Advances in Traditional Medicine (2023) 23:565–573
https://doi.org/10.1007/s13596-022-00634-6

RESEARCH ARTICLE

The efficacy of alum sitz baths followed by topical gall ointment in hemorrhoids—a single-arm clinical trial

Salma Chaush[1] · Nazim Husain[2] · Mohd Khalid[2] · Meenu Doni[2] · Mohd Qudrathullah Khan[2] · Md Majid Hussain[2]

Received: 6 November 2021 / Accepted: 20 January 2022 / Published online: 7 February 2022

Abstract

Hemorrhoidal disease is one of the most common gastrointestinal ailments affecting life quality of the patients. Unani classical literature is replete with anti-hemorrhoidal drugs, but scientific evidence is lacking. Therefore, *Safūf Zāj* (powdered alum) and *Marham-e-Māzū* (gall ointment) having potent anti-hemorrhoidal actions were selected to evaluate their efficacy in hemorrhoids. This clinical trial was conducted on 30 participants with hemorrhoids, aged > 18 years. All the participants received *Safūf Zāj* for sitz baths and *Marham-e-Māzū* to be applied twice daily for 2 weeks. Primary outcome measures were: change in pain intensity, anal itching, and defecate discomfort assessed on 100 mm VAS scale and per-rectal bleeding assessed on 4-point scale. Secondary outcome measures were: change in the size of the external hemorrhoidal mass assessed on 5-point scale, grade of internal hemorrhoid assessed by Goligher classification and quality of life (QoL) assessed on SF-12 questionnaire. The per-protocol analysis was done on 30 participants and statistically significant improvement was seen in primary and secondary outcome measures. Moreover, both the mental and psychological components of QoL were improved. The study inferred that therapeutic approach of *Safūf Zāj* and *Marham-e-Mazu* is safe and efficacious in hemorrhoids. Future studies with well-designed RCTs are highly recommended.

Keywords *Bawāsīr* · Piles · Hemorrhoids · *Safūf Zāj* · *Marham-e-Māzū*

Introduction

Hemorrhoidal disease is abnormally enlarged vascular anal cushions that consist of connective tissue, smooth muscle, and both arterioles and venules (Bhat 2017; Das 2014; Madoff 2016). Although the true prevalence and incidence of hemorrhoids are unknown (Mosavat et al. 2015), it is one of the common benign proctologic condition of anorectal disease around the world, with greater incidences in higher socioeconomic status (Lohsiriwat 2012). The main symptoms include rectal bleeding, pain, prolapsing mass, and itching sensation (Bhat 2017; Das 2014; Madoff 2016). It is not a fatal disease but physical and psychological symptoms can significantly influence the QoL (Poya et al. 2017).

The etiology is believed to be advancing age, strenuous lifting, straining during defecation, and prolonged sitting that weakens supporting tissue of the anal cushions causing venous dilation and prolapse (Lestar et al. 1989; Loder et al. 1994). Pathogenesis is still under debate; however, physicians believe weakening of the fastening connective tissues, downward displacement or prolapse of the hemorrhoidal mass, abnormal distention of the arteriovenous anastomoses within the cushions, and abnormal dilatation of internal hemorrhoidal venous plexus are the main pathological factors responsible for the development of hemorrhoids (Corman 1998; Thomson 1975).

Hemorrhoidal disease is classified as internal, external, and interno-external hemorrhoids based on their location (Shrivastava et al. 2018). External hemorrhoids are located below the dentate line in the distal one-third of the anal canal and are covered by anoderm (skin), while internal hemorrhoids commence beyond the dentate line covered with a mucus membrane. Interno-external hemorrhoids consist of features of both types of hemorrhoids

✉ Nazim Husain
nazimcrium@gmail.com

[1] Department of 'Ilaj bi'l Tadbir, Luqman Unani Medical College Hospital and Research Center, Bijapur, Karnataka 586101, India

[2] Department of Medicine (Unani), Luqman Unani Medical College Hospital and Research Center, Bijapur, Karnataka 586101, India

(Das 2014; Sun and Migaly 2016). Internal hemorrhoids are graded as Grade-I, Grade-II, Grade-III, and Grade-IV, based on Goligher classification (Margetis 2019).

The treatment is based on the type and grading of hemorrhoids. Grade-I and Grade-II of internal hemorrhoids can be coped conservatively for a short time but ultimately definitive treatment is needed as required for Grade-III and Grade-IV which includes sclerotherapy, cryotherapy, rubber-band ligation, electrotherapy, and surgical hemorrhoidectomy (Chugh et al. 2014). For symptomatic external or interno-external hemorrhoids with severe symptoms, surgical excision is the only treatment option.

In Unani literature, hemorrhoidal disease is described under the Arabic term *Bawāsīr* which is the plural form of *Basūr,* that means wart or polyp like swelling. *Bawāsīr* are enlarged or engorged veins of the internal mucous membrane of the rectum plus excessive growth at the mouth of vessels present in the anus (Dandroo et al. 2017). It is primarily caused by the accumulation of the *Sawdāwi* matter (Khan 2011). It has been classified based on shape, bleeding tendency, and location. Based on the shape, it may be classified as (a) *Sulūli*; (b) *'Inabi*; (c) *Tūti*; (d) *Nafakhi*; (e*) Nakhli*; (f) *Tīnī* and (g) *Tamri* (Ahmad al-Hasan 2010; Najar et al. 2018; Ibn Sina 2014). On the basis of bleeding tendency, it may be called as (1) *Bawāsīr Dāmiyyā*, (2*) Bawāsīr Ummiyya,* and based on location, it may be classified as (1) *Nabati* and (2) *Ghaira* (Ahmad al-Hasan 2010; Najar et al. 2018; Ibn Sina 2014).

The treatment approach is based on pharmacotherapy, diet therapy, and regimen therapy. Pharmacotherapy includes drugs possessing *Muhallil-i Waram* (resolvent), *Mulayyin* (laxative), *Musakkin-i Alam* (analgesic), and *Hābis-i Dam* (hemostatic) properties (Ahmad al-Hasan 2010; Ibn Sina 2014; Standard Unani treatment guidelines for common diseases. Vol. I. 2014). For this purpose, various single and compound drugs have been recommended including *Muqil (Commiphora mukul), Rasawt (Berberis aristata), Habb-e-Muqil, Habb-e-Rasaut, Habb-e-Bawāsīr Khūnī, Habb-e-Bawāsīr Bādī,* etc. (Ahmad al-Hasan 2010; Ibn Sina 2014; Standard Unani treatment guidelines for common diseases. Vol. I. 2014). Regimen therapy includes procedures like *Abzan* (sitz baths)*, Fasd* (venesection)*, Hijāma* (cupping), *Irsāl-i 'Alaq* (leeching), etc. Among these recommendations, *Safūf Zāj* and *Marham-i Māzū* are described to have anti-hemorrhoidal, analgesic, anti-inflammatory, antiseptic, powerful astringent, and wound healing properties, but these drugs had not yet been subjected to scientific parameters (Razi 2004). Therefore, *Marham-e-Mazu* and *Phitkiri* (Ahmad et al. 2011; Naim 2017) were chosen for the evaluation of their efficacy in hemorrhoids. Additionally, the study is aimed at exploring the improvement in overall well-being and QoL of the participants of *Bawāsīr.*

Materials and methods

Study design and setting

This study was a single-arm clinical trial conducted on outpatient population addressing the Moalajat department of Luqman Unani Medical College Hospital and Research Center, Vijayapura, Karnataka, India, from March 2020 to December 2020. The study was proposed as single-arm due to lack of feasibility of standard control in the setting and placebo may worsen hemorrhoidal manifestation.

Inclusion criteria

Male or female patients of age 18 to 65 years with symptomatic uncomplicated hemorrhoids of any type; internal, external, or interno-external and internal hemorrhoids patient with Golghar classification grade-I and grade-II were included.

Exclusion criteria

Participants aged less than 18 years with severe anemia (Hb-˂8gm); pregnant and lactating mothers; bleeding dyscrasias; systematic illness (including hypertension and diabetes mellitus) were excluded. Similarly, patients with severe complications during the study, allergy to the interventions, and the individuals who preferred to be excluded from the study were also excluded.

Withdrawal of participants

Participants were withdrawn if they had failed to follow the protocol therapy or if they had developed any adverse drug reaction or adverse event during the period of study.

Trial interventions

Marham-e-Māzū (gall ointment) and *Safūf Zāj* (powdered alum) were selected from authentic Unani pharmacopeial literature; *Qarabadeein-e-Majidi* and *Al-Hāwī* (Anonymous 1986; Kabeeruddin 2010). The drugs including galls of *Quercus infectoria* G.Olivier, alum, and wax (for ointment base) were provided by the Unani pharmacy of LUMC, Bijapur, and identified and authenticated in the department of pharmacology LUMC by the chief pharmacologist. For the preparation of *Marham-e-Māzū*, at first, 400 g of *Māzū* was ground in the mortar and pestle and sieved through sieve no 85; then 4 kg of Mom Safed (wax) was added to the finely powdered *Māzu* and again the whole formulation was ground in mortar and pestle to render into an ointment

(Anonymous 1986). For the preparation of *Safūf Zāj*, alum was roasted in an iron pan at moderate flame till it got melted and became dry and was rendered into a fine powder by mortar and pestle (Kabeeruddin 2010). The participants were instructed to dissolve 20 g of *Safūf Zāj* into 2 L of lukewarm water in a tub and sit into it for 10 min twice daily followed by topical application of *Marham-e-Māzū* in sufficient quantity for 2 weeks.

Study outcome measures

Primary outcome measures

Change in pain intensity, anal itching and defecate discomfort were assessed on a 100 mm visual analog scale (VAS) every week (0, 7th, and 14th days). Per-rectal bleeding was assessed on the 4-point arbitrary Likert scale (0-absent, 1-mild, 2-moderate, and 3severe) every week. However, change in the external hemorrhoidal mass was assessed on an arbitrary scale assuming the size of hemorrhoidal mass as lentil daal (~4–6 mm in diameter), rosary beads (~6–8 mm in diameter), pea (~8–9 mm in diameter), Kabuli chickpea (~9.0–10 mm in diameter) and groundnut (~15–20 mm in diameter) at every week.

Secondary outcome measures

Grades of internal hemorrhoids were evaluated by Goligher classification and QoL was assessed on the SF-12 version 1.0 (via https://orthotoolkit.com/sf-12/) questionnaire on 0, 7th, 14th days.

Safety and adverse event monitoring

The safety evaluation was done on clinical assessment and adverse event documentation.

Study duration and follow up

The duration of the protocol therapy was 2 weeks (14 days). The follow-up was done on the 7th and 14th-day from the baseline of the study & post-treatment follow-up on the 21st day. At every visit, participants were enquired about the progression or regression in their symptoms and were subjected to the clinical assessment, and findings were recorded in case report form.

Statistical analysis

The sample size was 30 participants which were taken on the basis of feasibility as no previous data is available on the trial drugs to derive the variables necessary for sample size calculation. Descriptive and inferential statistical analysis was done using SPSS version 23.0. Data were illustrated as the proportion (%), mean and standard deviation (SD) appropriately. Baseline and after treatment categorical and continuous variables were compared using one way ANOVA test, Chi-square/Fisher's exact test, and paired t-test. *p*-Value less than 0.05 was considered significant.

Ethical consideration

The study protocol was analyzed and validated by the local institutional ethics committee (BJP/LUMC/PG/IEC/04/2018–19/MOALIJAT/04), and prospectively registered with the Clinical Trials Registry-India (CTRI/2020/03/024135). The study was started only after explaining the study to participants and obtaining their written and signed informed consent. The study was executed conferring with updated tenets of the Declaration of Helsinki.

Results

Participant flow

A total of 80 patients were screened for eligibility in which 36 participants were enrolled, of which 30 patients completed the 14 days duration of treatment; 6 participants dropped out of the study due to loss to follow-up (Fig. 1).

Clinico-demographic profile

The mean ± SD age of patients was 35.03 ± 11.44 years. There were 19 (63.3%) females and 11 (36.7%) males. Of 30 participants, 90% participants had a history of a mixed diet

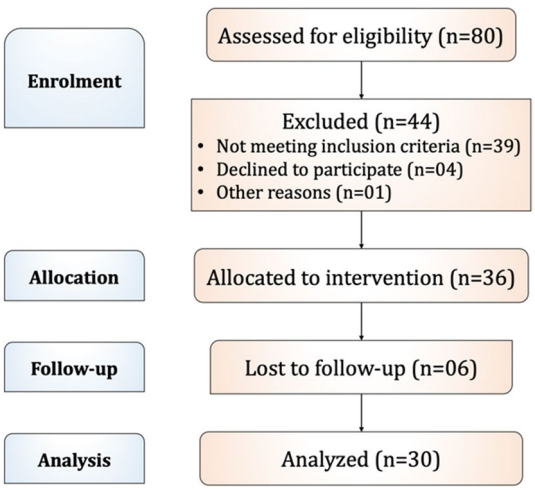

Fig. 1 Flow diagram of the participants included in the study

Table 1 Clinico-demographic profile of participants studied

Demographic profile	Value	*p*-Value* (Comparison among internal, external, and interno-external)
Age, years (mean ± SD)	35 ± 11 years	0.09
Gender Males, n, % Females, n,%	11 (36.7%) 19 (63.3%)	0.885
Marital status Married, n,% Unmarried, n,% Divorce, n,%	23 (76.7%) 6 (20.0%) 1 (3.3%)	0.118
Family history Present, n,% Absent, n,%	4 (13.3%) 26 (86.7%)	1.000
Mizāj (temperament) *Damawi*, n,% *Balghami*, n,% *Safrawi,* n,% *Sawdawi,* n,%	6 (20.0%) 8 (26.7%) 6 (20.0%) 10 (33.3%)	0.076
Diet Vegetarian, n,% Mixed, n,%	3 (10.0%) 27 (90.0%)	0.568
Socio-economic status Lower, n,% Lower middle, n,% Upper lower, n,% Upper middle, n,%	1 (3.3%) 13 (43.3%) 10 (33.3%) 6 (20.0%)	0.964

*One-way ANOVA

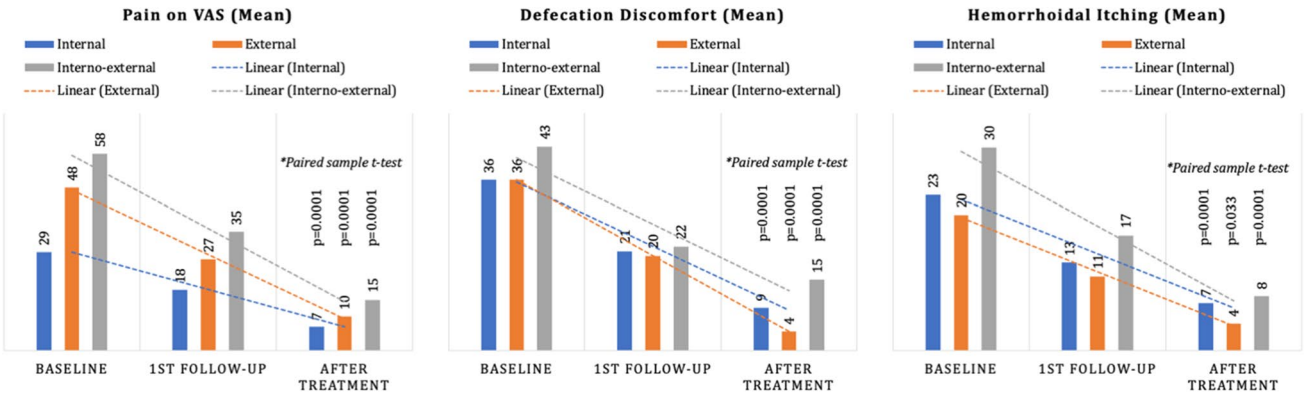

Fig. 2 Pain, defecate discomfort and hemorrhoidal itching assessment of patients studied at different study points

and only 10% had a vegetarian diet; 86.7% cases had no family history whereas only 13.3% cases had a positive family history; 76.7% were married, 20% were unmarried and 3.3% was divorcee; most of the participants were of the lower middle class (43.3%) followed by upper-lower (33.3%), upper-middle (20.0%) and lower (3.3%) strata (Table 1).

Types of hemorrhoids

Most of the cases had internal hemorrhoids (50%), followed by external hemorrhoids (30%) and interno-external hemorrhoids (20%).

Table 2 Per rectal bleeding: assessment of patients studied at different study points

Per rectal bleeding	Baseline assessment	1st follow-up	After treatment analysis	Statistical analysis
Internal hemorrhoids				
Absent	0 (0.0%)	3 (20.0%)	13 (86.7%)	% difference: 86.7% Negative ranks: 15 Positive ranks: 0 Ties: 0 $p<0.0001$
Mild	7 (46.7%)	9 (60.0%)	2 (13.3%)	
Moderate	5 (33.3%)	3 (20.0%)	0 (0.0%)	
Severe	3 (20%)	0 (0.0%)	0 (0.0%)	
External hemorrhoids				
Absent	7 (77.8%)	9 (100%)	9 (100%)	% difference: 22.2% Negative ranks: 2 Positive ranks: 0 Ties: 7 $p=0.157$
Mild	2 (22.2%)	0 (0.0%)	0 (0.0%)	
Interno-external hemorrhoids				
Absent	0 (0.0%)	2 (33.3%)	4 (66.7%)	% difference: 66.7% Negative ranks: 5 Positive ranks: 0 Ties: 1 $p=0.038$
Mild	2 (33.3%)	3 (50.0%)	1 (16.7%)	
Moderate	3 (50.0%)	1 (16.7%)	1 (16.7%)	
Severe	1 (16.7%)	0 (0.0%)	0 (0.0%)	

*Wicoxon Signed Ranks Test

Change in pain severity

The pain severity was measured on VAS score for pain in internal, external, and interno-external hemorrhoids was 29 ± 25, 48 ± 14, and 58 ± 10 at baseline; 18 ± 20, 27 ± 14 & 35 ± 08 at 7th-day follow-up; and 7 ± 16,10 ± 09 & 15 ± 05 on the 14th day respectively. Statistical analysis showed a significant ($p < 0.0001$) decrease in the severity of pain in all three types of hemorrhoids. The trend of pain severity continuously decreased with trial interventions (Fig. 2).

Change in defecation discomfort

With trial therapies defecation discomfort in internal, external, and interno-external hemorrhoids decreased continuously from 36 ± 18, 36 ± 11 & 43 ± 05 at baseline to 21 ± 16, 20 ± 09 & 22 ± 04 at 1st follow up and 09 ± 16, 04 ± 07 & 15 ± 05 at end of the trial respectively. The statistical analysis unveiled a significant ($p < 0.0001$) reduction in defecation discomfort in all three types of hemorrhoids (Fig. 2).

Change in hemorrhoidal itching

The patients experienced amelioration in hemorrhoidal itching severity with the progress of the trial. The Mean ± SD VAS score for itching in internal, external, and interno-external hemorrhoids was 23 ± 14, 20 ± 22, and 30 ± 06 at baseline; 13 ± 14, 11 ± 13, and 17 ± 05 at 1st follow up; and 07 ± 15, 04 ± 07, and 08 ± 04 at the end of the study respectively. The data shows that there were significant ($p < 0.0001$, $p < 0.033$, and $p < 0.0001$) decreases in the severity of Hemorrhoidal itching in all three types of hemorrhoids respectively (Fig. 2).

Change in rectal bleeding

Out of 15 internal hemorrhoids cases, all participants had a history of rectal bleeding at baseline in which 7 (46.7%) had mild, 5 (33.3%) had moderate and 3 (20%) had severe rectal bleeding. At 1st follow-up, there was a significant reduction in rectal bleeding as 3 (20%) were free from rectal bleeding; 9 (60%) cases had mild bleeding while only 3 (20%) had moderate rectal bleeding. At the final follow-up, most of the cases, 13 (86.7%) cases, had no rectal bleeding and only 2 (13.3%) cases had mild rectal bleeding. The pre-post difference was statistically significant ($p < 0.0001$) (Table 2).

Out of 9 external hemorrhoids cases, most of them 7 (77.8%) had no history of rectal bleeding at baseline, only 2 (22.2%) participants had a history of mild rectal bleeding. At 1st follow-up, there was statistically insignificant ($p < 0.157$) reduction in the rectal bleeding as 2 (22.2%) were free from rectal bleeding. Further, there was no recurrence of rectal bleeding in the final follow-up (Table 2).

Out of 6 Interno-external hemorrhoids cases, all participants had a history of rectal bleeding at baseline in which 2 (33.3%) had mild, 3 (50.0%) had moderate and 1 (16.7%) had severe rectal bleeding. At 1st follow-up, there was a significant reduction in rectal bleeding as 2 (33.3%) were

Table 3 Hemorrhoidal mass assessment of patients studied at different study points

Size	Baseline assessment	After treatment analysis	Statistical analysis*
Internal hemorrhoids			
Not applicable	15 (100.0%)	15 (100.0%)	No statistics was computed as variables are constant
External hemorrhoids			
Not measurable mass	0 (0.0%)	3 (33.3%)	% difference: 88.8% Negative ranks: 9 Positive ranks: 0 Ties: 0 $p=0.004$
Kabuli chick pea	2 (22.2%)	0 (0.0%)	
Lentil	0 (0.0%)	5 (55.5%)	
Pea	3 (33.3%)	0 (0.0%)	
Rosary	4 (44.4%)	1 (11.1%)	
Interno-external hemorrhoids			
Not measurable mass	0 (0.0%)	2 (33.3%)	% difference: 66.7% Negative ranks: 6 Positive ranks: 0 Ties: 0 $p=0.031$
Lentil	1 (16.7%)	3 (50.0%)	
Pea	2 (33.3%)	0 (0.0%)	
Rosary	3 (50.0%)	1 (16.7%)	

*Wicoxon Signed Ranks Test

free from rectal bleeding; 3 (50.0%) cases had mild bleeding while only 1 (16.7%) had moderate rectal bleeding. At the final follow-up, most of the cases 4 (66.7%) cases had no rectal bleeding and only 1 (16.7%) case had mild and 1 (16.7%) had moderate rectal bleeding. Statistical analysis revealed significant difference in pre-post variables ($p=0.038$) (Table 2).

Change in hemorrhoidal mass

Out of 9 (30%) external hemorrhoids cases, 2 (22.2%), 3 (33.3%) & 4 (44.4%) participants had size of hemorrhoidal mass as Kabuli chickpea, pea & rosary respectively at baseline. At the end of the trial, there was a substantial reduction in the size of the hemorrhoidal mass, as 3 (3.33%) patients had immeasurable mass and the rest 5 (55.5%) & 1 (11.1%) cases had lentil and rosary sized mass respectively. The total percentage change was 88.8% which inferred a statistically significant ($p=0.004$) result in favor of intervention reducing the external hemorrhoidal mass based on the reduction in size of hemorrhoidal mass.

Out of 6 (20%) interno-external hemorrhoids, 1 (16.7%), 2 (33.3%) & 3 (50.0%) cases had lentil, pea & rosary sized hemorrhoidal mass respectively at baseline. At the end of the trial, there was a significant reduction in the mass as 2 (33.3%) had unmeasurable mass, whereas 3 (50.0%) & 1 (16.7%) cases had lentil & rosary sized hemorrhoidal mass respectively. The total percentage reduction was 33.3% that was statistically significant ($p=0.031$) inferring that the interventions are efficacious in reducing the external palpable mass (Table 3). Although, for 15 cases of internal hemorrhoids, this assessment was not applicable as only grade-I and grade-II patients were included.

Table 4 Goligher grade assessment of patients studied at different study points

Grade	Baseline assessment	After treatment follow-up	Statistical analysis*
Internal hemorrhoids			
Absent	0 (0.0%)	7 (46.7%)	% difference: 46.7% Negative ranks: 7 Positive ranks: 0 Ties: 8 $p=0.016$
1	8 (53.3%)	1 (6.7%)	
2	7 (46.7%)	7 (46.7%)	
Total	15 (100%)	15 (100%)	
Interno-external hemorrhoids			
Absent	0 (0.0%)	1 (16.7%)	% difference: 33.3% Negative ranks: 3 Positive ranks: 0 Ties: 3 $p=0.25$
1	1 (16.7%)	2 (33.3%)	
2	5 (83.3%)	3 (50.0%)	
Total	6 (100%)	6 (100%)	
External hemorrhoids			
Absent	9 (100%)	9 (100%)	No statistics was computed as variables are constant

*Wicoxon Signed Ranks Test

Change in Grade

Out of 15 internal hemorrhoids cases, 8 (53.3%) participants had Grade-I and 7 (46.7%) had Grade-II hemorrhoids at baseline. After treatment, there was a significant reduction in Grade-I i.e., 7 (46.7%) out of 8 (53.3%) cases were relieved completely leaving only 1 (6.7%) case with Grade-I; while in the cases with Grade-II, no significant changes were seen. The percentage change was 46.7% in the participants having no grade which is a significant result in favor of the trial drugs ($p=0.016$) (Table 4).

Table 5 Physical and mental component (PCS & MCS) summary scale assessment

Type	N	Baseline (mean ± SD)	After treatment (mean ± SD)	Mean difference[a]	*p*-Value[b]
Physical score (PCS)					
Internal	15	34 ± 5	47 ± 5	03	0.0001
External	9	35 ± 6	52 ± 5	02	0.0001
Interno-external	6	31 ± 6	51 ± 4	01	0.0001
Total	30	37 ± 8	51 ± 6	02	0.0001
Mental score (MCS)					
Internal	15	35 ± 4	50 ± 5	00	0.0001
External	9	46 ± 8	56 ± 4	06	0.001
Interno-external	6	45 ± 7	56 ± 2	06	0.015
Total	30	49 ± 8	55 ± 4	05	0.0001

[a]Mean difference between after treatment variables and US population mean (50), [b]Paired sample *t* test

Out of 6 Interno-external hemorrhoid cases, 1 (16.7%) participant had grade-I while 5 (83.3%) had grade-II hemorrhoid at baseline. After-treatment evaluation it is revealed that 1 (16.7%) case relieved completely while 2 (33.3%) participants' grade-II was changed to grade-I. The total percentage change was 33.3% which is statistically insignificant ($p = 0.25$).

No analysis could be performed in external hemorrhoids as the grading does not applicable there (Table 4).

Change in quality of life

At baseline, the mean ± SD physical score (PCS) was 34 ± 5, 35 ± 6, & 31 ± 6 in internal, external & interno-external hemorrhoid respectively, while at the end of trial, there was an increase in mean PCS i.e., 47 ± 5, 52 ± 5, & 51 ± 4, which is statistically significant ($p < 0.0001$ for internal, external & interno-external hemorrhoid respectively) with reference to the difference between US mean population.

The mean ± SD MCS at baseline was 35 ± 4, 46 ± 8 & 45 ± 7 in internal, external & interno-external hemorrhoid respectively while after completion of therapy there was an increase in mean MCS i.e., 50 ± 5, 56 ± 4, & 56 ± 2, which is statistically significant ($p < 0.0001$, $p < 0.001$ & $p < 0.015$ for internal, external & interno-external hemorrhoid respectively) with reference to the difference between US mean population (Table 5). This infers significant change in mean MCS & PCS from pertinent positive to pertinent negatives with reference to mean US population.

Discussion

This study was commenced to investigate the clinical efficacy of *Ābzan* with *Safūf-i Zāj* (sitz baths with alum) followed by local application of *Marham-e-Mazū* (gall ointment) in *Bawāsīr*. Likewise, the study was aimed to explore a novel therapeutic approach in *Bawāsīr* to improve the overall well-being and QoL of the sufferer of *Bawāsīr*.

The mean ± SD of age was 35.03 ± 11.44 years; following Coulibaly et al., Ali et al. and Riss et al. who reported the common occurrence of piles in the age group of 30–39 years (Ali and Shoeb 2017; Coulibaly et al. 2016; Riss et al. 2012). Gender-wise, the female to male sex ratio was about 2:1, contrary to Najar et al. and Ravindranath et al. who found a higher incidence in male (Ravindranath and Rahul 2018; Sakr 2014). But Johanson and Sonnenberg has a viewpoint of equal incidence in women due to pregnancy, childbirth, increased pelvic pressure, and menstruation. Also, the lesser incidence may be due to fewer visits of women in the hospitals mentioning hemorrhoidal symptoms (Johanson and Sonnenberg 1990). The familial association was only 13.3% contrary to G. G. Ravindranath and B. G. Rahul who reported 73.8% of patients with positive family history. The majority of the cases studied hailed from lower-middle socioeconomic status contrary to Johanson et al. who reported hemorrhoids were 1.8 times more common in higher socioeconomic than in the lowest social class (Johanson and Sonnenberg 1990).

The per-protocol analysis unveiled that *Marham-e-Māzū* (gall ointment) and *Safūf Zāj* (powdered alum) significantly improved the primary and secondary outcomes (except a few), and the effect may be accredited to biomedical properties inherent in trial drugs. The trial drugs '*Zāj*' and '*Māzū*" are the potent *Habis al-Dam* (hemostyptic); *Mujaffif-e-Qūrūh*, and *Da'fi-i Ta'affun* (antiseptic) drug of Unani medicine (Kabeeruddin 2018; *The Unani pharmacopoeia of India part-I,vol 3*, 2007). Thus, reduction in rectal bleeding is mainly due to *Habis al-Dam* and *Mujaffif-e-Qūrūh* properties (Saffiuddin 2002) which act through constricting the blood vessels and decreasing exudation and thus helps in healing of wounds and ulcers (Standard Unani treatment guidelines for common diseases. Vol. I. 2014). Pharmacologically and clinically, Zāj (alum), as well as Mazū has

been reported for its antihemorrhagic and anti-ulcer activity. Gattegno B et al. concluded the significant effect of intravesical instillation of potassium alum in the treatment of hemorrhagic cystitis caused by cyclophosphamide (Gattegno et al. 1990). According to Al-Abbasi AM, application of aluminum potassium sulfate (> 99% pure) in tonsillar fossae during tonsillectomy procedures exhibited significant hemostatic effects (Al-Abbasi 2009). In another study, Takashi M. et al. and Goel AK et al. evaluated the anti-hemorrhagic action of alum irrigated intravesically, in massive bladder hemorrhage and found that it can check the blood promptly but not for much duration (Takashi et al. 1988). Altaei TS et al. conducted a randomized double-blind placebo control study and noted a significant reduction in the time required for complete healing of the ulcer when compared with the placebo group (ALtaei and AI-Jubouri 2005). Moreover, the effect has been ensured due to analgesic, anesthetic, and resolvent, the action of trial drug *Māzū*. Pharmacologically, *Quercus infectoria* has been affirmed for its anti-inflammatory, analgesic, and anesthetic action (Dar et al. 1976). Dar et al. reported that a dried acetone treated methanol extract of galls dissolved in the water had a significant analgesic effect in rats (Dar et al. 1976; Rastogi and Mehrotra 1993). In another study on isolated frog sciatic nerve, chloroform–methanol extract of *Quercus infectoria* galls showed local anesthetic activity by complete blockade of nerve conduction (Dar et al. 1976; Rastogi and Mehrotra 1993). Kaur et al. concluded the significant anti-inflammatory action of alcoholic extract of galls (Kaur et al. 2004).

The reduction in palpable mass may be due to *Habis al-Dam* (hemostyptic) and astringent actions of *Safūf Zāj* and *Māzū* (Mohammad Abdul Hakeem 2011). Moreover, *Māzū* is a potent antimicrobial drug that may inhibit superinfection in the setting of piles as reported by Hashim et al. (Hashim et al. 2013).

The significant amelioration in QoL may be due to analgesic, anesthetic, anti-inflammatory, and anti-hemorrhagic activities of trial drugs as reported by Dar et al. and Kaur et al. (Dar et al. 1976; Kaur et al. 2004).

Overall, the trial interventions were found to be effective and well tolerated, with no significant undesired effects observed during the research period.

Limitations

Some limitations ought to be taken into consideration for interpretation and generalization of study results such as nonspecific hemorrhoidal disease evaluation, small sample size, and absence of control in the study. Furthermore, because this was a validation trial, there was no assessment of the intervention's maximum tolerated dose because the treatments were chosen from the Unani pharmacopoeia and can only be administered according to the recommended dose and dosage form. Another limitation was dose and dosing frequency variation, even though the participants were first taught how to apply gall ointment and do sitz baths in the hospital, there was the chance of dose and dosing frequency variability. Moreover, the study was managed during the Covid-19 pandemic and nationwide lockdown which resulted in the enrolment of only patients from the hospital's immediate vicinity, posing a risk to the generalizability of the study. Thus, dose response multicentric, randomized control trials with a large sample size should be carried out on the specific type of hemorrhoidal disease to verify the proposed results.

Conclusion

The study inferred that *Safūf Zāj* (powdered alum) and *Marham-e-Māzu* (gall ointment) are efficacious, well tolerated, and economical regimen for the patients of Grade-I & II internal hemorrhoids, external hemorrhoids, and interno-external hemorrhoids. The interventions improved almost all outcomes except reduction in grade and per rectal bleeding in interno-external and external hemorrhoids respectively. Therefore, it can be concluded that *Safūf Zāj* and *Marham-e-Māzu* have potential properties for an alternative treatment for amelioration of hemorrhoids symptoms as well as quality of life. The drugs may be investigated further with carefully designed dose response multi-centric, randomized control trial with a larger sample size on specific type of hemorrhoidal disease to verify the proposed results.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s13596-022-00634-6.

Acknowledgements The authors express their sincere thanks to Dr. Mohd Aqil Quadri, Dr. Sumaiyya Tasneem Parapur and librarian of Luqman Unani Medical College Hospital and Research Center, Bijapur, India, for their cooperation.

Author contributions All authors have accepted responsibility for the entire content of this manuscript and approved its submission.

Funding None.

Declarations

Ethical statement The research involving human participants adhered to all applicable national regulations, institutional policies, and the precepts of the Helsinki Declaration (as revised in 2013), was approved by the authors' institutional ethics committee (Ref. No. BJP/LUMC/PG/IEC/04/2018-19/MOALIJAT/04), and was prospectively registered with the clinical trials registry-India (CTRI/2020/03/024135).

Conflict of interest Salma Chaush has no conflict of interest. Nazim Husain has no conflict of interest. Mohd Khalid has no conflict of inter-

est. Meenu Doni has no conflict of interest. Mohd Qudrathullah Khan has no conflict of interest. Majid Hussain has no conflict of interest.

Informed consent Informed consent was obtained from all individuals included in this study.

References

Ahmad W, Zeenat F, Hasan A, Abdullah A, Medicine U (2011) Mazu (Quercus infectoria , Oliv)—an overview IV, 17–22

Ahmad al-Hasan J (2010) Zakhira Khwarizm Shahi, 1st ed. Idara Kitab-us-Shifa, New Dehli

Al-Abbasi AM (2009) The benefit of alum in tonsillectomy. Gomal J Med Sci 7:124–127

Ali SA, Shoeb MFR (2017) Study of risk factors and clinical features of hemorrhoids. Int Surg J 4:1936. https://doi.org/10.18203/2349-2902.isj20172051

Altaei TS, Ai-Jubouri RH (2005) Evaluation of the efficacy of alum suspension in treatment of recurrent ulcerative ulceration. J Baghdad Coll Dent 17:45–48

Anonymous (1986) Qarabadeen I-majidi, 9th edn. Ajanta office and publications ltd, Delhi

Bhat S (2017) SRB'S manual of surgery, 5th ed. Jaypee Brothers Medical Publishers (p) Ltd., New Dehli

Chugh A, Singh R, Agarwal PN (2014) Management of hemorrhoids. Indian J Clin Pr 25:577–580

Corman ML (1998) Malignant tumors of anal canal. In: Corman ML (Ed). Colon and rectal surgery

Coulibaly A, Kafando R, Somda KS, Doamba C, Koura M, Somé CC, Ouédraogo T, Traoré S (2016) The haemorrhoids' pathology: epidemiological, diagnostic, therapeutic and evolutionary aspects. Open J Gastroenterol 06:343–352. https://doi.org/10.4236/ojgas.2016.611037

Dandroo JN, Fatimah M, Alam SS, Afreen S (2017) Prevalence of iron deficiency anaemia and risk factors in a sample of population of bleeding haemorrhoids (Bawaseer Khooni): an observational study. Res Rev J Surg 6:17–22

Dar MS, Ikram M, Fakouhi T (1976) Pharmacology of quercus infectoria. J Pharm Sci 65:1791–1794

Das S (2014) A concise textbook of surgery, 10th edn. S. Das, Kolkata

Najar FA, Faisal M, Khesal A, Ansari TA (2018) Prevalence of hemorrhoid among the patients visiting surgery OPD at Nium hospital. Eur. J. Biomed. 5:435–437

Gattegno B, Guillemenot F, Fiatte P, Cohen L, Becker A, Gluckman E, Thibault P (1990) Treatment of hemorrhagic cystitis caused by cyclophosphamide using intravesical instillation of potassium alum. Apropos of 5 cases. Ann Urol (paris) 24:190–192

Kabeeruddin HM. (2018) Makhzanul mufradat khwas al adwiya. Ajaz Publishing house, New Delhi, India

Hashim ST, Hamza IS, Hassan MA (2013) Identification of quantative chemical compounds of ethanolic extracts of Quercus infectoria and studies its inhibitory effect in some bacteria. Indian J Res 2:125–128

Johanson JF, Sonnenberg A (1990) The prevalence of hemorrhoids and chronic constipation. An Epidemiologic Study Gastroenterology 98:380–386. https://doi.org/10.1016/0016-5085(90)90828-O

Kabeeruddin M (2010) Bayaz-e-Kabeer, 1st edn. Idara Kitab-us-Shifa, New Dehli

Kaur G, Hamid H, Ali A, Alam MS, Athar M (2004) Antiinflammatory evaluation of alcoholic extract of galls of Quercus infectoria. J Ethnopharmacol 90:285–292

Khan MA (2011) Iksir-e-Azam, 1st edn. Idara Kitab us-Shifa, New Delhi

Lestar B, Penninckx F, Kerremans R (1989) The composition of anal basal pressure. Int J Colorectal Dis 4:118–122

Loder PB, Kamm MA, Nicholls RJ, Phillips RKS (1994) Haemorrhoids: pathology, pathophysiology and aetiology. Br J Surg 81:946–954. https://doi.org/10.1002/bjs.1800810707

Lohsiriwat V (2012) Hemorrhoids: from basic pathophysiology to clinical management. World J Gastroenterol 18:2009–2017. https://doi.org/10.3748/wjg.v18.i17.2009

Madoff RD (2016) Goldman-Cecil Medicine, Vol.-I, 25th ed. Elsevier Saunders

Margetis N (2019) Pathophysiology of internal hemorrhoids. Ann Gastroenterol 32:264–272. https://doi.org/10.20524/aog.2019.0355

Mohammad Abdul Hakeem (2011) Busatan al-Mufradat, 1st edn. Eijaz Publishing House, New Delhi

Mosavat SH, Ghahramani L, Sobhani Z, Haghighi ER, Heydari M (2015) Topical Allium ampeloprasum subsp Iranicum (Leek) extract cream in patients with symptomatic hemorrhoids: a pilot randomized and controlled clinical trial. J Evid Based Complementary Altern Med 20:132–136

Naim M (2017) Quercus infectoria (Mazu): a review. World J Pharm Res 6:176–185. https://doi.org/10.20959/wjpr20179-9211

Poya H, Singh R, Shukla A (2017) Lifestyle causes of arsha (piles): an ayurvedic review. Int J Res Ayurveda Pharm 8:29–31. https://doi.org/10.7897/2277-4343.08278

Rastogi RP, Mehrotra BN (1993) Compendium of Indian medicinal plants, Vol. II. CDRI, Lucknow

Ravindranath GG, Rahul BG (2018) Prevalence and risk factors of hemorrhoids: a study in a semi-urban centre. Int Surg J 5:496. https://doi.org/10.18203/2349-2902.isj20180339

Razi Z (2004) Kitab al-Hawi, vol XI. CCRUM, New Delhi

Riss S, Weiser FA, Schwameis K, Riss T, Mittlböck M, Steiner G, Stift A (2012) The prevalence of hemorrhoids in adults. Int J Colorectal Dis 27:215–220. https://doi.org/10.1007/s00384-011-1316-3

Saffiuddin A (2002) Unani Advia Mufrada, 9th edn. NCPUL, New Delhi

Sakr M (2014) Recent advances in the management of hemorrhoids. World J Surg Proced 4:55. https://doi.org/10.5412/wjsp.v4.i3.55

Shrivastava L, da Silva Borges G, Shrivastava R (2018) Clinical efficacy of a dual action, topical anti-edematous and antiinflammatory device for the treatment of external hemorrhoids. Clin Exp Pharmacol 8:1–7

Ibn Sina, (2014) Al-Qanoon fil-Tibb., vol 2. Idara Kitab-us-Shifa, New Delhi

Standard Unani treatment guidelines for common diseases. Vol. I., 1st ed, 2014. Central Council for Research in Unani Medicine, New Delhi

Sun Z, Migaly J (2016) Review of hemorrhoid disease: presentation and management. Clin Colon Rectal Surg 29:022–029. https://doi.org/10.1055/s-0035-1568144

Takashi M, Kondo A, Kato K, Murase T, Miyake K (1988) Evaluation of intravesical alum irrigation for massive bladder hemorrhage. Urol Int 43:286–288

The Unani pharmacopoeia of India part-I, vol. III, (2007). Govt of India, Ministry of health and family welfare Department of AYUSH, New Delhi

Thomson WHF (1975) The nature of haemorrhoids. Br J Surg 62:542–552. https://doi.org/10.1002/bjs.1800620710