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# AN OPEN LABEL RANDOMIZED CLINICAL STUDY TO EVALUATE THE EFFICACY OF *HABB-E-RASAUT* IN THE MANAGEMENT OF *BAWASEER-E- DAMWI*

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## ABSTRACT

*Bawaseer* (Haemorrhoids) arise from congestion of the internal and/ or external venous plexuses around the anal canal.[1] Haemorrhoids are dilated veins within the anal canal in the sub epithelial region formed by radicles of the superior and inferior rectal veins.[2] Multiple factor has been claimed to be the etiologies of haemorrhoidal development including constipation and prolonged straining. The abnormal dilatation and distortion of the vascular channel, together with destructive changes in the supporting connective tissue with the anal cushion is a paramount finding of haemorrhoiddiseases. Aim of the study, to evaluate the efficacy of *Habbe-Rasaut* in the managementof *Bawaseer-e-Damwi* (Haemorrhoid), to provide natural and cost effective Unani treatment for *Bawaseer-e-Damwi*(Haemorrhoid), to avoid the surgicalintervention and to develop a better understanding of the concept of *Bawaseer-e- Damwi* (Haemorrhoid) and its management in view of Unaniliterature. **Methods:** The present clinical study entitled as "An open label randomized clinical study, inclusion creiteria: An uncomplicated patient of *Bawaseer Damwi* (Hemorrhoid) was taken on the basis of clinical presentation, general and physical examination and per rectalexamination. Age group between 20-65 years of age, both male andfemale. Patients willing to participate and willing to give written informed consent. Patients attending OPD/IPD of reputed Unani medical college & hospital. Exclusion criteria: Patients suffering from any other systemic diseases like, Chronic Heart Diseases, Acute Renal Failure/Chronic Renal Failure, Diabetes mellitus, Tuberculosis, Endocrinedisorders. Pregnant women and lactatingmother. Patients with complicated *Bawaseer* (Haemorrhoid) such as a fistula or fissure or any malignant growth in analcanal and Mentally retarded patient. 2 Haboob given two times a day for90 days to all the patients. **Result:** The average improvement in **Per Rectal Bleeding**score at visit 2, visit 3 and visit 4 was 25.0%, 79.2% and 84.2% respectively (P-value<0.001 for all). The average improvement in **Anal pain** score at visit 2, visit 3, and visit 4 was 83.3%, 94.4%, and 100.0% respectively (P-value<0.001 for all).The average improvement in **Anal pruritus** score at visit 2, visit 3, and visit 4 was 74.1%, 93.1% and 93.1% respectively (P-value<0.001 for all).The average improvement observed in **Mass feeling** score at visit 2, visit 3 and visit 4 was 1.7%, 65.0% and 74.2% respectively (P- value<0.001 forall).The average improvement in **Constipation** score at visit 2, visit 3 and visit 4 was 10.8%, 60.8% and 85.0% respectively (P-value <0.001 forall). **Interpretation and conclusion:** Haemorrhoid is higher in those having *Saudawi* (melancholic blood) temperament. Derangement in quantity and quality of *sauda* and to some extent *Balgham* results in the development of piles. *Habb-e-Rasaut* which consists of *Rasaut, Guggul,* and *Post Halela zard* has been mentioned as *Mushil-e-Sauda* and *Mushil-e-Balgham* therefore, it helps in cleaning out (*Tanquia*) of causative matter and improving the condition, reduction in the symptoms of per rectal bleeding may be attributed to the action of *Habb-e-Rasaut* having Habis-*ul-dam* (haemostatic) and *Mohallil-e-Awram* (anti-inflammatory) properties, certainly helped in checking per rectal bleeding. *Habb-e-Rasaut* has some additional action such as *Muqawi Meda wa Ama* (Tonic for stomach and intestine), and *Muqawwi- e-Jigar* effects which help to improve function of digestive system.

**KEYWORDS:** *Bawaseer-e-damwi, Habb-e-Rasaut,* piles, VAS.

## INTRODUCTION

*Bawaseer* (Haemorrhoids) arise from congestion of the internal and/ or external venous plexuses around the anal canal.[1] Haemorrhoids are dilated veins within the anal canal in the sub epithelial region formed by radicles of the superior and inferior rectal veins.[2] Haemorrhoids is one of the oldest and commonest affliction which has been recognized since ancient time. The disease has universal distribution; perhaps five percent of general population suffers from Haemorrhoidal symptoms. But fifty percent of people aged fifty years or older have Haemorrhoid to some extent. Males are commonly

affected than females.[3] Haemorrhoids are rare in children but now a day's several reports state the occurrence of Haemorrhoids in children, and in elderly peoplealso.[4] The common man's term "piles" is derived from the latin word "pila" meaning a ball.[5,6,7] The word "Haemorrhoid" is derived from the Greek word Haema (Blood) and Rhoos (Flowing).[8]*Bawaseer* is plural of *basoor* which means wart or polyp like swelling.[9] It was probably *Buqrat* (Hippocrates) (460BC) who was the first to apply the name to the flow of the blood from the veins of the anus.[8] There is detailed description of *Bawaseer* in classical books authored by ancient unani physicians. *Buqrat* (Hippocrates) (460-377BC) described *Bawaseer* that it is the varicosities if internal mucus membrane of rectum in which the veins get swollen similar to the veins of the lowerlimb. [10]

*Habb-e-Rasaut* which comprises of *post Halela zard*, *Rasaut* and *Muqil*.[11,12] Their combined effects are *Mushil-e-Sauda, Kasir-e-Riyah* (carminative), *Muqavvi Meda-wa-Ama, Mohallil Awram* (Anti- inflammatory), *Musaffi Khoon* (Blood purifier), *Mulayyan* (Laxative), *Musakkin* (Analgesic), *Dafe-Bawaseer* (Anti-Haemorrhoidal), *Habis-e-Khoon-e- Bawaseer* (Anti-Haemorrhagic for Bleeding Piles) and all these effects may help to manage the condition of.[14,15,16,17,18,19,20]

## MATERIALS AND METHODS

**Study Design:** An open label randomized clinical study to evaluate the efficacy of Habb-e-Rasaut in the management of 'Bawaseer-e- Damwi' was conducted at reputed Unani Medical College & Hospital, under the department of *Moalijat*. Ethical clearance was obtained from institutional ethical committee. Present clinical study was conducted as per guide lines of Indian Council of Medical Research (ICMR).

**Sample size calculation**

**The sample size was 60 patients.**

**Selection criteria:** An uncomplicated patient of *Bawaseer Damwi* (Hemorrhoid) was taken on the basis of clinical presentation, general and physical examination and per rectalexamination. Age group between 20-65 years of age, both male andfemale. Patients willing to participate and willing to give written informed consent. Patients attending OPD/IPD of reputed Unani medical college & hospital.

**Exclusion criteria:** Patients suffering from any other systemic diseases like, Chronic Heart Diseases, Acute Renal Failure/Chronic Renal Failure, Diabetes mellitus, Tuberculosis, Endocrinedisorders. Pregnant women and lactatingmother. Patients with complicated *Bawaseer* (Haemorrhoid) such as a fistula or fissure or any malignant growth in analcanal and Mentally retarded patient.

**Participants:** Any patient, giving history of uncomplicated *Bawaseer* (Haemorrhoid) in the age group of 20 to 65 years, was selected from *Moalijat* OPD as a research subject. From the diagnosed patients, only those people who fulfill the inclusion criteria and willing to give written informed consent, were included in the study.

**The sample size was 60 patients**

**Investigations:** Haemogram was done before and after the treatment.

**Method of preparation, dosage and mode of administration of test drug:** All the crude medicine was purchased from authentic sources. Identification, quality confirmation was done at department of *Ilm-ul-Advia. Huboob* (pills) was prepared at department of *Ilm-ul-Saidla*, of Unani Medical College and Hospital according to the method described in Unani books with strictly following the good manufacturing practice (GMP) norms.

**Methods of preparation:** *Guggul*and *Rasaut* are soaked separately in water over night. Inmorning *Guggul* is heated, once it gets cooled it is rubbed with hands whereas Rasaut is rubbed without heating to the extent to get dissolved in water than kept for some time so thatany impurities if present can gets settle down at the bottom. If required these solutions can again be heated to make it thick. *Post halela zard* is crushed and sieved with the help of 80 number filter. Later on the solution of *Rasaut* and *Guggul*is added in it, so that a suitable consistency is reached to make pill or *Habb* of size number 4. It is stored in a clean and dry container

**Table-1: Ingredients of *Habb-e-Rasaut.***

| S.No | Ingredient | English name | Quantity |
|---|---|---|---|
| 1 | *Post-e-HalelaZard* | Terminalia chebula retz | 50 grams |
| 2 | *Rasaut* | Berberis aristata DC | 50 grams |
| 3 | *Guggul* | Commiphoramukul | 50 grams |

**Form of drug:** The drug was used in the form of *Habb* (Pills).

**Dose of drug:** 2 *Habb* twice a day with water

**Subjectiveparameter:** Rectalbleeding[21,22] Anal pain,[5,21,22] Analpruritus,[5,21] Mass feeling,[21,22]constipation [22]

**Study procedure:** The individual assessmentwas carried out on the basis of history, physical,general and systemic examination. The patients who fulfilled the inclusion criteria and had also given written consent were included in the clinical trial. Two Habb (pills) two times a day were given for a period of 90 days. Which was prepared from *Post Halela Zard*, *Rasaut* and *Guggul.* All the patients were informed about the duration of the study, expected disadvantages and advantages on consuming it. Observations were noted down in the case reportform. Patients were advised to come regularly in P.G. OPD, Dept. of *Moalijat* for their follow up.

**Treatment outcome:** It is inferred that most of the subjective parameters i.e. per rectal bleeding, anal pain, anal pruritus, mass feeling (prolapse) and constipation were improved. The average improvement in per rectal bleeding score at visit 2, visit 3, and visit 4 was 25.0%, 79.2%, and 84.2% respectively (P<0.001 for all) and average improvement in anal pain score at visit 2, visit 3, and visit 4 was 83.3%, 94.4%, and 100.0% respectively (P-value<0.001 for all). Anal pruritus score improvement on visit 2, visit 3, and visit 4 was found as 74.1%, 93.1%, and 93.1% respectively on an average. (P- value<0.001 for all). The average improvement in mass feeling (Prolapse) score at visit 2, visit 3and visit 4 was 1.7%, 65.0% and 74.2%respectively (P-value<0.001 for all). Constipation improved by 10.8%, 60.8% and 85.0% at visit 2, visit 3 and visit 4 respectively (P-value<0.001for all).

**Objective Parameter:** Proctoscopic examination: - Present: - If present- No. ofpiles, Absent. Haemogram- Before and after treatment forhaemoglobin.

## RESULTS

**Table 2: Demographic distribution of *Bawaseer-e-Damwi* (Haemorrhoids) patients (n=60).**

| **Age group** | **No of cases** | **% of cases** |
|---|---|---|
| **<25.0** | 22 | 36.7 |
| **25.0 – 34.0** | 24 | 40.0 |
| **>=35.0** | 14 | 23.3 |
| **Total** | 60 | 100.0 |
| **Sex** | **No. of cases** | **% of cases** |
| **Male** | 24 | 40.0 |
| **Female** | 36 | 60.0 |
| **Total** | 60 | 100.0 |
| **Marital status** | **No. of cases** | **% of cases** |
| **Married** | 24 | 40.0 |
| **Unmarried** | 36 | 60.0 |
| **Total** | 60 | 100.0 |
| **Diet Type** | **No. of cases** | **% of cases** |
| **Vegetarian** | 0 | 0.0 |
| **Mixed** | 60 | 100.0 |
| **Total** | **60** | **100.0** |
| **Diet Type (Spicy status)** | **No. of cases** | **% of cases** |
| **Spicy** | 56 | 93.3 |
| **Non Spicy** | 4 | 6.7 |
| **Total** | **60** | **100.0** |
| **Diet Type (Spicy status)** | **No. of cases** | **% of cases** |
| **Spicy** | 56 | 93.3 |
| **Non Spicy** | 4 | 6.7 |
| **Total** | **60** | **100.0** |
| **Diet Type (Spicy status)** | **No. of cases** | **% of cases** |
| **Spicy** | 56 | 93.3 |
| **Non Spicy** | 4 | 6.7 |
| **Total** | **60** | **100.0** |
| **According to occupation status** | | |
| **Occupational Status** | **No. of cases** | **% of cases** |
| **Student/unemployed** | 33 | 55.0 |
| **House Wife** | 11 | 18.3 |
| **Service(office work)** | 2 | 3.4 |
| **Worker (labour )** | 14 | 23.3 |
| **Total** | **60** | **100.0** |
| **Socio-economic status** | **No. of cases** | **% of cases** |
| **Lower Class** | 7 | 11.7 |
| **Upper Lower Class** | 0 | 0.0 |
| **Lower Middle Class** | 21 | 35.0 |
| **Upper Middle Class** | 27 | 45.0 |
| **Upper Class** | 5 | 8.3 |
| **Total** | 60 | 100.0 |

**Table -3: The distribution according to Mizaj of the cases studied (n=60).**

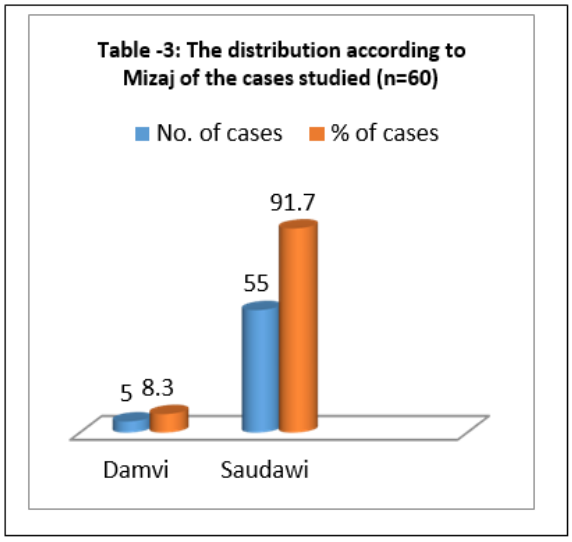
| Type of Mizaj | No. of cases | % of cases |
|---|---|---|
| **Damvi** | 5 | 8.3 |
| **Saudawi** | 55 | 91.7 |
| **Total** | **60** | **100.0** |

**Table 4: Improvement in Per Rectal Bleeding (n=60).**

| Per RectalBleeding | Visit 1 (n=60) | | Visit 2 (n=60) | | Visit 3 (n=60) | | Visit 4(n=60) | |
|---|---|---|---|---|---|---|---|---|
| | N | % | N | % | N | % | n | % |
| **Absent** | 0 | 0.0 | 5 | 8.3 | 38 | 63.3 | 43 | 71.7 |
| **Mild** | 36 | 60.0 | 51 | 85.0 | 21 | 35.0 | 17 | 28.3 |
| **Moderate** | 24 | 40.0 | 4 | 6.7 | 1 | 1.7 | 0 | 0.0 |
| **Severe** | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| **Total** | 60 | 100.0 | 60 | 100.0 | 60 | 100.0 | 60 | 100.0 |
| **% Change(Mean)** | 0.0% | | 25.0% | | 79.2% | | 84.2% | |

**Table 5: The statistical comparison of Improvement in Per Rectal Bleeding (n=60).**

| Comparisons (Pair-wise) | Test Statistic (Wilcoxon'sSigned Rank) | P-value | Significance |
|---|---|---|---|
| **Visit 1 v Visit 2** | 5.000 | 0.001*** | Highly Significant |
| **Visit 1 v Visit 3** | 7.323 | 0.001*** | Highly Significant |
| **Visit 1 v Visit 4** | 7.175 | 0.001*** | Highly Significant |



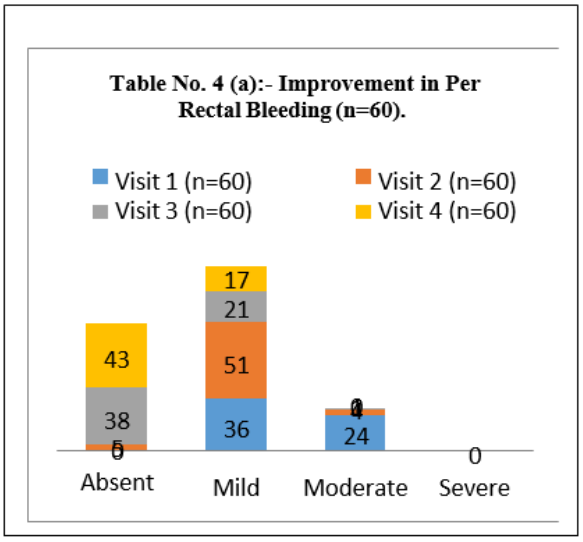




**Table 6: Improvement in Pain (n=60).**

| Pain score | Visit 1 (n=60) | | Visit 2 (n=60) | | Visit 3 (n=60) | | Visit 4 (n=60) | |
|---|---|---|---|---|---|---|---|---|
| | N | % | N | % | N | % | N | % |
| **Absent** | 42 | 70.0 | 57 | 95.0 | 59 | 98.3 | 60 | 100.0 |
| **Mild** | 18 | 30.0 | 3 | 5.5 | 1 | 1.7 | 0 | 0.0 |
| **Total** | 60 | 100.0 | 60 | 100.0 | 60 | 100.0 | 60 | 100.0 |
| **%changes (mean)** | 0.0% | | 83.3% | | 94.4% | | 100.0% | |

**Table 7: The statistical comparison of improvement in Pain (n=60).**

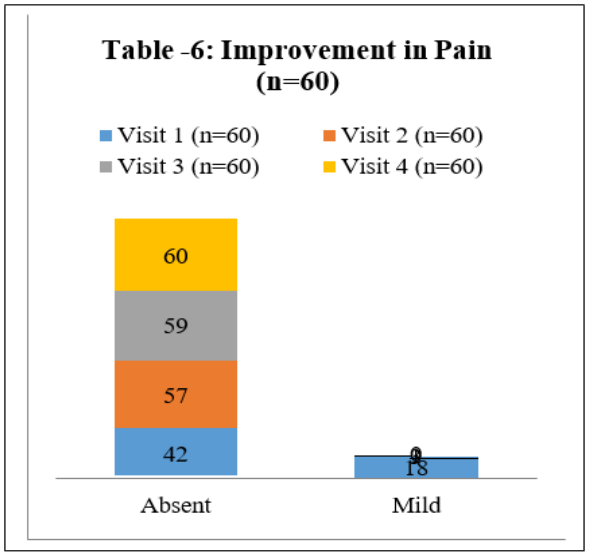
| Comparisons (Pair-wise) | Test Statistic(Wilcoxon's Signed Rank) | P-value | Significance |
|---|---|---|---|
| **Visit 1 v Visit 2** | 3.873 | 0.001*** | Highly Significant |
| **Visit 1 v Visit 3** | 4.123 | 0.001*** | Highly Significant |
| **Visit 1 v Visit 4** | 4.243 | 0.001*** | Highly Significant |

**Table 8: Improvement in Anal pruritus (n=60).**

| Anal pruritis score | Visit 1 (n=60) | | Visit 2 (n=60) | | Visit 3 (n=60) | | Visit 4(n=60) | |
|---|---|---|---|---|---|---|---|---|
| Grading | N | % | N | % | N | % | N | % |
| Absent | 31 | 51.7 | 51 | 85.0 | 58 | 96.7 | 58 | 96.7 |
| Mild | 28 | 46.7 | 9 | 15.0 | 2 | 3.3 | 2 | 3.3 |
| Moderate | 1 | 1.6 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| % changes (mean) | 0.0% | | 74.1% | | 93.1% | | 93.1% | |

**Table 9: The statistical comparison of improvement in Anal pruritus (n=60).**

| Comparisons(Pair-wise) | Test Statistic(Wilcoxon's Signed Rank) | P-value | Significance |
|---|---|---|---|
| Visit 1 v Visit 2 | 4.379 | 0.001*** | Highly Significant |
| Visit 1 v Visit 3 | 5.112 | 0.001*** | Highly Significant |
| Visit 1 v Visit 4 | 5.112 | 0.001*** | Highly Significant |



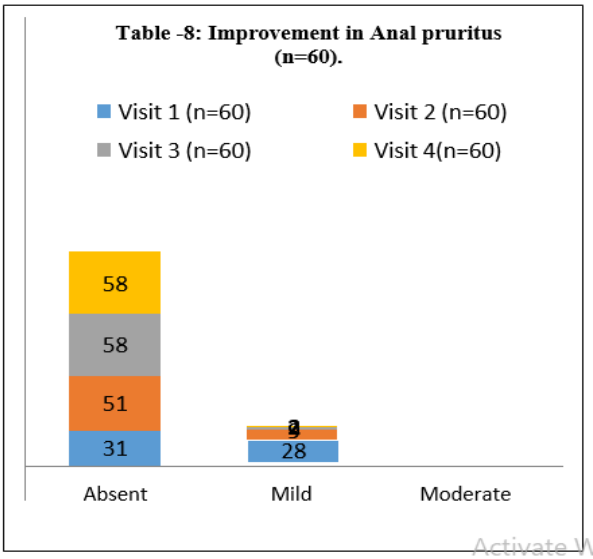




**Table -10: Improvement in Mass feeling (prolapse). (n=60).**

| Mass feeling prolapse | Visit1 (n=60) | | Visit2 (n=60) | | Visit3 (n=60) | | Visit4 (n=60) | |
|---|---|---|---|---|---|---|---|---|
| Grading | N | % | N | % | N | % | N | % |
| Absent | 0 | 0.0 | 1 | 1.7 | 39 | 65.0 | 44 | 73.3 |
| 1st grade | 59 | 98.3 | 58 | 96.6 | 20 | 33.3 | 16 | 26.7 |
| 2nd grade | 1 | 1.7 | 1 | 1.7 | 1 | 1.7 | 0 | 0.0 |
| 3rd grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| 4th grade | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |
| % changemean | 0.0% | | 1.7% | | 65.0% | | 74.2% | |

**Table -11: Statistical comparison of improvement in Mass feeling (prolapse). (n=60).**

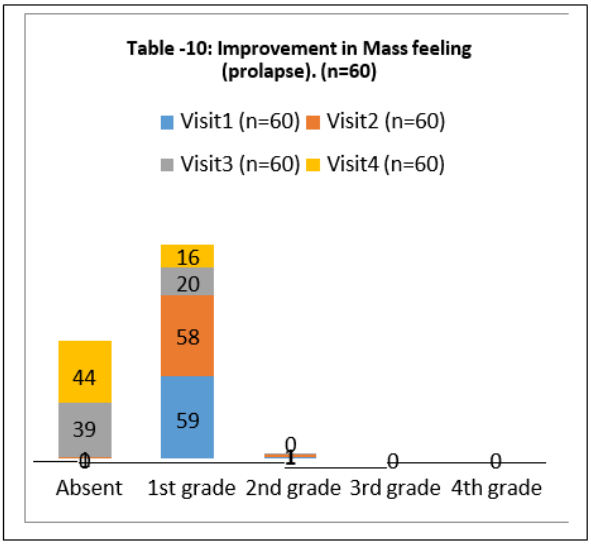
| Comparisons(Pair-wise) | Test Statistic(Wilcoxon's Signed Rank) | P-value | Significance |
|---|---|---|---|
| Visit 1 v Visit 2 | 1.000 | 0.317NS | Non-Significant |
| Visit 1 v Visit 3 | 6.245 | 0.001*** | Highly Significant |
| Visit 1 v Visit 4 | 6.708 | 0.001*** | Highly Significant |

**Table -12: Improvement in Constipation (n=60).**

| Constipation score | Visit1 (n=60) | | Visit2 (n=60) | | Visit3 (n=60) | | Visit4 (n=60) | |
|---|---|---|---|---|---|---|---|---|
| Grading | N | % | N | % | N | % | N | % |
| Absent | 0 | 0.0 | 1 | 1.7 | 29 | 48.3 | 43 | 71.7 |
| Mild | 44 | 73.3 | 54 | 90.0 | 30 | 50.0 | 17 | 28.3 |
| Moderate | 16 | 26.7 | 5 | 8.3 | 1 | 1.7 | 0 | 0.0 |
| % mean change | 0.0% | | 10.8% | | 60.8% | | 85.0% | |

**Table -13: The statistical comparison of improvement in Constipation (n=60).**

| Comparisons (Pair-wise) | Test Statistic (Wilcoxon's SignedRank) | P-value | Significance |
|---|---|---|---|
| **Visit 1 v Visit 2** | 3.464 | 0.001*** | Highly Significant |
| **Visit 1 v Visit 3** | 6.633 | 0.001*** | Highly Significant |
| **Visit 1 v Visit 4** | 7.681 | 0.001*** | Highly Significant |



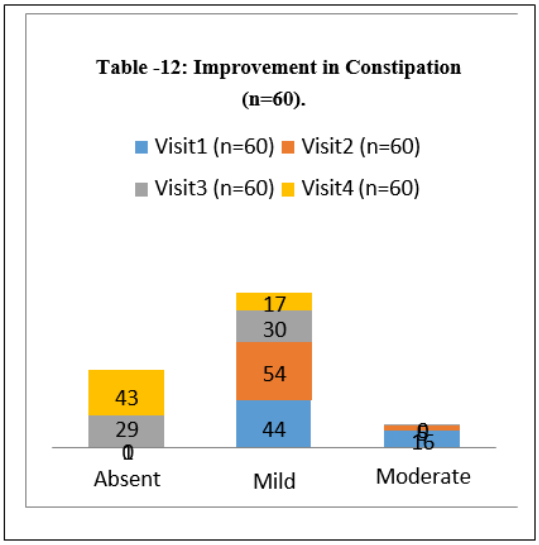




**Table 14: Reduction in No. of pile masses in 4 visits. (n=60).**

| No.of PileMasses | Visit1 (n=60) | | Visit2 (n=60) | | Visit3 (n=60) | | Visit4 (n=60) | |
|---|---|---|---|---|---|---|---|---|
| **Grading** | N | % | N | % | N | % | N | % |
| **0** | 0 | 0.0 | 1 | 1.7 | 39 | 65.5 | 45 | 75.0 |
| **1** | 53 | 88.3 | 52 | 86.6 | 18 | 30.0 | 14 | 23.3 |
| **2** | 7 | 11.7 | 7 | 11.7 | 3 | 5.0 | 1 | 1.7 |
| **% Meanchange** | 0.0% | | 1.7% | | 68.3% | | 77.5% | |

**Table -15: The statistical comparison of reduction in No. of pile masses in 4 visits. (n=60).**

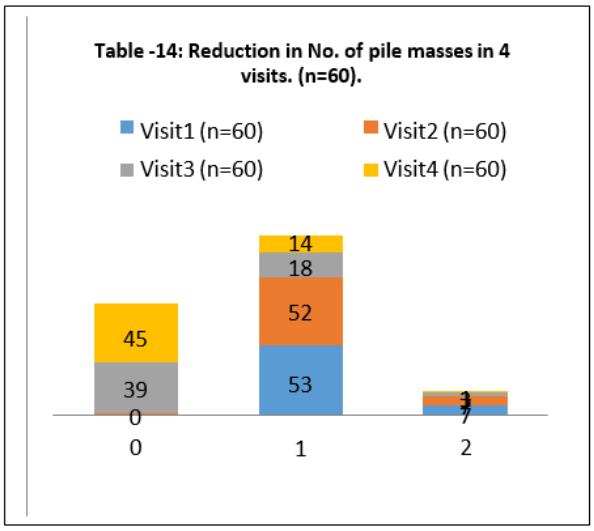
| Comparisons (Pair-wise) | Test Statistic(Wilcoxon's Signed Rank) | P-value | Significance |
|---|---|---|---|
| **Visit 1 v Visit 2** | 1.000 | 0.317$^{NS}$ | Non-Significant |
| **Visit 1 v Visit 3** | 6.557 | 0.001*** | Highly Significant |
| **Visit 1 v Visit 4** | 6.741 | 0.001*** | Highly Significant |

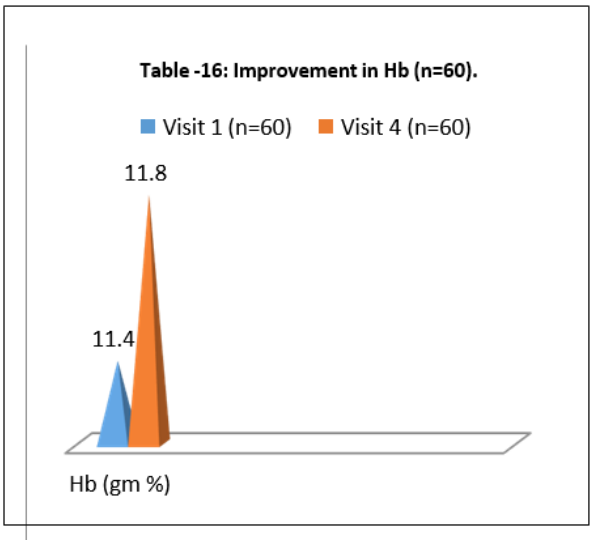
**Table -16: Improvement in Hb (n=60).**

| Parameter | Visit 1 (n=60) | Visit 4 (n=60) |
|---|---|---|
| **Hb (gm%)** | 11.4 ± 0.72 | 11.8 ± 0.96 |
| **% Change** | 0% | 3.17% |

**Table -17: The statistical comparison of improvement in Hb (n=60).**

| Comparisons(Pair-wise) | Test Statistic(Wilcoxon's Signed Rank) | P-value | Significance |
|---|---|---|---|
| **Visit 1 v Visit 4** | 3.333 | 0.001*** | Highly Significant |




## DISCUSSION

The aim of study, to evaluate the efficacy of *Habb-e-Rasaut* in the management of Bawaseer-e-Damwi, the present study is conducted in reputed Unani Medical College and hospital under the department of *Moalijat*. After completion of study the data was tabulated and statistically analyzed. The data on qualitative characteristics is shown as n (% of cases) and the data on quantitative characteristics is presented as Mean ± Standard deviation (SD). The statistical significance of difference of severity of qualitative and quantitative variables across several visits is tested using Wilcoxon's signed rank test. All the results are shown in tabular as well as graphical format to visualize the statistically significant difference moreclearly.

**Age:** In the present study, patients between 20 to 65 years were included. From the table no.10 and figure no. 22, out of 60 cases studied, 22 cases (36.7%) had age less than 25 years, 24 (40.0%) between 25 to 34 years and 14 cases (23.3%) had age more than or equal to 35 years. The mean ± SD, (Min - Max) of the ages of study groups was 29.7 ± 10.0 years. The minimum age was 20 years and maximum age was 58 years. According to Harrison's principles of internal medicine, the prevalence of hemorrhoid is not selective for age and this data also is not found following any trend. [13]

**According to sex**

Table no. 2 show that out of 60 cases studied, 24 cases (40.0%) were males and36 cases (60.0%) were females. Majority of the cases studied were females. As per different reports incidence in both sexes was approximately the same, this is not real reflection of male and female ratio ofgeneral population of India. On other hand according to Harrison's principles of internal medicine, the prevalence of haemorrhoid is not selective for sex.[13]

**According to marital status**

As shown in table no.2, out of 60 cases studied, 24 cases (40.0%) were married and 36 cases (60.0%) were unmarried. It is obvious that marital status is not an influencing factor for thisdisease.

**According to diet preferred**

As shown in table no. 2 out of 60 cases studied, 0 cases (0.0%) had vegetarian diet while all 60 cases (100.0%) had mixed diet. In most of the medical literature, it is mentioned that those people whose diet contains less quantity of fibers, consistently exhibit much higher incidence & symptoms of haemorrhoids. Fibers consist of indigestible complex carbohydrate that absorb water and also bulk up stool, which is softer and easier on the tissues of the rectum and anal canal to handle. Since major contribution to haemorrhoid is thought to be hard stool pulling on the supporting structure that anchor anal pillow in place, taking the simple step of increasing dietary fiber and fluid intake is critical to address haemorrhoids. As mentioned in classical Unani texts, the major cause for the developmentof haemorrhoid is *Saudavi maadda* and *ghaleez dam* (viscid blood).[9,13,23,24,25] According to Unani physicians, *ghaleez dam* is produced by *ghaleez* and *kaseef aghziya*, a wide variety of animal origin food lies in the category of *ghaleez* and *kaseef agziya*. Therefore, it can be inferred from the above data that haemorrhoid is found in excess in those patients who are on mixed diet. It is mentioned in the literature, those who eat more meat are prone to develop haemorrhoids.

**According to type of diet (Spicy status)**

As shown in table no.2, out of 60 cases studied, 56 cases (93.3%) prefer spicy diet and 4 cases (6.7%) had non-spicydiet. Majority of the cases studied prefer spicy diet. It is mentioned in Unani literature that excessive consumption of meat, hot chilies, and spicy food is a contributive factor.[13,25]

**According to regularity of diet**

As shown in table no 2, out of 60 cases studied 47 cases (78.3%) had regular diet and 13 cases (21.7%) had

irregular diet. Majority of the cases studied had regular diet. Though it seems that patients on regular time schedule of meal are prone to *Bawaseer*, but neither it is logical nor it was found mentioned in any study on thedisease.

**According to nature of work**

As shown in table no.2, out of 60 cases studied, 0 cases (0.0%) had sedentary work, 38 cases (63.3%) had moderate work and 22 cases (36.7%) had strenuouswork. Majority of the cases studied had moderate work. However, it was reported in both Unani and modern literature that people have sedentary life style are proneto piles but data projected in this study is not in the accordance of them. It may be either due to that highly educated and rich people having sedentary life avoid being part of clinical studies or regular visitors of O.P.D under study fall in middle class.

**According to occupation**

As shown in table no.2, study cases are enquired about their occupation as most of them are at potential risk factor for the development of haemorrhoids. Out of 60 cases studied, 33 cases (55.0%) were student/ unemployed, 11 cases (18.3%) were house wife, 2 cases (3.4%) were doing service i.e. office job and 14 cases (23.3%) worked as labour. It was observed that the incidence of haemorrhoid is more instudent/unemployed because they consume junk foods frequently and their physical activities are less or moderate which is known to be a risk factor for the development of hemorrhoids.

**According to socio-economic status**

As shown in table no.2, out of 60 cases studied, 7 cases (11.7%) were from lower socio-economic class. 0 cases (0.0%) belong to upper lower socio-economic class, 21 cases (35.0%) fall in lower middle socio-economic class, 27 cases (45.0%) were from upper middle socio-economic class and 5 cases (8.3) stand in upper socio-economic class. Majority of cases studied had upper middle socio- economic class.

**According to *Mizaj* (Temperament)**

From the table no.3, out of 60 cases studied, 5 cases (8.3%) were having *Damwi mizaj* and 55 cases (91.7%) have *Saudawi mizaj*. Majority of the cases studied were of *Saudawi mizaj*. It is mentioned in the classical Unani literature that the main humour responsible for generation of *Bawaseer* is *Sauda*. Even people with *Saudawi mizaj* are prone to *Bawaseer*. This finding is in accordance of Unani theory.[25]

**Effect on subjective parameters;Per Rectal bleeding**

It is evident from table no.4, out of 60 cases, on 1st visit (o day) 36 cases (60.0%) were having mild per rectal bleeding, 24 cases (40.0%) had moderate per rectal bleeding. On 2nd visit, 5 cases (8.3%) did not had bleeding, while 51 cases (85.0%) had mild, 4 cases (6.7%) had moderate per rectal bleeding. On 3rd visit that is on 60th day 38 cases (63.3%) devoid of bleeding. 21 cases (35.0%) had mild while 1 case (1.7%) had moderate per rectal bleeding whereas 0 cases had severe bleeding. On 4th visit i.e. on 90th day out of 60 cases 17 (28.3%) had per rectal bleeding and that was mild only. The study shows a gradual decrease in per rectal bleeding.

This reduction in the symptoms of per rectal bleeding may be attributed to the action of *Habb-e-Rasaut* which consists of *Rasaut* and *Guggul*. These drugs being *Habis-ul-dam* (haemostatic) and *Mohallil-e-Awram* (anti-inflammatory) certainly helped in checking per rectal bleeding and this effect is quite noticeable.[11,12] As for as severity of per rectal bleeding concerns, it was shows in table no. 5 that level of severity is highest in visit 1(60%) which dropped down to 28.3% in visit 4, which is highly significant (P<0.001). The severity score of per rectal bleeding improved by 25.0%, 79.2%, and 84.2% in visit 2, visit 3 and visit 4 respectively with P< 0.001 for all.

**Anal Pain**

As it is evident from table no.6, out of 60 cases, on 1st visit 42 (70.0%) cases did not have anal pain, 18 (30.0%) cases had mild pain. On 2nd visit that is 30th day, 57 (95.0%) cases did not have anal pain while 3 (5.0%) cases had mild anal pain. On 3rd visit that is on 60th day. 59 (98.0%) cases had no anal pain while only 1(1.7%) case had mild anal pain. On4th visit that is on 90th day no case of anal pain was noted. This reduction in the symptoms of anal pain is most probably due to the actions of drugs like *Rasaut, Guggul* and *Post Halela Zard* which are *Musakkin Alam* (analgesic), and*Mohallil-e-waram* (anti-inflammatory).[11,12]

The distribution of severity of pain is significantly higher at visit 1 compared to visit 2, visit 3 and visit 4 (P-value <0.001 for all). The severity of pain improved significantly at visit 2, visit 3, and visit 4 compared to visit 1 (P-value < 0.001 for all). The average improvement in pain at visit 2, visit 3 and visit 4 was 83.3%, 94.4% and 100.0% respectively (P-value < 0.00 for all). Table no-7

**Anal Pruritus**

From the table no.8, on the 1st visit (0 day) out of 60 cases, 31 (51.7%) cases did not have anal pruritus, 28 (46.7%) cases had mild itching while only 1 (1.6%) case had moderate anal pruritus. On 2nd visit (30thday), 51 (85%) cases did not have pruritus, mild itching was present in 9 (15.0%) cases, and no case of moderate anal pruritus was noted. On 3rd visit (60thday) there was no itching in 58 (96.7%) cases and only mild anal pruritus was noted in rest of the 2 cases (3.3%). On 4th visit (90th day) there are 58 (96.7%) cases who did not have any itching; only 2 (3.3%) case had mild type of anal pruritus. There was a gradual decrease in anal pruritus. This reduction in the symptom may be associated with the properties such as *Mohallil-e- waram* and *Musaffi khoon* of *Rasaut, Guggul* and *Post Halela*

*zard*, components of*Habb-e- Rasaut.* [11,12]

As shown in table no. 9, The average anal pruritus score is significantly higher at visit 1 compared to visit 2, visit 3 and visit 4 anal pruritus score (P-value<0.001 for all). The average improvement in anal pruritus score at visit 2, visit 3, and visit 4 was 74.1%, 93.1% and 93.1% respectively (P-value<0.001 for all). The severity of anal pruritus improvedsignificantly at visit 2, visit 3, and visit 4 compared to visit 1 anal pruritus score (P-value <0.001 forall).

**Mass feeling (Prolapse)**

As it is evident from table no-10, on the 1st visit 0 day, out of 60 cases, 59 (98.3%) cases showed mass feeling of grade 1 and only 1 patient (1.7%) had grade 2 prolapse. On 2nd visit that is 30th day, 1 (1.7%) case of grade 0, 58 (96.6%) case of grade 1, 1 (1.7%) case of grade2 were noted. On 3rd visit (60th day), 39 (65.0%) case of grade 0, 20 (33.3%) case of grade 1 and 1 (1.7%) case of grade 2 was noted. On 4th visit that is 90th day, 44 (73.3%) case of grade 0, 16 (26.7%) case of grade 1 are recorded. There was a gradual decrease in mass feeling (prolapse). Components of *Habb- e-Rasaut* are not only anti-inflammatory which help to reduce inflammation directly but they have *Musaffi-e-dam* and *Mushil-e-sauda a*ctivities also. [11,12]Theseaction of drugs removes morbid matters from body, which ultimately reduce the pressure on veins and decrease mass volume.

As shown in table no.11, The average mass feeling score is significantly higher at visit 1 compared to visit 2, visit 3 and visit 4 mass feeling score (P-value<0.001 for all). The average improvement observed in mass feeling score at visit 2, visit 3 and visit 4 was 1.7%, 65.0% and 74.2% respectively (P- value<0.001 forall).

**Constipation**

From the table no.12, on the 1st visit (0 day) out of60 cases none had constipation, 44(73.3%) cases had mild constipation whereas 16 (26.7%) cases had moderate constipation. On 2nd visit (30th day), constipation was absent in only 1 case (1.7%), 54 (90.0%) cases had mild constipation while 5 (8.3%) had moderate constipation. On 3rd visit, 29 (48.3%) cases did not have constipation while 30 (50.0%) cases had mild constipation whereas only 1 (1.7%) case had moderate constipation. On 4thvisit, In 43 (71.7%) cases constipation was absent, 17 (28.3%) cases had mild constipation whereas no case was observed for moderate or severe constipation. There was gradual decrease in constipation. This reduction in the symptoms of constipation may be associated with the *Kasir- e-Riya* and *Mulayyan* activities of*Habb-e- Rasaut.* [11,12]

As shown in table no-13 The average distribution of severity of constipation score is significantly higher at visit 1 compared to visit 2, visit 3, and visit 4 constipation score (P-value0.001 for all). The average improvement in constipation score at visit 2, visit 3 and visit 4 was 10.8%, 60.8% and 85.0% respectively (P-value <0.001 forall). Table no-13.

**Effect on Objective parameter:Number of pile mass**

As it is evident from table no.14, the no. of pile massesfound1in53(88.3%) peopleandonly 7(11.7%)had2 pilemasses onlyinvisit1.Onvisit2again7patients(11.7 %) had 2 pilemassesbut52 patients (86.6%)recorded to have only 1 pile mass while 1patient (1.7%) found having no any pile mass. On visit 3, 3 patients (5.0%) had 2 pile masses and 18 patients (18.0%) recorded to have only 1 pile mass while 39 patients (65.0%) found having no any pile mass. On visit 4 only 1 patient (1.7%) had 2 pile masses and 14 patients (23.3%) recorded to had only 1 pile mass while 45 patients (75.0%) found having no any pile mass. The average improvement in no. of pile masses at visit2, visit 3 and visit 4 was 1.7%, 68.3% and 77.5% respectively (P-value <0.001 for all). Table no-15. There was gradual and remarkable decrease in number of pile masses. This reduction may be attribute to reduction of intra-abdominal pressure which ultimately result in reduction of pile masses *Habb-e-Rasaut* is *mulayyan* and *kasir-e-Riya* in its effect, it removes the constipation and reduce intra-abdominal pressure. Besides, it is *mushily-e-Sauda* and *Balgham* also therefore helps in excreting execs quantity of *khilt-e-Sauda* and *Balghum* from blood. In this way, *Dam-e-ghaleez* get diluted and pressure on veins decreased, which ultimately reduce the dilatation of veins i.e. piles.

**Haemoglobin**

As it is evident from table no.16, the average Hb concentration is significantly higher at visit 4 compared to average Hb at visit 1 (P-value<0.001 for all). The average improvement in Hb at visit 4 was 3.17% (P-value<0.001). table no-17.

Thegradual and remarkable increase in haemoglobin may be linked to *Habisuddam* property of*Habb-e-Rasaut*. Haemorrhoids is one of the oldest and commonest affliction which has been recognized since ancient time and has been discussed by laureate unaniphysician since that time. They have discussed about various factors related to this disease like age, sex, diet and socio-economic status.

The disease has universal distribution; perhaps five percent of general population suffers from haemorrhoidal symptoms. But fifty percent of people aged fifty years or older have haemorrhoid to some extent.

Males are commonly affected than females. Haemorrhoids are rare inchildren but now a day's several reports state the occurrence of haemorrhoids in children, and in elderly people also. Among all above factors, those related to life style are modifiable such as diet; sedentary life style (less exercise) and consumption of meat, hot chilies, and spicy food are more prone to develop *Bawaseer*. It is unambiguous that chances of

haemorrhoid can be minimized by controlling these factors therefore; all the patients selected for this study were fully explained and counseled about healthy life style and dietary habits furthermore this is taken as obligation forfuturealso.

*Bawaseer* (Haemorrhoids) arise from congestion of the internal and/ or external venous plexuses around the anal canal. The main symptoms are bleeding during or after defecation, pain, and prolapse, Itching and peri-anal soiling. The basic cause of bulging of veins (piles) is increase in intra- abdominal pressure as in the case of constipation. *Habb-e-Rasaut* composition (*Post halela zard, Rasaut and Guggul*) has been proven to possess *Habis-ul-Dam* (Haemostatic), *Mohallil-e- Waram* (Anti-inflammatory) and *Mussakin-e-Alam* (Analgesic) and laxative and *Dafe Bawaseer* scientifically,and in this study it was found to subside all sign and symptoms i.e. per rectal bleeding, pain, prolapse and itching and anal soiling significantly. *Habb-e Rasaut* has compound like *Guggul* and *Post Halela Zard* having laxative and carminative properties. They help in removing constipation and ultimately lower intra- abdominal pressure and mitigate the symptoms and signs ofdisease.[11,12] According to Unani line of treatment the very first step has to be *Tanqiya mawad* (Diversion of morbid humor). Those therapeutic agents having *mushil* effect to that particular matter or *Khilt* have to be used. Post Halela Zard and Guggul present in *Habb-e-Rasaut* plays instrumental role in removing *Sauda* and *Balgham* in excess from body additionally. The test drug *Habb-e-Rasaut* composition of post *Haela zard and Guggul* is proved to be very useful in Bawaseer-e-Damwi. Reduction in the symptom of per rectal bleeding may be attributed to the action of *Habb-e-Rasaut* which consists of *Rasaut* and *Guggul* acting as *Habisud Dam* (haemostatic). Symptoms of anal pain reduced most probably due to the actions of all the drugs which are *Musakkin Alam* (analgesic), and *Mohallil-e-Waram* (anti-inflammatory). Relief in anal pruritus may be associated with combined properties such as *Mohallil-e- Waram* and *Musaffi khoon* of *Rasaut, Guggul* and *Post Halela zard*.[11,12] Furthermore, this study and old literature affirmed that incidence of haemorrhoid is higher in those having *Saudawi* (melancholic blood) temperament. *Habb-e-Rasaut* which consists of *Rasaut, Guggul,* and *Post Halela zard*, has been mentioned as Mushil-e-Sauda and *Mushil-e-Balgham* therefore, it helps in cleaning out (*Tanquia*) of causative matter and improving the condition. Apart from all the actions directly related to treatment ofestablished disease, *Habb-e-Rasaut* has some additional action which can be taken in observance in relation to haemorrhoid, *Muqawi Meda wa Ama* (Tonic for stomach and intestine), and *Muqawwi-e-Jigar* effects help to improve function of digestive system as well as regularize the metabolism. Reduced possibility of constipation and normalization of body metabolism decrease the chance of synthesis and accumulation of morbid humor which certainly turnout in less chance of settling of disease like *Bawaseer*. Therefore, it can be interpreted the *Habb-e-Rasaut* can be very instrumental in controlling and managing *Bawasee-e-Damwi* (Haemorrhoid). As far as adverse effect is concerned during the course of treatment; none was observed or reported by any of thepatient.

## CONCLUSION

This study validates the claims of *unani* scholars and it is specific for the treatment *Bawaseer-e- Damwi, Habb- e-Rasaut* has a noticeable efficacy and safety in *Bawaseer-e-Damwi. Habb-e-Rasaut* which consists of *Rasaut, Guggul,* and *Post Halela zard* has been mentioned as Mushil-e-Sauda and *Mushil-e-Balgham* therefore, it helps in cleaning out (*Tanquia*) of causative matter and improving the condition. We concluded that *Habb-e-Rasaut* ffectively and safely in the treatment of internal haemorrhoids and we recommend the multicenteric and big sample size researches with long-term follow up.

### Recommendation

Further, double- blind, randomized controlled trials on larger sample size for longer duration are recommended.

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