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**RESPONSIBLE EDITORS FOR THIS ISSUE**

Production Editor: *Ying-Yi Yuan*, Production Department Director: *Xu Guo*, Editorial Office Director: *Jin-Lei Wang*.

**NAME OF JOURNAL**

*World Journal of Clinical Cases*

**ISSN**

ISSN 2307-8960 (online)

**LAUNCH DATE**

April 16, 2013

**FREQUENCY**

Thrice Monthly

**EDITORS-IN-CHIEF**

Bao-Gan Peng, Jerzy Tadeusz Chudek, George Kontogeorgos, Maurizio Serati, Ja Hyeon Ku

**EDITORIAL BOARD MEMBERS**

<https://www.wjgnet.com/2307-8960/editorialboard.htm>

**PUBLICATION DATE**

June 26, 2022

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<https://www.wjgnet.com/bpg/gerinfo/242>

**STEPS FOR SUBMITTING MANUSCRIPTS**

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**ONLINE SUBMISSION**

<https://www.f6publishing.com>

## Randomized Controlled Trial

# Evaluation of the clinical efficacy and safety of TST33 mega hemorrhoidectomy for severe prolapsed hemorrhoids

Liu Tao, Jun Wei, Xu-Feng Ding, Li-Jiang Ji

**Specialty type:** Surgery**Provenance and peer review:**

Unsolicited article; Externally peer reviewed.

**Peer-review model:** Single blind**Peer-review report's scientific quality classification**

Grade A (Excellent): 0  
Grade B (Very good): B, B  
Grade C (Good): 0  
Grade D (Fair): 0  
Grade E (Poor): 0

**P-Reviewer:** Thacoor A, United Kingdom; Yumiba T, Japan**Received:** December 15, 2021**Peer-review started:** December 15, 2021**First decision:** January 26, 2022**Revised:** February 8, 2022**Accepted:** April 25, 2022**Article in press:** April 25, 2022**Published online:** June 26, 2022

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## Abstract

### BACKGROUND

The pathogenesis of hemorrhoids is mainly anal cushion prolapse. Although the traditional treatment has a certain curative effect, it is not ideal. The remission rate of postoperative symptoms is low. Even if temporary remission is achieved, patients with hemorrhoids easily relapse after 1-2 years. The new technique of using staplers to treat prolapsed hemorrhoids has good therapeutic effects in clinical practice.

### AIM

To explore the effect of TST33 mega stapler prolapse and hemorrhoid mucosal resection in the treatment of patients with severe prolapsed hemorrhoids.

### METHODS

A total of 204 patients with severe prolapse hemorrhoids who were admitted to the department of anorectal in our hospital from April 2018 to June 2020 were selected, and the patients were randomly divided into group A and group B with 102 cases in each group using a randomized controlled clinical research program. Patients in Group A were treated with a TST33 mega stapler and hemorrhoid mucosal resection to treat prolapse, and patients in Group B were treated according to the Procedure for Prolapse and Hemorrhoids; the operation time, intraoperative blood loss, hospital stay, the difference in operation time, intraoperative blood loss, hospitalization time, pain degree before and after operation, degree of anal edema, anal Wexner score, and surgical complications were compared between the two groups of patients.

### RESULTS

The operation time, intraoperative blood loss and hospitalization time in Group A were significantly lower than those in Group B ( $P < 0.05$ ). The cure rate of Group A was 98.04%, compared with 95.10% cure rate of Group B, and the difference

was not statistically significant ( $P > 0.05$ ). The visual analogue scale (VAS) at 12 h and 24 h postoperatively in Group A were significantly lower than those in Group B ( $P < 0.05$ ). The comparison of the VAS scores between Group A and Group B at 48 h, 72 h and 96 h postoperatively revealed that the difference was not statistically significant ( $P > 0.05$ ). One day postoperatively, the degree of perianal edema in Group A was compared with that in Group B, and the difference was not statistically significant ( $P > 0.05$ ). Seven days postoperatively, the degree of perianal edema in Group A was significantly lower than that in Group B ( $P < 0.05$ ). The comparison of anal Wexner scores between the two groups preoperatively and at 1 mo, 3 mo and 6 mo postoperatively showed that the difference was not statistically significant ( $P > 0.05$ ). The Wexner scores of the two groups at 1 mo, 3 mo and 6 mo postoperatively were significantly lower than the scores preoperatively ( $P < 0.05$ ). The postoperative complication rate of Group A was 2.94% lower than that of Group B (11.76%), which was statistically significant ( $P < 0.05$ ).

### CONCLUSION

TST33 mega anastomotic hemorrhoidectomy treatment for patients with severe prolapse hemorrhoids, leads to less postoperative pain, the rapid recovery of perianal edema and has fewer complications.

**Key Words:** TST33 mega stapler; Prolapse of hemorrhoids; Severe prolapsed hemorrhoids; Hemorrhoids; Circumcision

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**Core Tip:** Hemorrhoids are common benign perianal diseases, accounting for more than 80% of the incidence of all anorectal diseases. Severe prolapsed hemorrhoids due to the increase in hemorrhoid volume and defecation by fecal extrusion eventually lead to the fracture of anal muscle fibers.

**Citation:** Tao L, Wei J, Ding XF, Ji LJ. Evaluation of the clinical efficacy and safety of TST33 mega hemorrhoidectomy for severe prolapsed hemorrhoids. *World J Clin Cases* 2022; 10(18): 6060-6068

**URL:** <https://www.wjgnet.com/2307-8960/full/v10/i18/6060.htm>

**DOI:** <https://dx.doi.org/10.12998/wjcc.v10.i18.6060>

## INTRODUCTION

The symptoms are more serious and the hemorrhoids generally need to be pushed back with the hand after prolapse, so severe prolapsed hemorrhoids require surgical treatment[1,2]. The procedure for prolapse and hemorrhoids (PPH) can lift and pull the anal cushion by circular resection of the rectal mucosa approximately 2–3 cm above the tooth line and anastomosis. The advantage is that the short-term therapeutic effect is still acceptable, but the PPH is prone to various complications after surgery, the recurrence rate is high, and the long-term curative effect is poor. The use of tissue-selecting therapy staplers (TSTs) has been reported, but reports are rare. To some extent, this operation reduces the disadvantages of the PPH caused by circular resection, but because of selective resection, the use of TSTs does not change the high recurrence rate after PPH. The TST33 mega stapler has an open window, and the resection tissue boundary is open, so more pathological hemorrhoids are able to be resected. Under the premise of solving PPH complications, the use of TSTs also improves the postoperative recurrence rate to a certain extent[3]. To further summarize and analyze the surgical treatment methods for patients with severe prolapsed hemorrhoids, this study compared the effect of TST33 mega staplers to provide a basis for clinical practice, which is reported as follows.

## MATERIALS AND METHODS

### General information

A total of 204 patients with severe prolapsed hemorrhoids that were admitted to the anorectal department of our hospital from April 2018 to June 2020 were selected and randomly divided into Group A and Group B, with 102 cases in each group, by a single-blind, randomized and controlled clinical research scheme. Inclusion criteria: (1) The age range of patients is 19 to 65 years; (2) The diagnostic criteria for patients with severe prolapsed hemorrhoids refer to the criteria in the Chinese

Guidelines for the Diagnosis and Treatment of Hemorrhoids (2020)[3]; (3) Non-circular hemorrhoids Suspended for more than half a year, reaching III and IV degree; (4) Conservative treatment for more than 3 mo is not effective; and (5) The research plan obtains the informed consent of patients and their families. The exclusion criteria were as follows: (1) Patients with a rectal tumor; (2) Patients with a perianal abscess, or anal fistula formation; (3) Patients with liver and kidney function diseases; (4) Patients with coagulation diseases; (5) Patients with a history of drug use or addiction; and (6) Patients with mental or psychological diseases.

### **Surgical methods**

The patients in the two groups were given routine preoperative preparation, improved preoperative examination, and fasted on the day of operation. All patients were given intraspinal anesthesia, and the left lateral position was used for the operation.

**Group A:** For patients undergoing TST33 mega stapler hemorrhoid mucosal resection surgery, the appropriate anal mirror was selected (single opening, double opening or three opening anal mirror). The anal mirror was inserted and the inner tube was removed to expose the hemorrhoid tissue to be removed, and sutured with "0" silk sutures at the distance of 2.5-5 cm from the dentate line. Sutures were only placed in the mucosa and submucosa, a needle was placed in each opening suture, and a continuous bag was used. Sutures were only placed in the mucosa and submucosa, a needle was placed in each opening suture, and a continuous bag was used. The tail wing of the stapler was opened counterclockwise. After the head and body of the stapler were completely loosened, the head of the stapler was inserted into the anal expander. The two ends of the purse line were tightened and knotted around the central rod. The suture was exported from the symmetrical side hole of the stapler body through the suture export rod. Moderate traction was performed, the stapler was screwed clockwise, and the traction rectal tissue was pulled into the stapler nail slot. At this time, the feel knob was resistant, and the pointer of the stapler indicator window was displayed in the firing range. For female patients, surgeons paid attention to whether the posterior wall of the vagina was sutured. The stapler was hit, completing the cutting and anastomosis. For a fixed wait time of 30 s, the stapler was spun counterclockwise with a loose 3/4 circle tail, and removed. Observation of anastomotic stoma was performed if there was active bleeding. Line 8' sutures were used for hemostasis. The 'cat ear' in the middle of the anastomosis was ligated with "0" silk thread. External hemorrhoid stripping to the teeth near the line parallel low ligation was performed.

**Group B:** The PPH was used for the treatment of hemorrhoids, and a PPH stapler was used for the treatment of internal hemorrhoids. External hemorrhoid stripping to the teeth near the line parallel low ligation was performed.

The patients in the two groups could go to the recovery unit after anesthesia recovery, and their diet gradually changed from a half-stream diet to an ordinary diet. The total infusion volume was controlled within 500 mL 6 h after the operation to reduce the incidence of urinary retention. Antibiotics were routinely used for 5 d after the operation, and dressing treatment was performed after sitting in the bath.

### **Observation indices and evaluation criteria**

The operation time, intraoperative blood loss, hospitalization time, cure rate, pain degree, anal edema degree, anal Wexner score and surgical complications were compared between the two groups.

The criteria for healing[5] were postoperative defecation or standing for a long time and no hemorrhoid prolapse when coughing, tired, and loaded was defined as a cure.

The visual analogue scale (VAS) was used to evaluate the degree of pain[5], with 0 indicating no pain, and 10 indicating the most pain. The pain scores at 12 h, 24 h, 48 h, 72 h and 96 h postoperatively were observed.

Observe the edema around the anal margin on the 1<sup>st</sup> and 7<sup>th</sup> postoperative day. Degree I: no edema of the anal margin; degree II: mild edema of the anal margin occupies less than 1/4 circle of the perianal; degree III: edema of the anal margin occupies more than 1/4 circle of the perianal, and  $\leq 1/2$  circle; degree IV: Anal marginal edema occupies more than 1/2 circle perianal.

Anal Wexner score[7] evaluates the patient's preoperative and postoperative anal function, mainly from the patient's stool frequency, defecation difficulty, incomplete defecation feeling, the time required for each defecation, whether defecation requires assistance, and defecation Unsuccessful times/24 h, duration of constipation, a total score of 32 points, the higher the score, the worse the anal defecation function of patients.

### **Statistical analysis**

In this study, measurement indices such as operation time, intraoperative blood loss and hospitalization time were tested by normal distribution, which were in accordance with the approximate normal distribution or normal distribution and are expressed as mean  $\pm$  SD. The *t*-test was used for comparisons between the two groups. Non-counting data are represented by percentages, and the  $\chi^2$  test was used for comparisons. The Mann-Whitney *U* test was used for comparisons of grade counting data between the

groups. Professional SPSS 21.0 software for data processing was used, with the test level  $\alpha = 0.05$ .

## RESULTS

### **Baseline data comparison of patients in the A and B groups**

The baseline data for age, height, weight, course of disease, sex, prolapse of hemorrhoids, constipation, bleeding and pain were compared between Group A and Group B, and the difference was not statistically significant ( $P > 0.05$ , Table 1).

### **Comparison of surgery-related indicators between Group A and Group B**

The operation time, intraoperative blood loss and hospitalization time in Group A were significantly lower than those in Group B ( $P < 0.05$ , Table 2).

### **Comparison of cure rate between Group A and Group B**

The cure rate of Group A was 98.04%, compared with the cure rate of 95.10% for Group B, and the difference was not statistically significant ( $P > 0.05$ , Table 3).

### **Postoperative VAS scores for Group A and Group B**

The VAS scores of patients in group A at 12 h and 24 h after operation were lower than those in group B, and the difference was statistically significant ( $P < 0.05$ ). There was no significant difference between group A and group B at 48 h, 72 h, and 96 h after operation ( $P > 0.05$ ), as shown in Table 4.

### **Comparison of postoperative perianal edema between Group A and Group B**

One day postoperatively, the degree of perianal edema in Group A was compared with that in Group B, and the difference was not statistically significant ( $P > 0.05$ ). Seven days postoperatively, the degree of perianal edema in Group A was significantly lower than that in Group B ( $P < 0.05$ , Table 5).

### **Comparison of the anal Wexner score between the two groups**

Comparisons of preoperative, postoperative, 1 mo, 3 mo, and 6 mo, anal Wexner scores were made between the two groups, and the difference was not statistically significant ( $P > 0.05$ ). The Wexner scores of the two groups at 1 mo, 3 mo and 6 mo postoperatively were significantly lower than the scores preoperatively ( $P < 0.05$ , Table 6).

### **Comparison of the complication rate between two groups**

The postoperative complication rate of Group A was 2.94% lower than that of Group B (11.76%), which was statistically significant ( $P < 0.05$ , Table 7).

## DISCUSSION

Hemorrhoids are common diseases in the anorectal system. On the one hand, the occurrence of hemorrhoids is related to varicose veins. Hemorrhoids are caused by venous congestion of the rectal submucosal and anal skin hemorrhoids[8-10]. Subnuclear prolapse aggravates venous congestion, and venous congestion aggravates the development of hemorrhoids, forming a vicious cycle. Anastomotic hemorrhoid mucosal circumcision is a traditional surgical treatment, but it has been reported that the operation has more postoperative complications and patients are prone to recurrence, mainly because the stapler used in the operation does not have enough space to remove larger amounts of rectal mucosa, resulting in incomplete resection, so the long-term effect is not good. At the same time, prolapsed hemorrhoids will lead to their own rectal elongation, expansion, volume increase, rectal muscle thinning or disappearance of pathological changes, which cannot be effectively removed and easily lead to recurrence[11,12].

Selective supraclavicular mucosal resection was improved on the basis of traditional surgical suspension and devascularization. The mucosal and submucous tissues above the supraclavicular nucleus were selectively resected, and the normal mucosal tissues between the supraclavicular nuclei were retained, so the trauma to the patients was decreased. This study found that the operation time, intraoperative blood loss and hospitalization time in Group A were lower than those in Group B, suggesting that the use of TST33 mega stapler hemorrhoid mucosal resection in the treatment of severe prolapsed hemorrhoids has reduced trauma and shorter hospitalization times, which is basically consistent with the conclusions of previous studies[13,14]. TST33 mega stapler hemorrhoid mucosal resection surgery has a large window vision, and the operation is smoother. The large window has no resection limitation, and the resection range is greater, which can fully allow for the "pulling" effect but also protect normal tissue. At the same time, the operation height is reduced. The operation height of

**Table 1 Comparison of baseline data between group A and group B, *n* (%)**

Basic information	Group A ( <i>n</i> = 102)	Group B ( <i>n</i> = 102)	<i>t</i> / $\chi^2$ value	<i>P</i> value
Age (yr)	46.9 ± 8.1	45.0 ± 9.0	1.585	0.115
Height (cm)	168.1 ± 4.1	166.8 ± 5.4	1.936	0.054
Weight (kg)	66.3 ± 6.4	67.8 ± 7.8	-1.501	0.135
Course of disease (yr)	10.91 ± 1.20	11.15 ± 0.98	-1.564	0.119
Sex			1.012	0.314
Male	59 (57.84)	66 (64.71)		
Female	43 (42.16)	36 (35.29)		
Degree of hemorrhoid prolapse			1.357	0.244
III stage	69 (67.65)	61 (59.8)		
IV stage	33 (32.35)	41 (40.2)		
Constipate			3.526	0.060
Yes	41	43		
No	61	59		
Bleeding			1.225	0.268
Yes	88 (86.27)	93 (91.18)		
No	14 (13.73)	9 (8.82)		
Pain			1.079	0.299
Yes	84 (82.35)	78 (76.47)		
No	18 (17.65)	24 (23.53)		

**Table 2 Comparison of surgery-related indicators between group A and group B (mean ± SD)**

Groups	Operation time (min)	Intraoperative blood loss (mL)	Hospital stay (d)
Group A ( <i>n</i> = 102)	17.94 ± 3.60	4.81 ± 1.03	5.8 ± 1.2
Group B ( <i>n</i> = 102)	26.40 ± 4.11	10.52 ± 2.50	7.0 ± 1.4
<i>t</i> value	-6.396	-21.328	-7.668
<i>P</i> value	0.000	0.000	0.000

**Table 3 Comparison of cure rate between group A and group B, *n* (%)**

Groups	Cure	Get better
Group A ( <i>n</i> = 102)	100 (98.04)	2 (1.96)
Group B ( <i>n</i> = 102)	97 (95.10)	5 (4.90)
<i>t</i> value	1.331	
<i>P</i> value	0.249	

the PPH is 4 cm, and the operation height of the TST33 mega stapler is 2.5-3.5 cm. This height can partially remove hemorrhoid tissue and reduce the recurrence rate to a certain extent. In this study, the postoperative complication rate of Group A was 2.94% lower than that of Group B (11.76%), suggesting that TST33 mega stapler hemorrhoid mucosal resection can reduce the incidence of surgical complications in patients with severe prolapsed hemorrhoids.

This study also showed that the VAS scores at 12 h and 24 h after the operation in Group A were lower than those in Group B, suggesting that TST33 mega stapler mucosal resection for severe prolapsed hemorrhoids could significantly reduce postoperative pain. There are many influencing factors for postoperative pain. TST33 mega stapler hemorrhoid mucosal resection surgery is performed

**Table 4 Postoperative visual analogue scale scores of patients in groups A and B (mean  $\pm$  SD, scores)**

Groups	12 h after operation	24 h after operation	48 h after operation	72 h after operation	96 h after operation
Group A ( <i>n</i> = 102)	3.11 $\pm$ 0.98	3.30 $\pm$ 0.85	2.40 $\pm$ 0.76	1.48 $\pm$ 0.50	0.81 $\pm$ 0.30
Group B ( <i>n</i> = 102)	3.61 $\pm$ 1.00	3.59 $\pm$ 0.98	2.58 $\pm$ 0.65	1.62 $\pm$ 0.66	0.88 $\pm$ 0.28
<i>t</i> value	-3.607	-2.258	-1.818	-1.708	-1.723
<i>P</i> value	0.000	0.025	0.071	0.089	0.086

**Table 5 Comparison of the degree of perianal edema between group A and group B, *n* (%)**

Groups	I stage	II stage	III stage	IV stage
1 <sup>st</sup> day after operation				
Group A ( <i>n</i> = 102)	91	6	3	2
Group B ( <i>n</i> = 102)	76	15	6	5
<i>Z</i> value	-1.128			
<i>P</i> value	0.259			
7 <sup>th</sup> day after operation				
Group A ( <i>n</i> = 102)	93	6	2	1
Group B ( <i>n</i> = 102)	80	14	5	3
<i>Z</i> value	-2.286			
<i>P</i> value	0.022			

**Table 6 Comparison of anal Wexner scores between the two groups (mean  $\pm$  SD, scores)**

Groups	Preoperative	1 mo after surgery	3 mo after surgery	6 mo after surgery
Group A ( <i>n</i> = 102)	22.67 $\pm$ 3.70	14.38 $\pm$ 3.36	8.74 $\pm$ 2.60	6.16 $\pm$ 1.84
Group B ( <i>n</i> = 102)	23.25 $\pm$ 3.98	15.24 $\pm$ 3.62	9.40 $\pm$ 2.74	6.63 $\pm$ 1.81
<i>t</i> value	-1.078	-1.759	-1.765	-1.839
<i>P</i> value	0.282	0.080	0.079	0.067

**Table 7 Comparison of surgical complication rates between the two groups, *n* (%)**

Group	Anus drop	Anastomotic stenosis within 3 mo	Perianal infection	Urinary retention	Complication rate
Group A ( <i>n</i> = 102)	3	0	0	0	3 (2.94)
Group B ( <i>n</i> = 102)	7	3	0	2	12 (11.76)
$\chi^2$ value					5.829
<i>P</i> value					0.016

above the dentate line, where the dominant nerve is mainly the visceral nerve, which is not sensitive to pain. There is less resected rectal mucosa, so the postoperative pain is relatively reduced[15]. This study also found that 7 d after the operation, the degree of perianal edema in Group A was lower than that in Group B, suggesting that TST33 mega stapler hemorrhoid mucosal resection in the treatment of severe prolapsed hemorrhoids for postoperative perianal edema was reduced to some extent, and two surgical methods for the treatment of severe prolapsed hemorrhoids can improve anal function. TST33 mega stapler hemorrhoid mucosal resection reduces the number of anastomotic nails implanted and reduces the anal bulge, thus protecting anal contraction defecation functions[16,17].

In the process of the operation, we believe that attention should be given to the following aspects. First, the appearance of a "cat ear" between anastomotic stomas after TST operation is very common. Ligation with "0" silk thread is a simple, safe and reliable method. Second, surgeons should check

whether there is bleeding in the anastomotic stoma carefully before removing the anal mirror, and the bleeding tendency should be removed to stop bleeding by “8” sutures to strengthen the anastomotic stoma. Third, the size of the resected tissue should be evaluated before the operation and the height and mode of the purse suture should be adjusted according to the need to play an individualized treatment role. Fourth, the height of the purse-string should be appropriately lowered. Choose 2.5 cm-3.5 cm on the tooth line, and remove part of the internal hemorrhoid tissue, which has a certain value for improving the postoperative curative effect[18-20].

This study analyzed the advantages of TST33 mega stapler hemorrhoid mucosal resection in the treatment of severe prolapsed hemorrhoids and showed the reduced incidence of postoperative complications, which was in line with the patient-oriented treatment concept of modern surgery and provided a certain basis for the clinical operation in the treatment of severe prolapsed hemorrhoids. However, due to the small number of cases included in this study, the lack of a large sample with a long-term follow-up and survey, the long-term efficacy and recurrence need to be further evaluated by increasing the sample size, improving the corresponding observation index, and carrying out prospective studies with in-depth analysis.

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## CONCLUSION

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In summary, TST33 mega stapler hemorrhoid mucosal resection in the treatment of patients with severe prolapsed hemorrhoids yielded satisfactory results, less postoperative pain, perianal edema recovery block, and fewer complications.

## ARTICLE HIGHLIGHTS

### **Research background**

Although traditional treatment has certain curative effect, it is not ideal. Postoperative symptom relief rate is low. Even if temporarily relieved, hemorrhoids patients are easy to relapse.

### **Research motivation**

In this study, the authors further summarized and analyzed the surgical treatment methods for patients with severe prolapsed hemorrhoids, and compared the effect of TST33 mega staplers to provide a basis for clinical practice.

### **Research objectives**

This study aimed to explore the effect of TST33 mega stapler prolapse and hemorrhoid mucosal resection in the treatment of patients with severe prolapsed hemorrhoids.

### **Research methods**

A total of 204 patients with severe prolapsed hemorrhoids that were admitted to the anorectal department of our hospital from April 2018 to June 2020 were selected and randomly divided into Group A and Group B, with 102 cases in each group, by a single-blind, randomized and controlled clinical research scheme.

### **Research results**

This study found that the operation time, intraoperative blood loss and hospitalization time in Group A were lower than those in Group B, suggesting that the use of TST33 mega stapler hemorrhoid mucosal resection in the treatment of severe prolapsed hemorrhoids has reduced trauma and shorter hospitalization times, which is basically consistent with the conclusions of previous studies, TST33 mega stapler hemorrhoid mucosal resection surgery has a large window vision, and the operation is smoother. This study also showed that the visual analogue scale scores at 12 h and 24 h after the operation in Group A were lower than those in Group B, suggesting that TST33 mega stapler mucosal resection for severe prolapsed hemorrhoids could significantly reduce postoperative pain.

### **Research conclusions**

TST33 mega stapler hemorrhoid mucosal resection in the treatment of severe prolapsed hemorrhoids patients yielded satisfactory results, less postoperative pain, perianal edema recovery block, and fewer complications.

### **Research perspectives**

This study analyzed the advantages of TST33 mega stapler hemorrhoid mucosal resection in the treatment of severe prolapsed hemorrhoids and showed the reduced incidence of postoperative

complications, which was in line with the patient-oriented treatment concept of modern surgery and provided a certain basis for the clinical operation in the treatment of severe prolapsed hemorrhoids. However, due to the small number of cases included in this study, the lack of a large sample with a long-term follow-up and survey, the long-term efficacy and recurrence need to be further evaluated by increasing the sample size, improving the corresponding observation index, and carrying out prospective studies with in-depth analysis.

## FOOTNOTES

**Author contributions:** Tao L and Wei J design the study; Ding XF drafted the manuscript, Ji L and Tao L collected the data; Tao L and Ji L analyzed and interpreted data, Tao L and Wei J revised the manuscript.

**Supported by** Special Project of Diagnosis and Treatment Technology for Key Clinical Diseases in Suzhou, No. LCZX202022; and Changshu Municipal Science and Technology Bureau Supporting Project, No. CS201925.

**Institutional review board statement:** This study was approved by the Changshu Hospital Affiliated to Nanjing University of Chinese Medicine.

**Informed consent statement:** All study participants, or their legal guardian, provided informed written consent prior to study enrollment.

**Conflict-of-interest statement:** All authors report no conflict of interest.

**Data sharing statement:** No additional data are available.

**CONSORT 2010 statement:** The authors have read the CONSORT 2010 statement, and the manuscript was checked according to the CONSORT 2010 statement.

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**S-Editor:** Wang JL

**L-Editor:** A

**P-Editor:** Wang JL

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