

Evaluating the safety and efficacy of robotic assisted laparoscopic surgery in endometrial carcinoma

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Abstract

Robotic surgery is a form of facilitated laparoscopy that utilises robotic technology to enhance the performance of the operation by placing a computerised interface between patient and surgeon. The objective of the study was to study the feasibility and safety of robotic surgery in patients of endometrial carcinoma. 80 patients diagnosed with endometrial carcinoma underwent Robotic assisted laparoscopic surgery at Kokilaben Dhirubhai Ambani Hospital from a period of August 2016 to July 2019. Mean time calculated for preparing da Vinci for the surgery was 5.10 (0.54) min. Mean time calculated for da Vinci docking was 15.39 (2.48) min. Mean time calculated for surgeon console time was 188.20 (37.72) min. Mean time calculated for undocking da Vinci was 1.34 (0.48) min. Mean total da Vinci time calculated was 210.03 (37.53) min whereas

mean total OR time was 318.55 (66.24) min. Age, Obesity, and previous surgery do not seem to be contraindications.

Keywords: Robotic, laparoscopy, endometrial carcinoma, lymphnode staging

Introduction

Endometrial carcinoma is the most common pelvic gynaecological malignancy in industrialised countries and the incidence is increasing. In approximately 75% of cases, at diagnosis, the cancer is clearly confined to the uterus and is referred to as early stage endometrial cancer.¹

Surgical staging with total hysterectomy, bilateral salpingo-oophorectomy (BSO) and pelvic and Para-aortic lymphadenectomy (PAL) decreases the chances of adjuvant therapy, improves cost effectiveness of treatment and may provide therapeutic benefit.²⁻⁶

Historically, endometrial cancer has been surgically managed with laparotomy through a large vertical incision. Minimally invasive surgery (MIS) techniques have been advanced since the early 1990s with the first reports of laparoscopic assisted vaginal hysterectomy with PAL. More recently, robotic assisted laparoscopic surgical techniques (da Vinci system, Intuitive Surgical System, Inc, Sunnyvale, CA) have been described and adopted for treatment of endometrial cancer in many gynaecologic oncology centres.⁷⁻¹² It received FDA approval for the performance of hysterectomy in 2005. A second generation of the device, the da Vinci S, was released in 2006, and the third generation of the da Vinci robotic system, the Si model was released in 2009. Robotic surgery is a form of facilitated laparoscopy that utilises robotic technology to enhance the performance of the operation by placing a computerised interface between patient and surgeon. Robotic assisted laparoscopic hysterectomy (RALH) overcomes many of the difficulties associated with conventional laparoscopic hysterectomy. Advantages of robotic assistance include high definition 3 dimensional visions, wristed instrumentation for improved range of motion and surgical dexterity, robotic control of the camera which eliminates reliance on a surgical assistance, and improved ergonomics resulted in decreased surgeon fatigue.¹³

High precision and absence of tremors are useful for retroperitoneal lymph node dissection, adhesiolysis, parametrial ureteral dissection and accurate suturing. Although the increased cost of this technology is a criticism of robotics. However, because cost is tied to frequency of use, when used on a regular basis the cost becomes similar to laparoscopy and less expensive than laparotomy as a result of shorter hospital stay.

According to a recent survey of members of the Society of Gynaecologic Oncology, the rate of use of robotic surgery to treat gynaecologic malignancies has increased from 27% in 2007 to 97% in 2012.⁷

The objective of the study was to study the feasibility and safety of robotic surgery in patients of endometrial carcinoma. We have further defined the factors in patients with endometrial carcinoma undergoing robotic surgery that contribute to discharge as an inpatient which ultimately can be used to enhance preoperative counselling and postoperative resource utilisation and discharge planning. We acknowledge our limitation regarding the small sample size, unicentric study and time bound study. As the patient load is low and the surgery is new, patients were reluctant in the beginning to undergo the surgery.

Material and methods

In this prospective randomised study done at Kokilaben Dhirubhai Ambani Hospital Mumbai from August 2016 to July 2019, 80 patients with endometrial carcinoma that was clinically restricted to the uterus included. Consecutive type of non-probability sample size implied for the selection of subjects.

Inclusion Criteria

- Patients who presented with endometrial carcinoma and who are willing to undergo Robotic Assisted minimally invasive surgery.

Exclusion Criteria

- Patients with endometrial carcinoma not willing for Robotic Assisted minimally invasive surgery.
- Patients with gynaecological malignancy other than endometrial carcinoma.
- Patients with inadequate bone marrow function such as leukopenia, impaired renal or hepatic function, or severe hip disease precluding the use of the dorsal lithotomy position.

Robotic surgical procedures were performed by a single surgeon. The surgical team consisted of the primary surgeon, a gynaecologic resident as bedside assistant, and a dedicated surgical scrub nurse.

After obtaining institutional review board approval, we prospectively collected data about demographics, blood loss (defined as the total volume of suctioned fluids minus the volume of irrigation fluids used, at the end of the surgical procedure), overall operation room time (from taking the patient in OT to taking the patient out of OT), robotic docking time (from port placement to attachment of robot to the trocars), lymph node count, length of stay, analgesic-free postoperative day, and intraoperative complications.

All patients underwent preoperative radiological workup, consisting of chest radiography, pelvic ultrasonography, and computed tomography of the abdomen and pelvis. Patients were not considered candidates for robotic surgery if any of the following clinical conditions were present: inadequate bone marrow function such as leukopenia, impaired renal or hepatic function, or severe hip disease precluding the use of the dorsal lithotomy position. Neither high body mass index nor previous abdominal surgery was considered a contraindication for the robotic approach. The day before surgery, all patients received 40 mg subcutaneously of low-molecular-weight heparin as venous thromboembolism prophylaxis; in addition, mechanical bowel preparation was performed. Perioperative intravenous antibiotic (cefuroxime, 1.5Gm.) was administered.

We standardized the port positions as

1. A 12 mm camera port was placed 2 cm above the umbilicus.
2. An 8 mm robotic port on the either side was placed 10 cm lateral and 12 cm caudal to the camera port.

3. The right sided robotic port was a mirror image of the left robotic port.
4. One assistant 10 mm ports was placed on the right side 5cm lateral to robotic port

The robotic cart was docked from in between the legs.

A zero degree scope was used for the procedure

All patients underwent total robotic hysterectomy with bilateral salpingo-oophorectomy (BSO), and specimen sent for frozen section. We preferred to use V care uterine manipulator for ease of uterine dissection and manipulation. Pelvic and Para-aortic lymphadenectomy done based on intraoperative gross and microscopic findings. We did not routinely perform systematic Para-aortic lymph node dissection if the macroscopic evaluation of the uterus revealed a myometrial invasion less than 50% of the thickness with grade 1 or 2 cancer and tumour diameter less than 2 cm.

Quantitative data were statistically described in terms of mean (\pm SD), median and 5th and 95th percentile. Qualitative data were described in terms of frequencies (number of cases) and percentages. For comparing categorical data, chi square test will be performed. Exact test will be used instead when the expected frequency is less than 5. For comparing quantitative variables, unpaired t test was used.

A probability value (p value) less than 0.05 was considered statistically significant.

All statistical calculations were done using computer programs: Microsoft Excel 2007 (Microsoft Corporation, NY, USA) and SPSS (Statistical Package for the Social Science; SPSS Inc., Chicago, IL, USA) version 17.

Results

Demographics

Mean age of the patients included in this study is 54.23 (11.65) years with 95% CI of 35.10-72.95. Similarly

Mean BMI of the patients is 26.16 (4.84) Kg/M² with 95% CI of 19.83-33.07

Out of 80 patients, 38 (47.5%) patients do not have any associated comorbidity whereas 42 (52.5%) patients have associated medical comorbidities. Among them most common is history of hypertension and diabetes followed by hypertension.

30% women have undergone abdominal surgeries eg. LSCS, Appendectomy, cholecystectomy, myomectomy, hysterectomy, tubal ligation in the past.

Time taken for various steps

Mean time calculated for preparing da Vinci for the surgery was 5.10 (0.54) min. Mean time calculated for da Vinci docking was 15.39 (2.48) min. Mean time calculated for surgeon console time was 188.20 (37.72)

Table 1: Time taken for various steps

Time Taken for steps (mins.)	Mean	SD	Minimum	Maximum	Percentiles		
For preparing da Vinci for the surgery	5.10	0.54	4.00	7.00	4.00	5.00	6.00
da Vinci docking	15.39	2.48	10.00	21.00	12.00	15.00	20.00
Surgeon console time	188.20	37.72	90.00	290.00	129.05	184.00	250.65
Time to Undock da Vinci	1.34	0.48	1.00	2.00	1.00	1.00	2.00
Total da Vinci time	210.03	37.53	115.00	312.00	150.30	206.00	274.55
Total OR time	318.55	66.24	169.00	485.00	220.80	305.00	437.85

Lymphnode dissection and other variables studied

Out of 80 patients, only 77 patients underwent Robotic lymph node dissection. 65% patient underwent only pelvic lymph node dissection whereas 35 % patient underwent both pelvic and Para aortic lymph node dissection. In our study, mean No. of pelvic lymph node removed were 11.42(3.27) whereas mean no. of Para aortic lymph nodes removed were 4.53 (2.24). Estimated blood loss was 154.19 (72.75) ml, whereas patients length of stay is 5.68 (1.27) days. (Table 3)

min. Mean time calculated for undocking da Vinci was 1.34 (0.48) min. Mean total da Vinci time calculated was 210.03 (37.53) min whereas mean total OR time was 318.55 (66.24) min.(Table 1)

Time taken for individual steps

Mean time taken for adhesiolysis was calculated was 12.63 (6.09) min. Mean time calculated for Hysterectomy with BSO was 52.41 (10.27) min. Mean time calculated for pelvic lymph node dissection was 69.13 (11.93) min whereas for Para aortic lymph nodes it was 67.52 (9.99) min. Mean time calculated for vault suturing was 14.36 (3.58) min and time taken to achieve hemostasis was 13.44 (5.73) min. Mean time calculated for port closure was 5.22 (0.86) min.(Table 2)

Intraop complication

2 (2.5%) patients had sigmoid colon serosa tear, which was repaired robotically. None of the patient in our study had bladder injury or excessive hemorrhage.

Post op pain score

on Day 1, pain score as per the Visual Analogue Scale was 5.84(1.01), on Day 2 it was 3.80 (1.35) and on day 3 it was 1.91 (1.15)

Conversion rate

3 out of 80 (3.7%) patients surgery had to be converted in to open laparotomy at various stage. (Table 4)

Table 2: Time taken for individual steps

Time taken for Individual surgical steps (mins.)	Mean	SD	Minimum	Maximum	Percentiles		
					5th	50th	95 th
Adhesiolysis	12.63	6.09	2.00	30.00	3.00	12.00	26.00
Hysterectomy + Bilateral salpingo-oophorectomy or salpingo-oophorectomy	52.41	10.27	20.00	69.00	20.00	52.00	69.00
Lymph node dissection (Pelvic)	69.13	11.93	44.00	112.00	51.80	68.00	90.00
Para aortic dissection	67.52	9.99	50.00	89.00	52.00	64.00	87.00
Vault suturing	14.36	3.58	8.00	22.00	10.00	14.00	20.30
Hemostasis	13.44	5.73	3.00	27.00	5.00	13.00	24.00
Port closure	5.22	0.86	3.00	7.00	4.00	5.00	7.00

Relation of surgeon console time with BMI

Patients having BMI <25, mean surgeon console time was calculated as 182.90 (36.59) min whereas in patients with BMI >25, mean surgeon console time was calculated as 193.50 (38.53). The difference was not statistically significant(p<0.05).

abdominal surgery, mean surgeon console time was calculated as 193.50 (38.53). The difference was not statistically significant(p<0.05).

Relation of surgeon console time with previous H/O abdominal surgery

Patients having previous H/O abdominal surgery mean surgeon console time was calculated as 182.90 (36.59) min whereas in patients with no previous H/O

Table 3: Lymphnode dissection and other variables studied

Variables	Mean	SD	Minimum	Maximum	Percentiles		
					5th	50th	95th
No. of lymph nodes removed (pelvic)	11.42	3.27	7.00	30.00	7.00	11.50	15.05
No. of lymph nodes removed (paraaortic)	4.53	2.24	2.00	14.00	2.00	4.00	9.60
Estimated Blood Loss (ml)	154.19	72.75	50.00	350.00	50.00	150.00	300.00
Patients Length of stay (days)	5.68	1.27	4.00	11.00	4.00	6.00	7.95

Table 4: conversion to open surgery

Conversion to Open	N	%
No	77	96.3%
Increased abdominal pressure lead to hypotension and risk of respiratory suppression	1	1.3%
High grade endometrioid sarcoma	1	1.3%
Excessive bleeding and Inability to retract the bowels	1	1.3%
Total	80	100.0%

Discussion

To our knowledge, few articles have been published about the use of robotic technology to treat endometrial cancer. Table 5 shows comparison of perioperative outcomes for robotic surgical management of endometrial cancer among various studies done.^{7-9, 11, 12}

Mean console time

In present study mean console time is 188.2 min which is similar to study done by Bell et al.⁷ (184 min). It is found to be high in study done by Seamon et al.¹¹ (262 min) and Veljovich et al.¹² (283 min) whereas it was comparable to studies done by Boggess et al.⁸ (191 min) and DeNardis et al.⁹ (177 min) whereas study done by Lindfors et al.¹⁵, it was 205 mins.

Estimated blood loss

In present study, estimated blood loss is calculated as 154.2 ml, which is higher in comparison to other studies.

Estimated blood loss in a study done by Seamon et al.¹¹ was 99 ml, Boggess et al.⁸ found it as 75 ml and it was found lowest in a study done by Veljovich et al.¹² (67 ml). Bell et al.⁷ found it as 166 ml which is similar to present study.

Length of stay

The length of stay is calculated as 5.68 days which is higher in comparison to other studies. Mean length of stay was found as 1day in various studies done by Seamon et al.⁹, Boggess et al.⁸ and DeNardis et al.⁹ Bell

et al.⁹ found length of stay as 2.3 days and Veljovich et al.¹² found it as 1.7 days which is less in comparison to present study.

Lymph node count

The mean lymph node (pelvic) removed is found to be less (11.7) when compared to studies done by Boggess et al.⁸ (32.9). In a study done by Seamon et al.¹¹, mean number of nodes removed were 29, whereas in study done by DeNardis et al.⁹, it was calculated as 19. Bell et al.⁷ found it as 17 and Cragun et al.⁵ found it as 17.5 which are more in comparison to present study.

Conversion to Laparotomy

Conversion rate is found to be higher in studies done by DeNardis et al.⁹ (5.4%) and Boggess et al.⁸ (12.4%) whereas in present study it was 3.7%

Intraoperative complication

Intraoperative complications rate encountered in present study is 2.5 % which is less in comparison to studies done by DeNardis et al.⁹ (3.6%).

It was found to be less in studies done by Boggess et al.⁸ (1%) whereas no intraoperative complication was noted in a study done by Bell et al.⁷.

Table 5: comparison with previous studies

Authors	Present study	Seamon et al ¹¹	Boggess et al ⁸	Denardis et al ⁹	Bell et al ⁷	Veljovich et al ¹²
N	80	105	103	56	40	25
Age	54.23	59	62	59	63	53
BMI	26.16	34	32	29	33	26.3
Mean console Time (min)	188.2	262	191	177	184	283
EBL (ml)	154.2	99	75	105	166	67
LOS (d)	5.68	1	1.0	1.0	2.3	1.7
CTL (%)	3.7	12.4	3.0	5.4	-	NA
LN (n)	11.7	29	32.9	19	17	17.5
Intraoperative complication	2.5	-	1.0	3.6	0	-

Gehrig et al.¹⁴ published a study of the use of robotic surgery for endometrial cancer staging in 49 obese and morbidly obese women and compared the results with those in 32 patients treated laparoscopically. In both the obese and morbidly obese patients, robotic surgery was associated with shorter operative time, less blood loss, more lymph node retrieval, and shorter hospital stay

Conclusion

Above results and its comparison with historic data suggests that robotic hysterectomy can be performed safely and effectively with acceptable operating times in eligible patients. Robotic technology with its 3 dimensional visualisation and articulated instrumentation, overcomes many limitations of conventional laparoscopy and laparotomy.

We acknowledge our limitation regarding the usual biases of retrospective studies- use of historical controls and lack of randomisation. Due to prospective nature of data collection in the robotics versus retrospective review in the laparoscopic and laparotomy group, ascertainment bias may be introduced. In future, prospective studies will need to be performed to validate our findings and assess long term oncologic outcomes for endometrial cancer staging.

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