



Research Paper

Identification of microbial contaminants in sinus rinse squeeze bottles used by allergic rhinitis patients

Shaun A. Nguyen ^{a,*}, Marc P. Camilon ^a, Rodney J. Schlosser ^{a,b}

^a Medical University of South Carolina, Department of Otolaryngology, Head & Neck Surgery, Charleston, SC, USA

^b Ralph H. Johnson VA Medical Center, Charleston, SC, USA

Received 26 August 2018; received in revised form 27 November 2018; accepted 3 December 2018
Available online 5 January 2019

KEYWORDS

Allergic rhinitis;
Microbial
contaminants;
Sinus irrigation;
Sinus rinse;
Squeeze bottles

Abstract Objective: To identify whether irrigation devices become contaminated when used by patients with allergic rhinitis (AR).

Methods: Ten AR patients with no clinical or endoscopic evidence of active sinonasal infection were given a sinus rinse system and instructed on its proper use, cleaning, and storage. Two squeeze bottles (bottle A and bottle B) were given to each patient for twice-a-day rinsing. Bottle A was used in the morning and analyzed after four weeks. Bottle B was used in the evening and analyzed after 8 weeks of use. Microbial contaminants were cultured from the nose pieces and the inner surface of the bottles obtained from patients.

Results: Seventeen sinus rinse devices (17/20) from all individuals in this study grew bacteria commonly in the nozzles. Twenty-four bacterial isolates consisting of 14 different species were cultured and identified with most common organisms being bacilli and staphylococcus. In addition, no correlation was apparent between the length of bottle use and the degree of contamination ($r = 0.13$, $p = 0.76$). During the study period, no patient developed acute sinus infections.

Conclusion: Microbial contamination of the sinus rinse system occurs commonly, even in uninfected AR patients; however no evidence exists linking this to clinically relevant sinus infections.

Trial Registration: clinicaltrials.gov Identifier: NCT01030146.

* Corresponding author.

E-mail address: nguyensh@musc.edu (S.A. Nguyen).

Peer review under responsibility of Chinese Medical Association.



Production and Hosting by Elsevier on behalf of KeAi

Introduction

Large volume saline irrigation has demonstrated efficacy in patients with chronic rhinosinusitis (CRS) and allergic rhinitis (AR).^{1,2} It is generally well tolerated, however, some concerns have been raised regarding the potential for irrigation devices to become contaminated with bacteria and the possibility of causing or potentiating sinus infections. Prior studies examining contamination in CRS patients found that within 2 weeks of use, 25% of irrigation bottles demonstrated bacterial growth, often with virulent bacteria, such as *Pseudomonas*, however, absence of clinical infections in patients with culture positive bottles led them to conclude that contamination did not affect clinical outcomes.³ In contrast, Keen et al⁴ argued that contaminated bottles may be a source of bacteria in CRS patient sinus infections. They found that 97% of bottles used by CRS patients demonstrated bacterial growth and 51% of patients had concurrent sinonasal and bottle infection with *S. aureus*. In addition, it is well known that 75% of CRS patients are generally non-compliant with sterilization techniques and unique bottle designs to prevent reflux of irrigant back into the bottle do not decrease contamination.⁵ Thus the clinical relevance and the source of these bacteria is unclear. Given that many CRS patients have bacterial infections prior to beginning irrigations, we elected to examine patients without CRS, to determine if such contamination still occurred. The objective of the present study is to determine if contamination of irrigation devices occurs in patients with AR, and if the contamination is clinically relevant.

Methods

Study design and population

This was a prospective pilot study of 10 patients. The study was approved by the Office of Research Integrity at the Medical University of South Carolina (MUSC). MUSC IRB policies regarding informed consent and HIPAA were followed (HR #19154). Ten patients with AR as confirmed by the skin prick test (SPT) and on nasal steroids for at least one month were recruited for the study. Patients were asked to continue pharmacotherapy with nasal steroid along with low-pressure nasal irrigation with isotonic saline as an adjunctive therapy.

At the initial appointment, each patient was provided with two new sinus rinse bottles (NeilMed Pharmaceuticals, Santa Rosa, CA), labeled bottle A for morning use and bottle B for evening use. The patient was asked to return to the outpatient department at 4 weeks and at 8 weeks and thus were seen a total of three times during the study

period. The patient was given supplies and instructions on the use of low-pressure pump with isotonic saline to be performed twice-a-day for eight weeks. Each Patient was instructed to rinse the bottle with commercially bottled water followed by adding dishwashing liquid to the interior. Attach the cap and tube to the bottle; hold finger over the opening in the cap and shake the bottle vigorously. Squeeze the bottle hard to allow the soapy solution to clean the interior of the tube and cap. Empty out the bottle completely. Rinse the soap from the bottle, cap and tube thoroughly and place the items on a clean paper towel to dry. At the end of week 4, bottle A was collected and was exchanged for a new bottle. Culture testing (aerobes, anaerobes, and fungal) was done by swabbing the bottle and nose piece. At the end of week 8, bottle B was collected and similar culture testing was done.

Biostatistics

All graphs and data analyses were performed with SigmaPlot 12.5 and SigmaStat 3.5 (Systat Software, Inc., San Jose, CA). Subject information and demographic variables, such as age, ethnic group and gender, were described with summary statistics. Simple descriptive statistics such as frequency, mean, standard deviation, minimum, and maximum were calculated for all outcome variables.

Results

There were 10 patients in this study (6 females, 4 males) with a median age of 31 years (interquartile range, 22–51). Of the 10 patients, there were 6 Caucasians, 2 African Americans, and 2 Asians. All 10 patients completed the study with no missing appointment. Out of the 20 irrigation devices used (10 analyzed at week 4 and 10 analyzed at

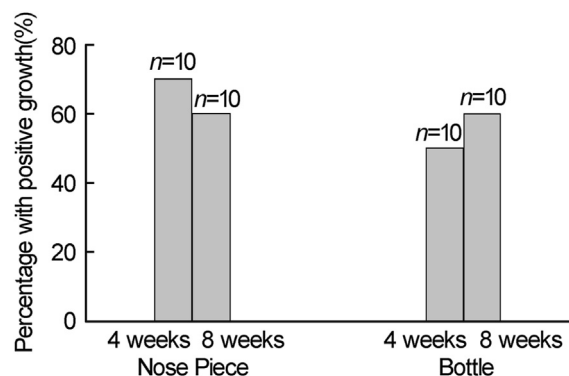


Fig. 1 Percentage with positive growth per nose piece and bottle at 4 and 8 weeks.

week 8), organisms were grown from 17 (85%). A total of 24 bacterial isolates with 14 different species were obtained from the nose pieces and bottles of the irrigation devices (Fig. 1). Yeast was obtained from one isolate. Of the 10 devices assessed at week 4, bacterial isolates were obtained from 9 (90%). This included 70% of nose pieces and 50% of bottles, specific organisms are detailed in Table 1. For devices analyzed at week 8, 80% were contaminated, including 60% of nose pieces and 60% of bottles (Table 1).

There was no significant correlation between the length of bottle use and the degree of contamination ($r = 0.13$, $p = 0.76$). None of the patients developed acute sinus infections during the study period.

Discussion

Our study demonstrates contamination of nasal irrigation devices used by patients with AR and no signs of acute or chronic rhinosinusitis. Of all irrigation devices used, 85% were found to be contaminated, including the majority of both nose pieces and bottles. Though a variety of organisms were cultured, the most common were bacilli and staphylococcus.

Our proportion of contamination agrees with CRS studies showing that the majority of devices used for nasal irrigation become contaminated with organisms. Keen et al⁴ assessed 11 patients with persistent CRS despite maximal medical treatment and sinus surgery who were already using nasal irrigation bottles. At every two weeks for six weeks, patients were given new bottles and their previous bottles were swabbed to test for contamination which yielded a sample of 43 bottles. They found that 42/43 (97%) of bottles demonstrated bacterial growth. Foreman et al⁵ tested 20 bottles that were used for 1 week without cleaning in patients with stable CRS who had not undergone surgery within 6 months prior to the study. Out of the 20 bottles, bacterial growth was

obtained from 19 (95%). In contrast, studies by Williams et al⁶ (29%), Welch et al³ (29%), and Lee et al⁷ (25%) all showed drastically lower rates of contamination. The low number of studies and differences in experiment methodology may account for the large range in contamination rate. The study conducted by Welch et al³ in particular may have had a low contamination rate due to the administration of antibiotics to all patients during the first 2 weeks of the study.

In previous studies of patients with CRS, *Staphylococcus aureus* and *Pseudomonas aeruginosa* were the most common bacteria isolated from the irrigation devices. The growth of these bacteria is not surprising with both commonly reported in the literature to be responsible for the majority of postoperative sinus infections.⁸ Keen et al⁴ demonstrated a contamination rate of 67% by *S. aureus* and 34% by *p. aeruginosa*. In contrast, there were very few cultures of *S. aureus* (1 of 20 bottles (5%)) from the bottles used by our patients with AR. Furthermore, *p. aeruginosa* was not cultured at all. *Coagulase Negative Staph (CNS)* was the most commonly cultured organism in this study (9 of 20 devices (45%)). It is unclear if this difference in species predominance is due to variations in potential colonizing bacteria in AR versus pathogenic bacteria in CRS.

Several studies suggest that duration of use is associated with an increase in contamination rate. Welch et al³ noted an increase from 25% contamination to 45% contamination from week 2 to week 4. However, as noted previously, patients were initially given antibiotics during the study period and there was a 45% patient dropout rate between weeks 2 and 4, which may have influenced their results. In the study by Williams et al,⁶ 6 bulb syringes were examined at weekly intervals for a total of 4 weeks. Although no bacterial contamination was noted after 7 d, bacteria were cultured at all other time points. Despite these supporting studies, Keen et al⁴ and Lewenza et al⁹ found that there was no significant correlation between contamination and

Table 1 Species of organism found in cultures of nasal irrigation devices after 4 and 8 weeks of use.

Species of organism	4 weeks		8 weeks	
	Nose pieces	Bottles	Nose pieces	Bottles
Coagulase Negative Staphylococcus	5	1	4	2
Acid fast bacilli		2		1
Corynebacterium	2		1	
Propionibacterium sp.	2		1	
Sphingobacterium sp.		1	1	1
Bacillus (not Anthracis)			1	1
Chryseobacteriumindologenes			1	1
Stenotrophomonas maltophilia		1	1	
Mycobacterium		1	1	
Yeast		1	1	
Alpha-hemolytic strep	1			
Cladosporium species				1
Methylobacterium				1
Staphylococcus aureus	1			
Sphingomonaspaucimobilis			1	

duration of use. Our data did not reveal any increase in contamination rate from 4 weeks to 8 weeks.

The clinical implications of device contamination remain unclear. The study by Welch et al³ did not show a correlation between the bacteria isolated from sinus and irrigation bottles. The absence of clinical infections in patients with culture-positive bottles led them to conclude that irrigation bottle contamination did not affect clinical outcomes. The studies by Keen et al⁴ and Foreman et al⁵ did not support this since *S. aureus* was cultured concurrently in the sino-nasal cavities and irrigation bottles of more than 80% of their patients. Furthermore, in the study by Keen et al,⁴ even after bottles were exchanged, growth of similar bacteria was seen in subsequent bottles, suggesting a dynamic transfer of bacteria between nose and bottle. These findings raise the possibility that contaminated irrigation bottles may prove to be a source of bacteria in post-operative sinus infections. Though all these studies were conducted with patients with CRS, it is possible that this transfer of bacteria occurs with devices used by AR patients as well. Given that none of our patients developed acute sinus infections, irrigation device contamination does not appear to have a significant effect on the outcomes of patients with AR and does not appear to be clinically relevant.

Review of the literature shows a clear need for future well-designed research to more closely examine aspects of bottle contamination in the use of treatment of patients with AR specifically. Future studies should include patient cultures in order to determine the source and direction of contamination. If the bacterial strains of a specific species are identified to be the same from both the patient and the bottle, then the evidence for bacterial recycling becomes definitive. If not, then it is entirely possible that environmental contamination may be occurring.

Limitations of this pilot study include the relatively small sample size, lack of patient cultures and varying severity of AR. The strengths of this study include a unique AR population without CRS, its prospective nature, no missing data, no drop-outs, and a diverse demographic of age and race. In addition, patients' adherence to standardized bottle sterilization techniques were not formally surveyed. On follow up patients were questioned if they felt comfortable cleaning their device.

In conclusion, our study demonstrates that contamination of nasal irrigation devices occurs in patients with AR. The organisms identified as contaminants are different from those more commonly seen in CRS and the irrigation devices of patients with CRS. No correlation between length of device use and degree of contamination was found. No adverse clinical effect due to the contamination was noted.

Declaration of interest

We declare that we have no financial and personal relationships with other people or organizations that can inappropriately influence our work, there is no professional or other personal interest of any nature or kind in any product, service and/or company that could be construed as influencing the content of this paper.

Acknowledgement

This study was funded by NeilMed® Pharmaceuticals, Inc., Santa Rosa, California, USA. They had no role in data collection, analysis or the writing of this manuscript.

References

1. Harvey R, Hannan SA, Badia L, Scadding G. Nasal saline irrigations for the symptoms of chronic rhinosinusitis. *Cochrane Database Syst Rev.* 2016 Apr 25;4:CD006394. <http://www.ncbi.nlm.nih.gov/pubmed/17636843>.
2. Hermelingmeier KE, Weber RK, Hellmich M, Heubach CP, Mösges R. Nasal irrigation as an adjunctive treatment in allergic rhinitis: a systematic review and meta-analysis. *Am J Rhinol Allergy.* 2012;26:e119–e125.
3. Welch KC, Cohen MB, Doghramji LL, et al. Clinical correlation between irrigation bottle contamination and clinical outcomes in post-functional endoscopic sinus surgery patients. *Am J Rhinol Allergy.* 2009;23:401–404. <http://www.ncbi.nlm.nih.gov/pubmed/19671255>.
4. Keen M, Foreman A, Wormald PJ. The clinical significance of nasal irrigation bottle contamination. *Laryngoscope.* 2010;120:2110–2114.
5. Foreman A, Wormald PJ. Can bottle design prevent bacterial contamination of nasal irrigation devices. *Int Forum Allergy Rhinol.* 2011;1:303–307. <http://www.ncbi.nlm.nih.gov/pubmed/22287436>.
6. Williams GB, Ross LL, Chandra RK. Are bulb syringe irrigators a potential source of bacterial contamination in chronic rhinosinusitis. *Am J Rhinol.* 2008;22:399–401. <http://www.ncbi.nlm.nih.gov/pubmed/18702905>.
7. Lee JM, Nayak JV, Doghramji LL, Welch KC, Chiu AG. Assessing the risk of irrigation bottle and fluid contamination after endoscopic sinus surgery. *Am J Rhinol Allergy.* 2010;24:197–199. <http://www.ncbi.nlm.nih.gov/pubmed/20537286>.
8. Brook I. Microbiology of sinusitis. *Proc Am Thorac Soc.* 2011;8:90–100.
9. Lewenza S, Charron-Mazenod L, Cho JJ, Mechor B. Identification of bacterial contaminants in sinus irrigation bottles from chronic rhinosinusitis patients. *J Otolaryngol Head Neck Surg.* 2010;39:458–463.