

RESEARCH ARTICLE

Haemostatic and Anti-inflammatory Effect of Habb-e-Muqil in Internal Hemorrhoids: An Open-label Randomized Clinical Trial

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Abstract: Background and Objective: Internal hemorrhoids (Bawaseer-e-Ghaira) are a common anorectal disorder, often presenting with rectal bleeding, prolapse, itching, and discomfort. While surgical interventions exist, they carry risks of pain, infection, and recurrence. Unani medicine offers Habb-e-Muqil, a polyherbal formulation, traditionally used for its haemostatic and anti-inflammatory properties. This study aimed to evaluate the efficacy and safety of Habb-e-Muqil in Grade I–III internal hemorrhoids. **Materials and Methods:** An open-label single-arm clinical trial was conducted at NIUM, Bangalore, from June 2023 to December 2024. Forty patients aged 18–60 years with Grade I–III internal hemorrhoids were enrolled. Participants received Habb-e-Muqil (200 mg, 2 tablets twice daily after meals) for 28 days. Clinical outcomes were assessed using PNR-Bleed classification, Hemorrhoid Severity Score (HSS), and proctoscopic examination for rectal bleeding, prolapse, mucosal inflammation, and number of hemorrhoidal columns. Follow-up assessments were performed at day 7, 14, 28 and 1month post treatment. **Results:** Habb-e-Muqil significantly reduced rectal bleeding from 45% at baseline to 0% by day 28 ($p < 0.001$). Prolapse of hemorrhoidal masses decreased from 70% to 35% ($p = 0.004$). HSS decreased from 13.2 ± 2.0 to 6.5 ± 1.1 ($p < 0.001$). Proctoscopy revealed resolution of pallor and inflamed mucosa in all patients by day 28 ($p < 0.05$). No adverse events were observed. **Conclusion:** Habb-e-Muqil demonstrates significant haemostatic and anti-inflammatory effects in the management of Grade I–III internal hemorrhoids and is safe and well-tolerated. It may serve as an effective conservative treatment alternative to surgical interventions.

Keywords: Internal hemorrhoids, Habb-e-Muqil, PNR-Bleed, Hemorrhoid Severity Score.

INTRODUCTION

Hemorrhoids (Bawaseer) are vascular cushions in the anorectal canal that may become symptomatic due to venous congestion, inflammation, or prolapse. Internal hemorrhoids commonly present with painless rectal bleeding, prolapse, mucus discharge, itching, and discomfort, significantly impacting quality of life. While conservative management includes lifestyle modification and increased dietary fiber, pharmacological interventions are often needed for symptomatic relief. ¹

Surgical treatments, although effective, carry risks such as postoperative pain, infection, anal incontinence, and

recurrence. ^{2, 3} The Unani system of medicine offers oral formulations such as Habb-e-Muqil, composed of ingredients like Commiphora mukul, Berberis vulgaris, and Tukhme Neeb, known for their haemostatic, anti-inflammatory, desiccative, and healing properties. These pharmacological actions address bleeding, inflammation, prolapse, and mucosal recovery, potentially providing a non-invasive therapeutic alternative. ^{4, 5, 6} The present study evaluates the efficacy and safety of Habb-e-Muqil in treating Grade I–III internal hemorrhoids using objective clinical scoring systems including PNR-Bleed and HSS.

Materials and Methods

Study Design and Ethics:

This was an **open-label, single-arm clinical trial** conducted at **NIUM, Bangalore**, from June 2023 to December 2024. Ethical approval was obtained from the **Institutional Ethics Committee (NIUM/IEC/2021-22/027/Jar/05)**, and all participants provided written informed consent.

Study Population:

Inclusion criteria: Adult males and females aged 18–60 years with **Grade I–III internal hemorrhoids** confirmed by proctoscopy.

Exclusion criteria: Patients with **fissure-in-Ano, fistula, colorectal malignancy, pregnancy, previous anorectal surgery, immunosuppressive conditions, bleeding disorders**, or on anticoagulants.

Sample Size:

A total of **40 patients** were enrolled, as determined using standard sample size calculation for clinical studies with **80% power and 95% confidence interval**, accounting for a 20% drop-out rate.

Intervention:

All participants received **Habb-e-Muqil 200 mg, 2 tablets twice daily after meals for 28 days**.

Clinical Assessment:

Patients were evaluated at **baseline, day 7, day 14, day 28 and 1 month post treatment**. Assessments included:

- **PNR-Bleed Classification:** Prolapse (P), number of hemorrhoidal columns (N), relation to dentate line (R), and bleeding (B) graded 1–5.
- **Hemorrhoid Severity Score (HSS):** Sum of PNR-Bleed scores (range 4–20).
- **Proctoscopy:** Evaluation of **rectal mucosa, bleeding points, inflammation, and prolapse**.

PNR-Bleed is based on the four main characteristics of the haemorrhoidal disease i.e. the degree of hemorrhoidal Prolapse (P), Number (N) of the primary hemorrhoidal columns involved, Relation (R) of the hemorrhoidal tissue to dentate line and the amount of Bleeding (B) from it. All the four components in this classification system are graded into five grades ranging from 1 to 5. Hemorrhoid Severity Score (HSS) is the total score obtained by the sum of the numerical grades of all four characteristics of hemorrhoids in “PNR-Bleed” classification.

For example, for a patient having hemorrhoidal prolapse that requires the manual reduction (P3) involving all the three primary hemorrhoidal masses (N4), which are interno-external with respect to the relation with dentate line (R4) and having frequent bleeding during defecation (B3), the HSS is 14/20 ($3 + 4 + 4 + 3 = 14$). Minimum HSS score is 4 and maximum score can be 20. HSS score of a normal person without any signs and symptoms of hemorrhoids is “4”. This new “PNR-Bleed” system of classifying the hemorrhoids and calculation of HSS seems to be more comprehensive, detailed, more objective and easily reproducible as illustrated in Table 1. ⁷

Laboratory Assessment: CBC, LFT, ESR, BT/CT, and stool examination were performed at baseline and post-treatment to monitor safety.

Statistical Analysis:

Data were analyzed using **IBM SPSS v22.0**. Continuous variables were expressed as **mean $\pm$ SD**, and categorical variables as **frequencies (%)**. **Paired t-test** was used for HSS, and **McNemar’s test** for categorical variables (bleeding, prolapse, mucosal changes). A **p-value <0.05** was considered statistically significant.

Table 1: PNR-Bleed Classification.

S.No.	Characteristic	Grade	Description
A	Degree of haemorrhoidal prolapse	1	No hemorrhoidal prolapse.
		2	Prolapse upon straining that reduces spontaneously.
		3	Prolapse upon straining that needs manual reduction.
		4	Prolapsed and irreducible hemorrhoids but without ischemic changes.
		5	Prolapsed and irreducible hemorrhoids with ischemic (gangrenous) changes.
B	Number of hemorrhoidal columns involved	1	None
		2	One
		3	Two
		4	Three
		5	Circumferential (presence of secondary hemorrhoids along with the involvement of all primary hemorrhoids)
C	Relation to dentate line	1	Nil (normal anal cushions)
		2	External hemorrhoids
		3	Internal hemorrhoids
		4	Interno-external hemorrhoids
		5	Thrombosed external hemorrhoids

D	Bleeding	1	Nil
		2	Mild; occasional episodes (during defecation)
		3	Moderate; frequent episodes (during defecation)
		4	Severe; persistent bleeding even without defecation with fall in Hb level (<10gm/dl); requiring hematinics.
		5	Very severe; bleeding in the form of jets and splashes with severe fall in Hgb level (<7gm/dl): requiring blood transfusion.

RESULT:

Patient Demographics

The mean age was 39.2 ± 9.8 years (range 18–60), with 22 males and 18 females. Duration of symptoms ranged from 1–24 months, median 8 months.

Per Rectal Bleeding

Table 2: Per rectal bleeding

Time point	Patients with Bleeding (n)	Percentage	P-value*
Baseline	18	45%	–
Day 7	12	30%	0.032
Day 14	6	15%	0.004
Day 28	0	0%	<0.001
1 month post treatment	0	0%	<0.001

*McNemar's test

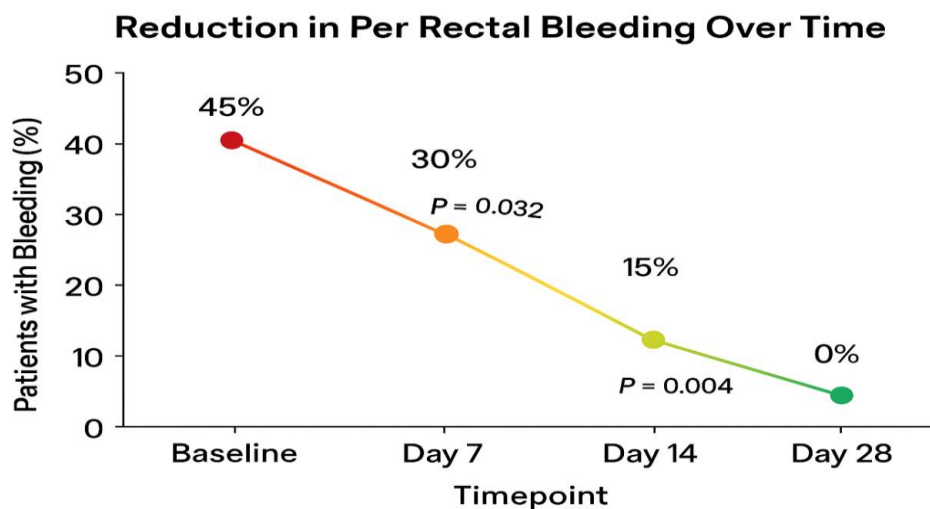


Fig. 1:

Reduction in per rectal bleeding over time.

Interpretation: Significant reduction in rectal bleeding confirms the **haemostatic effect** of Habb-e-Muqil.

Prolapse of Hemorrhoidal Mass

Table 3: Prolapse of Hemorrhoidal Mass

Time point	Patients with Prolapse (n)	Percentage	P-value*
Baseline	28	70%	–
Day 7	24	60%	0.125
Day 14	18	45%	0.018
Day 28	14	35%	0.004
1 Month Post Treatment	10	25%	0.002

*McNemar's test

Interpretation: Progressive decrease in prolapse ($p = 0.002$) indicates clinical improvement.

Hemorrhoid Severity Score (HSS)

Table 4: Hemorrhoid Severity Score (HSS)

Time point	Mean HSS $\pm$ SD	P-value*
Baseline	13.2 $\pm$ 2.0	–
Day 7	12.0 $\pm$ 1.8	0.042
Day 14	9.5 $\pm$ 1.6	<0.001
Day 28	6.5 $\pm$ 1.1	<0.001
1 month post treatment	5.5 $\pm$ 0.8	<0.001

*Paired t-test

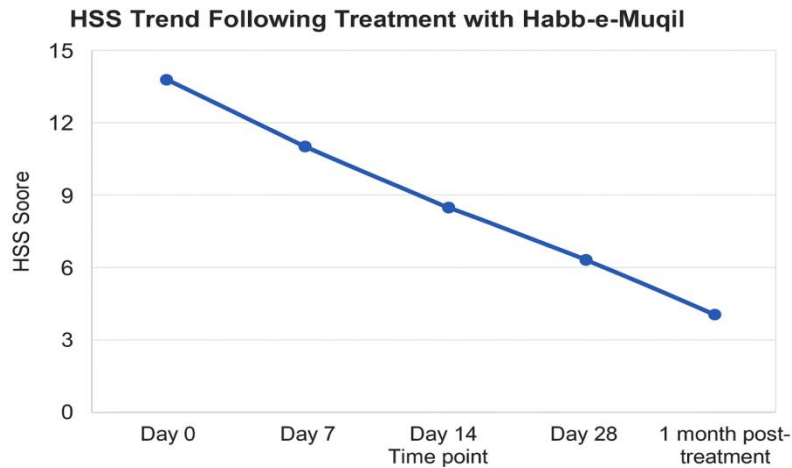


Fig. 2: Reduction in HSS scores with Habb-e-muqil over time.

Interpretation: Significant reduction in HSS demonstrates **overall improvement in hemorrhoid severity scores**.

Rectal Mucosa and Inflammation

Table 5: Rectal Mucosa improvement over time

Mucosal Condition	Baseline (n, %)	Day 28 (n, %)	P-value*
Pink	22 (55%)	32 (80%)	0.021
Pallor	8 (20%)	0 (0%)	0.015
Inflamed	10 (25%)	0 (0%)	0.008

*Mc Nemar's test

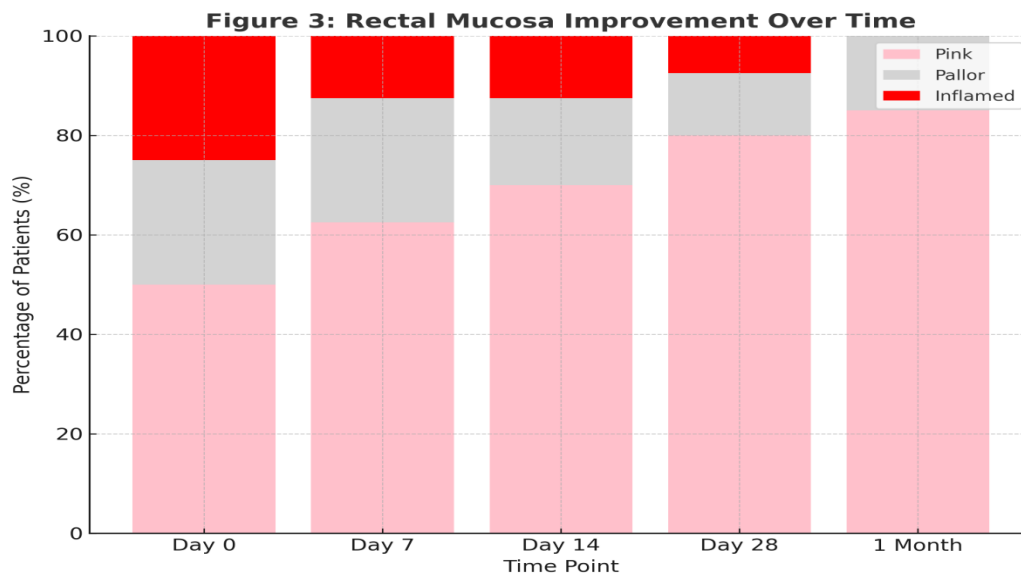


Fig. 3: Rectal Mucosa improvement over time.

Interpretation: Complete resolution of mucosal inflammation and pallor demonstrates **anti-inflammatory and healing effects**.

Table 6: PNR-Bleed Scores over Time

Time Point	Prolapse (P)	Number of Columns (N)	Relation (R)	Bleeding (B)	HSS (Mean $\pm$ SD)	p-value
Day 0	15 P2, 13 P3	12 N3, 28 N4	38 R3	13 B3, 5 B2	13.5 $\pm$ 2.1	-
Day 7	12 P2, 12 P3	10 N3, 25 N4	35 R3	10 B3, 2 B2	11.8 $\pm$ 1.9	<0.001
Day 14	8 P2, 10 P3	8 N3, 21 N4	28 R3	5 B3, 1 B2	10.0 $\pm$ 1.7	<0.001
Day 28	6 P2, 8 P3	5 N3, 16 N4	19 R3	0 B3, 0 B2	8.2 $\pm$ 1.5	<0.001
1 Month post treatment	4 P2, 6 P3	2 N3, 11 N4	13 R3	0 B3, 0 B2	6.5 $\pm$ 1.2	<0.001

Interpretation:

At baseline (Day 0), the majority of patients presented with advanced disease features. Prolapse was predominantly of grade P2 (n=15) and P3 (n=13), with most patients having three affected hemorrhoidal columns (N4, n=28) and all were internal hemorrhoids (R3, n=38). Bleeding was also severe, with 13 patients exhibiting grade B3 and 5 patients with B2 bleeding. The mean Hemorrhoidal Severity Score (HSS) at this stage was 13.5 $\pm$ 2.1, reflecting significant symptom burden.

By Day 7, there was a noticeable clinical improvement. The number of patients with higher prolapse grades reduced (P3 from 13 to 12), and the proportion with three columns involved (N4) dropped from 28 to 25, and (N3) from 12 to 10. Bleeding severity also decreased, with B3 cases reducing from 13 to 10 and B2 cases from 5 to 2. Correspondingly, the HSS showed a statistically significant decline to 11.8 $\pm$ 1.9 ($p < 0.001$), indicating early treatment response.

On Day 14, the trend of improvement continued. P3 prolapse cases declined further (n=10), N4 reduced to 21, N3 to 8 and R3 decreased from 38 at baseline to 28. Bleeding was markedly reduced, with only 5 patients in B3 and 1 in B2. The HSS continued its downward trajectory to 10.0 $\pm$ 1.7 ($p < 0.001$), demonstrating progressive clinical benefit.

By Day 28, prolapse and number of involved columns showed further regression (P3: n=8; N3: n=16), and there were **no cases of B2 or B3 bleeding**. R3 also declined to 19. The mean HSS significantly improved to 8.2 $\pm$ 1.5 ($p < 0.001$), suggesting sustained therapeutic efficacy.

At 1 month post-treatment, the improvements were consolidated. Only a small number of patients remained with P2 (n=4) and P3 (n=6) prolapse. N3 was seen in just 11 patients, and R3 in 13. Importantly, **no bleeding of grade B2 or B3 was observed**. The mean HSS reached its lowest level of 6.5 $\pm$ 1.2 ($p < 0.001$), indicating a **clinically and statistically significant reduction in overall disease severity** compared to baseline.

The data demonstrate a **gradual and consistent reduction** in all components of the PNR-Bleed scoring system—Prolapse, Number of columns involved, Relation, and Bleeding—over the course of one month. The **complete resolution of moderate-to-severe bleeding by Day 28**, combined with marked improvements in prolapse and relation scores, strongly supports the efficacy of the intervention. The progressive fall in HSS from 13.5 $\pm$ 2.1 to 6.5 $\pm$ 1.2 underscores the **clinical relevance and durability** of the treatment effect.

Safety Assessment

No adverse effects were observed. Laboratory parameters remained **within normal limits** throughout the study.

DISCUSSIONS

The study demonstrates that Habb-e-Muqil is effective in reducing rectal bleeding, prolapse, and mucosal inflammation in patients with Grade I–III internal hemorrhoids. The haemostatic effect is evident from complete cessation of bleeding by day 28 ($p < 0.001$), while significant reduction in prolapse ($p = 0.004$) reflects improvement in tissue integrity. Progressive HSS reduction validates overall clinical efficacy.

The formulation's active ingredients, including Commiphora mukul and Berberis vulgaris, likely contribute to venotonic, anti-inflammatory, and healing actions, supporting the observed clinical outcomes. 8, 9 A study by Anurekha J. et al. found that Guggulosomes, made from these drugs using sonication and trituration,

showed greater anti-inflammatory efficacy than Ibuprofen. Additionally, Guggulosomes found in muqil combined with Ibuprofen had synergistic effects, enhancing their overall effectiveness. 10, 11 The effects of these drugs, such as strengthening venous tone and providing anti-inflammatory, anti-microbial, and muscle-toning benefits, contribute to their efficacy in treating hemorrhoidal prolapse. 12, 13 No adverse effects indicate good tolerability.

CONCLUSION

The present study demonstrates that the therapeutic intervention produced a clinically meaningful and

statistically significant improvement in hemorrhoidal disease parameters over a one-month treatment period. Progressive reductions were observed in prolapse grade, number of hemorrhoidal columns involved, and relation scores, alongside a complete resolution of moderate-to-severe bleeding by Day 28. The marked and sustained decline in the Hemorrhoidal Severity Score underscores the efficacy, safety, and durability of the treatment effect. These results suggest that the intervention represents a promising and effective modality for the management of hemorrhoidal disease, offering both symptomatic relief and objective clinical improvement. Habb-e-Muqil is effective, safe, and well-tolerated for Grade I–III internal hemorrhoids, demonstrating significant haemostatic and anti-inflammatory effects. It can be recommended as a conservative alternative to surgical management, particularly in patients with bleeding-predominant hemorrhoids.

Limitations

- Lack of per-rectal USG or imaging to assess hemorrhoidal plexus layers.
- Single-arm study; no direct comparator.
- Limited sample size; larger multicentric trials are needed.

Financial Support and Sponsorship

Nil

Conflicts of Interest

None

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