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FEATURE ARTICLE

The Therapy of Rhinopathy as Associated with a Previous Abuse of Nasal Spray and with Vasomotor Influences

Results of Application of a Biotherapeutic Nasal Spray
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Abstract

This report describes the results of a study conducted on patients suffering from rhinopathy associated with a previous long-term application of medication (abuse of nasal spray) and with vasomotor influences. The study confirmed that the protracted application of a homeopathic, rhinologically administered medication was effective in treatment of such patients. Rhinomanometric measurement of air-flow resistance during nasal breathing among a selected population of patients served as the objective parameter for determining improvement in the patency of the nasal passages. The study covered 26 patients suffering from Rhinopathia vasomotorica and 25 patients with Rhinopathia chronica medicamentosa. All the patients had experienced impaired nasal breathing for at least six months before the beginning of treatment with the homeopathic nasal spray. Treatment took place during six months of the winter season, in order to minimize the interference of allergens from the environment. Dosage was two spray squirts into each nostril, administered three times daily. Both groups of patients experienced statistically significant reduction of air-flow resistance for breathing through the nose. After administration of the homeopathic medication was terminated, air-flow resistance remained at a constantly reduced level over the monitoring period of two weeks. Six of the 26 patients with Rhinopathia vasomotorica proved to be nonresponsive to this therapy. Among all other patients studied, however, the measured airway resistance closely approached levels considered normal in current medical publications. None of the patients

suffered from side effects. The pleasant mode of application contributed to the high level of patient compliance.

Situation

Nowadays Rhinopathia chronica medicamentosa and Rhinopathia vasomotorica are a very frequent diagnosis made by specialists and general practitioners. Rhinologically administered medication is currently prescribed to a massive extent in an attempt to relieve constriction in nasal passages - the widespread use of nasal sprays is sufficiently apparent from figures on their frequency of prescription. Even if the physician consulted refuses to continue prescribing a nasal spray for a particular patient, he or she can in most countries obtain it or its equivalent without great difficulty at the nearest pharmacy. At some point in time, however, some physician will generally be confronted with the patient again: for therapy of the dependence resulting from medication abuse.

Within the context of this widespread problem area in modern medicine, we conducted a study to determine the degree of effectiveness of the homeopathic product *Euphorbium compositum* Nasal Spray. We selected a test population from among patients who had suffered at least six months from nasal-spray abuse and from vasomotor rhinopathy. The symptom complex of such patients consists of course primarily of their difficulty in breathing through the nose, caused by a restriction of the patency of the nasal lumen. The subjective impression of having a "stopped-up nose" is amenable to objective assessment by the techniques of rhinomanometry (see Table 1).

The interrelationships between numerical values obtained by rhinomanometry and patients' subjectively

experienced restriction of nasal breathing have been researched and are well understood [7, 16, and 26]. These findings have provided the following assurance for our purposes here: without positive changes in the measurable air-flow resistance through the nose, documentation of an amelioration in symptoms beyond a placebo effect is not possible.

Research and development carried out by Masing, Bachmann, Dishoeck, Cottle, and others have now made widely available a selection of medical devices so simple in their practical employment that they now belong to the daily routine of all modern ear, nose, and throat specialists for purposes of diagnosis and therapy monitoring.

Active rhinomanometry with measurements made during respiration
Passive rhinomanometry with measurements made while the patient holds his breath
Anterior rhinomanometry with measurements made at the nostril entrance
Posterior rhinomanometry with measurements made at the choanae
Uni- or bilateral rhinomanometry with measurements made on one or both sides of the nose

Table 1: Methods for measuring patency of the nasal lumen

Methods

The method employed by us was developed by A.H.V. Dishoeck. The precision of this technique is slightly less than the other available methods, but we used it for its advantages of being very simple (a registration device is not required) and very fast (only a few minutes).

The test setup includes a nose attachment and a lateral connection tube. A conventional compressor provides a constant stream of air, which blows through the nosepiece. For these measurements, we used a constant flow-rate setting of 15 liters per minute (with accuracy tolerance of $\pm 5\%$). The equipment also features a humidifier and a heating element, which ensure a temperature of 27°C and a relative humidity of almost 100%. The connection tube on the nosepiece is hooked up to a micromanometer which can be calibrated within the pressure range of 0 - 20 cm of water, equivalent to approximately 0 - 20 mbar. We conducted our measurements with the rhinomanometer made by the company Heyer of Bad Ems, Germany, which is commercially available in this country.

Methods of measurement and recording

We measured the patency of our test-patients' nostrils by a conventional and proven technique: the passive anterior rhinomanometric method (PAR), which requires that the patient hold his breath and keep his mouth open.

According to studies made by Melon, the air-flow resistance in a human nose is directly proportional to the air pressure applied by the patient in exhaling or inhaling, provided that the rate of air flow is constant [25]. Conversely, Melon has also shown that the flow volume is inversely proportional to the air-flow resistance - an aspect especially significant in the event of constriction in the nasal passages. We therefore configured our measuring setup in such a way that the pressure on one side of the measuring system always equaled atmospheric pressure, and that the system on the other side measured the hyperbaric pressure created by an air-flow rate of 15 liters per minute. We employed the following procedure:

The pressure was measured at one nostril while the patient held his or her mouth open, and while the other nostril was tightly sealed. The patient's respiratory system, thus modified for test purposes, therefore consisted of

the following: one nostril, the choana, the pharynx, and the mouth.

To determine normal air-flow parameters for healthy patients, Clement and Dishoeck examined a population of 30 selected healthy control persons within the range of 15 - 35 years of age [8]. These persons underwent thorough prior examination to ensure that no abnormalities would distort the findings.

For healthy control persons, Clement and Dishoeck determined a mean differential pressure of 0.8 mbar (= 8 mm of water) per nostril, which corresponds to a calculable total differential pressure of 0.4 mbar. This pressure is proportional to the total air-flow resistance R. This value (0.4 mbar) may be considered to represent the normal air-flow pressure indication for normal, healthy persons.

For clear and simple presentation of the change in air-flow readings over the course of therapy with homeopathic nasal spray, we plotted the total differential pressure (ΔP) as a function of the length of time each patient employed the nasal spray. Our data are shown in box-plot form in Figs. 1 and 2. The first plot (Fig. 1) shows the results of nasal-spray therapy for patients in the test population suffering from Rhinopathia vasomotorica (without allergy), and the second shows the results for Rhinopathia chronica medicamentosa (abuse of conventional nasal sprays).

The following is a brief elaboration on a number of the statistical details involved in the box-plot mode of representation: Each of the rectangular boxes plotted contains 50% of all values measured on a certain date. The line between each box and the upper "X" covers the distribution of 25% of the measured values, and the line below each box to the lower "X" the remaining 25%. The asterisk (*) marks the median of the data for each date. Freak values are marked with 0, 02 or 03. A median which lies in the middle of a box generally signifies a symmetrical distribution; such a median will then correspond to the arithmetic mean. In the event of non-symmetrical distributions, on the other hand, the median will be less influenced by freak values.

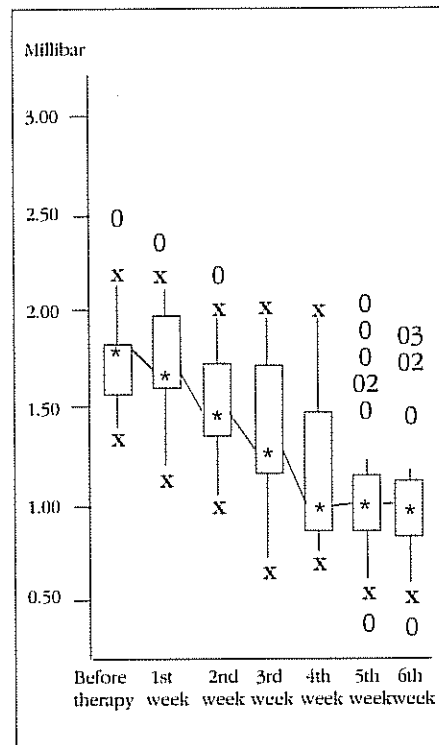


Figure 1
Group I: Patients suffering from Rhinopathia vasomotorica. Plot of the measured air-flow resistance in patients' noses during six weeks of therapy in the form of application of *Euphorbium compositum* Nasal Spray.

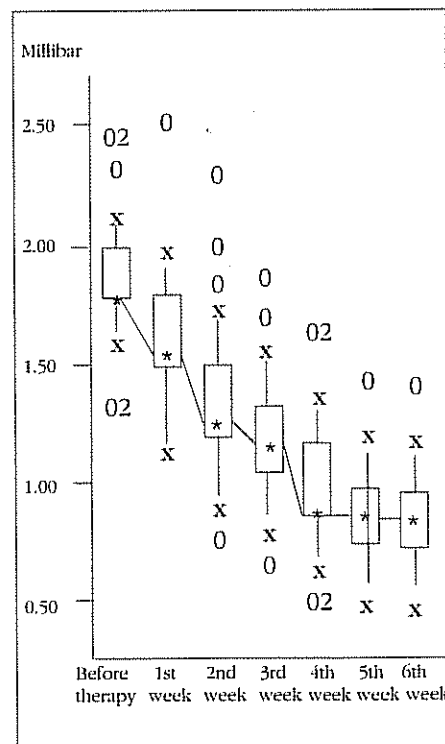


Figure 2
Group II: Patients suffering from Rhinopathia chronica medicamentosa. Plot of the measured air-flow resistance in patients' noses during six weeks of therapy in the form of application of *Euphorbium compositum* Nasal Spray.

Selection of Patients

Specific objective of testing:

We conducted our study to determine the effectiveness of the preparation *Euphorbium compositum* Nasal Spray, with use of the PAR as criterion of evaluation. The total patient population of 51 persons was broken down into the following two sub-populations:

- Group I: 26 patients suffering for at least six months from Rhinopathia vasomotorica.
- Group II: 25 patients with Rhinopathia chronica medicamentosa for at least six months.

In order to eliminate interference from pollinosis caused by seasonal allergens from the environment, we conducted our study for both sub-populations (all 51 patients) exclusively during the period from the beginning of November until the end of March. We performed manometric testing on all patients at regular intervals of seven days, with each patient being tested seven times over the six-week term of observation.

We gave the patients the following instructions on dosage: spray the preparation *Euphorbium compositum* Nasal Spray twice into each nostril, three times a day, during every day of the six-week test. Our physicians questioned the patients to monitor their compliance with these instructions: irregularities in compliance were observed, especially at the beginning of the study, but overall compliance was good throughout the entire term.

All 51 patients selected for this study had suffered from constricted patency of the nasal lumen for at least six months before our therapeutic testing began. Some had already suffered for years. Among the patients in Group I, 12 had received vasoconstrictor drugs, locally applied, for treatment of their symptoms before our test. From Group II, 25 patients had received local vasoconstrictors. Most of the patients from both groups had experienced short-term success with this earlier therapy. In addition, 2 patients from Group I and 7 from Group II had been

administered systemic therapy with various rhinologic medications. Fourteen patients from Group I had received no specific treatment before our study, neither in local nor systemic form.

Criteria for exclusion of patients

Persons were excluded from our study if they had experienced any one of the following:

- Specific surgical therapy within four weeks before the planned beginning of our test.
- Long-term medicamentous therapy, even though nonspecific in nature, which could influence the state of the nasal mucosae.
- Angina tonsillaris or polyposis nasii.
- Infection of the paranasal sinus cavities that could be detected by sonographic or radiological means.
- Otitis media, sinusitis, bronchitis, or recent influenza or colds.
- Acute infectious rhinitis.
- Intolerance to food or drugs (involving alpha-blockers, dihydralazine, guanethidine, clomethiazol, psychotropic drugs, or reserpine).
- Rhinitis as an occupational disease.
- Allergic reactions from any cause.
- Antibiotic therapy for other, nonspecific accompanying diseases.
- Inflammatory alterations in the nasal area: eczema or furuncles.
- Deviation or perforation of the nasal septum.
- Spina septi.
- Endocrine disorders: e.g., afflicting thyroid or adrenal gland; diabetes.
- Severe cardiocirculatory disorders.

The physicians in our study took case histories and made the examinations

necessary to ensure that all patients admitted to the study in fact satisfied the criteria. In addition, sonographic findings confirmed that none of the 51 patients accepted into the two groups were suffering from infection of the paranasal sinus cavities. In cases of doubt, radiological diagnosis was employed to ensure conformity with the criteria: this was necessary for 26 potential test patients. Other nonspecific accompanying diseases were discovered among 11 patients, including 5 who had received medicamentous therapy for them, which sub-group also included two with a history of having received beta-blockers for hypertension.

Local examination of the 51 accepted patients revealed swelling of the mucosae of the nasal conchae in all cases. Among 38 patients, reddening of the nasal mucous membranes was also found. Nasal secretion was serous for 27 patients, mucous for 16, and suppurative for none. No secretion was determined for 8 patients. Nine of the patients had nose crusts. Twenty-three were plagued by irritation and itching of the nasal tissues. Thirteen of those admitted reported an impaired sense of smell and five suffered impaired taste sensations. Seventeen of the test patients were moderate to heavy smokers.

We additionally took measures to ensure that allergic dispositions did not interfere with the performance and assessment of the homeopathic nasal spray being tested. Of the eight most widespread possibilities for allergy testing practiced in Germany, we employed the prick test and the paper radio immunosorbent test (PRIST) - the latter of which involves serological-immunological techniques - to discover whether the test patients suffered from allergies which might influence our findings.

In the prick tests for determination of individual skin reactions, null-reaction conditions were first initiated with the solvent of the allergen extract. We observed no reaction among any of the 51 patients. To test the reaction capability of the patients' skin, we further applied a histamine wheal with a 0.1% histamine solution. All the patients demonstrated normal sensitivity. An allergen skin test was then performed with house dust. We

observed definitely positive development of a dust wheal for only one of the 51 patients, with inconclusive reactions for an additional nine (all from Group I). For these nine inconclusive cases, we performed the PRIST procedure to verify the situation.

PRIST values are abnormally high not only for allergies which come about in conjunction with IgE: patients suffering from infectious disorders also demonstrate elevated levels for total IgE. As a result, the PRIST findings are meaningful for us in this context only insofar as a negative test value speaks for a nonexistent allergy, whereas an elevated value does not necessarily indicate an existing allergy. The negative findings obtained for all of the 10 patients who underwent PRIST testing signified that atopic disorders were not to be found among our test population.

Test Results

Group I: Rhinopathia vasomotorica patients

Group I of our total test population of 51 patients consisted of 26 test persons, of whom 13 were men and 13 were women. The mean age in Group I was 34, with the youngest 16 and the oldest 52. This group included 6 smokers.

Although the term "non-allergy-related Rhinopathia vasomotorica," as frequently employed in Germany, characterizes a symptom complex, it indicates nothing of the etiogenesis involved. Causal factors which contribute here are mechanical, chemical, physical, and/or psychic stimuli. In general, specialists are indicating an example of nonspecific reflectory hypersensitivity when referring to Rhinopathia vasomotorica. According to Bachmann, two chief forms of Rhinopathia vasomotorica are encountered today: intrinsic and cholinergic types. The intrinsic form is often associated with nasal polyps. The cholinergic form of Rhinopathia vasomotorica can and should be distinguished from Rhinopathia allergica through differential diagnostic methods. The following characteristics encountered with the cholinergic form of Rhinopathia vasomotorica enable such distinction: there is no skin-test

reaction; secretory eosinophils cannot be found; hypersensitivity to salicylate is not observed; cortisone and antihistamine have no desired therapeutic effect. Symptoms of Rhinopathia vasomotorica are elicited by inert dust, cigarette smoke, vapors and fumes, fog, ionizing radiation, and abrupt changes in atmospheric pressure and temperature.

There were 12 patients in Group I who had previously been unsuccessfully treated with locally administered rhinological medication. Fourteen of the total 26 had received no therapy at all. Of the entire group, none reported suffering particularly from conditions at his or her place of work. After other contributory factors were eliminated in accordance with the strict criteria as described above, it may be safely assumed that the primary causal element eliciting the symptoms of Rhinopathia vasomotorica for the patients in Group I is the general atmospheric situation encountered in the industrial Ruhr Area in Germany (in which the test patients live).

The box plot in Fig. 1 charts the course of therapy results with Euphorbium compositum Nasal Spray. The weekly examination intervals are plotted along the abscissa; the pressure difference ΔP , for the entire nose, which is proportional to the air-flow resistance - is plotted along the ordinate. Although the distribution of measured values in Group I at the various examination dates deviates slightly from a symmetrical configuration throughout the entire course of therapy, this distribution can be said to be symmetrical for the initial examination of the patients and for the fourth subsequent examination. This plot reveals that the mean total-nose differential pressure decreased from 1.80 mbar at the beginning of therapy to 1.00 mbar four weeks later. Even at this reduced level, however, it is still 0.6 mbar greater than the value of air-flow pressure considered normal for healthy persons, determined by Clement to be 0.4 mbar. On the basis of the z-t test for paired measurements, calculated for two sides, these test results may be considered highly significant (p less than 0.0005).

During the further course of therapy

and examination, throughout the fifth and sixth weeks, the measured pressure remains constant at the level of 1.0 bar: a value which most probably represents the normal value for this sub-population under the given conditions. From the fourth to the sixth week, the effect of data from patients totally nonresponsive to the therapy becomes noticeable in Fig. 1 as a result of the accumulation of extreme values. In a graphical depiction of the statistical spread involved here (not reproduced in this article), the nature of these extreme values becomes more apparent in their description of the subgroup which they represent.

Group II: Rhinopathia chronica medicamentosa patients

Group II of our total test population of 51 patients consisted of 25 test persons, of whom 18 were men and 7 were women. The mean age in Group II was also 34, with the youngest 13 and the oldest 51. This group included 11 smokers. Before taking part in our tests, all patients in Group II had locally employed nosedrops or spray to reduce swelling in the nasal passages. Seven of this group had also used systemically acting antihistamine preparations.

N.B.: The administration of vasoconstrictors should take place only on a short-term basis. Any long-term employment of such agents will definitely lead - sooner or later, depending on the particular case - to dependence of an addictive nature, and to development of the symptom picture of Rhinopathia chronica medicamentosa.

For therapy of Rhinopathia chronica medicamentosa, many physicians recommend a sudden and complete break with all types of nosedrops or spray. The cold-turkey approach, however, demands a great deal of patience and self-discipline from the patient - who, after all, has enough to contend with in his or her breathing difficulty. Oral medication for the treatment of stopped noses is also one of the possible ways out of this dilemma - one associated with unpredictable side effects, however. The preparation Euphorbium compositum Nasal Spray represents a more promising possibility to bridge this difficult withdrawal period.

According to Bachmann, the mucosae of the nasal conchae should, among abusers of conventional nosedrops or spray, return to normal within 8 -10 days after terminating the use of these preparations. Our findings contradict this statement. As shown by the box plot in Fig. 2, nasal resistance to air flow returned to a significantly lower, stabilized level only after four weeks: here, from 1.75 mbar at the beginning of our study, to the level of 0.85 mbar. As with Group I, this value is higher than the value considered normal by Clement: Group II patients dropped to a point which was 0.45 mbar greater than Clement's level for the healthy. Here as well, the stabilized lower air-flow-resistance levels achieved by the therapy with *Euphorbium compositum* Nasal Spray may be considered normal for patients under the conditions represented in Group II. On the basis of the t-test for paired measurements, calculated for two sides, the test results for Group II may likewise be considered highly significant (p less than 0.0005).

Neither local nor systemic side effects became apparent during the therapy with *Euphorbium compositum* Nasal Spray.

General assessment by the patients and physicians of the results of therapy was good to very good for most of the cases. On the basis of the rhinomanometric measurements, we were forced to consider six of the patients as resistant to therapy.

Patients resistant to therapy

Patients were classed as resistant to therapy if, after the seventh examination (after six full weeks of therapy), the differential pressure in the right and left nostrils had not decreased to a point below 3.0 mbar, or if the differential pressure for both sides (entire nose) had not sunk to a point below 1.5 mbar. The group of resistant patients included 6 test persons: two women and four men. These patients shared no apparently common factor.

Among the six therapy-resistant patients, three had received vasoconstrictor drugs in previous treatment. One patient with Laryngitis hyperplastica had additionally been

systemically treated with corticosteroids. None smoked. Despite their initial lack of success, three of these six patients wished to continue the therapy with *Euphorbium compositum* Nasal Spray after the end of six weeks. All of the therapy-resistant patients were in Group I.

In the computer plot showing the statistical spread of the air-flow pressure measurements for each of the patients, the therapy-resistant patients clearly segregate themselves from the rest of the patients in Group I.

Assessment of Test Results

Without doubt, the use of vasoconstrictors for rhinological purposes has proved highly effective in therapy of Rhinitis purulenta, sinusitis, and Otitis media. The administration of these agents, however, should take place only after definite diagnosis, and only under the supervision of a sufficiently qualified physician. Only in such a way can the patient avoid the dangers of unjustified or unnecessarily long therapy with vasoconstrictors.

It is, furthermore, especially difficult to correctly diagnose Rhinitis vasomotorica: successful diagnosis here is possible only by an experienced specialist after taking a comprehensive case history. The patient suffering from rhinological syndroms, however, all too frequently succumbs to the temptation to treat himself or herself with vasoconstrictors - and therefore falls prey to the vicious circle of detumescence and reactive hyperemia involved here. Once this situation has developed, and the medicamentous dependence of the patient becomes evident - without, furthermore, an alleviation of the original symptoms - it becomes very difficult for a physician to explain to the patient the habitative or even addictive nature of his or her complaints. It is especially problematical, furthermore, for the doctor to explain the necessity for changing to another form of therapy - and for working up the required patience and self-discipline - particularly since the first attempt has proved so deceptive.

In this study, we have demonstrated that the long-term and regular administration of *Euphorbium compositum* Nasal Spray enables patients suffering from either Rhinitis vasomotorica or Rhinitis chronica medicamentosa to experience readily noticeable improvement in their conditions of nasal congestion. The subjective impression of relief in breathing - impressive as it is - was effectively reinforced by equally impressive results in the form of objective data gained from easily understood measurements of air-flow resistance in the patients' noses. The successful therapeutic effects of *Euphorbium compositum* Nasal Spray were obvious to the patients, provided as they were with the first-hand evidence of their monitoring sessions every seven days. Our findings and their clear presentation to the patients furthermore represented a powerful incentive to them to faithfully administer the preparation on a regular basis.

The results of our study have therefore verified that the preparation *Euphorbium compositum* Nasal Spray represents a highly effective therapeutic agent of choice for patients suffering from Rhinitis vasomotorica and Rhinitis chronica medicamentosa.

Key words:

Rhinopathia vasomotorica;
Rhinopathia chronica medicamentosa;
Euphorbium compositum Nasal Spray;
vasomotor rhinitis;
abuse of nasal spray.

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