Original Article
Stapled trans-anal rectal resection can improve constipation symptoms and inflammatory reaction of patients with outlet obstructive constipation

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Abstract: Objective: To explore the effect of stapled trans-anal rectal resection (STARR) on constipation symptoms and inflammatory reaction in patients with outlet obstructive constipation (OOC). Methods: From January 2019 to June 2020, a retrospective analysis was conducted on the medical data of 124 patients with OOC admitted to our hospital. According to the different surgical methods, sixty patients were assigned to the control group (CG) treated with Bresler operation, and sixty-four patients were included in the research group (RG) receiving STARR. The total effective rate of treatment, the incidence of postoperative complications, and mid- and long-term recurrence rate were observed between the two groups. The anorectal dynamic indexes, the constipation scoring system (CSS), obstructive defecation syndrome (ODS), visual analogue scale (VAS) scores, and the changes of inflammatory cytokine [tumor necrosis factor-α (TNF-α) and interleukin-6 (IL-6)] were compared between the two groups, and the perioperative indexes were observed. Results: After operation, a remarkably higher total effective rate was observed in the RG as compared to the CG. The RG obtained lower results in terms of the incidence of postoperative complications, 3-year recurrence rate, operation cost, and intraoperative blood loss than CG. Compared with patients in the CG, those in the RG had shorter operation time, first exhaust time, time of leaving bed, and hospitalization time. Moreover, a shorter defecation time of patients in the RG was also obtained 14 days after treatment. In addition to rectal rest pressure that was similar between the two groups, the anal maximal contraction pressure, anal longest contraction time, anorectal relaxation pressure, and anal rest pressure were significantly higher in the RG than in the CG. After operation, remarkably lower CSS and ODS scores of patients were obtained in the RG than in the CG. The RG yielded lower VAS scores after operation and 24 hours after operation, and lower levels of TNF-α and IL-6 1 day after operation in contrast to the CG. Conclusion: STARR can effectively improve the clinical efficacy, ameliorate the symptoms of postoperative constipation, reduce the long-term recurrence rate, relieve postoperative pain, and better protect the anorectal function and mitigate inflammatory reaction for patients with obstructive constipation.

Keywords: Stapled trans-anal rectal resection, outlet obstructive constipation, constipation symptoms, inflammatory reaction

Introduction

Constipation refers to digestive tract diseases with main symptoms such as less intention, less frequent defecation, strenuous defecation, and dry stools [1]. Its pathogenic factors are complex, which are often related to gender, age, geographical distribution, diet habits, heredity, occupational environment, cultural differences, family economy, race, and personal character [2]. The middle-aged and elder populations are more susceptible to the disease, with a higher incidence among women than men [3]. Moreover, constipation is frequently accompanied by abdominal discomforts such as abdominal pain and distension, intense emotional changes, and psychological diseases such as insomnia, dreaminess, dysphoria, depression, and anxiety. The disease in the early stage may be considered harmless and trivial as it is easily tolerated [4]. However, long-term constipation is bound up with colorectal cancer and may even induce myocardial infarction and cerebrovascular disease [5]. Constipation can be divided into organic constipation and functional constipation according to

the etiology. Organic constipation mainly includes rectal and anal canal diseases, and intestinal canal organic diseases [6]. Functional constipation is mainly caused by colonic motor dysfunction with unclear pathogenesis. Key factors that have been realized to cause constipation include insufficient intake of cellulose in food that leads to less intestinal secretion and peristalsis, unhealthy defecation habits which are commonly seen in modern people with unhealthy lifestyles, old age, infirmity, and long-term medication [7]. According to the pathogenesis, constipation can be divided into slow transit constipation (STC) and outlet obstruction constipation (OOC) [8]. STC is caused by weakened intestinal motility and a prolonged transit of feces from the cecum to the rectum. Meanwhile, the retention of feces in the large intestine leads to the absorption of a large amount of water and then dry feces. Diabetes-induced constipation is mostly STC [9]. OOC is more common in clinical practice, mainly due to pelvic floor muscles dysfunction that leads to uncoordinated movement of the anal canal during defecation, causes of which mainly include puborectalis hypertrophy, rectal mucosa prolapse, and rectocele [10]. The vast majority of patients with OOC are women, frequently seen in multiparas and patients after hysterectomy [11].

Currently, clinical treatment is mainly to relieve symptoms and promote the recovery of regular defecation, including diet instruction, psychological guidance, drug therapy, biofeedback therapy, colon hydrotherapy, and surgical treatment [12]. Nevertheless, patients invariably turn to surgery given the unsatisfactory efficacy of conservative treatment [13]. Surgical methods include traditional rectal mucosa columnar suture ligation, rectal mucosa ligation, transrectal fixation, and Delorme operation [14]. In surgery, the surgical mechanical damage and the poor physical condition of the patients all aggravated the perioperative inflammation [15]. Stapler is a surgical instrument that integrates resection and suture, which has been widely used in anorectal surgery [16]. Stapled trans-anal rectal resection (STARR) treats OOC by removing redundant tissues of the rectum, to improve the defecation function after correcting two anatomical abnormalities and restoring rectal compliance [17]. STARR is extensively accepted and favored for its small

trauma, rapid postoperative recovery, and mitigated inflammatory response [18]. However, few scholars have been able to draw on any systematic research into the effect of STARR on constipation symptoms and inflammatory response in patients with OOC. Accordingly, this study included patients with OOC for STARR to discuss its effect on constipation symptoms and inflammatory reactions.

Materials and methods

Baseline data

From January 2019 to June 2020, a retrospective analysis was conducted on the medical data of 124 patients with OOC admitted to our hospital. According to the different surgical methods, sixty patients were assigned to the control group (CG) treated with Bresler operation, and sixty-four patients were included in the research group (RG) receiving STARR. In RG, there were 18 males and 46 females, aged 30-69 years, with an average age of (52.93±4.61) years. In CG, there were 15 males and 45 females, aged 28-70 years, with an average age of (50.88±4.36) years. This research has been ratified by the Ethics Committee of our hospital, and all patients and their families have been informed and affixed the full informed consent form. The ethics certificate number is 2018-12-16.

Inclusion and exclusion criteria

Inclusion criteria: (1) The patient met the diagnostic criteria for OOC [19]; (2) The patient met the surgical indications; (3) Difficult and incomplete bowel movement, with senses of obstruction in the anus and anus prolapse; (4) Rectal mucosal prolapse, rectal protrusion, perineal descent, pelvic floor spasm syndrome; (5) Contraction of the anus as the puborectalis and external anal sphincter muscles could not relax during defecation but contract with a higher tension.

Exclusion criteria were as below: (1) Comorbid with severe primary organ diseases and end-stage malignant tumours; (2) Patients with coagulation dysfunction; (3) Comorbid with hematological diseases and infectious diseases; (4) Patients with contraindication to surgical anesthesia; (5) Patients with cognitive dysfunction, central nervous system, and severe

peripheral nerve diseases; (6) Incomplete data; Patients who quit the experiment halfway.

Surgical methods

In both groups, patients were given routine examinations such as blood, urine, and electrocardiogram before operation.

CG: Patients were given Bresler operation. According to the patient's situation, general anesthesia or epidural anesthesia was applied, with the patient in the prone position and the anus fully expanded. The anus was penetrated by the finger to determine the extent of the rectum protrusion. Tissue forceps were applied to lift the intussuscepted and rectocele anterior wall tissues. The anterior rectal wall tissue from 1-7 cm of the dentate line was lifted and sutured to stop bleeding using a 45 cm endoscope cutting stapler. During the first two days after the operation, the patients were given liquid food and antibiotics to prevent infection.

RG: Patients were given STARR. General anesthesia or epidural anesthesia was applied according to the patient's conditions. With the patient in the lithotomy position and a transparent anal dilator secured, the full-thickness rectal semi-circumferential purse-string suture was performed with silk suture 7-0 on the anterior wall of the rectum at 3 cm from the dentate line. Then, an intestinal spatula was inserted into the rectum to prevent the mucosa of the rectum posterior wall from sliding into the staple cartridge. During the installation of the first stapler, with the purse-string line tightened, the anterior wall of the rectum was drawn into the staple cartridge. The mucosal bridge was cut after the withdrawal of the stapler, followed by the performance of full-thickness semi-circumferential purse-string suture of the posterior rectal wall, and the posterior rectal wall was excised with the second stapler. The anastomotic stoma was examined and the pulsating bleeding was treated in time. During the first two days after the operation, the patients were given liquid food and antibiotics to prevent infection.

Outcome measures

In this study, the primary indicators were the observation indexes that are essentially related to the research purpose and can accurately reflect the treatment effect, including total effective rate, incidence of postoperative complications, anorectal dynamics index, mid- and long-term recurrence rate; The indicators related to the research purpose were used as secondary indicators, including perioperative indicators, constipation scoring system (CSS) score, obstructive defecation syndrome (ODS) score, visual analogue scale (VAS) score, and inflammatory factor.

Total effective rate: The efficacy of all patients was analysed 1 month after surgery. The efficacy criteria were as below: Cured: Constipation improved obviously after the operation; patients defecated every 1 to 2 days with defecation time within 5 minutes; there was no sense of obstruction in the anus, and no sense of anus prolapse. Effective: During defecation, there was a slight sense of obstruction at the anus or a sense of prolapse in the lower abdomen; patients defecated every 1 to 2 days without auxiliary laxative, and the defecation lasted for 6-10 minutes. Ineffective: The constipation was not significantly improved; the sense of obstruction and lower abdomen prolapse was obvious when defecating; The defecation time was >10 min or laxatives were needed. Total effective rate = (cured cases + effective cases)/ total cases ×100%.

Perioperative indicators include operation time, operation cost, intraoperative blood loss, postoperative exhaust time, time of leaving bed, and hospitalization time.

Incidence of postoperative complications: Common postoperative complications include pain, bleeding, urinary retention, anal prolapse, and anastomotic stoma inflammation.

Anorectal dynamics index: The defecation time, anal maximal contraction pressure (AMCP), anorectal relaxation pressure (ARRP), anal rest pressure (ARP), rectal rest pressure (RRP), and anal longest contraction time (ALCT) were compared between the two groups before and 14 days after operation.

Mid- and long-term recurrence rate: The patients were followed up for 3 years after surgery with 1-year as the mid-term timepoint and 3-year as the long-term timepoint, and the recurrence was recorded.

CSS score [20]: It incorporates 8 items (defecation frequency, difficulty in defecation, feeling of incomplete defecation, abdominal pain, time of defecation every time, assisted defecation, number of patients who failed to defecate daily and duration of constipation history), with a total score of 0-30 points, of which 0 represents the best function and 30 represents the worst function.

Obstructive defecation syndrome (ODS) score: Longo OOC score (Longo score) [21] scale was applied to evaluate the constipation of patients. The test items include defecation frequency, defecation difficulty, duration, and discomfort. The total score of ODS is 0-40, and the higher the score, the more severe the symptoms of ODS.

VAS score: Visual analogue scale (VAS) [22] was applied to evaluate the pain degree in both groups after operation and 24 hours after operation. 0 points indicated no pain; A score of less than 3 indicated slight and tolerable pain; 4-6 points indicated obvious and intolerable pain that disrupts sleep; A score of 7-10 indicated intense pain that disrupts sleep. The lower the score, the lighter the pain symptoms.

Inflammatory factor: The venous blood (5 mL) was drawn from each patient in both groups before and 1 day after operation. Enzyme-linked immunesorbent assay (ELISA) was applied to test tumour necrosis factor-α (TNF-α) and interleukin-6 (IL-6) of patients in both groups before and 1 day after operation. The operation was carried out in strict accordance with the instructions of human TNF-α ELISA and human IL-6 ELISA (Shanghai Jingkang Bioengineering Co., Ltd., Shanghai, China, JK-(a)-4948, JK-(a)-1498) kits.

Statistical methods

SPSS24.0 (IBM Corp, Armonk, NY, USA) was applied for statistical analysis. GraphPad Prism 7 was applied to plot the graphics. The counting data were represented by [n (%)]. Chi-square test was applied to compare the counting data between groups. When the theoretical frequency in Chi-square test was less than 5, the continuity correction Chi-square test was adopted. The measurement data were represented by mean number ± standard deviation ($\bar{x}$±SD). The measurement data between groups were compared by the independent sample t test. Paired t test was applied for intra-group comparison before and after treatment. When P<0.05, the difference was statistically significant.

Results

Baseline data

There was no striking difference in baseline data such as gender, age, body mass index (BMI), course of disease, marriage, place of residence, educational background, smoking history, drinking history, hypertension, and diabetes between the two groups (P>0.05) (**Table 1**).

Total effective rate of treatment

One month after treatment, the RG obtained a total effective rate of 95.31%, which was significantly higher compared with that of 75.00% in the CG (P<0.01) (**Table 2**).

Perioperative index

The operation time, postoperative exhaust time, time of leaving bed, hospitalization time, operation cost, and intraoperative blood loss of patients in RG were remarkably lower than those in CG (P<0.01) (**Table 3**).

Incidence of postoperative complications

After therapy, patients in the RG had a lower incidence (10.94%) of adverse reactions, as compared to that of 31.67% in the CG (P<0.01) (**Table 4**).

Anorectal dynamics index

Before therapy, there was no great disparity in defecation time, AMCP, ARRP, ARP, RRP, and ALCT between the two groups. Fourteen days after therapy, compared with the CG, the RG yielded a shorter defecation time of patients, and higher AMCP, ALCT, ARRP, and ARP (P<0.05). However, the two groups did not differ with regard to RRP (P>0.05) (**Figure 1**).

Mid- and long-term recurrence rate

One year after operation, the two groups showed similar recurrence rates (P>0.05), but the recurrence rate in RG was remarkably lower

Table 1. Comparison of baseline data between the two groups [n (%)] ($\bar{x}$±sd)

Classification	RG (n=64)	CG (n=64)	t/χ^2 value	P value
Gender			0.154	0.693
Male	18 (28.12)	15 (25.00)		
Female	46 (71.88)	45 (75.00)		
Age (years old)	52.93±4.61	51.88±4.36	1.301	0.195
BMI (kg/m^2)	22.86±3.54	23.07±3.25	0.343	0.731
Course of disease (years)	7.26±0.54	7.31±0.42	0.572	0.567
Marital status			0.083	0.772
Married	40 (62.50)	39 (65.00)		
Unmarried or widowed	24 (37.50)	21 (35.00)		
Place of residence			0.573	0.449
City	31 (48.44)	25 (41.67)		
Rural	33 (51.56)	35 (58.33)		
Educational background			0.113	0.736
≥ high school	21 (32.81)	18 (30.00)		
< high school	43 (67.19)	42 (70.00)		
Smoking history			0.710	0.399
Yes	12 (18.75)	15 (25.00)		
No	52 (81.25)	45 (75.00)		
Drinking history			0.393	0.530
Yes	17 (26.56)	20 (33.33)		
No	47 (73.44)	40 (66.67)		
Hypertension history			0.705	0.400
Yes	26 (40.62)	20 (33.33)		
No	38 (59.38)	40 (66.67)		
Diabetes history			0.165	0.683
Yes	13 (20.31)	14 (23.33)		
No	51 (79.69)	46 (76.67)		

Table 2. Comparison of total effective rate between the two groups [n (%)]

Grouping	Cure	Effective	Ineffective	Total effective rate
RG (n=64)	50 (78.12)	11 (17.19)	3 (4.69)	61 (95.31)
CG (n=64)	20 (33.33)	25 (41.67)	15 (25.00)	45 (75.00)
χ^2	-	-	-	10.300
P	-	-	-	0.0013

than that in CG 3 years after operation (**Table 5**).

CSS score

There was no striking difference in CSS scores between the two groups before operation (P>0.05), and lower CSS scores were observed in the RG in contrast to those in the CG one month and six months after operation (P<0.05) (**Figure 2**).

ODS score

No great disparity in ODS scores was detected between the two groups before operation and one month after operation (P>0.05). Six months after operation, the RG garnered markedly lower ODS scores than CG (**Figure 3**).

VAS score

Strong evidence of remarkably lower VAS scores of patients in RG than CG after operation and 24 hours after operation was found (P<0.05) (**Figure 4**).

Inflammatory factor

The levels of TNF-α and IL-6 in both groups had no significant difference before operation (P>0.05). On the first day after operation, the levels of TNF-α and IL-6 in the two groups witnessed an increase, with lower levels observed in the RG compared with the CG (P<0.05) (**Figure 5**).

Discussion

OOC has a high incidence, accounting for about 60% of all chronic constipation, which takes a toll on patients' physical and mental health [23]. Conservative treatments, such as drug therapy, biofeedback therapy, colon hydrotherapy, and psychological intervention with limited efficacy may fall flat as the disease worsens [24]. Therefore, surgical treatment is the current main treatment, with an aim to fundamentally eliminate the abnormality that causes outlet obstruction, study the etiology, and limit the negative circulation caused by OOC [25].

With the development of medical instruments and the advancement of medical technology, the scheme of STARR shows a promising application prospect [26]. Therefore, we used this surgical method to treat patients with

Table 3. Comparison of perioperative indicators between the two groups ($\bar{x}$±sd)

Grouping	Operation time (min)	Postoperative exhaust time (h)	The time of leaving bed (h)	Hospitalization time (d)	Operation cost (yuan)	Intraoperative blood loss (ml)
RG (n=64)	19.21±2.82	9.12±1.07	8.06±0.49	5.04±0.64	7688.70±305.16	9.05±0.13
CG (n=64)	22.14±2.90	12.27±1.32	11.48±0.75	8.18±1.34	11596.23±354.74	13.65±1.45
t	5.703	14.640	30.240	16.820	65.880	25.280
P	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01

Table 4. Comparison of the incidence of adverse reactions between the two groups [n (%)]

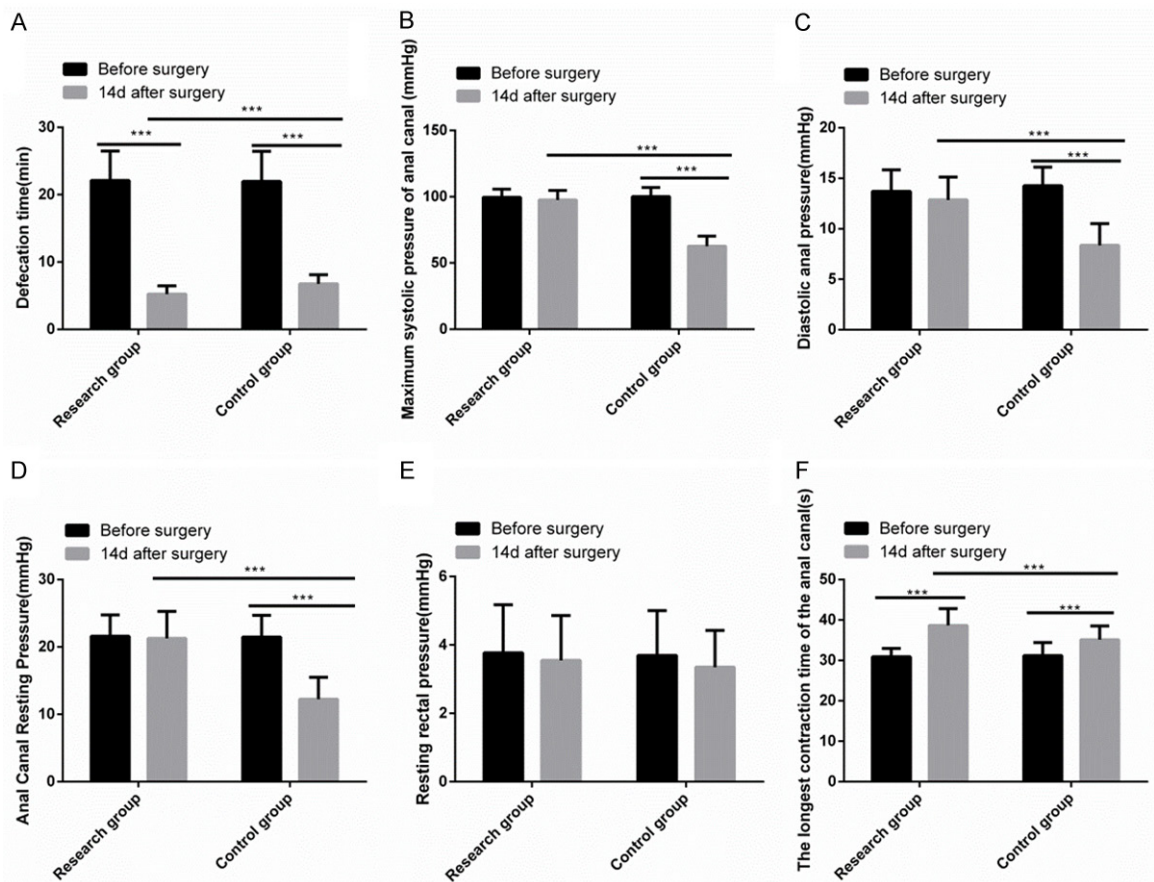| Groups	Pain	Bleeding	Urinary retention	Anal fall-swell	Anastomotic stoma inflammation	Total incidence rate
RG (n=64)	2 (3.13)	1 (1.56)	2 (3.13)	1 (1.56)	1 (1.56)	7 (10.94)
CG (n=64)	5 (8.33)	3 (5.00)	4 (6.67)	3 (5.00)	4 (6.67)	19 (31.67)
χ^2	-	-	-	-	-	8.030
P	-	-	-	-	-	0.0046

Figure 1. Comparison of anorectal dynamic indexes. Before therapy, there was no striking difference in defecation time (A), AMCP (B), ARRP (C), ARP (D), RRP (E), and ALCT (F) between the two groups. 14 days after therapy, the defecation time (A) of patients in RG was significantly shorter than that in CG, and the AMCP (B), ALCT (F), ARRP (C), and ARP (D) were significantly higher than those in CG, while there was no striking difference in RRP (E) between the two groups. Note: ***P<0.001.

OOC in this study, and retrospectively analysed and explored the effect of STARR on the constipation symptoms and inflammatory reaction.

Table 5. Comparison of mid- and long-term recurrence rate between the two groups [n (%)]

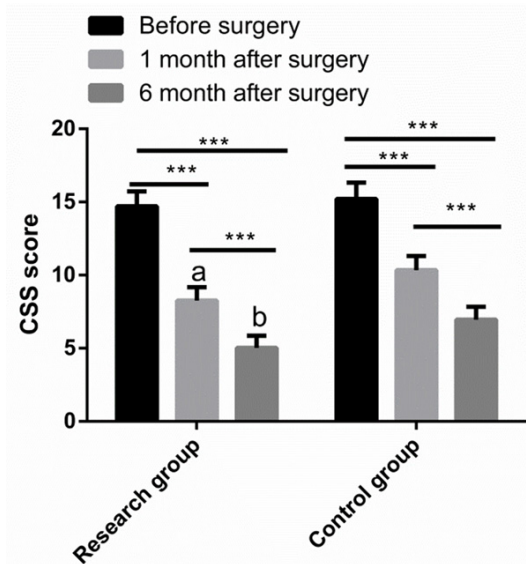| Groups	Recurrence rate after operation for 1 year	Recurrence rate after operation for 3 year
RG (n=64)	1 (1.56)	2 (3.13)
CG (n=64)	3 (5.00)	12 (20.00)
χ^2	0.411	6.829
P	0.5213	0.009

Figure 2. Comparison of CSS score. There was no striking difference in CSS scores between the two groups before operation, and the CSS scores of the patients in RG were significantly lower than those in CG one month after operation and six months after operation. Note: ***P<0.001; a means the comparison with the CG at 1 month after surgery, P<0.001; b represents the comparison with the CG at 6 months after surgery, P<0.001.

Research by Lin et al. [27] has revealed that STARR is safe and effective and can significantly improve the symptoms of obstructive constipation in patients with external rectal prolapse. STARR is characterized by the use of two staplers during the operation. The first one is used to remove the protruding part of the anterior wall of the rectum, and to remove the anterior part of rectal intussusception prolapse; the second one is used to remove the posterior part of rectal intussusception and prolapse of the posterior wall of the rectum. The correction of the abnormal anatomy of the rectum can relieve the symptoms. The use of two staplers can shorten the operation time, reduce intraop-
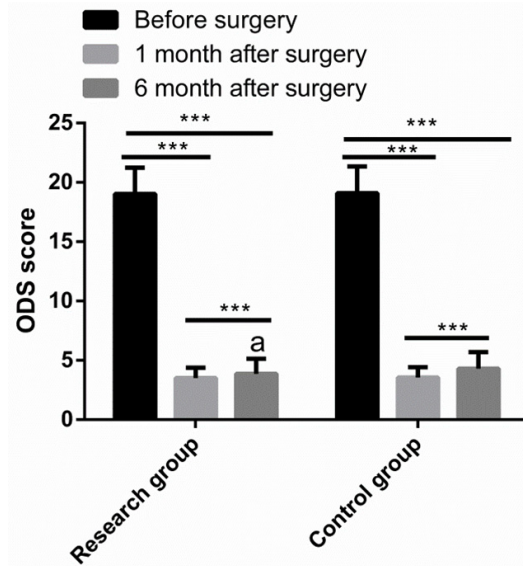

Figure 3. Comparison of ODS scores. There was no striking difference in ODS scores between the two groups before operation, and there was no striking difference in ODS scores between the two groups 1 month after operation, but the ODS scores in RG were significantly lower than those in CG 6 months after operation. Note: ***P<0.001. A represents the comparison with the CG 6 months after surgery, P<0.001.
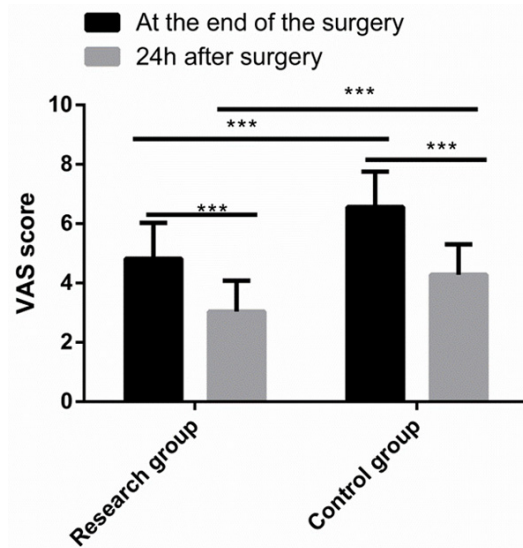

Figure 4. Comparison of VAS score. The VAS scores of patients in RG were significantly lower than those in CG at the end of operation and 24 hours after operation Note: ***P<0.001.

erative bleeding, and accelerate postoperative recovery. In addition, the study by Madbouly et al. [28] demonstrated that anastomotic transanal rectal resection could significantly amelio-
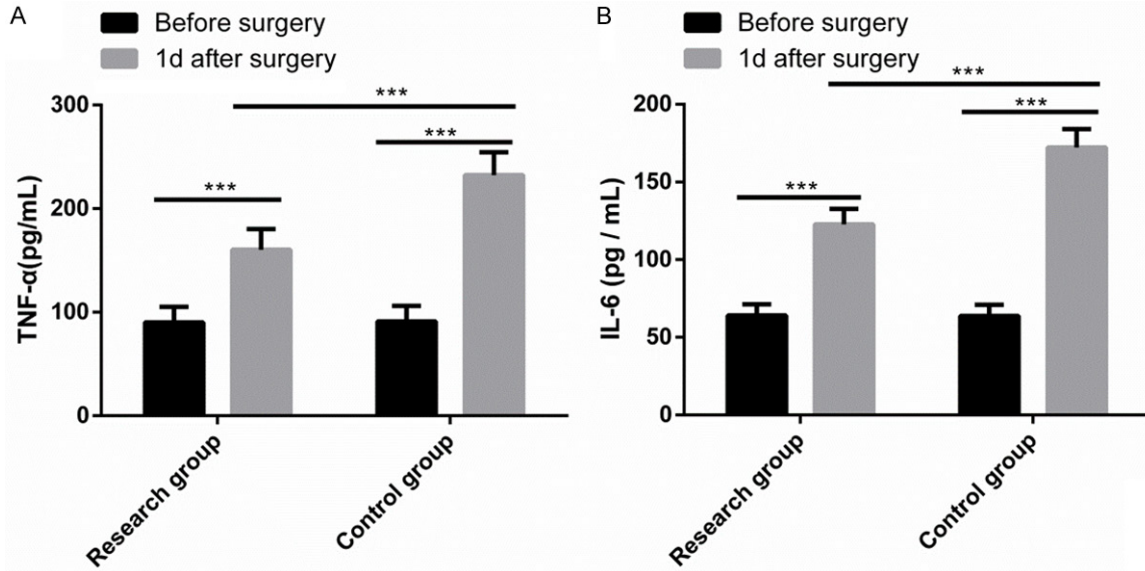
Figure 5. Comparison of inflammatory factors. On the first day after operation, the levels of serum TNF-α (A) and IL-6 (B) in the two groups were significantly higher than those before operation, and the RG was significantly lower than that in CG. Note: ***P<0.001.

rate the constipation symptoms, reduce the long-term recurrence rate, and improve the postoperative quality of life for elderly patients with obstructive constipation. In this study, it was found that the total effective rate of patients in RG was significantly higher than that in CG 1 month after operation, indicating that STARR can effectively enhance the efficacy, which is similar to the research results reported by Lin et al.

In this study, we also found that the operation time, postoperative exhaust time, time of leaving bed, hospitalization time, operation cost, and intraoperative blood loss of patients in RG were remarkably lower than those in CG, which indicated that STARR can effectively shorten the operation time, reduce the injury caused by operation and promote the postoperative recovery of patients. Research by Mascagni et al. [29] pointed out that STARR could significantly improve the operation effect and reduce postoperative complications for patients with obstructive constipation, which is similar to our research results. Meanwhile, this study revealed a lower incidence of postoperative complications in RG than CG, suggesting that this operation method can effectively reduce postoperative complications of patients, which is similar to the research results of Mascagni D. The anorectal dynamics index is a favorable index to evaluate the anorectal function.

The results of this study showed that the defecation time of patients in RG was markedly shorter than that in CG, and the AMCP, ALCT, ARRP, and ARP were significantly higher than those in CG 14 days after therapy, while there was no striking difference in RRP between the two groups, indicating that STARR can substantially relieve constipation symptoms and better protect the rectal function of patients. Research by Lin et al. [30] confirmed that anastomotic anorectal resection could effectively protect patients' anorectal function, which is consistent with our research results. Besides, research by Yu et al. [31] stated that the long-term effect of trans-anal anastomosis was remarkable in treating obstructive defecation syndrome, which could prominently reduce the CSS score and ODS score of patients after operation.

Moreover, it could significantly relieve postoperative pain and reduce the VAS score of patients after operation.

In this study, we evaluated the CSS scores and ODS scores of patients before operation, one month after operation, and six months after operation. It was found that the CSS scores of patients were lower than those in CG at one month and six months after operation, while the ODS scores had no significant difference at one month after operation, but were recorded

with a lower result than those in CG six months after operation. It shows that STARR exerts a remarkable treatment effect six months after operation, while no significant efficacy was observed one month after operation, indicating a better long-term effect of STARR, which is in conformity with the research results by Yu Y. In this study, we also evaluated the VAS scores of patients 24 hours after surgery, and the results showed that the VAS scores of patients in RG were lower than those in CG after surgery and 24 hours after surgery, indicating that STARR can effectively relieve the pain of patients, which is similar to the research results by Yu Y. Furthermore, the results demonstrated that there was no striking difference in the recurrence rate of patients 1 year after operation, but the recurrence rate of patients 3 years after operation in RG was remarkably lower than that in CG, indicating that STARR can prominently reduce the long-term recurrence rate, which is similar to the research results of Madbouly KM.

Finally, we also tested the inflammatory factors before and after operation. The results presented that the level of inflammatory factors in RG was remarkably lower than that in CG after operation, which suggested that STARR can effectively mitigate the inflammatory reaction of patients and alleviate the harm to the body. Research by Naldini et al. [32] pointed out that anastomotic anal resection could effectively drive down the complications and abate the inflammatory reaction in patients with obstructive constipation, which is consistent with our research results.

To sum up, STARR can effectively improve clinical efficacy, ameliorate the symptoms of postoperative constipation, reduce the long-term recurrence rate, relieve postoperative pain, and better protect the anorectal function and reduce inflammatory reaction for patients with obstructive constipation. However, there are still some shortcomings in this study. Firstly, the study sample size is rather small. Second, the study did not analyze the risk factors of recurrence during the long-term follow-up to provide clinical treatment plans. Therefore, our research will be carried out concerning the above perspectives in the future.

Disclosure of conflict of interest

None.

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