Symptomatic Treatment of Acute Upper Respiratory Infections: A Comparison of Homeopathic and Conventional Therapies

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This multicenter, prospective cohort study with parallel groups compared the efficacy of the homeopathic medication Gripp-Heel® to that of conventional allopathic therapy for acute upper respiratory infections (URIs). In both treatment groups, the severity of clinical symptoms declined significantly over the course of the study. Upon conclusion of therapy, 77% of patients in the test group were symptom-free, as compared to 49% of the reference group. No adverse drug events occurred in patients treated with the homeopathic medication, while the rate of adverse effects under conventional therapy was 5.8%. This study confirms that Gripp-Heel®, as used to treat acute URIs in daily practice, is just as effective as conventional allopathic medications. Furthermore, participating physicians reported better patient tolerance of the homeopathic medication.

Keywords: Common cold, upper respiratory infections (URIs), allopathy, homeopathy

A common cold or other typical upper respiratory infection (URI) is usually caused by one of approximately 200 types of viruses, the most common of which are rhinoviruses and adenoviruses. Other pathogens that cause URIs include the coronaviruses, respiratory syncytial viruses, and parainfluenza viruses. In a high percentage of cases, these viruses affect the organs of the upper respiratory tract and symptoms are confined to these organs. As the most common type of acute illness, URIs are responsible for many absences from work, school, and kindergarten. Epidemiological studies confirm that approximately 25% of the German population, for example, comes down with an upper respiratory infection three to six times each year, and 75% of all survey respondents reported having a cold at least once a year.[1] Infants and toddlers typically suffer from as many as eight feverish infections per year, most of which affect the upper respiratory tract. For young children, predisposing factors include not only immature immune systems and anatomical conditions such as tonsillar hypertrophy, but also noninfectious environmental factors such as exposure to tobacco smoke or other noxae.[2]

FOCUS ON SYMPTOM ALLEVIATION

Patients who take medication for URIs do so in the hope of achieving rapid symptom abatement. At the very least, they hope to avoid the worst by beginning treatment at the first sign of symptoms. Thus the therapeutic value of cold remedies lies in:

- relieving subjectively bothersome symptoms such as rhinitis or cough
- controlling difficulty in breathing or swallowing
- reducing malaise

Hence, any treatment of URIs focuses primarily on symptomatic relief and on strengthening the immune system.

HOMEOPATHY ALSO SUPPORTS THE IMMUNE SYSTEM

Chemical decongestants are a common and effective treatment for URIs. Other medications are often not helpful; antibiotics, for example, are useless unless secondary bacterial infections are present. For over 200 years, homeopathic treatment of acute upper respiratory infections has been based on a variety of medicinal herbs and other components. Phytotherapeutic ingredients used for this purpose include garden monkshood (*Aconitum napellus*), bryony (*Bryonia spp.*), and boneset (*Eupatorium perfoliatum*). For decades, Gripp-Heel® (a combination of these botanical ingredients plus *Lachesis* and phosphorus) has been used therapeutically to activate the body's endogenous defenses in upper respiratory infections. The purpose of this study was to investigate the efficacy and tolerability of Gripp-Heel® as compared to conventional allopathic treatments in patients with acute upper respiratory infections.

Table 1: Patient demographics

Criteria		Test Group (N = 82)	Reference (N = 181)	Statistics
Age (years)	Median (min/max)	34 (3/78)	33 (0/82)	p = 0.750 (ns)
Gender	Male N/% Female N/%	36/43.9 46/56.1	82/45.3 99/54.7	p = 0.894 (ns)
Height (cm)	M (SD)	161.99 (2.35)	153.02 (2.51)	p = 0.2249 (ns)
Weight (kg)	M (SD)	61.99 (2.17)	57.51 (1.94)	p = 0.4759 (ns)
Stressful job or family situation	N/%	7/8.5	20/11.0	p = 0.545 (ns)
Risk factors	N/%	15/18.3	20/11.0	p = 0.122 (ns)
Duration of illness < 1 week	N/%	77/93.9	151/83.3	p = 0.005 (s)

M = mean; SD = standard deviation, ns = not significant, s = significant

METHODS

For purposes of this study, patients with acute URIs were treated by family practitioners, internists, or otolaryngologists, some of whom were also licensed to practice homeopathy and/or naturopathy. New or returning patients were admitted to the study, but patients receiving ongoing long-term treatment were excluded. The patients in the test group (homeopathic medication) were not allowed to supplement their treatment with either conventional (allopathic) drugs or other homeopathic medicines. For the reference group, each physician selected analogous patients to receive a conventional therapy.

STUDY DESIGN

This investigation was conceived as a multicenter, prospective, noninterventional cohort study with parallel groups. 263 patients participated. The test group took Gripp-Heel®; the reference group took either a conventional single medication or a combination, with dosages selected by the attending physicians.

IMPLEMENTATION

Upon conclusion of treatment, data on individual patients were anonymized and documented in coded form in accordance with ICD-10/WHO. For each patient, the physician rated the initial severity (scale: symptom-free, mild, moderate, severe) of the patient's two most important clinical symptoms (primary/secondary pathognomonic symptoms) as well as the change in these symptoms over the course of therapy. Any adverse effects were also recorded, along with the physician's assessment of the patient's tolerance of the homeopathic or reference therapy (scale: very good, good, satisfactory, poor). The physicians also rated therapeutic outcome (scale: symptom-free, significant improvement, moderate improvement, symptoms unchanged, symptoms worsened) and patient compliance (scale: very good, good, fair, poor) in each case.

Table 2: Type, frequency, and initial severity of primary pathognomonic symptoms (N/%)

Type and frequency	Test group (N = 82)	Reference (N = 181)	Statistics
Cough/rhinitis/hoarseness	33/40.3	100/55.2	p = 0.028 (ns)
Headache/muscle aches	28/34.1	40/22.1	
Fever	19/23.2	29/16.0	
Other	2/2.4	12/6.7	
Severity			
Mild	12/14.6	9/5.0	p = 0.017 (ns)
Moderate	45/54.9	96/53.0	
Severe	25/30.5	76/42.0	

ns = not significant

Table 3: Type, frequency, and initial severity of secondary pathognomonic symptoms (N/%)

Type and frequency	Test group (N = 82)	Reference (N = 181)	Statistics
Cough/rhinitis/hoarseness	37/45.1	98/54.1	p < 0.001 (s)
Headache/muscle aches	25/30.5	28/15.5	
Fever	18/22.0	19/10.5	
Other	2/2.4	36/19.9	
Severity			
Mild	19/23.2	22/12.2	p = 0.040 (ns)
Moderate	48/58.5	99/59.7	
Severe	15/18.3	51/28.1	
No secondary symptom	–	9/5.0	

ns = not significant, s = significant

TARGET CRITERIA

- The primary criterion of efficacy was the percentage of cases in which primary/secondary pathognomonic symptoms abated completely.
- Secondary criteria of efficacy were:
  - time elapsed before onset of symptomatic improvement
  - physicians' rating of therapeutic outcome/efficacy
- Primary criteria of safety were:
  - the number of patients experiencing adverse effects (reported were: type, number, severity, duration, relationship to treatment, measures taken, and outcome)
  - physicians' rating of tolerability and patient compliance

STATISTICAL EVALUATION

After monitoring and query processing, data was entered and subjected to quality and plausibility tests, followed by descriptive analysis (which included between-group comparison of patients' master data and initial illness status and of group homogeneity). Logistic regression procedures were used to adjust for heterogeneities in initial status and for confounders, followed by hypothesis testing. The effect size of the adjusted rate of symptom abatement was calculated with 95% CI of the odds ratio. (Adjusted) time elapsed before onset of symptom abatement was evaluated using the Cox proportional hazard regression method (HR 95% CI).

RESULTS – TREATMENT GROUPS

In total, 263 patients (82 in the test group and 181 in the reference group) ranging in age from 0 to 82 years were included in the study. Analysis of patients' master data indicated that the treatment groups were largely comparable (Table 1). The physicians rated initial severity of the URI as "moderate to severe" in 85% of the patients in the Gripp-Heel® group and 95% of the reference group, indicating a tendency toward more severe illness in the reference group. With regard to clinical symptomatology, the pathognomonic symptoms cough, rhinitis, hoarseness, fever, and headache/body ache predominated in both groups (Tables 2-3). Most patients in both groups had been ill for less than one week (94% of the Gripp-Heel® group and 83% of the reference group, p = 0.005).

DOSAGES

In 95% of cases, Gripp-Heel® was prescribed in tablet form, with 55% of these patients taking the standard dosage of 1 tablet 3-5 times per day. The remaining 5% of patients in the Gripp-Heel® group received injections (i.m. or s.c.) of the medication at the standard dosage of 1-3 ampoules per week. In the reference group, treatment of symptoms usually consisted of either a single drug or a combination of any of the following types: cough suppressants, analgesics, antibiotics, decongestants, or cold/flu combination remedies. Choice of medication, dosage, and duration of treatment were left to the discretion of the physician in each case.

Table 4: Frequency of complete abatement of the primary pathognomonic symptom / Time elapsed before onset of abatement (not adjusted) (N/%)

Frequency	Test group (N = 82)	Reference (N = 181)	Statistics
Yes	63/76.8	114/63.0	P = 0.019 (s)
No or n/a	19/23.2	67/37.0	
Multivariate adjusted			P (Wald) = 0.162 (ns)
Odds ratio (95% CI)			OR (95% CI) = 0.62 (0.31-1.21)
Time elapsed before onset of abatement (not adjusted) (N/%)			
< 4 days	58/70.7	98/54.0	
4-7 days	16/19.5	55/30.4	
1-2 weeks	5/6.1	19/10.5	
2-4 weeks	–	2/1.1	$P_{(< 4 \text{ days})}$ = 0.001 (s)
> 4 weeks	–	3/1.7	$P_{(total)}$ = 0.109 (ns)
No improvement	–	1/0.6	
n/a	3/3.7	3/1.7	
Multivariate adjusted			P (Wald) = 0.008 (s)
Cox proportional hazard regression (95% CI)			HR (95% CI) = 1.57 (1.13-2.20)

ns = not significant, s = significant

Table 5: Frequency of complete abatement of the secondary pathognomonic symptom / Time elapsed before onset of abatement (not adjusted) (N/%)

Frequency	Test group (N = 82)	Reference (N = 181)	Statistics
Yes	62/75.6	14/57.5	P = 0.009 (s)
No or n/a	20/24.4	77/42.5	
Multivariate adjusted			P (Wald) = 0.224 (ns)
Odds ratio (95% CI)			OR (95% CI) = 0.66 (0.34-1.29)
Time elapsed before onset of abatement (not adjusted) (N/%)			
< 4 days	59/77.2	91/50.4	
4-7 days	17/20.6	44/24.3	
1-2 weeks	3/3.7	26/14.4	
2-4 weeks	–	5/2.8	$P_{(< 4 \text{ days})}$ = 0.001 (s)
> 4 weeks	–	–	$P_{(total)}$ = 0.004 (s)
No improvement	–	3/1.7	
n/a	3/3.7	12/6.6	
Multivariate adjusted			P (Wald) = 0.170 (ns)
Cox proportional hazard regression (95% CI)			HR (95% CI) = 1.27 (0.90-1.79)

ns = not significant, s = significant

THERAPEUTIC EFFICACY

In the symptomatic treatment of acute URIs, therapy with the homeopathic medication proved to be as effective as reference therapies with conventional drugs (adjusted for initial symptom severity). The chance of a patient becoming completely symptom-free within the test period, however, was 34-38% greater (depending on the individual symptom) for the Gripp-Heel® group than for the conventionally treated group. The median elapsed time before symptom abatement was 2 days for the test group versus 5.5 days for the reference group. With regard to the primary pathognomonic symptom, the difference in favor of the homeopathic medication was statistically significant (Table 4). The chance of a shorter elapsed time before symptom abatement occurred was 57% higher (statistically significant) for the test group than for the reference group with regard to the primary pathognomonic symptom and 27% higher with regard to the secondary pathognomonic symptom (Table 5). Upon conclusion of therapy, the physicians rated 77% of the test patients and only 49% of the reference group as symptom-free ($p<0.001$) (Figure 1).

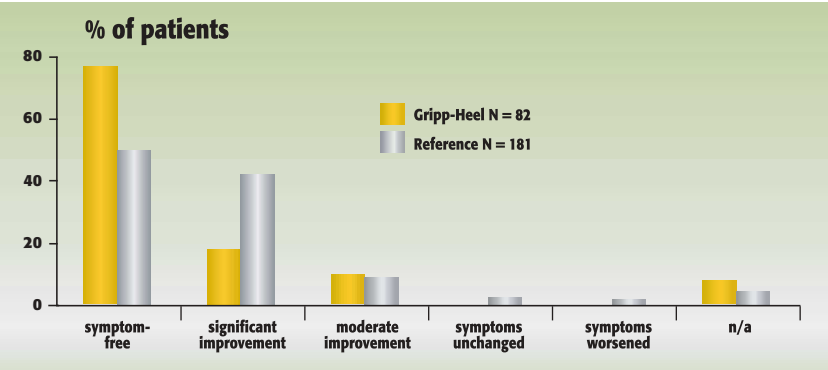

Fig. 1: Physicians' ratings of therapeutic outcomes (efficacy of treatment)

TOLERABILITY

In general, the homeopathic medication was very well tolerated by the patients; no adverse drug events occurred in the test group. In the reference group, the incidence of adverse effects (most common were gastrointestinal symptoms) was 5.8%. A similar difference was reflected in global assessments of tolerability. The physicians rated patient tolerance of the medication "very good" for 85% of the test group but for only 37% of the reference group ($p < 0.001$).

Similar differences in patient compliance were also observed. Physicians reported "very good" compliance for approximately 70% of patients treated with the homeopathic medication, but for only 44% of the reference group ($p < 0.001$).

DISCUSSION

In Germany, Gripp-Heel® has been marketed in its current formulation for several decades. More recently, several clinical studies have investigated its efficacy in adults and children with URIs.[3-5] All of these studies confirm the clinically relevant-therapeutic efficacy of Gripp-Heel® in treating upper respiratory infections, and risk-benefit assessment based on their results supports the conclusion that this homeopathic medication is not only reliably effective, but also well tolerated by both adults and children. Because of the primarily viral genesis of URIs, symptom alleviation is the focus of any therapy. Therefore, symptomatic relief and more rapid symptom abatement can serve as criteria for assessing the therapeutic efficacy of pharmaceuticals prescribed for this indication.

The present study proves that this homeopathic medication is at least as effective in reducing symptoms as the conventional reference therapy. The interval before onset of symptom abatement was shorter in the test group than in the reference group. Gripp-Heel®'s mechanism of action in the body has not yet been definitively explained, but *in vitro* studies indicate that it stimulates phagocytosis, which suggests activation of the non-specific endogenous defense system.[6]

In conclusion, it can be said that the results of this present study not only corroborate those of previous studies, but also confirm the product's excellent safety profile. In the current study, no adverse drug events were experienced by the test group. In comparison, a total of ten incidents of adverse effects were reported in the reference group, whose members were treated with various conventional medications (including cough suppressants, analgesics, antibiotics, decongestants, or cold/flu combination medications). In view of the efficacy and tolerability ratings supplied by the participating physicians, it is not surprising that "very good" compliance was significantly higher in the test group (70%) than in the reference group (44%).

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