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Radical Hysterectomy: A comparison of surgical approaches after adoption of robotic surgery in gynecologic oncology

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Abstract

Objective—To compare intra-operative, postoperative and pathologic outcomes of three surgical approaches to radical hysterectomy and bilateral pelvic lymph node dissection over a three year time period during which all three approaches were used.

Methods—We reviewed all patients who underwent radical hysterectomy with pelvic lymph node dissection between 1/2007 and 11/2010. Comparison was made between robotic, laparoscopic and open procedures in regard to surgical times, complication rates, and pathologic findings.

Results—A total of 95 radical hysterectomy procedures were performed during the study period: 30 open (RAH), 31 laparoscopic (LRH) and 34 robotic (RRH). There were no differences in age, body mass index or other demographic factors between the groups. Operative time was significantly shorter in the RAH compared to LRH and RRH (265 vs 338 vs 328 min, $p=0.002$). Estimated blood loss was significantly lower in LRH and RRH compared with RAH (100 vs 100 vs 350 mL, $p<0.001$). Thirteen (24%) of RAH required blood transfusion. Conversion rates were higher in the LRH (16%) compared to RRH (3%) although not significant ($p=0.10$). Median length of stay was significantly shorter in RRH (1 days) vs LRH or RAH (2 vs 4 days, $p<0.01$). Pathologic findings were similar among all groups.

Conclusion—Minimally invasive surgery has made a significant impact on patients undergoing radical hysterectomy including decrease in blood loss and transfusion rates however; operative

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times were significantly longer compared to open radical hysterectomy. Our findings suggest that the robotic approach may have the added benefit of even shorter length of stay compared to traditional laparoscopy.

Keywords

robotic surgery; gynecologic oncology; radical hysterectomy; cervical cancer; laparoscopy

Introduction

Total laparoscopic radical hysterectomy (LRH) was first reported in the early 1990's [1, 2]. Since that time there have been a number of single institution reports on the feasibility of laparoscopic radical hysterectomy and pelvic lymph node dissection in the treatment of early stage cervical cancer [3-6]. While many of these report a decrease in blood loss, shorter hospital stay, and shorter recovery time in comparison to laparotomy, the uptake of LRH among gynecologic oncologists has been relatively slow. In 2003 Frumovitz *et al.* performed a survey of Society of Gynecologic Oncologists (SGO) members regarding the use of laparoscopy in the treatment of gynecologic cancers. Only 11% of respondents stated that they offer patients LRH for the treatment of early stage cervical cancer. The most common reasons cited for not offering LRH were increase in operative time and lack of training [7]. In a follow up survey performed in 2008, after many of the single institution reports on LRH had been published, the number had only increased to 38% [8].

In 2005 the da Vinci® surgical system (Intuitive Surgical, Sunnyvale, CA) received clearance from the Food and Drug Administration for use in gynecologic procedures. Introduction of this robotic surgical system has addressed many of the obstacles of conventional laparoscopy including lack of depth perception, limited range of motion, camera instability, and a steep learning curve [9]. The feasibility of robotic-assisted radical hysterectomy for the treatment of early cervical cancer was first published only 3 years ago [10]. Since that time there have been several single institutions studies reporting their comparative outcomes to historical cases of either traditional laparoscopy or abdominal radical hysterectomy [11-14]. While the comparison to historical controls is helpful, comparing patients from different time periods could reflect changes in practice patterns and have inherent bias.

Our group at MD Anderson Cancer Center began offering patients LRH in 2004, and in 2007 published a comparison with abdominal radical hysterectomy for the treatment of early cervical cancer [15]. In 2007, several of the surgeons at our institution changed their preferred approach to robotic radical hysterectomy, while others have continued to perform both open and laparoscopic procedures. The purpose of this study was to compare intra-operative, postoperative and pathologic outcomes of three surgical approaches among consecutive cases of radical hysterectomy and bilateral pelvic lymph node dissection over a three year time period during which all three approaches were used.

Materials and Methods

With approval from our Institutional Review Board, a prospective database of all robotic procedures performed in the Department of Gynecologic Oncology at MD Anderson Cancer Center was established. All records from patients who underwent radical hysterectomy procedures from 2007-2010 were reviewed. Included in this were procedures performed at MD Anderson Cancer Center's main hospital and those performed at 2 local outreach hospitals (St. Luke's Episcopal Hospital and Lyndon B. Johnson Hospital) where our surgeons operate. Data collection included demographic characteristics, operative times, pathologic results, as well as intra-operative and postoperative complications. All pathologic specimens were reviewed by a gynecologic pathologist. Prior to sectioning the specimen, gross measurements of parametrial tissue and vaginal cuff length were recorded.

At our institution, new patients are assigned to a physician randomly based on physician availability, unless a direct referral is requested. Once a patient is determined to be a candidate for radical hysterectomy, the surgeon's preference and ultimately the patient's decision determine the surgical approach that will be utilized. We currently have a prospective randomized study comparing minimally invasive surgery (either robotic or laparoscopic) to exploratory laparotomy for the treatment of early stage cervical cancer [16]. All patients who qualify for the trial are offered participation in this study.

For a majority of the robotic procedures, the da Vinci S System was used (Intuitive Surgical, Sunnyvale, CA). Instruments included a monopolar scissor, fenestrated bipolar grasper, and a Cadere grasper. Docking time, recorded at the time of the procedures, was defined as time to advance the column to the operating table, fastening the robotic arms to the inserted trocars, and introducing the camera and instruments. We feel this reflects the additional time required to perform a robotic procedure compared to traditional laparoscopy. A V-Care uterine manipulator was used when the patient's anatomy allowed easy placement. In cases where the V-care could not be placed either a sponge stick or an EEA sizer was used [17].

For the statistical analysis, parametric continuous variables were compared using the t-test for independent samples and one-way analysis of variance. Bonferroni adjustment was used for between group comparisons. Chi-square tests were used to compare differences in categorical variables. The Kruskal-Wallis test was used to evaluate differences in non-parametric continuous variables. Two-tailed p-values were used and a value less than 0.05 were considered statistically significant. For all statistical analyses SPSS 17.0 (SPSS Inc., Chicago, IL) was used.

Results

During the 3 year study period, 95 consecutive cases of radical hysterectomy and pelvic lymph node dissection were performed. One patient in the RRH group refused bilateral pelvic lymphadenectomy and after extensive counseling had only a sentinel lymph node biopsy performed. RAH was performed in 30 patients. LRH was performed in 31 women and RRH was performed in 34 patients. The mean age for the entire cohort was 48.0 years (range 23.5 – 82.2). The mean body mass index (BMI) was 27.7 kg/m² (range 18.7 – 47.8).

The demographic characteristics for each group of patients are listed in Table 1. There were no differences in age, weight, BMI, race, stage, or histology among the three groups.

Intra-operative findings and complications are listed in Table 2. The mean total OR time for the RAH (265 min) was significantly shorter than both the LRH (338 min, $p=0.003$) and RRH (328 min, $p=0.02$) when adjusted for multiple comparisons. There was no statistically significant difference between the minimally invasive groups. The median docking time for the robotic cases was 6 min (range 3 - 20). There was no difference in preoperative hemoglobin between the groups (median RAH 12.9 g/dL, LRH 13.3 g/dL, RRH 13.1 g/dL, $p=0.25$). Estimated blood loss (EBL) was significantly lower in the LRH and RRH surgery group (mean 100 mL each, $p<0.01$). This was also reflected in the lower transfusion rates. Overall significant intra-operative complications were uncommon with no ureteral or bowel injuries in the RAH group. In the LRH group there was one vascular and 2 bladder injuries that were repaired at the time of surgery with no long term consequences. The robotic complications included 2 ureteral injuries; one was a ureteral transection that was recognized intra-operatively and a conversion to laparotomy was required to repair the ureteral injury. This patient had an extended hospital stay, EBL of 1600 mL, and required a postoperative transfusion. The second ureteral injury was a thermal injury also recognized at the time of surgery. Postoperatively a ureteral leak was detected and a stent was placed. Both of these patients have recovered without residual effects.

As expected, there was a significant difference in the median length of hospital stay between the surgical groups; RAH 4 days, LRH 2 days, RRH 1 day ($p<0.001$). There was no difference in time to return to normal void; RAH 10.5 days, LRH 11 days, RRH 9 days ($p=0.11$). There were no patients with long term voiding complications. Postoperative complications for each of the groups are listed in Table 3. Overall, infectious complication rates were higher among the RAH patients when compared to the LRH and RRH groups ($p<0.01$). Among the complications in the RRH, one patient required re-operation for a vaginal cuff separation. A second vaginal cuff separation was managed conservatively.

Final pathologic findings are listed in Table 4. There was no difference in the parametrial size or vaginal cuff length among the three groups. The majority of patients in all groups had negative margins. There was no difference in the total number of lymph nodes retrieved among the three surgical approaches ($p=0.26$). Among cases of cervical cancer, the percentage of positive nodal metastasis was higher in the RAH cases (31%) when compared to both LRH (10%) and RRH (10%) ($p=0.04$).

Discussion

The role of minimally invasive surgery in gynecologic oncology has expanded significantly over the last 10 years. In 2009, the first prospective randomized study comparing laparotomy to laparoscopy for the treatment of a gynecologic cancer was published. Over 2600 patients nationwide were enrolled in the GOG LAP2 study evaluating the role of minimally invasive surgery for the treatment of endometrial cancer. This landmark study reported similar operative outcomes and pathologic findings, with the known benefits of minimally invasive surgery; shorter hospital stay, decrease in blood loss, and shorter

recovery time [18]. Subsequently, laparoscopy has become part of the standard of care for the surgical management of endometrial cancer.

While the uptake of minimally invasive surgery for the treatment of endometrial cancer is widely accepted, the number of women being offered minimally invasive surgery for more complex procedures such as radical hysterectomy has not shown the same growth. According to a survey of the SGO members in 2008, when almost 90% of practicing gynecologic oncologist were performing laparoscopic staging for endometrial cancer only 38% were offering patients laparoscopic radical hysterectomy [8]. Since the FDA approved the da Vinci Surgical System for use in gynecology there have been a number of published reports on the feasibility of robotic radical hysterectomy.

Boggess *et al.* in 2008 published one of the largest series comparing 51 consecutive robotic radical hysterectomy cases to open historical controls [11]. When compared to open procedures, the robotic cases had a significantly lower blood loss, fewer complications and a shorter length of hospital stay. These findings have also been confirmed by other studies comparing the robotic to open approach [14, 19]. While these findings confirmed the advantages of minimally invasive surgery, the comparison group was a retrospective cohort that had surgery during a different time period. In addition, previous studies have shown that these advantages can also be achieved with traditional laparoscopy [3].

The data comparing robotic radical hysterectomy to traditional laparoscopy is more limited. Magrina *et al.* compared 27 robotic radical hysterectomy cases to historical controls (31 laparoscopic and 35 open). They reported lower blood loss and shorter length of stay for both minimally invasive approaches. Operative times, however were significantly shorter for the robotic and open approach when compared to laparoscopy suggesting a benefit of the robotic approach over traditional laparoscopy [13]. In our study, operative times for the open procedures were also significantly shorter than for either LRH or RRH. In addition, there were no major intra-operative complications in the open group. However, the robotic surgery group had a significantly shorter hospital stay even when compared to laparoscopy, with 62% of patients going home on postoperative day one. While this finding was statistically significant, it could reflect differing practice patterns among the primary surgeons. In addition, conversion rates to laparotomy were lower in the robotic group, although the difference did not reach statistical significance.

With the introduction of a new surgical technique, it is important to ensure that we are providing the same quality of surgery for our patients and ultimately equivalent or better oncologic outcomes. Previous studies have used uterine weight and lymph node counts as a surrogate marker for adequacy of surgical dissection. All of the published studies have shown similar findings between the robotic groups and the comparison group in this regard. In fact two authors reported higher lymph node counts in the robotic surgery cases suggesting that the robotic approach may be superior [11, 20]. In the current study we looked at additional pathologic parameters to ensure that the surgical specimen removed was similar among the three surgical approaches. The removal of the parametria and the upper vagina define a radical hysterectomy. We found that the surgical specimen removed during the robotic procedures were similar to both the open as well as laparoscopic procedures. In

all groups, a majority of patients had negative margins supporting the adequacy of the robotic approach to radical hysterectomy. The higher percentage of positive nodes found in the RAH group may reflect a surgeon's bias to doing larger tumors through an open approach.

While there has been a number of published series supporting the feasibility of robotic radical hysterectomy, they have primarily reflected a single surgeon's surgical experience and a comparison to historical controls. The main limitation of our study is its retrospective nature and the small numbers. The small numbers limited our ability to detect true differences in intra-operative and complication rates as well as conversion rates. The strength of this study is the comparison between the three surgical approaches in 95 consecutive cases after the implementation of robotic surgery. During the study time period, a majority of patients were offered a minimally invasive surgical approach but the decision between robotic surgery and laparoscopy was based on surgeon and patient preference. Although this is a single-institution study, the minimally invasive procedures were performed by 8 different faculty members with a broad range of minimally invasive surgery training and experience. While we were unable to perform a direct comparison between individual surgeons due to the limited number of cases performed by each individual as well as the varying degree of fellow involvement in each procedure, this variability may make our data more applicable to the practicing gynecologic oncologist.

Our data add to the current literature supporting the feasibility and safety of robotic radical hysterectomy that has continued to grow over the last several years. The benefits of minimally invasive surgery over open surgery were again demonstrated. In addition, our findings suggest that the robotic approach may have the added benefit of shorter length of stay and lower conversion rates when compared to traditional laparoscopy. We are currently leading a prospective randomized international trial comparing both robotic and traditional laparoscopy to standard laparotomy for the treatment of early cervical cancer. The results of this study will ultimately determine the role of minimally invasive surgery for the treatment of early cervical cancer.

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Research Highlights

- Minimally invasive radical hysterectomy was associated with decrease in blood loss and shorter hospital stay.
- Robotic radical hysterectomy had lower conversions rates compared to laparoscopy.

Table 1
Demographic Characteristics

	Laparotomy (n=30)	Laparoscopy (n=31)	Robotic (n=34)	p-value
Median Age (years)	48.1	44.2	52.1	0.27
Range	25.5 – 82.2	23.55 – 64.9	27.9 – 75.9	
Median Weight (kg)	66.1	76.3	71.7	0.15
Range	52.8 – 124.1	47.2 – 123.0	50.1 – 107.0	
Median BMI (kg/m ²)	26.2	29.5	26.9	0.16
Range	20.9 – 44.5	18.7 – 47.8	19.8 – 38.1	
Race				n/a
White	13	18	25	
Hispanic	13	8	6	
Black	3	3	1	
Asian	1	2	2	
Cervix Stage				n/a
IA1	2	2	4	
IA2	4	8	5	
IB1	17	20	23	
IB2/IIA	2	0	0	
Endometrial	5	1	2	
Histology				
Squamous	13	16	16	n/a
Adenocarcinoma	16	12	9	
Adenosquamous	1	1	2	
Other	0	2	7	

Table 2
Intra-operative Findings and Complications

	Laparotomy (n=30)	Laparoscopy (n=31)	Robotic (n=34)	P-value
Median Total OR time* (min)	265	338	328	0.002
Mean (Range)	265 (139 – 438)	338 (191 – 442)	328 (241 – 528)	
Median Docking Time (min); mean (range)	NA	NA	7.4; 6 (3 – 20)	
Median EBL (mL)**	350	100	100	<0.001
Mean (Range)	509.3 (50 – 1850)	171.0 (25 – 800)	115.5 (25 – 550)	
Transfusion	13 (24%)	5 (16%)	1 (3%)	<.001
Vascular Injury	0	1	0	n/a
Cystotomy	0	0	0	n/a
Ureteral Injury	0	2	2	n/a
Bowel Injury	0	0	0	n/a
Conversion	NA	5 (16%)	1 (3%)	.10

OR, operating room; EBL, estimated blood loss; NA, not applicable

* Total OR time includes skin incision to skin closure

** Excludes cases converted to laparotomy

Table 3
Postoperative Morbidity

	Laparotomy (n=30)	Laparoscopy (n=31)
Robotic (n=34)		
Infectious Morbidities	16	8
3 p<.001		
Febrile Morbidity	4	1
0		
Wound cellulitis/separation	4	2
1		
UTI	3	3
2		
Pneumonia	2	2
0		
Abscess	3	0
0		
Noninfectious Morbidities	2	2
2 n/a		
Prolonged ileus		
DVT/PE	0	1
0		
Cuff complication	0	0
2		
Port site hernia	0	1
0		

UTI, urinary tract infection; DVT, deep vein thrombosis; PE, pulmonary embolus.

Note: These numbers reflect incidence of morbidity and not number of patients experiencing postoperative morbidity as some patients may have experienced more than 1 of the complications listed.

Table 4
Final Pathologic Findings

	Laparotomy (n=30)	Laparoscopy (n=31)	Robotic (n=34)	P-value
Median size left parametria (cm)	3.5	3.3	3.5	0.48
Mean (range)	3.9 (2.2 – 6.5)	3.6 (2.0 – 7.0)	3.8 (2.0 – 9.5)	
Median size right parametria (cm)	3.6	3.0	3.5	0.16
Mean (range)	3.8 (1.7 – 6.5)	3.3 (2.0 – 6.0)	4.0 (2.0 – 10.0)	
Median length of vaginal cuff	1.5	1.5	1.5	0.10
length (cm) Mean (range)	1.9 (0.20 – 4.7)	2.1 (0.60 – 5.0)	1.8 (0.0 – 6.0)	
Patients with negative margins* (%)	25/26 (96)	29/30 (97)	32/33 (97)	0.99
Median total number of pelvic	19.0	14.0	17.0	0.26
lymph nodes Mean (range)	19 (5.0 – 42.0)	15.6 (5.0 – 40.0)	17.1 (2.0 – 32.0)	
Median number left pelvic LN	8.5	7.0	7.0	0.96
Mean (range)	8.1 (1.0 – 18.0)	8.3 (3.0 – 20.0)	7.7 (1.0 – 18.0)	
Median number right pelvic LN	10.5	7.0	9.0	0.01
Mean (range)	10.9 (3.0 – 24.0)	7.3 (1.0 – 20.0)	9.4 (1.0 – 20.0)	
Nodal metastasis* (%)	8/26 (31)	3/30 (10)	3/31 (10)	0.04

* Only cervical cancers included