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LEARNING CURVE IN LAPAROSCOPIC RADICAL HYSTERECTOMY – IS IT REALLY STEEP? A SINGLE INSTITUTION EXPERIENCE

Oncology

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ABSTRACT

Introduction: Radical hysterectomy with pelvic lymphadenectomy is the current gold standard treatment for early-stage cervical cancer. Total laparoscopic radical hysterectomy has been proven to be safe and feasible. But there are only a few literatures available on the learning curve for this procedure. We have reviewed literature, analysed and discussed the surgical & oncological safety, advantages and short term outcome of laparoscopic radical hysterectomy.

Objective: Aim of our study is to analyse our learning curve in total laparoscopic radical hysterectomy and to assess the surgical & oncological safety, advantages and short term outcome of laparoscopic radical hysterectomy

Materials And Methods: This is a retrospective study where medical records of patients who underwent laparoscopic radical hysterectomy at our department between 2015 and 2016 were reviewed retrospectively. Forty four patients included in the study were divided into the first 22 cases (phase I) and the second 22 cases (phase II). Disease and surgery related parameters were compared.

Results: There was a significant decrease in the mean operating time, conversion rate, complication rate, duration of hospital stay and time to normal residual urine in the phase II of learning curve. Operating time and blood loss were significantly less for patients who underwent upfront surgery than who received preoperative therapy

Conclusion: Although TLRH is a technically demanding procedure with steep learning curve, our early results are promising and comparable with series in literature. Extensive experience in open radical hysterectomy and familiarity in pelvic anatomy have made our learning curve less steep, making the procedure be performed with more ease and with less complications after the initial few surgeries. With increasing experience and appropriate patient selection, TLRH can be safely performed without compromising the oncological safety with all the advantages of minimal access surgery

KEYWORDS

I.Introduction

Cervical cancer is the fourth most common cancer in women worldwide with 85% of this disease occurring in developing countries, where cervical cancer is the leading cause of death in women [1]. Radical hysterectomy with pelvic lymphadenectomy is the current gold standard treatment for early-stage cervical cancer. Ever since Nezhat et al [2] and Querleu [3] described total laparoscopic radical hysterectomy (TLRH), there has been increasing evidence in the literature [4-9] proving its safety and feasibility over the conventional established advantages include reduced blood loss, fewer transfusions, shorter hospital stay, quick return to normal activities, better cosmetic effects, and reduced formation of adhesions [10]. The aim of this article is to describe our early experience in total laparoscopic radical hysterectomy (TLRH) in the management of cervical and endometrial cancer and analyse the learning curve. Learning curve periods have previously been reported for other advanced laparoscopic procedures [11, 12]. Only five studies are available in literature till date analysing learning curve in laparoscopic radical hysterectomy [9, 25-28]. Ours is the first of its kind in our part of subcontinent. We have reviewed literature, analysed and discussed the surgical & oncological safety, advantages and short term outcome of laparoscopic radical hysterectomy.

II. Materials And Methods

Medical records of patients who underwent laparoscopic radical hysterectomy at our department between 2015 and 2016 for following indications were reviewed retrospectively - 1. Non bulky early stage cervical cancer (stage IB1 & IIA1); 2. Bulky early stage (stage IB2 and IIA2) and stage IIB cervical cancer after preoperative chemotherapy (3 cycles of paclitaxel + cisplatin) or preoperative chemo radiation (50Gy EBRT) with no residual clinical disease in the parametrium; 3. Endometrial carcinoma with cervical stromal invasion. All operations were performed by a single surgeon who had extensive experience in abdominal radical hysterectomy, but with no prior laparoscopic experience, with first assistant at the level of consultant surgical oncologist and residents as camera surgeon. All surgeries used the same technique as described below. Dissection of planes and division of tissues were performed using Harmonic scalpel.

For TLRH, patient was placed in modified Lloyd Davis position. A small bolster was kept at the level of sacral promontory. Pneumoperitoneum is created by closed technique using Verre's needle. A total of 5 ports were used; A 10mm supra umbilical camera port; A 10mm right hand working port in McBurney's point on right side; A 5mm left and working port at the lateral border of rectus in midclavicular line. Two 5mm accessory ports were inserted on left side as mirror image of those on right side. The surgeon stood on the right side, the assistant surgeon on the left side and camera surgeon on the head end. Myoma screw and uterine manipulator were avoided. Round ligaments were held with bowel grasper to manipulate uterus. Procedure was begun with opening the peritoneum medial to the right infundibulo pelvic ligament. The ureter was identified and pushed laterally. The peritoneal cut was extended to pouch of Douglas. After completing the same procedure on left side, uterus was pulled anteriorly and pouch of Douglas peritoneum was opened. Dissection was continued between the two layers of Denonviller's fascia, dissecting the rectum off the posterior vaginal wall.

Round ligaments were divided on either side. The peritoneal cut was extended into uterovesical fold. Bladder was dissected off the uterus and anterior vaginal wall.

The left ureter was retracted medially and posterior leaf of broad ligament above the ureter was cut. Pararectal fossa was dissected. Internal iliac A was identified in the lateral boundary of the space. The uterine A which crosses the space was clipped and divided at its origin. Pararectal space dissection was continued upto the levator ani muscle. Ureter was retracted laterally and uterosacral ligaments were divided

preserving the hypogastric nerves in the medial wall of Okabayashi space. Paravesical spaces were dissected. Parametrium was divided with harmonic scalpel. The medial cut end of uterine A was lifted off the ureter and ureter was dissected upto ureteric tunnel. With adequate traction on bladder, ureteric tunnel was dissected. The paracolpos were exposed and divided as laterally as possible. Same procedure was repeated on the right side. Vagina was divided with adequate margin. The infundibulo pelvic ligaments were divided finally and radical hysterectomy specimen was retrieved through vagina using endobag.

Bilateral pelvic lymphadenectomy was completed by removing all lymphoareolar tissue between bifurcation of common iliac A superiorly, deep circumflex iliac vein inferiorly, genitofemoral N laterally, internal iliac A medially and obturator N posteriorly. Specimen was removed through vagina using endobag. Vault was left open. Port wounds were closed.

All patients had their Foley's catheter retained till 10th postoperative day. Catheter clamping was done on the last 3 days before trial removal on 10th day and post voidal residual urine was measured. Catheter was reinserted if residual urine was more than 50ml.

Patients with early stage cervical cancer with high risk features on postoperative histopathology and those who had residual disease in postoperative HPE after preoperative therapy, received adjuvant therapy as per our protocol.

The following data were retrieved from the medical records: (1) patients' characteristics including age, body mass index (BMI), and past operative history; (2) disease characteristics including histopathology findings and FIGO stage; (3) surgery-related data; operation time, estimated blood loss, length of hospital stay, and complications if any; and (4) pathologic data including number and status of dissected lymph nodes, status of parametrium and surgical margin. A total of 44 patients were included in the study. They were divided into the first 22 cases (phase I) and the second 22 cases (phase II), and the parameters between the phases were compared.

Statistical analyses:
The median values of continuous variables were compared using Mann – Whitney U test. The data were entered into a Microsoft Excel data base and analyzed using SPSS version 12.0 statistical software. $P < 0.05$ was considered significant in all statistical tests.

III. Results
The median age and BMI were 54 and 26.3 respectively. Most common histology observed was squamous cell carcinoma (79.5%) and most of the rest were adenocarcinoma (15.9%).

Table 1:

NUMBER OF PATIENTS		44
AGE		54 (33-75)
PARITY		2 (0-7)
BMI		26.3 (20.9 -31.6)
CA CERVIX		43
	IB1	11
	IB2	5
	IIA1	3
	IIA2	3
	IIB	21
CA ENDOMETRIUM		1
HISTOLOGY	SCC	35
	ADENO	7
	ADENOSQ	2
PREOP THERAPY	TOTAL	29
	CHEMO	12
	CHEMORT	17

The data on surgical outcome is presented in Table 2. The median operative time was 175 minutes. The median operating time in phase I was 190 minutes which reduced significantly (165 minutes) in phase II (p value 0.03). Also, it was significantly shorter ($p < 0.001$) for patients undergoing upfront surgery (140 minutes) than those who received preoperative therapy (190 min). The median operative time does not differ between patients with ideal BMI (177 min) and those who were overweight or obese (182 min). Patients who required conversion to open procedure for various reasons took longer operative time (210 minutes vs. 160 minutes).

Table 2:

Surgical time (min)	Overall	175
	Upfront	142.7
	Post chemo +/- rt	190.2
	Completed	160.1
	Converted	210.8
Blood loss (ml)	Overall	300
	Upfront	220
	Post chemo+/-rt	350
Transfusion rate		15.9 % (7/44)
Conversion rate (%)	Overall	27% (12/44)
	Upfront	13 % (2/15)
	Podt chemo +/-rt	34% (10/29)
Reason for conversion	Parametrial bleed	41.7% (5/12)
	Bladder injury	33.3% (4/12)
	Difficulty in bladder / rectal dissection	25% (3/12)
Mean nodal harvest	Overall	9.2
	Upfront	12
	Post chemo +/- rt	8.5
Return of bowel function	Overall	2.02
	Completed	1.47
	Converted	3.5
Hospital stay	Overall	5.41
	Completed	3.49
	Converted	10.58
Time to normal residual urine	Overall	15.79

The median blood loss was 300 ml with an overall transfusion rate of 15%. There was no significant difference in blood loss between phase I and II. But there was significant difference ($p < 0.001$) in blood loss between those who underwent upfront surgery (200 ml) and those who received preoperative therapy (350 ml).

Overall conversion rate was 27%. Conversion rate decreased from 36% in phase I to 18% in phase II. Conversion rate were higher with Patients who received preoperative therapy (34% vs 13%). Most common causes of conversion were parametrial bleeding (41.7%), bladder injury (33.3%) and dense fibrosis in recto vaginal or vesico vaginal plane (25%). All bladder injuries were promptly identified and repaired peroperatively without any post operative sequelae.

Median number of nodes retrieved was 10. There was no significant difference in nodal retrieval between the two phases or between those who underwent upfront surgery. We were able to achieve tumor free parametrial and vaginal margin in all our patient. Post operatively bowel function returned on an average of 2 days and median hospital stay was 4 days. There was no significant difference in Hospital stay between the two phases, whereas it was shorter for patient who underwent upfront surgery (3 vs 4 days p 0.04). It was also shorter for patients who had their procedure completed laparoscopically (3.5 days vs 10.58 days).

The median time to normal residual urine was 11 days, which significantly reduced from 18 days from phase I to 10 days in phase II (p 0.01).

Intraoperative and post operative complication rate in our series were 9 and 13.6 % respectively. There was a significant reduction in both rates in phase II (table 3and 4).

Table 3:

Complications	No. (%)
Intra operative	
Major vascular injury	0 (0)
Rectal injury	0 (0)
Ureter injury	0 (0)
Bladder injury	4 (9)

Postoperative	
Wound infection	0 (0)
Port site hernia	0 (0)
Port site metastasis	1 (2.3)

Deep vein thrombosis	0 (0)
Urinary fistula	1 (2.3)
UTI	1 (2.3)
Bladder dysfunction	23 (52%)

Table 4

Median	Our study							Chong et al [10]	Spirtos et al [22]	Diaz-Feijoo [21]	Malzoni et al [26]	Putambekar et al [23]
	OVERALL	EARLY	LATE		UPFRONT	POST CHEMO +/_ RT						
No of patients	44	22	22	P value	15	29	P value	50	78	20	77	248
FIGO stage	IB1 - IIB				IB1,IIA1	IB2,IIA2, IIB		Ia2 –IIB	IA2-IB1	IA2-IB1	IA1-IB1	IA2-IB1
Operating time (min)	175	190	165	**0.03**	140	190	**<0.001**	225	205	272.5	186	88
Blood loss (ml)	300	300	260	0.41	200	350	**<0.001**	333	225	400	57	200
Transfusion rate	15	18	12	0.49				12	1.3	5	0	
Pelvic node count	10	9.5	10	0.58	12	8.5	0.17	26.9	34	18.9	23	20.4
Time to normal residual urine	11	18	10	**0.01**	10	13	0.13	6.7	-	-	-	-
Return of bowel function	2	3	2	0.7	2	3	0.71	-	-	-	-	-
Hospital stay	4	4	3	**0.051**	3	4	**0.04**	7.3	2.9	4.9	4	3
Intra op cx rate (%)	9	13.6	4.5	**0.02**	6.7	10.3	0.51	4	9	-	0	6
Post op cx rate (%)	13.6	13.6	0	**0.001**	6.7	6.9	0.65	4	9	10	31	6.8
Conversion Rate (%)	27	36	18	**0.05**	13	34	0.04	-	-	-	-	0

One patient presented with ureterovaginal fistula in the 23rd postoperative day which was evaluated and managed by ureteric reimplantation with Boari's flap. One of our early patients developed port site recurrence after seven months, at the site of node retrieval, which was treated by wide excision and mesh repair after ruling out systemic metastasis. Following this complications, we routinely used endobag and preferred using per vaginal specimen retrieval.

IV.Discussion

There are accumulating evidences that minimally invasive surgery in gynec oncology is a safe procedure which does not affect oncological outcome compared to open techniques. TLRH has been shown to have added benefits of lower blood loss, less wound morbidity in terms of pain, infection and cosmesis and shorter hospital stay.

Though a learning curve is expected with a new advanced minimal access surgery, our median operating time was 175 minutes, which was even less in patients who did not receive any preoperative therapy. Patients with bulky disease (IB2 & II A2) and those with FIGO stage IIB, who received preoperative therapy as a part of institutional protocol, had an expected longer operating time. This was due to difficulties posed by post radiation fibrosis or desmoplastic response after chemotherapy in dissection of surgical planes. The operating time significantly reduced in phase II (table - 4). Results of our study compared favourably with other series in the literature, with reported mean operative time for TLRH ranged from 196 mins to 371 mins [15-24].

In the literature, median blood loss has been reported to range from 55 ml to 400 ml for TLRH [15-23]. Median blood loss in our study (300ml) remains comparable with the series in literature. For the same reasons mentioned above, blood loss was significantly higher in patients who received preoperative therapy. Variation among authors was noted concerning decrease of estimated blood loss [24, 25]. Our data did not show any statistically significant decrease in blood loss with increasing experience.

In most TLRH studies, intraoperative complications ranged from 0% to 15%, and complications included cystotomy, ureteric, rectal and vascular injuries [15-23]. Intraoperative complication rate in our study was 9% .We encountered four bladder injuries which were identified peroperatively and required conversion for repair. All but one of these complications occurred in patients who received preoperative therapy with resultant fibrosis and hence, difficult dissection. There were no rectal or vascular injuries in our study except for parametrial bleeding in 5 patients which required conversion to attain haemostasis. Intra operative complication rate significantly reduced with increasing experience in our study (Table 4).

Median nodal harvest was 10, which did not vary significantly between the two phases, reflecting the adherence to nodal clearance irrespective of the phase of learning curve. Smaller number of nodes harvested in our series is because the major component of our study population (66%) constituted those who received preoperative therapy. It has been proven in other pelvic malignancies that preoperative radiotherapy reduces the number of harvested nodes and reduced lymph node yield after neoadjuvant chemo radiation has no prognostic relevance. [26-29]

Conversion rate in our series was 27% most of which (83%) occurred in patients who received preoperative therapy. Conversion rate was less (18%) in the later phase of learning curve than in the early period (36%).

The postoperative complication rates reported in most TLRH studies ranged from 4% to 40%, with urological complications such as urinary tract infection, voiding dysfunction, and vesico vaginal or uretero vaginal fistulas being the most frequently reported complication [15-23]. In our study, the overall postoperative complication rate was 13.6 which included one port site metastasis and one ureterovaginal fistula. All these complications occurred in phase I of learning curve. The reported postoperative complication rates for RAH ranged from 4.4% to 20 % . The results of our study indicate that, TLRH performed by experienced surgeons, is a fairly safe procedure with low complication rates and non inferior to traditional RAH. Our results remain comparable with other series (table 4).

Bladder dysfunction was assessed using 'time to normal residual urine' as a reliable parameter. This significantly improved in the II phase .The ability of the surgeon to recognize and spare the hypogastric nerve and inferior hypogastric plexus improved with experience, which contributed to the rapid restoration of bladder function.[25]

Our study, analysing the learning curve in TLRH, is the first of its kind from our part of subcontinent, and sixth such article in world literature (Table 5). The learning period for TLRH to reach a significant improvement in performance was calculated to be between 9 and 50 cases in different case series (Table: 5) [24,25].

The operative time, conversion rate and complication rate in our series significantly came down after initial 22 cases (Table: 4). This relatively shorter learning curve is probably due to the experience of our surgeons in the field of abdominal radical hysterectomies as well as familiarity in the complex pelvic anatomy and surgical planes.

The volume of our study with 44 patients is adequate enough since, 3 out of the only 5 available studies had lesser patients to assess the learning curve (Table 5). Though it is true that expertise might vary

among surgeons, feasibility of a study involving multiple surgeons, on learning curve in advanced minimal access surgery is less likely. Two of the 5 studies on learning curve (Hwang et al & Chong lee et al) in TLRH had involved single surgeon like ours (Table 5). Two other studies (Tae – Wook Kong et al [25] and Reade et al [9]) involved 2 surgeons for different reasons (to compare between two surgeons [25] and to enhance case volume& experience. In one of the five aforementioned studies (Hwang et al), the surgeon had no previous laparoscopic experience [26]. Ours is a similar scenario, where the performing surgeon had no prior laparoscopic experience. Yet the smooth transition from open to laparoscopic radical hysterectomy was possible with conscious improvisation of techniques using critical review of our surgical videos, dedicated team work and familiarity with pelvic anatomy from vast open radical hysterectomy experience. However, we agree that, a learning process through routine laparoscopic surgery followed by advanced laparoscopic surgery shall be more appropriate in training of postgraduate students.

V.Conclusion

The main hurdle for surgeons to adapt to minimally invasive surgery is the apparent long learning curve due to technical complexity and need for a dedicated delicate team work. However, as witnessed

Table: 5	Our study	Morva et al [14]	Reade et al [8]	Hwang et al [13]	Tae-Wook Kong et al[12]	Chong - Lee et al [10]
No. of surgeons	Single surgeon	NA	2 surgeons	Single surgeon	2 surgeons	Single surgeon
Prior lap experience	NIL	YES	YES	NIL	YES	YES
No. of patients	44	28	42	70	42 /surgeon	100
Learning curve plateau after (no. of surgeries)	22	9	23	35	18	50

in literature and experience, once this is overcome, patients benefit from laparoscopy due to low perioperative complication rates and uncompromised oncological results.

Although TLRH is a technically demanding procedure with steep learning curve, our early results are promising and comparable with series in literature. Extensive experience in open radical hysterectomy and familiarity in pelvic anatomy have made our learning curve less steep, making the procedure be performed with more ease and with less complications after the initial few surgeries. With increasing experience and appropriate patient selection, TLRH can be safely performed without compromising the oncological safety with all the advantages of minimal access surgery.

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