

Schweizerische Zeitschrift für

GanzheitsMedizin

Journal suisse de médecine globale

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Clinical study on the efficacy and tolerability
of a homeopathic remedy

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Reprint from Schweiz. Zschr. GanzheitsMedizin 1996; 8 (1): 18–21





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In the fifth decade of life, function of the ovaries begins to diminish and they become less responsive to the action of the gonadotrophic hormones of the (anterior lobe of the) pituitary gland, which is manifested in laboratory examinations by a reduction in the level of oestrogen in the serum, and an increase in the plasma level of luteinizing hormone (LH) and, in particular, of the follicle stimulating hormone (FSH).

The cessation of follicle maturation acts, via negative feedback mechanisms, on the hypothalamo-pituitary system to stimulate the secretion of gonadotropin. During this premenopausal phase, a shortening the duration of the menstrual cycle brought about by the reduction in the duration of the follicle development phase takes place. The last menstrual period is known as the menopause, and the transitional phase beginning before the menopause and continuing for years after it, is termed the climacteric. This latter extends from the premenopause beginning from about the age of 45 to the postmenopause around the age 55 to 65.

Menosan is a complex homeopathic medication comprising four selected medicinal plants (*Agnus castus*, *Cimicifuge racemosa*, *Ignatia amara* and *Sanguinaria canadensis*) together with two constituents of animal origin (*Lachesis muta* and *Sepia off.*), each component of which has a proven efficacy in the treatment of menopausal complaints. In a multicentric case observation study conducted in the offices of 23 physicians on 77 climacteric women, the medication employed contained the above-mentioned components in identical potencies as the presently available Menosan, with the exception of *Lachesis muta*, the potency of which was D6 (X6). Since this increase in potency has no effect on the efficacy or tolerability of the complex remedy, the results of the study can be translated unreservedly to the analogous present-day product.

After only three weeks of treatment, an appreciable reduction in the typical menopausal symptoms, namely, hot flushes, nocturnal sweating, palpitations, headache, depression and fatigue, was noted. After 6 weeks of treatment with 3 × 20 drops of Menosan daily, the physicians' assessment noted complete, or largely complete, freedom from symptoms in 61% of the patients, an improvement in symptoms and a reduction in the frequency of hot flushes and episodes of nocturnal sweating in a further 22.1%, but no change in the symptoms of the remaining 16.9%. During the entire 6-week period of treatment no adverse events were recorded. These results indicate that the use of Menosan to treat climacteric symptoms, in particular hot flushes, is both effective and well tolerated.

Climacteric syndrome

For about 70% of all women, the climacteric is associated with a variety of symptoms known as the climacteric syndrome. This includes a complex of symptoms, varying in-

dividually in severity, which represent the somatic, neurovegetative and psychological correlate of the processes of adaptation to the altered hormonal status resulting from the gradual or progressive loss of ovarian function.

The menopause is not a simple

condition of oestrogen deprivation, but a phase of altered oestrogen metabolism. In the postmenopausal phase, the main source of oestrogen becomes its extra-ovarian – including the fatty tissue – synthesis, while the contribution made by the ovaries themselves becomes negligible. Typical symptoms are the intermittent experience of heat (hot flushes) reflecting vasomotor and thermoregulatory instability, often accompanied by episodes of sweating, giddiness and circulatory disorders. While the pathogenesis of these symptoms remains unexplained, there is a close temporal correlation between the appearance of hot flushes and LH secretion peaks.

When they occur at night, these hot flushes can cause chronic insomnia and thus emotional mood changes including irritability, nervousness, fatigue and depression. Headaches, too – including first-time migraine, or an increase in the number of attacks of pre-existing, migraine – may characterize the symptom complex during the climacteric.

In view of the increasing rejection of long-term hormone replacement treatment in practice – in particular due to the controversy surrounding the duration of the useful period of such therapy – a non-hormonal, well-tolerated and effective medication for the treatment of menopausal complaints, in particular the hot flushes, would be a valuable addition to the therapeutic arsenal.

Study design

With the aim of obtaining data on the efficacy and tolerability of Menosan in the treatment of menopausal symptoms, a case observation study designed as a multicentric, open investigation was carried out. During consultations prior to the start of therapy and after 3 and 6 weeks of treatment of the menopausal complaints, the symptoms diurnal hot flushes, noc-

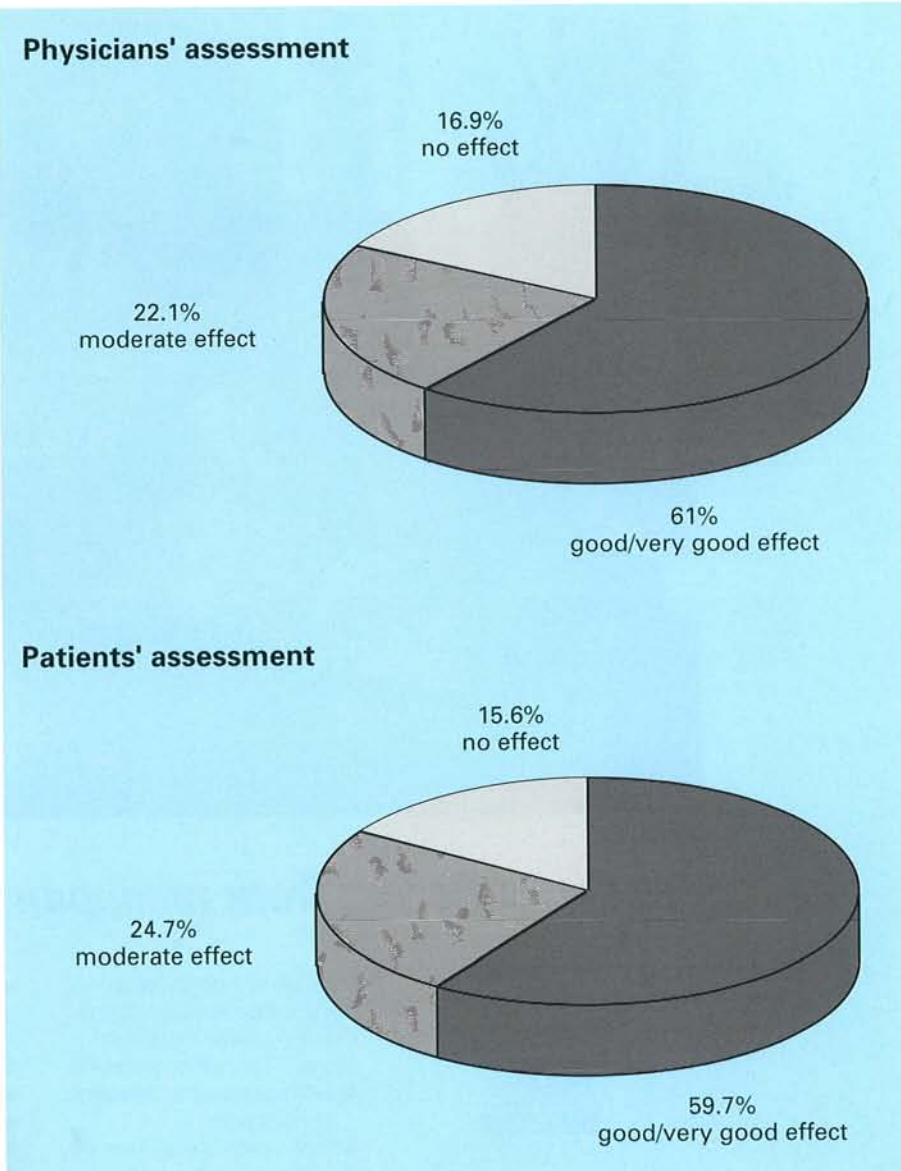


Figure 1: Climacteric symptoms: effects of treatment with Menosan (n = 77) over a period of 6 weeks as assessed by physicians and patients (good/very good effect: the symptoms have diminished very appreciably or have disappeared completely; moderate effect: the symptoms have decreased; no effect: no improvement was noted).

turnal sweating, palpitations, headache, depression and fatigue were recorded with the aid of a symptoms score. Taking part in the study were 23 general practitioners, of whom four provided mainly homeopathic treatment, 15 mainly allopathic, and 4 both conventional and complementary medicine-oriented therapies. After first giving their informed written consent, all those patients consulting the doctor for menopausal complaints and not taking medication for them,

were admitted to the study. During the 6-week period of observation, the dosage employed was 3×20 drops of Menosan daily, the drops being taken before meals in a little water and kept in the mouth for a short time before swallowing.

In view of the fact that they are easy to quantify and are typical symptoms of the climacteric, the frequency of hot flushes during the day and episodes of sweating during the night were selected as the main criteria for evaluating efficacy.

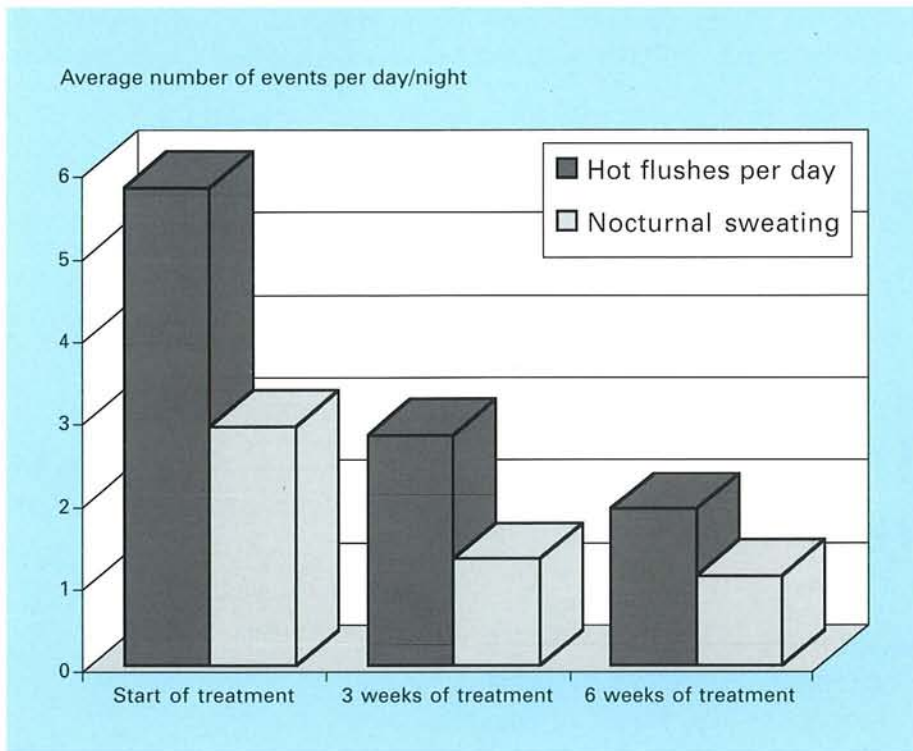


Figure 2: Climacteric symptoms: effects (course of the frequency of hot flushes and nocturnal sweating) of 6 weeks of treatment with Menosan (n = 77).

In addition, these two symptoms, together with such other symptoms as palpitations, headache, depression and fatigue were assessed subjectively by means of a scale of severity ranging from 0 to 3.

Results

In the period covered by the study and extending from January to July, 1990, the participating general practitioners in Holland recruited to the study 77 patients with climacteric complaints. The assessment by the physicians at the end of the 6-week treatment period, showed that 61% of the patients were completely, or almost completely, free of symptoms, 22.1% had experienced an improvement in their symptoms, and 16.9% had registered no change in their complaints. The assessment on the part of the patients themselves revealed a similar distribution of the effects

of treatment, a total of 84.4% noting an improvement in symptoms, while 15.6% indicated no change (Figure 1).

Concomitant medication

During the period under investigation, 42 of the patients used no concomitant medication. The remaining 35 patients took additional medication to treat non-climacteric complaints; this, however, had no influence on the overall menopausal symptom complex.

Discussion

In view of the improvement in the functional climacteric symptoms in more than 80% of the patients, the use of Menosan to treat this symptom complex may be considered effective. A particularly significant finding is the reduction in the typical symptom hot flushes, the frequency of which is readily ob-

jectifiable by the patient (Figure 2).

Furthermore, treatment with Menosan was extremely well tolerated, and not a single adverse event was reported.

A post-treatment survey conducted among the present group of patients revealed that 75% favoured therapy involving a non-hormonal approach over hormone replacement therapy. Although this result cannot be taken to be representative of the overall population of patients with climacteric symptoms – since 4 of the 23 doctors' offices involved had a predominantly homeopathic orientation – it does tie in with an increasing scepticism vis-a-vis the uncritical use of hormone replacement treatment.

On the basis of the results of the present study, Menosan can be considered to represent an alternative form of treatment for those patients who reject treatment by hormone replacement or in whom it is contraindicated. Furthermore, its use can also be approved to treat general neurovegetative and emotional disorders occurring during the climacteric, which can be compensated by the homeopathic mode of action of this medication.

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