

Efficacy of Safoof Habis-ud-dam (SHD) On Duration of Flow (DOF) in Puberty 'Kasrat-e-Tams' (Menorrhagia)

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Abstract

Puberty Menorrhagia is defined as excessive bleeding in amount (>80ml) or in duration (>7days) or both between menarche and 19 years of age. The SHD is a Unani formulation that has been claimed as a powerful haemostatic drug. The trial was a standard controlled randomized single blind study. The study was conducted on 55 unmarried girls aged between 12-19 yrs having regular cycle with heavy bleeding during menstruation at National Institute of Unani Medicine (NIUM) Hospital, Bangalore during the year of 2008-09. They were randomly allocated in test and control groups respectively and patients showed Pictorial Blood loss Assessment Chart (PBAC) score of more than 200 were included in the study. All the patients were given the treatment throughout menses period from 1st day till the bleeding stopped for three consecutive cycles. Evaluation of DOF was assessed by PBAC score in each cycle and the results were analyzed using appropriate statistical tests. There was significant reduction on DOF in both groups ($p < 0.001$) when compared with the mean score of PBAC before treatment. Mean reduction in PBAC score in SHD treated group was found to be more even than the standard drug ($p < 0.001$). The study demonstrated that the test drug SHD is effective in ameliorating the Puberty Menorrhagia. The study thus validated the claim of Unani medicine that the group of drugs possessing astringent and potent styptic activity may be used in arresting the Puberty Menorrhagia successfully.

Keywords: Puberty Menorrhagia, Safoof Habis-ud-dam (SHD), Duration of flow (DOF), Pictorial Blood loss Assessment Chart (PBAC) score.

Introduction

Menarche is a hallmark event in the life of all adolescent girls marking the transition from childhood to adulthood (Debra & Bradshaw 2000). Although mechanisms triggering puberty and menarche remain uncertain, they are dependent on genetics, nutrition, body weight and maturation of HPO Axis (Rao et al 2004). Puberty is defined as the period during which secondary sex characters begin to develop and the capability of sexual reproduction is attained. The problems that can be encountered during puberty are menstrual irregularities like Menorrhagia, Oligo-menorrhoea, Dysmenorrhoea, Amenorrhoea, Post Menopausal Syndrome (PMS) etc.

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Adolescence is a very important phase in every woman's life. This is a stage where the carefree and immature girls blossoms into a mature and a responsible adult woman. In many developing countries, especially in rural and underdeveloped areas, the girl is often considered to be an adult at the time when menstruation is established regularly. They tend to marry early and do not go to school (John & Ruth, 1987). During puberty, ovarian function is initially uniphasic, consisting of follicular ovarian activity without complete maturation and rupture of the follicle. As a result, varying amount of oestrogen stimulates the endometrium, but there is no biphasic interaction of progesterone hormone on the endometrium. Most young patients with anovulatory bleeding do not have excessive uterine bleeding, but some have extremely profuse and prolonged episodes of vaginal bleeding without suggestive of cyclic control (John, 1964).

The aetio-pathogenesis of '*Kasrat-e-Tams*' in respect of Unani concept, renowned physicians of Greco-Arab medicine have described it according to humors and temperament which include '*ghalba-e-dam*' (Plethora) in the uterine vessels that stimulate '*quwat-e-dafea*' (Expulsive power) of uterus resulting in excessive Menstrual Blood Loss (MBL). Apart from it, '*ghalba-e-safra*' also elevate innate heat in blood that alters '*mizaj*' of uterus and makes the uterine blood vessels more fragile resulting in excessive menstrual bleeding. '*Riqqat-e-dam*' (Excessive liquidity of blood) weakens '*quwat-e-masika*' (Retentive power) of uterus leading to excessive menstrual bleeding (Khan 1983).

The management of '*Kasrat-e-Tams*' depends upon the underlying cause but '*Habis wa Qbizud-dam*' (Astringent) drugs like Geru (*Bolus rubra/Ferrum haematite*), '*Dmmul Akhwain*' (Dracaena Cinnabari), '*Kaat-e-Safaid*' (*Acacia catechu* Willd), '*Sang-e-Jarahat*' (Soap-stone/Silicate of Magnesia) and '*Phitkari*' (Alum) are in use since ancient times in the form of decoction, powder or tablets.

Methodology

The study was carried out during the year 2008-2009, in the department of Obstetrics and Gynaecology, National Institute of Unani Medicine & Hospital, Bangalore. The study protocol was approved by the institutional ethical committee of NIUM, Bangalore vide its order No 6-79/06-07/NIUM. The study design was standard controlled randomized single blind study and the duration of Study was one year. In the sample size, 55 patients were enrolled in the study, 30 in test group and 25 in control group. Method of collection of data

was based on history taking and Pictorial blood loss assessment chart (Higham *et al.*, 1990).

Patients fulfilling the inclusion criteria were given the information sheet having details regarding the nature of study and the drug to be used and method of treatment. Patients were given enough time to go through the study details mentioned in the information sheet. They were given the opportunity to ask any question and if they agree to participate in the study, they were asked to sign the informed consent form. Written consent was taken from each patient in the presence of her parent or guardian.

Young girls in age group of 12-19 years complaining of excessive bleeding per vaginum during menstrual periods were interrogated thoroughly for detailed history particularly about amount and duration of flow and whether it is accompanied by pain or not. Last Menstrual Period (LMP) was noted and associated symptoms of anaemia were also enquired. At the time of their visit the subjects were provided a Pictorial Blood loss Assessment Chart (Annexure-1) to complete with their next menses and carefully instructed and explained how to fill it.

Research drug '*Safoof Habisuddam*' (SHD), a Unani Formulation which has got astringent and potent styptic properties and is claimed to be beneficial in Menorrhagia. '*Safoof Habis-ud-dam*' consists of ingredients are Dammul Akhwain (Singh, 1949) (*Dracaena cinnabari*), *Samagh-e-Arabi* (Prajapat 2005) (*Acacia arabica* Willd), *Gil-e-Surkh* (Singh, 1949) (*Bolus rubra*), *Sang-e-Jarahat* (Kokate 2008) Hydrated Magnesium Silicate and *Sadaf* (Singh 1949) *Ostrea gryphoides* Schl in equal quantity. The standard control drug was tablet Styptocid and each tablet contained Adrenochrome monosemicarbazone-0.5 mg, menadione sod. Bisulphate-10 mg, rutin-50 mg, vitamin C-37.5 mg, D 200 I.U and calcium dibasic phosphate-125 mg.

Three gram of *Safoof Habis-ud-dam* was administered orally twice a day with water from first day of cycle till bleeding stops. The duration of protocol therapy was three consecutive cycles. One tablet of Styptovit (standard drug) was also administered orally twice a day with water from first day of cycle till bleeding stops and the duration of protocol therapy was also 3 consecutive cycles.

Along with test and control drugs, '*Qurs Kushta Faulad*' (a Unani formulation used as haematinic) was also administered orally in the dose of one tablet twice a day for three months to the patients of both groups and the duration of protocol therapy was also 3 consecutive cycles.

Evaluation of efficacy of Research and Control Drugs in the treatment was based on Subjective parameters like excessive bleeding per vaginum and associated anaemia and Objective parameters like Higham Pictorial chart for the assessment of menstrual blood loss (MBL) while assessment of safety of treatment was done on (a) Haematological studies – Hb gm%, TLC, DLC, ESR and biochemical studies – SGOT, SGPT, Blood urea, Serum Creatinine before and after treatment.

Results were analysed on the basis of two categories, Relieved—when symptoms vanished and PBAC Score returned < 200 and Not Relieved—persistence of symptoms and PBAC Score ≥ 200.

To get results significant, descriptive statistical analysis was carried out. Results on continuous measurements were presented on Mean ± SD (Min-Max) and results on categorical measurements were presented in Number (%). Significance was assessed at 5 % level of significance. Student t test (two tailed, independent inter-group analysis) was applied to find the significance of study parameters on continuous scale between two groups and to find the homogeneity of parameters on continuous scale as + Suggestive significance (P value: 0.05<P<0.10), * moderately significant (P value: 0.01<P ≤ 0.05) and ** strongly significant (P value: P≤0.01).

Table 1 Comparison of Duration of flow (days per cycle) in two groups

DOF(days)	Control	Test	Significance
Before treatment	7.30±1.49	7.26±1.46	t=0.108;p=0.915
After treatment 1st cycle	6.52±1.27	6.07±1.14	t=1.310;p=0.196
After treatment 2nd cycle	6.22±0.95	5.67±1.33	t=1.656;p=0.104
After treatment 3rd cycle	5.65±1.30	5.52±1.4	t=0.348;p=0.729
After without treatment 1st follow up	5.83±1.27	5.74±1.38	t=0.227;p=0.822
Mean Changes from before treatment			
After treatment 1st cycle	0.78±0.85	1.19±1.47	-
After treatment 2nd cycle	1.09±1.00	1.59±1.45	-
After treatment 3rd cycle	1.65±1.40	1.74±1.35	-
After without treatment 1st follow up	1.48±1.56	1.52±1.65	-
P value from before treatment			
After treatment 1st cycle	<0.001**	<0.001**	-
After treatment 2nd cycle	<0.001**	<0.001**	-
After treatment 3rd cycle	<0.001**	<0.001**	-
After without treatment 1st follow up	<0.001**	<0.001**	-

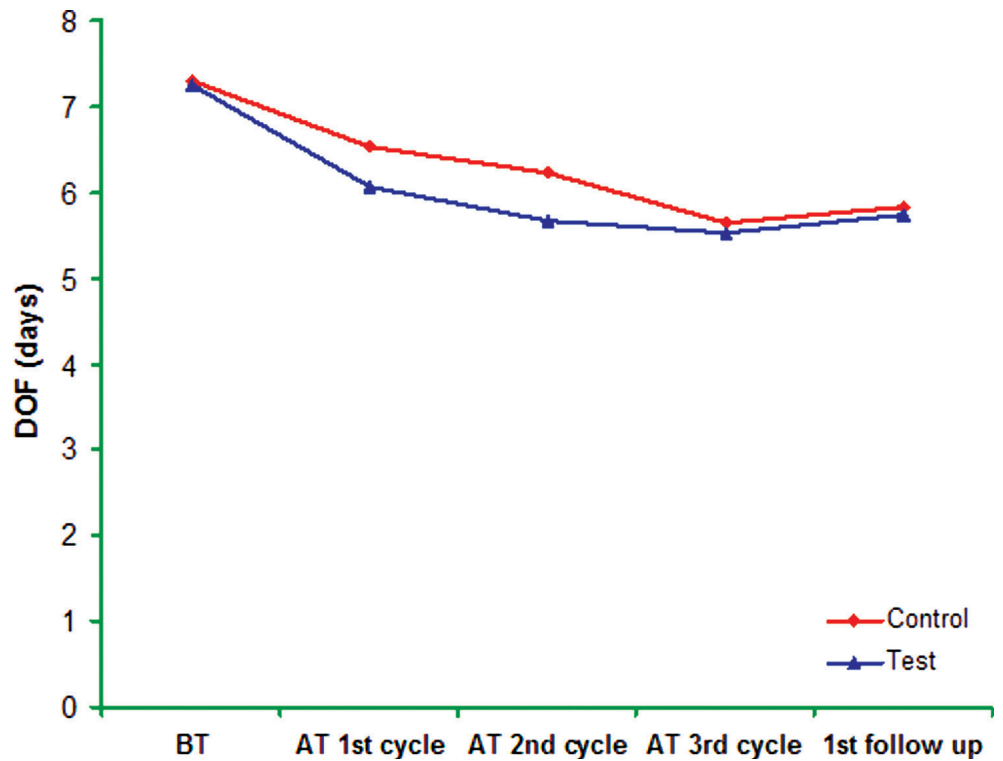


Fig. 1

Pictorial Blood Loss Assessment Chart (PBAC)⁶

The PBAC (Fig 1) was first introduced by Higham *et. al.* in 1990 as a visual representation of blood loss from which a numerical score is derived. The chart consists of a series of diagrams representing light, moderate and heavy soiled towels. In addition passage of clots (small size clot equal to 50 paisa coin and large size clot equals to 1 rupee coin) were also recorded. The score assigned were 1 for each light, 5 for moderate soiled and 20 for completely saturated with blood stained towel. Small and large clots scored 1 and 5 respectively.

Pictorial Assessment Chart- Scoring System:

S. No.:

Name of the Patient:

Age:

Day Start:

OPD/IPD, No:



LMP:

Score:

Score	PADS	1	2	3	4	5	6	7	8	9	10
1											
5											
20											
1	CLOTS: Small										
5	Large										

Results and Discussion

The mean score for DOF in control group at 0 day 1st month, 2nd month, 3rd month and at follow up were 7.30±1.49, 6.52±1.27, 6.22±0.95, 5.65±1.30 and 5.83±1.27 respectively, similarly the mean score for DOF in test group were 7.26±1.46, 6.07±1.14, 5.67±1.33, 5.52±1.4 and 5.74±1.38 respectively (Table 2 & Fig-1).

There was significantly decrease DOF in control group after 1nd month which remained significantly decreased till follow up (p<0.001). Similarly a significant decrease DOF in test group after 1nd month was found, which remained significantly decreased till follow up (p<0.001) when compared in both groups at 0 day.

According to Unani concept, *Habis—Qabiz* (Astringent and Styptic) drugs are the drug of choice in Menorrhagia and *Safoof Habis-ud-dam* has proved right choice for the present study as it had shown a good response in the relief of symptoms of the ailment. Safety profile was also found to be safe of the test drug.

Conclusion

The study demonstrated that the test drug SHD is effective in ameliorating the Puberty Menorrhagia. The study thus validated the claim of Unani medicine

that the drugs possessing astringent and styptic activity may be used in arresting the Puberty Menorrhagia successfully.

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