



Original Article

A Comparative Study of Treatment of *Hypericum perforatum* and Vitamin B6 for Mastalgi: Clinical Trial

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ABSTRACT

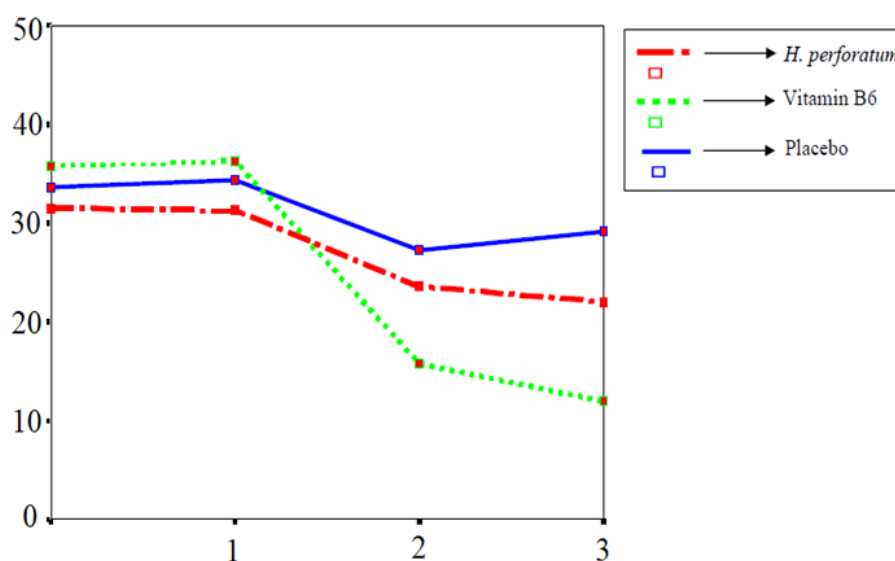
This study aimed to investigate the effect of vitamin B6 and *Hypericum perforatum* as a treatment for mastalgia. The double-blind randomized controlled trial (RCT) was conducted on 238 patients with premenstrual syndrome referred to gynecology clinic of Zeinabieh Hospital of Shiraz. Two months before the intervention, all patients completed a prospective menstrual daily questionnaire. The participants were randomized into three groups: I (receiving two tablets of *H. perforatum* containing 330µg of hypericin), II (receiving two tablets of containing 80 mg of vit B6) and III (receiving placebo), which were treated daily from the first to 30th day of menstrual cycle for two cycles. Pain intensity was assessed with a visual analogue scale. Data analyzed by SPSS-21. There was no significant difference in the mean age, weight and height between groups. The results showed that the studied groups had different behaviors with mutual effect at different times. The results of mastalgia severity changes were significant between groups, that showed the pattern of time changes of the groups was significantly different from each other ($p=0.048$). While vit B6 was more effective than placebo in relieving mastalgia ($P<0.001$), the difference between *H. perforatum* and placebo was not statistically significant ($P = 0.16$). *H. perforatum* showed no significant effect on mastalgia. Some factors such as affordability, availability and side effects should be considered to select the right candidate. Given the importance of providing women's health and that mastalgia can disrupt their activities, vit B6 can be prescribed as a useful way to relieve cyclic mastalgia.

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GRAPHICAL ABSTRACT



Introduction

Breast pain, also called mastalgia, can be divided into two main categories: cyclic and non-cyclic [1]. The prevalence of cyclic mastalgia is reported to be between 40 and 70% [2]. Mastalgia is one of the most common breast disorders in women, which interferes with the daily activities of two-thirds of affected women and one-tenth of whom will need treatment [3].

Mastalgia without an underlying disease is the dominant disease of western women, so that 7 out of 10 people suffer from it. Breast pain, also called mastalgia, is a common concern among 70% of women at some point in their menstrual cycle. Mastalgia is the most common breast symptom in patients who refer to surgical outpatient departments [1]. In 15% of cases, it may be severe enough for the patient to need repeated examinations and treatments. There are reports of disorders in sexual (48%), physical (37%), and social (21%) activities as a result of mastalgia; these factors play an important role in lowering the quality of life [2, 3]. Different clinical features of mastalgia include cyclic (associated with hormones) or noncyclic (associated with drugs, pathology, or extra-mammary causes) [4]. Among these, cyclic mastalgia is the most

common type and is seen in nearly 80% of women and is often described as abnormal breast swelling, tenderness, and lumpiness [5]. Cyclic mastalgia is associated with the exacerbation of symptoms such as bilateral breast tenderness, congestion, pain, burning, and heaviness in the premenstrual period [6]. The unknown pathophysiology and the involvement of hormonal, nutritional, metabolic, and psychological factors have complicated the treatment of mastalgia [7].

If the examinations do not show any abnormality in the breast, effective treatment strategies can be a combination of reassurance, breast support brassiere, and topical NSAID gel massage [8].

Suggested treatments for breast pain relief include danazol, bromocriptin, tamoxifen, evening primrose oil, calcium, vitamin E, vitamin B6, analgesics, diuretics, and the use of a proper diet, caffeine intake, and related exercises [9]. Mastalgia causes anxiety and strain in patients regarding the possible risk of breast cancer. On the other hand, affected people impose a large financial burden on the health care system due to unnecessary and numerous medical visits and various diagnostic procedures such as mammography and biopsy [10].

Treatment with antiestrogen (such as centchroman or tamoxifen) for three to six months is suggested as the second line of treatment of choice. Danazol may be prescribed in resistant cases. Many patients show resistance to treatments such as bromocriptine, tamoxifen, or gonadotropin-releasing hormone analogues due to their adverse effects. Widespread side effects of hormonal therapy have led the treatment to use vitamin B6 in the first stages of treatment [8]. In general, 92% of patients with cyclical mastalgia and 64% with non-cyclical mastalgia can obtain pain relief with conventional treatment. It is important to know that 20% of women with mastalgia respond to placebo and 20% of the mastalgias are resistant to any treatment.

The consumption of medicinal plants and herbal medicines has increased in recent years. In particular, there have been many recent studies on the use of herbal medicines, especially in gynecological problems, such as mastalgia [11].

Some herbal medicines have anti-inflammatory properties, such as flaxseed [12], chamomile [13, 14], Nigella Sativa [15], Vitex agnus-castus [16], and Cinnamon [17-19].

Perforatum improved premenstrual syndrome as showed in Stevinson and Ernst [20] and Hicks *et al.* [21]. Also, in Pakgohar *et al.* [22], 70% of breast pain was relieved in patients received Hypericum. However, Pakgohar *et al.* [22] assessed breast pain as one symptom of premenstrual syndrome. The aim of this study was to compare treatment of Hypericum perforatum and vitamin B6 severity of their mastalgia based on visual analogue scale (VAS) that is considered as a reliable and valid tool.

Martials and Methods

The present double-blind randomized controlled trial (RCT) was conducted on patients (women in the age group of 18 to 45 years old) with premenstrual syndrome (PMS) referred to gynecology clinic of Zeinabieh Hospital of Shiraz, Iran, to evaluate the effects of *H. perforatum* and vitamin B6 on PMS. The ethical review board and the faculty directorate, vice president of educational affairs and management of

educational affairs of Shiraz University approved the protocols of this research. Inclusion criteria were female patients aged between 18 and 45, and also self-reported PMS symptoms for more than six months. Exclusion criteria were females suffering from health or psychiatric problems, psychotropic drug intake, planned pregnancy, lactation, irregular menstruation, and failure to use an effective contraception.

Eligible participants signed a written informed consent prior to intervention. They were finally randomized into three groups, including Group I (receiving two tablets of *H. perforatum* containing 330 µg of hypericin), Group II (receiving two tablets of vit B6 containing 80 mg of vit B6), and Group III (receiving two tablets of placebo containing lactose and cellulose), which were treated daily from the first to the 30th day of menstrual cycle for two cycles. The sample size was estimated using data from a previous intervention study, which was determined to be 78 for each group. Concerning the dropout rate, the final sample size was determined to be 90 per group.

Ethical considerations were followed according to the declaration of Helsinki and confidentiality of information was considered. The samples could freely withdraw from participating in the study if they did not want.

A questionnaire involving demographic variables was completed for the participants. They were asked to report the severity of their mastalgia based on visual analogue scale (VAS) using a 10-cm ruler in which a score of zero indicates no pain and a score of 10 is the maximum pain.

The collected data were analyzed by SPSS version 15.0 (SPSS, Chicago, IL, USA) using repeated measures, paired sample t-test, and chi-square tests to analyze and compare the frequency distribution of side effects of drugs as well as determination of marital status, educational level, and sports status in the groups under study. All statistical tests were performed with a 95% confidence interval (95%CI) and an alpha coefficient of 0.05. In this study, a p-value less than 0.05 ($p < 0.05$) was considered to be a significance level.

Results and Discussion

The study participants included 251 females randomly divided into three groups including Group I (receiving *H. perforatum*, n = 85), Group II (receiving vit B6, n = 81), and Group III (receiving placebo, or control group, n = 85). There was no significant statistical difference in the mean age, weight, and height between the three groups in Table 1.

Figure 1 displays the mean changes in mastalgia severity at different times (two months before the intervention to two months after the intervention) between the study groups analyzed by repeated measures ANOVA test.

The results showed that the studied groups had different behaviors at different times. In other words, they had a mutual effect (p<0.001). According to the results of the repeated measures ANOVA test, the results of mastalgia severity changes were significant between the three groups, which means that the pattern of time changes of the groups was significantly different from each other (p=0.048). While vit B6 was more effective than placebo in relieving mastalgia severity (P<0.001), the difference between *H. perforatum* and placebo was not statistically significant (P = 0.16). *H. perforatum* showed no significant impact on mastalgia in Table 2.

Table 1: Repeated measures ANOVA test results for the demographic variables of the studied groups

Variables	Group I (receiving <i>H. perforatum</i> , n = 85)		Group II (receiving vit B6, n = 81)		Group III (receiving placebo, or control group, n = 85)		P- value
	Mean	Standard deviation	Mean	Standard deviation	Mean	Standard deviation	
Age	31.01	6.98	32.16	6.65	31.62	7.12	0.580
Weight	59.87	9.20	59.79	9.47	59.08	8.80	0.834
Height	162.29	6.31	160.41	6.30	178.91	161.10	0.364

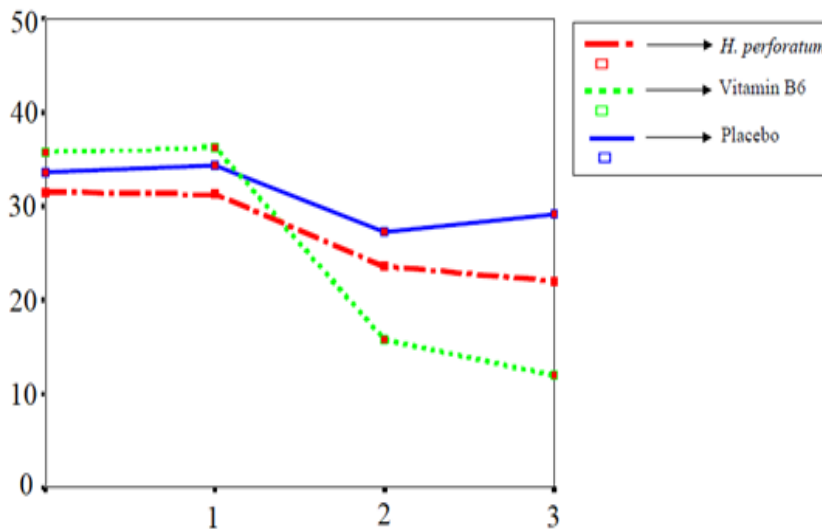


Figure 1: Mean changes in mastalgia severity at different times (two months before the intervention to two months after the intervention)

Table 2: Percentage of recovery after intervention in the studied groups

Variables	Group I (receiving <i>H. perforatum</i> , n = 85)	Group II (receiving vit B6, n = 81)	Group III (receiving placebo, or control group, n = 85)
Mastalgia	29	68	14

The cyclic mastalgia refers to an exacerbation of premenstrual symptoms, beginning in the luteal phase of the period, which presents with pain, congestion, heaviness, burning, and bilateral tenderness of the breast [23].

Some women with mastalgia may avoid exercise, physical activity, sexual activity, and work or school activities, which play a role in lowering their quality of life [24].

Mastalgia can occur for reasons that have not yet been clearly identified. Some sources have reported endocrine abnormalities as major etiologic factors, including psychoneurosis, elevated estrogen expression, hyperprolactinemia, and progesterone deficiency [25].

There are several treatment strategies for mastalgia, pharmacological and non-pharmacological approaches, danazol, LNRH analogues, gamma linoleic acid, analgesics, tamoxifen, gestrinone, testosterone, vitamins B6 and E, gabergoline, and bromocriptine. However, hormonal therapies are associated with serious complications and the effectiveness of any treatment method has not been superior to each other [7].

The results of this study showed that vitamin B6 caused a statistically significant decrease compared to placebo, while the difference between *H. perforatum* and placebo was not statistically significant.

Stevinson and Ernst [20], in America studied the effect of *H. perforatum* in the treatment of premenstrual syndrome. This research was conducted as a pilot without placebo on 19 patients. Patients were treated with hypericum tablets for two complete menstrual cycles (1 × 300 mg hypericum extract per day standardized to 900 microg hypericin). No serious complications were observed in this study. Premenstrual syndrome was significantly reduced. This study reported a 51% improvement in all symptoms. The most dramatic reduction was in symptoms such as crying (92%), depression (85%), anxiety (69%), insomnia (69%), and tension (71%). The symptoms in the first cycle were significantly reduced, while the symptoms in the second cycle were not significantly reduced compared to the first cycle

[20]. Hicks *et al.*, in America compared the effect of *H. perforatum* with placebo on premenstrual syndrome. The participants completed the daily status registration form for three consecutive cycles. The first cycle was considered as the baseline and no treatment was done. At the end of the first cycle, 129 affected women were randomly divided into two groups; 67 cases received two tablets (each 300 mg tablet contained 900 microg of hypericin) and another 62 people received two placebo tablets per day. Treatment was performed during two menstrual cycles. No serious complications were observed in this study. In both groups, the symptoms of premenstrual syndrome were significantly reduced, but no significant difference was seen between both groups [21].

Pakgozar *et al.* conducted a double-blind clinical trial on 70 students of Tehran University (Iran) with premenstrual syndrome. The patients were randomly divided into two groups of 35 people and were treated for two consecutive cycles with 30 drops of *Hypericum* or placebo twice a day, at least 7 days before menstruation. After completing the study, 70% of breast pain was relieved [22]. In the present study, the improvement rate in reducing mastalgia was 29%.

Mehni *et al.* showed that the extract of *perforatum* exerts its analgesic effect by inhibiting the synthesis of prostaglandin and other neural mediators [23].

In line with the present study, Yadollahi *et al.* conducted a clinical trial on 72 students. Patients were randomly divided into two treatment groups of vit B6 and *H. perforatum*. Vit B6 (80 mg daily) and *H. perforatum* tablets (160 mg three times a day) were prescribed one week before menstruation for two months. In terms of physical symptoms of premenstrual syndrome, the average decrease in vit B6 group compared to *H. perforatum* group showed a significant difference [24].

In a double-blind study conducted by Smallwood *et al.*, on 46 patients suffering from cyclic mastalgia, administration of vit B6 (200 mg) for two menstrual cycles was ineffective in comparison with placebo [25]. The reason for the non-alignment of the previous study with the

current study can be related to the different dose of vit B6, small sample size, and different population. In the study of Khosravani *et al.*, patients were divided into three groups, the first group received aspirin, the second group received a combination of retinol, vit B6, tacopherol, and the third group received placebo [26]. The findings of this study did not find any difference between the three groups. This study, unlike our study, did not find relief in mastalgia. The reason for the difference could be related to the small sample size and different population. Moreover, they used a combination of vitamins. In line with the present study, Soltany *et al.* conducted a study on 126 patients with cyclic and non-cyclic mastalgia for two menstrual cycles. Their findings showed that vit B6 (100 mg per day) was effective on both types of mastalgia compared to placebo [27]. A review of seven studies found that vit B6 was more effective than placebo in relieving mastalgia even at low doses [28].

According to the results of studies, Vit B6 deficiency causes a decrease in dopamine level in the kidney and as a result increases sodium secretion and causes water accumulation, which is subsequently associated with symptoms such as peripheral edema, edema, and discomfort in the breasts and abdomen. Therefore, administration of vit B6 can reduce the mentioned symptoms and premenstrual acne [29].

A confounding factor in evaluating the results is related to the effect of psychological factors in response to treatment. Many mastalgia sufferers are very worried that their breast pain may be a sign of breast cancer. Reassuring the patients in this regard removes their worries to a large extent and increases the response to treatment in all patients participating in the study, regardless of the type of the used drug. The reassuring effect in the treatment of mastalgia patients has been reported between 8 and 80%. Therefore, this confounding factor should be measured in future studies on mastalgia [30].

Conclusion

H. perforatum showed no significant impact on mastalgia. Some factors such as affordability, availability, and side effects should be considered to select the right candidate. Given the importance of providing women's health, which play an effective role in family functioning, and that mastalgia can disrupt their activities, vit B6 can be prescribed as a useful way to relieve cyclic mastalgia.

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Authors' Contributions

All authors contributed to data analysis, drafting, and revising of the paper and agreed to be responsible for all the aspects of this work.

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