

A randomized controlled study comparing the efficacy of soap versus soap-plus-microwave disinfection for irrigation device in children with acute rhinosinusitis

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Abstract

Background: Nasal irrigation is an effective component of sino-nasal disease management. Nonetheless, bacterial contamination is worrisome.

Objective: To study bacterial colonization incidence using squeeze-bottle nasal irrigation devices, after disinfection with soap or soap-plus-microwave technique, in pediatric acute rhinosinusitis.

Methods: A randomized, prospective, controlled study was conducted on acute rhinosinusitis children, aged 2-15 years. Each participant was randomized into a soap-cleaning or soap-plus-microwave group. For a two-week period, participants irrigated their nostrils with NSS twice daily and cleaned the bottle after each use. In the end, bottles were sent to a microbiological laboratory for bacterial identification.

Results: The mean 5S Score and satisfaction score gradually improved in both groups with no significant differences between groups. Bacterial identification frequency in the soap group was slightly higher than in the soap-plus-microwave one, without statistical significance. For safety and tolerability, all participants reported 100% adherence to nasal irrigation. The soap-plus-microwave group reported more minor adverse outcomes than the soap-cleaning one. No thermal deformation of irrigation bottles was observed.

Conclusion: Regular cleaning of nasal irrigation devices is needed to minimize bacterial contamination. Only soap or soap plus microwave disinfection appeared simple and safe for disinfection. Both techniques can equally minimize the rate of bacterial contamination. Although no gross thermal deformation at optimal power and duration, chemical irritants after high power or long microwave durations may be a concern.

Key words: acute rhinosinusitis, bacterial contamination, microwave disinfection, nasal irrigation device, pediatric rhinosinusitis

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Introduction

Pediatric rhinosinusitis is common and sometimes diagnosed in children with an acute upper respiratory infection.¹⁻⁴ If inadequately treated, it can interfere with quality of life and cause serious complications. In the past, the main medication prescribed was antibiotics,^{1-3,5} However, the most current guideline⁶ suggests that acute rhinosinusitis be treated symptomatically, with antibiotic use limited to only severe cases. Adjunctive treatments such as antihistamines, decongestants, and nasal irrigation are often helpful.^{2,3,6}

Nasal irrigation is considered an effective component in the management of sino-nasal disease, with several studies reporting its benefits as an adjunctive treatment for acute and chronic rhinosinusitis.⁷⁻⁹ Nasal irrigation not only decreases nasal symptoms but also improves nasal peak expiratory flow rates and radiological findings.¹⁰⁻¹⁶ thus, improving sleep patterns and quality of life.¹³⁻¹⁶ Nonetheless, concerns over bacterial contamination in nasal irrigation devices persist. Studies have observed that bacterial colonization increases with the use of a nasal irrigation device over 1-2 weeks, with the reported prevalence of device contamination after a few weeks of use being 30-100%.¹⁷⁻²⁰ Interestingly, bacterial contamination was not associated with worse nasal symptoms in these studies.

Until now, there have been no controlled trials comparing the effectiveness of different methods to disinfect nasal irrigation devices as well as no information regarding the bacterial colonization within nasal saline irrigation devices in children with acute rhinosinusitis. Our aim was to study bacterial colonization incidence within squeeze-bottle nasal irrigation devices in a pediatric population with acute rhinosinusitis, comparing disinfection between only soap-cleansing and a soap-plus-microwave technique. We also evaluated the satisfaction of disinfection techniques among the children's guardians.

Materials and methods

Participants

Our prospective randomized controlled study included 50 children with acute rhinosinusitis, from 2 to 15 years of age. They were recruited from a pediatric outpatient department and the pediatric allergy clinic at Thammasat Hospital between February 2019 and January 2020. Approval for the study was granted by the ethics committee MTU -EC-PE-2-095/61, and the clinical trial registration number was TCTR 20190515004. Informed consent was obtained from all parents before the study. Inclusion criteria were (1) children 2 to 15 years old; and (2) presumptive diagnosis of acute bacterial rhinosinusitis, criteria of which included: persistent nasal discharge or cough for more than 10 days without improvement; new onset of nasal discharge, development of a cough or fever five to six days following initial improvement; or high fever and purulent nasal discharge for at least three days.¹⁻⁴ Children with a history of

penicillin allergy, nasal anatomical defects or paranasal sinus defects, abnormal nasal ciliary function, immunodeficiency, and/or having complications from sinusitis were excluded, as were participants with a compliance rate < 80%.

Study design

Participants were instructed to complete the case record form (in the form of a diary card), 5S Score,²¹ and a satisfaction score using a five-point pictorial scale. Guardians for children aged < 13 years filled out the satisfaction score, which ranged from 1 (unsatisfactory) to 5 (excellent). The 5S Score is a validated instrument developed specifically for evaluating sinus symptoms in pediatric patients. Symptoms include nasal obstruction, daytime or nighttime cough, headache or facial pain, and colored nasal discharge. These are graded on a four-point scale of 0 (absent) to 3 (severe).

A nasal examination was performed on everyone at their first visit. Block randomization divided the children into two treatment groups, according to a computer-generated list: 25 participants disinfected their nasal irrigation device with soap or dishwashing liquid, and the other 25 used a microwave technique after soap-cleaning. Our investigator was blinded to the disinfection method allocation. Amoxicillin-clavulanic 40 mg/kg/day was prescribed for those who had no risk of antibiotic resistance or amoxicillin-clavulanic acid 80 mg/kg/day (maximum 4 g/day) for those at risk. Risk factors included < 2 years of age, prior antibiotic use within the past month, prior hospitalization in the previous five days, having comorbidities, being immunocompromised, or attending nursery school/day care.

Participants were allowed to continue all previous medications or adjunctive medications such as antihistamines and decongestants. All were instructed to irrigate their nostrils with NSS twice daily, for a period of two weeks. Participants and their guardians were told to clean their devices after use and record daily symptoms on the diary card. They were also evaluated for their tolerability, adverse events, and frequency of use of adjunctive medications. At the two-week follow-up, nasal evaluation was repeated, and the 5S Score, satisfaction score, and adverse events were reported. The nasal irrigation device was then sent to a microbiological laboratory for bacterial identification.

Nasal irrigation

The same nurse instructed everyone about the irrigation technique. Each participant was told to use a new squeeze-bottle nasal irrigation device (EEZNIS™) with NSS (composition: sodium chloride 2.16 gm in boiled water 240 ml) as irrigation fluid. EEZNIS™ is made of high-density polyethylene, which is food-safe. It is also relatively hard and can withstand somewhat higher temperatures such as 120°C/248°F for short periods of time. Nasal irrigation was performed until no further nasal discharge or the maximum irrigated solution (240 ml) was used up, twice daily.

Decontamination of nasal irrigation device

Participants were told to clean nasal irrigation devices twice daily. For the soap-only technique, the device was washed with soap or dishwashing liquid, rinsed with water, and then airdried after each use. For the soap-plus-microwave technique, the device was placed in a microwave oven at medium to high power (600-800 W) for two minutes after performing soap-cleaning; the soap-cleaning instructions were the same as the soap-only group. To minimize the risk of contamination, we provided patients with a zipper/Ziplock bag for collecting the device; the devices were kept in a 4°C refrigerator and were incubated within 24 hours.

Colonization of nasal irrigation devices

Nasal irrigation devices from each group were collected, and the nozzles and mouths of the squeeze bottles were swabbed. After swabbing, 2 ml of tryptic soy broth was added into the reservoir and swirled gently before collected 100 µl of sample for bacterial culture, per standard method. The bacteria were differentiated by morphology and preliminarily identified by the standard biochemical test for gram-positive and gram-negative bacteria then confirmed by MALDI TOF (Bruker, Switzerland).

Statistical analysis

Data were analyzed using SPSS for Windows v23.0. Mean 5S Scores and the five-point pictorial scales for satisfaction between groups were compared using independent-samples *t* test; nominal data analysis used a Chi-square test or Fisher's exact test adjusted for multiple comparisons: $p \leq 0.05$ was considered statistically significant.

Results

Participants with acute rhinosinusitis totaled 50 children, 32 boys and 18 girls, with an average age of 7.8 years (range 2.9-14.9 years), randomized into two groups. The group cleaning their devices with the soap technique consisted of 13 boys and 12 girls, with an average age of 7.4 years. The soap-plus-microwave group had 19 boys and 6 girls, with average age of 8.3 years. All participants were assessed at the two-week follow-up. Demographic data is given in **Table 1**, and there were no significant differences in age, sex, underlying diseases, 5S Scores, risk of antibiotic resistance, or previous experience with nasal irrigation. However, the soap-plus-microwave cohort appeared to have a greater history of previous rhinosinusitis three months prior than the soap one.

All participants in our study had compliance rates > 80%; 100% of them came to our second follow-up appointment. All irrigation bottles were sent to lab for bacterial colonization. The mean 5S Scores gradually improved in both groups, while the mean satisfaction scores were ranked as good to satisfactory with no significant differences between cohorts. Reduced use of adjunctive medication (antihistamines and decongestants) was observed in both groups. The soap-plus-microwave cohort demonstrated a greater reduction in adjunctive medication but without statistical significance: please see **Table 2**. There were no reports of upper respiratory infections during the two-week period.

Table 1. Demographic data, 5S Scores, and experience of nasal irrigation between soap-cleaning and soap-plus-microwave group.

Parameter	Type of device disinfection		<i>p</i> -value
	Soap	Soap plus MW	
Sex: male (N, %)	13 (52%)	19 (56%)	0.077
Age (years) median (IQR)	6.3 (6.3)	9.1 (5.3)	0.541
Underlying disease: AR (N, %)	17 (68%)	20 (80%)	0.837
5S Score (mean ± SD)	1.49 ± 0.51	1.37 ± 0.44	0.133
Previous sinusitis (N, %)	7 (28%)	14 (56%)	0.045
Previous antibiotic used (N, %)	9 (36%)	11 (44%)	0.564
Daycare/nursery stays (N, %)	4 (16%)	4 (16%)	1.000
Previous nasal irrigation (N, %)	23 (92%)	25 (100%)	0.562
• Daily	10 (40%)	10 (40%)	
• Symptomatic	13 (52%)	15 (60%)	

MW = microwave

To assess safety and tolerability, the children were asked about their sensations and feelings after nasal irrigation. At the first visit, 21/50 patients (8 in soap, 13 in soap plus microwave) reported some side effects: nasal irritation (3 in soap, 2 in soap plus microwave), nasal congestion (3 in soap, 4 in soap plus microwave) and tinnitus (3 in soap, 8 in soap plus microwave). One week later, 18 patients noted side effects: nasal irritation (2 in soap, 2 in soap plus microwave), nasal congestion (2 in soap, 5 in soap plus microwave) and tinnitus (3 in soap, 9 in soap plus microwave). At the final visit, 9 patients in the soap-plus-microwave cohort reported side effects, but no side effects were stated in the soap and water one. Of these, 4 had congestion, 3 experienced tinnitus, and 1 had nasal irritation. However, these unexpected symptoms were not serious enough to discontinue irrigation. These results are summarized in **Table 2**.

Bacteria were identified on the reservoir, cap, and mouth of the bottles in 68%, 68%, 56% of the 25 samples, respectively, within the soap group. For the soap-plus-microwave group, it was in 60%, 52%, and 56% of samples, respectively. The bacterial identification rate in the soap cohort appeared slightly higher than soap-plus-microwave one, without statistical significance. Commonly reported bacteria in the soap-plus-microwave group included *Pseudomonas aeruginosa*, *Acinetobacter baumannii*, and *Bacillus pumilus*; this was somewhat similar to the soap group in which was found *Pseudomonas aeruginosa*, *Klebsiella pneumonia*, and *Bacillus pumilus*. We also observed that the soap group had a higher rate of mixed organism bacterial contamination than the soap-plus-microwave one. Although there was a high rate of contamination in the bottles, no evidence of sinus reinfection appeared in any participants. Culture details are shown in **Table 3**.

Table 2. Comparing clinical outcomes and bacterial culture identification between soap-cleaning and soap-plus-microwave group

Parameter	Type of device disinfection		p-value
	Soap	Soap plus MW	
5S Score (mean ± SD)			
• First visit	1.49 ± 0.51	1.37 ± 0.44	0.133
• 1 week after nasal irrigation	0.60 ± 0.56	0.76 ± 0.63	0.281
• 2 weeks after nasal irrigation	0.48 ± 0.31	0.50 ± 0.36	0.403
Improvement of total nasal symptom score	0.99 ± 0.56	0.87 ± 0.49	0.212
Side effects (N, %)			
• First visit	8 (32%)	13 (52%)	0.350
• 1 week after nasal irrigation	6 (24%)	12 (48%)	0.417
• 2 weeks after nasal irrigation	0	9 (36%)	0.014
Satisfaction with nasal irrigation (mean ± SD)	4.88 ± 0.33	4.64 ± 0.57	0.171
Satisfaction with cleaning method (mean ± SD)	4.72 ± 0.54	4.60 ± 0.58	0.754
Antihistamine use ≥ 4 days/week (N, %)			
• 1 week after nasal irrigation	9 (36%)	10 (40%)	0.937
• 2 weeks after nasal irrigation	7 (28%)	2 (8%)	0.171
Decongestant use ≥ 4 days/week (N,%)			
• 1 week after nasal irrigation	11 (44%)	7 (28%)	0.389
• 2 weeks after nasal irrigation	7 (28%)	3 (12%)	0.361
Positive bacterial culture (N, %)			
• From reservoir	17 (68%)	15 (60%)	0.384
• From bottlecap	17 (68%)	13 (52%)	0.193
• From mouth of bottle	14 (56%)	15 (60%)	0.500

MW = microwave

Table 3. Bacterial culture results at 3 sites of nasal irrigation device between soap-cleaning and soap-plus-microwave group

Organism (N, %)	Bottle reservoir		Bottle cap		Mouth of bottle	
	Soap	Soap & MW	Soap	Soap & MW	Soap	Soap & MW
Mixed organisms	6 (24%)	4 (16%)	4 (16%)	1 (4%)	4 (16%)	2 (8%)
Single organism						
- <i>Pseudomonas aeruginosa</i>	2 (8%)	3 (12%)	1 (4%)	1 (4%)	0	1 (4%)
- <i>Pseudomonas stutzeri</i>	1 (4%)	0	0	1 (4%)	0	0
- <i>Pseudomonas mendocina</i>	0	0	0	0	0	0
Single organism (Continued)						
- <i>Acinetobacter baumannii</i>	0	3 (12%)	0	2 (8%)	0	1 (4%)
- <i>Acinetobacter bereziniae</i>	0	1 (4%)	0	0	0	0
- <i>Acinetobacter pittii</i>	0	0	0	0	0	1 (4%)
- <i>Acinetobacter junii</i>	0	0	0	0	1 (4%)	0
- <i>Enterobacter cloacae</i>	1 (4%)	0	0	0	0	0
- <i>Enterobacter aerogenes</i>	0	0	0	0	0	0
- <i>Enterobacter sakazakii</i>	0	0	1 (4%)	0	0	0
- <i>Escherichia coli</i>	0	0	0	0	1 (4%)	0
- <i>Rhizobium radiobacter</i>	0	0	0	0	0	0
- <i>Klebsiella pneumonia</i>	3 (12%)	1 (4%)	3 (12%)	1 (4%)	3 (12%)	1 (4%)
- <i>Bacillus pumilus</i>	3 (12%)	1 (4%)	8 (40%)	5 (20%)	5 (20%)	6 (30%)
- <i>Proteus spp</i>	0	0	0	1 (4%)	0	1 (4%)
- <i>Staphylococcus warneri</i>	0	0	0	0	0	0
- Gram-negative rod	1 (4%)	1 (4%)	0	1 (4%)	0	1 (4%)
- Non-fermentative bacteria	0	1 (4%)	0	0	0	0
No organisms	8 (32%)	10 (40%)	8 (32%)	12 (48%)	11 (44%)	11 (44%)

MW = microwave

Discussion

Nasal irrigation has been generally considered an effective adjunctive treatment of rhinosinusitis.^{8,9,22-24} While minor side effects sometimes presented, the benefits of nasal irrigation outweighed these for the majority of participants; however, concern persists regarding bacterial contamination in the irrigation device.

Prior studies have mostly been about adults using irrigation following endoscopic surgery or usage in patients with chronic rhinosinusitis. The devices can be a sanctuary for a large variety of bacteria,^{17,20,25-28} with bacterial contamination reportedly being 45-97%.^{17,25-27} *S aureus* was the most prevalent culture from chronic rhinosinusitis patients, followed by waterborne organisms such as coliforms and *Pseudomonas* species.^{18-19,25,27,29} A study on pediatric rhinosinusitis found bacterial contamination to be present in 76-86% of devices.²⁰ Interestingly, our data shows a lower rate of bacterial contamination as compared to other papers,^{20,25-28} our rates being 52-60% from the soap plus microwave-cleaning technique and 56-68%

from soap-cleaning. The most prevalent bacteria cultured in our samples were *Pseudomonas aeruginosa*, *Acinetobacter baumannii*, and *Bacillus pumilus*, with no sinus reinfection observed at the end of the study.

Various methods for disinfection nasal irrigation device have been studied. Keen et al²⁷ studied the efficacy of several cleaning techniques, including cold water, boiled water, detergent, Milton's solution, and microwave. All methods, except rinsing devices with cold water, had equally favorable disinfection results. Soap-based disinfection for nasal irrigation devices is simple and most commonly used: bottle contamination rates range from 25-50% in prior research.¹⁷⁻¹⁸ Microwave disinfection has shown promise in terms of rapid disinfection. Many studies have demonstrated significant effects on microorganism growth, varying based on frequency, power, duration of contact, and microbial species. Slobodan M. et al³⁰ published a systematic review about microwave effects on microbial culture growth: here, 800-1900 MHz at low power (1-2 W), for 30-180 minutes

intensified the growth of *E coli* and *Klebsiella pneumonia*, while 2450 MHz at 550 W for 5-30 seconds actually elevated common bacteria levels such as *P aeruginosa*, *S aureus*, and *S epidermidis*. However, medium to high power of more than 600 W for 2-5 minutes exterminated pathogens such as *E coli* and spores of *Bacillus cereus*, *P aeruginosa*, *S aureus*, *Candida albicans*, and *B subtilis*.³⁰ In addition, some environmental conditions, e.g., aridity or an increase in sodium chloride concentration, may diminish the deleterious thermal effects of microwaves on pathogens.^{30,31} Thus, the selection of adequate radiation power, frequency, contact duration, and suitable environment is critical as inappropriate settings may elevate microorganism growth instead.

Nonetheless, there are many claims yet little data on microwave disinfection and contamination risk in real life.²⁵ In a laboratory-based experiment, Nikolaou et al³² examined which microwave durations achieved an optimal degree of decontamination: higher levels of decontamination were observed at durations of 90-120 seconds. Unfortunately, Morong et al²⁵ observed that contamination still occurred in devices used by chronic rhinosinusitis patients after endoscopic sinus surgery, despite being given detailed instructions on microwave disinfection; however, microwaving under supervision significantly reduced the rate of contamination.

Our study is the first randomized controlled trial to compare the efficacy of soap-cleaning versus soap-plus-microwave disinfection of nasal irrigation devices. The rate of bacterial contamination was lower than previously seen,^{17,20,25-28} with mixed organisms present in 16-20% of our samples, in contrast to 60-68% in former reports. This may imply that regular disinfection with detailed instructions minimizes the risk of bacterial contamination. We also found that soap-plus-microwave disinfection appeared to decrease the risk of mixed organism contamination: the thermal effect of microwaves may be non-selective with a broader spectrum of microorganism species eradicated.

We also had lower rates of *Klebsiella pneumoniae* and *Bacillus pumilus* cultures but higher rates of *Pseudomonas aeruginosa*, *Acinetobacter baumannii*, and *Acinetobacter bereziniae* in the microwave group. This was despite previous data stating that microwave disinfection of 600-800 W for 2 minutes would eradicate *Pseudomonas* species (there was no reported data for *Acinetobacter* species). The remaining *Pseudomonas* species may have strongly adhered to the plastic and required more microwave wattage or a longer exposure. It is also possible the residual NaCl left in bottle diminished the disinfection process. While increasing wattage or exposure duration may help, there could then be issues with thermal deformation of the device. Although *S aureus* was one of the most prevalent bacteria cultured from chronic rhinosinusitis patients, we surprisingly found no evidence of *S aureus* in both groups. Perhaps any regular daily cleaning of the irrigation device minimizes *S aureus*.

Participants reported an average status of good to satisfactory for nasal irrigation and cleaning methods, having similar satisfaction scores in both groups with the soap-plus-microwave group displaying more minor adverse outcomes than the soap-washing one. This may be a result of sample selection as our initial data from day of recruitment also showed the soap-plus-microwave group having more side effects. While there was no evidence of bottle deformation after microwave disinfection, these side effects may imply precautions be taken: it is possible that some chemical reaction occurred in the nasal irrigation bottles and created irritating substances, especially under high power or long microwave durations. Further assessment on the thermoplastic properties of these bottles is required in regard to power and duration exposure.

To the best of our knowledge, this is the first study to compare the efficacy of soap versus soap plus microwave disinfection of squeeze-bottle nasal irrigation devices in children with rhinosinusitis. We found that only soap or soap plus microwave disinfection appeared simple and safe for disinfection. Both techniques can equally minimize the rate of bacterial contamination. However, our study has some limitations. First, for the soap disinfection method, we cannot control variation in personal technique during soap cleansing, e.g., choice of soap products, the duration of the cleaning, type of scrub and sponge used, etc. Second, for the soap-plus-microwave technique, we did give clear directions to the guardians, but we cannot be 100% certain that they followed each and every step correctly every single time. These all could be confounding factors affecting outcomes. In many ways, these confounding factors mirror what would happen in real life situations.

Conclusion

Nasal irrigation is considered an effective adjunctive treatment for pediatric rhinosinusitis. Although we identified no cross-contamination between devices and patients, regular cleaning of the irrigation device must be emphasized to minimize bacterial contamination. As for cleaning methodology, microwave irradiation after soap-cleaning is simple, with no thermal deformation at optimal power and duration, but it was not significantly superior to the soap cleaning method. High power and longer contact duration may be more effective, but patients should be aware of possible mucosal irritation or plastic deformation. More studies are required to determine the most effective cleaning technique for nasal irrigation devices.

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Disclosure

The authors declare that there is no conflict of interest.

Author contribution

- A.S. designed the study, analyzed data and wrote the manuscript.
- O.P. critically reviewed the manuscript and supervised the whole study process.
- S.C. and N. I. performed experiments.
- S.N. collected data, gave technical support, and conceptual advice.
- P.S. performed the statistical analysis and conceptual advice.
- All authors read and approved the final manuscript.

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