A Comparison of Patient Outcomes between Robotic and Open Radical Prostatectomy

by

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Abstract

Objective The purpose of the study is to compare the overall immediate patient outcomes and costs of two different surgical modality for radical prostatectomy.

Methods A retrospective observational two-comparison study is designed in 59 male patients who underwent either a robotic assisted radical prostatectomy (RARP) or open radical prostatectomy (ORP) to compare the patient outcomes during the first year of inception of the robotic-assisted program.

Results The RARP has shown to have longer surgical room time (2.90 hours +/- .49 vs. 2.27 hours +/- .36, $p = .000$) and is costly ($6777.69 +/- 993.14 vs. $5070.44 +/- 590.30, $p = .000$). However, the first pain score assessed upon arrival to surgical unit was less in RARP than ORP (1.64 +/- 2.00 vs. 3.22 +/- 3.09, $p < 0.05$). The intraoperative and perioperative patient outcomes were comparable between the two procedural methods including intraoperative estimated blood loss (145.14 mL +/- 67.83 vs. 219.05 mL +/- 301.45), transfusion rate (0 vs. 0), complication rate (25.0% vs. 17.4%), recovery length of stay (87.67 minutes +/- 34.35 vs. 79.04 minutes +/- 21.63), and overall hospital length of stay (30.28 hours +/- 12.59 vs. 29.44 hours +/- 6.84).

Conclusions This study observed that RARP is comparable with ORP in terms of intraoperative and perioperative patient outcomes including blood loss, complication rates, recovery and overall hospital length of stay. This result supports a new robotic surgery program as another safe option for prostate cancer

treatment for community hospitals. Our study did not show the superior patient outcomes over ORP, different from the previous studies. The difference may have been due to the comparative sample of ORP's having a majority of perineal approach rather than abdominal radical prostatectomies and/or the data collection period.

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Chapter 1. Introduction

Problem Statement

Because of PSA (prostate specific antigen) and the subsequent increase in prostate cancer screenings, the diagnosis rates of prostatic cancer have increased. Today, prostate cancer is the second most prevalent cancer (Yaxley et al., 2016). According to Ozkan and Rauf (2014), with the aging population globally, there will be 1.7 million new prostate cancer cases and approximately 0.5 million deaths due to prostate cancer in the year of 2030. According to Tewari et al. (2012, p. 2) more than 90% of these newly diagnosed prostate cancers will be identified "when the disease is organ confined and potentially curable by radical prostatectomy." The gold standard of treatment for a clinically localized prostatic cancer tumor is a radical prostatectomy, with a resultant life expectancy of greater than 10 years (Tewari et al., 2012). For more than 50 years, the standard surgical approach for radical prostatectomy included an open radical prostatectomy or radical perineal approach (Tewari et al., 2012).

Open radical prostatectomy (ORP) has been the accepted and widely utilized approach for eradicating localized prostate cancer (Tewari et al., 2012). The advances in minimally invasive surgical techniques, which aim to improve outcomes and reduce complications, have led urology surgeons to question and pursue application of laparoscopic techniques in radical prostatectomies. The first laparoscopic radical prostatectomy (LRP) was completed in 1997 (De Carlo et al., 2014). Although LRP demonstrated similar outcomes to the open surgical approach, the laparoscopic approach did not receive widespread acceptance due to the steep learning curve.

The learning curve was prolonged and difficult due to a two-dimensional view of field, lack of tactile feedback, as well as the needed hand-eye coordination (De Carlo et al., 2014).

With the evolutionary advent of The Da Vinci Robotic Surgical System manufactured by Intuitive Surgical, "the first reported robot-assisted radical prostatectomy (RARP) by Binder and Kramer in 2001" has led to a revolution in the preferred method by urology surgeons (Jackson et al., 2016). The proportion of robotic-assisted laparoscopic radical prostatectomy procedures has significantly increased nationwide: from 250 in 2001 to 46,000 in 2009 in the U.S. (Jackson et al., 2016). Within a few years of inception, high-volume centers were able to demonstrate better outcomes for incontinence, impotency, and cancer reoccurrence when compared to the open surgical approach (Sugihara et. al., 2014). Montorsi, Gandaglia, and Briganti (2015, p. 845) also found that the use of robotic assistance technology allows for smaller incisions and better outcome results including "lower blood loss, lower transfusion rates, shorter length of stay, and better functional outcomes." The Da Vinci Surgical System allowed for enhanced vision through a three-dimensional view of the surgical field, greater dexterity with more intuitive movement of the robotic arms, and greater precision with smaller and more agile instruments that bend and rotate beyond the human wrist capability (De Carlo et al., 2014). These enhanced capabilities in laparoscopy allow for an easier transition and decreased learning curve. In many smaller institutions or independent community-based facilities, the advantages have been offset by the high cost of The Da Vinci Surgical System.

Robotic Surgery and Healthcare Costs. The US healthcare system has been described as one of high cost, mediocre quality, and poor efficiency. Shi and Singh (2017) reported the US total health expenditure per capita and share of gross domestic product (GDP) to be 16.9 percent. The advancing technologies within surgical procedures and other service lines has impacted the percentage of the GDP negatively by increasing costs, without high-level evidence to support advancement of quality. According to Kim et al. (2013), an estimated 241,470 new diagnosed cases of prostate cancer in 2011, there were 12 billion healthcare dollars spent in treatment. The advent of robotic-assisted treatment options is anticipated to add another 1 billion healthcare dollars annually. As a healthcare executive, one has the responsibility and obligation to the community to scrutinize and critically examine different treatment options for patient-centered outcomes and health care value. This conundrum of cost and quality of care advancement can only be resolved by further research to analyze and determine the cost-benefit to patients. It is the researcher's intent that the results of this study will contribute to the body of knowledge in the areas of robotic assisted prostatectomies and quality of care outcome review, of a new start-up robotic program within an independent community hospital.

Purpose of the Study

There was limited research and information available on the implementation phase of a new robotic-assisted service within a community-based healthcare organization or academic center. The purpose of this study was to compare robotic-assisted radical prostatectomy (RARP) and open radical prostatectomy (ORP) and to add to the body of knowledge of robotic-assisted

radical prostatectomy focusing on the first year of implementation. This study aims to explore, through a retrospective chart review, whether the inception of robotic-assisted radical prostatectomy in an independent community hospital can improve patient perioperative outcomes as well as maintain profitability with overall cost in comparison to the open surgical approach. This study will answer the following research question: in men with localized prostate cancer or benign hypertrophy prostate with obstruction, how do robotic-assisted radical prostatectomy (RARP) and open radical prostatectomy (ORP) affect immediate intraoperative and perioperative outcomes, and cost during the hospital stay comparatively?

The immediate intraoperative metrics of comparison will include: operative and overall surgical time and estimated blood loss (EBL). The perioperative outcomes of comparison will include: transfusion rates, post-operative pain, complication rates, recovery room length of stay, and hospital length of stay. The cost comparison will include: procedural cost and overall hospital cost.

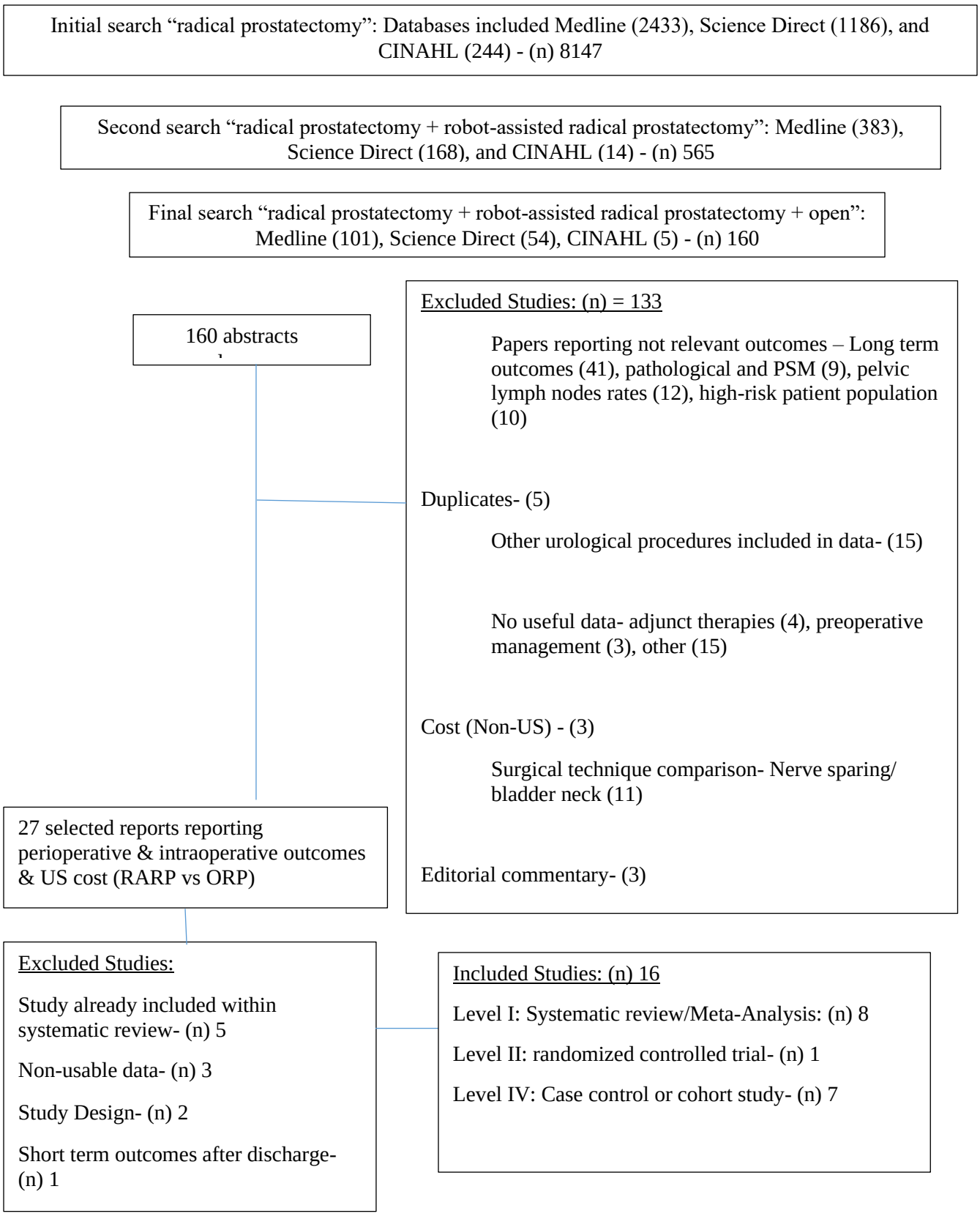
Chapter Two. Literature Review

A synthesis of the available literature will be reviewed in this chapter. The review is organized into the patient outcome of comparison (intraoperative surgical outcomes, perioperative outcomes, and cost). The focus of this study is to understand how robotic-assisted prostatectomy may impact the surgical and perioperative patient outcomes. The review will also include studies that have investigated the cost of robotic-assisted prostatectomy versus open prostatectomy procedures. The purpose of this review is to gain a better understanding of the outcome metrics when comparing robotic-assisted versus open, which would set expectations and goals for the implementation of a new robotic-assisted program.

Search Strategy and Results

Medline, Science Direct and CINAHL were queried for reports on two different radical prostatectomies (RARP and ORP) among the articles published between 2012 and 2017. Keywords used include: robotic-assisted radical prostatectomy, open radical prostatectomy, prostate cancer, and patient outcomes. Inclusion criteria includes (a) studies published between 2012 and 2017, (b) studies aim focused on evaluating intraoperative and perioperative outcomes and or costs segregated by surgical approach (RARP vs. ORP). Exclusion criteria includes (a) studies fail to provide usable, quantitative data, (b) studies aim to measure the long-term outcomes after radical prostatectomy, (c) duplicative studies, (d) comparison studies including laparoscopic radical prostatectomy, (e) studies aim to evaluate preoperative preparation and/or characteristics, (f) studies aim to compare other therapeutic options/adjunct therapies, (g) studies aim to evaluate PSM and reoccurrence rates/pathological review, (h) studies aim to focus on high

risk prostate cancer, and (i) commentaries. After all exclusions, the literature search resulted in a total of sixteen published studies/journal articles from January of 2012 to February of 2017. The included studies consisted of eight systematic review/meta-analysis, one randomized controlled trial with one surgeon, and seven cohort studies.


Initial search “radical prostatectomy”: Databases included Medline (2433), Science Direct (1186), and CINAHL (244) - (n) 8147
Second search “radical prostatectomy + robot-assisted radical prostatectomy”: Medline (383), Science Direct (168), and CINAHL (14) - (n) 565
Final search “radical prostatectomy + robot-assisted radical prostatectomy + open”: Medline (101), Science Direct (54), CINAHL (5) - (n) 160
160 abstracts
Excluded Studies: (n) = 133
Papers reporting not relevant outcomes – Long term outcomes (41), pathological and PSM (9), pelvic lymph nodes rates (12), high-risk patient population (10)
Duplicates- (5)
Other urological procedures included in data- (15)
No useful data- adjunct therapies (4), preoperative management (3), other (15)
Cost (Non-US) - (3)
Surgical technique comparison- Nerve sparing/ bladder neck (11)
Editorial commentary- (3)
27 selected reports reporting perioperative & intraoperative outcomes & US cost (RARP vs ORP)
Excluded Studies:
Study already included within systematic review- (n) 5
Non-usable data- (n) 3
Study Design- (n) 2
Short term outcomes after discharge- (n) 1
Included Studies: (n) 16
Level I: Systematic review/Meta-Analysis: (n) 8
Level II: randomized controlled trial- (n) 1
Level IV: Case control or cohort study- (n) 7

Review of Outcomes

Since its introduction in 2000, robotic-assisted radical prostatectomy has increased in popularity with urological surgeons as the preferred surgical method. "In 2010, an estimated 85% of radical prostatectomies performed in the United States were conducted using the robotic platform" (Pucheril et. al., 2016, p.31). The best evidence thus far has been observational cohort studies and meta-analyses. Despite the increased popularity, there have not been any large-scale randomized controlled research studies to prove efficacy and superiority over the gold standard of care of an open radical prostatectomy.

Operative/Surgical Time. The literature synthesis for operative times is conflicting. The majority of studies, however, report greater operative times for RARP. Three level IV cohort studies reported significantly greater operative times in the RARP cohorts. Davis (2014) and Jackson et al. (2016) found similar longer mean surgical time ORP 3.4hr vs. RARP 4.4hr; $p<0.0001$, and ORP 190+/-23, RARP 246+/- 62, $p<0.001$ respectively. Leow et al. (2016) reported that RARP had longer adjusted mean for operating room time (+131min, 95% CI +48 to +213; $p= 0.02$). However, the four systematic/meta-analyses research studies reported mixed findings. Two studies including those of Lim, Kim, Shin, and Rha (2013), and Novara et al. (2012) reported nonsignificant differences in operative times. However, De Carlo (2014) found an increased operative time with no significance reported. Moran et al. (2013) also found operative times for the RARP group to be longer than ORP group (WMD 37 min, 95% CI 17 - 58, $p< 0.001$). The only randomized controlled study conducted by Yaxley et al. (2016) of one experienced surgeon with greater than 1000 robotic-assisted cases reported decreased operative

times with a statistical significant difference (ORP 234 min vs RARP 202 min, $p < 0.0001$). The literature synthesis supports the idea of a surgeon having a significant learning curve with the new technology. This learning curve may be overcome with repetition and eventually lead to decreased operative times.

Estimated Blood Loss/ Transfusion Rates. The current literature search and syntheses demonstrates superiority of the RARP approach in respect to estimated blood loss and transfusion rates (Tewari et al., 2012). The research consistently found that the RARP approach resulted in less blood loss and decreased transfusion rates (Novara et al., 2012). Moreover, seven out of ten studies included in the search reported statistical significant differences in estimated blood loss and transfusion rates. Alemozaffar, Sanda, Yecies, Stampfer, and Kenfield (2015) found a significant difference in the mean estimated blood loss of the ORP group (824.2 mL) compared to the RARP group (186.0 mL; $p<0.001$); therefore, the authors also found the ORP group had a greater transfusion rate (30.5% vs. 4.9%; $p< 0.001$). Three of ten studies reported lower rates in both estimated blood loss and transfusion rates; however, the authors did not report significance (Lim, Kim, Shin, and Rha (2013); Moran et al. (2013); Tewari et al. (2012).

Hospital Length of Stay. The literature search and syntheses demonstrates superiority of the RARP approach in respect to hospital length of stay (LOS). There were ten studies included in the search that demonstrated a decreased length of stay, and 80 % of the studies reported statistically significant differences in favor of the RARP. Globally the length of stay has consistently been shorter with RARP. Tewari et al. (2012) reported that the hospital length of

stay both in the United States and non-United States are shorter (RARP- US 1.4 d and non-US 4.0 d compared to ORP- US 3.1 d and non-US 9.9 d).

Postoperative Pain. Only one randomized controlled trial study that of Yaxley et al. (2016), reported on postoperative pain when comparing RARP and ORP. The authors found that there was no significant difference in patient reported pain values at 24 hours post procedure during rest (ORP 3.02 vs. RARP 3.01). However, Yaxley et al. (2016) found that there was a statistically significant difference in patient reported pain values at 24 hours post procedure during activities in favor of RARP (ORP 5.83 vs. RARP 4.60; $p<0.0001$).

Overall Complication Rates. The majority of the studies in the literature search found superiority of RARP with overall complication rates revealing statistically significant differences in favor of RARP. There was one systematic level I study by Novara et al. (2012) that found a mean value of 9% lower complication rate, which did not reveal a significant difference in overall complication rates in comparing RARP and ORP (OR: 1.25; 95%CI 0.53 – 2.93; $p = 0.61$). Novara et al. (2012) found that the limited research did reveal some predictors associated with complication rates including patient characteristics such as presence of comorbidity and/or prostate volume. Novara et al. (2012) also found predictors associated with complication rates included cancer characteristics such as PSA, biopsy Gleason score, and surgical experience of physician. The remaining six studies established lower overall complication rates that were statistically significant as well. Moran et al. (2013) found in an analysis of 17 studies representing 6384 patients the overall complication rate was lower for RARP than ORP (RR 0.74, 95% CI 0.56 – 1.00, $p = 0.047$). Lim, Kim, Shin, and Rha (2013) also found in a

cumulative analysis of perioperative overall complication rates in non-comparative studies established significant advantage of RARP over both LRP and ORP (17.9% ORP, 11.1% LRP, and 7.8% RARP).

In a population based cohort study, Davis (2014) compared overall complications between ORP and RARP consisting of multiple US hospitals in the Premier Perspective Database. Davis (2014) found that in hospitals performing both ORP and RARP that the overall complication rate was 15.8% for ORP and 10.6% for RARP ($p< 0.0001$). Davis (2014) also found specific complications in favor of RARP and statistically significant included: stricture (4.8% vs. 3.2%), respiratory (2.3% vs. 1.4%), and cardiac (1.5% vs. 0.6%). Davis (2014) also found that institutions performing only ORP had a higher rate of overall complications than institutions performing ORP and robotics (17.9% ORP in non-robotic institutions vs. 15.8% ORP in robotic institutions).

In a systematic and meta-analyses by Tewari et al. (2012), the authors synthesized more than 400 studies comparing ORP, LRP, and RARP representing 286,876 patients. The total intraoperative complication rates were significantly higher in ORP (1.5%) versus RARP (0.4%). The total perioperative complication rate was also significantly higher in ORP (17.9%) versus RARP (7.8%), $p < 0.0001$ as well as LRP (11.1%) versus RARP (7.8%), $p = 0.002$. There was no significant difference in vessel, bladder, or bowel (not including rectal) injuries among the three surgical approaches. However, nerve injuries were significantly higher in LRP (1.0%) versus RARP (0.3%; $p= 0.0002$). Ureteral injuries were significantly higher in the ORP (1.5%) compared with RARP (0.1%; $p= 0.012$) and LRP (0.2%; $p = 0.02$). Tewari et al. (2012) did not

report a significant difference in rates of ileus, pulmonary embolism, myocardial infarction, bladder neck/anastomotic stricture, and/or sepsis. Hematoma and lymphocele were significantly lower in RARP (0.7% hematoma, 0.8% lymphocele) than ORP (hematoma: 1.6%; $p = 0.02$; lymphocele: 3.2%, $p = 0.0003$). Anastomotic leak and infection rates were lower in both RARP and LRP when compared to ORP as well.

Cost. The hospital economics, including the time of admission through discharge, was found to be higher for RARP. All five studies consistently reported higher costs for the RARP driven by the charges accrued during the surgical experience including surgical operative time and supplies. Leow et al. (2016) compared the costs of 629,593 men who underwent radical prostatectomy using the Premier Hospital Database. RARP was associated with higher 90-d direct hospital costs ($14, 897 vs. $9,558; adjusted difference + $4,528, 95% CI $2,928 to $6,127; $p < 0.001$). The shorter mean LOS for RARP did correspond with a significant decrease in room and board charges ($1,885 vs. $2,264; adjusted difference -$784, 95% CI -$1,384 to $181; $p < 0.001$). A subgroup analysis also revealed that the cost difference amongst the high-volume surgeons no longer showed a significant cost increase ($p = 0.15$).

In a meta-analyses conducted by Bilanji et al. (2016), the authors performed a multi-dimensional analysis of costs in relation to costs and benefits of RARP versus ORP including hospital, payer, and societal perspective. Based on a three-year care-pathway cost model, hospital economics found higher costs with RARP ($9,230) in comparison with ORP ($8,889) which is inclusive of OR charges, room and board, medications, PACU, anesthesia, labs, robotic system, and non-reimbursed complications including wound infection, pneumonia, ileus, and

transfusions. Payer economics, reimbursement, which includes the costs of procedure, facility fee, procedure-surgeon, complications, functional outcomes, and adjunct treatment differences were greater for ORP ($14,069) versus RARP ($12,618) (Bilanji et al. (2016). Due to lower complication rates and adjunct radiation and/or hormone therapy associated with ORP, the RARP saved insurance reimbursements by approximately $1,451 over three year period. Bilanji et al. (2016) also found in respect to the societal perspective that based on a 66% employment rate and average earning rate of $202.40 per day, RARP was associated with lower wage losses due to shorter post-procedure downtime/recovery time (ORP ($9,271) versus RARP ($8,068)). This led Bilanji et al. (2016) to propose that RARP provides an overall savings with a multi-dimensional perspective by demonstrating savings and benefits across the health care system that exceed the costs of the application.

Years of Provider's Experiences and Its Impact on Procedural Times and Patient Outcomes. The majority of studies in support of robotic-assisted procedures were performed after the initial learning curve of the physician and surgical team. The research varies in the number of cases that constitutes an appropriate number to overcome the initial learning curve for surgeons, with a range of 10 to 200 cases. The studies included in the literature search only address surgeon's experience. There was no analysis of the impact of inexperience or experience of the surgical team assisting the surgeon and their impact on key outcomes.

In a study by Davis, J.W. (2013), the author examined key outcome measures by surgeon case volumes. The surgeons participating in the study analysis had varying levels of experience ranging from 25 or more cases to greater than 100 cases performed. In analyzing the surgeons

with greater than 100 cases, the study demonstrated by comparing the cases in increments of 25 that "the conversion rate declined from 1.13% to 0.18%, the time decreased 5.0 to 3.9 hours, and the complications decreased 11.75% to 8.95% with the last completed 25 cases in comparison to the first 25 cases" (p. 563).

Summary

The question remains, do RARP perioperative outcomes support the growing trend of utilization for clinically localized prostate cancers despite the increased hospital costs? Without high level evidence, the debate continues as to which surgical approach is superior for radical prostatectomy. The majority of the literature and research studies have consisted of non-randomized longitudinal studies within high volume academic institutions. The high volume academic institutions have been able to demonstrate positive outcomes which include: less estimated blood loss intraoperatively, decreased length of stay, less postoperative pain, and less time to return to normal function; however, randomized controlled trials have been limited and the majority of research has been conducted within an academic setting after the initial learning curve. Many studies have limitations due to sample size, surgeon experience, non-randomization and lack of consistency in reporting outcome measures, thus not allowing one to determine the superior surgical approach.

Chapter 3. Methods

This chapter presents the methodology for the study. The study compares patient outcome measures and cost for the robotic-assisted radical prostatectomy (RARP) versus the open radical prostatectomy (ORP) using either an abdominal or perineal approach. The patient outcome measures of interest are classified as either operative or perioperative outcomes during the first year of implementation of a robotic-assisted program (October 25, 2016 to October 25, 2017). The operative measures of comparison include: operative and overall surgical time, in addition to estimated blood loss. The perioperative measures of comparison include: transfusion rates, postoperative pain, recovery room length of stay, complication rates, and hospital length of stay. In addition, the study compares the overall hospital cost and procedural operative costs as well.

Purpose and Research Question

The majority of research thus far have been in academic centers and comparison of perioperative complication rates after the initial learning curve has been completed. There have been very limited research and examination of comparison outcomes during the inception and first case series of implementation with robotic procedures within a community-based hospital. As described earlier, the purpose of the study was to understand the impact and compare the patient outcomes measures and cost during the initial and first year of implementation of a robotic-assisted program for prostatectomies. To approach this overall question, this study answers the following research question:

1. In men with localized prostate cancer or benign hypertrophy prostate with obstruction, how does robotic-assisted radical prostatectomy (RARP) compared with open radical prostatectomy (ORP) affect immediate intraoperative and perioperative outcomes, and cost during the hospital stay within a community-based healthcare organization?

Study Design

A retrospective observational two-comparison study is designed in 59 men patients who underwent either RARP or ORP to compare the patient outcomes and cost. Specifically, data extraction of all prostatectomy surgical procedures for comparison completed during the study time frame of October 25, 2016 to October 25, 2017. Data were extracted from nursing electronic medical record (EMR), physician operative dictation (EMR), physician orders listed within the electronic record (CPOE), quality occurrence reporting events, and the billing database.

Study Subject

Study participants were all men who underwent a surgical procedure (RARP or ORP) for a localized prostate cancer or benign hypertrophy prostate with obstruction during the time period of October 25, 2016 to October 25, 2017 at Augusta Health Medical Center.

Inclusion Criteria. Participants will be men who had undergone surgical intervention of either RARP or ORP with surgical dates that occurred during the first year of implementation of robotic-assisted program (October 25, 2016 to October 25, 2017). These criterion were chosen to ensure the inclusion of all surgical procedures throughout the learning curve of physician and staff, and the development of all structures and processes for a newly implemented program.

Exclusion Criteria. Exclusion criteria excluded any man who underwent a surgical intervention for prostate cancer in combination with another procedure during the same hospital stay, or those who underwent a RARP or ORP before or after the study time period.

Sample Size. The sample size was pre-determined by the number of medical records identified as having a surgical procedure of robotic-assisted prostatectomy or open radical prostatectomy via abdominal or perineal approach completed within a one year time frame of implementation of the robotic-assisted program. A single surgeon performed all of the robotic-assisted radical prostatectomy procedures included in this study. Two additional surgeons performed all of the open radical prostatectomies included in this study.

All medical records that identified patients treated with primary robotic-assisted radical prostatectomy or open radical prostatectomy for adenocarcinoma of the prostate or benign prostate hypertrophy with obstruction was utilized for comparison in this study. A consent was not obtained due to the research involving no more than minimal risk to the subjects. Subjects will not be identified by name or unique identifiers such as date of birth or social security number. The medical record account number will be collected and then deleted after verification of all data elements. The study will not require any time commitment of subjects. All data will be collected retrospectively through data mining and manual chart review.

Study Setting

Augusta Health is located in Fishersville, VA, a census-designated place in Augusta County, Virginia. Geographically, Augusta County is the second largest county in Virginia, encompassing over 970 square miles. Augusta County includes two independent cities: Staunton

and Waynesboro. Augusta Health is the only hospital in Augusta County. Its convenient location at the crossroads of interstate highways I-64 and I-81 allows Augusta Health to not only meet the needs of the communities it serves but also those of other localities near the Blue Ridge Mountains in the Shenandoah Valley, along with travelers to the area. The goal of Augusta Health is to be the first choice for healthcare services.

Augusta Health is a licensed 255-bed facility, recognized most recently in 2015 and 2016 as one of America's 50 Best Hospitals by Healthgrades (http://www.augustahealth.com). Augusta Health offers a variety of services including surgical services. The surgical suite consists of ten operating rooms, one cystoscopy suite, one hybrid interventional suite, and six endoscopy procedural rooms. Annually, there are approximately 16,000 surgical procedures completed including general, gynecological, urological, plastics, orthopedic including spine, ophthalmology, thoracic, retinal, vascular, ENT (ears, nose and throat), gastrointestinal endoscopy, and pain management.

In the second quarter of 2016, the Board of Augusta Health approved the purchase of the Da Vinci XI system in an effort to provide the latest technology and advancements in surgical interventions. On October 25, 2016, Augusta Health's surgical team completed the first robotic-assisted procedure, a robotic-assisted radical prostatectomy with an experienced urological surgeon, who had completed more than 50 cases robotically in other institutions and during his fellowship training and independent practice. The dedicated surgical team consisted of three circulators, three scrub personnel, and three first assistants, all of whom were provided training and education and are deemed competent and proficient.

Composition of Surgical Team and Training Education. For the Da Vinci XI Procedure, the surgical team (circulator, scrub nurse, and first assistant) training consisted of approximately eight hours of online completion of modules provided by Intuitive Surgical and an eight-hour classroom learning session provided by the Intuitive Surgical representative with hands on interactive demonstrations. These modules and hands-on training reviewed the robotic components including the image processing cart, surgeon console, and robotic patient-side tower. The training included instrumentation trays, disposable instrumentation, and docking procedure as well. The first assistants also received a hands-on pig lab with a surgeon at an Intuitive Surgical sponsored lab. In addition, all scrub and circulating personnel observed a minimum of one case prior to functioning in that specific role. Prior to the first case, one scrub nurse and circulator observed two cases at a nearby facility in Richmond, VA.

The medical staff credentialing board developed and defined the surgical algorithm of training which included approximately two hours of online modules provided by Intuitive Surgical specific to specialty, four hours of simulation on the surgeon console with greater than 90% rating on each assigned series, two onsite sessions consisting of robotic console instruction, docking, port placement, and overall review of each Da Vince XI component. The surgeon training also included a pig lab at an Intuitive Surgical sponsored lab and four proctored cases for inexperienced surgeons or one proctored case for experienced surgeons with documentation of successful robotic cases.

Implementation Plan

IRB procedure. Approval for the study was obtained from the Institutional Review Board Office of Research Subjects' Protections for use of Protected Health Information of Radford University (Appendix A), and Augusta Health Medical Center (Appendix B), the participating hospital.

Data Access & Data Collection/Management. Participation was a convenience sample identified through data mining of the electronic medical record database. Privacy and confidentiality were protected by using patient account number rather than names or unique identifiers. A waiver of consent was granted since this study had minimal risk, if any. Participants' names were not collected nor included in any data. The medical record account number was initially collected and subsequently deleted after verification of all data.

Data was stored on a password-protected USB drive. Appropriate precautions were used to protect information and security measures are in place to protect against the loss, misuse, or alteration of the information under our control.

Procedures to ensure all data were as clean and accurate as possible, as analyses were implemented by a manual validation of extracted data within the electronic medical record (EMR). Data quality was enhanced through use of programmed data quality checks to automatically identify and flag anomalous data.

Data were extracted from inpatient EMR, billing, and quality event reporting from the surgical procedural date through the discharge date. Potential predictive factors recorded at the time of admission and during the hospitalization were included. Data collection included: (1)

patient characteristics, (2) surgical operative experience (intraoperative period), (3) postoperative interventions, and (4) patient outcomes. There were data subsets within each of these four categories.

Different Radical Prostatectomy Modalities. All subjects in this study underwent either a robotic-assisted or open surgical prostate intervention for adenocarcinoma or benign prostatic hypertrophy with obstruction after verbal discussion with their surgeon. The surgical modality was chosen by the patient after treatment options, risks, and benefits were described and a surgical consent was obtained. All subjects were brought to the preoperative holding suite at a minimum one hour prior to surgical time to allow sufficient time for surgical preparation, which included: initiate intravenous fluids, surgical preoperative scrub, anti-embolism stockings, sequential compression devices, and nursing assessment followed by an anesthesia assessment by the anesthesiologist. The anesthesiologist discussed the anesthetic options in which all participants chose to undergo a general anesthetic in this study. All preoperative antibiotics and anticoagulant medications were administered upon entry to the operating room suite by the anesthesiologist.

Robotic-assisted radical prostatectomy. The patients were placed in dorsal lithotomy position, prepped and draped in the standard surgical fashion. An 8mm midline incision was made in the supraumbilical space. Then, a Verres needle was then placed through the incision and freely irrigated with normal saline. Once peritoneal insufflation was accomplished to 15mmHg using carbon dioxide gas, the Verres needle was removed and an 8mm robotic trocar with blunt obturator was placed. The obturator was then removed and a 0 degree laparoscope

lens was inserted. Abdominal cavity was inspected for viscus or vascular injury secondary to Verres needle or port placement. Under direct visualization with 0 degree lens, three additional 8mm robotic ports were placed right and left lateral to the umbilicus, and in the left lower quadrant. Two additional assistant ports, a 5mm and 12mm Airseal port, were placed in the right upper and right lower quadrants respectively. The patient was then placed in steep Trendelenburg position with an inclination of 30 degrees, having all pressure points padded appropriately. Da Vinci Surgical System was docked and surgical instrumentation inserted for manipulation. A nerve-sparing approach and pelvic node dissection were performed at the surgeon's discretion after considering PSA, Gleason score, number and location of positive cores, and intraoperative findings. At the end of the surgery, the Da Vinci Surgical System was undocked and the prostate was removed through the supraumbilical incision with the assistance of an Endocatch bag. The peri-umbilical port site was extended as needed. Incisions were closed appropriately and infiltrated with 0.25% Bipuvicaine. All incisions were then cleaned, dried, and sterilely dressed using Mastisol, Steri-strips, and Primapore dressings.

Open Radical Prostatectomy. The open radical prostatectomy was completed via two approaches, either through an abdominal or perineal incision. The abdominal approach does allow for nerve-sparing and bilateral lymph node dissection at the discretion of the surgeon; however, the perineal approach does not.

In the abdominal approach, patients were placed in a supine position and sterilely prepped and draped in the standard surgical fashion. A midline abdominal incision was made extending from umbilicus to pubis. A surgical retractor was inserted to expose the prostatic area.

A nerve-sparing approach and pelvic node dissection were performed at the surgeon's discretion after considering PSA, Gleason score, number and location of positive cores, and intraoperative findings. After mobilization and dissection of the prostate, the prostate was extracted through the abdominal incision. The fascia and subcutaneous layers were approximated with suture and the skin was closed with staples. Skin was cleaned, dried, and sterilely dressed with 4x4s and taped in place with paper tape.

In the perineal approach, patients were placed in high lithotomy and moderate Trendelenburg position with an inclination of 15 degrees. Patient prepped and draped in standard surgical fashion. An inverted U-shaped incision was made from ischial tuberosity to ischial tuberosity across the midline approximately 1.5 cm anterior to the rectal wall. A surgical retractor was placed to assist in exposure. Dissection was carried along the anterior rectal wall to the apex of the prostate. The endopelvic fascia was dissected and the prostate was detached and surgically extracted through the perineal incision. The rectum was then inspected for injury. Wound irrigated and surgical incision were approximated. The incision was cleaned, dried, and dressed sterilely with 4x4's and paper tape.

Analysis Plan

Outcome Variables. Data were extracted from inpatient EMR, billing, and quality event reporting from the surgical procedural date through the discharge date. Potential predictive factors recorded at the time of admission and during the hospitalization were included. Data collection included: (1) patient characteristics, (2) surgical operative experience (intraoperative

period) (3) postoperative interventions, and (4) patient outcomes. There were data subsets within each of these four categories. Table 1 lists the outcome variables collected.

Subject Account #	To be deleted after all data collection has been verified
Date of Procedure	
Procedure Name	
BMI	
Age	
Ethnicity: Hispanic, Non hispanic, unknown	
Employment status	
Insurance Type	
Surgical Room Time (In)	
Surgical Room Time (Out)	
Surgical Room Total (h:mm)	
Procedure Start Time	
Procedure Stop Time	
Procedure Total (h:mm)	
Docking On Time	
Docking Off Time	
Docking Total Time (h:mm)	
Estimated Blood Loss (mL)	
Units Blood Transfused	
Recovery Room LOS (minutes)	
Intra-op Narcotic Usage	
Recovery Room Narcotic Usage	
Post op Narcotic Usage	
Pain score q 8 hours post op	
Hospital Length of Stay (midnights & h:mm)	
Complications (Intra-op and Post-op)	
Cost (Overall facility fees)	
Cost (Procedural Cost)	

Table 1: Data Outcome Variables Collected for Study

Statistical Analysis. Demographic data such as age, race, employment status, BMI, and insurance type were analyzed using frequencies and percentage for nominal/categorical variables and mean and standard deviation for continuous variables. The differences in demographic data between RARP and ORP group were analyzed using the Chi square and Fisher-Exact test, for nominal/categorical variables and independent t-test for continuous variables.

Intraoperative and perioperative outcomes and cost will be reported as frequency and percentage for nominal/categorical variables and mean and standard deviation for continuous variables. The differences of intraoperative and perioperative and cost between RARP and ORP group will be analyzed using Chi Square or Fisher Exact test for nominal and categorical variables and independent t-test for continuous variables. Level of statistical significance is established as alpha = 0.05 and SPSS Statistics version 24 was used for statistical analysis. Because the study cohort was predetermined due to sample size being comprised of prostatectomies during a specified time period, a prospective sample size determination was not applicable.

Chapter 4. Results/ Findings

Sample Description and Recruitment

Participants for the study were recruited from a convenience sample of all men that had undergone a prostatectomy during the time frame of October 25, 2016 to October 25, 2017 from an independent community acute care hospital in Virginia. The entire study sample initially consisted of 65 surgical prostatectomy patients. Six robotic-assisted prostatectomy cases were removed due to cases being completed in combination with other surgical procedures (i.e., six cases in combination with umbilical hernia repair, lysis of adhesion, urethral dilatation and/or cystolithotomy) resulting in a final sample size of 59 surgical prostatectomy procedural patients used in data analysis. Table 2 lists the frequency 59 men who underwent surgical radical prostatectomies.

The sample of 59 surgical prostatectomies included 36 (61.0%) robotic-assisted prostatectomy procedures that were composed of both retropubic (n =31) and suprapubic (n=5) radical prostatectomy. Retropubic is characterized by enucleation of prostate through a direct incision of the anterior prostatic capsule; while the suprapubic is characterized by the enucleation of prostate through an extraperitoneal incision of the lower anterior bladder wall. In comparison to the open radical prostatectomies procedures were composed of only two abdominal retropubic radical prostatectomies and twenty one perineal radical prostatectomies.

Surgical Procedure	Frequency	Percentage	Cumulative Percentage
Robotic Assisted			
• Radical Retropubic	9	15.3	15.3
• Radical Retropubic with Lymph Node Dissection	22	37.3	52.6
• Suprapubic	5	8.5	61.1
Open			
• Abdominal Radical Retropubic with Lymph Node Dissection	2	3.4	64.5
• Radical Perineal	21	35.6	100.0

Table 2. Frequency of 59 Patients who Underwent Surgical Radical Prostatectomies

Patient Demographic Analysis

In comparing the RARP group (n =36) and ORP group (n =23), the data explored the differences in patient demographics including: age, BMI, and characteristics such as ethnicity, employment, and insurance. Table 3 lists the demographic characteristics of 59 men who underwent surgical prostatectomy.

In the sample population, the average age was 63.0 ± 6.9 years with a body mass index (BMI) of 29.5 ± 4.8. In comparing RARP and ORP, the age (62.14 +/- 7.34 vs. 64.37 +/- 5.96, p = .23) and BMI (28.8 ± 4.5 vs. 30.6 ± 5.2, p = .15) demonstrated no statistical significant difference. The ethnicity and employment status of both groups were found to be comparable.

However, the insurance coverage for the RARP group resulted in the majority of men having had Medicare insurance 16 (44.4%), while only 14 (38.9%) Blue Cross Blue Shield insurance; however in comparison, the open group (ORP) resulted in the majority of men having had 12 (52.2%) Blue Cross Blue Shield insurance, followed by 7 (30.4%) Medicare, which revealed a slight difference between the surgical modalities but not significant.

Patient Demographic	Overall	RARP	ORP	P-value
Age	63.0 (± 6.9)	62.1 (± 7.3)	64.4 (± 6.0)	NS
BMI	29.5 (± 4.8)	28.8 (±4.5)	30.6 (± 5.2)	NS
Ethnicity				
White	57 (96.6%)	35 (97.2%)	22 (95.7%)	NS
Nonwhite	2 (3.4%)	1 (2.8%)	1 (4.3%)	
Employment				
Employed	33 (55.9%)	20 (55.6%)	13 (56.5%)	NS
Retired	23 (39.0%)	14 (38.9%)	9 (39.1)	
Unemployed	1 (1.7%)	1 (2.8%)	0 (0.0)	
Disabled	2 (3.4%)	1 (2.8%)	1 (4.3%)	
Insurance				
Medicare	23 (39.0%)	16 (44.4%)	7 (30.4%)	NS
Blue Cross	26 (44.1%)	14 (38.9%)	12 (52.2%)	
Commercial	10 (16.9%)	6 (16.7%0	4 (17.45)	

Table 3. Demographic Data of 59 Patients who Underwent Surgical Radical Prostatectomies

Intraoperative Outcome Analysis

The operative outcomes defined for analysis between the RARP and ORP groups included: operative room time, surgical/procedure time, and estimated blood loss (EBL). Table 5 lists the patient outcome data.

Operative Room Time. The operative room time is defined as the time from patient entry to operative suite to patient exit of operative suite, also known as wheels in to wheels out. The operative room time is inclusive of positioning, anesthetic induction time, surgical/procedural time, emergence from anesthesia, and application of wound dressings. The overall operative room time was 2.65 hours ± .54. There was a statistically significant difference between the groups with respect to operative room time (RARP 2.90 ±.49 vs. ORP 2.27 ± .36, p = .000).

Surgical/Procedural Time. The surgical/procedural time is defined as the time of incision to closure of all incisions. The overall surgical/procedural time was 1.88 hours ± .610 (range, .49 - 3.43 hours). There was a statically significant difference between the groups with respect to surgical/procedural time (RARP 2.24 ± .42 vs. ORP 1.31 ± .38, p = .000).

Estimated Blood Loss (EBL). The EBL is defined as the amount of estimated blood loss during the operative procedure. This estimated blood loss is approximated by the surgeon. In this study there were two missing data points for estimated blood loss that were removed. The overall EBL was 172.37 mL ± 191.37 (range, 50 - 1400mL). There was one outlier (1400 mL) within the data points. The outlier was attributed to the one of the two abdominal open radical prostatectomy with lymph node dissection performed during the study time period. There was no significant difference in respect to EBL between the groups (RARP 145.1 mL ± 67.8 vs. ORP 219.1 mL ± 301.5, p = .28).

Perioperative Outcome Analysis

The perioperative outcomes defined for analysis between RARP and ORP groups included: transfusion rates, postoperative pain, complication rates, recovery room length of stay and hospital length of stay. Table 5 lists the patient outcome data.

Transfusion Rate. The data analysis revealed that of the 59 patients within the sample of prostatectomies, none received any blood transfusions during their hospital stay intraoperatively or postoperatively; therefore, there was no difference between the groups.

Postoperative Pain. Overall, 36 of 59 (61.0%) men who underwent a prostatectomy received narcotics for pain control within the recovery room. Of these who received narcotics, the majority of men was RARP, this was not a statistically significant difference at $p \leq 0.05$.

Postoperative narcotic orders varied by surgeon preference. The majority (69.4%) of the RARP postoperative narcotic orders included: PCA Hydromorphone IV, Oxycodone HCL PO, and Hydromorphone HCL PO. In comparison, the narcotic drug of choice for the ORP postoperative narcotic orders (86.99%) included: Morphine Sulfate IV and Oxycodone HCL PO.

In evaluating the postoperative pain, pain scores (Likert scale 0-10) were measured at 4 hour intervals for comparison: at arrival to surgical floor unit and every four hours at 1900, 2300, 0300, 0700, and 1100 military time. The pain score throughout the 4 hour intervals were not significantly different between the two groups (p = ns). However, the pain score at arrival was significantly lower in the RARP than in ORP (1.64 ± 2.00 vs. 3.22 ± 3.09, $p = 0.03$). Table 4 lists pain score data.

	Surgical Technique	N	Mean	Std. Deviation	P-value
Pain Score (0-10) First on Postop Floor	RARP	36	1.64	2.002	P < 0.05
	ORP	23	3.22	3.029	
Pain score (0-10) 1900 on Postop Day 0 =/- 2 hours	RARP	33	1.48	1.642	NS
	ORP	20	1.85	1.872	
Pain Score (0-10) Postop Day 0 at 2300 =+/- 2hours	RARP	33	1.09	1.646	NS
	ORP	23	1.04	1.821	
Pain Score (0-10)Postop Day 1 at 0300 +/- 2 hours	RARP	31	.77	1.499	NS
	ORP	23	1.43	2.519	
Pain Score (0-10)Postop Day 1 at 0700 +/- 2 hours	RARP	35	1.83	2.121	NS
	ORP	22	1.86	2.274	
Pain Score (0-10)Postop Day 1 at 1100 +/- 2 hours	RARP	30	2.90	2.746	NS
	ORP	21	2.33	2.033	

Table 4. Postoperative pain data for 59 Patients who Underwent Radical Prostatectomies

Complication Rate. Thirteen men (22.0%) who underwent a prostatectomy did experience a complication resulting in an extended length of stay greater than one midnight. The documented complications consisted of 5.1% small urine leak, 5.1% ileus, 3.4% re-admission within 7 days, 3.4% mild abdominal pain, 1.7% intra-op foley replacement (no free flow), 1.7% postop pain control, and 1.7% bleeding. None of the complications resulted in a long-term sequela.

The majority 9 (25.0%) of complications were attributed to the RARP group, while only 4 (17.4%) of complications were attributed to the ORP group which resulted in an extended the

length of stay. This was not a statistically significant difference (p = .49), suggesting that RARP is not more likely to have more intraoperative or perioperative complications resulting in an extended length of stay greater than one midnight than are ORP.

Recovery Room Length of Stay. The recovery room length of stay is defined as the immediate time of care following the surgical procedure to allow patients to awaken and recover from the anesthetic effects and manage pain to a tolerable level. The time is calculated from time of entry to department until patient has met discharge criteria from the unit. The discharge criteria included: appropriate airway patent and respiratory function for discharge destination, stable vital signs (blood pressure and pulse) as reflected by consecutive observations without significant hypotension or hypertension, sufficient level of consciousness to allow the patient to call for assistance, temperature greater than or equal to 36 degree Celsius, urine output that is at least 30ml/hr if foley catheter in place or bladder is not distended, surgical dressing sites dry and intact, and initiated pain and/or nausea treatment with the patient observed for a minimum of fifteen minutes after the last dose.

The overall recovery room length of stay was 84.31 minutes ± 30.13 minutes (range, 35 - 185 minutes). There was no significant difference between the groups with respect to recovery length of stay (RARP 87.7 minutes ± 34.35 vs. ORP 79.0 minutes ± 21.63, p = .29).

The data was further analyzed to compare the impact of providing Ofirmev 1000mg/ml intraoperatively on recovery length of stay. Of the 25 men who received Ofirmev intraoperatively, there was no significant difference in recovery length of stay between those

men who received Ofirmev intraoperatively and those men who did not (82.2 minutes ± 16.1 vs. 85.9 minutes ± 37.4).

The data was then analyzed to compare the impact of Toradol 30 mg IV administered intraoperatively on recovery room length of stay. Of the 17 men who received Toradol intraoperatively, there was again no significant difference in recovery room length of stay between those men who received Toradol intraoperatively and those men who did not (80.18 minutes ± 26.09 vs. 86.54 minutes ± 32.68).

Length of Stay (Hospital). The hospital length of stay was calculated from the time of admission to patient room on medical/surgical floor after the post-anesthesia recovery period to time of discharge to home. The overall hospital length of stay was 29.95 hours ± 10.66 (range, 16.21 - 73.29 hours). The one outlier (73.29 hours) was attributed to a robotic-assisted radical prostatectomy with lymph node dissection that had a perioperative complication of ileus, which resulted in a prolonged length of stay. There was no statistically significant difference between the groups with respect to hospital length of stay (RARP 30.28 hours ± 12.59 vs. ORP 29.44 hours ± 6.84, $p = .740$).

Cost Analysis

The cost defined for analysis between RARP and ORP groups included: procedural cost and overall hospital cost. Table 5 lists the patient outcome data.

Procedural Cost. The procedural cost reflected the direct costs of the surgical experience, which includes the disposable supply costs, pharmacy costs, OR staff salaries/benefits, and instrumentation costs. The overall procedural cost was $2,365.52 ±

$1,171.74 (range, $948.79 - $3,550.63). There was a statically significant difference between the groups with respect to procedural cost (RARP $3,260.69 ± $399.04 vs. ORP $964.39 ±$51.49, p = .000).

Hospital Cost (Overall). The hospital cost reflected the overall direct costs of the hospital admission, which was inclusive of procedural costs, pharmaceuticals, and disposable supply costs. The overall hospital cost was $6,112.15 ± $1,196.92 (range, $4,182.79 - $9,060.36). There was a statically significant difference between the groups with respect to overall hospital cost (RARP $6,777.69 ± $993.14 vs. ORP $5,070.44 ± $590.30, p = .000).

In further analysis, the overall hospital cost minus the procedural cost reflects the cost attributed to the postoperative care which is inclusive of disposable supplies, postoperative surgical room charge, equipment, and pharmaceuticals. Again there was a statically significant difference; however, the postoperative costs were in favor of the RARP group (RARP $3,739.00 ± $780.88 vs. ORP $4,236.11 ± $579.77, p = .007).

Patient Outcomes	Overall (n 59)	RARP (n 36)	ORP (n 23)	P-value
Intraoperative Outcomes				
Operative Room Time (hours)	2.65 (± .54)	2.90 (± .46)	2.27 (± .36)	P < 0.05
Surgical//Procedural Time (hours)	1.88 (± .61)	2.24 (± .42)	1.31 (± .38)	P < 0.05
Blood Loss (mL)	172.37 (± 191.37)	145.14 (± 67.83)	219.05 (± 301.45)	NS
Perioperative Outcomes				
Recovery LOS (minutes)	84.31 (± 30.13)	87.67 (± 34.35)	79.04 (± 21.63)	NS
Transfusion Rate	0	0	0	NS
Complication Rate	13 (22.0%)	9 (25.0%)	4 (17.4%)	NS
Hospital LOS (hours)	29.95 (± 10.66)	30.28 (± 12.59)	29.44 (±6.84)	NS
Cost				
Procedure Cost	$2,365.52 (± 1,171.74)	$3,260.69 (± 399.04)	$964.39 (±51.49)	P < 0.05
Overall Hospital Cost	$6,112.15 (± 1196.92)	$6,777.69 (±993.14)	$5070.44 (± 590.30)	P < 0.05

Table 5. Patient Outcome Data of 59 Patients who Underwent Surgical Radical Prostatectomies

Discussion

In this study of 59 men who underwent a prostatectomy via RARP or ORP, the researcher wanted to identify the impact of a new robotic-assisted program to patient outcomes in the prostatectomy population. Therefore, during the first year of inception, the data analysis compared patient demographics, surgical operative outcomes, perioperative outcomes, and cost between the two surgical modalities.

Patient Demographics. The data analysis demonstrated that there was no statistically significant differences among the patient demographics for the RARP versus ORP groups including: age, BMI, ethnicity, employment. There was a slight difference in the majority of

insurance coverage between the two groups; however this difference was not significant. Therefore, one can conclude based on this study, there was no difference in patient selection differences between surgical modalities.

Intraoperative Outcomes. Similar to recent studies, the intraoperative outcome analysis did reveal a significant difference demonstrating that both the surgical room time and procedural time were both significantly greater for the RARP group. However, in a study by Davis, J.W. (2013), the research found that in comparing surgeons with varying levels of experience (ranging from 25 to greater than 100 cases performed) that surgeons with greater than 100 cases decreased surgical time from 5.0 to 3.9 hours. In another study, Yaxley et al. (2016) of one experienced surgeon with greater than 1000 robotic-assisted cases reported decreased operative times with a statistical significant difference (ORP 234 min vs RARP 202 min, $p < 0.0001$). The literature synthesis supports the idea of a surgeon having a significant learning curve with the new technology, however, this learning curve may be overcome with repetition and eventually lead to decreased operative times.

Unlike the findings of recent literature findings, EBL did not demonstrate a statically significant difference. In comparison to the literature, the lack of statistical significance may be the result of the majority of ORP (n=21) included in this study were of the perineal approach. In a recent study by Alemozaffar et al. (2015) who found significant difference in EBL, the study's procedural composition consisted of 64% abdominal retropubic radical prostatectomies, 19% RARP, 3 % laparoscopic radical prostatectomies, and only 3 % radical perineal prostatectomies. Similarly, Tewari et al. (2012) compared 167,184 abdominal retropubic radical prostatectomies,

57,303 laparoscopic radical prostatectomies, and 62,389 robotic-assisted radical prostatectomies which resulted in a significant difference in EBL in favor of RARP.

Perioperative Outcomes. Unlike recent literature findings, this study found comparable perioperative outcomes between RARP and ORP groups including: transfusion rates, postoperative pain, complications, recovery room length of stay, and overall hospital length of stay. A major difference in comparison of this study and recent literature is the time period of data collection. This study compared outcomes during the inception period of a new robotic assisted program; however the majority of recent literature was conducted after the initial learning curve. Although the recent literature varies on the number of cases to overcome initial learning curve (10 to 200 cases), Davis, J.W. (2013), found that in analyzing surgeons with greater than 100 cases, the complications decreased 11.75% to 8.95% with the last completed 25 cases in comparison to the first 25 cases.

Unlike recent literature findings, the composition of procedure mix did not correlate as well. Our procedure mix for the open radical prostatectomy was largely composed of the perineal approach (21 of 23 procedures), unlike the majority of recent literature as stated earlier.

In addition, our study was limited to immediate perioperative outcomes. This study did not compare patient satisfaction, resumption of normal activities, functional outcomes, reoccurrence of cancer, pathological findings, and/or surgical margins.

Cost. Similar to the literature findings, the data analysis demonstrated that the RARP costs for both the operative procedure and overall hospital cost were significantly greater than the ORP costs. The extended surgical time and cost for newer technology directly impacts cost.

Leow et al. (2016) compared the costs of 629,593 men who underwent radical prostatectomy. Although the study found significant increased cost associated with the RARP, a subgroup analysis also revealed that the cost difference amongst the high-volume surgeons no longer showed a significant cost increase ($p = 0.15$). This suggests that with increased experience and repetition producing efficiency, the increased cost may be overcome with time and experience.

Although our study did not measure length of work release due to procedure recovery/downtime, this study demonstrated that 33 (55.9%) of men were employed. Bilanji et al. (2016) found in respect to the societal perspective that based on a 66% employment rate and average earning rate of $202.40 per day, RARP was associated with lower wage losses due to shorter post-procedure downtime/recovery time (ORP $9,271 versus RARP $8,068). This may suggest that from a patient perspective the ability to return to normal activities exceed the initial hospital costs of the RARP.

Limitations

This study had several limitations including lack of randomization as there was one surgeon who performed all RARP procedures and another surgeon who performed all ORP via perineal approach, and a third surgeon who performed the two ORP via the abdominal approach. The single surgeon performing RARP had approximately 50 completed cases prior to the initiation of this study. The two surgeons performing the open radical prostatectomies had greater than 500 completed cases prior to this study. Lack of randomization may be due to retrospective design as well. Additional limitations to this study included lacking documentation for pain scores every four hours and physician summary outlining the complications which led to

an extended length of stay, single site study, limited sample size due to time period included in study, lack of functional outcomes, lack of pathologic endpoints, and limited clinical data points beyond the hospital stay. Therefore, this study is only a partial analysis of the comparative effectiveness of patient outcomes.

Chapter 5. Conclusions

The RARP has shown to take longer procedural time and is more costly compared with ORP. However, the arrival pain score to surgical unit was less in RARP than ORP and the intraoperative and perioperative patient outcomes were comparable between the two surgical modalities including estimated blood loss, transfusion rate, complication rate, recovery length of stay, and overall hospital length of stay. With continued experience and volume to overcome the learning curve, the literature supports decreasing procedural time and no significant difference in cost over time. This result supports this new robotic surgery program as another safe option for prostate cancer treatment for community hospitals.

References

Alemozaffar, M., Sanda, M., Yecies, D., Mucci, L. A., Stampfer, M. J., & Kenfield, S. A. (2015). Benchmarks for operative outcomes of robotic and open radical prostatectomy: Results from the health professionals follow-up study. *European Urology, 67*(3), 432-438. doi:http://dx.doi.org.lib-proxy.radford.edu/10.1016/j.eururo.2014.01.039

American Association of Colleges of Nursing. (2006). *The essentials of doctoral education for advanced nursing practice*. Washington, DC: Author.

Ayanian, J. Z., & Markel, H. (2016). Donabedian's lasting framework for health care quality. *New England Journal of Medicine, 375*(3), 205. doi:10.1056/NEJMp1605101

Bijlani, A., Hebert, A. E., Davitian, M., May, H., Speers, M., Leung, R., . . . Tewari, A. (2016). A multidimensional analysis of prostate surgery costs in the united states: Robotic-assisted versus retropubic radical prostatectomy. *Value in Health, 19*(4), 391-403. doi:http://dx.doi.org.lib-proxy.radford.edu/10.1016/j.jval.2015.12.019

Bolenz, C., Freedland, S. J., Hollenbeck, B. K., Lotan, Y., Lowrance, W. T., Nelson, J. B., & Hu, J. C. (2014). Costs of radical prostatectomy for prostate cancer: A systematic review. *European Urology, 65*(2), 316-324. doi:http://dx.doi.org.lib-proxy.radford.edu/10.1016/j.eururo.2012.08.059

Daubert, G. L., & McCurdy, D. A. (2017). CMS finalizes Medicare OPPS, ASC rates and policies for CY 2018. Retrieved from https://www.healthindustrywashingtonwatch.com/2017/11/articles/regulatory-developments/medicare-medicaid-services-regulations/cms-finalizes-medicare-opp

Davis JW. (20140501). Learning curve assessment of robot-assisted radical prostatectomy compared with open-surgery controls from the premier perspective database. *Journal of Endourology, 28*(5), 560-6. doi: 10.1089/end.2013.0534

De Carlo F. (20140101). Retropubic, laparoscopic, and robot-assisted radical prostatectomy: Surgical, oncological, and functional outcomes: A systematic review. *Urologia Internationalis, 93*(4), 373-83. doi: 10.1159/000366008

Di Pierro, G. B., Wirth, J. G., Ferrari, M., Danuser, H., & Mattei, A. (2014). Impact of a single-surgeon learning curve on complications, positioning injuries, and renal function in patients undergoing robot-assisted radical prostatectomy and extended pelvic lymph node dissection. *Urology, 84*(5), 1106-1111. doi:http://dx.doi.org.lib-proxy.radford.edu/10.1016/j.urology.2014.06.047

Jackson, M. A., Bellas, N., Siegrist, T., Haddock, P., Staff, I., Laudone, V., & Wagner, J. R. (2016). Experienced open vs early robotic-assisted laparoscopic radical prostatectomy: A 10-year prospective and retrospective comparison. *Urology*, *91*, 111-118. doi:http://dx.doi.org.lib-proxy.radford.edu/10.1016/j.urology.2015.12.072

Kim, S. P., Shah, N. D., Karnes, R. J., Weight, C. J., Shippee, N. D., Han, L. C., . . . Thompson, R. H. (2013). Hospitalization costs for radical prostatectomy attributable to robotic surgery. *European Urology, 64*(1), 11-16. doi:http://dx.doi.org.lib-proxy.radford.edu/10.1016/j.eururo.2012.08.012

Leow, J. J., Chang, S. L., Meyer, C. P., Wang, Y., Hanske, J., Sammon, J. D., . . . Trinh, Q. (2016). Robot-assisted versus open radical prostatectomy: A contemporary analysis of an all-payer discharge database. *European Urology, 70*(5), 837-845. doi:http://dx.doi.org.lib-proxy.radford.edu/10.1016/j.eururo.2016.01.044

Lim, S. K., Kim, K. H., Shin, T. Y., & Rha, K. H. (2013). Current status of robot-assisted laparoscopic radical prostatectomy: How does it compare with other surgical approaches? *International Journal of Urology, 20,* 271-284. doi:10.1111/j.1442-2042.2012.03193.x

Moran, P. S., O'Neill, M., Teljeur, C., Flattery, M., Murphy, L. A., Smyth, G., & Ryan, M. (2013). Robot-assisted radical prostatectomy compared with open and laparoscopic approaches: A systematic review and meta-analysis. *International Journal of Urology, 20*, 312-321. doi:10.111/iju.12070

Novara, G., Ficarra, V., Rosen, R. C., Artibani, W., Costello, A., Eastham, J. A., . . . Wilson, T. G. (2012). Systematic review and meta-analysis of perioperative outcomes and complications after robot-assisted radical prostatectomy. *European Urology, 62*(3), 431-452. doi:http://dx.doi.org.lib-proxy.radford.edu/10.1016/j.eururo.2012.05.044

Nayeemuddin, M., Daley, S. C., & Ellsworth, P. (2013). Modifiable factors to decrease the cost of robotic-assisted procedures. *AORN Journal, 98*(4), 343-352. 10.1016/j.aorn.2013.08.012

Pearce, S. M. (20160701). Comparison of perioperative and early oncologic outcomes between open and robotic assisted laparoscopic prostatectomy in a contemporary population based cohort. *Journal of Urology, 196*(1), 76-81. doi:http://dx.doi.org/10.1016/j.juro.2016.01.105

Pucheril, D. (20160401). Prostate cancer: A clinician's guide to avoiding and managing common complications during and after robot-assisted laparoscopic radical prostatectomy. *European Urology Focus, 2*(1), 30-48. doi:http://dx.doi.org/10.1016/j.euf.2016.03.013

Shi, L., & Singh, D. (Eds.). (20147). *Essentials of the US health care system* (Fourth ed.). Burlington, MA: Jones & Bartlett Learning.

Tewari, A., Sooriakumaran, P., Bloch, D. A., Seshadri-Kreaden, U., Hebert, A. E., & Wiklund, P. (2012). Positive surgical margin and perioperative complication rates of primary surgical treatments for prostate cancer: A systematic review and meta-analysis comparing retropubic, laparoscopic, and robotic prostatectomy. *European Urology, 62*(1), 1-15. doi:http://dx.doi.org.lib-proxy.radford.edu/10.1016/j.eururo.2012.02.029

Yaxley, J. W., Coughlin, G. D., Chambers, S. K., Occhipinti, S., Samaratunga, H., Zajdlewicz, L., . . . Gardiner, R. A. (2016). Robot-assisted laparoscopic prostatectomy versus open radical retropubic prostatectomy: Early outcomes from a randomised controlled phase 3 study. *The Lancet*, *388*(10049), 1057-1066. doi:http://dx.doi.org.lib-proxy.radford.edu/10.1016/S0140-6736(16)30592-X

Appendix A

Radford University IRB approval

Radford University's Institutional Review Board
P.O. Box 6926 Radford, VA 24142 | Phone: (540) 831-5290 | Fax: (540) 831-6636 | irb-iacuc@radford.edu

MEMO DATE:	30-Oct-2017
TO:	Mullenbach, Kereen R
FROM:	Laura Noll lnoll@radford.edu *Radford University IRB*
RE:	Approval for FY18-011: Robotic Surgery: Prostatectomy Surgical Approach Comparison.
STUDY TITLE:	Robotic Surgery: Prostatectomy Surgical Approach Comparison.
IRB REFERENCE #:	FY18-011
SUBMISSION TYPE:	Initial Application
ACTION:	Approved
EFFECTIVE DATE:	30-Oct-2017
EXPIRATION DATE:	29-Oct-2018
REVIEW TYPE:	Expedited Review

This is to confirm that the above-referenced study submitted for Expedited Review to Radford University's Institutional Review Board (IRB) has been granted approval.

Your IRB-sanctioned approval ends on 29-Oct-2018, by which date a closure report is due. If you wish to continue your research beyond this date, you must request a continuance no later than 10 days prior to the expiration of this approval. Because your study requires documentation of informed consent, you must use the stamped copy of your approved consent document.

If you should need to make changes in your protocol, please submit a request for modification before implementing the changes. Modifications are made via the InfoEd system. Please contact our office for assistance, if needed.

As the principal investigator for this project, you are ultimately responsible for ensuring that your study is conducted in an ethical manner. You are also responsible for filing all reports related to this project.

If you have any questions, please contact Laura Noll at (540) 831-5290 or lnoll@radford.edu. Please include your study title and reference number in all correspondence with this office.

Good luck with this project!

Appendix B

Augusta Health IRB Approval

Augusta Health
PO Box 1000
Fishersville, VA 22939

Phone (540) 332-1000 Staunton
Phone (540) 932-1000 Waynesboro
Toll Free 1-800-932-0252
www.augustahealth.com

Notice of Expedited IRB Approval

Principal Investigator: Vickie Taylor, RN, BSN, MSN

Protocol Title: Robotic Prostatectomy and Traditional Surgery Patient Outcome Comparison

Type of Review: Initial – EXPEDITED – Category 5

IRB Study Number 17-07

Date of Approval: June 29, 2017

The Augusta Health Institutional Review Board has reviewed your study submission and has determined that it is acceptable to proceed with initiating this study involving a through a retrospective chart review. This study is Data Gathering and there is No Risk to patient and Consent is not needed.

Please note that this approval expires at 12am on **June 29, 2018**. At that time, all study activity must cease. If you wish to continue this study beyond the expiration date, you must submit a request for renewal to the Human Protections Administrator or IRB Chairperson at least thirty (30) days prior to the expiration date.

The Augusta Health Institutional Review Board, FWA 00003292, is duly constituted, fulfilling all requirements for diversity, and has written procedures for initial and continuing review of human subjects research protocols. The AH IRB complies with all US regulatory requirements related to the protection of human research participants, specifically 45CFR46, 21CFR50, 21CFR56, 21CFR312, 21CFR812, 45CFR164.508-14. In addition, the AH IRB complies with the guidelines of the Office of Human Subjects Protection of the OHHS.

Rob Ginsberg, MD
IRB Authorized Signature

6/29/17
IRB Signature Date