**Name of Journal:** ***World Journal of*** ***Gastroenterology***

**Manuscript NO: 40054**

**Manuscript Type:** **ORIGINAL ARTICLE**

***Retrospective Study***

**Application of modified primary closure of the pelvic floor in laparoscopic extralevator abdominal perineal excision for low rectal cancer**

Wang YL *et al.* Pelvic Reconstruction in LELAPE

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**Author contributions:** Wang YL and Dai Y designed the study; Wang YL, Zhang X and Dai Y performed the surgery; Mao JJ performed subject follow up and control subject data collection; Zhang WQ and Dong SH performed the statistical analysis; Zhang X, Zhang FP, Zhang WJ and Dong H wrote the manuscript; Wang YL, Zhang X, Mao JJ, Zhang WQ, Dong H, Zhang FP, Dong SH, Zhang WJ, Dai Y revised the manuscript for final submission.

**Supported by** the National Key and Development Program of China, No. 2016YFC0106003; the National Natural Science Foundation of China, No. 81700708/H0712; and the Key and Development Program of Shandong Province, No. 2016GSF201125.

**Institutional review board statement:** This study was approved by the Ethics Committee of Scientific Research of Shandong University Qilu Hospital.

**Conflicts of interest statement:** The authors declare that there are no conflicts of interest related to this study.

**Data sharing statement:** No additional data are available.

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**Manuscript source:** Unsolicited manuscript

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**Telephone:** +86-531-82166391

**Received:** May 31, 2018

**Peer-review started:** May 31, 2018

**First decision:** June 15, 2018

**Revised:** June 18, 2018

**Accepted:** June 30, 2018

**Article in press:**

**Published online:**

**Abstract**

***AIM***

To introduce a novel modified primary closure technique of laparoscopic extralevator abdominal perineal excision (LELAPE) for low rectal cancer.

***METHODS***

We retrospectively analyzed data from 76 patients with rectal cancer undergoing LELAPE from March 2013 to May 2016. Patients were classified into the modified primary closure group (32 patients) and the biological mesh closure group (44 patients). Total operating time, reconstruction time, postoperative stay, total cost, postoperative complications and tumor recurrence were compared.

***RESULTS***

All surgery was successfully performed. The pelvic reconstruction time was 14.6 ± 3.7 min for the modified primary closure group, which was significantly longer than that of the biological mesh closure group (7.2 ± 1.9 min, *P* < 0.001). The total operating time was not different between the two groups (236 ± 20 *vs* 248 ± 43 min, *P* = 0.143). Postoperative hospital stay was 8.1 ± 1.9 d and the total cost was 9297 ± 1260 USD for the modified primary closure group; both of which were significantly less than those of the biological mesh closure group (*P* = 0.001 and *P* = 0.003, respectively). No difference in other perioperative data, long-term complications or oncological outcomes was observed.

***CONCLUSION***

The modified primary closure method for reconstruction of the pelvic floor in LELAPE for low rectal cancer is technically feasible, safe and cost-effective.

**Key words:** Extralevator abdominoperineal excision; Rectal cancer; Pelvic floor; Laparoscopy

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**Core tip:** The modified primary closure approach requires closure of the pelvic peritoneum laparoscopically and layered closure of the perineal defect. By using this modified approach, the length of hospital stay and the total cost were decreased significantly, while other clinical outcomes did not differ except a relatively longer time for the pelvic reconstruction (14.6 ± 3.7 *vs* 7.2 ± 1.9 min). The conclusion comes to that the modified primary closure method for reconstruction of the pelvic floor in laparoscopic extralevator abdominal perineal excision for low rectal cancer is technically feasible, safe and cost-effective.

Wang YL, Zhang X, Mao JJ, Zhang WQ, Dong H, Zhang FP, Dong SH, Zhang WJ, Dai Y. Application of modified primary closure of the pelvic floor in laparoscopic extralevator abdominal perineal excision for low rectal cancer. *World J Gastroenterol* 2018; In press

**INTRODUCTION**

To improve the oncological outcome of patients with low rectal cancer, extralevator abdominal perineal excision (ELAPE) has been introduced to reduce the rate of positive circumferential margin (CRM) and intraoperative perforation (IOP)[[1-4](#_ENREF_1)]. Assisted by laparoscopy, ELAPE can minimize physical invasion while ensuring oncological benefits[[5](#_ENREF_5),[6](#_ENREF_6)]. However, the extended resection of ELAPE may increase the risk of severe perineal wound complications, including perineal hernia, with a reported incidence of 20%-26%[[7](#_ENREF_7)]. Thus, how to reconstruct the pelvic floor and close the perineum after massive resection has become a major concern and challenge in laparoscopic ELAPE (LELAPE). The established reconstruction methods include: primary perineal closure, omentoplasty, biological or synthetic mesh placement, myocutaneous flaps, and negative wound pressure therapy[[8-12](#_ENREF_8)]. These methods all have their own advantages as well as restrictions, and no consensus has been reached so far. In traditional abdominoperineal resection (APR), the pelvic peritoneum is usually closed prior to reconstruction of the pelvic floor, in order to separate the small intestine from the presacral operating field, which is technically challenging in LELAPE. Recently, we have modified the primary closure technique by adding the procedure of laparoscopic pelvic peritoneum suture, and applied it to LELAPE. In the present study, we compare this method with biological mesh closure in the reconstruction of the pelvic floor after LELAPE, and evaluate its feasibility, safety and cost-effectiveness.

**MATERIALS AND METHODS**

***Study design***

We retrospectively analyzed the data from 76 patients with rectal cancer undergoing LELAPE from March 2013 to May 2016. Patients were classified into the modified primary closure group (32 patients) and the biological mesh closure group (44 patients). Total operating time, reconstruction time, postoperative stay, total cost, postoperative complications and tumor recurrence were compared. The protocol was approved by the Ethics Committee of Qilu Hospital, Shandong University, Jinan, China.

***General procedure***

We have described the LELAPE procedure in a previous report[[13](#_ENREF_13)]. The abdominal procedure was performed with the patient being placed in the Trendelenburg position, and the port placement was set up as shown in Figure 1A. After laparoscopic exploration, dissection and division of the pedicle of the inferior mesenteric vessels were performed. The sigmoid colon was mobilized from medial to lateral and the rectum was mobilized following the total mesorectal excision principle. The sigmoid mesentery was trimmed at the rectosigmoid junction where the rectum was transected with an endoscopic linear stapler (Figure 1B). The distal rectum and mesorectum were pushed down to the pelvic cavity (Figure 1C).

***Modified primary closure***

For modified primary closure, the pelvic peritoneum was closed with continuous suturing using a barbed suture (Covidien, Shanghai, China) (Figure 1D and E) before creation of a colostomy. For tension-free suturing, the adjacent pelvic peritoneum was dissected to reduce tension if necessary (Figure 1F and G). The patient was turned over to the prone jackknife position. The levator ani was transected at its origin and a cylindrical specimen was removed. The procedure was completed with the placement of one negative-pressure drainage tube in the presacral space and layered closure of the ischiorectal fat and skin. The drainage tube was removed when the drainage fluid was clear and < 10 mL in volume. The coccyx was not routinely removed.

***Biological mesh closure***

For biological mesh closure, the patient was changed to a prone position for perineal dissection after creation of a colostomy. The levator ani was transected at its origin and a cylindrical specimen was removed. A human acellular dermal matrix mesh (Ruinuo, Qingyuanweiye Bio‑Tissue Engineering Ltd., Beijing, China) was implanted and fixed to the tendinous arch by continuous prolene sutures (Covidien) for reconstruction of the pelvic floor (Figure 1H). The procedure was completed with the placement of one negative-pressure drainage tube below the mesh and layered closure of the ischiorectal fat and skin. All the operations were finished by the same surgical group.

***Statistical analysis***

Numerical data were expressed as mean ± SD and analyzed with Student’s *t* test. Categorical data were analyzed with the *X2* test or Fisher’s exact test. Repeated measures analysis of variance was performed for postoperative drainage and temperature change. All analyses were performed using SPSS 19.0 (SPSS Inc., Chicago, IL, United States). *P* < 0.05 was considered to be statistically significant.

**RESULTS**

The baseline characteristics, including male/female ratio, age, body mass index, neoadjuvant therapy, distance to anal verge, and postoperative TNM staging were comparable between the two groups (*P* > 0.05 each, Table 1). All patients were successfully followed up for 1 year postoperatively.

All operations were successfully performed without serious intraoperative complications. The pelvic reconstruction time was 14.6 ± 3.7 min for the modified primary closure group, which was significantly longer than that of the biological mesh closure group (7.2 ± 1.9 min, *P* < 0.001). The total operating time did not differ between the two groups (236 ± 20 *vs* 248 ± 43 min, *P* = 0.143). One patient developed bowel perforation due to a large tumor within the anterior wall of the rectum in the biological mesh closure group. No positive CRM was observed in either group. Intraoperative blood loss and recovery of bowel function were comparable between the two groups (both *P* > 0.05) (Table 2). The drainage tube was removed at 6.6 ± 1.1 d postoperatively in the modified primary closure group, which was earlier than in the biological mesh closure group (7.3 ± 2.0 d, *P* = 0.094). The volume of drainage fluid peaked at 2 d postoperatively and then decreased gradually, without any difference between the two groups (*P* treatment > 0.05, *P* interaction > 0.05) (Figure 2A). The temperature change after operation showed a similar pattern to drainage volume, with no difference between the groups (*P* treatment > 0.05, *P* interaction > 0.05) (Figure 2B). Postoperative hospital stay was 8.1 ± 1.9 d and the total cost was 9297 ± 1260 USD for the modified primary closure group; both of which were significantly less than those of the biological mesh closure group (*P* = 0.001 and *P* = 0.003, respectively) (Table 2). One patient in the biological mesh closure group developed intestinal obstruction at 40 d postoperatively. Conservative therapy did not work, and a laparoscopic exploration was performed at 42 d. The middle part of the ileum, ~100 cm to the ileocecal junction, adhered to the pelvic floor, leading to dilation of the proximal small intestine (Figure 3). The patient was healed by decompression of the small intestine and intestinal rearrangement under laparotomy.

In the modified primary closure group, five patients had perineal wound infection. Within the first 10 d postoperatively, three patients had haemoserous discharge from the perineal wound, and were healed following potassium permanganate hip bath after 1 mo. At 12 d, one patient showed purulent discharge, which was solved after daily dressing change and thermal therapy. At 15 d, the perineal wound broke down in one female patient with type 2 diabetes. Debridement and secondary suturing were performed at 33 d after daily dressing change. Likewise, in the biological mesh closure group, five patients had perineal wound infection within the first 10 d (Table 3), and recovered within 60 d after appropriate treatment. No difference in infection rate or grade was found between the two groups (*P* > 0.05 each). Perineal hernia is theoretically expected to be more frequent without placement of meshes. However, at 12 mo postoperatively, no perineal hernia occurred in either of the groups. Notably, four patients in the modified primary closure group and two in the biological mesh group experienced the feeling of bulging. Computed tomography (CT) at 12 mo showed that in the modified primary closure group, the small intestine was kept in the pelvic cavity with a clear descent of the pelvic peritoneum. In the biological mesh group, without suturing the pelvic peritoneum, the small intestine was also kept in the presacral space. No obvious difference in CT scan was detected between the two groups at 12 mo postoperatively (Figure 4).

Postoperative chemotherapy (XELOX or FOLFOX regimen) and radiotherapy were given to 23 and seven patients in the modified primary closure group, as well as 28 and 14 patients in the biological mesh closure group, respectively (*P* = 0.330 and *P* = 0.339). In the biological mesh closure group, local recurrence occurred in one patient receiving only postoperative chemotherapy with the XELOX regimen, and the patient was treated with radiotherapy subsequently. Three patients had minor liver metastases and were cured with local ablative treatment. In the modified primary closure group, minor lung metastasis and minor liver metastases were found in two patients, respectively. Both of the patients received local ablative treatment. No patients died in either of the two groups.

**DISCUSSION**

The necessity of reconstruction of the pelvic floor after ELAPE has been widely accepted in order to avoid postoperative perineal complications[[14](#_ENREF_14),[15](#_ENREF_15)]. However, the feasibility and superiority of various methods proposed for the reconstruction remain to be investigated. In the present study, we compared two methods, modified primary closure and biological mesh closure, in 76 patients with lower rectal cancer undergoing LELAPE. The major findings were that modified primary closure required longer reconstruction time, but shorter postoperative hospital stay and was more cost-effective, compared to biological mesh closure. No difference in other perioperative data, long-term complications or oncological outcomes was observed.

Various methods have been developed for perineal wound healing after ELAPE; among which, perineal closure with myocutaneous flaps, biological or synthetic mesh placement, and omentoplasty with perineal closure are most widely performed currently[[8-12](#_ENREF_8)]. Myocutaneous flaps can be obtained by various approaches, including gluteal rotation/advancement flaps[[16](#_ENREF_16)], inferior gluteal artery myocutaneous island transposition flap (IGAM)[[17](#_ENREF_17)], transverse rectus/vertical rectus abdominis (TRAM/VRAM)[[18](#_ENREF_18),[19](#_ENREF_19)] and gracilis[[20](#_ENREF_20)]. Myocutaneous flaps have the benefits of delivering good perfusion and oxygenation, facilitating the healing process of large perineal defect. However, this approach requires plastic surgeons and may cause additional complications (*e.g.*, a donor site hernia)[[14](#_ENREF_14)]. Mesh repair has the advantages of reducing operative duration, and accordingly, is more cost-effective compared to myocutaneous flaps[[21](#_ENREF_21)]. However, it should be noted that the inertness of biomesh might be a reason for small bowel obstruction[[22](#_ENREF_22)] and synthetic mesh carries potential for fistula formation[[23](#_ENREF_23)]. By contrast, omentoplasty with perineal closure represents a safer approach for reconstruction of the pelvic floor. Owing to its rich lymphovascular supply, the mobilized omentum in the pelvic cavity inhibits regional fluid collection, and hence prevents small intestine adhesion to the pelvic floor, dramatically reducing related complications[[24](#_ENREF_24)]. For some patients, this technique may not apply when it is technically not feasible to mobilize the omentum to reach the pelvic cavity, or the omentum has been resected previously.

The major strength of the modified primary closure method is the reconstruction of the pelvic peritoneum, which keeps the small intestine in the abdominal and pelvic cavities, thus avoiding adhesion to extraperitoneal tissues. In the present study, one case of intestinal obstruction in the biological mesh closure group appeared, which was caused by adhesion of the small intestine to the pelvic floor. However, probably due to insufficient study power, the rate of postoperative intestinal obstruction did not show any difference between the two groups. Compared with biological mesh closure, modified primary closure reduced postoperative hospital stay and total cost.

The pelvic floor is usually left open after APR because of the concern that incomplete closure of the pelvic floor may cause pelvic floor hernia and intestinal obstruction. However, APR per se is associated with clinically significant perineal hernia, albeit < 1% of the incidence[[23](#_ENREF_23)]. ELAPE requires extensive resection of the pelvic floor, and thus contributes to the development of perineal hernia, with an incidence of 2.8% *vs* 0.8% compared to traditional APR[[1](#_ENREF_1)]. As to LELAPE, perineal hernia could occur in nearly half of the patients without reconstruction of the pelvic floor[[25](#_ENREF_25)]. In LELAPE, closure of the pelvic peritoneum is more challenging because the distal rectum has not been removed at that time. When mobilizing the sigmoid and rectum, the peritoneum on both sides should be intentionally preserved for re-approximation of the pelvic peritoneum. One possible concern is that the intentionally preserved peritoneum may lead to compromised oncological outcomes. However, in the present study, the oncological outcomes did not show any difference between the two groups. The rectum should be transected at the sigmoidorectal junction area, or even lower if possible. A continuous suture with barbed thread is recommended to facilitate the procedure. In obese patients, the peripheral peritoneum should be dissected to reduce tension. The perineal wound was sutured directly in layers. No pelvic floor hernia and perineal hernia occurred in all of our patients with a mean follow-up of 12 mo. With regard to patients with rigid peritoneum after neoadjuvant radiotherapy or large pelvic peritoneum defect, this procedure may not be eligible and other reconstructive methods should be applied.

In conclusion, based on our preliminary experience, the modified primary closure method for reconstruction of the pelvic floor is technically feasible, safe and cost-effective. However, as the present study was retrospective, the safety and feasibility of this method still warrants high evidence level research.

**ARTICLE HIGHLIGHTS**

***Research background***

Laparoscopic extralevator abdominal perineal excision (LELAPE) has been introduced to reduce the rate of positive circumferential margin and intraoperative perforation, but its extensive dissection requires reconstruction of the pelvic floor.

***Research motivation***

To introduce a novel modified primary closure technique of LELAPE for low rectal cancer.

***Research objectives***

To assess the feasibility, safety and cost-effectiveness of the newly introduced technique by comparing with the traditional method.

***Research methods***

Data from 76 patients with rectal cancer undergoing LELAPE from March 2013 to May 2016 were retrospectively analyzed. Patients were classified into the modified primary closure group (32 patients) and the biological mesh closure group (44 patients). Total operating time, reconstruction time, postoperative stay, total cost, postoperative complications and tumor recurrence were compared

***Research results***

The modified primary closure of the pelvic floor requires longer reconstruction time but total operating time was not different compared with the biological mesh closure group. Postoperative length of hospital stay as well as the cost was less with the modified primary closure group. No difference in other perioperative data, long-term complications or oncological outcomes was observed.

***Research conclusions***

The modified primary closure method for reconstruction of the pelvic floor in LELAPE for low rectal cancer is technically feasible, safe and cost-effective.

***Research perspectives***

Future multicentered randomized controlled trials should be performed to confirm the conclusion in the present study.

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**P-Reviewer:** **S-Editor:** Wang XJ

**L-Editor:** **E-Editor:**

**Specialty type:** Gastroenterology and hepatology

**Country of origin:** China

**Peer-review report classification**

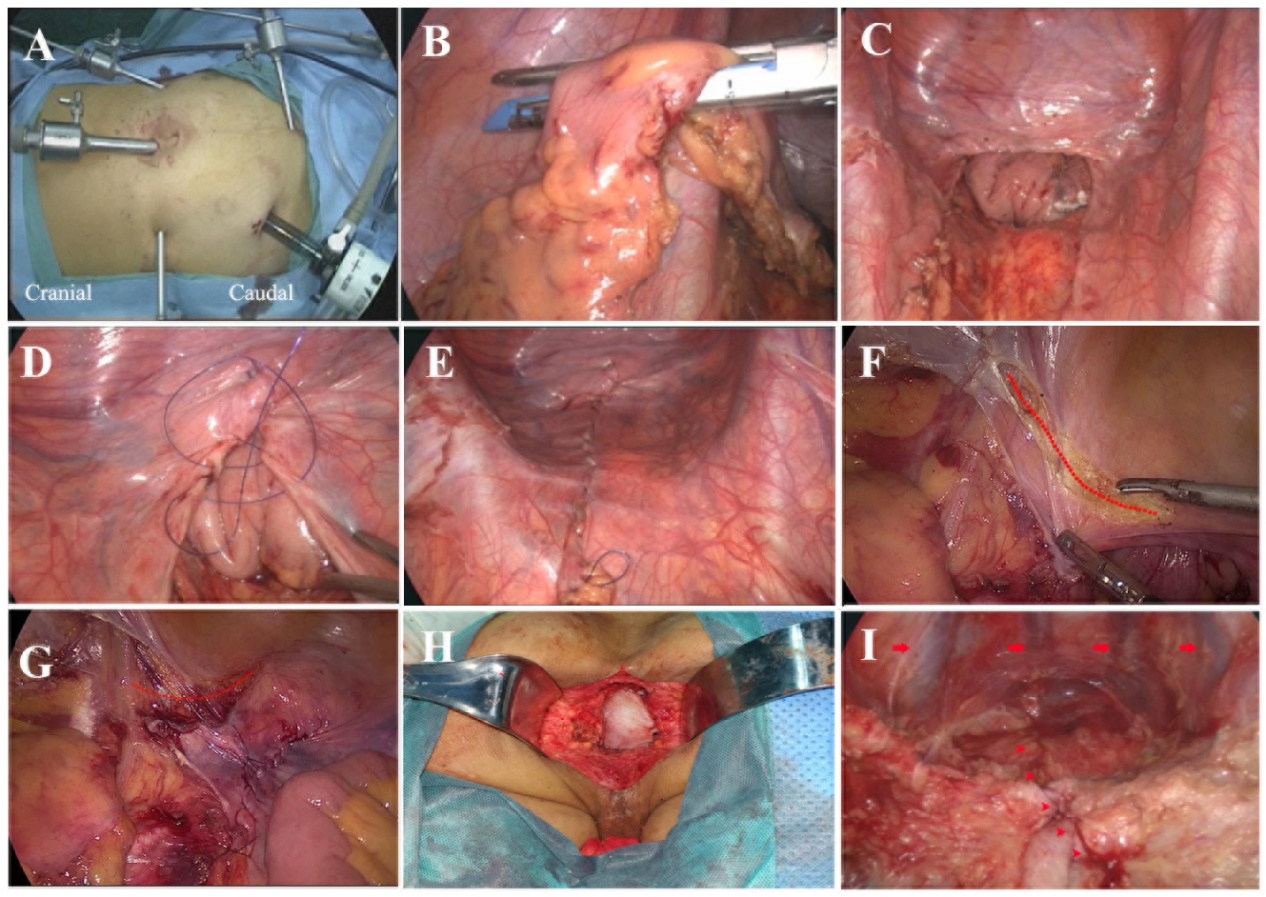
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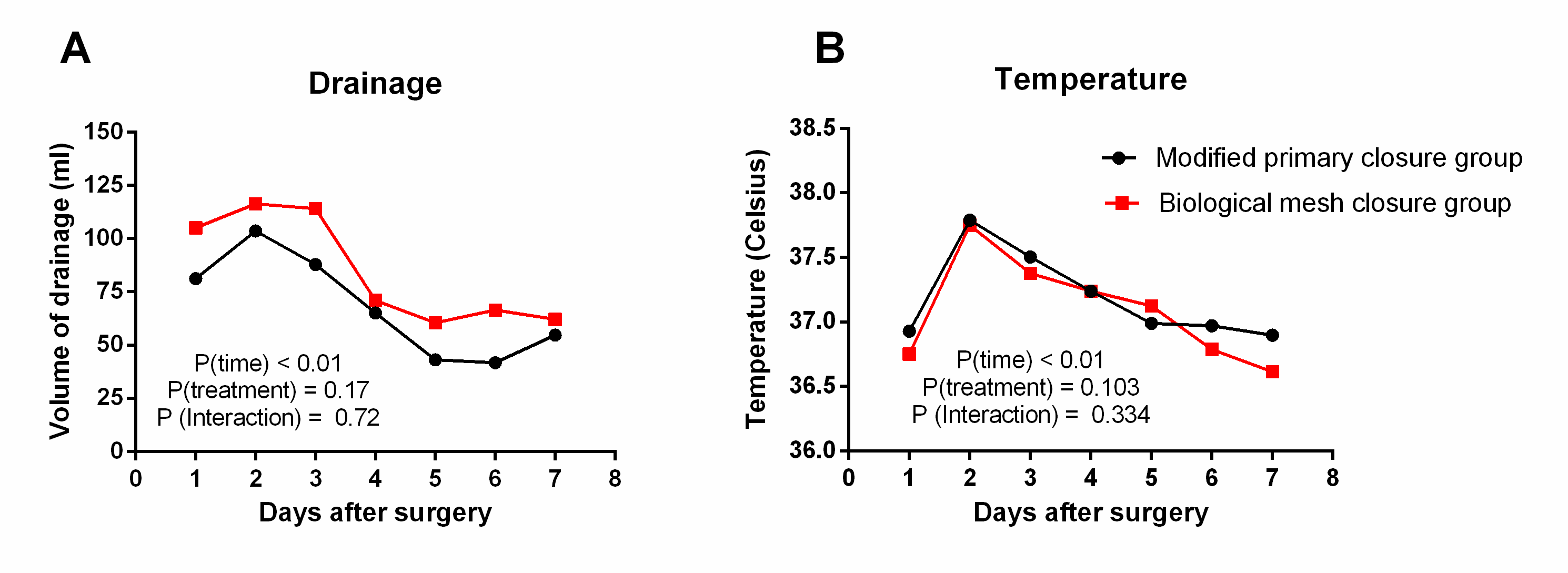
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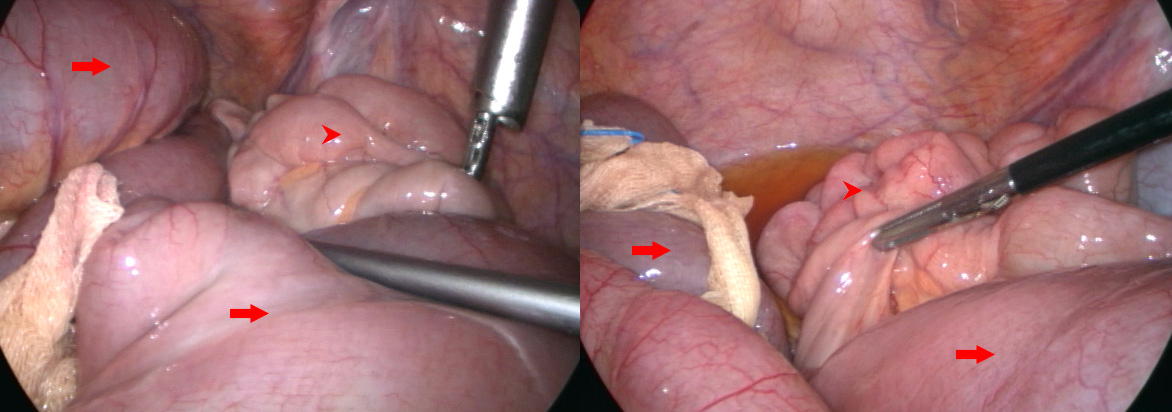
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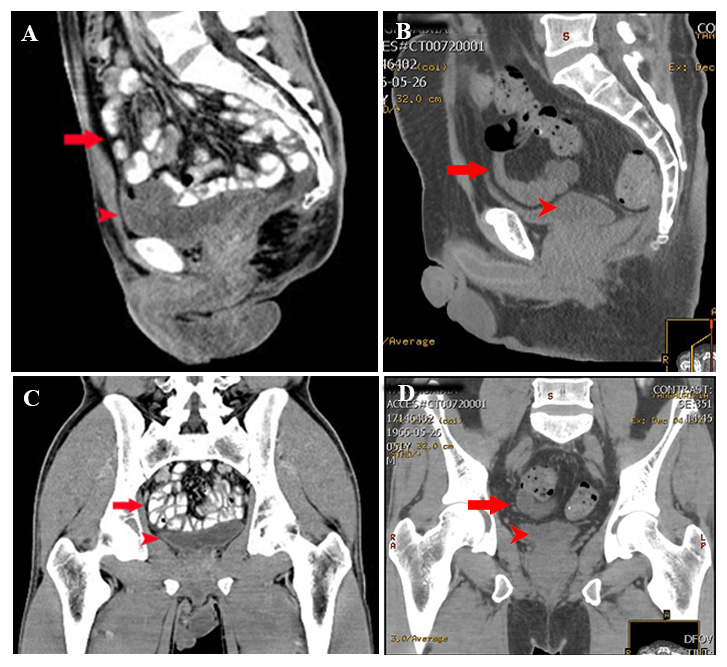
**Figure 1** **Surgical procedures**. A: Port placement; B: Transection of the rectum at the rectosigmoid junction with an ENDO-GIA; C: Distal rectum pushed down to the pelvis; D: Closure of the pelvic peritoneum with a continuous suture using a barbed thread; E: Closure of the pelvic peritoneum; F: Tension reduction of the adjacent peritoneum (dotted line shows the incised peritoneum); G: Closure of the peritoneum after tension reduction (dotted line shows the incised peritoneum); H: Reconstruction of the pelvic floor with biological mesh; I: View of the closed peritoneum from the perineal wound in the prone position (the arrows show the presacral veins, and the arrowheads show the closed peritoneum).

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**Figure 2** **Drainage and temperature changes.** A: Volume of the drainage postoperatively in the two groups; B: Temperature change postoperatively in the two groups.

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**Figure 3** **Laparoscopic exploration of the abdominal cavity in the patient with intestinal obstruction (arrow shows the proximal dilated small intestine, and arrowhead shows the distal normal small intestine).**



**Figure 4** **Postoperative MRI imaging.** A: Sagittal CT scan 12 mo postoperatively in the modified primary closure group; B: Sagittal CT scan 12 mo postoperatively in the biological mesh closure group; C: Coronal CT scan 12 mo postoperatively in the modified primary closure group; D: Coronal CT scan 12 mo postoperatively in the biological mesh closure group (arrow shows the small intestine, and arrowhead shows the bladder). MRI: Magnetic Resonance Imaging; CT: Computed tomography.

**Table 1 Baseline characteristics**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Modified primary closure**  **(*n* = 32)** | **Biological mesh closure**  **(*n* = 44)** | ***P* value** |
| Male/female | 24/8 | 31/13 | 0.662 |
| Age (yr) | 52.8 ± 12.2 | 58.2 ± 12.5 | 0.137 |
| BMI | 26.8 ± 3.2 | 25.7 ± 2.7 | 0.097 |
| Neoadjuvant therapy | 8 | 7 | 0.326 |
| Tumor location, Distance to anal verge (cm) | 2.6 ± 0.8 | 2.8 ± 0.9 | 0.278 |
| Postoperative TNM staging |  |  |  |
| II | 23 | 29 | 0.581 |
| III | 9 | 15 |

BMI: Body mass index.

**Table 2 Perioperative data**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Modified primary closure**  **(*n* = 32)** | **Biological mesh closure**  **(*n* = 44)** | **P value** |
| Reconstruction time (min) | 14.6 ± 3.7 | 7.2 ± 1.9 | < 0.001 |
| Total operative time (min) | 236 ± 20 | 248 ± 43 | 0.143 |
| Intraoperative blood loss (mL) | 165 ± 57 | 149 ± 52 | 0.242 |
| Positive CRM | 0 | 0 | N/A |
| Bowel perforation | 0 | 1 | 1.000 |
| Recovery of bowel function (h) | 22.8 ± 4.7 | 23.6 ± 5.0 | 0.475 |
| Intestinal obstruction | 0 | 1 | 1.000 |
| Drainage removal (days after surgery) | 6.6 ± 1.1 | 7.3 ± 2.0 | 0.094 |
| Postoperative hospital stay (d) | 8.1 ± 1.9 | 10.1 ± 2.8 | 0.001 |
| Cost (USD) | 9297 ± 1260 | 10719 ± 2360 | 0.003 |

CRM: Circumferential margin.

**Table 3 Follow-up data**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Modified primary closure (*n* = 32)** | **Biological mesh closure (*n* = 44)** | ***P* value** |
| Normal perineal wound healing1 |  |  |  |
| 10 d postoperatively | 29 | 39 | 0.546 |
| 30 d postoperatively | 27 | 41 | 0.270 |
| 60 d postoperatively | 32 | 44 | 1.000 |
| Perineal wound infection | 5 | 5 | 0.734 |
| Clear or haemoserous discharge | 3 | 1 | 0.304 |
| Pus/purulent discharge | 1 | 2 | 1.000 |
| Deep infection with or without tissue break down | 1 | 2 | 1.000 |
| Perineal hernia (at 12 mo postoperatively) | 0 | 0 | N/A |
| Feeling of bulge (at 12 mo postoperatively) | 4 | 2 | 0.233 |
| Postoperative chemotherapy | 23 | 28 | 0.330 |
| Postoperative radiotherapy | 7 | 14 | 0.339 |
| Local recurrence (at 12 mo postoperatively) | 0 | 1 | 1.000 |
| Liver/lung metastasis (at 12 mo postoperatively) | 2 | 3 | 1.000 |
| Death (at 12 m postoperatively) | 0 | 0 | N/A |

1Grade 0 or Grade I by the Southampton Wound Scoring System.