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Original article

Clinical efficacy of a *Unani* formulation '*Safoof Habis*' in menorrhagia: A randomized controlled trial

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Abstract

Aim: To evaluate the efficacy and safety of *Safoof Habis* in *Kasrate Tams* (menorrhagia) with validated menstrual pictogram.

Materials and methods: A single blind, randomized, standard controlled trial was conducted in the gynaecological outpatient of National Institute of Unani Medicine Hospital. Clinically diagnosed patients ($n = 52$) were randomized to the test ($n = 35$) and control ($n = 17$) groups. In the test group, *Safoof Habis* (Ingredient are Silicate of alumina and Iron oxide, Hydrated magnesium silicate and *Vateria indica* L.) 5 g twice daily and in the control group, tranexamic acid 500 mg, thrice daily were administered from day 1 to day 5 of menstrual cycle and *Qurs Kushta Faulad*, one tablet twice daily was administered in both the groups for three consecutive months. The primary outcome measure was to assess the efficacy and safety of this *Unani* formulation in menorrhagia with menstrual pictogram. The secondary outcome measures were to assess the effectiveness of test drug formulation on dysmenorrhea and hemoglobin concentration. The results were analyzed by Student's '*t*' test and Fisher exact test.

Results: The groups were homogenous in the terms of age, parity, socioeconomic status, marital status and biochemical parameters ($P > 0.05$). Post treatment when compared to baseline in same group showed significant reduction in menstrual blood loss in both the groups ($P < 0.001$). The comparison between test and control group showed that both groups were equally effective ($P = 0.265$). There was improvement in hemoglobin concentration in the test group ($P = 0.04$) and dysmenorrhea was reduced in both groups ($P < 0.001$).

Conclusion: *Safoof Habis* was found to be effective in reducing menstrual blood loss in menorrhagia.

Keywords: Menorrhagia; *Kasrate Tams*; *Safoof Habis*; Menstrual pictogram; Menstrual blood loss; Reproductive age; Randomized standard controlled trial

Introduction

Menorrhagia is a major public health problem [1] for women of reproductive age [2] and considered to be one of the most significant causes of ill health [3]. It is clinically defined as menstrual blood loss exceeding 80 ml per cycle [4] or duration lasting longer than 7 days or both [5]. Menorrhagia affects up to 20–30% of women during their reproductive years [6]. Menstrual blood loss (MBL) studies are relevant for developing world women as this could be an important cause of anemia and has major impact on the health related quality of life. Conservative medical treatment for the management of menorrhagia may result in a substantial reduction in menstrual blood loss thereby reducing the incidence of anemia. But these therapies have their own side effects including GIT disturbances, obesity, liver diseases, thromboembolic diseases, etc. [7]. *Unani* Scholars were of opinion that *Kasrate Tams* (menorrhagia) is caused by *Sue Mizaj Rehm wa Badan* (abnormal temperament of uterus and body), *Amraz Rehm* (diseases of uterus), *Ghalbae Khilt Safra* (dominance of bile humor), *Imtilae Badan* (congestion in the body), *Riqqat* and *Latafat Khoon* (decreased viscosity and liquefaction of blood), etc. They also said *Zoafe Quwate Masika* (weakness in retentive power) and *Qawi Quwate Dafiya* (increase in expulsive power) lead to this disease [8–10]. If not treated in time, leads to complications such as indigestion, weakness, abortion, defect in implantation, and intrauterine growth retardation. [8]. Thus, treatment is necessary. Treatment objective in menorrhagia is to

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improve quality of life as well as alleviating heavy menstrual flow. In *Kasrate Tams*, *Unani* drugs that are having *Qabiz* and *Habis* (astringent and styptic) properties are used. Hence, *Safoof Habis* was selected as it contains *Teen Ahmer*, *Sange Jarahat* and *Raal Sufaid* that are having above said properties.

Though, this formulation is in use since long time for *Kasrate Tams*, but till date, no studies have been carried out to show the efficacy of *Safoof Habis* in this disease. Hence, this study is of its first kind to evaluate the efficacy and safety of *Safoof Habis* and furthermore, menstrual blood loss was quantified objectively by well validated menstrual pictogram [3].

Material and methods

The hypothesis of this study was to compare the effectiveness of *Unani* drug formulation with standard drug and from baseline in reducing the menstrual blood loss in menorrhagia.

Study design

A prospective, single center, pre and post treatment evaluation, and a single blind, randomized standard controlled trial were conducted in the Gynaecological outpatient Department of National Institute of Unani Medicine Hospital during the year January 2008–January 2009. The study was started after approval from institutional ethical committee. Random allocation was performed using lottery method onto two groups, the test group ($n = 35$) and control group ($n = 17$) allowing 20% drop out. Under lottery method, small and identical paper slips were numbered, which were folded and mixed together in a drum thoroughly. A blindfold selection was then made of the number slips that were required for this study. After drawing out one slip and noting the number, the slip was again put back in the drum. The drum was reshuffled and second slip was drawn. This process was repeated till the sample size was completed. The slip that was drawn for second time was rejected. As per recommendation of Ethical Committee Members the sample size in control group was reduced to 15 patients since it was dissertation work. The data were analyzed and compared after completion of the trial.

Participants

Clinically diagnosed ($n = 52$) patients with history of menorrhagia were consented.

Only patients were blinded about the intervention. For this purpose, patients of control and test group were called for the follow-up at different occasion and all precautions were taken so that these patients did not interrogate with each other. Patients with hemoglobin above 8 g%, unmarried and married women aged 18–45 years with pelvic pathology such as endometriosis, pelvic inflammatory diseases, uterine fibroid, polyp and adenomyosis were included. Patients using oral contraceptive pills, intrauterine contraceptive device, diseases such as diabetes mellitus, hypertension, tuberculosis, severe anemia, ischemic heart disease, thyroid dysfunction, blood dyscrasias, and malignancy were excluded.

Patients who fulfilled the inclusion criteria were evaluated through complete history, physical examination and investigations. Menstrual blood loss was assessed with menstrual pictogram. All information was recorded in specially designed case record form. Baseline routine investigations such as complete hemogram, bleeding time, clotting time, platelet count, blood grouping, Rh typing and random blood sugar were done to exclude bleeding disorders and general diseases. Blood urea, serum creatinine, uric acid, SGOT, SGPT, and alkaline phosphatase were done before and after treatment to assess the safety of test and control drugs. Thyroid and hormone profile (FSH, LH, and serum prolactin) were investigated to exclude thyroid dysfunction and hypothalamic pituitary dysfunction respectively. Pelvic ultrasonography was done to find out pelvic pathology. The venous concentration of hemoglobin was measured before and at the end of the treatment.

Measurement of menstrual blood loss with menstrual pictogram during baseline cycle was compared to three consecutive treatment cycles. The patients were requested to use kotex napkin and record the details of their menstrual cycle i.e., date of start, duration of menstruation, subjective assessment of menstrual flow and any side effects. During revisit and at the final visit, subjects were also asked about their menstrual blood loss, whether increased or decreased by the treatment received. The data registered during the baseline visit, the re-visits and the final visit, focused primarily on the effect and safety of the treatment. After completion of three months of treatment, patients were advised for three consecutive monthly visits of follow-up to observe the progression or regression of symptoms.

Diagnostic criteria

Menstrual pictogram

To diagnose menorrhagia, menstrual pictogram that is a modification of the previous PBAC technique was used. It is a visual representation of blood loss from which a numerical score in milliliters is derived. The chart consists of five icons representing blood loss on towels and four icons representing blood loss on tampons. Three icons demonstrate variation in the size of blood clots and another three icons were included to represent the volume of blood lost in the toilet when changing sanitary wear. A numerical scoring system was devised to coincide with the amount of blood lost. The score is calculated in milliliters and is equivalent to the actual volume of blood lost [3]. A validation study by Wyatt et al. suggested significant positive correlation between women's ability to estimate her blood loss on sanitary wear using the menstrual pictogram and her actual blood loss assessed using the alkaline hematin technique [4].

An additional advantage of the menstrual pictogram is the estimation of the extraneous blood loss that cannot be assessed by PBAC. Wyatt et al. reported that menorrhagia was confirmed objectively in 36% of their study group presenting with menorrhagia when only the sanitary products were assessed. However, when extraneous blood loss was taken into consideration this figure increased to 74% [3,4].

Sensitivity and specificity

The menstrual pictogram had a sensitivity of 86% and specificity of 88% in diagnosing menorrhagia (as defined by the alkaline hematin method). The associated κ statistic for the comparison between the feminine hygiene product icons and the alkaline hematin assessment was 0.8 [4].

Visual analog scale for pain in dysmenorrhea

The intensity of pain in dysmenorrhea was calculated by visual analog scale for pain. It is a simple assessment tool of 10 cm line, '0' on one end and 10 cm on the other end [11]. '0' on one end indicates no pain and 10 cm on the other end represents the 'worst pain' ever experience that a patients mark to indicate the severity of pain [12].

Intervention

The component of *Safoof Habis* [13] was *Teen Ahmer* (Silicate of alumina and Iron oxide), *Sange Jarahat* (Hydrated magnesium silicate) and *Raal Sufaid* (*Vateria indica* Linn). The ingredients of the test drug's formulation were supplied by the pharmacy of National Institute of Unani Medicine. Identification of these drugs was done by the Regional Research Institute of Ayurveda (RRCBI/Mus.7-09), Bangalore. All the three drugs were taken in equal quantity and ground well after cleaning them to make fine powder. The powder was supplied in an individual pack for each patient and its compliance was checked after each course of treatment. No additional medication was allowed.

The standard drug, tranexamic acid (Clip-500 mg) was procured from the market. It was manufactured by FDC Limited, B. No. TXG8061, Mfg date 06/2008, Expiry date 05/2010).

In the test group, *Safoof Habis*, 5 g twice daily and in the standard control group, tranexamic acid 500 mg, thrice daily were administered from day 1 to day 5 of the menstrual cycle for three consecutive months. The test drug formulation has been taken from the pharmacopeia where the prescribed dose was twice a day and standard drug's dose is thrice or four times a day. Hence, it was given according.

Qurs Kushta Faulad (125 mg) 1 tablet twice daily was given orally in both groups for three consecutive months as an iron supplement. The ingredients of this *qurs* are Iron calx (31.25 mg) and starch (q.s.).

Outcome measures

The primary outcome of this study was to compare the efficacy of *Safoof Habis* with tranexamic acid and from baseline on menstrual blood loss in *Kasrate Tams* Safety of the test drug formulation was evaluated with biochemical tests and by observing the adverse drug effects clinically. The secondary outcomes were to evaluate the efficacy of test drug formulation on dysmenorrhea, and hemoglobin concentration.

Statistical analysis

The Statistical software SPSS 15.0 was used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables, etc.

The descriptive statistical analysis has been carried out in the present study. Results on continuous measurements are presented on mean $\pm$ SD (Min–Max) and results on categorical measurements are presented in number (%). P values lower than 0.05 were regarded as significant. The Student 't' test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups and Student 't' test (two tailed, dependent) has been used to find the significance of study parameters on continuous scale within each group. Student 't' test has been also used to find the homogeneity of parameters on continuous scale. Chi-square/Fisher exact test has been used to find the homogeneity of samples on categorical scale. Analysis of data was on intention to treat basis.

Results

A total no. of 81 patients were interrogated and screened for *Kasrate Tams* during the study period. Out of them 17 patients did not review and 64 were subjected to preliminary investigations in which 12 were excluded because of thyroid dysfunction, diabetes and endometrial thickness of more than 14 mm. Fifty-two patients were randomly allocated by lottery method to the test and control group allowing 20% drop out. Statistical analysis for efficacy and safety was performed on 30 patients in the test group and 15 patients in the control group to observe the results (Fig. 1). The parameters were evaluated before and after treatment.

Baseline characteristics and investigations of patients allocated to the test and control group:

It was observed that all parameters were statistically not significant ($P > 0.05$) before treatment in both groups. Hence, the groups were homogenous with respect to age, socioeconomic status, age of menarche, marital status and investigations. (Table 1) The mean age with standard deviation in the test group was 27.4 $\pm$ 7.3 years and 28.33 $\pm$ 7.08 years in the control group.

Primary outcome

The mean score (standard deviation) of menstrual blood loss recorded in menstrual pictogram in control and test group was 154.13 (19.89) and 162.37 (13.38), respectively, which was statistically similar between two groups at base line ($P = 0.107$). After treatment at last follow-up (F3), difference of mean score (standard deviation) of menstrual blood loss from baseline in control and test group was 80.17 (27.67) and 81.48 (17.38) respectively ($P < 0.868$), which was statistically not significant showing that both groups were effective (Table 2 and Fig. 2).

Comparative evaluation of safety parameters

In the study, it was found that all parameters were statistically not significant ($P > 0.05$) before and after treatment, except

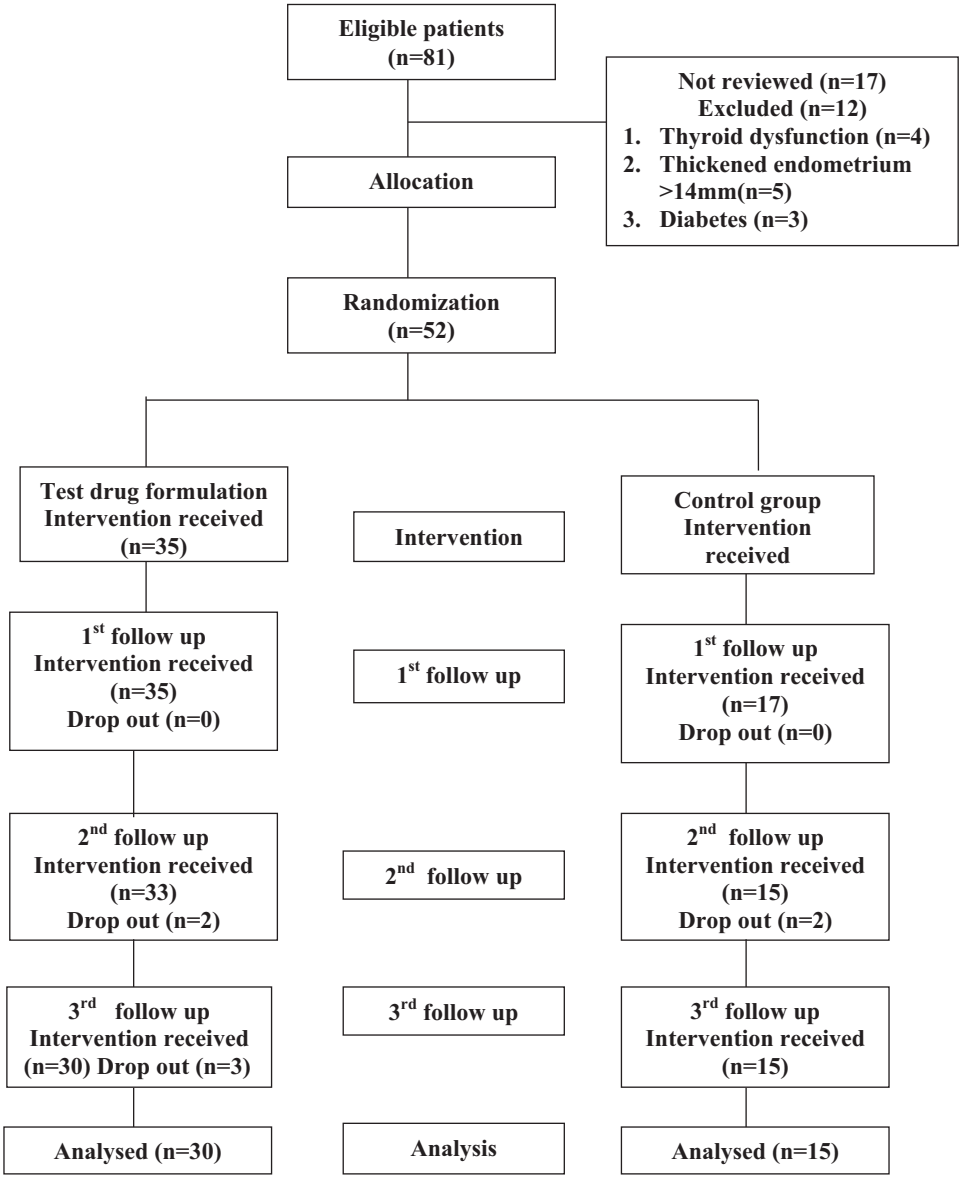

Fig. 1. Flow chart of participants.

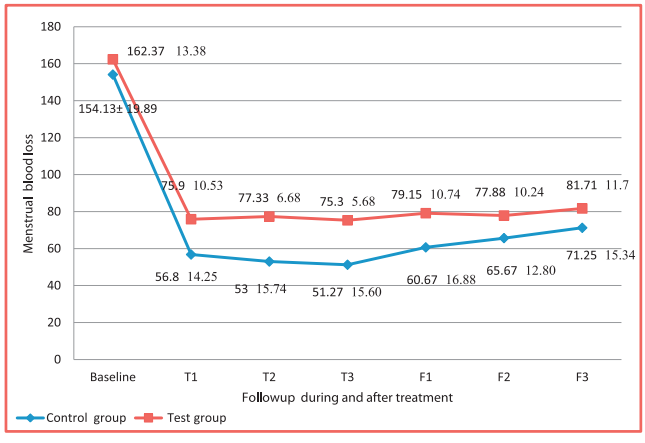

Fig. 2. Showing reduction in menstrual blood loss measured by menstrual pictogram. T1, T2, and T3: 1st, 2nd, and 3rd visit during treatment; F1, F2, and F3: 1st, 2nd, and 3rd follow-up after treatment. Data presented as mean±standard deviation.

serum creatinine ($P = 0.006$) that was statistically significant, but clinically, it was not significant as the value was within normal range. (Table 3).

Efficacy of the test and control drugs on dysmenorrhea

The mean ± SD of dysmenorrhea in the control group before the treatment was 5.00 ± 1.65 and after the treatment was 1.53 ± 1.46 ($P < 0.001$). The mean ± SD of the test group before and after the treatment was 4.13 ± 2.27 and1.83 ± 1.56 respectively ($P < 0.001$). There was significant reduction of pain after the treatment ($P < 0.001$) than compared to before treatment in both groups. The pain reduction was 69.4% and 54.9% in the control and test group respectively.

Effect on hemoglobin concentration

The mean ± SD of hemoglobin concentration in the control group before treatment was12.00 ± 1.43 and after the treatment

Table 1
Baseline characteristics and investigations of patients allocated to the test and control group.

Characteristics	Control group ($n=15$)	Test group ($n=30$)	P value
Age (years)	28.33 ± 7.08	27.4 ± 7.3	0.685
Age of Menarche(years)	12.87 ± 1.84	12.53 ± 0.86	0.411
Socioeconomic status			
Upper (I)	0	3(10)	
Upper middle(II)	4(26.66)	9(30)	
Lower middle(III)	2(13.33)	5(16.67)	0.150
Upper lower (IV)	6(40)	13(43.33)	
Lower(V)	3(20)	0	
Marital status			
Unmarried	3(20)	6(20)	1.00
Married	12(80)	24(80)	
Investigations: blood group			
A	5(33.33)	4(13.33)	
B	4(26.66)	13(43.33)	0.434
O	5(33.33)	11(36.66)	
AB	1(6.66)	2(6.66)	
Rh typing			
Positive	15(100)	28(93.33)	0.545
Negative	0	2(6.66)	
RBS mg/dl	86.93 ± 11.55	89.20 ± 14.71	0.605
BT (min)	2.87 ± 0.55	3.12 ± 0.76	0.255
CT (min)	4.40 ± 0.84	4.93 ± 0.88	0.059
Plateletcount (lakhs/cumm))	2.42 ± 0.74	2.64 ± 0.55	0.283
Hormonal assay			
FSH	8.54 ± 4.73	7.55 ± 3.61	0.440
LH	4.04 ± 1.96	4.83 ± 2.17	0.247
Serum prolactin	12.79 ± 9.66	9.39 ± 5.44	0.138
TSH	2.48 ± 0.84	2.32 ± 1.08	0.626
T_3	118.33 ± 27.22	125.3 ± 28.16	0.433
T_4	8.32 ± 1.93	8.45 ± 2.18	0.841
USG			
Normal	14	22	
Fibroid	1(3.33)	3(10)	
Adenomyosis	0	1(3.33)	
PCOS	0	1(3.33)	
Ovarian cyst	0	2(6.66)	
Bicornuate uterus	0	1(3.33)	

Data presented as: mean ± standard deviation and number (percentage).
Test used: unpaired '*t*' test, $P>0.05$, considered non significant.

was12.02 ± 1.36 ($P=0.947$). The mean ± SD of the test group was 11.73 ± 1.41 and12.32 ± 1.64 before and after the treatment respectively ($P=0.047$) with increase in hemoglobin after treatment.

Discussion

In this study, the primary outcome was to compare the therapeutic effect and safety of *Safoof Habis* and Tranexamic acid in women with menorrhagia before and after treatment in same group; and between test and control group. The comparison between two groups after treatment showed that there was no statistical significant difference between them ($P=0.265$) proving that the test drug formulation was as effective as the standard drug. Comparison between pre test and post test in same group showed that there was significant reduction in menstrual blood loss from the baseline ($P<0.001$).

After treatment during follow-up, it was observed that the effect of test drug formulation was long lasting than that of standard drug.

Unani scholars hypothesized that *Habisuddam* (hemostatic) drugs usually have *Barid wa Yabis* (cold and dry) temperament, hence helps to constrict the capillaries, blood vessels and surrounding structures thereby helps in hemostasis [14]. *Sange jarahat* and *Teen Ahmer* are having *Barid wa Yabis* temperament, and are able to help in hemostasis [15]. Moreover, *Kasrate Tams* is caused due to weakness of *Quwate masika* (retentive power) and increases force of *Quwat dafiya* (expulsive power) [9] and it is assumed that *Barid wa Yabis* drugs tone up the *Quwate ghazia* of *Rehm* (nutritive power of uterus) and ultimately rectify the abnormality of *Quwat masika* and *Quwate dafiya* [8]. *Raal Sufaid* contains tannin [16], which coagulates the cellular protein and contracts or blanches capillary endothelium, thus reducing the amount of menstrual blood loss [17]. *Teen Ahmer* and *Raal Sufaid* also contain calcium that helps to maintain hemostatic

Table 2
Efficacy of test and control drug on primary outcome variable (menstrual pictogram).

Menstrual pictogram (ml)	Control group ($n=15$)	Test group ($n=30$)	P value
Baseline	154.13 ± 19.89	162.37 ± 13.38	0.107
T1	56.80 ± 14.25	75.90 ± 10.53	<0.001**
T2	53.00 ± 15.74	77.33 ± 6.68	<0.001**
T3	51.27 ± 15.60	75.30 ± 5.68	<0.001**
F1	60.67 ± 16.88	79.15 ± 10.74	<0.001**
F2	65.67 ± 12.80	77.88 ± 10.24	0.003**
F3	71.25 ± 15.34	81.71 ± 11.7	0.035*
Difference for baseline			
T1	97.33 ± 24.54	86.47 ± 14.38	0.067+
T2	101.13 ± 24.01	85.03 ± 14.42	0.007**
T3	102.87 ± 25.16	87.09 ± 14.66	0.001**
F1	90.75 ± 32.73	81.92 ± 16.30	0.265
F2	85.75 ± 24.77	83.04 ± 16.94	0.695
F3	80.17 ± 27.67	81.48 ± 17.38	0.868
P value from baseline			
T1	$t=15.363$; $p<0.001$**	$t=32.922$; $p<0.001$**	–
T2	$t=16.317$; $p<0.001$**	$t=32.296$; $p<0.001$**	–
T3	$t=15.833$; $p<0.001$**	$t=32.526$; $p<0.001$**	–
F1	$t=9.604$; $p<0.001$**	$t=26.105$; $p<0.001$**	–
F2	$t=11.991$; $p<0.001$**	$t=24.990$; $p<0.001$**	–
F3	$t=10.038$; $p<0.001$**	$t=21.475$; $p<0.001$**	–

Data presented: mean ± standard deviation.
Test used: paired 't' test for pretest and post test comparison and unpaired 't' test for test and control group comparison, +suggestive significance (P value: $0.05<P<0.10$).
T1, T2, and T3: 1st, 2nd, and 3rd visit during treatment; F1, F2, and F3: 1st, 2nd, and 3rd follow-up after treatment.
* Moderately significant (P value: $0.01<P\leq 0.05$).
** Strongly significant (P value: $P\leq 0.01$)

mechanism [16,18,19]. It is also hypothesized that *Sange Jarahat* enhances the coagulation (antifibrinolysis) of blood [14]. Thus, all these properties of the test drugs have caused reduction in menstrual blood loss in menorrhagia.

It is known that Iron supplement and blood transfusion helps to reduce bleeding in anemia. Here it also might contribute to positive outcome, but in this study, it was given to prevent Iron deficiency anemia that might be caused by menorrhagia and to nullify the bias in the study it was given in both groups.

It validates the claim made by *Unani* physicians. However, none of the interventional studies have been documented using menstrual pictogram and test drug formulation in *Unani* system of medicine; therefore, it is difficult to correlate the finding with previous studies.

All the biochemical parameters that were assessed to observe safety of test drug formulation on vital organs of the body were within normal limits. Thus, the formulation was safe without adverse effects.

Effect on secondary outcome variables

Dysmenorrhea

The pain reduction was 69.4% and 54.9% in the control and test group respectively. This change was significant ($P<0.001$) indicating that both drugs were equally effective in reducing dysmenorrhea. Though these drugs are not having direct analgesic property but were able to reduced congestive dysmenorrhea. It might be due to vasoconstricting action of drugs on blood vessels of the uterus and related structures that reduces congestion thereby decreasing pain.

Hb concentration

Both groups were given *Qurs Kushta Faulad* but patients taking test drug formulation had improvement in the Hb concentration, most probably because of the effect of iron oxide present in *Teen Ahmer* [20].

The patients follow-up for three months showed no recurrence of this disease in both groups.

The strength of this study

It was the first of its kind of research, where menstrual pictogram was used in the interventional study to evaluate the efficacy of *Unani* drugs in menorrhagia. It was single blind randomized standard control trial. Compliance of the patients was good. Pelvic pathology was included and this formulation is cost effective and easily available.

The limitations of the study were unequal and of small sample size, power of the study was not calculated and gold standard alkaline hematin method was not used to quantify the menstrual blood loss. Further, double blinding was not done in view of small project, lack of manpower and infrastructure.

Further, clinical trials to evaluate the efficacy of the test drug formulation where menstrual blood loss should be quantified by gold standard alkaline hematin method are needed. It is also recommended that double blind, randomized standard controlled trial in large number of patients for longer duration is necessary as it contain minerals.

Table 3
Efficacy of test and control drug on hemoglobin and safety profile.

Bio-chemical parameters	Control group	Test group	*P* value
Hemoglobin			
BT	12.00 ± 1.43	11.73 ± 1.41	0.536
AT	12.02 ± 1.36	12.32 ± 1.64	0.551
P value	0.947	0.047*	–
Blood urea (mg/dl)			
BT	21.47 ± 4.79	21.70 ± 7.69	0.915
AT	22.60 ± 5.96	19.03 ± 5.51	0.053+
P value	0.434	0.103	–
Serum creatine (mg/dl)			
BT	0.75 ± 0.14	0.67 ± 0.11	0.085+
AT	0.84 ± 0.13	0.76 ± 0.12	0.033**
P value	0.069+	0.006**	–
Serum uric acid (mg/dl)			
BT	3.50 ± 0.77	4.05 ± 1.28	0.164
AT	3.98 ± 1.24	4.44 ± 1.05	0.198
P value	0.157	0.064+	–
SGOT (IU/L)			
BT	20.33 ± 5.74	20.33 ± 4.43	1.000
AT	22.33 ± 6.52	19.77 ± 5.95	0.193
P value	0.281	0.608	–
SGPT (IU/L)			
BT	19.27 ± 5.03	19.48 ± 5.14	0.902
AT	18.80 ± 5.82	18.83 ± 5.61	0.985
P value	0.801	0.575	–
Alkaline phosphatase (IU/L)			
BT	93.73 ± 22.69	103.90 ± 29.80	0.252
AT	116.73 ± 46.96	113.03 ± 35.14	0.768
P value	0.074+	0.145	–

Test used: paired and unpaired '*t*'test $P > 0.05$ not significant. +Suggestive significance (*P* value: $0.05 < P < 0.10$).
BT, before treatment; AT, after treatment.
* Moderately significant (*P* value:$0.01 < P \leq 0.05$).
** Strongly significant (*P* value: $P \leq 0.01$).

Conclusion

Kasrate Tams is considered as a common gynaecological complaint in women of reproductive age. Its effects range from social embarrassment to significant morbidity requiring blood transfusion and major operation. Hence, it should be treated. In conventional medicine effective medical therapy is available but proved to have many side effects.

We can conclude that *Safoof Habis* was efficacious, safe, well tolerated, and cost effective in the management of menstrual blood loss in *Kasrate Tams.* Despite a wide range of treatment options, this *Unani* formulation has trended toward conservative therapy for controlling costs, the desire of many women to preserve their uterus and replacing the hormonal therapy. Further, it is recommended that double blind, randomized standard controlled trial is needed in large population.

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Conflicting interest

The authors declare that there are no conflicts of interest.

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References

[1] The ESHREE Capri Workshop Group. Endometrial bleeding. Human Reproduction 2007;13(5):421–31.
[2] Fender GRK, Prentice A, Gorst T, Nixon RM, Duffy SW, Day NE. Randomised controlled trial of educational package on management of menorrhagia in primary care: the Anglia menorrhagia education study. BMJ 1999;318:1246–50.
[3] Wyatt K, Dimmock P, O'Brien S, Kirkham C, Warrilow G, Ismil K. Quantification of menstrual blood loss. The Obstetrician and Gynaecologist 2004;6:88–92.
[4] Wyatt k M, Dimmock PW, Walker TJ, Phil M, O'Brien MS. Determination of total menstrual blood loss. Fertility and Sterility 2001;76(July (1)):125–31.
[5] Kumar P, Malhotra N, editors. Jeffcoate's principles of gynaecology. 7th ed. New Delhi: Jaypee Brothers; 2008. p. 79–92, 598–617, 599, 601,603, 605, 606.
[6] Sengupta SB, Chattopadhyay SK, Dutta DC, editors. Gynaecology for post graduates and practitioners. New Delhi: B.I. Churchill Livingstone; 1998. p. 250–2.

[7] Lo L, Youde P. Modern management of menorrhagia. Hong Kong Practitioner 1996;18(2):61–6.
[8] Ibn Sina. Al qanoon, vol. II (translated by Husnain G). Delhi: Idara Kitabul Shifa; 2007. p. 331–7.
[9] Ibn rushd kitabul kulliyat. New Delhi: CCRUM; 1980. p. 116 [Urdu].
[10] Jurjani I. Zakheerae khwarzam shahi (Urdu translation by Khan H.H.), vol. VI. Delhi: Idara Kitabul Shifa; 2009. p. 590–8.
[11] Haslett C, Edwin Chilvers I, John AA, Colledge RN, editors. Davidson's principles and practice of medicine. 19th ed. Churchill livingstone: Idara Kitabul Shifa; 2002. p. 230.
[12] Visual analogue scale for pain, Journal of Clinical Nursing 10 (2001), 697–706. Available from: http://en.wikipedia.org/wiki/Pain_scale/html [accessed 02.03.10].
[13] Anonymous. Qarabadein sarkari unani, vol II. Andhra Pradesh: Govt Central Press; 1988. p. 19.
[14] Kabiruddin M. Kulliyat advia. Part I. Lahore: Malikdeen Mohd and Sons; 1958. p. 114, 115.
[15] Ghani N. Khazainul advia. Delhi: Idara Kitabul Shifa; 2002. p. 847, 720, 1168, 1169,1170.
[16] Anonymous. Standardisation of single drugs of Unani medicine. Part 1. New Delhi: CCRUM; 1987. p. 256–60.
[17] Kennedy C, Snell ME, Witherow RO. Use of alum to control intractable vesical haemorrhage. British Journal of Urology 1984;56:673–5.
[18] Wallis TE. Text book of pharmacognosy. 5th ed. New Delhi: CBS Publisher; 2005. p. 34–6.
[19] Keele CA, Neil E, Joels N. Samson Wright's applied physiology. 13th ed. Delhi: Oxford University Press; 1992. p. 546.
[20] Nadkarni AK. The Indian materia medica, vol. II. Bombay: Popular Prakasan; 1982. p. 14, 95–96.