Original Article

Efficacy of Habb-e-Sandroos in Internal Hemorrhoids: An open-labelled single-arm clinical study

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ABSTRACT

Aim

Hemorrhoids are one of the most common anorectal complaints reported in anorectal clinics with an estimated prevalence of 4.4% in the United States and 13-36% in the United Kingdom. It is one of the oldest diseases known to mankind with history seen in the ancient medical writings of every culture, including Babylonian, Hindu, Greek, Egyptian, and Hebrew. According to the Unani system of medicine, the cause of hemorrhoids is morbid *Khilt-e-Sauda* (black bile). *Habb-e-Sandroos* has hemostatic, astringent, desiccant, laxative, and anti-inflammatory activity and since ages used by Unani physicians to treat hemorrhoids, hence present study aimed to evaluate its effect in Internal hemorrhoids.

Methods

This single-arm open-labelled clinical trial was conducted among 30 male and female patients, aged 20 to 65years, with 1st and 2nd degree hemorrhoids confirmed by proctoscopy. *Habb-e-Sandroos*, 2 tablets each weighing 0.5g was given thrice a day for 45 days. The efficacy outcome was assessed by an arbitrary grading scale. ***Results:*** Significant changes were observed in efficacy outcomes. Follow up assessments were done on every fortnightly for the first forty-five days and monthly follow-up for two months without treatment. Study showed that *Habb-e-Sandroos* produced significant improvement in subjective parameters; bleeding per rectum ($p < 0.001$), prolapse of pile mass ($p < 0.001$), mucus discharge per-rectum ($p = 0.026$), and itching per rectum ($p = 0.003$) at 2 months from the baseline scores. Drug has promising results in Internal hemorrhoids and warrants further studies.

Conclusion

The result inferred that the test drug is safe and effective in improving the severity of symptoms of Internal hemorrhoids of 1st and 2nd Grade. It can be used as an alternate to conventional treatment.

Keywords

Internal Hemorrhoids; *Habb-e-Sandroos*; Unani medicine.

INTRODUCTION

Hemorrhoidal disease is a common proctological disorder. Hemorrhoids are vascular cushions in the anal canal and contribute to normal anal anatomy.[1] Throughout history, reports of hemorrhoidal illness have been made for ages. Primitive references are found in the Old Testament and in Egyptian, Babylonian, and Greek written sources.[2,3] The term "Hemorrhoid" is derived from two Greek words "Haima" - blood; "Rhoos" - flowing. Hippocrates, the famous Unani scholar, coined the term "hemoid" and defined it as "the flow of blood from the veins of the anus.[4] Hemorrhoids are classified as internal or external, separated by the dentate line and are considered a disease entity once they become symptomatic.[1] Internal hemorrhoids arise from the internal hemorrhoidal plexus, while external hemorrhoids arise from the external plexus. The anatomical boundary that

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divides the internal from the external hemorrhoidal plexus is the dentate line.[5,6,7] The normal internal hemorrhoidal plexus consists of 3 soft engorgements, referred to as anal cushions or "hemorrhoids".[8,9] Consequently, the term "internal hemorrhoids" does not signify a state of disease if viewed in its strict literal definition. However, in clinical practice, the term "internal hemorrhoids" is used to describe solely the disease resulting from the abnormal enlargement of anal cushions, i.e., their transformation to anal nodules.[7,8,9] More precisely, this definition is limited to symptomatic hemorrhoidal disease: i.e., anal cushions are named "Hemorrhoids" when they bleed and/or prolapse.[10] The internal hemorrhoidal plexus is placed submucosally above the dentate line and below the anorectal ring.[11] It extends from the upper border of the anatomical anal canal to the upper border of the surgical anal canal. It is located, therefore, outside the anatomical anal canal. It is covered by transitional columnar epithelium and originates embryologically in the cloacal part of the anal canal, which contains both ectodermal and endodermal elements.[8] This epithelium is approximately 1 cm long[8] and, as anatomically authentic rectal epithelium, it secretes mucus[7] and is not innervated by visceral pain fibers.[10]

Internal Hemorrhoidal disease is most commonly classified by the Goligher classification system, first described in 1975.[1]

Grade I – protrude into anal canal without prolapse

Grade II – prolapsing beyond the anal canal but reduce spontaneously

Grade III – prolapsing outside the anal canal on straining, requiring manual reduction

Grade IV – prolapsed constantly, irreducible.

Data from the National Ambulatory Medical Care Survey and National Hospital Ambulatory Medical Care Survey from 2010 show that hemorrhoids were the third most common outpatient gastrointestinal diagnosis with nearly 4 million office and emergency department visits annually.[12] It is unknown how common hemorrhoids are, and prevalence estimates differ greatly depending on the source of the data. According to self-report data from the National Health Interview Survey conducted between 1983 and 1986, 4.4% of people report having hemorrhoids.[13] In India, approximately 40,723,288 people are reported to have hemorrhoids. Current statistics suggest nearly half of the world`s population will experience some form of hemorrhoid at the age of 50.[14,15]The etiology of hemorrhoids is uncertain. Ever since work by Burkitt in the 1970s, hemorrhoids have been considered to be caused by a low-fiber diet and constipation.[16,17,18] Symptoms attributed to hemorrhoids include bleeding, pain, pruritus, fecal seepage, prolapse and mucus discharge.[5] However, it is not at all clear that hemorrhoids cause these symptoms as most complaints in the anal area are likely to be attributed to hemorrhoids.[19]Demand for hemorrhoid therapy has been predicted to increase 23% over the next twenty years.[20] Hippocrates approached the pathophysiology and the treatment of the disease in his treatise "On Hemorrhoids".[3]

Treatments for hemorrhoids include medical therapies, non-surgical office-based treatments, and surgery.[21] First-line therapy typically involves dietary modification with adequate fluid and fiber intake, along with avoiding straining and limiting prolonged time on the toilet.[22] For the rest, various surgical methods like hemorrhoidectomy, stapled hemorrhoidopexy etc. and office procedures like rubber band ligation, sclerotherapy, photocoagulation, cryosurgery, etc. are available with each having its own merits and limitations compared to others. Though hemorrhoidectomy is still considered the 'gold standard' treatment for hemorrhoids.[23]

In Unani medicine, the term *Bawaseer* is used to describe hemorrhoids. These are the abnormal swelling and dilatation of the veins in the anal region.[24] Renowned Unani scholar Ibn-e-Sina said that the cause of *Bawaseer* is morbid *Khilt-e-Sauda* (black bile) sometimes it may arise from *khilt-e-Balgham* (Phlegm).[25] In Unani System of Medicine, the physicians have classified *bawaseer* on various aspects, like shape, site, bleeding tendency etc. the term *Bawaseer Ghaira* is used to describe internal hemorrhoid.[26]

According to reports from the World Health Organization (WHO), almost 80% of the world's population is using traditional herbal medicine to diagnose, prevent, and treat diseases.[27]For the management of hemorrhoids, Unani physician has panoramic and compendious description. Various effective treatment drugs are available in Unani system of medicine. *Habb-e-Sandroos* has Haemostatic, Astringent, Desiccant, Laxative, Anti-inflammatory activity and since ages used by Unani physician to treat hemorrhoids [28,29] So, the present study aims to evaluate the efficacy of *Habb-e-Sandroos* in relieving the symptoms of Internal hemorrhoids.

MATERIALS AND METHODS

Study design and setting:

The current study was a single-arm open-labelled clinical trial. The trial was carried out in the hospital of the National Institute of Unani Medicine (NIUM), Bangalore, from August 2015 to January 2017.

PARTICIPANTS

The inclusion criteria for participation in the study were (1) diagnosed patients of 1st and 2nd-degree hemorrhoids confirmed by proctoscopy (2) patients of either sex between 20-65 years of age (3) Controlled Hypertensive Patients (4) Controlled Diabetic Patients. The Exclusion criteria were (1) 3rd and 4th degree internal hemorrhoids (2) patients with bleeding disorders (3) pregnant and lactating women (4) known severe systemic illnesses.

DATA COLLECTION TOOLS

All data was recorded on the case record forms designed specifically for the purpose of the study. Demographic details and socioeconomic status were assessed using Kuppuswamy's socio economic status scale 2015.[30] An arbitrary grading scale was adopted for assessment of the nature of bleeding and mucus discharge per rectum. Scores interpreted as 0 = No discharge per-rectum/No bleeding, + (mild)= Scanty mucus/ blood discharge per-rectum, + +(moderate)= Moderate degree of mucus/ blood discharge per-rectum and + ++(severe)= Profuse degree of mucus/ blood discharge per-rectum.

Assessment Parameters were

a) Amount of bleeding
b) Mucous discharge.
c) Itching.
d) Per-rectal examination.
e) Proctoscopic examination.

PATIENTS AT BASELINE

A total of 87 patients were screened for the study, 49 patients did not meet the inclusion criteria, 8 patients denied participation, and finally, 30 patients were enrolled in the study after taking written informed consent. The patients were clinically assessed by history taking and physical examination and other required laboratory parameters. All 30 patients completed the study. (Fig. 1.)

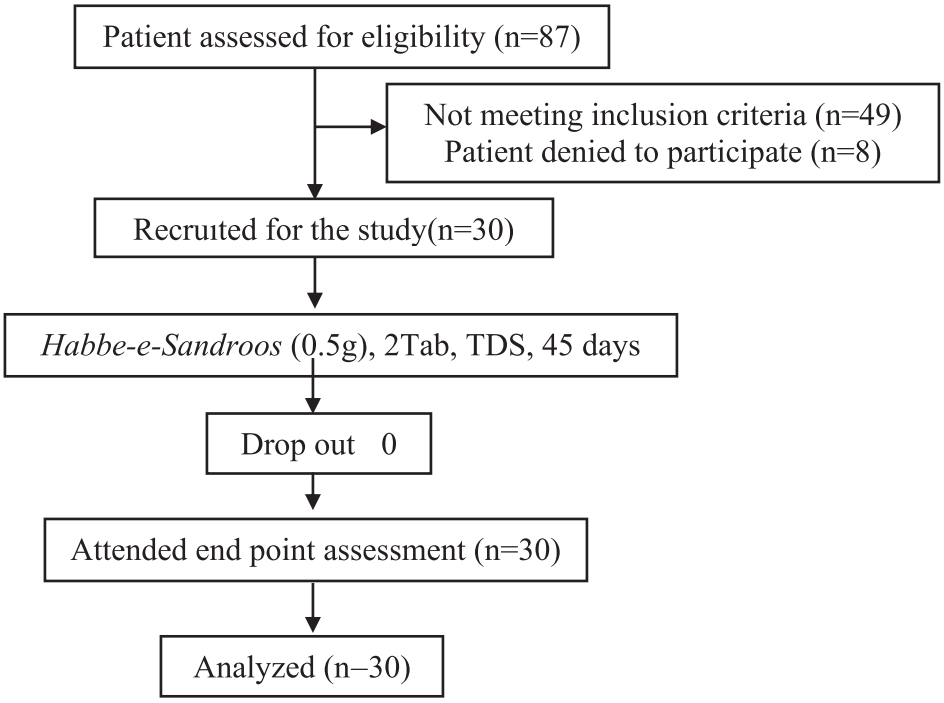

Fig. 1. Study flow chart.

Monitoring and follow up

Once participants had fulfilled the inclusion criteria, written informed consent was obtained

and baseline scores for subjective parameters were recorded and the assigned intervention and relevant instructions were given to participants. Patients were asked to attend the outpatient department (OPD) fortnightly for the first forty-five days. where scores were recorded and patients were given supplies of the same intervention. Monthly follow-up for two months after the cessation of the treatment protocol, was done to monitor the participants and record any recurrence of symptoms. Participants were asked about any adverse effects throughout the duration of the trial period. After completion of the trial, the baseline scores and post-follow-up without treatment at 2 months scores were statistically analysed in order to evaluate the efficacy of the treatment. Non-compliance with the trial protocol and adverse reaction to the intervention were considered to be withdrawal criteria.

INTERVENTION

Composition of the test drug[28]

1. *Sandroos* (Trachylobium hornemannianum) 3gm
2. *Post-e-Baize-e-Murgh Sokhta* (Egg shell) 3gm
3. *Sheetraj Hindi* (Plumbago zeylanica) 3gm
4. *Tukhm-e-Gandana* (Allium ascalonium) 3gm
5. *Khabsul Hadeed Sokhta* (ferric oxide) 0.5gm
6. *Muqil* (Commiphora muqil) 5gm

The drugs were procured from herbal drug store, Bangalore and were identified by the pharmacist of the NIUM pharmacy except for *Sandroos* and *Muqil* as are difficult to identify so, these two drugs were authenticated by the Institute of Trans-Disciplinary Health Sciences and Technology, Bangalore, where a voucher specimen was retained under code FRLHT ACC. No. 3871 and 3872 respectively. *Habb-e-Sandroos* was prepared according to the pharmacopial procedure at NIUM pharmacy. All the ingredients were finely powdered and tablets were prepared. Each tablet weighs 500mg (0.5g) and dispensed to the participants in a transparent polypack containing 90 tablets and were instructed to take 2 tablets orally, thrice daily for 45 days.

Statistical methods for data analysis

The statistical software packages SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver.2.11.1 were used for analysis of the data. Both descriptive and inferential statistical analysis was carried out in the present study. Results on continuous measurements are presented as Mean ± SD and results on categorical measurements are presented as number (%). Significance was assessed at the 5% level, with p-values ≤ 0.05 considered to be statistically significant. Dependent variables were normally distributed, samples drawn were random, and Microsoft word and Excel have been used to generate graphs, tables and charts. Student t test (two tailed, dependent) has been used to find the significance of study parameters on continuous scale within each group. Paired Proportion test has been used to find the significance of proportion in paired data.

ETHICAL CLEARENCE

The study protocol was in compliance with the Declaration of Helsinki and standards provided by the International Committee on Harmonization of Good Clinical Practice guidelines. Before the commencement of the trial, the study protocol was approved by Institutional Ethical Committee, NIUM, Bangalore with IEC No: NIUM/IEC/2014-15/JAR/01and all participants provided verbal and written informed consent.

RESULTS

A total of 87 patients were screened for the study, 49 patients did not meet the inclusion criteria, 8 patients denied participation, and finally, 30 patients were enrolled in the study after taking written informed consent.

The study included 3.3% males and 96.7% females with mean SD age of 36.90± 9.86yrs. The maximum number of patients were from urban habitat (93.3%) of lower middle class (50%), with mixed dietary habit (93.3%), and with history of constipation (96.7%). Mean SD BMI was 71.73±13.01. (Table 1)

Out of 30 patients, 21 (70%) patients were experiencing mild degree of bleeding, whereas 9 (30%) patients were having moderate degree of bleeding. 26 (86.7%) patients reported prolapse of pile mass whereas 4 (13.3%) patients reported no prolapse of pile mass. There was significant reduction in scores for subjective

parameters; bleeding per-rectum and prolapse of pile from the baseline at 2 months ($p < 0.001$). (Table 2)

For the subjective parameter mucus discharge per-rectum, 17(56.7%) patients reported no mucus discharge per-rectum whereas 13(43.3%) patients were having mucus discharge among them10 (33.3%) had moderate degree of mucus discharge whereas 3(10%) had mild degree of mucus discharge. The reduction in score at 2 months from baseline was moderately significant ($p=0.026$). (Table 2)

Out of 30 patients,17(56.7%) patients were having itching per rectum. After treatment progressive reduction was seen and the score was highly significant at 2 months from baseline ($p =0.003$). (Table 2)

There was no recurrence of symptoms after the post treatment follow-up for two month and no adverse reactions were reported during the study period.

Table 1. Baseline characteristics: Expressed in Mean, standard deviations (S.D.) and percentage

Clinical Profile		Number	Percentage (%)
Age (yrs)		36.90± 9.86	
Sex	Male	1	3.3
	Female	29	96.7
Socio Economic Status	Upper Middle	7	23.3
	Lower Middle	15	50
	Upper Lower	6	20
	Lower	2	6.7
Food	Vegetarian	2	6.7
	Mixed	28	93.3
Habitat	Rural	2	6.7
	Urban	28	93.3
Bowel Habit	Regular	1	3.3
	Constipation	29	96.7
BMI		71.73±13.01	

DISCUSSION

In the present study, we evaluated the efficacy of *Habb-e-Sandroos* in Internal Hemorrhoids.

Out of 30 patients 21 (70%) patients were having mild degree of bleeding whereas 9 (30%) patients were having moderate degree of bleeding. The number of patients with mild degree bleeding decreased progressively and the scores were 14(46.7%), 3(10%), 2 (6.7%) and 0 (0%) following the 15th, 30th, 45th day and 1st month follow-up respectively, whereas the moderate degree of bleeding stopped completely at the 15th day follow-up. The bleeding was completely stopped in both mild and moderate degrees of bleeding may be due to the haemostatic action of the test drug as described in Unani system of medicine.[28,31,32,33,34]

For the subjective parameter, prolapse of pile mass per rectum; out of 30 patients, 26 (86.7%) patients had prolapse of mass whereas 4(13.3%) patients had no prolapse of mass. There was progressive fall in the number of patients having prolapsed pile on the 15th, 30th, 45th, day follow-up and the scores were 6(20%), 6(20%) and 0(0%) respectively. The change was 86.7% i.e 100 % patients relieved at the end of 45th day follow-up this might be due to the properties of the test drug as *Mujafif-e-Ratoobat* (Desiccant), *Muqawvi-Azalaat* (muscular toner), *Habis* (Haemostatic), *Qabiz* (Astringent), antimicrobial, anti-inflammatory that helped in strengthening the venous tones and the overall layers of anorectum and anal cushion, there by regressed the diseased state of hemorrhoids to the normal state.[28,31,32,33,35]

Patient presented with mucus discharge per-rectum were out of total patients, 17(56.7%) patients had no mucus discharge per-rectum whereas 13(43.3%) patients had mucus discharge, among them 10(33.3%) had a moderate degree of mucus discharge whereas 3(10%) had mild degree of mucus discharge. There was observed progressive fall in the number of patients having mild degree of mucus discharge during follow-up as on 15th day 8(26.7%) followed by 1(3.3%) at 30th day, 0(0%) at 45th day. The moderate degree of mucus discharge completely stopped on the 15th day of follow-up. The improvement may be due to the actions of test drug as *Mujafif-e-Ratoobat* (Desiccant).[33]

Table 2 Effect of intervention on subjective parameters

Subjective Parameters	No. of Patient (Percentage)					
	Baseline	15th day	30th day	45th day	After1st month	After2nd months
Bleeding						
Nil	0(0%)	16(53.3%)	27(90%)	28(93.3%)	30(100%)	30(100%)
Mild	21(70%)	14(46.7%)	3(10%)	2(6.7%)	0(0%)	0(0%)
Moderate	9(30%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)
Severe	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)
Mucus Discharge						
Nil	17(56.7%)	22(73.3%)	29(96.7%)	30(100%)	30(100%)	30(100%)
Mild	10(33.3%)	8 (26.7%)	1 (3.3%)	0(0%)	0(0%)	0(0%)
Moderate	3(10%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)
Severe	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)
Prolapse of Pile						
No	4(13.3%)	24 (80%)	24 (80%)	30(100%)	30(100%)	30(100%)
Yes	26 (86.7%)	6 (20%)	6 (20%)	0(0%)	0(0%)	0(0%)
Itching per rectum						
No	13 (43.3%)	30 (100%)	30 (100%)	30(100%)	30(100%)	30(100%)
Yes	17 (56.7%)	0 (0%)	0 (0%)	0(0%)	0(0%)	0(0%)

Patients presented with itching per rectum. Out of 30 (100%) patients, 17 (56.7%) patients were having itching per rectum. After treatment 56.7% change was observed at the end of 15th day follow-up i.e.,100% affected patients were relieved. The test drug with the property as anti-inflammatory, analgesic, desiccant, antimicrobial, helped to reduce itching per rectum.[35,36,37]

This is the first clinical trial to investigate the effect of *Habb-e-Sandroos* in Internal Hemorrhoids. Our encouraging results can be used to determine the power of future controlled trials which are needed to confirm these results.

LIMITATIONS

The main limitations of our study are the small number of participants, the absence of a control group, and a follow-up time period that may lessen the strength of our results. Therefore, it requires extensive exploration of the efficacy and safety profile, in a randomised controlled design and with a larger sample size.

CONCLUSIONS

The results of 45 days of intervention of *Habb-e-Sandroos* confers therapeutic effects in patients of 1st and 2nd-grade Internal hemorrhoids by reducing the frequency of bleeding, prolapse of pile mass per rectum, mucus discharge per-rectum and itching per rectum. However, these results are too preliminary to reach the therapeutic application. Hence further studies through randomized controlled trial design are needed.

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AUTHORS'S CONTRIBUTION:

Dr. Mehjabeen Fatimah: Data gathering and idea owner of this study design, approval of final draft; Prof. S. Shah Alam: Editing; Dr. Mahfooz Alam: Data gathering and idea owner of this study design; Dr. Showkat Bashir Lone: Editing. Dr. Rabia Malik: Editing, Writing and submitting manuscript.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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