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Effect of Majoon Murmakki in Dysmenorrhoea (Usre Tams): A Standard Controlled Clinical Study

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ABSTRACT

Background: Dysmenorrhoea is a condition characterised by severe uterine pain during menstruation with a prevalence range between 50 to 87.8%. Many drugs have been tried to alleviate dysmenorrhea in women, but adverse events occur, therefore investigation of alternative treatments for dysmenorrhoea is warranted. The objective of this study is to compare the effect of Majoon Murmakki in dysmenorrhoea (*usre tams)*.

Materials and Methods: In a randomised standard controlled study, 45 patients of dysmenorrhea were randomly assigned to test (n=30) and control group (n=15). In test Majoon Murrmakki 3gm and control group mefenamic acid 500mg two times a day was given orally from 1st to 5th days of menstruation for two consecutive cycles. The primary outcome was assessed by subjective parameters viz. pain abdomen, nausea, vomiting, low backache diarrhoea fatigue and secondary outcome assessed by objective parameters viz. visual analogue scale for pain were assessed at each follow-up and improvement in the quality of life were assessed by SF-12 questionnaire before and after treatment.

Results: Significant relief was observed in dysmenorrhoea and associated symptoms. 26 (89.7%) of the patients in test and 13 (100%) in the control group were relieved with p<0.001 in subjective parameters as the primary outcome. 26 (89.7%) of the patients in test and 13 (100%) in the control group were relieved with p<0.001 in objective parameters as the secondary outcome. Intergroup comparison shows no significant difference in improving subjective and objective parameters with p=1.00 and p=0.540 respectively.

Conclusion: Majoon Murmakki is as effective as mefenamic acid in alleviating dysmenorrhea and associated symptoms.

Key Words: Usre tams, Dysmenorrhea, Majoon Murmakki, SF 12 questionnaire, Visual analogue scale

INTRODUCTION

Dysmenorrhoea is defined as the occurrence of painful cramps of uterine origin during menses and is one of the most common causes of pelvic pain which affects the quality of life of women in their reproductive age,[1] often accompanied by other biological symptoms including dizziness, fatigue, backache, headache, vomiting and diarrhoea all occurring just before or during the menstruation.[2] It may involve various types of pain, and may also precede menstruation for several days or occur during menstruation.[3] It has a high prevalence of worldwide[4] and affects the majority of women of reproductive age with 2-29% having severe pain.[5]. Dysmenorrhoea represent a substantial public health burden,[4] that exceeds all other gynaecologic complaints[1] and is one of the leading cause of absenteeism from school and work, loss of earnings and diminished QoL but still, it is undertreated.[1,4]

Dysmenorrhoea is conventionally treated with NSAIDs or oral contraceptive pills, the efficacy of which is supported by research evidence, however NSAIDs and OCPs have limitations; some women with dysmenorrhoea do not respond to NSAIDs and OCPs (with an estimated failure rate of >15% for NSAIDs); some cannot use these medications because of contraindication or adverse effects, some prefer not to use any medication. Therefore, investigation of complementary alternative treatments for dysmenorrhoea is warranted. Better management of dysmenorrhoea may not only improve women's quality of life but also reduce their risk of developing future pain.[6]

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Unani medicine plays an important role in treating various gynaecological disease, of which drugs like *habbul ghar, qust, zarawand, irsa,*[7] *turbud, rewand khatayi*, *hulba, post fali amaltas, jawtri*,[8,9] *ma'jūnmusakkin dard al-rahim, jawārish amber*[8] have been mentioned for the treatment of dysmenorrhea, of these M*urmakki* has been selected for the treatment of dysmenorrhoea in the present study. By thorough review of Unani literature, *murmakki* was found to have the properties like *musakkin awjāh* (analgesic), *muhallil awram* (anti-inflammatory), *mudirr-i-bowl wa hayḍ*(diuretic and emmenagogue), *mufattiḥ sudad* (deobstruent) among others.[10]

Besides, recent studies show that furanose squiterpenes with analgesic activity such as furanoelemanes, furanoeudesmanes and furanogermacranes, are present in the gum resin extract of myrrh.[11] With all these properties *murr* is anticipated to alleviate dysmenorrhoea and hence selected for the present study.

MATERIAL AND METHODS

This study was conducted in the department of Ilmul Qabalat wa Amraze Niswan, NIUM, Bengaluru from May 2019 to February 2020.

Ethical clearance and CTRI registration number: The institutional ethical committee approved the present study [IEC No: NIUM/IEC/2017-18/010/ANQ/02]; following which CTRI registration was accomplished vide number CTRI/2011/04/018446.After which the clinical study was carried out.

Study design: Single-blind randomized standard controlled trial.

Duration of study: One and a half year.

Sample size: 45

- **The sample size was calculated using formula** $N=2[(Z\alpha-Z\beta)\ \sigma|\mu_1-\mu_2]$[12]

Method of collection of data:

- History Taking & Clinical examination

Inclusion criteria:

- Patients in the age group of 18-35 years [13] with regular painful menstrual cycles i.e. 21-35 days with one or more associated symptoms like nausea, vomiting, low backache, diarrhoea, fatigue[14] &VAS score >7

Exclusion criteria:

- Systemic Illness like HTN/ DM, & H/o allergy /sensitive to NSAIDs, hormonal treatment last 2 months
- Lactating women

Treatment was subsequently started inpatient fulfilling the inclusion criteria. The test or control drug as randomised was given for 5 days from the first day of the menstrual cycle for two consecutive cycles. Assessment of subjective and objective parameters was done before, during and after treatment. Liver function test (LFT) & renal function test (RFT) were assessed pre and post-treatment for assessment of safety

Subjective parameters studied were pain abdomen, nausea, vomiting, low Backache, fatigue, diarrhoea and objective parameters were visual analogue scale (VAS) for pain & SF-12 scale for quality of life.

Test drug: *Murmakki* (*Commiphora myrrha*) was purchased from the local market and identified by the chief pharmacist of NIUM Bengaluru. M*a'jūn* was prepared with honey according to the standard method of preparation.

Dosage: 3 gm twice a day, orally

Standard control: Mefenamic acid 500 mg twice a day

Duration of treatment: from 1st to 5th days of menstruation for 2 consecutive cycles

Outcome measure:

Primary outcome measure:

Relieved: Relief in ≥ 3 subjective parameters, Not Relieved: Relief in <3 subjective parameters.

Secondary outcome measure

Relieved: if vas score <4 and SF-12 score >800, Not Relieved: if vas score >4 and / or SF-12 score <800

Statistical analysis

Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on the mean ± SD (min-max) and results on categorical measurements are presented in number (%). Significance is assessed at 5 % level of significance. The Statistical software namely SPSS 22.0, and R environment ver.3.2.2 were used for the analysis of the data (Table 1,2).

RESULTS AND DISCUSSION

Baseline characteristics

Age: The study participants were similar in both groups concerning baseline characteristics like age, marital status, socioeconomic status, BMI, diet, lifestyle and temperament with p >0.05 (Table 01).

Socio-economic status: In present study maximum number of patients, 22 (52.4%) belongs to the lower middle class, 17 (40.5%), 2 (4.8%) and 1 (2.4%) belongs to upper-middle, upper and lower class respectively. (Table 01) This is similar with the reports of Rehman et al.29 in which 18(40%) belong to lower middle, 14 (33.35%),10 (20%), 3(6.7%) upper middle, upper lower and upper class respectively.

Marital status: In the present study 25(59.5%) patients were unmarried and 17(40.5%) were married. (Table 01)

BMI: In present study majority of the patients 23 (54.8%) had normal BMI, followed by 10 (23.8%), 8 (19%) and 1 (2.4%) were overweight, underweight and obese respectively (Table 01) Mean +SD of BMI was 22.38+3.38. (Table 01)

Table 1: Baseline characteristics in two groups studied

Variables	Test Group (n=29)	Control Group (n=13)	Total (n=42)	P value
Age in years				
• 18-25	17(58.6%)	9(69.2%)	26(61.9%)	0.513
• 25-35	12(41.4%)	4(30.8%)	16(38.1%)	
Marital Status				
• Married	13(44.8%)	4(30.8%)	17(40.5%)	0.391
• Unmarried	16(55.2%)	9(69.2%)	25(59.5%)	
Socio Economic Status				
• I	1(3.4%)	1(7.7%)	2(4.8%)	0.306
• II	14(48.3%)	3(23.1%)	17(40.5%)	
• III	13(44.8%)	9(69.2%)	22(52.4%)	
• IV	1(3.4%)	0(0%)	1(2.4%)	
Diet				
• Veg	7(24.1%)	3(23%)	10(23.8%)	0.150
• Mixed	22(75.8%)	10(76.92%)	32(76.2%)	
BMI (kg/m²)				
• <18.5	5(17.2%)	3(23.1%)	8(19%)	0.049*
• 18.5-24.9	13(44.8%)	10(76.9%)	23(54.8%)	
• 25-29.9	10(34.5%)	0(0%)	10(23.8%)	
• >30	1(3.4%)	0(0%)	1(2.4%)	
Mean± SD	23.20±4.19	21.57±2.58	22.69±3.81	0.204

The test used: Chi-Square/Fisher Exact Test

Table 2: Associated symptoms of dysmenorrhea in two groups studied

Variables	Test Group (n=29)	Control Group (n=13)	Total (n=42)	P-value
Nausea	29(100%)	12(92.3%)	41(97.6%)	0.310
Vomiting	16(55.2%)	5(38.5%)	21(50%)	0.317
LBA	29(100%)	13(100%)	42(100%)	1.000
Diarrhea	11(37.9%)	4(30.8%)	15(35.7%)	0.654
Fatigue	27(93.1%)	10(76.9%)	37(88.1%)	0.162
Bloating	0(0%)	0(0%)	0(0%)	1.000
Breast Tenderness	7(24.1%)	0(0%)	7(16.7%)	0.079+

The test used: Chi-square/Fisher Exact Test

Effect of family history and parity

In present study 38 (90.5%) patients had a positive family history of dysmenorrhoea (Table 03) Similar findings were reported by Tabri N M *et al.*[37]and Rehman *et al.*,[29] wherein the family history was present in 74% and 63.33% respectively.

In present study 30(71.4%) of the patients were nulliparous (26 of these were unmarried and 4 were married), 8 (19%) of the participants had a history of 2 live births and 4 (9.5%) had more than 2 live births (Table 03) the results are consistent with the study conducted by Fletcher *et al.*[116] wherein the majority of the patients 88% are nulliparous and only 7% were parous.

Table 3: Significant history in two groups studied

Variables	Test Group (n=29)	Control Group (n=13)	Total (n=42)	P value
Family history				
• Present	25(86.2%)	13(100)	38(90.5%)	0.258
• Absent	4(13.8%)	0(0%)	4(9.5%)	
Parity				
• NA	17(58.6%)	9(69.2%)	26(61.9%)	
• 0-2	9(31%)	3(23.1%)	12(54.1%)	1.000
• 3-5	3(10.3%)	1(7.7%)	4(9.5%)	

Test used: Chi-Square/Fisher Exact Test

Pain in abdomen

All the patients in both the test and control group had pain in abdomen before treatment. In the 1st cycle 2 (6.9%) and 3 (23.1%) had no pain in the abdomen while 27 (93.1%) of patients in the test group and 10 (76.9%) of the patients in the control group had no relief; while In the 2nd cycle 20 (69%) in the test and 13 (100%) in the control group were relieved of pain only 9 (31%) of the patients in the test group had pain in the abdomen. In the after-treatment cycle, 6 (20.7%) and 3 (23.1%) had no pain in the abdomen while in 23(79.3%) in the test and 10 (76.9%) in control group pain reoccurred. The test group showed improvement of 20.75% at after treatment, p=0.005 and control group showed improvement of 23.71% at after treatment, p=0.036, considered significant. On intergroup comparison, w.r.t test group was not significant with p=1.000, suggesting that the test drug is as effective as the control in alleviating dysmenorrhea (Table 04).

Nausea

All the 29(100%) patients in the test group and 12 (92.3%) patients in the control group had nausea before treatment. In the 1st cycle, 17 (58.6%) and 13 (100%) patients in the test and control group respectively were relieved of nausea while 12 (41.4%) of patients in the test group had no relief;

while in the 2nd cycle 28 (96.6%) patients in the test and 13 (100%) in the control group were relieved of nausea and only 1 (3.4%) of the patients in the test group had nausea. In the after-treatment cycle, nausea was absent in all patients in the test group and 11(84.6%) in the control group; while in 2 (15.4%) patients in control group, nausea reoccurred. The test group showed improvement of 100.00% at after treatment, p <0.001 and the control group showed improvement of 76.9% at after treatment, p=0.036, considered significant. On intergroup comparison, w.r.t test group showed suggestive significance with p=0.091, suggesting that the test drug is as effective as or more superior to control in alleviating associated with dysmenorrhea (Table 04).

Vomiting

In present study vomiting was present in 15(51.7%) patients in the test group and 5(38.5%) in control group before treatment. In the 1st cycle 23 (79.3%) of patients in the test and 13 (100%) of patients in the control group had relieved of vomiting; in the 2nd cycle during treatment and the after-treatment cycle all the patients 29 (100%) and 13 (100%) in the test and control group respectively were relieved of vomiting. The test group showed improvement of 51.7% with p<0.001 and control group with 38.5% with p=0.137 considered not-significant. On intergroup comparison w.r.t test group was not significant with p=1.000, suggesting that the test drug is as effective as the control in alleviating vomiting associated with dysmenorrhea (Table 04)

LBA

All the patients in both the test and control group had LBA before treatment. In the 1stcycle 10 (34.5%) and 12 (92.3%) patients were relieved of LBA, while 19 (65.5%) of patients in the test group and 1 (7.7%) of the patients in the control group had no relief. In the 2nd cycle, 22 (75.9%) in the test and 13 (100%) in the control group were relieved of LBA and only 7 (24.1%) of the patients in the test group had LBA. In the after-treatment cycle, 19 (65.5%) and 11 (84.6%) had no LBA, while in 10(34.5%) in the test and 2 (15.4%) in control group LBA reoccurred. The test group showed improvement of 65.5%, with p<0.001, considered highly significant, while the control group showed improvement of 84.6% and is statistically not significant with p=0.137. On intergroup comparison, w.r.t test group was not significant with p=1.000, suggesting that the test drug is as effective as the control in alleviating LBA associated with dysmenorrhea (Table 04).

Diarrhoea

In the present study, diarrhoea was present in 12(41.5%) patients in the test group and 4(30.8%) in the control group before treatment. In the 1st cycle 27 (93.1%) patients in the test and 13 (100%) patients in the control group had relieved of diarrhoea; in the 2nd cycle during treatment and the after-treatment cycle all the patients 29 (100%) and 13 (100%) in the test and control group respectively were relieved of diarrhoea. The test group showed improvement of 41.4%, with p=0.036, considered significant; the control group showed improvement of 30.8% after treatment with P=0.137, statistically not significant. On intergroup comparison w.r.t test group was not significant with p=1.000, suggesting that the test drug is as effective as the control in alleviating diarrhoea associated with dysmenorrhea (Table 4).

Fatigue

In the present study, fatigue was present in 27(93.1%) patients in the test group and 10(76.9%) in the control group before treatment. In the 1st cycle, 14 (48.3%) patients in test and 12 (92.3%) of patients in the control group had relieved of fatigue; in the 2nd cycle, 23 (79.3%) patients in the test group and all the patients of the control group were relieved of fatigue. In the after-treatment cycle, 14 (48.3%) and 12 (92.3%) patients in the test and control group respectively were relived of fatigue while in 15 (51.7%) patients in test and 1 (7.7%) in control group fatigue reoccurred. The test group showed improvement after treatment is 41.4%, with p<0.001, statistically significant. Control group showed improvement at after treatment is 69.2% is statistically significant with p<0.001 with paired proportion test. On intergroup comparison, w.r.t test group was significant with p=0.007, suggesting that the test drug is inferior to control in alleviating fatigue associated with dysmenorrhea (Table 4).

Table 4: Assessment of subjective parameters

Pain in Abdomen	BT	C 1	C 2	AT	% difference	P - value
Test Group(n=29)						
• **Absent**	0(0%)	2(6.9%)	20(69%)	6(20.7%)	20.7%	0.005
• **Present**	29(100%)	27(93.1%)	9(31%)	23(79.3%)	-20.7%	
Control Group (n=13)						
• **Absent**	0(0%)	3(23.1%)	13(100%)	3(23.1%)	23.1%	0.0.036
• **Present**	13(100%)	10(76.9%)	0(0%)	10(76.9%)	-23.1%	
P value*	1.000	0.162	0.038*	1.000	-	
Nausea						
Test Group (n=29)						

Table 4: ***(Continued)***

Pain in Abdomen	BT	C 1	C 2	AT	% difference	P - value
Absent	0(0%)	17(58.6%)	28(96.6%)	29(100%)	100.0%	<0.001
Present	29(100%)	12(41.4%)	1(3.4%)	0(0%)	-100.0%	
Control Group (n=13)						
Absent	1(7.7%)	13(100%)	13(100%)	11(84.6%)	76.9%	0.036
Present	12(92.3%)	0(0%)	0(0%)	2(15.4%)	-76.9%	
P value*	0.310	0.008**	1.000	0.091+	-	
Vomiting						
Test Group (n=29)						
Absent	14(48.3%)	23(79.3%)	29(100%)	29(100%)	51.7%	0.001
Present	15(51.7%)	6(20.7%)	0(0%)	0(0%)	-51.7%	
Control Group (n=13)						
Absent	8(61.5%)	13(100%)	13(100%)	13(100%)	38.5%	0.137
Present	5(38.5%)	0(0%)	0(0%)	0(0%)	-38.5%	
P value*	0.426	0.153	1.000	1.000	-	
LBA						
Test Group (n=29)						
Absent	0(0%)	10(34.5%)	22(75.9%)	19(65.5%)	65.55	<0.001
Present	29(100%)	19(65.5%)	7(24.1%)	10(34.5%)	-65.5%	
Control Group (n=13)						
Absent	0(0%)	12(92.3%)	13(100%)	11(84.6%)	84.6%	0.137
Present	13(100%)	1(7.7%)	0(0%)	2(15.4%)	-84.6%	
P value*	1.000	0.001**	0.079+	0.282		
Diarrhoea						
Test Group(n=29)						
Absent	17(58.6%)	27(93.1%)	29(100%)	29(100%)	41.4%	0.036
Present	12(41.4%)	2(6.9%)	0(0%)	0(0%)	-41.4%	
Control Group (n=13)						
Absent	9(69.2%)	13(100%)	13(100%)	13(100%)	30.8%	0.137
Present	4(30.8%)	0(0%)	0(0%)	0(0%)	-30.8%	
P value*	0.513	1.000	1.000	1.000	-	
Fatigue						
Test Group (n=29)						
Absent	2(6.9%)	14(48.3%)	23(79.3%)	14(48.3%)	41.4%	<0.001
Present	27(93.1%)	15(51.7%)	6(20.7%)	15(51.7%)	-41.4%	
Control Group (n=13)						
Absent	3(23.1%)	12(92.3%)	13(100%)	12(92.3%)	69.2%	<0.001
Present	10(76.9%)	1(7.7%)	0(0%)	1(7.7%)	-69.2%	
P value*	0.162	0.007**	0.153	0.007**	-	

Test used: * Chi-Square/Fisher Exact Test and **Paired Proportion test

VAS Score

Mean ± SD of test group before treatment 1st cycle, 2nd cycle and after treatment are 9.03±0.73, 4.90±1.11, 1.79±1.61 and 3.14±1.30 respectively, there was a statistically significant decrease in VAS score with p-value <0.001 in the first cycle and continued till after treatment cycle with p< 0.001, considered highly significant. Similarly, in control group mean ± SD before treatment 1st cycle, 2nd cycle and after treatment are 8.77±0.93, 3.23±1.59, 0.00±0.00 and 2.77±1.64 respectively, there was a statistically significant decrease in VAS score with p-value <0.001 in the first cycle and continued till after treatment cycle with p< 0.001, considered highly significant. The intergroup comparison w.r.t test group after treatment there was no significant difference with p=0.439; suggesting that test drug is as effective as the control in improving the VAS scores in dysmenorrhea (Table 05). The effect of the test drug on VAS score in the present study is comparable with the studies conducted by Kannan P *et al.*[34] with treadmill exercise, Azima S *et al.*[21] with massage therapy and exercise, Harada *et al.*[35] using low dose oral contraceptives, Molins Cubero *et al.*[23] evaluating pain perception after pelvis manipulation, Mingxio *et al.*[13] with moxibustion, Molouk *et al.*[20] with cinnamon, Yasemin *et al.*[36] with the intervention of diet, Rehman *et al.*[29] using *Rheum emodi*, Asma *et al.*[22] with *Ferula asafoetida* showed similar outcome with p=<0.001.

Table 5: VAS score- A comparison in two groups of patients studied

VAS score	Test Group	Control Group	Total	P-value
RESULTS				
• BT	9.03±0.73	8.77±0.93	8.95±0.79	0.323
•	4.90±1.11	3.23±1.59	4.38±1.48	<0.001**
• C2	1.79±1.61	0.00±0.00	1.24±1.57	<0.001**
• AT	3.14±1.30	2.77±1.64	3.02±1.41	0.439
P VALUE BT				
• C1	<0.001**	<0.001**	<0.001**	-
• C2	<0.001**	<0.001**	<0.001**	-
• AT	<0.001**	<0.001**	<0.001**	-

The test used: Student t-test

SF-12

Mean ±SD of test group before and after treatment were 523.45±65.82 and 986.03±99.95 respectively with p-value <0.001, considered highly significant. Similarly, in control group mean ±SD before treatment and after treatment were 513.08 ±60.91 and 1034.62±31.61 respectively with p-value <0.001 and it is considered highly significant. The inter-group comparison concerning test group after treatment was not significant with p>0.05 suggesting that test formulation is as effective as the control in improving the quality of life in patients with dysmenorrhea (Table 06). The effect of test drug on quality of life is similar to that found in studies of Kannan P *et al*.[33] Rehman *et al*.[29] and Asma *et al*.[22] with significant improvement in each study with p<0.01.

Table 6: SF-12-A comparison in two groups of patients studied

SF-12	Test Group	Control Group	Total	P-value
BT	523.45±65.82	513.08±60.91	520.24±63.78	0.632
AT	986.03±99.95	1034.62±39.61	1001.07±88.31	0.100
P value	<0.001**	<0.001**	<0.001**	-

The test used: Student t-test

Primary outcome measure

In the present study, 26 (89.7%) of the patients in the test group and 13 (100%) in the control group were relieved. Statistical analysis shows no significant difference (p=1.00) in alleviating subjective parameters in two groups of patients studied, suggesting that test drug is as effective as control (Table 07)

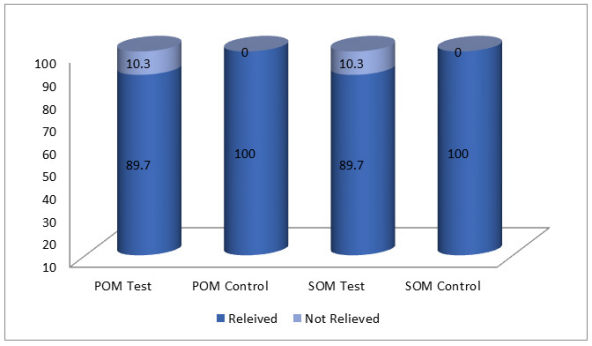
Secondary outcome measure

In the present study, 26 (89.7%) of the patients in the test group and 13 (100%) in the control group were relieved. Statistical analysis shows no significant difference (p=0.540) in improving objective parameters in two groups of patients studied, suggesting that test drug is as effective as control (Table 07)

Table 7: An outcome measure

Outcome measure	Relieved	Not Relieved	Total	P-value
Primary outcome measure (POM) Test group	89.7	10.3	90.5	1
Primary outcome measure (POM) Control group	100	0	7.1	<0.001**
Secondary outcome measure: (SOM) Test group	89.7	10.3	92.9	0.54
Secondary outcome measure: (SOM) Control group	100	0	7.1	<0.001**

Test used: Chi-Square/Fisher Exact Test



Limitations of this study are small sample size, validated scales for assessment of subjective parameters not used, differentiation of patients having primary or secondary dysmenorrhea was not done because of lack of basic investigations like USG. We recommend that studies with a larger sample size should be considered. Minimal investigations like USG pelvis should be done to differentiate the primary and secondary dysmenorrhea, and the effect of test drug on dysmenorrhea associated with different pathologies can be studied. Validated scales for assessment of subjective parameters should be incorporated.

CONCLUSION

The findings from the present study demonstrated that *majoon murmakki* is as effective as mefenamic acid in the management of *usr tamth* (dysmenorrhea). The effect of *majoonmurmakki*on *usrtamth* (dysmenorrhea) may be attributed to its properties like *musakkinawjāh* (analgesic), *muhallilawrām* (anti-inflammatory), *mudirr-i-bawlwahayd*

(diuretic and emmenagogue), *muffattih-i-sudad* (deobstruent) among others; also analgesic activity of furanoses-quiterpenes such as furanoelemanes,furanoeudes-manes and furanogermacranes present in the gum resin extract of myrrh. Hence, *Majoon murmakki* is a safe, herbal therapeutic option that can provide an alternate management option with no adverse events as caused by conventional treatments in *usrtamth* (dysmenorrhea).

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