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Original Article

Clinical efficacy and recurrence analysis of endoscopic rubber band ligation combined with external hemorrhoidectomy for mixed hemorrhoids

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Abstract: Objective: To evaluate the efficacy and safety of endoscopic rubber band ligation combined with external hemorrhoidectomy (ERBL+EH) for mixed hemorrhoids compared with Milligan-Morgan hemorrhoidectomy (MMH), and to identify risk factors for postoperative recurrence. Methods: A retrospective analysis was conducted on 330 patients with stage III-IV mixed hemorrhoids treated between January 2020 and December 2024. Patients underwent either ERBL+EH (n = 185) or MMH (n = 145). Baseline data, perioperative indicators, complications, treatment costs, and 1-year recurrence were assessed. Follow-up was conducted every 3 months. Group differences were analyzed using χ^2 or t-tests, and Cox regression was applied to identify independent risk factors for recurrence. Results: Baseline characteristics were comparable between groups ($P > 0.05$). ERBL+EH demonstrated significantly better perioperative outcomes, including reduced blood loss, shorter operation and wound healing times, faster pain relief, fewer incisions, and lower postoperative pain scores (all $P < 0.05$). Complication rates were lower in the ERBL+EH group, particularly anal stenosis, prolapse, incontinence, urinary retention, and incision edema, though postoperative bleeding rates were similar between groups. At 1 year, recurrence was significantly reduced with ERBL+EH (9.7% vs. 31.0%, $P < 0.001$), with longer time to recurrence (10 vs. 6 months, $P = 0.025$). Treatment costs were higher in the ERBL+EH group, but length of hospital stay was similar. Clinical efficacy showed a higher rate of marked improvement in the ERBL+EH group ($P < 0.001$). Multivariate Cox regression identified ERBL+EH as a protective factor against recurrence (HR = 0.218, $P = 0.006$), while stage IV disease, diabetes, spicy diet, and anal prolapse were independent risk factors. Conclusion: ERBL+EH is superior to MMH in perioperative outcomes, complication control, and recurrence reduction, offering a safe and effective treatment for mixed hemorrhoids, albeit at higher cost. Appropriate patient selection and optimized postoperative management may further enhance long-term outcomes.

Keywords: Mixed hemorrhoids, endoscopic rubber band ligation, external hemorrhoidectomy, recurrence rate, complications, cox regression

Introduction

Mixed hemorrhoids are a common pathological condition characterized by pathological features of both internal and external hemorrhoids. Typical symptoms include hematochezia, anal pain, hemorrhoid prolapse, and anal discomfort, which severely impair patients' quality of life and social functioning [1, 2]. The incidence of mixed hemorrhoids is relatively high in the adult population and continues to rise with lifestyle changes, poor dietary habits, and prolonged sitting or standing [3]. Constipation, low-fiber diet, and sedentary lifestyle are recognized as major risk factors for hemorrhoid disease [4], highlighting the importance of lifestyle interventions in prevention. Conventional treatments mainly include simple internal hemorrhoid ligation and external hemorrhoidectomy [5]. Internal ligation relieves symptoms by blocking hemorrhoid blood supply, with advantages of simplicity and minimal trauma, but carries a high recurrence rate and is inadequate for the complex pathology of mixed hemorrhoids [6]. Smith et al. [7] reported a recurrence rate of 48.4% after simple endoscopic rubber band ligation for grade III hemorrhoids, whereas hemorrhoidectomy achieved lower recurrence rate but was associated with more complications such as fistulas. External hemor-

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rhoidectomy directly removes external hemorrhoid tissue and achieves relatively low recurrence, but at the cost of greater surgical trauma, severe postoperative pain, prolonged recovery time, and risk of bleeding, anal stenosis, and incontinence. Previous studies indicate that recurrence remains high and conservative treatments offer limited efficacy, emphasizing the need for more comprehensive surgical approaches [8].

Endoscopic rubber band ligation combined with external hemorrhoidectomy (ERBL+EH), as an emerging comprehensive treatment approach, has gained increasing clinical attention in recent years. This combined surgery integrates the advantages of endoscopic technology and traditional surgery, aiming to enhance therapeutic outcomes in mixed hemorrhoids through the synergy of minimally invasive intervention and thorough lesion removal [9]. Endoscopic rubber band ligation enables precise localization of internal hemorrhoid lesions and blocks their blood supply, effectively alleviating symptoms such as hematochezia and prolapse, with the benefits of minimal invasiveness and rapid recovery. External hemorrhoidectomy directly removes external hemorrhoid tissue, eliminating local lesions and reducing recurrence due to residual tissue [10].

The theoretical advantages of ERBL+EH lie in its dual mechanism: endoscopic technology reduces surgical trauma and accelerates postoperative recovery, while external hemorrhoidectomy ensures long-term efficacy by addressing the limitations of simple ligation. This combined strategy is expected to provide superiority over traditional treatments in reducing intraoperative blood loss, shortening operation time, accelerating wound healing, alleviating postoperative pain, and decreasing complication rates [11]. Nevertheless, evidence on its clinical efficacy, postoperative complication profile, and long-term recurrence remains limited, requiring validation in large-sample, systematically designed studies. Therefore, this study was designed to comprehensively evaluate the efficacy and safety of ERBL+EH.

Materials and methods

Sample size calculation

The sample size was estimated based on the study by Van et al. [12]. Assuming a difference in recurrence rates of 41% between groups (47.5% in the ERBL group and 6.1% in the hemorrhoidectomy group), with an effect size (Cohen's h) of 1.02. With a significance level of 0.05 and 80% statistical power, the minimum required sample size was calculated to be 15 cases per group. To ensure sufficient statistical power and account for potential attrition, the actual sample size was adjusted according to clinical needs and anticipated dropout. Therefore, at least 15 patients per group were required to meet the power requirements.

General information

Clinical data of 330 patients with mixed hemorrhoids treated between January 2020 and December 2024 were retrospectively analyzed. Based on surgical method, patients were divided into the combined group (ERBL+EH, n = 185) and the control group (Milligan-Morgan hemorrhoidectomy [MMH], n = 145). This study was approved by the Ethics Committee of Xi'an Central Hospital. All patients voluntarily selected their surgical method after being fully informed of the advantages and limitations of each procedure; physicians did not influence treatment choice.

Inclusion and exclusion criteria

Inclusion criteria

A diagnosis with mixed hemorrhoids (internal and external) as per the *Guidelines for Clinical Diagnosis and Treatment of Hemorrhoids* [13, 14] and confirmed by clinical examination and endoscopic assessment; Hemorrhoids classified as stage III or IV, with significant symptoms such as hematochezia, hemorrhoid prolapse, or anal discomfort; Failed conservative treatments (e.g., dietary adjustments, medication) or voluntarily requested surgical treatment due to severe symptoms; Complete clinical data.

Exclusion criteria

Concurrent anal fissures, perianal abscesses, anal fistulas, incarcerated hemorrhoids, thrombosed external hemorrhoids, or other perianal diseases; Severe cardiovascular or cerebrovascular diseases, hepatic or renal insufficiency, or other systemic diseases contraindicating surgery; Malignant tumors or other life-threatening diseases; Pregnancy or lactation.

Surgical procedures

MMH

Preoperative preparation: Patients underwent bowel preparation with a 500 ml, 3% warm soapy water enema, the night before and the morning of surgery. All patients fasted on the day of surgery.

Surgical procedures: Under sacral anesthesia with 2% lidocaine, patients were placed in the left lateral decubitus position. Following routine disinfection, the anal canal was gently dilated to expose the hemorrhoidal tissue. A "V"-shaped incision was made at the distal margin of the external hemorrhoid, and dissection was extended proximally to approximately 0.5 cm above the dentate line, which served as the anatomical landmark to prevent injury to the anal transitional zone. The base of the hemorrhoid was clamped with a vascular clamp and ligated with silk suture 8-0. The hemorrhoidal tissue was excised approximately 5-6 mm distal to the ligation point. Remaining hemorrhoids were treated sequentially, ensuring staggered ligation sites and preservation of a mucosal bridge of at least 0.6 cm between incisions to minimize the risk of anal stenosis. After excision, anal sphincter tone was assessed, and partial internal sphincterotomy was performed if excessive tension was noted. Hemostasis was achieved with bipolar cautery at a power setting of 25-30 W. The wound was lightly packed with oil gauze and secured with a T-bandage.

Postoperative management: Patients were instructed to avoid prolonged sitting, standing, or straining during defecation within 24 hours and to refrain from heavy physical labor for 1 week. A low-residue diet was recommended for 3 days, with avoidance of alcohol and spicy food. Daily wound care and dressing changes were performed. Oral laxatives were prescribed if constipation occurred. In cases of urinary retention, postural adjustments or induced urination were attempted before catheterization. Postoperative bleeding was managed with local compression or re-suturing as necessary.

ERBL+EH

Preoperative preparation: Patients were instructed to consume a light dinner the night before surgery and to avoid meat, green vegetables, and seeded fruits. Oral intake was stopped 4 hours before anesthesia. Bowel preparation included three boxes of compound polyethylene glycol electrolyte powder (1 box dissolved in 1,000 ml water at 19:00 on the evening before surgery, 2 boxes dissolved in 2,000 ml water, administered 5-6.5 h or 9-10.5 h preoperatively). Patients were encouraged to walk and perform abdominal massage until clear watery stools were achieved. In addition, 100 ml of simethicone solution was administered to reduce intestinal gas.

Surgical steps: Under intravenous anesthesia with propofol, patients were placed in the left lateral decubitus position. Colonoscopy (Olympus) was performed to exclude other bleeding lesions; polyps, if present, were resected. The colonoscope was then replaced by a gastroscope fitted with a COOK ligation device. After adequate lubrication and CO_2 insufflation, the scope was advanced into the anal canal, and retroflexion was used to visualize internal hemorrhoids. Negative pressure (8-13 kPa) was applied to ensure complete suction of the hemorrhoidal cushion without tearing the mucosa. Once complete congestion was observed ("full house red"), a rubber band was released. Ligation was initiated approximately 1.5 cm above the dentate line to minimize postoperative pain, and no more than 7 bands were applied per session to minimize the risk of excessive ischemic necrosis or stenosis. After ligation, the anal cushions were inspected. If significant external hemorrhoid prolapse persisted, a fusiform incision was made to excise tissue up to 0.5 cm below the dentate line (chosen to avoid injury to the dentate line and anal transitional epithelium). Excision was performed using an electrosurgical knife set (cutting mode 30-35 W; coagulation mode 25 W). Hemostasis was achieved by bipolar cautery or absorbable suture ligation if necessary. The wound was dressed with sterile gauze.

Postoperative management: Both groups received the same postoperative care. Patients were advised to avoid prolonged standing, sitting, or straining within 24 hours and to refrain from heavy labor for 1 week. A low-residue diet was recommended for 3 days, with avoidance of spicy foods and alcohol. Laxatives were prescribed to prevent constipation. For patients with surgical incisions, herbal fumigation and topical ointments were applied after defecation; for those without incisions, routine cleansing was sufficient.

Data collection

Clinical data were obtained from electronic medical records and outpatient follow-up records, including the following variables: demographic information (age, sex, marital status, education level), clinical characteristics (body mass index [BMI], disease duration, and hemorrhoid stage III or IV), health status and lifestyle (history of hypertension, diabetes, smoking, dietary habits), perioperative indicators (intraoperative blood loss, operation time, wound healing time, anal pain relief time, number of incisions, and postoperative pain score [VAS, visual analog score]), postoperative complications (bleeding, anal stenosis, anal prolapse, anal incontinence, urinary retention, incision edema), hospital stay and costs (length of stay, treatment costs), postoperative efficacy (marked improvement, effective, ineffective, total effective rate), recurrence at 1 year postoperatively (recurrence status, average time to recurrence), and treatment method (MMH or ERBL+EH).

In this study, a "light diet" refers to a dietary pattern characterized by low fat, low spice, low fiber residue, and easy digestibility. Specifically, it includes steamed or boiled foods, soft vegetables (e.g., carrots, pumpkins), rice porridge, noodles, and lean protein sources such as fish or chicken. Patients were advised to avoid greasy, spicy, fried foods, high-fiber raw vegetables, alcohol, caffeine, and other foods that could cause constipation or gastrointestinal irritation.

Preoperative data (demographics, clinical characteristics, and health status) were obtained from electronic medical records. Intraoperative data (perioperative indicators) were extracted from surgical records. Postoperative hospitalization data included VAS scores, complications, length of stay, and costs. Follow-up data were collected through outpatient visits for wound healing time, complications, efficacy, and recurrence at 1 year. All data were reviewed by the research team for completeness, and patients lost to follow-up were excluded. Uniform assessment standards were applied to minimize bias.

Follow-up

To evaluate the clinical efficacy and recurrence, patients were followed for one year, with evaluations scheduled at 3, 6, 9, and 12 months postoperatively. Follow-up was conducted through outpatient visits, supplemented by telephone follow-up when necessary to reduce loss to follow-up. Recurrence was defined as the reappearance of hemorrhoidal symptoms (hematochezia, prolapse, or anal discomfort), confirmed by anoscopic examination. In cases with atypical findings or risk factors, colonoscopy was performed to rule out other colorectal pathology. This standardized definition ensured that recurrence was determined by both clinical symptoms and objective examination rather than subjective reporting alone.

Outcome measurements

<u>Primary outcomes</u>

The primary outcomes included 1-year recurrence rate, incidence of postoperative complications, and clinical efficacy. Recurrence was assessed every 3 months during follow-up. Complications included postoperative bleeding, anal stenosis, anal prolapse, anal incontinence, urinary retention, and incision edema, and their incidence rates were compared between groups. Clinical efficacy was categorized into three categories: marked improvement (complete resolution of symptoms and hemorrhoidal masses with restoration of normal anatomical structure), effective (significant improvement in symptoms with reduction of hemorrhoidal masses), or ineffective (no change in symptoms or signs). The effective rate was calculated as (marked improvement cases + effective cases) ÷ total cases × 100%. The distribution of efficacy was then compared between the two groups [7]. Cox regression analysis was used to identify independent risk factors for recurrence, including treatment method, disease duration, disease stage, history of diabetes, dietary habits, and anal prolapse.

<u>Secondary outcomes</u>

Secondary outcomes included baseline data, perioperative indicators, length of hospital stay, and treatment costs. Baseline data covered age, sex, BMI, disease duration, disease stage, health status, and lifestyle factors, and were analyzed to assess group comparability. Perioperative indicators included intraoperative blood loss, operation time, wound healing time, anal pain relief time, number of incisions, and postoperative VAS pain scores. Differences in hospital stay and treatment costs were also assessed to evaluate economic and recovery outcomes. Additionally, baseline characteristics and complications were compared between patients with and without recurrence to further identify potential influencing factors.

Statistical analysis

Data analyses were performed using SPSS 26.0 and R software. Baseline data were compared between groups using the chi-square test (with continuity correction for frequencies < 5) for categorical variables (e.g., age, sex, BMI, disease duration, disease stage). Continuous variables were assessed for normality using the Kolmogorov-Smirnov (K-S) test; normally distributed variables were expressed as mean ± standard deviation and compared using the independent samples t-test, while non-normally distributed variables were expressed as median (interquartile range, IQR) and compared using the Mann-Whitney U test.

The 1-year recurrence rate, incidence of complications, and distribution of clinical efficacy were compared between groups using the chi-square test. Cox regression analysis was used to identify independent risk factors for postoperative recurrence. Significant variables from univariate analysis were included in the multivariate Cox regression, and hazard ratios (HR) with 95% confidence intervals (CIs) were calculated. R software (*survival* and *survminer* packages) was used to plot cumulative incidence function (CIF) curves to analyze the impact of factors such as treatment method, disease duration, and disease stage on recurrence at postoperative 1 year. The *patchwork* and *cowplot* packages were used to optimize figure presentation. All statistical tests were two-sided, with significance level set at P < 0.05.

Results

Baseline data

There were no significant differences between the two groups in terms of age (P = 0.889), sex distribution (P = 0.462), BMI (P = 0.155), disease duration (P = 0.175), disease stage (P = 0.515), history of hypertension (P = 0.858), history of diabetes (P = 0.427), smoking history (P = 0.205), dietary habits (P = 0.376), marital status (P = 0.128), or education level (P = 0.843), ensuring comparability between the groups. Details are presented in **Table 1**.

Perioperative indicators

Significant intergroup differences were observed in perioperative outcomes. Compared with the control group, the combined group had less intraoperative blood loss (P < 0.001), shorter operation time (P < 0.001), faster wound healing (P < 0.001), earlier anal pain relief (P < 0.001), fewer incisions (P = 0.023), and lower postoperative VAS scores (P < 0.001), indicating superior perioperative performance of the combined procedure (**Table 2**).

Overall postoperative recurrence and complications

Postoperative complications included recurrence, bleeding, anal stenosis, anal prolapse, incontinence, urinary retention, and incision edema. Recurrence was the most common complication, occurring in 63 of 267 patients (23.6%), followed by incision edema (60/270; 22.2%). Other complications were less frequent: bleeding (9/321, 2.8%), anal stenosis (8/322, 2.5%), anal prolapse (48/282, 17%), incontinence (8/322, 2.5%), and urinary retention (19/311, 6.1%) (**Figure 1**).

Postoperative complications

The incidence of postoperative bleeding did not differ significantly between the two groups (P = 1.000). However, the combined group showed significantly lower incidence of incision edema compared to the control group (P < 0.001), and the incidences of anal stenosis, anal prolapse, incontinence, and urinary retention were also significantly lower in the combined group (P < 0.05) (**Table 3**).

Hospital stay and treatment costs

No significant difference was found in hospital stay between the two groups (P = 0.167). Specifically, the median hospital stay was 11 days in the control group and 10 days in the

Table 1. Comparison of baseline data between the two groups

Factor	Total	Control Group (n = 145)	Combined Group (n = 185)	Statistic	*P*-value
Age					
≥ 45	208 (63.03%)	92 (63.45%)	116 (62.70%)	0.019	0.889
< 45	122 (36.97%)	53 (36.55%)	69 (37.30%)		
Sex					
Male	185 (56.06%)	78 (53.79%)	107 (57.84%)	0.540	0.462
Female	145 (43.94%)	67 (46.21%)	78 (42.16%)		
BMI					
≥ 25	114 (34.55%)	44 (30.34%)	70 (37.84%)	2.018	0.155
< 25	216 (65.45%)	101 (69.66%)	115 (62.16%)		
Disease Duration					
≥ 4 years	189 (57.27%)	77 (53.10%)	112 (60.54%)	1.837	0.175
< 4 years	141 (42.73%)	68 (46.90%)	73 (39.46%)		
Disease Severity					
Stage III	219 (66.36%)	99 (68.28%)	120 (64.86%)	0.424	0.515
Stage IV	111 (33.64%)	46 (31.72%)	65 (35.14%)		
Hypertension History					
Yes	56 (16.97%)	24 (16.55%)	32 (17.30%)	0.032	0.858
No	274 (83.03%)	121 (83.45%)	153 (82.70%)		
Diabetes History					
Yes	37 (11.21%)	14 (9.66%)	23 (12.43%)	0.630	0.427
No	293 (88.79%)	131 (90.34%)	162 (87.57%)		
Smoking History					
Yes	226 (68.48%)	94 (64.83%)	132 (71.35%)	1.603	0.205
No	104 (31.52%)	51 (35.17%)	53 (28.65%)		
Dietary Habits					
Spicy	157 (47.58%)	65 (44.83%)	92 (49.73%)	0.783	0.376
Mild	173 (52.42%)	80 (55.17%)	93 (50.27%)		
Marital Status					
Married	298 (90.30%)	135 (93.10%)	163 (88.11%)	2.316	0.128
Other	32 (9.70%)	10 (6.90%)	22 (11.89%)		
Education Level					
≥ High School	155 (46.97%)	69 (47.59%)	86 (46.49%)	0.039	0.843
< High School	175 (53.03%)	76 (52.41%)	99 (53.51%)		

Note: BMI: Body Mass Index.

Table 2. Comparison of perioperative parameters between the two groups

Variable	Total	Control Group (n = 145)	Combined Group (n = 185)	Statistic	*P*-value
Intraoperative Blood Loss (mL)	7.00 (9.00)	14.00 (6.00)	4.00 (4.00)	14.341	< 0.001
Operation Time (min)	24.00 (20.00)	36.00 (9.00)	15.00 (6.00)	15.141	< 0.001
Surgical Wound Healing Time (days)	12.00 (4.00)	15.00 (4.00)	10.00 (3.00)	12.021	< 0.001
Anal Pain Relief Time (days)	4.00 (2.00)	4.00 (1.00)	3.00 (2.00)	7.421	< 0.001
Number of Incisions (count)	2.00 (2.00)	2.00 (2.00)	2.00 (2.00)	2.267	0.023
Postoperative VAS Score	4.00 (4.00)	5.00 (3.00)	4.00 (3.00)	3.488	< 0.001

Note: VAS: Visual Analog Scale.

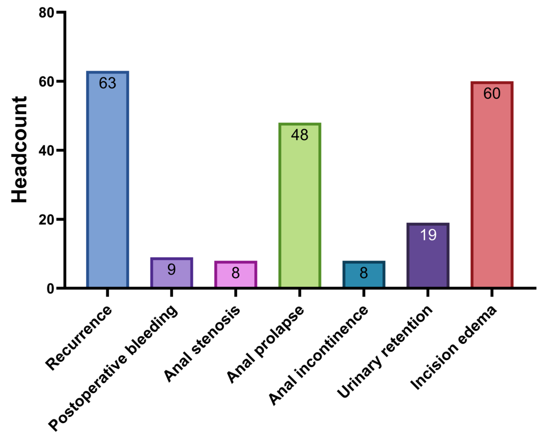

Figure 1. Statistics of overall recurrence and complications after surgery.

combined group. However, the median treatment cost was 9827.50 yuan in the combined group, significantly higher than 8853.00 yuan in the control group (**Table 4**).

Postoperative clinical efficacy

Postoperative clinical efficacy was superior in the combined group compared with the control group. Specifically, 178 patients in the combined group and 116 in the control group achieved marked improvement, while 7 and 29 patients, respectively, were classified as effective. The combined group showed a significantly higher proportion of patients with marked improvement (P < 0.001), but no difference was observed in the total effective rate (P > 0.05). Details are presented in **Table 5.**

Postoperative 1-year recurrence

At 1 year postoperatively, 18 patients in the combined group and 45 patients in the control group experienced recurrence. The recurrence rate was significantly lower in the combined group compared with the control group (P < 0.001). The average time to recurrence was 10 months in the combined group, significantly longer than 6 months in the control group (P = 0.023). Details are presented in **Table 6** and **Figure 2**.

Comparison of baseline data between patients with and without postoperative recurrence

Comparison of baseline data between patients with and without postoperative recurrence revealed significant differences in several factors. The recurrence group had a lower proportion of male patients (P = 0.039), longer disease duration (P = 0.029), higher incidence of diabetes history (P < 0.001), and increased prevalence of anal prolapse (P < 0.001) compared to the non-recurrence group. However, no significant differences were observed in age, BMI, smoking history, marital status, or postoperative complications such as postoperative bleeding, anal incontinence, and urinary retention (P > 0.05). Details are presented in **Table 7**.

Assignment of clinical variables and proportional hazards assumption testing

Clinical variables were assigned values, and the variance inflation factors (VIF) was calculated to assess multicollinearity. The VIF for treatment plan was 3.839, and other variables including disease duration and disease stage also demonstrated acceptable VIF values, indicating no significant multicollinearity (**Table 8**). Subsequently, to test the proportional hazards (PH) assumption in the Cox regression model, Schoenfeld residual analyses were performed. The global Schoenfeld test yielded a *p*-value of 0.1775, indicating no significant violation of the PH assumption. For individual variables, Schoenfeld residual *p*-values were all > 0.05, confirming that the PH assumption was satisfied (**Figure 3**).

Cox regression analysis of independent risk factors for postoperative recurrence

Univariate cox regression analysis

Univariate Cox regression analysis showed that the combined treatment significantly reduced the risk of postoperative recurrence compared to the control group (HR = 0.267, P < 0.001). Patients with a disease duration of ≥ 4 years had a significantly higher risk of recurrence than those with < 4 years (HR = 1.835, P = 0.027). Stage IV disease was associated with a higher recurrence risk compared to stage III (HR = 2.221, P = 0.002). Diabetic patients had a significantly higher recurrence risk than non-diabetic patients (HR = 3.974, P < 0.001). A spicy diet was associated with a higher recurrence risk compared to a mild diet (HR = 2.052, P = 0.006). Patients with anal prolapse also showed a markedly increased recurrence risk

Table 3. Comparison of postoperative complications between the two groups

Variable	Control Group (n = 145)	Combined Group (n = 185)	Statistic	*P*-value
Postoperative Bleeding (Yes/No)	4/141	5/180	< 0.001	1.000
Anal Stenosis (Yes/No)	7/138	1/184	4.633	0.031
Anal Prolapse (Yes/No)	29/116	19/166	6.191	0.013
Anal Incontinence (Yes/No)	7/138	1/184	4.633	0.031
Urinary Retention (Yes/No)	14/131	5/180	7.241	0.007
Incision Edema (Yes/No)	46/99	14/171	31.887	< 0.001

Table 4. Comparison of hospital stay and treatment costs between the two groups

Variable	Total	Control Group (n = 145)	Combined Group (n = 185)	Statistic	*P*-value
Hospital Stay (days)	10.00 (7.00)	11.00 (7.00)	10.00 (7.00)	1.381	0.167
Treatment Costs (yuan)	9459.00 (3794.00)	8853.00 (3470.00)	9827.50 (3651.00)	2.955	0.003

Table 5. Comparison of clinical outcomes between the two groups

Variable	Control Group (n = 145)	Combined Group (n = 185)	Statistic	*P*-value
Marked Improvement	116	178	21.994	4.690
Effective	29	7		
Ineffective	0	0		
Total Effective Rate	145	185	-	-

Table 6. Comparison of postoperative 1-year recurrence between the two groups

Variable	Control Group (n = 145)	Combined Group (n = 185)	Statistic	*P*-value
Recurrence	45	18	23.887	< 0.001
No Recurrence	100	167		
Average Time to Recurrence (month)	6.00 [5.00, 8.00]	10.00 [4.50, 10.75]	-2.229	0.025

(HR = 4.527, P < 0.001). Intraoperative blood loss (HR = 1.079, P < 0.001) and surgery time (HR = 1.056, P < 0.001) were also significantly associated with recurrence risk (**Table 9**).

Multivariate cox regression analysis

Multivariate Cox regression identified that the combined treatment remained as an independent protective factor against recurrence (HR = 0.218, P = 0.006). Stage IV disease remained a significant risk factor (HR = 2.25, P = 0.002). Diabetes (HR = 4.07, P < 0.001), spicy diet (HR = 2.262, P = 0.002), and anal prolapse (HR = 3.552, P < 0.001) were all identified as independent risk factors for recurrence. Although disease duration ≥ 4 years was associated with a higher risk of recurrence (HR = 1.653), the result did not reach statistical significance (P = 0.076). Intraoperative blood loss and surgery time did not show significant associations with recurrence in the multivariate model (P > 0.05). Details are presented in **Table 9**.

Comparison of CIF curves for recurrence between diabetic and non-diabetic patients

CIF analysis demonstrated that diabetic patients had a significantly higher recurrence rate compared with non-diabetic patients (P < 0.001, Figure S1A). In subgroup analyses, the control group showed a markedly higher recurrence risk in diabetic patients (P < 0.001, Figure S1B). However, no significant difference in the recurrence rate was observed between diabetic and non-diabetic patients in the combined group (P = 0.116, Figure S1C).

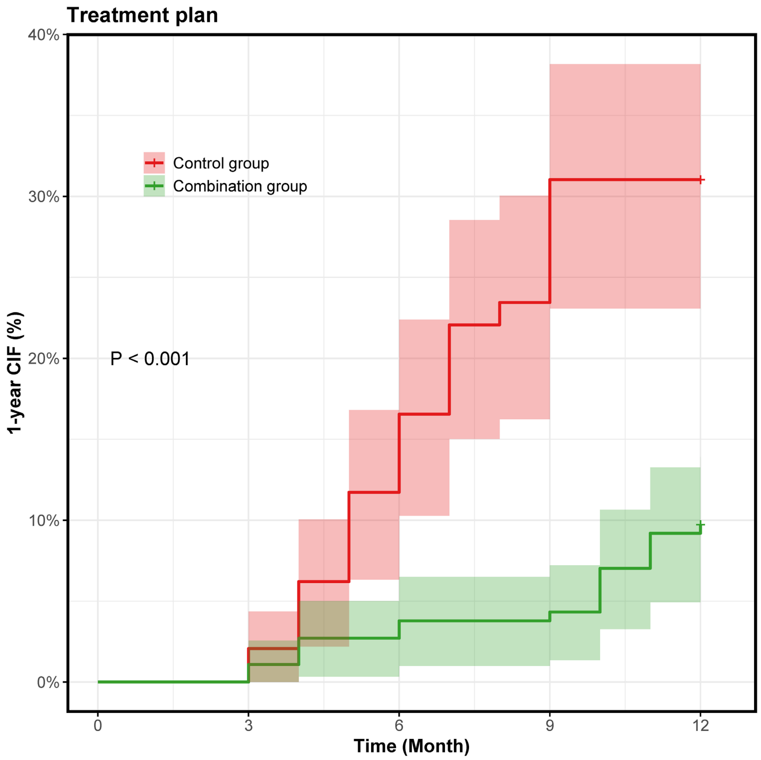

Figure 2. Comparison of post-operative 1-year recurrence between patients of combined and control group.

Comparison of intraoperative indicators, post-operative recovery, hospital stay, and treatment costs between diabetic and non-diabetic patients

Comparisons between diabetic and non-diabetic patients revealed no significant differences in terms of intraoperative blood loss (P = 0.669), surgery time (P = 0.754), or surgical wound healing time (P = 0.148). However, diabetic patients had a significantly longer anal pain relief time compared to non-diabetic patients (P = 0.045) (Table S1). In terms of hospital stay and treatment costs, there were no significant differences observed between the two groups (P = 0.121 and P = 0.202, respectively) (Table S2).

Discussion

Endoscopic technology enables precise localization and ligation of internal hemorrhoids, effectively blocking blood supply while minimizing intraoperative bleeding and tissue injury. By directly removing external lesions, operation and healing time are shortened along with reduced pain scores [15-17]. Current guidelines recommend lifestyle modifications, such as increased fiber intake and avoidance of straining during defecation, as first-line therapy for hemorrhoidal disease; excisional hemorrhoidectomy is reserved for grade III to IV prolapse or mixed hemorrhoidal refractory to conservative measures [18]. Studies indicate [19] that endoscopic techniques outperform traditional surgery in pain control and complication rates. In contrast, traditional MMH involves extensive dissection, causing greater trauma and prolonged recovery. Long et al. [5] demonstrated that combined approaches significantly reduced postoperative complications compared to MMH alone. These perioperative improvements enhance patient comfort and may underlie the reduced complication and recurrence rates observed with combined treatment.

The reduction in postoperative complications in this study is closely associated with the minimally invasive features of combined treatment. The combined group exhibited significantly lower rates of anal stenosis, anal prolapse, anal incontinence, urinary retention, and incision edema compared to the controls. This may be attributed to precise endoscopic ligation that minimizes anal sphincter interference, with optimized incision designs and refined postoperative care, including herbal fumigation and topical ointments. Xu et al. [20] reported that endoscopic rubber band ligation achieved complication rates comparable to those of traditional endoscopy, confirming the safety and reliability of endoscopic technology. Similarly, selective tissue-preserving strategies have been shown to reduce complications relative to traditional methods [21], reinforcing the advantages of minimally invasive surgery. In this study, no significant difference in postoperative bleeding was observed between groups. Importantly, the low complication rate in the

Table 7. Comparison of baseline data between patients with and without postoperative recurrence

Variable	Total	Recurrence Group (n = 63)	Non-Recurrence Group (n = 267)	Statistic	*P*-value
Age					
≥ 45	208 (63.03%)	35 (55.56%)	173 (64.79%)	1.867	0.172
< 45	122 (36.97%)	28 (44.44%)	94 (35.21%)		
Sex					
Male	185 (56.06%)	28 (44.44%)	157 (58.80%)	4.265	0.039
Female	145 (43.94%)	35 (55.56%)	110 (41.20%)		
BMI					
≥ 25	114 (34.55%)	24 (38.10%)	90 (33.71%)	0.434	0.510
< 25	216 (65.45%)	39 (61.90%)	177 (66.29%)		
Disease Duration					
≥ 4 years	190 (57.58%)	44 (69.84%)	146 (54.68%)	4.796	0.029
< 4 years	140 (42.42%)	19 (30.16%)	121 (45.32%)		
Disease Severity					
Stage III	219 (66.36%)	31 (49.21%)	188 (70.41%)	10.268	0.001
Stage IV	111 (33.64%)	32 (50.79%)	79 (29.59%)		
Hypertension History					
Yes	56 (16.97%)	8 (12.70%)	48 (17.98%)	1.008	0.315
No	274 (83.03%)	55 (87.30%)	219 (82.02%)		
Diabetes History					
Yes	37 (11.21%)	18 (28.57%)	19 (7.12%)	23.570	< 0.001
No	293 (88.79%)	45 (71.43%)	248 (92.88%)		
Smoking History					
Yes	226 (68.48%)	39 (61.90%)	187 (70.04%)	1.562	0.211
No	104 (31.52%)	24 (38.10%)	80 (29.96%)		
Dietary Habits					
Spicy	157 (47.58%)	40 (63.49%)	117 (43.82%)	7.909	0.005
Mild	173 (52.42%)	23 (36.51%)	150 (56.18%)		
Marital Status					
Married	298 (90.30%)	59 (93.65%)	239 (89.51%)	0.997	0.318
Other	32 (9.70%)	4 (6.35%)	28 (10.49%)		
Education Level					
≥ High School	155 (46.97%)	28 (44.44%)	127 (47.57%)	0.199	0.655
< High School	175 (53.03%)	35 (55.56%)	140 (52.43%)		
Postoperative Bleeding					
Yes	9 (2.73%)	2 (3.17%)	7 (2.62%)	< 0.001	1.000
No	321 (97.27%)	61 (96.83%)	260 (97.38%)		
Anal Stenosis					
Yes	8 (2.42%)	3 (4.76%)	5 (1.87%)	0.785	0.376
No	322 (97.58%)	60 (95.24%)	262 (98.13%)		
Anal Prolapse					
Yes	48 (14.55%)	24 (38.10%)	24 (8.99%)	34.742	< 0.001
No	282 (85.45%)	39 (61.90%)	243 (91.01%)		
Anal Incontinence					
Yes	8 (2.42%)	2 (3.17%)	6 (2.25%)	< 0.001	1.000
No	322 (97.58%)	61 (96.83%)	261 (97.75%)		
Urinary Retention					
Yes	19 (5.76%)	5 (7.94%)	14 (5.24%)	0.275	0.600
No	311 (94.24%)	58 (92.06%)	253 (94.76%)		

Incision Edema					
Yes	60 (18.18%)	13 (20.63%)	47 (17.60%)	0.315	0.575
No	270 (81.82%)	50 (79.37%)	220 (82.40%)		
Intraoperative Blood Loss (mL)	7.00 (9.00)	11.00 (10.50)	6.00 (9.00)	3.483	< 0.001
Surgery Time (min)	24.00 (20.00)	34.00 (16.50)	22.00 (18.00)	4.449	< 0.001
Surgical Wound Healing Time (days)	12.00 (4.00)	12.00 (4.00)	12.00 (4.00)	2.147	0.032
Anal Pain Relief Time (days)	4.00 (2.00)	4.00 (2.00)	4.00 (2.50)	0.881	0.378
Number of Incisions (count)	2.00 (2.00)	2.00 (2.00)	2.00 (2.00)	0.813	0.416
VAS score	4.00 (4.00)	5.00 (3.00)	4.00 (3.00)	1.751	0.080
Hospital Stay (days)	10.00 (7.00)	10.00 (7.00)	10.00 (7.00)	0.379	0.705
Treatment Costs (yuan)	9458.00 (3770.50)	9098.00 (3707.00)	9532.00 (3728.00)	0.186	0.853

Note: BMI: Body Mass Index, VAS: Visual Analog Scale.

Table 8. Assignment table and variance inflation factor

Variable Name	Assignment	VIF
Treatment plan	1 = Treatment plan, 0 = Combined Group	3.839
Course of disease	1 = ≥ 4 years, 0 = < 4 years	1.061
Severity of disease	1 = Grade III, 0 = Grade IV	1.083
History of diabetes	1 = Yes, 0 = No	1.139
Dietary habits	1 = Spicy, 0 = Mild	1.054
Anal prolapse	1 = Yes, 0 = No	1.044
Intraoperative blood loss	Continuous value (in mL)	2.436
Surgery time	Continuous value (in minutes)	2.242
Surgical wound healing time	Continuous value (in days)	2.634

combined group correlated with higher rates of marked improvement, indicating a positive relationship between reduced complications and enhanced efficacy.

The significantly lower recurrence rate observed in the combined group underscores long-term benefits of combined treatment. At 1 year postoperatively, the combined group had significantly lower recurrence rate sand longer average time to recurrence, reflecting the thoroughness of lesion management. Huang et al. [22] reported that modified tissue-selective technique achieved a recurrence rate of 0.65% compared to 5.88% for PPH, demonstrating sustained advantages. Endoscopic ligation disrupts internal hemorrhoid blood supply while external hemorrhoidectomy removes residual external lesions, and the combination of minimally invasive and comprehensive approaches synergistically reduces recurrence risk. The literature suggests that increasing the number of ligations significantly lowers recurrence rates in grade III hemorrhoids [23]. Garg et al. [24] emphasized the importance of lifestyle interventions, showing that avoidance of compulsive defecation, adherence to the "three minutes once daily" principle, and adequate fiber intake reduced recurrence after outpatient procedures. Similarly, adequate dietary fiber supplement combined with the TONE method (Three minutes, Once/day, No straining, Enough fiber) has been shown to prevent progression and bleeding episodes in advanced hemorrhoids [25]. Conversely, traditional MMH may inadequately address hemorrhoidal blood supply, and postoperative scarring can increase recurrence risk.

Economic outcomes must also be considered. Although treatment costs were higher in the combined treatment group due to the use of endoscopic equipment, anesthesia, and consumables, no significant difference was observed in hospital stay between the two groups, indicating accelerated recovery without increasing hospitalization burden. While initial costs are higher, the reduction in complications and recurrence may provide long-term cost-effectiveness by lowering the need for secondary interventions and follow-up care. The literature reported [5] that MMH+RBL+PFS achieved

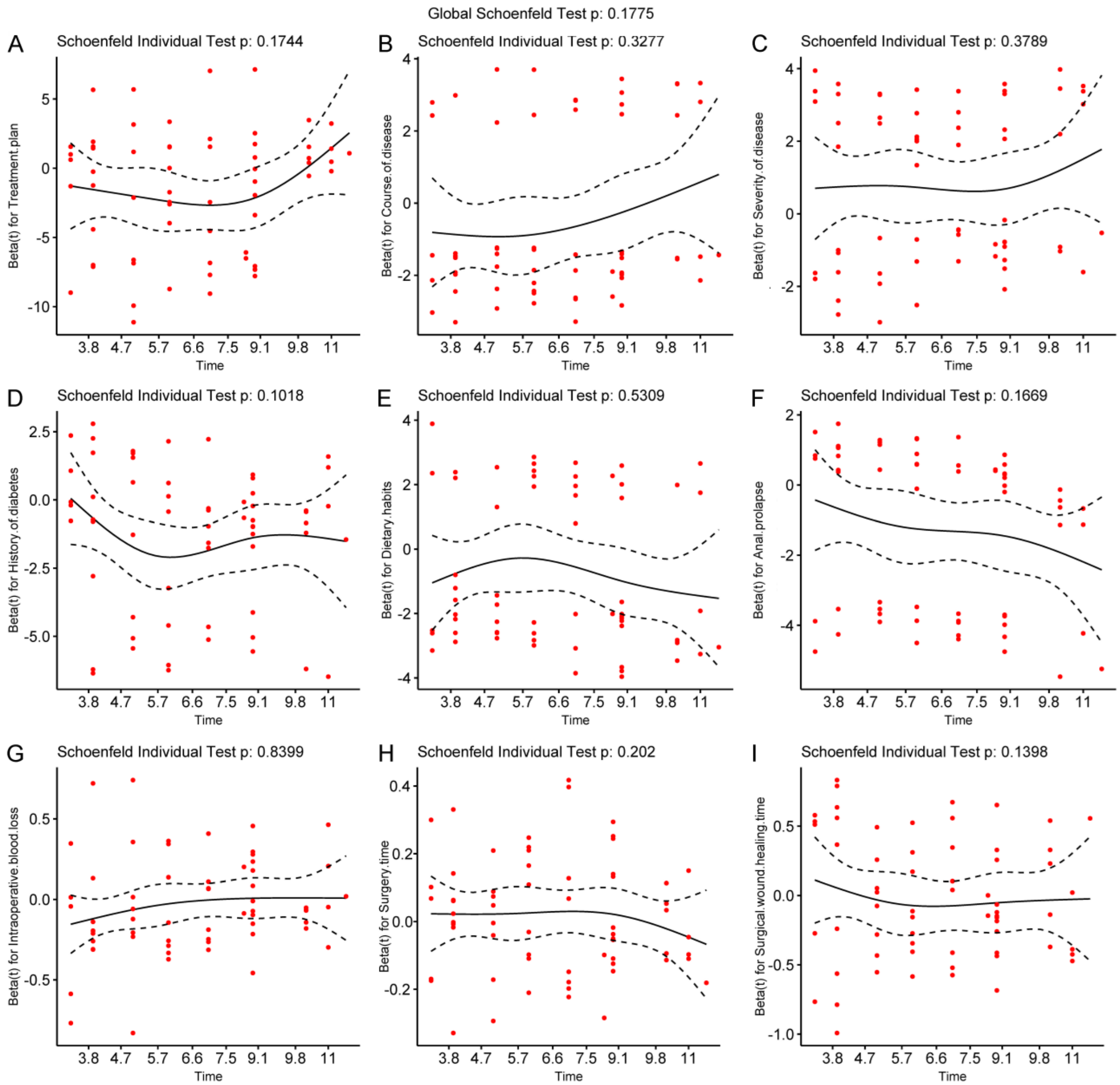

Figure 3. Visualization of Schoenfeld residuals for PH assumption testing. A. Treatment Plan - Schoenfeld residual plot for treatment method (Combined vs. Control group), P = 0.1744. B. Course of Disease - Schoenfeld residual plot for disease duration (≥ 4 years vs. < 4 years), P = 0.3177. C. Severity of Disease - Schoenfeld residual plot for hemorrhoid stage (Stage III vs. Stage IV), P = 0.5789. D. History of Diabetes - Schoenfeld residual plot for diabetes status (Yes vs. No), P = 0.1018. E. Dietary Habits - Schoenfeld residual plot for dietary patterns (Spicy vs. Mild diet), P = 0.5309. F. Anal Prolapse - Schoenfeld residual plot for presence of anal prolapse (Yes vs. No), P = 0.1696. G. Intraoperative Blood Loss - Schoenfeld residual plot for continuous variable of blood loss volume, P = 0.8309. H. Surgery Time - Schoenfeld residual plot for continuous variable of operation duration, P = 0.202. I. Surgical Wound Healing Time - Schoenfeld residual plot for continuous variable of healing duration, P = 0.1398.

higher patient satisfaction (91.41%) compares with MMH alone (81.10%), supporting the economic value of multimodal strategies. High rates of marked improvement and low complication incidence in the present study further indicate improved postoperative quality of life, reinforcing cost-effectiveness. Perioperative optimization, including shorter operation times and faster healing indirectly reduces hospital-related costs. In contrast, MMH alone, associated with greater trauma, higher complication and recurrence rates, is less favorable. Kodilinye et al. [11] confirmed the clinical utility of ERBL for symptomatic hemorrhoids, further validating the clinical value of endoscopic techniques. Future cost optimization through improved endoscopic equipment and surgical processes could enhance accessibility and

Table 9. Cox regression analysis of independent risk factors for postoperative recurrence

Variable	Univariate Cox Regression			Multivariate Cox regression		
	β	*P*-value	HR	β	*P*-value	HR
Treatment plan						
Control Group						
Combined Group	-1.319	< 0.001	0.267 (0.155-0.462)	-1.523	0.006	0.218 (0.074-0.645)
Course of disease						
< 4 years						
≥ 4 years	0.607	0.027	1.835 (1.071-3.143)	0.503	0.076	1.653 (0.949-2.88)
Severity of disease						
IV						
III	-0.798	0.002	0.45 (0.275-0.738)	-0.811	0.002	0.444 (0.265-0.746)
History of diabetes						
No						
Yes	1.380	< 0.001	3.974 (2.297-6.876)	1.404	< 0.001	4.07 (2.227-7.437)
Dietary habits						
Mild						
Spicy	0.719	0.006	2.052 (1.229-3.428)	0.816	0.002	2.262 (1.334-3.838)
Anal prolapse						
No						
Yes	1.510	< 0.001	4.527 (2.718-7.539)	1.268	< 0.001	3.552 (2.098-6.015)
Intraoperative blood loss	0.076	< 0.001	1.079 (1.038-1.121)	-0.039	0.246	0.961 (0.899-1.028)
Surgery time	0.054	< 0.001	1.056 (1.032-1.08)	0.015	0.473	1.015 (0.975-1.057)
Surgical wound healing time	0.069	0.087	1.072 (0.99-1.16)			

Note: HR: Hazard Ratio.

economic sustainability of combined treatment.

Multivariate analysis identified combined treatment as an independent protective factor against recurrence (HR = 0.218), whereas stage IV disease, diabetes, spicy diet, and anal prolapse were independent risk factors. These findings highlight that both surgical approach and patient-related characteristics jointly influence long-term outcomes in mixed hemorrhoids. The combined approach, which integrates ERBL with EH, offers both precision and completeness, thereby reducing residual lesions and minimizing trauma. This dual strategy is consistent with favorable results reported for hybrid procedures such as M-TST-CACP [22] and modified PPH [26].

Stage IV hemorrhoids typically involve more extensive tissue and vascular congestion, which increase surgical complexity and residual risk, as supported by research from Zhang et al. [27]. Diabetes contributes to impaired wound healing and chronic inflammation, leading to a higher recurrence rate, a pattern also seen in previous studies [5]. Wang et al. [28] demonstrated that wound healing in diabetic patients after anorectal surgery involves dysregulation of multiple signaling pathways, including PI3K-Akt, HIF-1, and estrogen signaling, which may explain delayed healing and increased recurrence risk. Spicy diets may aggravate anal irritation and contribute to straining during defecation, while anal prolapse reflects compromised structural support, both of which are linked to recurrence. The protective role of a mild diet aligns with findings by Li et al. [29], emphasizing the importance of dietary and lifestyle modification. This is further substantiated by case-control studies showing that low fiber intake, inadequate fluid consumption, and altered bowel habits significantly contribute to hemorrhoids and anal fissures [30]. Systematic reviews also identify dietary factors, constipation, and sedentary lifestyle as key modifiable risk factors in hemorrhoidal disease [4], reinforcing the necessity of comprehensive lifestyle interventions alongside surgical treatment.

Although shorter disease duration (< 4 years) was associated with reduced recurrence in univariate analysis, it did not remain significant in the multivariate model. Similarly, operative time and intraoperative blood loss lost significance after adjustment, likely reflecting confounding by disease severity or procedure type. Overall, recurrence is multifactorial. Optimizing outcomes requires not only appropriate surgical selection but also comprehensive pre- and postoperative management. These findings underscore the importance of early intervention, individualized risk assessment, and integration of surgical technique with metabolic and lifestyle control.

This study demonstrates that ERBL combined with EH is a preferred choice for patients with stage III-IV mixed hemorrhoids. Its advantages in efficacy, complication control, and perioperative outcomes yield long-term cost-effectiveness. Comprehensive preoperative evaluation of disease duration, stage, and comorbidities such as diabetes is crucial for tailoring treatment plans. Postoperative management should emphasize a light diet, constipation prevention, anal function protection for diabetic patients, strict blood sugar control and close follow-up.

Nevertheless, several limitations must be acknowledged. First, as a retrospective study, the design is inherently subject to selection bias and incomplete data. Second, the 1-year follow-up period is insufficient to fully assess long-term recurrence. Third, the single-center setting limits generalizability to broader populations. Fourth, important variables like cost breakdown, psychological factors, and postoperative compliance were not analyzed. Additionally, differences in anesthesia methods (intravenous propofol vs. sacral lidocaine) between the two groups may have influenced short-term outcomes such as postoperative pain and urinary retention. Although anesthesia type was not included in the recurrence risk model - because it is procedure-dependent rather than a fixed patient characteristic - it remains a potential confounder and was addressed as a limitation.

Future research should involve multicenter randomized controlled trials and extend follow-up to 3-5 years to evaluate long-term efficacy. Incorporation of genetic, psychological, and behavioral factors into recurrence risk models may further refine individualized risk assessment. Optimization of endoscopic equipment and surgical processes could reduce costs and improve accessibility. Finally, the use of standardized quality-of-life instruments would help capture functional outcomes beyond recurrence, enhancing the overall evaluation of treatment value.

Conclusion

Endoscopic rubber band ligation combined with external hemorrhoidectomy demonstrates clear advantages over traditional Milligan-Morgan hemorrhoidectomy by reducing recurrence rates, minimizing complication rates, and improving perioperative indicators. This comprehensive approach provides an effective and safe treatment option for mixed hemorrhoids. Further optimization of postoperative management and cost reduction can further enhance its clinical value and patient acceptance, supporting broader application in clinical practice.

Disclosure of conflict of interest

None.

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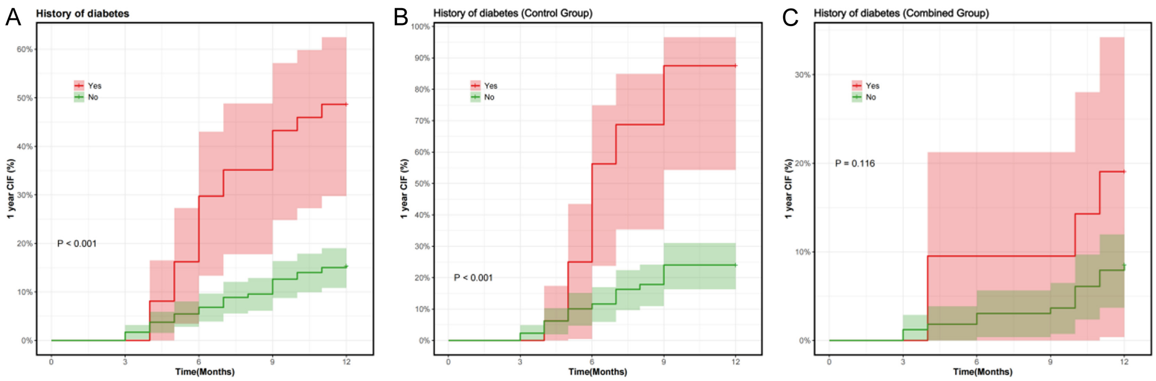

Figure S1. CIF curves for recurrence in diabetic patients. A. CIF curve of recurrence in diabetic patients. B. CIF curve of recurrence in diabetic patients in the control group. C. CIF curve of recurrence in diabetic patients in the combined group. Note: CIF: Cumulative Incidence Function.

Table S1. Comparison of intraoperative indicators and postoperative recovery time between diabetic and non-diabetic patients

Variable	Diabetic patients (n = 37)	Non-diabetic patients (n = 293)	Statistic	*p*-value
Intraoperative Blood Loss (mL)	7.00 [3.00, 16.00]	7.00 [4.00, 12.00]	0.427	0.669
Surgery Time (min)	24.00 [16.00, 34.00]	24.00 [15.00, 35.00]	0.314	0.754
Surgical Wound Healing Time (days)	12.00 [10.00, 13.00]	12.00 [10.00, 15.00]	-1.44	0.148
Anal Pain Relief Time (days)	4.00 [3.00, 5.00]	4.00 [2.00, 5.00]	1.948	0.045

Table S2. Comparison of hospital stay and treatment costs between diabetic and non-diabetic patients

Variable	Diabetic patients (n = 37)	Non-diabetic patients (n = 293)	Statistic	*p*-value
Hospital Stay (days)	9.00 [7.00, 12.00]	11.00 [7.00, 14.00]	-1.542	0.121
Treatment Costs (yuan)	10306.00 [8594.00, 11192.00]	9415.00 [7607.00, 11521.00]	1.276	0.202