Efficacy of A Compound Unani Formulation HABB-E-BAWASEER In The Management Of Haemorrhoids (BAWASEER)

*Mujahid Shaikh, Jalees Ahmed, Manzoor Ahmad, Akhtar Husain Chaudhary and Khurshid Ahmed
Dept. of Ilm-ul-Jarahat (General Surgery),
Z.V.M Unani Medical College & Hospital, Pune.
*Correspondenceaddress: mujahid100@gmail.com Mob.No: 8007070864

ABSTRACT
Background
Haemorrhoids (Bawaseer) has plagued for human being since ancient times. It is a very common disease affecting more than half of all people with symptomatic signs and symptoms. Current drug treatment protocols cannot cure the disease and they are palliative. According to Unani system of medicine many anti-haemorrhoid medicine are available in which Habb-e-Bawaseer is one of the medication choice.
Aim: this clinical study was undertaken to evaluate the efficacy of Habb-e-bawaseer in patients with 1 & 2 degree.
Material and methods: this study was carried on 60 patients in Z.V.M Unani Medical College & Hospital, Pune. They received Habb-e-Bawaseer 2 pills for 28 days. Subjective and objective variable include rectal bleeding, anal pain, anal pruritus, mass feeling (Prolapse), constipation, proctoscopic examination and haemoglobin were assessed before and after study. The data is analyzed with appropriate statistical test.
Conclusion: Habb-e-Bawaseer was found effective in treatment of uncomplicated Bawaseer (Haemorrhoid) of 1 & 2 degree.
Key words: Bawaseer, Haemorrhoid, Habb-e-Bawaseer, Unani system of medicine, Rectal bleeding, uncomplicated haemorrhoid

INTRODUCTION
Present time is the era of fast food, irregularity in food timing, improper diet, changing food style and mental stress coupled with sedentary life. All these factors disturb the digestive system resulting into many diseases. Among this haemorrhoid known as pile is quite common in the society.1
Haemorrhoids are one of the oldest diseases suffered by mankind2 well recorded in ancient texts of Greeks, Egyptians, Hindus, and Bible. Many great personalities have suffered from haemorrhoids like the Philistines, Napoleon Bonaparte and Don Juan Demoranna. It is said Napoleon Bonaparte lost his battle of Waterloo because of the delay in launching the attack due to a bad attack of bleeding haemorrhoids.3 According to NIH data, nearly 1 million cases are reported annually in US at the prevalence
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In the age group of 45-65 years, it is estimated that 50-86% of people around the world have haemorrhoids.\textsuperscript{4,5,6,7,8} According to several studies carried out in high risk groups the prevalence rate of haemorrhoids was found to be very high. A study carried out in 4 hospitals in Austria, for the screening of colorectal cancer in which 38.93% individuals were diagnosed as having haemorrhoids.\textsuperscript{9} Some researchers suggest that about 75% of people will have symptomatic haemorrhoids at some point in their lives.\textsuperscript{10} Haemorrhoids are most common among adult ages i.e. 45 to 65 years and also common in pregnant women, but in only 4% of general population they become enlarged and cause problems.\textsuperscript{4} Taking both symptomatic and asymptomatic haemorrhoids into concern the presence of haemorrhoids is marginally more in males but haemorrhoids that cause problems are found equally in men and women.\textsuperscript{8} Nearly half of the world’s population will experience some form of haemorrhoids especially when they reach the golden age of fifty.\textsuperscript{11}

According to recent studies, several theories have been postulated regarding the cause, including prolonged periods of driving, erect posture, chronic constipation and diarrhea, straining during defaecation, low fibrous diet, heredity, eating spicy foods, sitting on cold seats and benches, doing manual labour, lifting heavy weights, being overweight, pregnancy, weakening of the connective tissue in the rectum and anus that occurs with age.\textsuperscript{2,5,7,12} None of these theories has strong experimental support. Alcoholic cirrhosis or other causes of portal obstruction can cause severe haemorrhoids. More rarely but much more importantly, haemorrhoids may reflect collateral anastomotic channels that develop as a result of portal hypertension.\textsuperscript{13}

Tumors in the pelvis also cause enlargement of haemorrhoids by pressing on veins draining upwards from the anal canal.\textsuperscript{14}

One theory proposes that it is the shearing (pulling) force of stool, particularly hard stool, passing through the anal canal that drags the haemorrhoidal cushions downward.\textsuperscript{11}

Another theory suggests that with age or an aggravating condition, the supporting tissue that is responsible for anchoring the haemorrhoids to the underlying muscle of the anal canal deteriorates. With time, the haemorrhoidal tissue loses its mooring and slides down into the anal canal.\textsuperscript{11}

One physiological fact that is known about enlarged haemorrhoids that may be relevant to understanding why they form is that the pressure is elevated in the anal sphincter (the muscle that surrounds the anal canal and the haemorrhoids). The anal sphincter is the muscle that allows us to control our bowel movements. It is not known, however, if this elevated pressure precedes the development of enlarged haemorrhoids or is the result of the haemorrhoids. Perhaps during bowel movements, increased force is required to force stool through the tighter sphincter. The increased shearing force applied to the haemorrhoids by the passing stool may drag the haemorrhoids downward and enlarge them.\textsuperscript{11}

In an interesting study conducted by Ahmed and Thomson (1997) it was found that there is a correlation between failure to eat breakfast and the development of haemorrhoids.\textsuperscript{15}

According to Balch & Balch (2000), haemorrhoids are unique to human beings, indicating that our dietary and nutritional habits play an important role in this disorder.\textsuperscript{15} Habb-e-Bawaseer is one of the drug described in various ancient Unani literatures to be effective in Bawaseer further inquiry with Unani physician revealed that drug is highly effective and possess least chances of toxicity and side effect. Habb-e-Bawaseer contains Bisfiqij, Zaranbad, Maghz-e-Tukhm-e-Neem, Rasaut, Guggul and Gulab in equal proportion i.e. 1 Tola (12grams each) in the form of Habb (pills).\textsuperscript{16,17}

MATERIAL AND METHODSS

Study design

This study was conducted on an out-patient population addressing to the Jaraht (surgery) unit of Z.V.M Unani medical college and hospital, Pune, India in September 2014 to December 2014. After receiving informed
consent, eligible patient were enrolled in study and given Habb-e-Bawaseer, 2 pills, two times a day with water for 28 days.

**Eligibility criteria**
Patient with uncomplicated internal haemorrhoids grade 1 and 2, who were 20-60 years of age, were eligible if their diagnosis was clinically confirmed. Patients with any of the following criteria were ineligible: advance haemorrhoid requiring surgery, presence of any major systemic illness like renal failure, ischemic heart diseases etc. Concomitant use of medication known to affect pain or other symptoms of haemorrhoid was not allowed. Women who were pregnant or lactating were excluded, as patients with any important complication during the research were dropped out.

**Drug preparation and dosage**
The crude medicines were purchased from the authentic sources in Pune. Identification, quality confirmation were done at department of *Ilm-ul-Advia*, Habb (pills) were prepared at department of *Ilm-ul-Saidla*, Z.V.M Unani Medical College & Hospital, Pune, India according to the method describe in unani literature with strictly following the good manufacturing practice (GMP) norms. The *Habb* prepared from *Bisfaij, Zaranbad, Magh-Z-e-Tukhm-e-Neem, Rasaaut, Guggul and Gulab*, 2 Habb two times a day for 28 days given.

**Efficacy assessment**
Subjective parameter
1. **Per Rectum Bleeding**
   - Absent - Nobleeding
   - Mild – Bleeding indrops while defaecation occurring once or twice a week.
   - Moderate – Bleeding indrops while defaecation occurring for 7 to 10 days.
   - Profuse – Bleeding in streams or drops while defaecation continues for more than 10 days.
2. **Anal Pain**
   - Absent - No Pain
   - Mild – Interfering little with activity of daily living.
   - Moderate – Interferes significantly with activity of daily living.
   - Severe – unable to perform daily living
3. **Anal pruritus**
   - Absent - No Itching
   - Mild - Occasional Itching
   - Moderate - Frequent Itching
   - Severe - Regular Itching
4. **Mass Feeling (Prolapse)**
   - 1st degree – Haemorrhoidal mass does not come out of the anus while defaecation
   - 2nd degree – Haemorrhoidal mass come out only during defaecation and needs to be replaced manually, and then stay reduced.
   - 3rd degree – Haemorrhoidal mass come out during defaecation and need to be replaced manually, and then stay reduced.
   - 4th degree – The Haemorrhoidal mass that are permanently prolapsed.
5. **Constipation**
   - Absent – 1-2 times per 1-2 days
   - Mild – 2-3 times per week
   - Moderate – Once per week
   - Severe – Less than one per week

**Safety parameter**
- ECG
- LFT
- RFT

**Statistical Method**
The data on qualitative characteristics is shown as n (% of cases) and the data on quantitative characteristics is presented as Mean ± Standard error of mean (SEM). The statistical significance of difference of mean of quantitative characteristics between several visits is tested using Wilcoxon’s signed rank test. The entire data is entered and cleaned in MS Excel before
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The statistical analysis in SPSS. All the results are shown in tabular as well as graphical format to visualize the statistically significant difference more clearly.

The p-values less than 0.05 are considered to be statistically significant. All the hypotheses re formulated using two tailed alternatives against each null hypothesis (hypothesis of no difference). The entire data is statistically analyzed using Statistical Package for Social Sciences (SPSS ver 11.5, Inc. Chicago, USA) for MS Windows.

RESULT

60 patients were enrolled, demographic data observed and analysed which included 73.3% male and 26.7% female. Age range was 20 to 58 years with the average of 31.1(± 6.5) years. The most common age range was 25 to 34. 73.3% of participants were married. 95.0% of the participants were had mixed diet while 80.0% of the participant preferred spicy diet and 60.0% of participant had irregular diet.70.0% of the participant doing moderate type of nature of work. As per unani medicine concept 80.0% of participant had saudavi mizaj.

The most common referral cause was rectal bleeding while the most common symptoms was constipation. The base line prevalence of subjective and objective parameter are shown in table 1 and 2.

<table>
<thead>
<tr>
<th>Severity, n, (%)</th>
<th>Per Rectal Bleeding</th>
<th>Pain</th>
<th>Anal pruritus</th>
<th>Constipation</th>
<th>Mass feeling (prolapse)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO</td>
<td>7(11.7%)</td>
<td>54(90.0%)</td>
<td>19(31.7%)</td>
<td>9(15.0%)</td>
<td>NO 0(0.0%)</td>
</tr>
<tr>
<td>Mild</td>
<td>29(48.3%)</td>
<td>6(10.0%)</td>
<td>20(33.3%)</td>
<td>30(50.0%)</td>
<td>1st degree 39(65.0%)</td>
</tr>
<tr>
<td>Moderate</td>
<td>24(40.0%)</td>
<td>0(0.0%)</td>
<td>16(26.7%)</td>
<td>21(35.0%)</td>
<td>2nd degree 21(35.0%)</td>
</tr>
<tr>
<td>Severe</td>
<td>0(0.0%)</td>
<td>0(0.0%)</td>
<td>5(8.3%)</td>
<td>0(0.0%)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>No 7</td>
<td>54</td>
<td>19</td>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Yes 53</td>
<td>6</td>
<td>41</td>
<td>51</td>
<td>60</td>
</tr>
</tbody>
</table>

Table no. 1 subjective parameter at baseline

Objective parameter at baseline

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value at baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of pile masses</td>
<td>1.25 ± 0.06</td>
</tr>
<tr>
<td>Haemoglobin</td>
<td>12.5 ± 0.23</td>
</tr>
</tbody>
</table>

Values are Mean ± Standard error of mean (SEM)

Table no.2 Objective parameter at baseline

Effect on subjective parameter

Per rectum bleeding

The average per rectal bleeding score is significantly higher at visit 1 compared to visit 5. The average improvement in per rectal bleeding score at visit 5 was 91.5% (P-value<0.001).

Anal Pain

The average pain score is significantly higher at visit 1 compared 5 pain score (P-
value<0.001). The average improvement in pain score at visit 5 was 100.0% (P-value<0.001 for all).

**Anal pruritus**
The average anal pruritus score is significantly higher at visit 1 compared visit 5 anal pruritus score (P-value<0.001). The average improvement in anal pruritus score at visit 5 was 93.5% respectively (P-value<0.001).

**Mass feeling (Prolapse)**
The average mass feeling score is significantly higher at visit 1 compared to visit 5 mass feeling score (P-value>0.05). The average improvement in mass feeling score at visit 5 was 62.5% respectively (P-value<0.001).

**Constipation**
The average constipation score is significantly higher at visit 1 compared visit 5 constipation score (P-value<0.001). The average improvement in constipation score at 5 was 89.2% (P-value<0.001).

**Effect on objective parameters**

**Number of pile masses**
The average no. of pile masses is significantly higher at visit 1 compared visit 5 average no. of pile masses (P-value<0.001). The average no. of pile masses at visit 1 did not differ significantly compared to no. of pile masses at visit 2 (P-value>0.05). The average improvement in no. of pile masses at visit 5 was 59.7% (P-value<0.001).

**Haemoglobin**
The average Hb concentration is significantly higher at visit 5 compared to average Hb at visit 1 (P-value<0.001). The average improvement in Hb at visit 5 was 1.76% (P-value<0.001).

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Visit 1 00 day (n=60)</th>
<th>Visit 2 7 day (n=60)</th>
<th>Visit 3 14 day (n=60)</th>
<th>Visit 4 21 day (n=60)</th>
<th>Visit 5 28 day (n=60)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Per Rectal Bleeding Score</td>
<td>1.28 ± 0.09</td>
<td>0.83 ± 0.09</td>
<td>0.50 ± 0.08</td>
<td>0.22 ± 0.05</td>
<td>0.10 ± 0.04</td>
</tr>
<tr>
<td>% Change</td>
<td>0.00%</td>
<td>36.80%</td>
<td>62.30%</td>
<td>84.90%</td>
<td>91.50%</td>
</tr>
<tr>
<td>Pain Score</td>
<td>0.10 ± 0.04</td>
<td>0.03 ± 0.02</td>
<td>0.00 ± 0.00</td>
<td>0.00 ± 0.00</td>
<td>0.00 ± 0.00</td>
</tr>
<tr>
<td>% Change</td>
<td>0.00%</td>
<td>63.70%</td>
<td>90.00%</td>
<td>100.00%</td>
<td>100.00%</td>
</tr>
<tr>
<td>Anal Pruritus score</td>
<td>1.12 ± 0.12</td>
<td>0.78 ± 0.11</td>
<td>0.47 ± 0.09</td>
<td>0.30 ± 0.08</td>
<td>0.12 ± 0.04</td>
</tr>
<tr>
<td>% Change</td>
<td>0.00%</td>
<td>33.30%</td>
<td>65.00%</td>
<td>81.70%</td>
<td>93.50%</td>
</tr>
<tr>
<td>Mass Filling Score</td>
<td>1.35 ± 0.06</td>
<td>1.35 ± 0.06</td>
<td>1.08 ± 0.09</td>
<td>0.78 ± 0.09</td>
<td>0.62 ± 0.09</td>
</tr>
<tr>
<td>% Change</td>
<td>0.00%</td>
<td>0.00%</td>
<td>21.70%</td>
<td>47.50%</td>
<td>62.50%</td>
</tr>
<tr>
<td>Constipation Score</td>
<td>1.20 ± 0.09</td>
<td>0.93 ± 0.09</td>
<td>0.59 ± 0.08</td>
<td>0.27 ± 0.06</td>
<td>0.18 ± 0.06</td>
</tr>
<tr>
<td>% Change</td>
<td>0.00%</td>
<td>24.50%</td>
<td>53.00%</td>
<td>83.30%</td>
<td>89.20%</td>
</tr>
</tbody>
</table>

Values are Mean ± Standard error of mean (SEM). P-values by Repeated measures analysis of variance (ANOVA).

**Table No.3 Improvement of subjective parameter**
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Table No.4 Improvement of parameter

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Test Statistic (Wilcoxon’s Signed Rank)</th>
<th>P-value</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Per rectum bleeding</td>
<td>6.365</td>
<td>0.001***</td>
<td>Highly Significant</td>
</tr>
<tr>
<td>pain</td>
<td>2.236</td>
<td>0.001***</td>
<td>Highly Significant</td>
</tr>
<tr>
<td>anal pruritus</td>
<td>5.757</td>
<td>0.001***</td>
<td>Highly Significant</td>
</tr>
<tr>
<td>constipation</td>
<td>6.551</td>
<td>0.001***</td>
<td>Highly Significant</td>
</tr>
<tr>
<td>Mass feeling (Prolapse)</td>
<td>6.345</td>
<td>0.001***</td>
<td>Highly Significant</td>
</tr>
<tr>
<td>No. of pile masses</td>
<td>5.767</td>
<td>0.001***</td>
<td>Highly Significant</td>
</tr>
<tr>
<td>Haemoglobin</td>
<td>4.789</td>
<td>0.001***</td>
<td>Highly Significant</td>
</tr>
</tbody>
</table>

P-values by Wilcoxon’s signed rank test. P-value<0.05 is considered to be statistically significant. *P-value<0.05, ***P-value<0.01, ****P-value<0.001, NS: Statistically Non-Significant.

Table No.5 Before (Visit 1, 00 day) and after (Visit 5, 28 day) study Comparison of Subjective and Objective parameter

DISCUSSION

Though there is anecdotal evidence demonstrating the use of herbal medicines in ano-rectal diseases, scientific studies in this field are grossly inadequate. Herbal products are attracting attention in developed countries too, as an alternative to high cost modern drugs and associated side effects.

The present clinical study was conducted in Unani medical college and hospital under the department of Jarahat to find out Efficacy of a Compound Unani Formulation Habb-e-Bawaseer Comprises of Bisfaij, Zaranbad, Maghz-e-Tukhm-e-Neem, Rasaut, Guggul and Gulab, 2 Habbs twice a day for 28 days Observations were noted at 1 visit (0-day), 2 visit (7th day), 3 visit (14th day), 4 visit (21th day) and 5 visit (28th days).

In this study, more than 60% of patients were in age range 25.0 – 34.0 years, and this may show important effect of life style on hemorrhoids pathogenesis. More than 70% of participants were married that shows low prevalence in age below 30. Distribution of sex was not normal. This can be interpreted as more common risk factors in men than in women, The reason of this may be due to the higher attendance of male patient in hospital or it may be due to shy to talk about or consult the physician for anorectal disorder Mean duration of disease was about 1

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year. Embarrassment in expression of anal discomfort, symptom tolerability, and self-medication by soothing agents may be of delayed reference to the physician and varied prevalence and incidence in different society. Rectal bleeding was the most common referral cause, but among symptoms, constipation was the most. It can probably postulate that people are more sensitive to bleeding than other symptoms or signs. Furthermore bleeding makes patients motivated to seek treatment faster. Constipation was the most common finding and had a significant correlation with main signs of hemorrhoids such as prolapse, rectal bleeding anal pain and anal pruritus.

This can emphasize on role of constipation as an important etiologic factor. Some theories have mentioned regarding the cause of hemorrhoids. The following factors have been suggested to contribute the development of hemorrhoids: Heredity, anatomic feature, nutrition, occupation, climate, senility, endocrine changes, food and drugs, infection, pregnancy, exercise, coughing, straining, vomiting, constipation, psychological problems, but the actual cause is remaining unclear. Meanwhile there are some evidences suggesting the possible biochemical mechanism in the pathogenesis of hemorrhoids. According to Unani traditional medicine, the main mechanism in majority types of hemorrhoids is accumulation of a biochemically changed blood in anorectal veins, which is called melancholic blood.18,19,20

Based on Unani traditional medicine, Habb-e-Bawaseer is stated to possess are Mushil-e-Sauda, Kasir-e-Riyah, MuqavviMedawaAma, MohallilAwram, MusaffiKhoon, Mulayan, Musakkin, Dafe-Bawaseer, Habis-e-Khoon-e-Bawaseer.21,22,23,24,25,26 Properties and seems to act at a microcirculatory level. These properties cover the main therapeutic goals in hemorrhoids treatment.

Therapeutic objectives in treatment of piles include shrinkage of piles mass, subsiding inflammation and preventing infection in the anal region, preventing bleeding from the rectum, relieving itching in the anal region, and relieving constipation as well. Of all the above, reduction in inflammation, bleeding, and pain bring immediate relief to the patient, and is of considerable importance to the treating physician. The study results showed that the Habb-e-bawaseer was effective in ameliorating ano-rectal conditions and associated signs and symptoms of hemorrhoids.

The current study, although with a limited sample size was able to demonstrate the superior efficacy of Habb-e-Bawaseer, in improving the ano-rectal symptoms in patients, particularly with Grade I hemorrhoids. Prompt resolution of bleeding symptom on the 7th day was also observed. Treatment demonstrated a significant response in Grade I and Grade II hemorrhoids, bleeding, pain, anal pruritus, Prolapse, and constipation. The study also demonstrates the importance of traditional medicine in the normal routine of a patient with hemorrhoids unless there is an absolute need for surgical intervention.

Limitations of the study included small sample size (no sample size calculation), open label design.

Conclusion
The efficacy of Habb-e-Bawaseer in the treatment of uncomplicated haemorrhoids grade 1 and 2 was evidenced in this work. More researches should be done regarding its safety. Comparison with other drug protocols, also upper doses and longer period.

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