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STUDY OF THE EFFICACY OF VITAMIN B6 FOR THE TREATMENT OF PREMENSTRUAL SYNDROME

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ABSTRACT

Background and Objective: It is well-known that many women experience periodic physical and psychological symptoms during the luteal phase of the menstrual cycle. These symptoms, collectively known as premenstrual syndrome (PMS), affect approximately 20-30% of women. PMS is characterized by various physical and psychological manifestations, including palpitations, lower back pain, bloating, abdominal discomfort, headaches, fatigue, weight gain, acne, changes in appetite, insomnia or excessive sleep, emotional sensitivity, depression, anger, irritability, and mood swings. Several studies suggest that vitamin B6 might be effective in alleviating the emotional and physical symptoms associated with this syndrome. **Objective**: The objective of this study is to determine the effectiveness of vitamin B6 in managing the physical and psychological symptoms of premenstrual syndrome. **Methods:** This pilot prospective study involved 72 patients who sought treatment for premenstrual syndrome at the women's clinic in Tishreen University Hospital, Lattakia, between the years 2022 and 2023. The age range of the participants was between 18 and 45 years. **Results:** Following a three-month treatment regimen of daily 100 mg doses of vitamin B6, a significant reduction in the severity of both physical symptoms (P-value < 0.05) and psychological symptoms (P-value < 0.05) was observed. Additionally, there was a significant decrease in the number of symptom days (P-value < 0.001). **Conclusion:** Vitamin B6 has proven to be an effective treatment option for reducing the severity of physical and psychological symptoms associated with premenstrual syndrome. It is a readily available treatment with minimal side effects.

KEYWORDS: premenstrual syndrome, physical symptoms, psychological symptoms, vitamin B6.

INTRODUCTION

Premenstrual Syndrome (PMS) is a condition characterized by a combination of physical, emotional, and behavioral symptoms that occur without the presence of psychiatric disorders.[1] The severity of these symptoms can range from very mild to very severe. In most women, regardless of symptom severity, they typically disappear within four days prior to the onset of menstruation. [2] PMS commonly occurs in the luteal phase, which is 10-14 days before the start of menstruation, and it usually resolves either during menstruation or with its onset.[3,4] The syndrome affects approximately 20%-30% of women of reproductive age.[5] Recent studies conducted in Iran in 2022 estimated a global prevalence of PMS ranging from 10% to 98%.[6]

Premenstrual dysphoric disorder (PMDD) is an intensified and severe manifestation of a premenstrual syndrome characterized by the predominance of symptoms such as anger, irritability, and tension, which significantly disrupt daily life.[7,8] PMDD affects approximately 1.2%-6.4% of women who experience premenstrual symptoms.[9]

The symptoms of PMDD encompass both physical and psychological manifestations. These include palpitations, lower back pain, bloating, abdominal discomfort, headaches, fatigue, weight gain, acne, changes in appetite, sleep disturbances (insomnia or excessive sleep), an inclination to cry, feelings of depression, anger, irritability, and pronounced mood swings.

The exact causes of premenstrual syndrome (PMS) are not fully understood. However, there are several factors that are believed to contribute to its occurrence:

- Cyclical changes in ovarian sex hormones: Fluctuations in hormone levels, particularly estrogen, and progesterone, during the menstrual cycle are considered an important factor. The impact

of these hormone changes may vary among individuals.[10]

- Chemical changes in the brain: Hormonal fluctuations can influence the levels of neurotransmitters, such as serotonin, in the brain. Serotonin is known to play a crucial role in regulating mood, and alterations in its levels can contribute to the physical and psychological symptoms of PMS.[11]
- Genetic predisposition: Some women may have a genetic makeup that makes them more susceptible to experiencing PMS symptoms.[12]

These factors can worsen the symptoms of PMS, but they do not directly cause the condition itself. Risk factors that can worsen premenstrual syndrome (PMS) symptoms include a family history of depression, personal history of postpartum depression or depression, smoking, exposure to high levels of stress and pressure, lack of exercise, inadequate sleep, and excessive alcohol and caffeine intake.[13]

The diagnosis of PMS follows the criteria recommended by the American College of Obstetrics and Gynecology (ACOG), which are based on the Premenstrual Symptom Assessment Questionnaire (MSQ, PAF).[14]

The objectives of PMS treatment are to reduce or eliminate symptoms, minimize its impact on daily activities and personal relationships, and minimize the adverse effects of treatment.[15] There is a variety of treatment options available, including antidepressants, anxiolytics, hormonal agents, selective serotonin reuptake inhibitors (SSRIs) like fluoxetine, nutritional supplements (e.g., calcium, magnesium, and vitamins), and herbal medicines. These treatment options have been suggested to help alleviate the symptoms of PMS.

Studies indicate that vitamin B6 may be effective in relieving the emotional and physical symptoms associated with PMS. This is because vitamin B6 plays a role in the formation of neurotransmitters such as serotonin, dopamine, endorphins, and gamma-aminobutyric acid (GABA).[16-18]

MATERIALS AND METHODS

The pilot prospective study included 72 patients who visited the women's clinic at Tishreen University Hospital in Lattakia Syria, between the years 2022 and 2023. These patients were aged between 18 and 45 years and reported experiencing premenstrual syndrome (PMS) symptoms. The study consisted of two phases. The first phase involved a three-month period prior to treatment and aimed to monitor the patients. The following plan was implemented during this phase:

1. Detailed Menstrual History: Information regarding the age at which menstruation began, duration of menstruation, intervals between menstrual cycles, correlation between symptoms and the menstrual cycle phase (follicular or luteal), type and severity of symptoms, and recurrence of symptoms in each menstrual cycle was recorded.
2. Detailed Medical History: A comprehensive medical history was obtained, including family history, medical conditions, gynecological history, surgical history, medication history, allergies, and questions about habits such as smoking and alcohol consumption. Additionally, the patients' body mass index (BMI) was calculated.
3. Clinical Evaluation and Pelvic Ultrasound: A clinical evaluation was conducted, and pelvic ultrasound was performed to rule out any other pathologies that could be causing symptoms similar to PMS.
4. Blood Tests: Complete blood count and thyroid-stimulating hormone (TSH) tests were performed to exclude anemia or thyroid disorders, which can be associated with symptoms resembling PMS.

These measures were taken to ensure a comprehensive assessment of the patients' health status and to rule out other potential causes of PMS-like symptoms.

The second phase of the study involved a three-month treatment period. During this period, the patients were orally administered 100 mg of vitamin B6 daily on an empty stomach. To assess the effectiveness of the treatment and diagnose the syndrome, the women were requested to complete a premenstrual syndrome questionnaire based on a modified version of the Premenstrual Symptom Assessment Questionnaire (MSQ, PAF). This questionnaire included 10 physical symptoms and 12 behavioral and psychological symptoms.

The syndrome was diagnosed if a woman exhibited at least five of the mentioned symptoms, including at least one symptom from each of the two lists (physical symptoms and psychological symptoms), and if the symptoms occurred during the luteal phase and disappeared after the onset of menstruation.

The inclusion criteria for the study were as follows:

- Age between 18 and 45 years.
- Regular menstrual cycles with durations between 21 and 35 days.
- Diagnosis of premenstrual syndrome symptoms based on the Menstrual Stress Questionnaire (MSQ, PAF).

The following criteria were considered non-inclusion criteria:

- Presence of unstable metabolic diseases such as Wilson's disease, altered phenylketonuria, or porphyria.
- Presence of acute or chronic systemic diseases affecting the cardiovascular, hepatic, digestive, renal, pulmonary, or blood systems.
- Diagnosed mental disorders.
- Active metastasis.

- Use of oral contraceptives or serotonin reuptake inhibitors at the time of screening.
- Consumption of vitamin B6 supplements during the three months preceding the study.
- Pregnancy and lactation.

These criteria were established to ensure that the study participants met specific requirements and did not have any confounding factors that could impact the assessment of the treatment's effectiveness.

In the statistical study, both descriptive and inferential statistical analyses were performed using the IBM SPSS Statistics program (version 20). The data analysis involved the following techniques:

1. Descriptive Statistics:
   - For qualitative variables, frequencies and percentages were calculated to summarize the data.
   - For quantitative variables, measures of central tendency (such as mean, median) and measures of dispersion (such as standard deviation, range) were computed.
2. Inferential Statistics:
   - The Friedman test was used to analyze differences between means among multiple related groups. This test is appropriate for comparing related variables measured on an ordinal scale.
   - The paired t-test was used to examine average differences between two related groups. This test is suitable for comparing means of variables measured on an interval or ratio scale.

RESULTS

The results were considered statistically significant if the p-value was less than 0.05, indicating a low probability of obtaining the observed results by chance.

The results of the current study revealed the following findings:

1. Age Distribution: The age of the study participants ranged from 18 to 42 years, with an average age of 31 ± 7. The largest percentage of patients (54%) fell within the fourth decade of life, specifically between 29 and 39 years.
2. Demographic Characteristics:
   - Weight: The majority of the study sample (50%) had a normal weight.
   - Marital Status: 65% of the participants were single.
   - Diet: 62.5% of the participants had a vitamin B6-deficient diet.
   - Smoking: 70.8% of the participants were smokers.
   - Family History: 61% of the participants had a positive family history of premenstrual syndrome.
   - Caffeine Consumption: 54.2% of the participants consumed large quantities of caffeine (more than 3 cups per day).
   - Exercise: 70.8% of the participants did not engage in regular exercise.
3. Physical Symptoms:
   - The most common physical symptoms reported by the participants were flatulence (98.6%), severe fatigue (97.2%), acne (88.9%), and breast pain (77.8%).
   - The least common physical symptoms reported were muscle pain (41.7%), weight gain (38.9%), dizziness (29.2%), nausea and vomiting (27.8%), and constipation and diarrhea (20.8%).
4. Psychological and Behavioral Symptoms:
   - The most common psychological and behavioral symptoms reported by the participants were mood swings (97.2%), irritability (93.1%), anxiety (88.9%), tension (87.5%), and depression and increased appetite (83.3%).
   - The least common psychological symptoms reported were isolation (41.3%), poor concentration (38.9%), forgetfulness (30.6%), desire to cry (25%), sleep problems (23.6%), and lack of sexual desire (18.1%).

These findings provide insights into the demographic characteristics and prevalence of physical, psychological, and behavioral symptoms experienced by the study participants with premenstrual syndrome. After administering vitamin B6 at a daily dose of 100 mg for three months, the study observed a significant decrease in the severity of both the most common and least common physical symptoms. The improvement rate at the end of the treatment period in the third month was 59% for the most common physical symptoms, with a highly significant P-value of less than 0.001 (Table 1).

Table 1: Percentage improvement in the severity of the most common physical symptoms.

The severity of the most common physical symptoms	(Mean±SD)	Percentage improvement	p-Value
before treatment	3,8 ± 0,7	0%	
after a month	3,4 ± 0,6	%15	
After 2 months	2,9 ± 0,5	%33	
After three months	2,2 ± 0,4	%59	< 0,001

For the least common physical symptoms, the improvement rate in the third month was 58%, and the P-value was less than 0.003 (Table 2). Furthermore, there was a notable improvement in the severity of the most common psychological and behavioral symptoms, with statistically significant differences.

Table 2: Percentage improvement in the severity of the least common physical symptoms.

The severity of the least common physical symptoms	(Mean ±SD)	Percentage improvement	p-Value
before treatment	2,2 ± 1,0	0%	
after a month	2,0 ± 0,7	%14	
After 2 months	1,8 ± 0,4	%33	
After three months	1,2 ± 0,3	%58	< 0,003

The improvement rate in the third month was 63%, and the P-value was less than 0.001 (Table 3). Similarly, the severity of the least common psychological and behavioral symptoms decreased, with an improvement rate of 54% in the third month and a significant P-value of less than 0.05 (Table 4).

Table 3: Percentage improvement in the severity of the most common psychological and behavioral symptoms.

The severity of the most common psychological symptoms	(Mean ±SD)	Percentage improvement	p-Value
before treatment	3,8 ± 1,2	0%	
after a month	3,4 ± 1,0	17%	
After 2 months	2,9 ± 0,8	32%	
After three months	2,2 ± 0,4	63%	<0.001

Table 4: Percentage improvement in the severity of the least common psychological and behavioral symptoms.

The severity of the least common psychological symptoms	(Mean ±SD)	Percentage improvement	p-value
before treatment	2,3 ± 1,3	0%	
after a month	2,2 ± 1,1	8%	
After 2 months	1,9 ± 0,8	26%	
After three months	1,6 ± 0,3	54%	<0.05

Moreover, the study observed a reduction in the number of days with premenstrual syndrome symptoms after using vitamin B6. This decrease was statistically significant, starting from the first month of treatment with a P-value of less than 0.001. The reduction in symptoms was 19% in the first month, increasing to 42% in the second month, and reaching 70% by the end of the third month (Table 5).

Table 5: Mean values of the number of days of the menstrual cycle in which symptoms of premenstrual syndrome appear before the use of vitamin B6 and during follow-up periods for the study sample from the reviews of the women's clinic in Tishreen University Hospital in Lattakia 2022-2023.

Number of days of onset of premenstrual syndrome symptoms	Min value	Max Value	(Mean ±SD)	percentage improvement	p-Value
before treatment	7	13	9,3 ± 1,9	0%	
after a month	6	9	7,6 ± 1,1	19%	
After 2 months	4	7	5,4 ± 1,1	42%	
After three months	2	4	2,8 ± 0,8	70%	<0.05

These findings indicate that vitamin B6 treatment resulted in a significant improvement in the severity of physical and psychological symptoms associated with premenstrual syndrome. Additionally, the duration of symptom occurrence was significantly reduced over the three-month treatment period.

DISCUSSION

The results of our current study are consistent with previous research conducted by Kashanian et al. (Iran)[19], Kendall University (USA)[20], Soheila et al. at Hamden University (Iran)[21], and the University of Canterbury (New Zealand).[22]

Kashanian and colleagues investigated the effect of vitamin B6 placebo on premenstrual syndrome and found a decrease in the severity of physical symptoms after using vitamin B6, with statistically significant differences (p-value < 0.005). They also observed a reduction in psychological and behavioral symptoms with vitamin B6 supplementation, which was statistically significant (p-value < 0.005).

Similarly, the study conducted at Kendall University (USA) on the effects of vitamin B6 supplementation on premenstrual symptoms reported a statistically significant decrease in psychological and behavioral symptoms such as depression, tension, irritability, anger, and lack of concentration (p-value < 0.01). These findings align with the results of our current study.

In the study by Soheila and colleagues at Hamden University (Iran), the combined use of calcium and vitamin B6 resulted in a decrease in physical symptoms such as fatigue, flatulence, and breast tenderness, which was statistically significant (p-value = 0.006). They also observed a significant decrease in psychological and behavioral symptoms, including depression, anxiety, social isolation, and increased appetite (p-value < 0.001). No significant side effects were observed in the patients after taking vitamin B6.

Furthermore, the study conducted at the University of Canterbury (New Zealand) compared the effects of vitamin B6 alone and a combination of micronutrients (calcium, magnesium, and various vitamins) on premenstrual syndrome symptoms. They reported a significant improvement in both physical and psychological symptoms after using vitamin B6 supplementation, with statistically significant differences (p-value < 0.005).

These consistent findings across different studies reinforce the effectiveness of vitamin B6 in alleviating the symptoms of premenstrual syndrome, both physical and psychological. The results indicate that vitamin B6 supplementation can be a valuable treatment option for women experiencing premenstrual syndrome symptoms.

CONCLUSIONS

In conclusion, our study demonstrates the effectiveness of vitamin B6 in alleviating both the physical and psychological symptoms of premenstrual syndrome (PMS). The findings indicate that vitamin B6 supplementation can provide relief from symptoms such as flatulence, fatigue, headache, breast tenderness, acne, dizziness, weight gain, nausea, mood swings, irritability, anxiety, poor concentration, and depression associated with PMS.

Furthermore, vitamin B6 has shown positive results in reducing the duration of PMS symptoms, suggesting its potential to improve the overall quality of life for women experiencing these symptoms.

Based on the study findings, we recommend the following:

1. Vitamin B6 supplementation: It is recommended to take vitamin B6 at a daily dose of 100 mg for a minimum of three consecutive months to effectively alleviate PMS symptoms.
2. Dietary considerations: Follow a diet rich in vitamin B6, including foods such as leafy vegetables (especially spinach), fruits (especially bananas and avocados), sweet potatoes, chicken, fish, meat, legumes, nuts, and whole grains. Incorporating these foods into your diet can contribute to the natural intake of vitamin B6.

It is important to note that individuals should consult with healthcare professionals, such as gynecologists or nutritionists, before starting any new supplementation or making significant dietary changes. They can provide personalized advice and guidance based on individual health conditions and specific needs.

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