THE EFFECT OF OXY BUMP® OXYGEN NASAL SPRAY ON REDUCING ALLERGY SYMPTOMS

A controlled, crossover clinical trial

ABSTRACT

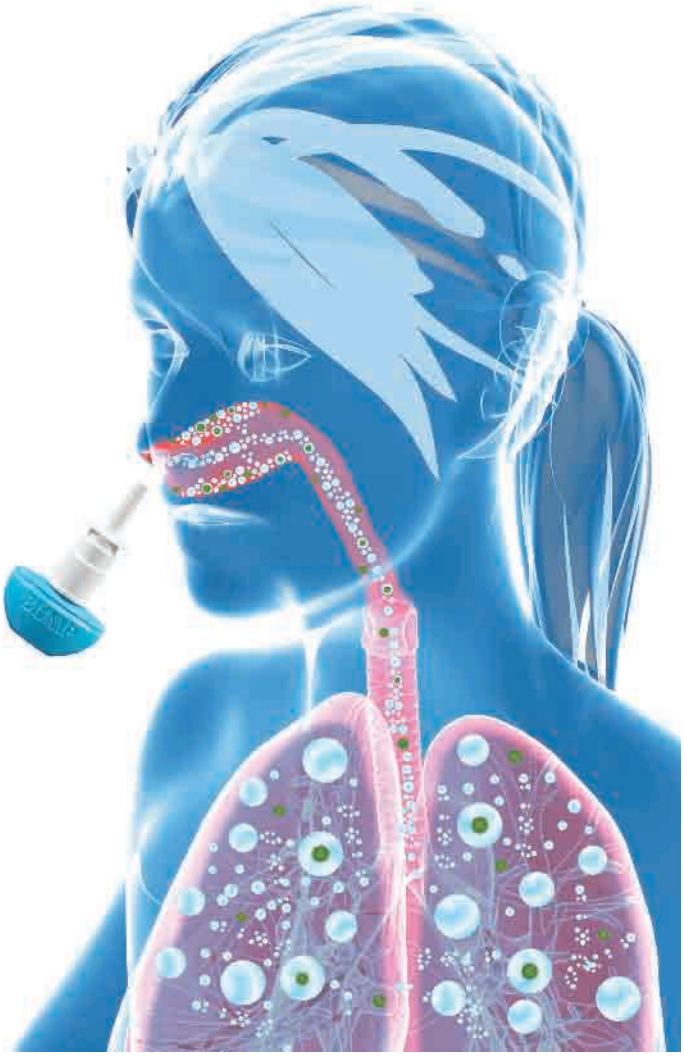
The objective of the study was to determine whether Oxy Bump® Oxygen Nasal Spray reduces nasal provocation and other allergy-related symptoms after exposure to a standardized allergenic challenge. When allergens reach the nose and sinuses, they trigger a cascade of effects including inflammation, runny nose, sneezing, itching eyes, etc. The Oxy Bump® Oxygen Nasal Spray uses oxygenated saline to reduce these effects by washing away the allergens and improving mucociliary function with an increased ciliary beat frequency. In conclusion, the Oxy Bump® Oxygen Nasal Spray provides fast and efficient relief of allergic rhinitis symptoms caused by the most common outdoor and indoor allergens.

BACKGROUND

Allergic rhinitis is considered as the most common type of rhinitis or the inflammation of the nasal mucosa [1]. Individuals with allergic rhinitis may exhibit many symptoms including stuffy and runny nose, sneezing, red, itchy, and watery eyes. Isotonic saline solutions for nasal irrigation have been described to be a simple, safe, and inexpensive treatment for allergic rhinitis, and were observed to attenuate nasal symptoms, enhance mucocilliary clearance time and improve quality of life [2]. Saline nasal irrigation may improve nasal mucosa function through several physiologic effects, including direct cleansing; removal of inflammatory mediators; and improved mucociliary function, as suggested by increased ciliary beat frequency [3]. Based on biochemical properties of oxygen, the stabilized oxygen supplement may be an effective bronchodilator, antibacterial, antioxidant, immune system booster, and detoxification agent through several mechanisms, among them enhanced respiratory gas exchange and carbon-dioxide release.[4]

STUDY PURPOSE

The purpose of the clinical study was to determine the efficacy of Oxy Bump® Oxygen Nasal Spray in improving allergic rhinitis and other allergy symptoms after exposure to common allergens. The study was done by an independent, third-party research organization.



Allergen Oxy Bump®

STUDY PRODUCT

The investigational study product for this trial was Oxy Bump® Oxygen Nasal Spray, a supplement spray containing a proprietary oxygen saline formulation made from natural ingredients with a neutral pH. An aerosolized allergen was used to create a standardized allergen exposure and was composed of a mix of tree pollen, grass pollen, dust mites, cat dander, and dog dander, sprayed twice in each nostril.

PNIF Meter

SUBJECTS

Subjects in this study were generally healthy individuals who complained of occasional environmental allergy symptoms. They were required to document a normal baseline nasal airflow (PNIF) level and also to demonstrate that when they were exposed to the standardized allergen they showed a significant reduction in nasal airflow.

CLINICAL TRIAL DESIGN

This was a controlled, crossover study. Subjects had their nasal airflow measured via PNIF. The PNIF (Peak Nasal Inspiratory Flow) measures the volume of nasal airway capacity by breathing through the PNIF Meter (Fig. above). Nasal Symptoms were measured by dedicated VAS (Visual Analog Scale) with symptom specific questions. For each visit, PNIF and Nasal Symptom VAS were assessed as a baseline control. Then the allergen was sprayed in each nostril followed by 2 sprays of Oxy Bump® after 5 minutes. PNIF and VAS data were collected again after 15, 30, 60 and 120 minutes.

STUDY RESULTS

KEY FINDINGS

Solid statistical significance has been observed in several endpoints by comparing the baseline visit (the no-treatment control visit) to the various treatment visits. This is meaningful both from the standpoint of potential product efficacy, but also because the limited sample size makes the achievement of statistical significance even more impressive. The following endpoints reached statistical significance when compared to the control (baseline) visit. Statistical significance is set at a p value <=0.05.

> Nasal Airflow increased by 60.73% during the first 30 minutes of the allergen challenge
> Nasal congestion, rhinorrhea, and itching eyes were significantly reduced

INCREASED BREATHING CAPACITY

Compared to control (without using Oxy Bump® Oxygen Nasal Spray) the Nasal Airflow Evaluation (PNIF) results show a significant increase in the airflow allowing participants to breathe better when they use Oxy Bump®.

Between 0 to 30 minutes, the increase of nasal airflow when using Oxy Bump® reached an impressive 60.73%, this means that the Oxy Bump® Oxygen Nasal Spray **allowed participants to breathe 60.73% better.** [p=0.010] (Fig.1)

Between 0 to 120 min a **26.68% increase in the nasal airflow** was measured showing the consistency of Oxy Bump® effect on nasal airflow. [p=0.019]

The area under the curve (AUC) illustrates that during the entire allergen challenge, **the effect of the product on nasal airflow was 30.13% greater.** [p=0.013]

Fig. 1

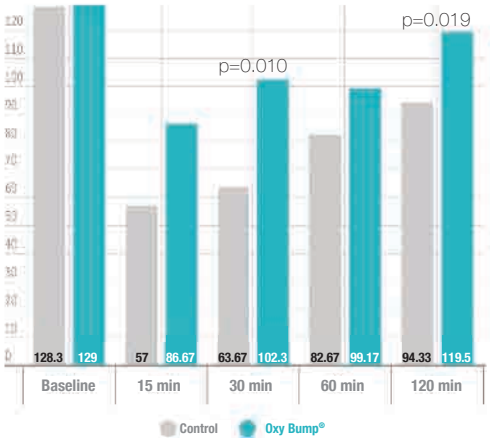
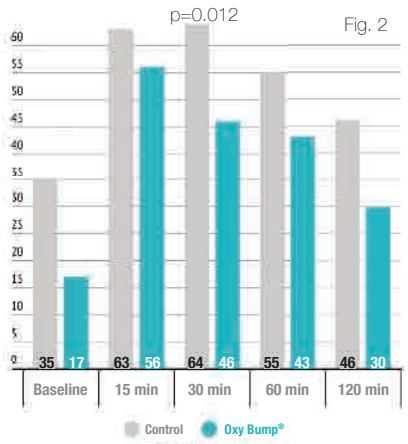


Fig. 2



REDUCED NASAL & SINUS SYMPTOMS

When subjects used Oxy Bump® Oxygen Nasal Spray, they had significant reduction in Nasal Congestion, Rhinorrhea and Itchy Eyes.

NASAL CONGESTION (Stuffy Nose)

According to the participants' answers to the VAS (questionnaire on a scale of 0=none to 100=severe), the nasal congestion symptom intensity was **reduced by 28.13% between 0 and 30 minutes**, compared to the control. [p=0.012] (Fig. 2)

The area under the curve (AUC) shows that through the entire allergen challenge, Oxy Bump® **reduced nasal congestion by 24.78%.** [p=0.024]

ITCHY EYES

Through the entire allergen challenge, Oxy Bump® **reduced itchy eye symptoms by 27.01%.** [p=0.039] (Fig.4)

Fig. 4

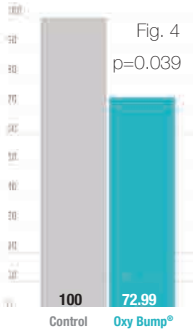
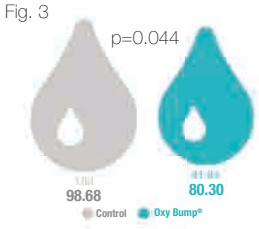


Fig. 3



RHINORRHEA (Runny Nose)

In total, Oxy Bump® **improved by 18.62% rhinorrhea symptom** as shown in the area under the curve (AUC) results. [p=0.044] (Fig.3)

CONCLUSION

This study demonstrates that the Oxy Bump® Oxygen Nasal Spray significantly reduces the amount of allergen induced nasal airway blockage, runny nose, and itchy eyes.

REFERENCES

[1] Small, P. and H. Kim, Allergic rhinitis. Allergy Asthma Clin Immunol, 2011. 7 Suppl 1: p. S3.
[2] Hermelingmeier, K.E., et al., Nasal irrigation as an adjunctive treatment in allergic rhinitis: a systematic review and meta-analysis. Am J Rhinol Allergy, 2012. 26(5).
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[4]: McCabe Ed: Flood Your Body With Oxygen, Therapy for Our Polluted World. Energy Publications, Miami Shores, FL, 2003.