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Treatment of allergic rhinitis and pollinosis

A clinical trial to investigate the efficacy and safety of the Homeopathic A. Vogel Hay Fever Spray

In patients with allergic rhinitis or pollinosis taking the homeopathic A. Vogel Hay Fever Spray a trend in reduction of evening symptoms was observed, whereas the morning symptoms remained unchanged. The majority of the patients as well as investigators assessed the therapy to have a good or very good efficacy, and about two thirds of the patients would use the spray again. Furthermore the treatment with the spray lead to a significant increase in quality of life, with almost half of the patients noticing an improvement. The tolerability of the A. Vogel Hay Fever Spray was judged by the vast majority of patients and investigators to be very good or good, and in only one patient occurred side effects which were related to the study medication.

Keywords: seasonal allergic rhinitis, homeopathic nasal spray, tolerability, symptom relief, A. Vogel Hay Fever Spray

Behandlung der allergischen Rhinitis und des Heuschnupfens

Klinische Studie zur Wirksamkeit und Verträglichkeit des homöopathischen Nasensprays Pollinosan

Bei Patienten mit einer allergischen Rhinitis oder Heuschnupfen wurde unter der Therapie mit dem homöopathischen Nasenspray Pollinosan ein Trend zu einer Abnahme der abendlichen Symptome verzeichnet, wogegen die morgendlichen Beschwerden im Wesentlichen unverändert blieben. Die Mehrheit der Patienten wie auch der behandelnden Ärzte schrieb der Therapie mit Pollinosan eine sehr gute oder gute Wirksamkeit zu, und rund zwei Drittel der Patienten würden den Nasenspray wieder verwenden. Ausserdem führte die Behandlung mit Pollinosan zu einem signifikanten Gewinn an Lebensqualität, wobei nahezu die Hälfte der Patienten ihren Gesundheitszustand als verbessert empfand. Darüber hinaus wurde auch die Verträglichkeit des Pollinosan-Nasensprays von der überwiegenden Mehrheit der Patienten und der Ärzte als sehr gut oder gut bewertet, und lediglich bei einem Patienten traten mit dem Präparat assoziierte Nebenwirkungen auf.

Schlüsselwörter: Saisonale allergische Rhinitis, homöopathischer Nasenspray, Verträglichkeit, Symptomlinderung, A. Vogel Heuschnupfen-Spray

Allergic rhinitis is an IgE-mediated inflammatory reaction of the nasal mucous membrane, which, depending on the causative allergens that are inhaled, occurs either perennially or seasonally. Seasonal allergic rhinitis and its special form pollinosis, otherwise known as hay fever, affects roughly 25 per cent of the population. It therefore ranks amongst the most common allergic conditions, the incidence of which has increased greatly in recent decades [1]. Allergic rhinitis not only has a negative effect on the quality of life of those suffering from it, it also constitutes a major risk factor for eventual bronchial asthma.

Like every other allergic condition, allergic rhinitis is also preceded by sensitisation, which, in turn, stimulates the immune system to produce specific antibodies in response to a high concentration of natural environmental allergens [2].

The most effective way of managing allergic rhinitis is to avoid contact with the allergens that cause it. This is usually not possible, however, during everyday life. Various topical and systemic medicines are available for treating allergic rhinitis. When used correctly, they bring about a rapid and prolonged improvement to symptoms [3, 4]. Minor seasonal rhinitis is normally treated with oral or topical second generation antihistamines, which are aimed primarily at relieving itching, sneezing attacks and eye symptoms. In addition to antihistamines, intranasal or oral decongestants may also be used. These reduce mucosal swelling in the nose and, as a result, lead to a reduction in nasal obstruction [5]. The only causal therapy available today for the management of allergic rhinitis is specific immunotherapy. This form of treatment is, however, only suitable for patients who are sensitised to only a few allergens or who are ill for a short time only [6].

Because alternative healing methods are becoming more and more accepted, there is also a growing demand for homeopathic remedies for the symptomatic treatment of allergic rhinitis. These remedies help to rapidly relieve symptoms and are extremely well tolerated by users. In this context, a clinical post-marketing surveillance study showed that the orally administered homeopathic complex Pollinosan consisting of *Ammi visnaga* D6, *Aralia racemosa* D6, *Cardiospermum halicacabum* D6, *Larrea mexicana* D6, *Luffa*

operculata D6, *Okoubaka* D6 and *Thryallis glauca* D6 is effective in the symptomatic treatment of allergic rhinitis [7]. As the intranasal administration of active substances has proved an effective means of treating allergic rhinitis, the present study investigated the therapeutic benefits of local treatment with a nasal spray containing the same homeopathic substances as the orally administered preparation.

Patients and methods

During the course of this open, multicentre study, the effectiveness and tolerability of A. Vogel Homeopathic Hay Fever Spray was investigated in the period from April 11 to August 14, 2003, among 63 patients suffering from either allergic rhinitis or hay fever for more than two years. Upon being given all relevant information and consenting by word of mouth, women and men aged over 18 from 11 Swiss general practices took part in the study. Patients suffering from bronchial asthma – with the exception of mild, periodically occurring forms – as well as patients with acute or chronic sinusitis and rhinitis medicamentosa were not permitted to take part in the trial. Similarly, patients taking sympathomimetics, corticosteroids, anti-allergic preparations, immunosuppressants or other medicines for the treatment of allergic rhinitis or hay fever were excluded from the study. In accordance with the legal requirements pertaining to clinical trials involving homeopathic remedies, the present study was submitted to the Swiss health authority "Swissmedic" and approved by the respective cantonal ethics boards.

In order to determine the effectiveness of the nasal spray, patients recorded the degree of severity of the six symptoms rhinorrhoea, nasal obstruction, sneezing attacks, pharyngeal irritation, coughing as well as stinging or watering eyes both in the morning and evening using a scale of 0 to 3 which corresponded to "not noticeable", "slightly noticeable", "noticeable" and "severe". The effectiveness of A. Vogel Homeopathic Hay Fever Spray was also quantified by both the treating physician and patients at the beginning of the study and after 14 days' treatment using a scale of 0 to 3 points corresponding to "poor", "satisfactory", "good" and "excellent". Patients also had to compare the effectiveness of the spray with that of other preparations and record values for eight physical and psychological components relating to quality of life using the standardised questionnaire SF-36. In addition to the therapeutic benefits of the spray, the incidence of side effects was established and the tolerability thereof rated by the treating physician and patients with the help of a scale ranging from 0 to 3 for "poor", "satisfactory", "good" and "excellent". The treating doctors also had to determine patient therapy compliance and acceptance of treatment by means of questioning the patients.

The patients applied 1 to 2 puffs of the homeopathic spray from a multiple-dose container into each nostril, 3 to 5 times a day during a 14-day period of treatment. A. Vogel Hay Fever Spray is a complex containing the same herbal components as Pollinosan Tablets, i.e. *Ammi visnaga* D6, *Aralia racemosa* D6, *Cardiospermum halicacabum* D6, *Larrea mexicana* D6, *Luffa operculata* D6, *Okoubaka* D6 and *Thryallis glauca* D6. The use of other nasal sprays or other locally applied rhinologics was not allowed for the duration of the whole study. Other medicines or accompanying treatment, which might have had an influence on the allergic rhinitis symptoms, were only permitted in urgent cases and their use had to be documented accordingly.

Data was analysed statistically using descriptive statistics. Values for individual symptoms and the cumulative value for all symptoms during the 14 days were hereby determined in both the morning and evening. Changes from the baseline value on day 1 were subjected to a t-test with a selected confidence interval of 95%.

Data was analysed, on the one hand, on an "intention-to-treat analysis" basis among those patients, who had used the nasal spray at least once and, on the other, using "per-protocol analysis" among those patients, who observed the study protocol correctly without breach thereof. In order to assess the tolerability of the spray, the data of all those patients who began the study were taken into account.

Results

Of the 63 patients who took part in the trial, roughly two thirds were female and the majority of participants were under forty years of age. Nearly all patients were treatment-compliant and used the nasal spray in accordance with the specified treatment regime. The median number of times the spray was applied per day and per patient was 3.4 ± 1.2 and the mean duration of treatment a little over 12 days **(tab. 1)**.

There was a total of 31 breaches of the study protocol during the course of treatment with A. Vogel Hay Fever Spray. This led to 23 patients being excluded from the per-protocol group. 17 of these breaches constituted cases where patients had discontinued treatment earlier than planned, 9 comprised cases where patients had used inadmissible additional medication and 3 breaches involved the inadmissible use of accompanying treatment. 2 further patients had to drop out because they were too young. As no significant differences were observed among the intention-to-treat group and the per-protocol group in respect of the effectiveness of the spray, only the study results of the intention-to-treat group are provided in the present publication.

At the beginning of the study, the symptoms rhinorrhoea, nasal congestion and sneezing attacks as well as stinging and watering eyes were moderately severe with values ranging from 0.8 to 1.2, whereas pharyngeal irritation and coughing were hardly noticeable. The values only dropped slightly during the two weeks. Merely the morning values for stinging and watering eyes as well as nasal congestion were lowered as a result of treatment with the hay fever spray from 1.0 to 0.6 and 1.0 to 0.7 respectively. The evening values for sneezing attacks

dropped following treatment with the nasal spray from 1.1 to 0.6. Whereas the overall value for morning symptoms essentially remained constant in the course of treatment, the overall value for evening symptoms was seen to drop considerably from 4.6 to 3.3.

The number of patients, who experienced a worsening of morning symptoms, no improvement or an improvement therein lay in the same range after 4, 8 and 14 days treatment. The number of patients with worsened or unchanged evening symptoms as a result of treatment with A. Vogel Hay Fever Spray dropped from 60.4% after 4 days to 44.2% after 14 days, whereas the number of patients with reduced symptoms rose during treatment from 39.5% to 55.8% **(fig. 1)**.

Upon completion of the study, 55% of all patients rated treatment with the spray as either excellent or good **(fig. 2)**. 43.8% of all patients also expressed that they believed the nasal spray to be good or excellent in comparison with the medication they had been using up until the beginning of the study. 52.5% of all treating physicians and 55% of all patients rated the effectiveness of the spray as either excellent or good **(fig. 2)**. The question pertaining to the patients' acceptance of the preparation, i.e. whether they would use the spray again, was answered with a yes in 69.8% of all cases.

By means of subgroup analysis, the effectiveness of the hay fever spray in respect of a change in the severity of individual symptoms was determined, with so-called responders, for those patients, whose overall value for morning and evening symptoms dropped upon treatment. According to the results of this analysis, the individual values of all morning and evening symptoms were lowered considerably in the course of treatment, with the greatest reduction thereby being seen in the morning and evening values for sneezing attacks and nasal congestion. A marked reduction in the overall value for symptoms was observed in this patient group following treatment with A. Vogel Hay Fever Spray (53.2% for morning symptoms and 53.5% for evening symptoms).

Tab. 1. Breakdown of study participants

	Overall group	Intention-to-treat-population	Per-protocol-population
Number of patients	63	58	40
Men	24	22	16
Women	39	36	24
Mean age (years)	33.3 ±12.3	33.1 ± 12.6	32.3 ± 12.1
Mean duration of treatment (days)	12.3 ± 3.1	12.4 ± 3.1	12.7 ± 2.4

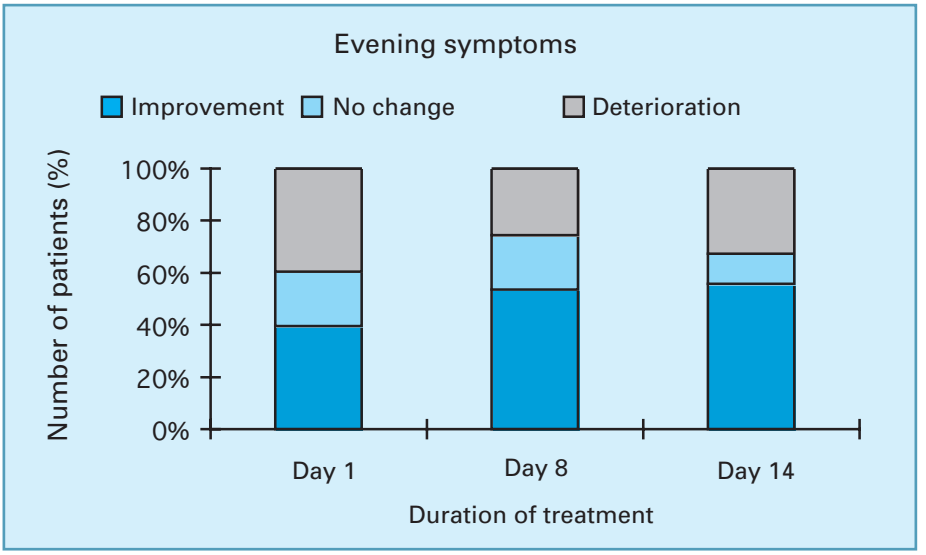

Fig. 1. Changes in evening symptoms during the course of treatment with A. Vogel Hay Fever Spray compared with day 0.

According to patient questioning, treatment with the spray brought about a significant improvement in the areas physical functioning, general perception of health, vitality, social functioning as well in the overall value relating to psychological parameters. No major change was observed, however, in the four other areas pertaining to quality of life or the physical overall value **(tab. 2)**. When questioned as to their present state of health, 17.5% of all patients said they felt it had "improved greatly" and 19.0% of all patients stated it had "improved slightly". 55.6% noticed no change in their general state of health.

During treatment with the spray, unwanted side effects occurred in five patients. Only those cases involving local irritation and a slight tickling sensation in the nose as well as sneezing attacks were, however, clearly connected with treatment. Two patients, who rated their side effects as moderate or even severe, discontinued treatment with the spray. 92.1% of all patients rated the tolerability of treatment with A. Vogel Hay Fever Spray as excellent or good and only 8.0% of all patients rated the tolerability thereof as merely satisfactory or even poor. The treating physicians judged the tolerability of treatment with the spray as excellent or good in 90.5% of all cases. Only 9.5% rated the tolerability of treatment as merely satisfactory **(fig. 3)**.

Discussion

The present open study was able to demonstrate that A. Vogel Homeopathic Hay Fever Spray is effective in the treatment of allergic rhinitis and hay fever at least among a section of the patients. Upon using the nasal spray several times during the day, a tendency for evening symptoms to subside was observed, this being most predominant in respect of nose and eye symptoms. The overall value for evening symptoms was reduced as a result of treatment with the spray by

Fig. 2. Assessment of the effectiveness of A. Vogel Hay Fever Spray by patients and treating physicians.

28.2%, whereas the overall value for morning symptoms essentially remained unchanged. The percentage of patients who experienced a reduction in evening symptoms upon using A. Vogel Hay Fever Spray rose form 39.8% after 4 days to 55.8% after 14 days compared with day 0. What is more, the majority of treating physicians and patients rated the effectiveness of the spray as either excellent or good. A significant improvement in quality of life in respect of physical functioning, the general health perception, vitality, social functioning as well as in the overall value for psychological parameters was also obtained as a result of treatment with the spray, and 36.5% of all patients felt that their state of health had improved. The discrepancy observed in this case between a relatively low reduction in symptoms (seen on the basis of the scores) on the one hand and a positive assessment of effectiveness on the other can be explained by the fact that an extremely heterogeneous patient population took part in the study. In addition, carrying out such a study is always plagued by problems due to the varying allergens and the interchanging exposure that are involved. These results are in line with the results of an earlier study conducted to investigate the effectiveness and tolerability of homeopathic tablets containing the same combination of ingredients as A. Vogel Hay Fever Spray, i.e. *Ammi visnaga* D6, *Aralia racemosa* D6, *Cardiospermum halicacabum* D6, *Larrea mexicana* D6, *Luffa operculata* D6, *Okoubaka* D6 and *Thryallis glauca* D6. In this earlier open, multicentre post-marketing surveillance study, treatment with 2 tablets 3 times daily or 20 drops of Pollinosan led to a significant or complete decrease in symptoms in 56.8% of the 199 hay fever patients taking part in the study. What is more, 31.7% of all the patients treated with Pollinosan experienced a slight improvement in symptoms, whereas 11.6% noticed no effect [7].

Tab. 2. Assessment of quality of life

	Beginning of treatment	End of treatment	Difference
Physical overall value	52.2 (6.4)	53.3 (4.5)	1.1 (6.5)
Psychological overall value	50.3 (7.9)	5.0 (6.2)	2.7 (7.5)*
Physical functioning	88.9 (13.5)	93.7 (7.1)	4.7 (11.9)*
Physical limitations affecting patient's role	84.8 (28.9)	92.1 (19.6)	7.1 (33.9)
Physical pain	88.4 (16.4)	87.2 (18.5)	-1.2 (14.5)
General health perception	73.9 (17.5)	77.1 (15.4)	3.3 (11.4)*
Vitality	56.6 (17.7)	62.8 (19.9)	6.8 (16.8)*
Social functioning	86.0 (17.5)	91.4 (13.8)	5.5 (17.2)*
Emotional problems affecting patient's role	92.3 (22.3)	96.2 (12.2)	3.8 (22.9)
Mental health	76.6 (14.9)	81.0 (13.5)	4.8 (12.9)
* statistically significant difference $p < 0.05$			

The effectiveness of A. Vogel Hay Fever Spray demonstrated in the present study is supported by the results obtained from the large-scale meta-analysis of 89 randomised, placebo-controlled, double-blind studies. This meta-analysis showed homeopathic treatment to be 2.45 times more therapeutically beneficial as opposed to placebo. The combined data of four studies included in this meta-analysis, where the effectiveness of homeopathic preparations for the treatment of allergic rhinitis was investigated, yield a significantly greater reduction (2.03 times greater) in eye symptoms in favour of the homeopathic remedies as opposed to placebo [8]. In keeping with these results, the meta-analysis of 11 clinical studies involving 1,038 patients suffering from acute hay fever showed that 1.25 times significantly greater relief of eye symptoms is able to be achieved using the homeopathic preparation *Galphimia glauca* compared with placebo [9]. In a randomised, double-blind study involving 146 hay fever patients, the six-week course of treatment with a homeopathic nasal spray containing *Luffa operculata, Galphimia glauca,* histamine and sulphur also led to an alleviation of allergic symptoms and to an improvement in quality of life similar to that of an intranasally administered chromoglycate [10].

In the present study, A. Vogel Hay Fever Spray was seen to be excellently tolerated, as side effects occurred in a total of merely five patients. The local irritation accompanied by a slightly tickly throat and sneezing attacks

Fig. 3. Assessment of the tolerability of A. Vogel Hay Fever Spray by patients and treating physicians.

experienced by one patient after having used the spray several times was the only case of side effects thought to be directly linked with treatment. This was only of a mild nature, however, and did not render it necessary for treatment to be discontinued. The majority of patients felt that they had tolerated treatment with the nasal spray extremely well and the treating physicians also assessed the tolerability of treatment with A. Vogel Hay Fever Spray as either excellent or good in the majority of cases. The tolerability of the spray demonstrated in the present study is in line with the results of the open study conducted to investigate the therapeutic benefits of Pollinosan Tablets. During the course of this study, no side effects were observed among any of the treated patients [7].

When treating allergic rhinitis, the minor tickling sensation in the throat and sneezing attacks that occur for a few seconds after using the nasal spray occurs with all intranasally applied active substances as a result of the nasal mucous membrane being hyperreactive, which, in turn, leads to local irritation in a relatively high number of cases [11]. In addition to an irritated and tickly throat and sneezing attacks, the intranasal administration of corticosteroids can, however, also result in temporary nose bleeding. According to a meta-analysis of 16 controlled studies, this is the case in 17 to 23% of all patients [12].

In summary, it may be said that a tendency for evening symptoms to subside is observed among patients with allergic rhinitis following the use of A. Vogel Homeopathic Hay Fever Spray. What is more, as A. Vogel Hay Fever Spray is extremely well tolerated, this homeopathic nasal spray presents itself as a suitable option for the symptomatic treatment of allergic rhinitis and hay fever.

References

1. Schäfer T and Ring J: Epidemiology of allegic diseases. Allergy 1997; 52 (Suppl 38): 14–22.
2. Bachert C, Borchard U, Wedi B, et al.: Leitlinien der DGAI zur allergischen Rhinokonjunktivitis. Allergologie 2003; 4: 147–162.
3. Rosenwasser LJ: Treatment of allergic rhinitis. Am J Med 2002; 113: 17S–24S.
4. Willsie SK: Improved strategies and new treatement options for allergic rhinitis. J Am Osteopath Assoc 2002; 102: S7–S14.
5. Ratner PH, Ehrlich PM, Fineman SM, et al.: Use of intranasal cromolyn sodium for allergic rhinitits. Mayo Clin Proc 2002; 77: 350–354.
6. Bousquet J, van Cauwenberge P, Khaltaev N et al.: Management of allergic rhinitis and its impact on asthma (ARIA). Journal of Allergy and Clinical Immunology 2001; 108: S147– S334.
7. Helweg JH: Pollinosan Study, September 1989.
8. Linde K, Clausius N, Ramirez G, et al.: Are the clinical effects of homeopathy placebo effects? A meta-analysis of placebo-controlled trials. Lancet 1997; 350: 834–843.
9. Ludtke R and Wiesenauer M: [A meta-analysis of homeopathic treatment of pollinosis with Galphimia glauca]. Wien Med Wochenschr 1997; 147: 323–327.
10. Weiser M, Gegenheimer LH, Klein P: A randomized equivalence trial comparing the efficacy and safety of Luffa comp.-Heel nasal spray with cromolyn sodium spray in the treatment of seasonal allergic rhinitis. Forsch Komplementarmed 1999; 6: 142–148.
11. Salib RJ and Howarth PH: Safety and tolerability profiles of intranasal antihistamines and intranasal corticosteroids in the treatment of allergic rhinitis. Drug Safety 2003; 26: 863–893.
12. Waddell AN, Patel SK, Toma FR, et al.: Intranasal steroid sprays in the treatment of rhinitis: is one better than another? The Journal of Laryngoscopy & Otology 2003; 117: 843–845.

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