

A Novel Method For Improving Compliance in Patients Using Continuous Positive Airway Pressure (CPAP) During Sleep

¹Keith Matheny, MD, FARS, ¹Ewen Tseng, MD, FACS, ¹Kenny Carter, MD, ¹Megan Matheny, and ²Tiffany Young, RN
¹Collin County ENT, Frisco, Texas Baylor University, Waco, Texas, and ²Northwest Arkansas Surgery Center, Fayetteville, Arkansas

ABSTRACT

Background: Obstructive sleep apnea (OSA) is associated with stroke, hypertension, cardiovascular disease and diabetes. It is estimated to affect ~200 million people worldwide. Continuous positive airway pressure (CPAP) during sleep has proven benefits; however, long term compliance is poor - often as low as 40%. Nasal discomfort, dryness and crusting are commonly reported by patients as reasons for poor compliance. We examined a novel method to decolonize and moisturize the nares in order to help improve CPAP compliance.

Methods: Following informed consent, a total of **26 CPAP** patients completed a baseline survey. They were then instructed on use of a pre-packaged, antiseptic nasal cleansing kit (NasoClenz) for use before and after CPAP. After two weeks of twice-daily cleansing, patients completed a second survey regarding CPAP comfort and compliance. A total of 52 surveys were completed in this data set. Nasal cultures were obtained from a small subset of patients before and after the intervention.

Results: **58%** of patients reported that the kit made CPAP more comfortable and increased their daily compliance with CPAP. **73%** reported an overall positive experience, and **81%** stated it would be beneficial to use this method on a routine basis. In the subset of patients cultured before the study, **50%** were colonized with antibiotic-resistant bacteria. In these patients, **66%** experienced a reduction or elimination in the bacterial growth following the intervention.

Conclusions: Nasal discomfort, dryness and crusting are common complaints leading to poor compliance with CPAP users. This novel method of nasal cleansing shows improved comfort and potential for intranasal decolonization with resulting promise for improving compliance with CPAP.

METHODS & MATERIALS

Following informed consent, a total of 26 patients who have used CPAP for more than 1 year were enrolled in this study. Patients were instructed to complete a baseline survey that related to their current usage of CPAP including their main complaints and issues that contribute to poor compliance. They were then instructed on the use of a pre-packaged, antiseptic nasal cleansing kit (*Silicon Valley Innovations, Inc*) (**Figures 1A & 1B**). The protocol specified intranasal cleansing with the antiseptic kit before and after use of CPAP for a two-week period of time. After two weeks of twice daily cleansing, these same patients completed a second survey regarding the impact of nasal cleansing on CPAP comfort and compliance. A total of 52 surveys were completed. Additional preliminary *in vitro* and *in vivo* antimicrobial studies were also completed during the course of this study.



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 & 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.

SURVEY RESULTS & CONCLUSIONS

Table 1

DEMOGRAPHICS	
26 Patients	17 Male, 9 Female
Age	Mean = 53
Years CPAP Usage	Mean = 4.5
Smoking History	None

Table 1: In this study, a total of 52 survey forms were completed by the 26 patients who participated. Demographics of this patient cohort are consistent with other studies that often show a larger percentage of male subjects. Similarly, the mean age was 53 years – consistent with the national average (55) as reported by US Center for Medicare & Medicaid Services (7/17/2020). The average length of time these patients had used CPAP was 4.5 years which may account for the above-average baseline compliance of 77%. There were no patients with a history of smoking in this group of subjects.

Table 2

% Participants	Baseline Survey Responses
23% (6/26)	Frequently skip wearing CPAP due to discomfort
35% (9/26)	Frequently have sleep disrupted due to CPAP use
58% (15/26)	Frequently experience nasal congestion, dryness or crusty buildup

Table 2: Baseline surveys indicate that compliance in this group of patients was good in the majority of patients with only 23% noting that they skip wearing their CPAP frequently due to discomfort. 35% noted sleep disruption due to CPAP use which is counter-productive, since the intent of CPAP is to improve sleep in these patients. The majority (58%) experience nasal symptoms including congestion, dryness & crusty buildup.

Table 3

% Participants	Post-Treatment Survey Responses
58% (15/26)	CPAP usage was better, specifically more comfortable
73% (19/26)	Noted overall positive experience using the cleansing kits
81% (21/26)	Reported NasoClenz kits are beneficial when used routinely with CPAP

Table 3: Post-treatment surveys indicate that the majority of patients (58%) reported an improvement of CPAP usage (specifically improved comfort) with use of the NasoClenz antiseptic kits before and after CPAP. 73% reported an overall positive experience using the kits, and 81% reported that the kits are beneficial when used routinely with CPAP.

ANTIMICROBIAL GEL TESTING

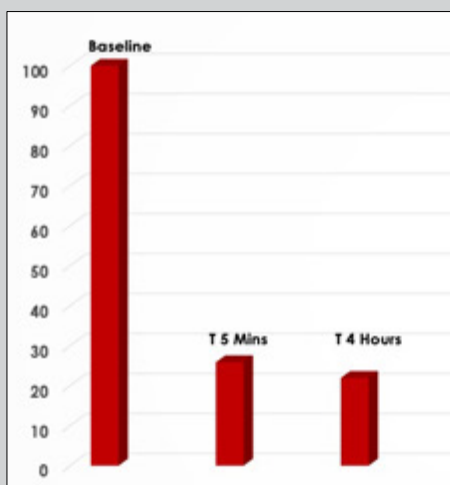


Figure 2 (left):

In a separate *in vivo* evaluation of the antiseptic gel (pending publication), a total of 54 test swabs were tested from 9 volunteer test subjects. The protocol was as follows:

- Each nostril was cultured for baseline bacterial count
 - Each nostril was then cleaned using the NasoClenz kit
 - At T 5 minutes and T 4 hours following a single cleansing, each nostril was cultured again
- Results showed an average of 74% reduction in bacterial colony forming units (CFU) after a single nasal cleansing
 - The antiseptic gel appears to continue to abate bacterial growth at 4 hours post cleansing

ANTIMICROBIAL GEL TESTING continued

Table 4

Table 4: Abbreviated <i>In vitro</i> bacterial kill times for sample organisms		
99.9% Reduction of Organism at 1 minute	99.9% Reduction of Organism at 2 minutes	99.9% Reduction of Organism at 5 minutes (see exceptions below)*
Bacteroides fragilis (ATCC 25285) (anaerobic)	Candida albicans (ATCC 10231)	Enterococcus faecalis (ATCC 29212)
Escherichia coli (ATCC 25922)	Enterobacter cloacae (ATCC 13047)	Enterococcus faecium (ATCC 8459)
Haemophilus influenza (CO2)	Escherichia coli (ATCC 11775)	Enterococcus faecalis (ATCC 19433) *99%
Klebsiella pneumoniae (ATCC 13883)	Klebsiella pneumoniae (ATCC 27736)	MRSA- Methicillin Resistant Staphylococcus aureus (ATCC 33592) *94.6%
Listeria monocytogenes (ATCC 7644)	Listeria monocytogenes (ATCC 19115)	Proteus mirabilis (ATCC 12453)
Staphylococcus haemolyticus (ATCC 29970)	Salmonella typhimurium (ATCC 14028)	Serratia marcescens (ATCC 14756)
Staphylococcus saprophyticus (ATCC 15305)	Staphylococcus epidermidis (ATCC 12228)	Staphylococcus aureus (ATCC 29213)
Streptococcus pneumoniae (ATCC 49619) (CO2)	Streptococcus pyogenes (ATCC 19615)	Staphylococcus aureus (ATCC 6538)
Streptococcus pyogenes (ATCC 14289)		

Table 4: *In vitro* testing of the NasoClenz antiseptic gel shows a broad spectrum of antimicrobial efficacy. The active agent (*benzalkonium chloride - BZK*) is a well-characterized agent used in numerous OTC products, cosmetics and household items as an antimicrobial and/or preservative depending upon concentration. In contrast to antibiotics, BZK is classified as a quaternary ammonium compound known to kill bacteria, viruses and mold via a mechanism of action similar to saponification. In some cases, use of topical BZK may potentially provide an advantage over the use of antibiotics since microbial resistance would not be anticipated. Further investigation in various clinical settings is warranted.

CONCLUSIONS

This initial study using the NasoClenz antiseptic and moisturizing kit before and after CPAP indicates a potential benefit for improving compliance and the overall CPAP experience in the majority (**81%**) of patients. Further studies to determine the degree of improved compliance is warranted and could conceivably integrate digital sleep monitoring for quantitative measurement of CPAP usage and quality/quantity of sleep. Further defining the antimicrobial impact of these cleansing kits would also be beneficial, particularly for those patients preparing for invasive nasal procedures or surgery.

This novel method of nasal cleansing & moisturizing provides a low-risk, comfortable and convenient method for improving CPAP compliance and may provide additional benefits for other patient populations as well.

DISCLOSURES:

Dr. Keith Matheny is Founder & Chairman: US ENT, Septum Solutions, Otologic Solutions & Sleep Vigil. He is a Consultant & Clinical Advisor: Intersect ENT/Medtronic & Silicon Valley Innovations, Inc. He serves on the Medical Advisory Board: SomnoMed