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EFFECT OF A UNANI FORMULATION IN HEAVY MENSTRUAL BLEEDING (*KAṬHRAT-I-TAMṬH*) – A CLINICAL STUDY

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ABSTRACT

Background and objectives: Heavy menstrual bleeding (HMB) is the most common clinical presentation of abnormal uterine bleeding (AUB). The objective designed for the study was to evaluate the effect of a Unani formulation in HMB (*Kaṭhrat-i-Tamṭh*).

Methods: An open observational single arm clinical study was carried out at the Department of *Ilmul Qabalat wa Amraze Niswan*, National Institute of Unani Medicine, Hospital, Bengaluru. Diagnosed cases (n=30) of HMB with pelvic pathology were included in the study. Unani formulation comprises of *Khurma (Phoenix dactylifera* Linn*), Rasaut (Berberis aristata), Talmakhana (Asteracantha longifolia* Linn*), Lodh pathani* (*Symplocosracemosa*Roxb) was administered orally in powder form in a dose of 3g with 2g sugar, twice daily for seven days/cycle for three consecutive cycles.Main outcome measures were clinical response of 30-50% in menstrual blood loss (MBL) assessed with pictorial blood loss assessment chart (PBAC) and duration of bleeding (DOB). Improvement in Hb% and quality of life (QOL) assessed with menorrhagia impact questionnaire (MIQ). Data were analyzed using paired Student 't' test,

Results: Clinical response of 30-50% in MBL and DOB was achieved in 86.7% ($p< 0.001$**) and 56.7% ($p< 0.001$**) patients respectively and improvement in Hb% and QOL was achieved in 16.7% ($p=0.228$) and 100% ($p< 0.001$**) patients respectively.

Conclusion: Unani formulation had a significant effect in controlling the bleeding by reduction in MBL and DOB with improvement in QOL

INTRODUCTION

HMB is the most common clinical presentation of AUB.[1,2]It is defined as excessive menstrual blood loss which interferes with the women's physical, emotional, social and maternal quality of life, and which can occur alone or in combination with other symptoms. Approximately 30% of women are affected with HMB during their reproductive years, but only one third of these women are confined to have underlying pathology of a type widely recognized to cause HMB.[1-5]

In classical Unani text, *Kaṭhrat-i-Tamṭh*is defined as excessive MBL either the bleeding is excessive in amount or duration. It is caused by *Sū'i-Miẓaj al-Rahim* (which results in weakness of uterine vessels leading to its rupture),*Qarha al-Rahim, Aakla al-Rahim, Bawasir al-Rahim.* Moreover, dilatation of uterine vessels is caused by *Riqqat-i-Khūn* due to *Ghalaba-i-Balg̃ham* or *Ḥiddat-i-Khūn* due to *Ghalaba-i-Ṣafra* or *Sawda'* resulting in *Ḍu'f Quwwat-i-Masika al-Rahim* leading to increased MBL. Excessive MBL leads to rapid pulse, giddiness, palpitation, increased thirst, generalised weakness &bodyache etc. and if it is not treated may leads to complications such as *Sū'al-Qinya*(iron deficiency anaemia), *Istesqa*(ascites)*, Ḍu'f-al-Kabid*etc.[6-11]The main goal of treatment in HMB is to improve QOL by controlling the bleeding,[12]to prevent & treat anaemiaand to restore an acceptable menstrual pattern.[5]

The treatment plan of *Kaṭhrat-i-Tamṭh* in Unani system of medicine is mainly based on concept that, treat the actual cause of HMB (*Iẓala-i-Sabab), Tanqiya-i-badan* with *T'deel Miẓaj*and *IstefraghMadda*in*Sū'i-Miẓaj sada and Maddi r*espectively, use of *Habis* and *Qabiḍ advia* to control bleeding and finally use of *Muqauwwi al-Rahim advia* to strengthen the uterus.[7] Several compound formulations are enlisted for the

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treatment of *Kaṭhrat-i-Tamṭh*. Unani formulation comprises of drugs such as *Khurma (Phoenix dactylifera* Linn*), Rasaut (Berberis aristata), Talmakhana (Asteracantha longifolia* Linn*), Lodh pathani* (*Symplocosracemosa*Roxb)[6] was selected as research drug to control bleeding in patients with HMB, as they exhibit the properties of *Habis, Qabiḍ, Muqauwwi, Kaṭheer-al-Tag̃hdia, Musammin-i-Badan, Mo'llid-i-Khūn,*[13-15]*Mo'llid-i-Mani, Musakkin-i-Badan,*[13,16] *Mohallil-i-Waram* [13,15-17]etc.

The main objective of the study was to evaluate clinically the effect of research drug in the management of HMB and the hypothesis tested was the research drug may be effective to control bleeding in patients with HMB.

MATERIALS AND METHODS

Study design: An open observational single arm clinical study was carried out in the Department of *Ilmul Qabalat wa Amraze Niswan,* National Institute of Unani Medicine Hospital, Bengaluru from Nov 2019 - March 2020.The research protocol was approved by Institutional ethical committee prior to its commencement under IEC no. NIUM/IEC/2017-18/012/ANQ/04. The trial was registered at Clinical Trial Registry of India (CTRI) under the registration number CTRI/2019 /02/017722.

Sample size estimation: Sample size was calculated for single group with pre and post assessment of duration of bleeding. From the previous study, mean of DOB was 10.6 with SD of 2.7.[18]The sample was calculated from the formula: $n=2[(Z_\alpha-Z_\beta)SD/\mu_1-\mu_2]^2$. It is validated from thumb rule for calculation of sample size i.e. $(SD/\mu_1-\mu_2)^2 \times 20$ for 95% confidence limit. It was found to be 28.57~ 30. So, the sample size was fixed at 30 for this study.

Eligibility criteria: Women with pelvic pathology (uterine fibroid, polyp, adenomyosis) in age group of 18-45 years with regular cycles (21-35 days) with MBL >80 ml for 2 out of 3 consecutive cycles,[19,20] with PBAC score >100[20]& endometrial thickness up to18mm were included and those with thyroid dysfunction, severe anemia, bleeding disorders, systemic diseases, malignancy, and on hormonal contraceptives in last 3 months were excluded. CT, BT, Platelet count, FBS, TSH and Pap smear were done for exclusion.

Procedure of study: At the beginning of the study, participants who are interested signed a written informed consent & included in the study. The included participants were enquired about the details of their demographics, menstrual cycle pattern & medical history. For all participants, information regarding the age, BMI, age at menarche, duration of cycle, number of days & amount of bleeding during menstruation prior to & also after the onset of treatment were recorded & assessed by Pictorial blood loss assessment chart scoring system, history of passing clots (suggestive of heavy bleeding), and dysmenorrhoea were also enquired**.** Complete physical examination was performed including gynecological examination. The socioeconomic status and *Miẓaj* was assessed by Kuppuswamy's socioeconomic modified scale and temperamental scale respectively. All participants were instructed to maintain a menstrual diary to grade bleeding each day during menstruation and were instructed not to use any medication during the trial. All findings were recorded in the case record form structured for the study. Following thorough evaluation of patients by history and clinical examination.

Intervention: Research drug (Unani formulation)[6]were purchased from the local crude drug market of Bengaluru and submitted to the Dept of Ilmul Saidla of NIUM, for preparation of powder and the same was send to FRLHT for identification and authentication of raw drugs. (FRLHT Acc. No.5535, 5536, 5537, 5538).All ingredients of research drug were taken in equal quantity and grinded to make fine powder and then dispersed in self-locking pack and was administered orally in a dose of 3g with 2g sugar,[6] twice daily for seven days/cycle for three consecutive cycles. For maintaining patient compliance, drugs were given to patients for 1 month only, convincing them to return and receive the remainder of treatment in subsequent follow ups.

Fig No.1: (a) *Khurma*-Fruit,[21](b) *Rasaut*-Extract, [22](c) *Lodh* –Bark[23](d) *Talmakhana* Seeds [24]

Subjective Parameters: At every visit,menstrual blood loss was assessed by reduction in amount of flow (no. of pads/cycle used by the patient) and recorded at baseline and every visit according to 3 pointer scale (mild- 1, moderate- 2, and heavy-3) and duration of bleeding was assessed by reduction in number of bleeding days.

Objective Parameters: At every visit, PBAC score was used to assess the amount of bleeding[25,26]and MIQ(validated questionnaire)[20,21,27]was used to assess the QOL of women suffering from HMB.

Main outcome measures: Main outcome measureswere clinical response of 30-50% in menstrual blood loss and duration of bleeding as well as improvement in Hb%[20,21]and QOL.

Adverse effect documentation:No adverse effect of research drug was reported during the study period as safety profile was with in normal limits.

Statistical Methods:Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean ± SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5% level of significance. Student t test (two tailed, dependent) has been used to find the significance of study parameters on continuous scale within each group.[28-31]The Statistical software namely SPSS 22.0, and R environment ver.3.2.2 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc**.**

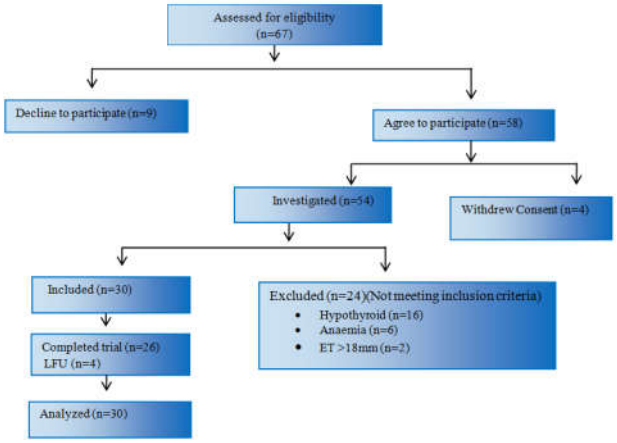

Fig 2 Flow chart of study participant

(LFU- loss to follow up)

RESULTS

Total 67 patient were assessed for eligibility, 9 patients declined and 58 were willing to participate in the study, 54 patients were investigated and 4 withdrew the consent; 24 out of 54 patients were excluded for not meeting the inclusion criteria and remaining 30 patient were included in the study, 26 patients completed the trial and 4 were lost to follow up (not turned up for post treatment follow up), but included in final analysis by last observation carry forward method. **(Fig. No.2)**

Table 1 Demographic Data of HMB

Demographic Data		No. of patient	%
Age in years (Mean age-33.57±7.14)	18-31	11	36.6
	32-45	19	63.4
Mean Age of Menarche	12.83±0.94		
Socio Economic Status	Lower middle	7	23.3
	Upper	5	16.7
	Upper lower	15	50.0
	Upper middle	3	10.0
Marital Status	Married	24	80
	Single	6	20.0
Educational Status	Illiterate	3	10.0
	Primary	8	26.7
	Secondary	5	16.7
	High school	7	23.3
	Graduate	3	10.0
	Post graduate	4	13.3
Dysmenorrhea	Absent	10	33.3
	Present	20	66.7
Miẓaj	*Balġhami*	3	10.0
	Damwi	15	50.0
	Ṣafrawi	12	40.0
BMI (kg/m^2)	< 18.5	1	3.3
	18.5-25	13	43.3
	25-30	11	36.7
	>30	5	16.7
Pap smear	BV	4	13.3
	Nor	11	36.7
	Inf	9	30.0
	NA	6	20.0

Data were presented as number (percentage), Student t test (two tailed, dependent)

Subjective Parameters

Table 2(a) Effect of Research Drug on MBL (Grading)

MBL(Grading)	BT	1st Cycle	2nd Cycle	3rd Cycle	AT	% difference
1	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0.0%
2	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	0.0%
3	30(100%)	30(100%)	30(100%)	30(100%)	30(100%)	0.0%
Total	30(100%)	30(100%)	30(100%)	30(100%)	30(100%)	-

Data were presented as number (percentage), Student t test (two tailed, dependent)
(MBL –menstrual blood loss, 1-mild, 2- moderate, 3- heavy)

Table 2(b) Effect of Research Drug on DOB (Days)

DOB (Days)	BT	1st Cycle	2nd Cycle	3rd Cycle	AT	% difference
1-5	1(3.3%)	8(26.7%)	9(30%)	15(50%)	15(50%)	46.7%
6-10	23(76.7%)	21(70%)	21(70%)	14(46.7%)	14(46.7%)	-30.0%
11-15	6(20%)	1(3.3%)	0(0%)	1(3.3%)	1(3.3%)	-16.7%
Mean ± SD	8.50±2.40	6.30±1.68	5.83±1.49	5.60±1.63	5.67±1.77	-
	-	<0.001**	<0.001**	<0.001**	<0.001**	

Data were presented as number (percentage) and Mean ± SD, Student t test (two tailed, dependent), ** strongly significant. (DOB- Duration of bleeding)

Objective parameters

Table 3(a) Effect of Research Drug on PBAC Score

PBAC Score	BT	1st Cycle	2nd Cycle	3rd Cycle	AT
Min-Max	205.00-1445.00	130.00-725.00	125.00-660.00	90.00-540.00	90.00-550.00
Mean ± SD	506.50±267.17	303.33±15 1.52	236.50±10 9.59	236.50±10 9.59	211.17±100 .04
difference	-	203.167	270	302.167	295.333
P value	-	<0.001**	<0.001**	<0.001**	<0.001**

Values are mentioned as Mean ± SD, Student t test (two tailed, dependent),** Strongly significant,(PBAC- Pictorial Blood Loss Assessment Chart)

Table 3(b) Effect of Research Drug on MIQ Score

MIQ Score	BT	1st Cycle	2nd Cycle	3rd Cycle	AT
Min-Max	6.00-21.00	12.00-36.00	12.00-36.00	18.00-36.00	18.00-36.00
Mean ± SD	13.23±3.85	22.57±5.15	27.33±4.71	28.30±3.73	28.43±3.70
difference	-	-9.333	-14.1	-15.067	-15.2
P value	-	<0.001**	<0.001**	<0.001**	<0.001**

Values are mentioned as Mean ± SD, Student t test (two tailed, dependent), ** Strongly significant, (MIQ- Menorrhagia Impact Questionnaire)

Table 4 Effect of Research Drug on Investigations

Investigations	Before Treatment	After Treatment	Difference	P value
Hemoglobin	10.94±1.40	11.16±1.35	-0.217	0.228
ALT	17.97±4.44	20.73±4.42	-2.767	0.002**
AST	17.57±3.57	20.03±3.93	-2.467	<0.001**
Alkaline Phosphate	85.09±12.74	89.63±10.49	-4.540	0.168
Blood Urea	22.00±3.94	23.20±3.33	-1.200	0.199
Serum Creatinine	0.77±0.12	0.80±0.10	-0.027	0.293

Values are mentioned as Mean ± SD, Student t test (two tailed, dependent), ** Strongly significant

Table 5 Effect of Research Drug on Outcome Measures

Outcome Measures	No. of patients(n=30)	%
Clinical Response (30-50%)		
• **MBL (PBAC)**	26	86.7
• **DOB**	17	56.7
Improvement		
• **Hb%**	5	16.7

• QOL	30	100.0

Data were presented as number (percentage), Student t test (two tailed, dependent) (MBL-Menstrual Blood Loss, PBAC-Pictorial Blood Loss Assessment Chart, DOB- Duration of bleeding, QOL-Quality of Life.

DISCUSSION

Main findings: The present study demonstrated that, clinical response of 30-50% in MBL and DOB was achieved in 86.7% (26/30) and 56.7% (17/30) patients respectively and improvement in Hb% and QOL was achieved in 16.7% and 100% patients respectively during the study period. No adverse effects of research drug were reported during the study period and 100% compliance to treatment was achieved in all patients.

Demographic data

Age: In this study, majority of patients 63.4% were in the age group of 32-45 years, while 36.6% were in 18-31 years of age. Higher incidence of HMB was observed above 30 years of age, which is in accordance with the study of Goshtasebi A.[32]*et al* reported 60.5%, Gottapu K.[33]*et al* reported 71%. Evidence suggest that MBL increases with age and the incidence of HMB is 50% in perimenopausal women.[34]The mean age of patient was 33.57±7.14, which is in consonance with the study of Bahman M.[35]*et al*reported 33.8±10.8, Zutshi V.[36]*et al* reported 34.55± 16.2, in two groups respectively.

Age of menarche: The mean age of menarche was 12.83±0.94, which is consistent with the study ofBahman M.[35]*et al* reported 12.9 ±1.9.

Marital status: In this study, maximum patients 80% were married, which is matching with the study of Aziz khani M.[37]*et al* reported 77.5%,Gottapu K.[33]*et al* reported 77%. This shows that HMB is common in married women.

Socio economic status: In this study, maximum patients 50% were from upper lower class, followed by 23.3% from lower middle class, 16.7% from upper and remaining 10% from upper middle class; which correlates with study of Fatima A.[38]*et al*, who reported 43.33% and 40% in test and control group respectively in upper lower class, Jahan D.[39]*et al* reported 25%, 45%, 5% and 25% in test and 40%, 25%, 5% and 25% in control group in upper lower, lower middle, upper and upper middle class respectively.

Educational status: In this study, 26.7% patients had education till primary school, followed by high school in 23.3%, secondary in 16.7%, post graduate 13.3%, graduate and illiterate, each 10%.

Dysmenorrhoea: In this study, maximum patients 66.7% had associated dysmenorrhoea, while remaining 33.3% had no history of dysmenorrhoea, which is in agreement with the study of Aziz khani M.[37]*et al* reported 66.7% & 65.4% in two groups, Gottapu K.[33] *et al* reported 59%. Patients having HMB may also suffer from dysmenorrhoea.

Miẓaj: In this study, 50% patient possesses *DamwiMiẓaj* followed by *ṢafrawiMiẓaj*in 40% and *BalġhamiMiẓaj*in 10 % patients of HMB**.** This shows thatHMB is common in patients with hot temperament. This correlates well with the theories of Unani physicians, who states that *Kaṭhrat-i-Tamṭh*is mostly caused by the weakness of *Quwwat-i-Masika Raḥim,* secondary to *Sū'i-Miẓaj al-Raḥim*either *ḤaarRaṭb or Ḥaar Yabis.*[4,7,8,40,41]

BMI: In this study, 43.3% patients had normal BMI, 36.7% were overweight and remaining 16.7% were obese. Gottapu K.[33]*et al* reported 59% patients had normal BMI, 25% were overweight, 9% were obese and 7% had morbid obesity. Further, it correlates with study of Peter AB.[42] e*t al* who states that HMB is highest among participant with normal BMI followed by overweight group.

Pap smear: In this study, normal smear was found in 36.7 % patients, inflammatory in 30%, bacterial vaginosis in 13.3% and not applicable in 20% patients. **(Table-1)**

Subjective parameters

MBL (Grading): At baseline, 100% patients had MBL grading as 3, which is considered as severe and it remains same during the trial. This shows that all patients
had PBAC score >100. **(Table-2a)**

Duration of bleeding(DOB): At baseline, 20% patients had DOB for 11-15 days which persist in 3.3% patients after treatment with a percentage difference of -16.7%. 76.7% patients had DOB for 6-10 days, which persist in 46.7% patients after treatment with a percentage difference of -30%. 3.3% patients had DOB for 1-5 days, which was improved in subsequent visits and after treatment, 50% patient had same DOB with a percentage difference of 46.7%.

Mean ± SD of DOB before treatment, 1st, 2nd and 3rd cycle during treatment and after treatment were 8.50±2.40, 6.30±1.68, 5.83±1.49, 5.60±1.63, 5.67±1.77 respectively, Gradual reduction in DOB was observed during treatment from 1st treatment cycle to post treatment follow up with $p < 0.001$, considered as highly significant. **(Table- 2b)**

This finding is in agreement with the study of Goshtasebi A.[32]*et al* reported reduction in DOB from 8.0±1.82 to 6.65±1.37 in control group and from 8.0±1.39 to 6.5±1.35 in test group in 3 months, Bahman M.[35]*et al* reported reduction in DOB from 7.8±2.6 to 5.9±1.7 in 2 months, Zutshi V.[36]*et al* reported reduction in DOB from 8.26±2.0, 6.40±2.6, 6.0±2.1 to 5.73±2.0 in 3 month, Qaraaty M.[43]*et al* reported reduction in DOB from 10.6 ±2.7, 8.8±2.3, 8.9±3.8 to 8.2±1.9 in 3 months.

Objective parameters

PBAC Score: Mean± SD of PBAC score before treatment, 1st 2nd and 3rd cycle during treatment and after treatment were 506.50±267.17, 303.33±151.52, 236.50±109.59, 236.50±109.59, 211.17±100.04 respectively. Significant reduction in PBAC score was observed during treatment from 1st treatment cycle to post treatment follow up with $p < 0.001$, considered as highly significant. **(Table-3a)**

This finding is in consonance with the study of Bahman M.[35]*et al* reported reduction in PBAC score from 264.2 ±198.9, 131.6±157.3, to 125.8±155.9 in 2 months, Goshtasebi A.[32]*et al* reported reduction in PBAC score from 304.4±192.71 to 143.13±96.0 in 3 months.

MIQ Score: Mean± SD of MIQ score before treatment, 1st, 2nd and 3rd cycle during treatment and after treatment were 13.23±3.85, 22.57±5.15, 27.33±4.71, 28.30±3.73, 28.43±3.70 respectively. Significant improvement in MIQ score was

observed during treatment from 1st treatment cycle to post treatment follow up with p< 0.001, considered as highly significant. This shows that research drug improved the QOL of women suffering from HMB. Patel NK.[27]*et al* reported mean MIQ score of 12 and 21 before and after treatment.

In this study, 53.4% improvement in MIQ score was observed (calculated in percentage of difference mentioned in table) which is in accordance with the study of Patel NK.[27]*et al* reported 57%. **(Table-3b)**

However, none of the clinical studies have been documented in Unani system of medicine using MIQ; hence, cannot be correlated with previous studies.

Safety profile: Research drug was safe as safety parameters were within normal limits, except ALT (p=0.002), AST (p<0.001) in which, strongly significant changes were observed during the trial (though the values are within normal range only) moreover, all ingredients of research drug are hepatoprotective[44-49]and no serious adverse effects were encountered during the study period, thus validating the safety of research drug. **(Table-4)**

Main outcome measures

Clinical response (30-50%): In this study, clinical response of 30-50% in MBL and DOB was achieved in 86.7% (26/30) and 56.7% (17/30) patients respectively.

Marked reduction in MBL and DOB probably may be due to astringent,[50-52]haemostatic, tonic, anti-inflammatory,[49,53-56]anti-oxidant,[44,57-59]nutritive,[44]haemopoietic,[44,57,60,61]activities of research drug. Moreover, these drugs consist of tannins, flavonoids, phenols, glycosides, steroids.[57,58,62,63] All these drugs may control the bleeding probably by constricting the capillaries and blood vessels due to its astringent and styptic properties.[45,46,52,64-66]

Improvement in Hb% & QOL: It was achieved in 16.7% and 100% patients respectively during the study period. Mild improvement in Hb% may be due to nutritive,[44] tonic,[49,53-56]immunity enhancer,and antioxidant[44,57-59]activities of research drug. 100% improvement in QOL of women suffering from HMB may be due to reduction in MBL and DOB. **(Table-5)**

Strength of the study: This is the first study reporting the effect of Unani formulation in HMB with inclusion of pelvic pathology and got response in improving QOL by reduction in MBL and DOB. Moreover, this study is first of its kind in which MIQ was used to assess the QOL of women suffering from HMB.

Limitation of the study: Single armed open clinical study, small sample size, short follow up, unpleasant taste of research drug.

Future recommendation: Future trial are recommended on large sample size to assess the long-term efficacy of research drug, with long follow up preferably randomized standard controlled clinical trial.

CONCLUSION

Finally, it can be inferred that research drug may be an effective therapeutic option in patients with HMB, as it has significant effect in controlling the bleeding by reduction in MBL and DOB with improvement in QOL.No adverse effects were encountered during the study period. Hence, research drug can be used as an alternative in HMB patients.

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Conflict of interest: None declared.

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