

ORIGINAL ARTICLE

Clinical Efficacy of *Trigonella foenum graecum* (Fenugreek) and Dry Cupping Therapy on Intensity of Pain in Patients with Primary Dysmenorrhea

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ABSTRACT **Objective:** To determine the efficacy and safety of fenugreek seed and dry cupping on intensity of pain in primary dysmenorrhea. **Methods:** Sixty patients with primary dysmenorrhea were enrolled in this prospective, open-labeled, randomized, standard-controlled study, conducted in the National Institute of Unani Medicine Hospital between February 2010 and April 2011. In group A (20 cases), 3 g powder of fenugreek seed (3 capsules, 1 g each) was given orally twice daily from day 1 to 3 of menstrual cycle. Group B (20 cases) received the same dose of fenugreek seed as group A along with dry cupping therapy [two 4.2-cm and one 2.5-cm cups (internal diameter)], which was applied below the umbilicus for 15 min on day 1 and day 3 of menstrual cycle for 3 consecutive months. The control group C (20 cases) was given mefenamic acid, 500 mg twice daily, on the same protocol. The reduction in menstrual pain intensity was measured with well validated Visual Analogue Scale and safety of fenugreek seed was evaluated by clinical examination and laboratory investigations. **Results:** Baseline characteristics and biochemical parameters were comparable and homogenous among all groups ($P > 0.05$). The percentage reduction in lower abdominal pain was 66.89%, 66.49%, and 62.88% in A, B and C groups respectively at the end of the treatment. No adverse drug effects were noticed. **Conclusion:** The fenugreek seed and dry cupping are efficacious, safe, cost effective, and well tolerated.

KEYWORDS randomized, standard-controlled trial, Fenugreek (Hulba), Hijamat bila shurt (dry cupping), primary dysmenorrhea, Visual Analogue Scale for pain intensity

Primary dysmenorrhea refers to painful menstruation in the absence of any underlying pelvic pathology,⁽¹⁾ whereas secondary dysmenorrhea is defined as painful menses associated with pelvic pathology.⁽²⁾ Primary dysmenorrhea is the most common gynecological disorder in menstruating women.⁽³⁾ It is now recognized as an important women's health issue⁽⁴⁾ with high prevalence,⁽¹⁾ estimated to be from 45%–95% among reproductive aged women.⁽⁴⁾ It affects the quality of life in 60%–90% of females.⁽⁵⁾ Moreover, absences from the school diminish opportunities for successful educational, psychosocial and cognitive development during the critical period of adolescent growth.⁽⁶⁾ Current evidence suggests that primary dysmenorrhea is associated with ovulatory cycles and is largely due to myometrial contractions induced by excess endometrial prostaglandins (PGs) production that occurs mostly in the first 48 h of menses.⁽⁷⁾ The local action of PGs on uterus is threefold viz., increase basal intrauterine pressure, constriction of uterine arteries with subsequent tissue ischemia and pain, finally, increase in the sensitivity of peripheral pain nerve endings.⁽⁸⁾

Most of the ancient Unani scholars described the term dysmenorrhea under the heading of 'aujæ rehm' that is pain of uterine origin.⁽⁹⁾ Pain is perception of incongruity afflicting the human body, which is an abnormal condition. Sudden and abnormal change in temperament, i.e. distemperament and breach of continuity, are the two main causative factors of pain.⁽¹⁰⁾ The causes of dysmenorrhea mentioned in the Unani system are distemperament, viscous phlegm and black bile, gas, amenorrhea, inflammation of uterus,⁽⁹⁾ cervical stenosis, uterine abscess, menorrhagia, hysteria and complication of various kidney and liver diseases, etc.⁽¹¹⁾ Sometimes, expulsive faculty of uterus becomes weak by obstruction formed by khilte ghaleez (i.e., balgham and sauda), which may be one of the causative factors

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DOI: 10.1007/s11655-016-2259-x

of dysmenorrhea.⁽¹²⁾

Though various treatments have been suggested for the management of dysmenorrhea, however, to date, no treatment is satisfactorily available without any side effects. By far, the pharmacological approach has been better documented for efficacy. Among them non-steroidal anti-inflammatory drugs (NSAIDs) are effective in 80% of cases,⁽¹³⁾ but have numerous side effects (digestive disorders, diarrhea, hemolytic anemia, seizures, etc). In spite of several effective therapies, such as analgesics and oral contraceptives the morbidity from dysmenorrhea remains a challenge to public health worldwide.⁽¹⁴⁾ Considering the present unconvincing scenario regarding the use of drugs and adverse effects thereof, researchers are pursuing the golden formula of turning to nature and traditional pathies.

Human beings are blessed with enormous varieties of herbs that are in use to treat various ailments and improve health, and these incredible herbs have provided mankind a wide range of drugs to alleviate suffering. Hulba (*Trigonella feonum graceum*) is one of the oldest known medicinal herbs in the recorded history. Hulba seed (fenugreek) and dry cupping therapy were selected in the present study as it is cited in the classical Unani text that it is useful to relieve pain caused by uterine diseases. Fenugreek seed has antispasmodic,⁽¹⁵⁾ emmenagogue,⁽¹⁵⁾ and anti-inflammatory⁽¹⁶⁾ properties. The drug is globally distributed, easy available and one of the proved analgesics. It is pharmacologically proven for anti-inflammatory,⁽¹⁷⁾ analgesics,⁽¹⁸⁾ diuretic,⁽¹⁹⁾ and immunomodulatory activities.⁽²⁰⁾ These properties are attributed to the presence of saponins, tannins and flavonoids.⁽¹⁷⁾

According to Unani scholars, hijamat bila shurt (dry cupping therapy) below the umbilicus relieves dysmenorrhea, especially in young girls.⁽²¹⁾ It works on the principle of imalae mawad (diversion/shunting of morbid matter/fluid from the affected area). It offers a non invasive approach with no side effects and no potential for drug interactions. There is some evidence that cupping is effective in the treatment of painful conditions such as osteoarthritis of knee joint or low back pain, and dysmenorrhea.^(22,23)

METHODS

Trial Design

A prospective, single center, open-labeled,

parallel, simple randomized, standard controlled, pre and post treatment evaluation trial was conducted to prove the efficacy and safety of fenugreek seed and dry cupping therapy. The research question was whether they are effective in reducing the severity of pain in women suffering from primary dysmenorrhea. The hypothesis of this study was the use of fenugreek seed in group A and fenugreek seed along with dry cupping therapy in group B compared with standard drug at 1, 2, 3 and 4 months from the baseline would be effective at reducing severity of pain in women suffering from primary dysmenorrhea. This study was dissertation work and approved by the institutional ethical committee for Biomedical Research, National Institute of Unani Medicine, Bangalore.

Inclusion and Exclusion Criteria

The inclusion criteria were female participants with primary dysmenorrhea aged 12–30 years having regular menstrual cycle (28 ± 7 days). The exclusion criteria were participants with congenital anomalies of uterus, secondary dysmenorrhea, organic pelvic pathology, membranous dysmenorrhea, systemic illness and on oral contraceptives or other hormonal agents.

Participants

Participants with primary dysmenorrhea for at least 6 months who provided informed consent were randomized and selected on the basis of clinical diagnosis. Participants with primary dysmenorrhea, who fulfilled the inclusion criteria, were recruited between February 2010 and April 2011 from the Department of Gynecology and Obstetrics, National Institute of Unani Medicine, Bangalore. The participants were assigned to 3 equal groups with aid of simple randomization done by computer generated random list (Graph Pad Software Quickcalcs). During the selection procedure complete history and investigations were carried out, which was recorded on a prescribed case record form. In socioeconomic history, participants were inquired about their monthly income, education and occupation, which were assessed by Kuppuswamy's Socioeconomic Scale.

The participants were asked about the improvement or worsening in their symptoms at every visit after menstruation for 3 consecutive months of treatment and 1 month of follow up. Adverse drug reactions were noted during the treatment protocol. The participants were withdrawn, who failed to follow

the protocol and the cases in which drug adverse reactions were observed.

Randomization

The patients were randomly allocated in a 1:1:1 ratio after screening. An open list of random numbers was obtained from computer generated randomization list. The random allocation sequence was prepared in single blocks, by means of a single sequence of random assignment. The sequence was concealed from the researcher until the interventions were assigned using an open list of random number.

Intervention

In group A, 3 g powder of fenugreek seed (3 capsules, 1 g each) twice daily was given orally from day 1 to 3 of menstrual cycle. Group B received the same dose of fenugreek seed as group A along with dry cupping therapy [two 4.2-cm and one 2.5-cm cups (internal diameter)], which was applied below the umbilicus for 15 min on day 1 and 3 of menstruation. The control group C, received standard drug mefenamic acid 500 mg twice daily for the same duration as the test drug, which was purchased from the market (Mefal-500, manufactured by Blue Cross, India).

Visual Analogue Scale for Pain Intensity

The efficacy of the fenugreek seed and dry cupping therapy were assessed by observing the change in the Visual Analogue Scale (VAS) score for pain intensity. The intensity of pain in dysmenorrhea was objectively assessed by colored 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 coloured VAS 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. The test retest reliability of VAS for pain intensity was 0.896.⁽²⁴⁾ Baseline VAS score was taken before starting the treatment and were assessed at every follow up for 4 consecutive cycles.

Percentage of pain reduction (%) = (baseline

VAS score – mean pain reduction of 3 consecutive cycles)/baseline VAS score × 100%. Satisfactory pain relief was considered when percentage of pain reduction was more than or equal to 50% and taken as unsatisfactory when percentage of pain reduction was less than 50% as described by Beecher.⁽²⁵⁾

Outcome

The primary outcomes were reduction in menstrual pain intensity measured with well validated VAS, and safety of the fenugreek evaluated by clinical examination and laboratory investigations. General, physical and systemic examination (including pelvic examination only in married women) was conducted to exclude general and systemic diseases, respectively. Routine investigations like complete blood picture, erythrocyte sedimentation rate, random blood sugar and routine urine examination were done to exclude general diseases. Alkaline phosphatase, serum glutamic oxaloacetic transaminase (SGOT), serum glutamic pyruvic transaminase (SGPT), serum creatinine and blood urea were done at baseline and at the end of the treatment to assess the safety of test and control drugs. The specific investigations such as coagulation profile [bleeding time, clotting time (CT), prothrombin time, platelet count], thyroid profile and pelvis ultra sonography test were done to exclude coagulation disorders, thyroid dysfunction and pelvic pathology, respectively.

Sample Size Estimation

Considering the VAS mean score for pain intensity of an earlier study, a total sample size of 50 participants would be required to have 80% power with an alpha 0.05, calculated with online sample size calculator. Hence, in the present study a total sample size of 60 patients was taken allowing for a 15% drop out rate.

Data Analysis

The statistical software namely SAS 9.2 was used for the analysis of the data. Descriptive statistical analysis has been carried out. Results on continuous measurements were presented on mean ± standard deviation ($\bar{x} \pm s$) and results on categorical measurements were presented in number (%). $P < 0.05$ was considered statistically significant. The following assumptions on were are made. Assumptions: (1) dependent variables should be normally distributed, (2) samples drawn from the population should be random,

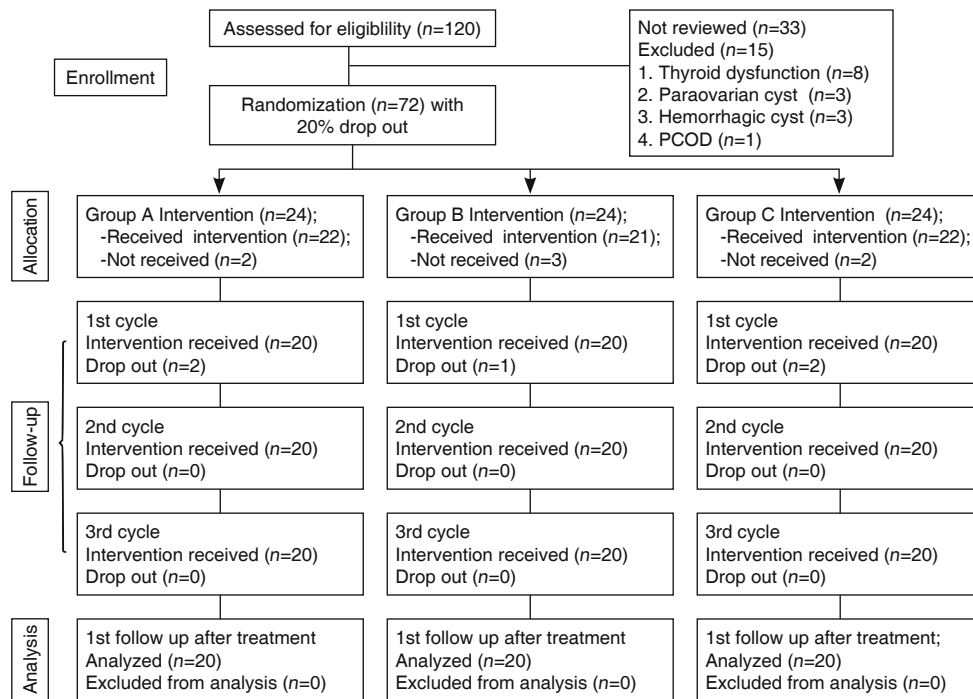


Figure 1. Flow Chart of Participants

and cases of the samples should be independent. Analysis of variance (ANOVA) was used to find the significance of study parameters among three groups of patients, Chi-square/ Fisher's exact test has been used to find the significance of study parameters on categorical scale between two or more groups.

RESULTS

Flow of Participants and Socio-Demographic Data

A total of 120 subjects were interrogated and screened for primary dymenorrhea; 87 agreed to participate and 15 were excluded because of thyroid dysfunction, paraovarian cyst, hemorrhagic cyst and polycystic ovaries. Seventy-two patients were randomly allocated in 3 groups, 24 in each group allowing 20% drop out (Figure 1). The socio-demographic data and investigations at baseline were not statistically significant ($P>0.05$) and was homogenous among all 3 groups (Table 1).

Effect on Lower Abdominal Pain and Backache Assessed by VAS

The VAS mean score at each follow-up from the baseline was statistically significant ($P<0.001$) in all groups. The percentage of the pain reduction of lower abdomen at end the treatment was 66.89%, 66.49%, and 62.88% in group A, B and C, respectively (Figure 2A).

The VAS mean scores for pain intensity of backache was statistically similar among the 3 groups at the baseline ($P=0.510$). In the third visit, VAS mean scores were reduced to 0.20 ± 0.89 , 0.05 ± 0.22 , and 0.16 ± 0.50 in group A, B and C, respectively ($P=0.725$ vs. baseline). The percentage of the pain reduction at the end of the treatment was 72.85%, 72.65%, and 70.2% in groups A, B and C, respectively (Figure 2B).

Safety

The biochemical parameters to assess the safety were statistically not significant after treatment from the baseline ($P>0.05$, Tables 3 and 4).

Pain Onset

All the participants had pain onset either few hours before or on first day of menstruation. In this study, it was found that at baseline 15 (75%), 15 (75%) and 8 (40%) participants had dysmenorrhea for 2 days in group A, B and C respectively. Dysmenorrhea was present for 3 days in 5 (25%), 3 (15%), and 8 (40%) subjects in group A, B and C respectively, whereas 1 (5%) and 4 (20%) participants had dysmenorrhea for 1 day in group B and C respectively.

DISCUSSION

Our study proved that fenugreek seed, fenugreek seed plus dry cupping was as effective as mefenamic

Table 1. Baseline Characteristics and Investigations of the Participants

Characteristics	Group A (20 Case)	Group B (20 Case)	Group C (20 Case)	P value
Age (Year, $\bar{x} \pm s$)	17.70 \pm 2.59	19.10 \pm 3.89	18.05 \pm 5.32	0.53
Religion [Case (%)]				
Hindu	1 (5)	1 (5)	5 (25)	0.19
Muslim	19 (95)	19 (95)	15 (75)	
Socioeconomic status [Case (%)]				
I (Upper)	0	1 (5)	3 (15)	
II (Upper middle)	14 (70)	17 (85)	16 (80)	0.09
III (Lower middle)	6 (30)	2 (10)	1 (5)	
IV (Upper lower)	0	0	0	
V (Lower)	0	0	0	
Occupation [Case (%)]				
Employed	0	2 (10)	2 (10)	
Laborer	1 (5)	1 (5)	0	0.29
Unemployed	6 (30)	10 (50)	6 (30)	
Student	13 (65)	7 (35)	12 (60)	
Habitat [Case (%)]				
Rural	2 (10)	1 (5)	0	
Urban	18 (90)	19 (95)	20 (100)	0.77
Marital status [Case (%)]				
Un married	20 (100)	19 (95)	18 (90)	0.76
Married and parous	0	1	2 (10)	
BMI [Case(%)]				
<18.5	6 (30)	7 (35)	4 (20)	
18.5–25.0	14 (70)	12 (60)	14 (70)	0.89
>25.0	0	1 (5)	2 (10)	
BMI (kg/m ² , $\bar{x} \pm s$)	20.13 \pm 2.05	20.70 \pm 3.51	20.26 \pm 5.46	
Age at menarche (Year, $\bar{x} \pm s$)	12.95 \pm 1.70	13.15 \pm 1.04	13.00 \pm 1.11	0.88
Duration of flow (Day, $\bar{x} \pm s$)	4.65 \pm 0.98	3.95 \pm 1.05	4.40 \pm 0.99	0.09
Duration of cycle (Day, $\bar{x} \pm s$)	29.3 \pm 1.17	28.95 \pm 1.70	28.3 \pm 1.62	0.70
Course of illness (Year, $\bar{x} \pm s$)	4.88 \pm 2.43	5.98 \pm 3.48	3.93 \pm 3.96	0.16
Duration of pain (Day, $\bar{x} \pm s$)	2.25 \pm 1.44	2.15 \pm 0.48	2.20 \pm 0.76	0.86
FH/O of dysmenorrhea [Case (%)]	13 (65)	9 (45)	6 (30)	0.08
Thyroid profile ($\bar{x} \pm s$)				
T3 (ng/dL)	114.01 \pm 20.9	111.20 \pm 16.97	118.72 \pm 17.56	0.46
T4 (μ g/dL)	8.55 \pm 1.49	8.33 \pm 1.15	8.08 \pm 1.21	0.55
TSH (mIU/L)	2.21 \pm 1.02	2.50 \pm 0.88	2.66 \pm 1.40	0.48
USG (normal) [Case (%)]	20 (100)	20 (100)	20 (100)	1.00

Notes: BMI: body mass index; FH/O: Family H/O; TSH: thyroid stimulating hormone; USG: ultrasonography

acid and safe in reducing primary dysmenorrhea as seen by reduction in total VAS score for pain intensity.

In this study, fenugreek seed was as effective as mefenamic acid, whereas fenugreek seed with dry cupping therapy was more effective than mefenamic acid not only during treatment but also after the

trial. The effect of fenugreek seed in reducing pain intensity during primary dysmenorrhea was owing to its antispasmodic,⁽¹⁵⁾ analgesic, and anti-inflammatory⁽¹⁶⁾ properties as mentioned in the classical Unani text. It is pharmacologically proved for anti-inflammatory,⁽¹⁷⁾ and analgesic activities.⁽¹⁸⁾ The anti-inflammatory and analgesic activity of fenugreek is because of

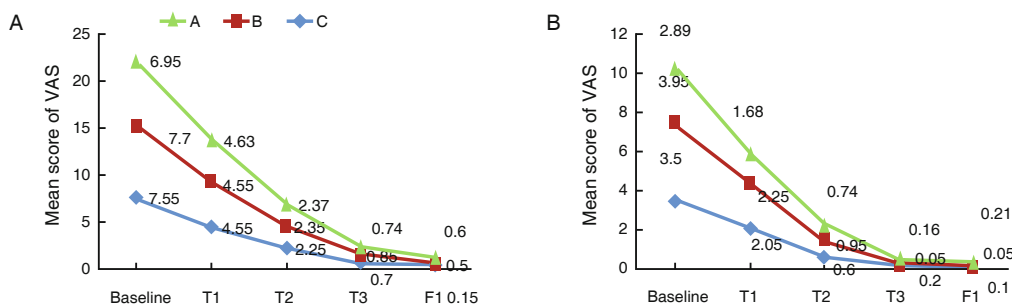


Figure 2. Comparison of VAS for Lower Abdominal Pain (A) and Backache (B) among Three Groups
 Notes: T1, T2, and T3: 3 treatment cycles; F1: Follow-up after treatment

Table 3. Comparison of Biochemical Parameters among Three Groups ($\bar{x} \pm s$)

Group	Case	Time	Hb (%)	TLC (cu/mm)	ESR (mm/h)	RBS (mg/dL)	CT (min)	Bleeding time (min)	Platelet count (Lakh/cumm)	Prothrombin time (s)
A	20	BT	11.80 ± 0.91	6665.00 ± 1909.88	12.80 ± 8.43	87.70 ± 16.19	4.17 ± 0.46	2.50 ± 0.43	2.33 ± 0.48	13.68 ± 1.01
		AT	11.46 ± 2.49	7580.00 ± 1801.10	10.00 ± 6.10	92.85 ± 11.52	4.33 ± 0.41	2.60 ± 0.62	2.14 ± 0.50	14.15 ± 0.83
		P value	0.53	0.12	0.21	0.26	0.25	0.67	0.22	0.11
B	20	BT	12.15 ± 1.17	7462.50 ± 1846.54	13.25 ± 6.46	86.35 ± 16.63	4.56 ± 0.68	2.44 ± 0.63	2.39 ± 0.65	14.04 ± 0.99
		AT	11.55 ± 1.46	7326.32 ± 2390.92	14.74 ± 7.87	88.37 ± 17.76	4.39 ± 0.79	2.35 ± 0.44	2.22 ± 0.68	14.69 ± 2.29
		P value	0.15	0.84	0.51	0.71	0.47	0.60	0.42	0.25
C	20	BT	11.98 ± 1.67	7474.74 ± 1552.94	13.47 ± 9.16	87.05 ± 11.95	4.14 ± 0.422	2.37 ± 0.67	2.45 ± 0.60	13.71 ± 3.05
		AT	11.70 ± 1.35	6795 ± 1334.74	17.05 ± 13.69	85.55 ± 17.62	3.90 ± 0.87	2.56 ± 0.75	2.25 ± 0.66	14.39 ± 1.36
		P value	0.19	0.18	0.24	0.70	0.40	0.89	0.27	0.70

Notes: BT: before treatment; AT: after treatment; the same below

Table 4. Comparison of Safety Parameters among Three Groups ($\bar{x} \pm s$)

Group	Case	Time	SGOT (IU/L)	SGPT (IU/L)	Alkaline phosphatase (IU/L)	Blood urea (mg/dL)	Serum creatinine (mg/dL)
A	20	BT	21.70 ± 7.38	18.75 ± 5.37	132.65 ± 69.56	18.15 ± 4.55	0.72 ± 0.12
		AT	21.55 ± 4.29	18.60 ± 4.98	125.45 ± 36.70	19.60 ± 4.90	0.71 ± 0.10
		P value	0.92	0.92	0.68	0.33	0.77
B	20	BT	21.10 ± 7.42	20.74 ± 7.87	122.80 ± 30.16	17.15 ± 2.74	0.72 ± 0.10
		AT	24.50 ± 6.92	26.53 ± 15.53	109.89 ± 32.44	19.95 ± 3.47	0.77 ± 0.07
		P value	0.14	0.14	0.20	0.31	0.07
C	20	BT	21.21 ± 9.88	17.58 ± 6.80	128.05 ± 78.31	22.05 ± 15.77	1.36 ± 2.82
		AT	20.30 ± 5.21	20.85 ± 5.82	157.70 ± 73.48	21.25 ± 7.35	0.75 ± 0.11
		P value	0.95	0.14	0.13	0.40	0.35

the presence of flavonoids and saponins bioactive compounds and different unsaturated acids of linoleic and linolenic acid series.⁽¹⁷⁾ The aqueous alcoholic extract of fenugreek proven to have steroidal saponins as diosgenin, tigogenin, yamogenin and gatogenin, to which, the anti-inflammatory activity may be attributed. The anti-inflammatory activity of ether extracts of different unsaturated fatty acids of linoleic and linolenic series present in fenugreek was detected by Frattini, et al.⁽²⁶⁾ It was reported previously that essential fatty acids may have an anti-inflammatory therapeutic activity. Ammar and coworkers⁽¹⁷⁾

mentioned that certain botanical lipid such as gamma linolenic acid can be converted rapidly to dihomo-gamma-linolenic acid, which has known anti-inflammatory and immunoregulating properties. Dihomo-gamma linolenic acid (DGLA) competes with arachidonate for oxidative enzymes, thereby reducing production of cyclooxygenase products derived from arachidonate. The benefit of anti-inflammatory effect of fenugreek seed is directed towards modulating once responsiveness to PG levels. The NSAIDs blocks PG and thromboxane formation by inhibiting cyclooxygenase activity, hence reducing pain

intensity.⁽¹⁷⁾ Apart from this fenugreek seed also contains magnesium, zinc, thiamine, vitamin E which are proved to be effective in dysmenorrhea.^(2,13)

Dry cupping works on the principle of imalae mawad (diversion/shunting of morbid matter/fluid from the affected area).⁽²⁷⁾ It is mentioned that shunting 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.⁽²⁸⁾ Likewise, it is hypothesized that dry cupping therapy also suppresses the prostaglandins and release of beta endorphins producing analgesia as it shunts the blood flow from the uterus. Hence, dry cupping therapy was effective in relieving primary dysmenorrhea. This proves the claim of ancient Unani scholars that it relieves dysmenorrhea, especially in young girls.⁽²⁶⁾ Additionally, at a biological level similar to Acupressure and Acupuncture, cupping therapy works by exciting or activating (1) the immune system, (2) Enkephalin secretion, (3) neurotransmitter release, (4) vasoconstriction and dilatation, and (5) the gates for pain in the central nervous system which interpret pain sensation.⁽²²⁾

Secondly, it is also mentioned that $A\beta$ sensory fibres from the peripheral tactile receptors can depress the transmission of pain signals. This effect presumably results from local lateral inhibition in the spinal cord that why such simple maneuver as rubbing the skin near painful areas is often effective in relieving pain. It also probably explains why liniments are often useful for relief of pain. This mechanism, psychogenic excitation of the central analgesia system is probably also basis of pain relief by acupuncture.⁽²⁹⁾ The same effect might have resulted by applying and creating suction by vacuum in dry cupping therapy. A preliminary study showed that dry cupping therapy was effective in primary and secondary dysmenorrhea.⁽²³⁾

It was found that majority of subjects had dysmenorrhea for 2 days i.e., 38 (63.33%), This finding correlates with the view of Morrow and colleagues⁽³⁰⁾ that dysmenorrhea last for up to 72 h, typically peaking in the first 24 to 48 h of the menstrual cycle as levels of prostaglandins are highest during this period. The concept of applying cups on day 1 and 3 of menstruation is because as severe pain persists for 24 to 72 h. Yusuff⁽³¹⁾ had mentioned that the intensity of the menstrual cramps of associated

symptoms of dysmenorrhea is directly proportional to the amount of prostaglandin $F2\alpha$ released.

All the groups were assessed for various biochemical parameters to evaluate the safety of the test and control groups. All parameters except clotting factor ($P=0.03$) at baseline and alkaline phosphatase ($P=0.04$) after treatment were statistically significant but clinically not significant as values were within the normal range. Hence, it is inferred that all the groups were safe.

The strength of this study was good compliance of the subjects, allocation done by randomization, and an interventional trial including early to late adolescents age and parous women with moderate to severe dysmenorrhea. The treatment effect was similar regardless of group, age, duration of illness and severity of dysmenorrhea. The limitations in the study were lack of power and smaller sample size.

The fenugreek and dry cupping were effective in primary dysmenorrhea. Further, phase III trials are recommended for longer duration and the efficacy of fenugreek seed and dry cupping therapy can be appraised in secondary dysmenorrhea. Moreover, to find the specific role of fenugreek seed and dry cupping therapy on prostaglandins, the levels are to be estimated in menstrual blood during menstruation before and after trial. Fenugreek is proven to be gastro protective, therefore, it can be recommended not only in dysmenorrhea but also in other types of painful condition instead of NSAIDs that causes gastric mucosal damage.

The present study concludes that fenugreek seed alone and fenugreek seed with dry cupping therapy is suitable option in reducing severity of pain in primary dysmenorrhea. Fenugreek seed and dry cupping therapy is cost-effective, safe and well tolerated by women. The effective rates are satisfactory.

Conflict of Interest

The authors declare that they have no competing interests. Funding has been received from Ministry of health and Family Welfare, Department of Ayurveda, Yoga, Unani, Sidda and Homopathy (AYUSH), India as unrestricted educational grant for a post graduate thesis.

Acknowledgements

The authors are thankful to the Director and AYUSH Department for providing all facilities.

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(Received July 24, 2012)
 Edited by ZHANG Wen