



The Effectivity of Laparoscopic-Dominant Individualized Levator-Ani Resection: A Retrospective Study

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Abstract

Objective: To investigate if Laparoscopic-Dominant Abdominoperineal Resection with individualized levator-ani resection (LDAPR) inhibits local recurrence and prolongs survival compared to Laparoscopic Abdominoperineal Resection (APR).

Methods: Rectal cancer surgery cases were retrospectively identified from September 2014 to December 2019. LDAPR treated group (55 patients) and the APR-treated group (71 patients) were included in the study. The operation time, Circumferential Resection Margin (CRM), Intraoperative tumor Perforation (IOP), postoperative complications, the two-year overall survival and local recurrence were compared in the two groups.

Results: The CRM and IOP were significantly reduced in the LDAPR compared to the APR group (3.6% vs. 16.9%, $t=5.522$, $P=0.019$; 3.6% vs. 14.1%, $t=3.926$, $P=0.048$). In terms of postoperative complications, the incidence of urinary retention in LDAPR was significantly reduced than the APR group (10.9% vs. 25.4%, $\chi^2=4.139$, $P=0.041$). Similarly, perineal pain at 6 months or 1 year after surgery was significantly down-regulated in LDAPR than in the APR group (72.7% vs. 88.7%, $\chi^2=5.320$, $P=0.021$; 18.2% vs. 43.2%, $\chi^2=8.288$, $P=0.004$). However, there was no statistically significant difference in the postoperative complications between the LDAPR and APR groups. Finally, LDAPR led to a significantly improved two-year overall survival and a reduced local recurrence compared to APR.

Conclusion: LDAPR reduce CMR, IOP, and local recurrence and simplified the perineum operation, subsequently protecting the pelvic autonomic nerves. Compared to the conventional APR, LDAPR is a promising procedure worth adopting for rectal cancer treatment.

Keywords: Abdominoperineal resection; Individualized levator-ani resection; Local recurrence; Low rectal cancer

Introduction

Low rectal cancer refers to malignant rectal tumors within 5 cm from the anal verge. Currently, surgery remains the main treatment method for common rectal cancer, with Abdominal Perineal Resection (APR) being the standard surgical procedure [1,2]. The use of the APR lies in the ability to remove the low tumor, related lymphoid tissue, and the elaborate structures from the deep pelvis [3]. The APR indications include ultra-low rectal cancer growths with the inability to obtain a negative distal margin, external sphincter involvement or the levator-ani complex invasion [4]. The patients with poor baseline function of the sphincter with rectal cancer are also well-suited to receive abdominoperineal resection.

However, despite the major progress in the multidisciplinary treatment approach to rectal cancer, about 40% of rectal cancer patients will undergo an abdominoperineal resection, resulting in a permanent colostomy [5]. In recent years, Holm et al. [6] reported a new surgical method for treating low rectal cancer, namely Extra Levator Abdominoperineal Excision (ELAPE) combined with different levator-ani. The surgical confluence plane is at the origin of the levator-ani muscle. The levator-ani muscle is completely removed, making the surgical specimen columnar, avoiding

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the formation of surgical waste, and reducing the positive rate of CRM and intraoperative perforation [7]. Nevertheless, because of extended resection, ELAPE surgery may lead to more complications such as sexual dysfunction, urination dysfunction, chronic perineal pain, and perineal hernia [8,9]. Due to the disadvantages of APR and ELAPE surgery, new technology is needed to avoid adverse surgical effects and complications.

Here, we propose a new method of combined abdominal and perineal resection, that is, individualized resection of the levator-ani muscle guided by laparoscopy to reduce the positive rate of CRM and IOP, reduce local recurrence, and simplify the operation of the perineum. Additionally, we provide evidence that LDAPR is a safe technology for rectal cancer. The primary endpoints were CRM (+), IOP, 2-year overall survival (2-year OS), and 2-year local recurrence (2-year LR). The secondary endpoints were the postoperative complications.

Materials and Methods

This study used medical records of rectal cancer surgery cases from September 2014 to December 2019. The experimental group included patients who had undergone laparoscopic-led individualized levator-ani resection from January 2017 to December 2019, while the control group included patients who had received laparoscopic conventional APR surgery from September 2014 to December 2016. The ethics committee of Zhangzhou Municipal Hospital Affiliated of Fujian Medical University approved this retrospective investigation and waived the regulations of informed consent due to the design of the study.

Inclusion criteria

Solitary rectal adenocarcinoma or carcinoma diagnosed by colonoscopy and biopsy, and the anus could not be preserved; the high-resolution MRI staging below T3a, and some T3b and T3c patients were reduced after neoadjuvant chemoradiotherapy; age <75 years old; no local infection such as anal fistula and perianal abscess; no severe cardiopulmonary, liver, and kidney dysfunction; laparoscopic surgery; no sexual dysfunction and urination before abnormal surgery function.

Exclusion criteria

Postoperative pathological findings of non-adenocarcinoma such as signet ring cell carcinoma and malignant melanoma; medical records of T4 stage; patients with distant metastasis or local inability to undergo R0 resection, but palliative resection is performed; Transition to laparotomy.

Surgical methods

Abdominoperineal resection (APR): The operation is divided into two phases; the abdominal and perineal phases. The abdominal phase is done according to the conventional surgical procedures that target the Total Mesorectal Excision (TME) plane. It follows the principle of LAR in laparoscopic anterior rectotomy that ensures the separation of the left Toldt space. The lymph nodes at the inferior mesenteric artery and the root of the vein are dissected at a high position and ligated. The mesorectum is later freed to the sacral promontory, separated along with the retrorectal space to the level of the levator-ani hiatus, and the separation is confirmed by touching the bony sense of the tip of the coccyx using an ultrasonic knife. Next, both sides of the mesorectum are further separated along the holy plane. The separation reaches the starting point of the levator-ani

fissure (both sides).

The peritoneum is incised in an arc at 0.5 cm on the peritoneal reflex line to ensure the integrity of the Denonvillier's fascia. In male patients, the Denonvilliers fascia needs to be transected when the sharp separation reaches the upper border of the prostate. In women, the strong separation can be performed directly along the Denonvillier fascia's surface to the levator hiatus's upper edge. The procedure results in complete separation of the terminal mesentery of the rectum. The sigmoid colon, located 15 cm from the proximal end of the tumor, is cut off with a laparoscopic linear incision and a closure device. The proximal colon is finally pulled out of the left lower abdomen for a permanent stoma.

Perineal phase: The anus is closed with a double purse suture. An oval incision is made at the key point of the perineal body in front of the anus, the tip of the coccyx at the rear, and on both sides of the medial border of the ischial tubercle. The subcutaneous tissue is incised layer by layer. The anococcygeal ligament is then cut in front of the tip of the coccyx, and the abdominal group is joined. The anterior wall of the anal rectal canal is then separated from the rectus muscle, the urethra and the prostate (posterior vaginal wall in women). This also enables the removal of the distal sigmoid colon and an eventual anal tissue perineal incision. The wound surface is left to undergo hemostasis, and then flushed. The perineal incision is finally sutured in a layer by layer pattern without closing the pelvic floor peritoneum.

Laparoscopic-dominant abdominoperineal resection with individualized levator-ani resection (LDAPR)

In the abdominal phase, the mesorectum is surgically freed to the levator-ani muscle insertion level similar to the APR group. The coccygeal anus ligament is removed under laparoscopic direct vision, and then the extent of levator-ani muscle resection is determined according to the tumor location and degree of invasion. The tumor is confined to T2, and the levator-ani muscle is cut and dissociated from a distance of 1.5 cm from the insertion point of the levator-ani muscle. The levator-ani muscle on the healthy side is preserved if there is no invasion on the contralateral side. All the levator-ani muscles on the affected side are resected in case the tumor invaded more than T3.

The healthy levator-ani muscle is preserved on the opposite side without invasion. If the tumor invades both sides, the scope of resection of the levator-ani muscle on both sides is determined according to the above method, and the depth of tumor invasion is also assessed. Part of the prostate and vagina could be removed if the anterior rectal wall tumor involved the anterior pelvic fascia. The coccyx tip would be removed together if the posterior wall tumor invaded the presacral fascia. There is no need to change the patient's position in the perineal group.

The surgical incision is made in a similar manner as described for the APR (control) group. Because the space between the levator-ani muscle and the perianal fat has been removed in the abdominal group, only the subcutaneous tissue and the perianal fat area need to be incised (the ischioanal fossa fat tissue is not completely removed) because it is very easy to join the abdominal group. The specimen is then held in one hand, and the rectourethral muscle and puborectalis muscle are cut off under the guidance of the fingers and separated from the urethra and prostate (the posterior wall of the vagina in women). For reconstruction, the perineal incision is finally

reconstructed through layer by layer suturing without closing the pelvic floor peritoneum.

The general data of the patients in these two groups were compared, including gender, age, BMI, distance from the inferior tumor to the anal verge (cm), tumor location, neoadjuvant therapy, ASA grading, pathological differentiation, p-T\N staging. Additionally, these two groups' operation conditions and postoperative recovery indicators were also compared, including operation time, intraoperative blood loss, postoperative to discharge time, positive IOP, and CRM (+). The postoperative complications of the two groups were also analyzed, including abdominal bleeding, chylous leakage, SSI, perineal incision healing, intestinal obstruction, pulmonary infection, deep vein thrombosis, urinary retention, perineal pain and discomfort. Finally, the 2-year overall survival and 2-year local recurrence were determined.

Statistical analysis

Data were analyzed using SPSS25.0 (SPSS Inc., Chicago, IL, USA). The normal distribution of the continuous data was tested by Shapiro–Wilk normality test and evaluated through an unpaired Student's t-test. Qualitative data were expressed by rate, and the comparison between groups was analyzed by chi-square test. Survival was determined using Kaplan-Meier analysis. P<0.05 was defined as a statistically significant difference.

Results

According to the inclusion and exclusion criteria, 55 LDAPR and

71 APR cases were selected. There were 55 males and 71 females. The average age of LDAPR and APR were 58.07 ± 12.19 and 58.11 ± 12.74 years, respectively. There was no significant difference in general data including the tumor location, distance from the anal verge, ASA scoring, pre-operative-T staging and pre-operative-N staging between the LDAPR and the APR groups (P>0.05) (Table 1).

Only 2 patients in the LDAPR group had CRM (+), which was significantly lower than that in the APR group, as shown in Table 2. The number of positive IOP in the LDAPR group was also significantly lower than that in the APR group. There was no statistically significant difference in the operation time, intraoperative blood loss, and postoperative hospital stay between the LDAPR and the APR group (P>0.05).

Table 2: Surgery data.

	LDAPR	APR	t/χ ²	P value
CRM				
Positive	2 (3.6)	12 (16.9)	5.522	0.019
Negative	53 (96.4)	59 (83.1)		
IOP				
Negative	53 (96.4)	61 (85.9)	3.926	0.048
Positive	2 (3.6)	10 (14.1)		
Surgery time (min)	138.53 ± 15	147.82 ± 30.31	-1.785	0.077
Blood loss (ml)	51.45 ± 25.49	56.62 ± 28.63	-1.053	0.294
Postoperative hospital stay (d)	6.45 ± 1.21	6.66 ± 1.25	-0.934	0.352

Table 1: General patients' information.

	LDAPR	APR	t/χ ²	P value
Gender, M	20 (46.4)	35 (49.3)	2.11	0.147
Age (year)	58.07 ± 12.19	58.11 ± 12.74	-0.018	0.986
BMI kg/m ²	21.23 ± 2.65	21.08 ± 3.14	0.278	0.782
Tumor Location				
Back	9 (16.4)	8 (11.3)	0.421	0.24
Front	8 (14.5)	8 (11.3)		
Right	25 (45.5)	26 (36.6)		
Left	13 (23.6)	29 (40.8)		
Distance from anal verge (cm)	2.28 ± 0.94	2.01 ± 1.08	1.232	0.22
Neoadjuvant therapy				
No	45 (81.8)	63 (88.7)	1.21	0.271
Yes	10 (18.2)	8 (11.3)		
ASA scoring				
I	29 (52.7)	33 (46.5)	0.508	0.776
II	18 (32.7)	27 (38.0)		
III	8 (14.6)	11 (15.5)		
Preoperative-T staging				
T1	15 (27.3)	19 (26.7)	3.69	0.158
T2	15 (27.3)	30 (42.3)		
T3	25 (45.4)	22 (31.0)		
Preoperative-N staging				
N0	27 (49.1)	30 (42.3)	2.58	0.275
N1	25 (45.5)	31 (43.7)		
N2	3 (5.4)	10 (14.0)		

Table 3: Postoperative complications.

	LDAPR (%)	APR (%)	χ ²	P value
SSI				
No	44 (80.0)	57 (80.3)	0.002	0.969
Yes	11 (20.0)	14 (19.7)		
Perineal incision infection				
No	50 (90.9)	63 (88.7)	0.159	0.69
Yes	5 (9.1)	8 (11.3)		
Intestinal obstruction				
No	49 (89.1)	65 (91.5)	0.217	0.641
Yes	6 (10.9)	6 (8.5)		
Lung infection				
No	52 (94.5)	67 (94.4)	0.002	0.965
Yes	3 (5.5)	4 (5.6)		
Deep vein thrombosis				
No	52 (94.5)	66 (93.0)	0.131	0.717
Yes	3 (5.5)	5 (7.0)		
Urinary retention				
No	49 (89.1)	53(74.6)	4.193	0.041
Yes	6 (10.9)	18 (25.4)		
Perineal pain (6-month after surgery)				
No	15 (27.3)	8 (11.3)	5.32	0.021
Yes	40 (72.7)	63 (88.7)		
Perineal pain (1-yera after surgery)				
No	45 (81.8)	41 (57.7)	8.288	0.004
Yes	10 (18.2)	30 (42.3)		

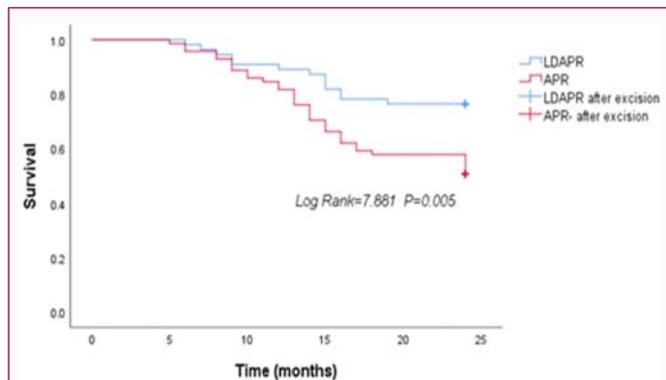


Figure 1: Kaplan-Meier curve of two-year overall survival in the LDAPR and APR groups.

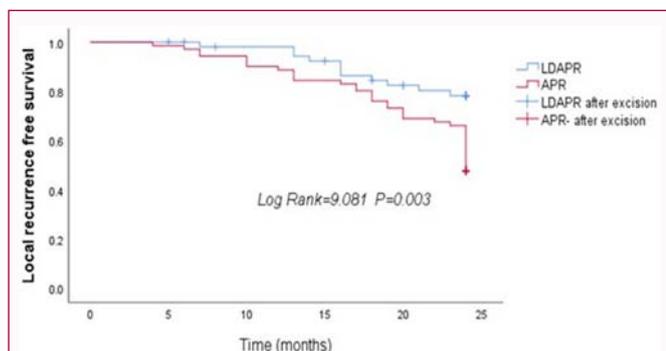


Figure 2: Kaplan-Meier curve of local recurrence in both the LDAPR and APR groups.

In addition, all patients in both the groups had a smooth recovery after the operation, and no deaths were reported, as shown in Table 3. There was no statistically significant difference in SSI, poor healing of the perineal incision, intestinal obstruction, pulmonary infection, and deep vein thrombosis between the LDAPR and APR groups (all $P > 0.05$). However, the LDAPR group had significantly lower urine retention and perineal pain compared to APR group ($\chi^2 = 4.193$, $P = 0.041$). We later made a two-year analysis of overall survival and local recurrence in both the LDAPR and the APR groups. According to our results, the LDAPR group demonstrated a significantly higher overall survival and local recurrence than the APR group. ($P < 0.05$), as shown in Figure 1 and Figure 2.

Discussion

Since the abdominal perineum combined with rectal resection (APR) was proposed in 1908, it has been used for 100 years as a standard surgical method to treat low rectal cancer [10]. The confluent plane of the abdominal perineum in APR surgery is at the levator-ani hiatus, and the mesorectum is cut at the insertion point of the levator-ani muscle so that the surgical specimen presents a narrow wasp waist shape in the lower part of the rectum (Figures 3a-3c), which is called the surgical waist. The surgical waist is precisely the high incidence area of surgical perforation and CRM positive rate [11,12]. According to a previous report, an analysis of 373 APR surgical samples in the Dutch TME trial found 13.7% of IOP and a 30.4% rate of CRM (+) cases [5]. Almost similar observations were made by Marr et al. [13] and Wibel et al. [14]. These findings showed that positive CRM and high IOP are independent risk factors for local recurrence after APR.

In recent years, Holm et al. [6] reported a new surgical method for

treating low rectal cancer, namely Extra Levator Abdominoperineal Excision (ELAPE) combined with different levator-ani. The surgical confluence plane is at the origin of the levator-ani muscle. The levator-ani muscle is completely removed, making the surgical specimen columnar, avoiding the formation of surgical waste, and reducing the positive rate of CRM and intraoperative perforation [7]. However, due to the extensive resection range, the complete resection of the levator-ani muscle and the ischioanal fossa fat makes perineal complications such as sexual dysfunction, urination dysfunction, and chronic perineal pain, and perineal hernia more complex than traditional APR surgery [15]. In addition, this combination surgery procedure involves a complex pelvic floor reconstruction technology and expensive an Acellular Dermal Matrix (ADM) patch, thus cannot be easily adopted in primary hospitals.

Our team evaluated the relevant evidence-based medical records and assessed advantages and disadvantages of traditional APR and ELAPE surgery. We propose a new combined abdominal and perineal resection method, Laparoscopic-Dominant Abdominoperineal Resection with personalized levator-ani resection (LDAPR). Different stages and positions are used to determine the resection range of the levator-ani muscle, reducing the amount of perineal tissue resection while ensuring the safety of the incision margin (Figures 4a-4c). We retrospectively compared the clinical data of LDAPR and APR. The CRM (+) of the two groups was 3.6% vs. 16.9%, ($t = 5.522$, $P = 0.019$), and the IOP was 3.6% vs. 14.1%, ($t = 3.926$, $P = 0.048$), with statistical significance of $P < 0.05$. On the 2-year local recurrence rate, LDAPR significantly reduced the local recurrence rate compared to the APR treatment. Further, compared with APR, the LDAPR has obvious advantages in CRM (+) and IOP, similar to the results of several ELAPE studies [7]. LDAPR reduced CRM (+), IOP, 2-year local recurrence, and increased 2-year overall survival.

The confluent plane of APR is at the insertion point of the levator-ani muscle, and the operation of the perineum has a poor visual field. Once the bleeding is blindly clamped, it is easy to damage the pelvic nerve, resulting in urinary retention, perineal pain, sexual dysfunction, and other related symptoms of pelvic nerve injury. ELAPE achieves oncological safety through extended resection, but its damage to the pelvic nerve is huge. Several studies have found that ELAPE can increase sexual dysfunction and urinary retention [15-17]. The symptoms of pelvic nerve injury are complex and diverse, and common manifestations include urinary retention, perineal pain, and sexual dysfunction.

The incidence of urinary retention in LDAPR is significantly lower than that in APR (10.9% vs. 25.4%, $\chi^2 = 4.139$, $P = 0.041$), and perineal pain is significantly lower than APR at 6 months or 1 year after operation, with statistical significance of 72.7% vs. 88.7%, ($\chi^2 = 5.320$, $P = 0.021$) and 18.2% vs. 43.2%, ($\chi^2 = 8.288$, $P = 0.004$). LDAPR reduces the occurrence of urinary retention and perineal pain, which may be attributed to the reduction of levator-ani muscle resection to avoid excessive resection and the protection of pelvic nerves under laparoscopic direct vision. International large-scale clinical trials have confirmed the application of the laparoscopic technique in rectal cancer in terms of the radical cure of the tumor and the safety of surgery [18-21]. Technically, laparoscopy requires less space for operation, enlarges the operative field, and is more flexible in operating low rectal cancer radical resection. In addition, under laparoscopic direct vision, the levator-ani muscle has a clear field of vision, blood vessels and nerves are visible, and the operation

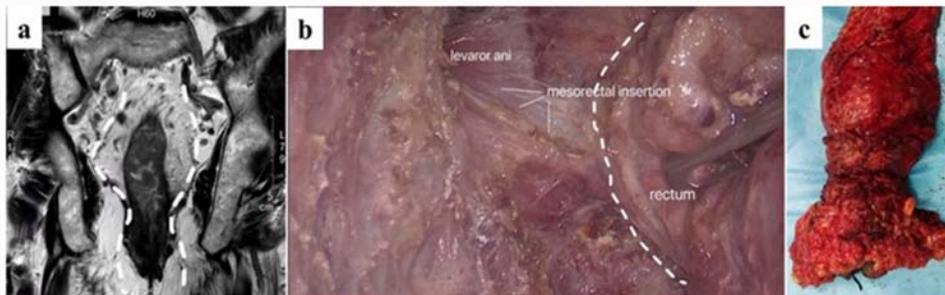


Figure 3: Demonstration of the APR surgery cut line. a) MRI image b) Surgery picture c) Surgical specimen.

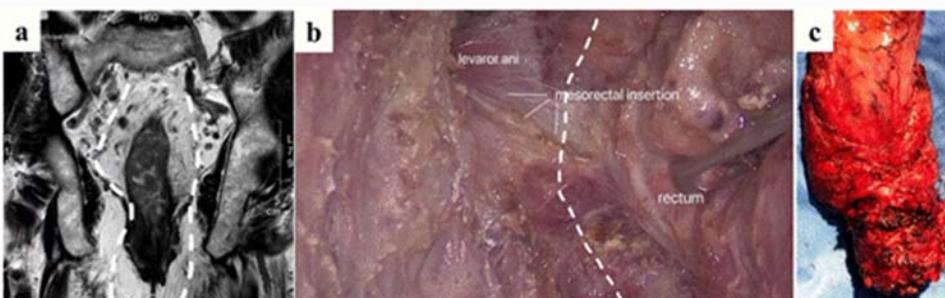


Figure 4: Demonstration of the LDAPR surgery outline. a) MRI image b) Surgery picture c) Surgical specimen.

is accurate. Blind clamp resection of the perineal approach is avoided, which is more conducive to protecting pelvic vessels and autonomic nerves.

Since the implementation of LDAPR surgery in 2017, our team has found that individualized excision of the levator-ani muscle under laparoscopic direct vision and avoiding the removal of the levator-ani muscle through the perineal approach can reduce the damage to the nerve collateral caused by poor visual field [22]. Maximizing the protection of the pelvic autonomic nerves related to urination and sexual function is also important in reducing the incidence of IOP and perineal complications. In addition, the confluent plane of the abdomen and perineum is reduced to the ischioanal fossa fat, and the perineal surgery group can easily reach the same level as the abdominal group. In LDAPR, there is no need to change the surgical position.

The surgical process is simplified, and individualized excision of the levator-ani can reduce the amount of perineal tissue resection, reduce the perineal defect, and directly suture the pelvic floor to avoid pelvic floor reconstruction. Further, during the implementation of LDAPR, much attention should be paid to the following issues: There is no standard for how much the levator-ani muscle should be removed, that is, the issue of safe incision margins. Our team cut off the tumor within T2 at 1.5 cm from the insertion point of the levator-ani muscle. In the T3 stage, all the levator-ani muscle is removed. Hence, it is unknown whether the scope can be further reduced.

Further studies should be done to clarify whether T0 tumor can further reduce the size of the levator-ani muscle resection. In this study, we did not close the pelvic floor peritoneum because of the risk of hiatal hernia, but there may be a pelvic floor hernia if the pelvic floor peritoneum is not completed. Whether the pelvic floor peritoneum should be closed also deserves further investigation. Preoperative accurate staging is the premise of individualized levator-ani resection, which requires routine high-resolution MRI and

intrarectal ultrasonography before LDAPR surgery is carried out to understand preoperative staging and guide surgery accurately.

There are some limitations to this study. First, a single-centre retrospective study with a small number of cases in this study may affect the survey results to a certain degree. Second, this study only compared overall survival and local recurrence two years after surgery and lacked long-term follow-up results. Further, we only studied perineal pain in pelvic autonomic dysfunction, which did not study sexual dysfunction.

Conclusion

In conclusion, LDAPR can effectively reduce the positive rate of CMR and IOP, minimize local recurrence, and simplify the operation of the perineum, which is beneficial to the protection of pelvic autonomic nerves. Consequently, adopting LDAPR is necessary for low rectal cancer surgery. However, more research remains necessary for the continuous improvement of LDAPR, and the long-term oncological effects require further follow-up exploration.

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