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Minimally invasive surgery for maximally invasive tumors: pelvic exenterations for rectal cancers

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Purpose: Trials comparing minimally invasive rectal surgery have uniformly excluded T4 tumors. The present study aimed to determine the safety of minimally invasive surgery (MIS) for locally-advanced rectal cancers requiring pelvic exenterations based on benchmarked outcomes from the international PelvEx database.

Methods: Consecutive patients of T4 rectal cancers with urogenital organ invasion that underwent MIS exenterations between November 2015 and June 2022 were analyzed from a single center. A safety threshold was set at 20% for R1 resections and 40% for major complications (≥grade IIIA) for the upper limit of the 95% confidence interval (CI).

Results: The study included 124 MIS exenterations. A majority had a total pelvic exenteration (74 patients, 59.7%). Laparoscopic surgery was performed in 95 (76.6%) and 29 (23.4%) had the robotic operation. Major complications were observed in 35 patients (28.2%; 95% CI, 20.5%–37.0%). R1 resections were found pathologically in nine patients (7.3%; 95% CI, 3.4%–13.4%). The set safety thresholds were not crossed. At a median follow-up of 15 months, 44 patients (35.5%) recurred with 8.1% local recurrence rate. The 2-year overall and disease-free survivals were 85.2% and 53.7%, respectively.

Conclusion: MIS exenterations for locally-advanced rectal cancers demonstrated acceptable morbidity and safety in term of R0 resections at experienced centers. Longer follow-up is required to demonstrate cancer survival outcomes.

Keywords: Rectal neoplasms, Locally advanced, Minimally invasive surgical procedures, Pelvic exenteration

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INTRODUCTION

Nearly 40% to 50% of rectal cancers are locally advanced at presentation [1], and about half of them would require extended or beyond total mesorectal excisions (TME) to achieve negative margins [2]. All trials that compared open against minimally invasive surgery (MIS) for rectal cancers, uniformly excluded such advanced rectal cancers [3–6]. Since the ACOSOG Z6051 and the ALaCaRT trials failed to demonstrate the non-inferiority of MIS in terms of composite pathological endpoint for rectal cancers without involvement of the mesorectal fascia [7,8], a randomized trial comparing MIS and open pelvic exenterations is not a foreseeable project. The oncological outcomes were not different in any of the trials [9,10]; yet, doubt remains regarding the safety of MIS in rectal cancers requiring adjacent organ resections.

Even though some high-volume exenteration units perform minimally invasive exenterations, the published data on the same is scarce. The PelvEx group performed a meta-analysis on the available comparative data of MIS against open exenterations with only 37 MIS exenterations from four pooled studies

[11]. Despite the increase in operative time, there was a significant reduction in hospital stay and overall morbidity rate with MIS exenterations. However, since the MIS numbers were very small, drawing definite conclusions is difficult with regard to its safety. Besides, there was no report on oncological outcomes. The other significant comparative data comes from a single-center experience of 61 MIS exenterations [12], where R0 resection rate and 3-year survivals were similar. However, significant selection biases exist, and data on a larger number of patients is needed.

The present study aimed to define the safety of MIS exenterations based primarily on major morbidity rate and R1 resections. The threshold was defined by the standards set by the PelvEx group for exenterations in primary locally-advanced rectal cancers. A 30-day major complication rate (≥grade IIIA) of 37.8% and R1/2 resection rate of 15.6% were found among 1,291 exenterations [13], and these were used as benchmark values. Secondarily, disease-free (DFS) and overall survival (OS) would be assessed.

MATERIALS AND METHODS

Study design, setting, and patients

The prospectively maintained data of pelvic exenterations from a single, tertiary colorectal cancer surgical unit was audited. Patients who operated between November 2015 and June 2022 for primary, locally-advanced rectal adenocarcinomas were included. Exclusions were the need for high sacral resection (S3 and above), lateral compartment resection (vascular resections, clearance of sciatic notch), recurrent rectal cancers, and non-adenocarcinoma histology (squamous cancer, gastrointestinal stromal tumors).

The STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) and SAMPL (Statistical Analyses and Methods in the Published Literature) guidelines were followed for study reporting.

Treatment

Rectal cancers were investigated with a colonoscopy, biopsy, magnetic resonance imaging (MRI) of the pelvis, and contrast-enhanced computed tomography of the chest and abdomen. Tumor location was measured on colonoscopy as the lower edge of the tumor from the anal verge. All patients were discussed in the multidisciplinary team (MDT) meeting for treatment planning. Preoperative radiation was delivered for all advanced tumors (≥T3 or ≥N1). The choice of radiation (long-course chemoradiation, 50 Gy in 25 fractions with concurrent capecitabine vs. short-course radiation, 25 Gy in five fractions) was at the discretion of the MDT. Similarly, the use of consolidation chemotherapy was also individualized. Response MRI was performed at least 6 weeks after completion of radiation.

Pelvic exenterations included the removal of one or more anterior urogenital organs *en bloc* with the rectum, either for margins or for disease infiltration [2]. Non-multivisceral resection or those requiring partial organ resections are categorized as extended TME and were not included. Thus, total pelvic exenterations [2], bladder sparing exenterations [14], and posterior pelvic exenterations were the operations performed [15], with or without sacral or perineal resections. The techniques for each of these are previously described, and all operations were performed by the same team of surgeons. The operative technique for the extirpative part of the procedure did not considerably change over the years. The choice for robotic or laparoscopic surgery was based on the availability of robotic theater rather than patient or tumor characteristics. Adjuvant chemotherapy and further follow-up were in accordance with the National comprehensive cancer network guidelines [16].

Variables

Patient and demographic characteristics recorded were age, sex, performance status on the Eastern Cooperative Oncology Group scale, comorbidities on the American Society of Anesthesiologists physical status classification, body mass index, preoperative hemoglobin, and albumin levels. Tumor-related factors noted were distance from anal verge, luminal occlusion, histologic subtype and differentiation, carcinoembryonic antigen levels, clinical T, N, and M stage, presence of extramural vascular invasion, and lateral pelvic nodes. Treatment variables entered were neoadjuvant radiation, chemotherapy, surgical approach (laparoscopic vs. robotic), surgery performed, lateral pelvic node dissection, sacral resection, perineal reconstructions, and the use of adjuvant chemotherapy.

Outcomes and safety thresholds

Postoperative and pathological outcomes were the short-term endpoints used. Operating duration, blood loss, and 30-day complications on the Clavien-Dindo classification [17] were recorded. Pathological factors were the Mandard tumor regression grade [18], pathological T and N stage, presence of lymphovascular and perineural invasion, and the status of circumferential resection margin (CRM). A positive CRM was considered when tumor was within 1 mm of the radial non-peritonealized resection surface.

Benchmark values for short-term outcomes of pelvic exenterations from the PelvEx data were used for deciding the safety thresholds [13]. A 30-day major complication rate (≥grade IIIA) of 37.8% and R1/2 resection rate of 15.6% were found for exenterations in locally-advanced rectal cancers [13]. Based on this, the upper limit of the 95% confidence interval (CI) for safety was set at 40% for major morbidity and 20% for R1 resections. Based on

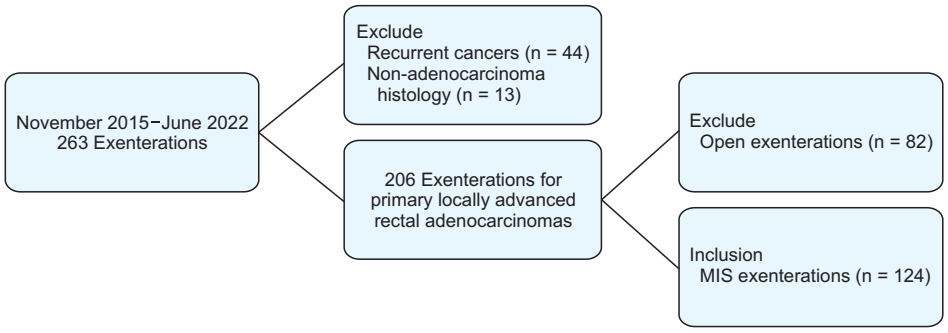

Fig. 1. Patient selection. MIS, minimally invasive surgery.

our previous data for MIS exenterations [12], a 30% major morbidity and 13% R1 resections were expected.

The number of patients required to demonstrate the safety with 95% CI would be 88 patients for morbidity and 101 for R1 resections. Thus, the inclusion of 124 patients in the study would suffice to meet the statistical thresholds.

Statistical methods

Data were recorded and analyzed using the IBM SPSS version 16 (IBM Corp., Armonk, NY, USA). For the various continuous variables, medians and interquartile ranges were calculated. Categorical variables were represented by numbers and proportions. Median follow-up was calculated by the reverse Kaplan-Meier method and survivals analysis was performed by the Kaplan-Meier curves.

OS was calculated from the date of operation to the date of death from any cause. Similarly, DFS was measured from the date of operation till recurrences or deaths. All patients were censored at their last follow-up.

RESULTS

Patients and intervention

One-hundred twenty-four patients underwent MIS exenterations during the study period (Fig. 1). The median age of our cohort was 47 years and 65.3% (81 patients) were male (Table 1). Poorly-differentiated tumors comprised on 29.8%, and 17 patients (13.7%) had signet ring cell histology. The majority were low rectal cancers (median distance from anal verge, 3 cm) and 12 patients (9.7%) in addition had curable distant metastasis.

Other than eight patients, all received preoperative radiation. Consolidation chemotherapy was given to 66 (53.2%). We performed a laparoscopic exenteration for 95 patients (76.6%) and the remainder had a robotic operation (Table 2). There were two conversions to open surgery (1.6%), both in laparoscopic exenterations. A total pelvic exenteration was carried out in 74 patients (59.7%), posterior exenteration in 36 (29.0%), and a bladder sparing exenteration in 14 (11.3%). Thirty-six patients had sphincter

Table 1. Baseline characteristics

Characteristic	Data
No. of patients	124
Age (yr)	47 (37–56)
Sex	
Male	81 (65.3)
Female	43 (34.7)
Site	
Rectum	117 (94.4)
Rectosigmoid	7 (5.6)
Performance status, ECOG scale	
0	17 (13.7)
1	89 (71.7)
2	12 (9.7)
3	6 (4.8)
Comorbidities, ASA PS classification	
I	77 (62.1)
II	44 (35.5)
III	3 (2.4)
Body mass index (kg/m^2)	21.82 (19.29–24.09)
Preoperative hemoglobin (g/dL)	11.4 (10.1–12.7)
Preoperative albumin (g/dl)	3.9 (3.4–4.1)
Distance from anal verge (cm)	3 (1–6)
Preoperative diversion	36 (29.0%)
Histologic differentiation	
Well-moderate	87 (70.2)
Poorly-differentiated	37 (29.8)
Signet ring cell cancer	17 (13.7)
CEA (ng/mL)	6.05 (3.07–23)
Lateral pelvic nodes	41 (33.1)

Table 1. Continued

Characteristic	Data
Preoperative T stage	
T3	18 (14.5)
T4	106 (85.5)
Clinical node positive	118 (95.2)
Extramural vascular invasion (n = 63)	19 (30.2)
M1 stage	12 (9.7)
Site of M1 (n = 12)	
Liver	6 (50.0)
Peritoneum	3 (25.0)
Extra-pelvic nodes	2 (16.7)
Lung	1 (8.3)

Values are presented as number only, median (interquartile range), or number (%).
ECOG, Eastern Cooperative Oncology Group; ASA PS, American Society of Anesthesiologists physical status.

Table 2. Treatment, operative, and postoperative characteristics

Characteristic	Data (n = 124)
Preoperative radiation	
No	8 (6.5)
Long course chemoradiation	84 (67.7)
Short course chemotherapy	33 (26.6)
Preoperative chemotherapy	66 (53.2)
Surgery	
Total pelvic exenteration	74 (59.7)
Posterior exenteration	36 (29.0)
Bladder sparing exenteration	14 (11.3)
Surgical approach	
Laparoscopic	95 (76.6)
Robotic	29 (23.4)
Sphincter preservation	36 (29.0)
Lateral pelvic node dissection	70 (56.5)
Urinary reconstruction	
Ileal conduit	72 (58.1)
Sigmoid conduit	4 (3.2)
Supra-pubic catheter	14 (11.3)
Ureteric reimplantation	1 (0.8)
Not applicable	47 (37.9)
Perineal reconstruction (n = 95)	66 (69.5)
Sacrectomy	5 (4.0)

Table 2. Continued

Characteristic	Data (n = 124)
Surgical duration (min)	520 (420–650)
Blood loss (mL)	700 (480–1,300)
Hospital stay (mL)	11 (8–15)
Clavien-Dindo complications	
0	48 (38.7)
I	12 (9.7)
II	29 (23.4)
IIIA	14 (11.3)
IIIB	17 (13.7)
IV	1 (0.8)
V	3 (2.4)
Complications, ASA PS grade ≥IIIA; 95% CI	35 (28.2); 20.5%–37.0%
Leak	
Urinary (n = 91)	13 (14.3)
Bowel (n = 36)	5 (13.9)
Surgical site infection	27 (21.8)
Small bowel obstruction	13 (10.5)

Values are presented as number (%) and median range unless otherwise specified.
ASA PS, American Society of Anesthesiologist physical status; CI, confidence interval.

preservation and 56.5% had a lateral pelvic node dissection.

Outcomes

The major morbidity rate at 30-days (≥grade IIIA) was 28.2% (35 patients). The upper limit of 95% CI was 37%; thus, the safety threshold of 40% was not crossed. The pathological CRM involvement was noted in nine patients (7.3%) with a 95% CI of 3.4% to 13.4%. Once again, the set safety limit was not crossed (Table 3). No patient had a positive distal margin.

At a median follow-up of 15 months, 44 patients (35.5%) recurred (Table 4). Local recurrences (with or without systemic relapses) were seen in 10 patients (8.1%). The median DFS was 31 months and the 2-year DFS and OS were 53.7% and 85.2%, respectively (Fig. 2).

DISCUSSION

In the present series of 124 MIS exenterations for primary advanced rectal cancers, the predefined safety limits for major operative complications and R1 resections were not crossed. Thus,

Table 3. Pathological and oncological outcomes

Variable	Data (n = 124)
Pathological T stage	
T0	17 (13.7)
T1/2	9 (7.3)
T3	42 (33.9)
T4	56 (45.2)
Pathological N stage	
0	74 (59.7)
1	35 (28.2)
2	15 (12.1)
Nodal yield	15.5 (0–66)
Extranodal extension	17 (13.7)
Lymphovascular invasion	24 (19.4)
Perineural invasion	23 (18.5)
Tumor regression grade (n = 113)	
1	17 (15.0)
2	24 (21.2)
3	32 (28.3)
4	32 (28.3)
5	8 (7.1)
Pathological complete response (n = 116)	12 (10.3)
Positive CRM (R1 resection); 95% CI	9 (7.3); 3.4%–13.4%
Adjuvant chemotherapy	87 (70.1)

Values are presented as number (%) and median (range) unless otherwise specified.
CRM, circumferential resection margin.

MIS exenterations appeared to have short-term safety comparable to international standards for open exenterations.

Pelvic exenterations are a major undertaking, and operative complications are a culmination of various factors. The patient and tumor characteristics, the receipt of neoadjuvant therapies, and the extent of surgical resection and reconstruction, all con-

Table 4. Oncological outcomes

Variable	Data (n = 124)
Follow-up (mo)	15 (10.74–19.76)
Recurrences	44 (35.5)
Pattern of recurrences	
Local	8 (6.5)
Distant	32 (25.8)
Peritoneal	10 (8.1)
Sites of distant relapse (n = 32)	
Lung	18 (14.5)
Liver	15 (12.1)
Nodal	11 (8.9)
Bone	4 (3.2)
Deaths	17 (13.7)
Disease-free survival (mo)	31 (17.25–47.74)
2 yr	53.7%
Overall survival	Not reached
2 yr	85.2%

Values are presented as median (95% confidence interval) or number (%) unless otherwise specified.

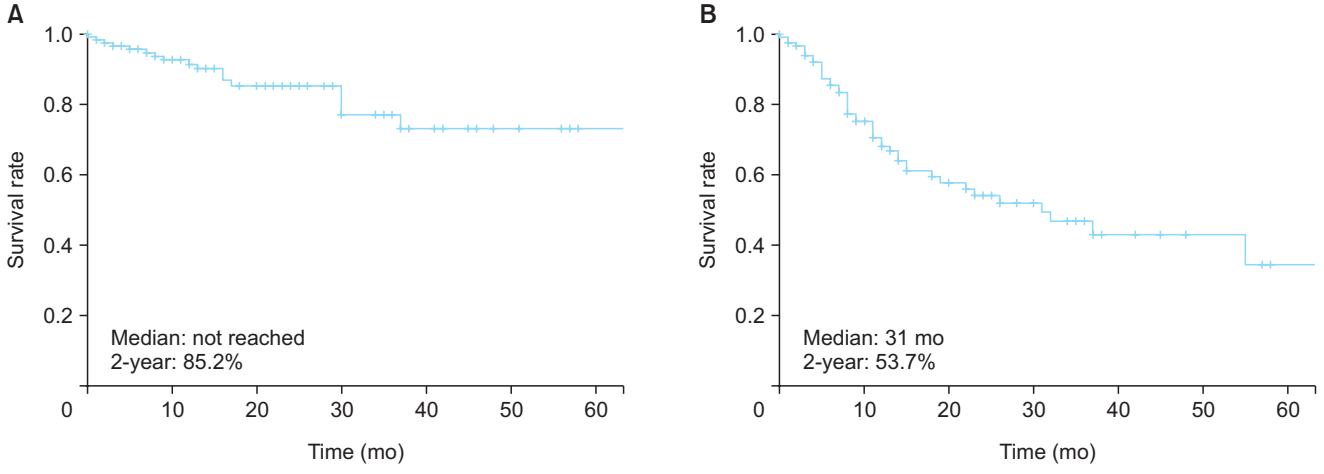

Fig. 2. Survival curves. (A) Overall survival. (B) Disease-free survival.

tribute to the morbidity. By adopting minimally invasive surgical approaches, the intention is to introduce a modifiable factor that can reduce some of the complications. However, one must be critical of new procedures with a patient-centric approach at all times.

Our group has adopted MIS for pelvic exenterations for all advanced rectal cancers except for recurrent cancers, diseases requiring high sacrectomy or vascular resections, and for those with prior pelvic operations with anticipated bowel adhesions. Thus, comparing our MIS exenterations against open would entail an uncorrectable selection bias. Therefore, we chose to compare the international standards with benchmarked outcomes from the PelvEx database [13]. Selection bias was therefore minimized as all consecutive eligible patients underwent MIS without exclusions or missing data.

To address the morbidity associated with pelvic exenterations, various measures were taken for standardization of the procedure and postoperative care over time. All ureteroenteral anastomoses were stented with the delayed removal of stents to reduce the incidence of clinically significant urinary leaks [19]. Perineal closures were routinely performed with versatile gluteal fasciocutaneous advancement flaps to overcome wound breakdowns and infections [20]. Finally, empty pelvis syndrome was mitigated with the use of pelvic spacer balloons [21]. Besides the standardizations in reconstructive phase of exenterations, the use of MIS probably helps by reducing blood loss, abdominal surgical site infection, early return from ileus, and earlier discharge from hospital [12,22].

R0 resections are key to achieving successful oncological outcomes after exenterative procedures. Over 90% of the present cohort had margin negative resections, suggesting non-inferiority to the open operations in the PelvEx data [13]. The above figure is in spite of 30% poorly-differentiated or signet ring cell cancers that are known to have higher positive margins [23]. Only two patients were converted to open surgery from MIS; one for bleeding and the other for an inadvertent ureteric injury. Selection of patients and operator experience is key, since it is worthless to pursue MIS with the risk of positive margins. Vascular (external iliac and proximal) and bone resections (S3 and above), although possible via MIS in highly experienced units, are surrogates for a very advanced infiltrative disease into the pelvic side walls, and remain absolute indications for an open operation at our center.

The principal drawback of our study is the absence of a comparator arm. We, therefore, used the international benchmarks set as the historical comparator. The retrospective nature of the study, despite prospective data entry, is associated with some variables with missing data.

Overall, the number of events (for complications or R+ resections) was few, and meaningful regression analysis to identify predictors of safety was not possible. Finally, the short follow-up duration of our cohort does not allow comparisons of survival outcomes.

Notwithstanding the above shortcomings, our study has important strengths. The present study describes the outcomes of the largest cohort of MIS exenterations for locally-advanced rectal cancers. The cohort is homogenous, and all patients had complete data on the primary outcomes to be analyzed. Lastly, the safety threshold was based on the upper limit of 95% CIs; hence, our results have statistical validity.

Our findings may not be universally applicable. Before embarking on MIS exenterations, the operating team was very well experienced in standard rectal resections [24], lateral pelvic node dissections [25], and open exenterations [19]. Thus, experience and deconstruction of the complex procedure are key to the successful safe performance of MIS exenterations.

The adoption of MIS for advanced and T4 rectal cancers is growing, and the short-term safety is well-established. However, long-term oncological results are still lacking with available data showing similar outcomes [12]. Although randomized evidence would be ideal, generating such evidence for MIS exenterations is a less likely possibility. A more relevant question today might be to elucidate differences between the MIS approaches. Future research should look into the cost-benefit analysis, patient-reported outcomes, and the long-term benefits vis-à-vis the environmental sustainability between laparoscopic and robotic operations [26]. Finally learning curves of minimally invasive exenterations with recurrence as the outcome can be examined in future studies.

In conclusion, MIS exenterations for locally-advanced rectal cancers demonstrated acceptable morbidity and safety in term of R0 resections at experienced centers. Longer follow-up is required to demonstrate cancer survival outcomes.

NOTES

Ethical statements

The current study is a subgroup analysis of a prospective Institutional Review Board (IRB) approved study (No. 1478). Signed informed consent was obtained from each patient during treatment and surgery. The study protocol followed the ethical standards of the institutional research committee and the 1964 Helsinki Declaration and its later amendments. Separate IRB review exemption was also approved for the present analysis.

Authors' contributions

Data curation: MK, AD, CN
Formal analysis, Visualization: MK
Investigation, Methodology: MK, AD, AS
Project administration: AD, CN, AS

Writing–original draft: MK
Writing–review & editing: MK, AD, AS
All authors read and approved the final manuscript.

Conflict of interest

All authors have no conflicts of interest to declare.

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