The Nasal Application of Homeopathic Medicines

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Abstract

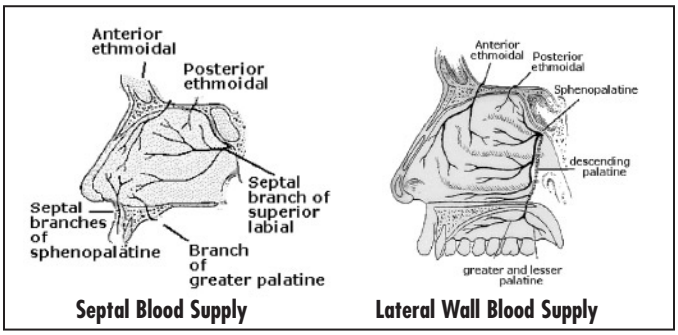
The purpose of this study is to show that, when compared to placebo, the intranasal administration of a combination homeopathic medicine is effective to control the symptoms of rhinoconjunctivitis. 42 unmedicated patients with allergic rhinoconjunctivitis were recruited. After appropriate informed consent, 7 patients were treated with a placebo of Aloe-glycerin gel without the homeopathic remedies four times a day for 1 week. 30 patients were treated with active nasal swabs as needed up to four times a day for 1 week. Those in the placebo group were then (crossed-over) treated for an additional week with the active homeopathic nasal gel swabs. 5 additional patients were treated with a sublingual mist of the same homeopathic remedy as needed up to four times a day for 1 week. Results showed a statistically significant improvement in all outcomes parameters when the active homeopathic nasal gel formula is compared to placebo. On average, Nasal symptoms improved 48%, placebo 17%. Eye symptoms improved 69%, placebo 14%. Sleep symptoms improved 48%, placebo 12%. Other symptoms improved 44%, placebo 12%. Activity impairment improved 50%, placebo 24%, and physical exam findings improved 51%, placebo 23%. Onset of effect after nasal administration of the active medication averaged 11.2 minutes. Average duration of effect of a single dose was 8.4 hours. The placebo group was compared to the active nasal swab group results using the following statistical parameters: NPar Tests, Wilcoxon Signed Ranks Test, T-Test. The Paired Samples Test results at 95% confidence level p<0.007.

Introduction

One of the earliest references to the nasal application of medicine was in the 1800's; when the first attempts at making a vaccine for the prevention of smallpox involved grinding the "scabs" from a small pox victim's skin into a powder and administering it to the nose via blowing the powder through a tube. Even then, it was recognized that people absorb things through their mucus membranes. Mucus membranes line the respiratory, digestive and urinary tracts and all medicines that aren't injected must pass through one or another. Most medications are, of course, eaten and pass through the digestive tract mucus membranes. The problem is that, if people have poor digestion, it affects their ability to absorb the medication through their membranes. Absorption of vitamin B 12 is a good example of a nutrient that can not be absorbed through digestive mucus membranes without adequate stomach acid and gastric intrinsic factor. It makes sense to look for an alternate route of medication delivery and the nose is perfectly suited for this purpose. It absorbs medication well because of its mucus membranes, nerve network, and excellent blood-supply.

Nasal Blood Supply

The nose, like the rest of the face, has an abundant blood supply. The arterial supply to the nose may be principally divided into[1] branches from the internal carotid,[2] branches from the external carotid. Veins in the nose essentially follow the arterial pattern. They are significant for their direct communication with the cavernous sinus and for their lack of valves; these features potentiate intracranial absorption.



Nasal Gel Characteristics

Nasal mucus membranes have been used to administer immunizations and allergy antigens.[1-9] It is known that the primary mechanism of allergic sensitization to inhalants is through dryness of the nasal mucosa. Repeated use of nasal sprays is irritating to the nose and solutions tend to run out of the nose or be swallowed before they can be absorbed well. It makes sense that a gel would serve to help correct the mucosal barrier defect caused by dryness. A gel also keeps any medication on the membrane longer than liquids. Aloe vera is thick and mucoid and when mixed with glycerine makes an excellent vehicle for the administration of medications to the nasal mucosa. Nasal administration of Aloe vera has been studied and showed to help allergic rhinitis. In a study by Yu, et al, ovalbumin sensitized white rats were used as animal models of allergic rhinitis. They were treated intranasally with Aloe vera. At the end of treatment the changes in the nasal mucosa were studied. Results showed that inflammatory reactions in the experimental group's nasal mucosa were remarkably relieved. It was concluded that Aloe vera is involved in the differentiation of CD4+ lymphocytes, by means of regulating the expression of Th1 and Th2 cytokines. The results suggest that intranasal Aloe vera treatment was an effective method to treat allergic rhinitis.[14]

Nasal Gel Absorption

Since homeopathic medicines are too dilute to be measured in human blood, hydroxocobalamin (vitamin B12) has been used to test the absorption of nasal gels. Van Asselt, et al, recruited 10 elderly healthy adults to study the nasal absorption of hydroxocobalamin. Blood samples were collected before administration and at 10, 20, 30, 40, 60, 120, 180 and 240 minutes after administration of either 750 or 1500 mcg of hydrocobalamin delivered via nasal spray. The maximal plasma concentration of 1900 pmol was reached in 35 minutes after 750 mcg hydroxocobalamin administration. The maximal concentration of 3500 pmol was reached at 28 minutes post-administration of 1500 mcg of hydroxocobalamin.[12]

In a study by Slot, et al, 6 patients with plasma cobalamin concentrations of < 200 ng/L were given single doses of 1500 mcg of hydroxocobalamin intranasally at days 0, 14, and 21. Plasma cobalamin concentrations were determined one hour after administration and on days 7, 21, 28 and 35. All patients showed substantial (8 fold over baseline) increases in cobalamin concentration one hour after administration. All patients showed a sustained increase 1 week after prior application.[10]

Homeopathic Medicines

Homeopathic medicines are drug products made by homeopathic pharmacies in accordance with the processes described in the ***Homeopathic Pharmacopoeia of the United States*** the official manufacturing manual recognized by the FDA. A plant substance, for example, is mixed in alcohol to obtain a tincture. One drop of the tincture is mixed with 99 drops of alcohol (to achieve a ratio of 1:100) and the mixture is strongly shaken. This shaking process is known as succussion. The final bottle is labeled as "1C." One drop of this 1C is then mixed with 100 drops of alcohol and the process is repeated to make a 2C. By the time the 3C is reached, the dilution is 1 part in 1 million! The liquid dilution is then added to distilled water or small lactose globules. The liquid or globules constitute the homeopathic medicine. Homeopathic nasal gels have not been studied.

Homeopathy and Allergies

A randomised, double blind, placebo controlled, parallel group, multi-center trial of homoeopathy versus placebo in perennial allergic was published by Taylor, et al, to test the hypothesis that homoeopathy is a placebo by examining its effect in patients with allergic rhinitis. 51 patients with perennial allergic rhinitis were recruited from four general practices and a hospital ear, nose, and throat outpatient department.

They were randomized and assigned to an oral 30c homoeopathic preparation of inhalant allergen or to placebo. Changes from baseline in nasal inspiratory peak flow and symptom scale score over third and fourth weeks after randomisation. The homoeopathy group had a significant objective improvement in nasal airflow compared with the placebo group (mean difference 19.8 l/min, 95% confidence interval 10.4 to 29.1, P=0.0001). Both groups reported improvement in symptoms, with patients taking homoeopathy reporting more improvement in all but one of the centers. On average no significant difference between the groups was seen on symptom scale scores. Initial aggravations of rhinitis symptoms were more common with homoeopathy than placebo (7 (30%) v 2 (7%), P=0.04). Addition of these results to those of three previous trials (n=253) showed a mean symptom reduction on symptom scores of 28% (10.9 mm) for homoeopathy compared with 3% (1.1 mm) for placebo (95% confidence interval 4.2 to 15.4, P=0.0007). It was concluded that the objective results reinforce earlier evidence that homoeopathic dilutions differ from placebo.[11]

Hypotheses

Nasal gel administration of homeopathic medications will ameliorate symptoms of rhinoconjunctivitis better than placebo.

Onset and duration of effect will be better than placebo.

Effect of the nasal gel will be comparable to sublingual spray of the same formula.

Research Objectives

To show that nasal gel administration of homeopathic medicines is effective at ameliorating the symptoms of rhinoconjunctivitis when compared to placebo.

To show that a combination homeopathic remedy is effective at ameliorating the symptoms of rhinoconjunctivitis when compared to placebo.

To show that nasal gel administration of the homeopathic remedy is comparable to sublingual administration of the same substance.

Materials and Methods

Entry Criteria and Treatment Protocol

42 unmedicated patients with allergic rhinoconjunctivitis were recruited. After appropriate informed consent, 7 patients were treated with a placebo of Aloe-glycerin gel without the homeopathic remedies four times a day for 1 week. 30 patients were treated with active nasal swabs as needed up to four times a day for 1 week. Those in the placebo group were then (crossed-over) treated for an additional week with the active homeopathic nasal gel swabs. 5 additional patients were treated with a sublingual mist of the same homeopathic remedy as needed up to four times a day for 1 week.

Subjective Data

The Rhinoconjunctivitis Quality of Life (RQLQ) Scale and the Work Productivity and Activity Impairment (WPAI) scales were administered before and after treatment to all participants.

Objective Data

A visual examination of nasal turbinates and transillumination of frontal and maxillary sinuses were performed pre- and post-treatment. Findings were graded as follows:

Turbinates were assigned one grade per nostril. Normal = 0, Mild Swelling = 1, Severe Swelling = 2. Maximum score = 4

Maxillary and Frontal Sinuses were assigned a grade of Normal = 0, Transillumination Deficit = 1 Maximum Score = 4

All examinations were performed by a single examiner.

Medications

All materials were prepared by Dolisos and packaged by Western Research Laboratory. The homeopathics were prepared in glycerin at Dolisos and delivered to Western Research Laboratories. The formula (see below) was mixed with Aloe vera gel and Q-tip swabs were used to administer the solution to the nasal mucosa. The placebo was prepared by Western Research Laboratories and was exactly like the active formula without the addition of the homeopathic remedy mixture. The sublingual mist was made from the undiluted Dolisos preparation packaged in a spray container. The homeopathic mixture was constructed from the highest indications for remedies listed in the reperatory and other homeopathic texts for rhinoconjunctivitis symptoms.

Homeopathic Rhinoconjunctivitis Formula

Arnica 6X, inflammation of mucus membranes
Histamine 100C antihistamine effects, allergies, asthma
Luffa officinalis 12X rhinitis, nasal inflammation
Euphorbium officinarium 4X dry, inflamed mucus membranes, sinus pressure
Hepar sulphuricum 12X burning pain in the nose, coryza
Bryonia 12X dry mucus membranes, dry cough
Mercurius iodatus flavus 12X sinus pressure and infections
Mucosa nasalis 8X nasal mucosal problems
Sabadilla 6X sneezing, congestion, watery eyes
Lemna minor 4X snoring, nasal obstruction, dryness of naso-pharynx
Lachesis 12X dry, tickling cough, breathing almost stops on falling asleep

Results

Results showed a statistically significant improvement in all outcomes parameters when the active homeopathic nasal gel formula is compared to placebo. Onset of effect after nasal administration of the active medication averaged 11.2 minutes *(Figure2)*. Average duration of effect of a single dose was 8.4 hours *(Figure3)*. On average Nasal symptoms improved 48%, placebo 17% *(Figure 4)*. Eye symptoms improved 69%, placebo 14% *(Figure 5)*. Sleep symptoms improved 48%, placebo 12% . Other symptoms improved 44%, placebo 12% *(Figure 6)*. Activity impairment improved 50%, placebo 24% *(Figure 7)*, and physical exam findings improved 51%, placebo 23% *(Figure 8)*. The placebo group was compared to the active nasal swab group results using the following statistical parameters: NPar Tests, Wilcoxon Signed Ranks Test, T-Test. The Paired Samples Test results at 95% confidence level $p<0.007$.

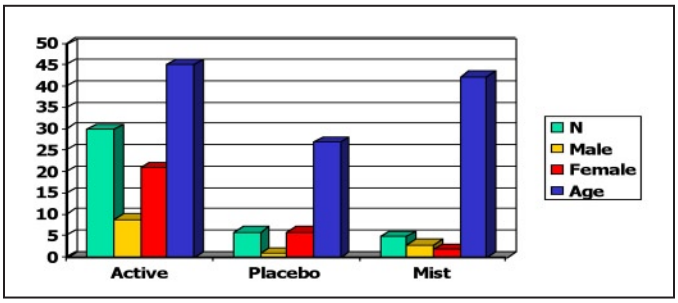


Figure 1: Demographics

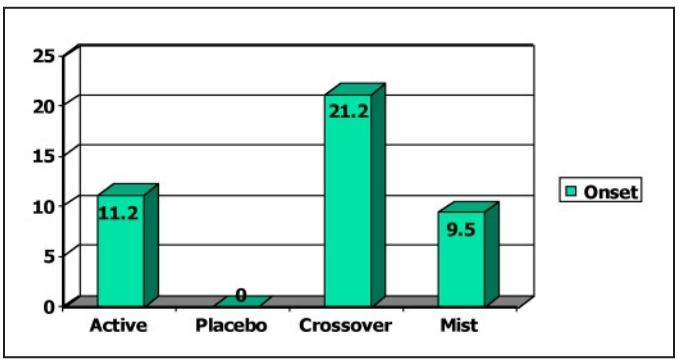


Figure 2: Pharmacokinetics onset (minutes)

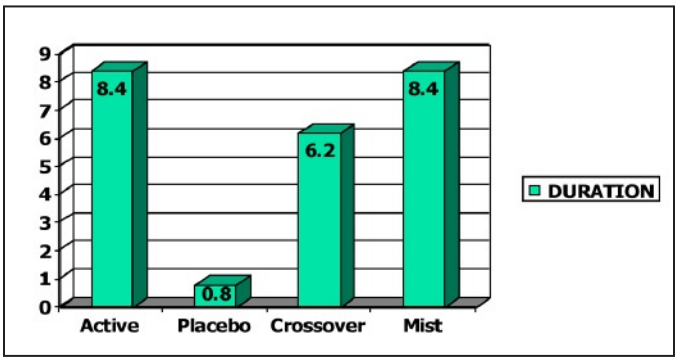


Figure 3: Pharmacokinetics duration (hours)

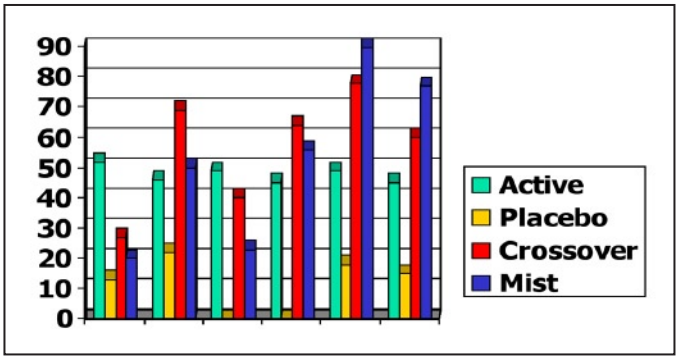


Figure 4: Nasal symptoms (% change)

Toxicity

36% of participants had mild adverse events with aggravation of symptoms (a common consequence of homeopathic treatment) affecting 14%, nasal tingling and nosebleed were also noted *(Figure 9)*.

Statistics

The placebo group was compared to the active nasal swab group results using the following statistical parameters: NPar Tests, Wilcoxon Signed Ranks Test and Student's T-Test,. The Paired Samples Test results at 95% confidence level p<0.007.

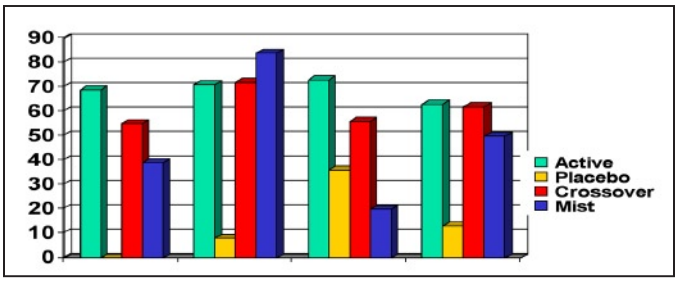


Figure 5: Eye symptoms (% change)

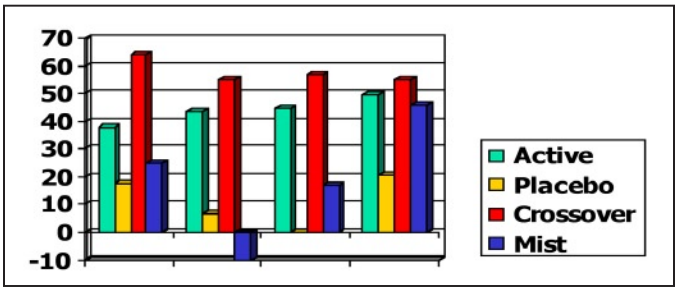


Figure 6: Other symptoms (% change)

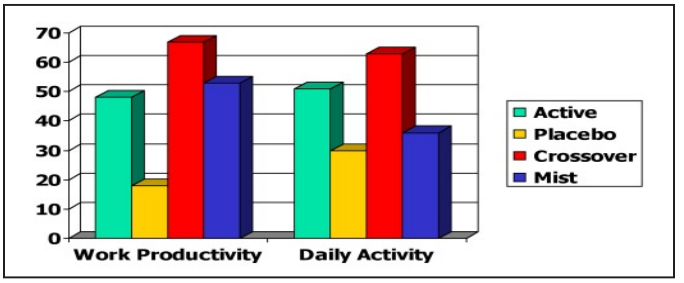


Figure 7: Activity impairment (% change)

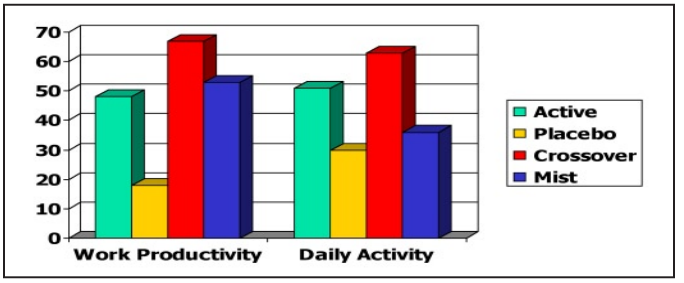


Figure 8: Physical exam changes (% change)

Nasal tingling	14%
Aggravation	14%
Nosebleed	4%
None	64%

Figure 9: Adverse effects

Conclusions

A combination homeopathic remedy is effective at ameliorating the symptoms of rhinoconjunctivitis when compared to placebo.

Nasal gel administration of homeopathic medicines is effective at ameliorating the symptoms of rhinoconjunctivitis when compared to placebo.

Nasal gel administration of the homeopathic remedy is comparable to sublingual administration of the same substance.

Toxicity is minimal, the treatment is well tolerated. The placebo had some activity due to the Aloe constituent.

Acknowledgements

I would like to thank Robert Waters, PhD., for his help with the statistics. I also want to thank Western Research Laboratories for supplying the placebos and homeopathic medications.

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