Efficacy of 'Sharbat Bazoori Motadil' in The Management of Primary Dysmenorrhea *(Usre Tams Ibtidayee)*: A Clinical Observation

***Najmus Sehar, Syed Manzar Ahsan and Tasleem Ahmad**

Regional Research Institute of Unani Medicine, 2nd Floor, Guru Govind Singh Hospital, Patna City, Patna-800008

Abstract

Usre tams Ibtidayee (primary dysmenorrhea) is painful menses in women with normal pelvic anatomy, usually beginning during adolescence and appearing within 6–12 months after the menarche. Objective of the present study was to evaluate the efficacy of 'Sharbat Bazoori Motadil' on the intensity of pain and others associated symptoms of *Usre tams Ibtidayee*. Patients suffering with regular and painful menstruation cycles were administered orally 20 ml of 'Sharbat Bazoori Motadil' with water, twice daily from 7th day before to the expected date of menstrual cycle for two consecutive cycles. It was found that after treatment the intensity of pain and associated symptoms; lumbago, lower abdomen pain, leg cramps and nausea were significantly ($p<0.05$) reduced by 50.7%, 88.4%, 66.2% and 73% respectively as compared to baseline. After treatment, reduction in the pain and others associated symptoms of *Usre tams Ibtidayee* was the main outcome measure. Highly significant improvements ($p< 0.001$, paired 't' test) in lower abdomen pain and nausea suggest that the results are really due to the therapy. In conclusion, Unani Paharmacopoeial formulation 'Sharbat Bazoori Motadil' was found effective in treatment of *Usre tams Ibtidayee* (Primary Dysmenorrhea) without any adverse effect on the human body.

Keywords: *Usre tams Ibtidayee*, Unani Medicine, Menstruation, Primary dysmenorrhea

Introduction

Usre-tams (dysmenorrhea) is defined as painful menstruation (Kantoori, 2007) and *Usre tams Ibtidayee* (primary dysmenorrhea) is painful menses in women with normal pelvic anatomy, usually beginning during adolescence (Avasarala *et al.*, 2008) and appearing within 6–12 months after the menarche. Primary Dysmenorrhea occurs almost invariably in ovulatory cycles. It is most common in women between the ages of 20 and 24 years, with most of the severe episodes occurring before 25 years of age (Dawood, 1987). About 88% of adolescents, experience their first painful menstruation within the 1- 2 years after menarche (Dutta, 1994). The cramps are most severe on the first or second day of menstruation. The pain is usually spasmodic in character and felt mainly in the lower abdomen, but it may radiate to the back and along the thighs (Abbaspour *et al.,* 2006). The cramp is commonly accompanied by one or more symptoms including nausea, vomiting, diarrhea, and lower backache etc. (Dutta, 1994; Khan, 1983; Gelani, 2007). Some 2–4 days before menstruation begins, prostaglandins proceed into the uterine muscle, where they build up quickly at menstrual onset

*Author for correspondence

and act as smooth muscle contractors that aid in the expulsion of the endometrium (Dawood, 1987).

According to Unani concept, the disease appears due to the dominance of phlegm and sauda. Menstrual blood become thick and its density is increased, which result less menstrual blood in quantity and the patients feel pain during the pre-menstrual cycle and during the Cycle (Azami, 1978). Swelling and accumulation of blood into the uterus are causes of this disease (Siddiqui, 2005). The famous Greek philosopher Hippocrates (460-377 BC) was of opinion that dysmenorrhea does not occur, when menstrual flow is regular and adequate in amount (Copeland *et al.,* 1993). According to Ibne sina, any obstruction in the flow of menstruation may cause usre tams; backache prior to menstruation is due to involvement of uterus (Kantoori, 2010). According to Zakarya Razi, causes of dard-rehm are warme rehm (inflammation of uterus), ihtebase tams (amenorrhea), sailan khoon (menorrhagia), sailan mani (leucorrhoea), displacement of uterus, cervical stenosis, uterine rupture, etc. (Al Razi, 2001). In usre tams menstrual blood is expel out in lesser amount (Khan, 1983) and women having scanty flow of menstruation usually suffer from pain (Kantoori, 2010). Mudir haiz drugs, which opens the blood vessels and makes blood lateef and hence induces the menstruation are recommended to relieve the pain, which occurs during menstruation. (Ibn Rushd, 1987; Khan, 2003)

Usre tams affects more than 50% of menstruating women in age group 18-25 years (Weisman *et al.*, 2009) and is a common cause of regular absenteeism of women in schools and work places resulting in loss of works hours and economic losses. (Padubidri *et al.*, 2008; Moore *et al.*, 1993). NSAIDS, hormonal pills and surgery intervention used in modern medicines produces more or less adverse effects in the human body therefore it is need of time to use Unani System of Medicine, which is safe, non-surgical, cost effective, having long lasting effect and almost no adverse effect in the human body.

The objective of this observational study was to evaluate the efficacy of 'Sharbat Bazoori Motadil', a Unani Pharmacopoeial formulation in the management of *Usre tams Ibtidayee*. (Anonymous, 1986)

Material and Methods

Study Drug: The study drug was 'Sharbat Bazoori Motadil' of which composition is given in Table-1 (Anonymous, 2006).

The present open observational study was carried out from April 2011 to March 2012 on 15 female patients of Usre tams in OPD of Regional Research Institute of Unani Medicine, Patna.

Table 1: Formulation of Sharbat bazoori Motadil of 10 ml preparation (Anonymous, 2006)

Sr.No.	Ingredients	Scientific names	Quantity
1	Bekh-e-Kasni	Cichorium intybus	1.818 gm
2	Bekh-e-Badiyan	Foeniculum vulgare	909 mg
3	Tukhm-e-Kasni	Cichorium intybus	909 mg
4	Tukhm-e-Khiyar	Cucumis sativus	909 mg
5	Tukhm-e-Khiyarza	Cucumis sativus	909 mg
6	Tukhm-e-Kharbuza	Cucumis melo	909 mg
7	Khar-e-Khasak-Khurd	Tribulus terrestris	909 mg
8	Qand Safaid	Saccharum officinarum	9.09 mg

Patients Selection:

The patients presenting signs and symptoms of *Usre tams* (Dysmenorrhea) i.e. lumbago, lower abdomen pain, leg cramps, nausea, vomiting, breast tenderness and diarrhea were subjected to inclusion and exclusion criteria before to their selection for this study.

Inclusion Criteria:

- Patients of *Usre tams* (Dysmenorrhea) between 18 - 30 years of age.
- Patients with regular menstrual cycle (28 $\pm$ 7 days).
- Patients with at least 4 painful menstrual cycles during the previous 6 months.

Exclusion Criteria:

- Patients with irregular menstruation cycles.
- Patients with underlying pelvic pathology
- Lactating or pregnant women.
- Diabetes patients
- Patients receiving oral contraceptives within 6 months prior to study entry.
- Patients receiving concomitant medications including antipsychotics, antidepressants, sedative hypnotics, antispasmodics, and corticosteroids.
- congenital malformations of genital tract
- Patients with abnormal uterine bleeding.

Diagnostic Criteria:

Diagnosis of each case was made with the help of history in respect of selected patients i.e. previous similar episode, physical and systemic examinations.

Treatment of Patients:

All patients of primary dysmenorrhea, selected as per the inclusion/exclusion criteria were diagnosed by giving them 20 ml of 'Sharbat Bazoori Motadil 'with water, twice daily before to 7th day of the expected date of menstrual cycle. The treatments were carried out for two consecutive menstrual cycles and two follow up on or after 15 days were taken in each month.

Safety Assessment:

The safety was assessed by monitoring adverse events volunteered by the patients or observed during the course of the study. No adverse effect of the 'Sharbat Bazoori Motadil' was either reported by the patients or was observed in OPD during the course of this study.

Statistical Analysis:

All the data at the baseline and after the treatment were statistically analyzed by applying paired 't' test. $p<0.05$ has been considered as statistically significant and $p < 0.001$ has been considered as statistically highly significant.

Observations

During the course of the study, patients were divided into three age groups viz. 18-20 years, 21-25 years and 26-30 years. It was observed that 7 cases (46.67 %), 5 cases (33.33 %) and 3 cases (20 %) belonged to age groups 18-20 years, 21-25 years and 26-30 years respectively. Among the 15 patients; 11 patients (73.33 %) were unmarried and 4 patients (26.67 %) were married**.** High incidence of disease was among the low age group 18-20 years i.e. 46.67% followed by the young women (33.33 %) of age group 21-25 years. This has been summarized in Table-2.

Patients were divided into four categories according to their occupations i.e. student, house-wives, teachers and private-service. The number of cases falling in each category was 6 (40%), 5 (33.33 %), 3 (20 %) and 1 (6.67 %) respectively. This has been mentioned in Table-3.

Patients were divided into 3 groups in accordance with their socio-economic status. Out of 15 patients enrolled in the study, 4 (26.67 %), 9 (60 %) and 2 (13.33 %) patients were belonged to Low Income Group (LIG), Middle Income Group (MIG) and Upper Income Group (UIG) respectively. This is mentioned in Table-3.

Table 2: Distribution of patients according to Age and Marital status.

Total No. of cases- 15

Age group (in years)	Married		Unmarried		Total	
	No.	% age	No.	% age	No.	% age
18-20	1	6.67	6	40	7	46.67
21-25	2	13.33	3	20	5	33.33
26-30	1	6.67	2	13.33	3	20
Total	4	26.67	11	73.33	15	100

Table 3: Distribution of patients according to their occupation and social status.

Total No. of cases- 15

Occupation	Social Status							
			Lower Income Group (LIG)		Middle Income Group (MIG)		Upper Income Group (UIG)	
	No.	% age	No.	% age	No.	% age	No.	% age
Student	6	40	2	13.33	3	20	1	6.67
House-wife	5	33.33	2	13.33	2	13.33	1	6.67
Teacher	3	20			3	20		
Private service	1	6.67			1	6.67		
Total	15	100	4	26.67	9	60	2	13.33

It was observed that 12 (80 %) patients were non-vegetarian and 3 (20 %) patients were vegetarian. High incidence of disease among the persons having non-vegetarian habits shows that they are more prone to dysmenorrhea. This has been shown in Table-4.

It was observed that life style of 11 (73.33%) patients were active and 4 (26.67%) were sedentary. High incidences of the disease were among the women with active life style. Thus young women, whose life-style are more active are more prone to this disease. This has been shown in Table-5.

Observation on reduction in intensity of the menstrual pain accompanied with one or more symptoms of Usre tams Ibtidayee like; lumbago, leg cramps, lower abdomen pain, nausea, vomiting, breast tenderness and diarrhea at the baseline and after the treatment with the Sharbat bazoori Motadil, have been depicted in Table-6 and Graph-1. Mean $\pm$ SEM scores of lumbago, leg cramps, lower abdomen

Table 4: Distribution of patients according to Dietary Habits.

Total No. of cases- 15

Dietary Habits	No. of Patients	Percentages (%)
Vegetarian	3	20.0
Non-vegetarian	12	80.0
Total	15	100.0

Table 5: Distribution of patients according to their life styles.

Total No. of cases- 15

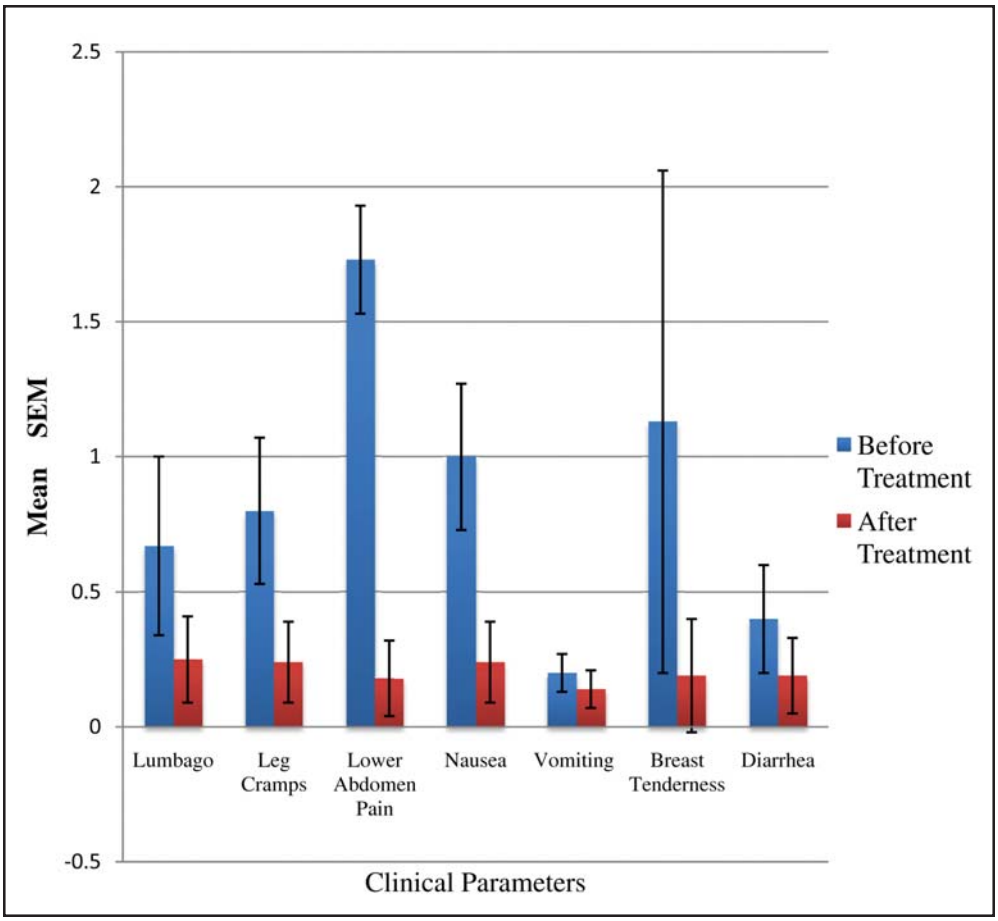
Life style	No. of Patients	Percentage
Sedentary	4	26.67
Active	11	73.33
Total	15	100

Table 6: Effect of 'Sharbat Bazoori Motadil' on clinical parameters of *Usre tams Ibtidayee* (primary dysmenorrhea)

Clinical Features	Mean ± SEM (Base line)	Mean ± SEM (After Treatment)	Percent Reduction	't'value	df	p value	Remarks
Lumbago	0.67 ± 0.25	0.33 ± 0.16	50.7	2.6458	14	<0.05	Significant
Leg Cramps	0.80 ± 0.24	0.27 ± 0.15	66.2	4.00	14	<0.05	Significant
Lower Abdomen Pain	1.73 ± 0.18	0.2 ± 0.14	88.4	11.5	14	<0.001	H.S.
Nausea	1.0 ± 0.24	0.27 ± 0.15	73.0	4.7845	14	<0.001	H.S.
Vomiting	0.20 ± 0.14	0.07 ± 0.07	65	1.4676	14	>0.05	N.S.
Breast Tenderness	1.13 ± 0.19	0.93 ± 0.21	17.6	1.8708	14	>0.05	N.S.
Diarrhea	0.4 ± 0.19	0.2 ± 0.14	50.0	1.8708	14	<0.05	N.S.

Statistical analysis by paired 't' test, n = 15, p<0.05 (Significant value), p<0.001 (Highly Significant value)

pain and nausea at the baseline i.e. 0.67 ± 0.25, 0.80 ± 0.24, 1.73 ± 0.18 and 1.0 ± 0.24 respectively, were found significantly reduced to 0.33 ± 0.16, 0.27 ± 0.15, 0.2 ±0.14 and 0.27 ± 0.15 respectively after the treatment. Scores of the clinical parameters before and after the treatment have been statically analyzed by



Graph 1: Effect of Sharbat Bazoori Motadil on Usre tams Ibtidayee (primary dysmenorrhea)

applying paired 't' tests. After the treatment, statically high significant decrease in the scores ($p<0.001$) were found in lower abdomen pain and nausea as compared to baseline.

Results and Discussion

In the present study, it was found that incidence of disease in women of age group 18-20 years and 21-25 years were 46.67% and 33.33% respectively i.e. (46.67% + 33.33%) 80% women in age between 18 to 25 years. This finding is in agreement with the study of Weisman A M that more than 50% of menstruating women are in age group 18-25 years (Weisman et al., 2009). It is also in consonance with the earlier observations that most of the severe episodes occur before 25 years of age (Dawood, 1987).

The prevalence of Usre tams Ibtidayee (primary dysmenorrhea) was found decreasing with increasing of age, indicating that (primary dysmenorrhea) Usre

tams Ibtidayee peaks in late adolescence and the early of 20 years and the incidence falls with increasing age.

Our results demonstrated that the prevalence of primary dysmenorrhea is dependent on family income. However, some researchers have indicated that economic status is not consistently associated with (primary dysmenorrheal) *Usre tams Ibtidayee* suggesting that further research is necessary by taking large sample to clarify this factor.

Highest incidence of disease was found in students (40%). Due to carrier building, students generally get married after twentieth and there is also greater awareness of the disease among the students. The incidence of menstrual pain is greatest in women in the late twenties and then declines with the age. This finding is in consonance with the described facts that primary dysmenorrhea is most common in women between the ages of 20 and 24 years, with most of the severe episodes occurring before 25 years of age (Dawood, 1987).

High incidence of the disease i.e. 73.33 % was found in women with active life style as compared to 26.67 % with sedentary life style. The women working in the offices in our present set up are under great social and cultural pressure and the high level of the stress is most significant predictors of the premenstrual symptoms and *Usre tams Ibtidayee*.

It was observed that high incidence i.e. 80 % cases were belonged to women having Non-Vegetarian habits. A low-fat, vegetarian diet reduces *Usre tams Ibtidayee* (Primary Dysmenorrhea) and premenstrual symptoms in women by its effect on serum sex-hormone binding globulin and estrogen activity. Ovulatory disturbances are also less frequent among vegetarians.

At the end of the study, the severity of lumbago, leg-cramp, lower abdomen pain and nausea were found significantly reduced by 50.7%, 66.2%, 88.4% and 73.0% respectively as compared to baseline. Decrease in symptoms like vomiting, breast tenderness and diarrhea were not found statically significant. After treatment, decrease in Mean $\pm$ SEM scores of the severity of lower abdomen pain and nausea were found highly significant ($p<0.001$) as compared to baseline, when the scores at baseline and after the treatment were statically compared by applying paired 't' test. Reduction in Mean $\pm$ SEM scores of the lumbago and leg cramp were found significant ($p<0.05$). The lumbago, leg-cramp, lower abdomen pain and nausea, which were the main causes of suffering of patients before and during the menstruation, were markedly reduced after the treatment. Reduction in intensity of lower abdomen pain, leg cramp, lumbago and nausea suggest that that relief to the patients suffering with *Usre tams Ibtidayee* (Primary Dysmenorrhea) was really due to the therapy but was not just a chance. Ingredients of compound drugs Sharbat bazoori Motadil has anti-Inflammatory, analgesic and mudir haiz

effect which opens the blood vessels and makes blood lateef and hence induces menstruation, ultimately it relieves the pain.

Conclusion

On the basis of above observations, it can be concluded that Unani Pharmacopoeial formulation 'Sharbat bazoori Motadil' is effective in management of *Usre tams Ibtidayee* (Primary Dysmenorrhea). The drug is cheaper, easily available and well tolerated by the patients without having any side effect. It can be propagated to use Sharbat bazoori Motadil for treatment of *Usre tams Ibtidayee* (Primary Dysmenorhea).

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