

Original Article

Short-term and Long-term Outcomes of Natural Orifice Specimen Extraction with Single-stapled Anastomosis versus Conventional Laparoscopic Anterior Resection for Rectosigmoid Cancer: A Propensity-score Matching Study

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Key Words

Natural orifice specimen extraction;
Single-stapled anastomosis;
Laparoscopic anterior resection;
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Purpose. Natural orifice specimen extraction (NOSE) is increasingly used in radical surgery of the abdominal and pelvic organs; however, it is still in the exploratory stage. This study aimed to evaluate the short- and long-term oncologic outcomes of NOSE with single-stapled anastomosis compared with those of conventional specimen extraction following laparoscopic resection for malignancy.

Methods. From January 2015 to June 2024, 326 patients diagnosed with rectosigmoid cancer were enrolled. We identified 29 patients who underwent laparoscopic anterior resection with NOSE and single-stapled anastomosis (NOSE-SS group) and 297 patients who underwent laparoscopic anterior resection with abdominal incision specimen extraction and double-stapled anastomosis (AISE-DS group) for analysis. Propensity score matching was performed to balance the clinicopathological characteristics of the two groups.

Results. Based on perioperative data and postoperative follow-up, patients in the NOSE-SS group experienced lower postoperative pain scores (2.98 ± 0.85 vs. 1.86 ± 0.74 ; $p < 0.001$) but had greater intraoperative blood loss (51.38 ml vs. 24.83 ml; $p = 0.037$). There were no significant differences in the operative time or complication rates between the two groups. Additionally, the long-term outcomes, including local recurrence, disease-free survival, and overall survival, showed no significant differences, with a median follow-up of 62 months in the NOSE-SS group and 40.5 months in the AISE-DS group.

Conclusion. NOSE with single-stapled anastomosis could be a safe and reliable technique for radical resection of rectosigmoid cancer in selected patients, with less abdominal wall trauma than conventional laparoscopy. Long-term oncological outcomes were not significantly different.

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Colorectal cancer (CRC) is the third most common cancer worldwide in terms of incidence and ranks second in cancer-related mortality.¹ The global incidence of CRC is increasing, with projections estimating more than 2.2 million new cases and 1.1 million deaths by 2030.² This trend is influenced not only by the adoption of a Western lifestyle and genetic and environmental factors but also by the widespread use of cancer screening tests, such as the fecal immunochemical test and advancements in colonoscopy.¹

Nowadays, radical surgery is still the primary treatment for CRC patients.^{3,4} Several prospective randomized clinical trials have demonstrated that laparoscopic colorectal surgery offers better short-term outcomes compared to traditional open surgery, while maintaining equivalent oncologic outcomes.^{5,6} Although laparoscopic colorectal surgery greatly reduces the trauma of surgery, it typically requires an abdominal incision to remove the specimen. This incision increases the risk of postoperative complications such as pain, surgical site infections, and incisional hernia. These complications can potentially delay the adjuvant chemotherapy.^{7,8} As a result, further efforts have been made to minimize surgical trauma.

The first use of natural orifice specimen extraction (NOSE) in colorectal surgery was reported in 1993 by Franklin et al.,⁹ who described laparoscopic colectomy with transanal specimen retrieval. This method spread owing to its favorable short-term outcomes in selected cases, including overall complications, incision-related complications, intraoperative blood loss, postoperative pain, return of gastrointestinal function, and length of hospital stay. However, NOSE requires a longer operative time than conventional laparoscopic resection.¹⁰⁻¹² Additionally, multiple stapler firings have been identified as a risk factor for anastomotic leakage.¹³ Therefore, reconstructing bowel continuity with a single-stapled anastomosis may help improve short-term outcomes.

Several researchers have questioned the safety of NOSE. This study aimed to evaluate the short- and long-term oncologic outcomes of NOSE compared with those of conventional specimen extraction following laparoscopic resection for malignancy.

Materials and Methods

Study population and design

We conducted a retrospective, single-center, comparative cohort study based on our institution's patient registry database from January 2015 to June 2024. This study enrolled patients diagnosed with sigmoid colon cancer or rectosigmoid junction colon cancer who underwent laparoscopic anterior resection. Patients were excluded for the following reasons: emergency surgery, diversion stoma, conversion to open surgery, or a history of other malignancies. Patients with suspected T4 tumors were excluded from undergoing the NOSE procedure. Ultimately, 326 patients were included in the analysis and divided into two groups: laparoscopic anterior resection with NOSE and single-stapled anastomosis (NOSE-SS group) and laparoscopic anterior resection with abdominal incision specimen extraction and double-stapled anastomosis (AISE-DS group). This study was approved by the Institutional Review Board of Chung Shan Medical University Hospital (IRB number: CS2-24020). All data in this study were encrypted and remained anonymous during the data analysis.

Surgical procedure

The laparoscopic NOSE technique involves 3 phases: (1) standard laparoscopic bowel resection with D3 lymph node dissection; (2) natural orifice specimen extraction; and (3) bowel reconstruction.

Oncological resection: Routine splenic flexure takedown, D3 lymph node dissection, low ligation of the inferior mesenteric artery to preserve the left colic artery, medial-to-lateral mobilization of the sigmoid colon, and sharp nerve-sparing pelvic dissection were performed.

NOSE (Fig. 1): The distal end was cut using scissors instead of an energy device after ligation of the proximal site with tape. Transanal specimens were extracted gently. To minimize the risk of tumor implantation, the anus was dilated with anal sizers, lubricated with jelly, and protected with a wound protector inserted transanally.

Bowel reconstruction (Fig. 1): The anvil was fixed to the proximal stump using a purse-string suture. We completed the single-stapled anastomosis after another purse-string closure after a circular stapler was inserted into the distal stump. This technique avoids the formation of ‘dog-ears’, which are potential weak points where the linear staple line meets the cross-stapled junctions in double-stapled anastomoses. Finally, the anastomosis was reinforced with silk sutures.

For conventional laparoscopic anterior resection, the distal limit of resection was stapled intracorporeally, whereas the proximal segment was extracted through a mini-laparotomy. After retrieval of the specimen, the anvil was inserted into the proximal stump. Double-stapled anastomosis was then performed under laparoscopic vision.

Adjuvant chemotherapy

Following the recommendations of the American Society of Colon and Rectal Surgeons, adjuvant chemotherapy was recommended for all patients with American Joint Committee on Cancer (AJCC) stage III or high-risk stage II colorectal cancers. Treatment options included 12 cycles of intravenous modified

FOLFOX (5-FU 2400-3000 mg/m² + Oxaliplatin 85 mg/m² + Leucovorin 200 mg/m²), or CAPEOX (825 mg/m² BID + Oxaliplatin 50 mg/m²), or oral Capecitabine (850-1250 mg/m² BID), or oral Uracil-Tegafur (250-300 mg/m²/day) for six months.¹⁴

Data collection and follow up

All patient information was obtained from the electronic medical records system of Chung Shan Medical University Hospital, including basic data (age, sex, body mass index [BMI], and comorbidity), tumor-related data (size and TNM stage), surgical data (surgical approach, operation time, and estimated blood loss), postoperative outcomes (pain score with visual analog scale [VAS], surgical morbidity according to the Clavien–Dindo classification¹⁵ and duration of postoperative hospital stay), oncological data (adjuvant chemotherapy regimen), and survival data (overall survival [OS], disease-free survival [DFS], and local recurrence rate).

Patients were followed up every 3 months during the first 2 years after surgery and every 6 months for the subsequent 3 years until the patient died or the study was terminated. Patients were followed up th-

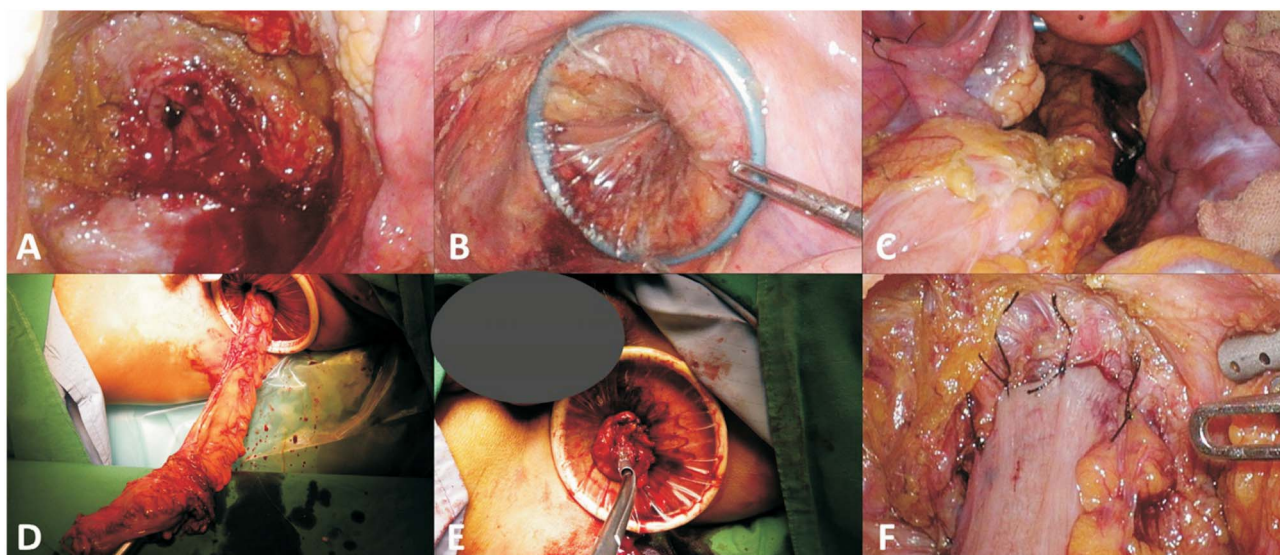


Fig. 1. Operative images of the natural orifice specimen extraction procedure. A: Cut the distal stump with endo-scissors; B: Place a wound protector transanally; C, D: Transanal specimen extraction; E: The anvil fixed at the proximal stump with purse-string suture after specimen resection; F: Interrupted reinforcement suture after single-stapling anastomosis.

rough outpatient clinic appointments. The median follow-up was 40.5 months in the AISE-DS group and 62.0 months in the NOSE-SS group until the end of the study in June 2024.

Statistical analysis

To reduce the inherent bias in this study, patients were matched 1:2 according to propensity scores calculated by logistic regression analysis with the following covariates: age, sex, tumor diameter, T stage, N stage, abdominal operative history, and comorbidities, including diabetes mellitus, hypertension, and chronic kidney disease. A logistic regression model was used to analyze the variable assignment based on the baseline data of 326 patients, and the matching tolerance was 0.01. Categorical variables were reported as percentages, whereas continuous variables were reported as a mean \pm SD. Chi-squared tests were performed to compare categorical data, whereas t-tests or Mann–Whitney U tests were used to compare continuous variables. The probabilities of local recurrence, OS, and DFS were estimated using the Kaplan–Meier method and the Cox proportional hazards model. All matching was performed using the Statistical Analysis Systems software package. All statistical analyses were performed using SPSS for Windows. Statistical significance was set at $p < 0.05$.

Results

From January 2015 to June 2024, we identified 29 patients who underwent laparoscopic anterior resection with NOSE and single-stapled anastomosis (NOSE-SS group) and 297 patients who underwent laparoscopic anterior resection with abdominal incision specimen extraction and double-stapled anastomosis (AISE-DS group). After propensity score matching, 29 and 58 patients were compared between the NOSE-SS and AISE-DS groups, respectively. Baseline characteristics, including sex, age, BMI, tumor size, T stage, N stage, history of abdominal surgery, and comorbidities, such as diabetes mellitus, hypertension, and chronic kidney disease, were well balanced between the

two groups (Table 1).

Short-term outcomes

A comparison of the perioperative results and short-term outcomes between the two groups is summarized in Table 2. The operative duration was not significantly different between the two groups, and the blood loss was greater in the NOSE-SS group than in the AISE-DS group (51.38 ml vs. 24.83 ml; $p = 0.037$). The average VAS score was calculated by taking the mean of the scores from the first three postoperative days. The NOSE-SS group had significantly better postoperative pain scores (2.98 ± 0.85 vs. 1.86 ± 0.74 ; $p < 0.001$). There was no significant difference in the gastrointestinal recovery time or duration of postoperative hospitalization. The overall morbidity rate was 8.0% (7/87), with no significant difference between groups. Minor complications (grade I/II) were noted in three patients in both groups. A major complication (grade III/IV) was noted in one patient in the AISE-DS group who suffered from acute kidney injury; this difference was not statistically significant. Anastomotic leakage or perioperative mortality was not observed in any patient.

Long-term outcomes

The most important concern regarding this new procedure is whether it has a negative impact on the long-term survival of patients. There was no significant difference in OS or DFS between the two groups (Fig. 2). With a median follow-up time of 62.0 months in the NOSE-SS group and 40.5 months in the AISE-DS group, local recurrence was observed in three patients (0.9%). After PSM, the rate of local recurrence at 3 years was 0% in both groups (Table 3). There was also no significant difference in 3-year DFS according to tumor stage between the two groups (Table 3). Furthermore, in the NOSE-SS group, 80% (4/5) of stage II patients and 72.7% (8/11) of stage III patients received adjuvant chemotherapy. In comparison, 80% (8/10) of stage II patients and 94.7% (18/19) of stage III patients in the AISE-DS group received adjuvant chemotherapy. Notably, no recurrence was observed

Table 1. Characteristic of two groups of patients

Variables	Before PSM			After PSM		
	AISE-DS (n = 297)	NOSE-SS (n = 29)	<i>p</i> -value	AISE-DS (n = 58)	NOSE-SS (n = 29)	<i>p</i> -value
Sex			0.002			0.611
Male	181 (60.94%)	9 (31.03%)		15 (25.86%)	9 (31.03%)	
Female	116 (39.06%)	20 (68.97%)		43 (74.14%)	20 (68.97%)	
Age			0.052			0.611
≤ 65	170 (57.24%)	22 (75.86%)		41 (70.69%)	22 (75.86%)	
> 65	127 (42.76%)	7 (24.14%)		17 (29.31%)	7 (24.14%)	
BMI	24.22 ± 3.88	22.81 ± 3.03	0.059	24.01 ± 3.78	22.81 ± 3.03	0.142
Diameter of tumor			0.054			0.717
≤ 5 cm	246 (82.83%)	28 (96.55%)		55 (94.83%)	28 (96.55%)	
5-10 cm	51 (17.17%)	1 (3.45%)		3 (5.17%)	1 (3.45%)	
Pathologic stage						
T			0.001			0.935
Tis/T1	52 (17.51%)	12 (41.38%)		25 (43.10%)	12 (41.38%)	
T2	41 (13.80%)	7 (24.14%)		12 (20.69%)	7 (24.14%)	
T3	156 (52.53%)	10 (34.48%)		21 (36.21%)	10 (34.48%)	
T4	48 (16.16%)	0 (0%)		0 (0%)	0 (0%)	
N			0.460			0.583
N0	162 (54.55%)	19 (65.52%)		37 (63.79%)	19 (65.52%)	
N1	82 (27.61%)	7 (24.14%)		18 (31.03%)	7 (24.14%)	
N2	53 (17.85%)	3 (10.34%)		3 (5.17%)	3 (10.34%)	
Co-morbidity						
Diabetes mellitus			0.169			0.150
No	222 (74.75%)	25 (86.21%)		42 (72.41%)	25 (86.21%)	
Yes	75 (25.25%)	4 (13.79%)		16 (27.59%)	4 (13.79%)	
Hypertension			0.238			0.760
No	140 (47.14%)	17 (58.62%)		32 (55.17%)	17 (58.62%)	
Yes	157 (52.86%)	12 (41.38%)		26 (44.83%)	12 (41.38%)	
Dyslipidemia			0.118			0.395
No	229 (77.10%)	26 (89.66%)		48 (82.76%)	26 (89.66%)	
Yes	68 (22.90%)	3 (10.34%)		10 (17.24%)	3 (10.34%)	
Chronic kidney disease			0.999			0.832
No	256 (86.20%)	25 (86.21%)		49 (84.48%)	25 (86.21%)	
Yes	41 (13.80%)	4 (13.79%)		9 (15.52%)	4 (13.79%)	
Abdominal OP history			0.272			0.510
No	242 (81.48%)	26 (89.66%)		49 (84.48%)	26 (89.66%)	
Yes	55 (18.52%)	3 (10.34%)		9 (15.52%)	3 (10.34%)	

PSM, propensity score matching; BMI, body mass index.

at the anastomotic site or along the transrectal route of specimen extraction in the NOSE-SS group.

Discussion

Laparoscopic radical resection for CRC has been widely used; however, an incision on the abdominal

wall could increase the risk of postoperative complications such as pain, surgical site infections, and incisional hernia, which might postpone the consequent treatment.^{7,8} In recent years, with the development of minimally invasive technique, NOSE has become one of the most popular producers, which has the short-term benefits of less trauma, less pain, shorter intestinal recovery time, and fewer complications but longer

Table 2. Perioperative factors and short-term outcomes

Variables	After PSM		p-value
	AISE-DS (n = 58)	NOSE-SS (n = 29)	
Operation time (min)	237.90 ± 69.09	242.60 ± 51.35	0.746
Blood loss (ml)	24.83 ± 35.11	51.38 ± 61.28	0.037
Margin free			none
No (0)	0 (0%)	0 (0%)	
Yes (1)	58 (100%)	29 (100%)	
Harvest lymph nodes	19.64 ± 7.21	18.17 ± 7.28	0.375
Positive lymph nodes	1.03 ± 2.30	0.86 ± 1.41	0.667
Time to flatulence (d)	1.60 ± 0.90	1.79 ± 2.24	0.664
Time to oral intake (d)	3.79 ± 1.15	4.48 ± 3.21	0.271
Length of hospitalization (d)	7.93 ± 2.97	8.76 ± 4.96	0.413
VAS (POD1)	2.98 ± 0.85	1.86 ± 0.74	< 0.001
VAS (average)	2.47 ± 0.53	1.25 ± 0.45	< 0.001
Postoperative complication			0.577
No (0)	54 (93.10%)	26 (89.66%)	
Yes (1)	4 (6.90%)	3 (10.34%)	
Leakage			-
No (0)	58 (100%)	29 (100%)	
Yes (1)	0 (0%)	0 (0%)	
SSI			0.477
No (0)	57 (98.28%)	29 (100%)	
Yes (1)	1 (1.72%)	0 (0%)	
PPOI			0.613
No (0)	57 (98.28%)	28 (96.55%)	
Yes (1)	1 (1.72%)	1 (3.45%)	
Pneumonia			0.613
No (0)	57 (98.28%)	28 (96.55%)	
Yes (1)	1 (1.72%)	1 (3.45%)	
Chylous ascites			0.155
No (0)	58 (100%)	28 (96.55%)	
Yes (1)	0 (0%)	1 (3.45%)	
Clavien-Dindo Classification			0.453
I (1)	3 (5.17%)	2 (6.90%)	
II (2)	0 (0%)	1 (3.45%)	
III (3A + 3b)	0 (0%)	0 (0%)	
IV (4A)	1 (1.72%)	0 (0%)	
V (5)	0 (0%)	0 (0%)	
Nil	54 (93.10%)	26 (89.66%)	

SSI, surgical site infection; PPOI, prolonged postoperative ileus.

operation time.^{10,12,16} The results of this study showed no significant differences between the groups in terms of operative time, gastrointestinal recovery, hospital stay, or overall complication rates. However, the NOSE-SS group reported significantly lower pain scores than the AISE-DS group. In contrast, intraoperative blood loss was significantly higher in the NOSE-SS group. This may be attributed to the use of

scissors rather than an energy device to cut the distal bowel margin, which could minimize thermal injury to the bowel.

The primary focus of the NOSE procedure is to ensure safety by strictly following tumor-free and aseptic principles. If a tumor ruptures during specimen extraction, there is a risk of tumor cell dissemination, which can compromise patient prognosis. Ac-

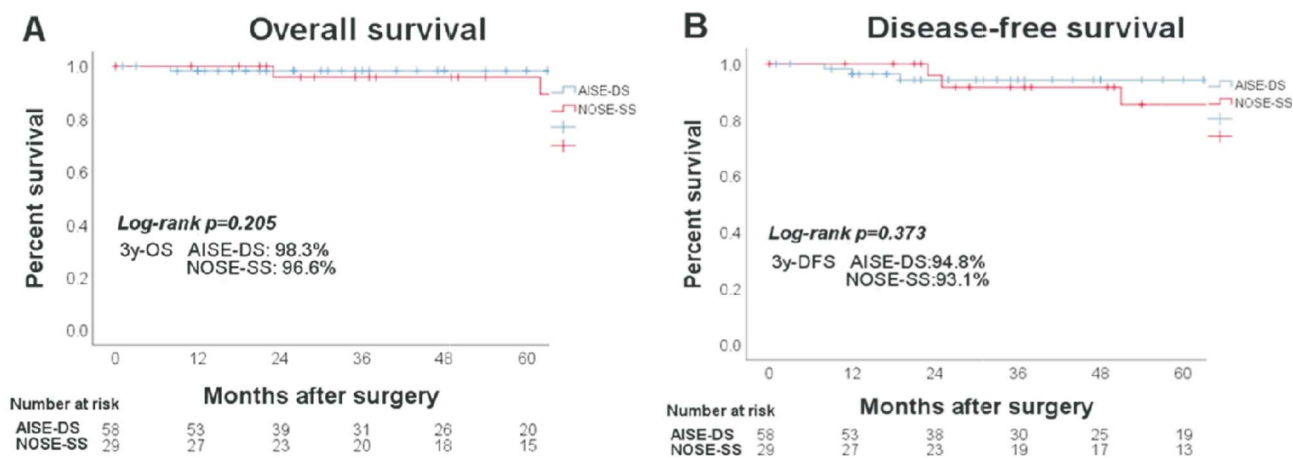


Fig. 2. Kaplan-Meier survival curve of overall survival (A) and disease-free survival (B) in the AISE-DS group and the NOSE-SS group after PSM.

Table 3. Three-year local recurrence and three-year DFS according to AJCC stage

Variable	After PSM		
	AISE-DS	NOSE-SS	<i>p</i> -value
3-year local recurrence (%)			
Stage 1	0% (0/23)	0% (0/11)	-
Stage 2	0% (0/10)	0% (0/5)	-
Stage 3	0% (0/19)	0% (0/10)	-
3-year DFS (%)			
Stage 1	95.7% (22/23)	90.9% (10/11)	0.703 ^a
Stage 2	100% (10/10)	100% (5/5)	-
Stage 3	100% (19/19)	90.9% (10/11)	0.186 ^a

AJCC, American Joint Committee on Cancer.

^a Log-rank test.

According to the international NOSE surgery consensus, the recommended maximum tumor sizes for transanal and transvaginal NOSE are 3 and 5 cm, respectively.¹⁷ While the tumor size can be estimated preoperatively using imaging, the final decision to proceed with a NOSE procedure often depends on intraoperative findings. This is because of the limitations of imaging in accurately assessing peritumoral desmoplastic reactions and the bulkiness of the mesocolon or mesorectum, which can significantly increase the overall specimen diameter. In addition, BMI limits of 30 for transanal NOSE and 35 for transvaginal NOSE have been suggested.¹⁷ Obese patients often have a bulkier mesocolon or mesorectum, which makes extraction difficult. In our study, all patients had a BMI below 30, and the highest BMI was 29.7. However, six patients had tumors larger than 3 cm, with the largest

measuring 6 cm. Although the tumor sizes exceeded the recommended limits, the NOSE procedures were completed smoothly. This success may be attributed to factors such as low BMI, use of a wound protector, adequate lubrication, and proper anal dilatation. We never experienced any specimen rupture or local recurrence at the extraction site during NOSE.

According to aseptic principles, a transrectal incision may lead to intestinal bacteria entering the abdominal cavity through the bowel. However, peritoneal contamination can be effectively avoided by prophylactic antibiotic administration, intraoperative transanal irrigation with copious amounts of povidone-iodine and normal saline, and use of a transluminal wound protector.¹⁷ In our study, we followed all of the suggestions mentioned above, and there was no difference in the overall complication rate between the two groups.

Intraoperative lymph node dissection plays a critical role in patient outcomes. In this study, the average number of lymph nodes harvested in both surgical groups exceeded 12, which is consistent with the standard principle.^{3,4} After a median follow-up of 62.0 months in the NOSE-SS group and 40.5 months in the AISE-DS group, the 3-year DFS rate for all tumor stages was 93.1% and 94.8% (log-rank test, $p = 0.373$) in the NOSE-SS and AISE-DS groups, respectively. There were no significant differences between the two groups in terms of DFS or OS. These results suggest that NOSE is oncologically safe.

Our study has several limitations. This was a single-center, retrospective study with a relatively small sample size. Although propensity score matching was used to adjust for the known confounding factors, the influence of unknown confounders cannot be ruled out. Consequently, certain findings in our study may not fully represent real-world data, particularly the differences in gender and age distribution, as well as the relatively high OS and DFS rates observed. These limitations reduced the strength of our findings and prevented us from drawing definitive conclusions.

Based on our short- and long-term outcomes, we continue to perform NOSE in selected patients with rectosigmoid cancer. Our findings suggest that NOSE is a feasible option for minimizing abdominal wall trauma during laparoscopic colorectal surgery for malignancies in selected cases. We look forward to larger multicenter studies to further validate and potentially expand the indications for NOSE with single-stapled anastomosis.

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原 著

經自然孔腔標本取出手術併單一縫合吻合術與傳統腹腔鏡前位切除術治療乙狀結腸直腸癌的短期與長期結果：傾向性配對分析研究

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目的 經自然孔腔標本取出手術在腹部和骨盆腔器官的根治手術中應用越來越廣泛，但仍處於探索階段。本研究旨在評估經自然孔腔標本取出手術併單一縫合吻合術與傳統腹腔鏡切除術在短期結果和長期腫瘤學結果上的差異。

方法 此為單一醫學中心回顧性研究，收錄從 2015 年 1 月到 2024 年 6 月，共有 326 名乙狀結腸直腸癌患者納入本研究。我們確定了 29 名接受經自然孔腔標本取出之腹腔鏡前位切除術並進行單一縫合吻合術的患者 (NOSE-SS 組)，以及 297 名接受腹腔鏡前位切除術並進行雙縫合吻合術的患者 (AISE-DS 組) 進行分析。使用傾向性配對匹配方法，以平衡兩組的臨床病理特徵。

結果 根據手術前後之統計數據及術後追蹤，NOSE-SS 組患者的術後疼痛分數顯著低於 AISE-DS 組 (2.98 ± 0.85 vs. 1.86 ± 0.74 ; $p < 0.001$)，但 NOSE-SS 組的術中出血量較多 (51.38 毫升 vs. 24.83 毫升; $p = 0.037$)。兩組在手術時間和併發症發生率上無顯著差異。此外，長期結果 (包括局部復發、無病生存期和總體生存期) 在兩組之間也無顯著差異，NOSE-SS 組的中位追蹤時間為 62 個月，而 AISE-DS 組為 40.5 個月。

結論 對於特定的乙狀結腸直腸癌患者，經自然孔腔標本取出手術併單一縫合吻合術是一種安全且可靠的根治性手術技術，與傳統腹腔鏡相比，可減少腹壁創傷，而且長期腫瘤學結果並無顯著差異。

關鍵詞 經自然孔腔標本取出手術、單一縫合吻合術、腹腔鏡前位切除術、結直腸癌。