



## Research paper

# Comparison of the effect of mefenamic acid and quince on the level of menstrual bleeding and hemoglobin: A randomized controlled clinical trial<sup>☆</sup>



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## ABSTRACT

**Introduction:** Menorrhagia is a common condition occurring in almost 30% of women. This study was conducted to compare the effects of mefenamic acid and quince on menstrual bleeding and hemoglobin levels in women.

**Materials and methods:** This triple-blind randomized controlled clinical trial was conducted on 146 women with heavy menstrual bleeding residing in Tabriz, Iran. Participants were divided into two groups through block randomization; one group was treated with quince ( $n = 72$ ) and the other with mefenamic acid ( $n = 74$ ). The quince group received a 250 mg dose of quince pill and the other group received a 500 mg dose of mefenamic acid pill every 6 h from their first day of menstruation to the fifth for three consecutive periods. Participants completed the menorrhagia questionnaire before and three months after the intervention and their hemoglobin levels were also measured before and three months after the intervention.

**Results:** The mean scores obtained on the menorrhagia scale and the mean hemoglobin levels did not differ significantly between the two groups before the intervention ( $P > 0.05$ ). After the intervention, however, the mean score obtained on the menorrhagia scale decreased significantly in both groups while their hemoglobin levels increased. There were no statistically significant differences between the two groups in terms of these variables ( $P > 0.05$ ).

**Conclusion:** The results of the study show that quince pill is equally effective in reducing menstrual bleeding and increasing hemoglobin levels as mefenamic acid. Quince pill thus appears to be an appropriate alternative for mefenamic acid due to its fewer side effects.

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## 1. Introduction

Menorrhagia is diagnosed with heavy menstrual bleeding and cramps that interfere with daily function [1,2]. This common condition occurs in almost 30% of women [3,4]. Although the exact cause of menorrhagia is yet unknown, recent studies have reported

fibrinolysis and prostanoid imbalance as the causes of heavy uterine bleeding during menstruation [5,6]. Menorrhagia is a common reason for which women visit their doctors and accounts for two-third of all the cases of hysterectomy [7,8]. Frequent bleeding at amounts higher than 80 ml during each menstruation results in anemia and a significant reduction in the quality of life [9–12].

The known treatments for menorrhagia include the administration of systemic progestin, topical progesterone, Danazol, gonadotropin-releasing hormone agonists, prostaglandin inhibitors, fibrinolytic inhibitors and desmopressin [13] and the performance of endometrial ablation [14]. All of these treatments may cause side effects. For example, the side effects of

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anti-inflammatory nonsteroidal drugs include nausea and vomiting, gastrointestinal disorders, diarrhea, anorexia, headache and dizziness [15]. In a study conducted by Dockeray et al., danazol caused more severe side effects and occurred in 75% of the patients compared to mefenamic acid, which caused side effects in 30% of the patients [16]. Due to the side effects of these medications, alternative therapies such as the use of herbs and other nutrients have become more emphasized in the treatment of complications [17]. In Iran, many people and health care professional have begun to seek natural therapies due to their greater efficiency, safety and tolerability and lower toxicity and adverse events in comparison with chemical medicines [18].

Quince, scientifically known as *Ayva* or *Cydonia oblonga* [19], is the sole member of the genus *Cydonia* in the family Rosaceae. The Rosaceae is the 19th largest family of plants and includes from 95 to more than 100 genera and 2830–3100 species. Other species of this family are annual or permanent plants [20]. This species is native to East Asia, Azerbaijan, Russia, Armenia, Iran, Turkmenistan and Afghanistan [19]. Quince contains tannins [21,22], carotenoids, coumarin, glycosides, heterogeneous polysaccharides, pectin [23], flavonoids [19], malic acid, vitamin B and C and provitamin A [21]. Sources of traditional medicine have reported the effectiveness of quince in the treatment of coughs, bronchitis, simple diarrhea, dysentery, abdominal pain, bloody mucus, uterine and hemorrhoid bleeding and vaginal discharges. These texts have also noted that quince reduces or stops uterine bleeding. This particular effect of quince is attributed to tannins [21,22].

According to previous studies, quince also has skin wound healing [24], anti-hyperglycemia [25], antioxidant [26,27] and antiemetic [28] properties and can reduce salivary secretion [21]. Based on a preliminary study, micronized flavonoids inhibit endometrial prostaglandin production and can thus help relieve abnormal uterine bleeding [29].

To the best of the researcher's knowledge, no studies have yet been conducted on the effect of quince on menstrual bleeding. The present study was therefore conducted to compare the effects of mefenamic acid and quince on menstrual bleeding and hemoglobin levels in women.

## 2. Material and methods

### 2.1. Study design and participants

The present triple-blind randomized controlled clinical trial was conducted on 146 women presenting to health centers in Tabriz, Iran, from February 2014 to April 2015. All the study participants, research assessors and data analyzers were blind to the type of intervention performed on the individual participants (triple-blinding).

The inclusion criteria of the study consisted of being 18–45 years old, having had heavy menstrual bleeding for several consecutive cycles (for at least three cycles prior to entering the study), having a body mass index (BMI) of 18.5–29.9, the lack of intermenstrual bleeding, being willing to participate in the study, being literate and having hemoglobin levels higher than 10. The exclusion criteria consisted of being or having been pregnant in the last 6 months, taking any medications affecting menstrual bleeding (such as danazol, systemic and topical progestin, prostaglandin inhibitors, fibrinolytic inhibitors and gonadotropin-releasing hormone agonists), having taken herbal medications over the past 6 months, having an intrauterine device inserted, having uterine fibroids and other uterine pathologies, suffering from hypothyroidism or hyperthyroidism and having coagulation disorders or known diabetes.

Sample size was calculated as 61 for each group using G-power and based on the data obtained in the study by Zamani et al. [30] on

menorrhagia severity score and taking account of the mean pre-intervention menstrual bleeding score (pre-intervention: SD1 = 17.6 and M1 = 22.2), an anticipated 40% reduction in the post-intervention mean score (post-intervention: SD2 = 17.6 and M2 = 13.32) and an  $\alpha = 0.05$  and a  $\beta = 0.2$ . A total of 73 participants were allocated to each group to account for a sample loss of 20%.

The present study is part of a larger study that investigates menstrual bleeding (using a menstrual questionnaire) and hemoglobin levels as its secondary objectives.

### 2.2. Randomization and intervention

Participants were allocated to two groups through block randomization with block sizes of 4 and 6 and an allocation ratio of 1:1; one group was treated with quince ( $n = 72$ ) and the other with mefenamic acid ( $n = 74$ ). To conceal the allocation, three small envelopes containing the corresponding medication and each covering one month's required dosage were placed inside identical large opaque envelopes and sequentially numbered. The allocation was carried out by an outsider person not involved in the study and using a computer-generated random number table.

One group received 250 mg doses of quince pill and the other 500 mg doses of mefenamic acid pill. Participants were asked to take one tablet with a glass of water every 6 h from the first day of their menstruation to the fifth for three consecutive periods.

To prepare the quince pills, quince (the fruit of *Cydonia oblonga*) was purchased and then identified in the Herbal Medicine Research Laboratory of the Pharmacy School of Tabriz University of Medical Sciences. The quinces were then cut into small pieces, dried in an oven at 35 °C and then powdered with a grinder. With respect to the pill doses required, appropriate amounts of quince were mixed with appropriate excipients (starch, microcrystalline cellulose and lactose). A solution containing HPMC 3% was added in as a binder in order to prepare quince granules. After drying the produced quince granules, magnesium stearate 1% was added in as a lubricant and sodium starch glycolate 3% as a disintegrant and were then mixed for about 10 min. The tablets were compressed on a single punch tableting machine (produced by Erweka in Germany), each containing 250 mg of quince.

The mefenamic acid powder required was procured from Alhavi Pharmaceutical Co., Tehran, Iran. Mefenamic acid tablets were prepared similarly as the quince tablets, except mefenamic acid powder replaced quince powder this round. Each mefenamic acid tablet contained 500 mg of mefenamic acid.

The prepared tablets were examined for their friability, hardness and disintegration time. All tablets had a friability less than 1%, a hardness of about 7 kp and a disintegration time below 5 min, which fell in the acceptable range of the US Pharmacopeia [31]. It should be noted that the mefenamic acid and quince tablets were similar in appearance (i.e., in shape and color).

### 2.3. Sampling

Sampling started after obtaining permission from the Ethics Committee of the Research and Technology Deputy of Tabriz University of Medical Sciences (ethics code: 92155) and registration of the study in the Iranian Registry of Clinical Trials (code: IRCT2013081310324N15).

Tabriz has a total of 27 health centers serving as its primary health settings. Sampling was carried out in 13 health centers in different areas of the city with different socio-economic statuses. The researcher first prepared a list of 18–45 year-old women presenting to each center and then called the women and invited those suffering from heavy menstrual bleeding who were interested in participating in the study. They were briefed on the objectives and methods of the study and any additional details

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