Impact of modified multiple thread ligations on operative outcomes of grade III hemorrhoids: A retrospective cohort study

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Abstract

Objective

To explore the operative outcomes of patients underwent modified technique of multiple thread ligations (MTL) with the stapled hemorrhoidopexy (SH) technique for the management of grade III hemorrhoids.

Methods

This retrospective cohort study included patients who underwent MTL (MTL group) or SH (SH group) for grade III hemorrhoids in the first affiliated hospital of Zhejiang University between June 2019 and May 2021. The primary outcome was the recurrence of prolapse within six months. Secondary outcomes were operative time, postoperative pain scores, hospital stay, the incidence of complications, Wexner incontinence score on day 1 postoperative, and quality of life of patients with constipation (Patient Assessment of Constipation-Symptoms [PAC-SYM] questionnaire and Patient Assessment of Constipation-Quality of Life [PAC-QOL] questionnaire).

Results

A total of 115 patients in MTL group and 115 matched (age, sex, incontinence score, baseline PAC-SYM and baseline PAC-QOL) patients in SH group were finally included. MTL and SH resulted in comparable recurrence within six months of follow-up, with five and seven cases of recurrence respectively (P = 0.352). The two groups had comparable outcomes in terms of postoperative pain, hospital stay, Wexner incontinence scores, and constipation-related quality of life (all P > 0.05). Multivariate analysis suggested the MTL technique was not associated with a lower risk of postoperative bleeding than the SH technique (OR(95%CI): 8.332(0.923 ~ 75.200), P = 0.059).

Conclusion

The modified MTL technique might achieve comparable operative outcomes compare to the SH technique for the management of grade III hemorrhoids.

Introduction

Hemorrhoids are three columns of vascular tissue, smooth muscle, and connective tissue lining the anal canal\(^1\). In healthy people they provide cushions that maintain continence\(^2\). However, the term hemorrhoid has become synonymous with hemorrhoidal disease. Hemorrhoidal disease occurs due to the enlargement and/or sliding of hemorrhoidal tissue resulting in symptoms and complications\(^3\). The symptoms may include bleeding, pain, pruritus, fecal seepage, prolapse, and mucus discharge\(^2\). Data on
the prevalence of symptomatic hemorrhoids is scare⁴, but they are thought to affect a considerable proportion of adults⁵. Treatment depends on their severity⁵. Conservative treatments such as dietary and lifestyle modifications to achieve a regular defecation with soft stool or oral phlebotonics to control symptoms are effective in the majority of patients in the early stages of the disease⁶. While topical medications can also be beneficial to many patients⁶. When intervention is required, there are many therapeutic options, including cryotherapy, infrared coagulation, sclerotherapy, rubber band ligation (RBL), doppler-guided hemorrhoidal dearterialization, hemorrhoidectomy, and various procedures of mucopexy and hemorrhoidopexy¹.

Hemorrhoidectomy has been strongly recommended for patients with grade III hemorrhoids⁷,⁸. However, conventional excisional hemorrhoidectomy, either open or closed, has disadvantages of high pain scores, high complication rates, and perceived recurrence⁹. Therefore, although excisional hemorrhoidectomy remains an important option for advanced hemorrhoids and complicated hemorrhoids, minimally invasive operations are preferred when appropriate⁹.

Stapled hemorrhoidopexy (SH) is associated with low pain scores and fast recovery compared with conventional hemorrhoidectomy¹⁰. Nevertheless, SH may cause some unacceptable complications, such as persistent proctalgia due to retained staples, new-onset fecal urgency, difficulty in defecation, or postoperative anorectal stenosis¹², even some cases of death have been reported previously¹³. RBL has been the preferred therapeutic option for grade I/II hemorrhoids after the failure of basic treatment and is safe and simple⁷,⁸. However, for grade III hemorrhoids, the routine use of RBL in preference to SH remains controversial and a previous study has shown that SH has significantly better outcomes than RBL¹⁴. As rubber bands are prone to fall off in the early stage in cases of multiple banding, hemorrhoid thread ligation may become a promising alternative.

This study aimed to compare the operative outcomes of patients underwent MTL with the SH technique for the management of grade III hemorrhoids.

**Methods**

**Study design and Patients**

This retrospective cohort study included patients with grade III hemorrhoids treated in the department of colorectal surgery in the first affiliated hospital of Zhejiang University between June 2019 and May 2021. The inclusion criteria were patients: 1) with a diagnosis of grade III hemorrhoids based on Goligher's classification¹⁵; 2) aged between 18 and 80 years. The exclusion criteria were: 1) patients with inflammatory bowel disease, incarcerated hemorrhoids, or anal fistula. The study was approved by the ethics committee of the first affiliated hospital of Zhejiang University, and the requirement for informed consent was waived by the committee due to the retrospective nature of the study.
Patients with grade III hemorrhoids and underwent MTL were recruited to the MTL group, and patients underwent SH group were recruited to SH group and selected by propensity score matching (PSM).

**MTL and SH**

All surgeries were performed in the prone jackknife position with caudal or epidural block or spinal anesthesia by the same surgical team. In the MTL group, a triple thread hemorrhoid ligator (ZDFR Medical Science and Technology Ltd., Guangzhou, China) was applied and self-assembled with three elastic threads. The MTL included the following steps (Figure 1-3): (1) A prolapse test was performed using gauze and an anoscope. (2) Ligation was performed in two layers—the first layer was placed on the up pole of the internal hemorrhoids, and the second layer was placed on the internal hemorrhoid tissue. The maximum number of ligation points on the same layer was three, and approximately 0.5-cm mucosal bridge was preserved to prevent anorectal stenosis. During the ligation process, a routine digital vaginal examination was recommended to prevent a rectovaginal fistula, and a digital rectal examination was performed to avoid anorectal stenosis. (3) The elastic threads were released to ligate loose rectal mucosa at -0.08 MPa. (4) For three more ligations, 0# MERSILK sutures (Ethicon Inc., Somerville, NJ, USA) were employed, and internal hemorrhoid ligations were performed at -0.08 Mpa, assisted by a hand-made knot pusher (Supplementary material Videos S1). For smaller hemorrhoids curved forceps were used to clamp and then make ligations by 0# MERSILK sutures.

In the control group, SH was performed using CPH32 (Frankenman International Ltd, Hong Kong, China) according to a standardized methodology\(^\text{16}\).

**Outcomes**

The primary outcome was the recurrence of prolapse after six months of follow-up. Secondary outcomes were operative time, postoperative pain scores, hospital stay, the incidence of complications, Wexner incontinence score\(^\text{17}\) at day 1 postoperative, and quality of life of patients with constipation. Recurrence was based on the findings of the patient’s complaint of a reappearing prolapse and the surgeon’s examination.

Patient demographics, operative data, and follow-up information were recorded. Follow-up was performed to record pain score of the 1\(^{st}\) postoperative day (using a Numeric Rating Scale), Wexner incontinence score 6 months after operation, and postoperative complications (including urinary retention, bleeding, anorectal stenosis, and rectovaginal fistula). Patients’ constipation symptoms and constipation-related quality of life were re-evaluated after six months of follow-up. Patients’ constipation symptoms were evaluated using the Patient Assessment of Constipation-Symptoms (PAC-SYM) questionnaire\(^\text{18}\), and patients’ constipation-related quality of life was assessed using the Patient Assessment of Constipation-Quality of Life (PAC-QOL) questionnaire\(^\text{19}\).

**Statistical analysis**
The statistical software package SPSS 23.0 (IBM Corp., Armonk, NY, USA) and GraphPad Prism 6.02 (GraphPad Software, San Diego, California, USA) was used for statistical analysis. Patients underwent SH were selected by PSM with a ratio of 1:1, matched based on age, sex, incontinence score, baseline PAC-SYM and baseline PAC-QOL. Kolmogorov-Smirnov and Shapiro-Wilk tests were used for testing normality. Continuous data that confirmed to normal distribution are expressed as mean ± standard deviation (SD) and compared by independent-samples t test. Continuous data that confirmed to skewed distribution are expressed as medians (interquartile ranges) and compared by Mann-Whitney U test. Categorical data were expressed as n and compared using Pearson's $\chi^2$ test or Fisher's exact probability test. Binary logistic regression was performed for multivariate analysis. Two-sided $P < 0.05$ was considered as statistically significant.

**Results**

There were 115 patients with grade III hemorrhoids eligible for inclusion, and 115 patients underwent SH were selected by PSM. The two groups of patients had comparable demographics after matching (Table 1 and Table S1).

### Table 1

Preoperative demographic characteristics of patients after PSM.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>MTL group (n = 115)</th>
<th>SH group (n = 115)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age*</td>
<td>43 (37–57)</td>
<td>45 (35–64)</td>
<td>0.671</td>
</tr>
<tr>
<td>Gender*</td>
<td></td>
<td></td>
<td>0.269</td>
</tr>
<tr>
<td>Male</td>
<td>55</td>
<td>61</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>65</td>
<td>54</td>
<td></td>
</tr>
<tr>
<td>Incontinence score*</td>
<td>0 (0–1)</td>
<td>0 (0–1)</td>
<td>0.768</td>
</tr>
<tr>
<td>PAC-SYM*</td>
<td>11 (9–12)</td>
<td>10 (7–12)</td>
<td>0.479</td>
</tr>
<tr>
<td>PAC-QOL*</td>
<td>55 (45–67)</td>
<td>56 (46–68)</td>
<td>0.113</td>
</tr>
</tbody>
</table>

*Matched parameters Data are presented as median (interquartile range) values unless otherwise specified. MTL = multiple thread ligations; SH = stapled hemorrhoidopexy; PAC-SYM = Patient Assessment of Constipation-Symptoms; PAC-QOL = Patient Assessment of Constipation-Quality of Life.

For the MTL procedure, the median number of ligations was 5 (4–6). Within six months of postoperative follow-up, the MTL technique resulted in five cases of recurrence, and the SH technique resulted in seven cases of recurrence ($P = 0.352$). Patients’ constipation symptoms and quality of life between the MTL and SH groups remained comparable, as evaluated by PAC-SYM and PAC-QOL respectively, at six months after surgery ($P > 0.05$). The median operative time was 16 min (15–18 min) in the MTL group versus 25 min (16–33 min) in the SH group ($P < 0.01$). The median length of hospital stay was 2 d (1–3 d) in the
MTL group versus 2 d (2–2 d) in the SH group (P > 0.05). On the 1st postoperative day, there were no significant differences in pain scores between the two groups (P = 0.658) (Table 2).

### Table 2
Postoperative and follow-up details of patients after PSM.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>MTL group (n = 115)</th>
<th>SH group (n = 115)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recurrence (6 months), (n)</td>
<td>5</td>
<td>7</td>
<td>0.352</td>
</tr>
<tr>
<td>Operative time (minutes)</td>
<td>16 (15–18)</td>
<td>25 (16–33)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Pain score (1st PD)</td>
<td>2 (1–3)</td>
<td>2 (2–3)</td>
<td>0.658</td>
</tr>
<tr>
<td>Hospital stay (days)</td>
<td>2 (1–3)</td>
<td>2 (2–2)</td>
<td>0.067</td>
</tr>
<tr>
<td>Complications (n)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urinary retention</td>
<td>18</td>
<td>21</td>
<td>0.598</td>
</tr>
<tr>
<td>Bleeding</td>
<td>1</td>
<td>8</td>
<td>0.035</td>
</tr>
<tr>
<td>Anorectal stenosis</td>
<td>1</td>
<td>5</td>
<td>0.213</td>
</tr>
<tr>
<td>Rectovaginal fistula</td>
<td>0</td>
<td>0</td>
<td>0.999</td>
</tr>
<tr>
<td>Incontinence score</td>
<td>0 (0–1)</td>
<td>0 (0–1)</td>
<td>0.571</td>
</tr>
<tr>
<td>PAC-SYM (6 months)</td>
<td>7 (4–10)</td>
<td>8 (6–10)</td>
<td>0.093</td>
</tr>
<tr>
<td>PAC-QOL (6 months)</td>
<td>50 (41–60)</td>
<td>53 (40–63)</td>
<td>0.228</td>
</tr>
</tbody>
</table>

PD: postoperative day. Data are presented as median (interquartile range) values unless otherwise specified. Abbreviations: MTL = multiple thread ligations; SH = stapled hemorrhoidopexy; PAC-SYM = Patient Assessment of Constipation-Symptoms; PAC-QOL = Patient Assessment of Constipation-Quality of Life.

Univariate analysis showed that the MTL technique was associated with a lower risk of postoperative bleeding than that with the SH technique (P < 0.05). There were five cases of anorectal stenosis in the SH group compared with one in the MTL group (P = 0.213), the stenosis was relieved by repeated digital rectal dilatation. There were no cases of rectovaginal fistula in either group (Table 2). However, by multivariate analysis of the surgical technique, sex, age, Wexner incontinence score, baseline PAC-SYM and baseline PAC-QOL, the MTL technique was not independent associated with a lower risk of postoperative bleeding (OR(95%CI): 8.332(0.923 ~ 75.200), P = 0.059).

**Discussion**

This study showed that MTL and SH were comparable in recurrence rates, postoperative pain, hospital stay, Wexner incontinence scores, and constipation-related quality of life. These results suggest that MTL might be feasible for the management of grade III hemorrhoids.
The usual treatment of hemorrhoids is guided by their grade\(^5\). RBL has evolved into an effective therapeutic method for the management of grade I/II hemorrhoids when basic therapy fails\(^7\)\(^8\). For patients with grade III hemorrhoids, hemorrhoidectomy is often the first treatment of choice, and RBL has been regarded as an alternative treatment\(^7\). Currently, the widely accepted theory of the pathophysiology of hemorrhoids is the cushion theory\(^20\). RBL conforms to the cushion theory for the treatment of patients with hemorrhoids; however, the technique of RBL seems imperfect, and its superiority over conventional hemorrhoidectomy or SH has not been proven for the management of grade III hemorrhoids\(^4\). The reasons may lie in the following aspects: firstly, for RBL, only internal hemorrhoids are ligated without fixation of the redundant rectal mucosa. For grade III hemorrhoids, it could be postulated that since both internal hemorrhoids and rectal mucosa have prolapsed, both internal hemorrhoid tissue and redundant mucosa should be fixed; thus, three ligations are usually insufficient. Secondly, for RBL, the rubber bands are prone to fall off at an early stage, which might lead to delayed hemorrhage.

The MTL technique may overcome the drawbacks of RBL for grade III hemorrhoids. Firstly, in contrast to RBL, in the current study, we placed two layers of ligations for fixation of not only the loose rectal mucosa but also the swollen internal hemorrhoid tissue, and the median number of ligations was five. Secondly, in addition to the three elastic thread ligations, 0\(^a\) MERSILK threads were manually placed for ligation of internal hemorrhoid tissues. By this modification, additional ligations were performed using only one ligator, which indicated a potential economic benefit of this technique. Thus, theoretically, the number of ligations that could be placed using one ligator could be unlimited. Silk thread used for the ligation of internal hemorrhoid tissue, which did not fall off in the early stage. Further, the principle of MTL seems to be similar to that of the Gant-Miwa procedure, which is a therapeutic option for full-thickness rectal prolapse\(^21\).

Safety is of paramount importance in treating hemorrhoids. Compared with SH, by univariate analysis, the overall incidence of postoperative complications of MTL was significantly decreased. During SH, a ring of rectal mucosa above the internal hemorrhoid is extracted, and disastrous complications have been reported due to perforation or bleeding from the anastomosis\(^13\). During RBL, it has been suggested to inject sclerosant agents into the ligated hemorrhoid sac empirically to prevent early fall-off of the rubber bands on the internal hemorrhoid tissue. During MTL, hemorrhoidal tissues could be ligated tightly using threads; thus, the risk of acute or delayed bleeding could be minimized, and only one case of delayed hemorrhage was reported due to the fall off of the ligated thread. Five cases of anorectal stenosis were reported in the SH group; nevertheless, no patients developed stenosis in the MTL group, in which the patients had preserved mucosal bridges. This indicated that MTL might have an advantage over SH in terms of anorectal stenosis. However, by multivariate analysis, the MTL technique was not associated with a lower risk of postoperative bleeding and urinary retention than the SH technique. A randomized controlled study with enlarged population is necessary in future to fully evaluate any safety benefits with MTL.
There are some limitations to this study. Firstly, for the MTL group, no pathologic specimen was obtained, and the technique cannot be accomplished by only one surgeon as an office-based procedure. Although comparable Wexner incontinence scores were reported, anorectal manometry and transanal endosonography were not routinely performed to evaluate the adverse effects of the two procedures. Secondly, because of the retrospective nature of the study, selection bias seems inevitable. Moreover, the study sample was relatively small, and some data were supplemented by phone follow-up, so measurement bias should also be considered.

In conclusion, the modified MTL technique might achieve comparable operative outcomes compare to the SH technique for the management of grade III hemorrhoids.

**Abbreviations**

MTL multiple thread ligations  
RBL rubber band ligation  
SH stapled hemorrhoidopexy  
PAC-SYM Patient Assessment of Constipation-Symptoms  
PAC-QOL Patient Assessment of Constipation-Quality of Life

**Declarations**

**Author Contributions**

Xile Zhou, Guixian Sheng and Long Zhao wrote the main manuscript text;  
Weiqing Jiang, Chaoxu Liu and Guosheng Wu prepared figures and tables;  
All authors reviewed the manuscript.

**Acknowledgements**

None

**Funding**

None

**Conflicts of interest**

The authors declare no conflicts of interest.
Ethical approval

All procedures performed in the study involving human participants were in accordance with the ethical standards of the Trust and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

References


Supplementary Table

Table S1. Preoperative demographic characteristics of patients before PSM.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>MTL group (n = 128)</th>
<th>SH group (n = 141)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age*</td>
<td>42 (36–58)</td>
<td>44 (34–66)</td>
<td>0.226</td>
</tr>
<tr>
<td>Gender*</td>
<td></td>
<td></td>
<td>0.034</td>
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<tr>
<td>Male</td>
<td>57</td>
<td>81</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>71</td>
<td>60</td>
<td></td>
</tr>
<tr>
<td>Incontinence score</td>
<td>0 (0–1)</td>
<td>0 (0–1)</td>
<td>0.347</td>
</tr>
<tr>
<td>PAC-SYM</td>
<td>11 (8–12)</td>
<td>10 (7–13)</td>
<td>0.447</td>
</tr>
<tr>
<td>PAC-QOL</td>
<td>51 (41–68)</td>
<td>59 (45–71)</td>
<td>0.030</td>
</tr>
</tbody>
</table>

Data are presented as median (interquartile range) values unless otherwise specified. MTL = multiple thread ligations; SH = stapled hemorrhoidopexy; PAC-SYM = Patient Assessment of Constipation-Symptoms; PAC-QOL = Patient Assessment of Constipation-Quality of Life.

Figures
A prolapse test using gauze and an anoscope before ligation;

Figure 1

A prolapse test is performed using gauze and an anoscope before ligation;
Figure 2

Steps of the modified technique of multiple thread ligations for the treatment of grade III hemorrhoids. The first layer of ligations is placed on the loose rectal mucosa above internal hemorrhoids using elastic threads with the first ligation (A), the second ligation (B) and the third ligation (C); The second layer of ligations is placed on the internal hemorrhoid tissue using 0# MERSILK threads with the fourth ligation (D), the fifth ligation (E) and the sixth ligation (F).
Figure 3

A prolapse test is performed using gauze and an anoscope after ligation.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- VideoS1MTL.mp4