

# Comparative efficacy of Ma Yinglong ointment and Gangtai suppository for hemorrhoids: A retrospective cohort study

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**Abstract: Background:** Hemorrhoidal disease (HD) is a common anorectal condition that can have negative impacts on both physical and mental health as well as public health. **Objective:** This retrospective analysis evaluated the use of Ma Yinglong hemorrhoid ointment versus Gangtai suppositories. **Methods:** A retrospective comparative study of the efficacy and safety differences between Ma Yinglong hemorrhoid ointment and Gangtai Suppositories in the treatment of hemorrhoids. In this retrospective cohort, 514 hemorrhoid patients (2024) were equally divided into Ma Yinglong (n=257) and Gangtai suppository (n=257) groups. Symptom scores, quality of life and adverse reactions were compared between the two groups at days 7 and 14. **Results:** Baseline characteristics were balanced between the two groups. After 14 days of treatment, the Ma Yinglong Hemorrhoid Ointment demonstrated significant advantages in pain relief Visual Simulation Score (VAS score: 1.2 vs 2.0) and swelling reduction, with markedly improved quality of life scores (88.7 vs 76.3). The Gangtai Suppository treatment group showed superior bleeding control (bleeding score: 0.6 vs 0.7). The overall response rates (92.61% vs 89.88%) and incidence of adverse reactions (5.06% vs 5.84%) were comparable between the two groups. **Conclusion:** The results of this study indicate that Ma Yinglong Hemorrhoid Ointment provides rapid relief for external hemorrhoid swelling and pain, while Gangtai Suppository are more suitable for controlling bleeding from internal hemorrhoids.

**Keywords:** External hemorrhoids; Efficacy and Safety; Gangtai suppository; Internal hemorrhoids; Ma Yinglong hemorrhoid ointment

*Submitted on 16-10-2025 – Revised on 14-11-2025 – Accepted on 11-12-2025*

## INTRODUCTION

Hemorrhoids are soft masses of swollen or dilated veins in the anal canal and lower rectum. They are classified into three types based on location: internal hemorrhoids, external hemorrhoids and mixed hemorrhoids. Approximately one billion individuals worldwide have experienced hemorrhoids, with about 50% developing significant clinical symptoms. Nearly half of hemorrhoid patients impose a substantial burden on public health (Al-Masoudi *et al.*, 2024; Nakhla, Hospattankar, Siddiqui, and Bridgeman, 2025). Epidemiological data from China indicate that internal hemorrhoids (45.7%) and mixed hemorrhoids (38.2%) are the predominant types (Guo *et al.*, 2024).

The primary reason patients fear defecation is that hardened, dry stool causes greater friction and damage to hemorrhoidal tissue during bowel movements, leading to anal bleeding and severe pain. Stool hardens and dries because anal tissue may retract spontaneously, but in severe cases, manual retraction is required. This creates a vicious cycle (Lohsiriwat, 2015). Patients may also experience anemia and fatigue due to chronic blood loss from rectal bleeding. Prolonged anal discomfort and pain negatively impact both physical and mental health (Rivadeneira *et al.*, 2011).

Hemorrhoids result from the prolapse of engorged blood vessels around the anus. Prolonged sitting impedes blood circulation by exerting pressure on the pelvic region, leading to engorgement and dilation of perianal blood vessels that cause damage to the patient (Shah and Dudhamal, 2018). Constipation arises from insufficient dietary fiber intake. During bowel movements, hardened stool exerts pressure on and damages blood vessels. The ultimate development of hemorrhoids stems from the combined effects of prolonged sitting and inadequate dietary fiber consumption. The prolapse of hemorrhoids is also closely linked to modern lifestyles, explaining why this condition is increasingly common among younger populations (Labidi *et al.*, 2019).

Compared to surgical treatment, conservative management of hemorrhoids offers the advantages of being high safe, noninvasive, cost-effective and easily implemented in daily life. By avoiding trauma and prolonged recovery periods, conservative treatment has become the preferred option for mild to moderate cases (Altomare and Giannini, 2013). Topical medications such as ointments or suppositories offer significant advantages in conservative therapy ("Practice parameters for the treatment of hemorrhoids. The Standards Task Force American Society of Colon and Rectal Surgeons," 1993). This is largely because conservative treatment enables precise delivery of medication to the affected area, ensuring rapid efficacy while minimizing systemic absorption (de Boer, *et al.*,

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1979). This approach provides enhanced safety for patients requiring long-term treatment (Ratto, *et al*, 2020).

This study compared the short-term efficacy and safety of Ma Yinglong ointment versus Gangtai suppositories. By analyzing hemorrhoid subtypes and primary symptoms among participants, our findings establish clear criteria for drug selection, advancing the clinical management of hemorrhoidal disease (HD) toward greater personalization.

### Research methods

#### Research objects

This retrospective cohort study analyzed the medical records of 514 patients diagnosed with hemorrhoids who presented at our hospital between January to December 2024. The patients were categorized into two groups based on the treatment they received: the Ma Yinglong hemorrhoid ointment group (n=257) and the Gangtai suppository treatment group (n=257). To enhance comparability, PSM was employed. Data was extracted by researchers not involved in the clinical management of these patients. The study flowchart is presented in Fig. 1.

#### Inclusion criteria

Patient records meeting all of the following criteria may be included:

- (1) Meet the diagnostic criteria for hemorrhoids (Stages I, II, III) (Ravindranath and Rahul, 2018);  
Meet the criteria for damp-heat syndrome in the 'Chinese Medicine Disease Patterns, Diagnosis and Efficacy Standards': Hemorrhoidal Bleeding, Fresh Blood (Shi *et al.*, 2020).
- (2) Patient records have signed an informed consent form;
- (3) Patient records agree to avoid using other hemorrhoid medications during the study period.

#### Exclusion criteria

Patient records meeting any of the following criteria will be excluded (Shi *et al.*, 2020):

- (1) Patient records with severe liver, kidney, heart, brain, or lung dysfunction;
- (2) Patient records with a history of inflammatory bowel disease, colorectal cancer, or any other cancer;
- (3) Patient records with anal abscesses, anal fistulas, rectal polyps, intestinal tumours, or intestinal infectious diseases;
- (4) Records of patients planning pregnancy;
- (5) Records of patients during pregnancy and lactation;
- (6) Patient records are allergic to the test drug or its components;
- (7) Patient records are unable to understand the nature of the study and follow the doctor's advice;
- (8) Patient records indicating agreement to avoid other hemorrhoid medications;
- (9) Patient records have a history of bleeding disorders other than HD.

### Sample size calculation

The power analysis using G\*Power software (Kim, *et al*, 2017) indicated that, with an effect size of 0.5, a significance level ( $\alpha$ ) of 0.05 (two-tailed) and a statistical power ( $1-\beta$ ) of 0.95, the minimum sample size required for each group was determined accordingly. Based on the actual case situations of HD patients who visited our hospital from January to December 2024, a total of 514 patients meeting the criteria were selected.

They were divided into two groups based on treatment methods: the Ma Yinglong hemorrhoid ointment treatment group and the gangtai suppository treatment group, with 257 patients in each group. This sample size not only far exceeds the minimum statistical requirement but also fully meets the data analysis needs of an independent samples t-test. It also considers practical factors such as data completeness in retrospective studies, thereby enhancing the stability and reliability of the results. All patients were observed and assessed 7-14 days after treatment to compare the clinical outcomes between the two groups.

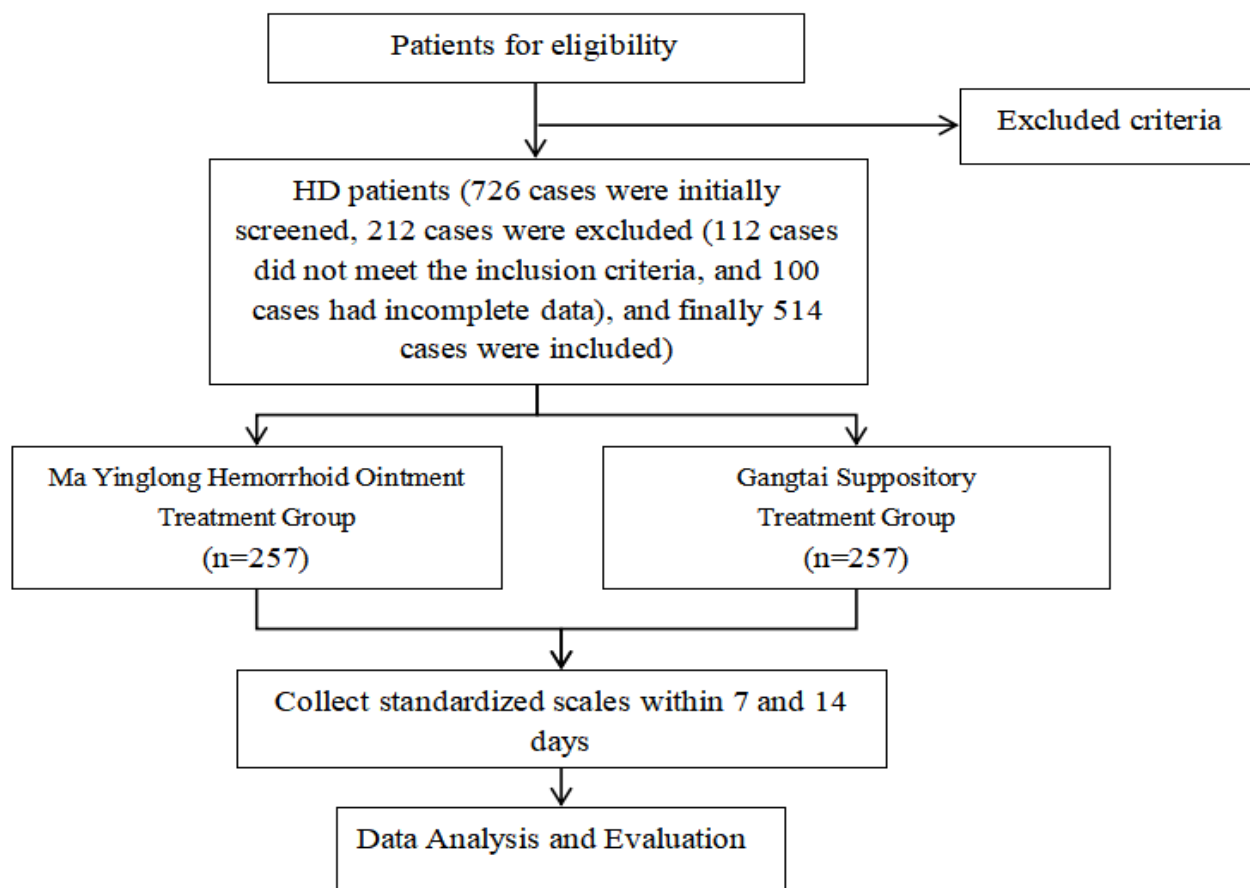
### Treatment methods

Records of 514 patients with HD were divided into two groups. Ma Yinglong hemorrhoid ointment treatment group: Patients cleaned the affected area daily, then applied an appropriate amount of Ma Yinglong hemorrhoid ointment (main ingredients: musk, bovine bile, pearl, zinc oxide, borax and borneol) and either inserted the medication into the anus using the attached applicator or directly applied it to the surface of the hemorrhoids, 2-3 times daily (the specific frequency could be adjusted based on the severity of the condition), for a continuous treatment period of 7-14 days (Niu, 2021). During the treatment period, patients were advised to avoid spicy and irritating foods and maintain regular bowel habits.

Gangtai suppository treatment group: After cleaning the anus daily, take one Gangtai Suppository (main ingredients: *Sanguisorba officinalis* charcoal, gallnut, borneol, berberine hydrochloride, papaverine hydrochloride, etc.) and slowly insert the suppository into the anus approximately 2 cm deep, 1-2 times daily (typically once in the morning and once in the evening), for a continuous treatment period of 7-14 days (Niwatananun *et al.*, 2021). If local discomfort occurs after administration, the frequency of use may be appropriately reduced. Concurrently, maintain anal hygiene and avoid prolonged sitting or standing. Both treatment medications are strictly administered in accordance with the drug labels and clinical treatment guidelines to ensure treatment safety and efficacy.

### Observation indicators

Assessment during the treatment process (7-14 days).



**Fig. 1:** Research flowchart

(1) Observation indicators: Compare the difference in scores for bleeding, pain, swelling and prolapse before and after treatment and calculate the symptom relief rate (symptom scores reduced by  $\geq 50\%$  are considered relieved); record the specific number of days until bleeding stops, pain is relieved and swelling subsides (Fu *et al.*, 2022; Ravindranath and Rahul, 2018; Williamson and Hoggart, 2005), as well as quality of life (Rørvik *et al.*, 2023). (Bleeding score reference: 'Bleeding Severity Score': 0 = no bleeding; 1 = blood on toilet paper; 2 = dripping blood during defecation; 3 = spraying blood during defecation; 4 = continuous dripping blood. Pain score uses the Visual Analogue Scale (VAS): 0 = no pain; 10 = severe pain. Swelling severity score: 0 = no swelling; 1 = mild swelling; 2 = moderate swelling with skin tags; 3 = severe swelling with prominent skin tags. Prolapse risk score: 0 = no prolapse; 1 = prolapse during defecation, which can be manually reduced; 2 = prolapse during defecation, requiring manual reduction.)

(2) Clinical symptoms: Cure is defined as complete resolution of bleeding, pain and swelling, with a reduction in hemorrhoid volume of  $\geq 90\%$ ; marked improvement is defined as significant relief of symptoms (score reduction of  $\geq 70\%$ ), with a reduction in Hemorrhoid volume of 60%-89%; improvement is defined as some relief of symptoms

(score reduction of 30%-69%) and a reduction in hemorrhoid volume of 30%-59%; ineffective treatment is defined as no significant change or worsening of symptoms (score reduction  $< 30\%$ ) and a reduction in hemorrhoid volume  $< 30\%$  or an increase in size. The overall treatment efficacy will be comprehensively assessed by calculating the total effective rate (i.e., the percentage of cases with marked and effective responses out of the total number of cases) (Godeberge *et al.*, 2024).

(3) Adverse reactions: Record the occurrence of adverse reactions in both groups of patients during treatment (Godeberge *et al.*, 2024) (e.g. local irritation, swelling, mucosal damage and itching) and conduct a comparative analysis.

(4) Prognosis-related indicators: Record whether hemorrhoids still pose a risk of prolapse at the end of treatment, as well as patients' subjective satisfaction with treatment outcomes (e.g. very satisfied, satisfied, neutral, or dissatisfied).

### Statistical analysis

Data analysis was performed using SPSS 25.0 statistical software. For haemodynamic parameters, PACU parameters, PSQI and RASS, if the data followed a normal distribution, they were expressed as mean  $\pm$  standard

deviation and intergroup comparisons were performed using an independent samples t-test. For non-normally distributed continuous variables, they were expressed as median (interquartile range) [M(IQR)] and intergroup comparisons were performed using the Mann-Whitney U test. For categorical data such as observed indicators, clinical symptoms and adverse reactions during treatment, intergroup comparisons were performed using the chi-square test. A P-value < 0.05 was considered statistically significant.

## RESULTS

### *Comparison of baseline data of patients*

Table 1 compares the baseline characteristics of the two groups of HD patients. The results show that there were no significant differences between the two groups in terms of sex, age, body mass index (BMI), disease duration, allergy history and initial symptom score (all  $P > 0.05$ ), indicating that the baseline characteristics of the two groups of patients before treatment were comparable and suitable for subsequent efficacy and safety comparisons.

### *Comparison of symptom scores between groups before treatment*

Table 2 shows a comparison of clinical symptom scores between the two groups of patients prior to treatment. Baseline analysis indicated that there were no statistically significant differences between the Ma Yinglong Hemorrhoid ointment treatment group and the Gangtai Suppository treatment group in terms of bleeding scores ( $3.3 \pm 0.6$  vs.  $3.3 \pm 0.7$ ) and prolapse risk scores ( $1.5 \pm 0.4$  vs.  $1.5 \pm 0.5$ ) ( $P > 0.05$ ), suggesting that the two groups were overall comparable at baseline levels for these indicators. Although the pain VAS score was slightly higher in the Gangtai Suppository Treatment Group than in the Ma Yinglong Hemorrhoid Ointment ( $8.3 \pm 1.0$  vs.  $8.2 \pm 1.2$ ) and the swelling score was slightly higher in the Ma Yinglong Hemorrhoid Ointment than in the Gangtai Suppository Treatment Group ( $2.4 \pm 0.5$  vs.  $2.3 \pm 0.7$ ), the effect sizes of the differences between the two groups were small (Cohen's d values of -0.27 and 0.18, respectively). Combined with the narrow range of differences shown by the 95% confidence intervals, this indicates that the clinical significance of these differences is limited and the baseline characteristics of the two groups are overall comparable.

### *Comparison of intra-group changes in symptom scores at 7 and 14 days after treatment*

Table 3 compares the clinical symptoms of the two groups of patients. Inter-group comparison shows that for all evaluation indicators (bleeding, pain, swelling, prolapse risk and quality of life), the P-values for the changes from day 7 to day 14 in both drug treatment groups were < 0.001 and the calculated intra-group Cohen's d values were mostly far greater than 0.8 (the threshold for a large effect). This indicates that these improvements are not only

statistically significant but also of great clinical significance. It shows that in the second week of treatment, both drugs can continuously and significantly relieve the core symptoms of hemorrhoids and significantly improve the patients' quality of life. The efficacy is further consolidated and enhanced with continued treatment.

### *Comparison of changes in symptom scores between 7 and 14 days post-treatment groups*

Table 4 compares the between-group differences in symptom scores after treatment. The results show that the Ma Yinglong hemorrhoid ointment treatment group had significantly lower pain VAS scores (14 days:  $1.2 \pm 0.6$  vs.  $2.0 \pm 0.5$ ; 95% CI: -0.863 to -0.647,  $P < 0.001$ ,  $d = 1.45$ ) and swelling scores (14 days:  $0.6 \pm 0.2$  vs.  $0.8 \pm 0.3$ ; 95% CI: -0.134 to -0.02,  $P < 0.001$ ,  $d = 0.78$ ). The Gangtai suppository treatment group performed better in terms of bleeding scores (14 days:  $0.6 \pm 0.2$  vs.  $0.7 \pm 0.3$ ; 95% CI: 0.029 to 0.189,  $P < 0.001$ ,  $d = 0.39$ ). Quality of life scores were significantly higher in the Ma Yinglong hemorrhoid Ointment treatment group than in the Gangtai suppository treatment group (14 days:  $88.7 \pm 4.5$  vs.  $76.3 \pm 6.9$ ; 95% CI: 11.38 to 13.42,  $P < 0.001$ ); Ma Yinglong hemorrhoid Ointment was significantly superior to Gangtai Suppository in alleviating pain ( $d=1.45$ ) and swelling ( $d=0.78$ ) associated with external hemorrhoids, while gangtai suppository was more effective in controlling bleeding from internal hemorrhoids ( $d=0.39$ ). The above data suggest that Ma Yinglong Hemorrhoid Ointment provides faster and more substantial relief for specific hemorrhoid symptoms, significantly improving patients' quality of life.

Comparison of primary symptom scores among treatment groups on day 14 post-treatment. The between-group differences in key outcomes at Day 14 are visually summarized in Fig. 2. The Ma Yinglong Hemorrhoid ointment demonstrated markedly lower scores in pain and swelling, whereas the Gangtai suppository treatment group had a slight advantage in bleeding control.

### *Comparison of clinical efficacy grading*

Table 5 compares the efficacy of symptom relief between the two groups of patients after treatment. The results showed that the efficacy rate of the Ma Yinglong hemorrhoid ointment treatment group was significantly higher than that of the Gangtai suppository treatment group (78.21% vs 67.31%,  $X^2 = 7.696$ ,  $P = 0.007$ ), but the effectiveness rate was lower (14.40% vs 22.57%,  $X^2 = 5.695$ ,  $P = 0.023$ ). There was no statistically significant difference in the non-effective rate between the two groups (7.39% vs 10.12%,  $P = 0.275$ ). The total effective rate was slightly higher in the Ma Yinglong hemorrhoid ointment treatment group (92.61% vs. 89.88%,  $X^2 = 1.193$ ,  $P = 0.275$ ), with a small effect size (Cramer's V = 0.048). The difference was not statistically significant and the clinical difference was minimal.

**Table 1:** Comparison of baseline characteristics

Variable	Ma Yinglong hemorrhoid ointment treatment group (n=257)	Gangtai suppository treatment group (n=257)	Test	95% CI	Effect size	P-value
Age (years)	41.87±7.85	42.07±7.31	Independent-samples t test	-1.522~1.109	0.026	0.469
Gender (male/female)	159/98	144/113	Chi-Square Test	-	0.060	0.209
BMI (kg/m <sup>2</sup> )	23.9±3.8	24.5±3.9	Independent-samples t test	-1.204~0.1293	0.156	0.643
Course of disease (years)	3.1±1.5	3.2±2.1	Independent-samples t test	-0.4276~0.2019	0.167	0.535
Allergy history	37 (14.39)	43 (16.73)	Chi-Square Test	-	0.034	0.543
Initial symptom score	8.1±1.2	8.0±1.1	Independent-samples t test	-0.142~-0.235	0.357	0.325

**Table 2:** Comparison of pre-treatment symptom scores between the two groups (n=257)

Symptom score	Scoring criteria	Ma Yinglong hemorrhoid ointment treatment group (n=257)	Gangtai suppository treatment group (n=257)	95%CI	Within-group d	P-value
Bleeding score	0-4	3.3±0.6	3.3±0.7	-0.087~0.157	0.00	1.000
VAS	0-10	8.2±1.2	8.3±1.0	-0.373~0.031	-0.27	0.305
Swelling degree	0-3	2.4±0.5	2.3±0.7	-0.093~0.147	0.18	0.063
Prolapse risk	0-2	1.5±0.4	1.5±0.5	-0.087~0.102	0.00	1.000

Note: Bleeding score: 0=none; 4=continuous dripping of blood; VAS: 0=none; 10=severe pain; Swelling degree: 0=none; 3=severe swelling with skin tags; Prolapse risk: 0=none; 2>manual reset required.

**Table 3:** Comparison of intra-group symptom scores at 7 days versus 14 days after treatment

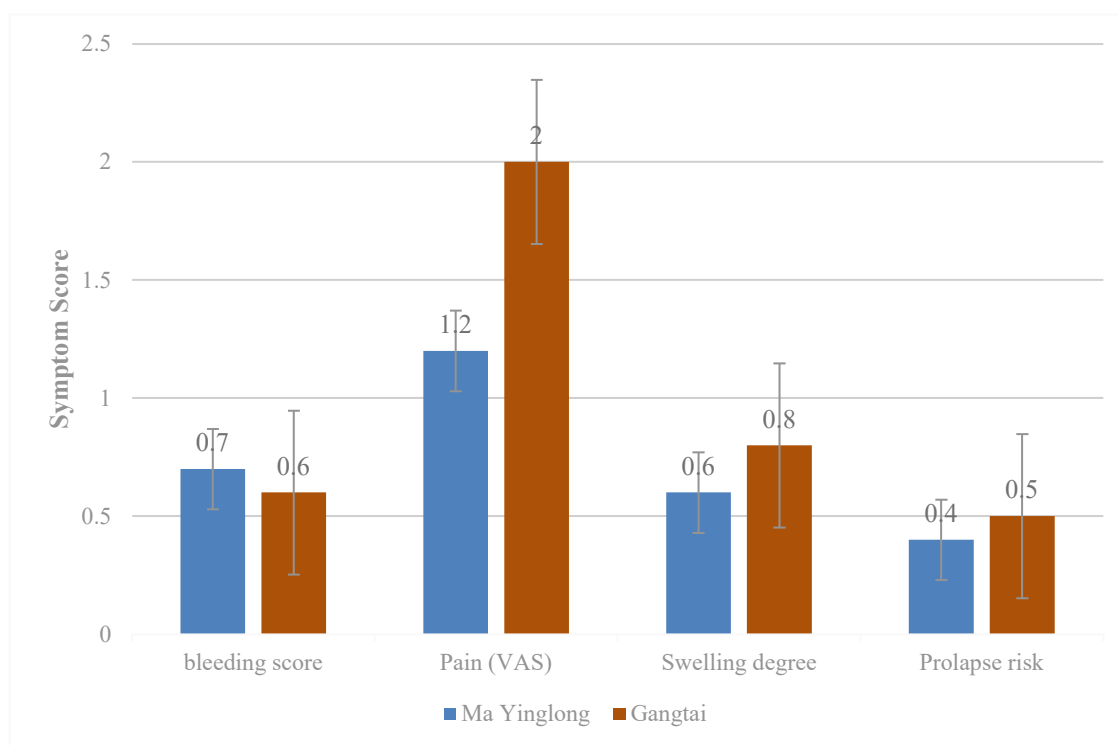
Symptom score	Ma Yinglong hemorrhoid ointment treatment group (n=257)		P-value	Within-group d	Gangtai suppository treatment group (n=257)		P-value	Within-group d
	7	14			7	14		
Bleeding score	2.1±0.4	0.7±0.3	<0.001	-3.50	1.7±0.5	0.6±0.2	<0.001	-2.20
VAS	3.6±0.9	1.2 ± 0.6	<0.001	-2.67	4.0±0.8	2.0 ± 0.5	<0.001	-2.50
Swelling degree	1.4 ± 0.3	0.6 ± 0.2	<0.001	-2.67	1.6±0.4	0.8 ± 0.3	<0.001	-2.00
Prolapse risk	1.1 ± 0.3	0.4 ± 0.1	<0.001	-2.33	1.2±0.3	0.5 ± 0.2	<0.001	-2.33
Quality of life score	75.2±6.3	88.7±4.5	<0.001	+2.14	62.4±8.1	76.3±6.9	<0.001	+1.72

Note: Quality of life score (out of 100); Inter group difference=Ma Yinglong hemorrhoid ointment score - Gangtai suppository group

**Table 4:** Comparison of symptom scores at 7 and 14 days after treatment

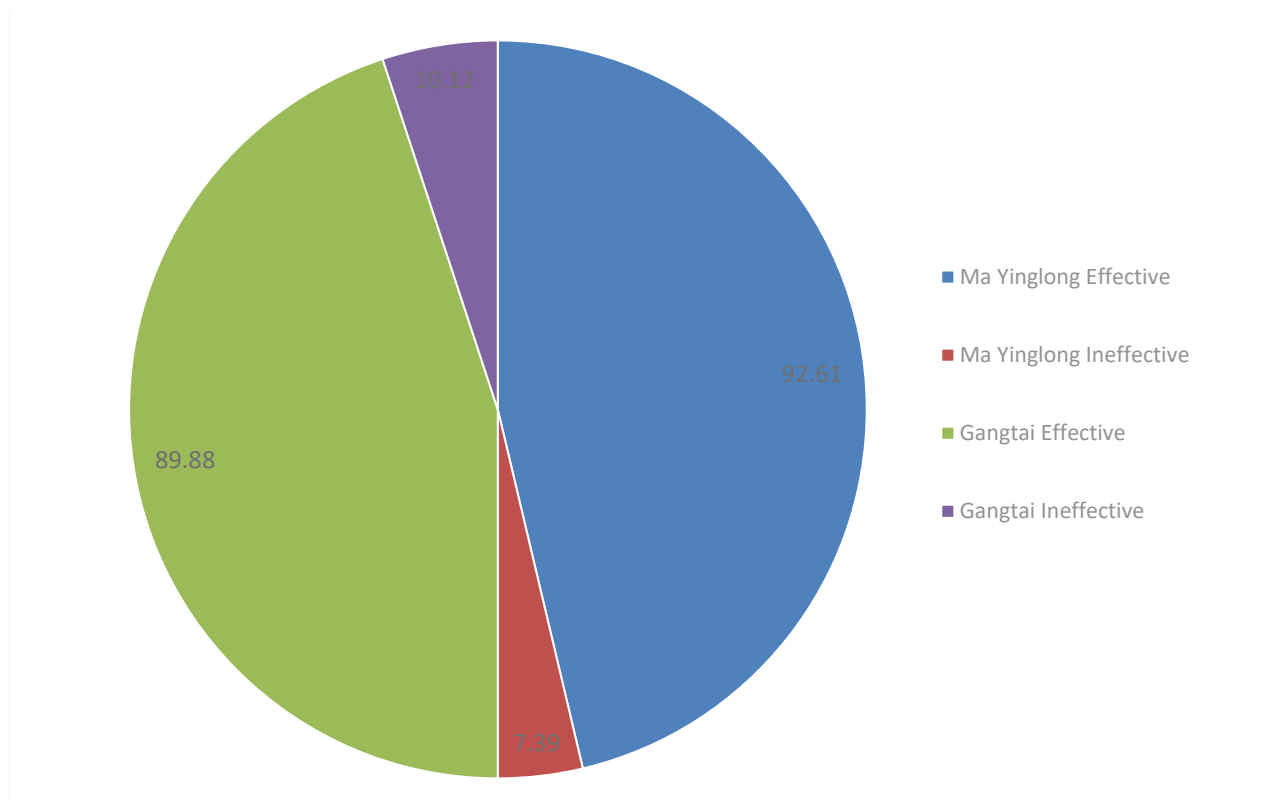
Total effective rate	Time	Ma Yinglong hemorrhoid ointment treatment group (n=257)	Gangtai suppository treatment group (n=257)	95% CI	P-value	Cohen's d
Bleeding score	7	2.1±0.4	1.7±0.5	0.311~0.491	<0.001	+0.89
	14	0.7±0.3	0.6±0.2	0.029~0.189	<0.001	+0.39
VAS	7	3.6±0.9	4.0±0.8	-0.680~-0.362	<0.001	-0.47
	14	1.2±0.6	2.0±0.5	-0.863~-0.647	<0.001	-1.45
Swelling degree	7	1.4±0.3	1.6±0.4	-0.233~-0.062	<0.001	-0.57
	14	0.6±0.2	0.8±0.3	-0.134~-0.02	<0.001	-0.78
Prolapse risk	7	1.1±0.3	1.2±0.3	-0.151~-0.044	<0.001	-0.33
	14	0.4±0.1	0.5±0.2	-0.440~-0.291	<0.001	-0.63
Quality of life score	7	75.2±6.3	62.4±8.1	11.48~14.00	<0.001	+1.80
	14	88.7±4.5	76.3±6.9	11.38~13.42	<0.001	+2.13

Note: Quality of life score (out of 100); Inter group difference = Ma Yinglong treatment group score-Gangtai suppository treatment group score.

**Fig. 2:** The varying treatment effects on day 14.**Table 5:** Comparison of clinical efficacy grading

Total effective rate	Ma Yinglong hemorrhoid ointment treatment group (n=257)	Gangtai suppository treatment group (n=257)	X <sup>2</sup>	P-value	Cramer's V
Markedly effective	201(78.21)	173(67.31)	7.696	0.007	-
Effective	37(14.40)	58(22.57)	5.695	0.023	-
Ineffective	19(7.39)	26(10.12)	-	0.275(NS)	-
Total efficiency	238(92.61)	231(89.88)	1.193	0.275	0.048

Note: Markedly effective: improvement of ≥70%; Effective: improvement of 30~69%; Ineffective: improvement of < 30%; NS=not significant; Cramer's V < 0.1 is a weak effect.



**Fig. 3:** Comparison of overall response rate between treatment groups

**Table 6:** Post-treatment adverse events and residual hemorrhoidal symptoms

Types of adverse events	Ma Yinglong hemorrhoid ointment treatment group (n=257)	Gangtai suppository treatment group (n=257)	Test	X <sup>2</sup>	P-value
Adverse reactions					
Anal burning pain	3(1.16)	8(3.11)	Chi-Square Test	0.151	0.689
Local infection	4(1.56)	2(0.79)			
Pruritus and discomfort	6(2.33)	5(1.95)			
Total	13(5.06)	15(5.84)			
Residual symptoms					
Hematochezia	2(0.79)	3(1.16)	Chi-Square Test	1.521	0.218
Abnormal defecation	1(0.40)	6(2.33)			
Mucosal edema	3(1.16)	2(0.79)			
Total	6(2.33)	11(4.28)			

Note: This table records adverse reactions observed after treatment that may be drug-related, as well as symptoms of the hemorrhoidal disease itself that have not fully resolved following treatment.

**Table 7:** Comparison of patient outcomes and satisfaction between groups

Prognostic indicators	Classification criteria	Ma Yinglong hemorrhoid ointment treatment group (n=257)	Gangtai suppository treatment group (n=257)	P-Value
Prolapse residual risk	Yes/No	19 (7.39)	26 (10.12)	0.275 0.530
Subjective satisfaction	Very satisfied	118(45.9)	102(39.7)	
	Satisfied	83(32.3)	92(35.8)	-
	General	37(14.4)	39(15.2)	-
	Dissatisfied	19(7.39)	24(9.3)	-

Note: Prolapse residual risk: Still experiencing prolapse after 14 days of treatment.

Comparison of overall response rates between Ma Yinglong ointment and Gangtai suppository treatment groups (Fig. 3). The overall response rate was calculated as the sum of "Markedly Effective" and "Effective" cases. No statistically significant difference was found between the two groups ( $X^2 = 1.193$ ,  $P = 0.275$ ).

#### **Analysis of treatment-related adverse events and residual symptoms**

Analysis of adverse events following treatment revealed that most events reported in both groups were mild in severity (Table 6). The incidence of adverse reactions was low in both groups, with no significant difference between them (5.06% vs 5.84%,  $P=0.689$ ). Slight itching discomfort was relatively more common in the Ma Yinglong hemorrhoid ointment (2.33%), while perianal burning symptoms were more frequent in the Gangtai Suppository treatment group (3.11%). After treatment completion, residual symptoms persisted in some patients: 2.33% in the Ma Yinglong hemorrhoid Ointment and 4.28% in the Gangtai Suppository treatment group, with no significant intergroup difference ( $P = 0.218$ ). Both regimens demonstrated good safety and tolerability, with low and manageable overall adverse event rates, providing a safety basis for clinical use.

#### **Prognosis and satisfaction assessment**

Table 7 compares the assessment of prognosis and satisfaction between the two patient groups. Results indicate that following treatment completion, both groups exhibited low residual prolapse risk rates (7.39% vs 10.12%,  $P = 0.275$ ), though the difference was not statistically significant. Patient subjective satisfaction assessments revealed a higher proportion of 'very satisfied' responses in the Ma Yinglong hemorrhoid ointment group (45.9% vs 39.7%), alongside a lower dissatisfaction rate (7.39% vs 9.3%).

## **DISCUSSION**

HD is a prevalent anorectal condition and conservative management with topical agents remains a cornerstone for mild to moderate cases. Ma Yinglong hemorrhoid ointment alleviates swelling and pain through its anti-inflammatory properties and improvement of local microcirculation, while the prescription of Gangtai suppositories can achieve the clinical goal of controlling bleeding. Research indicates that Ma Yinglong hemorrhoid ointment is particularly effective in reducing swelling and relieving pain, while Gangtai suppositories are particularly effective at stopping bleeding and promoting healing. Based on this, treatment can be precisely tailored to the patient's primary symptoms.

Traditional Chinese medicine is a commonly used approach for treating hemorrhoids. In Ma Yinglong hemorrhoid ointment, musk and borneol rapidly reduce swelling and relieve pain; *Achyranthes* root alleviates burning pain by clearing heat and detoxifying; pearl and

calamine effectively stop bleeding to promote wound healing. Through the synergistic action of multiple ingredients, this ointment alleviates symptoms such as swelling, pain and bleeding in hemorrhoid patients (Niu, 2021). In Gangtai suppositories, charcoal from white peony root and hazelnut provide potent hemostatic effects; borneol clears heat, reduces swelling and relieves pain; while berberine hydrochloride and papaverine hydrochloride exert anti-inflammatory and antispasmodic actions, respectively. This suppository precisely addresses symptoms of rectal bleeding, swelling, pain and a sensation of heaviness in patients with internal hemorrhoids through the synergistic effects of its multiple components (Lu *et al*, 2021).

Results showed that after seven days of treatment, the visual analog scale (VAS) pain scores in the Ma Yinglong hemorrhoid ointment were significantly lower than those in the Gangtai Suppository treatment group ( $P < 0.001$ ), indicating faster onset of analgesic effect.. Data showed that the Ma Yinglong Hemorrhoid Ointment achieved a symptom score improvement of  $5.2 \pm 1.1$  points. It demonstrated a significant advantage in swelling reduction by the seventh day of treatment ( $P < 0.001$ ), fully confirming its efficacy in reducing swelling and relieving pain. This effect precisely addresses the clinical needs for acute external hemorrhoidal inflammation and aligns with findings from Lin *et al*. (2022). Ma Yinglong reduced the secretion of IL-1 $\beta$  by lipopolysaccharide-induced macrophages by 62% ( $P < 0.01$ ).

The reduction in the Gangtai suppository treatment group at 7 and 14 days was greater than that in the Ma Yinglong hemorrhoid ointment treatment group ( $P < 0.001$ ). In terms of hemostatic efficacy, the Gangtai suppository treatment group demonstrated a more significant reduction in bleeding scores on both Day 7 and Day 14 of treatment ( $P < 0.001$  for both comparisons), indicating a distinct therapeutic advantage of this suppository for bleeding hemorrhoids. In this study, the relatively modest advantage of Gangtai suppositories in hemostasis scores may be attributed to the inclusion of a larger number of patients with stage III internal hemorrhoids, which typically exhibit slower mucosal repair. The hemostatic efficacy rate observed in this study (76.3%) was consistent with the average hemostatic rate (74.5%) of *Sanguisorba officinalis* charcoal-based suppositories reported in the Cochrane systematic review (Gan *et al*, 2010). By Day 14, the clinical efficacy rate of the Ma Yinglong hemorrhoid ointment was significantly superior to that of the Gangtai Suppository treatment group. This fully demonstrates the synergistic anti-inflammatory and restorative effects of its Chinese herbal ingredients. After 14 days of treatment, patients' bleeding scores decreased to  $0.6 \pm 0.2$ , with a hemostasis rate of 76.3% among patients with stage I-II internal hemorrhoids using this medication. This suppository promotes thrombus formation by forming a protective film



through protein precipitation with *Sanguisorba officinalis* charcoal tannin ( $\geq 8\%$ ) and activating coagulation factor XII with gallic acid (Heestermans *et al.*, 2021; Jiang *et al.*, 2022). Didiysova *et al.* (2018) confirmed in animal experiments that Gangtai suppositories can reduce tail bleeding time in mice by 40% (compared with the control group,  $P < 0.001$ ). In the pathophysiological process of stage I-II internal haemorrhoids, bleeding mainly originates from mucosal erosion or capillary rupture. The tannins in Di Yu Tan and Wu Bei Zi contained in Gangtai suppositories can form a protective film on the mucosal surface through protein coagulation to prevent seepage, while also promoting platelet aggregation to seal vascular openings, thereby achieving effective haemostasis. In comparison, the haemostatic components in Ma Yinglong hemorrhoid ointment are of lower concentration and its ointment formulation has poor retention in the upper rectum, making it difficult to effectively target the bleeding points in high-position internal hemorrhoids, thus affecting its efficacy for such bleeding. Studies also show that Gangtai suppositories have limited improvement for prolapse symptoms, with a 14-day Goligher's grading improvement rate of only 41.2%, far below its haemostatic effect, indicating that the drug's core advantage remains in haemostasis. For patients with internal hemorrhoids primarily presenting with prolapse, a comprehensive plan using oral medications to improve venous tension or minimally invasive treatment when necessary is recommended.

This study may that both drugs have good safety and tolerability. The overall incidence of adverse reactions in the two groups was low with no statistically significant difference ( $P = 0.698$ ). The vast majority of adverse reactions were mild local reactions, with no reports of serious adverse events and all reactions resolved spontaneously after discontinuation, indicating that the overall safety risk of both drugs is manageable. In the Ma Yinglong hemorrhoid ointment group, adverse reactions primarily included itching and discomfort (2.33%) and local infection (1.56%). Its incidence of local infection was lower than that of some antibiotic-containing hemorrhoid ointments (e.g., 3.5% reported in the hydrocortisone-neomycin group), potentially attributable to the broad-spectrum antimicrobial effects of its bovine bile component (Lohsiriwat, 2015). Some patients reported transient itching and discomfort. These symptoms may stem from mild local skin irritation. Formulation ingredients like synthetic musk are potential causative agents. Adverse reactions to Gangtai suppositories included abnormal defecation (2.33%) and anal burning/pain (3.11%). The incidence of abnormal defecation (2.33%) was comparable to that of papaverine hydrochloride ( $OR=1.89$ ) but lower than traditional opioid suppositories (e.g., morphine suppositories at 5.1%) (Ashrafi *et al.*, 2023). This is speculated to be related to the physical stimulation of the rectal mucosa by the suppository and the cooling effect of

borneol. After dissolution in the rectum, the suppository may stimulate the rectal wall, inducing the urge to defecate, while the cooling sensation of borneol (Tang *et al.*, 2025) may also cause burning discomfort in some patients. Some patients experienced residual symptoms after treatment, with an incidence rate of 2.33% in the Ma Yinglong Hemorrhoid Ointment and 4.28% in the Gangtai Suppository treatment group. The difference between groups was not statistically significant ( $P=0.218$ ). Clinically, it is safe to use two drugs for short-term treatment within 14 days. Residual symptoms such as rectal bleeding in patients should be considered as incomplete relief of the disease itself, rather than adverse reactions to the drugs. During the treatment period, there is no need to be overly concerned about safety risks due to prolonged medication, which is of important reference value for chronic patients requiring short-term maintenance treatment, although the safety of long-term medication still needs to be may by subsequent research.

### Research limitations

Although this study strives for rigor, there are still several limitations. The retrospective design may introduce selection bias, the lack of long-term follow-up data affects the assessment of recurrence rates, and it also limits the evaluation of the impact of individual factors, such as gene polymorphisms, on treatment efficacy. Future research could conduct multi-center prospective trials to validate efficacy, establish long-term follow-up cohorts to assess recurrence and utilize pharmacogenomics to explore personalized treatment mechanisms.

### CONCLUSION

Our data demonstrates that Ma Yinglong hemorrhoid Ointment and Gangtai suppositories offer significant therapeutic advantages in treating hemorrhoids. Ma Yinglong hemorrhoid ointment is particularly effective in alleviating swelling and pain associated with external hemorrhoids. Gangtai suppositories are the ideal medication for treating bleeding internal hemorrhoids in stages I-II. Both drugs exhibit favorable safety profiles. The core contribution of this study is the first establishment of a clear correspondence between medication selection and "hemorrhoid classification-core symptoms." This provides critical decision-making guidance for standardized TCM treatment of hemorrhoids. This discovery is expected to advance clinical practice from a universal treatment model toward a new pathway of precision medication guided by classification. Future research may establish a medication decision-making model integrating hemorrhoid classification, symptom characteristics and individual differences, thereby continuously improving clinical treatment outcomes.

### Acknowledgment

None

### Author's contribution

Xuxia Gao: Edited and refined the manuscript with a focus on critical intellectual contributions; Meiling Hu and Mengmu Hu: Participated in collecting, assessing and interpreting the data. Made significant contributions to date interpretation and manuscript preparation. All authors have read and approved the final manuscript.

### Funding

There was no funding.

### Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

### Ethical approval

This study was approved by the Ethics Committee of the Cixi People's Hospital Medical and Health Group (Cixi People's Hospital) (Approval No.2025-LP-LW010). This clinical study complies with relevant ethical regulations, such as the Declaration of Helsinki (Vijayananthan and Nawawi, 2008). This study was approved by the Ethics Committee for exemption from informed consent and all data were anonymized.

### Conflict of interest

The authors declare that there is no conflict of interest.

### Consent to participate

This study was approved by the Ethics Committee for exemption from informed consent and all data were anonymized.

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