 2012 (SRTP, 2013). This represents a 61.8 percent increase. The previously discussed data also shows an almost even number of patients receiving inotropic therapy to those utilizing ventricular assist devices (SRTP, 2013).

A review of current literature demonstrates a lack of relevant research regarding available education for SRNAs and CRNAs on ventricular/mechanical assist devices. A total of five articles were located that spoke directly to the nurse anesthetist population concerning VADs/MADs. There are far more articles available from anesthesiologist and medical sources on the use of VADs/MADs that the anesthetist would find to enhance their knowledge base. However, these articles lack the unique perspective of the SRNAs or CRNAs.

As previously discussed, the AANA presents the most valuable VAD/MAD educational module. The course is presented by Khoo, an SRNA whom provides the reader with an introduction to the biomechanics, indications, anesthetic implications, and complications of VADs. A written test evaluation is provided to validate this article as part of a continuing education credit course. However, this article's application is limited by its applicability to the non-cardiac surgical setting.

One outdated article and one article written for perioperative nurses were noted. This literature review clearly represents a current lack of "knowledge/research" regarding VADs/MADs with a CRNA or SRNA focus. The noted deficit further supports the need for more comprehensive education, designed specifically for the nurse anesthetist.

Project Description

The goal of this project was to educate current graduate level students within the Nurse Anesthesia Program at Adventist University of Health Sciences on the history, indication, function, and use of mechanical assist devices for heart failure patients. By providing a sound foundation for SRNAs as they transition to their role as CRNAs this fulfilled the educational gap related to VADs/MADs. Student Registered Nurse Anesthetists and CRNAs may encounter patients with these devices in a variety of settings. Having the knowledge base to safely and effectively provide care to these patients is essential to the promotion of the profession.

This education was provided in the form of a lecture. The lecture taught included a power point presentation. This presentation included both a discussion and an audiovisual component of current mechanical assist device related topics. The lecture was given during the fourth semester of the program and was one and a half hours in length.

This presentation may in the future be a building block for a learning opportunity for current CRNAs. Practicing CRNAs can enhance their understanding, reduce the self-perceived deficit and improve their confidence with providing anesthesia to the VAD/MAD patient population.

Consent was obtained on a voluntary basis. Participation was not mandatory. Risks within this evaluation process was minimal. Information was provided within the framework of the consent discussing the education, risks, and voluntary nature of participation. When obtaining consent all participants remained anonymous. This was done by utilizing a number assigned to each pretest and posttest. This number allowed for grading to be compared, but no other data about the participant was collected and thus remained anonymous.

Evaluation

Evaluation of the success of this project was in the form of written testing. Objectives of this project and major learning points were evaluated in this test. A pretest was provided before the lecture. The pretest provided the presenters with an adequate assessment of the baseline knowledge the SRNAs possessed at that time. A posttest was provided after the lecture determined the effectiveness of the presented material. Areas of assessment included the SRNAs ability to determine the appropriate indications, biomechanics, anesthetic implications, and complications associated with the use of VADs/MADs.

Post test scores measured the effectiveness of the lecture and indicated a better understanding of VADs and MADs. This statistical data was used to determine the success of the educational piece. An improvement between the pretest and posttest scores, in addition to an awareness to the educational deficit to the current students denoted success of the project. Not all components of the presentation were assessed. However, the pretest and posttest reflected and evaluated the most robust learning opportunities. These correlated to the most important clinical concepts related to the anesthetist's care of the patient with a VAD/MAD.

Statistical analysis of the pretest and posttest scores were evaluated with the assistance of Dr. Roy Lukman using paired t-test. Evaluation of the data collected ensured a concrete comparison of the success of the project. Through this numerical data the effectiveness of the presentation to expand the knowledge base of the SRNAs is reflected. Subjects had an opportunity to dialogue with the presenters to expand on the material presented and to clarify any existing questions regarding the educational piece. In addition, at the conclusion of the project the subjects verbalized the achievement of an enhanced knowledge base for VADs/MADs and anticipated a reduced level of stress if these devices are encountered in the clinical arena.

Results and Conclusions

Fourth semester SRNAs at Adventist University of Health Sciences were provided with a pretest, presentation, and posttest covering VADs and MADs. Of the 21 student participants in attendance, all 21 completed a pretest. The statistics from the pretest reflected a mean score of 4.4286, with a standard deviation of 2.06328. With respect to the sample size and standard deviation a standard error mean of 0.45025 was obtained.

All 21 participants were in attendance and engaged for the complete presentation. Once the presentation was completed the subjects were given an opportunity to question and clarify the presented material. No significant matters of confusion or misunderstanding were noted. Consistent with the number of participants who completed the pretest and presentation, 21 subjects then completed the posttest. The posttest was also subject to statistical analysis and was found to have a mean score of 6.8571, with a standard deviation of 0.85356. With respect to the same values mentioned above, a standard error mean of 0.18626 was obtained.

The pretest and posttest exhibited correlation through the before and after test question consistency and equal sample sizes. Sample statistics were then subjected to paired sample t-test. The paired differences between the pretest and posttest were noted to have a mean value of -2.42857, a standard deviation of 2.22646, and a standard error mean of 0.48585. With 95 percent confidence we can assume the interval difference lies between -3.44205 and -1.41510.

The obtained t value of -4.99 is associated with a p value of <0.05 , therefore statistical significance has been achieved. It can also be concluded that in almost all cases the mean test score significantly increased from the pretest to the posttest. With this data the researchers have concluded that, with implementation of the educational presentation the goals outlined have been achieved.

The objectives of this educational project were to broaden the knowledge base of fourth semester nurse anesthesia students. Education was provided on the function, role, history, and anesthetic considerations of mechanical and ventricular assist devices for heart failure patients. The background research that was completed overwhelmingly supported the need for improved education for SRNAs and CRNAs. Educational deficits were most significantly noted in the area of VAD/MAD knowledge and care principals in various anesthesia settings. Methods outlined were followed without waiver.

All administered assessment and learning tools were implemented according to plan. The pretest administered before the presentation established a baseline of knowledge that the SRNAs currently possessed. The posttest then evaluated the same areas of interest pertaining to VADs and MADs. Of the 21 subjects, 17 improved their scores on the posttest, three showed no change, and one subject's score declined from the pretest to the posttest. This decline can be noted as an outlier.

The quantitative data supports the attainment of the objectives that were set forth. Statistical analysis proves the validity of the research data and the confidence in which it was interpreted. In addition, the feedback received from the participants, although qualitative in nature and not distinguished as a measureable variable, supported the value of this educational presentation. Therefore, this project has been deemed to have been successfully carried out. Fourth semester SRNAs have expanded their knowledge base and are better prepared to encounter the VAD/MAD patient in the clinical setting. It is the hope of the researchers that this educational module can similarly assist CRNAs in the future.

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Appendix A

Informed Consent Form

ADU NAP CAPSTONE PROJECT – INFORMED CONSENT

Our names are Tamara Thomas and Andy Mattison, and we are MSNA students in the Nurse Anesthesia Program (NAP) at Adventist University of Health Sciences (ADU). We are doing a Capstone Project called Mechanical Assist Devices for Heart Failure Education. This project is being supervised by Dr. Steven Fowler DNP, CRNA. We would like to invite you to participate in this project. The main purpose of this form is to provide information about the project so you can make a decision about whether you want to participate.

Our project description:

The purpose of this project is to provide education on ventricular assist devices and mechanical assist devices to SRNAs with the intent to improve future knowledge base.

Participation in this project involves:

If you decide to participate in this project, you will be asked to complete an anonymous pre-assessment, attend a classroom presentation, and then complete an anonymous post-assessment. The assessment will determine the correlation between information acquired during the lecture and SRNAs' knowledge base, thus determining the efficacy of the lecture. Your participation by attendance at the presentation and completion of the survey is anticipated to take approximately 60 minutes.

Our decision to select you as students:

You have been invited to participate as part of a convenience sample of students currently enrolled in the ADU NAP. Participation in this project is voluntary. If you choose not to participate or to withdraw from the project, you may do so at any time.

Risks within this project:

Although no project is completely risk-free, we don't anticipate that you will be harmed or distressed by participating in this project.

Benefits within this project:

We expect the benefit to include a better knowledge base toward ventricular assist devices and mechanical assist devices. This knowledge base may also indirectly improve your potential care for this patient populace.

HOW WILL THE INVESTIGATORS PROTECT PARTICIPANTS' CONFIDENTIALITY?

The results of the project will be published, but your name or identity will not be revealed. To maintain confidentiality of assessments, the investigators will conduct this project in such a way to ensure that information is submitted without participants' identification. In order to maintain student anonymity, each test will use a set of numbers for identification in place of student

names. Each student will be provided with a number that will be used for both the pretest and the posttest. The investigators will not have access to any participants' identities.

WILL IT COST ANYTHING OR WILL I GET PAID TO PARTICIPATE IN THE PROJECT?

Your participation will cost approximately 60 minutes of your time, but will require no monetary cost on your part. You will not be paid to participate.

VOLUNTARY CONSENT

By signing this form, you are saying that you have read this form, you understand the risks and benefits of this project, and you know what you are being asked to do. The investigators will be happy to answer any questions you have about the project. If you have any questions, please feel free to contact Tamara Thomas at ta.dashun.thomas@my.adu.edu and Andy Mattison at Kenneth.mattison@my.adu.edu. If you have concerns about the project process or the investigators, please contact the Nurse Anesthesia Program at (407) 303-9331.

Participant Signature

Date

Participant Name (PRINTED LEGIBLY)

Appendix B

Power Point Lecture

Mechanical Assist Devices

Tamara Thomas, SRNA
 Andy Mattison, SRNA
 Mentor: Dr. Christopher Miller, MD
 Advisor: Dr. Stephen Fowler, CRNA, DNP

Function

- * Assists cardiac output
- * Improves end organ perfusion
- * Promotes coronary perfusion
- * Optimized cardio-pulmonary function
- * Cardiogenic shock criteria for implantation



History

- * VADs were invented in 1962 at Baylor by Domingo Liotta
- * First VAD inserted successfully in 1966 for a post cardiomy cardiogenic shock



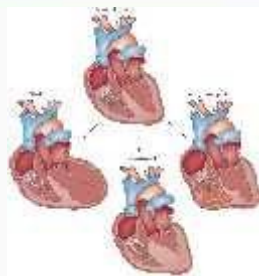
IABP

- * Polyethylene balloon utilized on a catheter
- * Inserted generally via the femoral artery
- * Best positioning is 2cm from the left subclavian artery in the descending aorta.
- * Helium or CO2 for inflation of the balloon



Heart Failure

- * Systolic vs Diastolic
- * Eccentric vs Concentric



Types of Devices

- * Short term or Long term
- * Right side or Left side or Both
- * Pulsatile vs Non-pulsatile
- * Implanted vs External
- * Right sided Impella still in trials and not FDA approved



Impella

Impella2.5 and CP



Impella5.0



Ventricular Assist Device



Impella RP



Indications

- * *Bridge to Recovery
- * Bridge to Immediate Survival
- * Bridge to Bridge
- * Bridge to Next Decision
- * *Bridge to Transplant
- * Bridge to Improved Candidacy
- * *Bridge to Destination

IABP vs Impella (PROTECT II trial) Assessing outcome during high risk PCI

IABP

- * Currently more common mode of treatment for PCI
- * Still showed an equivalent increase in LVEF (6%) and ASA class after revascularization

Impella2.5

- * 25% reduction in major adverse event after 90 days
- * Study stated better hemodynamic support then IABP during high risk procedures.

Pump Sizes

As the pumps get smaller...



Types of VADs

Short Term

- Abiomed BVS5000 – Pulsatile
- Abiomed AB5000 – Pulsatile
- Thoratec – Pulsatile
- CentriMag – Nonpulsatile

Long Term

- Heartmate XVE – Pulsatile
- Thoratec – Pulsatile
- IVAD – Pulsatile
- CardioWest TAH – Pulsatile
- Heartmate II – Nonpulsatile**
- Jarvik2000 – Nonpulsatile (in trials)

Non-Pulsatile

Advantages

- Reduced hemolysis
- Lower change of embolic event
 - Newer VADs have less contact with bearings

Disadvantages

- Possibility of poor functioning pulse oximetry
- Possibility of poor NIBP monitoring
- No pulse for arterial line insertion

Pulsatile

- Advantages
 - Pulse oximetry and NIBP function appropriately
- Disadvantages
 - Clotting and hemolysis
 - Typically external devices



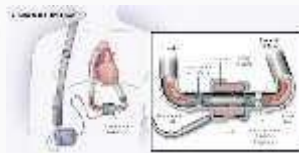
Heartmate II

- Bridge to Destination
- Afterload SVR
- Rotary laminar flow
- Into Intact
- Flow: inflow cannula, outflow conduit, rotary assembly, blades, drive line
- Flow: Controller, Battery, Console display (flow, speed RPM, Power consumption, PI), Drive line



Non-Pulsatile

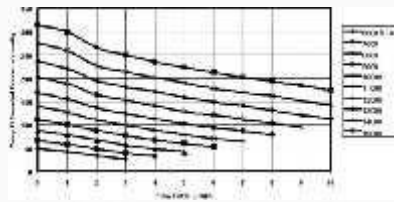
- Rotating axial or centrifugal



Heartmate II Pulsatility Index

- PI is the magnitude of flow pulses measured and averaged over 15 second intervals
- PI = VAD support
- PI = VAD support

H-Q Curve



Jarvik2000



Heart Mate II

Controller with batteries



Jarvik2000



Non-Pulsatile Xray
Specifically the Heartmate II



Complications

- * Infection
- * Bleeding with anticoagulation
- * Suction event
 - * Vacuum or gravity related issues
- * Coiling with Impella
- * Malposition to pump failure
- * Catheter kink or fracture
- * Hemolysis
- * Aortic dissection
- * AV or MV damage
- * Inflow or outflow cannula dislodgement with chest compressions
- * RV failure is the leading cause of mortality and morbidity after LVAD insertion

Suction Event

Recognize

- Hypotension
- Hypovolemia
- Arrhythmias
 - Including VT with loss/decrease in pump speed.
- Sudden pulsatility index (PI) decrease
- Sudden pump speed decrease

Evaluate

- RV failure
- Speed settings
- Volume status
- Inflow conduit
- Obstruction

Anesthetic Management

Preload/Afterload

- Starling's Law
- Total volume dependence
- Preload = Pump flow
- Afterload = LVAD
- Blunt SNS response

HR/ Arrhythmias

- Maintain SR
 - Rate control
- Evaluate cause and treat
 - Apply external/grounding pads
 - Defibrillation/cardioversion
 - Bipolar cautery

Suction Event Management

- Add volume or blood
- Decrease pump speed
- Reposition patient
- Surgically remove clot or other obstruction



Anesthetic Management Utilizing Pulsatility Index

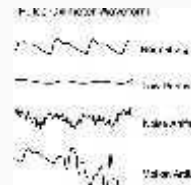
- Pulse oximetry corresponds to pulsatility index
- If the pulse ox waveform decreases in amplitude and mean pressure is decreasing consider volume before vasopressors
- Pulse oximetry variation may be a sign of volume related issues

Anesthetic Management

- RV improvement
 - Milrinone
 - Inhaled Nitric Oxide
 - Inhaled prostacyclin



Pulsatility Index vs Pulse Oximetry



Anesthetic Considerations

- * All Considered "Full Stomach"
 - * RSI
- * Neuraxial - advantageous but consideration must be given to anticoagulation
- * Regional techniques
- * Induction
 - * Minimise a decrease in contractility of right ventricle
- * Positioning
 - * Reverse Trendelenburg, Lateral, Trendelenburg, Prone
- * Blood products plasma and platelets. Use cautiously (periop bleeding)
 - * Antibodies may lead to future heart transplantation
- * HR is not dependable as it relates to anesthetic depth
- * Ventilation
 - * Negative pressure - desirable, positive pressure - undesirable*
 - * Spontaneous ventilation is preferred to facilitate venous return
- * Aline = ultrasound in non-pulsatile, serial ABGs with GA
- * PA and CVP monitoring
- * EEG monitoring (BIS), cerebral oximetry
- * No chest compressions
- * TEE for diagnostic imaging

Appendix C

Test Questions & Answer Key

1. The three main indications for Ventricular Assist Device (VAD) therapy include:
 - a. Bridge to transplant
 - b. Destination therapy
 - c. Bridge to recovery
 - d. All the Above

2. The criteria for Mechanical Assist Device (MAD) implantation for shock patients is:
 - a. Cardiogenic shock
 - b. Anaphylactic shock
 - c. Hypovolemic shock

3. Chest compressions are indicated for patients with a proper functioning VAD:
 - a. False
 - b. True

4. Obtaining a blood pressure with the most current VAD technology can be acquired with noninvasive measures:
 - a. True
 - b. False

5. MADs improve cardiac output by:
 - a. Increasing contractility
 - b. Increasing flow
 - c. Decreasing contractility
 - d. Adjusting Volume

6. An Impella RP sits between the inferior vena cava and _____.
 - a. Aorta
 - b. Pulmonary arteries
 - c. Mitral valve
 - d. Carotid artery

7. If a patient is experiencing suction events, a common way to alleviate this issue is by:
 - a. Decreasing Preload
 - b. Give the patient Lasix
 - c. Give Epinephrine
 - d. Increasing Preload
8. What is a common clinical and mechanical sign of a suction event?
 - a. Ventricular Tachycardia and a momentary decrease in pump RPMs
 - b. Sinus Bradycardia and constant RPM increase
 - c. 1st degree AV block with no change in pump speed
 - d. An unknown paced rhythm with a loss of pump speed

Answer Key

1. D
2. A
3. A
4. A
5. B
6. B
7. D
8. A