A Complex Homeopathic Preparation for the Symptomatic Treatment of Upper Respiratory Infections Associated With the Common Cold: An Observational Study

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Background: The use of complementary medicines is large and growing in both the United States and Europe.

Objective: To compare the effects of a complex homeopathic preparation (Engystol; Heel GmbH, Baden-Baden, Germany) with those of conventional therapies with antihistamines, antitussives, and nonsteroidal antiinflammatory drugs on upper respiratory symptoms of the common cold in a setting closely related to everyday clinical practice.

Design: Nonrandomized, observational study over a treatment period of maximally two weeks.

Setting: Eighty-five general and homeopathic practices in Germany.

Participants: Three hundred ninety-seven patients with upper respiratory symptoms of the common cold.

Interventions: Engystol-based therapy or common over-the-counter treatments for the common cold. Patients receiving this homeopathic treatment were allowed other short-term medications, but long-term use of analgesics, antibiotics, and antiinflammatory agents was not permitted. Patients were allowed nonpharmacological therapies such as vitamins, thermotherapies, and others.

Main outcome measures: The effects of treatment were evaluated on the variables fatigue, sensation of illness, chill/tremor, aching joints, overall severity of illness, sum of all clinical variables, temperature, and time to symptomatic improvement.

Results: Both treatment regimens provided significant symptomatic relief, and this homeopathic treatment was noninferior in a noninferiority analysis. Significantly more patients ($P < .05$) using Engystol-based therapy reported improvement within 3 days (77.1% vs 61.7% for the control group). No adverse events were reported in any of the treatment groups.

Conclusion: This homeopathic treatment may be a useful component of an integrated symptomatic therapy for the common cold in patients and practitioners choosing an integrative approach to medical care.

Key words: Complementary medicine, observational study, noninferiority, viral infections

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INTRODUCTION

The common cold is a prominent example of an ailment in which multiple therapeutic approaches are commonly used in both alternative and conventional medical practices. There is no universally accepted therapy for the common cold, and no licensed antivirals appear to be effective for this condition. Some strategies, such as prolonged prevention of community colds with interferon are associated with adverse effects and are not recommended.[1] Thus, most treatments are addressed toward symptomatic relief, and there is a substantial component of self-medication involved.

Alternative medications are frequently used for treatment of musculoskeletal symptoms, vertigo, or mild viral infections, such as the common colds. There are data from clinical investigations indicating that, for the symptomatic treatment of mild viral infections, a therapy based on a complex homeopathic remedy may be as effective as conventional therapies with antihistamines, antitussives, and nonsteroidal antiinflammatory drugs (NSAIDS).[2]

One antiviral agent widely used in alternative medical practice is Engystol (Heel GmbH, Baden-Baden, Germany), a complex homeopathic preparation based on two main active ingredients, *Vincetoxicum hirundinaria* (common name, swallowort) and sulphur, at high dilutions (10^{-6} to 10^{-30}). Both ingredients are listed in the *Homeopathic Pharmacopoeia of the United States*.[3] This homeopathic treatment is used for acute symptomatic therapy as well as for prophylactic treatment of infectious diseases. In recent years, studies have reported beneficial effects of Engystol in different settings, such as prophylaxis in patients with influenza and common cold,[4] and there are reports suggesting stimulation of phagocytic activity of granulocytes in vitro.[5] A recent assay (Enbergs H, *Immunol Invest.* 2006, in press) indicated that Engystol might increase the percentage of interferon-γ producing lymphocytes in vitro.

This pilot study attempts to assess the clinical benefits of this homeopathic treatment compared with conventional treatment

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strategies in a real-life scenario and provide information that would be useful to plan a larger scale randomized controlled clinical trial. The duration of this study was not more than two weeks per patient, which corresponds to the maximum duration of the illness that might be encountered in clinical practice.

In an attempt to capture as wide a range of patients and therapeutic strategies as possible, this study used a nonrandomized, observational approach and includes capturing data on the use of concurrent medications. A disadvantage associated with this choice of design is the possibility that patients groups would not be comparable for all variables at baseline, which confounds the analysis of the results. To attempt to address this confounder, propensity score analysis was applied to the data. Such methods have been used in other studies with alternative medicine, eg, in a recent comparison of the homeopathic therapy Cralonin with conventional medications in patients with mild heart failure.[6]

METHODS

This observational study was carried out in 85 practices in Germany from November 1, 2003, to February 29, 2004. Inclusion criteria were symptoms of upper respiratory infections associated with the common cold before entering the study. Patients were excluded who were currently receiving symptomatic treatment for the common cold; patients with secondary bacterial infections of the upper respiratory tract on antibiotic therapy; patients with asthma, allergies, or chronic infections; and patients recently treated with similar therapies to those in the study.

Each center enrolled up to five patients into the study. Patients received Engystol-based therapy or common over-the-counter (OTC) treatments (antipyretic/analgesic/antiinflammatory) for the common cold. The choice of treatment was a joint decision of the practitioner and the patient. Engystol was given as tablets (active constituents: *Vincetoxicum hirundinaria* D6, D10, D30; sulphur D4, D10). To reflect everyday treatment practices, in both groups, the doses were not stipulated in the protocol but were decided for each individual patient for a maximum of two weeks. No limit was set to the number of different therapies in the control group. In the homeopathic treatment group, patients were allowed other short-term medications, but the long-term use of analgesics, antibiotics, and antiinflammatory agents was not permitted.

All patients were informed about the background and purpose of the study, which was conducted in full compliance with the principles of the Declaration of Helsinki and with the German recommendations for the planning, execution, and evaluation of observational studies (Bundesanzeiger Federal Gazette No. 299 of December 04, 1998).

All variables were selected to reflect patients' experiences of illness. Treatment effects were evaluated on the following variables: fatigue, sensation of illness, chill/tremor, temperature, aching joints, overall severity of illness, and the sum of all clinical variables. For the variables fatigue, sensation of illness, chill/tremor, aching joints, and overall severity of illness, severity was assessed on a scale from zero to three, where zero was asymptomatic; one, mild symptoms; two, moderate; and three, severe symptoms. Temperature was measured in degrees Celsius. In patients with diagnosis of rhinitis, pharyngitis, laryngitis, or bronchitis, changes in symptoms related to these diagnoses were also monitored. Rhinitis was assessed on sneezing, burning, or tickling sensations; nasal congestion; and reduced sensation of smell and nasal speech. Pharyngitis was evaluated as throat burns, pain with swallowing, and redness of mucous membranes. The laryngitis variables were loss of voice, hoarseness, cough, and soreness of throat. Finally, bronchitis was evaluated on cough, hoarseness, productive cough, and chest pain.

Tolerability was assessed through the monitoring of adverse events. Furthermore, the practitioner as well as the patients did an assessment of overall tolerability during the course of the study. The subjective tolerability experience was graded on a four-term scale: 0, excellent (no adverse reactions); 1, good (occasional adverse reactions); 2, moderate (frequent adverse reactions), and 3, poor (adverse reactions associated with every administration of study medication).

Statistical comparisons were conducted with ANOVA and Fischer's exact test as appropriate. To adjust for patients groups not being statistically comparable for certain variables at baseline, propensity-score analysis was carried out as previously described.[6] Patients were stratified into quintiles according to propensity score based on all baseline variables. The two treatment strategies were analyzed for noninferiority of Engystol-based therapy compared with conventionally based therapy. The noninferiority analysis compared the lower border of the 95% confidence interval between the differences in change between Engystol-based and conventionally based therapies. The noninferiority limits were set to 0.2 units for all symptomatic scores, 0.2°C for temperature, and 0.4 scoring units for the differences between the summary score of all variables.

RESULTS

A total of 397 patients were available for analysis, 175 in the homeopathic treatment group and 222 in the control group. Baseline characteristics are given in Table 1. The patients groups were generally well-balanced at baseline. There was a slightly higher number of women (58.3%) in the homeopathic treatment group than in the control group (52.7%), and patients in this group were somewhat shorter than those in the control group, but the differences were not statistically significant. The treatment groups differed significantly on four characteristics ($P < .05$ for the difference): weight, incidence of tracheitis and acute bronchitis, and fatigue score. Patients receiving the homeopathic remedy tended to be lighter and have lower incidences of tracheitis and acute bronchitis than the control patients, but they had slightly higher scores on fatigue than the control patients. Propensity score stratification adequately compensated for these differences, which were reduced beyond the threshold of significance ($P < .05$).

The homeopathic treatment group received treatment in the form of tablets, commonly given three times daily (69.6%). This dosage was not fixed, and increased dosing was used intermittently by 73.7% of patients. The most commonly used other study treatments in the control group were paracetamol (42%), aspirin (16%), metamizol (18%), and ibuprofen (12%).