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Homeopathic Treatment of Gynecological Disorders

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Abstract

This multicentric prospective study systematically investigated usage indications, dosages, therapeutic efficacy, and tolerance of Hormeel S (drops). A total of 345 cases of treatment were documented by 41 physicians. The most frequent reasons for prescribing Hormeel S were premenstrual syndrome and menopausal symptoms. Hormeel S was reliably effective and well tolerated not only in combination with other forms of therapy but also when used alone.

Keywords: Hormeel S, menopausal symptoms, premenstrual syndrome.

Introduction

Hormonal dysfunctions are among the most frequent ailments of women of reproductive age. Premenstrual syndrome is most prominent in women in their twenties or older, while dysmenorrhea is observed primarily in very young women[4]. Delayed or skipped ovulation due to hormonal disturbances is also one of the most frequent causes of infertility in couples who have been attempting to conceive for years.[7] The menstrual cycle, however, is not exclusively hormonally regulated but is also linked to complex CNS functions. Therefore, menstrual disorders can also be either triggered or masked by psychological factors[9].

Because of the possibility of undesirable side effects, hormone substitution is not always the optimum solution to such problems[1]. Thus many women today are refusing hormone treatment and looking for therapeutic alternatives that are both better tolerated and convincingly effective. In comparison to hormone substitution therapy, both phytotherapy[1),11)] and homeopathic remedies[2)] have proved quite effective in treating functional menstrual disorders and female infertility. Gerhard et al. demonstrated the success of both individually selected homeopathic single remedies and homeopathic combination remedies (such as Hormeel S) in treating hormonal dysfunctions and fertility disorders[6),8)]. The advantages of homeopathic therapy over hormone substitution include better tolerance and the absence of multiple pregnancies or ovarian cyst formation[6),8)].

As is to be expected from the drug pictures of its components (Table 1), the homeopathic combination remedy Hormeel S (manufactured by Biologische Heilmittel Heel GmbH, Baden-Baden/Germany) has been used successfully for more than thirty years in treating hormonal dysfunctions (especially disorders of the menstrual cycle and related symptoms such as painful menstruation and menopausal complaints) and as an adjuvant therapy in female infertility. Although Hormeel S is commercially available in two forms – drops and injection solution – only the oral form was considered in this prospective study, whose purpose was to gather information on the usage indications, dosages, efficacy, and tolerance of Hormeel S.

Methods

Data on the patients' medical histories and treatment were recorded on standardized questionnaires. No criteria for inclusion or exclusion were defined, since this preparation-specific prospective study was intended to observe the entire spectrum of usage of Hormeel S (Table 2). Dosages, duration of treatment, and the option of implementing a concomitant therapy were left up to the attending physicians, who were required to record all data relevant to treatment on the questionnaires.

The physicians evaluated the success of the selected protocols in terms of two criteria: a) the point in time when improvement in symptoms was first observed, and b) overall assessment of the results of therapy, using a five-point scale ("very good" = complete freedom from symptoms, "good" = significant improvement, "satisfactory" = slight improvement, "no success" = symptoms remained the same, and "worse."

Upon conclusion of treatment, patient tolerance of Hormeel S was assessed according to the following scale: "excel-

lent," "good," "fair," and "poor." Undesired effects were recorded on a separate questionnaire.

Treatment data for 345 patients were recorded. All of the questionnaires returned to the investigators were suitable for inclusion in the descriptive statistical analysis.

Results

Patient Demographics

All 345 patients were female, with the emphasis in age distribution falling between 31 and 50 years (56%). The most frequent diagnoses listed during case-taking were premenstrual syndrome (PMS) and menopausal symptoms, but many other diagnoses were also reported, including menstrual disorders, ovarian insufficiency, dysmenorrhea, and hormonal dysfunction. The age range within each diagnostic group was typical of that syndrome (Table 3).

Duration of symptoms or illness prior to treatment ranged from several weeks or months to several years. Only 14% of the patients had been taking prescription medications immediately before being accepted into the study. (Most frequently prescribed were gynecological medications and spasmolytics; other prescriptions included various hormone preparations. Homeopathic remedies played only a minor role prior to the beginning of the prospective study.) Patients' reasons for requesting a change in medication included poor tolerance of the previous medication, lack of success of previous treatment, and the desire for a "natural" form of treatment.

Treatment with Hormeel S

The standard dosage recommended by the manufacturer is 10 drops 3 times a day. When treatment began, this standard dosage was prescribed for 60% of the patients, while 30% of patients received 10 drops 2 times a day and 4% received 10 drops once a day. (Other dosages ranged from a minimum of 5 drops 3 times a day to a maximum of 30 drops 3 times a day.) In approximately 95% of cases, the dosage of Hormeel S remained the same throughout the entire observation period.

Because of the nature of their symptoms, the majority of patients were treated with Hormeel S for a longer period of time (1 to 3 months in 75% of cases); the maximum treatment period was 5 months. Approximately 80% (275) of the patients were treated only with Hormeel S. In the remaining cases, additional medications (primarily gynecological preparations and spasmolytics) or non-drug therapies (acupuncture, Kneipp treatments, and physical therapy) were prescribed. There were no significant differences among the diagnostic groups with regard to dosage of Hormeel S, duration of treatment, or implementation of additional therapies.

Tolerance

In a total of three cases, undesired effects of the medication were described (restlessness, nervousness, nausea, intensification of pre-existing allergic rhinitis). In all three cases, the attending physicians doubted a causal connection to Hormeel S. In general, this prospective study shows that intolerance reactions are the exception rather than the rule when Hormeel S is adminis-

Constituents	Characteristics/symptoms
Acidum nitricum (nitric acid) D4	Inflammation of the skin and mucous membranes, (including urethra and vulva); skin tends to crack. Ulcerations. Benign and malignant growths. Diseases involving weight loss. Depressive moods.
Aquilegia vulgaris (columbine) D4	Sleep disorders with nervousness. Also dysmenorrhea, functional amenorrhea.
Calcium carbonicum Hahnemanni (inner white portion of oyster shell) D8	Disorders of calcium metabolism. Chronic diseases of the mucous membranes. Proliferative processes of the mucous membranes.
Cyclamen europaeum (Alpine violet) D4	Headaches. Menstrual disorders. Depressive moods.
Cypripedium calceolus var. pubescens (lady-slipper) D8	Sleeplessness (especially in over-stressed women).
Erigeron canadensis (fleabane) D3	Uterine hemorrhage (menorrhagia, metrorrhagia).
Ignatia (St. Ignatius's bean) D6	Nervous disorders. Depressive moods. Cramps in the hollow organs and muscles.
Origanum majorana (marjoram) D4	Heightened sexual arousal and nervous irritability.
Moschus moschiferus (glandular secretion from the male musk ox) D6	Nervous disorders such as excitability, fainting.
Nux moschata (nutmeg) D6	Nervous symptoms in the body. Digestive weakness with flatulence. Perceptual disorders such as mental fogginess. Also emotional lability, hypochondria, hysteria.
Pulsatilla pratensis (pasqueflower) D4	Inflammations and disorders of the female genitalia, vaginal inflammation with discharge, menstrual disorders of all types. Disorders of pregnancy and lactation. Headaches. Sleep disturbances, psychological disorders. Nervous disorders, depressive moods.
Senecio nemorensis ssp. fuchsii (groundsel, ragwort) D6	Bleeding or hemorrhage. Also irregular menses, dysmenorrhea (all symptoms improve after onset of menses).
Sepia officinalis (cuttlefish) D6	Many disorders of the female reproductive organs. Headaches. Sleep disturbances. Exhaustion. Psychological disorders and depressive moods. A general remedy for menopausal symptoms.
Thlaspi bursa-pastoris (penny cress) D3	Bleeding from the uterus or mucous membranes.
Viburnum opulus (guelder rose) D3	Painful menstrual bleeding.

Table 1: Constituents of Hormeel S and selected aspects of their drug pictures.

tered. This estimation was also confirmed by the participating physicians, who assessed overall tolerance of the preparation as "excellent" in 53% of all cases, "good" in 45%, and "fair" in 1%.

Results of Treatment

There were no marked differences among the various diagnostic groups with regard to the point in time when the therapy began to take effect. In every third patient, the effect was observed within two weeks, in 30% of patients after 2 to 4 weeks of treatment, and in every fourth patient only after 1 to 2 months of treatment.

According to the physicians' overall assessment of the therapy, complete freedom from symptoms was achieved in every fourth patient and clear improvement occurred in 6 out of 10 patients. Therapy was unsuccessful in 3% of the patients. Hormeel S was effective in treating all symptoms recorded. In the two largest diagnostic groups, "very good" and "good" results were achieved in over 80% of patients. 87% (240) of the patients treated only with Hormeel S achieved "very good" to "good" results (Table 4).

• Time frame:	March to October 1997
• Place:	Germany and Belgium
• Physicians:	41 licensed physicians 36 general practitioners 5 gynecologists
• Total number of questionnaires sent out:	810
• Total returned:	345 (42.6%)
• Structure:	prospective
• Observation period per patient:	5 months maximum
• Criteria for inclusion/exclusion:	none
• Documentation:	standardized questionnaires
• Number of patients per physician:	minimum 5, maximum 10

Table 2: Parameters of the prospective study.

Discussion

With the exception of puberty, menopause is the most profound change ever to occur in a woman's hormonal balance. During this phase, many women are subject to a variety of neurovegetative and neuropsychological symptoms caused by the steep drop in estrogen levels[12]. Although substitution therapy with estrogens can indeed alleviate such deficiency symptoms and inhibit pathological processes, administering hormones may be contraindicated if diseases of the liver, gallbladder, or pancreas are present or if the patient is at risk for thrombosis[12].

Age groups	Total (n = 345)	Premenstrual syndrome (n = 147)	Menopausal symptoms (n = 137)	Other (n = 61)
< 21 years	23 (6.7%)	19 (12.9%)	-	4 (6.6%)
21–30 years	60 (17.4%)	45 (30.6%)	1 (0.7%)	14 (23.0%)
31–40 years	81 (23.5%)	58 (39.5%)	1 (0.7%)	22 (36.1%)
41–50 years	112 (32.5%)	22 (15.0%)	77 (56.2%)	13 (21.2%)
51–60 years	45 (13.9%)	-*	42 (30.7%)	1 (1.6%)
61–70 years	16 (4.6%)	-*	-*	4 (6.6%)
> 70 years	7 (2.0%)	-	-*	3 (4.9%)
no data	1 (0.3%)	-	1 (0.7%)	-

Table 3: Type and frequency of the main reasons for administering Hormeel S; age distribution within these groups.

*Dropouts for reasons of age

Indications		very good	good	satisfactory	no success	no data
Patients receiving concomitant medication:						
total	(n = 345)	85 (24.6%)	193 (55.9%)	56 (16.2%)	9 (2.6%)	2 (0.6%)
premenstrual syndrome	(n = 147)	39 (26.5%)	84 (57.1%)	22 (15.0%)	1 (0.7%)	1 (0.3%)
menopausal symptoms	(n = 137)	34 (24.8%)	79 (57.7%)	20 (14.6%)	3 (2.2%)	1 (0.3%)
other diagnoses	(n = 61)	12 (19.6%)	30 (49.2%)	14 (23.0%)	5 (8.2%)	-
Patients not receiving concomitant medication:						
total	(n = 300)	73 (24.3%)	167 (55.7%)	49 (16.3%)	9 (3.0%)	2 (0.7%)
premenstrual syndrome	(n = 132)	36 (27.2%)	76 (57.6%)	18 (13.6%)	1 (0.8%)	1 (0.3%)
menopausal symptoms	(n = 128)	33 (25.8%)	71 (55.5%)	20 (15.6%)	3 (2.3%)	1 (0.3%)
other diagnoses	(n = 40)	4 (10.0%)	20 (50%)	11 (27.5%)	5 (12.5%)	-

Table 4: Treatment results within the various diagnostic groups.

PMS is characterized by physical and psychological changes varying in intensity from individual to individual. These changes (which may include nervousness, changes in the skin, or hot flashes) appear 7 to 10 days prior to menstruation and disappear when it begins. PMS symptoms are presumably caused by endocrine factors. At present, there is no consensus on how to treat PMS. According to the results of one American study, therapy with progesterone (a hormone produced by the corpus luteum) relieved PMS symptoms no better than a placebo[5]. Furthermore, many patients are skeptical of hormone therapy and increasingly ask their physicians to suggest alternative methods of treatment.

Hormeel S is a homeopathic remedy whose ingredients allow it to favourably influence a large number of many different gynecological disorders. For example, the component Pulsatilla is used in treating inflammations and functional disorders of the female genitalia, while Ignatia has a positive influence on nervous disorders and moodiness[2]. The homeopathic remedy Sepia is indicated for typical menopausal symptoms such as hot flashes, psychological depression, and irritability[10].

This prospective study demonstrates the use of Hormeel S in treating PMS and menopausal symptoms. In the great majority of the cases monitored in this study, Hormeel S therapy was effective and well tolerated.

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