

ORIGINAL ARTICLE

Comparison of efficacy between natural orifice specimen extraction without abdominal incision and conventional laparoscopic surgery in the treatment of sigmoid colon cancer and upper rectal cancer

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Summary

Purpose: To compare the short-term efficacy between natural orifice specimen extraction (NOSE) without abdominal incision and conventional laparoscopic surgery in the treatment of sigmoid colon cancer and upper rectal cancer.

Methods: A total of 86 patients scheduled to undergo laparoscope-assisted radical surgery of sigmoid cancer or upper rectal cancer from January 2015 to September 2017 (T₁₋₃ stages in preoperative imaging evaluation, no distant metastasis, and body mass index <28 kg/m²) were selected and randomly divided into the NOSE group (no abdominal incision, n=43) and conventional laparoscopy group (LA group, n=43). The operation time, amount of intraoperative bleeding, postoperative exhaust time, postoperative diet time, postoperative hospitalization duration, postoperative pain score and perioperative complications were compared between the two groups. The pathological conditions of surgical specimens were recorded. The postoperative recurrence rate of tumor and survival rate of patients were also recorded and compared.

Results: The general clinical features were comparable between the two groups, and there were no perioperative deaths. The operation time in NOSE group was slightly longer than that in LA group, without statistically significant difference (p=0.130). In NOSE group, the amount of intraoperative bleeding was significantly smaller than in LA group [(59.31±14.64) mL vs. (75.41±18.16) mL, p<0.001], the post-

operative visual analogue scale (VAS) score was significantly lower than that in LA group [(4.2±1.6) points vs. (5.9±1.4) points, p<0.001], and the postoperative exhaust time and regular diet time were significantly shorter than those in LA group [(2.1±1.0) d vs. (2.6±1.2) d, p=0.039, (3.8±1.1) d vs. (4.4±1.4) d, p=0.030]. The cosmetic result in NOSE group was better than that in LA group [(8.0±1.5) vs. (6.4±1.1), p<0.001]. Moreover, the comparison results of surgical specimens showed that there were no statistically significant differences in the intestine resection length, proximal and distal resection margins, tumor size, number of lymph nodes dissected and TNM stage of tumor between the two groups (p>0.05). The postoperative tumor recurrence rate had no significant difference between the two groups (p=0.359), and the Log-rank test revealed that the disease-free survival (DFS) rate had no statistically significant difference between the two groups (p=0.280).

Conclusions: NOSE without abdominal incision has a comparable short-term clinical efficacy to conventional laparoscopic surgery in the treatment of sigmoid cancer and upper rectal cancer, but it significantly reduces the amount of intraoperative bleeding and lowers the pain of patients, with rapid postoperative recovery and high safety, so it is worthy of clinical popularization.

Key words: no abdominal incision, laparoscopy, sigmoid colon cancer, rectal cancer, efficacy

Introduction

Colorectal cancer has an increasingly higher morbidity rate ranking 3rd among cancers, and it has become one of the most common malignant tumors, whose mortality rate ranks 5th among various

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malignant tumors [1]. At present, surgical resection is still the preferred treatment means for colorectal cancer. In the past 2 decades, laparoscopic surgery has made significant contributions to the treatment of colorectal lesions. It has been proved in a large number of studies that laparoscopic surgery, compared with open surgery, is safe and feasible with faster postoperative recovery of patients in the treatment of colon cancer [2-4]. Some studies have demonstrated that laparoscopic surgery has obvious advantages in both short- and long-term efficacy [5-8]. However, in the conventional laparoscope-assisted radical surgery of sigmoid cancer or upper rectal cancer, a 4-8 cm-long surgical incision needs to be made in the lower abdomen to take out the specimens and place the stapler, which not only increases abdominal wall injury and patient's pain, but also increases the occurrence of complications such as postoperative intestinal obstruction, incisional hernia and incision infection [9-11].

To further reduce the surgical trauma, the idea of "non-scar surgery" was put forward by some authors, and natural orifice transluminal endoscopic surgery (NOTES) is gradually emerging in China and foreign countries [12]. In laparoscopic colorectal surgery without abdominal incision, also known as laparoscopic NOTES, the surgical specimens are taken out and the anastomosis is done through the natural orifice without making an abdominal auxiliary incision based on conventional laparoscopic surgery [13]. The intestine is the most commonly-used natural orifice. In the present study, based on years of experience and conditions of laparoscopic surgery and combined with the related literature, appropriate cases were selected and treated with natural orifice specimen extraction (NOSE) without abdominal incision and radical surgery of sigmoid cancer, and the short-term surgical results were compared between NOSE without abdominal incision and conventional laparoscopic surgery in the treatment of sigmoid cancer and upper rectal cancer.

Methods

General data

A total of 43 patients scheduled to undergo laparoscope-assisted radical surgery of sigmoid cancer or upper rectal cancer in the hospital from January 2015 to September 2017 were selected and treated with NOSE without abdominal incision (NOSE group), while another 43 patients with the similar age and body mass index (BMI) receiving conventional laparoscope-assisted radical surgery of sigmoid cancer or upper rectal cancer during the same period were selected as conventional laparoscope group (LA group). Inclusion criteria: pa-

tients with T₁₋₃ stages in preoperative imaging evaluation, no distant metastasis and BMI <28 kg/m². There were no statistically significant differences in the age, gender, BMI, American Society of Anesthesiologists (ASA) score and preoperative T stage between the two groups ($p>0.05$), and these data were comparable (Table 1). All patients adhered to the *Declaration of Helsinki*, and signed the informed consent. This study was approved by the Ethics Committee of the Third Medical Centre, Chinese People's Liberation Army General Hospital.

Surgical methods

Preoperative preparation: The patients had semi-liquid diet the day before operation, took polyethylene glycol electrolyte powder or magnesium sulfate orally the night before operation for bowel preparation, fasted from food and water on the operation day, and received intravenous injection of cefuroxime to prevent infection during operation

NOSE group: After general anesthesia, a urethral catheter was inserted under a supine split position. A 1.0 cm-long incision A was made at the superior margin of umbilicus to establish pneumoperitoneum (pneumoperitoneum pressure: 15 mmHg), the Trocar was inserted and the laparoscope was placed for exploration. The 1.2 cm-long Trocar was placed in the right lower abdomen to establish the main operating hole B, while the 0.5 cm-long Trocars were placed in the left lower abdomen and the right upper abdomen to establish the auxiliary operating holes C and D. After that, the sigmoid mesocolon was cut along the midline, the Toldt's space was separated to the left, the arterial-venous roots of mesentery were contextualized and the artery and vein were ligated and cut off. Then, the Toldt's space was further expanded to the left, the peritoneum at the side of descending and sigmoid colon were separated, and the rectal peritoneum was separated according to the tumor site. The mesocolon was trimmed as required, the cutting point of colorectum was marked, and the distal rectum and proximal colon were ligated with #7 wire. The anus was dilated for 4 fingers to disinfect the anorectal cavity. The rectum was cut open at the distal end of the rectal ligature, the incision was disinfected, and the endoscopic sheath was placed through the hole D and pulled out through the rectal incision and anus, forming the natural orifice used to take out the surgical specimens. The colorectum to be resected was placed into the endoscopic sheath and pulled out slowly with pliers through the natural orifice, the proximal colon ligature was placed into the endoscopic sheath, and the intestine was cut off as required, so that the surgical specimens were completely dissected and taken out through the anus. The endoscopic sheath was also withdrawn. The nail base of stapler was sent to the stump of sigmoid colon through the anus, and the stump of rectum was broken off and closed using Endo-GIA and placed into the extraction bag. The proximal colon was cut at the ligation site, the incision was disinfected, the nail base of stapler was placed, the stump of intestine was occluded with Hem-o-lock clips, the nail base was

trapped and ligated with the snare, and the edge was trimmed. Then the intestinal wall was resected, placed into the extraction bag and taken out through the hole B. The stapler was placed into the anus, and the guide tube was connected to the nail base. After it was confirmed that there were no mesenteric volvulus and tension, the anastomosis was performed. Then the pelvic cavity was washed, the anastomosis was checked, the drainage tube was placed and the incision was sutured.

LA group: The methods of preoperative preparation, anesthesia, Trocar placement, vascular treatment and dissection of intestine were the same as those in NOSE group. The stump of rectum was broken off and closed using Endo-GIA under the laparoscope, and a 5.0 cm-long auxiliary incision was made at hole C, through which the mass was taken out. The proximal colon was treated, the nail base of stapler was placed, and the pneumoperitoneum was established again, followed by anastomosis. The subsequent steps were the same as those in NOSE group.

Observation indexes

Perioperative indexes included the operation time, amount of intraoperative bleeding, postoperative exhaust time, postoperative diet time, postoperative hospitalization duration, postoperative pain score and perioperative complications. The incidence rates of complications during postoperative hospitalization, such as respiratory infection, abdominal infection, incision infection, anastomotic leakage, intestinal obstruction and deep venous thrombosis, were recorded. The postoperative pain was evaluated using the visual analogue scale

(VAS) score ranging from 0 point (no pain) to 10 points (the worst pain). Before evaluation, the VAS score was carefully explained by the same doctor to patients, and the patients truthfully chose the score base on their own conditions: 7-10 points (stronger and unbearable pain), 4-6 points (strong and bearable pain affecting sleep), 1-3 points (slight and bearable pain) and 0 point (no pain). The cosmetic result was assessed by the patient on a scale from 1 to 10 points (10 points: the most satisfactory).

Surgical specimens: The intestine resection length, proximal and distal resection margins, tumor size, number of lymph nodes dissected and TNM stage of tumor.

Postoperative recurrence rate of tumor and survival status: The patients were followed up at 1, 2, 3, 4, 5, 6, 9 and 12 months after discharge, and those who survived for more than 1 year were followed up every 6 months until September 2018.

Statistics

SPSS 22.0 software (IBM, Armonk, NY, USA) was used for statistical analyses. Measurement data were expressed as mean ± standard deviation, and *t*-test was used for the comparison between two groups. Enumeration data were expressed as rate (%), and chi-square (χ^2) test was adopted for intergroup comparison. $P < 0.05$ suggested that the difference was statistically significant. The survival curves were plotted by Kaplan-Meier method. Whether there was a statistically significant difference in the PFS between two groups was detected via Log-rank test. $P < 0.05$ suggested that the difference was statistically significant.

Table 1. Baseline demographic and clinical characteristics of the studied patients

Parameters	NOSE group (n=43) n(%)	LA group (n=43) n(%)	p value
Age, years, mean±SD	56.48±10.23	58.02±9.66	0.475
Gender			0.453
Male	25 (58.1)	22 (51.2)	
Female	18 (41.9)	21 (48.9)	
BMI (kg/m ²), mean±SD	23.6±3.1	23.2±3.4	
Tumor location			0.919
Sigmoid	13 (30.2)	16 (37.2)	
Rectosigmoid	8 (18.6)	6 (14.0)	
Rectum	22 (51.2)	21 (48.8)	
ASA score			0.628
I	14 (32.6)	17 (39.5)	
II	23 (53.5)	22 (51.2)	
III	6 (13.9)	4 (9.3)	
Extent of primary tumor*			0.510
T ₁	11 (25.6)	14 (32.6)	
T ₂	8 (18.6)	13 (30.2)	
T ₃	24 (55.8)	16 (37.2)	

NOSE: Natural orifice specimen extraction; LA: Laparoscopic-assisted; BMI: body mass index; ASA: American Society of Anesthesiologists; *According to the American Joint Committee on Cancer, 7th edition.

Results

Preoperative general conditions

In the present study, 86 patients with colorectal cancer were enrolled, including 47 males (54.7%) and 39 females (45.3%), aged 44-71 years (mean 57.52±10.12). The mean BMI was 23.6±3.1 kg/m² and 23.2±3.4 kg/m², respectively, in the two groups. In terms of the tumor site, there were 13 cases (30.2%) in the sigmoid colon, 8 cases (18.6%) in the rectosigmoid colon and 22 cases (51.2%) in the rectum in NOSE group, while there were 16 cases (37.2%) in the sigmoid colon, 6 cases (14.0%) in the rectosigmoid colon and 21 cases (48.8%) in the rectum in LA group. In terms of the ASA score, there were 14 cases (32.6%) with grade I, 23 cases (53.5%) with grade II and 6 cases (13.9%) with grade III in NOSE group, while there were 17 cases (39.5%) with grade I, 22 cases (51.2%) with grade II and 4 cases (9.3%) with grade III in LA group. In terms of T tumor stage, there were 11 cases (25.6%) in T₁ stage, 8 cases (18.6%) in T₂ stage and 24 cases (55.8%) in T₃ stage in NOSE group, while there were 14 cases (32.6%) in T₁ stage, 13 cases (30.2%) in T₂ stage and 16 cases (37.2%) in T₃ stage in LA group. There were no statistically significant differences in the preoperative general conditions between the two groups (p>0.05) (Table 1).

Comparison of perioperative indexes

The operation time was 131.59±26.43 min and 123.28±23.87 min in the two groups, without statistical significance (p=0.130). The amount of intra-

operative bleeding in NOSE group was significantly smaller than that in LA group (59.31±14.64 mL vs. 75.41±18.16 mL, p<0.001). The postoperative hospitalization duration was 6.9±3.0 and 7.7±3.3 days in the two groups, with no statistically significant difference (p=0.243). In NOSE group, the postoperative VAS score was significantly lower than that in LA group (4.2±1.6 points vs. 5.9±1.4 points, p<0.001), and the postoperative exhaust time and regular diet time were significantly shorter than in LA group (2.1±1.0 vs. 2.6±1.2 days, p=0.039 and 3.8±1.1 vs. 4.4±1.4 days, p=0.030). The cosmetic result in NOSE group was better than in LA group (8.0±1.5 vs. 6.4±1.1, p<0.001). Moreover, the incidence rates of postoperative complications had no statistically significant differences between the two groups (p>0.05) (Table 2).

Comparison of pathological conditions of surgical specimens

The tumor diameter was 3.1±1.7 cm and 3.6±1.9 cm, respectively, the distance from the tumor to the anal edge was 13.8±5.5 cm and 14.3±6.1 cm, respectively, the intestine resection length was 17.9±4.3 cm and 18.7±5.2 cm, respectively, the length of proximal resection margin was 13.2±10.1 cm and 12.4±9.5 cm, respectively, the length of distal resection margin was 4.4±2.8 cm and 5.1±3.9 cm, respectively, and the number of lymph nodes dissected was 14.9±3.8 and 16.2±3.4, respectively, in the two groups, displaying no statistically significant differences (p>0.05). The tumor was well differentiated in 4 cases (9.3%) and 7 cases (16.3%), mod-

Table 2. Comparison of perioperative data and postoperative recovery parameters of the studied patients in two different groups

Parameters	NOSE group (n=43)	LA group (n=43)	p value
Operation time (min)	131.59±26.43	123.28±23.87	0.130
Blood loss (ml)	59.31±14.64	75.41±18.16	0.001
Hospital stay after surgery (days)	6.9±3.0	7.7±3.3	0.243
VAS score	4.2±1.6	5.9±1.4	0.001
Gas passage after surgery (days)	2.1±1.0	2.6±1.2	0.039
Regular diet after surgery (days)	3.8±1.1	4.4±1.4	0.030
Cosmetic result	8.0±1.5	6.4±1.1	0.001
Complications, n (%)			
Incision infection	0 (0)	2 (4.6)	0.494
Pulmonary infection	1 (2.3)	1 (2.3)	1.000
Intraperitoneal infection	0 (0)	0 (0)	1.000
Anastomotic leakage	1 (2.3)	0 (0)	0.315
Ileus	1 (2.3)	1 (2.3)	1.000
Deep venous thrombosis	1 (2.3)	0 (0)	0.315

NOSE: Natural orifice specimen extraction; LA: Laparoscopic-assisted; VAS: Visual analog scale.

Table 3. Pathological characteristics of the studied patients in two groups

Parameters	NOSE group (n=43)	LA group (n=43)	p value
Tumor diameter (cm)	3.1±1.7	3.6±1.9	0.202
Distance of tumor from anal verge (cm)	13.8±5.5	14.3±6.1	0.235
Resection length of intestine (cm)	17.9±4.3	18.7±5.2	0.439
Proximal resection margin (cm)	13.2±10.1	12.4±9.5	0.706
Distal resection margin (cm)	4.4±2.8	5.1±3.9	0.342
Lymph node dissection	14.9±3.8	16.2±3.4	0.098
Tumor differentiation, n (%)			0.750
Well	4 (9.3)	7 (16.3)	
Moderate	34 (79.1)	30 (69.8)	
Poorly	3 (7.0)	4 (9.3)	
Others	2 (4.6)	2 (4.6)	
TNM stage, n (%)			0.620
I	17 (39.5)	13 (30.2)	
II	21 (48.8)	23 (53.5)	
III	5 (11.6)	7 (16.3)	

NOSE: Natural orifice specimen extraction; LA: Laparoscopic-assisted; TNM: Tumor, Node, Metastasis

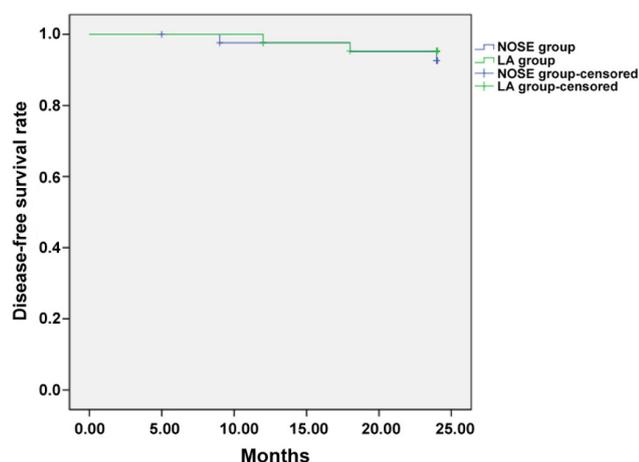


Figure 1. Kaplan-Meier survival curve of patients in NOSE and LA group. The difference of the disease-free survival rate of patients in the two group has no statistical significance (p=0.280).

erately differentiated in 34 cases (79.1%) and 30 cases (69.8%) and poorly differentiated in 3 cases (7.0%) and 4 cases (9.3%), respectively, in the two groups, showing no statistically significant differences (p>0.05). In terms of the TNM stage, there were 17 cases (39.5%) and 13 cases (30.2%) in stage I, 21 cases (48.8%) and 23 cases (53.5%) in stage II, and 5 cases (11.6%) and 7 cases (16.3%) in stage III, respectively, in the two groups, showing no statistically significant differences (p>0.05) (Table 3).

Follow-up results of patient’s survival

The patients were followed up for 12-45 months, and 1 case was lost to follow-up in NOSE

group at 31 months after operation and 2 cases were lost to follow-up in LA group at 18 and 26 months after operation. In NOSE group, the tumor relapsed in 3 patients at 37,39 and 44 months after operation, and the recurrence rate was 7.7% (3/39). In LA group, the tumor relapsed in 1 patient 34 months after operation, and the recurrence rate was 2.5% (1/40). The recurrence rate of tumor had no significant difference between the two groups (p=0.359). The Kaplan-Meier DFS of NOSE group and LA group are shown in Figure 1, and the log-rank test revealed that the DFS rate had no statistically significant difference between the two groups (p=0.280).

Discussion

Colorectal cancer is a common gastrointestinal malignant tumor. According to statistics, colorectal cancer has surpassed gastric cancer to become the second most frequently-occurring malignant tumor in urban areas. Reasonable and effective radical surgery is of great significance in increasing the survival rate and improving the quality of life of patients. With the continuous development of minimally-invasive surgery, the operation has developed from large incision to no incision and from multiple holes to single hole or natural orifice. The idea of NOTES was put forward by Kalloo et al of Johns Hopkins University in 2004 [14]. The common approaches of NOTES are the oral cavity, urethra, vagina and anus. Studies have reported that large surgical specimens can be taken out through the vagina. Considering the correlation between

sigmoid colon and rectum and the ethical dispute in transvaginal extraction, the transrectal specimen extraction was the preferred surgery in the present study, but larger specimens cannot be taken out through the rectum. The extraction means of surgical specimens include the incision protection ring, endoscopic sheath and specimen bag or transanal endoscopic surgical device [15-17]. In this study, the endoscopic sheath was used as the extraction passage of surgical specimens to take out the specimens together with the endoscopic sheath.

It was found in the present study that the operation time in NOSE group was slightly longer than that in LA group, but without statistically significant difference ($p>0.05$). The amount of intraoperative bleeding in NOSE group was significantly lower than that in LA group, which is consistent with literature reports [18,19]. The main reason is related to the time-consuming preparation of intraperitoneal anastomosis and higher complexity of surgery. Moreover, the postoperative exhaust time, regular diet time and postoperative VAS score in NOSE group were significantly shorter and lower than those in LA group, indicating that NOSE can significantly reduce the pain degree, shorten the postoperative exhaust time and benefit the rapid recovery of gastrointestinal function of patients. The incidence rates of complications, mainly auxiliary incision complications in LA group and 1 case of anastomotic leakage in NOSE group, had no statistically significant differences between the two groups. The anastomotic leakage occurred in the early stage of NOSE, which may be related to the surgical learning curve, indicating that although laparoscope-assisted surgery has been mature and perfect, experience remains to be accumulated in non-incision surgery. At the same time, it is realized that the technical difficulty of non-incision surgery is the complete intraperitoneal anastomosis. How to technically ensure the accurate and reliable complete intraperitoneal anastomosis is worthy of research and improvement.

The comparison results of surgical specimens showed that there were no statistically significant differences in the intestine resection length, proximal and distal resection margins, tumor size, number of lymph nodes dissected and TNM stage

between the two groups, suggesting that the effect of tumor removal in the surgery without abdominal incision is comparable to that in conventional laparoscope-assisted surgery. The postoperative recurrence rate of tumor and DFS rate during follow-up had no statistically significant differences between the two groups, but the results need to be verified via increased number of cases and long-term follow-up. The biggest controversy in laparoscopic colorectal surgery without abdominal incision lies in whether it will increase the risks of abdominal infection or dissemination of abdominal tumors. In the present study, no abdominal infection or abdominal abscess occurred after operation in both groups. Some authors studying the ascitic fluid bacterial culture found that the contamination rate of ascitic fluid in surgery without abdominal incision was higher than that in conventional laparoscope-assisted surgery, but without statistically significant difference [20], which suggests that the aseptic principle must be followed in the surgery without abdominal incision.

The present study is an early small-sample study, and there are influences of the learning curve, so the next step is to continue to improve the surgical methods and perform prospective comprehensive comparative study. The long-term efficacy of laparoscopic colorectal surgery without abdominal incision in the treatment of sigmoid colon cancer and upper rectal cancer remains to be confirmed by multi-center large-sample clinical studies.

Conclusions

NOSE without abdominal incision has a comparable short-term clinical efficacy to conventional laparoscopic surgery in the treatment of sigmoid cancer and upper rectal cancer, but it significantly reduces the amount of intraoperative bleeding and lowers the pain degree of patients, with rapid postoperative recovery and high safety, so it is worthy of clinical popularization.

Conflict of interests

The authors declare no conflict of interests.

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