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CLINICAL PAPER

Homeopathic treatment of premenstrual syndrome: a case series

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Objective: **Observational, prospective study to describe the homeopathic management of premenstrual syndrome (PMS) by a group of French physicians.**
Method: **Women with PMS for >3 months were prescribed individualized homeopathic treatment. The intensity of 10 clinical symptoms of PMS was scored individually at inclusion and at a 3–6 month follow-up visit: absent = 0, mild = 1, moderate = 2, severe = 3. Total symptom score (range: 0–30) was calculated and compared for each patient at inclusion and at follow-up. PMS impact on daily activities (quality of life, QoL) was compared at inclusion and follow-up as: none, mild, moderate, severe, very severe.**
Results: **Twenty-three women were prescribed homeopathic treatment only (mean age: 39.7 years). *Folliculinum* (87%) was the most frequently prescribed homeopathic medicine followed by *Lachesis mutus* (52.2%). The most common PMS symptoms (moderate or severe) at inclusion were: irritability, aggression and tension (87%), mastodynia (78.2%) and weight gain and abdominal bloating (73.9%); and the most common symptoms at follow-up were: irritability, aggression and tension (39.1%), weight gain and abdominal bloating (26.1%) and mastodynia (17.4%). Mean global score for symptom intensity was 13.7 at inclusion and 6.3 at follow-up. The mean decrease in score (7.4) was statistically significant ($p < 0.0001$). Twenty-one women reported that their QoL also improved significantly (91.3%; $p < 0.0001$).**
Conclusions: **Homeopathic treatment was well tolerated and seemed to have a positive impact on PMS symptoms. *Folliculinum* was the most frequent homeopathic medicine prescribed. There appears to be scope for a properly designed, randomized, placebo-controlled trial to investigate the efficacy of individual homeopathic medicines in PMS.**
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Keywords: Homeopathy; Observational study; Premenstrual syndrome; *Folliculinum*; Women's health; Symptoms management

Introduction

Premenstrual syndrome (PMS) is a common condition, affecting 3–5% of women of childbearing age,[1] and encompasses a broad range of somatic, mood and behavioural symptoms that appear during the luteal phase of the menstrual cycle (MC) and disappear when menstruation begins. Numerous symptoms have been described in daily diary recordings of patients and several symptom-based tools for the diagnosis of PMS and the more severe form of the condition, known as premenstrual dysphoric disorder (PMDD), have been proposed.[2–7] The social burden of PMS is high and the repeated cyclic nature of symptoms can cause significant impairments in personal/family relationships and everyday life[8].

Symptoms of PMS are severe enough to warrant treatment in 20–25% of women.[9] Treatment strategies are based on either suppression of the hormonal cycle leading to ovulation or treatment of individual symptoms that cause the most distress to patients.[10] The systematic review of the Cochrane Database 2009 by Brown *et al.*[1] supports the efficacy of selective serotonin reuptake inhibitors in patients with severe PMS, and a second review of the Cochrane Database 2009 by Lopez *et al.* showed possible efficacy of combined oral

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contraceptives containing drospirenone (plus ethinyl estradiol 20 μg).[11] However, side-effects including nausea, insomnia, intermenstrual bleeding, asthenia, breast pain and decreased libido have been reported with these treatments and often result in treatment withdrawal.[1,11]

Many women are now turning to therapies outside of conventional medicine such as homeopathy, acupuncture and cognitive-behavioural therapy in order to relieve their PMS symptoms.[12] Several recent studies and literature reviews report the efficacy of a number of herbal, vitamin, fatty acid and mineral-based remedies in women with PMS.[12–16]

We carried out this observational study in women with PMS in order to describe the homeopathic management of PMS by a group of general practitioners (GPs) and gynaecologists with experience in homeopathy and to assess the effect of homeopathic treatments in relieving PMS symptoms and improving quality of life (QoL).

Materials and methods

This prospective, observational study was carried out between September 2008 and April 2010 in seven centres in France. Seven GPs and gynaecologists with experience and expertise in prescribing homeopathic medicines participated in the study. These doctors had all received specific training in homeopathy during their Masters degree.

Patients

Physicians recruited the first women who presented at their surgery for the main reason of PMS, with symptoms present for >3 months, and if they were prescribed homeopathic treatment at the time of consultation. In these cases, the study was proposed to the women and if they agreed to participate the physicians completed the study documents according to the oral declarations made by the women concerning symptoms and QoL. No specific criteria were used for the diagnosis of PMS as it was an observational study based on the procedures used in daily clinical practice; the clinical symptoms of PMS were not prompted by the physician and the diagnosis was made by the physicians solely on the basis of the symptoms declared spontaneously by the patients. Thus, the symptoms reported by the women were not prompted by the clinical diagnosis established by the physician. The diagnosis depended on the competence of the physician to identify PMS.

Women were not included in the study if they had: any known neoplastic gynaecological pathology, hysterectomy, continuous progestative treatment (implant, vaginal ring, intrauterine device, pill) or combined oral contraceptives (oestrogen and a progestogen). Women were also excluded if they did not comply with treatment, if there was a change in their hormone status (introduction of an oestrogen and/or progestogen, amenorrhoea, pregnancy), if they underwent a hysterectomy and/or bilateral oophorectomy during the study period, or if they withdrew consent or were lost to follow-up.

All patients were required to attend an inclusion consultation and a follow-up consultation, usually between 3 and 6 months later. All women gave their informed consent to participate. Physicians were remunerated for participation in the study, but no patient received any payment or other incentive.

Therapy

All women were prescribed homeopathic medication by their physician (GP or gynaecologist) who recorded the treatment prescribed on the study documents. The choice of treatment, dosage and treatment duration were left to the discretion of the treating physician and were individualized for each patient.

Assessment of clinical progress

All patients were followed for a period of 3–6 months after initiation of treatment. As mentioned above, the intensity of symptoms and impact of PMS on QoL were recorded by the physicians according to oral declarations made by the women at inclusion and at the follow-up visit. The intensity of 10 clinical symptoms of PMS (mastodynia; irritability – aggression – tension; feeling depressed; asthenia; weight gain and abdominal bloating; feeling of bearing down; heaviness of lower limbs; back pain; headaches; skin manifestations) was scored individually at inclusion and at follow-up, as follows: symptom absent = 0, mild in intensity = 1, moderate in intensity = 2, severe in intensity = 3. The global score for the 10 symptoms was then determined by adding up the individual scores to give a final score ranging from 0 to 30. The global symptom score was then compared for each patient at inclusion and at the 3–6 month follow-up. Evolution of symptom intensity was rated as: aggravation (change from absent to mild, mild to moderate, moderate to severe); stable (no change); or improvement (change in intensity from severe to moderate, moderate to mild or mild to absent).

The impact of PMS symptoms on daily activities was assessed by the women as: none, mild, moderate, severe, very severe. Evolution of impact on daily activities was rated as: improvement (change from very severe to severe, severe to moderate, moderate to mild or mild to none); stable (no change); or aggravation (change from none to mild, mild to moderate, moderate to severe, or severe to very severe).

Statistical analysis

The following tests were used to compare the data collected at inclusion and at follow-up: Student's *t* test or Wilcoxon test (Shapiro–Wilk) for quantitative data, or generalized equations of estimation for qualitative data. Alpha risk was fixed at 5%. *p* Values were calculated using a GEE (generalized estimating equations) model.

All statistical analyses were carried out using SAS software.

Results

Study population

A total of 34 women with PMS were recruited during the study period. Five were excluded from the final analysis for the following reasons: wrongly included in the study