



EFFICACY OF HERBO-MEDICINAL FORMULATION IN HAEMORRHOIDS: AN OPEN LABELLED CLINICAL STUDY

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ABSTRACT

Haemorrhoids are one of the most common anorectal disorders encountered in the general population. Haemorrhoids are the most common (30-40%) cause of lower G.I. bleeding in India. The present study has been designed to validate the effect of Unani formulation in the management of *Bawaseer-e-ghaira* (Internal haemorrhoids of Grade-I and II degree) on scientific parameters. The ingredients of Unani formulation are- *Bisfaij*, *Zarnabad*, *Rasaut*, *Muqil*, *Maghztukhm Neem* and *Gulab*. This study was open observational clinical study. Thirty diagnosed Patients of Grade-I- and II-degree internal haemorrhoids who fulfilled the protocol criteria were selected for the study. Ethical clearance was taken from the IEC. Patients were given 2 Pills (500 mg each) twice a day for 45 days after taking written informed consent as per the study protocol. The outcomes were analysed using appropriate statistical test. There was 100% relief in bleeding with *p-value* < 0.001 and 85.7% relief in prolapse of mass with *p-value* 0.033 in the subjective parameters. Out of 30, 28 patients exhibited total number of 50 pile masses at baseline which, at endpoint of study, reduced to 6 (*p* < 0.001). Out of 30, 14 patients showed total number of 20 pile masses of grade-II, which at endpoint of study reduced to 6 (*p* < 0.05). The study concluded that Unani formulation (*Bisfaij*, *Zarnabad*, *Rasaut*, *Muqil*, *Maghztukhm Neem* and *Gulab*) is a efficacious formulation for internal haemorrhoids in respect of efficacy and safety.

Keywords: *Bawaseer-e-ghaira*; Internal haemorrhoids; Anal cushion; Unani Medicine.

INTRODUCTION

The term "Haemorrhoid" was most likely first used by Hippocrates (*Buqrat*) to explain the bleeding from the veins of the anus. It is derived from two Greek words "*haima*" means blood, "*rhoos*" means flowing. Haemorrhoids are dilated veins occurring in relation to the anus.¹⁻³ It is common in both the sexes.⁴ At least 50% of population experience problem of symptomatic haemorrhoids during their life, with around 5% of the population suffering at any given time.³

The term haemorrhoids should be restricted to clinical situation in which anal "cushions" are abnormal and causing symptoms.⁵ The haemorrhoids can be categorized as Internal, External and Intero-external types.¹

Unani formulation containing *Bisfaij* (*Polypodium vulgare* Linn.), *Zarnabad* (*Curcuma zedoaria* Rosc.), *Rasaut* (*Berberis aristata* DC.), *Muqil* (*Commiphora mukul*), *Maghztukhm Neem* (*Azadirachta indica* A. Juss.) and *Gulabis* very effective.⁶ It not only stops the bleeding but also corrects the functions of liver, spleen and intestine. Furthermore *Khilt-e-Sauda* is evacuated from the body.

MATERIALS AND METHODS

This Open labelled observational clinical study was conducted at OPD and IPD of National Institute of Unani Medicine (NIUM), Bangalore, from April 2017 to December 2017. Cases were

selected out of all the patients attending NIUM hospital based on inclusion criteria. Diagnosed patients of 1st and 2nd degree haemorrhoid confirmed by proctoscopy of either sex between the age group 20-60 years were taken into study. Patients having 3rd and 4th degree internal haemorrhoids, external haemorrhoids, pregnant and lactating women, severe systemic illnesses, recurrence in cases of post-haemorrhoidectomy, haemorrhoids associated with other Anorectal diseases like rectal polyp, fissure-in-ano, fistula-in-ano and carcinoma of rectum and anal canal were excluded from the study.

Written informed consent was obtained from all the cases. Research drug in form of pills (*habb*) was given to all the cases in a dose of 2 *Habb* (pills) orally daily after meals twice a day for 45 days. Dietary recommendations were advised as per the Unani principles with follow up on 15th, 30th and 45th day during the course of treatment and one follow up 15 days after the termination of trial. The data was collected by means of clinical history and ano-rectal examination. This study was done after ethical clearance by Institutional Ethics Committee (IEC), NIUM, Bengaluru under IEC No: NIUM/IEC/2015-16/029/Jar/04.

RESULTS

Out of 30 patients, 26.7% (8) were in the age group of 21-30 and 23.3% (7) in the age group 31-40, 26.7% (8) patients were in 41-50 and 23.3% (7) were in age group of 51-60 with mean being 39.83 ± 12.70. In our study the patient were almost equally distributed from 3rd to 5th decade. Out of total patients, males were

83.3% (25) while the females accounted for 16.7% (5). Most of participants i.e. 29 (96.7%) had mixed type food habit with predominantly non vegetarian and 12 (40%) were taking junk food and 1 (3.3%) patient was purely vegetarian. Table 1 illustrates the demographic data.

16.6% (5) were unskilled labourers, 6.7% (2) skilled labourers, 6.7% (2) teacher 6.7% (2) driver, 23.3% (7) tailor, 13.3% (4) office work, 10.0% (3) house wives, 13.3% (4) shopkeepers and 3.3% (1) student. Table 2 illustrates the occupation distribution. 80% (24) were having unsatisfactory bowel habit i.e. constipation, straining and passing of hard stool. Out of all, 23 (76.6%) patients had long toilet stay-time. The chief complaint was bleeding in 93.3% of the cases.

The number of patients having mild degree per rectal bleeding decreased progressively on the 15th, 30th, 45th day of follow up i.e. 8 (26.7%), 2 (6.7%) and 0 (0%); *p-value* < 0.001. respectively. No recurrence was noted in bleeding after 15 days of termination of trial.

Out of 30 patients, 46.7% (14) patients were having prolapsed haemorrhoids at baseline, but at the end of the study, this number reduced to 6.7% (2); *p-value* 0.033.

Out of 30, in 28 patients, total no. of 50 pile masses were present as grade-I. Out of these 14 (46.7%), 18 (60%) and 12 (40%) were present at primary (3, 7 and 11 O'clock) positions and 1 (3.3%), 2 (6.7%), 3 (10%) at secondary (1, 5, 9 O'clock) positions respectively. The outcome after the end of protocol was that 2 (6.7%) pile masses remained at 3 O'clock, 1 (3.3%) at 7 O'clock and 3 (10%) at 11 O'clock positions with *P value* < 0.001. Out of these 19 are at primary positions i.e. 5 (16.7%) at 3 O'clock, 5 (16.7%) at 7 O'clock and 9 (30 %) were present at 11 O'clock and 1 (3.3%) Pile mass was at secondary position i.e. 5 O'clock position. After the end of protocol there were 1 (3.3%) pile mass at 3 O'clock, 3 (10%) at 7 O'clock and 2 (6.7%) pile masses present at 11 O'clock.

At the end of protocol out of 20 grade-II pile masses, 6 converted to grade-I and 6 pile masses remained grade-II. Thus result showed progressive regression of the pile masses with *p value* < 0.05. Table 3 illustrates the subjective parameters before and after the treatment.

Table 1: Demographic data

Age in years	No. of patients	%
21-30	8	26.7
31-40	7	23.3
41-50	8	26.7
51-60	7	23.3
Total	30	100.0
Gender	No. of patients	%
Male	25	83.3
Female	5	16.7
Total	30	100.0
Diet	No. of patients (n = 30)	%
Vegetarian		
No	29	96.7
Yes	1	3.3
Mixed		
No	1	3.3
Yes	29	96.7
Junk		
No	18	60.0
Yes	12	40.0

Table 2: Occupation distribution of the patients

Occupation	No. of patients	%
Unskilled	5	16.6
Skilled	2	6.7
Tailor	7	23.3
Driver	2	6.7
Office work	4	13.3
Shopkeeper	4	13.3
House wife	3	10.0
Teacher	2	6.7
Student	1	3.3
Total	30	100.0

Table 3: Illustration of subjective parameters

Parameters	B.T.	A.T.	P- value
Bleeding	Mild	17 (56.7%)	0 (0%)
	Moderate	11 (36.7%)	0 (0%)
	Severe	0 (0%)	0 (0%)
Prolapsed	14 (46.7%)	2 (6.7%)	40.0%
Grade-I Mass	50	6	<i>P</i> < 0.001
Grade-II Mass	20	6	<i>P</i> < 0.05*

DISCUSSION

The majority of the patients in our study were belonging to age group 21 and 30 which is analogous to Albina *et al.*⁷ and Chandra *et al.*⁸ which shows 53.2% and 60% occurrence in 3rd to 4th decades respectively.

Male patients were 83.3% (25) while the females accounted for only 16.7% (5). This study is analogous to Satish *et al.*⁹ and Mitra *et al.*¹⁰ that showed male was predominant.

29 (96.7%) patients had mixed type food habit with predominantly non vegetarian and 12 (40%) had habit of junk food. Only 1 (3.3%) patient was purely vegetarian. The aetiology of haemorrhoids formation explained in Unani literature is the presence of *saudavimadda* and *ghaleez dam* (viscid saudavi dam) and these substances are produced by consuming non-veg and junk diet resulting into haemorrhoids formation.¹¹⁻¹³ Study conducted by Peery *et al.* supports that low-fiber diet is associated with an increased risk of haemorrhoids.¹⁴ Our study is in support of this theory and analogous to the study conducted by Satish *et al.*⁹ and Chandra *et al.*⁸ in which 64% and 75% participants were on mixed diet predominantly non vegetarian.

Out of 30, 80% (24) patients were having unsatisfactory bowel habit i.e. constipation, straining, and passing of hard stool. Out of all, 23(76.6%) patients had long toilet stay-time. Usual stay-time in toilet is about approximately (2-9) min. straining while sitting for long in toilet with an unsupported and relaxed perineum leads to engorgement of the anal cushions. Along with the loss of supporting muscle fibers the venous plexus distends causing the haemorrhoids to bulge.^{1,15,16} Satish *et al.*⁹ found 61.33% cases with straining in his study. Another studies conducted by Mitra *et al.*¹⁰ and Albina *et al.*⁷ also suggest that 86.7% participants had unsatisfactory bowel habits. Our study is analogous to these studies.

Majority of patients (93%) complained of bleeding per rectum in our study. Bleeding is the principal symptom in majority of patients as evidenced by Manish *et al.* (75%),¹⁷ Jamjoom *et al.* (100%),¹⁸ Murie *et al.* (97%),¹⁹ and Arabi *et al.* (88%).²⁰ Out of 30 patients, 17 (56.7%) patients were having mild degree of bleeding whereas 11 (36.7%) patients were having moderate degree of bleeding. No patient came with the severe degree of bleeding. 2 patients out of 30 had no complaint of bleeding. Our study has better result than study conducted by Sandhu *et al.*²¹ and Ukhalkar *et al.*²² The test drug has effective haemostatic action in treating haemorrhoidal bleeding.

Out of 30 patients, 46.7% (14) patients were having prolapse of pile mass at baseline which, at the endpoint of study, reduced to 6.7% (2); P-value 0.033. Our study shows better result in reduction of prolapse of masses compared to previous study such as conducted by Thanka *et al.*²³ Our test drug having medicinal properties like *mujafif-e-ratoobat* and *habis-wa-qabiz*, helps in strengthening the venous tones and anal cushion.

Out of 30, 28 patients were found to have a total number of 50 pile masses at baseline which, at endpoint of study, reduced to 6 (P < 0.001). Our study showed better results in reducing the number of pile masses as compared to study conducted by Tripathi *et al.*²⁴ Out of 30, 14 patients showed total number of 20 pile masses of grade-II, which at endpoint of study reduced to 6 (P < 0.05).

The test drug has functions as evacuator of *sauda* and *balgham*, haemostatic, laxative, astringent, tonic and demulcent. All these actions together help in reducing the size of pile mass.

CONCLUSION

This study was an open labelled observational clinical study. The results of the present study have demonstrated that Unani formulation was highly effective in relieving the hemorrhoidal symptoms i.e. bleeding, prolapsing pile mass. In majority of the cases, both the symptoms and objective scores were markedly reduced without producing complications and adverse effects.

Ethical approval

Ethical approval was obtained from Institutional Ethics Committee.

Consent

Written informed consent was obtained from the patients

REFERENCES

1. Williams NS, Bulstrode CJK, O'Connell PR. Bailey and Love's Short Practice of Surgery. 26th ed. Boca Raton: CRC press Taylor and francis group press; 2013. p. 1236-40, 1250-57.
2. MacKay D. Haemorrhoids and varicose veins: a review of treatment options. *Alternative Medicine Review* 2001 Apr 1; 6(2): 126-40.
3. Ganz RA. The evaluation and treatment of haemorrhoids: a guide for the gastroenterologist. *Clinical Gastroenterology and Hepatology* 2013 Jun 1; 11(6): 593-603.
4. Ashwin P, Kunal K, Sagar J. Euphorbia Prostrata-a clinically proven drug in haemorrhoids-multiple pharmacological actions targeting pathological processes. *International Journal of Medical and Health Sciences* 2015; 4(2): 269-73.
5. Courtney MT, Beauchamp RD, Evers BM, Mattox KL. Sabiston Textbook of Surgery. 17th ed. Pennsylvania USA: Elsevier Saunders; 2004. p. 1582.
6. Kabeeruddin HM. Bayaz-e-Kabeer. New Delhi: Idara Kitabus-Shifa; 2010. p. 164.
7. Albina, Ali T. Effect of habb-e-bawaseerkhooni in internal haemorrhoids: a controlled clinical trial. *Paripex - Indian Journal of Research* 2016; 5(10): 103-06.
8. Chandra B, Karthik KS, Kumari S, Suman RK. An evaluation of the effectiveness of Barron Band Ligation as a modality of treatment of haemorrhoids. *IOSR-JDMS* 2014; 13(10): 39-46.
9. Gireboinwad S, Shinde AM, Pote MP, Jambhulkar NU, Aiwale A. A comparative study of different treatment modalities of haemorrhoids. *Journal of Evolution of Medical and Dental Sciences* 2014; 3(34): 9020-8.
10. Mitra SK, Gupta A. Role of Pilo herb tablets and Ointment in the treatment of haemorrhoids. *World Journal of Pharmacy and Pharmaceutical Sciences* 2015; 4(08): 1640-47.
11. Zuhar Amami. *Kitab-ur-Taiseer-Fil-Mudawaat-wat-Tadbeer* (Urdu Translation by CCRUM). New Delhi: CCRUM; 1986. p. 152-3.
12. Tabri AHA. *Al-Moalajat-e-Buqratiya*. Vol. 2. New Delhi: CCRUM; 1997. p. 392-7.
13. Khan A. Akseere Azam (Alakseer, translated by kabeeruddin H). New Delhi: Idara Kitabus Shifa; 2011: 611. p. 663-673.
14. Peery AF, Sandler RS, Galanko JA, Bresalier RS, Figueiredo JC, Ahnen DJ, Barry EL, Baron JA. Risk factors for

- haemorrhoids on screening colonoscopy. Plos One 2015 Sep 25; 10(9): e0139100.
15. Norton JA, Bollinger RR, Chang AE, Lowry SF, Mulvihill SJ, Pass HI, et al. Surgery Basic Science and Clinical Evidence. New York: Springer; 2000. p. 731-34.
 16. Das S. A. Concise Textbook of Surgery. 7th ed. Kolkata: Dr. S. Das; 2012. p. 1075.
 17. Gupta M, Jain SK, Jain V, Jain S. A comparative study of the effectiveness of Rubber band ligation and suture ligation under vision as a treatment modality in second degree haemorrhoids. International organization of scientific research-Journal of dental and medical sciences 2015 Dec; 14(12): 78-81.
 18. Jamjoom AM, Jamal YS. A comparative study of different treatments of haemorrhoids. Annals of Saudi medicine 1991 Jan; 11(1): 73-9.
 19. Murie JA, Sim AJ, Mackenzie I. Rubber band ligation versus haemorrhoidectomy for prolapsing haemorrhoids: a long term prospective clinical trial. British Journal of Surgery 1982 Sep 1; 69(9): 536-8.
 20. Arabi Y, Gatehouse D, Alexander-Williams J, Keighley MR. Rubber band ligation or lateral subcutaneous sphincterotomy for treatment of haemorrhoids. British Journal of Surgery 1977 Oct 1; 64(10): 737-40.
 21. Sandhu P, Singh K. A randomized comparative study of micronized flavonoids and rubber band ligation in the treatment of acute internal haemorrhoids. Indian Journal of Surgery 2004 Sep 1; 66(5): 281.
 22. Ukhalkar VP, Rathi G, Jadav R, Tamoli S. An open labelled, single centre, prospective, clinical study to evaluate efficacy and safety of arw112 capsule in patients suffering from internal haemorrhoids. Int J Pharm Bio Sci 2015 Apr; 6(2): 309-23.
 23. Thanka. R. A Clinical study on the Efficacy of Homeopathic Remedies in Bleeding Haemorrhoids [https://www.homeobook.com/pdf/homeopathy-bleeding-haemorrhoids.pdf]. Cited on 22 Feb 2018. Available from: www.similima.com
 24. Tripathi RK, Bolegave SS, Shetty PA, Uchil DA, Rege NN, Chawda MB, Rege SA. Efficacy and safety of a polyherbal formulation in haemorrhoids. Journal of Ayurveda and integrative medicine 2015 Oct; 6(4): 225.

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