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Effect of Habb-E-Bawaseer Khooni in Internal Haemorrhoids: A Controlled Clinical Trial

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ABSTRACT

Haemorrhoids (Bawaseer) is the most common cause of bleeding before/during/after defecation. The well established & proven nonsurgical treatment modes like rubber band ligation, injection sclerotherapy and cryotherapy are not suitable for all degrees of heamorrhoids and even associated with their own complications. In this study randomized single blind controlled clinical trial was carried out to evaluate the efficacy and safety of Habb-e-Bawaseer Khooni, a compound drug of Dawakhana Tibbiya College and part of National Formulary of Unani Medicine, Part VI , in the patients suffering from 1st, 2ndand 3rddegree of internal haemorrhoids. The study was carried out of 60 patients attending surgery OPD, Ajmal Khan Tibbiya College Hospital during the period of June 2015-July 2016, out of which 30 cases belonged to Test Group and 30 belonged to control group. Encouraging results were observed in this study and Habb-e-Bawaseer Khooni not only offered significant improvement in general symptoms of internal haemorrhoids, but also reduced the size of 1st, 2nd and 3rd degree of internal haemorrhoids.

KEYWORDS Haemorrhoids in place of Haemorrhois

Introduction:

The life of modern era is full of fast food rich, unbalanced diet and tremendous mental stress. All these factors disturb digestive system and thus cause many diseases. Haemorrhoid is one among these digestive ailments (1). Among pregnant women and patients with hypertension haemorrhoids are commonly found (1, 2).

In Unani system of medicine haemorrhoids are called as 'Bawaseer', which is the most common cause of bleeding with stool and it may be associated with pain, itching, mucous discharge, discomfort and prolapse of haemorrhoids (1,3,4,5). The disease is not fatal but it's nagging symptoms significantly influences the quality of patient's life.

Now a days, the available nonsurgical treatment modes are Rubber band ligation, injection sclerotherapy and cryotherapy. These modalities are well proven and established, but these are not suitable for all degrees of hemorrhoids and are associated with their own complications. Haemorrhoidectomy is also associated with post-operative complications e.g. post-operative discomfort, recurrence, pain and delayed return to work (7). Despite many available treatments, the standard treatments are, at best imperfect (8).Therefore patients and surgeons are attracted to a medical treatment which is easy to administer and free of significant complications.

Prevention is the best treatment for haemorrhoids (9).Treatment of haemorroids with the use of medicinal plants, either internally or externally, is effective at early stages (8). Several single medicinal plants and compound drugs have been proved to be effective in treatment of early stages of haemorrhoids (10) e.g. ***Euphorbia prostrata*** has been proven to be effective for haemorrhoids in different ***in vivo, in vitro*** and clinical studies as well and now these drugs are easily available in market (11,12,13,14)

Unani system of medicine offers a range of single (mufrad) and compound (murakkab) drugs to control haemorrhoids (Bawaseer) with minimum or no adverse effects. Many preparations are mentioned in Unani Classical text books such as Habb-e Bawaseer (15,16,17), Habb-e-Rasaut (18), Habb-e-Bawaseer Khooni (19).

Habb-e-Bawaseer Khooni (HBK) is a very old product of Dawakhana Tibbya College, Aligarh Muslim University, Aligarh (U.P.), India. This product is a pharmacopial prepration (19) and has been offering relief to thousands of patients without any adverse effects reported so far, however no clinical trial has been conducted on this product to proove it's efficacy for the treatment of haemorrhoids, till date. Clinical trials have always been recommended by experts of medicine to establish the evidence based use of any Unani medicine. Therefore we planned to carry out a randomized single blind controlled clinical trial to evaluate the efficacy and safety of HBK in the patients suffering from internal 1st, 2ndand 3rddegree of internal haemorrhoids. The composition of HBK is given in Table 1.

Table 1 : Composition of Habb-e-Bawaseer Khooni

2 tablet of 400mg of Habb-e-Baswaseer Khooni contains			
Name of Drug	Botanical Name	Part used	Quantity
Rasaut Zard	Berberis vulgaris	fruit	45 mg
Neem	Azadirachta indica	fruit	36 mg
Bakain	Melia azadarach	fruit	36 mg
Harsinghhar	Nyctanthes arborijitis	stem	36 mg
Gandna	Allum ampeloprasum	seed	36 mg
Kali Zeeri	Centratherum anthelminticum	seed	36 mg
Taj Qalmi	Cinnamomum tamala	Bark	36 mg
Gulnar Farsi	Punica granatum	Flower and fruit	36 mg
Gul-E-Dhawa	Woodforrdia floribunda	Flower	36 mg
Gul Sadbarg	Tagetes erecta	Whole plant, flowers, leaves and root	36 mg

Material and Methods:

1. **Study design:** This study was a Randomized single blind controlled clinical trial.
2. **IEC Approval:** The drug is in use since decades and part of National Formulary of Unani Medicine part VI hence no ethical clearance was obtained.
3. **Consent:** Before starting the study a well informed consent was received from the patients, enrolled in the study.
4. **Centre of Recruitment:** Patients attending the Out patient department (OPD) of Jarahat (surgery) department, A.K. Tibbya College, A.M.U., Aligarh, were recruited in the study, during the period of June 2015-July 2016.
5. **Sample size:** Study was completed on 60 patients and they were randomly distributed in two groups.
6. Group A (Test Group) = 30 pts
7. Group B (Control Group) = 30 pts

Subject selection:

Inclusion Criteria: Patients of both sexes who met the following criteria were included in the study.

Patients aged between 20-70 years.

Patients with symptomatic First, second and third degree of haemorrhoids, confirmed by proctoscopic examination.

Exclusion criteria: The patients meeting any of the following criteria were excluded from the study.

External Haemorrhoids

Forth Degree of Haemorrhoids

Patients with internal haemorrhoids associated with other ano-rectal pathology like Fissure-in-ano, Fistula in Ano, Ulcerative colitis, Crohn's disease, Carcinoma Rectum.

Patients with severe anemia, Type 1 and type 2 diabetes mellitus, HBsAg positive, severe hepatic/renal or cardiovascular disorder.

Pregnant and lactating mothers

Investigations:

1. complete Haemogram
2. BT,CT
3. Blood sugar Fasting and post parandial
4. Urine-Routine and Microscopic
5. HBsAg
6. HIV1 and 2

Investigational Drug :

Group A (Test Group): Habb-e-bawaseer khooni, 2 tablet (400 mg) twice daily upto 6 week.

Group B (Control Group): Capsule Thank OD containing *Euphorbia prostrata* (100mg) -1 capsule once a day up to 6 week (Standard drug).

Follow up: every week

Criteria for assessment:

1. Per Rectum Bleeding (20,21)
2. No Bleeding
3. Mild bleeding with defecation (upto 10 drops)
4. Moderate bleeding (upto 10 to 20 drops)
5. Profuse bleeding (more than 20 drops)
6. Pain (22)

The severity of pain was assessed on Visual Analogue Scale (VAS), for which numerical are labeled

0	1	2	3	4	5	6	7	8	9	10
No pain	Mild		Discomforting		Distressing		Horrible		Excruciating	
Nil	Mild		Moderate				Severe			

No : 0
Mild : 1
Moderate : 2
Severe : 3

Mucous Discharge (22)

- Absent
- Discharge seen either after or before defecation without soiling undergarments
- Feeling of some discharge with soiling of undergarments
- Profuse discharge with soiling of undergarments

Anal Pruritus (20, 23)

- Absent
- Mild
- Moderate
- Severe

Burning (22)

- Absent
- Mild
- Moderate
- Severe

Grade of Haemorrhoidal size (20, 21)

I°= Swelling visible in proctoscopy and doesn't comes out of anus

II°= Haemorrhoid only comes out while defecation but reduces automatically

III°= Haemorrhoid only comes out while defecation and requires digital redeposition

IV°= Haemorrhoidal mass are prolapsed permanently

(11) Result assessment criteria (22)

Cured: When relief in sign and symptoms is more than 75%.

Improved: Relief in sign and symptoms ranges between 50-75%

Relieved: Relief in sign and symptoms ranges between 25-50%

Not Cured: Relief in sign and symptoms is less than 25%

(12) Statistical Analysis of study: The data was analysed statistically by using Javastat; Chi-square test and Fisher exact test; p-value as per SAS, SPSS software.

Results and Observations:

A total of 69 patients were enrolled in the study after applying inclusion and exclusion criteria. Out of 69 (4 in group A and 5 in group B) dropped the study before the accomplishment of the treatment due to ineffective results, thus the study was conducted on 60 patients (30 in group A and 30 in group B).

The analysed data included 72% male and 28% female patients (table 1) with Pearson chi-square statistic as 0.082 (p=0.774) and distribution of Direct / Indirect is statistically similar between two groups with p=1. The range of age was 20-60 years with most common age range of 31-40 years (table 2), 46.6% patients had vegetarian diet and 53.3% had mixed diet (table 3), The chi-square (Pearson) statistic is 2.411 (p=1.21). Distribution of Direct / Indirect is statistically similar between two groups with p=0.195

Table : 1

sex	group A	group B	Total
male	22	21	43 (72%)
female	08	09	17 (28%)
total	30	30	60 (100%)
Inference	The chi-square (Pearson) statistic is 0.082 (p=0.774) Distribution of Direct / Indirect is statistically similar between two groups with p=1		

Table : 2

Age group	group A	group B	Total=60
20-30	4	6	10 (16.6%)
31-40	10	12	22 (36.6%)
41-50	8	7	15 (25%)
51-60	6	4	10 (16.6%)
61-70	1	2	03 (5%)

Table : 3

Diet	group A	group B	Total=60
Veg	11	17	28 (46.6%)
Mixed	19	13	32 (53.3%)
Inference	The chi-square (Pearson) statistic is 2.411 (p=1.21) Distribution of Direct / Indirect is statistically similar between two groups with p=0.195		

Table 4 shows, Per rectal bleeding (86% vs 58%; p= 0.084) and pain on defecation (87% vs 74%; P=0.370) in the Study group during the follow up were significantly improved. Mucous discharge in the piles patients was found to be improved as (70% vs 55%; P=0.532) while burning during defecation was also improved in test drug group vs standard drug group as (52% vs 42%; P=0.634). Anal itching improved in test drug group vs standard drug group as (53% vs 39%; p=0.634). Constipation improved in test group vs standard drug group as (59% vs 24%; p=0.182).

Table : 4

Symptoms	Group A				Group B				Inference
	BT	AT	DIFF	%	BT	AT	DIFF	%	chi-square (Pearson) statistic with p-value
per rectal bleeding	28	04	24	86	26	11	15	58	2.994 (p=0.084)
pain on defecation	23	03	20	87	19	05	14	74	0.802 (p=0.370)
Discharge	20	06	14	70	18	08	10	55	0.391 (p=0.532)
Burning	21	10	11	52	24	14	10	42	0.882 (p=0.348)
Itching	19	09	10	53	23	14	09	39	0.226 (p=0.634)
Constipation	27	11	16	59	25	19	06	24	1.781 (p=0.182)
Inference	P value =0.0006 (Kruskall Wallis post test)								

BT= No. of patient before treatment, AT= No. of patient after treatment, DIFF= No. of patient who improved after treatment

Table 5 shows the degree of severity of each symptom in test group and control group. The results show that the test drug has almost equal results in every degree of severity including severe degree.

Table: 5

Symptoms	Degree of severity	Group A			Group B		
		B.T.	A.T.	*N	B.T.	A.T.	*N
Bleeding	Mild	2	0	2 (100%)	3	0	3 (100%)
	Moderate	23	4	19 (83%)	20	9	11 (55%)
	Severe	3	0	3 (100%)	3	2	1 (33%)
Pain	Mild	3	0	3 (100%)	4	2	2 (50%)
	Moderate	18	3	15 (83%)	13	3	10 (78%)
	Severe	2	0	2 (100%)	2	0	2 (100%)
Mucous discharge	Mild	4	2	2 (50%)	3	2	1 (33%)
	Moderate	16	4	12 (75%)	14	5	9 (64%)
	Severe	0	0	0 (00%)	1	1	0 (00%)
Burning	Mild	12	5	7 (58%)	10	6	4 (40%)
	Moderate	9	5	4 (44%)	14	8	6 (43%)
	Severe	0	0	0 (00%)	00	0	0 (00%)
Itching	Mild	6	4	2 (33%)	9	6	3 (33%)
	Moderate	10	4	6 (60%)	12	7	5 (42%)
	Severe	3	1	2 (67%)	3	1	2 (67%)
Constipation	Mild	8	3	5 (62.5%)	6	5	1 (17%)
	Moderate	13	5	8 (61.5%)	18	13	5 (27.7%)
	Severe	6	3	3 (50%)	1	1	0 (00%)

***** No. and percentage of patients relieved after treatment

In group A the number of patients with pile mass of grade 3, decreased from 4 to 0 and of grade 2 from 24 to 13 and in grade 1 the number of patients increased from 2 to 17 because after treatment the grades of haemorrhoids were decreasing and patients were shifting from a higher grade of pile mass to lower grade of pile mass. Where as in group B, number of patients in grade 3 decreased from 5 to 0, 23 to 15 in grade 2 and in grade 1 no of patient increased from 02 to 15 (table 6).

It indicates that the test drug has significant effect in treatment of internal haemorrhoids than the control group drug (P value =0.9914).

Table: 6

Gradation of pile mass	Group A		Group B	
	Pre tt	Post tt	Pre tt	Post tt
Grade 1	02	17	02	15
Grade 2	24	13	23	15
Grade 3	04	00	05	00
Inference	P value =0.9914 (Kruskall Wallis post test)			

Out of 30 patients (13) 43% patients were cured, 12 (40%) patients were improved, 05 (17%) patients were relieved in group A while in group B out of 30 patients 6 (20%) were cured, 11 (37%) improved,12 (40%) patients relieved and 1 (03%) patient did not get any significant relief (table 7).

It indicates that the test drug has significant effect in treatment of internal haemorrhoids than the control group drug (P value =0.1984).

Table: 7

Effect	Group A		Group B	
	no. of pts.	%	no. of pts.	%
cured (more than 75% relief in symptoms)	13	43	06	20
Improved (50-75% relief in symptoms)	12	40	11	37

Relieved (25-50% relief in symptoms)	05	17	12	40
Not cured (less than 25%)	00	00	01	03
Total	30	100	30	100
Inference	P value =0.1984 (Kruskall Wallis post test)			

Discussion:

The present study was conducted in Ajmal Khan Tibbya College and Hospital in Department of Jarahat (Surgery), to find out the efficacy of a Unani compound formulation and the study was based on symptoms and objective parameters.

In our study among recruited patients the maximum (72%) patients were male. The reason of this may be due to higher attendance of male patients in O.P.D. 37% (maximum) patients were in the age range of 31-40 years which represents the life style. Maximum patients (53.3%) were on mixed diet which indicates the low fiber diet as the predisposing factor for the haemorrhoids. Among symptoms rectal bleeding was the most common in both the groups and constipation was the second most common, as the bleeding motivates the patient to take the treatment faster. Constipation was reported by almost equal number of patients as by rectal bleeding, which emphasizes on the role of constipation as an important etiologic factor.

The study demonstrates that Habb-e-Bawaseer Khooni (HBK) is significantly and equally effective in relieving the symptoms and reducing the grade of pile mass as the control drug. HBK posseses the properties of Mushil-e-sauda, Kasir-e-riyah, Mohallil Awram, Dafe-Bawaseer, Mulayyan and Musakkin (24-29). Dafe-Bawaseer property of HBK is due to its contents which possess anti-inflammatory, analgesic, laxative and haemostatic action (30-34). It also possesses the laxative and stimulant activity of liver and stomach and improves the function of the respective systems (35-36).

The results of the present clinical study are highly encouraging; furthermore it has been observed that there were no unwanted effects throughout the study. The long term effects of HBK were not evaluated.

Conclusion:

Habb-e-Bawaseer Khooni offered significant improvement in symptoms and size of internal haemorrhoids, it not only reduced the size of 1st and 2nd degree but 3rd degree of internal haemorrhoids also. The improvement offered by the test drug (HBK) is superior to the control drug. HBK was well tolerated by the patients and no side effect was observed. We conclude that Habb-e-Bawaseer Khooni can be used effectively and safely in the treatment of internal haemorrhoids and we recommend the multicenteric and big sample size researches with long-term follow up.

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