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Original Article

An Open-Labelled Randomized Comparative Efficacy Study of Unani Formulations and *Hijama Bila Shart* in *Tashanuji Usr al-Tamth* (Spasmodic Dysmenorrhea)

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ABSTRACT

Objectives: To compare the efficacy of *Unani* formulations and *Hijama Bila Shart* in *Tashanuji Usr al-Tamth* (spasmodic dysmenorrhea). **Materials and Methods:** Diagnosed patients (*n*=40) were randomly allocated in 2 groups (A and B). Group A (*n*=20) received 200 mL *Joshanda* (decoction) of *Post Amaltas* (7 g), *Badiyan* (5 g), and *Pudina Khushk* (5 g) and 6 g *Sufuf* (*Tukhm Kharpaza* (5 g), *Hulba* (3 g), *Hab ul Qilt* (3 g), and *Maghz Tukhm Bakayan* (1 g), twice daily, 2 days before the onset of menstruation and continued for 3 days of menstrual cycle and *Hijama bila Shart* (dry cupping) were applied over the suprapubic region on day 1 to day 3 of the menstrual cycle in Group B (*n*=20) for three consecutive cycles. The primary outcome included a Verbal Rating Scale (VRS) for the severity of pain at baseline and at each follow-up. The secondary outcome included a multidimensional scoring system WaLIDD (working ability, location, intensity, days of pain, dysmenorrhea) score at baseline and post-intervention (4th cycle). With a 5% level of significance, the data was statistically analyzed. **Results:** In both groups significant pain relief was noted at each follow-up from baseline. Cupping therapy was more effective than oral medication. The mean WaLIDD score of group A and group B comparison at baseline [8.85±1.23 and 8.20±1.40] and post-intervention [4.10±2.69 and 4.20±2.40] was statistically not significant (p>0.05). However, the intragroup comparison showed significant differences in both groups. No side effects of drugs were noted. **Conclusion:** Both groups were effective, safe and cost-effective, in pain management of *Tashanuji Usr al-Tamth*. However, further randomized standard controlled trials in large samples are recommended.

Keywords: Cupping therapy, *Hijama Bila Shart*, Spasmodic dysmenorrhea, VRS, WaLIDD score.

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INTRODUCTION

Tashanuji Usr al-Tamth (spasmodic or primary dysmenorrhea) is a frequent ailment in young women, defined as cramping discomfort in the lower abdomen at the start of menstruation in the absence of any recognizable pelvic condition.[1] This condition manifests itself within 6 months of menarche, or earlier. The ovulatory cycles[2] causes a negative impact on a girl's psychology, behaviour, and quality of life. It has a detrimental impact not only on the lives of women, but also on the lives of their families, and is responsible for massive economic losses due to the high cost of pharmaceuticals, medical care, and lower productivity. According to WHO *"Health is a state of complete physical, mental and social well being and not merely the absence of disease or infirmity"*[3] but the anticipation of pain each month may eventually cause acute mental and physical distress making it a major problem. Dysmenorrhea is a significant public health burden because of its high frequency and as one of the top reasons for absence from school or work. Other implications of dysmenorrhea include inhibition of everyday activities and sleep disturbance. According to studies from India, the prevalence ranges from 50 to 87.5%. Pain is reported by 5 to 20% of women who have severe dysmenorrhea or pain that prohibits them from participating in their typical activities.[4]

Usr al-Tamth or *Auja al-Rahim* in Unani medicine treats menstrual discomfort or uterine pain, which are both related to gynecologic illnesses.[5,6] The other terms coined for *Usr al-Tamth* are *Usr-i-Duroor-i-Hayd* and *Usr-i-Hayd*.[7,8] Rāzī (868-925 AD) has described various causes of pelvic pain. In his view due to *"Mizaj al-Rahim"* the natural Quwa of the uterus gets weak which may cause pain.[9] Sīnā (980-1037 AD) termed dysmenorrhea as *"Auja al-Rahim"*. He said that pelvic pain is caused by

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"Sū'-i-Mizāj" of the uterus and *"Tamaddud Kuninda Riyah"* in the uterus. He also stated that the pain starts in the pelvis and radiates to the back and inner thighs and sometimes it mimics intestinal colic in *Waram-al-Rahim* patients will feel pain in the pelvic area according to the site of inflammation.[6] *Majūsī* in *Kitāb Kāmil aṣ-Ṣinā'a aṭ-Ṭibbiyya* have mentioned painful menstruation under *"Ihtibas-al-Tamth"*. He stated that women who menstruate for a longer duration suffer from severe pain due to the elimination of more blood in a short period.[10] *Hakeem Ajmal Khan* described dysmenorrhea as *Usr-i-Duroor-i-Hayd.* He mentioned that *Ihtibas-al-Tamth* is the cause of difficulty and pain during menstruation, either complete cessation or scanty flow of menstruation is accompanied by pelvic pain. According to him, pain starts one or two days before menstruation. Pain confined to the suprapubic region and back. The pain will be more in young girls, when girls attain menarche there will be more circulation in reproductive organs which causes pain before menstruation.[5,7]

In the conventional system of medicine, dysmenorrhea is associated with an excess of PGF2α in the uterus. Prostaglandin release into menstrual fluid is a constant continuous process.[11] The severity of menstrual cramps and related dysmenorrhea symptoms is proportional to the amount of PGF2 produced. Increased myometrial contractions with or without dysrhythmia are caused by either increased production of prostaglandin or greater sensitivity of the myometrium to normal prostaglandin synthesis.[12] There are different prostaglandins secreted by the endometrium. PGE2 causes myometrial contraction but vasodilatation, PGF2α causes vasoconstriction, as well as myometrial contraction, PGI2 (Prostacyclin), is responsible for muscle relaxation and vasodilatation.[13] It appears to be diminished in primary dysmenorrhea, which increases uterine activity and vasoconstriction because the uterotonic and vasoconstrictive effects of other prostaglandins are less inhibited.[11]

In primary dysmenorrhea, the pain sensation arises in the uterine origin and is related to muscle contractions.[14] The development of dysmenorrhea is probably tied to central sensitization. Limited studies have revealed an association between dysmenorrhoea and hypersensitivity to pain in which the variances registered in pain sensitivity amid dysmenorrheic and non-dysmenorrheic menstruators are initiated to be systemic rather than resulting from regional changes in the pelvis.[15] The menstrual pain is spasmodic, cramp-like, pain is frequently accompanied by moderate to severe nausea, vomiting, diarrhoea, fatigue, low backache and headache.[16-18] It is no doubt that NSAIDs appear to be very effective for pain relief in dysmenorrhea but they also have a risk of gastrointestinal and neurological adverse effects.

Many of the Unani physicians have treated painful menstruation with polyherbal formulations of *Mudirrat* and *Musakkinat* and they also stated that "*Hijama Bila Shart*" Dry cupping) is beneficial in treating primary dysmenorrhea and operates on the *Imala-i-Mawad* (morbid matter shunting) premise. *Post Amaltas, Pudina Khushk, Tukhm Kharpaza,* and *Badiyan* possess *Mudirr* (emmenagogue), *Muskkin-i-Alam* (analgesic), *Muhallil* (anti-inflammatory), and *Kasir-i-Riyah* (carminative) effect.[6] Further pharmacological studies have proven the anti-inflammatory property of *Cassia Fistula* Linn (*Post Amaltas*),[19] *Foeniculum vulgare* Mill (*Badiyan*),[20] *Mentha Piperita* (*Pudina Khushk*),[21] *Cucumis melo* Linn (*Tukhm Kharpaza*),[22] *Trigonella Foenum graceum* (*Hulba*),[23] and *Dolichos biflorus* Linn.[24]

By reviewing various Unani literature all phytochemical properties of the above medicine formulation were made in the form of *Joshanda* (decoction) and *Sufuf* (powder) to validate the claim of Unani physicians. Hence, this open-labelled randomized comparative efficacy study of polyherbal Unani formulations and *Hjama Bila Shart* in *Tashanuji Usr al-Tamth* was carried out.

MATERIALS AND METHODS

Study design

An open labelled, single centre, randomized controlled parallel design was conducted in the department of our Institute. The institutional ethical committee and the scientific review committee approved the study (IEC no. 16316221022D). Both oral and written consent were taken from the participants.

Participants

A total of 40 patients between the ages of 12 to 24 years with a regular menstrual cycle, who presented with complaints of recurrent cyclic pain on the first day of the cycle without any systemic illness were included. All married patients, patients above the age of 24 years with congenital abnormalities like the septate uterus or bicornuate uterus or acquired abnormalities like uterine fibroids, endometriosis, polyp or PID or patients with systemic illness including cardiac diseases, respiratory diseases, renal diseases or tuberculosis were excluded.

Procedure

Patients were recruited from the outpatient department. Patients were assessed with clinical history, physical, systemic, and gynaecological examination, VRS for pain intensity[25] and WaLIDD score[26] for pain severity. Investigations including complete blood picture, complete urine examination, erythrocytic sedimentation rate, random blood sugar, and Ultrasonography to differentiate with secondary dysmenorrhea were performed. Patients were called on day 1 for group A medicine and asked to continue the medication for 3 days. Group B patients were called on day 1 and day 2 for a cupping procedure. Treatment was given for 3 consecutive cycles. At each cycle patient's symptoms were recorded with side effects of both groups were noted. During the treatment period, patients were asked not to take any analgesics.

Assessment tools

Verbal Rating Scale (VRS)

The intensity of pain was measured subjectively by a 4-point Verbal Rating Scale (VRS). VRS requires the subjects to indicate the level of pain using adjectives such as no pain (0), mild pain (1), moderate pain (2) and severe pain (3).[25] The intensity is recorded at each follow-up.

WaLIDD (Working ability, Location, Intensity, Days of pain, Dysmenorrhoea) scoring

The severity of pain in each cycle is measured by WaLIDD (Working ability, Location, Intensity, Days of pain and Dysmenorrhea) scoring which is a newer tool to rate dysmenorrhea.[26] It is a multidimensional rating scale, that integrates features of dysmenorrhea including

Anatomical pain location (number of parts of the body, lower abdomen, lumbar region, lower limbs, inguinal region) 2. Wong-Baker pain range (does not hurt, hurts a little, hurts a little more, hurts even more, hurts a lot, hurts worst) 3. Number of days of pain during menstruation (0, 1-2, 3-4, ≥5). 4. Frequency of disabling pain to perform their activities (never, almost never, almost always, always). Each tool variable provided a specific score between 0 and 3 and the final score ranged from 0 to 12 points. The severity of dysmenorrhea by the WaLIDD scoring system is noted at baseline and after the completion (4th cycle) (Table 1).

Intervention

Criteria for selection of drugs:

Various Unani literatures like Al-Qanoon, Kamil-us-Sana'a, Al-Akseer, Haziq, and many more were reviewed and it is noted that many physicians had treated dysmenorrhea with *Mudirr-i-Hayd* and *Musakkin-i-Alam Adwiya*. Based on which a compound Unani formulation was made, the drugs which have been used have effects like *Mudirr-i-Hayd* (emmenagogue), *Musakkin* (analgesic), antispasmodic, *Kasir-i-Riyah* (carminative), *Musaffi-i-Khun* (blood purifiers).[27]

Group A

Group A included *Joshanda* and *Sufuf*. Table 2 summarizes the details of group A medicine with the method of preparation and dosage.

Duration of administration

2 days before the onset of the menstrual cycle and continued till the 3rd day of the cycle for three consecutive cycles and at 4th cycle assessment of efficacy was done without giving intervention.

Group B

Two medium-sized cups were placed on the lower abdomen, below the umbilicus, for 15 min on the 1st to the 3rd day of the menstrual cycle for three consecutive cycles, and efficacy was assessed without the use of cups on the 4th cycle.

Outcomes

The primary outcome was the reduction in pain intensity which was measured by VRS in each consecutive cycle and the safety of the drug and cupping therapy was assessed by clinical examination. The secondary outcome included WaLIDD score at baseline and after the intervention. Satisfactory pain relief was considered when the percentage (%) of pain relief was ≥50% depending on the scoring, 30-50% pain relief was considered partial relief and less than 30% no relief

Sample size estimation

The sample size of this study was calculated by the mean scores of the prior study.[28] The sample size was calculated by a computer-based application. A total sample size of 39 participants was required with a margin of error of 5% and 80% power of the study with a population size of 50. Hence in the present study, 40 sample size was taken.

Randomization and Blinding

Before starting the intervention, pre-study screening was done. Patients who were willing to participate and who met inclusion criteria were included in randomization. Patients were randomly selected at a 1:1 ratio in each group (n=20). All the patients were

Table 1: Working ability, Location, Intensity, Days of pain, Dysmenorrhoea (WaLIDD) Scoring System.

Working ability	Location	Intensity (Wong Baker)	Days of Pain
0. None 1. Almost never 2.Almost always 3. Always	0. None 1. 1 site 2. 2-3 sites 3. 4 sites	0. Does not hurt 1. Hurts a little bit 2. Hurts a little more-hurts even more 3. Hurts a whole lot-hurts worst	0: 0 1: 1-2 2: 3-4 3: ≥5
Score: 0: No dysmenorrhea; 1-4: Mild; 5-7: Moderate; 8-12: Severe Result: _____			

Table 2: Showing Details of the Group, A Medicine with the Method of Preparation.

Joshanda		
Drug Name	**Botanical Name**	**Dose**
Post Amaltas	Cassia Fistula Linn.	7 g
Baadiyan	*Foeniculum vulgare* Mill	5 g
Pudina Khushk	*Mentha piperita* Linn	5 g
Method of Preparation: All the above drugs in the mentioned quantity were soaked over the night in 500 mL of water and boiled in the morning till they were reduced to 400 mL. 200 mL lukewarm Joshanda was administered twice daily.		
Sufuf		
Tukhm Kharpaza	*Cucumis melo* Linn.	5 g
Hulba	*Trigonella foenum-graeum* Linn	3 g
Hab-ul-Qilt	*Dolichos biflorus* Linn	3 g
Maghz-e-Tukhm-e-Bakayan	*Melia azaderach* Linn	1 g
Method of Preparation: All the above drugs in mentioned quantity were cleaned and grinded into fine powder. 6 g powder was administered orally twice a day.		

aware of the mode of treatment they were taking. This study was open-labelled study.

Data Analysis

Data was analyzed in SYSTAT software. Results were evaluated and presented in tables and figures following the purpose of the study. Sociodemographic variables were analyzed. VRS and WaLIDD score was statistically analyzed for both groups and the mean difference was compared by paired t-test. Subjective symptoms of both groups were analyzed by $\chi 2$ tests.

RESULTS

Participant Flow

Initially, a total of 140 patients were recruited from the OPD and evaluated for primary dysmenorrhea. Patients were excluded after evaluation done by complete history, clinical examination and investigations. Forty patients who fulfilled the selection criteria and gave consent for participation were randomly allocated into 2 groups (20 in each) (Figure 1). The study was completed for a duration of 18 months, from December 2017 to May 2018.

Baseline Characteristics

Both groups were comparable with baseline characteristics. The mean age of subjects of Group A was 19.0±2.9 and the mean age of the group B was 18.6±2.9 years. In this study, the mean age at menarche calculated was 12.15±1.07, the majority of them falling between 11 and 13 years. A higher incidence 57.5% (n=23) was seen in lower middle-class status whereas the percentage of the upper class and lower class were minimal which is 2.5% each. Positive family history of primary dysmenorrhea was observed in 65% (n=13), and 45% (n=9) patients in groups A and B respectively.

Primary outcomes

The mean VRS score of Group A was 2.8±0.18 at baseline which significantly reduced to 1.15, 0.7 and 0.6 at the first, second and third cycles respectively (Table 3). The mean VRS score of group B was 2.6±0.21 at baseline which reduced to 0.6, 0.3 and 0.15 respectively. The intragroup comparison of both groups showed a statistical significance difference (p<0.001). The intergroup comparison showed *Hijama bila Shart* was more effective than oral medication. 80% (n=16) in group A had severe dysmenorrhea and 20% (n=4) had moderate dysmenorrhea at baseline (Figure 2a). In group B, 60% (n=12) had severe dysmenorrhea and 40% (n=8) had a moderate degree of dysmenorrhea at baseline. In the first cycle, the pain was completely reduced after cupping in 50% (n=10) of patients, 40% (n=8) had mild pain and 10% had moderate pain (Figure 2b).

Secondary outcomes

WaLIDD score

At baseline, the mean WaLIDD score in groups A and B were 8.85±1.23 and 8.20±1.40 respectively. Post-intervention, the mean score was 4.10±2.69 and 4.20±2.40 in groups A and B respectively. The intragroup comparison showed a statistically significant difference. However, group A and B comparisons showed no statistically significant difference (Table 4). In group A, at the 4th cycle without intervention, a total of 60% (n=12) patients had satisfactory relief in dysmenorrhea after the intervention that is ≥50% reduction in symptoms, 20% (n=4) had partial relief (30≤50%) and 20% (n=4) had no response (<30%) to therapy. In group B, at the 4th cycle without intervention 50% (n=10) had satisfactory pain relief, 35% (n=7) had partial pain relief and 15% (n=3) had no response to therapy (Table 5).

DISCUSSION

Tashanuji Usr al-Tamth (Spasmodic Dysmenorrhea) is the most common, highly prevalent and negatively impacting symptom around the world. School absenteeism, interference with daily living tasks, socialisation constraints, and sedative prescription use are all connected with a higher prevalence and degree of dysmenorrhea.

The intragroup comparison of the mean VRS score of both groups showed a statistically significant difference from baseline at each follow-up (p<0.001). The intergroup comparison between groups A and B also showed statistically significant differences at 1 cycle and III cycle follow-up. Hence, showing Group B was more effective than Group A. However, group A and B comparison showed no statistically significant difference in mean WaLIDD score post-intervention. The intragroup comparison showed a statistically significant difference in mean WaLIDD score at post-intervention from baseline Another study showed that decoction of *Cassia fistula* (*Post-i-Amaltas*) and in spasmodic dysmenorrhea, Myristica fragrans is excellent at relieving pain

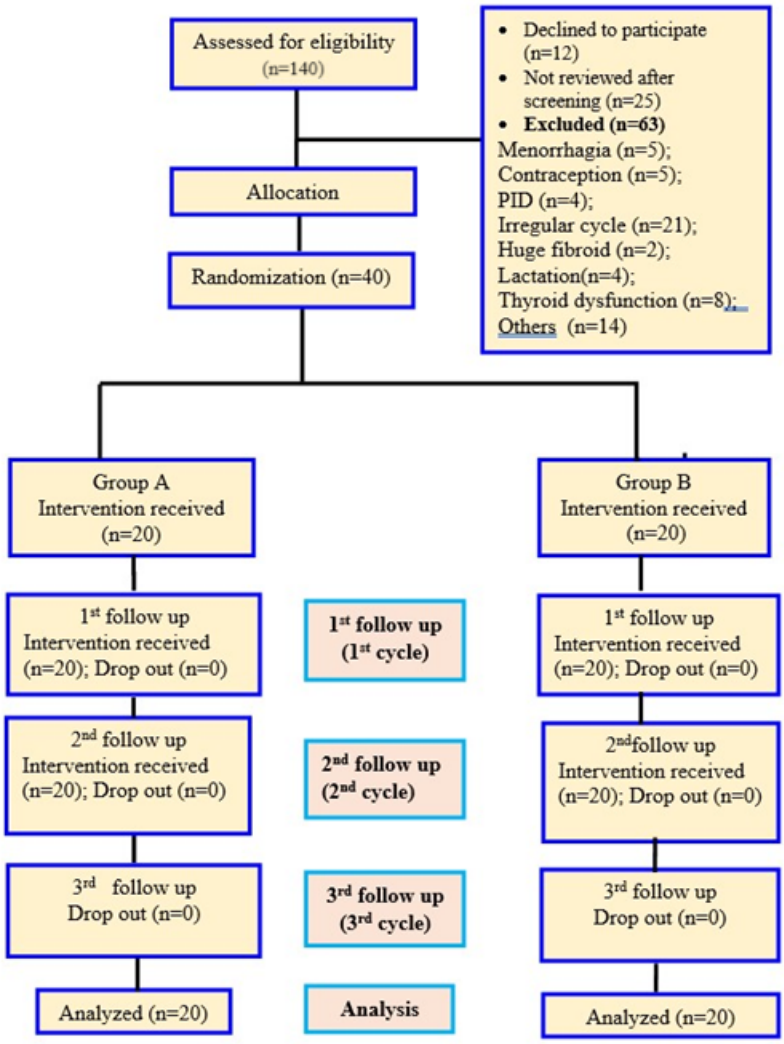

Figure 1: Flow Chart of Participants as per Consort.

Table 3: Showing VRS Score in both Groups Before Treatment and at Each Cycle.

VRS rating scale	At baseline	At I cycle	At II cycle	At III cycle
Group A (n=20)	2.8±0.41	1.15±0.58	0.7±0.73	0.6±0.68
Group B (n=20)	2.6±0.48	0.6±0.66	0.3±0.45	0.15±0.35
Unpaired t-test value	1.416	2.799	2.086	2.631
p value	0.164	0.008	0.043	0.012

Mean±SD.

Table 4: Comparison of Mean WaLIDD Score Before and After Treatment in both Groups.

Group	At baseline	Post-intervention	Paired *t*-test value	*p* Value
Group A (*n*=20)	8.85±1.23	4.10±2.69	7.947	<0.00001
Group B (*n*=20)	8.20±1.40	4.20±2.40	9.064	<0.00001
Unpaired *t*-test value	1.560	0.124	-	-
p value	0.12	0.901	-	-

Mean±SD.

Table 5: Therapeutic Response of Groups A and B Patients at 4th Cycle (without intervention).

Response	Group A		Group B	
	No. of patients (*n*=20)	Percent	No. of patients (*n*=20)	Percent
Satisfactory Relief (≥50%)	12	60	10	50
Partial Relief (30-<50%)	04	20	07	35
No relief (<30%)	04	20	03	15
Total	20	100	20	100

Mean±SD.

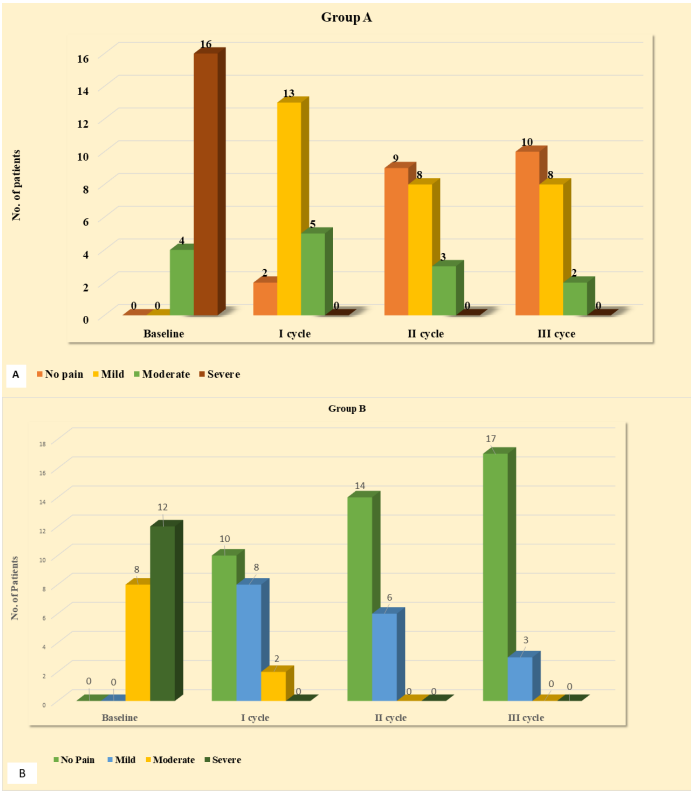

Figure 2: Showing Remission in Pain and Cycle-wise in A) Group A and B) Group B patients.

and improving HRQoL.[29] Inamdar *et al.* also demonstrated that fenugreek and dry cupping were effective in lowering the degree of discomfort in women suffering from primary dysmenorrhoea.[30] In their investigation, Khan *et al.* discovered that *Ferula asofetida* was effective in lowering the degree of discomfort in dysmenorrhea. However, these were randomised controlled trials.[31]

Group A (decoction of *C. fistula, F. Vulgare, M. Piperita* and powder of *C. melo, T. foenum graecum, D. bifloris* and *M. azadirach*) was found effective in relieving the severity of dysmenorrhea. The effects of these drugs may be attributed to ethnomedicinal properties including *Mudirr-i-Hayd, Musakkin-i-Alam,* and *Kasir-i-Riyah* properties. In various scientific studies, the effects of these drugs have been shown. Decoction of (*Post-i-Amaltas*) and *Myristica fragrans* is effective in relieving pain and improving HRQoL in spasmodic dysmenorrhea.[29] In an experimental investigation, *Cassia fistula* inhibits the 5-Lipoxygenase-mediated peroxidation of arachnoid acid, free radical-induced peroxidation, and so inhibits leukotriene formation, which limits prostaglandin synthesis by suppressing inflammatory mediators.[19] *Foeniculum vulgare Mill* (*Badiyan*) has been effective in reducing the severity of dysmenorrhea.[32] Methanolic extract acts on both cyclooxygenase and lipooxygenase pathways and reduces inflammation.[20] A crossover study showed the effectiveness of peppermint extract in reducing pain and its severity and all the clinical signs and symptoms associated with it. *Mentha Piperita* (*Pudina Khushk*) leaf extract inhibits myometrium contractile activity by inhibiting prostaglandin and oxytocin, blocks calcium channels, and has an antispasmodic effect on smooth muscles. The menthol component of peppermint also affects kappa opioid receptors, leading to a reduction in pain sensation. Menthol also inhibits IL-1 production and histamine secretion.[21] *Cucumis melo* Linn (*Tukhm Kharpaza*) extract showed an anti-inflammatory effect by abolishing the leukocyte influx.[22] *Trigonella foenum graceum* (*Hulba*) has potential analgesic and anti-inflammatory

activities and inhibits the production of inflammatory cytokines TNF-ALPHA.[23] *Dolichos biflorus* Linn. methanolic extracts significantly reduce oedema and were comparable with voveran, by directly inhibiting cyclooxygenase, lipooxygenase and prostaglandin production.[24]

During the 1st and 2nd days of the menstrual cycle, the maximum number of prostaglandins is released, which causes the greatest discomfort. Women with dysmenorrhoea receiving no medication have endometrial PGF2α levels higher than eumenorrheic women,[33] so the prevention of prostaglandin synthesis relieves the condition. In the present study cupping therapy was found to have a good effect on reducing pain alone at each cycle the mean difference of pain severity by VRS was very significant at each cycle ($p<0.001$) from baseline. In the previous study where the efficacy of *Hijama bila Shart* was assessed in the intensity of pain in dysmenorrhea, a significant reduction in pain was observed.[34]

Cupping therapy is an ancient, holistic method for the management of a variety of diseases[35] it is a complementary therapy that helps many patients beyond the pain-resolving treatments. *Hijama bila Shart* (dry cupping) works on the principle of *Imala-i-Mawad*. There is cognitive evidence that cupping causes comfort and relaxation on a systematic level, which leads to a rise in endogenous opioid production in the brain, which leads to better pain control. According to some researchers, the primary activity of cupping therapy is to increase blood circulation and eliminate toxins and waste from the body. Cupping therapy considerably reduces the number of lymphocytes in the affected area's blood while increasing the number of neutrophils, which is one of the antiviral processes that reduce pain scores.[36] Cupping has been shown to stimulate the autonomic nervous system and enhance subcutaneous blood flow. Many theories have been proposed to explain the wide range of effects of cupping therapy as well as its method of action.

Additionally, group A was found to have a long-term effect on pain and symptoms of dysmenorrhea as the follow-up cycle without intervention showed that 60% of patients showed the oral group had satisfactory pain relief compared to 50% of the cupping group.

Safety

There were no significant adverse effects noticed during the intervention.

Strengths

The strengths of the study were the allocation of subjects done by randomization, measurement of dysmenorrhea by multidimensional rating scale, good compliance of the patients and trial-wise reduction in the intensity of pain.

Limitations

The limitations were a smaller sample size, shorter duration of treatment and as dysmenorrhea is a subjective criterion, the measurement of pain depends on the expression of patients by their tolerability so there was a possibility of major bias. Standard control was not used.

Further recommendations

Further, it is recommended to study the mechanism of action of drugs on prostaglandin and the effectiveness of intervention in long-phase durations. Besides, randomized placebo-controlled trials in phases II, and III are required in larger samples.

CONCLUSION

The present study concluded that Unani herbal formulation and *Hijama bila Shart* were effective safe, and cost-effective in *Tashanuji Usr al-Tamth*. The polyherbal Unani formulation contains anti-inflammatory and analgesic properties. However, *Hijama bila Shart* was more effective than oral medication as per the VRS rating scale yet the WaLIDD score showed no significant difference between groups A and B. Further, RCTs are recommended.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

AUTHORS CONTRIBUTION

AB and SS: Concept, design, literature search, clinical studies, data acquisition, data analysis, statistical analysis, manuscript preparation, manuscript editing and manuscript review. **AS:** manuscript preparation, literature search, manuscript editing and manuscript review.

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