RESEARCH ARTICLE

Feasibility and Safety of Robotic Surgery for Gynecologic Cancers

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Abstract

Background: To determine surgical outcomes, perioperative complications, and patient outcomes in gynecologic cancer patients undergoing robotic surgery. Materials and Methods: Surgical outcomes, including docking time, total operative time, console time, estimated blood loss (EBL), conversion rate and perioperative complications were retrospectively reviewed in 30 gynecologic cancer patients undergoing robotic surgery. Patient outcomes included recovery time and patient satisfaction, as scored by a visual analogue scale (VAS) from 0-10. Results: The operations included 24 hysterectomies with pelvic lymphadenectomy (PLD) and/or para-aortic lymphadenectomy, four radical hysterectomies with PLD, and two radical trachelectomies with PLD. Mean docking time was 12.8±9.7 min, total operative time was 345.5±85.0 min, and console time was 281.9±78.6 min. These times were decreased in the second half of the cases. There was no conversion rate. Three intraoperative complications, including one external iliac artery injury, one bladder injury, and one massive bleeding requiring blood transfusion were reported. Postoperative complications occurred in eight patients, most were minor. Only one patient had port herniation that required reoperation. Mean hospital stay was 3.5±1.7 days, and recovery time was 14.2±8.1 days. Two-thirds of patients felt very satisfied and one-third felt satisfied; the mean satisfaction score was 9.4 +0.9. Two patients with stage III endometrial cancer developed isolated port site metastasis at five and 13 months postoperatively. Conclusions: Robotic surgery for gynecologic cancer appears to be feasible, with acceptable perioperative complication rate, fast recovery time and high patient satisfaction.

Keywords: Gynecologic cancer - minimally invasive surgery - robotic surgery

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Introduction

Minimally invasive surgery (MIS) has been accepted as the surgical treatment for gynecologic cancers, especially endometrial and cervical cancer. Endometrial cancer is the most common gynecologic cancer treated with laparoscopic surgery. It is feasible and has less operative morbidity, less blood loss, shorter hospitalizations, and better short-term quality of life than the laparotomy approach (Kornblith et al., 2009; Galaal et al., 2012; Wang et al., 2013). Similar results were reported for laparoscopic radical hysterectomy in cervical cancer (Magrina et al., 2008).

The da Vinci Surgical System® (Intuitive Surgical Inc, Sunnyvale, CA) was approved by the US Food and Drug Administration for gynecologic surgery in 2005. Advantages over traditional laparoscopy include three dimensional vision, better dexterity and precision from wristed instrumentation, eliminated reliance on an assistant for camera control, and more ergonomic control resulting in decreased surgeon fatigue. Recently, robotic surgery has become widely accepted and has surgical outcomes as favorable as laparoscopic surgery in the treatment of endometrial cancer and early stage cervical cancer (Yim and Kim, 2012). As with any new innovative technology, efficacy and safety should be proven. Therefore, we report on our initial 30 gynecologic cancer patients who underwent robotic surgery. The objectives of this study were to determine surgical outcomes, perioperative complications, and patient outcomes in terms of recovery time and patient satisfaction.

Materials and Methods

This is a retrospective review of the first 30 gynecologic cancers (endometrial cancer and cervical cancer) who underwent primary surgery using the da Vinci®–Si System (Intuitive Surgical Inc, Sunnyvale, CA) between December 2011 and February 2014 at King Chulalongkorn Memorial Hospital, Bangkok, Thailand. The surgery of endometrial cancer patients included hysterectomy with bilateral salpingo-oophorectomy

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and bilateral pelvic lymphadenectomy (PLD) and/or para-aortic lymphadenectomy (PALD). The surgery of cervical cancer included type III radical hysterectomy with bilateral PLD but radical trachelectomy with PLD in patients who desired fertility function.

The surgical teams included six surgeons and four nurses who were certified in robotic training. Each surgery was conducted by at least two surgeons, and included procedures such as hysterectomy, PLD, PALD, and vaginal cuff closure. All surgeons had previous experience in laparoscopic surgery. Five ports were used, a 12-mm trocar for a camera was placed at 25 cm above the symphysis pubis for the procedures that included paraaortic lymphadenectomy; otherwise the camera port was placed at the umbilical area. Two 8-mm robotic trocars were placed at 8-10 cm lateral and 3-5 cm below the camera port. The first arm port was on the right side connected to monopolar curved scissors and the second arm port was on the left side connected to fenestrated bipolar forceps. Another 8-mm robotic trocar for the third arm port was placed at 8-10 cm lateral and 3-5 cm below the second arm port. A double fenestrated grasper was used in this arm. For the assistant port, a 12-mm trocar was placed 5 cm above mid-distance between camera and the first arm port if the camera port was located at the umbilicus. This port was placed at 5-8 cm lateral and 3-5 cm below the first arm port if the camera port was placed above the umbilicus.

Demographic data such as age, parity, body mass index (BMI), and co-morbid medical conditions; and surgical-pathological data such as FIGO stage, histology, grade, and lymph node count were recorded. The surgical outcomes included docking time, total operative time (time from port placement to completion of skin closure), console time, estimated blood loss (EBL), laparotomy conversion rate, and intra- and postoperative complications. Postoperative complications were defined as any adverse events within the first 30 days after surgery. These included febrile morbidity, which was defined as body temperature more than 38 °C in two consecutive measurements at least six hours apart, but excluding the first 24 hours. Intravenous parecoxib (Dynastat®) 40 mg every 12 hours were given as a pain control regimen in the first 24 hours postoperatively and intravenous opioid (morphine 0.05 mg/kg or pethidine 0.5 mg/kg) as a rescue regimen. Celecoxib(Celebrex®) 400 mg or Etoricoxib (Arcoxia®) 120 mg were prescribed once daily starting on the second postoperative day (POD) and continued for seven days. If there was any contraindication, nonsteroidal anti-inflammatory drugs (NSAID) were prescribed. Postoperative pain was evaluated every six hours on the first to third POD by visual analogue scale (VAS): 0 – 10 scores (0 - no pain; 10 - worst pain). The worst score in each day was used for analysis. Furthermore, length of hospital stay, recovery time, and patient satisfaction were recorded. Satisfaction was graded as follows: 0 - very unsatisfied; 1 - somewhat unsatisfied; 2 - neither satisfied nor unsatisfied; 3 - somewhat satisfied; 4 - very satisfied. Satisfaction score by visual analogue scale (VAS) from 0-10 was also graded.

Data were shown as mean and standard deviation (SD) for continuous data, median and range for non-parametric continuous data, and percentage for discrete data. Surgical outcomes between the first and last 15 cases were compared using student's t-test and chi-square test for continuous and discrete data, respectively. A p value of less than 0.05 was regarded as statistically significant.

Results

Among 30 gynecologic cancer patients, 24 (80%) were endometrial cancer and six (20%) were cervical cancer patients. The mean age of all patients in this study was 49.5±12.6 years (21-70), median parity was 1 (0-3), mean BMI was 27.9±7.4 kg/m^2 (18.6-46.2). Demographic data according to cancer types are shown in Table 1. All endometrial cancer patients had endometrioid adenocarcinoma histology and 75% of patients were in stage 1. All cervical cancer patients were in stage IB1 and half of them had non-keratinizing squamous cell carcinoma.

Most endometrial cancer patients underwent hysterectomy with complete surgical staging, including PLD and PALD. Seven patients (29.2%) did not undergo PALD. These occurred in our initial learning curve of the first five patients and the remaining two patients had severe bowel adhesion and morbid obesity that precluded adequate exposure. Four cervical cancer patients

Table 1. Demographic and Surgical-Pathological Outcomes

		Endometrial cancer patients (N=24)	Cervical cancer patients (N=6)
Mean age (years)		53.7±9.5	32.7±9.3
Median Parity		1 (0-3)	0.5 (0-2)
Mean BMI (kg/m^2)		29.3±7.6	22.4±2.5
Co-morbidities			
Hypertension		10 (41.7%)	0 (0%)
Diabetes Mellitus		3 (12.5%)	0 (0%)
Dyslipidemia		6 (25%)	0 (0%)
Histology			
Endometrioid adenocarcinoma		24 (100%)	-
Non keratinizing squamous cell carcinoma		-	3 (50%)
Keratinizing squamous cell carcinoma		-	1 (16.7%)
Adenocarcinoma		-	1 (16.7%)
Adenosquamous carcinoma		-	1 (16.7%)
Tumor grade	1	17 (70.8%)	-
	2	3 (12.5%)	-
	3	4 (16.7%)	1 (16.7%)
Not graded		-	5 (83.3%)
FIGO stage	IA	15 (62.5%)	-
	IB	3 (12.5%)	6 (100%)
	II	4 (16.7%)	-
	IIIB	1 (4.2%)	-
	IIIC	1 (4.2%)	-
Mean Docking time (minutes)		13.5±10.4	9.8±6.3
Mean total operative time (minutes)		329.3±64.7	410.4±128.0
Port placement (minutes)		15.2±6.1	13.2±2.7
Hysterectomy (minutes)		83.8±26.0	213.75±58.3
Pelvic lymphadenectomy (minutes)		92.4±26.2	97.4±53.1
Paraaortic lymphadenectomy (minutes)		34.8±12.3	-
Vaginal cuff closure (minutes)		34.6±9.8	21.7±8.3
Mean console time (minutes)		264.9±55.0	350.0±122.3
Mean estimated blood loss (ml)		179±111.2	391.7±316.9
Mean number of pelvic nodes		15.4±6.1	18.5±4.6
Mean number of paraaortic nodes		5.4±3.9	-

Table 2. Summary of Surgical Outcomes and Perioperative Complications

Cancer	No. patients	FIGO stage	Procedures	Operative time (min) mean±SD (range)	Estimated blood loss (ml) mean±SD (range)	No.of lymph nodes mean±SD (range)	Intraoperative complications	Postoperative complications
Endometrial cancer	24	4 IA, 2 IB, 1 II	7 Hysterectomy±PLD	Total 340.7±28.0 (300-380)	242.9±113.4 (100-400)	16.1±5.7 (6-24)	1 external iliac artery injury	2 muscle pain at shoulder
				Console 273.9±32.2 (240-332)				
		11 IA, 1 IB, 3 II, 1 IIIB, 1 IIIC	17 Hysterectomy± PLD±PALD	Total 324.6±75.1 (200-513)	152.9±102.3 (50-500)	Pelvic 15.1±6.4 (6-25)	1 bladder injury	1 port herniation 1 subcutaneous emphysema 2 wound infection
				Console 261.2±62.6 (150-410)		Paraaortic 5.4±3.9 (0-14)		1 urinary tract infection 2 muscle pain at shoulder
Cervical cancer	6	IB1	4 RHND	Total 391.3±76.0 (320-490)	450±378.6 (200-1000)	19.5±5.4 (14-27)	1 blood transfusion	
				Console 325.0±65.4 (255-410)				
			2 Radical trachelectomy with PLD	Total 448.5±245.4 (275-622)	275.0±176.8 (150-400)	16.5±2.1 (15-18)		1 pressure sore at head
				Console 400.0±233.3 (235-565)				

*PLD – Pelvic lymphadenectomy, PALD – Paraaortic lymphadenectomy, RHND – Radical hysterectomy with pelvic lymphadenectomy

underwent radical hysterectomy with PLD and two had radical trachelectomy with PLD. We started robotic surgery for most cervical cancer patients after completing the first 12 endometrial cancer cases. There was no conversion to laparotomy in this study. Each procedure was performed by at least two surgeons. The percentage of procedure involvement from the first to last author was as follows, 66.7%, 76.7%, 63.3%, 16.7%, 30%, and 20%, respectively. The second and third authors were the initial surgical group who certified the robotic training program and operated the first six cases.

The first eight cases docked centrally, but the remaining did side docking. Mean docking time was 12.8±9.7 min, total operative time was 345.5±85.0 min, console time was 281.9±78.6 min, EBL was 221.7±186.0 ml. Docking time, total operative time, and console time were decreased when comparing the first 15 and the last 15 cases. Docking time was decreased from 15.9±12.7 to 9.7±3.7 min (p= 0.08), total operative time from 363.0± 100.2 to 328.0±65.5 min (p=0.41), and console time from 294.7±96.6 to 269.2±55.9 min (p=0.27). Subgroup analysis was done in endometrial cancer staging according to each procedure between the first and second half of patients. The times for port insertion (17±6.7 to 13.9±5.5 min), PLD (106.6±25.7 to 83.0 ±22.8 min), and PALD (37.0±18.9 to 33.7±8.5 min) were decreased, although a significant difference was shown only for PLD. Time for hysterectomy and cuff closure did not change (84±35.7 to 83.7±19.2 and 34.1±9.3 to 35.0±10.4 min). In these results, total operative time and console time were not significantly decreased (352.3±75.4 to 306.2±43.7; p=0.08 and 280.4±67.3 to 249.4±35.7 min; p =0.08). Furthermore, EBL was equal between both groups (179.2±111.7 ml).

Three intraoperative complications (10%), one external iliac artery injury, one bladder injury, and one massive bleeding requiring blood transfusion were recorded. Ten events (33.3%) of postoperative complications were recorded in eight patients (26.7%), four muscle pain at either or both shoulders, one subcutaneous emphysema extending from the neck to both thighs, one pressure sore at the head (occipital area), two wound infections, one urinary tract infection, and one port herniation at first arm port requiring re-operation. All events of muscle pain at the shoulder occurred in obese patients (BMI more than 30 kg/m^2). No febrile morbidity was demonstrated.

Mean hospital stay was 3.5±1.7 days (2-9), and recovery time was 14.2±8.1 days (7-30). Postoperative VAS pain scores on the first to third postoperative day (POD) were decreased, 3.9±2.5, 2.4±2.1, and 1.4±1.6 respectively. VAS pain score on the third day was available only in 23 patients. Only four patients (13.3%) needed one dose of rescue intravenous opioid for pain control in the first POD. Most patients (73.3%) felt very satisfied and

26.7% of patients felt satisfied. Mean satisfaction score was 9.4±0.9 (8-10).

Ten endometrial cancer patients received postoperative adjuvant treatment, three had concurrent chemoradiation (CCRT), three had pelvic external radiation with vaginal brachytherapy, and four had vaginal brachytherapy. None of the cervical cancer patients received any postoperative adjuvant treatment. At 11 months median follow up time (2-25 months), two endometrial cancer patients in stage III developed isolated port site metastasis. The first patient had 80% myometrial invasion, cervical invasion, and pelvic lymph node metastasis, and received adjuvant CCRT. Port site metastasis occurred at five months postoperatively and was treated with an excision procedure and radiotherapy at the area of port site metastasis. Eight months later, she developed lung metastasis and is receiving chemotherapy with paclitaxel and carboplatin. Another had deep myometrial invasion through the uterine serosa, cervical and upper vagina invasion; she also received CCRT. Port site metastasis occurred at 13 months postoperatively and was treated with excision and is receiving radiotherapy.

Discussion

Robotic surgery is rapidly emerging as an alternative MIS approach and is widely used worldwide. More than 1,400 systems have been installed across the United States and nearly 2,000 systems worldwide (Ramirez et al., 2012, Yim and Kim, 2012). Robotic surgery shows several advantages over conventional laparoscopy; these include a shorter learning curve and that experience in laparoscopy may be not prerequisite (Yim and Kim, 2012). However, major drawbacks are lack of tactile sensation, less cosmetically appealing due to more and larger incisions, a need for special training, and higher cost (Mohammadzadeh and Safdari, 2014). Recently, it was reported to have limited benefit to patients with benign gynecologic diseases in terms of effectiveness and safety (Liu et al., 2012). Nevertheless, undoubtedly, it has become the preferred MIS approach for most gynecologic oncologists. Most published articles about robotic surgery have been studies in endometrial cancer, followed by cervical cancer. Very few articles reported the use of robotic surgery in ovarian cancer. In fact, it may be not suitable for advanced stage ovarian cancer (Magrina et al., 2011).

To our knowledge, this is the first and largest series in Thailand that reported only on gynecologic cancer patients. This study showed the feasibility and safety of robotic surgery for surgical staging in endometrial cancer and surgical treatment in early stage cervical cancer, including radical and fertility preservative surgery. Different countries have different healthcare systems, which may have an impact on the implementation of robotic surgery. An important obstacle in our country is that MIS is not reimbursed by the national health system. However, we received funding from our hospital to perform 30 operations of robotic surgery. As demonstrated by these results, resources should be shared with all trained surgeons for improved learning curves.

Twenty-four endometrial cancer patients were studied in this study. Total operative time was longer (329 vs 219 minutes) and EBL was higher (179 vs 91.6 ml) than in previous systematic reviews (Gaia et al., 2010). Each patient was operated by different surgeons who might have had different skills and level of experience. Another possibility is that complete surgical staging included PLD and PALD and was performed in all endometrial cancer patients. Our previous study reported that in a situation where there is limited preoperative radiographic imaging and intraoperative frozen section to assess high risk factors, the role of complete surgical staging is still beneficial (Sirisabya et al,. 2009). These may be plausible explanations for the longer operative time. However, the number of pelvic and paraaortic lymph nodes were comparable (15.4 and 18.5, 5.4 and 10.3, respectively). Intraoperative and postoperative complications did not seem to be higher than previous reports. There was no conversion in our study, in contrast to the rates of 4.9% in a previous review (Gaia et al., 2010). Most postoperative complications were minor except one patient who presented with port herniation that required reoperation. There were no vaginal cuff complications or thromboembolic events in our study. Steep Trendelenburg position and patients' shoulders compressed to shoulder supports prevented slipping from the bed, for long operative time may cause of muscle pain at the shoulder. As a result, all events occurred in obese patients. However, these events occurred temporally and subsided within a week.

Only six cervical cancer patients were included in this study, four patients underwent radical hysterectomy and two radical trachelectomy. These operations were feasible, although operative time was longer than in a previous review (391 vs 230 minutes) (Kruijdenberg et al., 2011). There was only one major postoperative complication, massive bleeding requiring blood transfusion, but there was no conversion. A small number of patients may not be adequate to achieve proficiency. However, the number of retrieved pelvic lymph nodes was not different (20 vs 24) (Kruijdenberg et al., 2011). Robotic assisted radical hysterectomy showed equivalent progression-free and overall survival to conventional laparotomy (Cantrell et al., 2010). An ongoing randomized trial comparing laparoscopic or robotic assisted radical hysterectomy with abdominal hysterectomy may be able to confirm these results (Obermair et al., 2008).

Port site metastasis is an uncommon event that occurred in 1-2% of laparoscopic surgery for gynecologic cancers (Palomba et al., 2012). The incidence of port site metastasis following robotic surgery is unclear and the etiologies are multifactorial. Theoretically, robotic surgery should reduce the risk of port site metastasis. Less port manipulation and less repeat instrumentation should result in a lower risk of tissue trauma and contamination in robotic surgery than laparoscopy. However, the incidence from two case series was 1.1-1.9%, which is similar to laparoscopy (Ndofor et al., 2011; Lonnerfors et al., 2013). Most port site metastasis occurred in the specimen retrieval port and usually had other recurrent sites (Lonnerfors et al., 2013). Metastasis at the robotic arm port with isolated port site metastasis was the difference in our patients from

those in previous reports. Isolated port site metastasis is infrequently reported in endometrial cancer patients. To the best of our knowledge, there was only one case series reported of two patients with early stage (IA) (Grabosch and Xynos, 2013). However, high risk histology, advanced stage > stage III endometrial cancer or cervical cancer with lymph node metastasis has a higher risk of developing port site metastasis (Lonnerfors et al., 2013). All patients in our study had high risk factors with advanced stage. In our opinion, robotic surgery should be avoided with advanced stage disease, particularly with demonstrable obvious spread of disease outside the uterus.

Robotic surgery is found to have a faster learning curve than laparoscopic surgery. For laparoscopic hysterectomy and pelvic-paraaortic lymphadenectomy, competence of the surgeon may be achieved after 49 cases (Lim et al., 2011). A minimum 9 to 24 case was required to achieve proficiency for robotic hysterectomy and pelvic-paraaortic lymphadenectomy (Lowe et al., 2009, Seamon et al., 2009, Lim et al., 2011), and 24 to 28 cases for robotic radical hysterectomy (Schreuder et al., 2010, Yim et al., 2013). Proficiency is achieved after a larger number of procedures and continues to improve over time. Lim et al. reported that the proficiency for docking and port insertion was achieved after the 10th case and simple hysterectomy after the 8th case. The most difficult procedure was vaginal cuff closure (21st case), retroperitoneal node dissection and pelvic lymphadenectomy after the 55th case, and paraaortic lymphadenectomy after the 17th case (Lim et al., 2011). Our results were contrary to this report. Pelvic lymphadenectomy might not be the most important procedure; however for this procedure, we reported significantly decreased time after the first half of patients. The number of cases need to achieve competency may vary according to many factors, such as previous experience and individual skills of the surgeon and surgical teams. Establishment of the team, including scrub nurses, circulating nurses, and surgical assistants who are familiar with the robotic equipment is crucial to reduce the operative time and technical error (Ramirez et al., 2012). In our study, as different surgeons performed each case; it was difficult to find the exact number of cases required to achieve proficiency. Although operative time in this study was decreased, there was no significance. Selection bias influenced this result; uncomplicated cases were usually selected in the initial learning curve, more challenging cases such as obese patients, those with previous pelvic surgery or more radical operation were chosen after surgeons feel competent.

The cost of robotic technology remains a potential barrier to widespread use as a standard clinical practice. A major drawback is that the robotic cost includes both maintenance and equipment cost, which are more expensive than laparoscopy. Previous studies reported that laparotomy was considered as the most expensive approach followed by robotic and laparoscopic approach (Bell et al., 2008; Barnett et al., 2010). All costs, including in-patient hospital costs, costs of the robotic surgical system, and care-giving/lost productivity costs associated with recovery time were used in the analysis in the society perspective model. This showed that the laparoscopic approach was still the least expensive followed by robotic approach and laparotomy. The robotic approach would be least expensive when robotic disposable equipment costs less than $1,046 per case (Barnett et al., 2010). With advancing technology and market competition, the price for acquisition and maintenance of a robot may eventually decrease. Therefore, cost effectiveness of robotic surgery in different countries with different health systems should to be further determined.

In conclusion, robotic surgery for gynecologic cancer appears to be feasible and safe with acceptable perioperative complication rate, fast recovery time, and high patient satisfaction. It offers many advantages over laparotomy but has perioperative outcomes comparable with laparoscopic surgery. However, this supportive evidence is derived from non-randomized studies. A randomized, controlled trial is currently ongoing to confirm these outcomes and long term surgical outcomes, including patients' quality of life should be evaluated.

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