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Effect of *Sharbat Habbul Aas* in heavy menstrual bleeding-A pre and post interventional study

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Heavy menstrual bleeding (HMB) is the most common form of abnormal uterine bleeding (AUB), which is estimated to affect one-third of women worldwide. Current conventional treatments are associated with adverse effects; hence this study was conducted to evaluate the effect of *Sharbat Habbul Aas* in women with HMB.A pre and post interventional study was conducted to evaluate the effect of *Sharbat Habbul Aas* in HMB at National Institute of Unani Medicine Hospital, Bengaluru. The (n=32) diagnosed cases of HMB between 18-42 years of age fulfilling inclusion criteria were enrolled in the study. *Sharbat Habbul Aas* (comprising of *Habbul Aas, Gulnar, Phali Babul, Āb Behi, Āb Seb, Āb Anar,* and *Amrud*) was administered orally in adose of 24 mL twice daily for 7days per cycle for 3 consecutive cycles. Primary outcome was reduction in Pictorial blood loss assessment chart (PBAC) score and duration of bleeding (DOB) and secondary outcome were improvement in haemoglobin (Hb%) and quality of life (QoL), which were assessed during the trial. Results were analysed statistically by Wilcoxon Signed Rank Test and Paired Proportion test. Reduction in PBAC score and DOB was achieved in 96.9% and 31.25% of participants respectively. Improvement in QoL was achieved in100% of participants respectively. *Sharbat Habbul Aas* is an effective therapeutic option in HMB, with no adverse effects during trial. Hence, it can be used in women with HMB opting for herbal alternatives over conventional medicine. However, the safety findings are preliminary and require confirmation in larger studies with longer follow up.

Keywords: *Habbul Aas*, Heavy menstrual bleeding, *Kathrat-i-Ṭamth*, *Myrtus communis* Linn, PBAC score

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Heavy menstrual bleeding (HMB) is objectively defined as menstrual blood loss of 80 mL or more per menstrual period not related to pregnancy or any systemic or gynaecological disease. According to the International Federation of Gynaecology and Obstetrics (FIGO) "HMB is an excessive menstrual blood loss that interferes with the woman's physical, emotional, social, and material quality of life, and can occur alone or in combination with other symptoms"[1,2]. HMB is associated with other iron deficiency anaemia in 25% cases[2]. An estimated 40% of menstruating adolescent girls report HMB, an even higher prevalence than that reported among menstruating adult women[1].

Medical management for HMB includes nonsteroidal anti-inflammatory drugs, antifibrinolytics, progestogens, combined oral contraceptive pills, and gonadotropin-releasing hormone agonists (GnRH agonists). However, these treatments have different side effects and sometimes do not show adequate efficacy[3,4]. In recent years, there has been a tendency toward using herbal supplements in disease treatment worldwide. It is generally believed by the public that herbal remedies are safer and have fewer side effects than medical drugs[4].

In the Unani system of medicine (USM), *Sharbat Habbul Aas*, a polyherbal formulation containing *Myrtus communis* Linn. (Habbul Aas), *Acacia arabica* (Phali Babul), *Punica granatum* (Anar), *Psidium guajava* (Amrud), *Cydonia oblonga* (Behi), *Malus pumila* (Seb), and *Punica granatum* (Gulnar) has been traditionally used to treat HMB[5]. These drugs exhibit astringent, hemostatic and anti-inflammatory properties[6–14]. Major phytoconstituents relevant to the reported astringent/hemostatic properties of the ingredients of *Sharbat Habbul Aas* have been mentioned in (Table 1). Despite promising individual reports, there remains a scarcity of well-structured pre-post interventional studies assessing the polyherbal formulation- *Sharbat Habbul*

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Aas within clinical setting. This study aims to fill this gap by evaluating its safety and efficacy in women aged 18-42 years with HMB, using PBAC score, duration of bleeding (DOB), haemoglobin levels and menstrual bleeding questionnaire (MBQ). It was hypothesized that research formulation would be effective in ameliorating HMB.

Materials and Methods

Study design and setting

A single centered, pre–post interventional study without control was conducted at the Department of Ilmul Qabalat wa Amraze Niswan, National Institute of Unani Medicine Hospital (NIUM), Bengaluru, India.

Sample size estimation

The minimum sample size calculated was 27, based on previous study conducted by Uma rami *et al*. With additional 20% drop out, total sample size considered was 32. Sample size formula used was: $n= [2(z_{1-\alpha/2} + z_{\beta})^2 / (\delta_{diff}/\sigma_{diff})^2] + [(z_{1-\alpha/2})^2/2]$.

Selection of participants

Thirty-two women aged 18-42 years with a history of heavy menstrual bleeding (PBAC score >100 and/or duration of bleeding >7 days) for at least 2 out of 3 consecutive cycles; and diagnosed with thickened endometrium, adenomyosis, or ≤3 uterine fibroids (<3 cm) on ultrasound were enrolled in the study after obtaining written informed consent. These ultrasound-defined conditions were considered as the underlying pelvic conditions within the predefined study population. The study was designed to assess the overall clinical response to the research formulation in women fulfilling the predefined HMB criteria and was not powered for comparison of treatment response according to individual pelvic pathology. Also women with systemic conditions (Hypertension, diabetes and thyroid dysfunction), bleeding disorders, severe anemia (Hb <7 g%), malignancy, surgical cause of HMB or history of use of hormonal contraceptives in the past three months were excluded.

Study procedure

Enrolled participants were enquired about the details of their demographics, menstrual cycle pattern and duration. Additionally any previous medical, surgical or familial history was confirmed. The socioeconomic status and *Miẓaj* (temperament) were assessed by Modified Kuppuswamy's socioeconomic scale (updated 2022) and temperamental scale respectively. Complete physical examination was performed in all participants to exclude general or systemic manifestation. All participants were instructed not to use any medication during the trial. Investigation like clotting time (CT), bleeding time (BT), hemoglobin (Hb%), Platelet count, fasting blood sugar (FBS), thyroid stimulating hormone (TSH), Ultrasonography (USG) pelvis and Pap smear were done to exclude any pathology. Safety profile including alanine aminotransferase **(**ALT), aspartate aminotransferase **(**AST), alkaline phosphatase (ALP), serum creatinine and blood urea were done before and after trial to assess the safety of the research formulation. Hb% was repeated at the end of trial to note the improvement in hemoglobin.

Intervention

Patients received *Sharbat Habbul Aas* 24 mL orally, twice daily from day 1 to day 7 of menstrual cycle, for a total of three consecutive cycles. The formulation comprised *Myrtus communis* (Habbul Aas), *Acacia arabica* (Phali Babul), *Punica granatum* (*Gulnar*), *Psidium guajava* (Amrud), *Cydonia oblonga* (Behi), *Malus pumila* (Seb), and *Punica granatum* (Anar)[5]. *Gulnar* was used as a substitute due to not availability of *Tarasees* (*Tectona grandis* Linn). Ingredients were sourced from a licensed herbal pharmacy in Bengaluru, authenticated by the Central Ayurveda Research Institute [(RRCBI-13286), (RRCBI-mus 341), (RRCBI-mus 350)], and voucher-indexed (144/IQ/Res/2023) at Dept. of Ilmul Advia (Pharmacology) of NIUM, Bengaluru.

Preparation

Dried Phali Babul (30 g), Gulnar (30 g), Habbul Aas (140 g), and Amrud (140 g) were soaked in water

Table 1 — Major phytoconstituents relevant to the reported astringent/hemostatic properties of the ingredients of *Sharbat Habbul Aas*

S.no	Ingredient	Scientific name	Phytochemical constituent with possible astringent/hemostatic property	Reference
1	Habbul Aas	*Myrtus communis* L.	Tannins including gallotannins and ellagitannins, gallic acid, ellagic acid	15
2	Phali Babul	*Acacia arabica* L.	Tannins, gallic acid, catechin, ellagic acid	16
3	Anar, Gulnar	*Punica granatum* L.	Tannins particularly punicalagin, punicalin, ellagitannin, gallic acid, ellagic acid	17
4	Amrud	*Psidium guajava* L.	Tannins	18
5	Behi	*Cydonia oblonga* Mill.	Tannins and procyanidins	13
6	Seb	*Malus pumila* Mill.	Tannins, procyanidins, catechin and epicatechin	19

overnight and decocted to half volume on the consecutive day. One litre fresh juice was extracted from each of Behi (30 Kg), Seb (30 Kg) and Anar (30 Kg). These juices were added to decoction and boiled till it reduced to one-third volume. Sugar (30 Kg) and citric acid (50 g) was added to the decoction and bought to boil to obtain a syrupy consistency. Syrup so obtained was stored in transparent plastic bottles and dispensed to the participants in each cycle before the onset of menses.

Assessment tools

Subjective parameters

Duration of bleeding (*DOB*)

Duration of bleeding was assessed at every visit and after trial for reduction in number of bleeding days.

Objective parameters

Pictorial blood assessment chart (*PBAC*)

The Pictorial Blood Assessment Chart (PBAC) is a simple, inexpensive, semi-quantitative tool for assessing menstrual blood loss. It uses pictorial representations of progressively blood-stained sanitary products, with each degree of staining assigned a corresponding score (Fig. 1). Participants record the number and degree of staining of the sanitary products used during each menstrual period. The chart also permits recording of blood clots and episodes of flooding. The scores for all products and associated bleeding characteristics are summed to obtain the total PBAC score for the menstrual cycle. A total PBAC score of >100 has been associated with menstrual blood loss of >80 mL and has been used as an indicator of heavy menstrual bleeding[20,21].

Menstrual Bleeding Questionnaire (*MBQ*)

It is a validated patient reported outcome measure designed to assess the impact of menstrual bleeding on quality of life (QoL) in women suffering from HMB. It was filled by the participant after initial screening and during the treatment. Among the parameters measured by MBQ was impairment in social activities, work performance, physical activities, productivity, hygienic condition, and psychological well-being. The questionnaire comprises a total of 20 items, grouped into four domains: bleeding heaviness, bleeding irregularity, pain and quality of life. Each item is scored according to the response options specified in

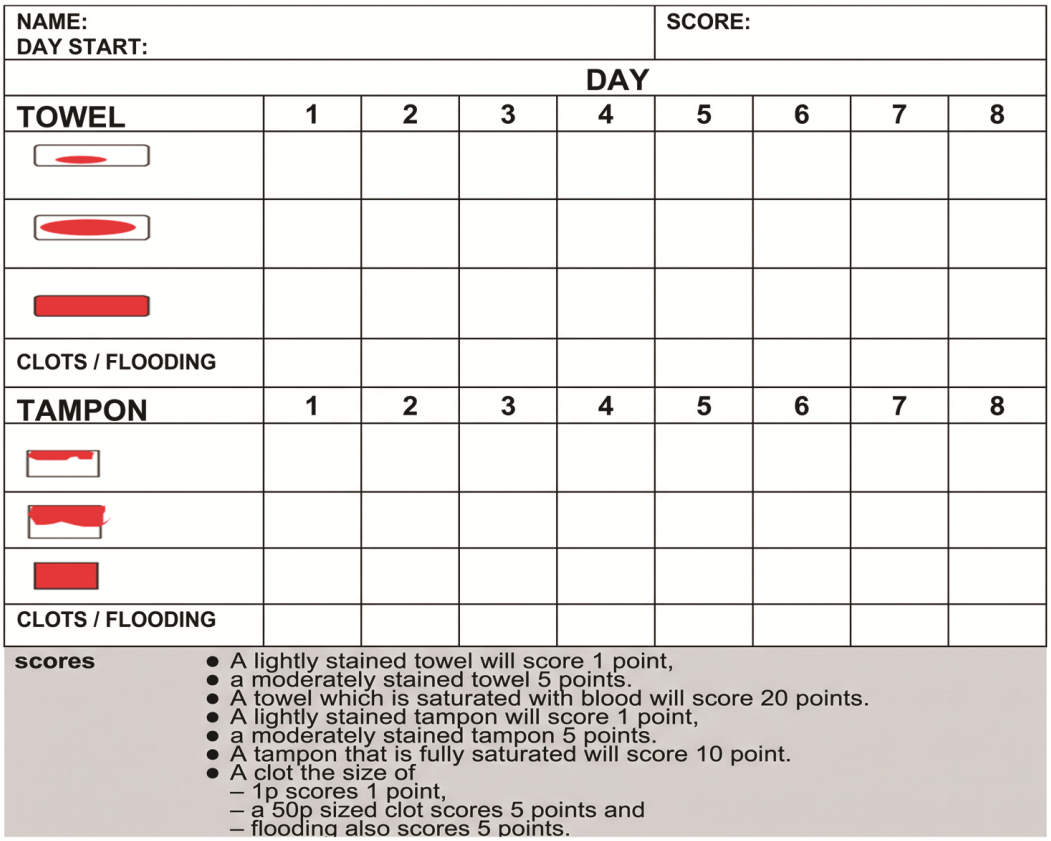


Fig. 1 — Pictorial blood assessment chart[21]

the questionnaire and the item scores are combined to generate an overall MBQ score. The total score ranges from 0 to 75, with higher scores indicating greater menstrual bleeding related symptom burden and a greater negative impact on QoL[22].

Follow up and compliance

Follow ups occurred monthly during treatment and once post-treatment, with repeat assessments of DOB and PBAC. Safety profile, hemoglobin and MBQ was repeated at the end of the study. Adherence was monitored by collection of returned syrup bottles.

Outcome measures

Primary outcomes

Reduction in PBAC score and duration of bleeding (DOB) of ≥30% was considered clinically significant.

Secondary outcomes

Improvements in hemoglobin and QoL (assessed using MBQ). A ≥30% reduction in MBQ score was considered significant.

Data analysis

Data were statistically described as mean ±standard deviation and frequencies (percentages) when appropriate. All statistical analysis were performed using IBM-SPSS statistics for windows version 28.0 (IBM Corp. released 2021 Armonk, NY, USA). Data for continuous variables were presented as mean ± SD (min–max) and categorical as number (%). Data were checked for normality using the Shapiro Wilk test. Since the data did not follow a normal distribution, the Friedman test (a nonparametric repeated-measures ANOVA) was conducted to assess changes across multiple cycles, followed by Wilcoxon Signed-Rank tests with a Bonferroni correction for post hoc pair wise comparisons. Statistical significance was set at $p < 0.05$. Graphs and tables were generated using Microsoft Word and Excel.

Results

A total of (n=76) patients were screened for eligibility, out of which (n=60) agreed and (n=16) denied to participate. Among (n=60) who were investigated, (n=26) were excluded as they did not meet the inclusion criteria, therefore (n= 34) were enrolled in the study, two patients dropped out (1 conceived and 1 was out of the station), (n= 32) completed the trial and were included in the final analysis based on per protocol analysis (Fig. 2).

Participant profile

The study included 32 women with mean age 26.69 ± 6.9 years. Average age at menarche was

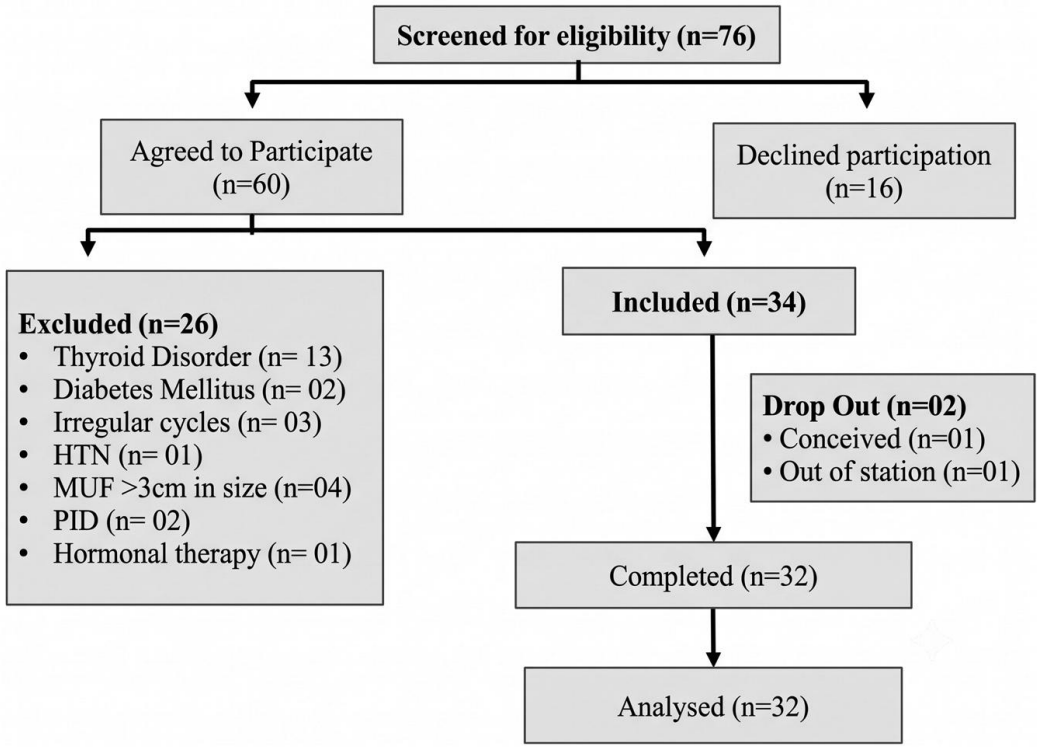


Fig. 2 — Study flow chart

12.53 ± 1.34 years and mean BMI was 25.30 ± 5.84. Most participants were single (59.4%) and belonged to upper-lower (46.9%) and lower-middle (37.5%) socioeconomic strata. Dysmenorrhea was reported by 84.4%. Temperament analysis showed 75% had *Damawī mizāj* (Table 2).

Safety parameters

Liver and renal function tests (AST, ALT, alkaline phosphatase, blood urea, serum creatinine) showed no significant changes post-intervention ($p > 0.05$). No serious adverse effects were reported (Table 3).

Table 2 — Demographic data of study participants

Quantitative parameters		
Age (Years)	Frequency (N)	Percentage (%)
≤20	8	25.00%
21-30	15	46.90%
31-40	8	25.00%
>40	1	3.10%
Mean ± SD	26.69 ± 6.902	
AOM (Years)		
<13 Years	20	62.50%
>13 Years	12	37.50%
Mean ± SD	12.53 ± 1.344	
BMI (Kg/m^2)		
<18.5	5	15.6%
18.5-24.9	12	37.5%
25.0-29.0	8	25.0%
30.0-34.9	5	15.6%
>35.0	2	6.3%
Mean ± SD	25.295 ± 5.840	
Qualitative parameters		
Marital status	Frequency (N)	Percentage (%)
Married	13	40.6%
Single	19	59.4%
Socioeconomic status		
Upper lower	15	46.90%
Lower middle	12	37.50%
Upper middle	4	12.50%
Upper	1	3.10%
Mizāj (Temperament)		
Balghamī	6	18.8%
Damawī	24	75.0%
Ṣafrāwī	2	6.3%
Dysmenorrhea		
Present	27	84.4%
Absent	5	15.6%
Pap smear		
Inflammatory	8	25.0%
Normal	5	15.6%
Not applicable	19	59.4%
DOB>7 days		
Yes	14	43.80%
No	18	56.30%

AOM: Age of menarche; BMI: Body mass Index; DOB: Duration of bleeding

Primary outcomes

Duration of bleeding (DOB)

At baseline, prolonged menstrual bleeding (DOB>7 days) was observed in 14 out of 32 participants. The overall mean duration of bleeding for all participants at baseline was 7.63 ± 2.27 days. Following the treatment, 9 (64.28%) out of 14 participants who initially had prolonged bleeding experienced a reduction of ≥30%, indicating a normalization of bleeding duration. Additionally, the remaining participants also showed improvement, leading to an overall reduction in bleeding duration across the group with overall significant reduction of ≥30% in 10 (31.25%) out of 32 participants. Post-treatment, the mean duration of bleeding for all participants significantly decreased to 5.34 ± 0.83 days with a mean difference from baseline of 2.28, which is highly significant ($p < 0.001$) (Table 4).

PBAC score

At baseline all participants had PBAC Score > 100. Improvement of PBAC of ≥30% was achieved in 31 (96.9%) participants. PBAC reduced from

Table 3 — Effect of research formulation on safety profile

Safety parameters	BT	AT	p value
AST	18.61 ± 5.77	16 ± 5	0.05
ALT	20.10 ± 5.39	18 ± 4	0.08
Alk. Phosphatase	92.7 ± 23.2	100 ± 24	0.055
Blood Urea	18.3 ± 4.6	20 ± 3	0.116
Serum Creatinine	0.69 ± 0.11	0.7 ± 0.1	0.076

Data presented as mean ± SD; p> 0.05 considered as non significant; Test used: Wilcoxon Signed Rank Test

Table 4 — Effect of research formulation on primary outcome (DOB and PBAC)

Outcome	BT	1 Cycle	2 Cycle	3 Cycle	AT
DOB (days)					
Mean ± SD	7.63 ± 2.268	6.72 ± 0.958	6.28 ± 0.729	5.81 ± 0.693	5.34 ± 0.827
Mean Difference		0.91	1.34	1.81	2.28
p value		<0.001***	<0.001***	<0.001***	<0.001***
PBAC					
Mean±SD	473.78 ± 446.970	403.91 ± 343.763	329.53 ± 290.551	257.66 ± 211.377	215.66 ± 193.311
Mean Difference		69.875	144.25	216.125	258.125
p value		<0.001***	<0.001***	<0.001***	<0.001***

Data presented as Mean ± SD; p< 0.001 considered as highly significant; Test used for paired comparison: Wilcoxon Signed Rank Test; Test used for comparison at each follow up: Friedmans test

473.78 ± 446.97 to 215.66 ± 193.31 (mean difference 258.125; $p < 0.001$) (Table 4).

Secondary outcomes

Hemoglobin

While the reduction in mean hemoglobin levels from 11.83±1.40 to 11.3±1.6 was statistically significant (*p = 0.007*), the change was not clinically meaningful. The decrease was mild (0.53 g/dL) and within acceptable physiological limits. Moreover, 7 participants demonstrated an increase in Hb levels, suggesting inter-individual variability and the influence of other factors such as diet and baseline iron stores. Therefore, the observed statistical significance does not reflect a negative clinical impact of the intervention on hemoglobin status. This may indicate that research drug formulation fails to increase haemoglobin level (Table 5).

MBQ quality-of-life score

MBQ value decreased from 29 ± 7 to 15 ± 5 ($p < 0.001$). 100% of participants achieved ≥30% improvement in MBQ score (Table 5).

Discussion

Our findings suggest that *Sharbat Habbul Aas*, administered orally for seven days across three successive menstrual cycles, was associated with reduction in menstrual blood loss and bleeding duration in women with heavy menstrual bleeding (HMB). A significant reduction in PBAC score (Mean difference 258.125) in 96.9% and shortened bleeding duration (Mean difference 2.3 days) in 31.25% participants highlight its therapeutic potential. Quality of life measures, indicated by MBQ scores, also showed universal improvement, supporting both clinical and patient centered benefits. However in the absence of a control group, the observed changes cannot be attributed solely to the intervention.

These results align with classical Unani principles describing the use of *Sharbat Habbul Aas* in HMB[5]. Ingredients such as *Myrtus communis*, *Punica granatum*, and *Acacia arabica* are known in traditional medicine for their capacity to modulate uterine bleeding[6-8]. No serious adverse effects were reported during the three treatment cycles, and no clinically significant changes were observed in the assessed liver and renal safety parameters. However, the small sample size and limited duration of follow-up do not permit conclusions regarding the long-term safety of the formulation.

These results are in close alignment with previous clinical trials on *Punica granatum* (Golnar), *Myrtus communis* (Habbul Aas), *Cydonia oblonga* (Behi) and *Acacia arabica* (Phali Babul) which have also demonstrated a reduction in bleeding days and volume. Bahman *et al.*[23] observed that one tea spoon of quince paste thrice a day for two consecutive months was effective in reducing the intensity and duration of menstrual bleeding and improving QoL in women with HMB (p=0.001), similar to the present study.

Goshtasebi *et al*,[8] reported a decrease in DOB from 8 ± 1.39 to 6.5 ± 1.35 days in women treated with Persian Golnar against tranexamic acid for 3 months. Additionally, PBAC mean ± SD score was reduced from 304.9 ± 176.1 to 164.60 ± 100.2 after the third treatment cycle (p< 0.001). Similar findings were reported by Ashteany *et al*.[10] and Yousefi *et al*,[9] where participants receiving Persian Golnar for three consecutive menstrual cycles experienced a significant reduction in blood loss. Yousefi *et al*,[9] observed decrease in PBAC score from 201.62 ± 144.11 to 109.44 ± 69.57 (p<0.001). These finding are comparable to present study.

A study by Umarami *et al*,[6] reported reduction in PBAC score from 231.05± 42.49 to 95.70 ± 12.41 (p<0.001) in participants receiving *Myrtus communis* fruits for first five days of menstrual cycle consecutively for two cycles. Whereas, Qaraaty *et al*,[25] reported a decline in mean duration of bleeding from 10.6 ± 2.7 days to 8.2 ± 1.9 days ($p = 0.01$) in participants receiving 15 mL oral myrtle syrup daily for 7 days during menstruation for 3 consecutive cycles. These findings align with present study.

Fazmiya *et al*,[7] reported decrease in mean PBAC score from 635.322 ± 504.23 to 67.70 ± 22.37 in participants receiving *Acacia Arabica* gum (*Gond Babul*) and camphor (*Kafoor*) vaginal suppositories for 7 days for three consecutive menstrual cycles demonstrating a statistically significant difference ($p < 0.001$).

Table 5 — Effect of research formulation on secondary outcome (hemoglobin and MBQ)

Parameter	BT	AT	p value
Hemoglobin (g/dL)			
Mean ± SD	11.83 ± 1.40	11.3 ± 1.6	0.007*
MBQ			
Mean ± SD	29 ± 7	15 ± 5	<0.001***

Data presented as Mean ± SD; p< 0.05 considered as significant; p< 0.001 considered as highly significant; Test used: Wilcoxon Signed Rank Test

Regarding hemoglobin levels, a statistically significant reduction was observed post-treatment ($p = 0.007$), though this change was not clinically meaningful. Inter-individual variability and extrinsic factors such as diet and iron stores likely influenced this outcome. Prior trials using Golnar and Myrtus preparations have generally reported either non-significant changes or mild increases in hemoglobin levels, suggesting that such herbal interventions primarily exert hemostatic rather than hematinic effects[8,9].

Importantly, QoL, as measured by the MBQ, improved significantly in all participants with 100% achieving ≥30% improvement. While most prior studies focused on symptom reduction and patient satisfaction, few have utilized MBQ scores; nonetheless, those that assessed QoL outcomes reported significant enhancement following herbal treatment, albeit with slightly lower percentages[6,8,24].

Taken together, the results of this trial are consistent with, earlier randomized controlled studies evaluating traditional Unani and herbal medicines for HMB. These findings support the potential therapeutic utility of polyherbal formulations in the management of HMB.

This is the first study reporting the effect of a polyherbal formulation- *Sharbat Habbul Aas* in HMB with the inclusion of pelvic pathology such as adenomyosis, uterine fibroid. However, the study was not designed or powered to determine differential treatment responses according to individual pelvic pathology. Moreover, this study is the first of its kind in which MBQ (Menstrual Bleeding Questionnaire) was used to assess the QoL of women suffering from HMB. A minimum attrition rate and good compliance were observed in the study subjects in the current study. The limitations of present study include- absence of a control group which limits our ability to conclusively determine causality, modest sample size, single centered study, insufficient batch-to-batch standardization and quality-control testing. Confidence intervals and formal effect size estimates were not included in the present analysis and should be incorporated in future adequately powered studies to provide estimates of the magnitude and precision of the observed changes.

Conclusion

In this single-arm pre–post interventional study, administration of *Sharbat Habbul Aas* was associated with reductions in PBAC score and duration of menstrual bleeding and improvement in MBQ score over three treatment cycles. The findings are preliminary and cannot establish a causal treatment effect in the absence of a concurrent control group. Larger controlled studies with standardized formulation and longer follow-up are required to confirm the efficacy and safety of the formulation.

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Conflict of Interest

Authors have no conflict of interest to disclose.

Author Contributions

HK: Methodology, Investigation, Data curation, Conceptualization; IS: Review, Editing, Methodology, Formal analysis; AAK: Drafting the article, Editing, Data curation. All authors have approved the final draft of manuscript.

Ethical Approval

This study adhered to the principles of the Declaration of Helsinki and was approved by Institutional Ethics Committee (IEC No. NIUM/IEC/ 2021-22/013/ANQ/05) and the trial was registered at the clinical trial registry of India under identifier: CTRI/2023/05/052713. (https://ctri.nic.in/Clinicaltrials/ advsearch.php).

Informed Consent

All participants were fully informed about the purpose, risks and benefits of the study and were giving enough time to consider their participation and ask questions, if any. A written informed consent was obtained from each participant before enrollment.

Use of Artificial Intelligence (AI)

The authors declare that no generative Artificial Intelligence (AI) tool was used in the writing of the manuscript, data analysis, or creation of figures/tables.

Data Availability

The authors confirm that the data supporting the findings of this study are available within manuscript. Raw data and other documents related to this study

are available from the corresponding author upon reasonable request.

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