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A Prospective Randomised Trial to Study the Efficacy of Vitamin B6 (Pyridoxine) and Vitamin E in Patients of Premenstrual Syndrome

Shikha Singh, Rekh Rani, Asha, Ragini and Divya Yadav Sharma*

S N Medical College Agra, Uttar Pradesh, India

**Corresponding author*

Abstract	Article Info
<p>The present study was focused on to randomised trial to study the efficacy of Vitamin B6 (Pyridoxine) and Vitamin E in Patients of Premenstrual Syndrome. A total of 90 females of age group 17-25 years with premenstrual symptoms(psychological or somatic), fulfilling the ICD-10 and DSM-IV criteria were randomly allocated into three groups A,B,C having 30 subjects in each group. During this study it was found that there was the symptom score of group A and B has significant reduction over group C, hence it is beneficial to give vitamin E and B6 for reducing the symptoms of premenstrual syndrome over placebo treatment. Results for comparison in groups A and B were insignificant. Vitamin E and B6 were equally effective for the improvement in symptoms of premenstrual syndrome.</p>	<p>Accepted: 25 August 2017 Available Online: 20 September 2017</p> <hr/> <p>Keywords</p> <p>Vitamin B6 (Pyridoxine), Vitamin E, Premenstrual Syndrome</p>

Introduction

Premenstrual syndrome is a common cyclical disorder of young and middle aged women and is characterized by emotional and physical symptoms that consistently occur during the luteal phase of menstrual cycle. Symptoms can be severe enough to disrupt everyday life. Mild physiological symptoms arise in almost 95% of all women of reproductive age. Nearly 5% of symptomatic women complain of completely disrupted everyday life.¹Somatic symptoms of premenstrual syndrome include bloating, weight gain, tenderness of breast, abdominal discomfort, fatigue, headache.

Frequently reported affective fluctuations are dysphoria, irritability, nervousness, tension, and aggression.² Till date the pathogenesis remains unclear and speculative.³ Most interventions, however, based on informal

observations, retrospective studies, or non controlled trials. The role of some vitamins like Vitamin B6 and Vitamin E also documented. The efficacy of vitamin B-6 and Vitamin E has not yet been proved in women with premenstrual syndrome. This study was conducted to compare the improvement of symptoms in subjects given Vitamin E, Vitamin B6 supplementation, and placebo therapy during premenstrual period

Materials and Methods

The study was carried out in the Department of Obstetrics and Gynecology S N Medical College Agra in the year 2014-2015.

A total of 90 females of age group 17-25 years with premenstrual symptoms(psychological or somatic), fulfilling the ICD-10 and DSM-IV criteria wererandomly allocatedinto three groups A,B,C having 30 subjects in

each group. From 16th day of the menstrual cycle up to the start of next menstrual period:

Group A was given vitamin E- 400mg
Group B -100 mg pyridoxine,
Group C- placebo tablets

All these 90 patients were given a questionnaire based on premenstrual symptoms (Weight Gain, Generalized Swelling, Acne, Breast Tenderness, Abdominal Bloating, and Mood Changes) and their severity (No Symptoms-0; Mild-1; Moderate-2; Severity-3). A relevant history and informed consent were obtained. All the three groups were assessed based on their symptom scores. The symptom score was measured at the start of supplementation and then after the supplementation at the end of 1st, 3rd and 6th month and the change in symptoms were also assessed on the basis of the questionnaire. All the patients in the three groups were comparable regarding, Age, Age of menarche, working status, Education, and Parity.

Results and Discussion

Weight Gain

The Vit-E group has been shown a significant 71% reduction (initial 45 to 13 at 6th month) in weight gain score. Similarly, a 38% reduction in scores of weight gain in Vit-B6 group (initial 52 to 32 at 6th month) was also observed at 6th month but not as marked as in Vit-E group.

Headache

The headache scores observed with a marked and gradual reduction in Vit-E and Vitamin-B6 groups in comparison to placebo, 70% and 67.6% at 6th month respectively.

Generalised Swelling

No Significant reduction in scores of generalized swelling except Vit-E group at 6th month (60%; 35 to 14) was observed.

Breast Tenderness

A marked and gradual reduction in scores for Tenderness of breast has been observed in both Vit-E and Vitamin-B6 groups in comparison to placebo, 86% (51 to 7) and

67% (46 to 15) at 6th month respectively in comparison to placebo.

Acne

A marked and gradual improvement in scores for Acne has been observed in Vit-E group (80%; 23 to 5) in comparison to placebo (33%; 18 to 12) but not in Vit-B6 group (11%; 46 to 15) at 6th month.

Abdominal Bloating

Improvement in abdominal bloating scores found to be more pronounced in Vit-B6 group (54.8%; 62 to 28) than Vit-E (27.2%; 52 to 41) group in comparison to placebo at 6th month.

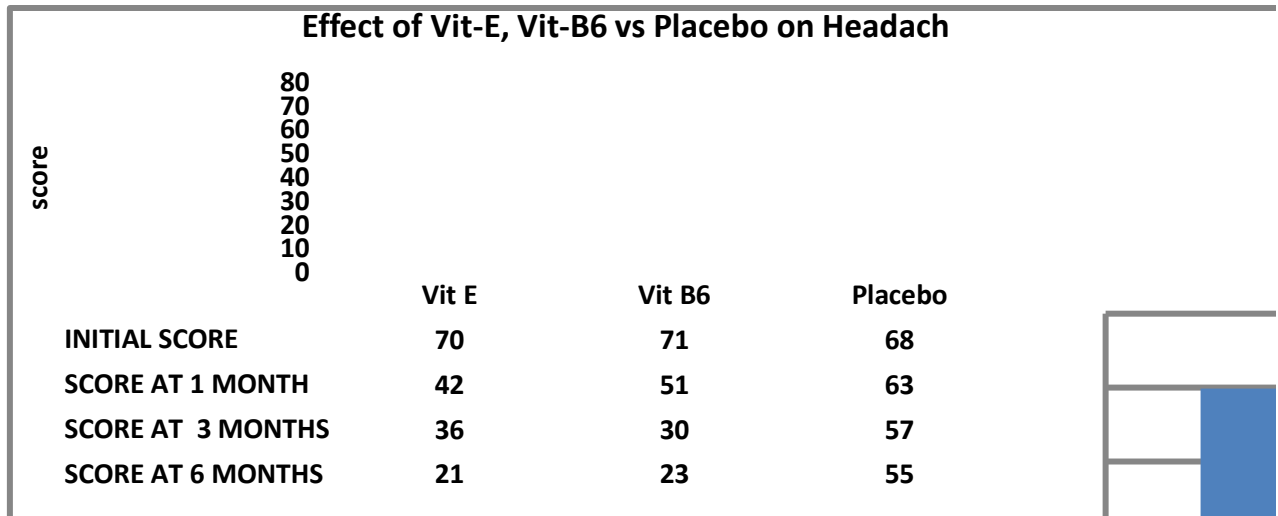
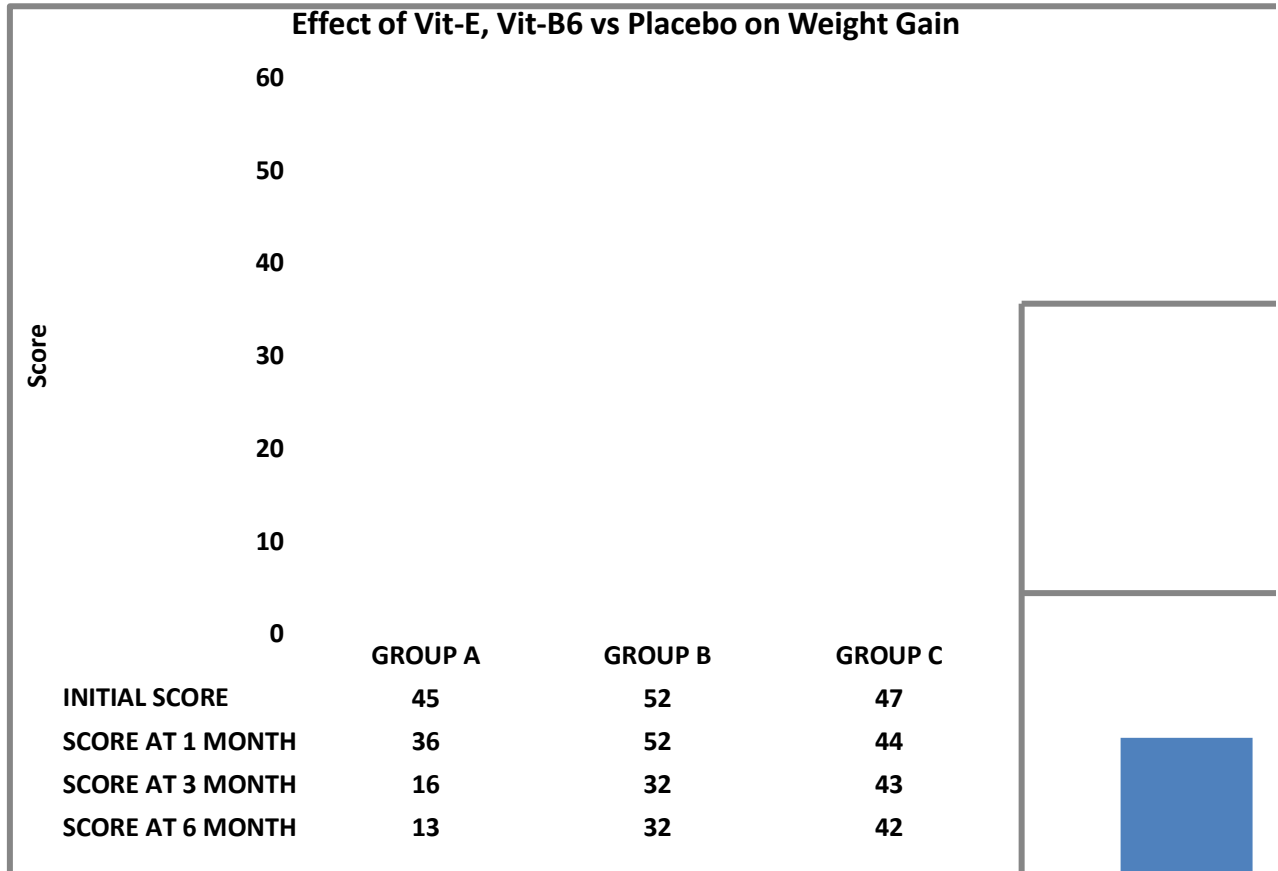
Mood Changes

Improvement in abdominal bloating scores found to be more pronounced in Vit-B6 group (46%; 43 to 23) than Vit-E (4%; 45 to 42) group in comparison to placebo (23%; 51 to 39) at 6th month. Even Vit-E found not better than placebo.

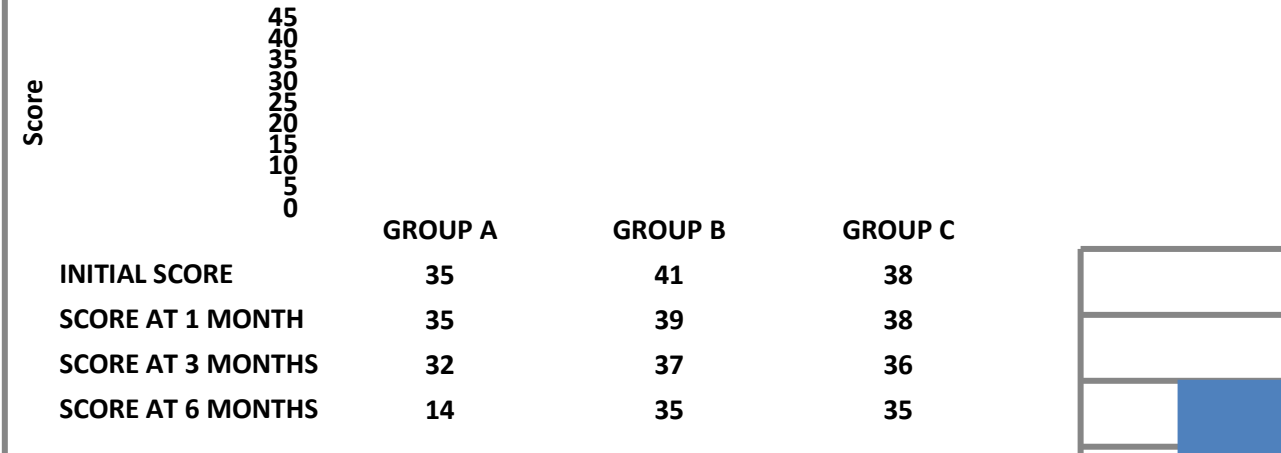
Current study suggested that Vitamin E and Vitamin B6 improve the mean score of various symptoms of PMS as reflects in result section and there are some other RCTs which are also showing some similar kind of results.

A meta-analysis of Nine published trials representing 940 patients with premenstrual syndrome suggests that doses of vitamin B-6 up to 100 mg/day are likely to be of benefit in treating premenstrual symptoms and premenstrual depression.⁴ Results from 4 RCTs with doses of vitamin B-6 up to 100 mg/day were conflicting, 3 RCTs suggested improved premenstrual depression and irritability in very few patients, but these were very small sample size studies and third one suggested no improvement better than placebo.^{5, 6, 7, 8}

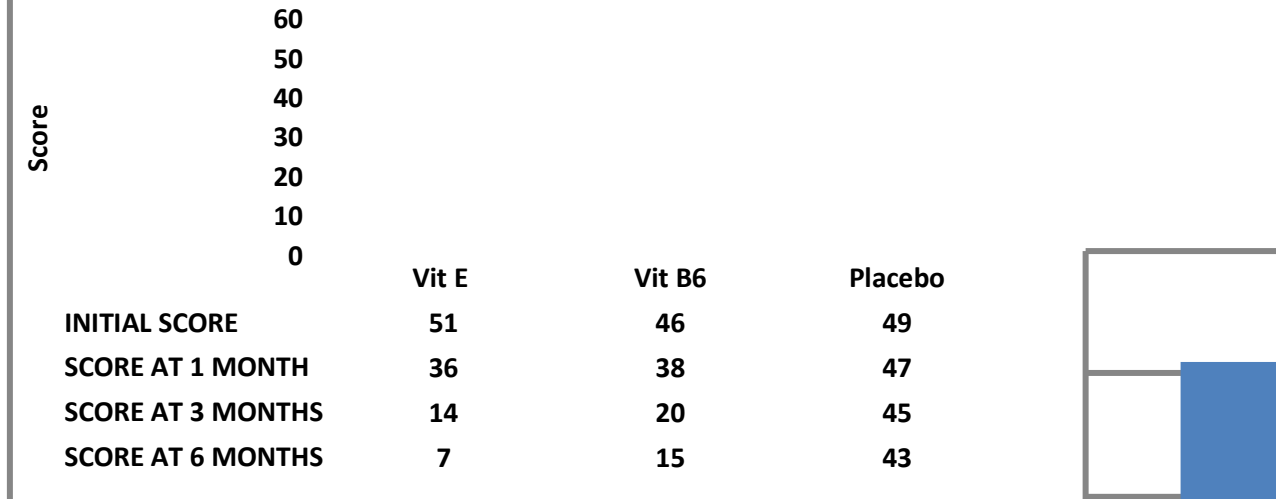
In contrary to that one RCT where 150 mg/day of vitamin B-6 used suggested that beneficial effect of pyridoxine seen on autonomic and behavioral symptoms, with no effect observed on depression and anxiety.⁹ With larger doses like 500 mg/day of vitamin B6 Improvement in total premenstrual symptoms in 21 subjects on pyridoxine out of 25 patients treated with vitamin B6.¹⁰



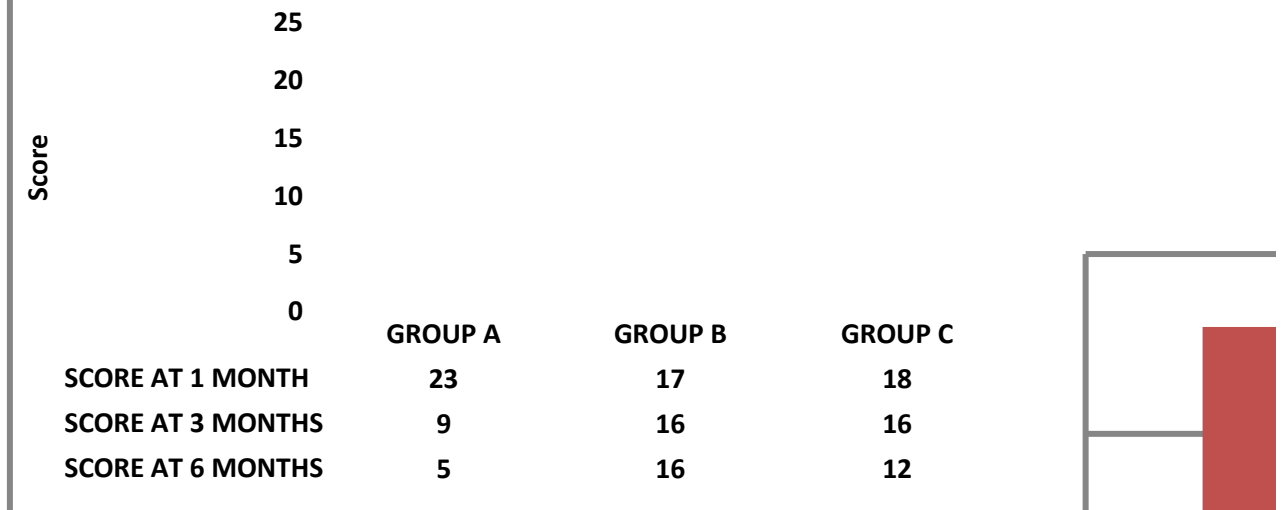
Effect of Vit-E, Vit-B6 vs Placebo on Generalised Swelling



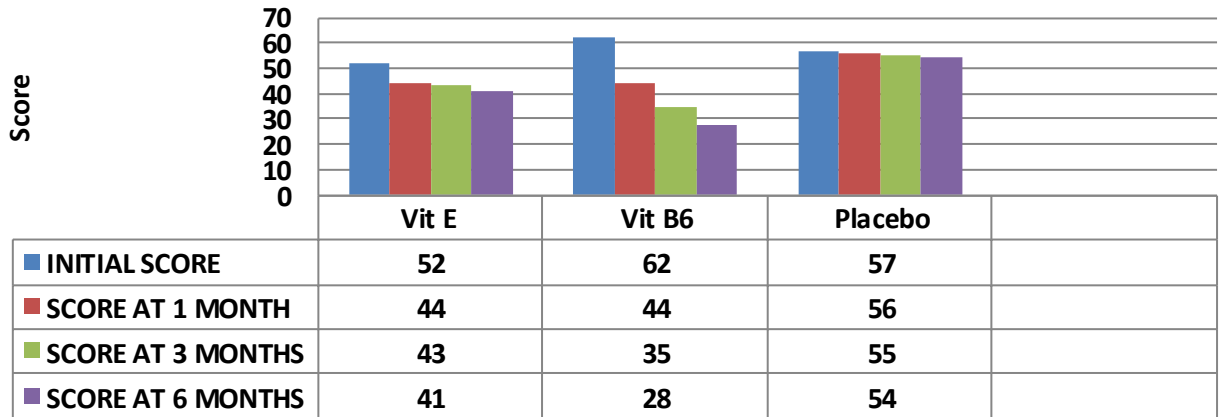
Effect of Vit-E, Vit-B6 vs Placebo on Breast Tenderness



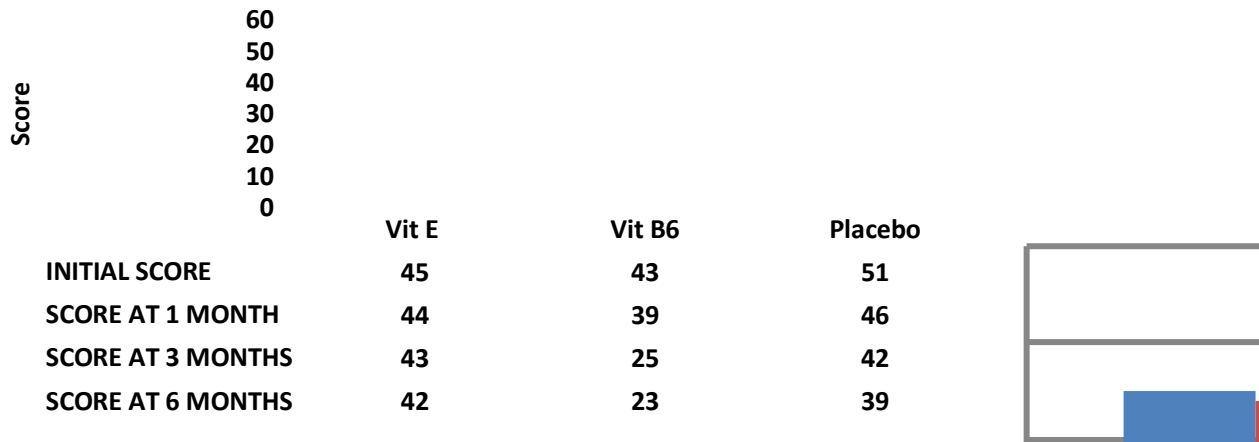
Effect of Vit-E, Vit-B6 vs Placebo on Acne



Effect of Vit-E, Vit-B6 vs Placebo on Abdominal Bloating



Effect of Vit-E, Vit-B6 vs Placebo on Mood Change



Distribution of Patients on The Basis of Symptoms at Initial Stage, Group A (Vitamin E)

SCORING	NO SYMPTOMS (0)	MILD (1)	MODERATE (2)	SEVERE (3)
1. HEADACHE	-		20	10
2. WEIGHT GAIN	1	13	16	-
3. GENERALISED SWELLING	5	15	10	-
4. ACNE	16	4	8	2
5. BREAST TENDERNESS	2	9	15	4
6. ABDOMINAL BLOATING	-	11	16	3
7. MOOD CHANGES	1	16	10	3

In another study carried out by Bertone-Johnson *et al.*, on the effect of vitamin E and placebo on PMS, it was demonstrated that vitamin E (100 mg/day) and placebo had a similar effect on syndrome severity.^[11]

London *et al.*, also conducted a study on vitamin E and placebo in 1987. They reported that using 400 IU of vitamin E can alleviate the symptoms of PMS, but no significant difference was found between the two groups.^[12] Also, Dolatian *et al.*, assessed the effectiveness of vitamin E, vitamin B6, and placebo on PMS in 93 patients in Tehran. They found that 100 mg of vitamin E, 40 mg of vitamin B6, or placebo, all had a similar effect in the treatment of PMS.^[13] Pourmohsen *et al.*, in their study on the effect of calcium, vitamin E, and placebo, reported that after 3 months of intervention with 1000 mg of calcium plus 400 IU of vitamin E, the severity of symptoms showed a significant decrease in the intervention versus placebo group.^[14] A current RCT suggests that the mean score of the syndrome significantly decreased in all the three groups (12, 16, and 8 participants had decreased scores in vitamin D, vitamin E, and placebo, respectively). The differences between groups were not significant ($P > 0.05$). But maximum effect was observed in Vit-E group.^[15] A more recent larger RCT though suggests that in group that, received Vit E, had significant difference after treatment; regarding their physical symptoms ($p = 0.000$), mental symptoms (0.001) and their physical & mental symptoms (0.000).^[16]

The symptom score of group A and B has significant reduction over group C, hence it is beneficial to give vitamin E and B6 for reducing the symptoms of premenstrual syndrome over placebo treatment. Results for comparison in groups A and B were insignificant. Vitamin E and B6 were equally effective for the improvement in symptoms of premenstrual syndrome. Last but not the least, all the patients suffering from PMS should inherent certain changes in their lifestyle such as taking healthy diet and exercising.

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