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Therapy of the Menopausal Syndrome with Mulimen - Results of a Multicentric Post-Marketing Survey

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EDITOR'S NOTE:

Mulimen is a combination homeopathic preparation for a wide range of feminine complaints. In addition to the menopausal uses described in this article, Mulimen is also indicated for pre-menstrual syndrome.

Abstract:
A total of 82 female patients with pre-climacteric and menopausal syndromes were treated with the preparation Mulimen and were subsequently observed over a period of twelve weeks. As a rule, these women received a dosage of 40 - 60 and 80 - 100 drops daily. Very good therapeutic results were documented for 58.5% of the cases. Significant relief was especially apparent for the following symptom complexes: depressive mood, nervousness, and the outbreaks of sweating typical for the climacterium. The patients tolerated the medication well; in only one case (stomach complaints) were side-effect difficulties reported in conjunction with the therapy.

The female menopause is a period of intensive hormonal adjustment which can for most women be accompanied by considerable discomfort. It is certainly not seldom that the severity of menopausal complaints approaches that of an indisputable disease which requires specific therapy.

Hormonal adjustment, however, represents only one aspect of the menopausal syndrome: there is, indeed, no direct relationship between estrogen deficiency and severity of the climactic symptom complex (1). In addition to physically measurable parameters, individual psychic factors are superimposed on the symptom picture.

The possibilities of therapy of autonomic menopausal deficiency symptoms, psychic alterations, and post-menopausal syndrome include the following conventional methods: substitution therapy using hormones, prescription of sedatives, as well as the administration of tranquilizers.

In their attitudes toward these orthodox treatment possibilities, women assume an ambivalent standpoint, particularly with respect to hormonal therapy. They of course positively assess the freedom from symptoms which hormones allow. At the same time, however, they are suspicious of the dependence of their general emotional and psychic health on the substances which such therapy entails. Widely prevailing fear of iatrogenic damage and the undesired side effects of hormone administration certainly plays a major role in the misgivings of many women. Biological remedies are therefore finding increasing acceptance in this area and are being consequently more frequently administered by prescribing therapists - whether as single medication or in combination with other conventional agents with the aim of dosage reduction.

Mulimen

The preparation Mulimen, developed by the German company Fides, represents a homeopathic remedy administered as drops which has proven effective and reliable in the therapy of gynecological disorders. It is manufactured in the USA by the company BHI under license from Fides. In the USA, it is available in tablet form only, with the same formulation as the drops. The ingredients of Mulimen -

including Agnus castus, Cimicifuga racemosa, Hypericum, and Sepia - enable regulatory intervention with action effective equally throughout the autonomic, endocrine, and psychic processes of the female organism.

Mulimen has also proven effective in therapy of the following symptoms: Parametropathia spastica (hypogastric plexus irritation), menstrual difficulties, and emotional upset/depressive mood. The preparation is accordingly effective in treatment of preclimacteric and menopausal syndromes, as attested by the results of published studies (2 - 4).

Methods and patients selected for the post-marketing survey of Mulimen.

Post-marketing surveillance was conducted for Mulimen among women suffering from preclimacteric and menopausal syndromes. Data gained on the prescription, administration, and results of therapy were studied and assessed as summarized below.

A total of 15 physicians, including 11 specialists for gynecology, took part in the post-marketing survey conducted in 1989 for Mulimen. The survey featured the use of standardized questionnaires to collect data on the following: diagnosis, accompanying illnesses, adjuvant therapy, dosage, tolerance, and results of therapy.

In addition, the survey compiled data in the form of scored ratings, from 0 to 3, to depict the symptoms of women who had taken Mulimen. The following symptoms were scored: hot flashes, outbreaks of sweating, insomnia, nervousness and irritability, depressive mood, vertigo, concentration difficulty, headaches, articular pain, and tachycardia. Each patient was surveyed on the above complex of symptoms after periods of 2, 4, 8 and 12 weeks.

The following scoring scheme was employed:

0 no symptoms
1 slight symptoms
2 moderate symptoms
3 severe symptoms.

Women were admitted to this survey only under the condition that they had not received hormone therapy. There were 82 women admitted, with a mean age of 50 years. Preclimacteric syndrome had

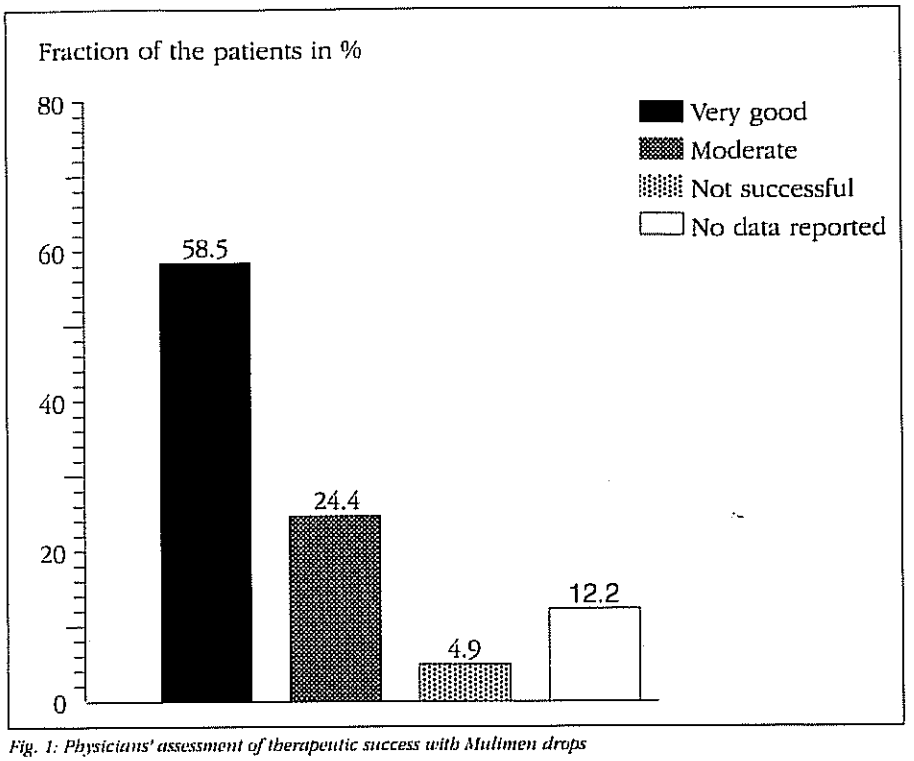

Fig. 1: Physicians' assessment of therapeutic success with Mulimen drops

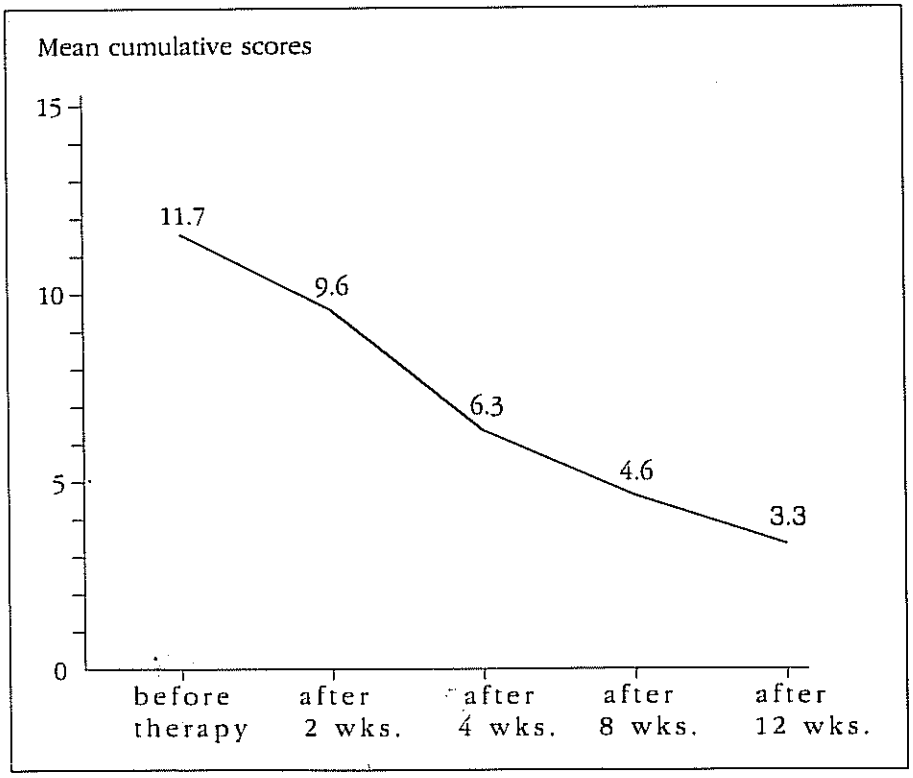

Fig. 2: Improvement in complaints as shown by a plot of mean cumulative scores - at beginning of therapy, and after 2, 4, 8, and 12 weeks of therapy

been diagnosed for 54.9% of the patients, and menopausal syndrome for 45.1%. A considerable share (46.3%) of the patients admitted to the study had suffered from their symptoms for considerable lengths of time, i.e., for more than one year, before treatment with Mulimen began.

Twenty percent of the patients suffered from accompanying disorders. Physicians prescribed adjuvant therapy for 14% of all the women. The high percentage of faulty or incomplete data in these areas, however, would support the assumption that the actual share of patients suffering from accompanying disorders was higher.

Excessive urination urgency was experienced by 19.5% of the patients, and 26.8% reported increased breast tension.

The attending physicians generally prescribed Mulimen in the dosage recommended by the manufacturer: 60 - 100 drops daily. The most frequently prescribed dosage range during the first two weeks of therapy with Mulimen was 80 - 100 drops daily. In 45.1% of the cases, for example, dosage was either 4 x 20 drops, or 3 x 30 drops, or 1 x 100 drops. In 31.7% of the cases, the recommended dosage was 40 - 60 drops daily at the beginning of therapy. This dosage, with 47.6% of patients, proved to be the most favored in the course of longterm medication by the twelfth week of observation. The most frequently prescribed single dosage was 20 drops, taken three times a day.

Results of therapy with Mulimen

It was possible to collect documentation for 79.3% of the patients over twelve weeks of therapy. Two of the patients prematurely discontinued therapy. Of these, one woman terminated the medication after stomach complaints had been determined in conjunction with Mulimen. The other woman stopped taking Mulimen after only two weeks, after experiencing no therapeutic success. Therapy was terminated by 8.5% of the patients after 4 weeks, and 11% after 8 weeks. Their tolerance to Mulimen was rated good by 74.4% of the women, and 24.4% provided no response to the tolerance question. As stated above, one woman reported intolerance to the preparation.

The assessment of patients and physicians of the success of Mulimen therapy was almost identical. Fig. 1 depicts the physicians' evaluation. Doctors rated therapeutic success very good for 58.5% of the cases, and unsuccessful for 4.9%. No assessment of therapy was provided in 12.2%.

Table 1: Percent frequency of scores obtained for the individual criteria of health, and their progress throughout 12 weeks of therapy with Mulimen.

Scores for health criteria	Before beginning of (%)	After ... weeks (%)			
		2	4	8	12
Hot Flashes					
none	8.5	11.0	17.1	29.3	43.9
slight	18.3	28.0	39.0	40.2	25.6
moderate	34.1	29.3	23.2	9.8	6.1
severe	35.4	12.2	3.7	2.4	1.2
no data	3.7	19.5	17.1	18.3	23.2
Outbreaks of sweating					
none	12.2	17.1	24.4	39.0	50.0
slight	28.0	30.5	37.8	31.7	22.0
moderate	37.8	28.0	19.5	9.8	4.9
severe	19.5	4.9	-	1.2	-
no data	2.4	19.5	18.3	18.3	23.2
Insomnia					
none	20.7	24.4	35.4	45.1	51.2
slight	28.0	30.5	31.7	31.7	22.0
moderate	24.4	23.2	13.4	4.9	3.7
severe	20.7	1.2	1.2	-	-
no data	6.1	20.7	18.3	18.3	23.2
Depressive mood					
none	23.2	32.9	36.6	47.6	57.3
slight	28.0	19.5	32.9	25.6	14.6
moderate	30.5	24.4	14.6	7.3	3.7
severe	15.9	3.7	-	-	-
no data	2.4	19.5	15.9	19.5	24.4
Nervousness / irritability					
none	11.0	14.6	30.5	35.4	47.6
slight	31.7	32.9	40.2	41.5	25.6
moderate	32.9	31.7	11.0	3.7	3.7
severe	20.7	1.2	1.2	-	-
no data	3.7	19.5	17.1	19.5	23.2
Concentration difficulties					
none	42.7	42.7	47.6	58.5	58.5
slight	31.7	28.0	30.5	19.5	14.6
moderate	19.5	9.8	4.9	2.4	2.4
severe	1.2	-	-	-	-
no data	4.9	19.5	17.1	19.5	24.4
Tachycardia					
none	39.0	45.1	54.9	65.9	58.5
slight	34.1	26.8	22.0	11.0	13.4
moderate	17.1	6.1	1.2	1.2	1.2
severe	3.7	1.2	1.2	1.2	1.2
no data	6.1	20.7	20.7	20.7	25.6
Vertigo					
none	56.1	54.9	57.3	63.4	67.1
slight	19.5	15.9	19.5	15.9	7.3
moderate	9.8	8.5	2.4	1.2	1.2
severe	8.5	1.2	-	-	-
no data	6.1	19.5	20.7	19.5	24.4
Headaches					
none	47.6	50.0	61.0	64.6	61.0
slight	35.4	26.8	15.9	12.2	9.8
moderate	4.9	2.4	3.7	3.7	4.9
severe	8.5	1.2	1.2	-	-
no data	3.7	19.5	18.3	19.5	24.4
Joint pain					
none	62.2	57.3	61.0	63.4	62.2
slight	22.0	19.5	18.3	15.9	13.4
moderate	7.3	3.7	-	-	-
severe	2.4	-	-	1.2	-
no data	6.1	19.5	20.7	19.5	24.4

More conclusive, however, than the above blanket data on failure or success of therapy are the data provided below in Table 1 which record the change in rating scores, throughout the course of therapy, for each of the symptoms typical of preclimacteric and menopausal syndromes. These data offer a detailed chronological profile of the effect of Mulimen therapy on the overall symptom picture. See Table 1 for this record of the patients' assessment of their own states of health during the twelve weeks of therapy.

Table 1 clearly reveals improvement in complaints for the symptoms denoted by outbreaks of perspiration, depressive moods, and nervousness / irritability. After twelve weeks, approximately 50% of the women were without outbreaks of sweating, and 57.5% did not suffer from depressive moods. There were also significant improvements with respect to nervousness and irritability, with the result that 47.6% of the women reported no complaints of this kind after therapy.

The individual results obtained on the patients' general assessment of health during the course of therapy with Mulimen have been combined to form cumulative score values. The respective mean values obtained here have been plotted in Figure 2 to show cumulative results after 2, 4, 8, and 12 weeks of therapy with Mulimen. This plot therefore gives an effective overall picture of the progress of therapy. The values plotted in Figure 2 on the y axis from 0 to 15 could feasibly range from 0 (for complete freedom from all symptoms) to 30 (for severe complaints for all symptoms).

Figure 2 consequently shows the progress of improvement in complaints: from a mean score of 11.7 (S +/- 5.5) at the beginning of Mulimen therapy, to a mean score of 3.3 (S +/- 3.3) after 12 weeks.

Summary

The post marketing survey summarized here confirms that Mulimen can be administered with good success in treatment of preclimacteric complaints and the menopausal syndrome. The tolerance of women patients to the preparation is good, with the result that it may also be applied as long-term therapy. Mulimen has proved especially valuable in treatment of complaints typically accompanying the menopause: outbreaks of sweating, as well as psychic disorders such as heightened nervousness and depressive mood. On the basis of the favorable risk-benefit ration and positive compliance behavior of the patients in medication administration, Mulimen can be highly recommended as the first medication of choice for treatment of menopausal symptoms.

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