ORIGINAL RESEARCH

Observation on Efficacy of Selective Malposition Ligation Combined with Hemorrhoid and Fistula I in Complex Mixed Hemorrhoid

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ABSTRACT

Objective • The efficacy of selective malposition ligation combined with hemorrhoid and fistula I prescription and the improvement of complications were assessed to improve surgical efficiency and safety.

Methods • 423 patients undergoing complex mixed hemorrhoid surgery at different time points were included as research objects and enrolled into group A (malposition ligation), group B (selective malposition ligation), and group C (selective malposition ligation and hemorrhoid and fistula I), each with 141 cases.

Results • The scores for visual analogue scale (VAS), edema, and hemorrhage of group C 8h, 1 day, 2 days, 3 days, 5 days, and 7 days after surgery were all inferior to those in groups A and B, while that of group B was inferior to that in group A ($P < .05$). The duration of wound healing of group C (15.33 ± 2.78 days) was shorter than that of groups A (21.78 ± 3.22 days) and B (18.34 ± 3.01 days), and this duration of group B was shorter than that of group A ($P < .05$). The total effective rate of group C (96.45%) was superior to that of groups B (96.45%) and A (82.27%). The total effective rate of group B was superior to that of group A. The falling-off rate of the rubber ring in groups C and B was inferior to that in group A. The incidence of total complications in group C (9.93%) was inferior to that in groups B (30.50%) and A (30.50%), while that of group B was inferior to that in group A ($P < .05$).

Conclusion • After selective malposition ligation, the oral intake of hemorrhoid and fistula I could promote the recovery of wounds among patients with complex mixed hemorrhoids and reduce the incidence of postoperative hemorrhage and edema. Hence, it has significant clinical application values. (*Altern Ther Health Med.* 2024;30(12):208-216).

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INTRODUCTION

Mixed hemorrhoid frequently occurs above and below the dentate line at the same position in the anus. Lumps appear in varicose veins, and internal and external lumps connect without obvious boundaries. The main clinical symptoms of mixed hemorrhoids include hematochezia, anus mass, swelling, foreign body sensation, pain, local secretion, and pruritus.[1,2] According to an epidemiologic study, the proportion of urban and rural residents with mixed hemorrhoids aged 18 and above accounts for 98.09% of all people with anorectal disease.[3] Clinical observation demonstrates that mixed hemorrhoids may develop into complex mixed hemorrhoids that affect more than two different points if the treatment is delayed.[4] The protection of anal function is the key and challenging aspect in the treatment of complex mixed hemorrhoids.

Postoperative anal stenosis, edema, pain of the anal edge, and a long course of the disease are some of the major problems associated with surgical intervention.[5,6] At present, there are plenty of surgical treatment methods for complex mixed hemorrhoids, such as segmental dentate internal ligation and external suture,[7] the procedure for prolapse and hemorrhoids (PPH),[8] Ruiyun procedure for hemorrhoid (RPH) automatic ligation,[9] and Endoscopic rubber band ligation for internal hemorrhoids (EPH).[10] Segmental dentate internal ligation and external sutures are characterized by a small damaged area and fast recovery. However, it is time-consuming and may cause anal stenosis and lead to closure function abnormality. In the case of PPH, anal pad tissues are preserved as much as possible and postoperative pain and anal function abnormality are completely treated. However, PPH is costly and can result in a lot of complications. Hence, it cannot be extensively used at present. Although RPH hemorrhoid automatic ligation is fully automated with convenient operation, causing mild pain, fewer complications, no scarring, and without damage to normal anal structure and appearance, the lifting effect is usually poor and even falling off and hemorrhage occurs due to the limited number of rubber rings and the different levels of technologies. Automated ligation is realized by EPH which shortens the duration of traditional ligation, saves effort to perform traditional ligation, overcomes the difficulty in exposure, reduces the incidence of

complications, and relieves significant pain in the treatment of complex mixed hemorrhoids.

Besides, the various problems caused by the above therapies are improved to enhance surgical efficacy and safety to some extent. In addition, surgical treatment methods can be selected based on the location of hemorrhoids because of the individualized choice of the surgical point of ligation.[11] Hence, the plane and surgical points are flexibly selected in selective malposition ligation according to the actual position of hemorrhoids and the degree of prolapsus. In contrast, the ligation site is only fixed 2 cm and 4 cm above the dentate line, and 4 points are selected in 2 selected planes in traditional malposition ligation.[12] For instance, the plane should be lowered to and chosen near the dentate for patients with obvious prolapsus of the mucosa.[13] The selected point is not fixed, it is chosen according to the location of the hemorrhoids. Hence, selective malposition ligation has more significant lifting and suspension effects than ordinary "malposition ligation".[14] Despite good clinical application effects, postoperative complications of complex mixed hemorrhoids cannot be avoided completely. Hence, hemorrhoid and fistula I prescriptions were developed for the treatment of anorectal disease, hematochezia, constipation, and other clinically common complications. The prescription was applied based on the treatment principles of clearing heat and promoting diuresis, moistening the intestine, and facilitating feces excretion, hemostasis, and benefiting vital energy. After the surgery for complex mixed hemorrhoids, constipation, pain, hemorrhage, and incision edema often occur. When constipation occurs, patients struggle to defecate, resulting in early falling off of ligated rubber rings and poorer efficacy. Furthermore, constipation aggravates postoperative pain, hemorrhage, and incision edema.[15] Hence, hemorrhoid and fistula I prescription could notably reduce the incidence of common postoperative complications, including constipation, pain, hemorrhage, and incision edema.

Innovatively adopting selective malposition ligation combined with hemorrhoid and fistula I, this study aims to assess the efficacy of this combined therapy in the treatment of complex mixed hemorrhoids. Our primary objective is to evaluate the impact of this innovative approach on the cure rate, surgical efficacy, and safety, with a focus on reducing the incidence of postoperative complications such as hemorrhage, constipation, pain, edema, and relapse. By doing so, we aim to provide new insights and methods for enhancing surgical outcomes and safety in the management of complex mixed hemorrhoids. This study also aspires to generate substantial social and economic benefits through the advancement of surgical techniques and patient care in this clinical context.

RESEARCH METHODS

Research objects

The determination of the research sample size was based on the sample estimation method using equation (1), which gave an initial estimate of 384 cases. To ensure robust statistical power and to account for potential factors such as participant dropout and other unforeseen circumstances, a 10% increase in the sample size was deemed necessary. This adjustment aimed to enhance the study's resilience to variations in participant adherence, data collection challenges, or other factors that might affect the completeness of the dataset

In the research, 423 patients with complex mixed hemorrhoids visiting our hospital at a certain time point between February 1st, 2021 and January 31st, 2024 were selected. Surgical indications of all patients met the standards for complex mixed hemorrhoids stipulated by the Anorectum Branch of the China Association of Chinese Medicine.[16] There were 289 cases with complex mixed hemorrhoid III and 134 with IV. 273 cases suffered from annular internal mixed hemorrhoids and 150 suffered from incarcerated internal hemorrhoids. Based on different treatment methods, the patients were enrolled into groups A, B, and C. Groups A, B, and C (141 cases in each) underwent malposition ligation, selective malposition ligation, and selective malposition ligation combined with hemorrhoid and fistula I, respectively. Age, gender, and weight of all patients were recorded and the efficacy among three groups was observed and their application values were assessed. The implementation of this research has been approved by the Relevant Medical Ethics Committee.

$$N = (Z^2 \times (P \times (1 - P)))/E^2$$

N referred to the sample size and Z represented the statistical number of samples. When the selected confidence degree amounted to 95%, $Z = 1.96$. E denoted error value, which was considered as 5%. The probability value (P) was equal to .5.

Selection criteria

Inclusion criteria. (a) All patients had surgical indications. (b) All patients were aged 18 and above and under 80 (both male and female). (c) Patients who had agreed to participate in the treatment and signed informed consent forms.

Exclusion criteria. (a) Patients with perianal abscess, anal fissure, anal fistula, and serious digestive tract diseases. (b) Patients with a history of serious cardiovascular and cerebrovascular diseases and diabetes. (c) Patients with abnormal liver function. (d) Patients who suffered from psychiatric disorders and were unable to cooperate with normal treatment. (e) Patients with coagulation abnormalities. (f) Patients who refused to sign informed consent forms.

Elimination and falling off criteria. (a) Patients without undergoing the treatment in strict accordance with the treatment plan so that the assessment of research efficacy is affected. (b) Patients with so poor compliance with the research that research assessment is affected. (c) Patients with incomplete clinical data, which was not conducive to the judgment of research results. (d) Patients with severe postoperative complications.

Surgical methods

In Group A, malposition ligation was performed as follows. An anoscope was inserted into the patient's anus to

examine hemorrhoids. Thereafter, automated ligation was carried out as follows. The anoscope was placed at points 1, 5, 7, and 11, 2 cm above the dentate line. Next, points 2, 4, 8, and 10 were selected 4 cm above the dentate line for ligation.

Groups B and C both received selective malposition ligation. Before the surgery, the anoscope was inserted into the patient's anus to examine the prolapsus of the mucosa. Then, 2 planes were selected on the dentate surface according to the prolapsus of the mucosa. In addition, 4 points were selected for ligation according to the prolapsus of hemorrhoids on each plane.

Postoperative treatment

After the surgery, patients in groups A, B, and C were instructed to lie flat for 8 to 12 hours and consume liquid food for 3 days. Additionally, they were advised to avoid spicy and pungent foods. Post-defecation care included a sitz bath and dressing change with potassium permanganate (1:5000) until the surgical wound recovered. Notably, patients in group C were administered an oral prescription referred to as 'hemorrhoid and fistula I,' developed within our hospital and grounded in traditional Chinese medicine principles.

The 'hemorrhoid and fistula I' prescription was meticulously composed, incorporating the following herbal ingredients: Amur Cork-tree, Baical Skullcap Root, Garden Burnet Root, Peony Root, Fried Pagodatree Flower, Hairyvein Agrimonia Herb, and Broiled Milkvetch Root. Patients were instructed to orally take 30 mL of the prescription each time, three times per day, until the surgical wound healed. This dosage regimen aligns with established traditional Chinese medicine principles, aiming to optimize the therapeutic effects of the prescribed herbal components.

Observation indexes and evaluation criteria

Anal pain score. The Visual Analogue Scale (VAS) scoring method was employed for pain assessment. Changes in anal pain among patients in the three groups were observed 8 hours (8H), 1 day (1D), 2 days (2D), 3 days (3D), 5 days (5D), and 7 days (7D) after surgery. A 10 cm scale was utilized as the quantification tool for VAS, with values selected by the patients themselves. The total VAS score ranged between 0 and 10 points, where point 0 represented no pain, and point 10 represented severe and intolerable pain.

Scores for edema of anal edge. Following the guidelines outlined in the 'Therapeutic Criteria for Diagnosis of Diseases and Syndromes of Traditional Chinese Medicine,' a single experienced physician with over 20 years of relevant experience consistently observed and assessed the edema of the anal edge among patients in the three groups 8 hours (8H), 1 day (1D), 2 days (2D), 3 days (3D), 5 days (5D), and 7 days (7D) after surgery using visual measurement. The physician utilized specific scoring criteria, as presented in Table 1, to evaluate the severity of edema.

The 'Therapeutic Criteria for Diagnosis of Diseases and Syndromes of Traditional Chinese Medicine' served as a comprehensive guide, providing a framework for the systematic evaluation of edema scores. The scoring criteria in Table 1 were designed to capture nuances in the level of edema of the anal edge, with higher scores indicating a more pronounced degree of edema. This rigorous and standardized approach ensured consistency in the assessment process and enhanced the reliability of the edema scores recorded at different time points post-surgery.

Table 1. Scoring Criteria for Edema of Anal Edge

Score	Level of edema
0 point	No edema
1 point	The skin of the anal edge bulged and edema ranged less than 1/4 of the anal edge
2 points	The skin of the anal edge bulged and edema ranged between 1/4 and 1/2 of the anal edge
3 points	The skin of the anal edge bulged and edema ranged more than 1/4 of the anal edge

Table 2. Scoring Criteria for Hemorrhage

Scores	Hemorrhage
0 point	No bleeding
1 point	Little bleeding occurred, such as toilet paper bleeding after defecation
2 points	Dropwise bleeding frequently occurred, which could be stopped by hemostatics
3 points	Massive bleeding occurred and it needed to be stopped by suture and ligation

Table 3. Assessment Criteria for Clinical Efficacy

Recovery	Symptoms	R_{JFJ}
Healing	Symptoms and signs generally disappeared, pain and edema disappeared, and no infectious seepage appeared at incisions.	$R_{JFJ} \geq 90\%$
Effective	Symptoms and signs dramatically changed, pain and edema disappeared, and no infectious seepage appeared at incisions.	$90\% > R_{JFJ} \geq 70\%$
Showed effect	Symptoms and signs, pain, edema, and infectious seepage that appeared at incisions were relieved.	$70\% > R_{JFJ} \geq 30\%$
Invalid	Symptoms and signs were not improved remarkably.	$R_{JFJ} < 30\%$

Scores for incision hemorrhage. The changes in surgical incision hemorrhage among patients in 3 groups 8h (8H), 1 day (1D), 2 days (2D), 3 days (3D), 5 days (5D), and 7 days (7D) after surgery were observed and scored. The scoring criteria are displayed in Table 2.

Duration of postoperative wound healing. Duration of postoperative wound healing among patients in 3 groups was observed (from the end of the surgery until epithelium grew at the incisions and covered them).

Assessment of clinical efficacy. Based on the Therapeutic Criteria for the Diagnosis of Diseases and Syndromes of Traditional Chinese Medicine, the scores for pain, edema, and hemorrhage were combined with clinical manifestations and then summed as total scores for the patient's clinical manifestations. The decline in total scores for 3 groups before treatment and 7 days after treatment were recorded and the efficacy of 3 therapies was assessed. The calculation was done using equation (2). Specific assessment criteria for efficacy are presented in Table 3.

$$R_{JFJ} = ((J_{before} - J_{after}) / J_{after}) \times 100\%$$

R_{JFJ} denoted the decline rate of symptom score, J_{before} represented the total symptom score before treatment, and J_{after} referred to the total symptom score after treatment.

Incidence of complications. The falling off of ligated rubber rings and the incidence of postoperative constipation, pain, hemorrhage, edema, anal infection, and stenosis among 3 groups were observed.

Figure 1. Summary and Comparison of General Clinical Data Among 3 Groups (A) Gender, (B) Age, (C) BMI, (D) Clinical staging, and (E) Disease types

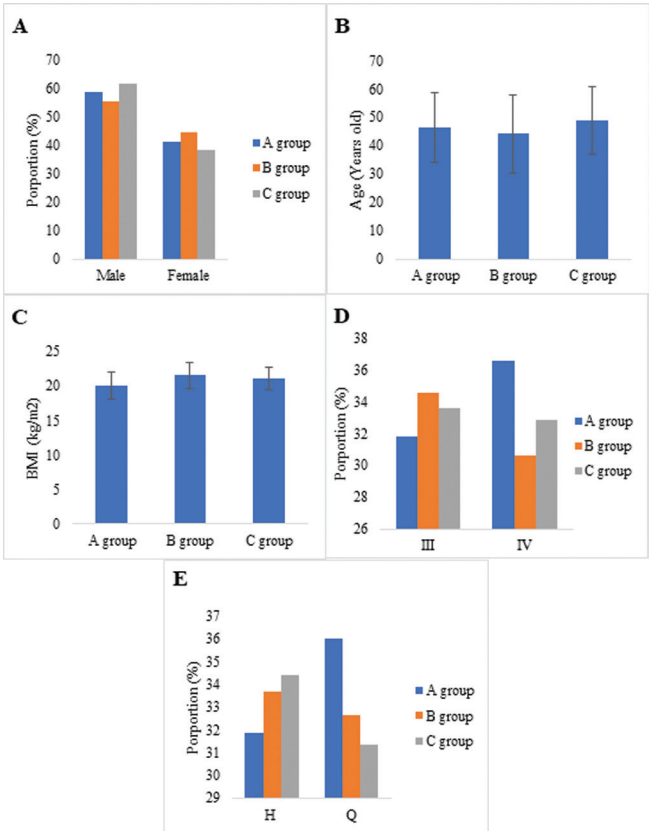


Table 4. Summary of VAS Scores for Postoperative Anal Pain Among the 3 Groups

Time points	VAS scores (points) Mean ± SD		
	Group A (n = 141 cases)	Group B (n = 141 cases)	Group C (n = 141 cases)
8H	6.34 ± 0.78	6.28 ± 0.76	3.23 ± 0.53[a]
1D	6.02 ± 0.79	5.94 ± 0.82	3.14 ± 0.55[a]
2D	5.66 ± 0.72	5.52 ± 0.70	3.02 ± 0.49[a]
3D	5.42 ± 0.73	5.31 ± 0.76	2.84 ± 0.50[a]
5D	5.12 ± 0.80	5.01 ± 0.72	2.69 ± 0.52[a]
7D	4.89 ± 0.86	4.62 ± 0.77	2.57 ± 0.49[a]

[a]suggests that the comparison of VAS scores of group C with groups A and B revealed statistical significance ($P < .05$).

Statistical methods

Data analysis was conducted using SPSS 23.0 software. For measurement data, descriptive statistics are presented as mean ± standard deviation ($\bar{x} \pm s$) and analyzed using the independent samples *t* test. Enumeration data were expressed as [n(%)] and analyzed using the chi-square (χ^2) test. A significance level of $P < .05$ was considered to indicate statistical significance.

RESULTS

Statistics on general data of 3 groups

General clinical data (gender, age, body mass index (BMI), clinical staging, and disease types) of 3 groups were summarized. In terms of gender ratio, the proportion of males in groups A, B, and C amounted to 58.87% (83 cases), 55.32% (78 cases), and 61.70% (87 cases), respectively, while that of females in 3 groups was 41.13% (58 cases), 44.68% (63 cases), and 38.30% (54 cases) (Figure 1A). As to age distribution, age of patients in groups A, B, and C ranged between 20 and 79 years with an average of 46.28 ± 12.32 years, between 18 and 76 years with an average of 44.21 ± 13.77 years, and between 18 and 80 years with an average of 48.83 ± 11.91 years, respectively (Figure 1B). Regarding BMI range, BMI in groups A, B, and C ranged between 18 and 23 kg/m^2 with the average of 20.04 ± 2.01 kg/m^2, between 19 and 24 kg/m^2 with the average of 21.54 ± 1.87 kg/m^2, and between 18 and 24 kg/m^2 with the average of 21.09 ± 1.68 kg/m^2, respectively (Figure 1C). As for clinical staging, the number of patients at stage III in 3 groups was 92 (31.83%) in group A, 100 (34.60%) in group B, and 97 (33.56%) in group C, and the number of patients at stage IV in 3 groups was 40 (36.57%) in group A, 41 (30.60%) in group B, and 44 (32.84%) in group C (Figure 1D). In terms of disease types, the number of patients with annular mixed hemorrhoids in 3 groups was 87 (31.87%) in group A, 92 (33.70%) in group B, and 94 (34.43%) in group C, and the number of patients with incarcerated internal hemorrhoids amounted to 54 (36.00%), 49 (32.67%), and 47 (31.33%) in groups A, B, and C, respectively (Figure 1E). There were no apparent statistical differences in the distribution of gender, age, BMI, clinical staging, and disease types ($P > .05$), indicating that the research was feasible.

Scores for anal pain

The changes in anal pain among patients in groups A, B, and C 8h, 1D, 2D, 3D, 5D, and 7D after surgery were scored by VAS (Table 4). It was found that VAS scores showed a descending trend in the 3 groups from 8h until 7 days after surgery. Besides, VAS scores for group C 8h, 1D, 2D, 3D, 5D, and 7D after surgery were all inferior to those for groups A and B, and the differences were statistically significant ($P < .05$). No remarkable difference was detected in VAS scores between groups A and B ($P > .05$).

The observed differences in VAS scores are clinically significant as they suggest that the treatment intervention in group C resulted in a more effective reduction of anal pain compared to groups A and B. This finding underscores the potential benefits of the specific intervention implemented in group C for managing postoperative anal pain, contributing to improved patient comfort and overall satisfaction with the treatment.

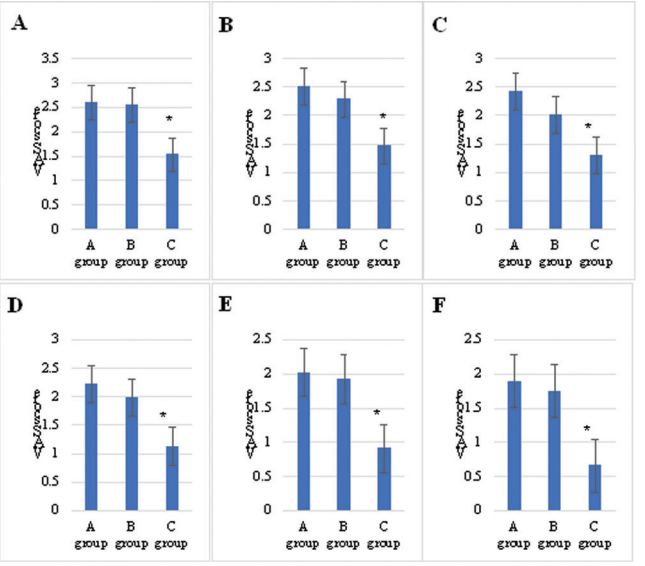
Scores for edema of anal edge

Edema of the anal edge among patients in groups A, B, and C 8h, 1D, 2D, 3D, 5D, and 7D after surgery was assessed (Figure 2A to 2F). Edema scores for group A at the above time points corresponded to 2.60 ± 0.54, 2.51 ± 0.57, 2.42 ± 0.53, 2.22 ± 0.50, 2.02 ± 0.52, and 1.89 ± 0.57 points, respectively. Edema scores for group B at the above time points were 2.54 ± 0.52, 2.28 ± 0.50, 2.01 ± 0.60, 1.98 ± 0.59, 1.92 ± 0.21, and 1.75

± 0.60 points, respectively. Edema scores for group C at the above time points were 1.53 ± 0.56, 1.46 ± 0.62, 1.30 ± 0.58, 1.13 ± 0.55, 0.91 ± 0.54, and 0.66 ± 0.61 points, respectively. It was demonstrated that edema scores for group C at these time points were all inferior to those for groups A and B (P <.05). However, no apparent difference was detected in edema scores between groups A and B (P > .05).

The clinical significance of these findings lies in the superior postoperative outcomes observed in group C, suggesting that the specific intervention employed in this group effectively mitigated anal edema compared to the treatments provided to groups A and B. This outcome has practical implications for improving patient comfort, promoting surgical recovery, and enhancing overall treatment efficacy.

Figure 2. Comparison of Edema Scores for 3 Groups at Different Time Points (A) 8h, (B) 1D, (C) 2D, (D) 3D, (E) 5D, and (F) 7D



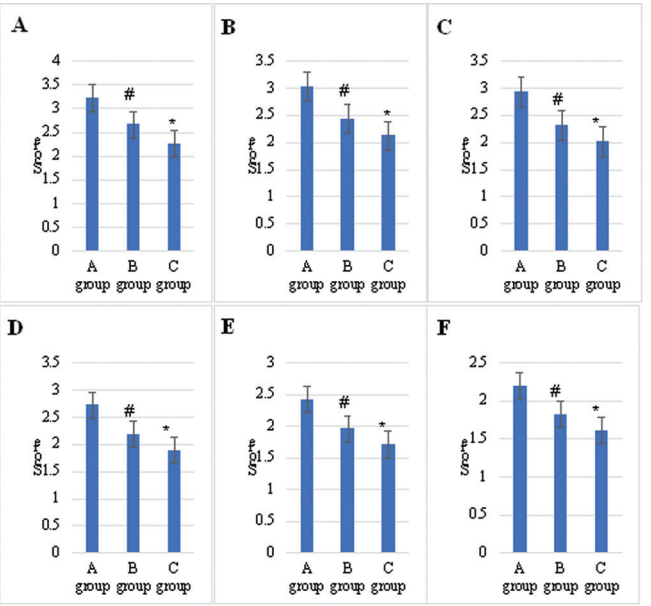
* Suggests that the edema score for group C compared to those of groups A and B is statistically significant (P < .05).

Scores for incision hemorrhage

The scores for incision hemorrhage among patients in groups A, B, and C 8h, 1D, 2D, 3D, 5D, and 7D after surgery were assessed (Figure 3A to 3F). Scores for incision hemorrhage in group A at the above time points corresponded to 3.22 ± 0.69, 3.03 ± 0.69, 2.93 ± 0.60, 2.72 ± 0.66, 2.42 ± 0.67, and 2.20 ± 0.60 points, respectively. Scores for incision hemorrhage in group B were 2.66 ± 0.56, 2.43 ± 0.53, 2.31 ± 0.55, 2.19 ± 0.52, 1.96 ± 0.47, and 1.82 ± 0.46 points, respectively. Scores for incision hemorrhage in group C were 2.26 ± 0.48, 2.13 ± 0.49, 2.01 ± 0.47, 1.89 ± 0.44, 1.71 ± 0.39, and 1.61 ± 0.34 points, respectively. It was found that the scores for incision hemorrhage in group C at the above time points were all inferior to those in groups A and B. Besides, the scores for incision hemorrhage in group B were inferior to those in group A (P < .05).

The clinical significance of these findings lies in the enhanced postoperative outcomes associated with lower incision hemorrhage scores in group C, suggesting that the specific intervention in this group may contribute to reduced bleeding and improved overall surgical recovery.

Figure 3. Comparison of Hemorrhage Scores for 3 Groups at Different Time Points (A) 8h, (B) 1D, (C) 2D, (D) 3D, (E) 5D, (F) 7D



* Suggests that the hemorrhage score for group C compared to those of groups A and B is statistically significant (P < .05).
# Suggests that the hemorrhage score for group B compared to that of group A is statistically significant (P < .05).

Comparison of duration of wound healing

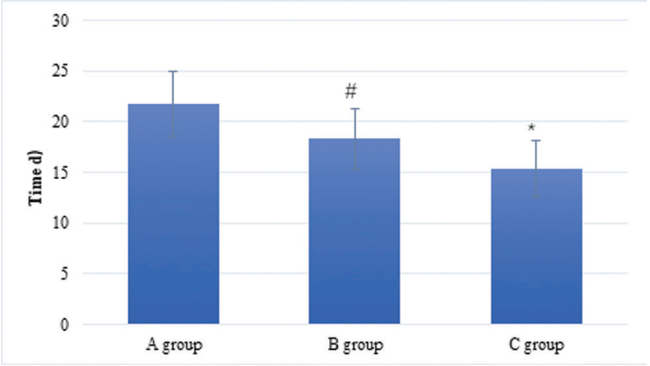
The duration of postoperative wound healing among patients in groups A, B, and C was summarized (Figure 4). The duration of complete epithelial growth and cover at the incision in 3 groups corresponded to 21.78 ± 3.22 days in group A, 18.34 ± 3.01 days in group B, and 15.33 ± 2.78 days in group C. It was found that the duration of wound healing in group C was shorter than that in groups A and B (P < .05). The duration of wound healing in group B was shorter than that in group A (P < .05).

The clinical significance of these findings is substantial, as a shorter duration of wound healing implies accelerated recovery, reduced postoperative complications, and an overall improvement in patient outcomes. The interventions in groups B and C, as evidenced by the shorter duration of wound healing, may contribute to enhanced postoperative recovery, allowing patients to return to normal activities sooner and reducing the risk of complications associated with prolonged wound healing.

Decline in total scores before and after treatment

Total scores for clinical manifestations among patients in the three groups before treatment and 7 days after treatment are presented in Table 5. The 'reduction rate of symptom scores' refers to the percentage decrease in the total scores for

Figure 4. Comparison of Duration of Wound Healing in 3 Groups at Different Time Points

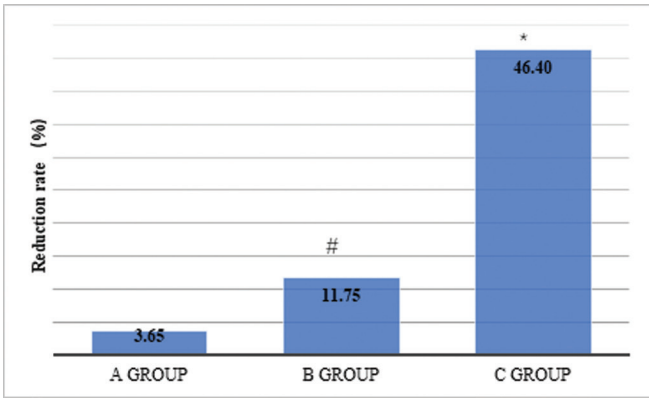


* Suggests that the duration of wound healing in group C compared to groups A and B is statistically significant ($P < .05$).
# Suggests that the duration of wound healing in group B compared to group A is statistically significant ($P < .05$).

Table 5. Total Scores for Clinical Manifestations Before and After Treatment

Groups	Total scores (points) Mean ± SD	
	Before treatment	7 days after treatment
Group A (n = 141 cases)	9.32 ± 2.32	8.98 ± 2.14
Group B (n = 141 cases)	9.28 ± 2.02	8.19 ± 2.01
Group C (n = 141 cases)	9.03 ± 2.15	4.84 ± 1.33

Figure 5. Comparison of the Reduction Rate of Symptom Scores



* suggests that the reduction rate in group C compared to groups A and B is statistically significant ($P < .05$).
# Suggests that the reduction rate in group B compared to group A is statistically significant ($P < .05$).

clinical manifestations from before treatment to 7 days after treatment. Specifically, it represents the extent to which the symptoms improved following the intervention.

In groups A, B, and C, the reduction rate of symptom scores was calculated as 3.65%, 11.75%, and 46.40%, respectively. Notably, the reduction rate in group C was significantly superior to that in groups A and B, and the reduction rate in group B was superior to that in group A ($P < .05$) (Figure 5).

This metric provides a quantitative measure of the improvement in clinical manifestations, offering insight into the effectiveness of the interventions administered in each group.

Table 6. Summary of Clinical Efficacy Among Patients in the 3 Groups

Groups	Clinical efficacy				Total effective rate (%)
	Cured	Effective	Showed effect	Invalid	
Group A (n = 141 cases)	43	49	12	37	73.76
Group B (n = 141 cases)	55	42	19	25	82.27[b]
Group C (n = 141 cases)	90	32	14	5	96.45[a]

[a]Suggests that the total effective rate in group C compared to groups A and B is statistically significant ($P < .05$).
[b]Suggests that the total effective rate in group B compared to group A is statistically significant ($P < .05$).

Table 7. Incidence of Complications in the 3 Groups

Complications	Group A (n = 141 cases)	Group B (n = 141 cases)	Group C (n = 141 cases)
Falling off of rubber rings	29	15	12
Constipation	24	10	5
Hemorrhage	33	17	9
Edema	32	18	6
Anal infection	19	10	2
Anal stenosis	17	10	2
Total number of patients with complications	43	24	14

Comparison of clinical efficacy

The clinical efficacy among patients in groups A, B, and C is presented in Table 6. The total effective rate in the three groups was calculated based on predefined criteria, which included reduction in symptoms, improvement in specific clinical parameters, etc. The total effective rate was found to be 73.76% in group A, 82.27% in group B, and notably higher at 96.45% in group C.

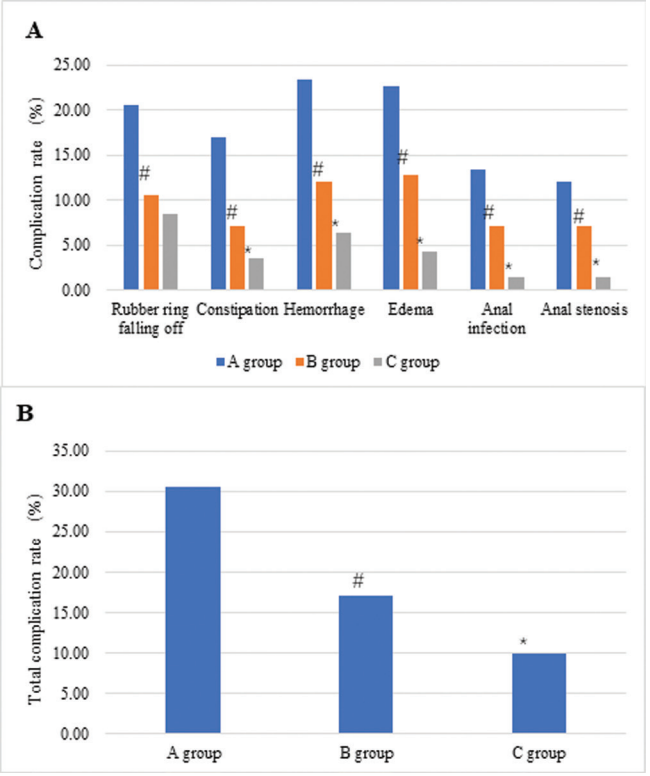
The determination of the total effective rate aimed to assess the overall treatment outcomes across the defined criteria. Notably, the total effective rate in group C demonstrated a significant superiority over that in groups B and A. Additionally, the total effective rate in group B was found to be superior to that in group A ($P < .05$).

Incidence of complications

The incidence of postoperative complications among patients in groups A, B, and C is illustrated in Table 7. The proportions of patients with falling off of ligated rubber rings corresponded to 20.57% in group A, 10.64% in group B, and 8.51% in group C. The proportions of cases with constipation were 17.02% in group A, 7.09% in group B, and 3.55% in group C. The proportions of cases with hemorrhage in groups A, B, and C were 23.40%, 12.06%, and 6.38%, respectively. The proportions of cases with edema were 22.70% in group A, 12.77% in group B, and 4.26% in group C. The proportions of cases of anal infection in groups A, B, and C corresponded to 13.48%, 7.09%, and 1.42%, respectively. The proportions of cases with anal stenosis in groups A, B, and C corresponded to 12.06%, 7.09%, and 1.42%, respectively. Besides, the incidence of total complications in groups A, B, and C were 30.50%, 17.02%, and 9.93%, respectively.

The incidence of falling off of ligated rubber rings in groups C and B was notably inferior to that in group A ($P < .05$). In this regard, no remarkable difference was detected between groups C and B ($P > .05$). Interestingly, the incidence of constipation, hemorrhage, edema, anal infection, anal

Figure 6. Comparison of Incidence of Complications: (A) Incidence of different complications and (B) Incidence of total complications



* Suggests that the incidence of complications in group C compared to groups A and B is statistically significant ($P < .05$).
# Suggests that the incidence of complications in group B compared to group A is statistically significant ($P < .05$).

stenosis, and total complications in group C were all inferior to that in groups A and B. Furthermore, the incidence of the above complications in group B was inferior to that in group A ($P < .05$) (Figure 6).

DISCUSSION

In China, the incidence of hemorrhoid disease is high and is often summarized as "hemorrhoid disease occurs among 9 out of 10 people".[33] Mixed hemorrhoid is the most common type among all anorectal diseases. Its Chinese name is the same as the English name.[17,18] There are several clinical treatment methods available for mixed hemorrhoids. However, most patients do not undergo early and timely treatment due to no obvious clinical symptoms, which further aggravates mixed hemorrhoids. Consequently, it develops into a complex mixed hemorrhoid. Complex mixed hemorrhoid leads to perianal muscular chassis, swelling, recurrent infection, pain and hemorrhage during defecation, or anemia.[19] In such cases, conservative therapy is no longer applicable because some irreversible phenomena appear in lesions, their surrounding tissues, and the physiological functions of anus. Besides, incarceration and necrosis of hemorrhoids may occur if patients are not appropriately treated for a long time.[20] At present, clinical surgical treatment methods have some advantages as well as various shortcomings, which often lead to anal function abnormality, constipation, infection, and other postoperative complications.[21] Therefore, a new selective malposition ligation combined with hemorrhoid and fistula I was put forward and its application value was verified through clinical research.

Efficacy of Selective Malposition Ligation (Group A) and Malposition Ligation (Group B)

Selective malposition ligation is based on malposition ligation. According to the actual position and the degree of prolapsus of hemorrhoids, plane, and point are flexibly selected. If patients suffer from obvious mucosa prolapsus, the plane should be lowered and a new plane should be selected near the dentate line. Hence, selective malposition ligation has higher pertinence. In the research, the efficacy of selective malposition ligation (group B) and malposition ligation (group A) was compared and analyzed. It was demonstrated that there were no dramatic differences in VAS scores and edema scores between the 2 groups 8h, 1D, 2D, 3D, 5D, and 7D after surgery. The finding revealed that selective malposition ligation had insignificant effects on alleviating postoperative pain and edema among patients. Since surgical procedures for the 2 groups were generally consistent, incisions were very similar without significant differences in pain. However, hemorrhage scores, duration of wound healing, and incidence of total complications in group B were inferior to those in group A. In contrast, the reduction rate of symptom scores and total effective rate in group B were superior to those in group A. The above outcomes suggested that selective malposition ligation had significant efficacy and could effectively alleviate complications, which was related to the pertinence of the selection of surgical plane and point by selective malposition ligation. One of the major principles of clinical treatment is the accurate selection of disease location for the stipulation of treatment plans and reasonable treatment for patients based on a full understanding of disease development, lesion position, and the severity of lesions. It is also one of the important bases for clinical improvement of efficacy.[22,23]

Comparison of Surgical Efficacy and Complications Among Groups A, B, and C

The alleviation of postoperative complications is still a hot topic in the clinical field. To relieve postoperative complications among patients, such as constipation, pain, hemorrhage, and incision edema, selective malposition ligation was combined with hemorrhoid and fistula I (group C) and applied. It was found that VAS scores, edema scores, hemorrhage scores, and duration of wound healing of group C 8h, 1D, 2D, 3D, 5D, and 7D after surgery were notably superior to those of groups A and B, which demonstrated that postoperative oral intake of hemorrhoid and fistula I (group C) could improve pain, anal infection, and hemorrhage. Hemorrhoid and fistula I was mainly composed of amur cork tree, baical skullcap root,

garden burnet root, peony root, fried pagoda tree flower, hairy-vein agrimonia herb, and broiled milkvetch root. Garden burnet root and pagoda-tree flower had the effect of cooling blood for hemostasis. Hairyvein agrimonia herb had the effect of astringency and hemostasis. The above herbal medicines all showed significant hemostasis effects. According to relevant studies, the incidence of postoperative anal edema was associated with long postoperative defecation, difficult defecation due to dryness, and perianal blood circulation.[24-26] Hemorrhoids and fistula I had the effects of moistening the intestine, facilitating feces excretion, and benefiting qi for activating blood circulation. Hence, it could improve postoperative edema. Wound healing was not only affected by wound size but also related to infection, blood circulation, and nutritional status.[27-29]

Feasibility and Application Prospect of Postoperative Chinese Medicine Care

Amur cork tree, baical skullcap root, and garden burnet root in hemorrhoid and fistula I could clear heat and remove toxicity, peony root could activate blood circulation, and broiled milkvetch root could tonify deficiency to promote wound healing, which was conducive to postoperative rehabilitation and reduction in the incidence of postoperative complications. In addition, the reduction rate of symptom scores and total effective rate in group C were superior to those in groups A and B. The incidence of constipation, hemorrhage, edema, anal infection, and stenosis, and total complications in group C were all inferior to that in groups A and B ($P < .05$). The finding further indicated that surgical treatment combined with postoperative Chinese medicine care could improve surgical efficacy and reduce the incidence of postoperative complications.

At present, surgical treatment methods are combined with Chinese medicine care in multiple studies for the treatment of hemorrhoid diseases, such as peony root injection combined with elastic band ligation therapy for II and III hemorrhoids,[30] rehabilitative aromatherapy baths for patients undergoing hemorrhoid PPH,[31] and external application of light pill for the treatment of edema of anal edge after complex mixed hemorrhoid surgery.[32] The above therapies all had apparent clinical application effects, which suggested that postoperative Chinese medicine care was feasible. What's more, it was demonstrated that Chinese medicine treatment had a broad application prospect in the treatment of clinical diseases.

Potential Limitations of the Study

While our study provides valuable insights into the efficacy of selective malposition ligation combined with postoperative Chinese medicine care for the treatment of complex mixed hemorrhoids, it is essential to acknowledge certain limitations that could impact the generalizability of our findings.

Patient Selection and Confounding Variables. The patient selection process adopted for this study and the potential influence of confounding variables may introduce biases into our results. Although efforts were made to maintain consistency in patient characteristics across groups A, B, and C, individual variations and external factors could contribute to variability in outcomes. The retrospective nature of the study might limit our ability to control for all potential confounders, and future research with a more rigorous study design could address this limitation.

Generalizability. Our study was conducted in a specific clinical setting, and the results may not be universally applicable to diverse patient populations or healthcare settings. The efficacy of the interventions may vary based on factors such as patient demographics, comorbidities, and surgical practices. Therefore, caution should be exercised when extrapolating our findings to broader clinical contexts.

Lack of Blinding. The absence of blinding in our study, inherent to the nature of the interventions, may introduce bias in the assessment of outcomes. Both patients and healthcare providers were aware of the treatment received, which could impact subjective measures such as pain scores. Future studies incorporating blinding strategies could enhance the reliability of our findings.

Postoperative Chinese Medicine Care. While the combination of selective malposition ligation with postoperative Chinese medicine care demonstrated positive outcomes, it is essential to recognize that the specific components and dosages of the herbal prescription were not extensively detailed. Further research providing a comprehensive analysis of the composition and dosage of the Chinese medicine used could contribute to a deeper understanding of its role in postoperative care.

Despite these limitations, our study provides a foundation for future research endeavors, and addressing these concerns in subsequent studies would contribute to a more robust understanding of the clinical applications of our proposed interventions.

Comparison with Existing Research and Novel Contributions

To contextualize our findings, we compared the outcomes of our study with existing research in the field of complex mixed hemorrhoid treatment. The current study adds valuable insights and brings several novel contributions to the existing body of knowledge.

Several studies have explored the efficacy of surgical interventions for complex mixed hemorrhoids, with a focus on techniques such as malposition ligation. Our study extends this research by introducing the concept of selective malposition ligation and, notably, by combining it with postoperative Chinese medicine care. This unique approach, to the best of our knowledge, has not been extensively investigated in the literature.

Our comparison of selective malposition ligation (group B) with traditional malposition ligation (group A) revealed comparable results in terms of pain scores and edema. However, notable differences emerged in hemorrhage scores,

duration of wound healing, and the incidence of total complications, with group B showing favorable outcomes. This suggests that the pertinence of surgical plane and point selection in selective malposition ligation may contribute to its enhanced efficacy.

Furthermore, the introduction of postoperative Chinese medicine care (group C) demonstrated a significant improvement in various outcomes, including pain, anal infection, hemorrhage, and overall wound healing. While the combination of surgery and traditional Chinese medicine has been explored in the treatment of hemorrhoids, our study's focus on postoperative care with a specific herbal prescription adds a novel dimension to this approach. Moreover, Hemorrhoids are usually a long-standing or recurrent disease, and in some cases may require long-term management and treatment. [34]

In summary, our study not only builds upon existing knowledge regarding surgical interventions for complex mixed hemorrhoids but also introduces a novel treatment paradigm by incorporating selective malposition ligation and postoperative Chinese medicine care. These novel aspects contribute to the growing understanding of comprehensive treatment strategies for this challenging health condition.

CONCLUSION

The efficacy and the effects of alleviating complications of selective malposition ligation combined with hemorrhoid and fistula I, selective malposition ligation, and malposition ligation in the treatment of complex mixed hemorrhoids were analyzed and compared. It was suggested that oral intake of hemorrhoid and fistula I after selective malposition ligation could promote wound rehabilitation after complex mixed hemorrhoid surgery and reduce the incidence of hemorrhage, edema, and other postoperative complications. Therefore, it had high clinical application values. Nonetheless, the research results were not compared with relevant studies and supported by them. The research scope was valid. Hence, the range of research objects should be further expanded and verified with more in-depth studies to highlight the apparent application values of Chinese medicine treatment in alleviating complications after future hemorrhoid surgery.

AUTHOR DISCLOSURE STATEMENT

The authors declare that they have no competing interests.

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REFERENCES

1. Yu JH, Huang XW, Wu ZJ, Lin HZ, Zheng FW. Clinical study of use of large C suture in procedure for prolapse and hemorrhoids for treatment of mixed hemorrhoids. *J Int Med Res*. 2021;49(3):300060521997325. doi:10.1177/0300060521997325
2. Zhang AM, Chen M, Tang TC, Qin D, Yue L, Zheng H. Somatosensory stimulation treatments for postoperative analgesia of mixed hemorrhoids: protocol for a systematic review and network meta-analysis. *Medicine (Baltimore)*. 2019;98(6):e14441. doi:10.1097/MD.0000000000014441
3. Chen ZQ, Liang RW, Zhang GX, Xie HJ, Shi R. [Application of sub-circumcision of hemorrhoid mucosa in patients with circular mixed hemorrhoids]. *Zhonghua Wei Chang Wai Ke Za Zhi*. 2021;24(12):1107-1110. doi:10.3760/cma.j.cn441530-20200814-00480
4. Wu J, Yu K, Lv C, Lu W, He H. Segmental resection combined with anoplasty for the treatment of circumferential mixed hemorrhoids. *Braz J Med Biol Res*. 2019;52(5):e8102. doi:10.1590/1414-431x20198102
5. Xu S, Qiu J, Zhang H, Lu J, Huang W. Influences of Hiao's double-C nursing model combined with pain care on postoperative satisfaction with pain control and complications in patients with mixed hemorrhoids. *Am J Transl Res*. 2021;13(9):10676-10684.
6. Feng J, Cheng J, Xiang F. Management of intractable pain in patients treated with hemorrhoidectomy for mixed hemorrhoids. *Ann Palliat Med*. 2021;10(1):479-483. doi:10.21037/apm-20-2385
7. Lin X, Anorectal DO. Clinical application of retaining segmented segmental tooth internal ligation for mixed hemorrhoids. *China & Foreign Medical Treatment*. 2018;14(1):429-433.
8. Jiang H, Hao X, Xin Y, Pan Y. Comparison of clinical outcomes of multi-point umbrella suturing and single purse suturing with two-point traction after procedure for prolapse and hemorrhoids (PPH) surgery. *Int J Surg*. 2017;47:77-82. doi:10.1016/j.ijsu.2017.09.053
9. He YH, Tang ZJ, Xu XT, et al. A Randomized Multicenter Clinical Trial of RPH With the Simplified Milligan-Morgan Hemorrhoidectomy in the Treatment of Mixed Hemorrhoids. *Surg Innov*. 2017;24(6):574-581. doi:10.1177/1553350617731205
10. Shang QX, Dept C. Mixed hemorrhoids surgically treated with internal ligation & external incision plus juxtaposition suture: effect observation on 80 cases. *Chinese Journal of Coloproctology*. 2019;14(6):74-81.
11. Lin S, Zang M. Effectiveness of Mayinglong Musk Hemorrhoid Ointment on Wound Healing and Complications after Internal Hemorrhoid Ligation and External Hemorrhoidectomy. *Evid Based Complement Alternat Med*. 2022;2022:5630487. doi:10.1155/2022/5630487
12. Komporozos V, Ziozia V, Komporozou A, Stravodimos G, Kolinioti A, Papazoglou A. Rubber band ligation of symptomatic hemorrhoids: an old solution to an everyday problem. *Int J Colorectal Dis*. 2021;36(8):1723-1729. doi:10.1007/s00384-021-03900-2
13. Jia XQ, Cao WW, Quan LF, et al. Effect of High Suspension and Low Incision Surgery Based on Traditional Ligation of Chinese Medicine in Treatment of Mixed Haemorrhoids: A Multi-centre, Randomized, Single-Blind, Non-inferiority Clinical Trial. *Chin J Integr Med*. 2021;27(9):649-655. doi:10.1007/s11655-021-3329-2
14. Kang DW, Kim BS, Kim JH, Kim KR, Kang GS. A comparative study of rubber band ligation versus BANANA-Clip in grade 1 to 3 internal hemorrhoids. *Ann Coloproctol*. 2023;39(1):41-49. doi:10.3393/ac.2021.00717.0102
15. Jin L, Yang H, Qin K, et al. Efficacy of modified rubber band ligation in the treatment of grade III internal hemorrhoids. *Ann Palliat Med*. 2021;10(2):1191-1197. doi:10.21037/apm-19-657
16. Mott T, Latimer K, Edwards C. Hemorrhoids: Diagnosis and Treatment Options. *Am Fam Physician*. 2018;97(3):172-179.
17. Luo X, Xia Y, Gu M, Yao J. Analgesic Effect of Ropivacaine Combined with Hydromorphone following Surgery for Mixed Hemorrhoids: A Pilot Study. *Pain Res Manag*. 2022;2022:2033580. doi:10.1155/2022/2033580
18. Lu B, Du J, Wu X. The effects of modified Buzhong Yiqi decoction combined with Gangtai ointment on the wound healing and anal function in circumferential mixed hemorrhoid patients. *Am J Transl Res*. 2021;13(7):8294-8301.
19. Huang H, Gu Y, Li Y, Ji L. Modified tissue-selecting therapy stapler combined with complete anal canal epithelial preservation operation for the treatment of circumferential mixed haemorrhoids: a protocol for single-blind randomised controlled study. *BMJ Open*. 2021;11(11):e052982. doi:10.1136/bmjopen-2021-052982
20. Pei X, Song S, Li H, Lu D. Efficacy and safety of acupoint catgut embedding in treating postoperative pain of mixed hemorrhoids: A randomized controlled trial protocol. *Medicine (Baltimore)*. 2021;100(19):e25948. doi:10.1097/MD.0000000000025948
21. Romaguera VP, Sancho-Muriel J, Alvarez-Sarrdo E, Millan M, Garcia-Granero A, Frasson M. Postoperative Complications in Hemorrhoidal Disease and Special Conditions. *Rev Recent Clin Trials*. 2021;16(1):67-74. doi:10.2174/1574887115666200406114218
22. Aibuedefe B, Kling SM, Philp MM, Ross HM, Poggio JL. An update on surgical treatment of hemorrhoidal disease: a systematic review and meta-analysis. *Int J Colorectal Dis*. 2021;36(9):2041-2049. doi:10.1007/s00384-021-03953-3
23. De Robles MS, Young CJ. Rubber Band Ligation of Hemorrhoids is often a Necessary Complement in the Management of Hemorrhagic Radiation Proctitis. *Scand J Surg*. 2020;109(2):108-114. doi:10.1177/1457496918822619
24. Liu T, Zhou H, Lu H, et al. MiR-4729 regulates TIE1 mRNA m6A modification and angiogenesis in hemorrhoids by targeting METTL14. *Ann Transl Med*. 2021;9(3):232. doi:10.21037/atm-20-3399
25. Zhao J, Dou L, Fan R, Fang L, Li S, Peng J. Clinical study of Huaiqin ointment in the treatment of anal edema after hemorrhoid operation. *Minerva Surg*. 2022;77(5):504-506. doi:10.23736/S2724-5691.21.09211-X
26. Chen C, Wang S, Chen J, et al. Escin suppresses HMGB1-induced overexpression of aquaporin-1 and increased permeability in endothelial cells. *FEBS Open Bio*. 2019;9(5):891-900. doi:10.1002/2211-5463.12622
27. Chen S, Huan Z, Zhang L, Chang J. The clinical application of a silicate-based wound dressing (DermFactor˚) for wound healing after anal surgery: A randomized study. *Int J Surg*. 2018;52:229-232. doi:10.1016/j.ijsu.2018.02.036
28. Gao H, Cheng X, Liu R, et al. Clinical study of herbal mixture "Diding Oral Medicine" as an alternative to preventative antibiotics in perioperative hemorrhoids: A CARE-compliant article. *Medicine (Baltimore)*. 2021;100(18):e25661. doi:10.1097/MD.0000000000025661
29. Dönmez C, Yalçın FN, Boyacıoğlu Ö, et al. From nutrition to medicine: assessing hemorrhoid healing activity of Solanum melongena L. via *in vivo* experimental models and its major chemicals. *J Ethnopharmacol*. 2020;261:113143. doi:10.1016/j.jep.2020.113143
30. Huang DD, Liu ZM, Zhang D, et al. [Analysis on clinical efficacy, safety and economy of Shaobei injection and elastic band ligation in the treatment of grade II or III hemorrhoids]. *Zhonghua Wei Chang Wai Ke Za Zhi*. 2020;23(12):1194-1199. doi:10.3760/cma.j.cn.441530-20200526-00312
31. Zeng A, Gu G, Deng L. Effect of Kangfuxin Solution Fumigation Bath on Postoperative Patients with Hemorrhoid PPH and Influence on the Postoperative Complications. *Evid Based Complement Alternat Med*. 2021;2021:6473754. doi:10.1155/2021/6473754
32. Wu J, Lu W, Yu K, Liu H. Clinical study of external application of liuhe dan in the treatment of anal edge edema after mixed hemorrhoid operation. *Pak J Pharm Sci*. 2019;32(3 Special):1431-1435.
33. Shen Q. Ten people with nine traditional Chinese medicine hemorrhoids prevention and treatment. *Medical Reference*. 2001;1:31-31.
34. Iversen L. Younger Adults and the Coping of Chronic Disease - Community Health Nursing as A Flexible Approach to Care. *J Mod Nurs Pract Res*. 2023;3(4):23. doi:10.53964/jmnpr.2023023