Antihomotoxic Treatment of Hay Fever

A Study with 1090 Patients

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*In the USA marketed as BHI Hayfever Nasal Spray

Summary

Within the context of a prospective drug monitoring study, data were gathered on the application, the effectiveness, and patients' tolerance of Luffa comp.-Heel nasal spray and Luffa compositum Heel tablets, as part of therapy of a large patient population undergoing treatment for hay fever. Standardized data-collection forms were used for data acquisition. Those conducting the study documented therapeutic data for a total of 1,090 patients. Physicians prescribed Luffa comp.-Heel nasal spray and Luffa compositum Heel tablets in combination for 82% of the patients. In general, dosage was as follows: nasal spray applied 3-5 times a day, and one tablet taken three times a day. Of the entire patient population, 70% received the Luffa compositum product (s) as monotherapy. The term of treatment varied according to the prevailing extent of airborne pollen. Ratings of "very good" or "good" were achieved by 72% of the patients upon completion of therapy; an additional 17% received a "satisfactory" rating. Only 11% completed therapy with unsuccessful results. Despite the occurrence of adverse side effects in three cases, patients' tolerance of Luffa comp.-Heel nasal spray and Luffa compositum Heel tablets can be assessed as very good.

1. Introduction

The last 50 years have witnessed a drastic rise in the occurrence of hypersensitivity reactions (allergies), especially in industrialized countries. An estimated eight million persons currently suffer in Germany alone from forms of allergy: i.e., 10-12% of the population. Other studies have concluded that 30% of the German population is allergic to some degree, and that as many as one in every five school children demonstrates allergic symptoms. The factors responsible for this situation include a general increase of allergens in the environment (e.g., through industrial emissions), and the resulting general immune deficiency among the population. Additional developments contributing to the spread of allergic disorders also include changes in consumer behavior involving, for example, habits in consumption of foods and medication, employment of additives to foods and beverages, and the use of preservatives [1 - 5].

Hay fever (rhinitis allergica) is the most widespread of allergic affections. With as many as 5.1 million prescriptions issued in Germany for hay fever during the year 1993 alone, this disorder also represents a significant factor on the national economic scale. Hay fever involves a Type I specific hypersensitivity reaction (IgE-elicited immediate reaction) which is generally caused by the protein constituents in botanical pollen. Characteristic symptoms are sneezing attacks, edemas afflicting the mucosae of the nasal concha, hypersecretion of mucus, conjunctivitis, exogenous allergic bronchial asthma (in around 30% of all cases), contact urticaria, as well as general feverish reactions. The occurrence of hay fever is related to the season of the year, and correlates with the blossoming of trees (February to May), grasses (May to August), and herbs (July to October). This seasonal type of allergy must be distinguished from allergies which manifest themselves throughout the entire year: e.g., those elicited by house dust mites and by animal hair [6 - 7].

The most common forms of treatment of hay fever include prophylactic measures such as avoidance of allergens, hyposensitization, and acupuncture: efforts which have generally resulted in little success. The application of chemically defined medication is primarily based on the possibility of inhibiting the pathogenetic development of the illness on the cellular level: i.e., inhibition of the production, secretion, or receptor-bonding of inflammatory and bronchoconstrictive mediators such as histamine, leukotriene, or platelet-activating factor. In their daily professional encounters with hay fever patients, physicians prescribe rhinologics, mast-cell stabilizers such as cromoglicine acid, sympathomimetic drugs such as imidazole derivatives, glucocorticoids, and antihistamines. The physician must be aware, of course, that administration of such medication is associated with a relatively high potential for adverse effects. One must regularly expect the occurrence of anaphylactic reactions, hypersensitivity reactions at the skin and joints, hyperemia, immune-suppressive effects, sedation, and disturbances of the central nervous system. The danger of rebound effects is great: e.g., development of rhinitis medicamentosa. Due to the potential for adverse drug reactions, application is generally contraindicated for children and pregnant women [8 - 9].

Combined administration of the two homeopathic medications Luffa comp.-Heel nasal spray and Luffa compositum

Constituents	Attenuation	Drug pictures
Luffa comp.-Heel Nasal Spray:		
Luffa operculata	D4, D12, D30	Common cold; hay fever
Histaminum	D12, D30, D200	Allergic disorders of the skin and mucous membranes
Thryllais glauca	D4, D12, D30	Allergies of the skin and mucous membranes
Sulfur	D12, D30, D200	Stimulation (reversal) remedy for chronic and inflammatory disorders; nervous disorders; general weakness and debilitation
Luffa compositum Heel Tablets:		
Luffa operculata	D12	Common cold; hay fever
Aralia racemosa	D1	Common cold; allergic illnesses of the respiratory organs
Arsenum jodatum	D8	Common cold; bronchitis; glandular swelling
Lobelia inflata	D6	Hay fever; asthma; autonomic disorders of the respiratory center with drop in blood pressure

Table 1: Drug pictures of the constituents of Luffa comp.-Heel Nasal Spray and Luffa compositum Heel Tablets.

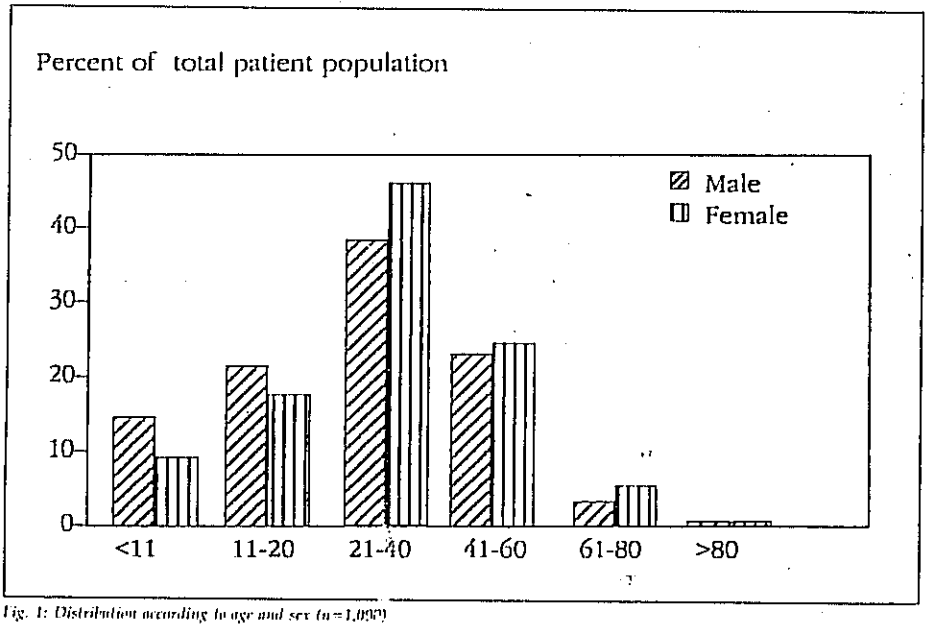

Fig. 1: Distribution according to age and sex (n = 1,090)

Allergen	Number of patients
Grass pollen	361 (33.1%)
Tree pollen	237 (21.8%)
Herb pollen	23 (2.1%)
House dust mites	72 (6.6%)
Animal hair	23 (2.1%)
Miscellaneous	14 (1.3%)
Cause unknown	566 (51.9%)

Table 2: Causes of hay fever (some patients indicated more than one cause; n = 1,090).

Heel tablets ensures a gentle yet effective therapeutic approach to hay fever (manufacturer: Biologische Heilmittel Heel). Formulation for these two preparations took place on the basis of homeopathic drug provings conducted on healthy test persons. The individual constituents of these products are associated with drug pictures which are definitely related in their therapeutic orientation to the symptom pictures presented by hay fever [10 - 17]. See Table 1.

The present drug monitoring study was conducted parallel to introduction of Luffa comp.-Heel nasal spray and Luffa compositum Heel tablets onto the market, in spring of 1994. The objective of this study was to collect data on the application, effectiveness, as well as patient tolerance to these products among various sub-groups of a large patient test population.

2. Methodology

The present multicentric drug monitoring study was conducted during the period from March to October, 1994, in Germany and Belgium. It was prospectively oriented.

The study was scheduled in such a manner so as to cover the various hay fever phases: trees, grasses, and herbs. Data acquisition took place on standardized data-collection forms. There were no criteria for inclusion or exclusion of test persons: i.e., each attending physician exercised complete freedom with respect to dosage, term of treatment, and adjuvant therapeutic measures. At the conclusion of each patient's treatment, the physician used the following scale to provide global assessment of the results of therapy: very good (complete freedom from symptoms), good (appreciable relief), satisfactory (slight improvement), unsuccessful (no change in symptoms), and worsening of the symptom complex. A special form was provided for the physicians to record the appearance of any adverse events — whether observed by the physician or spontaneously reported by the patient, and independently of any connection with the medication administered.

3. Results of therapy

Patients

A total of 126 physicians took part in the present multicentric drug monitoring study: primarily general practitioners, internists, and ear-nose-throat specialists. These physicians documented treatment data collected from 1,090 patients. Fig. 1 describes the age and sex structure. This graph indicates that the patients aged 21 to 40 represented

Medication before study (n = 600)		Accompanying medication (n = 267)	
Main group	Number of patients	Main group	Number of patients
Antiallergics	372 (62.0%)	Antiallergics	73 (27.3%)
Corticosteroids	32 (5.3%)	Homeopathic preparations	44 (16.5%)
Medication containing minerals	15 (2.5%)	Immunotherapeutic agents	8 (3.0%)
Ophthalmic preparations	31 (5.2%)	Medication containing minerals	16 (6.0%)
Rhinologics	207 (34.5%)	Neural therapy	10 (3.7%)
		Ophthalmic preparations	47 (17.6%)
		Rhinologics	31 (11.6%)

Table 3: Comparison of the medication which was employed before the drug monitoring study (Medication before study), with medication prescribed as adjuvant measures (Accompanying medication) during the drug monitoring study. (The classification of the medication in the individual groups took place in accordance with the main-group listing in the 1994 edition of the German Physician's Desk Reference. The following list includes only those medications which were prescribed for at least two percent of the patients. Some patients received more than one preparation.)

the largest single age group of the total population: approx. 42%. The population was composed of 55% women and 45% men.

Cause and duration of hay fever

When asked for the cause of their hay fever, half of the patients indicated that they did not know. About one patient in three named grass pollen (e.g., barley, oats, rye, wheat, or plantain), and around one in five named tree pollen (e.g., birch, oak, alder, hazelnut, plane, red beech, or willow) as the causative element for their allergy (some patients listed more than one allergen). The perennial allergens such as house dust mites and animal hair played a minor role in the patients' assumptions (see Table 2). Analysis of the data on the duration of the allergy to date revealed that the majority of the patients (70 percent) had suffered from hay fever for more than two years and that around one in three, for less than one year.

Previous treatment

As expected from the great number of patients who had suffered from hay fever for a lengthy period of time, the proportion of patients who had been previously treated (by medicamentous and/or physical means) was considerable: 55%. The medications which had been prescribed were primarily antiallergics and rhinologics (see Table 3). Only one percent of the patients had received homeopathic medication, and non-medicamentous forms of therapy had been applied only in isolated cases. Hyposensitization had been employed for 22.3% of the patients.

Dosage and length of antihomotoxic therapy

Since the nasal spray investigated here primarily acts locally (topically), and since the tablets principally have systemic effects—i.e., since these two forms of administration complement each other in their therapeutic action—the present drug monitoring study was designed to simultaneously monitor parallel application of Luffa comp.-Heel nasal spray and Luffa compositum Heel tablets. Fig. 2 demonstrates that the attending physicians in the majority of cases preferred the combination application of these two medicinal forms. The manufacturer recommends the following dosage:

- Luffa comp.-Heel nasal spray: 1-2 spurts into each nostril, 3-5 times per day.

-Luffa compositum Heel tablets: 1 tablet 3 times a day (in case of acute symptoms, one tablet every 15 minutes over a period lasting up to a maximum of two hours)

For approximately 92% of the patients in the study, the physicians prescribed the nasal spray in accordance with the recommended dosage. The minimum prescribed dosage was 1 spray spurt per nostril twice a day and the maximum, 2 spray spurts per nostril 6 times a day. The doctors in the study prescribed the tablets in accordance with the above-stated recommended dosage for 82.1% of the patients. The minimum-prescribed tablet dosage was 1 tablet once a day and

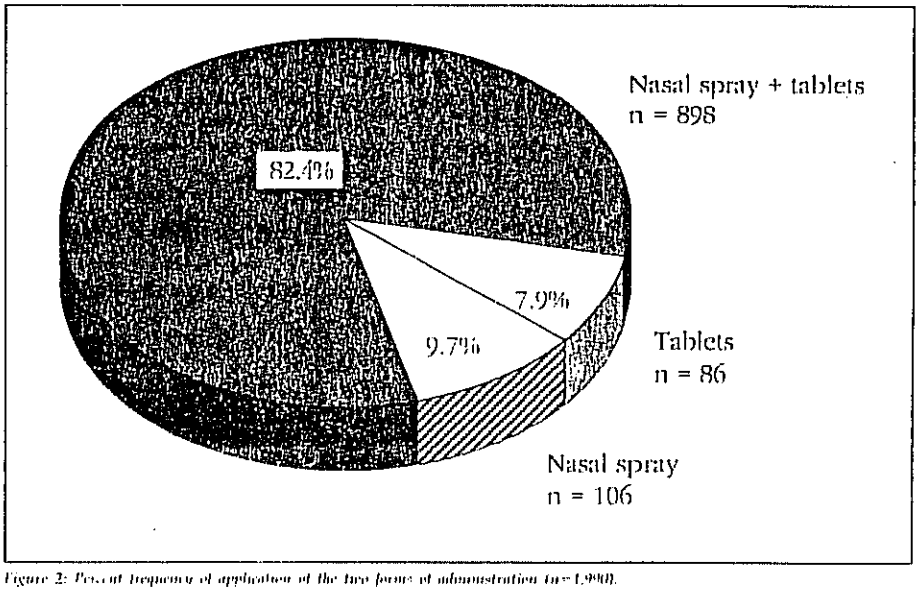

Figure 2: Percent frequency of application of the two forms of administration (n=1,990).

the maximum, 1 tablet 6 times a day. A total of 35.7% of the patients took advantage of the recommended acute dosage during acute hay fever attacks. These data evidence that the attending physicians, in the great number of cases, prescribed both preparations according to the recommendations of the manufacturer. Since, however, the severity of symptoms will — particularly in cases of hay fever — vary greatly depending on the individual patient, and since the duration of periods of high pollen count will more or less directly depend on climatic conditions, the daily application frequency and the term of therapy varied greatly from patient to patient in this study. As an approximate breakdown, the following general picture became apparent for the patients covered here: about one patient in four was treated up to two weeks; around half the patient population, between two and six weeks; and the remaining 25%, longer than six weeks.

Accompanying forms of therapy

Drug monitoring studies principally allow the adjuvant application of other medication or physical therapy. In this study, 70% of the patents received treatment in the form of monotherapy: i.e., treatment without the application of accompanying therapeutic measures. The remaining 30% were prescribed accompanying medicamentous and/or physical therapy (see Table 3). Upon comparison of the percent frequency of application of the various types of medication in the period preceding the present drug monitoring study, with the frequency of such administration during this study, the following noteworthy development becomes apparent: the use of antiallergics decreased by more than half during the study; the administration of chemically defined rhinologics, by 66%; and corticosteroids, by almost 100% (only one patient continued to receive them). For treatment of eye symptoms, on the other hand, ophthalmic preparations were administered slightly more frequently during the study than before. The following basic trend, however, became apparent upon analysis of data from this study: that application of the two homeopathic hay fever preparations enabled significant reduction of the administration of allopathic medication. Accompanying physical therapy played only a minor role in this context: the primary forms administered were acupuncture, bioresonance therapy, inhalation, and electrotherapy.

Patients' tolerance

The physicians participating in this study documented a total of nine patients who demonstrated adverse effects. For seven of them, local irritation in the vicinity of the nasal mucosae developed in conjunction with application of the nasal spray (5 patients experienced more pronounced runny nose or an aggravation in sneezing, and 2 felt sensations of burning or stinging in the area of the nose). In one case, the patient suffered from stomach ache after taking the tablets, and one additional patient became restless and perspired more freely after application. The cause of the local irritation in the form of burning or stinging could be intolerance to the benzalkonium chloride used as a preservative in the nasal spray. An increase in nasal secretion and in the severity of sneezing can be interpreted in the sense of homeopathic primary therapeutic reactions (initial worsening of the original symptoms), or as a stimulation of functions which are part of the Excretion Phase. In such cases, such symptoms could not accurately be classified as adverse effects.

In the case of the patient with stomach pain, the symptoms may involve intolerance to the lactose used as diluent in the tablets. In the last case of intolerance, the medication was improperly administered. The patient suffered from a thyroid disorder which — because of the constituent arsenum iodatum — is a contraindication for the preparation Luffa compositum Heel in tablet form. Since this patient suffered from hyperthyroidism as accompanying disease, the preparation should not have been administered. In summary, it may be concluded that only three cases entailed the possibility of a causal relationship between the application of the two homeopathic medications and the adverse effect. A side-effect rate of 0.28% therefore results from calculations based on these data (both forms of administered combined). These results signify that an adverse drug reaction can be expected only in rare cases upon application of these two homeopathic preparations. Patients' tolerance to Luffa comp.-Heel nasal spray and Luffa compositum Heel tablets can consequently be assessed as very good.

Results of treatment

Upon conclusion of teatment of each patient — i.e., as a rule, at the end of the duration of the airborne-pollen period responsible as allergen in each case — the participating physicians made their overall ratings for the results of therapy achieved for each case. Approximately 72% of the patients treated experienced either "very good" or "good" results after application of the homeopathic hay fever preparations. For only one patient in ten was the outcome of therapy unsuccessful (see Fig. 3). There was no correlation between the results of therapy and the type of allergen responsible for the hay fever: in other words, the effectiveness of Luffa comp.-Heel nasal spray and Luffa compositum Heel tablets applied equally to patients suffering from botanical pollen (trees, grasses, and herbs), from house dust, as well as from animal hair. Likewise noteworthy are the results of treatment for the 122 children (less than 11 years old), since effective and low-risk possibilities of treatment are especially important for this group of patients. Eighty-two percent of the children completed their treatment with either "very good" or "good" results (with an additional 11.5% satisfactory results, 5.7% unsuccessful outcome, and 0.8% worsening).

An additional objective of this drug monitoring study was also establishing an answer to the question as to whether Luffa comp.-Heel nasal spray and Luffa compositum Heel tablets in fact represent an effective alternative to treatment of hay fever. Both the great proportion of patients who received monotherapy

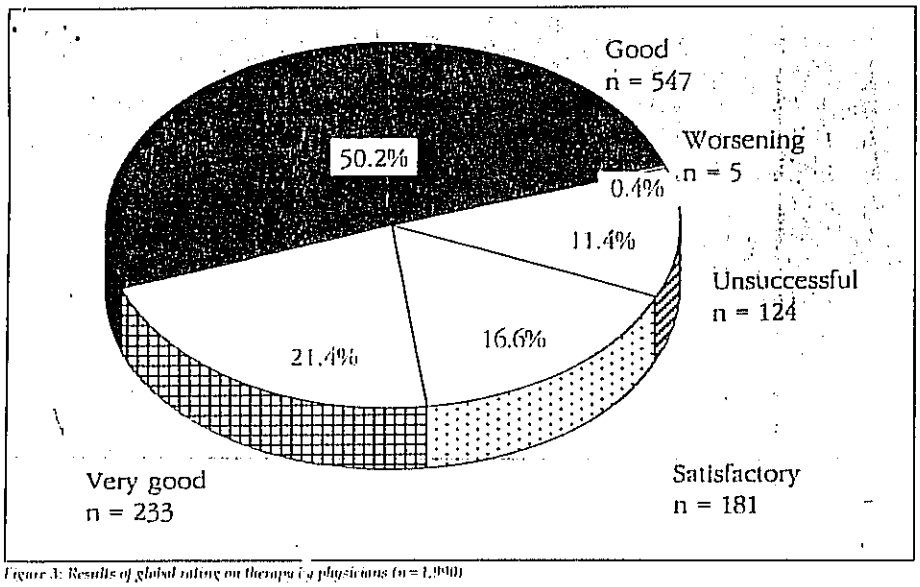

Figure 3: Results of global rating on therapy by physicians (n = 1,090)

(70.4%), as well as the results of therapy in this group, confirm that the application of these two homeopathic preparations alone is sufficient — whereby the combined application of both forms of administration is particularly effective by virtue of their different modes of therapeutic action (local and systemic). See Fig. 4. In phases of acute exacerbation — e.g., development of bronchial asthma, or the presence of pronounced ophthalmic symptoms — the adjuvant application of allopathic preparations can become not only advisable but also unavoidable.

4. Interpretation of results

In our day and age, in which the prevalence of allergies is rapidly growing, there is consequently an ever-greater demand for effective and well-tolerated concepts for therapy of these illnesses. Hay fever represents a typical example of such proliferation of allergies, especially in industrialized countries. The present drug monitoring study verifies that both effective as well as low-risk treatment of hay fever is possible as a rule with antihomotoxic medication — and that Luffa comp.-Heel nasal spray and Luffa compositum Heel tablets represent an alternative on the pharmaceutical market consisting of those rhinologics which do not contain corticosteroids. In cases in which the hay fever develops further into bronchial asthma, or in which pronounced ophthalmic symptoms are involved, adjuvant application of allopathic medication is indicated.

The results of the present drug monitoring study also reveal that the combined administration of Luffa comp.-Heel nasal spray and Luffa compo situm Heel tablets offers advantages for the patient. Treatment of hay fever with these medications is associated with low risk of adverse effects, good toleration by patients, the opportunity of application for all patient groups (e.g., with respect to the age of the patient and the type of the responsible allergen), ease of dosage, as well as possibility of long-term therapy. Verification of reliable effectiveness and satisfactory application of both preparations for the various patient groups is also provided by the fact that approximately 93% of the patients remained at the initially prescribed level of dosage throughout the entire term of therapy, that around 7% of the patients were even able to complete treatment with a reduced dosage, and that only 0.4% required an increased dose.

Clinical studies are not yet available which attest to the therapeutic effectiveness of Luffa comp.-Heel nasal spray or Luffa compositum Heel Tablets for treatment of hay fever. The effectiveness, however, of the constituents Galphimia glauca (Thyrallis glauca, contained in the nasal spray) and Luffa operculata (contained in both the nasal spray and in the tablets) has been investigated in a number of clinical studies for the therapy of rhinitis, and has been described in reports of therapeutic experience. In a multicentric, randomized double-blind study, the effectiveness of Galphimia glauca 4X in treatment of hay fever was compared with that of the placebo ethanol (with 86 patients over a period of

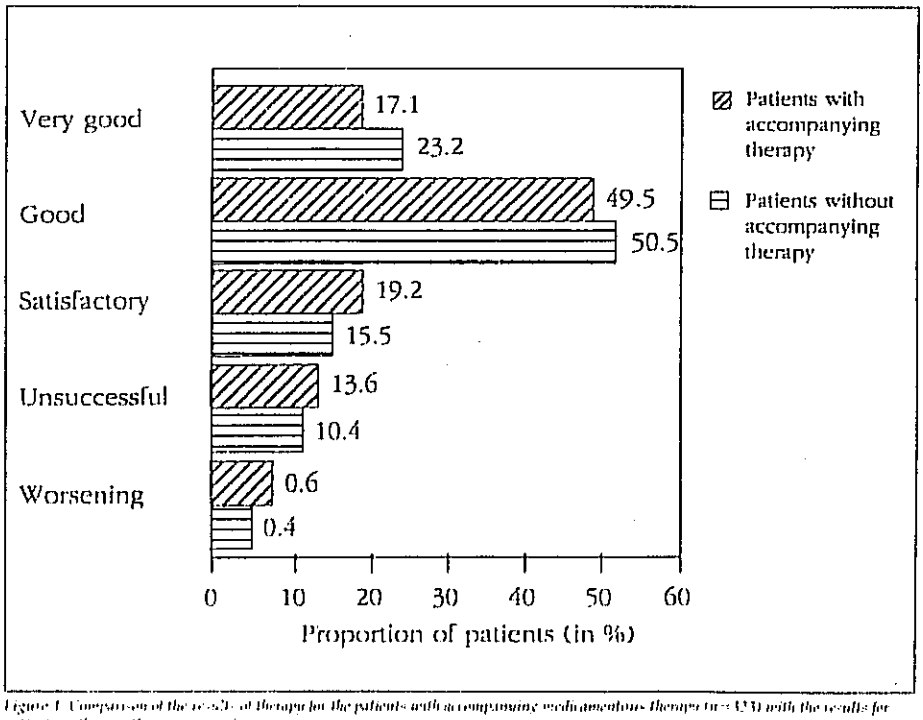

Figure 4: Comparison of the results of therapy for the patients with accompanying medicamentous therapy (n = 93) with the results for patients with monotherapy (n = 93)

observation of 5.5 weeks). This study revealed that Galphimia glauca 4X was significantly more effective. The study verified that therapeutic success was in fact achieved in the sense of freedom from symptoms, or in the form of definite alleviation, for 80 percent of the patients [18]. An additional controlled, randomized, strictly double-blind study conducted on 164 patients compared the effectiveness of the homeopathically prepared constituent Galphimia 6X, a conventional Galphimia 10^{-6} dilution, and a placebo, in therapy of pollinosis. The average term of therapy was five weeks. Although no statistical significance became apparent, use of the Galphimia 6X preparation achieved the best therapeutic results [19]. A further double-blind study investigated the quality of therapeutic action of various homeopathic attenuations of Galphimia glauca for the treatment of hay fever: 4X, 4C, 2C, and 4LM. The average term of therapy was five weeks. A total of 216 patients was included in this study. After differences in effectiveness were determined during the early stage of the study (for treatment of eye and nose symptoms), these differences decreased progressively with continuation of the study. For all patient groups, final results revealed that the therapy ended in success for approximately 85% of the patients [20]. In a study made in the context of general medical practice, Kuhnke tested the effectiveness of Luffa operculata (4X and 6X) with more than 600 patients with various illnesses (chronic and acute) of the upper respiratory passages [21]. As a rule, physicians administer Luffa operculata as monotherapy, with a recommended dosage of 8-10 drops, taken 4 times a day. The average term of therapy during this study was 4-6 weeks. In the majority of cases, positive treatment results were obtained.

In conclusion, the following question arises with this drug monitoring study: how can we explain the manner in which the constituents of Luffa comp.-Heel nasal spray and Luffa compositum Heel tablets act with respect to hay fever? Reports are not available from any special investigations which may have been conducted on the process of therapeutic action involved with the various constituents of these preparations. It has been generally assumed, however, that these constituents exert their effects as so-called paramunity inducers. The action of these inducers is based on an adaptation-pharmacology principle which may also be considered in the sense of pharmacology of micro-doses [22, 23].

References

1. Glück U. Pollinosis und orales Allergiesyndrom. HNO 1990; 38: 188-190.

2. Horak J, Jäger S. Ursache des Heufiebers. Med. Klin. 75 1980; 13: 532-538.

3. Wüthrich B, Schlumpf M. Epidemiologie der Atopien. Umweltkrankheiten Nr. 1. Sozialpädiatrie 14, 1992; 8: 606-612.

4. Ricken K-H. Infektanfälligkeit und Allergien im Kindes- und Jugendalter sowie deren Behandlungs- möglichkeiten mit Biotherapeutika/Anti-homotoxika. Biologische Medizin 23, 1994; 1: 14-24.

5. Röttger C. Alles gegen Allergien. Patientenratgeber aus der Reihe "Gesundheit aus der Apotheke"; Govi-Verlag 1994.

6. Haidvogl M. Heuschnupfen. Der Kinderarzt 1991; 22,4: 657-660.

7. DAZ-Workshop Selbst- medikation: Heuschnupfen. Deutsche Apotheker-Zeitung 1983; 123, 25: 1211-1214.

8. Czarnetzki BM. Chemotaktische Mediatoren. Allergologie 1985; 8: 63-68.

9. Doenike A, Lorenz W (Eds.). Histamin und Histamin-Rezeptor-Antagonisten. Springer-Verlag Berlin, Heidelberg, New York, Tokyo, 1985.

10. Aufbereitungsmonographie: Aralia racemosa. Bundesanzeiger 86, 1994.

11. Aufbereitungsmonographie: Arsenum jodatum. Bundesanzeiger 86, 1994.

12. Aufbereitungsmonographie: Histaminum dihydrochloricum. Bun-desanzeiger 22a, 1988.

13. Aufbereitungsmonographie: Lobelia inflata. Bundesanzeiger 190a, 1985.

14. Aufbereitungsmonographie: Luffa operculata. Bundesanzeiger 129a, 1988.

15. Aufbereitungsmonographie: Sulfur. Bundesanzeiger 104a, 1990.

16. Aufbereitungsmonographie: Thryallis glauca. Bundesanzeiger 22a, 1988.

17. Böttcher-Haase C, Lido H, Stübler M. Arzneimittelprüfungen von Luffa operculata bis 1986. AHZ 1988; 233, 3: 89-96.

18. Wiesenauer M, Häussler S, Gaus W. Pollinosis-Therapie mit Galphimia glauca. Fortsch. Med. 1983; 101, 17: 811-814.

19. Wiesenauer M, Gaus W. Double-blind trial comparing the effectiveness of the homeopathic preparation galphimia potentisation D6, galphimia dilution 10^{-6} and placebo on pollinosis. Arzneimittelforschung/ Drug Res. 1985; 35, 11: 1745-1747.

20. Wiesenauer M. Eine Langzeitstudie unter Praxisbedingungen. Zeitschr. Allg. Med. 1986; 62: 388-392.

21. Kuhnke I. Luffa operculata, ein nachhomöopathischen Gesichtspunkten neu aufgefundenes Mittel bei Krankheiten im-Nasen-Rachen-Raum. Allg. Homöopath. Z. 1968; 213, 7: 289-295.

22. Hänsel R. Traditionelle Reizkörpertherapie, gesehen als Immun-stimulation. Dtsch. Apoth. Ztg. 1984; 124: 54-59.

23. Wagner H. Immunstimulantien und Phytotherapeutika. Z. Phytother. 1986; 7: 91-98.

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