

Symptomatic Treatment of Rhinitis and Sinusitis

Ultra-low-dose Nasal Spray Effectively Reduces Severity of Symptoms

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Abstract

Objective: To obtain additional information about the effectiveness and safety of a homeopathic medication (Euphorbium comp.-Nasal Spray SN) in the primary treatment of rhinitis and sinusitis in 91 patients.

Methods: The present study is an observational, open, prospective, multicenter, noninterventional cohort study.

Results: A total of 91 patients (aged 1-82 years), diagnosed as having rhinitis (n=77) and/or sinusitis (n=35), were treated with Euphorbium comp.-Nasal Spray SN. The applied dosage was predominantly 1 or 2 sprays in each nostril 3 times per day. The duration of treatment was a mean±SD of 26.7±13.4 days. The outcome measure was the severity of disease-specific symptoms (eg, headache, secretion, itching, and fatigue). The main findings were a significant decrease in the severity of the symptoms and global improvement of symptom scores within the first 2 days for 30 patients (33%). The tolerability of the treatment was assessed as “good” or “very good” in 84 (92%) of the patients by physicians; 77 (85%) of the patients self-assessed tolerability as good or very good. Finally, there were no concerns regarding patient compliance, which was rated as very good or good in 82 (90%) of the patients.

Conclusions: This observational study was performed to obtain data on the therapeutic potential and tolerability

of the homeopathic preparation Euphorbium comp.-Nasal Spray SN. Data suggest that Euphorbium comp.-Nasal Spray SN effectively manages the symptoms of rhinitis and/or sinusitis and is very well tolerated and accepted by patients.

Introduction

The use of homeopathic medicines is well established in Europe, especially France, the United Kingdom, and Germany. Euphorbium comp.-Nasal Spray SN is an ultra-low-dose combination medication produced according to the rules of the *German Homeopathic Pharmacopoeia*.

The indications for the use of Euphorbium comp.-Nasal Spray SN include symptoms of rhinitis of various origins. In practice, the medication is also sometimes used for the auxiliary treatment of atrophic rhinitis (ozena) and chronic sinusitis. The objective of this observational study was to gather information regarding the effectiveness and safety of Euphorbium comp.-Nasal Spray SN. The study collected relevant data from 32 office-based practitioners (3 general practitioners, 9 surgeons, 1 licensed practitioner, and 19 others, not specified) who prescribed/recommended this medication to the appropriate patients. The study was prepared, performed, and analyzed according to the standards of the German Federal Institute for Drugs and Medical Devices;

and followed the principles of the Declaration of Helsinki.

Methods

Design

This observational study was designed as an open, prospective, multicenter, noninterventional cohort study. The 32 participating practitioners treated the patients according to their own discretion. There were no exclusion criteria: every patient with associated symptoms was included in the study based solely on the judgment of a participating practitioner. This kind of study was performed to achieve a closer approximation of actual clinical treatment practices, which can often not be achieved in controlled randomized studies. This design allowed the physicians to include and evaluate a broader range of patients. The use of concomitant (pharmacological and nonpharmacological) therapies was permissible. The study was conducted between July 2002 and October 2002. Patients were examined initially and at the final visit. Standardized questionnaires (ie, case record forms) were used for recording the medical histories and treatment of the patients; demographic data; disease or diagnosis (specification, cause, severity, and duration); disease-specific symptoms (specification and severity); dosage of Euphorbium comp.-Nasal Spray SN used; concomitant drug or nondrug

Euphorbium, the name-giving ingredient of *Euphorbium comp.-Nasal Spray SN*, is prepared from the hardened sap of *Euphorbia resinifera*, a native of Morocco.



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therapy used; onset of improvement; occurrence of adverse drug reactions; global evaluation of the compliance of the patient; and global evaluations of the tolerability and overall result of treatment.

Outcome Measures

The severity of disease-specific symptoms was rated by the following 5-point scale: none, mild, moderate, severe, or very severe. The onset of efficacy was assessed by using the following 8-point scale: immediately after the first dose, after 1 day, after 2 days, after 3 days, after 4 to 7 days, after more than 1 week, no improvement, and treatment discontinued. The global evaluation of the overall result of treatment (assessed by the physician and the patient) was determined using the following 4-point scale: very good (complete absence of symptoms), good (definitive improvement in symptoms), satisfactory (slight improvement in symptoms), and no improvement (symptoms remain the same or worsening of symptoms).

Safety Measurements

The safety measurement included recording any adverse drug reactions during treatment. The global evaluation of tolerability (assessed by the practitioner and the patient) was measured by the following 4-point scale: very good (no adverse reactions), good (infrequent adverse

reactions), moderate (frequent adverse reactions), and poor (medication could not be used because of strong adverse reactions). These ratings of symptom intolerance were collected and recorded after every application of *Euphorbium comp.-Nasal Spray SN*.

Treatment Compliance

The global evaluation of compliance of the patient (assessed by the physician) was determined by the following 4-point scale: very good (patient adheres strictly to the scheme of the therapy), good (patient adheres mostly to the scheme of the therapy), moderate (patient adheres minimally to the scheme of the therapy), and poor (patient does not adhere at all to the scheme of the therapy).

Data Analysis

No follow-up was performed. All case record forms were reviewed for completeness and consistency. There were no changes to the protocol. The statistical analysis was performed descriptively.

Results

Patients

A total of 91 patients were included in the study. Most patients (48 [53%]) were male. The mean±SD age of the patients was 30.4±20.2 years (range, 1-82 years). The mean±SD weight of the patients

was 53.0±19.4 kg, and the mean±SD height of the patients was 152.6±21.5 cm.

Diagnosis

The most common diagnoses were rhinitis (77 patients) and sinusitis (35 patients), with the potential for more than 1 diagnosis. The causes of the disease were primarily allergy (35 patients with overall allergy and 19 with house dust allergy) and the common cold (15 patients). The severity of the disease was assessed as mild in 45 patients (50%), moderate in 24 patients (26%), and severe in 13 patients (14%). There were no data collected for 9 patients (10%). The following categories were used to mark the duration of disease: less than 3 days, 4 to 7 days, 1 to 2 weeks, 2 to 4 weeks, 1 to 3 months, 3 to 6 months, 6 to 12 months, and longer than 1 year.

The most frequently reported disease-specific symptoms were rhinorrhea, sneezing, pruritus, and nasal obstruction.

Treatment

The mean±SD duration of treatment was 26.7±13.4 days. The minimum observation period was 3 days; and the maximum, 79 days. The proper dosage of *Euphorbium comp.-Nasal Spray SN*, according to the manufacturer's recommendations, is 1 to 2 sprays into each nostril 3 to 5 times daily for adults and

1 spray into each nostril 3 to 4 times daily for children younger than 6 years. The dosages applied met the manufacturer's recommendations, with the most common dosage being 1 or 2 sprays into each nostril 3 times daily (60 patients [66%]). Seven patients (8%) used a lower than recommended dose. Of the 91 patients, 46 (51%) received only Euphorbium comp.-Nasal Spray SN and 45 (49%) received additional treatment. The additional treatments included drug therapy (n=29), non-drug therapy (n=7), and both drug and nondrug therapy (n=9). Drug therapy included other homeopathic medications; antibiotics; antiallergic, rhinological, analgesic, antitussive, and broncholytic agents; and sympathomimetic drugs. Nonpharmacological therapy included neural therapy, laser therapy, inhalation, and moxa. The most frequent concurrent medications were homeopathic drugs (n=12), antibiotics (n=9), and antiallergy drugs (n=7); the most frequent concurrent nonpharmacological therapies were neural therapy (n=5) and laser therapy (n=4).

Effectiveness

The scale used to assess the severity of disease-specific symptoms was as follows: 0, none; 1, mild; 2, moderate; 3, severe; and 4, very severe. At both the initial and final visits, the intensity of 3 disease-specific symptoms per patient was assessed and a mean symptom score was calculated using these data to determine the general reduction in symptom severity by the end of treatment. In the total patient population, the rating of the disease-specific symptoms decreased from a mean of 2.45 at the admission visit to 0.65 at the final visit. No relevant differences were found in the evaluation of single most frequent symptoms (ie, rhinorrhea, sneezing, pruritus, and nasal

obstruction). Global improvement scores were collected within the first 2 days for 30 patients (33%). The overall assessment of effectiveness was rated by physicians (based on the 5-point scale) as "very good" or "good" in 78 (86%) of the patients; 70 (77%) of all patients rated the efficacy of the therapy as very good or good during self-assessment. Interestingly, 38 (83%) of the 46 patients who received monotherapy with Euphorbium comp.-Nasal Spray SN had very good or good results, according to practitioners; 39 (85%) of the patients self-assessed their results as very good or good.

Global Evaluation of Tolerability

Both the physicians and the patients rated the tolerability of Euphorbium comp.-Nasal Spray SN positively. Physicians recorded tolerability as very good or good in 84 (92%) of the patients; 77 (85%) of the patients self-assessed tolerability as very good or good.

No adverse drug reactions were reported during the observation period. Finally, there were no concerns regarding patient compliance, which was rated as very good or good in 82 (90%) of the patients.

Conclusions

This observational cohort study was performed to assess the therapeutic potential and tolerability of the homeopathic medication Euphorbium comp.-Nasal Spray SN. A total of 91 patients, primarily diagnosed as having rhinitis or sinusitis, were treated with Euphorbium comp.-Nasal Spray SN monotherapy or in combination with other medications or nondrug therapies. The mean treatment duration was 26.7 days. Half of the patients received additional treatment. Global improvement within the first 2 days was

documented for 30 (33%) of the patients. In the total patient population, the rating of the disease-specific symptoms decreased from a mean of 2.45 at the baseline examination to 0.65 at the end of the observation period. No relevant differences were found in the evaluation of single symptoms, such as rhinorrhea, sneezing, pruritus, and obstruction. The overall outcome of therapy was positive in most patients. In the patients who were treated with monotherapy, the results of treatment were comparable to those of the total patient cohort, with 83% of the patients using monotherapy with Euphorbium comp.-Nasal Spray SN achieving very good or good results compared with 86% of those in the total patient cohort. In addition to therapeutic effectiveness, this study demonstrates excellent tolerability of Euphorbium comp.-Nasal Spray SN. The health care practitioners and patients assessed the tolerability of Euphorbium comp.-Nasal Spray SN as very good or good in most cases. Also, during the total period of observation, no adverse drug effects were reported. In conclusion, this study demonstrates that the ultra-low-dose combination medication Euphorbium comp.-Nasal Spray SN is well established in the practice of general medicine in which it is prescribed, as either a stand-alone therapy or an adjunct to mainstream medical therapy. The applied dosages met the manufacturer's recommendations. The investigation suggests that this medication is both effective and well tolerated. Therefore, a positive benefit to risk ratio can be expected for Euphorbium comp.-Nasal Spray SN in the treatment of rhinitis and sinusitis. ■

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