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Original Article

Retrospective study on the effect of laparoscopic and open total mesorectal excision for middle/low T3 rectal cancer

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Abstract: Objective: This study aimed to discuss the feasibility, safety, eradication effect, short-term outcomes, and mid- to long-term survival rates of laparoscopic total mesorectal excision (TME) in treating middle/low T3 rectal cancer. Methods: Patients with middle/low T3 rectal cancer that received an operation in our hospital from January 2009 to December 2012 were nonrandomly divided into laparoscopic and laparotomic groups. Comparative analysis was carried out to compare the clinical data and postoperative follow-up results of the two groups. Results: In the laparoscopic group, 85 cases were treated with laparoscopic TME without transfer to laparotomy. In the laparotomic group, 102 cases were treated with traditional TME. No significant difference was found between the two groups in average operation duration, resection range, postoperative complications, and length of hospital stay. However, the intraoperative blood loss and postoperative recovery of intestinal functions of the laparoscopic group were better. The median follow-up times for all cases, laparoscopic group, and laparotomic group were 23 (6-52), 21, and 24.5 months, respectively. The rates of local recurrence, distant metastasis, and tumor-free survival showed no significant difference between the two groups during the follow-up period. Conclusions: Laparoscopic TME can eradicate tumors with equal effect as laparotomic surgery and deserves to be popularized in clinical applications.

Keywords: Laparoscopy, total mesorectal excision (TME), T3 rectal cancer, mid- and long-term survival rate

Introduction

Total mesorectal excision (TME) was first proposed by Heald et al. [1] in 1982. A series of researches has confirmed that TME can lower local recurrence and increase survival rate. Therefore, TME is considered as the standard surgical method for treating low rectal cancer and ultra-low rectal cancer [2, 3].

Since the 1990s, laparoscopy has been applied to assist in the treatment of malignant colorectal neoplasms. Some prospective comparative studies [4-8] confirm the clinical feasibility and safety of laparoscopic colorectal surgery. However, the feasibility and safety of laparoscopic TME for treating middle or low rectal cancer is uncertain. Whether laparoscopic surgery can achieve eradication effect and increase mid- and long-term survival rates also remain undetermined.

The muscular and serosal layers of the rectal wall can hinder the transfer and spread of cancer cells to some extent. The serosal layer has more abundant lymphatic vessels than the muscular layer. Once tumors penetrate the serosal layer, the surrounding tissues, blood vessels, and lymphatic vessels become highly vulnerable. Thus, the probability of tumors entering and metastasizing to the lymphatic vessels is increased [9]. The depth of invasion of T3 rectal cancer is between the muscular and serosal layers. Once the range of invasion exceeds the serosal layer and reaches the surrounding or distant organs, the best timing of radical excision is missed.

This retrospective study compared laparoscopic surgery with traditional open surgery to evaluate the feasibility, safety, eradication effect, short-term outcomes, and mid- and long-term outcomes of these two methods in treating mid-

Table 1. Demographic data of the LAP group and OPEN group

	LAP (*n*=85)	OPEN (*n*=102)	*P*
Age (years)	62.14 ± 14.67 (23-92)	60.37 ± 12.30 (32-87)	0.293
Male/female	55:30	69:33	0.672
Distance from tumor to the anal verge	7.30 ± 3.01 (3-15)	7.24 ± 2.59 (2-15)	0.983
>7 cm (n)	48	61	0.645
>7 cm (*n*)	37	41	
Tumor staging			
Stage III	46	57	0.809
Stage III	39	45	

dle/low T3 rectal cancer, so as to provide a clinical basis for the application of laparoscopic surgery in treating T3 rectal cancer.

Material and methods

Study population

From January 2009 to December 2012, 187 consecutive patients with middle/low rectal cancer underwent TME operations at Department of General Surgery, Shanghai Ruijin hospital, Shanghai Jiaotong University School of medicine. They all enroll in the retrospective study. The demographic data such as age, gender, histological information such as distance from the distal margin of tumor to the anal verge, and clinical stage of the tumor, surgery data such as method of surgery, postoperative complications, surgery cost, and follow-up data including local recurrence rate, distant metastasis were collected. According to the surgery method, the 187 cases were divided into two treatment groups, i.e. laparoscopic (LAP) and open (OPEN) groups. Written informed consents were obtained from each patient before the operation and the institutional review board approval was obtained before the initiation of this review. The study was approved by the Ethics Committee of Ruijin Hospital, Shanghai Jiaotong University School of Medicine.

Operation

Surgery of patients in both groups was carried out by two groups of surgeons with the purpose of tumor eradication (tumor-free technique or radical excision with sufficient surgical margin) and TME (Heald et al. 1982). The surgical methods included anterior resection of the rectum and abdominoperineal resection of the rectum. Before operation, cathartics and oral antibiotics were administered for bowel preparation in both groups. Intravenous-inhalational anesthesia was performed.

Postoperative treatment and following-up

All patients started to receive adjuvant chemotherapy (5-FU/CF or FOLFOX4) 4 weeks postoperatively. Oral Xeloda was administrated for some patients who were unwilling to receive intravenous chemotherapy. Follow-up was conducted once every 2-3 months in the first 2 years after surgery, and once every 6 months from the third year. The survival status, local recurrence or distant metastasis, and time of recurrence were investigated. Rates of local recurrence, distant metastasis, survival, and tumor-free survival were compared between the two groups.

Statistical methods

All samples were analyzed using normality test by SPSS 13.0. The indicator was expressed as the mean (range), or $\bar{x} \pm s$ when data were distributed normally. Paired comparison of means was performed with Mann-Whitney *U* test and grouped *t* test, and multi-group comparison was performed with Kruskal-Wallis *H* test. Rates were compared with the x^2 test. Survival rates were calculated using the Kaplan-Meier method and compared with the log-rank test. $P < 0.05$ was considered statistically significant.

Results

For this retrospective study, 187 cases were recruited, including 85 cases in the laparoscopic group and 102 cases in the open group. General data showed no significant difference between the two groups (**Table 1**).

Table 2. Comparison of postoperative complications between LAP and OPEN group

	LAP (*n*=85)	OPEN group (*n*=102)	χ^2	*P*
Hemorrhage	4 (4.71%)	5 (4.90%)		
Incision infection	4 (4.71%)	4 (3.92%)		
Urinary retention	0	3 (2.94%)		
Urinary tract infection	1 (1.12%)	3 (2.94%)		
Pulmonary infection	1 (1.12%)	0		
Intestinal obstruction	0	4 (3.92%)		
Anastomotic leakage[a]	5 (5.88%)	3 (2.94%)		
Pelvic effusion	2 (2.35%)	2 (1.67%)		
Rectovaginal fistula	0	1 (0.98%)		
Infection of deep vein[b]	0	4 (3.92%)		
Others[c]	1 (1.12%)	1 (0.98%)		
Total incidence	16 (18.82%)	26 (25.49%)	1.18	0.277

Notes: a. In the laparoscopic group, two cases of anastomotic leakage were complicated by hemorrhage and incision infection, respectively. b. In the open group, three cases of infection of deep vein were complicated with anastomotic leakage (two cases) and acute kidney failure (one case). c. One case of diabetic ketoacidosis was found in the laparoscopic group and one case of acute kidney failure was found in the open group.

Operation treatment and post-operative recovery

None of the 85 cases treated with laparoscopic TME were transferred to laparotomy. In the laparoscopic group, 66 cases received anterior resection of the rectum, whereas the other 19 cases received abdominoperineal resection of the rectum. Laparotomic TME was carried out for the 102 cases in the open group. A total of 76 cases received anterior resection of the rectum, and 26 cases received abdominoperineal resection of the rectum. The rates of sphincter preservation were 60.4% (29/48) and 57.4% (35/61) cancer in the two groups, respectively. The difference was not significant (x^2=0.102, *P*=0.749).

The average lengths of specimens excised in the laparoscopic group and open group were 14 (9-30) cm and 15 (8-35) cm, respectively (*P*=0.293). The maximum diameter of the tumor was 4 (1.8-10) cm in the laparoscopic group and 4 (1.5-7) cm in the open group (*P*=0.703). The number of lymph nodes dissected in the laparoscopic group and open group was 12 (8-23) and 12 (9-32), respectively (*P*=0.768). The distal margin of all specimens was negative. For the cases with sphincter preservation, the distance of the tumor from the distal margin was 2.5 (1.5-5.5) cm in the laparoscopic group and 2.5 (1.4-5) cm in the open group (*P*=0.456). All the indicators mentioned above showed no significant difference between the two groups.

The time of operation was 125 (45-245) min and 135 (75-320) min in the laparoscopic group and open group, respectively, showing a significant difference (*P*<0.01). The intraoperative blood loss in the laparoscopic group was significantly lower compared with the open group [40 (10-300) mL and 80 (10-2000) mL, respectively; *P*<0.01].

In the laparoscopic group, the time of the first anal exsufflation, the time of first intake of liquid diet, and the time of first intake of semiliquid diet after surgery was 2 (1-10) d, 3 (1-10) d, and 5 (2-15) d, respectively. The corresponding time in the open group was 4 (2-13) d, 5 (2-19) d, and 7 (4-27) d, which were significantly later compared with the laparoscopic group (*P* < 0.01). The mean time of postoperative hospital stay in the laparoscopic group was significantly shorter compared with the open group [12 (7-44) d and 16 (10-58) d, respectively; *P*<0.01]. The indwelling time for the catheter was 6 (2-20) d in the laparoscopic group, which was significantly shorter than that of the open group [9 (3-27) d; *P*<0.01].

In the two groups, no deaths occurred during the hospitalization period and the complications were similar. No significant differences existed between the incidences of postoperative complications in the two groups, which were 18.82% (16/85) and 25.49% (26/102), respectively (**Table 2**).

Comparison of hospitalization expenses

The cost of operation in the laparoscopic group was considerably higher than that of the open group (*P*<0.01). The former was 17,744.81 ± 4657.88 (5756.74-27,781.69) yuan, while the latter was 10,651.60 ± 3845.53 (4419.04-19,849.00) yuan. However, the cost of medicine in the laparoscopic group [3944.60 ± 2307.63 (820.17-13,720.58) yuan] was significantly lower compared with the open group

Table 3. Comparison of surgical outcomes of the two groups

	LAP (*n*=85)	OPEN (*n*=102)	*P*
Median follow-up time (months)	21 (6-46)	24.5 (6-52)	0.082
Rate of loss to follow-up	7.06%	7.84%	0.839
Local recurrence	1.26%	6.38%	0.189
Anastomotic stoma (*n*)	1	3	
Pelvic cavity (*n*)	0	2	
Perineum and anus (*n*)	0	1	
Distant metastasis	20.25%	19.15%	0.856
Hepatic metastasis[A] (*n*)	11	10	
Pulmonary metastasis (*n*)	4	7	
Bone metastasis (*n*)	2	2	
Total survival rate	78.6%	71.7%	0.648
Total survival rate of stage II cases	88.9%	81.9%	0.913
Total survival rate of stage III cases	66.5%	61.7%	0.453
Tumor-free survival rate	68.5%	63.0%	0.767
Tumor-free survival rate of stage II cases	82.8%	79.1%	0.536
Tumor-free survival rate of stage III cases	52.8%	54.0%	0.685

Note: A. The laparoscopic group and open group each had one case of hepatic metastasis complicated with pulmonary metastasis.

[9793.16 ± 8449.03 (766.34-48,742.27) yuan] (*P*<0.01). The total expenses showed no significant difference between the two group (*P*=0.851).

Following-up

The follow-up time in the laparoscopic group was 21 (6-46) months, and 7.06% cases (6/85) were lost for the follow-up. The follow-up time in the open group was 24.5 (6-52) months, and 7.84% cases (8/102) were lost. The rates of loss to follow-up had no significant difference (*P*=0.839).

In the laparoscopic group, we found 1 case of local recurrence and 16 cases of distant metastasis; among the 16 cases, 11 died. The total mortality was 13.92% (11/79). In the open group, 6 cases were local recurrence, 4 were deaths (4.26%), and 18 were distant metastasis; among the 18 cases, 15 died. The total mortality was 20.21% (19/94). No significant differences were found between the two groups in terms of mortality (**Table 3**).

During the whole follow-up period, no significant differences existed between the total survival rates of the laparoscopic group and the open group (*P*>0.05), which were 78.6% and 71.7%, respectively. The overall survival rates of the cases with stage II (III) rectal cancer were 88.9% (66.5%) in the laparoscopic group and 81.9% (61.7%) in the open group, with no significant difference (*P*>0.05). See **Table 3** and **Figure 1A-C**.

During the whole follow-up period, the disease-free survival rates of the laparoscopic group and open group were 68.5% and 63.0%, respectively (*P*>0.05). The disease-free survival rates of the cases with stage II and III rectal cancer were 82.8% and 52.8% in the laparoscopic group, and the rates in the open group were 79.1% and 54.0%, respectively (*P*>0.05). [See **Table 3** and **Figure 2A-C**].

Discussion

The application of laparoscopy in the treatment of colorectal cancer has been widely accepted in the past decade, and its surgical safety and eradication effect have been confirmed [10, 11].

The depth of invasion of T3 rectal cancer is between the muscular layer and serosal layer. Once the cancer cells have invaded the surrounding organs or transferred to distant organs, the best timing of radical surgery is lost. Thus far, there have been no reports on the surgical safety, feasibility, eradication effect, short-term outcomes, and mid- and long-term survival rates of laparoscopic surgery in T3 rectal cancer.

Nelson et al. [12] indicated that sphincter-preserving operation is safe for patients with T3 or T4 rectal cancer that is more than 2 cm above the pectinate line. In the laparoscopic surgery performed for T3 rectal cancer in this study, TME was successfully carried out for 85 cases, with no intraoperative transfer to laparotomy. For the middle rectal cancer that was 7 cm above the anal verge, low anterior resection of the rectum was performed laparoscopically with comparable success rate as in laparoto-

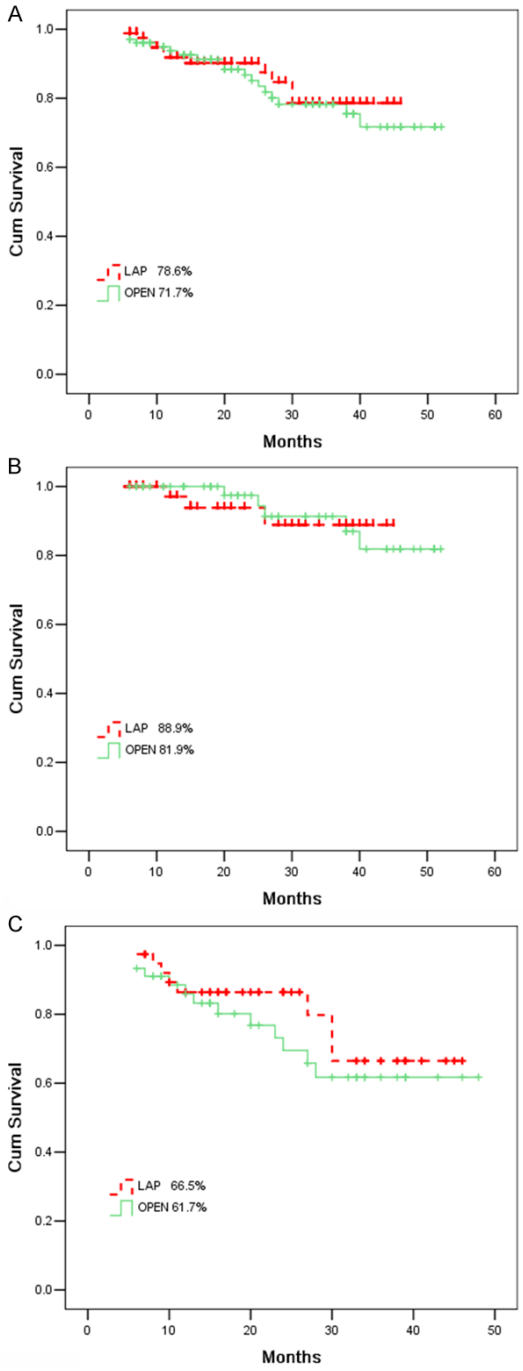

Figure 1. Overall survival (LAP vs. OPEN group). A. Overall survival of total patients; B. Overall survival of patients with stage II disease; C. Overall survival of patients with stage III disease. During the whole follow-up period, no significant differences existed between the total survival rates of the laparoscopic group and the open group ($P>0.05$), which were 78.6% and 71.7%, respectively. The overall survival rates of the cases with stage II (III) rectal cancer were 88.9% (66.5%) in the laparoscopic group and 81.9% (61.7%) in the open group, with no significant difference ($P>0.05$).

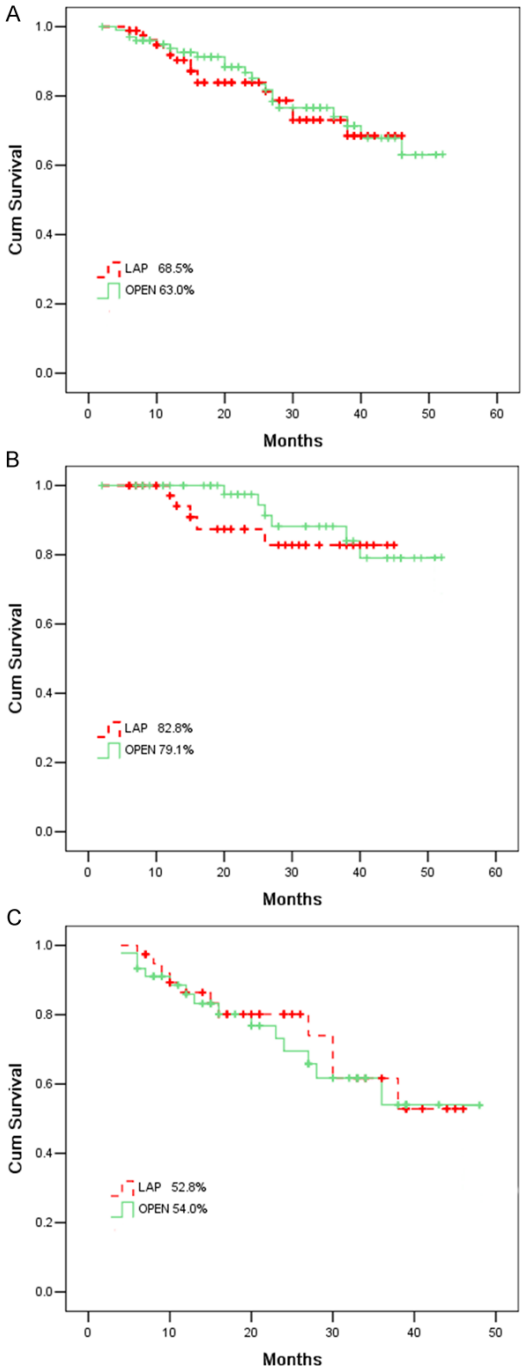

Figure 2. Disease free survival (LAP vs. OPEN group). A. Disease free survival of total patients; B. Disease free survival of patients with stage II disease; C. Disease free survival of patients with stage III disease. During the whole follow-up period, the disease-free survival rates of the laparoscopic group and open group were 68.5% and 63.0%, respectively ($P>0.05$). The disease-free survival rates of the cases with stage II and III rectal cancer were 82.8% and 52.8% in the laparoscopic group, and the rates in the open group were 79.1% and 54.0%, respectively ($P>0.05$).

my. Among the 48 cases with a distance from the tumor to the anal verge of <7 cm, the laparoscopic group showed no difference from the open group in the rate of sphincter preservation. Among the 29 cases receiving sphincter-preserving operation, there were 7 cases in which the distance from the tumor to the anal verge was 5 cm, 2 cases with a distance of 4 cm, and 20 cases with a distance of >5 cm. Therefore, the application of laparoscopic technology in T3 rectal cancer is safe and feasible for sphincter-preserving operations. Treating T3 rectal cancer in middle and advanced stages by laparoscopic TME is also feasible.

Past study [13] indicated that the duration of operations in laparoscopic TME was prolonged compared with open surgery. However, the laparoscopic group had shorter durations of operation in this study. We believe that the laparoscopic TME has more advantages [14] in treating T3 rectal cancer for patients with middle and advanced stage disease.

The two groups showed no significant difference in the incidence of postoperative complications during the hospitalization period, and the types of complications were also similar (**Table 2**). Many researches [4-8] have confirmed that laparoscopic surgery has obvious advantages over open surgery in short-term outcomes such as the postoperative recovery of gastrointestinal functions. Similar results were also obtained in this study.

The TME for rectal cancer must conform to the principle of tumor eradication and TME [1]. The above principles should be taken into consideration when assessing the eradication effect of laparoscopic TME for T3 rectal cancer. The pathological examination of specimens in this article indicated that the extent of resection in laparoscopic surgery was the same as in open surgery. The length of the resected specimen, the number of dissected lymph nodes, and the distance from the distal margin showed no significant difference between laparoscopic surgery and open surgery. This means that laparoscopic surgery for T3 rectal cancer can also eradicate the tumors as with open surgery.

The rate of local recurrence is an important indicator of eradication effect in rectal cancer. Reduction of local recurrence is always a major challenge. Since the invention of TME by Heald in 1982, the rate of local recurrence for rectal cancer has declined significantly [15, 16]. Leroy et al. [4] observed that the rate of local recurrence after laparoscopic TME is 6%. Kim et al. [17] reported that the rate of local recurrence is 2.9% for 312 cases of rectal cancer after laparoscopic TME (median follow-up duration of 30 months). Among 183 cases of T3 rectal cancer, 166 cases were followed up, with a rate of local recurrence of 4.20% (7/166). In this article, all the cases were treated according to the principle of tumor eradication and TME. Follow-up visits indicated that the rate of local recurrence of the laparoscopic group was only 1.26%, which showed no significant difference with the open group (6.38%) and was even lower than that in the above reports. Given the anatomical properties of high rectal cancer, the principle of treating high rectal cancer is similar with that for sigmoid colon cancer. Therefore, the rate of local recurrence is more important in evaluating the surgical outcome of low rectal cancer than for high rectal cancer. About half of the local recurrence occurs within 2 years after surgery [18]. In this article, the median follow-up duration of all cases was 23 months. The cases of low rectal cancer with lymphatic metastasis had a higher incidence of local recurrence, the time of which was usually within 2 years after surgery (**Table 3**). We believe that for T3 rectal cancer of the middle and advanced stages, local recurrence can still be controlled using laparoscopic surgery by conforming to the principle of tumor eradication. The rates of distant metastasis for laparoscopic surgery and open surgery were 20.25% and 19.15%, respectively, with no significant difference.

We have gained a preliminary understanding on the mid- and long-term outcomes of laparoscopic TME for rectal cancer. In the follow-up on 194 cases of rectal cancer by Barlehner et al. [6], the 5-year survival rate was 76.9% after laparoscopic TME (median follow-up duration was 46.1 months). In the literature by Morino et al. [5], the 5-year survival rate of the cases of rectal cancer was 74% after laparoscopic TME. In this article, the survival rates of the laparoscopic group and the open group were compared among the cases of T3 rectal cancer. The median follow-up time between the two groups was 21 and 24.5 months, respectively. The

total survival rate and tumor-free survival rate of the laparoscopic group were 78.6% and 71.7%, and those of the open group were 68.5% and 63.0%, respectively. The two indicators of the laparoscopic group were slightly higher, but no significant difference exists. Stratification analysis based on TNM staging was carried out. The total survival rate and tumor-free survival rate showed no significant difference at each stage (**Table 3**; **Figures 1** and **2**). Comparing the two indicators in our article with those in the above reports was inappropriate to because our study was a nonrandomized controlled study with a shorter follow-up time and fewer cases. However, the laparoscopic TME for T3 rectal cancer achieved the same mid- and long-term outcomes as in traditional open surgery in terms of rate of local recurrence, rate of distant metastasis, and survival rate. A prospective randomized controlled trial with a large sample size is needed to evaluate the long-term survival rate.

The high cost of the operation is a factor restricting the development and popularization of laparoscopic surgery. In this study, the average cost of surgery in the laparoscopic group was significantly higher than that of the open group ($P<0.01$). However, the average cost of Western medicine in the laparoscopic group was lowered considerably ($P<0.01$). This finding was mainly due to the faster restoration of gastrointestinal functions in patients treated with laparoscopic surgery and the lower need for postoperative drug administration and intravenous infusion. Faster recovery shortened the time of hospital stay for patients with T3 rectal cancer, and thus the hospitalization expenses were reduced. No significant differences in total expenses were recorded during the hospitalization period in the two groups. Thus, laparoscopic surgery for T3 rectal cancer did not increase the medical cost. Eradication effect of laparoscopic surgery in T3 rectal cancer and the mid- and long-term survival rates.

Taken together, middle/low T3 rectal cancer treatment by laparoscopic TME is safe and feasible, with better short-term outcomes than open surgery. Moreover, this laparoscopic surgery also conforms to the principle of TME, and can eradicate tumors and achieve a high mid- and long-term survival rate.

Disclosure of conflict of interest

None.

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