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Evaluation of Laparoscopic Sphincter Saving Surgery in Management of Rectal Cancer

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ABSTRACT

Background: Sphincter-saving surgery for rectal carcinoma (RC) has been classically performed by open surgery. Laparoscopic restorative proctectomy (LRP) has been evolved for the same purpose, but its benefits are controversial representing an enigma in the choice of management of RC.

Objective: The aim of this study was to evaluate the feasibility, adequacy, safety, short- and long-term outcomes of LRP.

Patients and methods: This was a prospective observational study included 35 patients suffering from middle and distal third RC admitted electively to Sohag University Hospital and Colorectal Unit in Ain Shams University. Patients were evaluated and analysed regarding efficacy of LRP, length of stay and different risk factors for post-operative complications.

Results: Regarding operative outcomes the mean operative time was 189 minutes, and mean operative blood loss was 95.4 mL, while operative complications happened in 8.5%. Post-operatively, complications happened in 22.9%. The mean post-operative hospital stay was 4.2 ± 1.4 days. Higher American Society of Anesthesiologists (ASA) risk scoring and advanced pathological stage proved to be independent risk factors responsible for complications. During follow-up, local recurrence was evident in 5.7% and distant recurrence developed in further 5.7%. Disease-free survival rate was 80.02 %, and overall survival rate was 91.3% for stage II and 83.3% for stage III.

Conclusion: LRP can be done safely reflecting adequacy of the procedure with a comparable complication rate and long-term outcomes to conventional surgery, which makes it a good alternative to conventional technique.

Keywords: Rectal cancer, Laparoscopic surgery, Total mesorectal excision.

INTRODUCTION

RC constitutes more than one third of colorectal cancers and 6% of all body cancers [(1)]. It represents a challenge due to its unique anatomy viz; difficult exposure in a narrow pelvis, low intestinal transection, total mesorectal excision (TME), and challenging nerve-sparing maneuvers [(2)].

TME in RC resection provides reduction in local recurrence rate from 25% to 10%, and when combined with neoadjuvant radiation therapy, an additional 50% reduction in local recurrence is achieved [(3)]. TME with its hallmarks of less blood loss and saving of autonomic nerves has encouraged many surgeons for its standardization in radical rectal cancer resection. In the same time the introduction of staplers made very low anastomosis in the distal rectum a possible issue increasing the scope of sphincter saving surgery in RC [(4)].

Jacobs *et al.* [(5)] reported their first laparoscopic colorectal resection in 1991. Since then laparoscopic colectomy for colon cancer has become the standard worldwide, in 2004, the first laparoscopic TME for rectal cancer was done and becomes widely adopted [(6)] proved to be safe and effective with oncological outcomes comparable to conventional surgery [(7)], but laparoscopic proctectomy in treatment of RC is still controversial.

Laparoscopy has changed lower rectal surgery from being in a hidden area to be a visible one providing a magnified view of the pelvis with better visualization than conventional surgery which makes preservation of autonomic nerves easier with better preservation of the urinary and sexual functions [(8)]. Not only it has a similar efficacy compared to conventional surgery in mid and distal RC, but also achieved better short-term outcomes [(9)] including less tissue trauma, better cosmesis, less analgesics, less intra-operative blood loss, less wound complications, less post-operative pain, earlier recovery of bowel movement and return to normal activities, faster return to work and shorter hospital stay.

LRP has its own limitations and is technically difficult, with a long learning curve, particularly due to the narrow and deep pelvic cavity and anatomical complexity especially in lower RC, which is associated with more comorbidity [(6, 10)]. Another challenge for laparoscopic instruments is that they are straight and may have difficulty at the pelvic inlet to navigate around the sacral promontory and reach

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the pelvic floor, particularly in a narrow and obese pelvis [11].

The purpose of this study was to evaluate the efficacy of LRP in treatment of low and mid RC.

PATIENTS AND METHODS

This was a prospective single arm observational study conducted from January 2017 till December 2019 with follow-up till December 2020 on patients presented electively with a diagnosis of rectal adenocarcinoma. The study was conducted at General Surgery Department, Sohag University Hospital and Colorectal Unit in Ain Shams University.

Inclusion criteria: Patients presented with a histological proof; stage II or III, located in the distal or middle third and with a functioning, disease-free sphincter mechanism.

Exclusion criteria: Patients whose tumors were locally advanced (not responding to neo-adjuvant therapy), acute bowel obstruction or perforation from cancer, infiltrating the anal sphincter, resection for recurrent disease, those who received adjuvant therapy for a previous pelvic cancer, past history of complicated laparotomy, general contraindications to laparoscopy and severe medical illness (ASA > 2).

Diagnosis was based on clinical examination including digital examination and confirmed by endorectal ultrasonography, abdominal CT scan, abdominal ultrasound, colonoscopy to exclude synchronous tumors and to take biopsies for pathology. Pelvic MRI was performed to exclude tumor invasion. Laboratory investigations included serum carcinoembryonic antigen (CEA) and tests for physical fitness.

A clinical audit was held in a multidisciplinary approach including colorectal surgeon, hepatobiliary surgeon, medical oncologist, gastroenterologist, radiation oncologists and pathologist to choose the proper management plan.

Neoadjuvant chemoradiotherapy was given to patients with locally advanced disease (cT_{3-4} and/or cN_{1-2}) for down-staging with a reassessment CT at 4 weeks after completion of the course and operation was scheduled 6 weeks after.

Patients who fulfilled the inclusion criteria underwent LRP after pre-operative preparation in the form of mechanical bowel preparation and prophylactic antibiotics.

Surgical technique:

Patients were placed in a modified lithotomy position, with the legs positioned in a 20° to 25° abducted position. CO_2 pneumoperitoneum then achieved at 12 to 14 mmHg, followed by insertion of the standard five trocars and if an additional trocar is necessary, suprapubic one (5 mm) was added.

For dissection and mobilization of sigmoid colon and rectum the peritoneum was incised at the level of the sacral promontory using a medial to lateral approach preserving the left ureter and gonadal vessels (Fig. 1). The dissection was continued superiorly to the level of the root of the inferior mesenteric artery (IMA) and all tissue anterior to the IMA was completely removed followed by clipping of IMA and vein at their origin and division using scissors (Fig. 2). With identification and preservation of superior hypogastric plexus, supracolic splenic flexure mobilization and lateral release of the colon off the left paracolic gutter till complete mobilization of the splenic flexure and sigmoid colon was achieved.

TME was started with sharp dissection using scissors or monopolar hook preserving inferior hypogastric nerves (Figs. 3, 4 & 5) till the rectal hiatus was reached, then transection of rectum with at least 1cm safety margin distal to the tumor using articulated endo-GIA™ (Fig. 6). Thus, the rectum enveloped within the fascia propria recti was completely mobilized.

The sigmoid and stapled proximal rectum was extracted via a wound protector through a small incision of 3 to 4 cm extended from the lower-right port (Fig.7), which was also used as the site of ileostomy in those with lower RC. A positive leakage test and incomplete donuts in those with comorbidities and elderly patients ≥ 50 years old.

Resection of the proximal colon was done (20 cm proximal to the lesion) and the wound protector was then twisted and clamped with a Kocher clamp. Pneumoperitoneum was regained and restoration of continuity of gut was accomplished under laparoscopic guidance by using EEA circular stapler and anastomosis was checked by air leak test (Figs. 8 & 9). The tissue donuts were carefully inspected for completeness and sent for routine pathologic evaluation (Fig.10). Eventually, incisions for trocars were closed and a pelvic drain was inserted from the left lower quadrant incision.

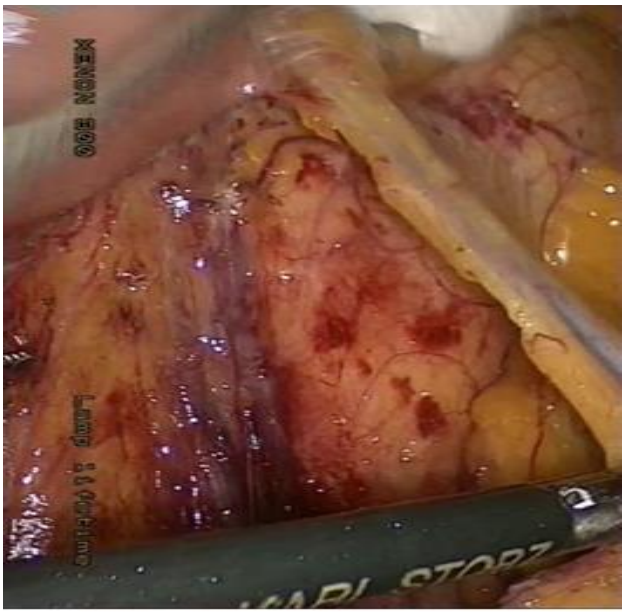

Figure (1): Medial to lateral dissection

Figure (2): Dissection and ligation of IMA

Figure (3): Preservation of superior hypogastric plexus

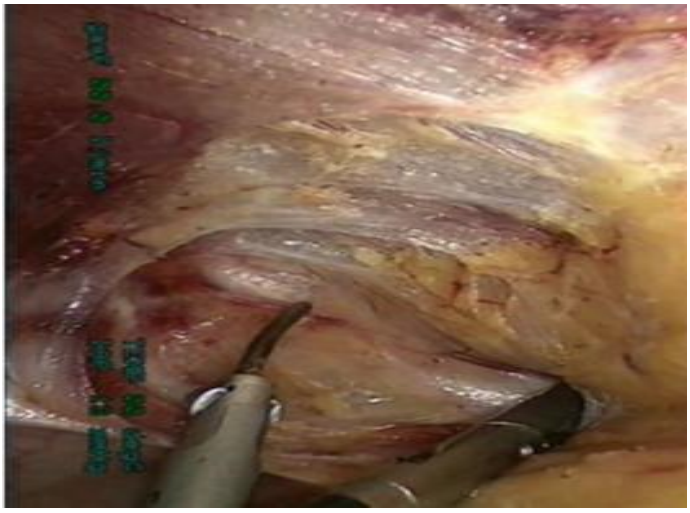

Figure (4): Posterior dissection of the rectum

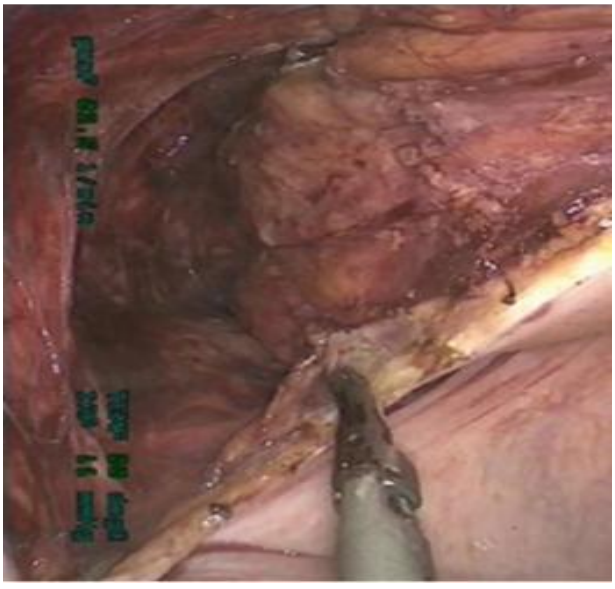

Figure (5): Lateral dissection of the rectum

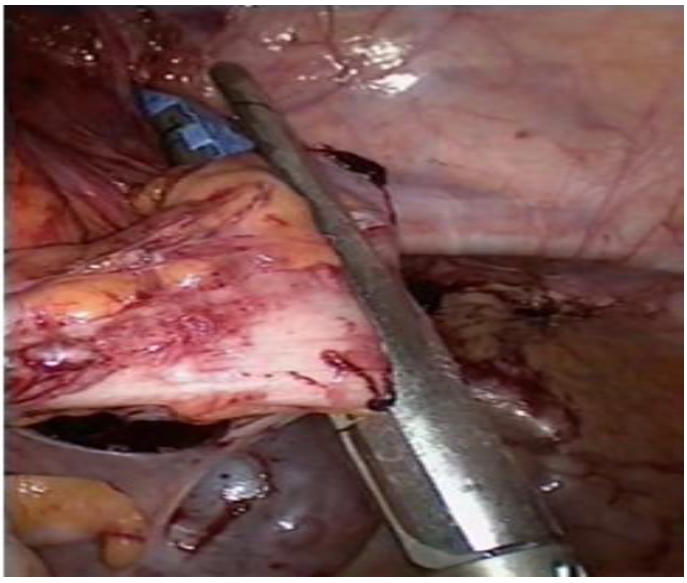

Figure (6): Proximal resection of the specimen with endo GIA

Figure (7): Extraction of the specimen through wound protector

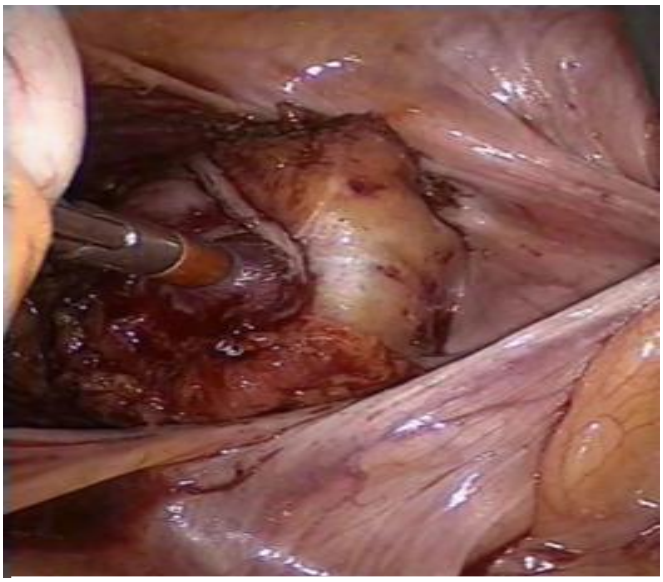

Figure (8): Double-stapled anastomosis using circular stapler

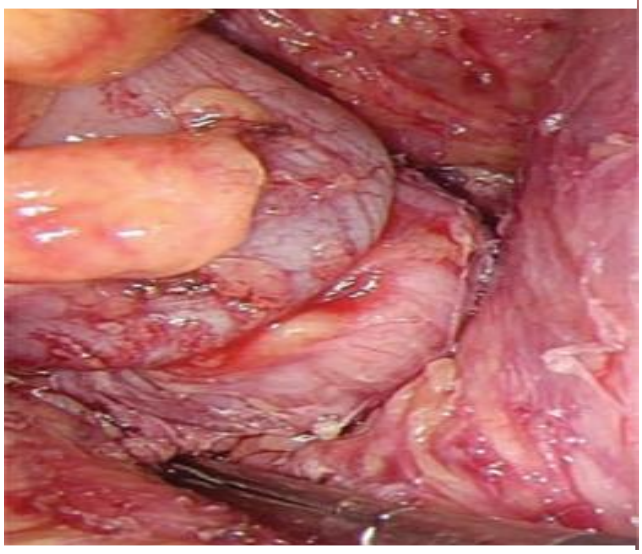

Figure (9): Colo-anal anastomosis after firing of the circular stapler

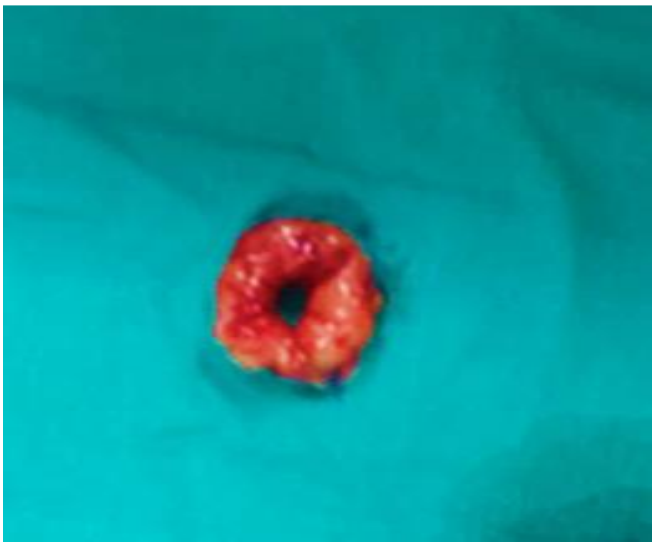

Figure (10): Showing complete donut after stapling

The resected tumors were examined for depth of invasion (T-stage) and distance from proximal and distal surgical resection margins. The perirectal lymph nodes (LN) deposits (N-stage) were carefully dissected, counted, and sampled for assessment of metastasis and pathologic staging. Circumferential resection margins (CRMs) (closest distance between the radial resection margin and the tumor tissue) were considered positive if malignant cells were found at microscopy at a distance of less than 1 mm between the outermost part of the tumor and the CRM or between LN bearing tumor cells and the CRM.

Post-operatively patients run through ERAS (Enhanced recovery after surgery) protocol and the drain was removed at the third post-operative day. All patients were discharged after removal of the drain. Routine Gastrografin® enema was performed before stoma closure, usually 8 weeks post-operative or after completion of adjuvant therapy if indicated.

Adjuvant chemotherapy based on 5-fluorouracil was used for all fit patients where is doubt of local clearance. Those who received preoperative chemoradiotherapy and radical surgery were exempted from this line, also unfit elderly. Patients were followed up monthly for 6 months then every six months for one year by history, physical examination, and serum CEA. Rectal electromyography in some selected patients. If recurrence was suspected, endoscopic examination and CT scan were performed, mean follow-up 20 months.

Data recorded were patients' demographics, co-morbidities, operative details including operative time, amount of intra-operative blood loss and operative complications. In addition,

histological results, days to pass flatus and first bowel movement, time to resume a liquid diet, complications, length of hospital stay, readmission and mortality and long-term outcomes, all were subjected to analysis.

Ethical consent:

An approval of the study was obtained from Sohag University and Ain Shams University Academic and Ethical Committee. Every patient signed an informed written consent for acceptance of the operation. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical analysis

The collected data were evaluated and analysed using the SPSS® software package (IBM-SPSS® 21, Chicago, IL, USA). Parametric variables were expressed as mean and standard deviation (SD), and nonparametric variables as median and interquartile range. Univariate and multivariate logistic regression analyses were done to determine factors affecting occurrence of complications, two-sided P-value < 0.05 with 95% confidence interval (CI) was considered as statistically significant. Kaplan-Meier survival analyses were made for overall and disease free survival. Log rank test was used to compare survival of different stages of the disease. The cut-off for significance of used statistical analyses was rated as $P < 0.05$.

RESULTS

Between January 2017 and December 2019, 35 consecutive patients fulfilled the inclusion criteria were included in the study. Patients' demographics are listed in Table (1) and clinical and tumor characteristics are listed in Table (2).

Table (1): Patients' demographics

Parameter	Number of patients	Percentage
Age (years)		
• 20-30	2	5.7%
• 30-40	4	11.4%
• 40-50	5	14.3%
• 50-60	11	31.4%
• 60-70	13	37.1%
Mean ± SD: Range	54.4 ± 20.3: (28-77)	
Gender		
• Male	22	63%
• Female	13	37%
Smoking		
• Smokers'	14	40 %
• Non-Smokers'	21	60 %
Pre-operative Co-morbidities		
• Cardiac	9	25.7%
• Diabetic	13	37.1%
• Hepatic	2	5.7%
• Renal	1	2.9%
Total number of patients had Co-morbidities	13 patients (37.1%)	
Body mass index (kg/m^2)		
• 18-25	19	54.3%
• 25-30	13	37.1%
• ≥30	3	8.6%
Mean ± SD	23.89 ± 5.4 (18-30 kg/m^2)	

Table (2): Demonstration of clinical and tumor characteristics

Parameter	Number of patients	Percentage
Clinical presentation		
• Bleeding per rectum	30	85.7%
• Change in bowel habits	21	60%
• Abdominal pain	9	25.7%
• Systemic symptoms (decreased appetite and weight loss)	5	14.2%
ASA classification		
• Class I	22	62.9%
• Class II	13	37.1%
Tumor location in rectum	15	42.9%
• Middle third	20	57.1%
• Lower third		
UICC stage		
• Stage II (T_3-T_4,N_0)	22	62.9%
• Stage III(T_2-T_4,N_1)	13	37.1%
Neoadjuvant therapy	12	34.3 %

Regarding the operative outcomes; the mean operative time was 189 minutes (range140–280 minutes). In first five patients ranged from 200 to 280 minutes then decreased at the end of study to 140 minutes. While the mean operative blood loss was 95.4 mL (range 75-120 mL). Diverting ileostomy was constructed in 25 patients (71.4%). Intra-operative complications were encountered in three patients (8.5%). Bleeding happened in one patient (2.9%) and was controlled by clips, bladder perforation occurred in the second patient (2.9%) with successful laparoscopic repair, while ureteric injury occurred in the last patient (2.9%) who was managed by repair over double JJ stent, which was removed 2 months post-operative.

Regarding post-operative course, the mean time for return of bowel function was 1.6 days (range, 1-2 days), while resumption of oral feeding was 2.3 days (range, 2-4 days). Eight patients (22.9%) developed post-operative complications, 2 patients (5.7%) had ileus which improved by conservative measures and one patient (2.9%) developed leakage on the fifth post-operative day and was managed successfully with drainage and diverting stoma. Ten days after discharge pelvic abscess occurred in one patient (2.9%) that was managed successfully by percutaneous drainage and insertion of pelvic drain under cover of antibiotics, 2 patients (5.7%) had wound infection treated by open wound care and 2 patients (5.7%) had anastomotic stenosis which responded to dilatation at the time of ileostomy closure. The mean post-operative hospital stay was 4.2 ± 1.4 days (range, 4-6 days). The 30-day readmission rate was 1 patient (2.9%), and 15 (42.7%) received adjuvant therapy.

Analysis of the variables affecting the occurrence of post-operative complications by Univariate Logistic regression showed that patients with co-morbidity were more likely to have complications than others P=0.002. Also, patients with ASA II were more likely to develop complications P= 0.004, and in the same time pathological stage III was associated with a higher complication rate P= 0.004 (Table 3).

Table (3): Univariate logistic regression analysis of factors affecting occurrence of post-operative complications

Factor	Odds ratio	(95% CI)	P value
Co-morbidity			
• No	1	(2.78-	0.002
• Yes	15	80.86)	
ASA grade			
• ASA I	1	(2.16-	0.004
• ASA II	10.63	52.15)	
Pathological staging			
• Stage II	1	(9.04-	0.004
• Stage III	10.8	2.10)	

According to Multivariate Logistic regression of predictors for post-operative complications, including significant factors identified in Univariate analyses, advanced ASA score and advanced pathological stage were significantly independent risk factors responsible for the occurrence of complications (Table 4).

Table (4): Multivariate logistic regression analysis of factors affecting occurrence of post-operative complications in patients treated with LRP (including significant factors in Univariate analysis)

Factor	Odds ratio	(95% CI)	P value
Co-morbidity			
• No	1	(0.14-	
• Yes	3.83	102.98)	0.42
American society of anesthesiologists Grade			
• ASA I	1	(2.06-	0.007
• ASA II	14.00	94.84)	
Pathological staging			
• Stage II	1	(2.41-	0.001
• Stage III	26.93	30.83)	

The pathological and oncological characteristics of the resected tumors were as following; There was involvement of the distal margin in one patient (2.8%) while CRM was

involved (<1 mm) in 3 patients (8.5%). The mean number of LN harvested was 20.4 (range, 17-24). According to pathological staging, 28 patients (80%) were pT_3N_0 and 7 patients (20%) were $pT_{1-3}N_{1-2}$. On follow-up 2 patients (5.7%) had anastomotic stenosis, which responded well to dilatation at the time of ileostomy closure. Low anterior resection syndrome occurred in 20 patients (57.1%); fifteen patients (42.8%) experienced six or fewer bowel movements per day.

Regarding the functional outcome at 12 months post-operative and after closure of ileostomy, fecal incontinence was documented in 5 patients (14.3%). They were managed conservatively with good response at 6 months post-operatively, 4 men (11.4%) had persistent erectile dysfunction at the conclusion of follow-up. Regarding the oncological outcome and after follow-up for a median of 22 months (range 12–36 months); two patients (5.7%) developed local recurrence, one patient (2.9%) was stage II and the other (2.9%) was stage III and two more patients (5.7%) developed distant recurrence, all were treated with systemic chemotherapy. The disease free survival rate at 36 months was 80.02 % with no significant difference between Stage II and stage III (p= 0.25) as shown in table (5). There were 3 reported deaths (8.5%); one (2.8%) due to pulmonary embolism 10 days postoperatively and 2 patients (5.7%) died 13 months and 30 months post-operatively from extensive liver metastases.

Table (5): Disease-free survival rate of studied population

	At 12 months	At 24 months	At 30 months	At 36 months	P value
All	100%	90.03 %	80.02	80.02	
Stage II	100%	93.33	81.67	81.61	0.25
Stage III	100%	66.67	66.67	64.3	

The overall 3-year survival rates were 88.6%; 91.3% for stage II and 83.3% for stage III with no significant difference between survival in stage II and stage III **(Fig. 11)**.

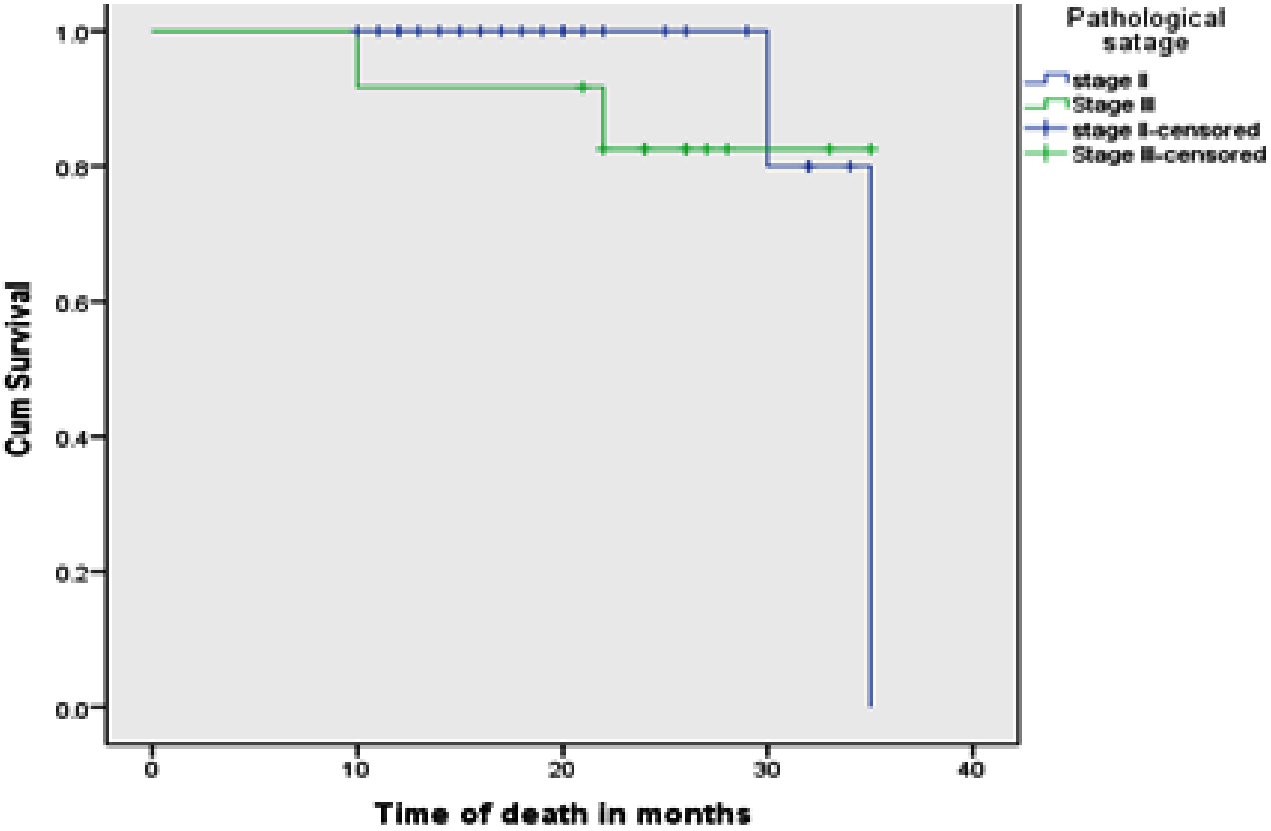

Figure (11): Kaplan-Meier survival graph of overall survival of studied population by stage of the disease.

DISCUSSION

Minimally invasive procedures for treatment of RC are not easy to perform but when performed by trained surgeons, they are considered as the preferred approach for treatment of RC, providing good outcome especially when this is conducted in a multidisciplinary approach [12].

Bleeding per rectum was the commonest complaint in our patients (85.7%), which is in line with others, this may be attributed to early surface erosion induced by the malignancy [13].

Neoadjuvant chemoradiotherapy in RC is associated with tumor down staging, significantly higher rate of pathologic complete response, significantly less advanced pT and pN stage, and fewer cases with venous, perineural, or lymphatic invasion, increased tumor resectability. The use of this line made it possible to treat very low RC by sphincter sparing that obviates the need for abdominoperineal resection [14]. In our study neoadjuvant chemoradiotherapy was used in (34.3%) of patients; locally advanced disease (cT_{3-4} and/or cN_{1-2}), in order to do a down staging of the tumors. Surgery was done 6 weeks after neoadjuvant therapy, which was confirmed to be safe and the standard of care [15].

When operative time of LRP is analysed there will be heterogeneity in the results comparing different studies and also when these studies are compared with conventional surgery. This depends mainly on operating surgeons and on the learning curve, a matter which decreases with time [16]. In our study operative time decreased from the beginning of the study to the end; this is attributed to increase in learning curve among operating surgeons.

One of the main advantages of LRP is reduction of the intra-operative blood loss due to magnification of operative field and the use of energy devices, which minimize blood loss [17]. Regarding blood loss in our study; the mean operative blood loss was 90.4 ± 8.3 mL (range, 75-120 mL).

A similar disease-free survival is achieved when the distal resection margin was >1 cm or <1 cm from the cancer [18]. Meanwhile, about 4-5% of patients may have intramural tumor cell spread distal to the tumor of < 1 cm particularly if it was not high grade tumor. Thus, preservation of the sphincter apparatus is possible in distally seated tumors and simultaneously approving radicality [13]. But, of more importance the circumferential resection margin, which has largely replaced distal margin in predicting local recurrence and disease-free survival [19]. In our series the oncological principles of rectal surgery were applied. To improve the local recurrence control, laparoscopic TME was practiced and a minimal 1 cm distal margin of resection was obtained, as a standard procedure [20], which was involved in one patient (2.8%). A small figure in relation to the others reflecting the small number of series while CRM was involved (< 1 mm) in 3 patients (8.5%) reflected as 11.4% recurrence rate, this correlates with the others, which reflects the adequacy of the technique [21].

The incidence of perioperative complications reflects the safety of any surgical procedure. To master this technique and to reduce the post-operative complications needs higher number of patients [22]. Intra-operative hemorrhage is the most common intra-operative complication [23]. Intra-operative complications occurred in 8.5% of patients under study. Intra-operative bleeding occurred in 2.9% and managed laparoscopically, may be smaller than other studies due to the smaller number of the study group. Urinary injuries to the bladder or ureter occurred in 2%-2.8% of LRP. Ureteric injury occurred during mobilisation of sigmoid colon or along the lateral pelvic sidewall on entry into the pelvis. Bladder injury may happen due to electrocoagulation tears during the dissection of the rectum anterior wall [24]. In our study urinary injury occurred in 5.7%, which was discovered and managed intra-operatively without conversion to conventional technique.

LRP has a risk of anastomotic leak [11], with an incidence of 4.2% to 26% and is associated with mortality rate reaching 40%. Male gender and low anastomosis are risk factors for this probably due to narrower pelvis and deficient blood supply for distal anastomoses, also long operative time if there was no diverting ileostomy. The preoperative chemoradiation, advanced tumor stage, perioperative bleeding and multiple firings of the linear stapler increase the risk of leak following LRP for RC, a diverting stoma is mandatory in patients with ≥ 2 of the aforementioned risk factors [25]. In our study, anastomotic leak was 2.9% and was managed successfully with drainage in the presence of protective stoma. Although, diverting ileostomy did not prevent this but the severity of the sepsis-related morbidity is decreased [26]. **Sciuto *et al.*** [27] recommended the use of diverting stoma for high-risk patients viz; lower RC, those with comorbidities and elderly patients ≥ 50 years old [27]. In our study, we adopted the same policy and we were not confronted with stoma-related morbidities as it was temporal.

After statistical analysis of risk factors, which may significantly influence the occurrence of surgical complications, we concluded that these independent risk factors are co-morbidity. This is in line with others [28] as it leads to impaired healing of a surgical wound or its infection. Pathological staging may be due to bleeding problems secondary to irradiation changes in the tissue and ASA grade, which may be explained as the elderly patients have a higher ASA grade reflecting underlying systemic illnesses, which has risk of serious complications or death [29].

The shorter hospital stay, the less morbidity rate, and early return to work make laparoscopy cost effective technique decreasing health care expenditure and improves patients' outcomes also overweighing the cost of the equipment. In our study, the mean postoperative hospital stay was a 6.77 ± 1.7 day, which is in line with others [30].

The incidence of anastomotic stricture following anterior resection ranges from 0-30%, which is increased with the use of staplers [25]. In the present study, we had 5.7% anastomotic stricture which responded well to dilatation at the time of ileostomy closure.

Low anterior resection syndrome was present in 55.2%-58% of patients who underwent LRP being more frequent after a low anastomosis and in young patients who received neoadjuvant chemoradiotherapy [31]. In our study, it occurred in 57.1%.

In spite of efforts to identify and preserve nerves during open TME, the incidence of sexual dysfunction ranged from 10-35% of patients [32], but patients who underwent LRP has significant lower rates of sexual dysfunction than those who underwent open surgery [33]. In our study, after 1 year follow-up erectile impotence occurred in 11.4%, which is in agreement with others [32, 33].

In the present study, the overall recurrence rate after the procedure at 3 years was 11.4%. These results are similar to results of previous study [34]. The survival rate, the overall 3-year survival rate was 88.6% and disease free survival rate at 36 months was 80.02%, which is similar to results of the **Laurent *et al.*** [35].

CONCLUSION

According to our results and data from other authors in comparison to the conventional open surgery, LRP for RC can be done feasibly and safely with favorable short-term post-operative outcomes and equal long-term and functional outcomes reflecting adequacy of the procedure making it a good alternative to conventional methods.

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Conflict of interest: Nil.

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