Author/s:
Piromchai, P;Phannikul, C;Thanaviratananich, S

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Syringe with Nasal Applicator versus Syringe Alone for Nasal Irrigation in Acute Rhinosinusitis: A Matched-Pair Randomized Controlled Trial

Patorn Piromchai Chayakorn Phannikul Sanguansak Thanaviratananich

Department of Otorhinolaryngology, Faculty of Medicine, Khon Kaen University, Khon Kaen, Thailand

Keywords
Nasal irrigation · Adapter · Rhinopharyngitis · Rhinitis · Sinusitis · Rhinosinusitis · Common cold

Abstract
Background/Aims: Nasal saline irrigation is a common procedure to relieve nasal symptoms in upper respiratory tract diseases. There is no consensus on the recommended nasal saline delivery devices. The objectives of this study were to evaluate efficacy, satisfaction, adherence, and adverse effects in patients with acute upper respiratory tract diseases using a syringe with a nasal applicator for nasal irrigation. ***Methods:*** Patients with acute nasopharyngitis, acute rhinitis, or acute rhinosinusitis were randomly allocated to use either (1) a syringe with a nasal applicator or (2) a syringe alone to irrigate one nostril. After the patients had completed irrigation with the allocated device in one nostril, they were instructed to perform nasal irrigation using the other device in the other nostril. All patients were instructed to use a syringe with a nasal applicator at home. The efficacy, satisfaction scores, adherence, and adverse effects were recorded. ***Results:*** Sixty-four patients were enrolled. The mean age of the patients was 33.95 years (18–59 years). The mean duration of symptoms was 4.80 days. None of the enrolled patients regularly performed nasal irrigation. Forty-two had acute nasopharyngitis, 10 had acute rhinitis, and 12 had acute rhinosinusitis. At baseline, the mean overall efficacy score for the syringe with a nasal applicator was 8.17 ± 1.43, and that for the syringe alone was 5.95 ± 2.02 (MD 2.23, $p < 0.001$, 95% CI 1.75–2.70). At 1 week, the syringe with the nasal applicator had significantly higher scores in 3 of 4 domains, including symptom relief, ease of use, and patients' willingness to recommend the device to others, compared to baseline ($p < 0.05$). None of the enrolled patients had epistaxis, retained/dislodged the applicator during irrigation, or experienced an allergic reaction to the applicator after 1 week of nasal irrigation. ***Conclusion:*** Use of a syringe with an applicator for nasal irrigation yielded high scores in overall efficacy.

Introduction

Nasal saline irrigation is a common procedure to relieve nasal symptoms in upper respiratory tract infection such as nasopharyngitis (common cold) and rhinosinusitis [1–3]. The physician usually prescribes normal saline along with the appropriate medications (e.g., antihistamines, nasal steroids, or antibiotics) to treat these conditions [1, 4, 5].

There are various nasal saline delivery devices that are used for this purpose, including syringes, irrigation pots [6], metered dose pumps [7], squeezable bottles, and pulsating devices [8]. According to a recent multicentre survey, syringes with a nasal adapter and squeezable bottles

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karger@karger.com
www.karger.com/bmh

Patorn Piromchai
Department of Otorhinolaryngology
Faculty of Medicine, Khon Kaen University
Khon Kaen 40002 (Thailand)
patorn@kku.ac.th

were the most effective methods and recommended by the patients [9].

At our institute, the most commonly prescribed device is the syringe without nasal adapter. However, there are problems with this particular delivery method, in that the hard syringe tip can cause epistaxis leading to mucosal damage, and that it can cause leakage of saline from the nostril [9]. The nasal adapter for syringe irrigation is usually made from silicone and comes in various diameters to fit the nostrils of patients of all age groups. The nasal adapter helps to prevent both mucosal damage and saline recirculation/leakage from the nostril [9].

The objectives of this study were to investigate the effectiveness, satisfaction scores, adherence, and adverse events of using a syringe with a nasal applicator versus a syringe alone for nasal irrigation in acute upper respiratory tract infection.

Subjects and Methods

Study Design and Setting

This randomized controlled trial was conducted from May 2017 to March 2018 at the Department of Otorhinolaryngology, Faculty of Medicine, Khon Kaen University, Thailand.

Participants

Patients aged 18–60 years with acute upper respiratory tract infection such as acute nasopharyngitis (common cold), acute rhinitis, or acute rhinosinusitis who were evaluated by a physician and capable of performing nasal irrigation without assistance were invited to participate in this study. We excluded patients with nasal anatomical abnormalities including a deviated nasal septum, marked unilateral swelling of the inferior turbinate, or nasal masses (tumours or nasal polyps). We also excluded patients who already regularly performed nasal irrigation.

Randomization

The randomization list was computer generated by a statistician based on the block randomization method with randomly selected block sizes. The allocation assignment was sealed in opaque, sequentially numbered envelopes. If a patient was eligible for the trial, the envelope would be opened by a research assistant.

Blinding

This was a single-blind study. The attending physicians and evaluators were blinded to patient allocation, but the patients knew which treatment they were receiving.

Treatment Regimen

In the outpatient department, the patients were asked to watch an instructional video on the correct way to perform nasal irrigation and given time to ask the attending nurse questions. After finishing the introductory session, the patients were asked to perform nasal irrigation themselves. The nasal applicator was used on a random side of the nose, and a syringe without a nasal applicator was used on the other. The patients were instructed to perform nasal irrigation on the other side immediately after the first side was done (Fig. 1).

Fig. 1. Syringe with nasal applicator.

Medication was prescribed according to the standard guidelines for their diseases. The co-medication included acetaminophen to relieve fever, and dextromethorphan if the patient had a cough. No decongestant was given. A second-generation antihistamine was used only in patients with allergic rhinitis.

At home, the patient was instructed to perform nasal irrigation using a syringe with a nasal applicator twice a day for 1 week.

Outcomes and Follow-Up

Results regarding the overall effectiveness of each irrigation method were obtained from the patients at the first visit. Information regarding resolution of symptoms, adherence, and patient satisfaction was acquired by telephone interview 1 week after the first visit.

Statistical Analysis

The sample size was calculated based on an expected difference in effectiveness scores of 1 ± 3 points (from 0 to 10). In order to attain a significance level of 0.5 and power of 90%, we determined that a total of 64 patients would be required.

Statistical analyses were performed using SPSS version 20. Data are described as either means (for the continuous variables) or frequencies and percentages (for the categorical variables). Significant differences between groups were determined using the paired *t* test for continuous variables. The χ^2 test or the Fisher exact test were used to determine whether there was a significant difference between the expected frequencies and the observed frequencies. For all tests, $p < 0.05$ was considered statistically significant.

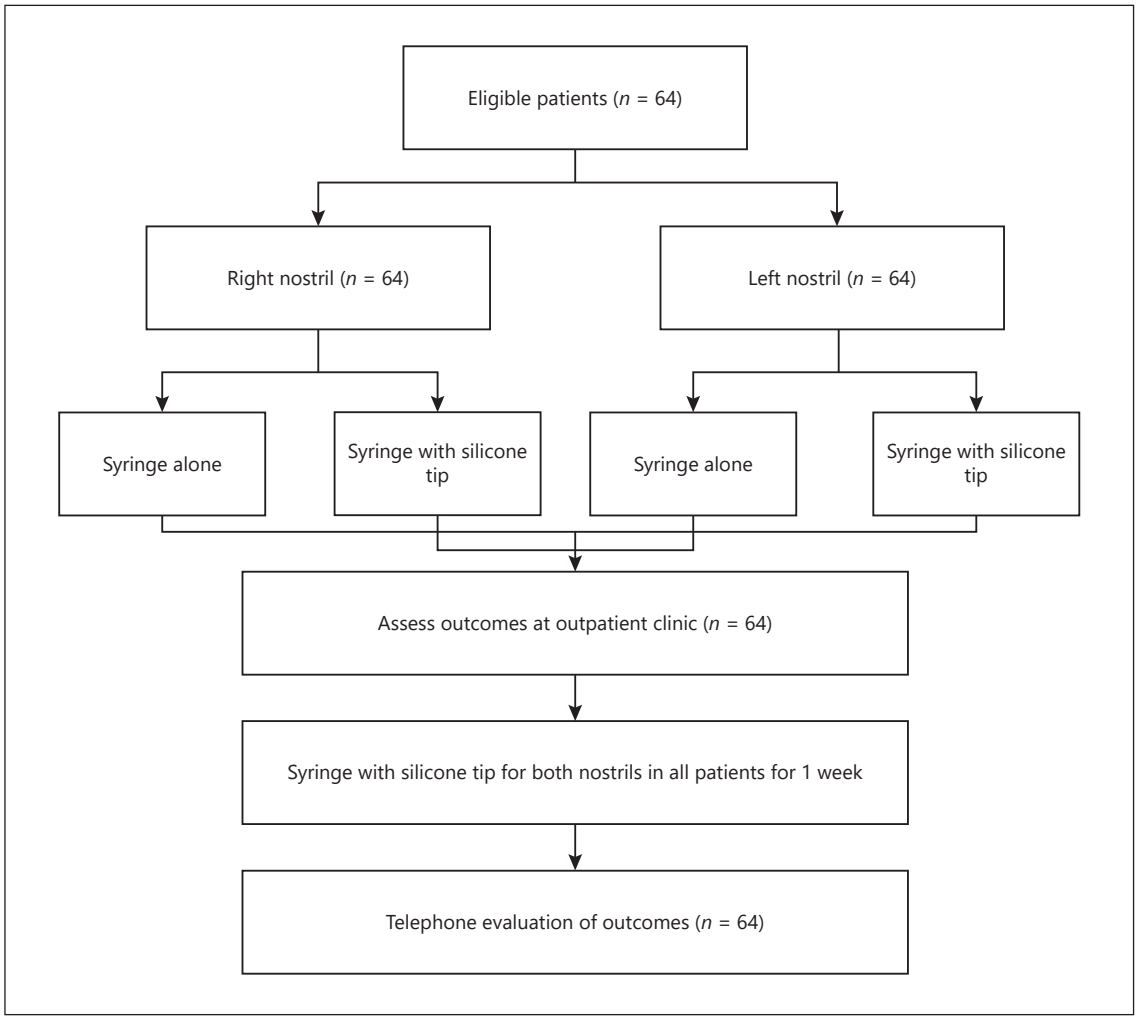

Fig. 2. Participant flow diagram.

Results

A total of 64 patients participated in our study, 13 of whom were male and 51 of whom were female. The mean age of the patients was 33.95 years (from 18 to 59 years). The mean duration of symptoms was 4.80 (±3.05) days. Twenty-four of the patients had underlying diseases. Sixteen had allergic rhinitis, 1 patient had chronic rhinosinusitis, and 7 patients had hypertension, rheumatoid arthritis, asthma, or migraine headache. None of the enrolled patients regularly performed nasal irrigation. Forty-two patients had acute nasopharyngitis, 10 had acute rhinitis, and 12 had acute rhinosinusitis. The participant flow diagram is shown in Figure 2.

A numeric rating scale from 0 to 10 was used to evaluate the overall efficacy of the two methods of nasal irrigation. The mean overall efficacy score for the syringe with a nasal applicator was 8.17 ± 1.43, and that for the syringe alone was 5.95 ± 2.02. The mean difference in these scores was statistically significant (MD 2.23, $p < 0.001$, 95% CI 1.75–2.70). All patients used the syringe with the nasal applicator at home for 1 week. The mean overall satisfaction score was 8.84 ± 1.30, which was slightly higher than at baseline (Table 1).

The efficacy of the syringe with the nasal applicator was evaluated in terms of 4 domains including (1) symptom relief, (2) ease of use, (3) learning curve, and (4) whether or not the patient would recommend the device to others. The patients were asked to rate the devices in each domain at their first visit and 1 week later. The scores ranged from 0 to 10 (0 being "strongly disagree" and 10 being "strongly agree"). There were statistically significant increases in scores in 3 of the 4 domains, including symptom relief, ease of use, and will-

Table 1. Overall efficacy scores of the syringe with a silicone tip and the syringe alone

	Syringe with silicone tip (n = 64)	Syringe alone (n = 64)	Mean difference (95% CI)	p value
Overall effectiveness score	8.17±1.43	5.95±2.02	2.2 (1.75–2.70)	<0.001

Table 2. Effectiveness of the syringe with a silicone tip at the first visit and after 1 week

Domains	First visit (n = 64)	At 1 week (n = 64)	Mean difference (95% CI)	p value
Symptom relief	8.32±1.61	8.92±1.26	0.60 (0.32–0.87)	<0.001
Ease of use	8.67±1.43	8.98±1.09	0.11 (0.09–0.53)	0.006
Quick learning curve	9.02±1.43	9.23±1.19	0.22 (0.01–0.44)	0.057
Would recommend to others	8.72±1.62	9.12±1.26	0.41 (0.16–0.66)	0.002

ingness to recommend the device to others ($p < 0.05$; Table 2).

None of the enrolled patients had epistaxis, retained/dislodged the nasal applicator during irrigation, or experienced allergic reactions to the nasal applicator. In terms of adherence, 93.8% of the patients used the device for nasal irrigation at least 4 days in the first week. When asked which device they would prefer to use regularly, 96.9% indicated that they would prefer to use the syringe with the nasal applicator.

Discussion

According to standard guidelines for various upper airway conditions – such as those laid out in the European Position Paper on Rhinosinusitis and Nasal Polyps [10], the BSACI guideline for the diagnosis and management of allergic and non-allergic rhinitis [11], and the American Academy of Otolaryngology-Head and Neck Surgery Clinical Practice Guideline in Adult Sinusitis – nasal irrigation is a recommended add-on therapy for the above nasal conditions [12].

Although these guidelines recommend nasal irrigation, they do not indicate any preference with regard to the type of nasal irrigation to be used. In a recent Cochrane review evaluating nasal irrigation for allergic rhinitis, the researchers performed a subgroup analysis for the type of irrigation device. However, there was heterogeneity among the studies that were reviewed, and the results were inconclusive [3, 13, 14].

One study evaluated the distribution of saline in the nasal cavity and sinuses using technetium-99m sulphur colloid using three nasal irrigation methods including a metered nasal spray, nebulization, and nasal douching. They found that douching was significantly more effective in penetrating the maxillary sinus ($p = 0.036$) and frontal recess ($p = 0.003$). The sphenoid and frontal sinuses were poorly irrigated by all three techniques [7].

To our knowledge, this is the first randomized controlled study to compare the efficacy of a syringe with a nasal applicator versus a syringe alone. We found that the overall efficacy score of the syringe with the nasal applicator was statistically higher than that of the syringe alone (MD 2.23, $p < 0.001$, 95% CI 1.75–2.70).

Furthermore, symptom relief and satisfaction scores increased after the patients had used the device for a week. No patient in this study experienced any adverse event. Most of the patients exhibited good compliance and used the device for at least 4 days during the first week. Four patients who only used the device for 3 days found that their conditions had improved within that time.

Nearly all enrolled patients indicated that they would prefer using a nasal applicator if they had to perform nasal irrigation regularly. Some participants suggested that the nasal applicator should be provided in various sizes so it could fit into the nostril at a proper depth. Other comments were that they should be offered with fruity aromas and that the device usage instructions should be shortened. Nasal irrigation devices, such as squeeze bottles, are prescribed at our outpatient clinic on a daily basis. However, as nasal irrigation is an add-on therapy,

patients need to buy the device and will not be reimbursed by the government health fund. By contrast, patients can receive reimbursement for syringes, and the silicone nasal applicators are less than half the price of squeeze bottles.

One limitation of this study is that we included only patients with acute upper airway conditions such as acute rhinitis and acute nasopharyngitis. Nasal irrigation device use in patients with chronic conditions, such as allergic rhinitis and chronic rhinosinusitis, should be evaluated in a future trial.

The match-pair randomized controlled trial design can help controlling a confounding factor that could potentially affect the outcomes of the experiment. However, it is very impracticable for a patient to perform two types of nasal irrigation. We decided that the patients should only use the syringe with a nasal adapter at home. Thus, the data for the 4 domains (symptom relief, ease of use, learning curve, and whether or not the patient would recommend the device to others) were data without a control group. An individually randomized trial is warranted to confirm the long-term effects of these two treatments.

Conclusion

Use of a syringe with an applicator for nasal irrigation yielded high scores in overall efficacy.

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Statement of Ethics

This study was approved by the Khon Kaen University Ethics Committee in Human Research (HE601024) and registered in the Thai Clinical Trials Registry (TCTR20180202003). Written informed consent to participate in this study was provided by all patients enrolled. All authors abided by the Declaration of Helsinki.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

P.P. conceptualized, designed and supervised the study, raised funding for the study, performed data analysis, interpreted results, and drafted the manuscript. C.P. and S.T. contributed to participant recruitment, follow-up, and data collection. All authors contributed to the interpretation and discussion of the results, and read and approved the final manuscript.

References

1 Piromchai P, Kasemsiri P, Laohasiriwong S, Thanaviratananich S. Chronic rhinosinusitis and emerging treatment options. Int J Gen Med. 2013 Jun;6:453–64.
2 Principi N, Esposito S. Nasal Irrigation: An Imprecisely Defined Medical Procedure. Int J Environ Res Public Health. 2017 May;14(5):E516.
3 Chong LY, Piromchai P, Sharp S, Snidvongs K, Philpott C, Hopkins C, et al. Biologics for chronic rhinosinusitis. Cochrane Database Syst Rev. 2020 Feb;2:CD013513.
4 Piromchai P, Thanaviratananich S, Laopaiboon M. Systemic antibiotics for chronic rhinosinusitis without nasal polyps in adults. Cochrane Database Syst Rev. 2011 May;(5):CD008233.
5 Head K, Chong LY, Piromchai P, Hopkins C, Philpott C, Schilder AG, et al. Systemic and topical antibiotics for chronic rhinosinusitis. Cochrane Database Syst Rev. 2016 Apr;4:CD011994.
6 Ho EY, Cady KA, Robles JS. A Case Study of the Neti Pot's Rise, Americanization, and Rupture as Integrative Medicine in U.S. Media Discourse. Health Commun. 2016 Oct;31(10):1181–92.
7 Wormald PJ, Cain T, Oates L, Hawke L, Wong I. A comparative study of three methods of nasal irrigation. Laryngoscope. 2004 Dec;114(12):2224–7.
8 Macdonald KI, Wright ED, Sowerby LJ, Rotenberg BW, Chin CJ, Rudmik L, et al. Squeeze bottle versus saline spray after endoscopic sinus surgery for chronic rhinosinusitis: a pilot multicentre trial. Am J Rhinol Allergy. 2015 Jan-Feb;29(1):e13–7.
9 Piromchai P, Puvatanond C, Kirtsreesakul V, Chaiyasate S, Thanaviratananich S. Effectiveness of nasal irrigation devices: a Thai multicentre survey. PeerJ. 2019;7:e7000.
10 Fokkens WJ, Lund VJ, Mullol J, Bachert C, Alobid I, Baroody F, et al. European Position Paper on Rhinosinusitis and Nasal Polyps 2012. Rhinol Suppl. 2012 Mar;23:3 p preceding table of contents, 1–298.
11 Scadding GK, Kariyawasam HH, Scadding G, Mirakian R, Buckley RJ, Dixon T, et al. BSACI guideline for the diagnosis and management of allergic and non-allergic rhinitis (Revised Edition 2017; First edition 2007). Clin Exp Allergy. 2017 Jul;47(7):856–89.
12 Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, Brook I, Ashok Kumar K, Kramper M, et al. Clinical practice guideline (update): adult sinusitis. Otolaryngol Head Neck Surg. 2015 Apr;152(2 Suppl):S1–39.
13 Head K, Snidvongs K, Glew S, Scadding G, Schilder AG, Philpott C, et al. Saline irrigation for allergic rhinitis. Cochrane Database Syst Rev. 2018 Jun 22;6:CD012597.
14 Piromchai P, Kasemsiri P, Reechaipichitkul W. Squeeze bottle versus syringe nasal saline irrigation for persistent allergic rhinitis – a randomized controlled trial. Rhinology. 2020 May.