

Comparative evaluation on efficacy of *Habb-e-Rasuat* versus *Habb-e-Muqil* in Internal Haemorrhoids of Grade I and II (*Bawaseer Ghaira*) – An open label Randomized clinical trial.



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Abstract:

Background and Objective: Hemorrhoids are a prevalent anorectal condition worldwide, with substantial social and economic consequences. Conservative treatments typically include life-style modifications, increased fiber intake, and non-surgical methods such as Sclerotherapy and rubber band ligation. When these measures fail, surgical interventions are often required. Though effective, surgery carries potential complications like bleeding, pain, prostatitis, urinary retention, stricture formation, anal incontinence, and infections, prompting a shift towards less invasive options. In Unani medicine, remedies like *Habb-e-Rasuat* and *Habb-e-Muqil* treat internal hemorrhoids (*Bawaseer-e-Ghaira*) by relieving symptoms and addressing the root cause. Given the potential benefits of these treatments, it is essential to evaluate their efficacy using modern scientific parameters. A clinical investigation comparing the effects of *Habb-e-Rasuat* and *Habb-e-Muqil* on internal hemorrhoids could provide a viable alternative to expensive and painful surgical procedures.

Materials and Methods: A randomized, open-label clinical trial was conducted at NIUM hospital involving 40 participants divided into two groups. Group A (20 participants) received *Habb-e-Rasuat* (200 mg; 2 pills twice daily), and Group B (20 participants) received *Habb-e-Muqil* (200 mg; 2 pills twice daily). The efficacy of the treatments was evaluated based on subjective and objective assessment parameters by using PNR-Bleed classification and HSS (Haemorrhoid severity score) such as rectal bleeding, prolapse of pile mass, Number of haemorrhoidal columns, rectal mucosa, grading of pile mass, bleeding points, and anal sphincter spasm.

Results: Both groups showed significant improvement in symptoms. Group B (*Habb-e-Muqil*) demonstrated superior results in reducing rectal bleeding, (P-values < 0.001-0.002), while Group A (*Habb-e-Rasuat*) was more effective in alleviating prolapse of pile mass (P-value < 0.001). Both treatments were equally effective in reducing number of haemorrhoidal columns, anal inflammation, and sphincter spasm with no adverse effects observed. PNR-B and HSS scores have shown significant improvements in the symptoms of Haemorrhoides (P-value < 0.001).

Interpretation and Conclusion: The study suggests that both *Habb-e-Rasuat* and *Habb-e-Muqil* provide similar improvement in overall outcomes for treating internal hemorrhoids by addressing a broader range of symptoms. *Habb-e-Muqil* was better in reducing bleeding and *Habb-e-Rasuat* fared better in reducing the size of prolapsed pile mass, and mucosal inflammation.

Keywords: Hemorrhoids, PNR-Bleed, *Habb-e-Rasuat*, *Habb-e-Muqil*, Unani medicine.

Introduction

Hemorrhoids, or *Bawaseer*, are anorectal vascular cushions that become symptomatic due to congestion, inflammation, or prolapse. The condition is widespread, with epidemiological studies estimating a lifetime prevalence of up to 75% in India and affecting a substantial proportion of adults globally.¹ Internal hemorrhoids (*Bawaseer-e-Ghaira*) commonly present with painless rectal bleeding, prolapse during defecation, itching, mucus discharge, and varying degrees of discomfort. In their early stages, symptoms are often managed conservatively through increased dietary fiber, hydration, and improvement in bowel

habits. However, during acute episodes or persistent cases, symptomatic management is often supplemented with pharmacological or topical therapy to alleviate inflammation, reduce bleeding, and provide analgesic relief.²

Conventional management includes suppositories, ointments, and non-operative procedures like sclerotherapy or ligation. Despite these options, complications such as postoperative pain, recurrence, infection, and anal incontinence continue to challenge clinical outcomes. Further more, surgical interventions, while effective, are invasive and often associated with prolonged recovery and adverse effects.^{2,3}

Within the Unani system of medicine, two oral formulations—*Habb-e-Rasuat* and *Habb-e-Muqil*—have been used extensively for the treatment of internal hemorrhoids. These polyherbal remedies contain ingredients such as *Berberis vulgaris*, *Commiphora mukul*, *Geeru*, and *Tukhme Neeb*, among others, each chosen for specific properties such as haemostatic (*Habis-ud-dam*), anti-inflammatory (*Muhallil-e-Waram*), desiccative (*Mujaffif*), healing (*Mudammil*), and laxative (*Mullayin*). Collectively, these actions target the underlying mechanisms of hemorrhoids—bleeding, venous congestion, inflammation, and tissue damage—while improving bowel clearance and mucosal recovery.^{4, 5, 6} The purpose of the present open-label randomized clinical trial was to compare the therapeutic outcomes of *Habb-e-Rasuat* and *Habb-e-Muqil* in the treatment of Grade I and II internal hemorrhoids. The study was designed to evaluate each formulation's efficacy in terms of symptom relief (bleeding per rectum, prolapse, defecation discomfort etc), improvement in rectal mucosa and sphincter status, and overall safety profile. By doing so, the trial aims to identify whether these Unani formulations may provide a safe, well-tolerated, and effective alternative to more invasive treatment modalities for internal hemorrhoids.

Methodology

This was a randomised, comparative clinical study, carried out in the surgery unit of the National Institute of Unani Medicine (NIUM) in affiliation with Rajiv Gandhi University of Health Sciences (RGUHS), in southern Karnataka, between June 2023 and December 2024. Ethical approval was obtained from the institutional Ethical and Research Committee of NIUM, with the protocol number NIUM/IEC/2021-22/ 027/Jar/ 05.

Study Population

Adult males and females aged 18–60 years with first-and second-degree haemorrhoids, who consented to treatment and based on randomization were allotted in group A and group B accordingly. With either Tablet (*Habb-e-Rasuat*) or Tablet (*Habb-e-Muqil*), were recruited into the study. Diagnosis was made from combination of clinical information and proctoscopic evaluation, while colonoscopy was done, when indicated, to rule out the possibility of other lesions. Excluded from the study were Patients with other anorectal lesions such as fissure-in-ano, fistula-in-ano, anorectal neoplasia, pregnant ones and those who had previous anorectal surgery, as well as patients with immunosuppression due to diabetes mellitus, retroviral disease/STDs or on any form of

immunosuppressant therapy and those with bleeding disorders or on anticoagulants.

Sample size and Sampling method

The sample size was estimated using the sample size formula for experimental studies by Alok Tripathi et-al.

$Z\beta$ is 0.84 (from Z table), at 80% power.

$Z\alpha/2$ is 1.96 (from Z table), at 95% confidence level.

P1 and P2 are proportions of patients treated with Tablets (*Habb-e-Rasuat*) and (*Habb-e-Muqil*) respectively that showed desired therapeutic effect). Considering 20 % drop out rate minimum sample size was estimated to be 20 in each group (total 40).

The patients recruited were randomized into two groups, by simple randomization, using sixty ballot papers labelled with either of the treatment options, twenty in each group (Group A & B). Each pre-labelled paper was sealed in an opaque envelope, and the envelopes were mixed together and shuffled. Each of the recruited patients picked a sealed envelope at random and the procedure selected by each patient was carried out on him or her.

Procedure:

Pre-Treatment assessment with CBC, ESR, BT, CT, LFT, Stool for Ova and Cyst and proctoscopy with or without colonoscopy were done on all the patients. The patients who were older than 50 years had colonoscopy done, to exclude other sources of bleeding in them; likewise, patients who had alarming symptoms such as tenesmus, weight loss and anorexia, to rule out the possibility of colorectal malignancy. This was followed by a post-treatment assessment with CBC, LFT and stool for ova and cyst for improvement and to rule out any adverse drug effects.

Group A (Oral administration of Tablet/*Habb-e-Rasuat*): Given as an oral formulation of two pills (tablets) each 200mg twice a day after meals (800mg/day) for a period of 1 month.

Group B (Oral administration of Tablet/*Habb-e-Muqil*): Given as an oral formulation of two pills (tablets) each 200mg twice a day after meals (800mg/day) for a period of 1 month.

Post-Treatment Evaluation

After enrolling the patients into respective groups, the follow up was followed on day 0, day 14, day 28 during treatment and after 1 month of completion of the treatment. On each follow up the patient was examined and proctoscopic findings were enlisted on case report format of the patient. The following Assessment Parameters were assessed:

• Local Examination:

A) Inspection:

1. Mass per rectum: Yes/No
2. Any Discharge: Yes/No (Blood/Mucus/Mixed)

3. Any regional infection: No/Yes (fungal/viral/other)

4. Openings around anal canal: No/Yes

• **B) Digital Examination:**

1. Tenderness: Yes (Mild/Moderate/Severe)/No

2. Tone of internal anal sphincter: Normal/Lax/Hypertonia (+1/+2/+3) (Involuntary)

3. Condition of rectal mucosa: Smooth/adhered/Lax.

4. Mass felt P/R: No/Yes (Ant/RL/Post/LL)

5. Gloved finger smeared with: Nil/Blood/Mucus/Stool.

• **PROCTOSCOPIC FINDINGS:**

1. Condition of rectal mucosa: Pinkish/Pallor/Inflamed

2. Bleeding points: Yes/No

3. Site(s) of bleeding: Primary position, Secondary position

4. Position: Primary position (3/7/11 O' clock), Secondary position

5. Grade of pile: 1st Degree, 2nd Degree

Assessment of outcome: Post treatment assessment was done using a structured questionnaire for the patient using PNR-Bleed classification and HSS (Haemorrhoid severity score). 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. 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

S.No.	Charecteristic	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 Hb level (<7gm/dl): requiring blood transfusion.

Documentation of hemorrhoidal grades was done after completing the history and clinical examination especially the P/R proctoscopy of the patient using PNR Bleeding. To describe and to document for further references, we will write the first four letters of the pneumatic "PNR-Bleed" i.e. P N R B and add a numerical subscript of the grade of involvement in every characteristic, in a particular patient. For example a hemorrhoidal mass that prolapses on straining but reduces spontaneously (Grade 2), involving only one hemorrhoidal column (Grade 2), internoexternal (Grade 4) in relation to

dentate line with only mild occasional bleeding (Grade 2) will be written as "P2N2R4B2" and its total hemorrhoidal score will be 10/20.

Hemorrhoid Severity Score (HSS) based on this "PNR-Bleed" classification, introduce the another concept of scoring the severity of hemorrhoids. 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".⁷ Resolution of other haemorrhoidal symptoms was assessed using a structured questionnaire, and the treatment efficacy was defined in terms of the presence or absence of those symptoms.

Statistical analysis

Data collected were analysed by computer analysis using the IBM SPSS Statistics for Windows, version 22.0 Armonk, NY: IBM Corp. The frequency distribution of the variables was presented in tables and charts. The mean and standard deviation of the age were determined, as well as the median duration of symptoms. The Student's *t*-test was

used to determine the statistical significance, and the Chi-square was used to test the distribution of demographic and clinical variables among the two groups. The Chi-square was also used to test the resolution of haemorrhoidal symptoms with significance level taken at 95% confidence interval ($P < 0.05$).

Results

A total of forty patients were recruited for the study and were randomized equally into the Habb-e-Rasuat (Group A) and Habb-e-Muqil (Group B). Their ages ranged from 18 to 60 years with mean age of 46.8 ± 10.34 years. In Group A, the mean age was 39.00 ± 9.022 years while in Group B; it was 39.30 ± 9.868 years. There was no significant difference in the mean age of the two groups ($P = 0.71$).

The classification of PNR-Bleed per patient is as shown in Table 2.

Groups	Baseline	After 2 weeks	After 4 weeks	After 1 month of completion of treatment
Group A	$^{15}P_{2\&3} \ ^{15}N_4 \ ^{15}R_3 \ ^{11}B_{3\&2}$	$^{15}P_2 \ ^9N_3 \ ^9R_3 \ ^8B_{3\&2}$	$^{10}P_2 \ ^2N_2 \ ^2R_3 \ ^7B_2$	$^2P_2 \ ^2N_2 \ ^2R_3 \ ^5B_2$
Group B	$^{14}P_{2\&3} \ ^{17}N_{4\&5} \ ^{17}R_3 \ ^9B_{3\&2}$	$^{12}P_2 \ ^{11}N_3 \ ^5 \ ^{14}R_3 \ ^5B_{3\&2}$	$^9P_2 \ ^5N_2 \ ^6R_3 \ ^1B_2$	$^7P_2 \ ^7N_2 \ ^7R_1 \ ^0B_2$

In this the numerators denotes the number of the patients, while as the denominators mention grading of that clinical variety. e. g, $^{15}P_2$ indicates that there are total 15 patients with grade 2nd degree prolapse of pile masses. In group A patients Out of 20 at the time of first visit (baseline), 15 patients were having grade 2nd & 3rd degree prolapse ($^{15}P_{2\&3}$) with 3 haemorrhoidal columns ($^{15}N_4$) involved, all present above the dentate line (R_3) and 11 patients with grade 2nd & 3rd bleeding per rectum. After treatment and the follow ups at 2 and 4 weeks, there was a significant improvement in all clinical parameters and after 1 month of follow up (post treatment), only 2 patients were having 2nd degree prolapse (2P_2) involving only one haemorrhoidal column (2N_2), lying above the dentate line (2R_2) with five having mild bleeding per rectum (5B_2), as shown in Fig; A. ($P < 0.05$).

Similarly in Group B patients at the first visit, out of 20 a total of 14 patients were having 2nd & 3rd

degree prolapse of pile masses ($^{14}P_{2\&3}$), 17 patients were having 3 and more than 3 with circumferential involvement of haemorrhoidal columns ($^{17}N_{4\&5}$), with second degree piles ($^{17}R_3$) and bleeding with mild to moderate in 9 patients ($^9B_{3\&2}$). After treatment and the follow ups at 2 and 4 weeks, there was a significant improvement in all clinical parameters, and after 1 month of follow up (post treatment), 7 patients were having grade 2nd prolapse involving only 1 haemorrhoidal column and no patient with any bleeding per rectum ($^7P_2 \ ^7N_2 \ ^7R_1 \ ^0B_1$), as shown in Fig; B. ($P < 0.05$).

Thus it could be assessed that reduction/regression of prolapse of piles was more effective in Group A as compared to Group B, while as resolution of bleeding per rectum was seen more in Group B as compared to Group A. This could be due to the haemostatic effect of the drug.

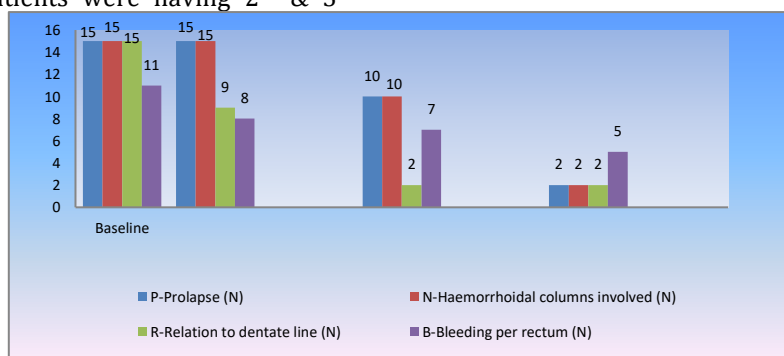


Fig. A: Group A with PNR-Bleed

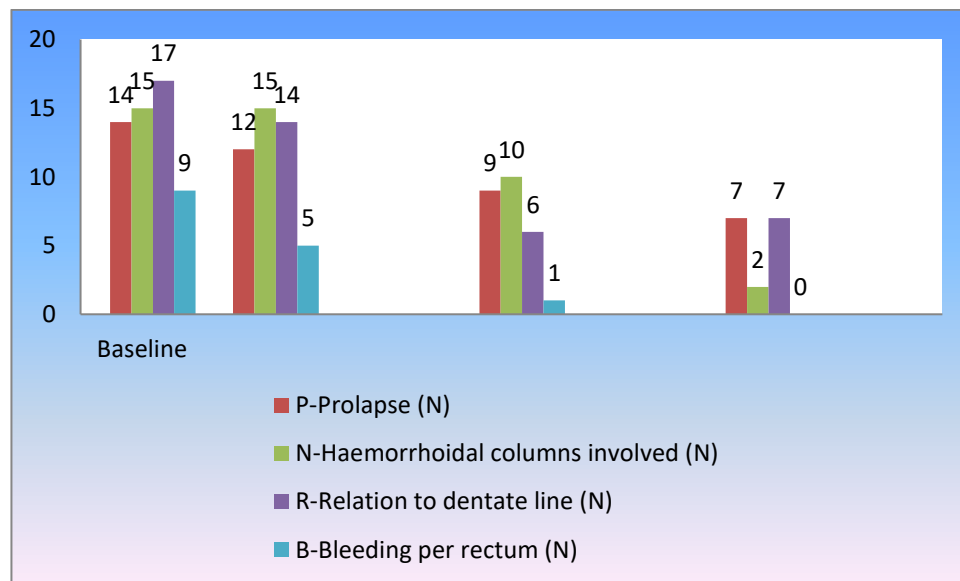


Fig. B: Group B with PNR-Bleed

Hemorrhoid Severity Score (HSS)

Minimum HSS score is 4 and maximum score can be 20. HSS score of a normal person without any signs and symptoms of haemorrhoids is "4". The HSS scoring is illustrated in the underlying table no. 3 as shown, and graphically in Fig. C.

Groups	Baseline	After 2 weeks	After 4 weeks	After 1 month of completion of treatment
Group A (HSS Score)	12	11	9	5
Group B (HSS Score)	13	12	9	6

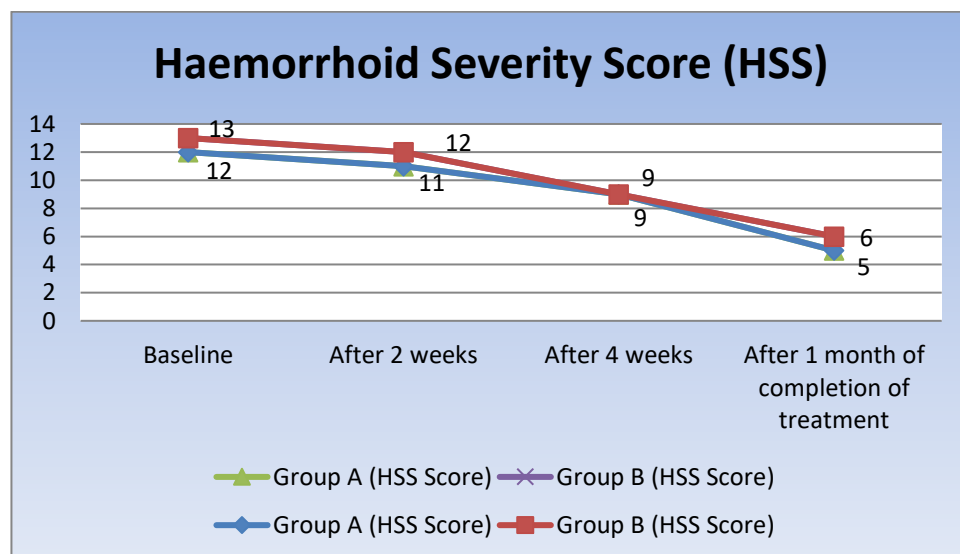


Fig. C: HSS Scoring in Group A and B

As shown in Figure C, the scoring of HSS has gradually decreased to its normal values in both the groups, suggesting that both the drugs of group A and B have a potential beneficial effect in the treatment of first and second degree piles. ($P < 0.001$).

Table 4: Assessment of rectal mucosa at 1 month from baseline

Rectal Mucosa		Baseline	2WK	4WK	1 MONTH	P value
Group A	pink	12(60%)	16(85%)	18(90%)	18(90%)	<0.001
	pallor	3(15%)	2(10%)	2(10%)	2(10%)	
	inflamed	5(25%)	2(10%)	0(0.0%)	0(0.0%)	
Group B	pink	11(55%)	13(65%)	14(70%)	15(75.0%)	<0.001
	pallor	4(5.0%)	2(5.0%)	1(5.0%)	0(5.0%)	
	inflamed	5(5.0%)	5(0.0%)	5(0.0%)	5(0.0%)	

In addition to it, assessment of rectal mucosa was performed by proctoscopy on every visit. There was a significant improvement in both the groups ($P < 0.001$), as shown in Table 4. However there was a significant reduction in the inflammation of mucosa in group A as compared to group B, this could be due to an anti-inflammatory effect of the drug (*habb-e-rasuat*), similarly complete resolution of pallor mucosa was seen in group B patients, this could be due to the haemostatic effect of the drug (*Habb-e-Muqil*).^{8,9}

Discussion:

A total of 40 individuals were enrolled in the current study and split into two groups, A and B. Twenty people were randomly selected for each group, with Group A receiving treatment with *Habb-e-Rasuat* and B with *Habb-e-Muqil*.

Per rectal bleeding is one the most common symptoms of internal hemorrhoids. In this study, around 50% of patients complained of P/R bleeding. In Group A (20 patients), 11 (52.4%) experienced rectal bleeding on day 0. This number dropped to 8 (9.5%) after 2 weeks, 7 (4.8%) after 4 weeks, and 5 (4.8%) by the end of the first month of follow-up. In Group B (20 patients), 9 (45%) had rectal bleeding on day 0. After 2 weeks, the number decreased to 5 (25%), then to 1 (5%) after 4 weeks, and eventually to 0 (0%) by the end of the first month. No recurrences were recorded till the follow-up period. The reduction in rectal bleeding over time was statistically significant, with a p-value of < 0.001 , indicating that both treatments were effective. However, Group B patients, who took *Habb-e-Muqil*, showed a slightly better response, further supporting the haemostatic effects of these Unani medications. The data is summarized in Table No. 2 and Figures A and B. The study suggests that a larger sample size may be needed to better distinguish between the haemostatic effects of *Habb-e-Muqil* and *Habb-e-Rasuat*. The results were found to be superior to those in a study by Khan et al.⁹⁵

Prolapse of Mass per rectum is among the common symptoms of haemorrhoids, and around 72.5% patients in our study presented with Mass P/R. In Group A (20 patients), 15 patients (75%) initially presented with a grade 2 and 3 degree prolapsed pile mass, while five patients (25%) did not. Over

the follow-up period (2 weeks, 4 weeks, and 1 month), the number of patients with prolapse decreased from 15 (75%) at 2 weeks to 10 (50%) after 4 weeks, and finally to two (10%) by the end of the first month.

In Group B (20 patients), 14 (70%) had a prolapsed pile mass at the start, while six (30%) did not. During the follow-up, the number of patients with prolapse reduced from 14 (70%) at baseline to 12 (60%) at 2 weeks, nine (45%) at 4 weeks, and seven (35%) by the end of the first month. No recurrence of prolapse was reported in either group after the conclusion of the treatment protocol. The results indicate that *Habb-e-Rasuat* (used in Group A) showed a more significant reduction in prolapse, with a p-value of < 0.002 , compared to *Habb-e-Muqil* in Group B. 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.^{11,12} 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. 5, 14, 35, 36, 37 The results are summarized in Table No. 2 and Figure No. A & B. The study carried out by Khan et al addressed results of a comparable type.¹⁰

In the case of number of the haemorrhoidal columns involved, there was a significant decrease in both the groups with $P < 0.001$, showing their effectiveness in decreasing the number of piles.

Assessment of the rectal mucosa on proctoscopic examination was done on every visit of the patient. There was a significant decrease in both the groups ($P < 0.001$), as shown in Table 4. There was a significant reduction in the inflammation of mucosa in group A as compared to group B, this could be due to an anti-inflammatory effect of the drug (*habb-e-rasuat*), similarly complete resolution of pallor mucosa was seen in group B patients, this could be due to the haemostatic effect of the drug (*Habb-e-Muqil*),^{11, 12, 13} and this is further supported by the studies of Khan et-al.¹⁰

Conclusion

Upon completion of the protocol, both groups experienced total relief from the subjective complaints of piles. Patients in Group B (who were taking *Habb-e-Muqil*) showed a slightly higher impact on reductions in bleeding per rectum (P-value < 0.001), showing its superior haemostatic effect as compared to *Habb-e-Rasuat*. The reduction in the size of prolapse of pile masses was seen more in Group A patients taking *Habb-e-Rasuat* (P-value < 0.002)), when compared to patients in Group A.

In the objective parameters of the rectal mucosa, bleeding points, number of haemorrhoidal columns, and grading during an examination, both of these medications had shown equal effectiveness in these parameters with significant p values of <0.001.

For patient whose primary concern is prolapse, *Habb-e-Rasuat* is recommended because it is associated with a significantly higher rate of resolution of prolapse of pile mass, compared to *habb-e-muqil*. When the primary concern is anal bleeding, *habb-e-muqil* is recommended due to its higher haemostatic effect as compared to *Habb-e-rasuat*.

The safety of the study medications was demonstrated by the differences in the blood and biochemical test values being found within normal ranges in both groups. The study drugs were determined to be well-tolerated, and no side effects were noted.

Based on this study, we recommended that both the drugs should be promoted in the treatment of internal haemorrhoids in our environment because of their effectiveness and applicability.

Limitations of the study

- Per-rectal USG to assess the condition of the wall and it's the layers
- Radiography of hemorrhoidal plexus (assess exact change)
- The study should be carried out on a large sample size.

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Nil

Conflicts of interest

There are no conflicts of interest.

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