

Homeopathic Treatment of Gynecological Disorders: Results of a Prospective Study

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Abstract

This multicentric prospective study systematically investigated the usage indications, modes of application, therapeutic efficacy, and tolerance of Mulimen® drops and injectable Mulimen®. Thirty-one gynecologists provided documentation on a total of 269 cases. Primary usage indications were mood disorders, dysmenorrhea, pelvic congestion, and menopausal symptoms. When used either alone or in combination with other therapies, both forms of Mulimen® proved to be reliably effective and well tolerated.

Resumen

Este estudio multicéntrico y prospectivo investigó sistemáticamente las indicaciones del uso, los modos de aplicación, la eficacia terapéutica, y la tolerancia de las gotas orales y las ampollas inyectables de Mulimen®. Un grupo de 31 ginecólogos suministraron una documentación sobre un total de 269 casos. Las indicaciones del uso primario fueron para los trastornos del humor, la dismenorrea, la congestión pélvica, y los síntomas de la menopausia. El uso de ambas formas de Mulimen®, solo o en combinación con otras modalidades, proveyó una eficacia confiable que se toleraba bien.

Introduction

Approximately 80% of all women suffer from abdominal cramps, back pain, headache, or nausea during menstruation. During perimenopause and during and after menopause itself, psycho-vegetative symptoms such as sleep disorders, depression, and hot flashes are also relatively fre-

quent. The relatively high incidence of gynecological disorders is due to the more complex hormonal regulation of the female body, on the one hand, and on the other to the regulation of the hormonal system by the autonomic nervous system. This complex system, which is in turn controlled by higher systems such as the hypophysis and hypothalamus, determines the physiological course of ovulation and menstruation. From menarche to postmenopause, a period of 40 years on the average, the female body is influenced by the proper functioning of this higher regulatory system. It is easy to imagine, therefore, that even slight disruptions are sufficient to induce physical and psychological changes. The emphasis of the symptom complex varies with the woman's stage of physiological development, and it is not unusual for several symptoms to appear at the same time. Although it is true that menstrual irregularities can often be stabilized and symptoms relieved through the use of hormone preparations, these medications have undesirable side effects.¹

As already mentioned, hormone substitution therapy can be useful in treating more pronounced physical and psychological symptoms. But since long-term treatment with sex hormones can be associated with certain risks, treatment with homeopathic medications, for example, is an obvious choice. The homeopathic remedy Mulimen® (mfg: FIDES, Baden-Baden, produced and distributed in the U.S. by Heel Inc.) contains ingredients that have stimulant and regulatory effects on endocrine and autonomic functions (Table 1). The ingredients *Vitex agnus-castus*, *Cimicifuga racemosa*, *Gelsemium sempervirens*, *Calcium carbonicum Hahnemanni*, *Kalium carbonicum*, and especially *Sepia officinalis* comprehensively address psychological symptomatology. In particular, the components *Vitex agnus-castus*, *Ambra grisea*, *Hypericum perforatum*,

and *Gelsemium sempervirens* elevate and stabilize the patient's mood.

The goal of the present prospective study was to observe the effect of both forms of Mulimen® (drops and injectable solution) over their entire range of usage indications. Foremost in our minds was the question of whether this homeopathic remedy could prove useful as an alternative to hormone preparations.

Methodology

Data on anamnesis and treatment were recorded on standardized questionnaires. No criteria for inclusion or exclusion of subjects were defined (Table 2). Dosage of Mulimen®, duration of therapy, and possible implementation of concomitant therapy was left up to the attending physicians, but all data relevant to treatment had to be recorded on the questionnaires. The success of the form of therapy selected was evaluated by the physicians on the basis of two criteria: 1) point in time at which an improvement in symptoms was first noted; and 2) evaluation of final results by both physician and patient on a five-point scale: "very good" = complete freedom from symptoms, "good" = clear improvement, "satisfactory" = slight improvement, "no success" = symptoms remained the same, and "worse." Tolerance of Mulimen® was to be evaluated upon conclusion of treatment by both physicians and patients according to the following scale: excellent, good, moderate, and poor. Undesired effects were to be recorded on a separate questionnaire.

Results

Patient Demographics

In spite of the low rate of return (28.5%), all of the returned questionnaires (n = 269) were suitable for inclusion in

Ingredient	Characteristics/Symptoms
Ambra grisea 4X	Functional disorders, especially of the autonomic nervous system. Menorrhagia following exertion or excitement. Restlessness accompanied by dyspnea and palpitations. Tendency to intermenstrual bleeding.
Calcium carbonicum Hahnemanni 8X	Symptoms appear before and during menstruation. Irritability and headache beginning with ovulation.
Cimicifuga racemosa 4X	Spasms in the area of the reproductive organs. Symptoms during menstruation, pregnancy, or menopause. Nervous excitability and depression. Irritability and mood swings.
Gelsemium sempervirens 4X	Cardiac symptoms related to nervousness. Dysmenorrhea, tendency to cramps, delayed menses, suppressed menstruation.
Hypericum perforatum 3X	Intervenes in autonomic, endocrine, and psychological processes by way of neurohormonal regulatory mechanisms. Has an astringent, anti-inflammatory, and moderately sedative effect. Elevates mood. Indicated for delayed menses with a feeling of tension around the uterus; premenstrual diarrhea, headache, and backache. Irritability and mood swings.
Kalium carbonicum 4X	Hot flashes. Feeling of exhaustion; back pain. Restless sleep with nightmares. Oligomenorrhea. Delayed or excessively early, usually heavy menses, often accompanied by constipation. Tendency to edema. Tendency to uterine hemorrhage.
Sepia officinalis 8X	Menstrual irregularities, usually in the form of amenorrhea or scanty and delayed menses with (pre)menstrual symptoms. Menopausal hot flashes, feelings of indifference and apathy (especially toward work and family), little zest for life.
Urtica urens 3X	Premenstrual water retention, edematous swellings, menorrhagia.
Vitex agnus-castus 3X	Regulates ovarian hormone production by way of the hypophysis. Relieves cyclical disorders caused by insufficiency of the corpus luteum. Has a positive effect on extragenital symptoms of hyperestrogenism, and especially on pelvic congestion, migraine-like headaches, smooth muscle spasms, and edematous swelling.

Tab. 1: Ingredients of Mulimen® with their characteristics/symptoms

the (descriptive) statistical analysis. With the exception of a single male (!) patient (diagnosis: mood disorders; additional hormone treatment with testosterone) all of the patients for whom data were reported were female, with the age emphasis falling between 31 and 50 years (48%). The diagnoses suggested most frequently during anamnesis were mood disorders (38%), dysmenorrhea (32%), pelvic congestion (14%), and menopausal symptoms (10%). In addition to these major categories, a large number of additional single diagnoses (9%) were listed, such as perimenopausal symptoms, mastopathy, and oligomenorrhea. Multiple diagnoses were reported for some patients.

The following symptoms were prominent among patients in each of the main diagnostic groupings:

- Mood disorders: depression, sleep disorders, hot flashes, outbreaks of perspiration, palpitations, headache.
- Dysmenorrhea: painful menses, irregular menstrual cycles, abdominal pain, headache.
- Pelvic congestion: abdominal pain, back pain, painful menses, spastic colon.
- Menopausal symptoms: hot flashes, outbreaks of perspiration, sleep disorders, depression, palpitations.

Forty-four % of the patients were in the climacteric phase, which includes perimenopause, menopause, and postmenopause (menopausal symptoms: 100%; mood disorders: 70%; pelvic congestion: 23%; menstrual disorders: 8%). The distribution of patients of various ages among the main diagnostic groups was predictable (Table 3).

Both within the entire patient population and within the main diagnostic groupings, duration of symptoms prior to seeking treatment varied greatly among individual patients, ranging from a few weeks to months and even several years. The degree of severity of symptoms also ranged

• time frame:	March 1996 to December 1996
• country:	Germany
• physicians participating:	31 licensed gynecologists
• total number of questionnaires mailed:	945
• total return:	269 (28.5%)
• format of the study:	prospective
• observation period per patient:	maximum 4 months
• criteria for inclusion/exclusion:	none
• documentation:	standardized questionnaires
• number of patients per physician:	minimum 5, maximum 10

Table 2: Parameters of the prospective study

from "mild" to "moderate" and "severe," with a noticeable concentration falling into the "moderate" category (61%). Approximately half of the patients had received medication for their symptoms very shortly before being accepted into the prospective study; this treatment had included various hormone preparations, analgesics, and gynecological medications. Homeopathic remedies played only a subordinate role prior to the beginning of the prospective study.

Treatment with Mulimen®

The manufacturer of Mulimen® recommends a standard dosage of 15-20 drops 4 to 5 times a day (for acute symptoms, 10 drops every 30 minutes for a period of 2-3 hours) or, for the injectable solution, 1 or 2 injections of 1 or 2 ampules per week (i.m., s.c., or i.v.). With regard to the frequency with which drops or injections were selected for administration, there was a strong preference (83%) for the oral form

in this prospective study. In most cases, both forms of the medication were administered in accordance with the manufacturer's recommendations.

In approximately 82% of cases, the dosage of Mulimen® prescribed at the beginning of treatment was maintained throughout the observation period. In the remaining cases, the dosage was reduced during the course of treatment. In treating acute symptoms, the acute dosage listed above was prescribed relatively frequently (25%) in the groups diagnosed with dysmenorrhea and pelvic congestion. Depending on type of diagnosis recorded, degree of severity, and duration of symptoms prior to treatment, the duration of therapy varied from patient to patient. Overall, however, it can be said that the majority of patients (71%) were treated with Mulimen® over a longer period of time (>2 months), as was to be expected.

For approximately 80% of the patients, Mulimen® was the only therapy they received. In the remaining cases, additional

medications were prescribed (18%) or non-pharmaceutical concomitant therapies were implemented (2%). The main additional medications prescribed were hormone preparations, analgesics, and gynecological medications. With regard to dosage of Mulimen®, duration of treatment, and implementation of concomitant therapies, there were no obvious differences among the different primary diagnostic groupings.

Results of Therapy

There were also no obvious differences among the diagnostic groups with regard to how long it took for the treatment to take effect (physician's assessment). Improvement in symptoms was noted within 1-4 weeks of therapy in 56% of the patients, within 1-2 months in an additional 26%, and only after 2-4 months in 9%. Physician and patient evaluations of the therapy confirm these assessments: Either complete freedom from symptoms or significant improvement was achieved in 75% of the patients, while the treatment was unsuccessful for 7%. (Since patient evaluations of therapy did not differ significantly from the physicians' evaluations, only those of the physicians are reported here.)

The therapeutic efficacy of Mulimen® extended to all of the reported usage indications. In all four primary diagnostic groups, very good and good results were achieved in 75-80% of cases (Figure). That Mulimen® can also be used successfully as the sole therapy for all of the listed indications is confirmed not only by the fact that 80% of the patients received Mulimen® alone but also by the results achieved within this group (Table 4).

Tolerance

The physicians did not report a single instance of undesired side effects of this medication. Thus this prospective study confirms that intolerance reactions are not to be expected among patients taking Mulimen®. This is especially significant in view of the fact that gynecological disorders generally require long-term treatment. The physicians reported that tolerance of Mulimen® was "very good" in 28% of cases and "good" in 61% (9% moderate, 2% N/A).

		Age Groups (in years)						
Usage indications		<21	21-30	31-40	41-50	51-60	61-70	>70
Total	(n=269)	8	19	22	26	19	5	1
Mood disorders	(n=102)	-	5	19	41	22	10	3
Menstrual symptoms	(n=87)	22	39	22	15	2	-	-
Pelvic congestion	(n=39)	5	28	36	13	18	-	-
Climacteric syndrome	(n=27)	-	-	-	19	66	15	-
Other	(n=24)	4	13	38	33	8	4	-

Table 3: Type and frequency of main usage indications of Mulimen® and age distribution within them (listed as percentages and rounded off; multiple listings occurred)

Discussion

In approximately 40% of all women of childbearing age, hormonal dysregulation, usually psychovegetative in origin, leads to more or less pronounced gynecological symptoms. Dysmenorrhea is the most frequent complaint. Additional relatively common disorders include premenstrual syndrome and pelvic congestion. The latter involves chronic—rarely acute—pains and cramps in the area of the true pelvis. Excluding any organic causes such as inflammations or tumors, painful intercourse points to a psychogenic disturbance.

Women with dysmenorrhea, migraine-like headaches, and lower back pain often also complain of depression or other mood disorders. Unfortunately these symptoms, which may be more or less pronounced, still tend to be disregarded, probably because in most cases it is difficult to objectify them sufficiently. Relatively frequently, therefore, such patients are prescribed analgesics, hormone preparations, spasmolytics, antidepressants, and sometimes even neuroleptics. The use of hormone preparations is certainly unavoidable in many cases, but the other types of drug therapy are often unnecessary and may carry the risk of addiction in addition to numerous side effects.

The use of homeopathic remedies to influence gynecological disorders is play-

ing a growing role in the practice of medicine. As a rule, homeopathic preparations are gentle, have a wide range of uses, and are well tolerated. They are particularly suited to the treatment of psychological symptoms because they can achieve long-term stabilization of the patient's psychological balance. In treating both functional disorders of the menstrual cycle and female sterility, treatment with homeopathic remedies has proved its value time and time again alongside hormone substitution therapy. Gerhard *et al*² demonstrated that both individually selected homeopathic single remedies and homeopathic combination preparations were capable of successfully treating hormonal dysfunctions and difficulty in conceiving. The authors see homeopathic therapy as a useful alternative to hormone substitution. The advantages include better tolerance of the homeopathic remedies and no risk of ovarian cysts or multiple births.

The results of this prospective study confirm that therapeutic success is possible in treating various gynecological disorders with the homeopathic remedy Mulimen®. Either complete freedom from symptoms or obvious improvement was achieved in three out of four patients. The therapeutic efficacy of Mulimen® extends to all of the reported usage indications (mood disorders, dysmenorrhea, pelvic congestion, and menopausal symptoms). In all four main diagnostic groups, "very good" and "good"

results were achieved in over 75% of patients. In this connection, it is interesting to note both that approximately 80% of the patients were treated with Mulimen® alone and that Mulimen® also seems to have an analgesic effect, since it was used successfully by many women with painful symptoms.

The results of this prospective study coincide with statements about Mulimen® that appeared in earlier publications. In 1986 Baur published the results of his experiences with Mulimen® therapy for pelvic congestion. A total of 114 patients ranging in age from 17 to 44 years received individually determined dosages of the preparation for 2-3 menstrual cycles. After an average treatment period of 4.4 weeks, 64 patients (56%) were completely symptom-free.³ Similarly, Sahelian reported on Mulimen® therapy in 50 patients, ages 17 to 70, with pelvic congestion. In 68% of these cases, freedom from symptoms occurred within the 12 weeks of treatment.⁴

Wiegand had equally positive experiences in using Mulimen® to treat intermenstrual bleeding in patients (aged 18 to 29 years) taking oral contraceptives.⁵ In 44 out of 46 cases, intermenstrual bleeding stopped after a maximum of three months. Fäusle investigated the effect of Mulimen® on premenstrual syndrome (n = 60, ages 35-45) and observed obvious improvements with regard to the severity of symptoms (mastodynia, depression, irritability, and sleep disturbances) after three cycles.⁶ Borho investigated the effect of Mulimen® on 82 patients (average age 50 years) with perimenopausal and menopausal symptoms (duration of treatment = 12 weeks). In approximately 60% of these cases, a significant improvement in symptoms (depression, nervousness, irritability, and outbreaks of perspiration) was achieved.⁷

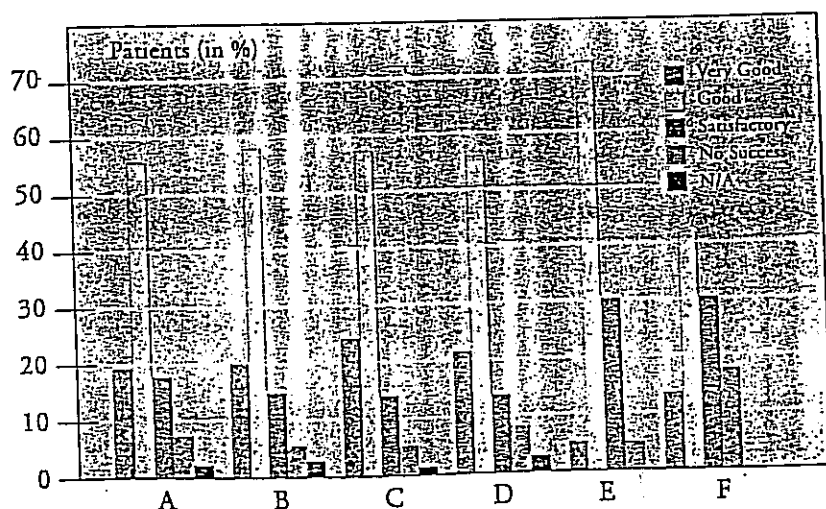


Figure: Physicians' evaluation of results of therapy for the patient population as a whole and for the primary diagnostic groups. (A=total, n=269; B=mood disorders, n=102; C=menstrual disorders, n=87; D=pelvic congestion, n=39; E=climacteric syndrome, n=27; F=other diagnosis, n=24). Multiple diagnoses occurred.

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Results of Treatment (physicians' evaluation) in patients receiving Mulimen® alone.						
Indications		Very Good	Good	Satisfactory	No Success	N/A
Total	(n=221)	20	57	15	7	1
Mood Disorders	(n=88)	20	57	15	7	1
Menstrual Disorders	(n=70)	27	59	13	1	-
Pelvic Congestion	(n=35)	20	57	11	9	3
Climacteric Syndrome	(n=19)	16	42	21	21	-
Other	(n=18)	6	72	17	6	-

Table 4: Patients receiving Mulimen® alone: Physicians' evaluation of results of therapy (numbers are in % and rounded off; multiple diagnoses occurred)

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Note: In the U.S. Mulimen® is known as PMS Mulimen® and is available only in tablet form.

BIOMEDICAL THERAPY

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