Original Article

Efficacy of Vitamin B_6 in the Treatment of Premenstrual Dysphoric Disorder

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Abstract

Background: Many etiological factors have been proposed for Premenstrual Dysphoric Disorder (PDD) and different drugs and techniques have been suggested for its treatment. This study was designed to assess the efficacy of vitamin B_6 in the treatment of PDD.

Methods: In a randomized double-blind placebo controlled study, 121 Women, aged 20-45 years, who according to DSM-4 criteria, had PDD were randomly divided into two groups to receive orally either vitamin B_6 (group A) 40 mg twice daily during luteal phase of their menstrual cycle or starch as placebo. Vitamin B_6 and starch both were prepared in gelatin capsules with the same shape and color. Emotional and somatic scores for the severity of PDD symptoms were determined and compared between the two groups.

Results: Emotional score decreased significantly in group A compared to group B and basal value. No changes in somatic scores were observed.

Conclusion: It seems that vitamin B6 is an effective drug for relief of emotional symptoms in PDD.

Key words: Premenstrual Dysphric Disorder, Vitamin B_6, Premenstrual Tension.

Premenstrual dysphoric disorder (PDD), defined as premenstrual syndrome or premenstrual tension, appears in at least 5% of child bearing women and consists of emotional and somatic symptoms[1]. These symptoms appear at the late phase of menstrual cycle and disappear with the beginning of the next menstruation[2]. Premenstrual syndrome dose not constitute a single entity, instead different symptom profiles can occur, in different combinations[3]. For accurate diagnosis the symptoms should be present during the last week of the luteal phase, begin to remit within a few days after the onset of the follicular phase, and be absent in a week after beginning of menses. Many etiological factors and a large number of treatment methods have been proposed for this syndrome which is largely the result of the multifactorial and bio-psycho-social nature of the syndrome and the wide overlap of this disorder with other gynecological and psychiatric conditions[4]. Many drugs such as mefenamic acid, lithium, anxiolytics, diuretics, oral contraceptives, tamoxifen, danazol and vitamin B_6 have been used for relief of the premenstrual symptoms, but their effects have been difficult to evaluate[5, 6]. One of the most popular, but controversial treatments for PDD is vitamin B_6. While some of the researchers found this drug to be effective for treatment of PDD[7, 8], others concluded that the existing evidences for its effectiveness are week[9] and the medication may have only a placebo effect[10]. The most important reason for use of this drug is the role of B_6 in the synthesis and regulation of biogenic amines, especially serotonin[3] which is the most important neurotransmitter that modulates human feelings and emotions[4]. This study was designed to evaluate the efficacy of B_6 in the treatment of PDD in a sample of women with PDD.

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Materials and Methods

After institutional approval and informed patients' consent, 121 women with a DSM-4 based diagnosis of PDD, admitted in an outpatient primary psychiatry clinic in Isfahan, Iran, from April 2002 to October 2002 were included in this study. Patients with obvious psychiatric disorders requiring medical treatment and those on oral contraceptives were excluded from the study. Subjects were randomly divided into two groups to orally receive either vitamin B_6 40 mg twice daily (group A, n=60) or starch (group B, n=61) as placebo. Vitamin B_6 and placebo were prepared in gelatin capsules with the same shape and color, and were administered during the luteal phase of the menstruation (from the 15th day after beginning of menses to the first day of the next cycle). The subjects were followed up for three consecutive menstrual cycles by a practitioner who was not aware of the type of intervention. Clinical interviews were performed during follow up and a two part questionnaire consisting of three emotional and five somatic symptoms were completed. Emotional symptoms were depression, irritability and anxiety. Somatic symptoms consisted of tiredness, headache, back pain, breast tenderness and swollen limbs. Frequency of each symptom was rated daily as follows: 0 (never), 1 (occasionally), 2 (usually), 3 (almost always) and 4 (always). These scores were cumulated for one week before menstruation. Therefore the score of each symptom could vary from 0 to 28 and the total score of the emotional component ranged from 0 to 84 and that of the somatic component from 0 to 140. The emotional and somatic scores were obtained in the menstrual cycle immediately before intervention and for three consecutive menstrual cycles after intervention.

Data were presented as mean ± SD. Mean values of emotional and somatic scores were compared between groups A and B using Student t-test. Within group comparison was performed with paired sample t-test. A P value < 0.05 was considered as statistically significant. Data were analyzed on a computer using SPSS 10.0.

Results

Twenty seven patients failed to complete the were lost to follow-up (12 in group A and 15 in group B). Therefore final analysis was performed on the remaining 94 patients (46 in group A and 48 in group B). The two groups were not significantly different from the standpoint of age and marital status (table 1). Baseline emotional and somatic scores were comparable between the two groups (table 1).

Table 1: Demographic characteristics of cases. Data are mean ± SD or n (%)

	Group A (n=46)	Group B (n=48)	Total (n=94)
Age	31.4 ± 6.2	30.2 ± 5.5	30 ± 7.1
Married	33 (72)	36 (75)	69 (73)
Single	13 (28)	12 (25)	25 (27)

No statistically significant differences between groups

Group A = Vitamin B_6, Group B = Placebo

Emotional scores decreased significantly in group A after intervention compared to the basal values and those in group B but the changes in somatic scores were not significant (figure 1).

Discussion

Vitamin B_6 is believed to affect brain monoamines metabolism specifically by an alteration in the metabolism of tryptophan. B_6 is a necessary co-factor for metabolism of tryptophan to 5-HT (serotonin). On the other hand, imbalance in the steroid hormones may cause a relative deficiency of vitamin B_6[3]. There are controversial reports on the efficacy of B_6 in the treatment of PDD. Some researchers concluded that B_6 had no beneficial effect upon PDD[10, 11] while others showed a favorable response[12]. Although it has been indicated that the efficacy of vitamin B_6 may be simply due to its placebo effect, but the result of this study shows that vitamin B_6 is superior to placebo in treatment of PDD. Authors propose that, as the beneficial effects of vitamin B_6 were seen only on emotional (but not somatic) premenstrual symptoms, the isolation of these two types of symptoms in this study could better demonstrate the therapeutic effects of the medication.

Emotional symptoms of PDD (specially depression) are particularly likely to interfere with daily activities and reduce the quality of a woman's life. Since B_6 is a cheap and relatively safe drug, it may be an efficient treatment for PDD. The neuropathic adverse effects of B_6 are only developed in high doses[13, 14].

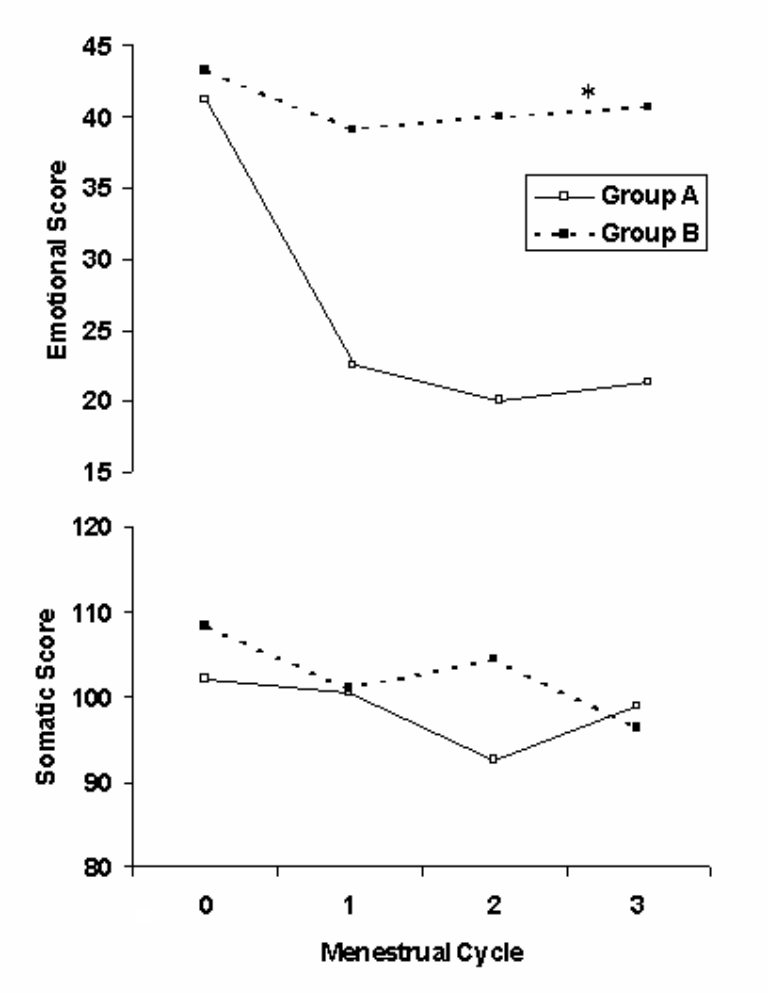

Figure 1. Emotional and somatic scores before intervention (cycle 0) and for three cycles after intervention (cycles 1 – 3).

*P < 0.05 compared to basal value and group B

Group A = Vitamin B_6, Group B = Placebo

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