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ORIGINAL ARTICLE

Laparoscopic Radical Hysterectomy in Early Cervical Cancer: Is There a Future?

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Abstract

Introduction Since the time minimally invasive surgery (MIS) has been introduced into the field of oncology, it has taken over open surgery in almost all systems except few. Cervical carcinoma is one such malignancy where laparoscopy is struggling to find its place. Though initial studies were encouraging, the prospective studies, including LACC trial, were not in favor of MIS.

Aims and Objectives The aim is to retrospectively analyze the outcomes in terms of oncological clearance and survival in patients with early cervical cancer treated with open (ORH) or laparoscopic radical hysterectomy (LRH).

Methods The records of patients treated with ORH or LRH from 2013 to 2020 in our institute were analyzed. The parameters collected were demographic data, preoperative stage, grade, histopathological reports, and number of lymph nodes harvested. The overall survival and disease-free survival (OS, DFS) are calculated.

Results A total of 50 LRH and 36 ORH were performed between 2013 and 2020. Margins were free in all cases in both groups. There was no significant deference in histopathological parameters. The 3-year OS was 93.48% and 97.06% in LRH and ORH ($P=0.3$). The same for <2 cm tumors were 100% and 95.25% ($P=0.7$). The DFS at the end of 2 and 5 years was 96% and 85% for LRH while that of ORH group were 94.44% and 84.92% ($P=0.9$).

Conclusion There was no significant difference in histopathological parameters, OS or DFS between lap and open radical hysterectomies. Large randomized controlled studies that have overcome the shortcomings of LACC trial are needed to confirm the findings.

Keywords Carcinoma cervix · Laparoscopic radical hysterectomy · LACC trial · Cervical cancer

Introduction

Carcinoma cervix is fourth most common cancer in women worldwide while it stands as second in India. According to GLOBACON data, this also happens to be the second most common cause of cancer related deaths among Indian women. In year of 2020, 1,23,907 new cases were reported in India while 77,348 people had died of the same disease [1]. The data from the rural areas are even more alarming where the accessibility to heath care is difficult with scarce resources and health education has not found its way into primary health care centers. According to National Family Health Survey, percentage of women ever undergone cervical cancer screening in India is 1.9% (2.2% urban and 1.7% rural) which is significantly lower than that of developed countries [2].

The standard modes of treatment for carcinoma cervix depend on the stage of the disease like any other cancer. Stage IA, non-bulky IB and stage IIA1 are usually treated with radical hysterectomy with pelvic lymph node dissection while concurrent chemoradiation can also be offered. In India, nearly 22% patients belong to stage I [3]. All other stages are usually treated with definitive chemoradiation which includes external beam radiation and brachytherapy.

Since the time MIS has been introduced to the field of surgical oncology, MIS has shown to confer multiple benefits to patients including less post-operative pain, reduced wound and pulmonary complications, less blood loss, early recovery, shorter hospital stay and early return to work. It

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has either replaced or considered as an alternative to standard open surgeries in treatment of many cancers including esophagus, stomach, colon, rectum, prostate, bladder and endometrium. Carcinoma cervix is one of the very few malignancies where the role of MIS still remains a question.

The early retrospective studies showed promising results with robotic and laparoscopic radical hysterectomies in early carcinoma cervix with similar overall and DFS [4–7] and then came a series of prospective studies with similar encouraging results paving way for MIS in cancers of cervix [8, 9].

When Ramirez et al. published the outcomes of LACC trial, the largest RCT comparing MIS with standard open radical hysterectomies in 2018, the results came as a shock to the field of MIS [10]. This study along with another retrospective study of 2461 patients from National Cancer Database showing inferior outcomes in minimally invasive arm made the researchers to scrutinize the previous reports [11]. But neither LACC nor NCDB studies were powered to answer the questions regarding the tumors less than 2 cm and former was not without its own set of shortcomings.

We hereby report our institutional experience in the last 8 years on open and laparoscopic radical hysterectomies. We have analyzed the oncological safety, morbidity profile and overall survival in both cohorts and compared them against each other.

Materials and Methods

It is a retrospective study on patients with carcinoma cervix operated in our institute from 2013 to 2021. The patient particulars including age, complications, post-operative histopathology reports, morbidity, survival and recurrence data were collected from the cancer registers, operative records, pathology registers and follow-up records. We defined the overall survival from the date of surgery to the last follow-up or death and DFS from date of surgery to recurrence. The vaginal manipulator was not in any of our patients, and intracorporeal colpotomy was practiced in our institution.

Inclusion Criteria

Patients with biopsy confirmed cancer of the cervix with histologies including squamous, adenosquamous and adenocarcinoma. FIGO staging (2009 edition) was used and stages IB1, IIA1, IIA2 were included. All patients had ECOG performance status ≤ 2 with age between 18 and 70 years. Patients who accurately staged in the preoperative setting with MRI or CECT abdomen and pelvis were included in the study.

Exclusion Criteria

Patients treated for some other malignancy previously or with synchronous second malignancy, recurrent disease after definitive chemoradiation (CRT), and patients who have received any form of preoperative therapies are excluded from the study.

Statistical Analysis

The presentation of the categorical variables was done in the form of number and percentage (%). On the other hand, the quantitative data with normal distribution were presented as the means $\pm$ SD. The data normality was checked by using Kolmogorov–Smirnov test. The following statistical tests were applied for the results:

1. The comparison of the variables which were quantitative and normally distributed in nature were analyzed using Independent *t* test.
2. The comparison of the variables which were qualitative in nature were analyzed using Fisher's exact test as at least one cell had an expected value of less than 5.

The data entry was done in the Microsoft EXCEL spreadsheet and the final analysis was done with the use of Statistical Package for Social Sciences (SPSS) software, IBM manufacturer, Chicago, USA, ver 25.0.

For statistical significance, *P* value of less than 0.05 was considered statistically significant.

Results

Demographics

A total of 86 patients were included in the study of which 50 had undergone LRH while rest 36 were treated with open radical hysterectomy (ORH). In 4 patients, the laparoscopy was converted to open surgery, in 2 patients due to difficulty in ureteric dissection and in others to control the intra-operative bleed. All the conversion to open happened in 2015, during initial period of commencement of laparoscopic radical hysterectomies in our center. The boundaries of pelvic lymph node dissection in both open and laparoscopic approach were as follows: genitofemoral nerve laterally, ureter medially, bifurcation of the common iliac artery cranially, the deep circumflex iliac vein caudally, and the obturator nerve inferiorly.

The mean age of presentation in our study was 55 years (54 for LRH and 55 for ORH). 93% of the preoperative

Table 1 Comparison of age (years) between LAP and open

Age (years)	LAP ($n=50$)	Open ($n=36$)	Total	P value
Median (25th–75th percentile)	54 (42.75–61.5)	55 (41.5–61)	55 (42–61.5)	0.899‡

Table 2 Comparison of biopsy between LAP and open

Biopsy	LAP ($n=50$)	Open ($n=36$)	Total	P value
CIS	1 (2%)	1 (2.78%)	2 (2.33%)	0.473*
SCC	48 (96%)	32 (88.89%)	80 (93.02%)	
Adenocarcinoma	1 (2%)	3 (8.33%)	4 (4.65%)	
Total	50 (100%)	36 (100%)	86 (100%)	

Table 3 Comparison of preoperative FIGO stage between LAP and open

Preoperative FIGO stage	LAP ($n=50$)	Open ($n=36$)	Total	P value
CIS	1 (2%)	1 (2.78%)	2 (2.33%)	0.917*
IB1	34 (68%)	25 (69.44%)	59 (68.6%)	
IIA1	15 (30%)	10 (27.77%)	25 (29.06%)	
Total	50 (100%)	36 (100%)	86 (100%)	

Table 4 Comparison of post-operative FIGO stage between LAP and open

Post-operative FIGO stage	LAP ($n=50$)	Open ($n=36$)	Total	P value
CIS/non malignant	13 (26%)	5 (13.89%)	18 (20.93%)	0.524*
IA1	1 (2%)	0 (0%)	1 (1.16%)	
IA2	0 (0%)	1 (2.78%)	1 (1.16%)	
IB1	14 (28%)	16 (44.44%)	30 (34.88%)	
IB2	11 (22%)	8 (22.22%)	19 (22%)	
IIA1	10 (20%)	4 (11.11%)	14 (16.27%)	
IIA2	1 (2%)	2 (5.56%)	3 (3.48%)	
Total	50 (100%)	36 (100%)	86 (100%)	

biopsy reports were of squamous cell carcinoma, 5% adenocarcinoma while 2% were carcinoma in situ. In the preoperative assessment, majority of our patients, i.e., 68.6% ($n=59$) belonged to FIGO stage IB1 and 29% ($n=25$), were found to be in stage IIA1, 2% with CIS (Table 1, 2, 3, 4).

Surgical Outcomes

The average blood loss was significantly lower in laparoscopic group (160 ml) in comparison to open group (200 ml) ($P=0.03$), and though the length of stay was shorter in LRH arm when compared to ORH, it was statistically not significant. (10.2 days vs. 11.8 days).

In the post-operative histopathology, 18 patients (13 in LRH arm and 5 in ORH arm) were found to have CIS and despite of repeated sampling from different parts of the cervix invasion was not made out. 56% ($n=49$) of the study population belonged to stage IB and 19.6% ($n=17$) were of stage IIA. About 2.2% ($n=2$) were found to have microscopic cancer (FIGO IA). The mean tumor sizes in LRH and ORH arms were 2.5 and 2.1, respectively. About 72% ($n=49$, 23 in LRH and 26 in ORH) had superficial stromal invasion while 28% ($n=19$, 14 in LRH and 5 in ORH) had deep stromal invasion. In 16% ($n=11$, 5 in LRH, 6 in ORH) of the patients, lower uterine segment was found to be involved in the histopathology. Perineural invasion was not detected in any patient while 2 patients in the open arm and 1 in laparoscopic arm had Lymphovascular invasion. No patient in our study had involvement of parametrial or vaginal margin and 3 patients in open and 2 in laparoscopic arm had lymph nodal metastasis. There was no significant difference in the number of lymph nodes harvested in both the arms with the mean being 8. ($P=0.2$) (Table 5, 6, 7, 8, 9, 10, 11, 12).

Five patients with nodal metastasis, 3 patients with stromal invasion into middle 3rd of stroma with LVSI and 1 patient with deep stromal invasion received adjuvant radiation to pelvis. With respect to all the parameters mentioned above, both arms were comparable without any statistically significant difference between the two groups.

Morbidity Profile

One patient in laparoscopic group had ureteric injury and was treated with DJ stenting and none had bladder or rectal injuries. Temporary bladder dysfunction was seen in 4 patients in laparoscopic group and 2 in open group, and all were successfully treated with continued catheterization and pelvic floor exercises.

Table 5 Comparison of stroma between LAP and open

Stroma	LAP ($n=37$)	Open ($n=31$)	Total	*P* value
Minimal invasion	3 (8.11%)	5 (16.13%)	8 (11.76%)	0.114*
Stroma invasion 1/3rd	20 (54.05%)	21 (67.74%)	41 (60.29%)	
Stroma invasion 2/3rd	14 (37.84%)	5 (16.13%)	19 (27.94%)	
Total	37 (100%)	31 (100%)	68 (100%)	

Table 6 Comparison of vagina between LAP and open

Vagina	LAP ($n=37$)	Open ($n=31$)	Total	*P* value
Free	26 (70.27%)	28 (90.32%)	54 (79.41%)	0.069*
Vaginal involvement up to 1/3rd	11 (29.73%)	3 (9.68%)	14 (20.59%)	
Total	37 (100%)	31 (100%)	68 (100%)	

*Fisher's exact test

Table 7 Comparison of LUS between LAP and open

LUS	LAP ($n=37$)	Open ($n=31$)	Total	*P* value
Free	32 (86.49%)	25 (80.65%)	57 (83.82%)	0.515†
Involved	5 (13.51%)	6 (19.35%)	11 (16.18%)	
Total	37 (100%)	31 (100%)	68 (100%)	

†Chi square test

Table 8 Comparison of VN margin between LAP and open

VN margin	LAP ($n=37$)	Open ($n=31$)	Total	*P* value
Free	37 (100%)	31 (100%)	68 (100%)	NA
Total	37 (100%)	31 (100%)	68 (100%)	

Table 9 Comparison of PM margin between LAP and open

PM margin	LAP ($n=37$)	Open ($n=31$)	Total	*P* value
Free	37 (100%)	31 (100%)	68 (100%)	NA
Total	37 (100%)	31 (100%)	68 (100%)	

Table 10 Comparison of LVI between LAP and open

LVI	LAP ($n=37$)	Open ($n=31$)	Total	*P* value
No	37 (100%)	30 (96.77%)	67 (98.53%)	0.456*
Yes	0 (0%)	1 (3.23%)	1 (1.47%)	
Total	37 (100%)	31 (100%)	68 (100%)	

*Fisher's exact test

Table 11 Comparison of PNI between LAP and open

PNI	LAP ($n=37$)	Open ($n=31$)	Total	*P* value
Nil	37 (100%)	31 (100%)	68 (100%)	NA
Total	37 (100%)	31 (100%)	68 (100%)	

Table 12 Comparison of nodes harvested between LAP and open

Nodes harvested	LAP ($n=50$)	Open ($n=36$)	Total	*P* value
Median (25^{th}–75th percentile)	8 (7–10)	7 (6–9.25)	8 (7–10)	0.218‡

‡Mann Whitney test

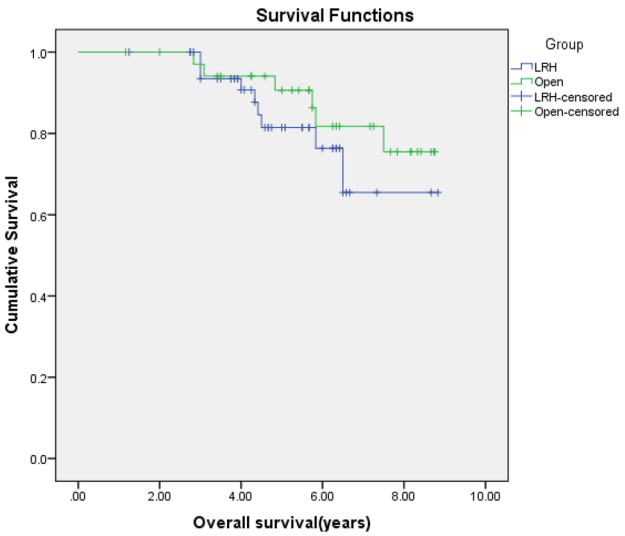

Fig. 1 Kaplan–Meier survival analysis curve for overall survival of LRH and open

Survival Outcomes

The median follow-up period was 65 months, 55.5 months for LRH and 69.5 months for ORH. There were 11 recurrences 6 in LRH arm and 5 in ORH arm and all were local recurrences. Survival analysis by Kaplan–Meier showed similar overall survival between the groups ($P=0.55$). The overall survival at the end of 3 and 5 years were 93.48% and 81.44% for laparoscopic group while that of open group

were 97.06% and 90.6%. (Fig. 1) When the subanalysis of the same for the tumors < 2 cm was done, the results were similar without statistically significant difference (OS at 3 and 5 years—100% and 83.08% for LRH, 95.25% and 85.15%, $P = 0.7$) (Fig. 2). The DFS at 2 and 5 years were found to be 96% and 85.6% for LRH group and 94.44% and 84.92% for ORH group ($P = 0.9$). (Fig. 3) Again, the subgroup analysis for tumors < 2 cm showed similar results (DFS at 2 and 5 years—100% and 90% in LRH, 95.45% and 80.01% in ORH). (Fig. 4) (Table 13, 14, 15, 16). The recurrence pattern in LRH and ORH arms were similar and has been depicted in Table 17.

Discussion

Since the time Hans Christian Jacobaeus first introduced a laparoscope into a human patient, the laparoscopy has taken over the open surgery in almost all organs except a few. Though field of surgical oncology was slow to accept MIS into its armamentarium, now it has become an integral part of management of cancer patients [12]. Cervix is one of the very few organs where laparoscopy is still struggling to find place. LRH was first reported by Nezhat et al. in 1992; since then, many centers have been performing LRH [13]. The rates steadily increased in last decade as many retrospective studies reported a similar or non-inferior oncological outcomes in terms of overall survival and recurrence rates in LRH when compared to ORH [4–9]. According to a meta-analysis conducted by Zhang et al. in 2016, LRH was associated with less blood loss, wound-related complications, shorter hospital stay and longer operative time when compared

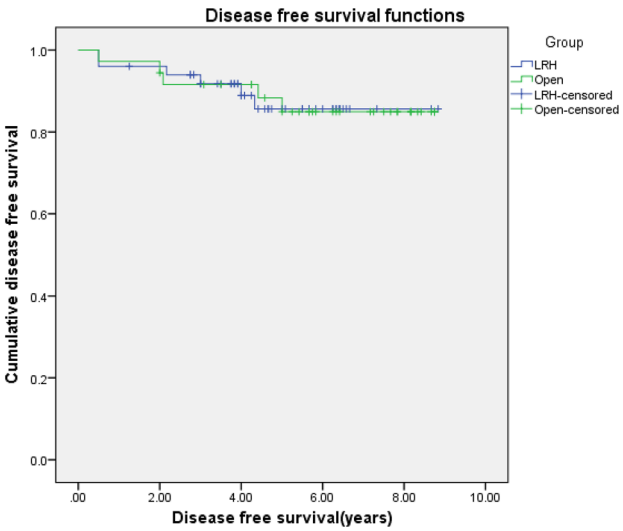

Fig. 3 Kaplan–Meier survival analysis curve for disease-free survival of LRH and open

to ARH. LRH was comparable with ARH in number of lymph nodes retrieved, urinary complications, rectal injuries, and lymphedema [14]. In our study, we found significantly less blood loss in laparoscopic group while there was not much of a difference in length of hospital stay or lymph node harvest in both the groups. Though an early discharge is expected in laparoscopic surgery, we could not appreciate the same in our study as many patients from rural areas were discharged after catheter removal on POD10 for logistical reasons. In our study, one patient had ureteric injury in LRH arm, while there were no instances of rectal or bladder injuries. We did

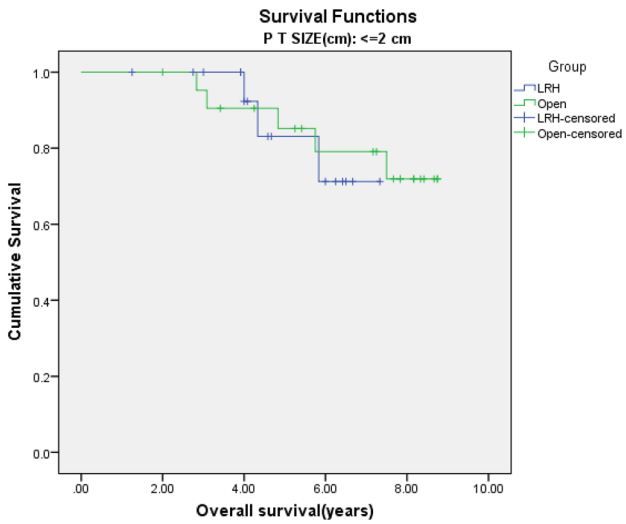

Fig. 2 Kaplan–Meier survival analysis curve for overall survival of LRH and open in tumor size ≤ 2 cm

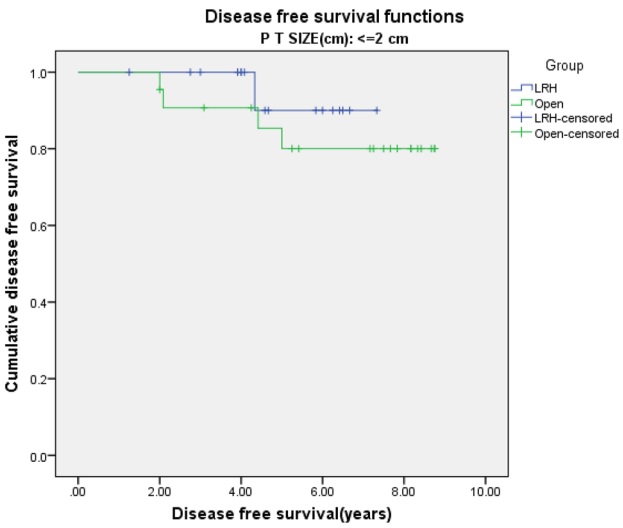

Fig. 4 Kaplan–Meier survival analysis curve for disease survival of LRH and open in tumor size ≤ 2 cm

Table 13 Kaplan–Meier survival analysis curve for overall survival of LRH and open

Group			LRH	Open
Total *N*			50	36
N of events			9	6
Censored		*N*	41	30
		Percent	82.00%	83.33%
OS at the end of 3 years			93.48%	97.06%
OS at the end of 5 years			81.44%	90.63%
OS at the end of 10 years			65.44%	75.48%
Mean	Estimate		7.50264	7.93218
	Standard error		0.39307	0.30806
	95% Confidence interval	Lower bound	6.73223	7.32838
		Upper bound	8.27306	8.53598
P value			0.329	

Log rank test

Table 14 Kaplan–Meier survival analysis curve for overall survival of LRH and open in tumor size ≤ 2 cm and > 2 cm

Group		≤ 2 cm		> 2 cm	
		LRH	Open	LRH	Open
Total *N*		18	22	19	9
N of events		3	5	4	1
Censored	*N*	15	17	15	8
	Percent	83.33%	77.27%	78.95%	88.89%
OS at the end of 3 years		100.00%	95.24%	94.12%	100.00%
OS at the end of 5 years		83.08%	85.15%	77.01%	100.00%
OS at the end of 10 years		71.21%	71.88%	0.00%	75.00%
P value		0.769		0.519	

Log rank test

not come across any case of permanent bladder dysfunction while there was no difference in temporary bladder dysfunction between the groups.

Results of LACC trial, a multi-center randomized controlled trial with 319 patients in MIS arm and 312 in ORH arm, came as a shock to field of MIS. Ramirez et al. reported a significantly less DFS at 4.5 years (86.0% vs. 96.5%) and overall survival at 3 years (3-year rate, 93.8% vs. 99.0%) in MIS arm in comparison to ORH arm [10]. This trial, though considered as a landmark trial in MIS in carcinoma cervix, is not without controversies. Only 14 out of 33 centers in the trial had reported recurrences and data from remaining 19 centers were not separately analyzed. This led to the question on proficiency of the surgeons in the trial centers [15]. This was supported by the fact that the minimal access arm recruited an average of only 2.1 cases per year per participating hospital which was very low for current standards [16, 17]. According to current data, morbidity after LRH steadily decreases and nodal accrual increases after 25–50 cases of LRH (learning curve) [18]. So, less than standard surgical proficiency and not MIS might have been the reason for increased parametrial positivity in LRH (7%) in comparison

Table 15 Kaplan–Meier survival analysis curve for disease-free survival of LRH and open

Group			LRH	Open
Total *N*			50	36
N of events			6	5
Censored		*N*	44	31
		Percent	88.00%	86.11%
DFS at the end of 2 years			96.00%	94.44%
DFS at the end of 5 years			85.61%	84.92%
DFS at the end of 10 years			85.61%	84.92%
Mean	Estimate		7.94958	7.87343
	Standard error		0.3388	0.37217
	95% Confidence interval	Lower bound	7.28554	7.14397
		Upper bound	8.61362	8.60288
P value			0.996	

Log rank test

Table 16 Kaplan–Meier survival analysis curve for disease survival of LRH and open in tumor size ≤ 2 cm and > 2 cm

Group			≤ 2 cm		> 2 cm	
			LRH	Open	LRH	Open
Total *N*			18	22	19	9
N of events			1	4	4	1
Censored		*N*	17	18	15	8
		Percent	94.44%	81.82%	78.95%	88.89%
DFS at the end of 2 years			100.00%	95.45%	89.47%	88.89%
DFS at the end of 5 years			90.00%	80.01%	75.79%	88.89%
DFS at the end of 10 years			90.00%	80.01%	75.79%	88.89%
Mean	Estimate		7.03333	7.69382	5.36667	5.75926
	Standard error		0.2846	0.48541	0.4752	0.61981
	95% Confidence interval	Lower bound	6.47551	6.74241	4.43527	4.54443
		Upper bound	7.59116	8.64523	6.29806	6.97409
P value			0.396		0.481	

Log rank test

Table 17 Recurrences

Recurrences	LAP	Open
Total	6	5
Vault	3	2
Pelvic	2	2
Para aortic	1	1

to ORH (4%) in LACC trial. Uterine manipulator was used in many centers in study. Inadequate data set is also one of the factors that is been quoted as reason for the unexpected and controversial results of LACC trail as only 39% of patients in the study had complete data. The open arm in the study performed unusually good with DFS of 96.5% and recurrence of 2.2%, while the contemporary studies outside the study show a DFS for 5 yrs ranging from 75 to 90%, OS 75–95%, recurrence 2–25% [15]. However, this is the only randomized trial available to compare the efficacy of these two approaches.

The results of LACC trial were supported by a retrospective analysis by Melamed et al. including 2461 patients, at a median follow-up of 45 months; the 4-year mortality was 9.1% in MIS cohort and 5.3% in open surgery (HR, 1.65; 95% CI, 1.22 to 2.22; $P=0.002$) [11]. In our study, we could not appreciate any statistically significant difference in overall survival at 3 and 5 years between the arms and the same was true for 2- and 5-year DFS. This could be due to the fact that tumor size was less than or equal to 2 cm in nearly 50% of our study population, a subgroup of LACC trial upon which latter was not powered to comment.

Cervical cancer with tumor size ≤ 2 cm is considered a low-risk type. Many studies have reported significantly better 5-year overall survival for tumors less than 2 cm ranging from 95.2 to 97% which has led to changes in 2018 update of FIGO surgical staging [19]. However, the controversy is still ongoing over the best treatment option for patients with tumor size less than 2 cm and whether laparoscopy is safe in this specific subset. Few studies have reported similar OS and DFS compared to that of open surgery (Kim et al., Pedone et al.) while few others (Odetto et al., Paik et al., Uppal et al.) have reported worse oncological outcomes with laparoscopic surgery and hence the question remains unanswered [20–23]. In our study, the subset analysis of 3-year overall survival for tumors less than 2 cm did not show any statistically significant difference between the two groups (100.00% and 95.24% for LRH and ORH, $P=0.7$) and the same was true for tumors more than 2 cm (94.12% and 100.00% for LRH and ORH, $P=0.5$).

Upon the release of LACC results, the researchers turned their attention toward the factors that could have contributed to poor oncological outcomes in laparoscopic radical hysterectomies. The higher incidence of local recurrence in LRH has been attributed to tumor dissemination due to CO_2 pneumoperitoneum, steep Trendelenburg position during LRH and the use of uterine manipulator [24]. We have never used uterine manipulator in our institute for laparoscopic or open radical hysterectomies. Kong et al. reported a recurrence rate of 16.3% in LRH with intracorporeal colpotomy compared to 5.1% ($P=0.06$) in vaginal colpotomy group (5.1%, $P=0.06$) and the rate of a positive surgical margin was higher in the intracorporeal colpotomy group. Meanwhile, the 2-year DFS was 93.7% in the vaginal colpotomy group in comparison to 80.8% in the intracorporeal colpotomy group [24]. These results stress upon the importance of minimal tumor handling and avoidance of tumor spillage in minimally invasive surgeries.

Many surgeons modified their techniques during the coming years and reported encouraging results. Kanao et al.

implemented 'no-look no-touch technique' in LRH and reported similar overall survival, DFS, and loco-regional recurrence rate in this modified laparoscopic group compared that of open surgery group [25]. SUCCOR trial, an international observational study on 1272 patients, concluded that similar oncological outcomes in terms of overall and DFS can be obtained if we form a vaginal protective cuff around the tumor and refrain from using uterine manipulator [26].

In our institute, we have never used uterine manipulator. Vaginal cuffing was not practiced in the institute and all the patients underwent intracorporeal colpotomy and hence we could not analyze effects of vaginal cuff or difference between two types of colpotomies.

Limitations of the Study

The observations of our study come with the set of limitations, the very first being the retrospective nature of the study with its inherent biases. Though the groups were matched with respect to basic parameters, the sample size was very small. Since the laparoscopy was introduced later in the study, the median follow-up period for LRH arm is less than that of ORH arm.

Conclusion

Oncological outcomes of LRH were comparable to that of open radical hysterectomy in early-stage carcinoma cervix. Prospective randomized controlled trials addressed to overcome the shortcomings of LACC trial are required for further evaluation in this context.

Acknowledgement The study was conducted according to the standards of institutional ethical committee, and the patient consents were waived due to retrospective nature of the study.

Declarations

Conflict of interest The authors declare no conflict of interest.

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