



Impact of a Novel Nasal Cleansing Kit on Relief of Allergy Symptoms

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ABSTRACT

Background: The World Health Organization has reported that 40% of the world's population is sensitized to foreign particles in the air, with 10-30% suffering from allergic rhinitis¹. Yet, a universal method for routine nasal hygiene has not been adopted. This study examined the impact of an antiseptic nasal cleansing kit (NasoClenz[®]) in patients with chronic allergy symptoms.

Methods: Following informed consent, nasal, respiratory and other symptoms were examined in 30 patients. An antiseptic nasal cleansing kit was used twice daily for two weeks. A modified RCAT-survey was administered before and after the two week period. Nasal cultures were obtained from a subset of 9 patients before and after the study period*.

Results: At baseline, (15/20) 75% of patients reported exposure to allergens in their daily life with (19/20) 95% of patients reporting respiratory and allergy symptoms. Nasal and allergy symptoms that impacted home and work life were reported in 65% and 60% respectively. After the two-week routine use of the nasal cleansing kits, 84% of subjects with severe symptoms reported a reduction, and 58% reported a reduction in allergy symptoms that impact work & home life. Frequent coughing and/or shortness of breath was decreased in 71% of symptomatic patients. Before the study, 44% of the nasal cultures tested positive for mold. After two weeks of twice daily nasal cleansing, mold was eliminated in 50% of those subjects*.

Conclusion: In this group of symptomatic chronic allergy patients, routine use of a novel nasal cleansing kit (NasoClenz[®]) led to a marked reduction in allergy symptoms with a majority of patients reporting improvement in symptoms that had previously impacted their daily work and home life.

*These culture results have been previously reported in a separate study

METHODS & MATERIALS

Following informed consent, a total of 30 agricultural workers volunteered to use a novel nasal cleansing kit twice daily for a period of two weeks. The NasoClenz® kit (Silicon Valley Innovations, Sunnyvale, CA) includes an applicator and proprietary antiseptic gel with (0.13%) benzalkonium chloride as the active ingredient (shown in **Figures 1A & 1B**). All instructions were provided by a nurse (in English and/or Spanish) on how to use the product in a twice daily regimen. A modified RCAT-survey was administered prior to beginning the daily protocol. Patients were instructed to cleanse the nostrils morning and evening for a two-week period of time. Following the treatment period, the survey was administered once again. Patients were also instructed on how to complete both the pre and post-treatment surveys.



Figure 1A: The NasoClenz® kit includes an anatomically designed applicator made from medical grade elastomer that is soft and flexible. A proprietary gel formulation contains an antimicrobial for cleansing as well as emollients for moisturizing the nasal tissues. Used together, the kit cleanses and moisturizes the skin and hair inside the nostrils.



Figure 1B: The applicator is anatomically designed to comfortably fit a variety of nostril sizes as it flexes while being gently inserted into the nostril after a small amount of gel is applied. The applicator is then rotated to distribute the gel onto the skin and hair inside the nostrils providing a gentle method of debridement to address airborne particulate matter and intranasal crusting.

RESULTS

Table 4: A total of 20/30 (66%) of patient volunteers completed the two week protocol and all surveys, while 33% did not complete the final survey.

Table 4

% Participants	Survey Responses Regarding Cleansing Kit
70% (14/20)	Indicated this was an innovative solution & had a positive experience
80% (16/20)	Noted the cleansing kit was easy to use
65% (13/20)	Really liked/loved the cleansing kit
100% (20/20)	Felt using the gel & applicator was comfortable
55% (11/20)	Reported the kit helped keep the nose clean
95% (19/20)	Reported the gel was moisturizing for the nose
5% (1/20)	Did not like using the cleansing kit
95% (18/19)	Reported they would like to continue using this type of cleansing kit

RESULTS continued

Table 1		PRE TREATMENT
% of Subjects	Survey Results Reported (Pre-treatment)	
95% (19/20)	Respiratory problems/allergy symptoms	
75% (15/20)	Exposure to dust/allergens at work	
65% (13/20)	Frequent nasal symptoms (e.g. dry crusty nose/congestion)	
60% (12/20)	Frequent allergy symptoms impacting work & home life	
35% (7/20)	Frequent coughing/shortness of breath impacting work & home life	

Table 1: Completed surveys from 20/30 participants indicated that 95% of patients in the study group suffer from respiratory problems and significant allergy symptoms. 75% indicated that they are exposed to allergens at work, and the majority had frequent nasal symptoms that impacted their work and home life. Additionally, at least 35% described frequent respiratory symptoms such as coughing or shortness of breath that impacted work and home life.

Table 2		POST TREATMENT
% of Subjects	Survey Results Reported (Post-treatment)	
70% (14/20)	Used cleansing kit at least every other day or more	
95% (19/20)	Reported the gel was moisturizing	
10% (2/20)	Frequent nasal symptoms (e.g. dry crusty nose/congestion)	
25% (5/20)	Frequent allergy symptoms impacting work & home life	
10% (2/20)	Frequent coughing/shortness of breath impacting work & home life	

Table 2: Following a two-week period of twice-daily use of the NasoClenz kit, this same group of patients completed the same survey. 70% of volunteers used the kit at least every other day or more even though the protocol called for twice-daily use. 95% found the gel to be moisturizing and there was a marked reduction in the frequent nasal, respiratory and allergy symptoms that they experienced.

Table 3		COMPARISON OF PRE & POST TREATMENT
% Reported Reduction Of Symptoms		
84% (65% to 10%)	Reduction of frequent nasal symptoms (e.g. dry crusty nose/congestion)	
58% (60% to 25%)	Reduction of frequent allergy symptoms impacting work & home life	
71% (35% to 10%)	Reduction of frequent coughing/shortness of breath impacting work & home life	

Table 3: This table illustrates the comparison of the pre-treatment survey results versus the post-treatment results. Participants noted a marked reduction (84%) in their frequent nasal symptoms. Similarly, the majority (58%) reported a reduction of frequent allergy symptoms impacting their work and home life and interestingly, 71% noted a reduction in respiratory symptoms such as coughing and shortness of breath.

CONCLUSIONS & COMMENTS

This study evaluated use of a novel nasal cleansing kit for debridement and moisturizing of the nostrils. Allergic rhinitis is a growing healthcare concern for more than 50 million people in the US. The enormity of this area of medicine results in significant medical and economic impacts around the world. Evidence suggests that environmental exposure to deteriorating air quality and allergens from various sources such as seasonal pollens, wildfires, and smog (organic toxins) is causing increasing incidence and concern. This is supported by the recent report in *Frontiers in Public Health*.² Inflammation in the nose occurs after exposure to these types of particles, yet novel approaches to controlling the instigation of allergic symptoms is a compelling and long overdue area for innovation.

The role of the nose as a central player in allergies is obvious with a constellation of clinical symptoms including runny itchy noses, chronic sinusitis, chronic rhinitis, nasal crusting, dry irritated nasal membranes and upper respiratory symptoms that are classic³. These symptoms are a direct result of the inflammatory response that is triggered by exposure to various allergens or particles breathed into the nose.

We hypothesized that cleansing the skin and hair inside the nostrils could potentially help to alleviate allergy symptoms thus decreasing the classic clinical constellation of symptoms. In this study we used an innovative method for cleaning the nasal passages of agricultural workers. The reported data show a marked decrease in nasal allergen related symptoms as well as upper respiratory symptoms such as coughing and/or shortness of breath. While these results are promising, further investigation with a larger cohort of participants over an extended period of time would be useful.

	Patient Survey Responses
70% Participants	Indicated the cleansing kit was an innovative solution & provided a positive experience
100% Participants	Reported that using the gel & applicator was comfortable
84% (pre vs post)	Reduction of frequent nasal symptoms (e.g. dry crusty nose and/or congestion)
71% (pre vs post)	Reduction of frequent coughing/shortness of breath impacting work & home life
58% (pre vs post)	Reduction of frequent allergy symptoms impacting work & home life

From these data, we conclude that routine, intranasal cleansing with a comfortable antiseptic kit is worthy of additional study as a potentially cost-effective, low-risk method for relief of allergy symptoms.

REFERENCES

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DISCLOSURES

Dr. Arman Kalamkarian is on the Clinical Advisory Board of Silicon Valley Innovations, Inc.

Dr. Keith Matheny is on the Clinical Advisory Board of Silicon Valley Innovations, and has an ownership position in Collin County ENT, Sleep Vigil and Septum Solutions.

Tiffany Young, RN is a clinical consultant for Silicon Valley Innovations, Inc.