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Robotic-assisted versus conventional laparoscopic hysterectomy for endometrial cancer

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ABSTRACT

Objective: The safety and efficacy of robotic-assisted laparoscopic hysterectomy (RALH) compared with conventional total laparoscopic hysterectomy (TLH) for surgical staging of endometrial cancer has not been clearly established. With the commencement of a robotic program at our institution, our objective was to evaluate and compare the surgical outcomes of RALH with TLH for endometrial cancer.

Methods: A retrospective cohort study was performed on 39 patients who underwent RALH and 41 patients who underwent TLH for endometrial cancer at a tertiary care academic institution.

Results: In the setting of endometrial cancer RALH is significantly longer to perform than TLH (mean operating time 133 min vs 107 min, $p = 0.0001$). There is higher estimated blood loss in TLH cases than RALH cases (78 mL vs 22 mL, $p = 0.015$). Women who underwent RALH had a shorter length of stay (1.3 days vs 1.8 days, $p = 0.006$) than TLH patients, and six cases (15%) of the RALH group were discharged on the same day of surgery. There were no differences between the RALH and TLH groups in intraoperative or postoperative complications and there were no conversions to laparotomy.

Conclusion: RALH is safe and feasible for the treatment of endometrial cancer, with low morbidity, less blood loss and shorter length of stay than TLH. RALH is associated with longer mean operating times than TLH and this may improve with enlisting a consistent experienced team. Prospective randomised studies which include analysis of quality of life measures and long-term outcomes are required to further establish the role of RALH in the surgical staging of endometrial cancer.

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Introduction

Endometrial cancer is one of the most common gynaecologic malignancies, with an increasing incidence in the developed world. [1] It is primarily treated with total hysterectomy, bilateral salpingo-oophorectomy, and surgical staging [2]. Minimally invasive surgery is preferable to laparotomy due to reduced blood loss and length of stay, faster return to activity, and better cosmesis [3–5]. However, laparoscopic surgery is limited by two-dimensional vision, incomplete articulation of instruments, and ergonomic restrictions, prompting the development of surgical robots in recent years to overcome these issues. Robotic-assisted laparoscopic hysterectomy (RALH) has been established as safe and effective when compared with laparoscopic hysterectomy in benign gynaecology. [6–8] However, high quality studies comparing the two in endometrial cancer are limited and results are

conflicting. Several non-randomised studies and reviews describe excellent results with RALH, including good lymph node yield, low blood loss, comparable operative time, low complication and conversion rates and short hospital stays [9–18]. In contrast, a Cochrane review found limited evidence on the effectiveness and safety of RALH compared with laparoscopic or abdominal hysterectomy for gynaecological cancer [19].

Robotic surgery is still in the early stages of adoption in Australia and further evidence regarding its utility is needed. A robotic program for endometrial cancer commenced at our institution in June 2017, prompting this study to evaluate and compare the outcomes of RALH cases with a historical cohort of women who underwent total laparoscopic hysterectomy (TLH) for endometrial cancer.

Materials and methods

We conducted a retrospective observational study on women who underwent TLH and RALH for endometrial cancer from 7th May 2014 to 22nd August 2018 at Liverpool Hospital, a tertiary care academic centre in Sydney, Australia. Ethics approval and waiver of

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consent were granted by the South Western Sydney Local Health District Human Research Ethics Executive Committee.

Only one surgeon performed RALH at Liverpool Hospital during the study period. Before the commencement of the robotic program on 28th June 2017, endometrial cancer patients were treated with either TLH or open surgery after multidisciplinary team review. As we aimed to compare the two minimally invasive techniques of TLH and RALH, we included all cases of TLH performed by the same surgeon who subsequently performed the RALH cases. It should be noted that after the commencement of robotic surgery at our institution, endometrial cancer patients were either treated with RALH or open surgery, and the majority of cases were RALH. This was secondary to institutional encouragement to utilise the newly installed robotic system and the surgical ability to perform RALH on complex cases which may previously have required open surgery. A single case of TLH was performed in September 2018 due to the unavailability of the robotic system on that occasion.

TLH and RALH cases performed by our surgeon were identified via the electronic Gynaecology Surgical Database of the Obstetrics and Gynaecology Department of Liverpool Hospital. All RALH were performed on the Da Vinci Xi Surgical System (Intuitive Surgical Inc, Sunnyvale California, USA). Our surgeon is a certified Gynaecological Oncologist and was the primary surgeon in all cases, assisted by a Fellow, a registrar and a resident. He had performed over 700 cases of both TLH and RALH at the time of the study in other institutions, however, all other members of the surgical and operating theatre team were new to robotic surgery.

Patients were included in the study if they have had endometrial cancer treated with TLH or RALH (with or without removal of tubes and ovaries, and with or without removal of pelvic lymph nodes). Patients were excluded if they had surgery performed for indications other than endometrial cancer. All TLH cases performed between May 2014 to May 2017 were included in the study if they met the above criteria, with the addition of the one case performed in September 2018. A similar number of RALH cases were included, and these patients underwent surgery between June 2017 to November 2018.

Data were collected from medical records from the Clinical Information Unit of Liverpool Hospital (both paper-based and electronic). Additional data for RALH cases were retrieved from the prospectively maintained electronic Gynaecology Surgical Database. Fig. 1 shows the study flow chart. Data collected included: (1) patient characteristics such as age, height, weight, BMI, medical co-morbidities, previous abdominal/pelvic surgery, (2) tumour characteristics such as histological type, grade and FIGO stage, (3)

surgical metrics including total operation time (defined as the time from initial skin incision to skin closure), docking time and console time (for robotic cases), (4) lymph node yield, (5) estimated blood loss, (6) intraoperative complications including conversion to laparotomy and postoperative complications up to 12 weeks after surgery (graded using the Clavien Dindo classification system [20]), and (6) length of stay.

Surgical techniques

There was little variation between surgical techniques employed for TLH and RALH procedures, with the main difference being one extra port for RALH cases (5 ports compared to 4 in TLH), as shown in Table 1. The exception to this was a single case of RALH which was performed via a single (umbilical) port incorporating a camera port, two instrument ports and an assistant port. In both RALH and TLH cases, the large port was used to retrieve bagged lymph node specimens, to introduce suture material, and in robotic cases, for suction/irrigation instruments. In the single-site RALH case, suction/irrigation was provided via the accessory port within the umbilical port, and bagged lymph node specimens were retrieved vaginally at the time of delivery of the uterus. In both RALH and TLH cases, the hysterectomy, salpingo-oophorectomy and pelvic lymphadenectomy were performed completely laparoscopically. The uterus was removed vaginally and the vaginal vault was closed laparoscopically using 0 barbed suture in both groups. There was one patient in the TLH group who required vaginal closure of the vault due to technical difficulties.

Statistical analysis

Statistical analyses were conducted using the SAS Enterprise Guide Version 9.4 (SAS Institute Incorporated, Cary, NC, USA). Categorical variables were analysed using the chi-square test and continuous variables were analysed using the two-sample T-test (independent standard T-test). P values of 0.05 or less were considered statistically significant.

Results

A total of 39 women who underwent RALH and 41 women who underwent TLH were included in our study. Table 2 shows that patients were well matched in age and body mass index. There were more patients with diabetes in the RALH group compared with the TLH group (59.5 % vs 30 %, $p = 0.009$) but there were no other significant differences in co-morbidities. The histological indications for surgery are listed in Table 3; there were similar numbers of each histological type in both RALH and TLH cohorts.

There were no significant differences between the RALH group and the TLH group in the size of uteri removed (mean 138 g for RALH and 120 g for TLH, $p = 0.303$) and the number of lymph nodes harvested (median 6 for RALH and 7 for TLH, $p = 0.689$). The cohorts did not differ in FIGO Stage or histological grade (Table 4). Two cases in the RALH group were reclassified as undifferentiated adenocarcinoma post-operatively (from carcinosarcoma and endometrioid adenocarcinoma pre-operatively) after histopathological review. There were no changes to histological diagnosis postoperatively in the TLH group.

Mean operating times were significantly longer for RALH patients than TLH patients (133 min versus 107 min, $p = 0.001$). The average time taken to perform the surgery at the console in RALH (console time) was 89 min (Table 5). There was a higher estimated blood loss in the TLH group, mean 78 mL, compared with 22 mL in RALH group. Neither group reported any intraoperative complications nor conversions to laparotomy. There were 3 cases of post-operative complications in each group (all classified Clavien Dindo

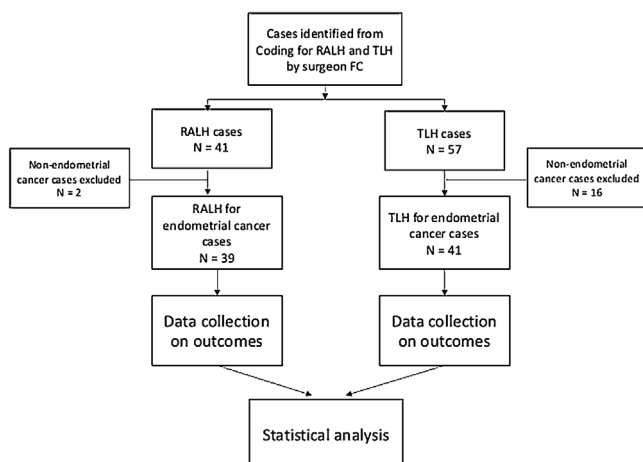


Fig. 1. Flow diagram of study.

Table 1
Surgical techniques for RALH vs TLH cases.

Surgical techniques	RALH	TLH
Abdominal entry	Veres needle at left upper quadrant*	Veres needle at left upper quadrant
Port sites and sizes	15 mm assistant port at left upper quadrant, 8 mm camera port at or above umbilicus, 8 mm port at right upper quadrant and right lateral abdomen, 8 mm port at left lateral abdomen.*	5 mm port at left upper quadrant, 12 mm port at or above umbilicus, 5 mm ports at left lower quadrant and right lower quadrant.
Uterine manipulator	Disposable	Disposable
Hysterectomy and BSO	Laparoscopic	Laparoscopic*
Vault closure	Laparoscopic	Laparoscopic

BSO = Bilateral salpingo-oophorectomy
 * One case of RALH performed via single port at umbilicus with Hasson open entry 3 cm incision.
 *One case of TLH required vaginal approach to vault closure due to technical difficulty.

Table 2
Patient characteristics by mode of surgery.

Patient Characteristics	RALH (n = 39)	TLH (n = 41)	P value
Mean age (years)	64.6 +/- 10.43 (range 35–84)	63.7 +/- 10.12 (range 39–89)	0.693
Mean BMI (kg/m ²)	37.6 +/- 10.63 (range 19–63)	33.8 +/- 9.96 (range 19.5–62)	0.104
Co-morbidities, n (%)	29 (78.4)	26 (65.0)	0.194
• Cardiovascular	5 (13.5)	3 (7.5)	0.39
• Pulmonary	22 (59.5)	12 (30)	0.009
• Diabetes	9 (24.3)	6 (15)	0.30
• Gastrointestinal	18 (48.7)	18 (45)	0.75
• Other	19 (51.4)	18 (45)	0.58
• Previous abdominal surgery			

Table 3
Histological indications for surgery.

Indication for surgery (histological type)	RALH n (%)	TLH n (%)	X ² test
Endometrioid adenocarcinoma	34 (87.2)	38 (92.7)	p = 0.47
Serous papillary adenocarcinoma	1 (2.6)	2 (4.9)	
Clear cell carcinoma	1 (2.6)	0 (0)	
Carcinosarcoma	3 (7.7)	1 (2.4)	

Table 4
Histopathological findings.

Histopathological findings	RALH	TLH	P value
Size of uterus (g), mean (range)	138 (34–550)	120 (47–297)	0.303
Lymph node yield, median (interquartile range)	6 (2–11)	7 (3–13)	0.689*
Stage, n (%)	23 (59)	29 (70.7)	0.13
IA	10 (25.6)	6 (14.6)	
IB	3 (7.7)	0	
II	3 (7.7)	6 (14.6)	
III-IV			
Grade, n (%)	23 (59)	27 (69.2)	0.542
1	6 (15.4)	7 (17.1)	
2	6 (15.4)	6 (14.6)	
3	4 (10.3)	1 (2.4)	
Other			

*Wilcoxon rank test.

Class 1). In the RALH group there was one case of lower limb lymphoedema, one patient with mild lower limb paraesthesia, and one patient with transient obturator nerve injury which resolved after 12 weeks of physiotherapy. The TLH group also included one case of lower limb lymphoedema, a patient with a vault haematoma which was treated conservatively, and a case of umbilical port wound infection treated with oral antibiotics.

The mean length of stay for patients who underwent RALH was shorter than that for TLH patients (1.26 days vs 1.78 days) and this difference reached statistical significance ($p = 0.006$, 95 % CI -0.89 to -0.16). Six patients (15 %) in the RALH group and none in the TLH group were discharged on the day of surgery ($p = 0.009$).

Discussion

Australia is a first world country where robotic surgery is not widely performed. Our health system is a dichotomy between public (government-funded) and private (enterprise-driven) sectors, and the majority of robotic surgeries are performed in the latter. Our institution was the first public facility in its city and state to commence a robotic surgery program in endometrial cancer and reviewing the outcomes of this program provides valuable information for similar institutions.

This study reports the outcomes of the first 39 patients who underwent RALH for endometrial cancer at our institution. Although the surgeon was experienced in both RALH and TLH, the rest of the surgical team (Fellows, registrars and residents), as well as the theatre staff, were new to robotic surgery. We found a statistically significant increase in total operation time for RALH compared with TLH, consistent with current literature. [6–9]

Table 5
Outcomes by mode of surgery.

Surgical outcomes				
Outcomes	RALH	TLH	Mean difference	P value
Mean operating time (mins)	132.9 ± 32.3	107.1 ± 24.4	25.8 (95 % CI 13.1–38.5)	0.0001
Mean console time (mins)	89	N/A		
Mean intraoperative blood loss (mL)	22.3 (Range 5–80)	77.7(Range 10–800)	–55.4 (95 % CI 99.8–11.0)	0.015
Intraoperative complications	0	0	N/A	
Conversion to laparotomy	0	0	N/A	
Postoperative complications	3 (7.7)	3 (7.3)	N/A	0.95
Mean length of stay (days)	1.26 (Range 0–4)	1.78(Range 1–4)	–0.52 (95 % CI -0.89 to -0.16)	0.006
Same day discharge, n (%)	6 (15.4)	0 (0)	N/A	0.009

[12,13,21–23]. The only randomised trial comparing RALH and LH in endometrial cancer, however, found RALH was faster to perform compared to LH but the authors concede that their unit was well-experienced in robotic surgery [24]. There are several possible explanations for the prolonged operative time for RALH, including inexperienced staff, inconsistent staff, and individual case factors. An analysis of the mean docking time for the first 13 cases of RALH (19.3 min) in comparison with the second 13 cases (21.4 min) and the last 13 cases (27.0 min), showed that the mean docking time increased over the study period, suggesting that gain in experience with the robotic system did not improve docking time. However, over the study period there was considerable change in staff (rotation of registrars and residents to a different team at the end of term and theatre nurses taking recreational leave and being relieved by inexperienced staff). It may be possible to reduce these times by enlisting a consistent team of experienced theatre staff. Individual patient characteristics may also contribute to prolonged operative times, for example, some cases involved extensive laparoscopic adhesiolysis to separate the omentum from the anterior abdominal wall prior to inserting further ports and docking the robot. There are no provisions to record such events in the current Gynaecological Surgical Database. Future studies should include detailed descriptions of each surgery in order to capture all variables that may prolong operative times.

It is important to acknowledge the potential differences in methods used to record theatre times. At Liverpool Hospital there is a mandatory log of all robotic cases performed which requires documentation of patient in theatre time, surgery start time, robot docking time, undocking time, skin closure time, and patient out of theatre time. Non-regular staff documenting times (usually the scout nurse) may interpret surgery start time as the commencement of patient positioning or skin preparation rather than skin incision time. These parameters need to be clearly defined in the logbook to standardise times recorded, particularly when relief staff are on duty.

The current study found that RALH cases were associated with a significantly lower estimated blood loss (EBL) than TLH cases, consistent with recent literature. [10–14] It is also notable that the EBL is consistently low for robotic cases whereas TLH cases were associated with a wider range of EBL (10–800 mL). Due to the retrospective nature of our study, pre- and post-operative haemoglobin levels were not consistently recorded. However, these figures are unlikely to have clinically significant differences as the EBL, in general, were low in both groups. Robotic hysterectomy appears to be as safe as TLH as there was a low rate of complications and no conversions to laparotomy in either group. Although we recorded the lymph node yield, using this as an indication of the sufficiency of dissection may be confounded by higher BMI and does not necessarily correlate with long-term survival. [25] Nevertheless, TLH and RALH performed equally in this aspect.

There was a small but significant difference in mean length of stay between the robotic group (mean 1.26 days) and the TLH group (1.78 days, $p = 0.006$). Notably, 15 % of RALH cases were discharged on the same day as surgery. Robotic hysterectomy is a feasible day procedure and this may revolutionise patient management in gynaecologic oncology. [26–28] Furthermore, it may represent significant cost savings to the institution and may help offset the longer operation times associated with robotic surgery. Previous studies have noted that robotic surgery is more costly than conventional laparoscopy [29–32], As it is beyond the scope of the current study, future research incorporating cost-benefit analysis is necessary to establish the economic validity of a robotic program in gynaecologic oncology.

We acknowledge several limitations to our study. This study demonstrates the experience of a single surgeon at a single institution, limiting the generalisability of the results. As with all retrospective studies, our results may be affected by the possibility of confounding and selection bias. The surgical approach was not randomised but was influenced by surgeon preference and institutional factors. Women with endometrial cancer often have significant co-morbidities and high BMI, whereby the superior ergonomics and improved instrumentation of the surgical robot are advantageous. [33,34] These factors potentially influenced our surgeon to elect the robotic approach over conventional laparoscopy when it became available at our institution. Lastly, despite our small sample size ($n = 80$) limiting the power of our results, it is comparable to those of randomised trials comparing RALH and TLH ($n = 100, 62$ and 101) [6,8,24]. Future studies should include objective measures of blood loss and post-operative pain, analysis of quality of life and other patient-reported outcomes, and long-term follow up.

The strengths of this study include cohorts well-matched in age, BMI, and most major co-morbidities as well as in clinicopathologic features of their endometrial cancer. The procedures being performed by a single experienced surgeon ensures that a consistent surgical technique is employed in both robotic and laparoscopic cases and that a surgical learning curve is not a confounding factor in this study.

Conclusion

The importance of this study is to provide data on surgical outcomes and complications of a newly instituted robotic program at a tertiary care academic institution in Australia, where robotic surgery is not yet commonplace. Our study shows that robotic hysterectomy for endometrial cancer staging is safe and feasible. It is comparable to TLH in surgical complication rate, with the advantages of less estimated blood loss and shorter length of stay, enabling same-day discharge for a major gynaecological procedure. Robotic surgery is associated with longer mean operating

times than TLH but this may be improved with employing a consistent, experienced OR team. As we have not demonstrated an absolute advantage of RALH over TLH, prospective randomised studies which include cost analysis, quality of life measures and long-term outcomes are required to further establish the role of robotics in the surgical staging of endometrial cancer.

Source of funding

None

Prior presentation

This project was presented at the AAGL 48th Annual Congress in Minimally Invasive Gynecologic Surgery in Vancouver, Canada, November 9–13, 2019.

Institutional review board

Ethics approval and waiver of consent were granted by the South Western Sydney Local Health District Human Research Ethics Executive Committee (2019/ETH12774).

Data availability statement

Data is not available for third party use as this is not covered by the Ethics approval for this project.

Precis

Robotic-assisted laparoscopic hysterectomy is associated with longer operative times but less blood loss and shorter length of stay than conventional laparoscopic hysterectomy in patients with endometrial cancer.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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