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Efficacy of Mucoregulatory Therapies Administered by Micronized Vaporization Compared to Nasal Spray in the Treatment of Upper Airway Respiratory Inflammation

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Keywords

COVID-19, Fever, Respiratory Diseases, Rhinovirus.

Introduction

Upper respiratory tract diseases include inflammatory and infectious conditions such as rhinitis, sinusitis, pharyngitis, tonsillitis, laryngitis, and epiglottitis. They are often caused by viruses (cold, influenza, RSV, COVID-19) or bacteria. They manifest with symptoms such as congestion, sore throat, cough, and difficulty breathing. They can progress to more serious infections such as bronchiolitis or pneumonia, requiring specific diagnoses and targeted treatments to relieve symptoms and prevent complications, especially in children and the elderly. Common upper respiratory tract diseases include: Common cold: A viral infection, usually benign, causing a runny nose and congestion. Influenza: An acute, contagious viral illness with fever, muscle aches, and respiratory symptoms. Rhinitis/Sinusitis: Inflammation of the nasal mucosa (rhinitis) or sinuses (sinusitis), often allergic, causing congestion and pain.

Main causes: Viral infections: Cold viruses (Rhinovirus, Coronavirus), influenza viruses, RSV, Adenovirus. Bacterial infections: Can complicate viral infections. Allergies. Environmental irritants: Pollution, smoke.

Common symptoms: Runny or stuffy nose, sneezing, congestion. Sore throat, hoarseness. Cough (dry or productive).

Aerosol therapies for the upper respiratory tract (nose, throat, sinuses) are treatments that use very fine particles of thermal water or nebulized medications to hydrate, decongest, thin mucus, and reduce inflammation. They are useful for sinusitis, rhinitis, pharyngitis, laryngitis, and dry coughs. They are often administered using nasal masks, nasal prongs, or nasal douches, along with medications such as mucolytics, corticosteroids, or antibiotics prescribed by a doctor for acute and chronic conditions [1-8].

How they work [9]:

- Nebulization: A jet of air mixed with steam breaks fluids into microscopic particles that are inhaled.
- Particle size: Larger particles settle in the upper respiratory tract (nose, pharynx), while smaller particles reach the lungs.
- Devices: Mouthpiece dispensers or nasal masks, prongs, or micronized nasal douches are used to better reach the desired areas.

Common indications:

Infections and inflammation: colds, sinusitis, pharyngitis, laryngitis.

- Cough: Dry (allergic) or productive (to loosen mucus).
- Allergies: Allergic rhinitis.
- COPD: To relieve symptoms and improve clearance of secretions.

Medications used (always with a doctor's prescription)
- Mucolytics: (e.g., acetylcysteine, ambroxol) to loosen phlegm.
- Corticosteroids: To reduce inflammation and allergic reactions.
- Antibiotics: For bacterial infections.
- Bronchodilators: (e.g., salbutamol, salmeterol) to open the airways, especially in asthma.
- Saline: To hydrate and cleanse the mucous membranes.

Objectives

To establish the efficacy of administering various mixtures (typically based on acetylcysteine, levocabastine, sodium cromoglicate, naphazoline, and hyaluronic acid) via a Vitalis gasifier nebulizer, compared with nasal spray nebulization of the same active ingredients (acetylcysteine, hyaluronic acid, levocabastine, sodium cromoglicate, and naphazoline).

Materials and Methods

The experiment uses an ultrasonic aerosol called Vitalis (Nebutechmed, Singapore). Vitalis vaporizes using a pulsed ultrasonic vibration at a frequency of 3 MHz. The resulting dry, saturated vapor, at room temperature, is mixed with an airflow from a turbine aspirator and delivered at a positive pressure of approximately 1 atmosphere. The air/vapor mixture produced in this manner has little tendency to condensate [9,10].

Study Organization

Five groups of 40 patients with acute rhinosinusitis were consecutively examined. The following were assigned to alternating enrollment:
- **Group A:** therapy with a local mucolytic (acetylcysteine) nasal spray or a mucolytic "mucus regulation" mixture administered with Vitalis (therapeutic mixture MR - Acetylcysteine).
- **Group B:** therapy with an antihistamine (levocabastine) nasal spray or an allergy control mixture administered with Vitalis (therapeutic mixture AC - Levocabastine).
- **Group C:** therapy with a membrane-stabilizing antihistamine (sodium cromoglicate) nasal spray or an allergy control mixture administered with Vitalis (therapeutic mixture AC - Sodium cromoglicate).
- **Group D:** therapy with a nasal vasoconstrictor (naphazoline) nasal spray or a cold killer mixture (therapeutic mixture CK - naphazoline).
- **Group E:** therapy with a moisturizer (hyaluronic acid) nasal spray or an allergy control mixture Immunity boost delivered with Vitalis (IB therapeutic blend - Hyaluronic Acid).

The therapeutic blends used for comparison were as follows:

Mucus regulation

L-N-Acetylcysteine
Ambroxol HCl
Hyaluronic acid sodium salt 0.8% solution (8g x 1000ml H_2O)
Lactoferrin 97%
Bromhexine HCl 0.025% solution (0.25g x 100ml)
Chlorphenamine maleate 0.025% solution (0.25g x 100ml)
β-glucan 0.05% solution
Myo-inositol

Cold Killer

L-N-Acetylcysteine
Ambroxol HCl
Hyaluronic acid sodium salt 0.8% sol.
Lactoferrin 97%
Naphazoline HCl (0.1% sol.)
Chlorphenamine maleate (10 mg/ml sol.)
Trehalose (3% sol.)
D-Panthenol

Allergy Control

L-N-Acetylcysteine
Ambroxol HCl
Hyaluronic acid sodium salt 0.8% sol.
Lactoferrin 97%
Sodium cromoglycate
Levocabastine HCl sol. 0.5 mg/ml
Chlorphenamine maleate
Naphazoline nitrate

Immunity Boost

L-N-Acetylcysteine
Ambroxol HCl
Hyaluronic acid sodium salt sol. 0.8%
Lactoferrin 97%
Echinacea Angustifolia T.M.
Myo-inositol
Vitamin E acetate (tocopheryl acetate) powder 50%
Zinc acetate 2H2O
Vitamin C

We therefore composed 5 groups of a total of 200 patients aged 12 to 60, divided into subgroups of 20 patients to compare the single-active ingredient nasal spray treatment with each corresponding individual mixture according to clinical indication.

The endpoints considered were:
- Days required for resolution of symptoms (nasal obstruction, rhinorrhea, facial pain/pressure, headache, cough, fever, reduced sense of smell)
- Addition of other therapies (oral cortisone and/or antibiotics) and
- Safety of administration of the 4 inhaled therapeutic mixtures via Vitalis.

Results

All five groups demonstrated efficacy in the treatment of respiratory inflammatory diseases.
The average symptom resolution was 7 days in patients treated

with the nasal spray (groups A, B, C, and D) and 4 days in patients treated with Vitalis (groups A, B, C, and D).

For group E, the average symptom resolution was 9 days in patients treated with the nasal spray and 6 days in patients treated with Vitalis.

No significant side effects related to the product were reported in any of the groups: no local or systemic events were recorded in either group.

In groups A and E, oral cortisone (betamethasone) was added: in 8 patients in the nasal spray group and in 3 patients in the Vitalis group.

In groups A, D, and E, oral antibiotic therapy (clarithromycin) was required: in 10 patients in the nasal spray group and in 6 patients in the Vitalis group.

Discussion

The administration of mucolytic and mucus-regulating active ingredients through the Vitalis vaporizer proved effective, with no significant differences compared to the administration of the single active ingredient via nasal spray. However, the duration of symptoms was shorter and the need for antibiotics and corticosteroids was reduced in the Vitalis group compared to the nasal spray group.

Nasal obstruction, mucous discharge, facial heaviness, and reduced sense of smell were effectively treated by the administration of respiratory mixtures through the Vitalis nasal cannula.

Noteworthy were the absence of side effects in both groups and the high level of patient compliance with inhalation of the ingredients administered as gases with Vitalis.

Conclusions

The administration of the above-mentioned aerosol mixtures via Vitalis, a medical device, has proven useful for the administration of mucolytic, antiallergic, vasoconstrictive, and hydrating medications in rhinosinusitis. The results confirmed the efficacy, safety of treatment, and shorter resolution times in acute rhinosinusitis compared to the administration of individual active ingredients with nasal spray devices.

The pharmacological mixtures described, especially when administered with Vitalis, have proven remarkably effective in combating the symptoms of respiratory diseases that affect a large portion of the world's population, resulting in significant biological and social costs.

The widespread and routine use of this technology, combined with the pharmaceutical principles we describe, will represent a key therapeutic tool in the near future for reducing respiratory symptoms, improving the clinical condition of patients with multiple comorbidities, and preserving the quality of life of those affected by inflammatory respiratory diseases with a significant epidemiological impact and widespread diffusion.

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