



Efficacy of *Tukhme Khurfa* (*Portulaca oleracea* L.) in abnormal uterine bleeding-an observational clinical study

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ABSTRACT

Background: Abnormal Uterine Bleeding (AUB)- a term used to describe any type of bleeding that does not fall within the normal ranges for the amount, frequency, duration, or cyclicity. The estimated worldwide prevalence of subjective, self-defined abnormal uterine bleeding varies greatly from 4% to 52%. It is one of the frequently encountered gynecological problems responsible for about one-third of patients visiting gynecological OPD. It interferes with a women's physical, social and emotional quality of life.

Objective: The aim of the study was to evaluate the efficacy of tukhme khurfa(*Portulaca oleracea* seeds) in the management of abnormal uterine bleeding.

Material and methods: The study was designed, an open observational clinical study conducted in the Dept. of Ilmul Qablat was Amraze Niswan, NIUM hospital, Bengaluru. 30 women age group of 18-45 years with abnormal uterine bleeding were allocated. Roasted powder of tukhme khurfa in the form of a capsule (2gms) thrice a day was given for two consecutive cycles. Follow up was done before and after each menstrual cycle during treatment and after treatment once in a month for two consecutive cycles. Primary and secondary outcomes were assessed by Pictorial blood assessment chart (PBAC) at each follow-up. Hemoglobin percentage, Short form survey (SF-12), menstrual regulation, before and after treatment

Results: Statistical analysis was done by using Fisher exact. There was a significant reduction in PBAC score, improvement in SF-12 score with p-value of < 0.001. The menstrual regulation also achieved in 26(86.7%) out of 30 patients.

Interpretation and conclusion: Tukhme khurfa can be considered as an effective alternative medicine in the management of abnormal uterine bleeding. There was no adverse effect noted.

Keywords: Abnormal uterine bleeding, Tukhme khurfa, PBAC, SF-12.

1. INTRODUCTION

Normal menstruation is defined as bleeding from secretory endometrium associated with ovulatory cycles, not exceeding a length of five days. Any bleeding not fulfilling these criteria is referred to as abnormal uterine bleeding (AUB). It is one of the frequently encountered gynecological problem responsible for about one-third of patients visiting gynecological OPD. [1] It describes a range of menstrual bleeding symptoms, the most common of which is heavy bleeding. It affects women of all ages and is the commonest gynecological reason for referral to secondary care. [2] Women with AUB suffer a diminished quality of life, lose work, productivity and utilize expensive medical resources. [3]

According to the classical Unani literature abnormal uterine bleeding has been given under the heading of Istehaza, in this bleeding is irregular, excessive, in amount or occurs for a long duration. [4, 5] One of the main function of the uterus is to excrete the khooni-hayd (menstrual blood) which should be normal in amount and duration if the balance is maintained between quwwate masika and quwwate dafi'a of rahim, and any kind of imbalance between these causes menstrual irregularities.[4]

Istehaza, occur due to mudafi'ati tabi'at, and disease of uterus like quruh akila, bawasir, shiqaq al-rahim which leads to weakening of uterine vessels or it may be due to su'-i-mizaj harr yabis, or barid yabis or ratb which causes vasodilatation. Seldom is the cause of excessive bleeding the decrease in the viscosity or increased hararat of blood. [4, 5]

It can be caused by a wide variety of structural and functional causes. Common structural causes include fibroids, polyps, adenomyosis or neoplasia.[1] It may be acute or chronic and can be caused by disorders of ovulatory function, abnormalities in local or systemic haemostasis, or any number of structural abnormalities including polyps, adenomyosis, leiomyomas (also known as fibroids or myomas), and premalignant endometrial disease or uterine carcinoma or sarcoma.

It may be a consequence of the use of intrauterine contraceptive devices or a spectrum of pharmacological agents ranging from gonadal steroids to medications that impact dopamine metabolism and subsequently ovulatory function.[6] The FIGO classification system of causes of AUB is stratified it into 9 basic categories that are arranged according to the acronym PALM-COEIN: i.e. polyp, adenomyosis, leiomyoma, malignancy and hyperplasia, coagulopathy, ovulatory disorders, endometrium, iatrogenic, and not classified.[7,8,9] The treatment for AUB includes both medical therapies and surgical procedures. Medical therapies are recommended as a first-line treatment and include oral contraceptives (OCs), progestins, tranexamic acid, mefenamic acid, danazol, and gonadotropin releasing hormone analogs. Women seeking treatment for AUB who also require contraception have a choice of OCs, long-acting progestogens, or levonorgestrel-releasing intrauterine system (LNG-IUS). Hysterectomy is an invasive surgical option that usually recommended only after other therapies have failed and for women who do not wish to retain their fertility. Endometrial ablation techniques, including first-generation (transcervical resection of the endometrium [TCRE], roller-ball, and laser ablation) and second-generation (thermal balloon, microwave, radiofrequency, cryoablation, and hydrothermal ablation), are less invasive surgical alternatives to hysterectomy. [10]

In unani system of medicine numbers of drugs are available simple as well as compound formulations to treat Istehaza. The drugs which are used to treat Istehaza, said to have habis (haemostatic) and qabid (astringent) properties e.g. anjabar, geru, sange jarahat, dammul akhwain, etc.[11,12]

In compound drugs number of compositions are there e.g. qurse kuharba, qurse tabasheer, sharbate anjbar, safoofe habis, qurse habis,[13] qurse gulnar, qurse qabid etc.[13,14]

Tukhme khurfa(*Portulaca oleracea* L. seeds) has an astringent and haemostatic property which is used to prevent bleeding. It also has properties like refrigerant, alterative, antibacterial [15,16,17,18,19], wound-healing, analgesic, and anti-inflammatory.[6,19,20]

2. MATERIAL AND METHODS

An observational study was carried out on the patients of Dept. of OBG, National Institute of Unani Medicine, Bengaluru during the period of 2016-2017. The study protocol was approved by Institutional Ethical Committee, NIUM, Bengaluru under IEC No: NIUM/IEC/2015-2016/013/ANQ/05 after which the clinical study was started. Written consent was taken from the patients before starting the trial. The trial has CTRI no which is registered with clinical trial registration code CTRI/2018/03/012593.

Study design: An observational clinical study

Sample size: 30

Study Participants:

Total (n=71) patients were assessed out of which (n=35) patients refused for participation, 36 patients investigated, 6 excluded during evaluation (systemic illness-2, hypothyroidism-1, and anemia-3).

Selection criteria

All Patients were in reproductive age group (18 to 45 years) with heavy irregular bleeding, vaginal bleeding increased in amount or duration, a patient affected by abnormal uterine bleeding for 3 months were included. Pregnancy and lactation, systemic, metabolic illness and malignancy, severe anemia (<8gm %), IUCDs, recent H/o chicken guinea and dengue were excluded.

Study Procedure:

The patients fulfilling the inclusion criteria were enrolled after explaining the study in detail and receiving the informed consent. Detailed clinical history including the socioeconomic status of the patient, which was assessed by Kuppuswamy's Socioeconomic Scale. Assessment of mizaj of every patient was done according to parameters mentioned in the Unani classical literature. In each patient, history was evaluated and a complete physical examination including breast, abdominal examination and per vaginal examination was performed. Personal details, history, clinical features, and investigations were recorded in the CRF structured for the study.

Clinical history of each patient which was carefully recorded in detail includes;

Amount, duration and pattern of uterine bleeding and its relation to last menstrual period. The amount of bleeding was assessed with a number of pads changed per day, the presence of clots and presence or absence of anemia. Assessment of menstrual blood loss is done by using the pictorial blood assessment chart.[21] Assessment for the quality of life was done by using SF-12 score.[22] Each patient was subjected to a biochemical test (SGOT, SGPT, Alkaline phosphatase, Blood urea, Serum creatinine) for the safety of the patient as well as specific investigation like Haemogram, TSH, RBS, CUE, USG-Pelvis.

Intervention

Roasted powder of Tukhme khurfa (*Porulacca oleracea* L. seeds) in the form of a capsule (each 2gm) thrice a day was given for 10 days starting from the first day of menses for two consecutive cycles.

Assessment follow up

Patients were followed before and after each menstrual cycle during treatment, and after treatment once in a month for two consecutive cycles. During treatment amount of bleeding was assessed by asking duration of the cycle, duration of flow, amount of flow which was assessed by calculating the total no. of pads used in one cycle. Apart from that improvement in the quality of life was assessed by using SF-12 questionnaire before and after treatment.

Subjective parameters were heavy irregular bleeding per vaginum and Objective parameters were PBAC score, Hb %, SF- 12 score. Outcome measures were assessed as primary and secondary parameters. The primary outcome was assessed by Change in PBAC score and menstrual regulation. where as a Secondary outcome: Change in Hb% and change in SF-12 score.

Withdrawal criteria: Those who were a failure to follow the protocol and any adverse reaction or adverse event.

Statistical Analysis

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 (%). The significance is assessed at 5 % level of significance. The statistical software namely SPSS 18.0, 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.

3. RESULTS

Table.1: Baseline demographic data of the patients with AUB

Characteristic	Test group	
	N0	%
Age(years)		
>20	1	3.3
20-30	14	50.0
31-40	11	36.7
41-50	3	10.0
Total	30	100.0
Marital status		
Married	23	76.7
Unmarried	7	23.3
Total	30	100.0
Occupation		
Employed	1	3.3
Housewife	22	73.3
Student	7	23.3
Total	30	100.0
SES		
Lower	1	3.3
Lower middle	7	23.3
Upper lower	5	16.7
Upper middle	15	50.0
Upper	2	6.7
Total	30	100.0
Habitat		
Rural	3	10.0
Urban	27	90.0
Total	30	100.0
Diet		
Mixed	28	93.3
Veg	2	6.7
Total	30	100.0

Table 2: Assessment of duration of the cycle in AUB

Duration of the cycle (days)	Min-Max	Mean \pm SD	Difference	t value	P value
Before treatment	11.00-60.00	27.40 \pm 15.56	-	-	-
First cycle	13.00-112.00	32.67 \pm 18.59	-5.267	-1.468	0.153
Second cycle	11.00-63.00	23.87 \pm 10.06	3.533	1.217	0.233
First follow up	15.00-64.00	28.83 \pm 13.49	-1.433	-0.495	0.624
Second follow up	14.00-41.00	25.30 \pm 6.41	2.100	0.754	0.457

Table 3: Assessment of duration of flow in AUB patients

Duration of flow	Min-Max	Mean \pm SD	difference	t value	P value
Before treatment	3.00-15.00	8.43 \pm 2.58	-	-	-
First cycle	3.00-9.00	5.13 \pm 1.43	3.300	7.688	<0.001**
Second cycle	3.00-7.00	4.13 \pm 0.86	4.300	9.394	<0.001**
First, follow up	3.00-7.00	4.37 \pm 1.03	4.067	8.660	<0.001**
Second, follow up	3.00-9.00	4.60 \pm 1.13	3.833	7.875	<0.001**

Table 4: Assessment of amount of flow in AUB patients

Amount of flow	Min-Max	Mean \pm SD	difference	t value	P value
Before treatment	7.00-73.00	33.90 \pm 15.56	-	-	-
First cycle	6.00-24.00	11.40 \pm 4.01	22.500	8.639	<0.001**
Second cycle	5.00-17.00	8.40 \pm 2.65	25.500	9.088	<0.001**
First follow up	4.00-17.00	8.87 \pm 2.75	25.033	9.406	<0.001**
Second follow up	5.00-12.00	8.57 \pm 1.57	25.333	8.860	<0.001**

Table 5: Assessment PBAC Score in AUB patients

PBAC Score	Min-Max	Mean \pm SD	difference	t value	P value
Before treatment	230.00-1520.00	712.60 \pm 310.21	-	-	-
First cycle	120.00-480.00	220.70 \pm 86.23	491.900	9.159	<0.001**
Second cycle	89.00-340.00	160.33 \pm 54.21	552.267	9.870	<0.001**
First follow up	80.00-340.00	173.67 \pm 55.97	538.933	10.099	<0.001**
Second follow up	85.00-240.00	167.33 \pm 34.58	542.267	9.434	<0.001**

Table 13: Therapeutic outcome of AUB patients

Therapeutic outcome	Test group(n=30)		
	BT	AT	P value
PBAC score	712.60±310.21	173.67±55.97	<0.001**
SF-12	386.33±202.43	946.00±96.23	<0.001**

4. DISCUSSION

Demographic data

In the present study we have observed that most of the patients 14(50.0%) were in the age group of 20-30 years followed by 11(36.7%) in the age group 31-40 years, 3(10.0%) in the age group of 41-50 years and 1 in <20 years. Finding of a study conducted by Nadia et al [23] is also similar to the present study. Another study by Azita et al [24] also correlates with the present study. The maximum incidence of AUB was noted in married women 23(76.7%) out of 30, followed by 7(23.3%) in unmarried women, this finding is similar with a study conducted by Gotappu et al. [25]

15(50.0%) patients in the present study were from upper middle class. The finding is similar with a study conducted by Ajit et al. [26] It has shown in present study that most of the patients 27(90%) belong to an urban area, then rural area 3(10.0%), these findings were similar with Dubey et. al [27] study. In the present study, it has been observed that most of the patients having mixed diet i.e. 28(93.3%) followed by vegetarian 2(6.7%). In a study carried out by Vijay et al. [28] Out of 54, 46 participants were having mixed dietary habits which coincide with the present study.

In this study it has been observed that majority of the patients 11(36.7%) have age of menarche at 13 years, 10(33.3%) patients at 12 years, 7(23.3%) at 14 years, followed by 2(6.7%) at 11 years with Mean \pm SD: 12.77 \pm 0.90. A study carried out in NIUM Bengaluru by Danish et al. [29] showed that a maximum number of patients attended menstruation at the age of 13 years. The findings of this study correlate with the present study. It is found that incidence of AUB are more common among women having over weight 17(56.7%) i.e. BMI 25-30 kg/m² with mean \pm SD: 25.67 \pm 4.12, 9(30%), having normal BMI (18.5-25kg/m²), 2(6.7%) under weight (<18.5 kg/m²) BMI, 2(6.7%) obese having BMI >30kg/m². A study conducted by Saba et al. [30] in NIUM showed that AUB is more common in patients having BMI 18.5-25 kg/m². This is contradictory to present study this may be due to different study settings. Mizaj of the 13 (43.3%) patients were damwi. Damwi mizaj was predominant among all types of mizaj, 10 (33.3%) were having balghami mizaj, 7 (23.3) patients had safrawi mizaj and none of the patients had sawdawi mizaj. Unani physicians like Ibn Sina, who has stated that excess of khilt-i-dam in body is responsible for Istehaza when khilte-i-dam is more in amount then tabi'at-i-da'fia of body expelled out this excess blood.[4] Findings are also reported similar with study conducted by Saba et al.[30]

Subjective parameters:

Heavy irregular bleeding per vaginum was assessed by duration of cycle, duration of flow, amount of flow.

Duration of cycle has been shown in terms of days. Duration of cycle before treatment was assessed as Mean \pm SD; which was 27.40 \pm 15.56. In first cycle it was 32.67 \pm 18.59 with P value 0.153, suggestive of significance. In second cycle it was 23.87 \pm 10.06 with p value 0.233, which is statistically not significant. In first follow up it was 28.83 \pm 13.49 with p value of 0.624. In second follow up it was 25.30 \pm 6.41 with p value of 0.457, which was also not significant.

In classical unani literature AUB has been given under the heading of istehaza, in this bleeding is irregular, excessive, in amount or occurs for long duration.[4,5] AUB used to describe any type of bleeding that does not fall within the normal ranges for amount, frequency, duration or cyclicity.[31]

Mean \pm SD of duration of flow was assessed as number of days of bleeding per cycle. Duration of flow before treatment, first cycle, second cycle, first follow up, and second follow up was assessed i.e. 8.43 \pm 2.58, 5.13 \pm 1.43, 4.13 \pm 0.86, 4.37 \pm 1.03, 4.60 \pm 1.13 respectively with p value of <0.001. It shows statistically highly significant reduction in duration of flow. A study conducted by Shobeiri et al. [32] reported that reduction in duration and volume by 80% of the patients with AUB. Ibn sina quoted that khurfa has astringent action because of this action it is helpful in abnormal uterine bleeding.[33] Gallen defined khurfa, in its first quwwat as mubarrid in 3rd degree, murattab in 2nd degree and in second quwa, it has rad'e (derivative) property. Because of mubarrid and qabid properties, it constricts the blood vessel's lumen; hence reduce uterine bleeding. [34]

Amount of flow was assessed by calculating the total number of pads used in one cycle. Before treatment it was 33.90 \pm 15.56. Mean \pm SD in first cycle, second cycle, first follow up, second follow up was assessed and it was 11.40 \pm 4.01, 8.40 \pm 2.65, 8.87 \pm 2.75, 8.57 \pm 1.57 respectively with p value <0.001 which is highly significant and indicate that there is a marked reduction in amount of

flow. In Unani literature it has been described that khurfa has astringent and mucilaginous property because of this it makes the blood less viscous to more viscous, hence bleeding is reduced. [35,36,37]

A drug used in the present study has its chemical constituent's tannins. [38] Tannins act as astringent, contract the blood vessels, and coagulate the secretion. It is converted into gallic acid in the intestine and until this change does not occur it cannot be absorbed to act as a remote or systematic astringent. [39]

Objective parameters:

PBAC score:

In present study mean score of menstrual blood loss was calculated in terms of menstrual pictogram (PBAC score). Mean±SD before treatment was 712.60±310.21. In the first cycle, the second cycle, first follow up, second, follow up it was 220.70±86.23, 160.33±54.21, 173.67±55.97, 167.33±34.58 respectively with p-value of < 0.001 which is considered highly significant. A study conducted by Azita et al. [24], the PBAC score before treatment and after treatment was 304.44 (192.72), 143.13(96.07) respectively in control group and in test group it was 304.92 (176.17) and 164.60(100.24) with p-value of p< 0.001). There is a significant reduction in PBAC within the group it correlates with the present study.

SF-12 score:

AUB has a broad impact on HRQoL and puts a heavy economic burden on society. [10] The eight domains of the SF-12 score measures are as follows: physical functioning; role limitations due to physical health; role limitations due to emotional problems; energy/fatigue; emotional well-being; social functioning; pain; general health.[40] The Mean±SD before the intervention was 386.33±202.43 and after intervention, it was 946.00±96.23 with p-value <0.001 and mean differences of 559.667. It shows strongly significant improvement in the quality of life.

One study conducted by Matteson et al. [41] showed within a national population-based sample, women with AUB suffered a reduction in quality of life and diminished physical and mental health status as measured by the SF-12. This is similar to the present study.

Therapeutic outcome of AUB patients:

In this study Mean±SD of PBAC score before and after treatment was 712.60±310.21 and 173.67±55.97 with p-value of <0.001 which is highly significant. It demonstrates that in present study tikhme khurfa is effective and safe in reducing the PBAC score as well as improving the quality of life of patients with AUB.

5. LIMITATIONS OF THE STUDY

- Small sample size. AUB was diagnosed based on self-reported information of participants.
- A placebo-controlled or standard controlled arm to demonstrate the efficacy of our drug could confirm the observed effects.
- After treatment scan was not done so any evidence of the effect of the drug on pelvic pathology, this will limit the study.

6. FURTHER RECOMMENDATION

- Based on literature review only minimal studies have been observed on tikhme khurfa hence it is recommended to conduct clinical trials on a large number of patients.
- More comparative studies on large sample size recommended for better results.
- Phase III clinical trials can be carried out to confirm the efficacy and potency of the research drugs.

7. CONCLUSION

There was a significant reduction in PBAC score in all the patients. The menstrual regulation was achieved in 26(86.7%) patients. There was also a significant improvement in the quality of life of all the patients with p-value of <0.001. In the present study we have observed that tikhme khurfa is effective in the patients of AUB, which is due to the properties of khurfa like; haemostatic, astringent, anti-inflammatory, antioxidant etc. No adverse effect was noted, all the safety parameters were within normal limit. From this study, we can conclude that tikhme khurfa (portulacca oleracea seed) is safe, feasible, effective, in Istehaza (Abnormal uterine bleeding).

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