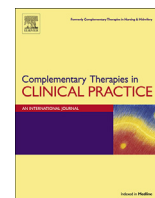




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Comparison the effect of mefenamic acid and *Teucrium polium* on the severity and systemic symptoms of dysmenorrhea



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ABSTRACT

Background: Primary dysmenorrhea is a prevalent problem and its effects decrease the quality of life in many women across the world. The aim of this study was to research the effect of *Teucrium polium* compared to mefenamic acid on primary dysmenorrhea.

Materials and Methods: This triple-blind, randomized, clinical trial study was performed on 70 single female students between 20 and 30 years old educating in Shahid Beheshti University (Tehran, Iran) from October 2014 to February 2014. They were allocated randomly into two groups: In *T. polium* group (n = 35) who took 250 mg of *T. polium* powder q6h for the first 3 days of menstruation for two cycles. The second group (n = 35) received 250 mg mefenamic acid. Dysmenorrhea severity was determined by visual analog scale (VAS).

Results: There were no differences between two groups for demographic or descriptive variables. Comparing the VAS showed that the participants in *T. polium* and mefenamic acid groups had lower significant pain in the 1st and the 2nd months after the treatment (P < 0.05). No side effects were reported in the *T. polium* and Mefenamic Acid groups.

Conclusion: *T. polium* was as effective as mefenamic acid in decreasing the pain severity in primary dysmenorrhea.

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1. Introduction

Dysmenorrhea refers to painful uterine contractions associated with spasmodic pain in the abdomen which occurs during menstrual bleeding [1,2]. Primary dysmenorrhea is the main cause of work absenteeism and reduced quality of life [3,4]. The pain is not associated with a pelvic disorder in primary dysmenorrhea. However, it greatly occurs more in the young but may last until the fifth decade of life. Dysmenorrhea is caused by ischemia-associated uterine contractions and increases sensitivity in uterine nerves [5]. It also happens in terms of prostaglandins, vasopressin and leukotrienes in the endometrium [2].

It is reported that the prevalence of primary dysmenorrhea ranges from 16 to 90% in the reproductive ages [6] Various ways

have been recommended to treat the primary dysmenorrhea, such as yoga, massage, transcutaneous electrical nerve stimulation, vitamins, nutritional supplements and herbal medicine.

Prescribed medications include prostaglandin synthesis inhibitors and non-steroidal anti-inflammatory drugs (NSAIDs) to reduce the pain. Non-pharmaceutical treatments are acupuncture and surgery, of which some may have adverse effects or be contraindicated in certain groups of women [2,5,7–9].

In recent years, there has been a growing interest in using medicinal plants to prevent and treat of several illnesses across the world, particularly in Iran due to satisfactory successes in treating many diseases and undesirable side effects of chemical drugs [7,10]. Traditional medicines, like herbal medicine, have been used for dysmenorrhea treatment across the world, such as Fenugreek.

Valeriana officinalis, thymus vulgaris, etc [8,9,11]. *Teucrium polium* belonging to the family of Lamiaceae, is a perennial plant, which is covered with dense long and soft hairs with the height of 30–50 cm in its rather woody bushes and a dwarf, pubescent, aromatic shrub,

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posing oval leaves with enrolled margins and dense head of white flowers. The color of flowers varies from white and off white to yellow and pink. The plant grows in arid and rocky areas of Europe, Mediterranean Basin, North Africa and South West Asia including Iran [7]. *T. polium* (locally called as kalporeh in Khuzestan Province, Iran) is used traditionally as a remedy in treating headache, convulsion and dysmenorrhea and moreover, its hypoglycemic, hypolipidemic and antibacterial effects have been reported in recent studies. Additionally, it is also used traditionally to cure gastrointestinal disorders [12]. The present study was performed to compare the Effect of Mefenamic Acid and *T. polium* in the Severity of Dysmenorrhea among students. The paper also considered the ongoing studies in the world in the field of traditional medicine and abundance of some plants mentioned as herbs with analgesic and anti-inflammatory effects among Iranian traditional medicines.

2. Material & methods

2.1. Participants

This was a triple-blind, randomized, placebo controlled trial study, consisted of unmarried students living in a dormitory at Shahid Beheshti University (Tehran, Iran) from October 2014 to February 2014 with moderate-to-severe dysmenorrhea experiences.

It was estimated that 70 participants were required to reach a statistical significance at 95% confidence interval. Randomly computer-generated numbers were employed to divide participants into two groups for taking *T. polium* ($n = 35$) or Mefenamic Acid ($n = 35$). Participants, researchers and statistic advisor were kept blinded in allocating treatment. Dysmenorrhea-related variables, including age, age of menarche, age of dysmenorrhea and BMI were the same in two groups. Other variables, such as underlying diseases (Diabete, Chronic hypertension, Infectious diseases) which may be influenced by *T. polium* in such people were controlled by excluding those samples from the study. Students with irregular menstrual cycles, endometriosis, history of medication usage, experienced acute stress, and/or vaginal symptoms (burning, irritation, itching, or discharge) were excluded. It was supposed that people with allergy to *T. polium* or other plants or those who had used herbal drugs during the previous 3 months or had not used it properly should have been excluded. Although a case with allergy to *T. polium* and Mefenamic Acid was not found.

2.2. Procedures

T. polium (from one geographical region) was purchased from Barijesans Pharmaceuticals (Kashan, Iran). After the identification and the verification of *T. polium* samples in Pharmacogenosy Laboratory at the Faculty of Pharmacology of Shahid Beheshti University of Medical Sciences, the samples were ground down. *T. polium* powder was placed into capsules (250 mg) by an automated machine. The safety dose, based on the PDR (Herbal Medicine) book [13], was 250 mg for *T. polium*. Also the toxicity dose of plant on kidney and liver [14,15] is caused by permanent usage therefore it does not happen to alternative use of the plant (3 days monthly in dysmenorrhea) [12]. Chemical composition of the plant included: cedrol, guaiol, lindool, beta pinene [12]. The Mefenamic Acid capsule (250 mg) purchased from Razac Pharmaceuticals company (Tehran, Iran) The capsules were similar in shape, color, and packaging. *T. polium* and Mefenamic Acid capsules were taken four times a day [For the first 3 days of menstruation]. The intervention continued for two consecutive menstrual cycles. The subjects were allowed to take NSAIDs such as ibuprofen and Acetaminophen, if required. However, they were asked to take these medications ≥ 1 h after taking the given capsules by researcher and write down pain

severity before consuming the sedative and they were excluded from the study.

Content and test–retest methods were employed to assess the validity and reliability before the intervention and during each treatment cycle, ($r = 0.85$) of the questionnaire. The following demographic data was collected: age, body mass index (BMI), educational level, occupation of the parents, exercise program, and stressful factors in the past 6 months. A self-reported checklist was used for collecting data on the number of sedative drugs taken for dysmenorrhea and pain severity.

During the first three days of menstruation, the pain severity was scored in each sample three times a day on a 10 cm visual analog scale (VAS) when samples felt the most pain in 8–13, 13–18, and 18–24 h (per 8 h) and was classified as “mild” (score of 1–3), “moderate” (4–7), or “severe” (8–10) [16].

VAS validity has been established in many studies, in which it has a wide range of applications and is considered as one of the most useful and reliable measures for pain [18,19,22]. The imprint codes were recorded on a separate sheet for the capsules, drug intervention performed in the second and third menstruations.

2.3. Statistical analyses

SPSS ver20 (SPSS, Chicago, IL, USA) was used to analyze statistically. Descriptive data is presented as frequencies, mean values and standard deviations and t-test which are used for comparison of age, age of menarche and other variables between the two groups.

The Repeated Measure test was employed to compare pain severity among three menstrual cycles. The Mann–Whitney test was used for comparison of satisfaction in both groups. $P < 0.05$ was considered significant.

2.4. Ethical considerations

The study protocol was approved by the Research and Ethics Committee of International Branch, Shahid Beheshti University of Medical Sciences and registered in the Iranian Registry of Clinical Trials (Number IRCT2014120917501N1). Students were aware of the purpose and methods of the study and provided with written consent forms for participation.

3. Results

Pain severity at baseline had no significant differences between the groups (Table 1). In the *T. polium* group, pain severity reduced from 7.20 (2.1) at baseline to 3.34 (2.3) in the second cycle (Table 2), and it decreased from 6.48 (1.6) to 2.7 (1.4) in the Mefenamic Acid group (Table 3). Pain severity differed in each intervention cycle between the two groups, with more reduction in the *T. polium* group in each cycle (Table 4). There was no difference in pain severity between two groups (Fig. 1). No side effect was reported in both groups of *T. polium* and Mefenamic Acid.

4. Discussion

This was the first report of a comparative study on the effects of *T. polium* and Mefenamic Acid on the alleviation of pain in Primary Dysmenorrhea.

Females with dysmenorrhea suffer from excessive production of endometrial prostaglandins [3]. It is seen that *T. polium* (locally called 'kalpooreh') possesses therapeutic effects against diabetes, fungal infections, with analgesic and anti-inflammatory properties. It is also used traditionally as a remedy in treating headache, dysmenorrhea, convulsion and gastrointestinal disorders

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