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Clinical Efficacy of Hulba (*Trigonella foenum graecum* Linn.) and Dry Cupping (Hijamat Bila Shurt) in the Management of Primary Dysmenorrhoea (Usre Tams Ibtidae) ’

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ABSTRACT

Primary dysmenorrhoea (*Usre tams ibtidaee*) is the most common gynecological disorder in menstruating women. It is a common menstrual cramps with high prevalence rate; responsible for the highest incidence of absenteeism resulting in loss of working hours. In addition both work & school performances are found to be poor in women on their days with dysmenorrhoea. Thus, proper treatment is essential to over the hardship, so, in present study the objective is to evaluate the efficacy and safety of hullba and hijamat bila shurt in the management of dysmenorrhoea. A randomized, standard controlled clinical trial was conducted in OPD of DUMCH-RC from August 2014 to February 2016. A total of 60 patients diagnosed with primary dysmenorrhoea aged between 12-30 years were assigned randomly to the interventions. The test group A (n=20) received 3gm of *Hulba* (*Trigonella foenum graecum*) twice daily from day 1 to day 3 of menstrual cycle. The test group B (n=20) received same dose of *Hulba* with dry cupping (*hijamat bila shurt*). These interventions were given for three consecutive cycles. The results were analyzed and compared statistically by using Analysis of variance (ANOVA), Chi-square or Fisher Exact test to find the significance of study parameters. The groups showed similarity in terms of baseline characteristics and biochemical parameters ($P>0.05$). The inter group comparison showed that group A was equally effective as group B and C ($P>0.05$), whereas group B was more- effective than group C ($P=0.02$) in reducing pain intensity. The associated symptoms were also improved in all groups. No adverse drug effects were observed. *Hulba* was as effective as mefenamic acid, whereas *Hulba* with *dry cupping* was more effective than mefenamic acid in reducing pain intensity and discomfort. The test drug (*Hulba*) and dry Cupping were found to be more effective in the management of primary dysmenorrhoea.

Keywords: *Primary.dysmenorrhoea; Usre Tams Ibtidae; Hulba; Hijamat bila shurt; Visual Analogue Scale.*

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INTRODUCTION

Dysmenorrhoea is the painful periods of young women. Primary dysmenorrhoea refers to painful menstruation in the absence of any underlying pelvic ailments¹. It is common menstrual cramps that are recurrent and are not due to any pathology e.g. endometriosis, adenomyosis, uterine fibroids and infections etc.¹ Pain usually begins 1 or 2 days before, or when menstrual, and is felt in the lower abdomen, back, or thighs, and can be accompanied by nausea and vomiting, fatigue, and even diarrhoea. Menstrual cramps usually become less painful as a woman ages. Pain can range from mild to severe, can typically last 12 to 72 hours.² it is the most common gynecological disorder in menstruating women². It is considered very essential women's health hazards³ with high prevalence.¹ Most of the women experience some kind of pain during menstrual cycle which remains unnoticed but it certainly restricts their daily activities.⁴

The prevalence of primary dysmenorrhoea is estimated to be from 45-95% among the women of reproductive age group.³ 60-90% of females It is the single largest cause of absence from class and work among women of menstruating age.⁵ Such absences diminish opportunities for successful educational, psychosocial and cognitive development during the critical period of adolescent growth.⁶ Between 30% and 90% of women reported to experience pain at menses, whereas 10% to 20% of women reported such severe pain that they are unable to perform their work or have to miss school.^{7,8}

Pathology Current evidence suggests that primary dysmenorrhoea is associated with ovulatory cycles and is largely due to myometrial contractions induced by excess endometrial prostaglandins production that occurs mostly in the first 48 hours of menses.⁹ The local action of PG on uterus is threefold i.e., increase basal intrauterine pressure, constriction of uterine arteries with subsequent tissue ischemia and pain, finally, increases the sensitivity of peripheral pain nerve endings.^{10, 11}

Most of the ancient Unani Physicians described the term dysmenorrhoea under the heading of 'aujae rehm' that is pain of uterine origin.^{12, 13} Waja (pain) is perception of incongruity afflicting the human body, which is an abnormal condition. Sudden and abnormal change in temperament i.e., sue mizaj mukhtalif and tafarruq wa ittesal (breach of continuity) are the two main causative factors of pain.^{14,15} The causes of usre tams mentioned in Unani system are sue mizaj mukhtalif ghaleez balgham wa -sauda, reeh, dard kuninda rutoobat, ahtabase tams, warme rehm, 2I insadade fame rehm, dabeela, sailane khoon, sailane mani, ikhtenaqur rehm and as a complication of various kidney and liver diseases etc.^{13,16} Sometimes quwate dafia of rehm becomes weak by sudda formed by khilte ghaleez (balgham and sauda), which may be one of the causative factors of usre tams.¹⁷

Though various treatments have been suggested for the management of dysmenorrhoea however, up till now no treatment is satisfactorily available without any side effects. By far, the pharmacological approach has been better documented for efficacy. Among them NSAIDs are effective in 80% of cases¹⁸ but have a number of adverse effects (digestive disorders, diarrhea, hemolytic anemia, seizures etc). In spite of several effective therapies, such as analgesics and oral contraceptives the morbidity from dysmenorrhoea remains a challenge to public health worldwide.¹⁹ However to develop an ideal analgesic free from adverse reactions and dependence has remained a dream of pharmacologist. Considering the present unconvincing scenario regarding the use of drugs and adverse effects thereof, researches are pursuing the golden formula of turning to nature and traditional pathies.

Hulba is one of the oldest known medicinal herbs in the recorded history. According to Unani Physicians Hulba has dafae tashannuj,²⁰ mudirre haiz,^{20' 21} mulattif,^{22'23} muhallil,^{21'24} and munzij²⁵ properties hence, it was selected. The drug is globally distributed, easy available and one of the proved analgesics. It is pharmacologically proved for anti-inflammatory,²⁶ analgesics,²⁷ diuretic,²⁸ and immunomodulatory activities.²⁹ These properties are attributed to the presence of saponins, tannins and flavonoids.²⁶

According to Unani physicians, dry cupping below the umbilicus relieves dysmenorrhoeal, especially in young girls.^{13,30,31} It works on the principle of imalae mawad (Diversion/shurting of morbid matter/fluid) from the affected area.³² Dry cupping appears to have a role in the management of pain from dysmenorrhoea which is currently dominated by pharmaceutical and some surgical treatments. It offers a non invasive reach no side effects and no potential for drug interactions.

Though, Hulba and dry cupping are in use since long time for usre tams, but validation and documentation ase not available till date. Therefore a Prospective, single center, open labeled, simple randomized standard controlled, pre and post evaluation trial was conducted on sixty subjects to prove efficacy and safety of Hulba and dry cupping. The research question was whether Hulba and dry cupping are effective in primary dysmenorrhoea and its associated symptoms. The hypothesis was the use of Hulba in one group, Hulba with dry cupping in other group in woman with primary dysmenorrhoea compared with standard drug would at 1, 2, 3, 4 months from the baseline to be effective at reducing severity of dysmenorrhoea and overall improvement in other symptoms associated with it.

AIMS AND OBJECTIVES: The objectives of this present study were

1. To study the various clinical aspects of Primary dysmenorrhoea in the light of classical Unani literature
2. To evaluate the efficacy and safety of *Hulba* and dry cupping in the management of Primary dysmenorrhoea
3. To compare the results statistically with standard control

MATERIALS AND METHOD

A randomized standard controlled study was carried out to evaluate the efficacy and safety of *Hulba* and dry cupping in the management of primary dysmenorrhoea with well validated Visual Analogue Scale for intensity of pain. The hypothesis of this study was the use of *Hulba* in one group, *Hulba* with *Dry cupping* in other group in woman with primary dysmenorrhoea compared with standard drug would at 1, 2, 3 and 4 months from the baseline to be effective at reducing severity of primary dysmenorrhoea and overall improvement in menstrual symptoms. This study was approved by the institutional ethical committee. Subjects with primary dysmenorrhoea who fulfilled the inclusion criteria were recruited between August 2014 to February 2016 from the Department of Ilmu Qabalat wa Amraz-e-Niswan, DUMCH-RC. A total of 60 subjects were divided into three equal groups with aid of simple randomization done by computer generated random list by Graph Pad Software Quickcalcs.

Study Design: Simple randomized standard controlled trial

Duration of Study: 1 year and 6 months

Criteria for Selection of Subjects:

Inclusion Criteria:

1. Subjects aged 12-30 years having regular menstrual cycle (28 ± 7 days)
2. Nulliparus and pares subjects with the history of primary dysmenorrhoea

Exclusion Criteria:

1. Subjects with congenital anomalies of uterus, secondary dysmenorrhoea, any organic pelvic pathology and membranous dysmenorrhoea
2. Subjects with any systemic illness like hypertension, diabetes mellitus, thyroid dysfunction, cardiovascular and renal diseases
3. Subjects on oral contraceptives or other hormonal agents

Sample Size: Total 60 subjects (20 in each group)

Group A: Test drug

Group B: Test drug with dry cupping

Group C: Standard drug

Method of Collection of Data:

By clinical examination, Visual Analogue Scale for pain intensity and investigations.

Procedure:

A total of 60 eligible subjects, aged 12-30 years with painful menstruation for at least six months who provided informed consent were randomized and selected on the basis of clinical diagnosis.

During the selection procedure complete history and investigations were carried out, which was recorded on a prescribed case record form. (Annexure I) The subjects were enquired about their name, age, sex, marital status, menstrual history, parity and address. The chief complaints, duration of suffering in detail were noted in chronological order. Subjective assessment of associated symptoms (fatigue, headache, anxiety, nausea and vomiting) were done before and after the trial on the basis of 4 point scale (0=none, 1=mild, 2=moderate, 3=severe).

Emphasis was also given on family history of dysmenorrhoea, past history of taking medications for dysmenorrhoea, and other gynecological and systemic disorders. Dietary and other habits were inquired in personal history. In socioeconomic history, Subjects were inquired about their monthly income, education and occupation, which were assessed by Kuppuswamy's Socioeconomic Scale. (Annexure II) The mizaj was assessed by using temperamental scale (on the basis of alamate ajnase ashra) as described by ancient Unani physicians. (Annexure III). General, physical and systemic examination (including pelvic examination only in married women) was conducted to exclude general and systemic diseases respectively.

Diagnostic Criteria:

VAS for Pain Intensity:

The intensity of pain in dysmenorrhoea was objectively assessed by colored Visual Analogue Scale (VAS) for pain. It is a 10 cm line labelled scale which has 'no pain' or 'zero' on left side and 'worst possible pain' or 'ten' on the right side. The colored scale was taken to ease the subjects in marking the intensity of the pain. The subjects were asked to mark on the scale according to the severity or intensity of their pain. The test retest reliability of VAS for

pain intensity was 0.896. "Baseline VAS score was taken before starting the treatment and were assessed at every follow up for four consecutive cycles.

The colored Visual Analogue Scale for pain intensity was graded as:

0 -1(Green Colour)	:	No pain to distress
2-4 (Greenish Yellow)	:	Annoying to uncomfortable
4-6 (Yellow)	:	Uncomfortable to dreadful
6-8 (Yellowish red)	:	Dreadful to horrible
8-10 (Red)	:	Horrible to agonizing (Annexure IV)

Percentage of pain reduction score was calculated by

$$\frac{\%PR - \text{Baseline VAS score} - \text{Mean pain reduction of three consecutive cycles} \times 100}{\text{Baseline VAS score}}$$

Satisfactory pain relief was considered when % pain reduction was more than or equal to 50% and taken as non satisfactory when % pain reduction was less than 50% as described by Beecher.³³

Informed consent:

Subjects who fulfilled the inclusion criteria were shown information sheet having details regarding the nature of study, and the drugs to be used. Subjects 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.

Investigations:

1. Routine investigations like complete blood picture, ESR, RBS and routine urine examination were done to exclude general diseases.
2. SGOT, SGPT, alkaline phosphatase, serum creatinine and blood urea were done before and after trial to assess the safety of test and control drug.

Specific Investigations:

Coagulation profile (BT, CT, PT, Platelet count), thyroid profile and pelvis ultra-sonography test were done to exclude coagulation disorders, thyroid dysfunction and pelvic pathology respectively.

Intervention:

Criteria of Selection of Test Drug and *Dry cupping*:

The test drug, *Hulba* and *dry cupping* are in use since long time to relieve pain related to uterus. *Hulba* has properties like *musakkin* (analgesic), *mudirre haiz wa bowl*

(emmenagogue, and diuretic), *dafae tashannuj* (anti spasmodic), *muhallil* (anti-inflammatory), *kasire riyah* (carminative), and *muwallide dum* (haematinic). Dry cupping works on the principle of *imalae mawad*.²³

Test Drug: Orally

Hulba (*Trigonella foenurn graecum*) was studied as a test drug, which was obtained from the local market of Deoband.

Method of Preparation, Route of Administration and Dosage:

Orally: Fine powder of *Hulba* 3gm was filled in the capsules and administered twice daily from 1st to 3rd day of menstruation for three consecutive cycles.

Locally: Dry cupping(dry cupping): Three medium size cups were applied below the umbilicus for 15 minutes on 1st and 3rd day of menstruation.

Standard drug:

Route of administration and dosage of standard drug:

Mefanamic acid 500mg twice daily was given orally from day 1 to day 3 of menstruation (Tab. Mefanamic acid (Mefal-500) 500 mg purchased from the market. It was manufactured by Blue Cross, B.No HK 925, Mfg date- 03/2014, Date of expiry -9/2016).

Duration of Treatment: Three months.

Outcome Measurements:

The primary outcomes were menstrual pain intensity, measured with well validated Visual Analogue Scale and safety of the test drug, evaluated by clinical examination and laboratory investigations. The secondary outcome variable was associated symptoms (fatigue, headache, anxiety, nausea and vomiting). Subjective assessment were done before and after the trial on the basis of 4 point scale (0—none, 1 mild, 2= moderate, 3=severe).

Assessment and Follow up During Study Period:

The efficacy of the test drug and dry cupping were assessed by observing the change in the rating score of subjective and objective parameters. At- every visit after menstruation for three consecutive months of treatment and one month of follow up the subjects were asked about the improvement or worsening in their symptoms, which were recorded in the case record form. After completion of the trial, the pre and post treatment values were statistically analyzed and compared to evaluate the efficacy and safety of the treatment.

Adverse Effects Documentations:

Adverse drug reactions were noted during or after treatment.

Documentation: The records were submitted to the department after completion of study.

Withdrawal Criteria: Failure to follow the protocol and the cases in which drug adverse reaction were noted.

Statistical Software:

The Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc. Statistical Analysis: Descriptive statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean \pm SD (MM-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance. The following assumptions on data are made, Assumptions: 1. Dependent variables should be normally distributed, 2. Samples drawn from the population should be random, Cases of the samples should be independent. Analysis of variance (ANOVA) has been used to find the significance of study parameters between three groups of patients, Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups. The level of significance was 5% and 95% Confidence Interval has been computed to find the significant features.

RESULTS AND DISUCSSION

A total no of 130 subjects were interrogated and screened for *usre tams* in this study. Out of them 40 did not review and 90 were subjected to preliminary investigations in which 18 were excluded. 72 patients were randomly allocated in three groups, twenty in each group allowing 20% drop out. To observe the efficacy and safety, statistical analysis was done in all the three groups. The parameters were evaluated before and after the trial.

Primary Outcomes:

Efficacy of Test and Control Groups on Visual Analogue Scale for Pain Intensity for Lower Abdominal Pain in *Usre Tams Ibtidaee*: Mean scores and SDs of pain intensity recorded by VAS was statistically similar among the three groups at the base line (P=0.215). In first visit, the mean scores and SDs were significantly reduced from base line i.e., 3.9 ± 0.9 , 4.0 ± 1.60 and 4.5 ± 1.40 in group A, B and C respectively (P=0.915). In second visit, the mean scores and SDs were 2.15 ± 1.11 , 2.5 ± 1.8 , and 2.4 ± 1.10 in group A, B and C respectively and in third visit, the mean scores and SDs of VAS were reduced to 0.71 ± 0.70 , 0.89 ± 1.69 , and 0.72 ± 0.61 in group A, B and C respectively (P=0.910) from baseline, In follow up, after treatment the mean scores and SDs of

VAS were 0.51 ± 0.59 , 0.16 ± 0.38 and 0.61 ± 0.57 in group A, B and C respectively ($P=0.01$) from baseline. The inter group comparison in follow up (F1) showed that group A was statistically not significant compared to group B and C ($P>0.05$), whereas group B was statistically not significant compared to group B and C ($P>0.05$), whereas group B was statistically significant compared to group C ($P=0.01$). The intra group comparison of VAS at each follow up during treatment and after treatment from the baseline was statistically strongly significant ($P<0.001$). The percentage of the pain reduction at the end of three months of treatment was 65.13%, 64.50%, and 60.9% in A, B and C group respectively. (Table 1) The odd ratio of group A compared to group C of lower abdominal and low back pain was 2.53 and 1.47 in the first cycle, whereas odd ratio of lower abdominal and low back pain was 0.90 and 1.08 in second cycle respectively. The odd ratio of lower abdominal pain as well as low back pain was 1 both in third cycle. (Table 2) The odd ratio of group B compared to group C of lower abdominal and low back pain was 3.17 and 1.29 in the first cycle, whereas odd ratio of lower abdominal and low back pain was 0.90 and 1.03 in second cycle respectively. The odd ratio of lower abdominal and low back pain was 0.95 and 1 in third cycle respectively. (Table 3).

Table 1: Comparison of Visual Analogue Scale for Lower Abdominal Pain in Three Groups of Subjects

VAS	Group A (n=20)	Group B (n=20)	Group C (n=20)	P Value
To	6.2 ± 101	6.9 ± 1.3	7.0 ± 1.4	0.215
T1	3.9 ± 0.9	4.0 ± 1.50	4.5 ± 1.40	0.915
T2	2.15 ± 1.11	2.5 ± 1.8	2.4 ± 1.10	0.950
T3	0.71 ± 0.73	0.89 ± 1.69	0.72 ± 0.61	0.910
F1	0.51 ± 0.59	0.16 ± 0.38	0.61 ± 0.57	0.01 ⁺
P Value from T0				
T1	$P<0.001^{**}$	$P<0.001^{**}$	$P<0.001^{**}$	$P<0.001^{**}$
T2	$P<0.001^{**}$	$P<0.001^{**}$	$P<0.001^{**}$	$P<0.001^{**}$
T3	$P<0.001^{**}$	$P<0.001^{**}$	$P<0.001^{**}$	$P<0.001^{**}$
F1	$P<0.001^{**}$	$P<0.001^{**}$	$P<0.001^{**}$	$P<0.001^{**}$
% of Pain Reduction	65.13%	64.50%	60.9%	

Data presented: Mean \pm Standard Deviation

Test used: One-way ANOVA, + suggestive significance (P value: $0.05 < P < 0.10$),

** Strongly significant (P value $P < 0.001$)

Follow up (F1) Inter group comparison P values:

A Vs B: $P=0.08$, **A Vs C:** $P=0.61$, **B Vs C:** $P=0.02^+$

Table 2: Comparison of Odd Ratio and 95% CI to treat for at least 50% pain

	Improved with		% Improved		Odd Ratio	95% CI
	Group C	Group C	Group A	Group C		
1 st cycle		3/20	40.0	15.8	2.53	0.78-8.15
2 nd cycle	18/20	20/20	90.0	100.0	0.90	0.78-1.04
3 rd cycle	20/20	20/20	100.0	100.0	1.000	-
1 st follow up	20/20	20/20	100.0	100.0	1.000	-
Lock back pain						
1 st cycle	8/12	5/11	66.7	45.5	1.47	0.68-3.14
2 nd cycle	11/12	10/11	91.7	90.9	1.08	0.78-1.29
3 rd cycle	12/12	11/11	100.0	100.0	1.00	-
1 st follow up	12/12	11/11	100.0	100.0	1.00	-

Table 3: Comparison of Odd Ratio and 95% CI to treat for at least 50% pain

	Improved with		% Improved		Odd Ratio	95% CI
	Group B	Group C	Group B	Group C		
1 st cycle	10/20	3/20	50.0	15.8	3.17	1.03-9.77
2 nd cycle	18/20	20/20	90.0	100.0	0.90	0.78-1.04
3 rd cycle	19/20	20/20	95.0	100.0	0.95	0.86-1.05
1 st follow up	20/20	20/20	100.0	100.0	1.00	-
Lock back pain						
1 st cycle	10/17	5/11	45.5	45.5	1.29	0.61-2.77
2 nd cycle	16/17	10/11	90.9	90.9	1.03	0.83-1.29
3 rd cycle	17/17	11/11	100.0	100.0	1.00	-
1 st follow up	17/17	11/11	100.0	100.0	1.00	-

Efficacy of Test and Control Groups on Visual Analogue Scale for Pain Intensity for Low Back Pain in *Usre Tams Ibtidaee*:

Mean scores and SDs of pain intensity recorded by VAS was statistically similar among the three groups at the base line (P=0.505). In first visit, the mean scores and SDs were significantly reduced from base line i.e., 2.01 ± 2.00 , 2.15 ± 1.69 and 1.58 ± 1.80 in group A, B and C respectively (P=0.668). In second visit, the mean scores and SDs were 0.59 ± 1.1 , 0.96 ± 1.26 and 0.70 ± 1.25 in a group A, B and C respectively (P=0.697) and in third visit, , the mean score and SDs, of VAS, were reduce to 0.22 ± 0.78 , 0.06 ± 0.21 and 0.18 ± 0.50 in group A, B and C respectively with P=0.725 from baseline. In follow up, after treatment, the mean scores and SDs were 0.10 ± 0.45 , 0.06 ± 0.22 , and 0.20 ± 0.51 in group A, B and C respectively with P=0.482 from baseline. The intra group comparison of VAS in first cycle from baseline was not statistical significant in group A and C (P>0.05), whereas it was moderately significant in group B (P<0.01). The intra group comparison of VAS in second and third visit from the baseline and in first follow up was statistically strongly significant (P<0.001). The percentage of the pain reduction at the end of three

months of treatment was 71.6%, 71.00%, and 70.01% in A, B and C group respectively. (Table 4 and Fig 1).

Table 5: Comparison of Visual Analogue Scale for Lower Back Pain in Three Groups of subjects

VAS for LBA	Group A (n=20)	Group B (n=20)	Group C (n=20)	P Value
To	3.25 ±2.8	3.7±2.2	2.80±2.77	0.50
T1	2.01±2.00	2.18±1.69	1.58±1.80	0.668
T2	0.59±1.1	0.96±1.26	0.70±1.26	0.71
T3	0.22±0.79	0.06±0.21	0.18±0.50	0.76
F1	0.10±0.45	0.05±0.20	0.20±0.51	0.49
P Value from T0				
T1	P>0.05	P<0.01*	P>0.05	
T2	P<0.001**	P<0.001**	P<0.001**	
T3	P<0.001**	P<0.001**	P<0.001**	
F1	P<0.001**	P<0.001**	P<0.001**	
Percentage of Pain Reduction				

Data presented : Mean ± Standard Deviation

Test used: One way ANOVA,+ suggestive significance (P value: 0.01<P≤0.05),

** Strongly significant (P value P<0.001)

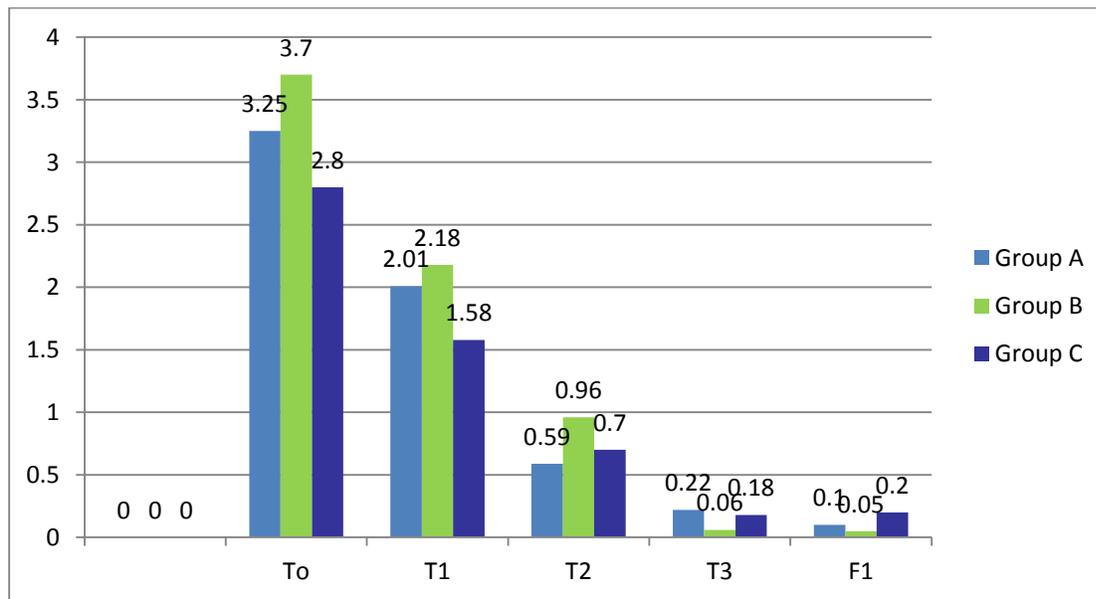


Figure 1: Comparison of Visual Analogue Scale for Lower Back Pain in Three groups of subjects.

DISCUSSION

In this present study, Hulba was as effective as mefenamic acid, whereas Hulba with dry cupping was not only more effective than mefenamic acid during treatment but also after the trial. The

effect of Hulba was owing to its dafae tashannuj²⁰, dafae dard, mudirre haiz²⁴, mulattif²³ and muhalli^{22,24} properties. It is pharmacologically proved for anti-inflammatory,²⁶ analgesic," diuretic,²⁸ and immunomodulatory activities.²⁶ The aqueous alcoholic extract of Hulba proved to have steroidal saponin as diosgenin, tigogenin, yamogenin and gatogenin, to which, the anti-inflammatory activity may be attributed.

Dry cupping works on the principle of imalae mawad (Diversion of morbid matter/fluid) from the affected area.¹⁴ It is stated that shurtting of blood flow away from the viscera results in relieving the congestion in the pelvic area, and suppresses the prostaglandins and release of beta endorphins producing endogenous analgesia.³⁴ Likewise, on the same basis, it is hypothesized that dry cupping also suppresses the prostaglandins and release of beta endorphins producing analgesia as it shurtts the blood flow from the uterus. Hence, dry cupping was effective in relieving usre tams. This proves the claim of ancient Unani hukma that it relieves dysmenorrhoea, especially in young girls.¹⁴

Majority of subjects had balghami mizaj i.e., 34(56%). This indicates that usre tams ibtidae is likely to be dominated by balghami constitution. The causes described for usre tams are sue mizaj and ghalzate khilt. They were of the opinion that Hulba has har wa yabis mizaj, which helps to rectify the sue mizaj owing to its munzij, mulattif and mukhrije balgham properties.^{23,24} This observation confirms the claims of Unani physicians

SUMMARY

Inspite of several effective therapies such as analgesics and oral contraceptives, the consequences of dysmenorrhoea remains a challenge to public health worldwide. Therefore, it needs safe & effective treatment. Hulba and dry cupping are in use since antiquity for usre tams ibtidae but validation and documentation are sparse. Thus, the present simple randomized standard controlled study was conducted to assess the efficacy and safety of Hulba and dry cupping in its management.

The effect of treatment was observed by assessing the primary and secondary outcomes for four consecutive months. The biochemical and safety parameters were done pre and post treatment in all groups to assess the safety. Clinical and laboratory findings were analyzed statistically to assess the significant changes. Hence more intensive and extensive studies are required to confirm the efficacy of test drug Hulba and Dry cupping and then attempts should be taken to prove its efficacy and introduce at on large scale healthcare delivery system by using government agencies for improving general quality of life of adolescents and young menstruating women.

CONCLUSION

The present study was conducted on sixty subjects to prove the efficacy and safety of Hulba and hijamat bila shurt. Hulba was found to be as effective as mefanamic acid, whereas Hulba with dry cupping was more efficacious than mefanamic acid in reducing pain intensity and agony along with overall improvement was noticed in other associated symptoms like nausea vomiting fatigue, headache etc.

No adverse effects have been observed either in the subjects of test group or standard group. The biochemical and safety parameters were within the normal range before and after trial, proving that all groups were safe. Majority of the subjects had balghami mizaj in this study. The presence of abnormal khilt balgham in the uterus is responsible for producing tashannuj. This confirms the claims of Unani physicians that usre tams ibtidaee is caused by sue mizaj and ghalzate khilt. The prevalence of primary dysmenorrhoea in this study was observed in adolescents, .average age of menarche was 13 years with a predominant family history. It is observed that Hulba with dry cupping was effective even after completion of the trial. In this study, Hulba was found to be efficacious because of its dafae tashannuj, dafae dard, mudirre haiz, mulatiff and muhallil properties. It is pharmacologically proved for its anti-inflammatory, analgesic, diuretic, and immunomodulatory activities. It is suggested that dry cupping shurtts the blood flow from the uterus suppressing the prostaglandins and release of beta endorphins- producing analgesia. Therefore, dry cupping was effective ill relieving usre tams. Hence, further it is recommended in secondary dysmenorrhoea, large sample size for longer duration with scientific validation by estimating prostaglandin level in menstrual blood.

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