The Effect of Vitamin B6 on Cyclic and Non-Cyclic Mastalgia

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ABSTRACT

Introduction: Mastalgia is the most common breast-related complaint of patients seeking medical care. Vitamin B6 used as initial treatment for mastalgia in some studies. The aim of this study was to evaluate the effect of vitamin B6 on cyclic and non-cyclic mastalgia. Material and method: In a prospective study, women complaining mastalgia, referred to general surgery clinic of Amir-al-Moemenin Hospital Semnan, Iran, evaluated. All the patients received Vitamin B6 100mg BD for two months. They were recorded their severity of breast pain in a pain diary, assessed by visual analogue scale score. At the end of the second month patients divided as cyclic and noncyclic groups according to their pain patterns. Severity of the pain was assessed by two factors for every patient: the mean pain score and the number of the days with severe pain [VAS score: 7-10] which compared in the two groups. Results: A total of 72 patients evaluated. The mean pain score and the prevalence of severe pain decreased significantly in both groups. The difference of the mean pain score between cyclic and noncyclic mastalgia was not significant but the difference of the prevalence of severe pain was statistically significant in cyclic mastalgia. Conclusion: Vitamin B6 can relieve breast pain in both cyclical and noncyclical mastalgia but it is more effective in cyclical mastalgia by reducing the prevalence of severe pain in these patients.

INTRODUCTION

Mastalgia is the most common breast-related complaint of patients seeking care at both primary care clinics and breast referral centers [1]. In a study, pain was the most common breast symptom, prompting medical evaluation and accounting for 47% of breast-related visits [2]. Many patients with breast pain seek medical advice because of a fear that the pain may be related to cancer [3]; however, pain is reported to be associated with breast cancer in only 8-10% of all cancer cases [4].

Mastalgia can be classified as cyclic mastalgia, noncyclic mastalgia, and extramammary pain [5]. Cyclic mastalgia, by definition, occurs in premenopausal women and connotes breast pain that is clearly related to the menstrual cycle. Noncyclic mastalgia is defined as constant or intermittent breast pain that is not associated with the menstrual cycle. Extramammary pain from various sources may present with symptoms of breast pain. Cyclic mastalgia accounts for approximately two thirds of breast pain in specialty clinics, whereas noncyclic mastalgia accounts for the remaining one third [4]. The distinctions are important because the evaluation and the likelihood of response to intervention vary among the different types of breast pain [3].

Many pharmacological agents have been tried in the therapy of mastalgia. The drugs available for the treatment of mastalgia are Danazol, Tamoxifen, Bromocriptine, Evening Primrose Oil, Gamolenic acid, LHRH analogue Goserline, oral contraceptive pills, diuretics and topical NSAIDs gels with varying efficacy and side effects. Some of the effective non-hormonal agents in mastalgia are Non-steroidal anti-inflammatory gels, reassurance and breast support with sports bra. There is considerable debate about drug of choice for management of mastalgia [6]. Despite the pervasive nature of this condition, it has received little attention clinically. This relative inattention may be due to the misconception that breast pain is a normal part of the perimenstrual symptom complex and that there is no acceptable treatment available [1]. Vitamin supplements such as B6 used as initial treatment in some studies [7, 8, 9]. The aim of this study was to compare the effectiveness of Vitamin B6 in control of cyclic and noncyclic mastalgia.

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MATERIAL AND METHODS

This prospective study was conducted by Semnan University of Medical Sciences, Semnan, Iran and on women complaining mastalgia, referred to general surgery clinic of Amir-al-Moemenin Hospital between February 2012 and March 2014.

Inclusion criteria: All women in reproductive age group with regular menses having mastalgia were recruited in the study after signing a consent form.

Exclusion criteria: Past history of breast carcinoma or family history of breast carcinoma, patients who consumed oral contraceptive or received hormone replacement therapy, lactation and pregnancy.

After an initial clinical assessment and breast imaging with ultrasound and mammogram for cases above age 40 years to exclude any lump or mammary ductal disease, patients were asked to keep a record of their breast pain in a pain diary. In this diary, patient filled the occurrence of pain on a day to day basis. The time of menses was also marked on the pain diary. The severity of mastalgia was assessed by visual analogue scale score [VAS] ranging from 0–10, zero [0] indicating no pain and 10 indicating extreme pain. All the patients were received Vitamin B6 [manufactured by Ramopharmin Pharmaceutical Lab. Tehran-Iran] 100mg BD for two months. At the end of the second month the charts were taken back and analyzed. Patients divided in two groups according to their pain patterns in dairy charts as cyclic and noncyclic groups. A diagnosis of cyclical mastalgia, using a modification of the criteria proposed by the mastalgia clinic at Cardiff, Wales, was made if a patient had perimenstrual breast pain for 5 days or more per cycle with a severity score greater than 4 cm on the visual analog scale [1]. Other patients regarded to have noncyclical mastalgia. Pain was categorized as mild [VAS score: 1-3], moderate [VAS score: 4-6] and severe [VAS score: 7-10]. Severity of the pain was evaluated by two factors for every patient: the mean pain score and the number of the days with severe pain [VAS score: 7-10] which compared in the two groups.

Results:

A total of 72 patients, 44 with cyclic and 28 with noncyclic breast pain were enrolled in the study. Patient’s characteristics in terms of age, mean pain score and prevalence of severe pain were similar in both groups [table 1].

According to table 2, the mean pain score decreased significantly after treatment in both cyclic and noncyclic patients [p<0.01], but in comparing the two groups of cyclic versus noncyclic, it was not statistically different [1.07 versus 1.05, p>0.05]. Prevalence of severe pain decreased significantly after treatment in both groups and also there was a statistically difference between cyclic and noncyclic patients regarding this factor [21.37% in cyclic versus 12.86% in noncyclic patients, p<0.01]. No side effect was seen in any patients.

Table 1: Comparison of baseline characteristics.

<table>
<thead>
<tr>
<th></th>
<th>Non cyclic Cases</th>
<th>Cyclic Cases</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Count</td>
<td>28 [38.88%]</td>
<td>44 [61.11%]</td>
<td></td>
</tr>
<tr>
<td>Age [years]</td>
<td>37.81 ± 8.33</td>
<td>36.78 ± 8.09</td>
<td>&gt; 0.05</td>
</tr>
<tr>
<td>Mean of pain score</td>
<td>0.74 ± 0.38</td>
<td>0.72 ± 0.49</td>
<td>&gt; 0.05</td>
</tr>
<tr>
<td>Prevalence of Severe pain</td>
<td>7.36%</td>
<td>8.32%</td>
<td>&gt; 0.05</td>
</tr>
</tbody>
</table>

Table 2: Comparison of treatment response in cyclic and noncyclic patients.

<table>
<thead>
<tr>
<th></th>
<th>Non cyclic</th>
<th>Cyclic</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean of Pain score</td>
<td>1.71</td>
<td>1.64</td>
<td></td>
</tr>
<tr>
<td></td>
<td>After treatment</td>
<td>0.64</td>
<td>0.59</td>
</tr>
<tr>
<td></td>
<td>p</td>
<td>&lt; 0.01</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>Prevalence of Severe pain</td>
<td>1.07</td>
<td>1.05</td>
<td>&gt; 0.05</td>
</tr>
<tr>
<td></td>
<td>Base</td>
<td>18.56%</td>
<td>26.36%</td>
</tr>
<tr>
<td></td>
<td>After treatment</td>
<td>5.70%</td>
<td>4.99%</td>
</tr>
<tr>
<td></td>
<td>p</td>
<td>&lt; 0.01</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td></td>
<td>Decrease</td>
<td>12.86%</td>
<td>21.37%</td>
</tr>
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</table>

Discussion:

The results of this study indicate that Vitamin B6 at a dose of 200 mg daily, can relieve breast pain in both cyclical and noncyclical mastalgia but it is more effective in cyclical mastalgia by reducing the prevalence of severe pain in these patients.

Cyclical mastalgia is an under-recognized and poorly understood disorder that is common among patients in the primary care setting and those referred for surgical consultation. Studies have shown that in a standard breast clinic or general surgery practice setting, 15% of premenopausal women will have clinically significant cyclical mastalgia [10]. A study of women attending a breast clinic with benign problems found that women with cyclical mastalgia were significantly more likely to
report that their breast problem interfered with physical activity, social life, and work than those who did not have mastalgia [11]. Minor breast discomfort and swelling within the few days before onset of menses is considered a normal physiological occurrence [12]. Women who experience more severe and prolonged pain are considered to have cyclic mastalgia. Despite extensive studies done to identify causative histopathological, hormonal, nutritional, or psychiatric abnormalities, few consistent findings have been uncovered, and the etiology of cyclic mastalgia is unknown [4]. Noncyclic mastalgia involves constant or intermittent pain that is not associated with the menstrual cycle. Less common than cyclic mastalgia, it accounts for approximately 31% of women seen in mastalgia clinics [10]. Noncyclic breast pain may result from pregnancy, mastitis, trauma, thrombophlebitis, macrocysts, benign tumors, or cancer; however, only a minority of breast pain is explained by these conditions [4]. Little is known about the cause of frequent noncyclic mastalgia or its impact on women’s lives. The underlying physiology may be different for noncyclic versus cyclic breast pain, and noncyclic breast pain appears less likely to respond to hormonal therapies [13].

In clinical practice, 78% to 85% of symptomatic women are reassured after normal findings on evaluation and do not want specific intervention to alleviate the breast pain. Approximately 10% to 22% experience more severe pain and elect treatment to improve or relieve symptoms [14]. There is overlap between the initial therapeutic approaches for patients with cyclic and noncyclic mastalgia; however, response to intervention varies [4]. Several vitamins have been evaluated as potential treatments for breast pain, including vitamins B1, B6, and E [15, 16]. While several studies report that 200–600 IU of vitamin E per day, taken for several months, reduces breast pain [15, 17], most double-blind trials have found that vitamin E does not relieve this symptom [18, 19]. Small studies of vitamins B1 and B6 showed no benefit compared with placebo for the treatment of cyclic breast pain [20, 21]. However, the effectiveness of vitamin B6 remains uncertain. Some studies found that B6 supplementation reduces breast pain [22]. In addition, vitamin B6 is effective for relieving the symptoms of premenstrual syndrome (PMS) such as breast tenderness [23]. Approximately 19% of the women took vitamins to reduce PMS. Meta-analysis concludes that doses of 50 to 100 mg elemental vitamin B6 are also significantly better than a placebo in relieving PMS [24] and high dose of vitamin B6 results in clinical improvement of mastalgia as one of its somatic symptoms [25].

This study showed that vitamin B6 reduces breast pain in both cyclical and non cyclical mastalgia especially in cyclical type. The previous studies indicated that drug treatment seemed more beneficial in cyclical mastalgia [13, 26]. These are consistent with the finding of the present study. Although some studies concluded that at this time, evidence is insufficient to support routine use of vitamins for breast pain [16, 27], it is used as initial treatments by non-specialist surgeons [7]. Breast specialists were more likely to begin treatment with primrose oil, tamoxifen, vitamin B6, and analgesia, reserving other hormonal therapies for more difficult cases [28].

The major limitation of this study is the lack of control group. We suggest a randomized double blinded clinical study to reach a more certain results, especially because some study claimed that vitamin B6 appear to exert only a placebo effect [29].

**Conclusion:**

Vitamin B6 can relieve breast pain in both cyclical and noncyclical mastalgia but it is more effective in cyclical mastalgia by reducing the prevalence of severe pain in these patients.

**REFERENCES**


