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Prospective Study on the Use of Endo-Stapler for Enclosed Colpotomy to Prevent Tumor Spillage in Gynecologic Oncology Minimally Invasive Surgeries

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ABSTRACT

Background and Objectives: This is a prospective trial of the endo-stapler application for vaginal closure before colpotomy in cases of carcinoma endometrium and carcinoma cervix, managed by minimally invasive surgery with due consideration of its surgical technique and short-term oncologic follow-up outcomes.

Methods: This was a prospective, single center study completed between March 1, 2020 and December 31, 2022. A total of 62 patients (43 cases of carcinoma endometrium and 19 cases of carcinoma cervix) were recruited for the study. Oncologic survival outcomes at the end of 1 and 2 years were documented.

Results: There were no major intraoperative bowel, urinary, or vascular injuries. None of the cases required conversion to laparotomy peroperatively. Our study had 8 patients with carcinoma endometrium (8/43) and 7 patients of carcinoma cervix (7/19) who have completed 24 months of follow-up without any recurrence to date.

Conclusion: Endo-stapler application for enclosed colpotomy to prevent tumor spillage is a futuristic step in gynecologic oncology cases managed by laparoscopy.

Key Words: Carcinoma cervix, Carcinoma endometrium, Endo-stapler, Minimally invasive surgery, Prospective study.

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INTRODUCTION

Minimally invasive surgery (MIS) in the management of carcinoma cervix was introduced by Nezhat et al., in 1992.[1] Since then it has been routinely implemented as a favorable approach to treatment in gynecologic oncology surgeries and its result have been comparable to open laparotomy surgeries, according to some published studies.[2] But, the milieu changed considerably after the outcomes proposed by the prospective Laparoscopic Approach to Cervical Cancer (LACC) trial in 2018.[3] This study showed significant inferiority of the MIS approach in terms of overall survival (OS) and disease-free survival (DFS) compared to open radical hysterectomy (ORH). Subsequently, many flaws have been elucidated in the LACC trial which might have affected the concluding outcomes of the MIS in study, and among these, the major step responsible could be an intracorporeal colpotomy where there is a risk of tumor spillage and spread due to inherent pneumoperitoneum during the procedure. Since then, the prevention of tumor spillage in MIS for gynecologic oncology, as in cases of carcinoma endometrium and carcinoma cervix, has been a topic of debate. Many preventive maneuvers have been proposed to prevent tumor spillage in gynecologic oncology cases performed with MIS, with various supporting evidence from the literature.[4,5] A recent article was published on the application of an endo-stapler for vaginal closure before colpotomy in cases of gynecological malignancies managed by MIS.[6] Endo-stapler application techniques for enclosed colpotomy in cases of carcinoma endometrium and carcinoma cervix are different. There are a few steps of divergence in both of these scenarios regarding the endo-stapler application. Cases of carcinoma endometrium require endo-stapler application for vaginal closure after the completion of a simple extra fascial hysterectomy or Type A hysterectomy (Querleu-Morrow classification)[7] without the need for ureteric tunnel dissection. Whereas the cases of carcinoma cervix have endo-stapler application for vaginal closure after the completion of surgical steps for radical hysterectomy or Type C hysterectomy (Querleu-Morrow classification), and to ensure the completeness of the specimen. In cases of carcinoma cervix, the entirety of the specimen (parametrium and vaginal margin) is very

crucial as it may affect OS and DFS, in terms of recurrence. During endo-stapler application wholeness of the specimen along with the prevention of damage to surrounding structures such as the ureter, and pelvic autonomic nerves is to be maintained. Damage to these pelvic autonomic nerves can lead to bladder and bowel dysfunction. A detailed anatomical understanding of the parametrium, paracolpium, pelvic autonomic nerves, and their plexus awareness along with proficient surgical expertise is required to achieve the same.

There are no prospective trials to date on the application of endo-stapler for vaginal closure before colpotomy in gynecologic malignancy cases managed by MIS with consideration of surgical and oncologic follow-up outcomes. Through this study, we aimed to explore short-term oncology outcomes, surgical and functional outcomes, and the efficacy of endo-stapler application in gynecologic malignancy cases managed by MIS.

MATERIAL AND STUDY DESIGN

This was a prospective, single center study without a control arm, and data collection occurred between March 1, 2020 and December 31, 2022 (34 months). A total of 62 patients during the mentioned duration (N = 62) were recruited in the study. Ethical approval was obtained per Declaration of Helsinki norms. Informed written consent was taken after explaining the detailed surgical procedure, and mode of treatment (MIS) versus other modes of surgical approach available (ORH).

Inclusion Criteria

1. Histopathologically confirmed cases of carcinoma endometrium with pre-operative imaging and intraoperative findings of disease not infiltrating to surrounding structures with probability of FIGO Stage I-III (FIGO staging 2009) (N=43).
2. Early-stage cervical cancer of (FIGO Stage IA2, IB1, IB2,IB3, and IIA) (Revised FIGO staging 2018) (N=19) by clinical and radiological staging.[8]

Exclusion Criteria

1. Histopathologically confirmed cases of carcinoma endometrium with pre-operative imaging and intraoperative findings of disease infiltrating to surrounding structures.
2. Patients with cervical carcinoma (stage IB3) who opted for primary chemoradiation.
3. Patients with carcinoma endometrium and carcinoma cervix who opted for open laparotomy.
4. Medically unfit for the surgery or not willing to be included into the trial.

The details relevant to the study were accessed from patients' medical records, surgical video recordings operative notes, and their follow-up documentation. The patients' demographic and epidemiological profiles, clinicopathological descriptions, and peroperative surgical specifications were recorded. All surgical (intra- and postoperative complications), if any, were noted. Oncological outcomes in terms of DFS and OS at the end of 1 and 2 years of study were documented. The primary outcomes in terms of oncological outcomes as the efficacy of vaginal endo-stapler application, DFS, and OS at the end of 1 year and 2 years of study were documented. The secondary outcomes as lymphedema, and bladder and bowel functionality were also assessed.

Pre-operative Preparation

Pre-operative imaging (magnetic resonance imaging (MRI) of abdomen-pelvis) was performed in all cases of carcinoma endometrium. MRI abdomen-pelvis or positron emission tomography– computed tomography (PET-CT) whole body was executed as pre-operative imaging in cases of carcinoma cervix, for pre-operative radiological staging. Bowel preparation was done in all cases with three tablets of bisacodyl per oral, the night before surgery.

Surgical Technique

All patients under general anaesthesia were given a modified Lloyd Davis position with 30° tilt toward the operating surgeon, standing on the left side of the patient. The pneumatic compression devices were used for all the patients during the whole surgery to avoid the risk of deep vein thrombosis. The bladder catheterization was done in all cases. The primary trocar (10 mm) was entered 2 cm above the umbilicus after Verres needle CO_2 insufflation. The head's low position was given after the primary trocar entry to keep the bowel away from the pelvic cavity. The ancillary trocars (5 mm), two on each side were inserted under vision, in a straight line from the primary trocar to the tip of the iliac crest and at equidistant from each other as shown in **Figure 1**. The para-aortic lymphadenectomy from level III to level IV[9] in cases of carcinoma endometrium required a sixth trocar (10 mm) at the supra-pubic location (2 cm cranial from pubic symphysis),

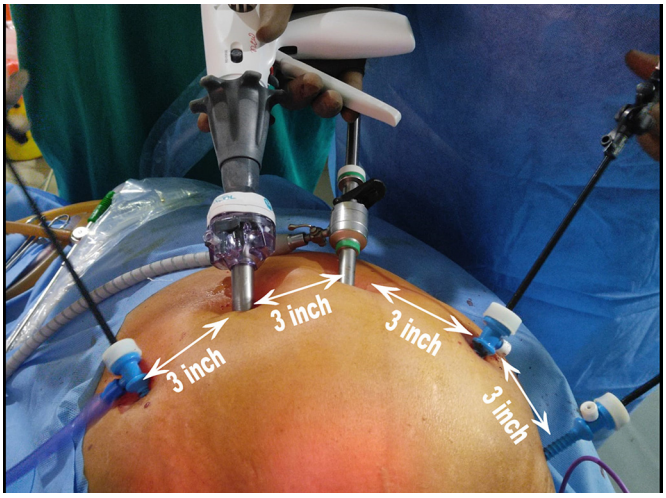

Figure 1. Image showing port position for endo-stapler application.

to be used as a primary trocar for the camera port. All the cases were operated on by a single surgeon under a three-dimensional laparoscopy system.

The various maneuvers used during surgery to prevent tumor spillage were:[6]

- The uterus was not manipulated vaginally and the vaginal end was packed with a mop soaked in povidone-iodine solution to prevent tumor spillage in the vagina. The uterine manipulation was done intraperitoneally by the use of a laparoscopic grasper by the assistant.
- At the beginning of surgery, the bilateral fallopian tubes were blocked at the corneal end to prevent retrograde spillage.
- Before concluding the surgery with an intracorporeal colpotomy, an endo-stapler was applied at the vaginal end to prevent the tumor spillage in the pelvic cavity and vagina.

Surgical Steps

As mentioned earlier, there are several dissimilar steps regarding the endo-stapler application technique for the vaginal closure before colpotomy in both the case scenario of carcinoma endometrium and carcinoma cervix, which are explained below.

Carcinoma Endometrium Case. Total laparoscopic hysterectomy (Type A, [Querleu-Morrow classification]) was performed as routine. Except that the bladder separation was associated with proper dissection of the vesicouterine ligament anteriorly on both sides, below the cervix for a vaginal length of approximately 2 cm. The aforementioned step along with posterior peritoneum and bilateral uterosacral ligament dissection will help to further lateralize bilateral ureters without the need for ureteric tunnel dissection for a safe endo-stapler application in cases of carcinoma endometrium. Posteriorly recto-vaginal space dissection was done to apply endo-stapler below the cervix and to keep the rectum away.

Bilateral pelvic lymph node dissection was completed till inferior mesenteric artery (IMA) (Level I-III)[9] through the same port position.

Before proceeding with colpotomy, vaginal closure is done with endo-staplers to prevent tumor spillage. The endo-stapler is introduced through the right upper port (as modified from our previous technique of endo-stapler introduction through the lower port[6]) by increasing the diameter from 5 mm port to 12 mm (**Figure 1**). This port position is ergonomically more favorable. Endo-stapler application from the right upper port is more convenient to get proper angulation without exercising undue pressure over pelvic major vessels (**Figure 2**), which was a major predicament while applying an endo-stapler from the right lower port (**Figure 3**).

The endo-stapler is applied below the cervical bulge. The safety of surrounding vital structures such as bilateral ureters, posteriorly rectum, and anteriorly bladder are ensured before applying the stapler (**Figure 4**). The surgical endo-stapler is fired one time to close the vagina. The stapler places three triple-staggered rows of titanium alloy staples on either side of the cut line and in built knife blade in endo-stapler cuts simultaneously between them. Once the vagina was divided, the stapler is released and withdrawn. The upper part of the vaginal cuff that is

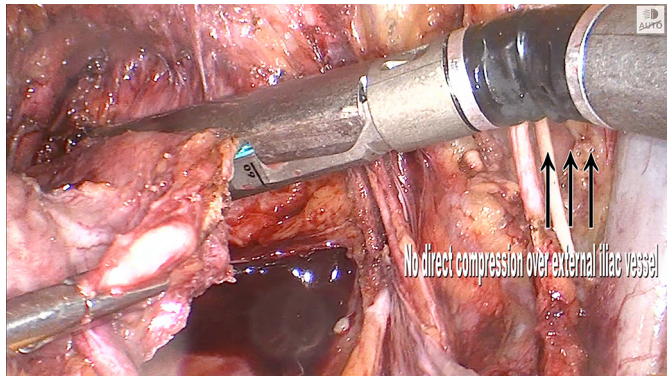

Figure 2. Intraoperative image with arrows indicating no compression over external iliac vessels during right upper port endo-stapler application.

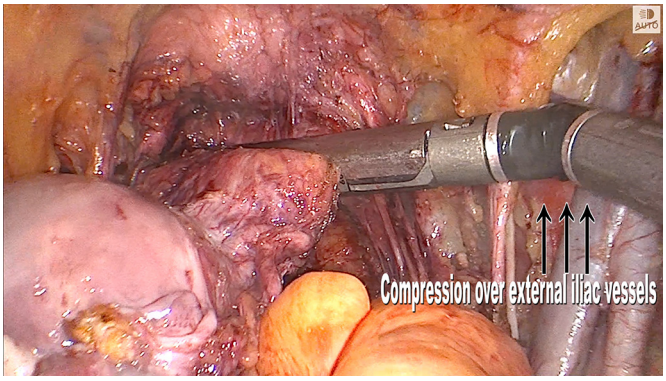

Figure 3. Intraoperative image with arrows indicating compression over external iliac vessels during right lower port endo-stapler application.

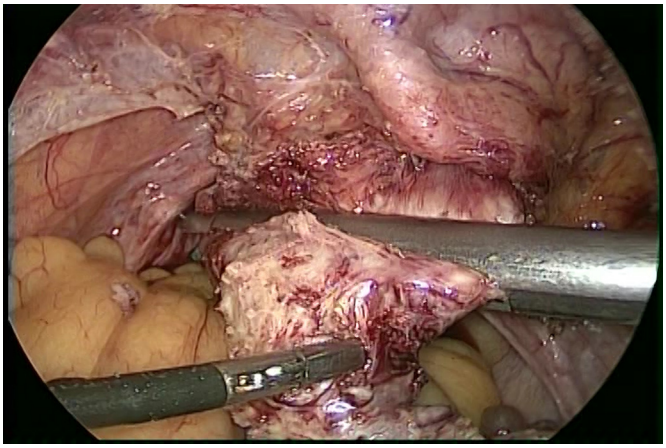

Figure 4. Intraoperative image showing endo-stapler application in a case of carcinoma endometrium after a simple extrafascial hysterectomy.

sealed with endo-stapler is excised with cold scissor and sent for pathological examination as an extra-surgical margin. The main specimen of uterus with cervix with its sealed vaginal end along with pelvic lymph nodes is removed through the freshly unsealed vagina in endobag (**Figure 5**). Finally, the opened end of vaginal cuff is closed with intracorporeal suturing.[6]

Para-aortic lymph node dissection is conducted till the left renal vein (Level IV). The central camera port is shifted at the supra-pubic location for this lymph node dissection. The operating surgeon stands on the right side of the patient. The specimen is removed through a 10 mm supra-umbilical port site in an endobag.

Carcinoma Cervix Case. Laparoscopic Type C1 [Querleu-Morrow classification]: Nerve-preserving Radical Hysterectomy (LRH) with systematic pelvic lymphadenectomy and para-aortic lymphadenectomy was performed in all clinical stages IB and onwards, as a part of surgical staging. The port position remained the same all through the complete surgery (**Figure 1**).

Figure 5. Image showing specimen in a case of carcinoma endometrium after a Type A hysterectomy.

Initially, all six avascular pelvic spaces (bilateral lateral pararectal, bilateral medial paravesical, vesicovaginal, and rectovaginal space) are dissected to assess the operability of the case as discussed in an article by Limbachiya et al. in 2018.[10]

Further, Okabayashi space, medial to the ureter is explored to expose the inferior hypogastric nerve. Ureteric tunnel dissection is executed with complete lateralization of the bilateral ureter till its entry into the bladder along with sparing of the inferior hypogastric nerve and its plexus and its associated branch to the bladder.[11] Laterally, commonly the nerve lies in lateral parametria and divides into two branches, one goes towards the uterus and the other follows along with the ureter culminating at its entry into the bladder in Yabuki space. Nerve

supply to the uterus is invariably sacrificed in all cases. Thus all cases in our study had bilateral bladder nerve sparing. Ventral parametria recognized and excised. The same surgical steps are replicated on the opposite side.

Bilateral pelvic lymph node dissection was performed till levels I, and II. The para-aortic lymph node was dissected till IMA (Level III) through the same port position and retrieved in the endobag.

Dorsal parametria and paracolpium at the rectum, lateral parametria, and paracolpium till internal iliac vessel, ventral paracolpium lying caudal, and lateral to ureter entry into bladder were transected. An adequate vaginal length, with approximately 2–3 cm clinically free margin, is achieved ensuring completeness of the specimen. Further endo-stapler is applied to acquire all the parameters as described above (**Figures 6–8**). The endo-stapler application leads to a complete and concrete sealing of the vaginal end which is usually not achievable through other proposed methods of vaginal closure, as elaborated in **Figure 7**.

Figure 6. Image showing specimen in a case of carcinoma cervix after a laparoscopic radical hysterectomy (Type C1).

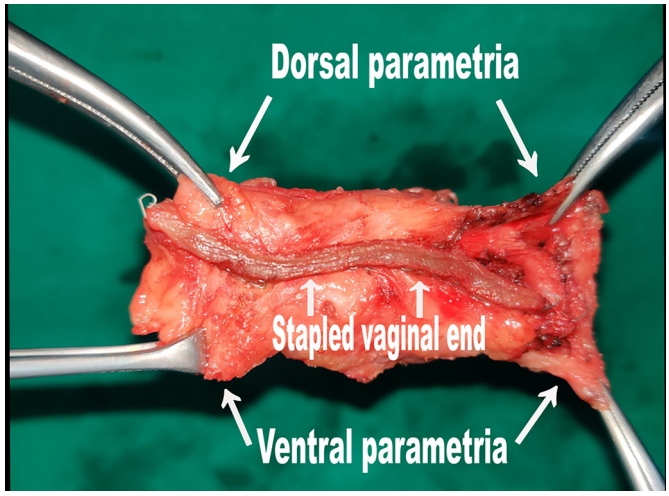

Figure 7. Image showing specimen in a case of carcinoma cervix with closed stapled vaginal end.

Postoperative Procedure

The postoperative intraperitoneal drain was not kept in any of the cases. All the patients were motivated for early mobilization and anticoagulant therapy was given postoperatively for 3 weeks in all cases. Prophylactic bilateral lower limbs stockings were advised in all cases. Patients were started orally on a liquid diet, 4 hours after the surgery. Most of the patients were discharged on postoperative day one of the surgery.

Oncologic Follow-up Protocol

All the patients were called for follow-up as per the standard oncologic protocol after completing the adjuvant therapy if required. The patients were followed up every 3 months, for the first 2 years and thereafter every 6 months for the next 3 years, through an outpatient visit. Further patients were asked to follow-up yearly. The follow-up visit had a relevant symptomatic questionnaire, physical examination including per-vaginal and per-rectal examination, vaginal vault cytology (annually), and imaging (CT scan abdomen-pelvis and thorax, or PET-CT scan whole body) when clinically indicated.

RESULTS

Carcinoma Endometrium Cases

A total of 43 cases (N = 43) of endometrial cancer (FIGO Stage I-III) (FIGO staging 2009) have been operated on during the study duration. Various other epidemiological

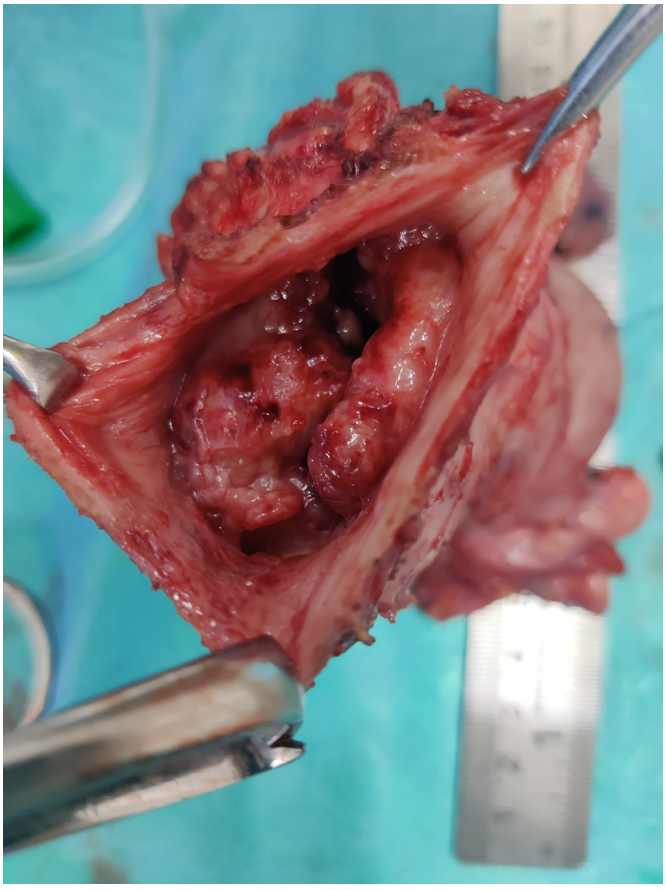

Figure 8. Image showing specimen in a case of carcinoma cervix with adequate vaginal margin.

parameters and statistics have already been enumerated explicitly in tabular form (**Table 1**). A few specific and pertinent points have been discussed here further.

Lymph-vascular space invasion (LVSI) was observed to be positive in a total of 10 cases (10/43, 23%), of which 7 cases (7/10, 70%) had high grades and poor histology. Eight cases with LVSI positivity (8/10, 80%) had lymphatic metastasis (LNM) on final histopathological examination (stage IIIc). Lymph node positive was found in one case with LVSI negative. Myometrial invasion greater than 50% was found in 13 cases of which 5 cases (5/13, 38%) were LVSI positive and also associated with LNM. Seven cases (7/43) had uterine papillary serous carcinoma, of which 3 cases (3/7) had cervical metastasis (diagnosed on pre-operative endocervical curettage), so LRH type C1 [Querleu-Morrow classification] was done.

Endometrial polyp as an associated pathology was noted in 8 cases (8/43, 19%). Of these, 5 cases (5/8, 63%) were detected to have high-grade pathology (3 cases of uterine papillary serous carcinoma, 1 had uterine carcinosarcoma, and 1 was to be a case of high-grade endometroid adenocarcinoma).

Benign gynecological pathologies (adenomyosis, fibroid) were observed to be accompanied in a total of 24 cases (24/43, 56%). Six cases had both associated pathologies (6/43, 14%). Associated benign gynecological pathologies cases were found to be more common with low-grade malignancy (grade 1, 14/24, 58%) and with less than 50% myometrial invasion (21/28,75%).

There were no major intraoperative bowel, urinary, or vascular injuries. None of the cases required conversion to laparotomy peroperatively. There were no significant complications noted related to the surgery per se, except postoperative lymphorrhoea. Lymphorrhoea cases were conservatively managed with prophylactic bilateral lower limbs stockings. This usually resolves within approximately a median of 28 days (range 25–45 days). Patients with body mass index (BMI) $> 35\,kg/m^2$ were generally observed to be associated with major complications such as lymphorrhoea (7/9, 77%), paralytic ileus.

We had 4 cases (**Table 1**) of stage IA grade 3 patients, of which 2 cases had been given adjuvant vaginal cuff radiation and 2 cases had adjuvant pelvic radiation in view of presence of high intermediate and high risk factors.[12,13] The patients with stage IB and stage II were given radiotherapy (external beam radiotherapy with vaginal boost) as an adjuvant treatment. The patients with stage III carcinoma were given adjuvant chemo-radiotherapy (carboplatin AUC5 with paclitaxel $175\,mg/m^2$ with external beam radiotherapy and vaginal boost).

Carcinoma Cervix Cases

A total of 19 cases (N = 19) of early-stage cervical cancer of (FIGO Stage IA2, IB1, IB2, IB3, and IIA) Revised FIGO staging 2018 has been operated on during the study duration. Various other epidemiological parameters and vital statistics have already been enumerated in **Table 2**. A few specific and pertinent points have been discussed here further.

MRI (abdomen-pelvis) was performed in 11 cases (11/19) as an adjunct to pre-operative imaging and staging for local tumor extension and pelvic and para-aortic lymphadenopathy determination, while 8 cases had pre-operative PET-CT. Four cases had tumor extension to the upper vagina and parametria in MRI pelvis (4/11, 36%) but final histopathology was negative for the same. In contrast, 2 cases (2/11, 18%) that had normal imaging findings were noted to have a positive microscopic lesion in lateral parametria on final histopathology.

Table 1.
Demographic Characteristics, Symptomatology, and Clinicopathological Characteristics in Patients of Carcinoma Endometrium

Characteristic	Total Patients (N = 43)	Lymph-vascular Space Invasion (N = 10)	Lymph Node Metastasis (N = 9)	Adenomyosis (N = 17)	Fibroid (N = 13)
Age (years) Median (range)	62 (41 – 86)				
≤40	0				
>40–49	4				
≥50–59	15				
≥60–69	19				
≥70–79	2				
≥80–89	3				
Body Mass Index (kg/m^2)	29 (20–52)				
≤24.9	8				
≥25–29.9	15				
≥30–34.9	9				
≥35–39.9	5				
≥40	6				
Symptoms					
Postmenopausal bleeding	33				
White discharge	10				
Menorrhagia	4				
Comorbidities					
Diabetes mellitus	12				
Hypertension	14				
Histopathology					
Endometrioid adenocarcinoma	(N = 34)	(N = 10)		(N = 17)	(N = 13)
Grade 1	17	0		10	4
Grade 2	13	3		2	6
Grade 3	4	1		1	0
Serous cell carcinoma	7	5		3	2
Clear cell carcinoma	1	0		1	0
Carcinosarcoma	1	1		0	1
Myometrial invasion					
<50%	28	4		13	8
=50%	2	1		1	0
>50%	13	5		3	5
Pelvic lymph nodes (numbers)					
Median (range)					
Right	14 (12–20)				
Left	13 (13–21)				
Para-aortic lymph nodes (numbers)	12 (10–18)				
Median (range)					

Table 1. Continued

Characteristic	Total Patients (N = 43)	Lymph-vascular Space Invasion (N = 10)	Lymph Node Metastasis (N = 9)	Adenomyosis (N = 17)	Fibroid (N = 13)
FIGO stage					
IA	23	2			
IB	8	0			
II	2	0			
IIIA	1	0			
IIIB	0	0			
IIIC1	6	5	6		
IIIC2	3	3	3		
IV	0	0			
Operative time (minutes) Median (range)	180 (120–240)				
Blood loss (ml) Median (range)	80 (50–150)				
Hospital stay (days) Median (range)	1 (1–3)				
Adjuvant therapy					
Observation	19				
Radiotherapy (voxel-based, external beam radiation)	14				
Chemoradiotherapy	10				
Chemotherapy	0				

There were 7 cases of lymph node positivity in carcinoma cervix (**Table 2**). Out of theses 7 cases, 4 cases had pre-operative MRI as an imaging modality while 3 cases had pre-operative PET-CT. Lymph nodes with a size of more than 1 cm are typically noted in pre-operative imaging (MRI or PET-CT), but microscopic lesions of 3–4 mm may be missed. As observed in our study, 2/7 (28%) cases had pre-operative MRI and 3/7 (42%) cases had pre-operative PET-CT, in which the lymphnode disease were missed on pre-operative imaging (**Table 3**).

Tumor size greater than 4 cm was observed in 10 cases (10/19), of which 8 cases (8/10, 80%) were LVSI positive and 7 cases (7/10, 70%) had positive lymph nodes on final histopathology. The rest of the 9 cases (9/19) had tumor sizes less than 4 cm, of which only one case (1/9, 11%) was LVSI positive with negative lymph nodes. None of the case had lymph node positivity without LVSI. Cervical stromal invasion greater than 50% was observed in 13 cases, of which 9 cases (9/13, 69%) were LVSI positive and 6 cases (6/13, 46%)had positive lymph nodes. Para-aortic lymph node dissection (cranially up to the origin of IMA) was performed in all cases with clinical stage IB and onwards, as a part of surgical staging.

Only 3 cases (3/19) required prolonged bladder catheterization for 14 days postoperatively due to retention of urine. Ureteral stenting was not needed in any case. Lymphorrhoea was the most common complication observed in our study. None of the cases required conversion to laparotomy per-operatively (**Table 4**).

The patients with carcinoma stage IB 3 (3/19) and stage III C (7/19) were given concurrent chemo-radiotherapy (external beam radiotherapy, 45–50 Gy with vaginal boost) with the once-weekly infusion of cisplatin (40 mg/m^2) regime.

Oncologic Follow-up Outcome (Table 5)

Carcinoma Endometrium

Our study had 8 patients of carcinoma endometrium (8/43) who have completed 24 months of follow-up without

Table 2.
Demographic Characteristics, Symptomatology, and Clinicopathological Characteristics in Patients of Carcinoma Cervix

Characteristics	Total Number (N = 19)	Lymph-vascular Space Invasion (N = 9)	Lymph Node Metastasis (N = 7)	Parametrium Metastasis (N = 2)
Age (years)	43 (38–69)			
Median (range)				
Body Mass Index (kg/m^2)	23.2 (20.8–33.6)			
Median (range)				
Symptoms				
Leucorrhoea	8			
Menorrhagia	6			
Postmenopausal bleeding	6			
Post coital bleeding	3			
Histology				
Squamous cell carcinoma	16			
Keratinizing	13			
Nonkeratinizing	3			
Adeno-squamous	1			
Adenocarcinoma	2			
Tumor size (cm)				
<2	1			
≥2–< 4	8	1		
≥4	10	8	7	2 (microscopic foci)
Depth of cervical stromal invasion				
<half	3			
=	3			
>half	13	9		
Pelvic lymph-nodes				
Median (range)				
Right	14 (9–18)			
Left	16 (10–17)			
Presacral lymph-nodes	5 (5–8)			
Para-aortic lymph nodes till inferior mesenteric artery	8 (6–10)			
FIGO stage (2018)				
IA	0			
IB	(N = 12)			
IB1	2			
IB2	7			
IB3	3			
IIA, IIB	0			
IIIA, IIIB	0			
IIIC	(N = 7)			

Table 2. Continued

Characteristics	Total Number (N = 19)	Lymph-vascular Space Invasion (N = 9)	Lymph Node Metastasis (N = 7)	Parametrium Metastasis (N = 2)
IIIC1	7			
IIIC2	0			
IV	0			
Operative time (minutes)	120 (65–150)			
Median (range)				
Blood loss (ml)	60 (50–100)			
Median (range)				
Hospital stay (days)	1 (1–3)			
Median (range)				
Adjuvant therapy				
Observation	9			
Radiotherapy	0			
Concurrent chemoradiotherapy	10			
Chemotherapy	0			

any recurrence to date and among these, 4/8 cases have completed 28–30 months of follow-up, and 1 case had a maximum follow-up of 34 months. There was only one mortality in the carcinoma endometrium group at 18 months of follow-up due to a nononcology-related cause.

Carcinoma Cervix

Seven patients of carcinoma cervix (7/19) have completed 24 months of follow-up without any recurrence to date, among these, 3 cases have completed 28–30 months, and 1 case had a maximum follow-up of 33 months. One case in the carcinoma cervix group (1/19) had bilateral lower limbs lymphedema at the end of 12 months of follow-up.

Table 3.
Diagnostic Efficacy of Pre-Operative Imaging and Lymph Node Status in Carcinoma Cervix

Lymph Node Metastasis (N = 7)	Magnetic Resonance Imaging (N = 4)	Positron Emission Tomography–Computed Tomography (N = 3)	Total
Lymph node positive (>1 cm)	2	—	2
Lymph node negative (<1 cm)	2	3	5

DISCUSSION

Obese women with (BMI ≥ 30 kg/m^2) have a significantly increased risk of perioperative complications mainly

Table 4.
Postoperative Complications

Total Cases (N = 62)	Carcinoma Endometrium (N = 43)	Carcinoma Cervix (N = 19)
Lymphorrhea	9	4
Urinary dysfunction incontinence, retention	0	3
Uretero-vaginal fistula, vesico-vaginal fistula	0	0
Secondary hemorrhage	0	0
Infection	0	0
Paralytic ileus	2	0
Pulmonary embolism/Deep vein thrombosis	0	0
Vaginal vault bowel evisceration	1	0
Lymphodema	0	1

Table 5.
Oncologic Follow-up

Duration (in months)	Carcinoma Endometrium (N = 43)	Carcinoma Cervix (N = 19)	Recurrence Rate
12 months	19	5	0
24 months	8	7	0

during open surgery and morbidly obese patients are at the highest risk. Our study had 20 patients with BMI ≥ 30 kg/m^2, among these 6 patients (6/20) had BMI ≥ 40 kg/m^2. All these patients had successful completion of surgery through laparoscopy, vanquishing all the probable complications of laparotomy, such as wound infection, future risk of hernia, prolonged immobilization, and thus increased risk of deep vein thrombosis. This further increases the hospital stay, cost factor, and then results in the delay of adjuvant therapy (if required) and consequently affecting the prolonged oncological outcome. None of the cases in our study required conversion from laparoscopy to laparotomy. Similar findings were supported by a few other studies in the literature.[14] Laparoscopic surgery may be advantageous in preventing a majority of these peri-operative complications, specifically in this group of patients, and should therefore be the favored approach.

According to NCCN guidelines and revised FIGO staging 2018,[15] concurrent chemoradiotherapy is recommended as a primary treatment for stage IB3 carcinoma cervix cases and onwards. But in our study, 10 cases (10/19) of stage IB3 were treated with primary staging surgery. Since, even if pre-operative imaging was negative for lymph node involvement, the microscopic disease may still be found in the histological examination which influences the proper staging and thus further extent of adjuvant therapy.

An increase in tumor size in carcinoma cervix cases leads to the advancement of the carcinoma stage. This may extend the surgical dissection to get an adequate vaginal length, where there might be a possibility of greater spillage owing to tumor size. The same concern was also elucidated in a study by Muallem et al.[16] This can be conspicuously overcome by a single endo-stapler application, as even in ORH, applying a bilateral clamp or a suture below the tumor is not easy, and still, there are chances of tumor spillage. Endo-stapler application, in carcinoma cervix cases, helps in the retrieval of a thorough specimen which includes dorsal, lateral, ventral parametria, and associated paracolpium as well, along with an adequate vaginal length without compromising pelvic autonomic nerve function. Application of endo-stapler in carcinoma endometrium, without ureteric tunnel dissection, is challenging. This requires great laparoscopic surgical expertise, skill, and experience. Rather than alteration of the mode of approach (ORH vs MIS) for the therapy of gynecologic oncology cases, it is the proper execution of oncologic principles along with the experience and surgical expertise of the operating surgeon that is most crucial for the result of any surgery. The same point of view was opined by Nezhat et al., in a study in 2019.[17] The operating surgeon in our study had considerable experience with the laparoscopic surgical management of cases of carcinoma cervix and carcinoma endometrium. A recent study in by Saini et al., in 2023, highlights the association of intra-operative tumor spillage and cancer recurrence with further suggestions that the need for alternative surgical technique could lead to preferable surgical oncologic outcomes.[18]

We would like to just enumerate the fact that LVSI was found to be associated with LNM in our study, which correlates with other studies in literature.[19–21] Also, surgical staging was observed to be more affirmative as compared to radiological staging in carcinoma cervix cases in our study, which is further supported by other studies.[22,23]

Many factors might contribute to the inferiority of MIS in comparison to ORH, as per the LACC trial. But one of the most important factors, open colpotomy with aerosolization of tissue, can be considerably overcome with our proposed technique of enclosed colpotomy with the use of an endo-stapler. Kampers et al., in 2021[24] advocated the same perspective that various other protective manoeuvres if used collectively (as mentioned earlier)in combination with enclosed vaginal colpotomy in the management of cases of carcinoma cervix by MIS may result in improved OS and DFS. Also, Greggiet et al.[25] and the systematic reviews by Zhao et al.[26] reported no significant difference in recurrence rates between cases managed by LRH and ORH. The most widely accepted explanation by Roseler et al. (2021) is that MIS approach surgery has a better lymphatic tissue clearance owing to a detailed anatomical exposure with proper delineation of surgical landmarks.[27]

The pros of our study are its detailed step-by-step description of the technique for endo-stapler application in cases of carcinoma endometrium and carcinoma cervix which is an easily replicable technique. All cases were performed by a single surgeon, so our technique is standardized. None of the cases required prolonged catheterization

(>14 days) for any urinary dysfunction, and no patients had any rectal dysfunction in the postoperative period. No other significant side effects related to surgery were observed in our study, except lymphorrhoea. There were no recurrences documented to date. The cons in our study could be a shorter follow-up of the patients, a small sample size, a single center, no control arm, and still, a complete 5-year follow-up would be desirable for an assessment of oncologic outcome.

CONCLUSION

The use of an endo-stapler for enclosed colpotomy to prevent tumor spillage is an excellent step forward to enhance the oncologic outcome in gynecologic oncology cases managed by MIS. Further prospective trials with a controlled arm are required to validate our hypothesis that the application of an endo-stapler decreases the risk of tumor spillage, and thus affects the future recurrence of the disease. Our study had a satisfactory follow-up of 2 years, but still, a further 5-year follow-up evaluation would be highly warranted.

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