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Effect of Zenasinil® Spray in Patient with Upper Respiratory Tract Diseases

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ABSTRACT

Inflammatory and infectious diseases of the upper respiratory tract affect the rhino-nasal tract, pharynx, and larynx, and include conditions such as chronic tonsillitis, chronic rhino sinusitis, and rhinitis. Zenasinil® spray is a medical device indicated in the fluidification and removal of nasal secretions, especially in cases of nasal dryness. It is also an adjuvant for the removal of secretions by washout. Thanks to its actions, it helps prevent inflammation due to mucus accumulation and restore normal breathing conditions. Furthermore, the medical device may be useful as an adjunct in improving tubal ventilation. The aim of the present retrospective clinical survey was to evaluate the effect of the administration of Zenasinil® spray, alone or in combination with conventional drugs, in paediatric population with upper respiratory tract disease. Results demonstrated a marked reduction in symptoms such as dense nasal secretions, nasal congestion, poor appetite, and sleep disturbances among 23 children diagnosed with different upper respiratory tract conditions such as rhinitis, nasopharyngitis, tracheitis, and cough. The promising results of the present retrospective clinical survey must be confirmed by randomized, placebo controlled clinical trials in order to recommend Zenasinil® spray as an adjuvant treatment in upper respiratory tract disorders.

Keywords: Nasal Congestion; Rhinitis; Nasal Administration; Upper Respiratory Tract Disease

Abbreviations: AR: Allergic Rhinitis; NAR: Non-Infectious Rhinitis; CARIFS: Canadian Acute Respiratory Infection and Flu Scale

Introduction

Inflammatory and infectious diseases of the upper respiratory tract affect the rhino nasal tract, pharynx, and larynx, and include conditions such as chronic tonsillitis, chronic rhino sinusitis, and rhinitis. These conditions contribute to increased morbidity and healthcare costs, representing one of the greatest burdens on public health worldwide, both as the primary route of entry for infections into the body and due to their association with other chronic diseases, such as asthma, autoimmune disorders, cardiovascular diseases, and obesity [1]. Specifically, rhinitis is a condition that encompasses many different subtypes and is characterized by a set of nasal symptoms such as nasal congestion/obstruction, rhinorrhoea, sneezing, and nasal itching, resulting from inflammation and/or dysfunction of the nasal mucosa. There are three widely recognized subtypes of rhinitis: allergic rhinitis (AR), infectious rhinitis, non-allergic, non-infectious rhinitis (NAR) [2]. Allergic rhinitis is a type 1 IgE-mediated hypersensitivity reaction to a variety of inhaled environmental allergens, characterized by anterior or posterior rhinorrhoea, nasal congestion/blockage, nasal itching, and sneezing, occurring for more than one hour on two or more consecutive days [2-4]. Non-allergic rhinitis is a chronic rhinitis that occurs in the absence of clinical signs of endo-nasal infection and systemic allergic inflammation (i.e., negative skin prick tests – SPT, negative total serum IgE, and negative RAST tests) [2-5].

Viral rhinitis is the most common form of upper respiratory tract infection, and is usually caused by viruses rather than bacteria. The most frequent viral causes include rhinovirus, coronavirus, adenovirus, influenza virus, parainfluenza virus, respiratory syncytial virus, and enterovirus [2-6]. Currently, pharmacological therapies for these conditions include for allergic rhinitis: intranasal corticosteroids, second-generation oral antihistamines, intranasal antihistamines, and

intranasal cromones [2-7]. In case of non-allergic rhinitis: oral second generation antihistamines, intranasal corticosteroids, decongestants, anticholinergics and nasal saline [8]; and for viral rhinitis anti-inflammatory drugs, anti-viral molecules such as zanamivir or interferon-alpha [9,10]. In addition to the mentioned pharmacological treatment, topical treatment with specific device not containing active pharmaceutical ingredients could be an optimum therapeutic option in order to enhance the efficacy and reduce the dose of drugs and their side effects. In fact, not pharmacological treatments, in different therapeutic areas, often result in optimum efficacy together with high patient compliance [11]. Zenasinil® spray is a medical device indicated in the fluidification and removal of nasal secretions, especially in cases of nasal dryness. It is also an adjuvant for the removal of secretions by washout. Thanks to its actions, it helps prevent inflammation due to mucus accumulation and restore normal breathing conditions. Furthermore, the medical device may be useful as an adjunct in improving tubal ventilation.

The beneficial effects of Zenasinil® spray are due to its specific formulation based on a patented technology ARGINECID® with a synergetic action that moisturises the nasal mucosa and softens mucous secretions promoting their removal. The aim of the present study was to evaluate the effect of the administration of Zenasinil® spray in paediatric population with upper respiratory tract diseases.

Materials and Methods

Settings

The clinical survey has been conducted by an Italian paediatrician and is based on its clinical experience in patients taking Zenasinil® spray. The retrospective observational survey was conducted in accordance with the Standards of Good Clinical Practice of the European Union and the ethical principles expressed in the Declaration of Helsinki. Data were retrospectively collected in the period August 2023 – February 2024 by the paediatrician located in Lazio a region in the centre of Italy. Ethical approval was not necessary according to National Code on Clinical Trias declaration [12], because this data derives form a real life retrospective study. The aim of the present study was to evaluate the effect of Zenasinil® spray administration in patient with inflammatory upper respiratory tract conditions at T0 up to six months, performing therapeutic cycle of administration according to Zenasinil® spray instruction for use.

Study Population, Treatment and Evaluated Parameters

A specialist in paediatrics conducted a clinical evaluation beginning in August 2023, enrolling paediatric patients with defined upper respiratory tract diseases. Inclusion criteria included diagnoses such as rhinitis, nasopharyngitis, tracheitis, and persistent cough. A total of 23 paediatric patients met these criteria and were enrolled in the study, with a mean age of 6.7 years. At baseline, during the first medical examination, participants were assessed using the Canadian Acute Respiratory Infection and Flu Scale (CARIFS)-a validated 18-item questionnaire completed with parental assistance. The CARIFS covers three domains: symptom severity, functional impact on the child, and parental burden [13]. For the purpose of evaluating the potential effectiveness of the medical device under investigation, the following symptom items were considered of particular relevance: poor appetite, disturbed sleep, and nasal congestion. Each of these items was scored on a 4-point Likert scale ranging from 0 (no symptoms) to 3 (severe symptoms). Following this initial assessment, each patient was instructed to use Zenasinil® spray, a nasal medical device, as per the manufacturer's recommended posology: two sprays per nostril, three times daily. Participants were scheduled for a follow-up clinical visit six months after initiating treatment. At the six-month follow-up, patients were re-evaluated using the same CARIFS questionnaire to assess changes in symptomatology.

As before, the items were rated from 0 to 3, where higher scores indicated greater symptom severity. Some of participants also received concomitant pharmacological treatment, including anti-inflammatory agents, antihistamines, and had already used other decongestants before treatment with Zenasinil® spray. These co-treatments were administered based on individual clinical needs and physician discretion. About 80% of enrolled patients showed relapses in the last 3 months before the treatment with Zenasinil® spray.

Data and Statistical Analysis

Data were summarized as media +/- standard deviation

Results and Discussion

At the first visit (T0), about 87% of the enrolled children presented with yellow or greenish dense nasal secretions (Figure 1), typically associated with conditions such as rhinitis, nasopharyngitis, tracheitis, and cough. By the follow-up visit after 6 months (T6), most of the patients showed a significant improvement, with 70% of reduction from baseline with children no longer exhibiting dense secretions following treatment with Zenasinil® spray alone or in combination with conventional pharmacological treatments. The clinical improvements observed following treatment with Zenasinil® spray, confirm the mechanism of action established for the medical device: to effectively fluidify and dilute nasal mucus, facilitating its clearance and improving mucociliary function. In addition to nasal discharge, three other symptoms were closely monitored: nasal congestion; poor sleep quality and reduced appetite. These were assessed both in terms of how many children were affected and the severity of each symptom. Regarding nasal congestion (Figure 2) a notable shift was observed. At the initial visit (T0), none of the children were free from nasal congestion, but after the six month follow-up (T6), 74% reported no symptoms at all. Furthermore, cases of moderate and severe congestion lowered of about 75% and 80% (with respect to T0), respectively, with a mean reduction of nasal congestion score of 75% after Zenasinil® spray administration.

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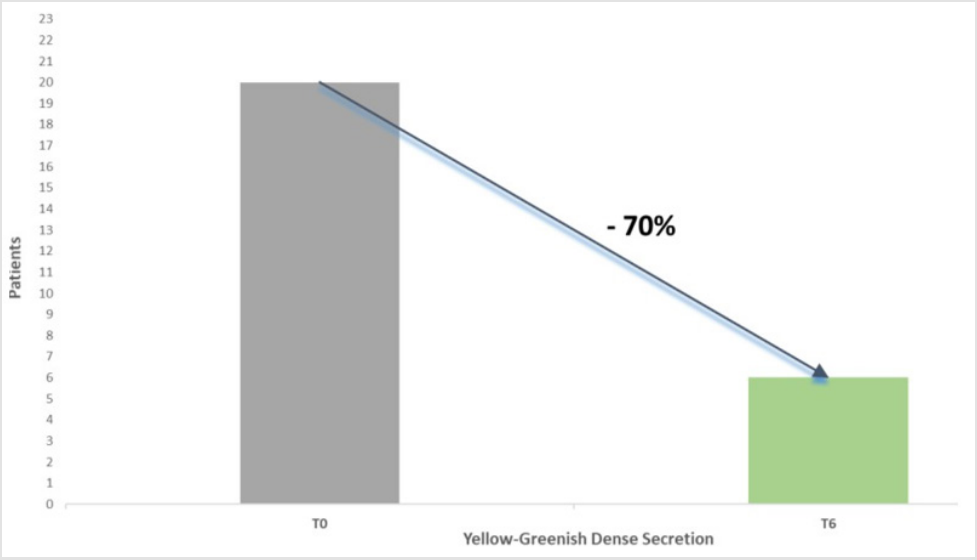

Figure 1: Number of patients with yellow or greenish dense secretions at T0 (grey) and after six month (T6) of the treatment with Zenasinil® spray (green).

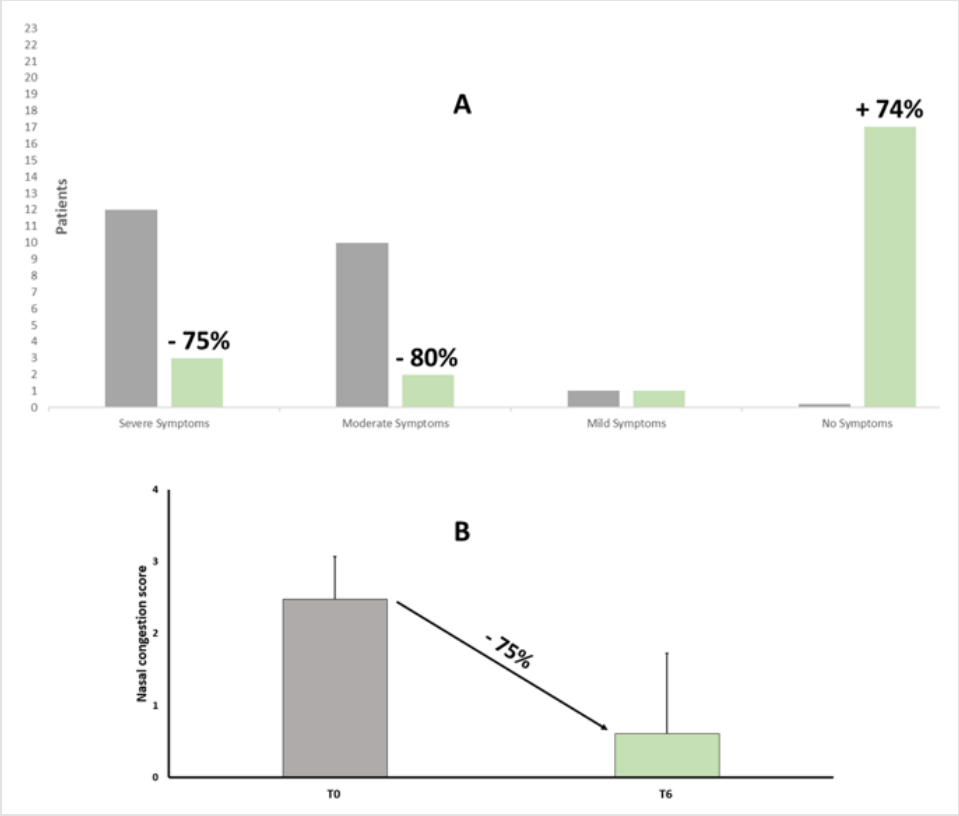

Figure 2: Distribution of symptoms rank for nasal congestion:

A. Severe, moderate, mild and no symptoms at T0 and T6: grey and green slash respectively.

B. Mean +/- standard deviation of nasal congestion score at T0 and T6.

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This aligns with Zenasinil® spray mechanism of action: it helps to reduce the viscosity of nasal mucus that is responsible of congestion supporting nasal drainage and preventing inflammation linked to mucus accumulation. This ultimately contributes to better breathing. Sleep quality also improved considerably (Figure 3). Initially (T0), 22% of the children had no issues with sleep, but after 6 months of using Zenasinil® spray alone and in combination with conventional pharmacological treatments, that number rose to 91%, showing a 69% improvement. Cases of severe sleep disturbances were totally reduced, while cases of mild and moderate sleep disturbances decreased by 80% and 84% respectively with respect to T0. A mean reduction of the insomnia score (as evidence of sleep quality) of 92% after Zenasinil® spray administration was recorded. These results again reflect the benefits of nasal fluidification, as improved airflow during the night is known to positively affect sleep, and nasal obstruction is frequently identified as a contributing factor to sleep- disordered breathing [14]. Appetite was the third key symptom evaluated. At baseline (T0), just over half of the children (52%) had no issues with appetite, but this percentage increased to 91% at T6-an improvement of 39%. Cases of moderate and severe appetite loss were totally reduced while cases of mild appetite loss also reduced by 67% with respect to T0, with a mean of reduction of loss of appetite score of 89% after Zenasinil® spray administration (Figure 4).

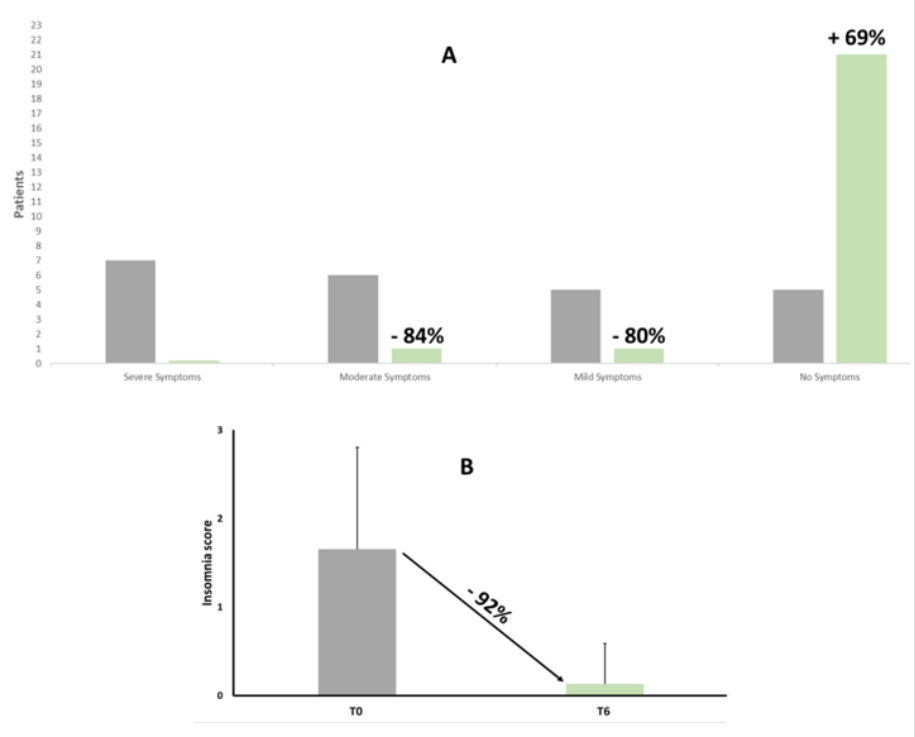

Figure 3: Distribution of symptoms rank for insomnia:

A. Severe, moderate, mild and no symptoms at T0 and T6: grey and green slash respectively.

B. Mean +/- standard deviation of insomnia at T0 and T6.

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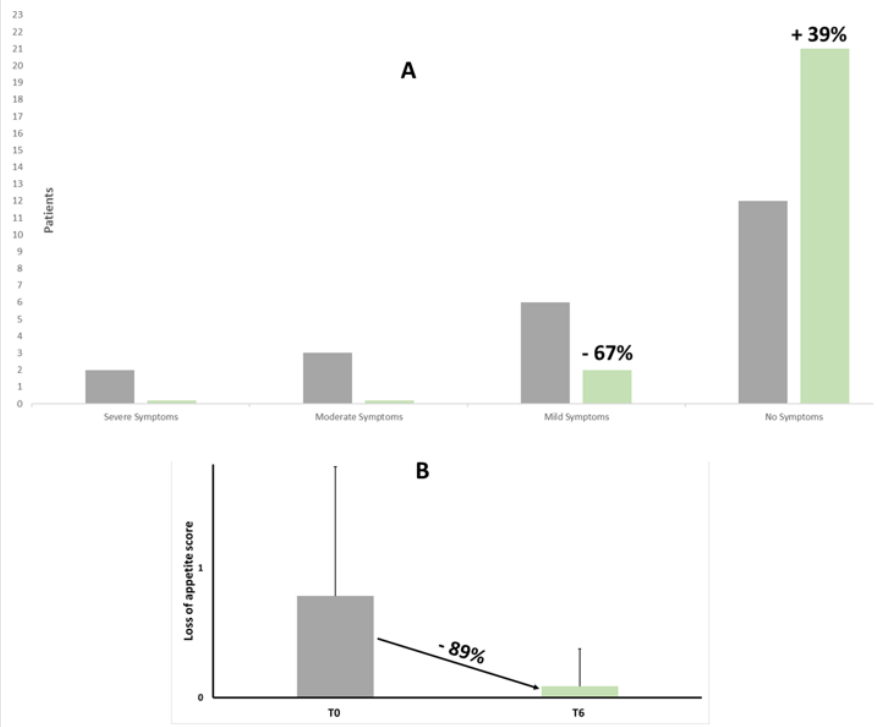

Figure 4: Distribution of symptoms rank for loss of appetite:
A. Severe, moderate, mild and no symptoms at T0 and T6: grey and green slash respectively.
B. Mean +/- standard deviation of loss of appetite score score at T0 and T6.

This improvement is supported by research indicating a strong relationship between rhino-sinusitis and diminished olfactory or gustatory function, which can impair appetite and even lead to weight loss or malnutrition. By improving nasal airflow and helping to restore the sense of smell, Zenasinil® spray not only enhances the sensory experience of eating but also supports better nutrition and overall quality of life [15]. It's important to point out that for all treated patients no side effects and drop out were detected indicating an optimum safety profile for Zenasinil® spray. The observed effect in this retrospective clinical survey are related with the components of the patented technology of Zenasinil® spray; in fact, high molecular weight hyaluronic acid, due to its highly polymeric and hygroscopic nature, attracts water within the nasal cavities, thereby improving mucus viscosity and facilitating its elimination [16-18]. At the same time, bioactive metabolites from Iceland moss (Cetraria islandica), bind to mucus mucins, promoting their removal along with external irritants such as dust particles and allergens [19]. Finally, the optimized Zenasinil® spray formulation, thanks to the synergistic effect of its ingredients, actively contribute in reducing symptomatology in upper respiratory tract disease also in association with conventional pharmacological drugs.

Conclusion

The present retrospective clinical survey was conducted to evaluate the effect with the use of Zenasinil® spray alone or in combination with conventional treatments in a paediatric population. Results demonstrated a marked reduction in symptoms such as dense nasal secretions, nasal congestion, poor appetite, and sleep disturbances among 23 children diagnosed with different upper respiratory tract conditions such as rhinitis, nasopharyngitis, tracheitis, and cough. Following the treatment, an increased number of children were free from these symptoms, indicating a clear clinical improvement. The data support the efficacy, safety, and ease of use of the Zenasinil® spray in paediatric patients experiencing nasal congestion and associated upper respiratory symptoms. Controlled and randomized clinical trials with a wide range of population evaluated are necessary to confirm the interesting results reported in this retrospective survey and to recommend Zenasinil® spray as an adjuvant treatment in upper respiratory tract disorders.

Conflicts of Interest

We declare that Umberto Di Maio is a Shedir Pharma Group member, Antonino Bagnulo, Maria Potenza and Andrea Cerciello are Neilos S.r.l. members.

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Authors' Contributions

All authors contributed equally to the manuscript and read and approved the final version of the manuscript.

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