ISSN 1015-0684

Schweizerische Zeitschrift für
GanzheitsMedizin
Journal suisse de médecine globale

Dysmenorrhoea and premenstrual syndrome: Treatment with Menstruasan

Clinical study on the efficacy and tolerability of a homeopathic remedy

M. Brautigam
F. H. Degenring

Reprint from Schweiz. Zschr. GanzheitsMedizin 1996; 8 (2): 87–90

Dr. Becker & Partner AG
Verlag für GanzheitsMedizin
CH-4002 Basel

84696.00

M. Brautigam
F. H. Degenring

Dysmenorrhoea and premenstrual syndrome: Treatment with Menstruasan

Clinical study on the efficacy and tolerability of a homeopathic remedy

Menstruasan is a homeopathic combination of five medicinal plants *(Aristolochia clematitis, Cimicifuga racemosa, Cyclamen europaeum, Potentilla anserina* and *Pulsatilla pratensis)* and a constituent of animal origin *(Lachesis muta)*. Within the framework of a multicentric case observation study carried out in the offices of 20 general practitioners the substance was tested in 92 patients with dysmenorrhoea (painful menstruation) or premenstrual syndrome (PMS). The tested combination also contained *Hydrastis canadensis*, which, however, owing to the absence of any positive contribution to the efficacy in the claimed and tested fields of application, was left out of the present formulation.
Already after a period of administration of four weeks, a reduction in lower abdominal pain, back pain, bloating, irritability, depressive mood, lethargy and premenstrual mastodynia (breast tenderness) was observed. After 2 to 3 months of treatment with 3 × 20 drops of Menstruasan daily, a reduction in the symptoms score was observed for both dysmenorrhoea and premenstrual syndrome, which stabilised during the following treatment period to the end of the observational period after 4 months. According to the assessment of the efficacy made by the physicians after 4 months of treatment, 97% of the 76 patients experienced an amelioration of symptoms, with 72% claiming a good to very good effect, while in 3% the symptoms remained unchanged. Tolerability was assessed to be good in 97% of the cases and moderate in 3%. Thus, the use of Menstruasan to treat premenstrual and dysmenorrhoea complaints can be considered both effective and very well tolerated.

During the reproductive phase, most women experience menstrual cycle-associated symptoms, such as dysmenorrhoea and/or PMS. With a prevalence in industrial countries of 60% of all post-puberty women, dysmenorrhoea represents one of the most common gynaecological complaints. Of these women 6% are so severely affected that they become incapable of working for a period of 1–3 days each month. The attacks of colicky, suprapubic pain that sometimes radiates into the back and to the insides of the thighs, reach a peak 24 to 36 hours after the start of the menses. They are usually accompanied by abdominal symptoms including nausea, vomiting and diarrhoea, and may even lead to syncope or collapse. Pathogenetically, a variety of factors may be responsible for the condition, such as elevated plasma concentrations of the pituitary hormone, vasopressin, and an increased production of prostaglandins in the uterus, which are associated with dysrrhythmic prolonged contractions and ischaemic pain, and an oestrogen-induced retention of water by this organ. It is also responsible for a psychogenic modulation of pain perception.

While dysmenorrhoea occurs mainly in the second and third decades of life, and tends to disappear with increasing age, and after the birth of a baby, PMS appears predominantly in the 4th and 5th decades. Some 30% of menstruating women of this age are affected, 5% of them severely, by this com-

plaint, and suffer from emotional or physical changes that are initiated by elevated levels of gestagen in the second half of the menstrual cycle; these changes intensify prior to the start of menstruation and usually clear up completely 2 days after bleeding begins. There appear to be no laboratory chemical correlates to this clinical presentation. The symptoms, which begin 7 to 10 days prior to the menses, can involve any of the organ systems. A characteristic picture includes psycho-emotional changes, including irritability, emotional instability, depression, aggression, nervousness and anxiety, and also headaches, bloating, mastodynia and peripheral oedema which leads to an increase in weight of more than 1.5 kg as a result of the retention of water. In many case, PMS «merges» into dysmenorrhoea during the course of menstruation. The pathogenesis of dysmenorrhoea remains unexplained. Possible mechanisms under discussion include a neurotransmitter dysfunction involving beta-endorphin and serotonin, an imbalance of the prostaglandins and sex hormones resulting in a relative deficiency of progesterone, retention of fluid by the action of aldosterone, vasopressin and prolactin, and a deficit of the vitamins A, B_6, the B-complex, magnesium and zink.

Study design

Within the period covered by the study – January 1 to September 15, 1994 – 20 general practitioners in Holland recruited 92 women whose average age was 34 years (range: 14–50 years). 32 women of this group suffered from dysmenorrhoea, 52 experienced premenstrual tension, and 10 had both conditions. In eight of the women, no unequivocal diagnosis was possible.

Twenty-four of the patients abandoned treatment prematurely from lack of motivation. A final assessment of tolerability and efficacy on the part of the physicians was based on 76 of the 92 women originally recruited. All of the patients – who consulted the physicians on account of dysmenorrhoea, and neither used an intrauterine device nor had begun treatment of their symptoms – gave their informed consent to be included in the study. Concomitant medication for any symptoms other than those mentioned above was employed by 21 patients during the four-month treatment period. Thirteen of the patients had been taking oral contraceptives over several menstrual cycles prior to the start of the case observation study.

During the four-month open case observation study, five consultations took place at monthly intervals, at each of which the severity and duration of the symptoms lower abdominal pain, back pain, depression, lethargy, irritability, mastodynia and bloating, were scored on a four-step scale (0 = none present, 1 = mild, 2 = moderate, 3 = severe), on the basis of the patient's history, the clinical presentation, and the entries in the patients' diaries. At the end of the four-month period of treatment, the physicians made a global assessment of efficacy and tolerability on the basis of a four-step score (0 = none/poor, 1 = moderate, 2 = good, 3 = very good. Treatment consisted of the usual dosage of 3 × 20 drops per day taken in a little water before meals.

For statistical evaluation, both parametric and non-parametric (ANOVA, Friedman) and descriptive methods, as well as a correlation analysis, were employed.

Results

The results described below are also shown in **Figure 1**.

- The severity of lower abdominal pain showed a significant reduction in the mean score from 1.5 to 0.8.
- In the case of back pain, severity decreased significantly from a mean score of 1.1 to 0.7.
- The severity of depressive mood decreased significantly from a mean score of 1.1 to 0.5.
- The mean score recorded for irritability decreased significantly from 1.7 to 0.6.
- The severity of lethargy decreased significantly from a mean score of 1.3 to one of 0.5.
- Mastodynia decreased significantly in severity from a mean score of 1.0 to 0.4.
- The severity of bloating decreased significantly from a mean score of 1.5 to 0.6.
- The general feeling of malaise decreased significantly from a mean score of 1.0 to 0.4.

On the basis of the entries in the patients' diaries, a significant reduction in symptoms was noted for lower abdominal pain, back pain, irritability, depressive mood, lethargy and bloating; in contrast, the duration of mastodynia remained unchanged.

The physicians' concluding evaluation established at the end of the 4-month period of treatment in a total of 76 patients revealed for both dysmenorrhoea and PMS, very good results in 6.6%, good results in 65.8%, moderate results in 25%, and no change in 2.6% of the patients **(Figure 2)**. The self-assessment of the complaints by the patients themselves confirmed the findings noted by the physicians and showed a very good level of efficacy of Menstruasan in 9.2%, a good effect in 59.2%, a moderate effect in 23.7%, and no effect in 7.9% of the cases.

The physicians judged tolerability to be very good in 49 cases and good in 25 cases, moderate in 2 cases and poor in none of the 76 patients.

In the assessment of the patients themselves, tolerability was judged to be very good in 46 cases, good in 27 cases and moderate to poor in 3 cases.

Among all 92 patients recruited to the study, 36 reported experiencing the following adverse events: back pain ×1, insomnia ×4, nausea ×3, psoriasis ×1, irritability ×1, mastodynia ×1, headache ×1, in-

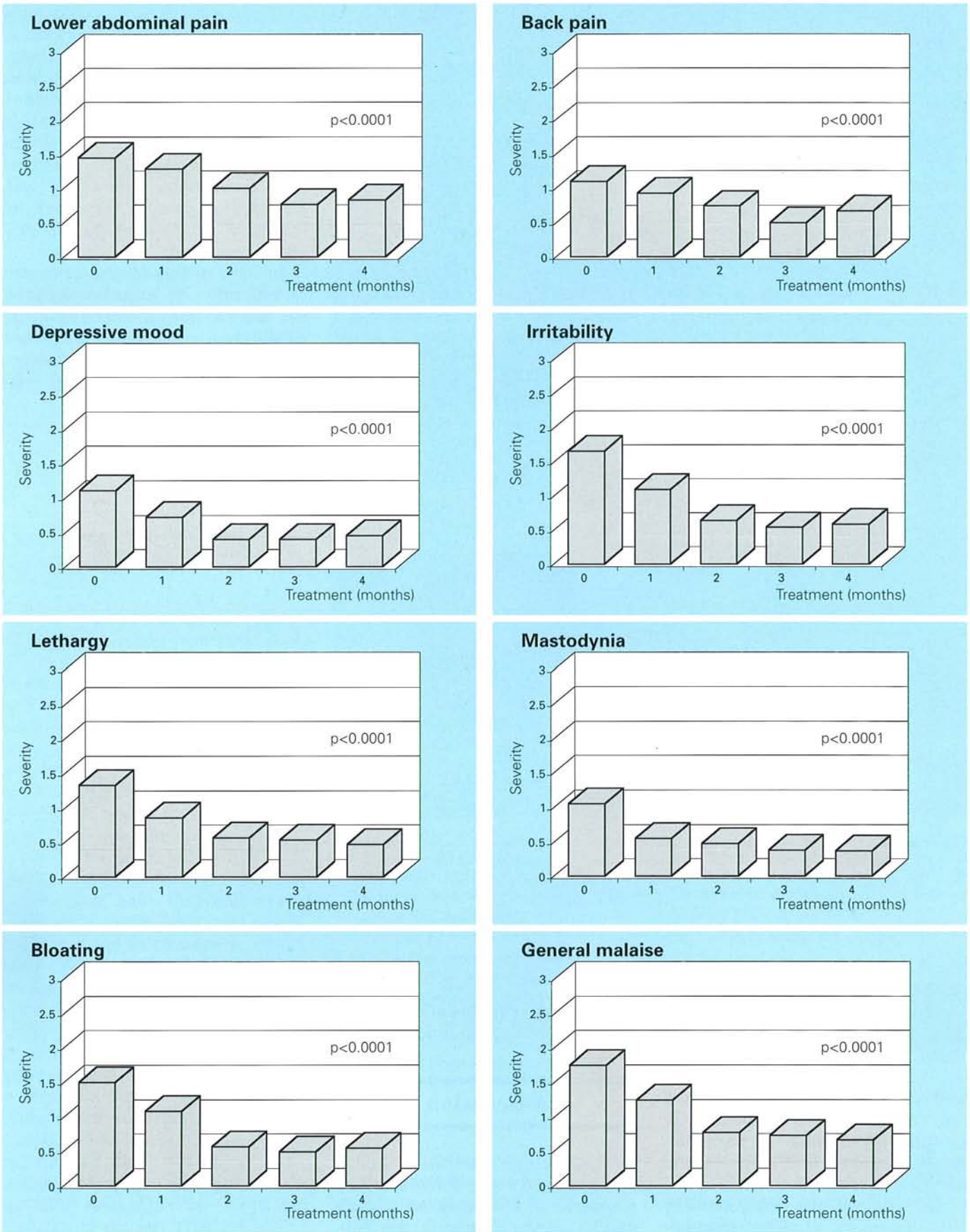

Figure 1: Dysmenorrhoea and premenstrual syndrome: effects of treatment with Menstruasan (n = 76). Severity of symptoms: 0 = none present; 1 = mild; 2 = moderate; 3 = severe.

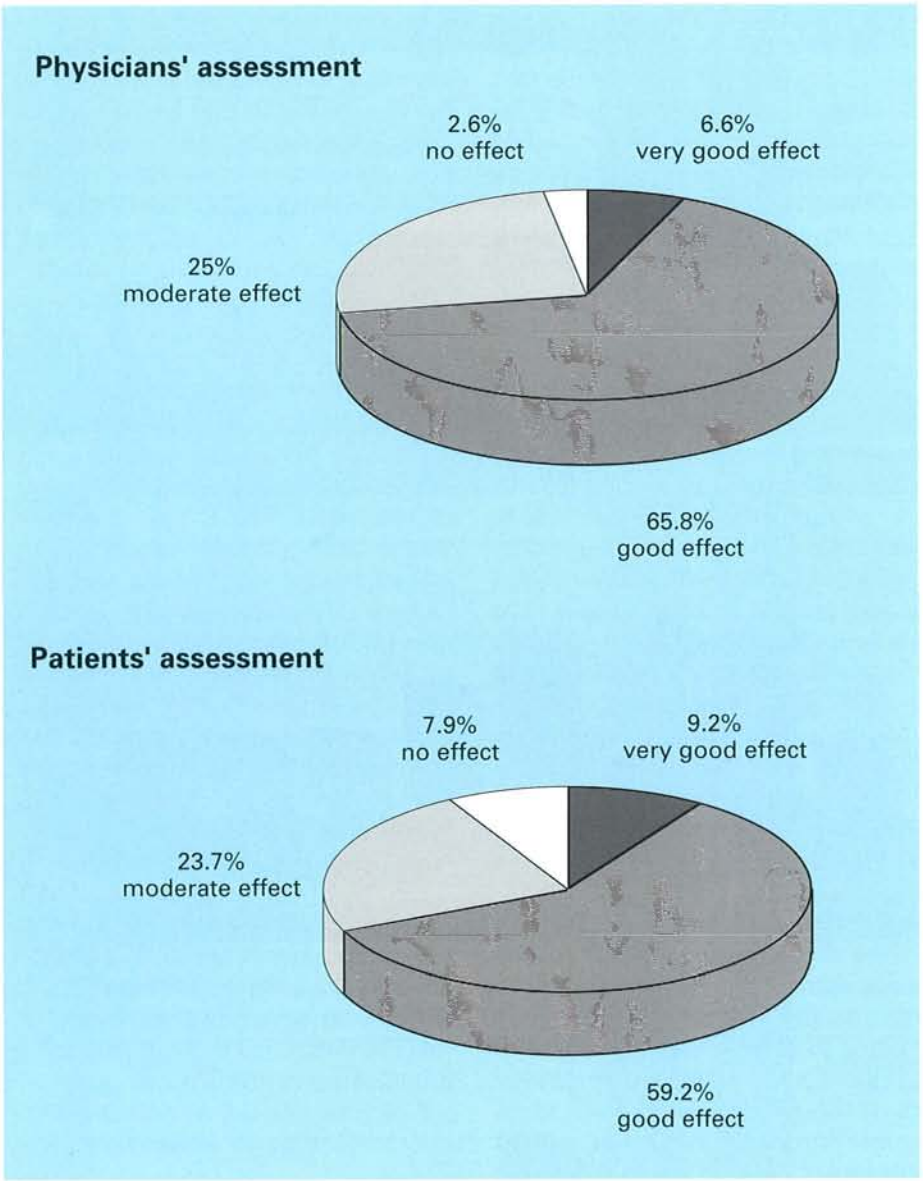

Figure 2: Dysmenorrhoea and premenstrual syndrome: effects of treatment with Menstruasan (n = 76) over a period of 4 months as assessed by physicians and patients (very good effect: symptoms have disappeared; good effect: symptoms have decreased appreciably; moderate effect: symptoms have decreased; no effect: no improvement noted).

tramenstrual bleeding ×1, giddiness ×1, dysuria ×1, anorexia ×1, dysmenorrhoea ×1, nervousness ×1, vaginal discharge ×3, abdominal pain ×1, breast tenderness ×4, menstruational problems ×1, cramps ×2, oedema ×1, parasthesia of the hands ×1, acne ×1 and constipation ×1.

According to the assessment by the physicians, a causal relationship to the medication is extremely unlikely, since all of these events are typical symptoms of the underlying gynaecological illness.

Discussion

The present case observational study carried out in doctors' offices shows that Menstruasan significantly ameliorates both the individual symptoms of the two disorders and the general feeling of malaise, and also favourably influences the subjective symptoms of the patients. The statistical analysis revealed a significant reduction in all of the individual symptoms. To achieve an optimal effect, a treatment period of at least two to three months proved to be particularly favourable. Tolerability was assessed as good to very good by 96.1% of the patients, and 97.4% of the physicians.

In view of this high percentage of high efficacy coupled with good tolerability, Menstruasan can be considered to represent a rational form of treatment of dysmenorrhoea and the premenstrual syndrome (PMS).

Author's address

Dr. med. Friedrich H. Degenring
Bioforce AG, CH-9325 Roggwil