

Original Research Article

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Evaluation of a gravity-driven automated nasal irrigation system compared with manual syringe irrigation: a randomized crossover trial

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ABSTRACT

Background: Large-volume saline nasal irrigation is widely recommended for sinonasal hygiene, but device design and pressure control influence effectiveness and tolerability. A novel automated irrigation device (NasiCare) utilizes gravity-regulated flow to deliver consistent low-pressure irrigation and may improve user experience compared with manual syringe use. Objectives were to compare the effects of an automated nasal irrigation device versus manual syringe irrigation on mucociliary clearance (MCC), safety, and user satisfaction in healthy adults.

Methods: In this prospective, single-blind, randomized crossover trial, 40 healthy volunteers aged 18-60 years completed two intervention visits: automated NasiCare irrigation and manual syringe irrigation. MCC was assessed using saccharin transit time (STT) pre- and post-irrigation. Adverse effects were recorded using a standardized checklist, and user satisfaction was evaluated across four domains (0-10 visual analog scale).

Results: Baseline pre-irrigation STT did not differ significantly between devices (median 6.58 vs. 6.95 minutes; $p=0.380$). Both devices resulted in significant post-irrigation STT improvement ($p<0.001$ for each), with no difference in post-irrigation STT (median 4.76 vs. 4.91 minutes; $p=1.000$) or STT change (1.59 vs. 1.53 minutes; $p=0.085$). Adverse events were infrequent and similar between groups, although nasal pain or tightness occurred only with syringe irrigation. Satisfaction scores were significantly higher for NasiCare across all domains, including overall satisfaction (median 10.0 vs. 7.0; $p<0.001$).

Conclusions: Automated low-pressure nasal irrigation provides MCC benefits comparable to manual syringe irrigation while demonstrating superior user acceptability and similar safety. These findings support the automated device as a reliable and more user-friendly alternative for routine nasal irrigation.

Keywords: Nasal irrigation, Mucociliary clearance, Saccharin transit time, Randomized crossover trial, Patient satisfaction

INTRODUCTION

Nasal irrigation is a well-established therapeutic modality utilized to cleanse the nasal cavity and paranasal sinuses through the application of saline solution. This procedure effectively flushes out mucus, allergens, and particulate debris. The physiological benefits of this intervention

include enhanced nasal airflow, reduction of mucosal inflammation and microbial burden, improved topical drug delivery, and acceleration of MCC.^{1,2}

Saline nasal irrigation is commonly employed in the management of various conditions, such as allergic rhinitis, acute and chronic rhinosinusitis, and for

postoperative care. Consequently, it is strongly recommended within both national and international clinical practice guidelines.³⁻⁵

Devices employed for nasal irrigation exhibit considerable variation in their fundamental design, volume capacity, and pressure delivery mechanics.⁶ The therapeutic effectiveness of this procedure is highly dependent on these parameters, as they directly influence the degree of intranasal fluid distribution and sinonasal lavage. Generally, large-volume systems (typically defined as ≥ 60 ml per nostril), such as the Neti pot, squeeze bottle, or bulb syringe, are considered more efficacious than small-volume systems (e.g., nasal sprays or drops) due to their superior ability to cover the mucosal surface and achieve paranasal sinus penetration.^{1,7,8} However, the delivery pressure is an equally critical determinant. Devices are often categorized based on their volume and pressure output: high-volume/low-pressure devices (typically gravity-driven, like the Neti pot) offer sustained, gentle fluid delivery associated with better patient comfort; conversely, high-volume/high-pressure devices (manually powered squeeze bottles) can generate greater shear force, which is beneficial for dislodging tenacious mucus and crusts, although excessively high pressure may increase the potential for fluid retention in the sinuses or discomfort.⁹ While the most frequently utilized high-volume device is the syringe, owing to its low cost and high availability, its reliance on manual action introduces variability in the operator's pressure control, carrying a greater potential for patient discomfort or inconsistent therapeutic benefit, particularly within pediatric and elderly populations.^{9,10}

In recent developments, an automated nasal irrigation device (NasiCare) has been introduced, engineered to deliver a steady, user-controlled saline flow. Crucially, system utilizes gravity to regulate outflow pressure, thus ensuring consistent, low-pressure delivery independent of user force. This technological innovation potentially offers improved consistency in irrigation parameters and enhanced ease of use compared to traditional manual methods. However, the efficacy and patient acceptability of this system, relative to standard manual syringe-based irrigation, have not yet been systematically investigated in cohort of healthy adult volunteers.

The study's primary objective was to compare the MCC efficacy of the automated NasiCare device versus a standard manual syringe, using STT as the objective outcome measure. Acceptability was assessed via evaluation of side effects and user satisfaction in a crossover design.

METHODS

This study was conducted at the Center of Excellence for Asthma, Allergy and Pulmonary Diseases, Thammasat University Hospital, Pathumthani, Thailand, between

August and December 2024. The study was approved by the institutional ethics committee (MTU-EC-PE-5-127/67).

Study design and population

This study employed a prospective, single-blind, randomized crossover trial involving forty healthy adult volunteers aged 18-60 years. Inclusion criteria mandated good general health, ability to communicate in Thai, and willingness to complete both study visits. Exclusion criteria ensured the absence of factors that could confound mucociliary function, including a history of allergic rhinitis, sinusitis, nasal polyps, a recent upper respiratory tract infection (within two weeks), or recent use of intranasal corticosteroids, antihistamines (oral or intranasal), or nasal decongestants. Participants were randomly assigned to one of two intervention sequences (1:1 ratio) using computer-based block randomization (block sizes of 2 and 4): Group A received the NasiCare device in visit 1 and the syringe in visit 2; group B received the syringe in visit 1 and the NasiCare device in visit 2. The two sessions were conducted on separate days to eliminate potential carryover effects. Sample size calculation, based on non-inferiority testing with a significance level (α) of 0.05 and a power of 80%, determined that 36 participants were required; therefore, 40 were enrolled to account for a 10% dropout rate.

Intervention and outcome procedures

At each visit, the primary outcome, MCC efficacy, was objectively measured using the STT. Before irrigation, a 5 mg saccharin particle was placed on the anterior inferior turbinate of the test nostril using sterile forceps while the participant sat upright with their head slightly tilted forward. The time recorded from placement until the participant reported a sweet taste in the throat defined the pre-irrigation STT. Nasal irrigation was then performed in the same test nostril using a standardized head-tilt technique with 200 ml of isotonic saline delivered by either the automated NasiCare device (single-use, flow-activated pump) or a conventional 50 ml syringe. Participants rinsed with water and rested until any residual sweet taste resolved. Post-irrigation STT was measured using the identical procedure. The primary outcome was the change in STT (pre- to post-irrigation) for each device. Secondary outcomes included the presence of adverse effects (retained saline sensation, salty taste, ear pain/fullness, choking, nasal pain/tightness, epistaxis, and headache, recorded as yes/no) and satisfaction scores assessed immediately post-irrigation using a 0-10 visual analog scale across four domains: ease of use, learning to use the device, overall satisfaction, and willingness to recommend.

Statistical analysis

Descriptive statistics for non-normally distributed continuous data were reported as the

median±interquartile range (IQR). Categorical data were presented as counts and percentages. The Wilcoxon signed-rank test was used to compare STTs (pre-irrigation, post-irrigation, and change in STT) and satisfaction scores between groups. McNemar's test compared the frequency of reported side effects. A two-sided $p<0.05$ was designated as the threshold for statistical significance.

RESULTS

Participant characteristics

A total of 40 healthy adult participants were enrolled in the study, and all completed both intervention visits (Table 1). The median age was 34.0 years (IQR 13.0) in the NasiCare-first group and 30.5 years (IQR 9.0) in the syringe-first group. Median body weight was 62.5 kg (IQR 15.5) and 63.5 kg (IQR 19.5), and median height was 160.0 cm (IQR 8.0) and 165.0 cm (IQR 8.5) in the respective groups. The majority were female, accounting for 90% (n=18) and 65% (n=13), respectively.

Underlying medical conditions were present in 3 participants (15%) and 4 participants (20%). Prior nasal irrigation experience was high in both groups, with infrequent use reported by 70% (n=14) and 60% (n=12), respectively.

STT

The median pre-irrigation STT was 6.58 minutes (IQR 3.00) for the NasiCare group and 6.95 minutes (IQR 3.21) for the syringe group, demonstrating no statistically significant baseline difference ($p=0.380$) (Figure 1A). Following nasal irrigation, STT decreased significantly in both groups compared to their respective baselines ($p<0.001$), confirming the effectiveness of both methods in enhancing MCC. The median post-irrigation STT was 4.76 minutes (IQR 2.25) for the NasiCare group and 4.91 minutes (IQR 2.59) for the syringe group

(Figure 1B). The STT improvement, calculated as the difference between pre- and post-irrigation STT, was 1.59 minutes (IQR 2.58) for NasiCare versus 1.53 minutes (IQR 2.73) for the syringe (Figure 1C). Critically, no statistically significant difference was found between the devices for either the post-irrigation STT ($p=1.000$) or the STT improvement ($p=0.085$). Significant improvements in MCC were observed from baseline to post-irrigation for both NasiCare and syringe conditions (both $p<0.001$) (Figure 2).

Adverse events

The most frequently reported adverse events were saline retention and salty taste (Figure 3). Saline retention occurred in 11 participants (27.5%) following NasiCare and 17 participants (42.5%) following syringe use ($p=0.180$). Salty taste was reported by 19 participants (47.5%) in the NasiCare group and 16 participants (40.0%) in the syringe group ($p=0.508$). Other events were infrequent.

Notably, nasal pain or tightness was reported exclusively in the syringe group (n=4, 10.0%). Overall, no statistical significant differences between the two devices for the frequency of any individual adverse event ($p>0.05$ for all comparisons) were found.

User satisfaction and acceptability

The NasiCare device demonstrated significantly higher median satisfaction scores across all four evaluated domains compared to the standard syringe (Figure 4).

Specifically, the median scores for NasiCare were consistently higher, including overall satisfaction (10.0 (IQR 1.0) vs. 7.0 (IQR 3.2)) and ease of use (9.5 (IQR 1.2) vs. 7.0 (IQR 3.0)). The Wilcoxon signed-rank test confirmed that all differences were statistically significant ($p<0.001$), indicating superior user acceptability of the automated device.

Table 1: Demographic characteristics of participants in each group.

Variables	Group A (NasiCare first), (n=20)	Group B (Syringe first), (n=20)
Age (in years)	34.0±13.0	30.5±9.0
Body weight (kg)	62.5±15.5	63.5±19.5
Height (cm)	160.0±8.0	165.0±8.5
Sex (female)	18 (90%)	13 (65%)
Underlying disease	3 (15%)	4 (20%)
	Hypertension: 1	Hypertension: 1
	Diabetes: 1	Obesity: 2
	Hyper-prolactinemia: 1	Migraine: 1
Nasal irrigation experience		
Never used	5 (25%)	8 (40%)
Infrequent use	14 (70%)	12 (60%)
Frequent use	1 (5%)	0 (0%)

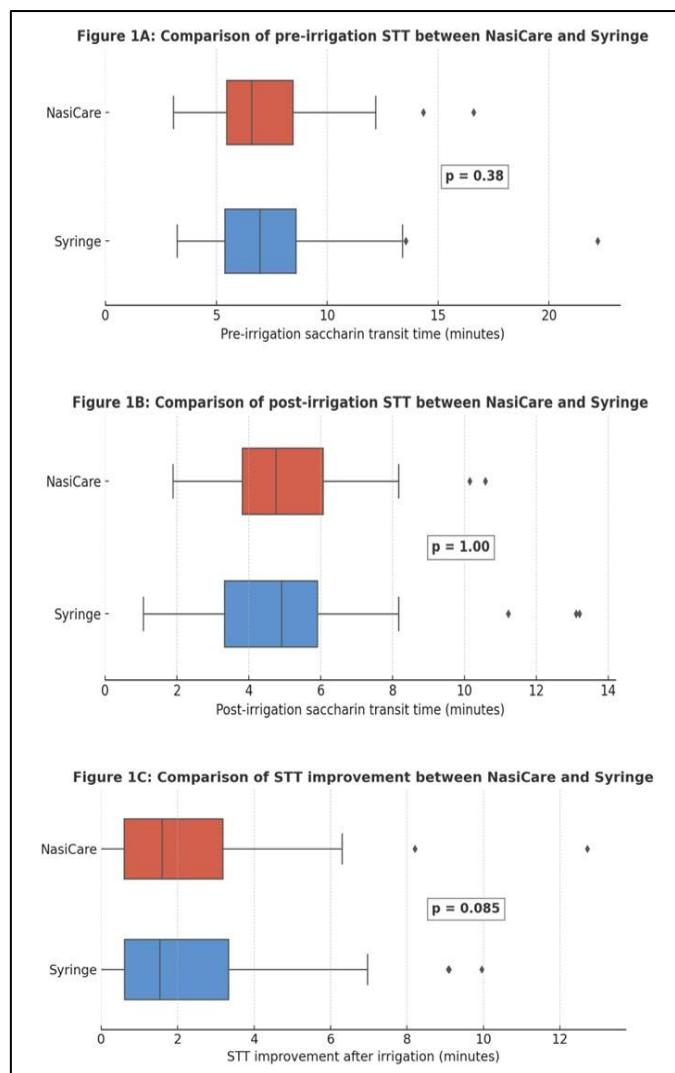


Figure 1 (A-C): Comparison of STT outcomes between automated nasal irrigation (NasiCare[®]) and manual syringe irrigation in healthy adults.

*(A) Pre-irrigation STT values demonstrated no significant baseline difference between devices ($p=0.38$). (B) Post-irrigation STT values were significantly reduced from baseline in both groups, with no significant difference between devices ($p=1.00$). (C) STT improvement (pre- to post-irrigation change) was comparable between devices, supporting non-inferiority of the automated system ($p=0.085$).

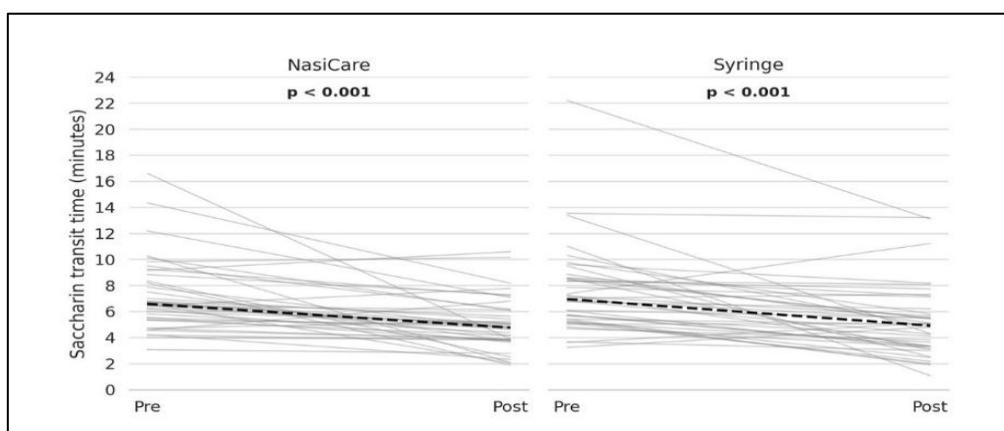


Figure 2: Pre- and post-irrigation STT for automated nasal irrigation (NasiCare) and manual syringe irrigation.

*Individual participant trajectories (gray lines) show a reduction in STT following irrigation with both devices. The dashed black line represents the group median trend. Significant improvements in mucociliary clearance were observed from baseline to post-irrigation for both NasiCare and syringe conditions (both $p<0.001$).

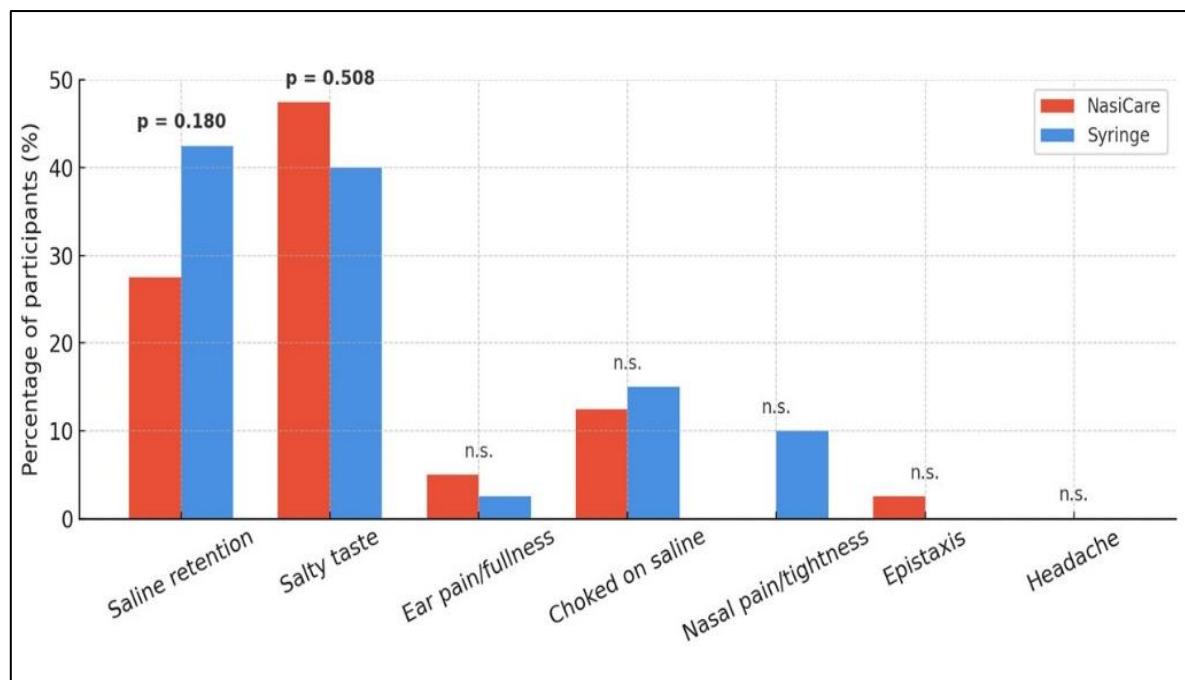


Figure 3: Reported adverse effects following automated nasal irrigation (NasiCare) and manual syringe irrigation.

*Bar charts display the percentage of participants reporting each adverse event. The most common complaints were saline retention and salty taste in both groups. No statistically significant differences were observed for any adverse effect between devices.

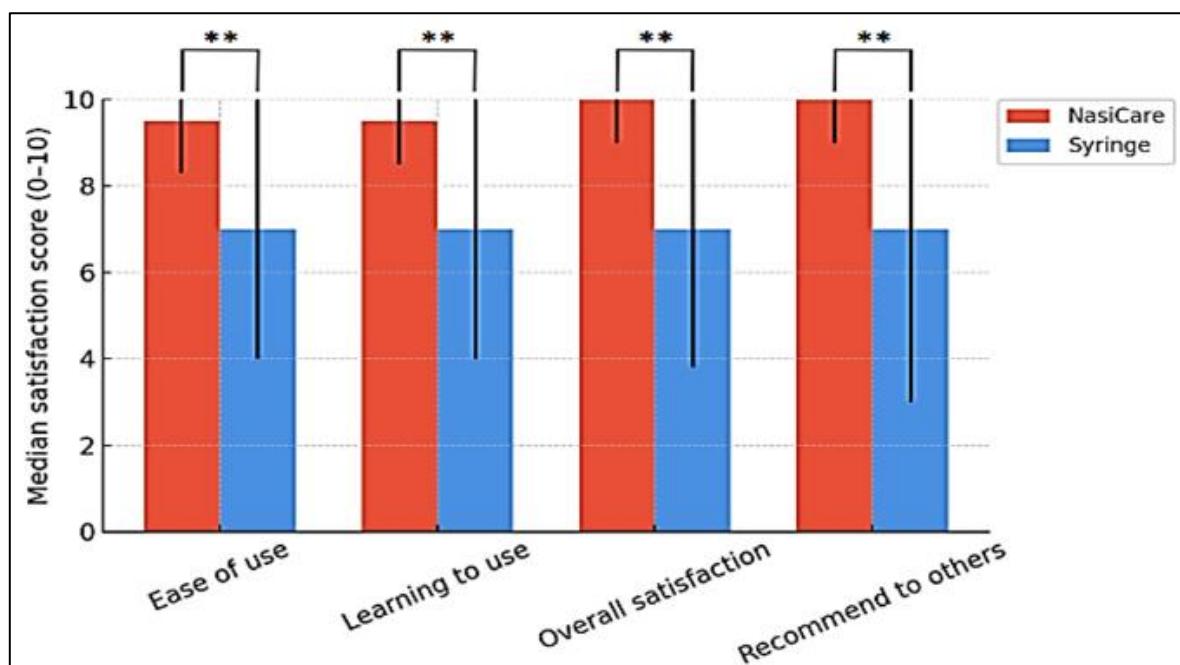


Figure 4: Comparison of satisfaction scores between automated nasal irrigation (NasiCare) and manual syringe irrigation.

*Median satisfaction scores (0-10 scale) across four domains-ease of use, learning to use, overall satisfaction, and willingness to recommend-were significantly higher for the automated device compared with the manual syringe (Wilcoxon signed-rank test, $p<0.001$ for all comparisons). Error bars represent the interquartile range.

DISCUSSION

Nasal irrigation is widely used to enhance MCC and maintain sinonasal health, with strong evidence supporting its benefit in conditions such as allergic

rhinitis and chronic rhinosinusitis.^{1,6,9,10} Large-volume irrigation methods are generally more effective than low-volume systems due to superior sinonasal lavage.^{6,7} However, device design and pressure control remain important determinants of comfort and irrigation quality.

Manual syringe-based irrigation, while inexpensive and accessible, is operator-dependent and may produce excessive or inconsistent pressure, potentially reducing tolerability and treatment reliability.^{2,11,12}

This randomized crossover study compared automated, gravity-driven nasal irrigation system (NasiCare) with standard manual syringe in healthy adults. Both devices significantly improved MCC, as demonstrated by reduced STT from baseline. Magnitude of improvement didn't differ significantly between modalities, supporting non-inferiority of automated device in terms of physiological efficacy. These results consistent with prior studies indicating that when volume is standardized, post-irrigation enhancement of mucociliary function is comparable across different delivery mechanisms despite variations in pressure settings.^{1,7}

Saccharin test is a well-established method for assessing mucociliary function following various interventions.¹³⁻¹⁸ Pre-irrigation STT values in our healthy cohort were consistent with previously reported means of 7-8 min, although higher values have been described in certain populations.^{11,19} Variability may reflect differences in population characteristics/saccharin testing methodology.¹² A related study in healthy traffic officers also demonstrated improved STT after isotonic saline irrigation consistent with our observed reduction of approximately 2 minutes.¹³ Collectively, these data support that both automated and manual large-volume irrigation methods similarly enhance MCC in healthy individuals. Both irrigation methods demonstrated favorable tolerability, with no significant between-group differences in adverse event frequency. Most common complaints were saline retention and salty taste, similar to prior studies.¹¹ Notably, nasal pain or tightness was reported only with syringe irrigation.

This may reflect the high or abruptly changing pressure occasionally generated during manual compression, consistent with literature noting potential for mucosal irritation or transient barotrauma when irrigation pressure is not controlled. The absence of ear-related symptoms in this healthy cohort may relate to the lack of nasal obstruction or eustachian tube dysfunction, which otherwise predispose to pressure-related ear discomfort.

Regarding tolerability, both devices were generally well accepted. The most frequently reported adverse effects were saline retention and salty taste, with no statistically significant differences between groups. Less common symptoms-including ear pain/fullness, choking, nasal discomfort, and epistaxis-were infrequent, and no participant reported headache. These observations are consistent with a multicenter study in patients with chronic rhinosinusitis, which reported saline retention (15.3%), salty taste (14.4%), and ear pain/hearing loss (11.2%) as the most common complaints.¹¹ Based on clinical experience with NasiCare, some physicians have observed that patients tend to report fewer side effects

related to ear pain or fullness, likely due to the device's ability to generate a consistent flow and low pressure during irrigation. However, in our study, the absence of ear pain/fullness may be explained by the study in healthy participants, who typically lack nasal obstruction or congestion-factors that would otherwise increase intranasal pressure and contribute to ear discomfort.

Participants rated automated device significantly higher across all satisfaction domains, including ease of use, learning curve, overall satisfaction and willingness to recommend with scores exceeding those reported in multicenter studies of large-volume, low-pressure devices.²⁰ As consistent irrigation is necessary to maintain therapeutic benefit and prolonged STT (>30 min) indicates impaired MCC improved acceptability is clinically relevant.^{21,22} Automated device's intuitive design and controlled low-pressure flow likely reduce procedural difficulty and discomfort, helping overcome common barriers associated with manual syringe irrigation.

The results of this study suggest that the automated NasiCare system provides comparable physiological benefit to manual syringe while offering a more favorable user experience. These advantages may translate to improved adherence and greater sustained benefit in real-world clinical populations. Future studies should include individuals with allergic rhinitis, chronic rhinosinusitis/postop nasal conditions, where potential differences in sinonasal fluid distribution, symptom outcomes, and adverse effects may be more pronounced. Longer-term usage patterns and objective compliance metrics should also be evaluated. This study benefits from a randomized crossover design and use of a validated physiologic outcome (STT), along with standardized assessment of adverse events and satisfaction.

However, the inclusion of only healthy adults' limits generalizability, the sample size may have reduced power to detect subtle differences, and self-reported outcomes may introduce bias. Future studies should evaluate automated irrigation devices in patients with sinonasal disease, include larger cohorts, and assess usability and tolerability in pediatric populations.

CONCLUSION

Both automated and syringe-based nasal irrigation were effective in improving MCC in healthy adults. Although efficacy was comparable, the automated device (NasiCare) yielded higher satisfaction and was equally well tolerated. These findings support its potential as a user-friendly alternative, particularly for long-term use.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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