EFFECT OF STROKE VOLUME VARIATION MONITORING ON ACUTE KIDNEY INJURY AFTER ROBOTIC ENHANCED RECOVERY PROTOCOL SURGERY

by

Lloren Mckenzie Hile

A doctoral scholarly project submitted to the faculty of
The University of North Carolina at Charlotte
in partial fulfillment of the requirements
for the degree of Doctorate of Nursing Practice

Charlotte

2023

Approved by:

_____
Dr. David Langford

_____
Dr. Karen Lucisano

_____
Dr. Job Chen

_____
Dr. Patricia Crane

_____
Dr. Jennifer Richards

_____
Dr. Mike Turner

ABSTRACT

LLOREN MCKENZIE HILE. Effect of Stroke Volume Variation Monitoring on Acute Kidney Injury after Robotic Enhanced Recovery Protocol Surgery.
(Under the direction of DR. DAVID LANGFORD)

Acute kidney injury (AKI) is one of the most common complications after abdominal, colorectal, and gynecologic surgeries at a large urban trauma center in the southeast. This is exacerbated by the conditions of robotic enhanced recovery protocol (ERP) procedures. Robotic surgery and enhanced recovery protocols each have characteristics that lead to an increased risk of acute kidney injury. Stroke volume variation (SVV) is obtained from an invasive monitor that can measure the fluid balance of an individual under general anesthetic with mechanical ventilation. This measure is not used for every procedure in the operating room and is typically reserved for high-risk individuals or specific procedures. This project used a retrospective correlational approach to examine the difference in AKI occurrence between a group with SVV monitoring and a group without SVV monitoring. The data were collected from the electronic medical record from May 2022 through August 2022. These groups had similar age and gender profiles. The non-SVV group had a higher average anesthesia time and American Society of Anesthesiologists (ASA) score. The non-SVV group had a 15% occurrence of AKI, while the SVV group had 0% AKI occurrence. This project showed a relationship between SVV monitoring and a decreased occurrence of AKI and suggests that SVV monitoring should be considered for patients at a high risk of developing an acute kidney injury.

DEDICATION

This scholarly project paper is dedicated to my parents and brother, Martin, Llori, and Wade Hile who have always pushed me to work hard and pursue my dreams. They created a safe and loving environment that made me into the person I am today. Additionally, Reid and Jack Farber who have been vital to my success in nurse anesthesia school and a constant stream of love and support. Thank you all for your joy and peace that has brought me through this process.

ACKNOWLEDGEMENTS

I would like to acknowledge the help of many team members, without whom this project would not have been possible. My team members, Mark Fortygin and Ana Arias, who contributed to the two other arms of this project were instrumental in the success of this project. Dr. Sherry Bernardo, the Director of Anesthesia Clinical Quality and Practice at Atrium Health, gave access to data and aided in navigating the EHR for data collection. Dr. Deepu Ushakumari who aided in the development of our individual project topics. Dr. Elena Meadows was an important partner in developing the project topic and project plan. Dr. Karen Lucisano had a significant role in the data collection and analysis of the project. Dr. Job Chen was an immense help in developing the statistical analysis of the results. Finally, the project director Dr. David Langford who had an influential position in the project development from start to finish.

TABLE OF CONTENTS

LIST OF TABLES vii
LIST OF FIGURES viii
LIST OF ABBREVIATIONS ix
CHAPTER 1: INTRODUCTION 1
Problem statement 1
Background 3
Purpose 4
PICOT Question 5
CHAPTER 2: LITERATURE REVIEW 6
CHAPTER 3: METHODOLOGY 9
Conceptual/theoretical framework 9
Methodology and study design 9
Setting 9
Sample 10
Measurement tools 10
Data collection 11
Data management/confidentiality 12
Data analysis 13
CHAPTER 4: RESULTS 14
CHAPTER 5: DICUSSION 16
Implications 16
Limitations/strengths 17
Recommendations 18
REFERENCES 19
APPENDIX A: Data Sheet 23
APPENDIX B: Timeline 24
APPENDIX C: Wake/Atrium IRB Approval 25
APPENDIX D: UNCC IRB Approval 26

LIST OF TABLES

TABLE 1: Descriptive analysis and comparison between nonsvv and svv groups 14

LIST OF FIGURES

FIGURE 1: Descriptive analysis and comparison between nonsvv and svv groups 13

LIST OF ABBREVIATIONS

AH	Atrium Health
AKI	acute kidney injury
ASA	American Society of Anesthesiologists
CMC	Carolinas Medical Center
EHR	electronic health record
ERP	early recovery protocol
GDT	goal-directed therapy
KDIGO	kidney disease improving global outcomes
NSAID	non-steroidal anti-inflammatory drugs
SVV	stroke volume variation
UOP	urine output

CHAPTER 1: INTRODUCTION

Problem Statement

Two improvements in surgical techniques include using robotic equipment and reducing patient's use of opioids called Enhanced Recovery Protocol (ERP). Patients undergoing robotic procedures with enhanced recovery protocols may have an increased risk of developing an acute kidney injury (AKI). Robotic surgeries and enhanced recovery protocols (ERP) each have attributes that, when combined, place patients at risk for developing AKI. The Kidney Disease Improving Global Outcomes (KDIGO) guidelines define AKI as an "increase in serum creatinine >0.3 mg/dL in 48 hrs or urine output (UOP) <0.5 ml/kg/hr for 6-12 hours" (KDIGO, 2012). More concerning, AKI development can lead to increased complications and hospital costs (Joo et al., 2016; Kong et al., 2018). While studies have examined AKI development in these populations separately, the risks associated with robotic ERPs have not yet been studied.

There is an average of five robotic cases per day at Atrium Health (AH) Carolinas Medical Center (CMC), leading to approximately 25 cases per week, totaling 1,300 cases per year (Atrium Health, 2019). In addition, AKI is the most common complication in both colorectal and abdominal service lines and the fourth most common complication in the gynecologic service line at CMC Main (CMS MedPar, 2018).

There are factors related to the technique of robotic surgeries that could increase the risk of developing AKI. These factors include abdominal insufflation with carbon dioxide and extreme Trendelenburg positioning in some procedures (Naito et al., 2020; Sato et al., 2020). Insufflation pressure can collapse the vasculature in the abdomen and reduce renal blood flow, while steep Trendelenburg drives blood volume toward the head. In addition, robotic surgeries

generally have longer surgical times than open procedures, increasing patients' exposure to anesthesia and surgical stress (Joo et al., 2016).

Enhanced Recovery Protocols (ERP) are being implemented in hospital systems across the country to improve patient recovery times and reduce reliance on opioids. Enhanced recovery protocols are a series of guidelines for surgical procedures meant to decrease recovery times after surgeries and improve patient outcomes (Zorrilla-Vaca et al., 2020). One of the complications of ERP have been increases in AKI development (Koerner et al., 2019). A primary tenet of enhanced recovery protocols is restricted fluid administration during procedures, which may lead to decreased renal perfusion. Another foundation of enhanced recovery protocols is the decreased use of opioids, which relies on more nonsteroidal anti-inflammatory drug (NSAID) use which potentially affect kidney function (Zorrilla-Vaca et al., 2020). Inhibition of the vasodilatory effects of renal prostaglandins from NSAIDs, paired with perioperative conditions such as reduced blood flow to the kidneys, place patients at increased risk for reduced kidney function (Bell et al., 2018). Many factors of ERP procedures could impact the risk of AKI development, but there is uncertainty about which factor has a more significant effect.

In addition to the surgical and ERP factors that may place patients at risk, individual patient risk factors can affect AKI development. For example, one study found that robotic surgery patients who were obese, had diabetes, had increased baseline glomerular filtration rate (GFR), and men had a higher rate of AKI development (Martini et al., 2019). Another study examining patients participating in ERPs found that patients with hypoalbuminemia, age greater than 60 years old, male, American Society of Anesthesiologists (ASA) physical status classification III-IV, and pre-existing chronic kidney disease were more likely to develop AKI (Zorrilla-Vaca et al., 2020).

Background

Stroke volume (SV) is the amount of blood ejected from the heart after each contraction. Stroke volume variation (SVV) occurs when respiration changes hemodynamics due to pressure changes in the thoracic cavity. During spontaneous respiration, pulse pressure (systolic blood pressure minus diastolic blood pressure) and stroke volume decrease during inspiration and increase during expiration (Frazier, 2007; Michard, 2005). During mechanical ventilation under general anesthesia, this phenomenon is reversed due to the positive pressure used during inspiration (Michard, 2005).

SVV is one indicator of fluid balance and can indicate if the patient is hypovolemic and needs additional fluid administration (Frazier, 2007). The superior vena cava is more collapsible when there is less volume to withstand the pressure exerted by the lungs (Michard, 2005). In addition, the chambers in the heart are also more sensitive to changes in pressure when there is less volume, leading to more variation in stroke volumes (Michard, 2005). Therefore, if the patient is dehydrated, the SVV will increase (Frazier, 2007; Michard, 2005). The optimal SVV is <13% to ensure adequate fluid balance (Frazier, 2007).

There are specific parameters that must be met in order for SVV calculations to be reliable. The patient must be on mechanical ventilation with 8 ml/kg tidal volumes and a controlled respiratory rate (Frazier, 2007). These parameters make perioperative monitoring ideal because all patients will be mechanically ventilated and sedated. Measurement during spontaneous respiration is not accurate because of the changes in respiratory rate and tidal volume (Frazier, 2007). Arrhythmias can significantly affect the SVV; therefore, patients should have a normal sinus rhythm (Frazier, 2007). Increasing positive end-expiratory pressure (PEEP)

can also increase SVV; PEEP should be kept stable throughout the monitoring period (Frazier, 2007).

Essentially, goal-directed therapy is a term used to describe the use of additional hemodynamic measurements in lieu of traditional blood pressure and heart rate monitoring to guide treatment and optimize patient outcomes. Stroke volume variation is one of the measurements that can be used to guide goal-directed therapy (GDT) (Wu et al., 2021). Goal-directed therapy uses hemodynamic parameters to optimize oxygen delivery and cardiac output (Giglio et al., 2019). SVV is one of these measurements that can help guide fluid administration to optimize oxygen delivery to the tissues (DO_2) (Frazier, 2007). This includes oxygen delivery to the cells of the kidney which affects AKI development. Thus, SVV can be used as a tool to guide CRNA intervention to ensure the kidneys are receiving adequate blood flow.

Purpose

This project determined the role of stroke volume variation (SVV) in the development of AKI in robotic ERP procedures as they are used at Atrium Health Carolinas Medical Center. This is a sub study of a larger project examining several factors that may contribute to AKI development in patients undergoing robotic ERP procedures. This topic was identified as an area of concern by the Anesthesia Department at Atrium Health.

A retrospective chart review examined patients with SVV monitoring and patients without SVV monitoring during similar robotic ERP surgeries and compared serum creatinine levels within 48 hours postoperatively. Stroke volume variation is a variable that anesthesia providers can use to manage fluid administration and was examined to determine its effect on post-operative creatinine levels, an indirect measure of AKI. Future projects can work towards

developing practice guidelines related to using SVV as a measure to reduce AKI occurrence at Atrium Health.

PICOT Question

In adult patients undergoing robotic ERP general surgery procedures, is stroke volume variation monitoring related to AKI development in the 48-hour postoperative period? Acute kidney injury will be determined by comparing preoperative serum creatinine levels to those within the 48-hour postoperative period.

CHAPTER 2: LITERATURE REVIEW

Electronic databases were searched throughout Fall 2021 and Spring 2022 to obtain literature review data. Database access was obtained through the North Carolina Area Health Education Center (AHEC) digital library. PubMed Medline, PubMed Central, Cumulated Index to Nursing and Allied Health Literature, and Cochrane library were utilized. Boolean search operators used were "acute kidney injury AND enhanced recovery protocol", "acute kidney injury AND stroke volume variation." “Stroke volume variation” was often one of the measurements used in goal-directed therapy (GDT), which is a broad term used to describe a hemodynamic variable that has a target level to optimize blood flow and oxygen delivery to the tissue.

Goal-directed therapy (GDT) has been compared to traditional fluid management and studied in relation to multiple postoperative outcomes in surgical procedures. Goal-directed therapy protocols use SVV monitoring to guide fluid administration to ensure oxygen delivery to the tissues. Wu et al. (2021) studied traditional blood pressure management using a mean arterial pressure (MAP) greater than 65 compared to GDT using SVV monitoring in patients undergoing partial nephrectomy. Of 144 patients, half were assigned to the control group (traditional blood pressure management) and half assigned to the GDT group. They found a relative reduction of AKI incidence of 39.9% in the GDT group; however, the results were not statistically significant (Wu et al., 2021).

Peng et al. (2014) also studied GDT using SVV monitoring compared to a control group in major orthopedic surgery. They did not measure AKI as an outcome but did measure other parameters that can be linked to AKI development. Peng et al. (2014) found that the GDT group

required less fluids intraoperatively, had improved hemodynamics, and improved perioperative gastrointestinal function.

Calvo-Vecino et al. (2018) did not exclusively use SVV monitoring; however, a GDT protocol was in place that looked at additional invasive hemodynamic measures compared to traditional blood pressure and heart rate monitoring. This study was performed among 450 patients undergoing gastrointestinal surgery. They found a reduction of many complications, such as AKI, pulmonary edema, pneumonia, and surgical site infection, among the group that received GDT guided by invasive hemodynamic monitoring.

Elgendy et al. (2017) compared GDT and traditional therapy in high-risk groups undergoing major abdominal surgery. They did not find a difference in blood transfusion or vasopressor use between the two groups. The GDT group did receive more colloid, while the control group received more crystalloid. There was no difference in the total hospital stay time; however, the GDT group did have a shorter intensive care unit (ICU) stay than the control. There were five deaths during hospitalization for the control group and three for the GDT group. While AKI was not a measured outcome of this study, it is clear that GDT created better outcomes for high-risk patients.

Mayer et al. (2010) used SVV monitoring compared to traditional monitoring among high-risk surgical patients and found a decrease in length of stay among the GDT group (15 days) compared to the control group (19 days). The GDT group also had significantly fewer complications after surgery. There was no difference in ICU length of stay or postoperative mechanical ventilation. More colloids were administered to the GDT group, while the control received more crystalloids. The number of postoperative deaths was the same between the two groups.

A meta-analysis of randomized control trials enrolling 9308 patients in GDT versus control groups was performed by Giglio et al. (2019), with AKI being the primary outcome. They found that GDT significantly reduced the occurrence of AKI. The method of GDT that had the most significant outcome on AKI was guided by oxygen delivery (DO2), cardiac output (CO), and the use of both fluid and inotropes to manage hemodynamics. One of the most significant factors for AKI development was tissue hypoperfusion and hypoxia, leading to a cascade of events that ended in organ damage. Hypoperfusion can be prevented by ensuring adequate intravascular volume and perfusion pressure. They also found that lactic acidosis often led to AKI development and GDT failed to prevent AKI once acidosis had developed.

Many studies examined the utilization of GDT therapy and SVV monitoring on AKI and other postoperative outcomes. The findings of these studies have varied results, with some showing a reduction in adverse outcomes for GDT groups and others showing no difference. However, in none of the groups did GDT therapy have an adverse effect on postoperative outcomes. These studies show that high-risk surgical patients can benefit from receiving goal-directed therapy to decrease adverse postoperative outcomes.

CHAPTER 3: METHODOLOGY

Conceptual/Theoretical Framework

The conceptual framework for the project is the Plan-Do-Study-Act (PDSA) model (PDSA, 2022). The "Plan" is to identify the relationship between SVV monitoring and AKI development in the 48-hour postoperative period. The "Do" step was retrieving data from the electronic medical record. The data was "Studied" and analyzed to determine how SVV monitoring affected the occurrence of AKI in this population. In the final step of the model, if the findings show that SVV monitoring is related to AKI occurrence, the "Act" phase will result in recommendations future scholarly project groups to develop and implement protocols in an effort to decrease AKI development.

Methodology and Project Design

This project is a quality improvement project which aims to highlight practices at a specific medical center and their relationship to AKI and patient outcomes after robotic surgery. Data collection and analysis used a retrospective correlational design. Curtis et al. (2016) state that a correlational study is used to determine the prevalence and relationship between variables. Patient records were retrieved for robotic ERP procedures from May through August of 2022. The variables examined were SVV monitoring and AKI occurrence. A group with SVV monitoring and without SVV monitoring were examined and an increase in creatinine after the procedure determined the occurrence of acute kidney injury (AKI) between the two groups.

Setting

The patients included in the project were adults undergoing robotic ERAS procedures at Atrium Health CMC. Atrium Health CMC is a Level 1 Trauma center serving the large urban city of Charlotte, North Carolina. In 2018, 43% of AH CMC patients came from Mecklenburg

County, and 57% came from surrounding counties (Atrium Health, 2019). The hospital has 38 operating rooms, including four dedicated c-section rooms and one trauma room.

There were 43,331 surgeries performed at AH CMC and AH Mercy in 2018, averaging 833 operations per week (Atrium Health, 2019). In the AH CMC operating rooms, 41.8% of the patients were racial and ethnic minorities, and 26.7% were elderly (Atrium Health, 2019). Among surgical patients, 7% of the patients were self-pay, 28.2% paid with Medicare, 18.9% paid with Medicaid, and 42.8% were paid via private insurance (Atrium Health, 2019).

Sample

The sample was extracted from the medical record. Eligible records were adult patients (18 years and older) undergoing robotic ERP general surgery procedures at AH CMC with a preoperative and postoperative creatinine measurement. The use of an arterial line connected to an EV1000 monitor was necessary for the SVV group. The sample was obtained from electronic health records from May 2022 through August 2022. Twenty patients met the sampling criteria for the SVV group and twenty patients were used in the non-SVV group for a total of 40 patients. The types of surgeries included are under the general surgery service. Patients eligible to be in the sample needed to be admitted for at least one night to obtain a postoperative creatinine level. Patients having pre-existing kidney disease, urologic procedures, surgeries converting to open technique, outpatient robotic ERP procedures, and emergent procedures were excluded from the sample.

Measurement Tools

The measures used in the project were physiologic measures captured from electronic health records that include preoperative and postoperative creatinine and SVV recording as well as demographic and descriptive information. The demographic information includes age and

biological sex. The descriptive information includes anesthesia time and American Society of Anesthesiologist (ASA) status. The ASA status is a classification system used to communicate the patient's pre-existing medical co-morbidities and consists of a score from I-IV, with I being the lowest risk and IV being the highest risk. The change in creatinine level from the preoperative to the postoperative period was examined to assess the occurrence of AKI. Measurement of AKI uses the KDIGO guidelines, which define AKI as an "increasing serum creatinine (SCr) ≥0.3 mg/dL in 48 hrs or urine output <0.5 mL/kg/hr 6-12 hrs" (KDIGO, 2012). Urine output is not always accurately tracked postoperatively; thus, for this project creatinine level is a better measure.

The clinical question is whether SVV monitoring leads to better fluid management by the anesthesia provider leading to decreased AKI occurrence. The project coordinator gathered retrospective data from the EHR to assess the pre-operative and post-operative creatinine levels of 20 patients who had SVV monitoring and 20 patients who did not have SVV monitoring. The 48-hour postoperative creatinine level was used to determine if an AKI occurred. The data was analyzed to determine if the presence of SVV monitoring correlates with a decreased AKI occurrence.

Data Collection

Data collection occurred retrospectively using the electronic health record at Atrium Health. Atrium Health converted to a new EHR system in May of 2022, so access to patient data was limited to the start of the new EHR system. Data from the medical records was de-identified after being released to the project coordinator who then created a database what was reviewed to assure the sample met the sampling criteria All surgeries from May 1st, 2022 to August 30th,

2022 were included. The data collection sheet can be found in Appendix A. The following criteria were used to prepare the data.

- Data were filtered to only the operating rooms with robotic capabilities.
- Age was filtered to only include patients over than 18 years old
- A filter was applied to assess for multimodal pain management which was used to determine that an enhanced recovery protocol was used.
- Patient records were examined to determine if SVV measurement was utilized.
- SVV monitoring was only used in general surgery cases, therefore the non-SVV group was also filtered to only general surgery cases.
- The records were examined for inclusion of preoperative and postoperative creatinine levels.
- Any patient with a pre-operative GFR <60 was excluded from the data set.

These filters were used to find the SVV group, all patients who fit the criteria were included. Then, the non-SVV group was selected to be the same size as the SVV group and fit the necessary criteria. The timeline for the project is presented in Appendix B.

Data Management and Confidentiality

The resulting patient data were de-identified and transferred into a password protected Microsoft Excel sheet for data analysis. The data are only available to project directors and authorized research team members. The project was reviewed by the hospital and university Institutional Review Board (IRB) and determined to be a quality improvement project that required no further approval. The IRB letter is in Appendix C and D.

Data Analysis

Analysis of variance and chi-squared test were used to analyze the data. Analysis of variance was used to test the mean difference between the SVV and non-SVV group for age, ASA score, and anesthesia time. The chi-squared test was used to test the difference in the categorical variables gender and AKI occurrence between the SVV and non-SVV group. P-values for age, ASA score, and anesthesia time are based on analysis of variance. P-values for gender and AKI occurrence are based on the chi-squared test.

CHAPTER 4: RESULTS

The sample size in this project was 40 patients, 20 in the SVV group and 20 in the non-SVV group. These patients had robotic surgery under general anesthesia between May 1, 2022 and August 30, 2022, on the general surgery service, were over the age of 18, used an enhanced recovery protocol, had a pre-operative GFR greater than 60, and had a pre-operative and post-operative creatinine level. There were two other patients who received SVV monitoring, but due to their pre-existing kidney disease they were excluded from the study.

The two groups did not differ in sex (χ^2 (1) = 0, p = 1.00) and age (F = 0.20, p = .655). The gender of both groups was 45% female. The average age of the SVV group was 63.75 years (SD=12.02), and the average age of the non-SVV group was 61.95 years (SD=13.24). The patients in the SVV group had a higher average ASA score (3.05 ± 0.22) than the non-SVV group (2.85 ± 0.37) (F=4.34, p=.044). Patients in the SVV group had a longer anesthesia time in minutes (383.10 ± 131.6) than patients in the non-SVV group (278.05 ± 122.79) (F=6.81, p=.013). The average SVV in the SVV group was 11.44 ± 2.78. Those in the SVV group were less likely to develop AKI (0%) than patients in the non-SVV group (15%) with a chi-squared value of χ^2 (1) = 26.88, $p < .001$. Development of AKI was indirectly measured by the difference in postoperative and preoperative creatine levels and defined as an increase greater than 0.3 mg/dL.

Figure 1

Descriptive analysis and comparison between nonsvv and svv groups

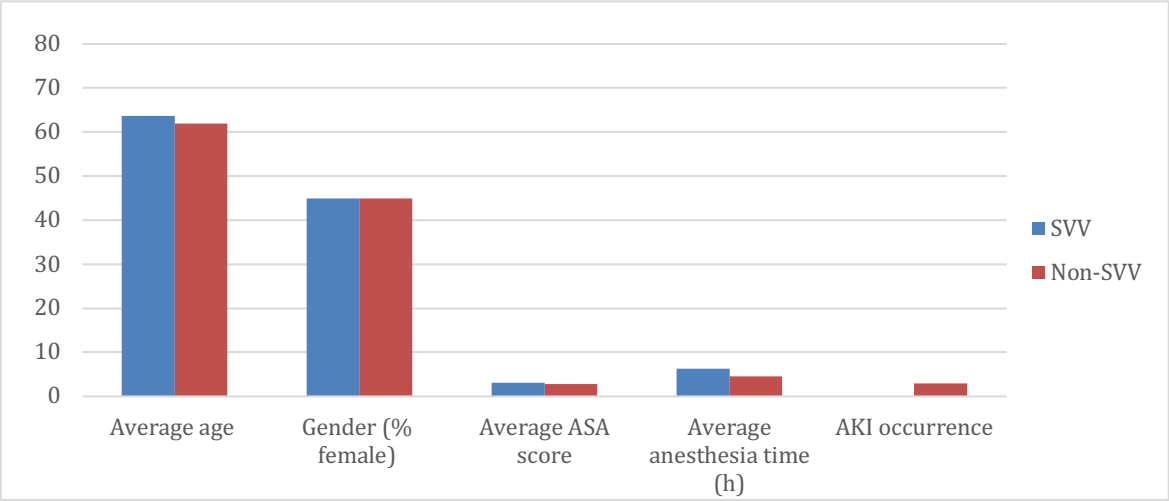


Table 1

Descriptive analysis and comparison between nonsvv and svv groups

	Non-SVV (n = 20)	SVV (n = 20)	p-value
Age	61.95 ± 13.24	63.75 ± 12.02	p = .655
Sex (% of female)	n = 9, 45.0%	n = 9, 45.0%	p = 1.00
ASA	2.85 ± 0.37	3.05 ± 0.22	p = .044
Anesthesia time (minutes)	278.05 ± 122.79	383.10 ± 131.61	p = .013
SVV	Not monitored	11.44 ± 2.78	
AKI occurrence	n = 3, 15.0%	n = 0, 0.0%	p < .001

CHAPTER 5: DISCUSSION

Implications

The results of this project suggest that SVV monitoring during robotic enhanced recovery procedures does correlate with a decrease in the occurrence of AKI. This correlation is enhanced by the demographics of the SVV and non-SVV group. The SVV group had a higher average anesthetic time, age, and ASA score. All of these factors would lead to an increased risk for AKI, yet no AKIs as measured by elevated creatinine levels were found in this group. Additionally, the average SVV was 11.44, which is below the recommended level of 13. This may indicate that SVV monitoring improved fluid management and led to improved renal perfusion, which is why none of these patients experienced AKI.

The non-SVV group was similar in size, gender, and age to the SVV group. The non-SVV group was also comprised of patients undergoing general surgery to eliminate bias between surgery types. The non-SVV group had lower average ASA scores and anesthesia time, which puts this group at less risk for AKIs. Despite these differences, the non-SVV group had three AKIs compared to zero in the SVV group. The lack of SVV monitoring meant the provider had to rely on traditional monitoring of blood pressure and heart rate, which may not reflect an accurate fluid balance. The non-SVV patients were more likely to develop AKI (p-value <0.05).

While it is evident that SVV monitoring did correlate with a decreased risk of AKI, SVV monitoring itself is not benign. The current equipment requires an arterial line, which comes with risks of nerve damage, blood vessel damage, hematoma and infection. These risks must be considered when determining if a patient is appropriate for SVV monitoring. In addition, this type of monitoring can add cost when it is used in surgery. Further work is required to identify patients who would benefit the most from the additional monitoring and the development of

policies supporting SVV monitoring in patients at high-risk for developing AKI who are undergoing a robotic ERP procedure.

Limitations and Strengths

Although this project was able to produce an adequate sample size and statistically significant results, challenges were experienced during the project. This project was one arm of a larger project examining AKI occurrence among robotic ERP surgeries. The other project variables of NSAID administration and hypotension were not compared to this project. A limitation of the project was a new EHR system that was implemented during the project development which limited the ability to retrieve records. Only the case records that were on the new EHR system, starting May 2022, were accessible, therefore limiting the sample size and may have affected internal validity. Another challenge that limited sample size was the lack of routine SVV monitoring that occurred in robotic surgeries. Over the four months of the data collection period, only 20 eligible patients received SVV monitoring. The lack of monitoring is partially due to the limited availability of equipment and additional time needed to set up the equipment.

It would have been helpful to have the specific insufflation times for each procedure as it is known that insufflation time is related to reduced kidney perfusion and was an important variable that was not controlled between the groups. Some of the common robotic procedures performed, such as gynecologic and urologic could not be included in the study. Many gynecological procedures were not included because the patients did not stay in the hospital long enough to get a post-operative creatinine value. Urologic procedures, such as prostate surgery, were not included due to the direct interference with the renal system anatomy. Groups were not

able to be matched exactly for demographics such as age and biological sex, however groups did not statistically differ by age or sex.

This project addressed questions in a large medical center about reducing the incidence of AKI in its robotic ERP surgical patients. Stroke volume variation monitoring was shown to be associated with a lower the incidence of AKI among this surgical population. This information should be taken into consideration by the medical facility and used along with other project results to create a protocol for reducing AKI among this surgical population.

Recommendations

Recommendations for this project would be to increase the sample size and the time period available for future observations. Further, expanding the sampling frame to include other types of surgeries is important. It would be helpful to examine the effect across general surgery, thoracic surgery, and gynecologic surgery instead of only general surgery. The project supports further exploration of increasing the use of SVV monitoring in the operating room for robotic ERP cases. The findings from this arm and the other two arms of the larger project will be returned to the Director of Anesthesia Quality where the clinical issue originated. Adherence to national guidelines and development of “best practice” procedures such as better screening would be the next steps in addressing the issue of AKI in this facility

REFERENCES

Calvo-Vecino, J. M., Ripollés-Melchor, J., Mythen, M. G., Casans-Francés, R., Balik, A., Artacho, J. P., Martínez-Hurtado, E., Serrano Romero, A., Fernández Pérez, C., Asuero de Lis, S., & FEDORA Trial Investigators Group (2018). Effect of goal-directed haemodynamic therapy on postoperative complications in low-moderate risk surgical patients: A multicentre randomised controlled trial (FEDORA trial). *British Journal of Anaesthesia*, *120*(4), 734–744. https://doi-org.ahecproxy.ncahec.net/10.1016/j.bja.2017.12.018

CMS Medpar. (2019). Room for Improvement: Complications in the Abdominal, Colorectal, Gyn Service Line.

Curtis, E. A., Comiskey, C., & Dempsey, O. (2016). Importance and use of correlational research. *Nurse Researcher*, *23*(6), 20–25. https://doi.org/10.7748/nr.2016.e138

Elgendy, M. A., Esmat, I. M., & Kassim, D. Y. (2017). Outcome of intraoperative goal-directed therapy using VIGILEO/FloTrac in high-risk patients scheduled for major abdominal surgeries: A prospective randomized trial. *Egyptian Journal of Anaesthesia*, *33*(3), 263–269. https://doi.org/10.1016/j.egja.2017.05.002

Frazier, J. (2007). *Stroke volume variation "can we use fluid to improve hemodynamics"*. Retrieved January 29, 2022, from https://anesthesia.ucsf.edu/sites/anesthesia.ucsf.edu/files/wysiwyg/Edwards_SVV_handout.pdf

Giglio, M., Dalfino, L., Puntillo, F., & Brienza, N. (2019). Hemodynamic goal-directed therapy and postoperative kidney injury: An updated meta-analysis with trial sequential analysis. *Critical Care (London, England)*, *23*(1), 232. https://doi.org/10.1186/s13054-019-2516-4

Joo, E. Y., Moon, Y. J., Yoon, S. H., Chin, J. H., Hwang, J. H., & Kim, Y. K. (2016). Comparison of acute kidney injury After robot-assisted laparoscopic radical prostatectomy versus retropubic radical prostatectomy. *Medicine*, 95(5). https://doi.org/10.1097/MD.0000000000002650

KDIGO clinical practice guideline for Acute Kidney Injury. (March, 2012). Kidney Disease Improving Global Outcomes. https://kdigo.org/wp-content/uploads/2016/10/KDIGO-2012-AKI-Guideline-English.pdf.

Koerner, C. P., Lopez-Aguiar, A. G., Zaidi, M., Speegle, S., Balch, G., Shaffer, V. O., Staley, C. A., Srinivasan, J., Maithel, S. K., & Sullivan, P. S. (2019). Caution: Increased acute kidney injury in enhanced recovery after surgery (ERAS) protocols. *The American Surgeon*, *85*(2), 156–161.

Mayer, J., Boldt, J., Mengistu, A. M., Röhm, K. D., & Suttner, S. (2010). Goal-directed intraoperative therapy based on autocalibrated arterial pressure waveform analysis reduces hospital stay in high-risk surgical patients: a randomized, controlled trial. *Critical Care (London, England)*, *14*(1), R18. https://doi.org/10.1186/cc8875

Michard F. (2005). Changes in arterial pressure during mechanical ventilation. *Anesthesiology*, *103*(2), https://doi.org/10.1097/00000542-200508000-00026

Naito, A., Taguchi, S., Suzuki, M., Kawai, T., Uchida, K., Fujimura, T., Fukuhara, H., & Kume, H. (2020). Transient acute kidney injury observed immediately after robot-assisted radical prostatectomy but not after open radical prostatectomy. *Molecular and Clinical Oncology*, *13*(3), 18. https://doi-org.ahecproxy.ncahec.net/10.3892/mco.2020.2087

Peng, K., Li, J., Cheng, H., & Ji, F. H. (2014). Goal-directed fluid therapy based on stroke volume variations improves fluid management and gastrointestinal perfusion in patients

undergoing major orthopedic surgery. *Medical Principles and Practice: International Journal of the Kuwait University, Health Science Centre*, *23*(5), 413–420. https://doi.org/10.1159/000363573

Plan-do-study-act (PDSA) directions and examples. AHRQ. (2020, September). Retrieved March 25, 2022, from https://www.ahrq.gov/health-literacy/improve/precautions/tool2b.htm

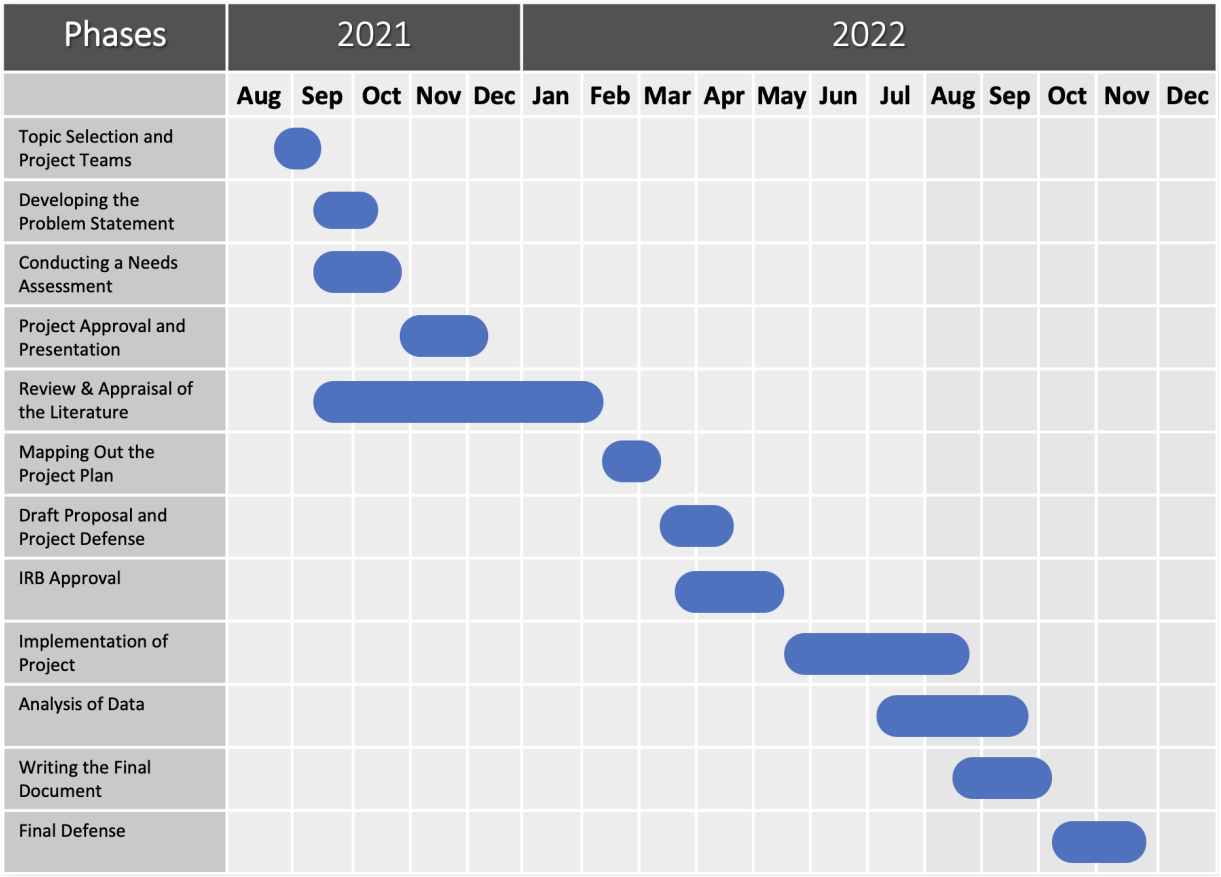
Sato, H., Narita, S., Saito, M., Yamamoto, R., Koizumi, A., Nara, T., Kanda, S., Numakura, K., Inoue, T., Satoh, S., Abe, K., & Habuchi, T. (2020). Acute kidney injury and its impact on renal prognosis after robot-assisted laparoscopic radical prostatectomy. *The International Journal of Medical Robotics and Computer Assisted Surgery*, *16*(5), 1–7. https://doi.org/10.1002/rcs.2117

Zorrilla-Vaca, A., Mena, G. E., Ripolles-Melchor, J., Lorente, J. V., Ramirez-Rodriguez, J. J., & Grant, M. C. (2020). Risk factors for acute kidney injury in an enhanced recovery pathway for colorectal surgery. *Surgery Today*, 51(4), 537–544. https://doi.org/10.1007/s00595-020-02107-2

Appendix A: Data Sheet

Patient #	Surgery Date	Anesthesia time	Surgical service	Age	Gender	ASA score	Preop Crt	Postop Crt	Difference in Crt
1									
2									
3									
Etc.									

Appendix B: Timeline



Appendix C: Wake/Atrium IRB Approval

MEMORANDUM

To: Elena Meadows
Clinical and Translational Science Institute {CTSI}

From: Jeannie Sekits, Senior Protocol Analyst
Institutional Review Board

Date: 7/12/2022

Subject: Not Human Subjects Research: IRB00086555
Enhanced Recovery after Robotic Surgery & Acute Kidney Injury

The Wake Forest University School of Medicine Institutional Review Board has reviewed your protocol and determined that it does not meet the federal definition of research involving human subject research as outlined in the federal regulations 45 CFR 46. 45 CFR 46.102(f) defines human subjects as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."

The information you are receiving is not individually identifiable. In recent guidance published by the Office of Human Research Protections (OHRP) on the Guidance on Research Involving Coded Private Information or Biological Specimens, OHRP emphasizes the importance on what is being obtained by the investigator and states "if investigators are not obtaining either data through intervention or interaction with living individuals, or identifiable private information, then the research activity does not involve human subjects."

Note that only the Wake Forest University School of Medicine IRB can make the determination for its investigators that a research study does not meet the federal definition of human subject research. Investigators do not have the authority to make an independent determination that a study does not meet the federal requirements for human subject research. Each project requires a separate review and determination by the Board. The Board must be informed of any changes to this project, so that the Board can determine whether it continues to not meet the federal requirements for human subject research. If you have any questions or concerns about this information, please feel free to contact our office at 716-4542.

Appendix D: UNCC IRB Approval

UNIVERSITY OF NORTH CAROLINA CHARLOTTE | DIVISION OF RESEARCH

To:	Ana Arias University of North Carolina at Charlotte
From:	Office of Research Protections and Integrity
Date:	27-Jul-2022
RE:	Determination that Research is not Human Subjects and does not require IRB Approval
Study #:	IRB-23-0030
Study Title:	Enhanced Recovery After Robotic Surgery & Acute Kidney Injury

This submission was reviewed by the Office of Research Protections and Integrity, which has determined that this submission does not constitute human subjects as defined under federal regulations 45 CFR 46.102(e) and 21 CFR 56.102(e) and does not require IRB approval.

Study Description:
This quality improvement (QI) project was chosen by the Safety and Quality Coordinator for the Anesthesia Department at Atrium Health (AH) Main facility. This project will look specifically at factors leading to acute kidney injury (AKI) in robotic surgeries with early recovery after surgery (ERAS) protocols at AH Main. In 2018, AKI was the most common complication in colorectal and abdominal surgeries at AH Main, and the fourth most common complication in gynecologic surgeries. The three team members will each be looking at a specific variable that could be affecting AKI development. The variables being examined are stroke volume variation (SVV), hypotension, and non-steroidal anti-inflammatory (NSAID) administration. These variables were chosen because they are all within the control of the anesthesia provider during the perioperative period. This QI project uses a retrospective, correlational design. Data will be collected via electronic health record (EHR) review and stored in the RedCap secure database. Patients will be deidentified in RedCap- medical record number (MRN), name, and any other identifying information will not be stored. The data that will be recorded is patient age, patient gender, surgical procedure, preoperative creatinine value, postoperative creatinine value, average SVV, minutes with MAP <65, and NSAID dose administered. The comparison of preoperative creatinine and postoperative creatinine will be used to determine if an AKI occurred within the 48-hour postoperative period.

Please be aware that approval may still be required from other relevant authorities or "gatekeepers" (e.g., school principals, facility directors, custodians of records), even though IRB approval is not required.

If your study protocol changes in such a way that this determination will no longer apply, you should contact the above IRB before making the changes.