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Original Article

A Superiority Trial of Combined Therapy of Dry Cupping along with Oral Anethum graveolens Seeds vs Dry Cupping alone in Spasmodic Dysmenorrhea

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ABSTRACT

Objective: With reported prevalence of 90%, dysmenorrhea is considered as the most common menstrual complaint which accounts for frequent short-term absenteeism from school in young girls and affects the women's ability to perform routine work. This study was conducted with the main objective to compare the effect of combined therapy of local application of dry cupping along with oral use of Anethum graveolens seeds with dry cupping alone in spasmodic dysmenorrhea.

Method: This prospective patient blinded randomized comparative study was carried out at Hospital of Luqman Unani Medical College and Research Center Vijayapur, Karnataka, India. In this trial clinically confirmed 40 patients of spasmodic dysmenorrhea were assigned randomly either received 2 capsules of 500mg of powdered Anethum graveolens seeds orally BD from 1st to 3rd day of menses along with dry cupping below the umbilicus for two consecutive menstrual cycles or received placebo capsules containing roasted wheat flour along with dry cupping below the umbilicus for same duration. Reduction in the VAS pain score was the primary outcome and imrovement in the quality-of-life was kept as secondary outcome measure which was assessed by SF-12 questionnaire.

Result: In both the groups significant reduction in the VAS pain score and improvement in SF-12 score was observed from baseline to 1st and 2nd cycle. However, the changes in efficacy parameters were significantly more pronounced in combined therapy group compared to single therapy group.

Conclusion: These results showed significantly higher efficacy of combined therapy in spasmodic dysmenorrhea, so can be an alternative to treat severe pain of spasmodic dysmenorrhea.

Keywords spasmodic dysmenorrhea; dry cupping; quality of life; *Anethum graveolens*; Unani; *hijama*

INTRODUCTION

In spasmodic dysmenorrhea patient experiences cramping pain during menses which radiates to the lower back or anterior thigh. In some patients, this kind of dysmenorrhea accompany with nausea, vomiting, headache, diarrhea, headache, fatigue, nervousness, and dizziness either shortly before or at the onset of menses and lasts for one to three days. The prevalence varies between 50% to 90%.[1,2,3] Every month for a few days, the quality of life is affected by spasmodic dysmenorrhea as poorer mood and poorer sleep quality during menstruation has been reported in women with spasmodic dysmenorrhea compared to non dysmenorrhoeic women.[4] Though the etiology of spasmodic dysmenorrhea is not precisely understood, excessive prostaglandin release, particularly $PGF_{2\alpha}$ is believed to cause dysmenorrhoeic pain.[5] A variety of pharmacological and non-pharmacological methods are available to treat spasmodic dysmenorrhea including non-steroidal anti-inflammatory drugs (NSAIDs) and oral contraceptive pills, etc.[6] Though considerable effect of NSAIDs and oral contraceptive pills has been reported, the failure rate is still be as high as 20% to 25%.[7] Additionally, these therapies may be contradictory or not tolerated by some women with spasmodic dysmenorrhea.[8]

Renowned Unani physicians have mentioned dysmenorrhea in classical texts as "*dard reham*"[9,10] or "*aujae rehm*".[10] *Dard*

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rehm can occur due to uterine abscess, uterine rupture, uterine cancer, uterine displacement etc., and also occurs during menses. The later one is the actual description of dysmenorrhea in the Unani text and to treat that they have advised the use of drugs having *mudire haiz* property either orally or locally.[9] To treat dysmenorrhea, several drugs have been mentioned for oral as well as local application. *Tukhm shibat* (seeds of *Anethum graveolens*) is one of them which can be given locally or orally to relief *dard-e-reham*.[11,12]

Anethum graveolens or Dill from Umbelliferae family, is an annual herb that grows abundantly in the Mediterranean region, Europe as well as central and southern region of Asia. Traditionally, Dill has gained the popularity as an aromatic herb and spice to treat gastrointestinal disturbances like flatulence, indigestion and colicky pain.[13] As a medicinal herb Dill has been recorded 5000 years ago in Egypt when it was called as a "soothing medicine".[14] In experimental studies dill showed antispasmodic and analgesic activity.[14,15] In clinical trial also dill was found effective in reducing pain severity in patients of spasmodic dysmenorrhea.[16-18] However, *Anethum graveolens* caused less reduction in the severity of pain as compared to mefenamic acid.[17]

Dry cupping (*hijama bila shurt*) has been mentioned in Unani texts to be effective in *dard rehm*. It is a therapeutic procedure involving the blood draw by creating vacuum over the skin to the area without any cutaneous incision. It causes *imalae mawad* i.e., diversion of morbid matter from the affected area.[19] Studies reported the effectiveness of dry cupping in spasmodic dysmenorrhea.[20] The main aim of this trial was to scientifically compare the effect of combined therapy of dry cupping and oral use of *Anethum graveolens* seeds with dry cupping alone in reducing the pain of spasmodic dysmenorrhea. It was hypothesized would be more effective than single therapy. The inference was accomplished by appropriate statistical analysis.

MATERIALS AND METHODS

Study design

This prospective patient blinded randomized comparative trial was carried out at Luqman Unani Medical College Hospital and Research Centre Vijaypur in the department of *Ilmul Qabalat wa Amraze Niswan*, where the combined therapy of oral Anethum graveolens seed powder along with dry cupping below the umbilicus was compared with single therapy of dry cupping below the umbilicus.

Participants

40 females with complain of painful menstruation attended the gynecologic outpatient department, were enrolled in the study after ensuring the inclusion criteria. Married and unmarried women above the age of 18 years with regular menstrual cycle (21-35 days) diagnosed with spasmodic dysmenorrhea were kept as inclusion criteria. Pregnant and lactating women, taking hormonal contraceptives and intrauterine contraceptive devices and women diagnosed with organic pelvic pathology or severe systemic illnesses were excluded. During first visit (which was a standard control cycle where tablet containing mefenamic acid was given to all patients), in-depth history was taken, thorough examination along with the necessary investigations including urine routine examination, random blood sugar, hemoglobin percentage and pelvic ultrasonography was done. Patients fulfilling all the inclusion criteria were provided a sheet containing all the information regarding the trial. Also, they were given with enough time and opportunity to go through the trial related information sheet and they were made ensure that they are free to clear any queries or doubt regarding the study and they have right to refuse consent or to withdraw the treatment during any part or any time of the trial without explaining the reason behind. After getting the willingness, patients were asked to enroll in the trial and sign the informed consent form. According to the random chart patients were given either test drug or control drug. During treatment patients were followed before menstruation, day 1, day 2 and after completion of the menses for two consecutive cycles. Assessment of pain was done during each cycle and the quality of life was assessed before and after completion of the therapy. After completion of the therapy patients were followed for next month to observe the recurrence of pain symptom.

Preparation of drugs

Test drug (seeds of *Anethum graveolens*) was purchased from crude drug market of Vijaypur city which was identified by Dr. Sayyed Saleemuddin, Professor, Department of *Ilmul Advia* (Pharmacology), Luqman Unani Medical College Vijaypur, Karnataka India. The sample is kept in the department of pharmacology for future reference. In the pharmacy of the Luqman Unani Medical College, Vijaypur drug was finely powdered and filled in the capsules of 500mg which was further packed into the opaque plastic lock bags containing 12 capsules in each bag and given to the patients. Patients were instructed to take 2 capsules BD with water for first 3 days of menses. For placebo roasted wheat flour was filled in the 500mg capsules which was packed into the lock bags and was given to the patients in the same dosage and duration like test drug. Two glass cups of medium size were applied below the umbilicus for the duration of 15 minutes on 1st and 2nd day of the menstrual period. The duration of therapy was two consecutive cycles. Compliance of the oral medications was assessed by examining the lock bags in which the capsules were dispensed. Similarity of the interventions was achieved by keeping the same color of the capsule filled with either powdered *Anethum graveolens* seeds or roasted wheat flour. Further the capsules were dispensed in lock bags and to a single patient at a time.

Outcome measures

Reduction in the pain assessed by VAS was kept as primary outcome measure which is a unidimensional measure to measure the pain intensity. Due to its simplicity and adaptability, broad

range of populations and settings are using this instrument. With this instrument, pain is rated subjectively where a straight horizontal line of 10 cm is drawn. The extreme limits of the parameter are kept at the ends of the line; hence the left end is usually labelled as 'no pain', and the right end as 'extreme pain' and ask the patient to mark on the line. The score is determined by measuring the distance (mm) between the "no pain" and the patient's mark point with the help of the ruler, providing a range of scores from 0-10cm. Further the final obtained score is graded as no pain if the score is 0-4 mm; mild pain if the score is 5-44 mm; moderate pain if the score is 45-74 mm; and severe pain if the score is 75-100 mm. Secondary outcome measure was quality of life improvement is assessed by SF-12 questionnaire which is a 12 items self-evaluation instrument that provide assessment of quality of life in eight domains that include physical functioning, social functioning, role limitations due to emotional problems, role limitations due to physical problems, bodily pain, vitality, mental health and general health perception. Among 12 items, each item is scored separately and finally categorized into physical component summary score (PCS) and mental component summary score (MCS). Better life quality scores higher.

Estimation of sample size

For this study the calculation of sample size was carried out by taking assumptions by survey experts from the previous literature. Assumed effect size was kept as 1.99 and assumed standard deviation was taken as 2.12 to demonstrate a difference by a new treatment with respect to costs and risks. With above assumptions, a sample size with 36 participants including 18 in each group was observed sufficient to get a clinically important difference of 1.99 between compared groups in reducing VAS score for dysmenorrhoeic pain. Further by assuming 2.12 as a standard deviation, using a two tailed t test of difference between means with 80% power and a 5% level of significance, and considering a dropout rate of 10%, the sample size required was exactly 40 (20 per group).

Safety assessment

In both the groups, to find out the possible cause effect relationship with drug administration, record of the adverse effects along with the characteristics (onset, severity and duration) was maintained and recorded during the entire trial period. Patients who were unable in following the protocol therapy and those who developed adverse drug reaction, withdrawn from the trial.

Randomization and allocation concealment

Random allocation of the patients were done into 1:1 ratio with the help of online randomization generator

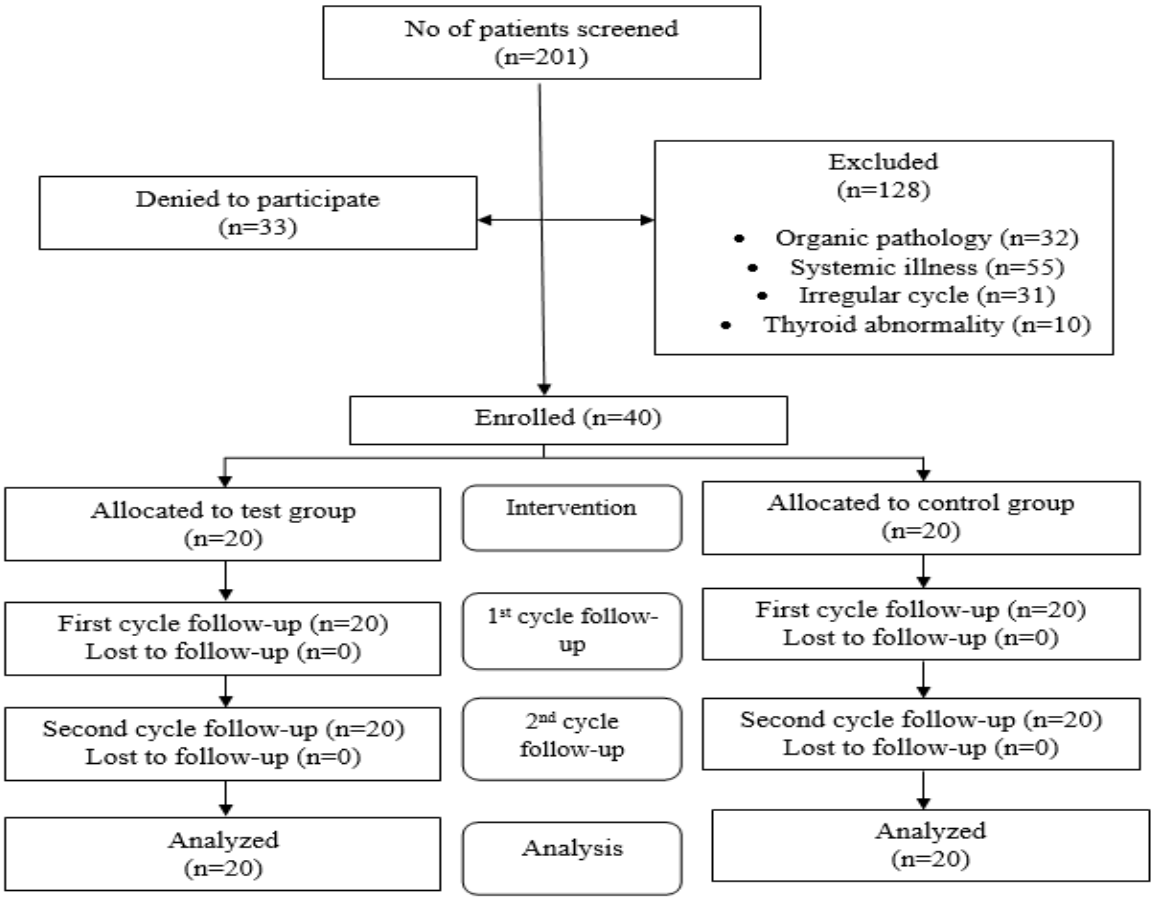

Figure 1. Flow chart as per the CONSORT statement

(www.randomization.com) to both the group with 20 patients in each group. Patients were unaware about the arm of the study in which they have been allocated. The researcher who was assigned for data collection did not have the knowledge about the sequence as the sequence generation was accomplished by another researcher which was kept hidden from the data collector until the interventions were assigned to each patient.

Ethical clearance

The study was ethically approved by Institutional Ethical Committee under reference number IEC No: BJP/LUMC/PG/IEC/04/2018-19/IQAN/01, and was carried out according to the Declaration of Helsinki. The trial was made prospectively registered with Clinical Trial Registry India with registration code CTRI/2020/02/023172.

Statistical analysis

The presentation of results on continuous measurements and categorical measurements are done as Mean ± SD (Min-Max) and in number (%) respectively. 5 % level of significance was considered to assess the significance. Student t test (two tailed, independent) and Student t test (two tailed, dependent) has been used to find the significance of study parameters on continuous scale for intergroup and intragroup analysis respectively. To find the significance of study parameters on categorical scale between two or more groups Chi-square/ Fisher Exact test has been used. Significant figures: moderately significant (P value: $0.01<P \leq 0.05$), strongly significant (P-value: $P \leq 0.01$). For data analysis, SPSS 18.0, and R environment ver.3.2.2 statistical software has been used and Microsoft word and Excel have been used to generate graphs, tables.

RESULT

Participant flow

For eligibility checking, 201 patients were screened among whom 33 patients denied to get participated and 128 were not meeting the criteria, so excluded from the study. A total of 40 patients were randomly allocated Figure 1.

Baseline characteristics

At baseline, both the groups were found statistically similar with respect to age, religion, education, socioeconomic status, occupation, diet, age of menarche, length of the menstrual cycle, duration of flow and amount of flow Table 1.

Primary Outcome

Both the groups were statistically similar with respect to the pain severity assessed by VAS score with a p value of 0.163. In both the groups VAS score was significantly reduced (p value <0.001) from baseline with a mean difference of 2.46 and 4.10 in cycle 1 and cycle 2 in test group and 1.52 and 2.55 in cycle 1 and cycle 2 in control group respectively. When these changes were compared by student t test, significantly more reduction in the VAS score was observed in test group Table 2.

Secondary Outcome Parameters

Both the groups were similar at baseline with respect to physical and mental component summary of the SF-12 score. The mean score of total participants were 26.64±4.31 and 32.55±2.53 for PCS and MCS respectively. Significant improvement in the PCS and MCS score was observed in both the groups during first and second cycle. Further the PCS and MCS scores were significantly more in test group Table 3.

DISCUSSION

This was the first study where the combined therapy of local application of dry cupping along with oral use of *Anethum graveolens* seeds was compared with dry cupping alone in spasmodic dysmenorrhea. In previous studies *Anethum graveolens* seeds has been given orally to treat primary dysmenorrhea, showed inconsistent result. Further, there are studies reporting the effectiveness of dry cupping in primary dysmenorrhea.[19,20] The result of the present study showed significantly better result of combined therapy indicating the effect of *Anethum graveolens* seeds in spasmodic dysmenorrhea. Similar to our results *Heidarifar et al* reported that dill was found effective in reducing the severity of dysmenorrhea in comparison to mefenamic acid in a double blind randomized controlled trial.[16] Another randomized clinical trial by *Mohammadinia et al* found that *Anethum graveolens* is effective in reducing pain in patients of dysmenorrhea with less side effects compared to mefenamic acid.[17] Further in experimental trial, *Anethum graveolens* aqueous extract exhibited significant analgesic effect in 250 mg/kg dosage compared with the tramadol in Wister rats.[14] *Anethum graveolens* reduced inflammatory pain in mice, probably by inhibiting inflammatory mediators.[21] Further in another experimental study hydroalcoholic extract of *Anethum graveolens* showed short analgesic effect in mice.[22] The decoction of *Anethum sowa* Linn. leaves and stem also exhibited significant analgesic response against acetic acid generated writhing in mice model.[23] Dill fruit hydroalcoholic extract showed relaxatory effect on ileum contraction induced by $BaCl_2$ in rats which was found greater than spasmogens.[24] Similarly, Dill methanolic extract significantly reduced spontaneous and acetylcholine induced contraction in isolated rat ileum.[25]

Table 1. Demographic distribution of the patients in test and control group

Variables	Test Group	Control Group	Total	P-value
Age in Years				
18-24	16(80%)	11(55%)	27(67.5%)	0.184[a]
25-29	2(10%)	4(20%)	6(15%)	
30-34	1(5%)	4(20%)	5(12.5%)	
35-39	1(5%)	1(5%)	2(5%)	
Mean ± SD	22.90±4.86	25.00±4.94	23.95±4.95	
Religion				
Muslim	20(100%)	20(100%)	40(100%)	1[b]
Education				
Under-Graduation	16(80%)	15(75%)	31(77.5%)	1[b]
Higher Secondary	4(20%)	3(15%)	7(17.5%)	
Post-Graduation	0(0%)	1(5%)	1(2.5%)	
Secondary	0(0%)	1(5%)	1(2.5%)	
Social Economic Status				
Lower Middle	0(0%)	2(10%)	2(5%)	0.565[a]
Upper Middle	14(70%)	13(65%)	27(67.5%)	
Upper	6(30%)	5(25%)	11(27.5%)	
Diet				
Mixed	20(100%)	20(100%)	40(100%)	1[a]
Vegetarian	0(0%)	0(0%)	0(0%)	
Habitat				
Urban	20(100%)	20(100%)	40(100%)	1[a]
Rural	0(0%)	0(0%)	0(0%)	
Marital Status				
Married	3(15%)	5(25%)	8(20%)	0.695[a]
Unmarried	17(85%)	15(75%)	32(80%)	
Body Mass Index				
<18.5	0(0%)	0(0%)	0(0%)	0.131[a]
18.5-24.9	19(95%)	17(85%)	36(90%)	
25.0-29.9	1(5%)	3(15%)	4(10%)	
>30.0	0(0%)	0(0%)	0(0%)	
Mean ± SD	21.80±1.33	22.50±1.52	22.15±1.45	
Family History of Dysmenorrhea				
1 degree relative	15(75%)	14(70%)	29(72.5%)	0.723[b]
2 degree relative	5(25%)	6(30%)	11(27.5%)	
Age of Menarche (Years)				
11	3(15%)	1(5%)	4(10%)	0.780[a]
12	13(65%)	14(70%)	27(67.5%)	
13	4(20%)	5(25%)	9(22.5%)	
Mean ± SD	12.05±0.60	12.20±0.52	12.12±0.56	0.407
Duration of the Cycle (Days)				
28	13(65%)	17(85%)	30(75%)	0.144[b]
30	7(35%)	3(15%)	10(25%)	
Mean ± SD	28.70±0.97	28.30±0.73	28.50±0.87	0.152
Duration of Flow (Days)				
1	0(0%)	0(0%)	0(0%)	0.163[a]
2	0(0%)	0(0%)	0(0%)	
3	1(5%)	4(20%)	5(12.5%)	
4	12(60%)	11(55%)	23(57.5%)	
5	7(35%)	3(15%)	10(25%)	
6	0(0%)	2(10%)	2(5%)	
Mean ± SD	4.30±0.57	4.15±0.87	4.22±0.73	0.525
Amount of Flow				
Severe	0(0%)	0(0%)	0(0%)	1[a]
Moderate	20(100%)	20(100%)	40(100%)	
Total	20(100%)	20(100%)	40(100%)	

CONCLUSION

The effect of cupping therapy or *Anethum graveolens* as a single therapy has been studied in the previous trials with inconsistent results. It has been observed from this study result that combined therapy showed better result than single dry cupping therapy. It can be a better alternative for severe grade of dysmenorrhea. However,

Table 02. Comparative analysis of pain Severity by VAS Score [a]Student t test(paired); [b]Student t test (Unpaired); **

Pain Severity by VAS Score	Test Group	Control Group	Total	P Value
Baseline	6.37±0.22	6.61±0.26	6.49±0.27	0.163
Cycle 1	3.91±0.49	5.08±0.41	4.50±0.74	<0.001**[b]
Cycle2	2.27±0.26	4.06±0.37	3.16±0.95	<0.001**[b]
Difference				
Cycle 1	2.46	1.52	1.99	-
Cycle2	4.10	2.55	3.32	-
P value				
Cycle 1	<0.001**[a]	<0.001**[a]	<0.001**[a]	-
Cycle2	<0.001**[a]	<0.001**[a]	<0.001**[a]	-

Table 03. Comparison of PCS and MCS component of SF-12 Scale in test and control groups.

SF-12 Score	Test Group	Control Group	Total	P Value
Physical Component Summary				
Baseline	26.02±4.05	27.26±4.57	26.64±4.31	0.370[b]
Cycle 1	73.52±4.12	51.49±3.24	62.5±11.74	<0.001**[b]
Cycle2	84.14±4.61	68.74±7.69	76.44±10	<0.001**[b]
Difference				
Cycle 1	-47.50	-24.22	-35.86	-
Cycle2	-58.11	-41.48	-49.79	-
P value				
Cycle 1	<0.001**[a]	<0.001**[a]	<0.001**[a]	-
Cycle2	<0.001**[a]	<0.001**[a]	<0.001**[a]	-
Mental Component Summary				
Baseline	33.14±2.51	31.96±2.48	32.55±2.53	0.143[b]
Cycle 1	79.47±4.5	49.69±9.25	64.58±16.7	<0.001**[b]
Cycle2	86.18±2.93	64.64±6.3	75.41±11.94	<0.001**[b]
Difference				
Cycle 1	-46.33	-17.73	-32.03	-
Cycle2	-53.04	-32.68	-42.86	-
P value				
Cycle 1	<0.001**[a]	<0.001**[a]	<0.001**[a]	-
Cycle2	<0.001**[a]	<0.001**[a]	<0.001**[a]	-

the small sample size and loss of long term follow up was the limitation of the present trial. So, the authors are recommending to conduct a well-designed trial with large sample size along with long term follow up.

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CONFLICT OF INTEREST

None declared

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