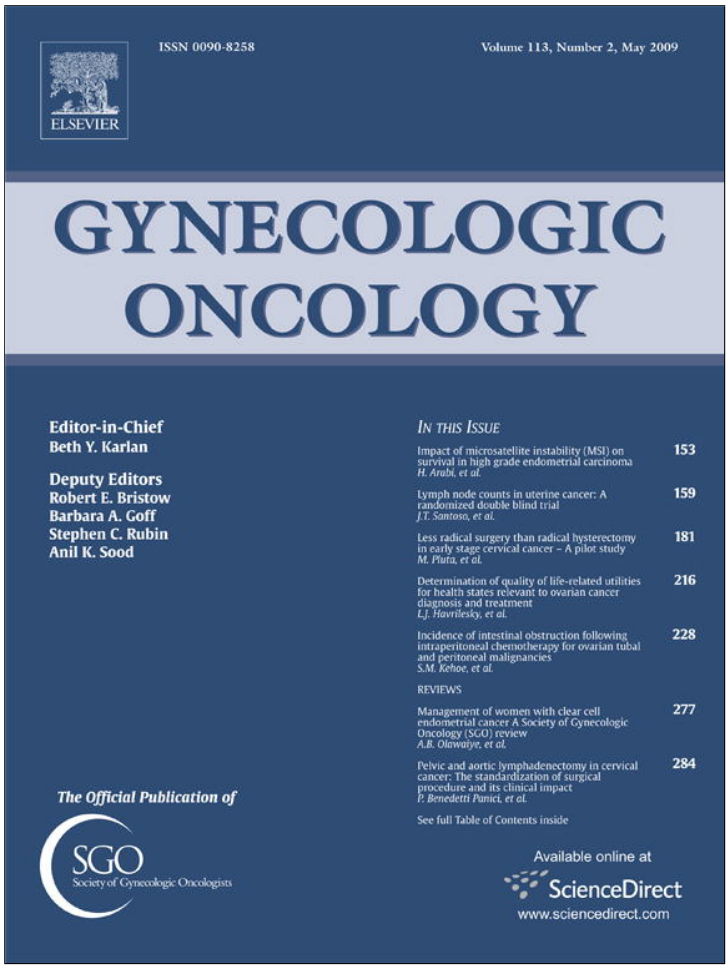

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A multi-institutional experience with robotic-assisted radical hysterectomy for early stage cervical cancer

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ABSTRACT

Objective. The purpose of the study is to report a multi-institutional experience with robotic-assisted radical hysterectomy to treat patients with early stage cervical cancer with respect to perioperative outcomes.

Methods. A multi-institutional robotic surgical consortium consisting of five board-certified gynecologist oncologist in distinct geographical regions of the United States was created to evaluate the utility of robotics for gynecologic surgery (benign and malignant). Between April 2003 and August 2008, a total of 835 patients underwent robotic surgery for benign gynecologic disorders and/or gynecologic malignancies by a surgeon in the consortium. IRB approval was obtained and data was collected in a prospective fashion at each institution. For the purposes of the study, a multi-institutional HIPPA compliant database was then created for all patients that underwent robotic-assisted surgery between the April 2003 and August 2008. This database was queried for all patients who underwent a robotic-assisted type II or III radical hysterectomy for Stage IA1 (+vsi)-IB2 cervical carcinoma. Forty-two patients were identified. Records were then reviewed for demographic data, medical conditions, prior abdominal or pelvic surgeries, and follow-up. The perioperative outcomes analyzed included: operative time (skin–skin), estimated blood loss (EBL), length of hospital stay, total lymph node count, conversion to laparotomy, and operative complications.

Results. From a database of 835 patients who underwent robotic surgery by a gynecologic oncologist, a total of 42 patients who underwent a robotic-assisted type II ($n=10$) or type III ($n=32$) radical hysterectomy for early stage cervical cancer were identified. Demographic data demonstrated a median age of 41 and a median BMI of 25.1. With regard to stage, seven patients (17%) were Stage IA2, twenty-eight patients (67%) were Stage IB1 and six patients (14%) were Stage IB2. There was a single patient with Stage IA1 cervical cancer with vascular space invasion who underwent a type II radical hysterectomy. The overall median operative time was 215 min. The overall median estimated blood loss was 50 cc. No patient received a blood transfusion. The median lymph node count was 25. The median hospital stay was 1 day. Positive lymph nodes were detected in 12% of the patients. Pelvic radiotherapy or chemo-radiation was given to 14% of the patients based on final surgical pathology. Intraoperative complications occurred in 4.8% of the patients and included one conversion to laparotomy (2.4%) and one ureteral injury (2.4%). Postoperative complications were reported in 12% of the patients and included a DVT (2.4%), infection (7.2%), and bladder/urinary tract complication (2.4%) The conversion rate to laparotomy was 2.4%.

Conclusions. Robotic-assisted radical hysterectomy is associated with minimal blood loss, a shortened hospital stay, and few operative complications. Operative time and lymph node yields are acceptable. This data suggests that robotic-assisted radical hysterectomy may offer an alternative to traditional radical hysterectomy. This series contributes to the growing literature on robotic-assisted radical hysterectomy and prospective comparisons with traditional radical hysterectomy are needed.

Introduction

The use of minimally invasive surgery (laparoscopy) for the treatment of endometrial and cervical cancer was first described in the early 1990s. These initial experiences demonstrated the safety and feasibility of minimally invasive surgery to treat these disorders [1–6].

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In addition, it has been demonstrated that minimally invasive surgery is associated with less blood loss, shorter hospital stay, less post-operative pain, improved cosmesis, and a faster recovery when compared to traditional approaches [7–11]. Yet despite these advantages, recent surveys of practicing gynecologic oncologist revealed that most respondents believed minimally invasive surgery (conventional laparoscopy) had only a minimal role in the management of cervical cancer [12]. It is likely that well-known barriers to the utilization of advanced minimally invasive procedures such as association with a long learning curve, lack of training, complexity of operations, limitation of technology and instrumentation, and the necessity of an expert assistant were responsible for this sentiment.

Recent advances in the field of minimally invasive surgery have focused on the incorporation of robotic technology for the treatment of gynecologic malignancies. The da Vinci surgical system is a robotic surgical platform that was FDA approved in April 2005 for gynecologic applications. Since that time, a small number of investigators have reported limited series documenting their experience with robotic surgery for the treatment of endometrial and cervical cancers [13–19]. Boggess et al. recently reported the largest series to date documenting the outcomes of 51 consecutive patients who underwent robotic radical hysterectomy with excellent outcomes [20]. In these initial reports, it appears that the barriers to conventional laparoscopy can be overcome with robotic surgery for complex operations. For example, the robotic system incorporates a 3-D stereoscopic vision system and wristed instrumentation that provides improved dexterity and precision. The system allows for complex procedures to be completed by a single surgeon with a novice bedside assistant alleviating the need for an expert assistant. It more mimics traditional surgical approaches to pelvic surgery as compared to conventional laparoscopy and has recently been associated with a shortened learning curve [16,18]. These advantages potentially make it the ideal tool for performing complex oncologic procedures such as a radical hysterectomy that requires delicate dissection (cardinal ligament, ureter, and pelvic vessels) while maintaining oncologic radicality.

Finally, evidence has accumulated in the literature suggesting that a minimally invasive radical hysterectomy is associated with a similar oncologic outcome as traditional approaches [7,21–25]. Recognition of the underutilization of a minimally invasive (laparoscopic) approach for radical hysterectomy in the United States has led gynecologic oncologists to examine the use of robotic radical hysterectomy for early stage cervical cancer [16–20]. This study was undertaken to analyze a multi-institutional experience with robotic-assisted radical hysterectomy for cervical cancer.

Materials and methods

A multi-institutional robotic surgical consortium consisting of five board-certified gynecologist oncologists in distinct geographical regions of the United States was created to evaluate the utility of robotics for gynecologic surgery (benign and malignant). Regions of the United States represented included the Southeast, the Midsouth, and the Midwest. Between April 2003 and August 2008, a total of 835 patients underwent robotic surgery for benign gynecologic disorders and/or gynecologic malignancies by a surgeon in the consortium. IRB approval was obtained and data was collected in a prospective fashion at each institution. For the purposes of the consortium, a multi-institutional HIPPA compliant database was then created for all patients that underwent robotic-assisted surgery between the April 2003 and August 2008. This database was queried for all patients who underwent a robotic-assisted type II or III radical hysterectomy for Stage IA1 (+vsi)-IB2 cervical carcinoma. Forty-two patients were identified. Records were then reviewed for demographic data, medical conditions, prior abdominal or pelvic surgeries, and follow-up. The perioperative outcomes analyzed included: operative time (skin–skin), estimated blood loss (EBL), length of hospital stay, total lymph node count, conversion to laparotomy, and operative complications.

All members of the consortium were among early adopters of robotic technology for use in gynecologic surgical applications in their respective regions of the country. For credentialing and training purposes, each surgeon completed an on-line training course, a 1–2 day porcine surgical lab, case observations, and individual case proctoring (2–5 cases per surgeon) prior to receiving robotic surgical privileges at their respective institutions. The length of robotic surgical experience for all surgeons in the consortium ranged from 2–5 years for all surgeons at the time of data analysis. Prior experience with advanced laparoscopy also varied among the surgeons from no prior experience reported by one surgeon to another having served as a postgraduate instructor on advanced laparoscopy at SGO annual meetings. However, none of the surgeons had previously performed a laparoscopic radical hysterectomy prior to implementation of robotics at their respective institutions. All surgeons were well versed on the technique of traditional open type II and type III radical hysterectomy. Practice patterns varied among the members from private practice to university-affiliated private practice to university-affiliated academic practice. All radical hysterectomies were performed with either the da Vinci S or da Vinci Standard Surgical System.

Results

From a database of 835 patients who underwent robotic surgery for gynecologic diseases (benign and malignant), a total of 42 patients who underwent a type II or III robotic-assisted radical hysterectomy for cervical cancer were identified. Ten patients underwent a robotic-assisted type II radical hysterectomy and thirty-two underwent a robotic-assisted type III radical hysterectomy. All five members of the consortium had performed at least one robotic radical hysterectomy at the time of manuscript submission. With regard to patient demographics, the median age was 41 and the median BMI was 25.1. Cancer stage was analyzed and demonstrated that there was one patient with Stage IA1 disease with vascular space invasion, seven patients (17%) with Stage IA2 disease, twenty-eight patients (67%) with Stage IB1 disease, and six patients (14%) with Stage IB2 disease. One-half of the patients reported a prior abdominal surgery. One or more medical comorbidities such as diabetes, hypertension, chronic obstructive pulmonary disease and obesity were reported in approximately one-third of the patients.

Operative outcomes were analyzed for all cases identified. In addition, operative outcomes were analyzed for all type II and type III robotic-assisted radical hysterectomy, and individual surgeon experience. The overall median operative time was 215 min. The overall median estimated blood loss was 50 cc. No patient received a blood transfusion intraoperatively or postoperatively. The overall median lymph node count was 25. The median hospital stay was 1 day. Positive lymph nodes were detected in 12% of all patients. No positive parametrial or vaginal margins were reported. Adjuvant pelvic radiotherapy or chemo-radiation was given to 14% of all patients.

Table 1
Operative findings

Operative findings	Overall	Type II	Type III
	$n=42$	$n=10$	$n=32$
Median operative time	215 min (120–606)	166 min (120–243)	216 min (165–606)
Median estimated blood loss	50 cc (25–150)	40 cc (25–200)	50 cc (25–200)
Median nodal count	25 (12–60)	22 (12–25)	25 (12–60)
Median postoperative stay	1 day	1 day	1 day
Conversion to laparotomy	1	None	1
Transfusions	None	None	None

Table 2
Operative outcomes by surgeon

Surgeon (# cases)	OR Time	EBL	Nodes	Hosp stay	Intraoperative complication	Total # of robotic cases
A[a] ($n=12$) Type II and III	240 (120–300)	75 (25–200)	25 (12–49)	1	Conversion to laparotomy (1)	101
B* ($n=25$) Type II and III	186 (134–606)	50 (25–150)	25 (14–60)	1	Ureteral injury (1)	452
C ($n=3$) Type II	230 (223–243)	25 (25–100)	12 (12–20)	1	–	146
D ($n=1$) Type II	166	200	23	1	–	80
E ($n=1$) Type III	270	150	10	1	–	56

All data in Table 2 represent median values.
Range shown in parentheses.
[a] SGO laparoscopy instructor.
* No prior advanced laparoscopic experience.

Data not analyzed included median tumor diameter, median length of the parametria, median length of the vaginal margin, or number of parametrial lymph nodes. Indwelling bladder catheters were removed by postoperative day #7 in all patients but two (4.8%). These two patients received indwelling or self-intermittent catherization. Bladder dysfunction resolved in one patient by postoperative day #14 and the other by postoperative day #21. Operative outcomes were then analyzed separately for a type II and type III approach. The median operative time for type II and type III radical hysterectomy was 166 min and 216 min respectively. The median estimated blood loss for type II and type III radical hysterectomy was 40 cc and 50 cc respectively. The median lymph node count for type II and type III radical hysterectomy was 22 and 25 respectively (Table 1). Operative outcomes by individual surgeon were analyzed and are shown in Table 2. Due to the small number of cases, a formal learning curve assessment was not performed.

Operative and postoperative complications associated with robotic assisted radical hysterectomy were collected and analyzed. Intraoperative complications occurred in two patients (4.8%) and included one conversion to laparotomy to repair a bladder injury adjacent to the trigone and one ureteral injury. Postoperative complications were reported in 12% of the patients and included a DVT (2.4%), pyelonephritis (2.4%), prolonged bladder catherization of 21 days (2.4%), and infection (4.8%). No patient was readmitted to the hospital after discharge. No patient experienced a bowel injury or bowel obstruction, incisional hernia or dehiscence, ICU admission, symptomatic lymphocyst, or reoperation from a complication of robotic surgery. The conversion rate to laparotomy was 2.8% among all patients (Table 3).

Discussion

The concept of laparoscopic management of gynecologic malignancies has gone from a perceived near impossibility to a fully recognized option for many patients over the last decade [6]. The goal of laparoscopic surgery is to duplicate traditional open procedures via small incisions in the skin with surgical outcomes equivalent or superior to a traditional surgical approach. Unfortunately, a laparoscopic approach has not been recognized or accepted to treat endometrial and/or cervical cancers by the majority of gynecologic oncologists in the United States according to surveys by Frumovitz et al. and Nauman et al. [12,26]. Recently, robotic surgery which is FDA approved has become an option in the definitive surgical management of early stage endometrial and cervical cancers. With recent reports demonstrating the safety and feasibility of robotic-assisted surgery in the field of gynecologic oncology, we sought to evaluate a multi-institutional experience of robotic-assisted surgery for gynecologic malignancies with the focus of this manuscript on robotic-assisted radical hysterectomy for cervical cancer.

Table 3
Operative and postoperative complications

Complications	Intraoperative	Postoperative
Ureteral Injury	1	0
Bladder/urinary	0	1
Bowel injury/obstruction	0	0
Blood transfusion	0	0
Hernia/dehiscence	0	0
Reoperation rate	0	0
Infection	0	3
Lymphedema	0	0
Symptomatic lymphocyst	0	0
Conversion to laparotomy	1	–
Deep venous thrombosis	0	1
Total complications	2	5
Total patients	42	42
Percent complication	4.8%	12%

To date, no prior multi-institutional experiences with robotic-assisted radical hysterectomy for early stage cervical cancer have been reported. Our data was collected in a prospective fashion from the onset of each author's robotic program and represents all robotic-assisted radical hysterectomies performed by the authors. The strength of our series is that it allows for analysis and evaluation of data from multiple institutions with surgeons of various levels of experience and expertise with robotic surgery. The weakness of our series is in its retrospective nature, lack of a comparison group, and our total number of patients in this study is relatively small. In addition, two of the authors had performed only one robotic-assisted radical hysterectomy at the time of manuscript submission. However, each surgeon had performed over 50 robotic surgeries for benign and malignant gynecologic conditions.

The data reported in this series is compelling when compared to historical data on laparoscopic radical hysterectomy with regard to operative time, estimated blood loss, hospital stay, and overall complications. In this manuscript, we report a median operative time of 215 min, an estimated blood loss of 50 cc, a nodal yield of 25, hospital stay of 1 day, and a 4.8% intraoperative and a 12% postoperative complication rate. Our conversion rate was a very low 2.4% for all patients. A review of the literature on laparoscopic radical hysterectomy demonstrates that the procedure is also safe and feasible, but is associated with an operative time range of 205 min–371 min, an estimated blood loss of 200 cc–445 cc, a nodal yield ranging from 13–25, a hospital stay ranging from 1–7.5 days, and an overall complication rate of 11%–20% [7,21–25]. The authors recognize that not all papers on laparoscopic radical hysterectomy are referenced in this manuscript, but feel that the referenced papers provide a good cross section of the data.

A review of the literature on robotic assisted radical hysterectomy demonstrates that our experience is consistent with the data currently published. In 2006, Abeler et al. described their initial experience with robotic radical hysterectomy with an operative time of 241 min and a blood loss of 71 cc [27]. In 2008, Kim et al. reported on 10 cases with an operative time of 207 min, blood loss of 355 cc and a nodal yield of 27. No conversion to laparotomy was reported [28]. Fanning et al. reported on their recent experience with robotic radical hysterectomy for cervical cancer. They reported operative time of 390 min with all procedures completed robotically without conversion to laparotomy. Their reported hospital stay was 1 day and surgical blood loss was 300 cc [17]. Magrina et al. reported their experience with open,

laparoscopic, and robotic-assisted radical hysterectomy from a prospective database. Robotic surgery was associated with less blood loss and a shorter operative time as compared to laparoscopy with equivalent nodal yields. In the robotics subgroup, no intraoperative complications were reported [18]. Finally, in the largest report to date, Boggess et al. reported on a case-control series of robotic versus open type III radical hysterectomy. They reported statistically significant differences in operative time, blood loss, and node retrieval all in favor of a robotic approach. Although this paper represents a single surgeon experience, the data is compelling and suggests that a robotic approach may be preferable to an open approach [20]. Thus, to summarize the referenced data (including this manuscript) on robotic radical hysterectomy as compared to the referenced literature on laparoscopic radical hysterectomy, it appears that several surgical outcomes (ebl, operative time, node retrieval, and hospital stay) are equivalent and may be superior in some aspects for patients undergoing a robotic-assisted approach. The authors acknowledge that only limited comparisons with radical hysterectomy between robotics and traditional laparoscopy were performed to date.

One unique aspect of our experience with robotic surgery is that none of the authors had previously performed a laparoscopic radical hysterectomy prior to performing a robotic-assisted radical hysterectomy. However, all members were well versed in the open techniques. Only two members of the consortium routinely utilized advanced laparoscopy prior to initiating their robotic surgical program, and only one received extensive training with advanced laparoscopy during their gynecologic oncology fellowship. It is our opinion that a strong background in laparoscopy is clearly not a prerequisite to becoming a successful robotic surgeon. However, it is our opinion that a background in laparoscopy may shorten the learning curve in the adoption phase of robotics. Whether this ultimately translates into better surgical outcomes is unclear at this point in time. Thus, surgeons with little or no background in laparoscopy, who are dedicated and well prepared, should be able to incorporate robotics into their practice. We are currently analyzing our entire database to establish learning curve parameters for robotic hysterectomy in benign and malignant (cervical and endometrial cancer) gynecologic conditions. Interestingly, our data from this series suggest that robotic technology may level the playing field between the novice and expert minimally invasive surgeon when applied to complex operations such as a radical hysterectomy (Table 2). Finally, there is recently published evidence suggesting a shortened learning curve associated with robotic technology [29].

In conclusion, the data reported in this manuscript adds to the literature on robotic-assisted radical hysterectomy and supports its safety and feasibility. It also suggests that robotic technology may be associated with improved operative outcomes as compared to a traditional laparoscopic approach for radical hysterectomy based on a review of the current literature. Long-term follow-up data is not available at this time regarding recurrence rates and overall survival. We anticipate numerous additional publications on robotic technology for endometrial and cervical cancer in the coming years, as well as the results of future randomized trials comparing a minimally invasive radical hysterectomy (laparoscopic or robotic) to traditional radical hysterectomy for the treatment of cervical cancer. While it is the author's opinion that robotics represents a tremendous technological leap over traditional laparoscopy and offers the potential to redefine how gynecologic oncologists consider surgical options for their patients with early stage cervical cancer, further study in a prospective fashion will be required to further define its role.

Conflict of interest statement

M. Patrick Lowe MD: Intuitive Surgical, Covidien.
Todd Tillmanns MD: Intuitive Surgical, Covidien.

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