

Research Digest

Poor-quality studies suggest that vitamin B₆ use is beneficial in premenstrual syndrome

QUESTION

Is the use of vitamin B₆ (pyridoxine hydrochloride) effective for relieving overall premenstrual symptoms and depressive premenstrual syndrome?

DATA SOURCES

Studies were identified by searching MEDLINE (1966-1998), EMBASE (1988-1996), PsychLIT (1974-1997), CINAHL (Cumulative Index to Nursing and Allied Health) (1982-1997), and the Cochrane Controlled Trials Register with the terms premenstrual syndrome, pyridoxine, premenstrual tension, late luteal phase dysphoric disorder, and premenstrual dysphoric disorder. Bibliographies of relevant articles were scanned, and pharmaceutical companies were contacted.

STUDY SELECTION

Published and unpublished studies in any language were selected if they were randomized, double-blind, placebo-controlled studies for which data could be acquired. Studies involving multivitamin supplements were included if the supplement contained ≥ 50 mg of vitamin B₆. Authors were contacted if additional information was required.

DATA EXTRACTION

Data were extracted on participants, dose and preparation of vitamin B₆, outcome measures, results, withdrawals, side effects, and quality scores. Main outcome was subjective lessening of overall premenstrual symptoms, and a secondary outcome was a decrease in depressive premenstrual symptoms. High-quality studies had scores of 3 on the Jadad scale (maximum: 5 points) and of 6 on the authors' quality rating scale (maximum: 8 points).

MAIN RESULTS AND CONCLUSIONS

Ten studies with 12 comparisons met the inclusion criteria. Sample sizes ranged from 31 to 434 patients (mean: 98 patients). Doses ranged from 50 mg per day (3 comparisons) to 600 mg per day (1 comparison). Quality scores on the Jadad scale were 1 (3 studies), 2 (1 study), and 3 (3 studies) points. On the authors' quality rating scale, scores were 3 (2 studies), 4 (5 studies), 5 (2 studies), and 6 (1 study) points. Quality scores were not used to exclude trials from the analysis because few high-quality studies were found.

Pooled results showed that vitamin B₆ relieved premenstrual symptoms (combined odds ratio: 2.12; 95% confidence interval: 1.80-2.48). One study led to heterogeneity ($P < 0.001$), and the removal of this study results in

a combined odds ratio of 1.69 (95% confidence interval: 1.39-2.06). The three high-quality studies according to the Jadad scale showed a benefit for the use of vitamin B₆, whereas the one high-quality study according to the authors' quality rating showed no effect; this study had low power for detecting any differences. No dose response was found in the nine trials. A meta-analysis of randomized, double-blind, placebo-controlled trials shows that the use of vitamin B₆ relieves overall premenstrual and depressive premenstrual symptoms. Most studies were of poor quality.

Commentary

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Epidemiologic surveys have estimated that as many as 75% of women with regular menstrual cycles experience some physical and psychological symptoms premenstrually.¹ Vitamin B₆ (pyridoxine hydrochloride) use is one of the numerous treatments suggested for premenstrual syndrome (PMS). Wyatt and colleagues have systematically reviewed trials comparing the efficacy of vitamin B₆ with placebo in women with PMS. Although their meta-analysis includes a few more trials than a previous review published in 1991,² they, too, conclude that "there is insufficient evidence of high enough quality to give a confident recommendation for using vitamin B₆ in the treatment of premenstrual syndrome" (p 1378).

The authors used extensive data sources and rigorous selection criteria to identify 10 relevant trials. They used two different scales to evaluate the methodologic quality of each trial. Nine trials (after excluding 1 trial that caused statistical heterogeneity) were included in the meta-analysis, although only four were rated as high-quality studies on either of the two scales. The nine trials differed in many ways, including the outcomes, the dosage of vitamin B₆, and whether the intervention was vitamin B₆ alone or as the ingredient of a multivitamin. Moreover, the authors did not consider the severity of premenstrual symptoms.

This is an important variable because women who meet criteria for premenstrual dysphoric disorder, the more severe form of PMS, usually do not respond to more conservative interventions, such as vitamin B₆.³ The lack of a dose response adds to the uncertainty about the effectiveness of vitamin B₆ for PMS.

This review highlights the need for well-designed trials to compare the use of vitamin B₆ with placebo to establish more accurate recommendations for treatment. In the meantime, what do clinicians tell patients? Given that vitamin B₆ is readily available, relatively inexpensive, and generally has minimal adverse effects in doses of less than 200 mg, clinicians may suggest that patients take = 100 mg per day as a conservative treatment option before considering drugs with stronger evidence of effectiveness such as selective serotonin reuptake inhibitors.

1 Steiner M, Yonkers KA. *Depression in women*. London (UK): Martin Dunitz Ltd; 1998.

2 Kleijnen J, Ter Riet G, Knipschild P. Vitamin B₆ in the treatment of the premenstrual syndrome: a review. *Br J Obstet Gynaecol* 1990;97:847-852.

3 Steiner M. Premenstrual syndromes. *Annu Rev Med* 1997;48:447-455.

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BMJ
1999;318:1375-1381.

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This paper was originally
published in
Evidence-Based Nursing
2000;3:18.