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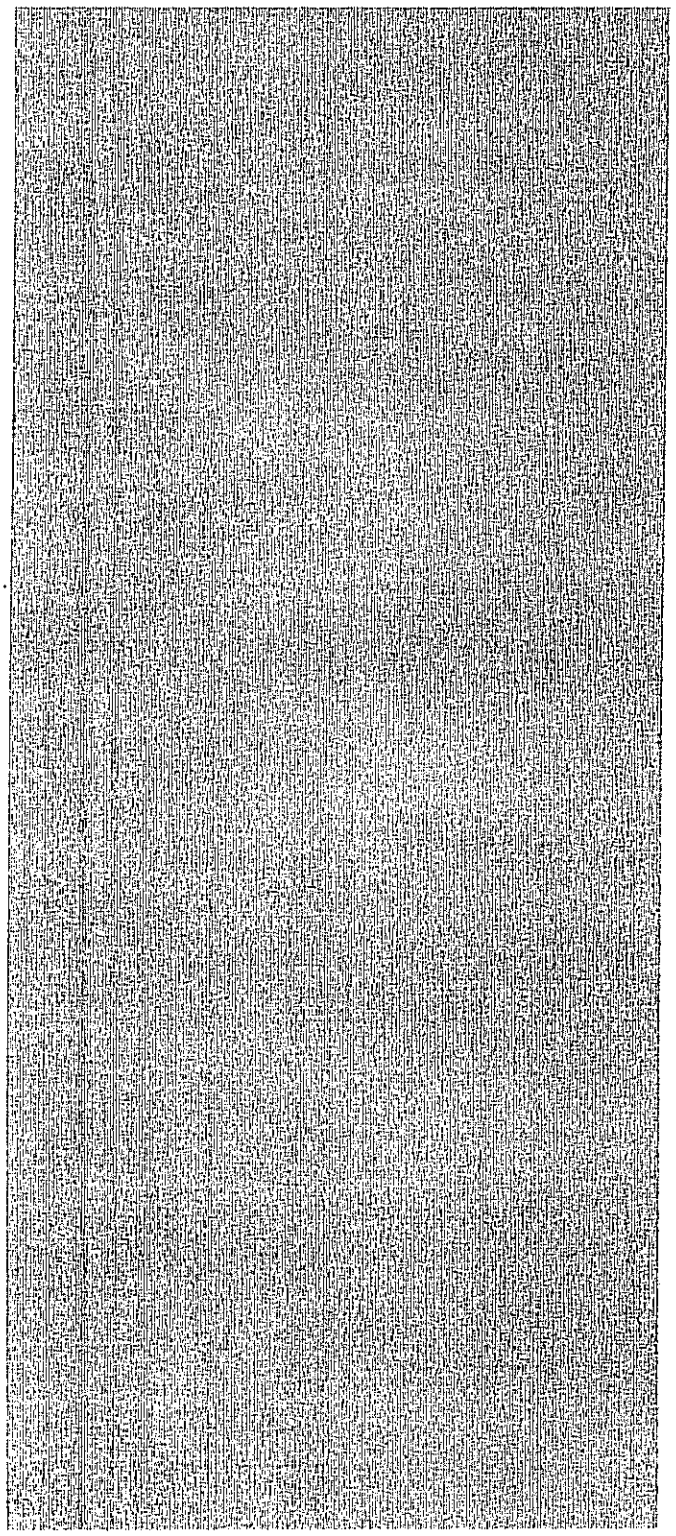

Modern Homeopathic Therapy for Coughs

Results of a Prospective Cohort Study

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Abstract

The purpose of this prospective cohort study was to document usage indications, efficacy, and tolerability of Husteel in treating coughs of varying etiology. A total of 339 patients, most of whom were suffering from acute bronchitis with moderate symptoms, were observed during a maximum of six weeks of Husteel therapy. Objective criteria applied in assessing efficacy were: 1) reductions in clinical symptoms (expectoration of phlegm, nausea/vomiting, pain during coughing, respiratory spasms, attacks of coughing) and 2) physicians' ratings of overall efficacy. Overall ratings were also employed to assess patient tolerance of the medication.

In 45% of the patients, significant improvements in clinical symptoms occurred within the first three days of treatment, and for the majority of patients both subjective well-being and clinical symptoms improved significantly by the end of the treatment/observation period. Efficacy was rated "very good" or "good" in over 95% of cases, regardless of whether Husteel was administered alone or in combination with other medications. Patient tolerance of Husteel was rated "very good." This study confirms that Husteel safely and effectively treats coughs of varying etiology.

Keywords: Antihomotoxic medicine, cohort study, cough, homeopathy, Husteel

Introduction

Cough is the second most frequent reason (after vertebral problems) for consulting a physician, and the number of patients with respiratory symptoms greatly exceeds those with either cardiovascular disease, gastrointestinal symptoms, or psychosomatic disorders.[10, 11] Essentially, coughing is a protective reflex by the body, an attempt to keep the airways open by removing excessive secretions or foreign objects, for example.[7] Especially in winter, cough is a frequent symptom of illnesses ranging from simple upper respiratory infections to viral influenza. In most such cases, the cough is productive – that is, the body attempts to clear the airways of viscous phlegm.[2] In contrast, unproductive or "dry" cough occurs when the bronchi overreact to irritation due to infections, nicotine, allergens, or cold air.[9]

A cough may be due to any one of a number of different causes:

- respiratory infections
- airway hyperreactivity
- bronchial asthma
- rhinosinusitis
- chronic bronchitis
- malignant or benign tumors
- inhalation of a foreign object
- interstitial pneumopathies
- pulmonary-arterial hypertension
- gastroesophageal reflux
- left ventricular insufficiency
- medications such as beta blockers and ACE inhibitors
- psychological causes[5]

It is natural to suspect acute bronchitis when a patient complains of cough. As a rule, confirming this suspicion does not require tremendous diagnostic effort. Since acute bronchitis normally heals spontaneously, ruling out other causes and confirming the diagnosis generally requires nothing more than a thorough physical examination and questioning the patient. Neither microbiological nor radiological tests are essential, nor is laboratory testing.

A cough that persists for more than eight weeks, however, may be due to a tumor, asthma, or some other serious cause, and multilevel differential diagnosis becomes necessary:

Level 1: physical examination; interview the patient about the duration, character, and timing (day or night) of the cough, occupation, allergies, reflux symptoms, current medications (e.g., ACE inhibitors)

Level 2: chest x-ray, pulmonary function test

Level 3: nonspecific inhalation provocation test, ENT examination; sonogram, x-ray, or CAT scan of the sinuses, if needed

Level 4: 24 hour pH testing, CAT scan of the chest, bronchoscopy[13]

The ideal cough medicine should:

- suppress nonproductive cough without inhibiting removal of bronchial secretions through coughing
- have an anti-inflammatory effect on the bronchi
- have minimal side effects
- be nonaddicting[9]

The antihomotoxic combination remedy Husteel (manufactured by Biologische

Heilmittel Heel, Baden-Baden, Germany) is produced according to the guidelines of the German homeopathic pharmacopoeia (HAB). It contains Arsenicum iodatum, Belladonna, Scilla, Cuprum aceticum, and Causticum Hahnemanni. Based on the drug pictures of these ingredients, Husteel can be used to treat both productive and dry coughs whose etiologies include upper respiratory infections, asthma, or cardiovascular diseases (Table 1).

Ingredient	Drug picture
Arsenicum iodatum (arsenic tri-iodide)	rhinitis, bronchitis (esp. with dry cough), swollen glands (including hilus), geriatric heart conditions
Belladonna (nightshade)	respiratory infections with high fever
Scilla (sea onion)	cardiac insufficiency (also as a result of chronic congestive bronchitis; cor pulmonale)
Cuprum aceticum (copper acetate)	diseases involving spasms: asthma, whooping cough, angina pectoris
Causticum Hahnemanni	respiratory diseases, mood disorders

Table 1: Ingredients of Husteel and their drug pictures

Methods

Patient sample

The purpose of this prospective cohort study was to investigate usage indications, therapeutic efficacy, and tolerability of Husteel in patients with coughs of varying etiology. Data on the treatment of 339 patients were systematically recorded by the 71 physicians (family practitioners, internists, and pediatricians) who participated in the study. To ensure a representative patient sample, the only criteria established for including or excluding patients were that no other cough medications were to be prescribed and that the treatment/observation period was not to exceed six weeks.

Procedure

Data compiled at the initial examination of each patient included the patient's age and gender; the cause, type (acute/chronic), duration, and severity of the cough; and the dosage of Husteel prescribed. Additional medications or non-drug therapy for the underlying illness was permitted as long as no other cough medicines were used during the course of the study. Patients were monitored at an optional interim examination and at a mandatory exit examination after a maximum of six weeks of treatment and observation. These examinations included questions about current clinical symptoms of the cough (see below).

Criteria

To document the course of therapy, the following parameters were recorded:

- ratings of the severity of clinical cough symptoms (expectoration of phlegm, nausea/vomiting, pain during coughing, respiratory spasms, attacks of coughing) on a scale of 0-3 (0 = no symptoms, 1 = mild, 2 = moderate, 3 = severe)
- patient's current subjective state of health (scale: 3 = good, 2 = fair, 1 = poor, 0 = very poor)
- overall severity of the cough (scale: 0 = no cough, 1 = mild, 2 = moderate, 3 = severe)
- onset of improvement in symptoms: after first use/one day/2 days/3 days/4-7 days/1-2 weeks/2-3 weeks/3-4 weeks/ >4 weeks
- overall results of therapy: very good (complete freedom from symptoms), good (obvious improvement/reduction in cough symptoms), fair (slight improvement/reduction in cough symptoms), no success (symptoms remained unchanged), worsening of symptoms
- overall tolerability of Husteel: very good (no intolerance reactions), good (occasional intolerance reactions), fair (frequent intolerance reactions), poor (intolerance reactions after every use). Incidents of adverse effects, whether spontaneously reported by the patient or elicited by the physician's questioning, were reported on a separate questionnaire.
- patient compliance with the therapeutic regimen: very good, good, fair, poor.

Statistical assessment

Exploratory analysis of the data was performed by calculating and graphing absolute and relative frequencies. Mean sum and symptom scores were calculated, based on the basis of physicians' ratings of the severity of individual clinical symptoms and overall severity of the cough and on patients' ratings of their current general health.

Results

Patient demographics

Approximately 60% of the 339 patients were female. Patients of all ages (< 1 to 87 years) were included in the study. Children (infants, toddlers, and schoolchildren under 12 years of age) made up a conspicuously high proportion (22%) of the total patient population (Table 2). Twenty-four percent of the patients demonstrated general risk factors such as tobacco consumption, obesity, hypertension, various forms of heart disease, or diabetes mellitus.

The cause of the cough (ICD-10: R05) was listed as bronchitis in 63% of the cases and as upper respiratory infection in 31%. Other causes (including allergies, asthma, and chronic cough reflex) were listed for 6% (see Table 2). Among the bronchitis cases, the acute form of the disease was more common (79%) than either the chronic form (13%) or spastic bronchitis (8%). The diagnosis "upper respiratory infection" encompassed a number of viral infections and inflammatory respiratory diseases such as pharyngitis and rhinitis.

The cough was acute in 76% of the patients treated with Husteel, chronic in 11%, and recurrent in 7%. The duration of the illness prior to beginning treatment was less than one week in 63% of the patients, up to one month in 24%, and more than four weeks in the remaining 13%. Four-

Parameter	Frequency (n / %)
Patients	339 / 100
Gender	
– female	198 / 58.4
– male	135 / 39.8
– not given	6 / 1.8
Age (in years)	
– mean / standard deviation	34.3 / 22.9
– minimum	<1
– maximum	87
Cause of cough (underlying illness)	
– bronchitis	248 / 62.6
– upper respiratory infection	124 / 31.3
– other	24 / 6.1
Duration of illness	
– < 3 days	132 / 38.9
– 4-7 days	83 / 24.5
– 1-2 weeks	68 / 20.1
– > 2 weeks	50 / 14.7
– not given	6 / 1.8
Overall severity of the cough	
– mild	56 / 16.5
– moderate	232 / 68.4
– severe	40 / 11.8
– not given	11 / 3.2
Type of cough	
– acute	265 / 75.9
– chronic	38 / 10.9
– recurrent	23 / 6.6
– not given	23 / 6.6

Table 2: Demographic and diagnostic data on patients (multiple listings occurred)

teen percent of the patients had undergone prior treatment (with antitussives/expectorants, antibiotics, or bronchodilators/antiasthmatics) for either the cough or the underlying illness.

Symptoms

The participating physicians classified the overall severity of the cough as "mild" in 17% of the patients, "moderate" in 71%, and "severe" in 12%; the average score was 2.0. At the same time, 96% of the patients assessed their general health as fair to poor (average score 1.5). A slight majority (56%) of the patients had productive coughs. At the beginning of the observation period, average symptom scores varied significantly among the five clinical signs of cough. For example, the symptom "attacks of coughing" was most pronounced with a score of 1.8, while the symptom "nausea/vomiting" was least pronounced with a score of 0.4 (on a scale of 0 to 3, where 0 = no symptoms and 3 = severe symptoms).

Treatment

The manufacturer's standard recommended dosage of Husteel is five to ten drops one to three times a day. For acute attacks of coughing, the dosage can be increased to five to ten drops every 30 to 60 minutes for up to 12 times a day. At the beginning of treatment, 51% of the patients were prescribed the standard dosage, to be supplemented with the acute dosage as needed, while 40% of the patients were prescribed only the standard dosage and 9% only the acute dosage. In most cases, the initial dosage was maintained throughout the period of treatment and observation (mean duration 18.7 days +/- 12.7); in only 7% of the cases was the dosage reduced during the treatment period.

A total of 39% of the patients also received medications other than Husteel. These medications, most of which targeted underlying illnesses, included analgesics/anti-inflammatories, rhinologics, influenza medications, immune modulators, and antibiotics. In some individual cases, steam inhalation or steam baths were prescribed as adjuvant therapies. In 61% of the cases, Husteel was the only therapy prescribed.

Results of therapy

Improvement/reduction in all five clinical signs was noted over the course of therapy. For example, the average score for the symptom "cough attacks" fell from 1.8 to 0.3, while the score for "pain during coughing" fell from 1.2 to 0.1 (Figure 1). Improvement in clinical symptoms was noted in 12% of the patients within the first day of treatment with Husteel and in 45% within the first three days.

The criteria "general health," established to describe the patients' subjective state of health, also clearly documents the efficacy of Husteel in treating coughs of varying etiology. The average score increased/improved from 1.5 points ("fair" or "poor") at the beginning of treatment to 2.9 points ("good") by the conclusion of therapy.

The physicians rated the success of therapy as "very good" or "good" in 96% of the cases, and 95% of the patients reported the same degree of success. In the group treated only with Husteel, the success rate was slightly higher, 98%, as reported by both physicians and patients (Figure 2).

Compliance as a measure of patient satisfaction with treatment (risk-versus-benefit assessment) was rated "very good" or "good" by the physicians in 95% of the cases.

Tolerability

The physicians rated overall tolerability of Husteel as "very good" or "good" in all cases except one. One patient with acute bronchitis experienced swelling of the throat for approximately one hour on the fourth day of treatment. The cause of this adverse incident was either cross-hypersensitivity to pollack or a reaction to the homeopathic ingredients Belladonna and Arsenicum iodatum.

Discussion

Coughing as a symptom of increased bronchial reactivity is triggered by any of a number of different causes, ranging from external irritation through bacterial and viral upper respiratory infections to systemic illnesses.[5, 7, 8] Multifaceted therapy that dissolves mucus/encourages expectoration, dilates the airways, and suppresses the central cough reflex is most likely to produce rapid relief.[3]

Recurrent viral and bacterial infections can weaken immune functions associated with the mucous membranes and disrupt removal of secretions, thus adversely affecting pulmonary function. In the worst case scenario, chronic emphysema/bronchitis or bronchial asthma may develop. The primary objective of therapy for cough should be to prevent the illness from becoming chronic.

Determining the cause of a cough generally does not require a major, specialized diagnostic effort. Physical examination and thorough interviewing of the patient, however, are all the more important and often

suffice to determine whether the cough is associated with:

- acute viral or bacterial infections (such as simple upper respiratory infections without bronchitis symptoms, viral infections with acute bronchitis, bronchopneumonia, spastic bronchitis)
- chronic/degenerative inflammatory pulmonary disease (emphysema, bronchiectasis)
- risk factors (e.g., smoking)

Non-chemical medications such as phytopharmaceuticals can play an important role in cough therapy.[1, 3, 6, 7, 8, 12] Because of the many possible causes of coughs and the variety of associated symptoms, phytotherapeutics with broad-based effects are often indicated. Due to their high content of etheric oils and saponins, these preparations possess antitussive and expectorant properties and have symptomatic effects.[1, 6, 8] In high doses, however, etheric oils (e.g., oils of peppermint, spruce needle, eucalyptus) not only inhibit mucus production and ciliary movement but may also cause adverse effects such as bronchial spasms, asthma attacks, allergic reactions, or gastric irritation. Aspiration of etheric oils can also produce adverse effects, and topical applications may cause granulomas. Saponin-containing herbs (ivy leaf, primrose root) can also cause gastric irritation and allergic reactions. To prevent mineral corticoid effects (sodium retention, calcium loss, hypertension, and edema), licorice preparations should never be used for longer than four to six weeks.

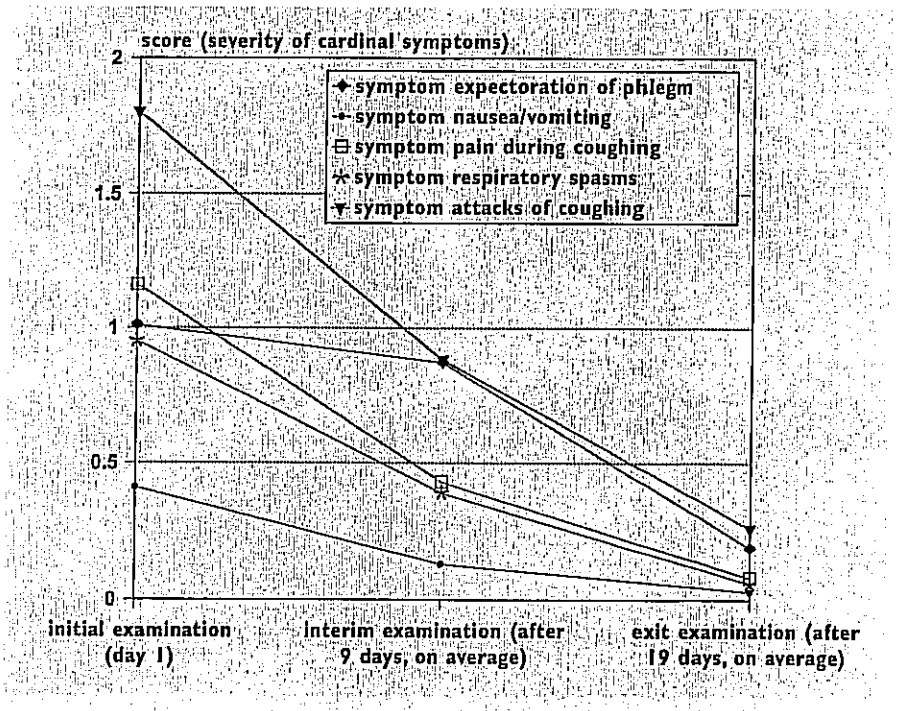

Fig. 1: Changes in cough symptoms during the investigation period (Scale: 0 = no symptoms, 1 = mild, 2 = moderate)

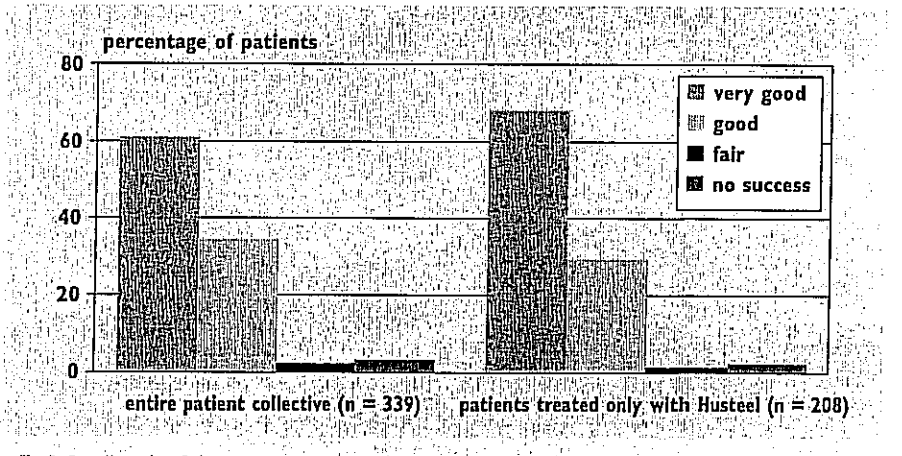

Fig. 2: Overall results of therapy

Conclusions

Although spontaneous healing is the rule with "normal" coughs, the results of this study confirm the therapeutic benefits of Husteel in treating coughs due not only to bronchitis and upper respiratory infections but also to other causes such as asthma. Independent of the type of underlying illness (acute/chronic), 45% of the patients noted significant improvements within the first three days of treatment, both in their general health and in individual symptoms (expectoration of phlegm, nausea/vomiting, pain during coughing, bronchial spasms, and attacks of coughing).

Although this medication-specific cohort study did not compile data on a control group, the investigation confirms that Husteel encourages spontaneous healing (i.e., supports the body's regenerative ability) in coughs of varying etiology. This statement is supported by:

a) data on overall improvement (i.e., reduction in the degree of severity) of cardinal clinical symptoms
b) consistently positive assessments of therapeutic benefits by the participating physicians, even when Husteel was the only form of therapeutic intervention
c) consistently good patient compliance

The relatively high percentage (22%) of children in the patient population is worth noting, since the option of reliably effective cough therapy without side effects is especially important for this patient group.

The goal of therapy with antihomotoxic (homeopathic) combination medications is not only to achieve symptomatic improvement but also to stimulate and support spontaneous healing through the immuno-

logical bystander reaction, which is triggered by a combination of several suitable ingredients.[4]

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