ALTERNATIVE THERAPIES IN WOMEN'S HEALTH

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INSIDE

Calcium and Magnesium for Premenstrual Syndrome

By Judith L. Balk, MD, FACOG

IN 400 BC, HIPPOCRATES DESCRIBED TEMPESTUOUS PREMENSTRUAL behavior, and he attributed the symptoms to agitated blood seeking escape from the womb.[1] Over the past 2,000 years, we have made substantial progress in understanding premenstrual syndrome (PMS), but this condition still is not understood completely.

Definition and Prevalence

PMS is defined as "the cyclic occurrence of symptoms that are of sufficient severity to interfere with some aspects of life and that appear with consistent and predictable relationship to the menses." Although the symptoms themselves are fairly common, the restriction of the symptoms to only the luteal phase is pathognomonic of PMS.[2] Premenstrual symptoms are common and often are considered to be a normal aspect of menstrual cycles, with surveys finding that up to 85% of menstruating women report one or more premenstrual symptoms. However, the definition of PMS requires that the symptoms be of sufficient severity that they interfere with aspects of life, and only 5-10% of menstruating women meet this criteria.[2] More recently, the fourth edition of the Diagnostic and Statistical Manual of Mental Disorders includes premenstrual dysphoric disorder (PMDD), which differs from PMS in the severity of the emotional symptoms that a patient experiences.

Etiology

No one etiology has been found for PMS. Since the description of PMS decades ago, many etiologies have been suggested, from hormonal factors to nutritional factors to central nervous system factors. Most likely, there are interactions between these factors. For instance, there may be central nervous system-mediated neurotransmitter interactions with sex steroids.[2] Also, sex steroid hormones have been found to modulate serum ionized magnesium and calcium levels throughout the menstrual cycle, possibly causing PMS in vulnerable women.[3]

Diagnosis

Four key elements are required to make the diagnosis of PMS.[2]

Diagnosis must be made by maintaining a prospective diary for at least two menstrual cycles. The key elements are shown in Table 1. Symptoms consistent with PMS are shown in Table 2.

Treatment

Because the etiology is not precisely understood, the treatment options for PMS are many. Both lifestyle and pharmacologic management have been studied and commonly are used. A standard approach is to begin lifestyle modification prior to pharmacologic management, reserving pharmacologic management for those who fail to benefit from lifestyle modification. Lifestyle modifications include mind-body approaches, aerobic exercise, and supplementation with vitamins, minerals, and complex carbohydrates. Pharmacologic management includes selective serotonin reuptake inhibitors, anxiolytics, diuretics, GnRH analogs, and oral contraceptive pills. Because many studies use different diagnostic criteria and heterogeneous patient populations, making firm conclusions about which patients benefit from certain approaches is difficult.

Many types of dietary supplements have been advocated for the reduction of PMS symptoms.[4] Conflicting results have been found with trials of vitamin B_6. Similarly, evening primrose oil has conflicting results; however the most rigorous studies demonstrated no benefit. Supplements for which there is limited evidence for efficacy include magnesium, vitamin E, and carbohydrate supplements. The one supplement that has been shown to have significant benefit is calcium.

Calcium, Magnesium, and PMS

Ovarian hormones influence calcium, magnesium, and vitamin D metabolism. In a small prospective study, 10 women with regular menstrual cycles had concentrations of hormones, ionized calcium, and magnesium levels measured in five different stages of the menstrual cycle: menstrual phase, early follicular, late follicular, ovulatory/early luteal, and luteal phases.[3] In each woman, calcium and magnesium levels consistently changed during the menstrual cycle. The authors conclude that the changes could produce premenstrual symptoms in certain women.

Clinical trials of magnesium supplementation are not highly convincing. One study was a small, double-blind, randomized clinical trial of 32 women with PMS by Moos Menstrual Distress Questionnaire (MMDQ), a validated tool for measuring PMS.[5] Patients were randomly assigned to receive either magnesium pyrrolidone carboxylic acid (360 mg magnesium) or placebo, three times per day from day 15 of the menstrual cycle to the onset of menses. The MMDQ scores for pain were reduced in both groups, whereas magnesium treatment significantly reduced total MMDQ scores and assessment of negative affect. However, the groups appeared to differ at baseline with respect to the total score. Also, studies of PMS typically show a placebo response, at least initially, but this study demonstrated no placebo effect at the end of the first two months. However, once the placebo group began the active treatment, scores did decrease.

A double-blind crossover study over four menstrual cycles also investigated the effects of magnesium supplementation on PMS.[6] Premenstrual symptoms were grouped into four categories: anxiety-related, craving-related, depression-related, and hydration-related, (i.e., swelling, bloating, and breast tenderness). Subjects received either placebo or 200 mg of magnesium, as magnesium oxide, for two cycles and then crossed over to receive the other, either magnesium or placebo for two more cycles. In the second month of treatment, there was a statistically significant reduction in symptoms within the hydration-related subgroup with magnesium compared to placebo. No changes were seen in the other subgroups.

Alternative Therapies in Women's Health, ISSN 1522-3396, is published monthly by Thomson American Health Consultants, 3525 Piedmont Rd., NE, Bldg. 6, Suite 400, Atlanta, GA 30305.

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GST Registration Number: R128870672.

Application to mail at periodical postage rates is pending at Atlanta, GA 30304.

POSTMASTER: Send address changes to *Alternative Therapies in Women's Health*, P.O. Box 740059, Atlanta, GA 30374.

Back issues: $45. Missing issues will be fulfilled by Customer Service free of charge when contacted within one month of the missing issue's date.

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Subscription Prices

United States
$319 per year (Student/Resident rate: $150).
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$349 per year plus GST (Student/Resident rate: $165 plus GST).

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This publication does not receive commercial support.

Table 1

Key elements to diagnosis of PMS

Timing	Restricted to the luteal phase of the menstrual cycle
Symptoms	Affective and somatic symptoms consistent with PMS
Severity	Must impair some facet of the woman's life
Other causes	Exclusion of other diagnoses that may better explain the symptoms

Table 2

PMS symptoms

Affective	**Somatic**
Depression	Breast tenderness
Angry outbursts	Abdominal bloating
Irritability	Headache
Anxiety	Swelling of extremities
Confusion	
Social withdrawal	

Table 3

Calcium content of foods

Food	Serving Size	Calcium Content
Fat-free, plain yogurt	1 cup	450 mg
Calcium-fortified orange juice	8 oz	300 mg
Dried figs	10	269 mg
Tofu made with calcium	½ cup	260 mg
Cheddar cheese	1 oz	204 mg
Salmon, canned with bones	3 oz	180 mg
Cottage cheese	1 cup	138 mg
Spinach	½ cup	122 mg
Broccoli	1 cup	90 mg

Source: Pennington JAT. *Bowes and Church's Food Values of Portions Commonly Used.* 17th ed. Philadelphia: Lippincott Williams & Wilkins Publishers; 1998.

Calcium has been studied extensively for PMS, and the results are fairly convincing. As Thys-Jacobs notes, there is striking similarity between the symptoms and PMS and hypocalcemia.[7] A literature review of Medline from 1967 to 1999 concluded that calcium supplementation of 1,200-1,600 mg/d, unless contraindicated, should be considered a sound treatment option in women who experience premenstrual syndrome.[8]

A large, multicenter study enrolled healthy, premenopausal women with moderate-to-severe PMS.[9] Symptoms were prospectively documented over two menstrual cycles with a daily rating scale that had 17 core symptoms and four symptom factors (negative affect, water retention, food cravings, and pain). Almost 500 women enrolled in this study, with 466 valid for the efficacy analysis. Subjects were randomized to receive either placebo or 1,200 mg elemental calcium per day in the form of calcium carbonate for three menstrual cycles. The primary outcome was the 17-variable symptom complex score. Groups were similar at baseline. Compared to those in the placebo group, subjects in the calcium-treated group had lower symptom complex scores for both the second and third treatment cycles. By the third treatment cycle, calcium effectively resulted in an overall 48% reduction in total symptom scores from baseline compared with a 30% reduction in the placebo group. All four symptom factors were also significantly reduced by the third treatment cycle. The authors note that calcium supplementation may act by repleting an underlying physiologic deficit, suppressing parathyroid hormone secretion, and ultimately reducing neuromuscular irritability and vascular reactivity.

Contraindications and Dosage

The safe, tolerable maximum dosage of calcium is 2,500 mg per day. Calcium should not be taken at the same time as iron because calcium blocks iron absorption. The recommended dosage for PMS is 1,200-1,600 mg per day calcium, in divided doses. It is difficult to achieve this dosage by food intake alone. (*See Table 3 for food sources of calcium.*) Patients with vitamin D toxicity and those with hypercalcemia and risk factors for hypercalcemia should not use supplemental calcium. Low-dose magnesium, such as 200 mg of magnesium oxide, can be used to reduce mild symptoms of fluid retention. High doses of magnesium can cause diarrhea. Patients with renal disease should use magnesium only under the supervision of a physician.

Conclusion

Calcium supplementation has strong evidence for efficacy in improving PMS symptoms. Less evidence exists for using magnesium for PMS. Calcium has other benefits besides treating PMS, such as beneficial effects on bone. Also, low calcium intake has been implicated in the development of hypertension and colon cancer.[10] Calcium can be a first-line approach to treating PMS, once the diagnosis is clearly made using prospective

charting. If calcium is not beneficial in improving PMS symptoms, the other lifestyle and pharmacologic approaches can be tried. ❖

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Can Chaste Tree Berry Extract Help with PMS Symptoms?

Source: Schellenberg R. Treatment for the premenstrual syndrome with agnus-castus fruit extract: Prospective, randomized, placebo controlled study. *BMJ* 2001;322:134-137.

Abstract: This randomized, double-blind, placebo-controlled, parallel group comparison was conducted at general medicine clinics to compare the efficacy and tolerability of agnus-castus fruit (*Vitex agnus-castus* L extract Ze 440) with placebo in women with premenstrual syndrome (PMS) over three menstrual cycles. The study evaluated 170 women (active 86; placebo 84), with mean age of 36 years, mean cycle length of 28 days, and mean duration of menses of 4.5 days. Participants received one tablet daily of agnus-castus (dry extract tablets) or matching placebo, given for three consecutive cycles. The main efficacy variable was change from baseline to endpoint (end of third cycle) in women's self-assessment of irritability, mood alteration, anger, headache, breast fullness, and other menstrual symptoms including bloating. Secondary efficacy variables included changes in clinical global impression (severity of condition, global improvement, and risk or benefit) and responder rate (50% reduction in symptoms). The researchers found that improvement in the main variable was greater in the active group compared with placebo group. Seven women reported mild adverse events (four active; three placebo), none of which caused discontinuation of treatment. The authors conclude that dry extract of agnus-castus fruit is an effective and well-tolerated treatment for the relief of PMS symptoms.

Source: Atmaca M, et al. Fluoxetine versus *Vitex agnus-castus* extract in the treatment of premenstrual dysphoric disorder. *Hum Psychopharmacol* 2003;18:191-195.

Abstract: Clinical trials have demonstrated that serotonin reuptake inhibitors and *Vitex agnus-castus* (AC) extract are effective for the treatment of premenstrual dysphoric disorder (PMDD). However, no study to date had compared the efficacy of the SRIs with AC extract. Therefore, the aim of the present study was to compare the efficacy of fluoxetine, a selective serotonin reuptake inhibitor, with that of the AC extract, a natural choice. After a period of two screening months to screen the patients for suitability, 41 patients with PMDD according to DSM-IV were recruited into the study. The patients were randomized to fluoxetine or AC for two months of single-blind, rater-blinded, and prospective treatment. The outcome measures included the Penn daily symptom report, the Hamilton depression rating scale, and the clinical global impression-severity of illness and -improvement scales. At endpoint, using the clinical criterion for improvement, a similar percentage of patients responded to fluoxetine (68.4%, n = 13) and AC (57.9%, n= 11). There was no statistically significant difference between the groups with respect to the rate of responders. This preliminary study suggests that patients with PMDD respond well to treatment with both fluoxetine and AC. However, fluoxetine was more effective for psychological symptoms while the extract diminished the physical symptoms.

■ COMMENTS BY MARY L. HARDY, MD

The symptoms of premenstrual syndrome (PMS) are all too familiar to the majority of women. Estimates of prevalence for PMS range from 30-80% with 5% of the menstruating population reporting severe symptoms.[1,2]

According to a recent telephone survey of a representative sample of childbearing-aged women, disturbance of mood is the most commonly reported severe symptom of PMS.[1] Premenstrual dysphoric disorder (PMDD), a severe form of PMS defined in the DSM-IV, is mainly characterized by cyclical symptoms, such as depressed mood, anxiety, or irritability, which disrupt daily activity.[3] Physical symptoms generally associated with PMS (bloating, cramps, etc.) often are present as well, and the disability experienced may be as high as that associated with major depression.

Conventional therapy for PMDD focuses on use of selective serotonin reuptake inhibitors (SSRI) to address the reported mood instability. [4] Despite the fact that this medication has been shown to be effective, the side effect profile of SSRIs has discouraged full compliance. In fact, women with PMS are very likely to use over-the-counter and alternative remedies for symptomatic relief, in part because this is largely a self-diagnosed illness and also to limit side effects of treatment. Estimates for lifetime use of complementary or alternative medicine (CAM) by PMS sufferers have been as high as 91%.[2] CAM users with PMS are likely to be regular consumers of these therapies with the most popular choices being vitamin B_6, evening primrose oil, Chinese or other herbs, homeopathy, and acupuncture.[2] A growing body of clinical evidence supports the use of CAM therapies for PMS. A recent review of this subject cites positive studies for a number of therapies, including one for an herbal extract of the plant *Vitex agnus-castus* (VAC) or chaste tree berry.[5] A plant native to the Mediterranean, VAC contains iridoids, flavinoids, progestin-like compounds, and essential oils, which are reported to have hormonal effects, such as promoting progesterone, opposing androgens, and decreasing prolactin.[6] All of these are activities that could address the underlying mechanisms of PMS. In light of this, two recent trials that examined the efficacy of VAC for PMS and PMDD bear closer examination.

First, a double-blind, placebo-controlled trial examined the efficacy of VAC extract vs. placebo for the relief of PMS.[7] In this trial, 170 women who met a diagnostic criteria for PMS were given either a standardized extract of VAC or placebo for three months. The VAC extract was a proprietary extract prepared from the berries using 60% ethanol and an extract ratio of 6-12:1 (a relatively concentrated product). Patients took one 20 mg tablet per day, which had been standardized to casticin, one of the major flavinoids in this plant. The principle outcome measured was the reduction in the score of self-rating visual analogue scales (VAS) for each of six major PMS symptoms (irritability, mood alteration, anger, headache, other physical symptoms, and breast fullness). Patients rated the severity of their PMS symptoms using these scales on entrance into the study retrospectively for their three previous cycles and prospectively at the end of three cycles of treatment. Response to treatment was defined as a 50% or greater reduction in the VAS symptoms scores. Physicians, who were blinded to the intervention, also independently rated the patient response to treatment using the global clinical impression (CGI) scale.

Results showed that more than twice as many patients responded to treatment in the treatment group as in the placebo group (52% vs. 24%). Significant improvements in five of the six symptoms scales was reported ($P < 0.001$), with the other physical symptoms scale not showing a significant decline. Physician evaluations of efficacy were significant and favored treatment. When the women who were taking oral contraceptive pills (OCPs) were removed from the analysis, there was no change in the significance of the outcomes. Few adverse events were reported and the authors believed the VAC extract was well-tolerated.

There are two significant potential limitations of this study. First, it was sponsored by the company that makes the extract, thus raising the possibility of a bias in favor of a positive outcome. Second, asking the women to rate their initial symptoms retrospectively may have exaggerated the severity of their starting symptoms. If women had a bias in rating their symptoms higher in memory than they were in fact, this would tend to make the treatment appear more effective than it might otherwise. Finally, in support of this study, a relatively large number of women were enrolled from several different centers and they appeared to use an appropriate extract for a significant length of time with good clinical results after three months.

The second trial examined the efficacy of a VAC extract vs. fluoxetine, an accepted active therapy for the treatment of PMDD. Forty-two patients who met DSM-IV criteria for PMDD were enrolled in a single-blind, randomized, controlled trial.[8] Their PMDD symptoms were rated using a standardized instrument, the Penn daily symptom reports (DSR) for the two cycles prior to entry into the trial and for the eight weeks of active therapy. Physicians also assessed the patients' mood using the Hamilton Depression Rating Scale (HAM-D) and their response to therapy using the CGI scales. The prescribing physician knew the group assignment, but both the patient and the physician assessor were blinded. Patients were given 20-40 mg per day of either fluoxetine or a VAC extract. The dosing schedule was flexible and was allowed to increase based on symptom

severity. Unfortunately, the VAC extract used was not described in any detail in this trial.

Results showed that the mean HAM-D scores at the start of therapy were 15.9 in the VAC group and 15.2 in the fluoxetine group, and were compatible with moderate depression. The mean DSR scores were high, twice the score needed to diagnose severe PMDD. The HAM-D scores and the DSR scores decreased for both groups by approximately 50% after eight weeks (HAM-D: VAC 7.4 and fluoxetine 7.2; DSR: VAC 82.8 and fluoxetine 85.6). The differences from baseline were significant in each group ($P < 0.05$), but the changes between groups were not significant, with the exception of the HAM-D score at one month. Treatment at that point favored fluoxetine, but the differences between the two groups were not significant at the end of the second month. Adverse effects were generally self-limited or not serious but somewhat greater for the fluoxetine group. Both medications were characterized by the authors as well-tolerated.

The limitations of this study are based on the lack of specificity of the VAC product used and the relatively small number of patients enrolled. Because the characteristics of the VAC extract used were not described, clinically it will be harder to apply the results of this trial to our populations. Thus, it cannot be replicated with certainty in our own practices. Further, it is possible that this study was under-powered and did not have sufficient numbers of patients to demonstrate differences between two active therapies. However, the within group comparisons do demonstrate a significant response to therapy (> 50% decrease in HAM-D and DSR scores) in both groups, thus bolstering the claim that the VAC extract tested was as effective as fluoxetine for PMDD after two months of treatment. Patients' initial symptoms were assessed prospectively, thus limiting the possibility of recall bias, a definite strength in the design of this trial.

How can these trials and the other studies on VAC guide our clinical choices? VAC extracts do seem to be helpful for the symptoms of PMS and its more severe form, PMDD. These extracts appear to be well-tolerated, but need at least two to three months (two to three cycles) to be fully effective. They represent a reasonable intervention for mild PMS (first-line therapy) or for PMDD, especially for patients unwilling or unable to use the conventional SSRIs. In at least the first trial, positive benefit was similar in patients who used OCPs and those who did not. It has, however, been postulated that VAC extracts may improve fertility in patients with irregular menses and/or interfere with the mechanism of action of OCPs. This theoretical concern never has been demonstrated and the pregnancy rates in these trials did not confirm this, but they really weren't designed to reveal this outcome, if present. Thus, caution should be exercised in counseling patients regarding barrier methods of birth control in addition to OCPs, if using a VAC extract.

It seems reasonable to recommend to our patients with PMS or PMDD to undertake a trial of a standardized extract of VAC for two months for the relief of symptoms associated with menstruation. The dose for these standardized extracts was 20-40 mg per day. This recommendation would work best in the context of a generalized intervention that includes recommendations for exercise, stress relief, dietary modifications, and perhaps additional supplements. ❖

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CE Objectives

After reading *Alternative Therapies in Women's Health*, the health care professional will be able to:

1. evaluate alternative medicine and complementary therapies for women's health concerns;

2. identify risks and interactions associated with alternative therapies;

3. discuss alternative medicine options with patients; and

4. offer guidance to patients based on the latest science and clinical studies regarding alternative and complementary therapies.

CE/CME Instructions

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After completing this activity, you must complete the evaluation form provided and return it in the reply envelope provided at the end of the semester to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you.

CE / CME Questions

18. According to the American College of Obstetricians and Gynecologists, the prevalence of PMS in healthy menstruating women is:
a. 90-100%
b. 70-80%
c. 0-50%
d. 5-10%

19. The key elements to the diagnosis of PMS are:
a. Timing
b. Severity
c. Symptoms
d. Exclusion of other causes
e. All of the above

20. Calcium supplementation has only anecdotal evidence supporting its use.
a. True
b. False

21. *Vitex agnus-castus* contains:
a. iridoids.
b. flavinoids.
c. progestin-like compounds.
d. essential oils.
e. All of the above

22. The active ingredients in chaste tree berry are reported to have hormonal effects, including promoting progesterone, opposing androgens, and decreasing prolactin. These effects are thought to address the underlying mechanism of PMS.
a. True
b. False

Answers: 18. d, 19. e, 20. b, 21. e, 22. a

CAM Center Profile: Rush University College of Nursing

A nursing program in Chicago has expanded its complementary and alternative medicine (CAM) educational offerings to include web mini-courses and continuing education (CE) conferences. The program now hopes to take some of its CAM educational modules and offer them to the general nursing public for CE credit.

In 2000, the Rush University College of Nursing received a five-year, $1.2 million grant from the National Center for Complementary and Alternative Medicine to provide an educational program on CAM therapies for nursing faculty, students, and practicing nurses. When it received the grant, Rush planned a two-pronged approach: to integrate information on CAM therapies into the undergraduate and graduate nursing curricula, and then to develop and implement CE programs in CAM for nursing faculty and practicing nurses.

The program organizers began by developing a list of competencies—what they saw as the critical issues that nurses need to address when it comes to complementary therapy. "We came up with five broad areas," says Janice M. Zeller, PhD, RN, FAAN, director of the CAM Education Program. For example, one of the competencies is "Incorporate assessment of CAM practices into standard history and physical examinations."

Both the undergraduate and graduate students share the same broad competencies. Each competency is further broken down into one or two "behavioral objectives." The behavioral objectives may vary depending on the type of student. "In some cases, we expect a higher level of performance from the master's students," Zeller says.

The program was designed to allow it to continue in the easiest way possible after the conclusion of the grant. One way was to develop on-line modules about CAM therapies and insert them into pre-existing courses. These web-based modules address topics such as alternative healing systems; the biological basis for, safety, and efficacy of selected CAM therapies; and societal, cultural, and ethical issues pertaining to CAM therapies. There is also a web-based CAM Overview course that all students in the undergraduate and master's program are required to complete.

"In some ways, [placing the modules into pre-existing courses] was a little more work because we had to see if the course director would be willing to set aside time for the students to take this content," Zeller says. The faculty, however, saw the CAM education as a need because students were already asking questions about the therapies.

To test student knowledge, faculty members give students a pretest at the beginning of each on-line module, and then give them the same test at the end of the module. Students are also asked to fill out a survey on their opinions about the module and what they might suggest to change it. Students are questioned about their knowledge, attitude, and experience with complementary therapies before entering the program and upon its completion.

Rush began putting its first group of baccalaureate students through the CAM education program in the fall of 2001. The master's students are part-time and can enter the program in any quarter.

Rush is also into its second phase of its plan for the CAM program, which is developing on-site CE programs. Students can attend brown bag programs, lectures, workshops, and summer institutes. Over the next year, the program hopes to take some of the educational modules developed for Rush students, revise them, and make them available for the general nursing public to earn continuing education credits. "We are working with an outside vendor to be able to provide those materials on-line," Zeller says.

In addition, the program has received money from a private donor; the program organizers hope it will allow them to add some of the CAM education material developed for the nursing program to the university's medical school curriculum. "We have met with the dean of the medical school as well as the CEO of the institution," she says. "They feel that our broad competencies are suitable for any health care provider, but we have to work on carving out what sub-competencies might be more relevant for medical students."

The need to teach health care providers about CAM is critical, according to Zeller. Greater numbers of Americans are using complementary therapies and are spending more out-of-pocket on CAM, in some cases more than they spend on conventional therapies. "Essentially, the horse is out of the barn, so to speak."

"We are trying to educate our students for today but also realizing that this is such a rapidly changing field," she continues, "they need to know how to evaluate information when it arises, and where to go to get cutting-edge information as it develops over time." ❖

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