

Anti-Haemorrhagic Activity of Polyherbal Formulation in Menorrhagia: A Randomized Controlled Trial

Danish Jahan^{1*}, Wajeeha Begum², Mariyam Roqaiya², Yousuf Khalil Hussaini³

¹National Institute of Unani Medicine, Kottigepalya, Bengaluru, Karnataka, India

²Luqman Unani Medical College, Hospital & Research Centre, 12 Naubag, Bijapur, Karnataka, India

³Jamia Tibbiya Deoband, Uttar Pradesh, India.

*Correspondant author: Danish Jahan, National Institute of Unani Medicine, Kottigepalya, Bengaluru, Karnataka, India, Tel: +91 9535181736, E-mail: dr.danishjahan@gmail.com

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Abstract

Background: Menorrhagia i.e., excessive menstrual blood loss is a common problem that interferes with women's physical, emotional, social and material quality of life. Unani physicians have mentioned so many herbal formulations to treat menorrhagia. This study was aimed to compare the efficacy of polyherbal unani formulation and tranexamic acid on menorrhagia.

Materials & Methods: This prospective randomized single blind standard controlled trial was conducted in Department of Niswan wa Qabala, National Institute of Unani Medicine. 40 patients were assigned to test (20) and control (20) groups. Both the test as well as control was given orally for five days from first day of menstrual cycle for two consecutive cycles. Assessment of efficacy was based on pictorial blood loss assessment chart (PBAC) to assess the amount of blood loss. Hb% and quality of life were also assessed as secondary outcome. Chi-square/Fisher Exact test has been used to find the significance of study parameters on categorical scale between groups.

Results: There was no significant difference found between the groups on all parameters assessed which shows that the test drug can be an alternative for tranexamic acid after clinical trial on large sample size and for longer duration.

Conclusion: Test drug has been found having equal effect with tranexamic acid. There is need for further study on large sample size.

Keywords: Menorrhagia; Polyherbal; Anti-haemorrhagic

Introduction

Heavy flow during periods is called menorrhagia or kasrate tams and it is one of the most common reasons for women to be referred to gynecologists. It is the main presenting problem in at least half of those who undergo hysterectomies [1]. Prevalence of menorrhagia is approximately 10% to 15% in women of reproductive age [2]. It has two conditions, either flow increases in amount or duration [3,4].

Indeed, the associated discomfort, anxiety and impaired quality of life lead many women to surgical procedures, ranging from endometrial ablation to hysterectomy, often in the absence of any detectable pathology [5]. Several drug classes are recommended for the treatment of heavy menstrual bleeding (HMB); however, most of them are not accepted by patients because of either failure in controlling the bleeding or side-effects [6].

Unani physicians have stated that in kasrate tams excessive flow of blood is mainly due to two causes that is weakness in quwate masika (retentive power) or increase in quwate dafiya (excretory power) or both. Cause of weakness of quwate dafiya is any type of sue mizaj (abnormal temperament), mainly sue mizaj haar yabis (hot & dry),

which causes weakness of uterus and its vessels and leads to opening of mouth of vessels and rupture of vessels.

Cause of excess functioning of quwate dafiya (excretory power) is due to khilt lazaa, hararat and hiddat (excess heat) of blood. This hiddat and lazaa again causes opening of mouth of blood vessels [7,8].

In unani literature numbers of drugs are available single as well as in compound form to treat haemorrhage. Almost same drugs have also been mentioned for menorrhagia. These drugs are effective to control bleeding by having its haemostatic and astringent property e.g., anjabar, geru, sange jarahat, dammul akhwain, etc. [9,10]. A polyherbal unani formulation sharbate anjbar is the most popular and most common composition to treat haemorrhage [11-13].

Sharbate anjbar is available with different formulations which are being used from many years for haemorrhage. So considering the above fact, the present study was carried out in Dept. of Ilmu Qabalat wa Amraze Niswan, NIUM Hospital, Bangalore, to scientifically evaluate the efficacy of sharbate anjbar in the management of menorrhagia.

Sharbate anjbar is having four drugs beekhe anjabr (*Polygonum bistorata*), aqajia (*Acacia arabica*), sandal surkh, sandal sufaid (*Santalum album*) [12,13]. These drugs have habis (hemostatic) and qabiz (astringent) properties.

Materials and Methods

A prospective single blind randomized standard controlled study was conducted in the Dept. of Ilmul Qabalat wa Amraze Niswan, NIUM Hospital, Bangaluru from November 2014 to March 2015 to compare the efficacy of polyherbal unani formulation and tranexamic acid on menorrhagia. The study protocol was approved by Institutional Ethical Committee, NIUM Bangalore.

Inclusion criteria were married as well as unmarried women of reproductive age group complaining of heavy menses with regular cycles. Patients with irregular and inter-menstrual bleeding, patient suffering from systemic illness, blood dyscrasias, malignancy and severe anaemia (Hb% less than 7.5 g), unwillingness or inability to comply the requirements of the protocol were excluded from the study.

In each patient, history was evaluated and a complete physical examination including breast and abdominal examination and per vaginal (in married patients) examination was performed. Personal details, history, clinical features and investigations were recorded in the case record form (CRF) structured for the study.

Following thorough evaluation of patient by history and clinical examination, patients were advised for necessary investigations. Complete blood picture with ESR, BT, CT, Platelet count, Random blood sugar, Complete urine examination, Blood urea, serum creatinine, SGOT, SGPT, alkaline phosphatase, Whole abdomen scan Thyroid profile, Pap smear (in married patients) were investigated.

After a control cycle, (Figure 1) total of 40 patients meeting the inclusion criteria were randomly assigned to test (20 patients) and control (20 patients) groups after explaining the study in detail and receiving the informed consent. Randomization was done by using computer generated random table.

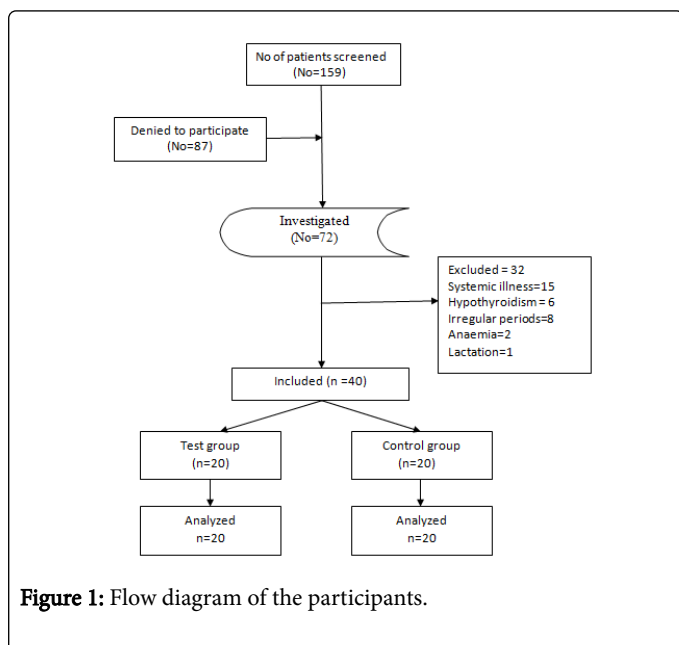


Figure 1: Flow diagram of the participants.

For the test group a polyherbal syrup formulation *sharbate anjbar* was selected which contains *beekhe anjbar*, *aqaqia*, sandal surkh, and sandal sufaid. These drugs were purchased from local drug retailer of Bangalore by purchase committee and were identified by Dept. of Pharmacology, NIUM.

Syrup was prepared in pharmacy of this institute according to the standard unani method of preparation and given in the dose of 25 ml BD for 5 days during menses from the first day of menstrual cycle for two consecutive cycles. In the control group standard drug tranexamic acid 500 mg BD was also given for 5 days from the first day of menstrual cycle for two cycles. Assessment of blood loss during periods was done by PBAC score and assessment in improvement of quality of life was done by SF-36 score.

Patients were assessed for two consecutive cycles during the treatment and one cycle after the treatment. During treatment amount of bleeding were assessed by asking duration of cycle, amount of flow which was assessed by calculating the total no. of pads used in one cycle and duration of flow from both the groups.

Apart from that improvement in quality of life was assessed by using SF-36 questionnaire before and after treatment. Effectiveness of trial drugs were assessed by Pictorial blood loss assessment chart (PBAC score) to assess the amount of blood loss, SF-36 score to assess quality of life and improvement in Hb%.

Chi-square/Fisher Exact test has been used to find the significance of study parameters on categorical scale between groups.

Results and Discussion

Baseline demographic profile was same between the two groups with p value >0.05 (Table 1). As shown in Table 2, baseline PBAC score in test group was 496.55 ± 256.37 and in control score was 595.70 ± 379.76 which is not significant between the groups with p value of 0.339. During first treatment cycle score was calculated as 160.30 ± 54.20 in test group and 257.25 ± 257.77 in control group with p value of 0.108. During second cycle 124.65 ± 46.57 score was calculated in test group and 220.95 ± 246.06 in control group which is statistically significant between the groups with p value of 0.094. During after treatment follow up cycle the score was calculated as 109.50 ± 38.50 in test group and 291.85 ± 483.95 in control group which is not significant with p value 0.101. Mean difference in groups were found 387.05 in test group and 303.85 in control group.

Characteristic	Test group		Control group		P value
	No	%	No	%	
Age (years)					
Nov-20	5	25	3	15	
21-30	9	45	8	40	
31-40	4	20	7	35	P=0.787
41-50	2	10	2	10	
Total	20	100	20	100	
Marital status					
Married	11	55	14	70	
Unmarried	9	45	6	30	P=0.327
Total	20	100	20	100	
Occupation					
Employed	1	5	1	5	

House wife	10	50	16	80	
Student	9	45	3	15	P=0.100
Total	20	100	20	100	
SES					
Lower	0	0	1	5	
Lower middle	9	45	5	25	
Upper lower	5	25	8	40	P=0.699
Upper middle	5	25	5	25	
Upper	1	5	1	5	
Total	20	100	20	100	
Habitat					
Rural	1	5	2	10	
Urban	19	95	18	90	P=1.000
Total	20	100	20	100	
Diet					
Mixed	17	85	18	90	
Veg.	3	15	2	10	P=0.633
Total	20	100	20	100	

Table 1: Baseline demographic of the patients with menorrhagia in test and control group.

PBAC Score	Test group	Control group	P value
Baseline	496.55 ± 256.37	595.70 ± 379.76	0.339
First cycle	160.30 ± 54.20	257.25 ± 257.77	0.108
Second cycle	124.65 ± 46.57	220.95 ± 246.06	0.094+
After treatment follow up	109.50 ± 38.50	291.85 ± 483.95	0.101
Difference	387.05	303.85	-
P value (Before – After)	<0.001**	<0.001**	-

Table 2: PBAC Score of patients studied.

In present study it is obvious that the test drug has almost equal effect with control drug in improvement of PBAC score. PBAC score to assess the menstrual blood loss has been used in various previous studies conducted. Jaisamrarn et al. [14] has showed a significant decrease in PBAC score from 350.5 to 178.6 with 49% decrease in mean menstrual blood flow after two cycles which was significant. One more study conducted by Lee et al. [15] showed significant reduction in PBAC score from 262.0 to 125.0 with 47.4% decrease in mean menstrual blood flow.

Significant improvement in PBAC score in test group is attributed due to haemostatic property of sharbate anjbar by which it reduces bleeding [11-13]. Ingredients of sharbate anjbar contains tannin, gallic

acid, ellagic acid and flavonoids which are potential styptic and astringent there by reduces heavy menstrual blood loss [7,10,16-19]. *Acacia arabica* one of the ingredients has also been studied for its coagulation property in the mice [20]. Another study has shown that *Acacia arabica* along with *Moringa oleifera* are haemostatic and hasten blood coagulation [21].

SF-36 Score	Test group	Control group	P value
Before treatment	233.75 ± 90.42	185.55 ± 61.06	0.055+
After treatment	777.70 ± 35.65	697.15 ± 161.89	0.036*
Difference	543.95	511.6	-
P value (Before – After)	<0.001**	<0.001**	-

Table 3: SF-36 Score of patients studied.

Table 3 shows mean SF-36 score. Before treatment it is 233.75 ± 90.42 in test group and 185.55 ± 61.06 in control group with a p value of 0.055 and after treatment it is calculated as 777.70 ± 35.65 in test group and 697.15 ± 161.89 in control group with p value of 0.036. Mean difference is 543.95 in test group and 511.60 in control group. On inter group comparison before treatment findings were suggestive significant (p value: 0.05<p<0.10) in both the groups. After treatment findings were moderately significant with p value of (p value: 0.01<p ≤ 0.05). In test group drug was found more effective in improving quality of life than control group.

Menorrhagia is a common gynecological condition that has a significant impact on the wellbeing and quality of life of many women's. In present study SF-36 questionnaire was used to evaluate the impact of treatment on women's quality of life and it is obvious that test drug is significant in improving women's quality of life. These findings are similar with the studies conducted by Pattison et al. [22] and Marjoribanks et al. [23]. In these studies, significant improvement in quality of life was observed after treatment.

SF-36 Score	Test group	Control group	P value
Before treatment	233.75 ± 90.42	185.55 ± 61.06	0.055+
After treatment	777.70 ± 35.65	697.15 ± 161.89	0.036*
Difference	543.95	511.60	-
P value (Before –After)	<0.001**	<0.001**	-

Table 4: Hemoglobin % of patients studied.

Table 4 is showing improvement in Hb% in mean ± SD. Baseline Hb % was found 11.71 ± 1.45 in test group and 11.66 ± 1.54 in control group with p value of 0.908 and after two treatment cycles it was found 11.96 ± 1.43 in test group and 11.56 ± 1.68 in control group with p value of 0.428. On intergroup comparison after treatment findings were not significant (p>0.05). On intra group comparison findings were also not significant (p>0.05) but in test group drug was found more effective in improving Hb% than control group. Besides these no adverse effect was found in both the groups.

Limitation of the study

Small sample size.

Conclusion

Present study shows that sharbate anjabar is found to have almost equal effect with tranexamic acid on all the parameters studied but sample size was small so study on large sample size is needed before keeping it as an alternative for menorrhagia.

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