CellMed
Orthocellular Medicine and Pharmaceutical Association

Original Article

Efficacy of *Qurṣ Kahruba* in *Kathrat-i-Ḥayḍ* (Heavy Menstrual Bleeding): A Single-Arm Self-Control Study

Ambar Siddiqui[1†], K. Tabassum[2†], Arshiya Sultana[3*†], Arfa Begum[1], Mohd Shariq[4]

[1] *PG scholar, Department of Ilmul Qabalat wa Amraze Niswan (Gynaecology and Obstetrics), National Institute of Unani Medicine, Ministry of AYUSH, GOI, Bengaluru, Karnataka, India, ceaser3011@gmail.com; arfasiddiqui770404@gmail.com*
[2] *Associate Professor, Department of Ilmul Qabalat wa Amraze Niswan (Gynaecology and Obstetrics), National Institute of Unani Medicine, Ministry of AYUSH, GOI, Bengaluru, Karnataka, India; email:drtabassum.nium@gmail.com*
[3] *Professor, Department of Ilmul Qabalat wa Amraze Niswan (Gynaecology and Obstetrics), National Institute of Unani Medicine, Ministry of AYUSH, GOI, Bengaluru, Karnataka, India;drarshiya@yahoo.com*
[4] *Medical Officer, CHC Sitapur, UP, India; email: mdarslan1989@gmail.com*
[*] *Correspondence: drarshiya@yahoo.com*
[†] *Equally contributed to this study*

ABSTRACT

Background and Objectives: *Kathrat-i-Ḥayḍ*, or Heavy Menstrual Bleeding (HMB), is one of the most common reasons women are referred to gynaecologists, with a prevalence of 10-15%. Despite its frequency, scientific validation has been lacking. Therefore, an attempt was made to evaluate the efficacy of *Qurs Kahruba* in treating HMB.

Methodology: Diagnosed patients (n=30), both married and unmarried, aged between 18-40 years, with regular cycles experiencing heavy bleeding in duration, amount of flow, or both, were included in the study conducted at NIUM Hospital. *Qurs Kahruba* was administered orally as two tablets thrice daily for 5 days during menstruation for 3 consecutive cycles.

The primary outcome was measured using the PBLAC (Pictorial Blood Loss Assessment Chart) scale to assess the effect of *Qurs Kahruba* on menstrual blood loss at each cycle. The secondary outcome involved using the Multi-Attribute Utility Assessment (MAUA) scale to determine the improvement in quality of life (QoL) at each follow-up. Results were analyzed using the Student's t-test and paired proportion tests.

Result: The PBLAC scores at baseline and after the 3rd cycle were 555.63±172.72 and 103.87±39.72, respectively, showing a significant difference (P <0.001). The MAUA scores at baseline and after the 3rd cycle were 35.90±17.34 and 97.39±2.86, respectively, also demonstrating a significant difference (P <0.001) and indicating an improvement in quality of life (QoL).

Conclusion: *Qurs Kahruba* was found effective in reducing HMB in terms of both duration and amount of flow, as well as in improving the quality of life (QoL) of the patients. Furthermore, it was found to be safe and well-tolerated by the patients.

Keywords *Kathrat-i-Ḥayḍ*; Heavy Menstrual Bleeding; MAUA scale; PBAC score; *Qurṣ Kahruba*; Quality of life

INTRODUCTION

According to the National Institute for Health and Care Excellence (NICE) recommendations, heavy menstrual bleeding (HMB) affects many women of reproductive age. It impacts the quality of life for 20–30% of women aged 18 to 54 due to physical, emotional, and social implications, such as iron deficiency anaemia, the cost of sanitary products, disruptions to daily activities, and increased medical expenses. HMB typically occurs every 21–35 days.[1,2] It accounts for 12% of gynaecological referrals at outpatient clinics making it the most common reason for such referrals.[3] It has two conditions, either increased flow with blood loss exceeding 80 mL or duration lasting longer than 7 days.[4] According to a review of epidemiologic studies, the prevalence of objectively measured HMB has been reported to be 9-14%.[5]

[*]Correspondence: Arshiya Sultana
E-mail: drarshiya@yahoo.com
Received Jan 30, 2024; **Accepted** May 24, 2024; **Published** May 31, 202
doi: http://dx.doi.org/10.5667/CellMed.2024.007

Menorrhagia can be idiopathic or associated with underlying uterine lesions such as polyps or fibroids, adenomyosis, endometriosis, hyperplasia, PID, anatomical abnormalities, systemic illnesses, hormonal imbalances, or specific drugs. Dysfunctional uterine haemorrhage refers to idiopathic menorrhagia that is not related to a specific underlying illness. [2]

In conventional medicine, a wide variety of treatments have been suggested for HMB including oral contraceptive pills, progestin-containing intrauterine contraceptive devices (IUCDs), nonsteroidal anti-inflammatory drugs (NSAIDs), tranexamic acid, Gonadotrophin releasing hormone (GnRH) agonist, and surgical options include endometrial ablation, dilatation and curettage, uterine artery embolization (UAE) and hysterectomy.[1, 6]

In classical Unani literature, HMB is referred to as *Kathrat-i-Ḥayḍ*,[7] where the cause may be attributed to *Kathrat-i-Ḥayḍ*, D*u'f Quwwat Māsika* (weakness of retention power) and *Qawi Quwwat Dāfiẏa* (strengthen of evacuation power) of the uterus Various Unani remedies, including compound formulations like *Qurs Kahruba* have been traditionally employed to address HMB. [8] *Qurs Kahruba* comprises ingredients such as *Kahruba, Samagh arabi, Nishasta, Kateera, Maghz Tukhm Khyar, Maghz Tukhm Kaddu Sheerin Gulnar* and *Aqaqiya.* These components are believed to possess qualities like *Habis* (haemostatic), *Qabiz* (astringent), *Muqawwi* (Tonic), *Mujafif* (desiccant)*, Rade, Mubarid* and (refrigerant) potentials.[9] Pharmacologically, the constituents of *Qurs Kahruba* are known to exhibit antioxidant, anti-coagulant, anti-inflammatory, antispasmodic, and analgesic properties. This is attributed to their rich content of phytochemicals like tannins, anthocyanins and flavonoids. Tannins, in particular, are recognized for their hemostatic and styptic attributes due to their astringent effects. Tannins are known for their hemostatic and styptic properties due to their astringent effects. [10-31] They induce the contraction of capillary endothelium, thereby assisting in reducing uterine bleeding. Through protein precipitation, tannins facilitate tissue and blood vessel constriction, effectively managing bleeding.[32]

Despite the long-standing use of *Qurs Kahruba* for treating HMB, there remains a lack of studies to validate its efficacy. Therefore, the objective of the study was to determine the efficacy of *Qurs Kahruba* in HMB.

MATERIALS AND METHODS

Study design, location and ethical consideration: In Bengaluru, India, the Department of Ilmul Qabalat wa Amraze Niswan at the National Institute of Unani Medicine and Hospital (NIUM) conducted a single-arm, self-control, pre- and post-intervention study during 2017–18. The study protocol received approval from the Institutional Ethical Committee of NIUM under the IEC number NIUM/IEC/2016-17/014/ANQ/06, and it was registered with the India Council for Medical Research's (ICMR's) clinical trial registry under the registration number CTRI/2018/03/012647.

Participants: Diagnosed women (n=30) of reproductive age who presented with HMB and who fulfilled the inclusion criteria were selected for inclusion as participants in this study.

Inclusion criteria: Women both married and unmarried between the ages of 18-40 years with regular cycles with heavy bleeding for more than 7 days or an amount of flow more than 80 ml or both were eligible. Participants with hemoglobin more than 7 mg/dl. Participants with fibroid size less than 3 or 3 cm.

Exclusion criteria: Participants with hemoglobin (Hb%) less than 7 mg/dl, systemic diseases such as hypertension, diabetes mellitus, thyroid dysfunction and blood dyscrasias. Further, participants with a history of endometriosis, adenomyosis, endometrial polyp, fibroid size more than 3 cm and malignancy.

Data collection: Patients complaining of heavy menstrual bleeding were thoroughly questioned about the length of their cycle, duration of flow, number of clots passed, amount of flow, correlation with pain, and other relevant factors. After obtaining informed consent, patients meeting the inclusion criteria were enrolled in the study. A comprehensive medical history and physical examination were performed, including a pelvic exam for married patients. All data were recorded in a case record form created for the study.

Socioeconomic status (SES) was evaluated using Kuppuswamy's scale, which considers monthly income, employment, and education. Family, medical, and drug allergy histories were also collected, along with any previous family history of similar conditions.

Routine investigations included hemoglobin percentage (Hb%), clotting time (CT), bleeding time (BT), fasting blood sugar (FBS), thyroid-stimulating hormone assay (TSH), platelet count, and a pelvic scan for exclusion purposes. To assess the safety profile of *Qurs Kahruba*, tests for serum glutamic-oxaloacetic transaminase (SGOT), serum glutamic pyruvic transaminase (SGPT), alkaline phosphatase, blood urea, and serum creatinine were conducted at baseline and post-intervention. Participants were monitored for adverse reactions throughout the trial.

Assessment tools

Pictorial Blood Loss Assessment Chart (PBLAC) score: The PBLAC chart is a simple, non-laboratory method that relies on self-reported scores provided by women to semi-objectively diagnose menorrhagia. Higham et al. first described this approach, where menorrhagia was initially assigned a score of 100. The PBLAC chart has demonstrated a sensitivity of 80% and specificity of 88% in identifying menorrhagia.[33]

Quality of life assessed by the Multi-attribute Utility Assessment (MAUA) Scale: Boyle and Torrance provided strong validation for the Multi-attribute Utility Assessment (MAUA) scale, which permits explicit consideration of non-medical domains. This scale is utilized to evaluate clinical outcomes from the viewpoint of women experiencing menorrhagia. It enables the assessment of the severity of both the disease process itself and the treatments used to address it. Scores from each statement checked across the six sections of the scale are added together to reach the final result. On a scale of 0 to 100, the final score is a utility score. This will serve as a representation of the patient's current health. These scores are then added together to yield an overall utility for the patient in her current health state of 81.8 on a 100 multi-attribute utility scale (0 worst affected-100 unaffected).[6]

Follow-up procedures: Participants were followed after each menses for four consecutive menstrual cycles, three treatments and a follow-up cycle. At each follow-up, blood loss and Quality of Life (QoL) were assessed by using the PBAC score and MAUA scales respectively. Patients were also enquired about any adverse effects of the drug during the trial.

Intervention: *Qurṣ Kahruba* was selected as the test drug for the trial.[8] This tablet contains *Kahruba* (*Vateria indica* L.)*, Samagh arabi* (*Acacia arabica* Linn.)*, Nishasta* (*Triticum aestivum* L.)*, Kateera* (*Cochlospermum religiosum* L.)*, Maghz Tukhm Khyar* (*Cucumis sativus* L.)*, Maghz Tukhm Kaddu Sheerin* (*Lagenaria siceraria*), each 11 g, *Gulnar* (*Punica granatum* L.), and *Aqaqiya* (*Acacia arabica* Willd.) each 1 g, with a binding agent, *Loab Ispaghol* (*Plantago ovata* Forsk.), to form the tablet. The tablets were prepared according to Unani's standard parameters. Participants were advised to orally take two tablets orally thrice daily for 5 days from day 1 of the menstruation for three consecutive cycles, and compliance was monitored after each course of treatment.

Parameter of efficacy

The primary therapeutic outcomes were categorized based on reductions in PBLAC score: no improvement (>180 ml), moderate improvement (score between 80-180 ml), and marked improvement (score between 50-80 ml). Secondary outcome, Quality of life, assessed by the MAUA scale, was graded as no improvement (score 0-33), moderate improvement (score 34-65), and marked improvement (score 66-100).

The primary outcome measure involved assessing the reduction in PBLAC. Score total score from baseline to each follow-up for 3 consecutive cycles and one follow-up after completing the trial. Secondary outcome measures included improvement in Quality of life assessed by the MAUA scale at baseline and after treatment.

Sample size estimation: The sample size justification was based on the nature of the study, which is not a prevalence study but rather aimed at comparing results before and after the trial in cases of HMB. It was determined that a minimum of 30 patients, with an additional 10% allowance for dropout, would be required to achieve statistical significance at a significance level (P-value) of less than 0.05 and statistical power of 0.20.

The sample size estimation was based on the mean and standard deviation (SD) derived from a previous study [32] where the mean ± SD of the PBLAC score was 125.8 ±155.9. This information was used to calculate the required sample size to achieve statistical power for the current study. The following formula was used to calculate the sample size

$$\mathbf{n= (Z_{\alpha/2})^2\ \sigma^2 / d^2}$$

n= Sample size required

$d = \mu_1-\mu_2$

d= Clinically significant difference

μ_1= Mean score from baseline to three cycles in the previous study = 125.8

$\mu 2$ = Mean score from baseline to three cycles in proposed drug =102.7

σ = Standard deviation= 155.9

$Z_{\alpha/2}$ = Using a 95% confidence level, and α= 0.05, the Z critical value is 1.96

When calculated for required improvement in PBLAC score the sample size calculated was 30.

Informed consent

Patients fulfilling the inclusion criteria mentioned above will be shown an information sheet having details regarding the nature of the study and the drugs to be used. Patients will be given enough time to go through the study details mentioned in the information sheet. They will be allowed to ask any question and if they agree to participate in the study, they will be asked to sign the informed consent form.

Data analysis

Statistical software: SPSS 18.0 and R environment ver.3.2.2 were used for data analysis, and Microsoft Word and Excel were utilized to generate graphs and tables.

Statistical analysis: The current study employed descriptive and inferential statistical analysis. Continuous measurement results are reported as Mean SD (Min-Max), while categorical measurement results are displayed as Numbers (%). A 5% level of significance is employed to determine significance. The following data assumptions are made: Assumptions: 1. Dependent variables should be regularly distributed, 2. Population samples should be taken at random, and sample cases should be independent. To determine the significance of research parameters on a continuous scale within each group, the student "t" test (two-tailed, dependent) was utilized. Paired Proportion test has been used to find the significance of proportion in paired data. Significant figures are

+ Suggestive significance (P value: $0.05<P<0.10$)

* Moderately significant (P value:$0.01<P \leq 0.05$)

** Strongly significant (P value : $P \leq 0.01$)

RESULTS

Recruitment of participants

Sampling started in 2017 and continued until 2018. The researcher invited 106 women aged 18 to 40 years to participate. Out of these, 91 were screened, 15 declined participation, and 32 met the inclusion criteria. Ultimately, 32 participants were included in the study, but 2 participants dropped out during the second cycle due to distance constraints. Thirty participants completed the intervention, and their data were analyzed (See Figure 1).

Sociodemographic and obstetrics variables: Table 1 presents the socio-demographic, *Mizaj* and Contraceptive parameters of the participants. The study found that the mean age of the participants was 30.03±7.62 and the mean BMI of participants was 24.66±4.07 kg/m.[2]

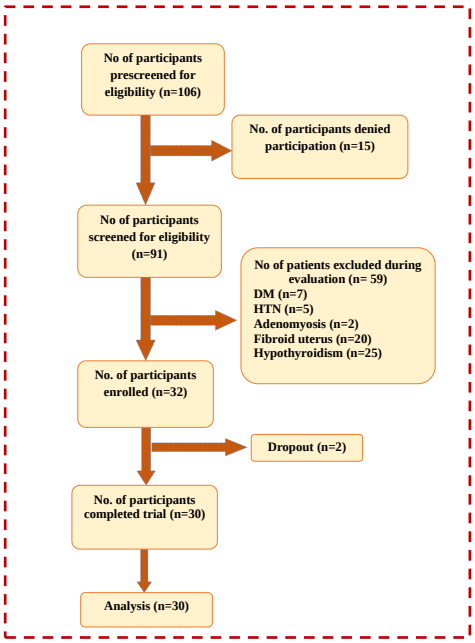

Figure 1. Flow chart of participants recruited.

Parameter of efficacy: The main therapeutic outcome in the 3rd cycle showed that 86.7% (n=26) participants experienced normal menstrual flow, demonstrating an improvement in quality of life (QoL) with marked improvement. Additionally, 13.3% (n=4) showed moderate improvement in HMB and QoL.

Primary outcome measure: In this study, blood loss assessment was conducted before, during and after the trial using the PBLAC score. At baseline, the mean±SD of the PBLAC score was 555.63±172.72. Significant improvement was observed after the 1st, 2nd and 3rd cycles, with scores of 285.87±107.86, 168.80±73.88 and 103.87±39.72, respectively. After the trial, the mean± SD of the PBLAC score was 75.13±14.92, indicating a statistically significant reduction (*P* <0.001) as shown in Table 2.

Duration and amount of menstrual flow in the menstrual cycle: Tables 4 and 5 summarized the duration of the amount of menstrual flow at each follow-up. The findings reveal a significant reduction in both the duration and amount of flow observed at each follow-up assessment. Specifically, 80% of participants exhibited a duration of menstrual flow of less than 7 days, indicating a positive response to the treatment.

Table 1. Sociodemographic, *Mizaj* and contraceptive parameters of participants.

Variables	No of Participants (n=30) No (%)
Age (year)	
<20	6(20.0)
20-30	11(36.7)
31-40	13(43.3)
Marital Status	
Married	20(66.7)
Single	10(33.3)
Socio Economic Status	
Lower Middle	7(23.3)
Upper	10(33.3)
Upper Middle	13(43.3)
Occupational distribution	
Housewife	20(66.7)
Student	9(30.0)
Teacher	1(3.3)
BMI (Kg/m2)	
<18.5	2(6.7)
18.5-25	13 (43.3)
25-30	12 (40.0)
>30	3(10.0)
Mizaj	
Balghamī	4(13.3)
Damawī	22(73.3)
Safrāwī	4(13.3)
Contraceptives	
Absent	1(3.3)
Barrier method	3 (10.0)
Copper T	2(6.7)
Tubectomy	14(46.7)
Not applicable	10(33.3)

Investigation and safety biochemical profile: The mean Hemoglobin levels before and after the trial were 11.02±1.79 and 11.66±1.68 g/dl, respectively, with *P*=0.115, indicating no significant difference. Clinically, no adverse effects of the test drug were reported by the participants. Table 6 summarizes the safety biochemical biomarkers before and after the trial. There was no significant difference observed before and after the trial

Table 2. Primary outcome: Pictorial Blood Loss Assessment Chart score before, during and after trial.

Pictorial Blood Loss Assessment Chart score	Min-Max	Mean ± SD	difference	t value	*P* value
Before Trial	259.00-953.00	555.63±172.72	-	-	-
First cycle	103.00-554.00	285.87±107.86	269.777	7.592	<0.001**
Second cycle	63.00-354.00	168.80±73.88	386.833	12.324	<0.001**
Third cycle	57.00-196.00	103.87±39.72	451.767	14.570	<0.001**
After Trial	55.00-120.00	75.13±14.92	480.500	15.091	<0.001**

Student "t" test (Paired), *P* <0.001** highly significant

Table 3. Multi Attributed Utility Assessment (MAUA) Scale before, during and after trial.

Multi-Attributed Utility Assessment (MAUA)Scale	Min-Max	Mean ± SD	difference	t value	*P* value
Before Trial	9.40-64.70	35.90±17.34	-	-	-
First cycle	28.40-73.70	55.94±14.71	-20.033	-7.963	<0.001**
Second cycle	44.50-100.00	82.73±10.17	-46.830	-14.257	<0.001**
Third cycle	77.00-100.00	93.69±5.72	-57.783	-17.765	<0.001**
After Trial	93.90-100.00	97.39±2.86	-61.487	-19.873	<0.001**

except, in SGOT (*P*=0.078). However. after the trial, the values were normal limits.

DISCUSSION

This self-control pre-and post-intervention study confirms the efficacy of *Qurs Kahruba* as an alternate therapy in managing HMB. The main therapeutic outcome in the third cycle demonstrated that 86.7% (n=26) of participants achieved normal menstrual flow with a marked improvement in QoL, while 13.3% (n=4) showed moderate improvement in HMB and QoL. These results highlight the notable advantage of *Qurṣ Kharuba* in controlling heavy menstrual bleeding among participants. Studies conducted by Jahan D et al.,[34] Fatima et al.,[35] and Kotagasti et al.[36] also reported the beneficial effects of Unani medicines in the treatment of HMB.

According to the Unani concept, HMB primarily sterns from two causes: D*u̇f Quwwat Māsika* (weakness of retention power) and *Qawi Quwwat Dāfiẏa* (strengthening of evacuation power) of the uterus, or a combination of both. The condition is often associated with *Sū'-i-Mizāj Harr Yabis* (hot and dry dystemperament), which weakens the uterus and its vessels, leading to increased blood vessel dilation.[37, 38]

The reduction in the duration of flow may be attributed to the medicinal properties of the tested drug. *Kahruba, Gulnar, Aqaqia,* and *Samagh Arabi* possess *Habis* (styptic) and *Qabiz* (astringent) properties, which work to constrict the blood vessels. Additionally, *Katira, Kahruba, Nishasta, Samag arabi* exhibit *Mujaffif* (desiccant), *Mubarid* (refrigerant) properties, promoting the absorption of bodily fluids and thereby reducing the blood flow.[12] Pharmacological studies have also reported the anti-inflammatory and antioxidant properties of these ingredients, which contribute to the reduction of menstrual blood flow. Furthermore, the *Barudat ws Yabusat* nature of the ingredients enhances *Quwat Māsika* of the uterus, while *Qabiz* property further supports this effect by alleviating spasms in the uterus, which helps in vasoconstriction. Consequently, the reduction in both the duration and amount of flow observed in the study can be attributed to the therapeutic response elicited by the test drug.

This compound formula consists of *Kahruba* (*Vateria indica* L.), a resin known for its various properties. Upon distillation, it yields an oleo resin containing essential oil consisting of phenolic constituents and azulenes.[13] These components confer properties such as astringent, antibacterial, antidiarrhoea, and emmenagogue.[13]

Samagh Arabi (*Acacia arabia* L.), an Indian gum, is also part of the formula. Its chemical constituents include arabic acid, calcium, magnesium and potassium.[14] *Samagh Arabi* is known for its anti-inflammatory, anti-asthmatic, emollient[15] and anti-carcinogenic activities**.** *Nishasta* (*Triticum aestivum* Linn) is comprised of chemical constituents including glycolipids, sterols, alkaloids, 1,4-benzoxazinone derivative and phenolic compounds.[16] These constituents contribute to its diverse range of properties, including hypolipidemic,[17] anti-obesity, anti-cancer, anti-colitis, anti-inflammatory and antioxidant activities.[18] *Kateera (Cochlospermum religiosum L.)* is rich in various bioactive compounds, including alkaloids, sterols, glycosides, saponins, flavonoids, tannins, phenols, and anthocyanins. These constituents contribute to its diverse pharmacological properties, which include antimicrobial and hepatoprotective activities. Additionally, *Kateera* exhibits anti-carcinogenic properties, making it potentially beneficial in cancer prevention and treatment.[19,20] *Tukhm Khayar*

Table 4. Assessment of duration of menstrual flow (DOF) in days before, during and after trial.

DOF in days	Before Trial	First Cycle	Second Cycle	Third Cycle	After Trial	% difference
<7	3(10%)	11(36.7%)	12(40%)	24(80%)	27(90%)	80.0%
7-14	24(80%)	19(63.3%)	18(60%)	6(20%)	3(10%)	-70.0%
>14	3(10%)	0(0%)	0(0%)	0(0%)	0(0%)	-10.0%
Total	30(100%)	30(100%)	30(100%)	30(100%)	30(100%)	-

P<0.001**, Significant, Paired proportion test, 80% Improvement

Table 5. Assessment of the amount of menstrual flow (Pads/Cycle) before, during and after trial.

Amount of flow p/c	Min-Max	Mean ± SD	difference	t value	*P* value
Before Trial	15.00-65.00	35.23±13.28	-	-	-
First cycle	11.00-39.00	22.70±7.04	12.533	5.996	<0.001**
Second cycle	9.00-33.00	15.70±5.78	19.533	8.357	<0.001**
Third cycle	6.00-16.00	10.97±2.88	24.267	9.841	<0.001**
After Trial	5.00-12.00	8.60±1.73	26.633	10.995	<0.001**

Student's t-test (Paired), *P* <0.001** highly significant

(*Cucumis sativus* L.) is enriched with flavonoids and tannins,[21] which contribute to its diverse pharmacological activities. These include antidiabetic, anti-helminthic,[22] antibacterial, antifungal, cytotoxic, antacid, carminative, hepatoprotective, wound healing, and antimicrobial properties.[23] *Tukhm Kaddu Sheerin* (*Lagenaria siceraria* Standl.) mainly contains aglycones[13] saponin, and fatty oil.[24] These components confer antioxidant,[25] anti-inflammatory, analgesic and antihypertensive properties.[26] *Gulnar* (*Punica granatum* L.) is rich in flavonoids, tannins, and triacylglycerols. It possesses various pharmacological activities including antihelminthic,[21] antispasmodic,[27] anti-fungal activity, antibacterial activity and antiviral properties.[28] *Aqaqia (Acacia arabica* Willd), pods are rich in polyphenols including gallic acid, m-digallic acid, (+)-catechin, chlorogenic acid, gallolyated flavan-3,4-diol and robidandiol (7, 3', 4', 5'-tetrahydroxyflavan-3, 4-diol),[14] as well as tannin.[28] These compounds contribute to its diverse pharmacological activities, such as antispasmodic, antifungal, antibacterial, and antiviral activities.[29,30] *Ispaghol* (*Plantago ovate* Forsk) contains mucilage, fatty oil, albuminous matter, aucubin (C13 H19 O8 H2O), and plantiose sugar.[31] These compounds contribute to its antispasmodic, antifungal, antibacterial, and antiviral activities.[29,30]

All the ingredients of *Quṛṣ Kahruba* contain tannins and flavonoids,[32] which have significant therapeutic implications. Tannins possess potent styptic and astringent properties. leading to the contraction of capillary endothelium and reducing exudation and blood loss. Additionally, tannins aid in blood coagulation, thereby decreasing excessive menstrual blood loss. Changes in prostaglandin secretion from $PGE_{2\alpha}$ which are found in the endometrium of women with heavy periods towards vasoconstrictor i.e., $PGF_{2\alpha}$.[39] Flavonoids have been shown to inhibit inflammatory mediators, contributing to their anti-inflammatory effects The anti-inflammatory activity of ingredients of *Quṛṣ Kahruba* i.e., *Samagh Arabi, Gulanr* and *Nishasta* has been established in various studies. These ingredients help in reducing inflammatory mediators such as TNFα and IL6, thereby controlling bleeding effectively. *A. arabica* another ingredient, has been studied for its coagulation properties in mice, which further aids in controlling heavy bleeding. Overall, the combination of tannins and flavonoids present *in Quṛṣ Kahruba* contributes to its efficacy in managing heavy menstrual bleeding.[32]

There were no statistical differences between pre-and post-trial biochemical markers suggesting that *Qur Kahruba* did not have any detrimental effects on the organs or bodily fluids of the participants. Additionally, no clinical reports of adverse effects were noted throughout the study. These findings indicate that *Qur Kahruba* appears to be a safer option compared to several traditional medications, such as Oral Contraceptive Pills (OCPs), which are commonly used to treat HMB.

Strength of the study: The strength of this study lies in its validation and evaluation of the clinical efficacy of *Qurs Kahruba* in improving menorrhagia. This was assessed using a well-validated Pictorial Blood Assessment Chart (PBAC) score questionnaire and the Menorrhagia and Uterine Assessment (MAUA) scale for quality of life (QoL). The study observed a statistically significant reduction in symptoms with good patient compliance.

Table 6. Assessment of biochemical safety parameters before and after trial.

Variables	Before Trial	After Trial	difference	t value	*P* value
Serum Glutamic Oxaloacetic Transaminase (SGOT) (IU/L)	23.83±7.35	32.07±23.63	-8.241	-1.826	0.078
Serum glutamic pyruvic transaminase (SGPT) (IU/L)	21.08±8.33	31.87±56.60	-10.785	-1.020	0.316
Alkaline Phosphatase (ALP) (IU/L)	190.24±57.90	191.46±87.80	-1.213	-0.073	0.943
Serum Creatinine (mg/dl)	0.73±0.14	0.78±0.18	-0.043	-1.008	0.322
Urea (mg/dl)	22.55±5.10	24.83±7.46	-2.281	-1.456	0.156

P value >0.05, non-significant

Limitations and recommendations of the study: The main limitation of the study was its single-arm and self-controlled design. Additionally, the small sample size and short duration further constrained the study. Consequently, randomized controlled trials (RCTs) in phase II and III clinical trials with longer follow-up periods are necessary to establish the long-term efficacy and safety of the experimental drug. More research into the safety profile of *Qurs Kahruba* is also needed to validate these findings.

CONCLUSION

Qurs Kahruba has demonstrated effectiveness in reducing HMB in terms of both duration and amount of flow, as well as improving quality of life. Furthermore, it was found to be safe and well-tolerated by the participants. The improvement observed in HMB with *Qurs Kahruba* was often comparable to that seen with conventional and complementary therapies commonly used for HMB. These findings suggest that *Qurs Kahruba* may offer a safe alternative to other traditional drugs for the management of HMB.

ACKNOWLEDGEMENTS

Nil

CONFLICT OF INTEREST

None to declare

CONTRIBUTION OF THE AUTHOR

Amber Siddiqui, K Tabassum and Arshiya Sultana equally contributed to this study and contributed to data collection, analysis, data curation, writing draft and editing the final copy. Arfa Begum and Mohd Shariq proofread and edited the draft and final copy.

REFERENCES

1. Fazmiya MJA, Sultana A, Heyat MBB, Parveen S, Rahman K, Akhtar F, et al. Efficacy of a vaginal suppository formulation prepared with *Acacia ara bica* (Lam.) Willd. gum and *Cinnamomum camph ora* (L.) J. Presl. in heavy menstrual bleeding anal yzed using a machine learning technique. Front P harmacol. 2024 Feb 12;15:1331622.

2. Szczepaniak P, Zabczyk M, Undas A. Increased plasma clot permeability and susceptibility to lysis are associated with heavy menstrual bleeding of unknown cause: a case-control study. PloS one. 2015 Apr 24;10(4):e0125069.

3. Zutshi V, Palani Yamma D. A clinical evaluation of safety and efficacy of Evercare capsules in menorrhagia: An open clinical study. Indian Medicinal Journal: 2010;l104 (7):221-27

4. Javan R, Yousefi M, Nazari SM, Amiri P, Mosavi-Jarrahi A, Modiramani P, Naghedi-Baghdar H. Herbal medicines in idiopathic heavy menstrual bleeding: a systematic review. Phytother Res. 2016 Oct;30(10):1584-91.

5. Jensen JT, Parke S, Mellinger U, Machlitt A, Fraser IS. Effective treatment of heavy menstrual bleeding with estradiol valerate and dienogest: a randomized controlled trial. Obstet Gynecol. 2011 Apr 1;117(4):777-87.

6. Shaw RW, Brickley MR, Evans L, Edwards MJ. Perceptions of women on the impact of menorrhagia on their health using multi-attribute utility assessment. BJOG. 1998 Nov;105(11):1155-9.

7. Khan. GJ. Hkm. Makhzanul Hikmat. Vol.2. (Aijaz Publishing house: New Delhi, 1996) 393-94 p.

8. Khan H M A. Aksir-e-Azam. 1st Ed. (Idarae Kitabus Shifa: New Delhi, 2011) 801-805 p.

9. Kabeeruddin M. Maghzinul Murakkabat. (Ejaz Publishing House: New Delhi; YNM) 47-48 p.

10. Shrijani JK, Karunakar Hegde, AR Shabaraya. A Review on Pharmacological Activities of Vateria Indica Linn. Inter J Pharma Chem Res. 2018; 4(11):1-8

11. NICE Guidelines. Treatment options for heavy menstrual bleeding, the management of menorrhagia. Effective Health Care. 2014;9:1-1

12. Hakim MA. Bustanul Mufredat. (Idara Kitabus Shifa: New Delhi, 2002) 251-252 p.

13. Khare CP. Indian Medicinal Plants. (Rajkamal Electronic Press: Delhi, 2007) 696-697 p.

14. Kritikar KR, Basu BD. Indian Medicinal Plants (Oriental Press: Uttaranchal, 2006) 241-15, 922- 25, 980-81,1084-87).

15. Jyoti A, Manisha V. Phytochemical and HPTLC analysis of roots of *Acacia arabica* Willd. Sch Acad J Pharm. 2014; 3(2):133-39.

16. Luyen BT, Thao NP, Tai BH, Lim JY, Ki HH, Kim DK, Lee YM, Kim YH. Chemical constituents of *Triticum aestivum* and their effects on adipogenic differentiation of 3T3-L1 preadipocytes. Arch Pharmacol Res. 2015 Jun 1;38(6):1011-8.

17. Kothari SA, Jain AK, Mehta SC, Tonpay SD. Hypolipidemic effect of fresh *Triticum aestivum* (wheat) grass juice in hypercholesterolemic rats. Acta Pol Pharm. 2011 Mar 1;68(2):291-4.

18. Mohan Y, Jesuthankaraj GN, Ramasamy TN. Antidiabetic and antioxidant properties of *Triticum aestivum* in streptozotocin-induced diabetic rats. Advances in Pharmacological Sciences. 2013;2013.

19. Jamuna Bai A, Ravishankar Rai V, Samaga PV. Evaluation of the antimicrobial activity of their

medicinal plants of South India. Malaysian J Microbiol. 2011;14-18

20. Babiker R, Merghani H T, Elmusharaf K, Badi M R, Lang F, Saeed M A. Effects of gum arabic ingestion on body mass index and body fat percentage in healthy adult females: two-arm randomized, placebo-controlled, double-blind trial. Nutrition Journal. 2012;11.

21. Miguel GM, Neves AM, Antunes DM. Pomegranate (*Punica granatum* Linn): A medicinal plant with myriad biological properties- A short review: Journal of Medicinal Plant Research. 2010;4(25):2836-47

22. Minaiyan M, Zolfaghari B, Kamal A. Effect of hydroalcoholic and buthanolic extract of Cucumis sativus seeds on blood glucose level of normal and streptozotocin-induced diabetic rats. Iranian J Bas Med Sci. 2011 Sep;14(5):436.

23. Al Akeel R, Mateen A, Alharbi KK, Alyousef AA, Al-Mandeel HM, Syed R. Purification and MIC analysis of antimicrobial proteins from *Cucumis sativus* L. seeds. BMC Complemen Altern Med. 2018 Dec; 18(1):121.

24. Chopra N.R., Nayar L.S., Chopra C.I. Glossary of Indian Medicinal Plants. (NSCAIR: New Delhi, 1996) 83 p.

25. Deshpande JR, Choudhari AA, Mishra MR, Meg hre VS, Wadodkar SG, Dorle AK. Beneficial eff ects of Lagenaria siceraria (Mol.) Standley fruit epicarp in animal models. Indian J Exp Biol. 20 08;46(4):234-42.

26. Ghule B V, Ghante M H, Upaganlawar AB, Yeole PG. "Analgesic and anti-Inflammatory activities of Lagenaria siceraria Stand. fruit juice extract in rats and mice. Pharmacognosy Magazine. 2006;2(8): 232-8.

27. Ali A, Akhtar N, Khan BA, Khan MS, Rasul A, Shahiq-uz-zaman, Khalid N, et al. Acacia nilotica: A plant of multipurpose medicinal uses. Journal of Medicinal Plants Research. 2012; 6 (9):1492-6.

28. Ray AB, Sharma BK, Singh U. Medical properti es of plants: Antifungal, anti-fungal and anti-viral activities.(International Book distributing company: Lucknow, 2004) 3,4,46-64, 479.

29. Bieber EJ, Sanfilippo JS, Horwitz IR. Clinical Gynecology. (Churchill Livingstone: Canada, 2006) 91-96, 159-165, 179-189, 385-288, 843-857 p.

30. Majoosi ABA. Kamilus Sana (Urdu trans. by Kantoori GH). (Idarae Kitabus Shifa: New Delhi, YNM) 784,785 p.

31. Karimzadeh G, Omidbaigi R. Growth and seed characteristics of Isabgol (Plantago ovata Forsk) as influenced by some environmental factors. Journal of Agricultural Science and Technology. 2004; 6: 103-110.

32. Bahman M, Mirahi A, Hajimehdipoor H, Tansaz M. The effect of Quince paste on menorrhagia: A clinical study. IJPSR. 2018;33:10-8.1654-1659.

33. Kılıç SÇ, Sarper N, Zengin E, Gelen SA. Screening bleeding disorders in adolescents and young women with menorrhagia. Turkish Journal of Hematology. 2013 Jun;30(2):168.

34. Jahan D, Begum W, Roqaiya M, Hussaini YK. Anti-Haemorrhagic activity of polyherbal formulation in menorrhagia: A randomized controlled trial. Altern Integr Med 5: 219. doi: 10.4172/2327-5162.1000219.

35. Fathima A, Sultana A. Clinical efficacy of a Unani formulation '*Safoof Habis'* in menorrhagia: A randomized controlled trial. Eur J Integr Med. 2012 Sep 1;4(3):315-22.

36. Kotagasti T. Prevalence of different menstrual irregularities in women with abnormal uterine bleeding (AUB) - An observational study. Int J Cur Res Rev 2015; 7(10): 66-70.

37. Ibn Sīnā ḤA. Al-Qānūn fi'l Ṭibb. (Urdu trans. by Kantoori GH). (Idarae Kitabus Shifa: New Delhi, 2007) 269-270,1089-1091 p.

38. Jurjani I. Tarjuma Zakheerae Khawarzum Shahi. (Urdu trans. by Khan AH). Vol VI. (Munshi Nawal Kishore: Lucknow, 2007) 590-597 p.

39. Maybin JA, Critchley HO, Jabbour HN. Inflammatory pathways in endometrial disorders. Molecular and Cell

40. ular Endocrinology. 2011 15;335(1):42-51.