



Efficacy of *Saussurea costus* (Qost) Oil as an Iranian Traditional Medicine Product on Primary Dysmenorrhea: Case Series

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Abstract

Dysmenorrhea is known as painful menstruation with considerable effects on women's mental status and quality of life with some limits for treatment. The objective of this prospective case series was to evaluate effects of *Saussurea Costus* (Qost) oil, an Iranian Traditional Medicine (Persian Medicine) product, on the primary dysmenorrhea. In this case series, 13 patients were included to study and treated with local Qost oil for 6 weeks. The oil was rubbed (without massage) 15 drops every 12 hours to the sub-navel region until pubis. The improvement of dysmenorrhea, evaluated with VAS score based on the last periodic cycle before the study and the last cycle after the completion of the intervention, which continued 6 weeks (at least one period for each patient). Then, 4 weeks after the end of the intervention (equivalent to one period for each patient), the evaluation was performed. The mean VAS score of patients before intervention was 7.77. The score after the end of intervention up to 4 weeks after the end of intervention improved to 1.85. (76.191%). During this study, no side effects were reported in the patients, and no patient was excluded from the study. Due to easiness of use and low invasion of topical treatment, it can be suitable for dysmenorrhea controlling. Upon the beneficial effects of Qost oil on uterine diseases and pains in Persian Medicine sources, usage of that oil in double blinded clinical trial in the subject of dysmenorrhea is suggested.

Keywords: Qost oil; Dysmenorrhea; *Osre Tams*; Persian medicine

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Introduction

In conventional medicine, dysmenorrhea is recognized as painful menstruation. Based on the existence or nonappearance of pelvic pathology, it is categorized into two primary and secondary forms [1]. The primary dysmenorrhea is known to occur with a colic pain in the lumbosacral and suprapubic area, which can begin a few hours before the onset of menstruation and remains until 48 or 72 hours later. Dysmenorrhea is one of the common reasons of pelvic pain in women and has a significant consequence on women's mental status and quality of life. Primary dysmenorrhea is associated with an increase in prostaglandins, which causes painful uterine contraction and fluid retention. The most common medical treatments for primary dysmenorrhea are the use of prostaglandin synthetase inhibitors such as non-steroidal anti-inflammatory (NSAIDs) drugs [2]. The use of NSAIDs is communal, regardless of its complications. Besides, it does not afford a respectable answer in 25% of tried cases. [3]. Adverse effects of medical treatments and/or their failure rates in treating menstrual pain have led many women to seek complementary and alternative treatment options for primary dysmenorrhea. Numerous non-allopathic treatments for primary dysmenorrhea such as diet supplementation and modification, exercise and acupuncture, use of magnets and manual therapies have been reported [2]. Dysmenorrhea is one of the samples of (Osre Tams) disease in Persian Medicine (PM) due to vascular stricture and menstrual blood density that can affect the menstrual flow through the endometrium [4,5]. According to

this view, drugs that can reduce the concentration of humors and dilute blood, or cause faster menstrual bleeding, or can correct the menstrual bleeding duct; can improve the pain (dysmenorrhea) [4]. In PM, local medicines are used to treat various diseases of some organs including the uterus. [6]. Upon PM view, Qost oil is one of the medicinal products of this school of medicine that controls uterine pains with warming, purgation and strengthening the uterus and other organs [7]. The plant *Saussurealappa* or *Saussureacostus* has been used for more than two thousand years in various medical schools. The root of this plant had been used in treatment of pain, paralysis and inflammation of the lungs [8-10]. It has several terpenes with anti-inflammatory and anti-tumor properties [8]. In PM, Qost plant has many medicinal properties. This plant dilutes and dissolves the pathogenic humors and substances in the body. It also cleans the surface of the ducts in the body. It prepares viscose and dense disposable materials, for excretion from the body. Also it can return the cellular metabolism to a balanced level by heating the organ [11]. It is recommended to relieve uterine pains with topical use of Qost oil [7]. It is moreover beneficial for a variety of uterine pains by oral intake, and sitting in the decoction of it. In this manuscript, we investigated the effect of topical lubricating use of Qost oil on primary dysmenorrhea in the form of case series.

Report of Cases

In this case series, to evaluate the therapeutic effects of the Qost oil on primary dysmenor-

rhea, among women with urogenital disorders that referred to the Ahmadih Persian Medicine center, 13 patients with primary dysmenorrhea were included in this study according to the following criteria.

Inclusion Criteria

1. Women with a regular period of menstruation irrespective of age.
2. Their cycles ensued every 24-32 days.
3. Subjects self-reported that symptoms of primary dysmenorrhea happened during all of their menstrual cycles during the previous year.
4. Subjects who reported low back pain, lower abdominal pain and general abdominal pain related with dysmenorrhea were involved. Lower abdominal pain was comparable to pelvic pain.

Exclusion Criteria

Subjects who had a history or ultrasound examination of polycystic ovarian syndrome, uterine fibroids, pelvic inflammatory disease, endometriosis or any gynecologic cancers such as ovarian, uterine or cervical types, were excluded. Also, pregnant, subjects with a history of skin allergy, taking routine drugs for treatment of dysmenorrhea, history of pelvic surgery in the last year and PID in examination, were excluded.

How to Evaluate

Visual analogue scales (VAS) criteria measured pain severity in patients at baseline, end of intervention and 4 weeks after the completion of the study. VAS is a scale that used to determine the intensity of a variable that is expressed as 0-10. The higher intensity of the evaluated vari-

able is closer to 10 [12]. Zero means no pain and ten is most pain. Mild pain is defined in the range of 0-3, moderate pain 3-7 and severe pain 7-10 [1].

Plant Material

Dried roots of *Saussurea costus* (Falc.) Lipsch (qost) were acquired from local herbal marketplace in Tehran. The plant sample was branded by an experienced botanist and a receipt specimen was reserved at the Herbarium of Faculty of Pharmacy, Tehran University of Medical Sciences, Tehran, Iran (PMP-240).

Preparation of Qost oil

To prepare hydro alcoholic extract we shuddered 100 gram of plant's root powder in 600 mL 25% ethanol for 24h with constant shuddering. The extract was mixed with 800 gram cold pressed sesame oil and the mixture was boiled until all water was dissolved [11].

Treatment Intervention

After the initial test on the arm, fifteen drops (2.3 mL) of oil were used by local use twice a day to the zone between the navel and pubic region without massage (to examine purely the effect of oil).

Side Effect Controlling

Drug Complaint Questionnaire was prepared based on Common Terminology Criteria for Adverse Events (CTCAE) Version 4.0. Evaluation of possible side effects was done on weeks three and six of the study and patient's reports were recorded. In addition to preventing pos-

sible skin complications for all specimens, the first dose of 3 to 5 drops of oil was used for testing on the arm.

Duration of the Study

The duration of treatment was 6 weeks. Persistence of treatment effect was studied in 4 weeks after the end of treatment. The VAS score was used based on the last cycle before the start of study and the last cycle after the completion of intervention which lasted 6 weeks. Then, 4 weeks after end of the intervention (equivalent to a period for each patient), evaluation of the effect of drug on the VAS criteria was performed too. Patients were advised to use Mefenamic acid capsule to control dysmenorrhea if needed. Finally and the number of Mefenamic consumed evaluated.

Results

The 13 married patients who entered the study were between 31- 54 years old and their mean of body mass index was 41.25 with literacy and normal financial situation. No patient was excluded during the study.

Based on the VAS criteria, severity of pain in the patients in this study was between 2 and 10 in the first cycle (VAS = 2-10). At the end of the study, among ten patients with severe dysmenorrhea, 7 patients recovered completely (53.84%). In two patients, the severity of pain improved from severe to moderate dysmenorrhea (15.38%), and one patient with severe dysmenorrhea did not show any changes (7.69%). A patient with moderate dysmenorrhea had no change in her score at the end of the study (7.69%). Among two pa-

tients with mild intensity that were included in the study with a VAS score of 2, in one patient the VAS score ranged from 2 to 1 (7.69%) and no change in the other patient (7.69%). The VAS score changes during the study are presented in Table 1. The mean number of Mefenamic acid capsules that consumed in the first cycle was 3.076, which reached 0.769 at the end of the intervention (75% reduction in consumption). This reduction at the end of study (4 weeks after the end of the intervention), reached to 0.615 (81.11% reduction in consumption). No side effects were reported in these 13 patients.

Overall, the mean score of VAS in the patients before intervention was 7.77. This decrease was significantly reduced after the intervention to 1.85. The percentage of reduction was 76.119%. Four weeks after the intervention, this average remained at 1.85 (Figure 1).

Discussion

Upon PM perspective, periodic pains that occur in periodic hemorrhage can be caused by three major factors: vascular constriction that runs menstrual bleeding [13], concentration of menstrual bleeding due to the overcoming of soda humor or phlegm humor [13, 14] and inflammation in the menstrual blood vessels that leads to blood moving with resistance and pressure, and pain caused by the disturbance of the menstrual blood flow. Therefore, to control of dysmenorrhea; any drug that reduces the concentration of humors or dilute the blood, can accelerate the uterine blood flow and help to eliminate the relative obstruction due to the concentration in the ducts. In this regard, use of local and topical

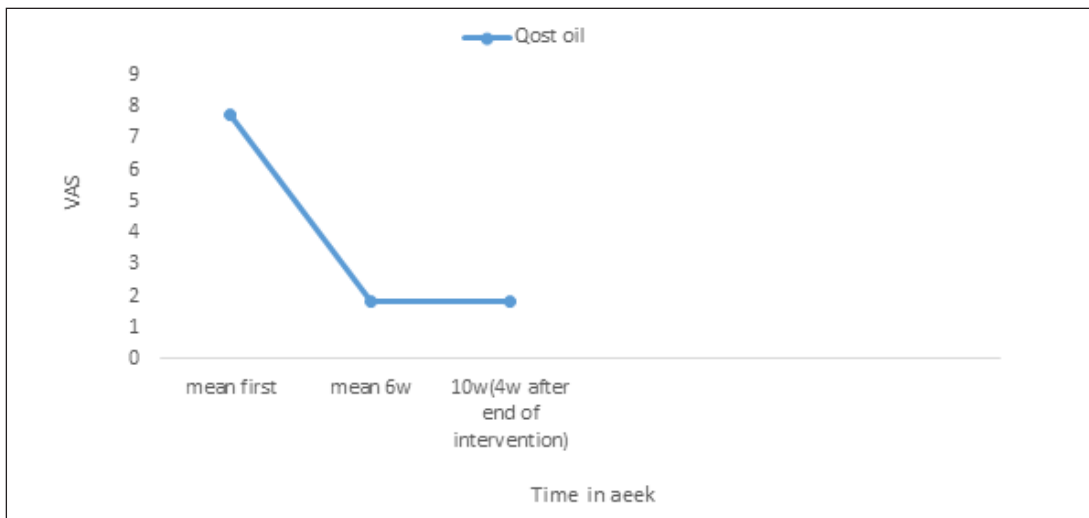


Figure 1. VAS changes before and after the intervention (first and second menstruation) and 4 weeks after the end of intervention (third menstruation)

Table 1. VAS score changes during the study

Patients code	VAS score before intervention (First menstruation)			VAS score 6 weeks - later End of intervention Second menstruation			VAS score 4 weeks - after the end of intervention (third menstruation)		
	mild	moderate	severe	mild	moderate	severe	mild	moderate	severe
1			8	0			0		
2	2			2			2		
3			9		5			5	
4		4		1			1		
5			10			10			10
6			8	0			0		
7			9	0			0		
8			10	0			0		
9			10	0			0		
10			10		5			5	
11	2			1			1		
12			9	0			0		
13			10		5		0		

medication on abdomen and lower back is also appropriate [13]. In PM view, oils are one of the topical drugs that are produced in a singular or complex form [15]. The form of drugs, depending on the materials that used to make them, can affect the humors and deep organs [4, 16]. In this school of medicine, topical medi-

cines are effective in treating diseases of various organs, including the uterus, bladder and stomach. “Tackmeed” (what is heated on the limb) and mineral oils are two types of topical treatments that are used to heat up the chosen area [6,7]. Upon PM view topical use of Qost oil on the abdominal region can dissolve the

concentration of blood circulation in the pelvic that leads to dysmenorrhea. In addition, Qost oil improves dysmenorrhea by warming up the uterus and increasing effective blood flow [4, 7]. A review study has been surveyed the effect of some plants on dysmenorrhea based on traditional medicine litterateurs. They have been discussed the efficacy of several plants such as *Saussurea lappa* (*Saussurea costus*) that used in treatment of primary dysmenorrhea in the decoction form [14]. Also the therapeutic effects of Qost oil in a clinical trial on female urinary incontinence have been proven [11]. Among the published articles in 2019, a randomized double-blinded clinical trial was planned into two groups on 82 students with primary dysmenorrhea. In the first 3 days of menstruation during the following two cycles, the control group consumed 250 mg Mefenamic acid capsules and the intervention group consumed 250 mg Rosemary (*Salvia Rosmarinus*) capsules. The visual analogue scale (VAS) measured the severity of pain and Hingham chart to control the volume of bleeding in menstruation. At the end of study Rosemary capsules decreased primary dysmenorrhea and the menstrual bleeding the same as Mefenamic acid capsules [17]. The strength of mentioned study is that it is short-term and its effect on reducing the volume of bleeding has also been considered. The Rosemary capsule eliminates painkillers needing, which is also considered in our case report. In addition, the persistence of the drug effect after its cessation is also observed in our study. Another Complementary Medicine randomized double-blind clinical trial study, has been

assessed the efficacy of mixed essential oils on menstrual cramps of primary dysmenorrhea. Essential oils joint with lavender (*Lavandula officinalis*), marjoram (*Origanum majorana*) and clary sage (*Salvia sclarea*) and in a 2:1:1 ratio was concentrated in unscented cream at 3% concentration. The period of pain was provocatively reduced from 2.4 to 1.8 after aromatherapy intervention in the essential oil group [18]. Regardless of the difference in the type of study, the similarity between the study and our study, is topical form of drug using. In our study, using the single pharmacological form of the oil, could reduce costs and make it easier to control the effects of the drug. In another clinical trial study that examined lavender (*Lavandula officinalis*) inhalation efficacy on symptoms of primary dysmenorrhea, it was found that the intervention group had a significant therapeutic answer compared with placebo in decreasing symptoms of dysmenorrhea ($p < 0.001$) [19]. The follow-up time in this study was 4 menstrual cycles. The volume of menstrual bleeding in the lavender group was reduced compared with the placebo group but the difference was not statistically significant ($p = 0.25$) [19]. In the mentioned study, a simple and effective treatment method has been used. Beside, using a breathing pathway for delivering the drug to the body can be more restrictive than the oily method used in our study. In another study, the use of dietary supplementation with omega-3 fatty acids had beneficial effects on the symptoms of dysmenorrhea in adolescents [20]. In mentioned study, forty-two adolescents with dysmenorrhea assigned to two groups randomly. 21 girls ex-

pected fish oil (720 mg Docosahexaenoic acid, 1.5 mg vitamin E and 1080 mg Icosapentaenoic acid) daily for 2 months. Another group received placebo. The Cox Menstrual Symptom Scale was utilized to evaluate response to treatment. After 2 months of fish oil therapy there was an obvious decrease in the Cox Menstrual Symptom Scale from a baseline mean value of 69.9 to 44.0 ($p < 0.0004$) [20]. From the perspective of PM, the use of supplements can improve the dysmenorrhea by strengthening the function of organs, including the uterus, which is evident in the mentioned article. In our study, topical application of Qost oil, in addition to the mechanisms mentioned above, strengthens the uterus and improves its function. Beside, it does not involve the gastrointestinal tract in the treatment process. One meta-analysis surveyed the effect of Prasaplai on primary dysmenorrhea. The Prasaplai is a medicinal plant preparation used in Thailand and contains of ten herbs. The study proposes that Prasaplai developed pain in primary dysmenorrhea without significant adverse effects. Supplementation of this herbal preparation with other medications can suggest an alternative for pain decrease in primary dysmenorrheal [21]. Although the mentioned study has produced good results, the lack of multiplicity of drug combinations and the localized nature of the drug using method in our study, make Qost oil recommendable for the design of broader clinical studies.

Therefore, it seems that designing clinical trial studies for a more detailed survey of Qost oil effects on primary dysmenorrhea will be helpful.

Conclusions

In dysmenorrhea, attention to the effects of topical medicines, due to the convenience of the consumption method, is recommended. Consideration to the temperament and mal temperament of the uterus can also help to choose the appropriate topical medication for the treatment of dysmenorrhea. Due to the dissolving, heating and strengthening properties of Qost oil, it can help to clean and warm up the pelvic area and increase the blood flow of pelvic area to improve the function of the uterus. Therefore, this oil can be suitable treatment method for a clinical trial study challenge to fully investigate its effects on primary dysmenorrhea.

Conflict of Interests

The authors of this article have no conflict of interest in the publication of the article.

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Contributing Contributors

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