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Efficacy of buffered hypertonic saline nasal irrigation in children with symptomatic allergic rhinitis: A randomized double-blind study☆

A. Satdhabudha [a,*], O. Poachanukoon [b,c]

[a] Division of Pulmonology, Department of Pediatrics, Thammasat University, Prathumthani, Thailand
[b] Division of Allergy and Immunology, Department of Pediatrics, Thammasat University, Prathumtani, Thailand
[c] Medicinal Herb Research Unit for Asthma, Faculty of Medicine, Thailand

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ABSTRACT

Background: Nasal irrigation has been used as an adjunctive therapy of allergic rhinitis (AR). Available evidence suggested that buffered hypertonic saline (BHS) is superior to buffer normal saline (BNS) for relief nasal symptoms.
Objective: To evaluate the effectiveness of BHS nasal irrigation in the management of children with symptomatic AR.
Design: This was a randomized, prospective, double-blind placebo-controlled study.
Methods: The present study was a randomized prospective double-blind placebo-controlled study. Eighty-one children with symptomatic AR who had a total nasal symptom score (TNSS) ≥ 4 were included in this study. Each participant was randomly treated with either normal saline (NSS) or BHS by a blinded investigator. Nasal saccharine clearance time (SCT) and TNSS were measured before and 10 min after nasal irrigation. Quality of life (QoL) was assessed using the questionnaire for Thai allergic rhinoconjunctivitis patients (Rcq-36). The 7-point Likert scale for satisfaction was also performed. All participants were assigned to perform nasal irrigation twice daily for the period of 4 weeks. During this period, they recorded TNSS, side effects and antihistamine use on daily diary card. A physical examination and subjective evaluation were performed at 2nd and 4th week visits, and daily diary cards were collected.
Results: Patients with BHS were significantly improved in SCT (39.2% versus 15.5%, $P = 0.009$) and TNSS (82.7% versus 69.3%, $P = 0.006$) compared to the NSS group. However, at 2nd and 4th week both groups had improvement in TNSS and QoL compared to baseline visit. There was a significant improvement in mean QoL score in BHS group at 2nd week visit compared to NSS group ($P = 0.04$) but not at the 4th week. Nasal congestion but not TNSS was significantly improved in the BHS group ($P = 0.04$). Moreover, a decreased use of oral antihistamine was observed in BHS group ($P = 0.04$). There were few complaints reported, and side effects were seen equally in both groups.
Conclusion: Nasal irrigation with BHS causes an improvement in SCT, TNSS and QoL compare to NS in children with symptomatic AR.

1. Introduction

Allergic rhinitis (AR) is the one of most common chronic diseases in Thailand. It affects both adolescents and younger children, with prevalence estimates ranging from approximately 10–45% [1–6]. The incidence of AR is ever higher because of an increase of environmental pollution due to industrialization and urbanization. Although AR is not life-threatening, AR symptoms, including sneezing, rhinorrhea, nasal itching and congestion, have an impact on the physical, social and emotional function and a deleterious impact on quality of life (QoL) [7]. Avoidance of the allergen is the best treatment, but pharmacotherapy has an important role in treatment. Furthermore, nasal irrigation with saline may be useful as an adjunctive treatment [8–10]. Nasal irrigation can facilitate the evacuation of potential allergens and irritant-containing mucus, improve mucociliary transport function of the nasal mucosa and improve nasal patency.

It has been suggested that buffered hypertonic saline (BHS) is superior to buffered normal saline (BNS) [11–13] and hypertonic saline (HS) is better to normal saline (NSS) [14,15]. The possible explanation is that hypertonicity can cause reduction of mucosal edema due to osmotic pressure-induced water transport through the mucosal epithelial membrane thereby

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* Corresponding author. Tel.: +66 813414900; fax: +66 035379968.
E-mail address: araya221@gmail.com (A. Satdhabudha).

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reducing nasal congestion and improving mucociliary clearance [16]. Alkaline pH is also better for ciliary function [16]. However, there are contradictory reports with regard to the use of HS especially in AR patient. The major controversies center around whether HS is more irritating and whether HS is superior to NS in terms of improving mucociliary clearance. Concern about irritation comes from the observation that hyperosmolar saline stimulates the secretion of histamine and Substances P and activates nociceptive nerves [17,18]. For instance, Baraniuk et al. [17] reported that the nasal hypertonic saline leads to substance P release and glandular secretion by means of stimulating nociceptive nerves and induces sensation of pain, nasal blockage, and rhinorrhea. The significant changes of pain sensation and nasal blockage were present at a concentration of 2.7%, whereas rhinorrhea was detectable only above a concentration of 5.4%. The more concentrated the saline solution, the greater the intensity of symptoms. However, there were no changes in plasma extravasation, vascular tone or mucosal thickening at these concentrations. On the other hand, Garavello et al. [19] found that with 3% hypertonic saline applied to AR child patient cause no sign of that unsatisfied side effect.

With regard to mucociliary clearance, 3% hypertonic saline was shown to improve mucociliary clearance time. Hauptman et al. [11] compared the efficacy between BNS and BHS and found that BNS and BHS both improved the mucociliary clearance time but BHS was more irritating. In particular, Brown et al. [10] and Harvey et al. [20] reported that nasal irrigation caused a significant improved in saccharine clearance time (SCT) and total nasal symptom score (TNSS) especially in HS. Ural et al. [21] reported that Nasal irrigation with isotonic or hypertonic saline can improve mucociliary clearance time in various nasal pathologies. He meets that, isotonic saline improved mucociliary clearance times significantly in allergic rhinitis when compare to 3% hypertonic saline, By the reason mentioned above, this study try to decrease the concentration of hypertonic solution in the attempt to lower side effect and increase efficacy by adding baking soda which will raise pH value [12,13]. It therefore remains unclear whether HS would be superior to NS and well-tolerated in children with AR. However, exact optimal salinity and pH of nasal irrigation fluid are still not known. The concentration of 0.9%, 2%, 2.3% and 3% saline solution had been reported [15,22], but salinity between 0.9% and 2% saline solution have not been studied.

Until now, there were no previous controlled trials studies comparing the effectiveness on SCT and allergic symptom of the NSS and HS use in children with symptomatic AR. The purpose of this study was to compare the effect of BHS and NSS on SCT and TNSS and to compare patient satisfaction with respect to nasal irrigation, QoL, and side effects in a pediatric population of AR patients.

1.1. Objective

To evaluate the effectiveness of BHS nasal irrigation in the management of children with symptomatic AR.

2. Materials and methods

2.1. Participants

A randomized prospective double blind placebo controlled study was designed. Eighty-one children with AR, aged 6–15 years, were recruited from a pediatric allergy clinic, Thammasat Hospital, between June and November 2010. Approval for the study was granted by the Institutional Ethics Committee of the Thammasat Hospital, and informed consent was obtained from all parents before study entry. The inclusion criteria for this study were as follows: (1) age 6–15 years, (2) diagnosed AR obtained by history, physical examination and positive skin prick test or nasal cytology. (3) TNSS ≥ 4 at the first visit of this study. Patients with a history of nasal anatomic defects, abnormal nasal ciliary function and rhinosinusitis or upper respiratory tract infection in the preceding 2 weeks were excluded. In addition, patients with compliance rate estimated at less than 80% were excluded.

2.2. Study design

All participants were asked to complete the case record form (CRF), TNSS and QoL using specific questionnaire for Thai allergic rhinoconjunctivitis patients (Rcq-36) [23]. A physical examination and SCT were carried out in all patients at the baseline visit. Patients were randomized according to a computer-generated list. An independent study nurse dispensed BHS and NSS according to the computer-generated randomization list. Patients and the investigator were blinded to solution allocation. Patients were randomly divided into two groups. Forty patients were randomized to receive two times daily nasal irrigation with 1.25% BHS (composition: sodium chloride 3 g and baking soda 1 g in boiled water 240 ml). Forty-one patients were allocated to receive NSS (composition: sodium chloride 2.16 g in boiled water 240 ml) as irrigation fluid, contained in similar package as the BHS. The pH values of BHS and NSS were 8 and 6, respectively. All patients were instructed about irrigant usage by the same nurse. A brief demonstration of proficiency with the nasal irrigation technique was required before departure. Each group was suggested to use 20 ml-disposable syringe for irrigation 240 ml/time, twice a day for a period of 4 weeks. Patients were asked to report symptoms of burning sensation and other side effects during the application of both solutions. At 10 min after complete nasal irrigation, patients were asked about TNSS, satisfaction score for nasal irrigation using 7-point Likert scale. SCT were performed again after completion of nasal irrigation. All participants and parents recorded daily symptoms on a diary card and were followed-up at 2 and 4 weeks. The TNSS, QoL score, 7-point Likert scale for satisfaction with use of nasal irrigation, frequency of oral intake of antihistamine/decongestant and clinical findings were recorded at each visit. Furthermore, patients were also evaluated for their tolerability, irrigation technique and adverse events. Patients were discontinued from the study if they were found to be inconsistent with nasal irrigation (used nasal irrigation $< 80\%$ of total period).

During the study, patients were allowed to continue previous medications for control of rhinitis symptoms, such as intranasal corticosteroid and leukotriene modifiers. However, oral antihistamines and decongestant were used only when required. For newly diagnosed cases, the same type of antihistamine (loratadine) was used, and intranasal corticosteroid was used if the participants had more severe allergic symptom (TNSS ≥ 12).

2.3. Total nasal symptom score (TNSS)

Nasal symptoms recorded in the study were nasal obstruction, nasal itching, nasal discharge and sneezing. All symptoms were graded on a 4-point scale using the following system: 0 = none, 1 = mild (symptoms that are present but not particularly bothersome), 2 = moderate (symptoms that are bothersome but do not interfere with daily activities) and 3 = severe (symptoms that are bothersome and interfere with daily activities or disturb sleep). The scores were summed to give the TNSS. Symptoms were recorded before and 10 min after the treatment and at both followed-up visits (2 and 4 weeks). The same physician recorded all TNSS.

2.4. Specific questionnaire for Thai allergic rhinoconjunctivitis patients (Rcq-36) [23]

Rcq-36 is a disease-specific questionnaire for allergic rhinoconjunctivitis patients that was validated in Thai by Bunnag et al. [22]. It is composed of 36 items in 7 domains of rhinitis symptoms (RS), eye symptoms (ES), other symptoms (OS), physical functioning (PF), role limitations (RL), sleep problem (SP), social functioning (SF), emotions (E) and overall health (OH). Response to each item was ranked from 1 (no impairment at all) to 5 (indicating maximum impairment). Patients were asked to recall the problems mentioned in the questionnaire during the previous 2 weeks. All sets of questions were answered verbally by patients. Each item was equally weighted. Scores of items belonging to each domain were summed and the overall score was the summation of total 7 domains. Results were expressed as mean score per item in each domain and for all 36 questions, ranging from 1 to 5. The Rcq-36 was completed by each patient at all three visits.

2.5. Saccharine clearance time (SCT)

The nasal mucociliary clearance was measure during SCT method [24]. First subjects were seated with their head upright. The patient's nose was examined with the use of a nasal speculum and a headlight. A rhinoprobe was used to place a small piece of saccharine on the medial aspect of the inferior turbinate approximately 1 cm posterior to the nasal vestibule. Then subjects were instructed to avoid sniffing or sneezing during this test. The SCT was recorded as the subject's first perception of a sweet taste. Each patient underwent SCT before nasal irrigation and at 10th minute after nasal irrigation.

2.6. 7-Point Likert scale [27] for satisfaction to use nasal irrigation [25]

At trial entry and at 2nd and 4th weeks follow-up, patients were asked to score the child's health status on a 7-point Likert scale. Responses were recorded on a scale from 1 (indicating unsatisfactory) to 7 (indicating excellent).

2.7. Daily diary of nasal symptom score, side effects and daily medications used

Patients and their parents were instructed to record their daily nasal symptoms, side effects and medications used (antihistamine and decongestant) on diary card in the evening after performing the nasal irrigation. Nasal symptoms were measured using a 4-point scale with score ranging from 0 to 3 as follows: 0, none (symptoms not noticeable); 1, mild (symptoms noticeable but not bothersome); 2, moderate (symptoms noticeable and bothersome some of the time); 3, severe (symptoms bothersome most of the time and/or very bothersome some of the time). Four nasal symptoms, including rhinorrhea, nasal stuffiness/congestion, nasal itching and sneezing, were recorded daily by patients. In case of young children, parents were allowed to record the symptoms. The side effects from nasal irrigation and medications used were also recorded every day.

2.8. Statistic analysis

Data were analyzed using SPSS for Windows version 15.0. Mean of SCT, TNSS, QoL score, 7-point Likert scale for satisfaction to use nasal irrigation between two groups were compared using independent-samples t test. The number of antihistamine/pseudoephridine, compliance and side effects were compared using a Chi-square test or Fisher's Exact test adjusting for multiple comparisons. $P \leq 0.05$ was considered significant in all comparisons.

3. Results

Eighty-one AR children participated in the study including 49 boys and 32 girls, with an average of 10.53 ± 2.37 years (range 6.1–15.5 years). Patients were randomized into two groups. One group received 1.25% BHS (24 boys and 16 girls, with an average age of 10.3 ± 2.2 years). The other group received NSS (25 boys and 16 girls, with an average age of 9.9 ± 2.5 years). At baseline there were no significant differences in demographic data, TNSS, SCT, 7-point Likert scale for satisfaction to use nasal irrigation and QoL by Rcq-36 questionnaire (Table 1).

It was noted that both solutions improved SCT. However, patients treated with BHS had a statistically greater improvement in SCT compare to those treated with NSS ($P < 0.05$ compared between groups in the same period). Both solutions improved nasal symptoms acutely (10 min after nasal irrigation). More improvement of TNSS was seen in the BHS than NSS group (6.05 ± 3.3 versus 4.39 ± 2.3, $P = 0.01$). The only Symptom score that differed significantly between groups was itching (1.5 ± 1.5 in BHS versus 0.8 ± 1.4 in NSS, $P = 0.045$). The results of pre and post-nasal irrigation SCT and TNSS are shown as Table 2. The differences in SCT and TNSS between the BHS and NSS groups are shown in Table 3.

Of 81 patients, 76 were finally assessed (94%); 1 patient was not available for 3rd visit, 1 patient was admitted to the hospital, and 1 was excluded because of low compliance. The remaining 2 patients had nasal burning in the first use of liquid nasal irrigation (1 from BHS group and 1 from NSS group). There were 48 of 76 patients were newly diagnosis of AR. Each of them received the same medications during the study. In these newly AR patients, we found significant clinical benefit in both BHS and NSS groups. Both solutions improved TNSS and all nasal symptoms at 2nd and 4th weeks.

Among participants, there were no significant baseline differences in QoL scores. Participants completed 3 QoL surveys at a rate of 100%. We found statistically significant improvement of QoL from baseline in both groups at 2nd and 4th weeks. We saw more

Table 1
Demographic data, TNSS, SCT, satisfaction and QoL score between two groups.

Parameter	BHS ($N = 40$)	NSS ($N = 41$)	P-Value	95% CI
Age[a] (years)	10.3 ± 2.2	9.9 ± 2.5	0.13	−0.31 to 2.3
Male[b]	24 (60%)	25 (61%)	1.0	
New case[b]	25(62%)	23(56%)	0.65	
Duration AR[a] (years)	3.4 ± 2.1	4.4 ± 2.7	0.07	−2.1 to 0.09
Severity AR[b]				
Mild	37 (92%)	36 (87%)	0.71	
Mod-severe	3 (7%)	5 (12%)		
Frequency AR[b]				
Intermittent	14 (35%)	16 (35%)	0.82	
Persistent	26 (65%)	25 (61%)		
QOL[a]	59.2 ± 10.9	61.1 ± 14.7	0.49	−7.7 to 3.8
RS	17.3 ± 4.3	17.5 ± 5.2	0.82	−2.3 to 1.9
ES	7.6 ± 3.5	6.9 ± 2.7	0.37	−0.7 to 2.0
OS	10.3 ± 4.4	11.2 ± 4.6	0.34	−2.9 to 1.0
PF	3.8 ± 1.8	4.1 ± 1.6	0.44	−1.1 to 0.5
RL	3.9 ± 1.7	4.2 ± 1.9	0.48	−1.1 to 0.5
SP	4.4 ± 1.8	4.9 ± 2.4	0.25	−1.5 to 0.4
SF	3.3 ± 0.8	3.5 ± 0.9	0.25	−0.6 to 0.2
E	8.5 ± 3.1	8.6 ± 3.3	0.96	−1.5 to 1.4
OH	3.7 ± 0.6	3.5 ± 0.7	0.38	−0.2 to 0.4

Rhinitis symptoms (RS), eye symptoms (ES), other symptoms (OS), physical functioning (PF), role limitations (RL), sleep problem (SP), social functioning (SF), emotions (E) and overall health (OH).
[a] Data are reported as mean ± SD.
[b] Data are reported as number (percent) of patients.

Table 2
SCT and TNSS before and after nasal irrigation between two groups.

Parameters	Before nasal irrigation		After nasal irrigation		Improvement of score	
	BHS	NSS	BHS	NSS	BHS	NSS
SCT (min)	279.5 ± 125.1	259.4 ± 122.7	159.4 ± 88.8[+]	195.3 ± 100.9[+]	120.1 ± 108.3	6.2 ± 120.2[*]
TNSS	7.3 ± 3.5	6.3 ± 2.4	1.3 ± 1.3[+]	1.9 ± 1.8[+]	6.1 ± 3.3	4.4 ± 2.3[*]
Sneezing	1.5 ± 1.5	1.2 ± 1.1	0.2 ± 0.4[+]	0.2 ± 0.7[+]	1.3 ± 1.5	1.1 ± 1.2
Congest	2.3 ± 1.1	2.1 ± 1.1	0.4 ± 0.6[+]	0.5 ± 0.7[+]	1.9 ± 1.0	1.7 ± 1.2
Itching	1.6 ± 1.5	1.1 ± 1.3	0.1 ± 0.3[+]	0.2 ± 0.6[+]	1.5 ± 1.5	0.8 ± 1.4[*]
Rhinorrhea	1.9 ± 1.4	1.9 ± 1.2	0.6 ± 0.7[+]	1.1 ± 0.9[*,+]	1.3 ± 1.3	0.8 ± 1.5

[*] $P < 0.05$ compared between group in the same period.
[+] $P < 0.05$ in the same group (compared before and after treatment).

Table 3
Difference in SCT and TNSS between BHS and NSS group.

	BHS	NSS	*P*-Value	95%CI
SCT (min)	39.1 ± 26.08	15.5 ± 50.02	0.009	5.96–41.4
TNSS	82.7 ± 16.5	69.3 ± 25.4	0.006	3.9–22.9
Sneezing	89.1 ± 23.9	80.17 ± 46.95	0.39	−11.6 to 29.4
Congestion	84 ± 25.4	78.8 ± 39.4	0.503	−10.1 to 20.4
Itching	99 ± 5	80 ± 44.1	0.038	1.1–36.9
Rhinorrhea	62.7 ± 46.7	38.9 ± 70.9	0.1	−4.9 to 52.6

improvement of QoL score in the BHS than NSS groups at 2nd week's visit (42.2 ± 6.3 versus 48.9 ± 14.4, $P = 0.01$). The domains that differed significantly between groups were other symptoms (6.5 ± 1.2 in BHS versus 8.7 ± 3.1 in NSS, $P = 0.002$) and sleep problems (3.3 ± 0.6 in BHS versus 4.0 ± 1.5 in NSS, $P = 0.03$). There was no statistically significant difference in QoL scores at 4th week follow-up. These results are summarized in Table 4.

The satisfactions of nasal irrigation were determined by 7-point Likert scale at 2nd and 4th weeks. The mean scores represented an average status of good to satisfactory, and there was no statistically significant difference in mean scores between groups. Details are shown in Table 4.

The data at 4th weeks found that daily use nasal irrigation was significantly more prevalent in BHS group than the NSS group (73.9% versus 57%; $P = 0.013$). We also assessed the efficacy in controlling AR related symptoms in pediatric patient by comparing the consumption of pharmaceuticals such as antihistamine, decongestant and intranasal corticosteroid. Reduced use of antihistamines was observed in patients allocated to nasal irrigation with BHS at the 2nd weeks follow-up (11 patients (44%) versus 17 patients (73.9%), $P = 0.02$). However, antihistamine use was not statistic different at the 4th weeks (shown as Table 4). Decongestant use did not differ significantly. During 4-week follow-up, none of the 48 newly diagnosed cases of AR used

Table 4
Effectiveness of treatment between two groups in newly diagnosis of AR at 2 and 4 weeks.

Parameters	First visit (baseline)		2nd visit (2 weeks)		3rd visit (4 weeks)	
	BHS ($N = 25$)	NSS ($N = 23$)	BHS ($N = 25$)	NSS ($N = 23$)	BHS ($N = 25$)	NSS ($N = 23$)
TNSS[a]	7.2 ± 3.1	6.5 ± 2.4	1.6 ± 1.8[+]	2.6 ± 3.0[+]	1.9 ± 1.8	2.4 ± 2.4
Sneezing	1.5 ± 1.5	1.2 ± 1.1	0.6 ± 0.8[+]	0.8 ± 1.2	0.6 ± 0.8	0.6 ± 0.9
Congest	2.2 ± 1.0	2.2 ± 1.1	0.2 ± 0.5[+]	0.7 ± 1.0[*,+]	0.4 ± 0.7	0.6 ± 0.9
Itching	1.5 ± 1.4	1.1 ± 1.4	0.3 ± 0.7[+]	0.8 ± 1.0	0.3 ± 0.5	0.4 ± 0.7
Rhinorrhea	2.0 ± 1.3	1.8 ± 1.1	0.5 ± 0.8[+]	0.4 ± 0.9[+]	0.6 ± 0.9[#]	0.8 ± 1.0[#]
QOL[a]	59.6 ± 12.2	61.2 ± 15.3	42.2 ± 6.3[+]	48.9 ± 14.4[*,+]	43.0 ± 9.2	47.6 ± 11.4
RS	17.6 ± 4.2	16.8 ± 5.5	12.1 ± 3.8[+]	13.7 ± 4.6[+]	11.6 ± 4.1	12.6 ± 3.6
ES	7.8 ± 3.8	7.7 ± 2.9	4.9 ± 1.9[+]	5.5 ± 2.3[+]	4.8 ± 1.9	5.7 ± 2.6
OS	10.5 ± 4.6	11.0 ± 4.1	6.5 ± 1.2[+]	8.7 ± 3.1[*,+]	7.3 ± 2.4	8.3 ± 2.6
PF	3.8 ± 1.6	4.0 ± 1.6	3.1 ± 0.3[+]	3.4 ± 1.2	3.0 ± 0.2	3.6 ± 1.1[*]
RL	3.6 ± 1.6	3.9 ± 1.3	3.4 ± 1.3	3.4 ± 1.3	3.3 ± 1.2	3.8 ± 1.9
SP	4.5 ± 1.9	5.1 ± 1.9	3.3 ± 0.6[+]	4.0 ± 1.5[*,+]	3.6 ± 1.2	3.9 ± 1.6
SF	3.2 ± 0.7	3.6 ± 1.0	3.0 ± 0.0	3.5 ± 2.1	3.2 ± 0.6	3.3 ± 0.9
E	8.7 ± 3.4	9.1 ± 3.7	5.9 ± 2.3[+]	6.6 ± 2.2[+]	6.2 ± 2.6	6.4 ± 1.7
OH	3.6 ± 0.7	3.4 ± 0.7	4.2 ± 0.5[+]	4.0 ± 0.6[+]	4.2 ± 0.6[#]	4.0 ± 0.6[#]
Daily nasal irrigation			23 (92%)	23 (92%)	17 (73.9%)	12 (57.1%)[*]
Satisfaction[a]	5.9 ± 1.5	5.9 ± 1.2	6.0 ± 1.6	5.9 ± 1.2	5.8 ± 1.3	6.1 ± 1.1
Medication use[b]			11 (44%)	17 (73.9%)[*]	14 (56%)	14 (66.7%)
Episode URI[b]	NA	NA	NA	NA	4 (16%)	6 (28.6%)
Side effect[b]	7 (28%)	10 (43.5%)	1 (4%)	1 (4.3%)	3 (12%)	1 (5%)

Rhinitis symptoms (RS), eye symptoms (ES), other symptoms (OS), physical functioning (PF), role limitations (RL), sleep problem (SP), social functioning (SF), emotions (E) and overall health (OH). Nasal irrigation (NI) and URI (upper respiratory tract infection).
[a] Data are reported as mean ± SD.
[b] Data are reported as number (percent) of patients.
[*] $P < 0.05$ compare between group in the same period.
[+] $P < 0.05$ in the same group (compare first and second visit).
[#] $P < 0.05$ in the same group (compare first and third visit).

intranasal steroid. When we compared episodes of upper respiratory tract infection, we found decreased infection in the BHS group than NSS group, but this difference was not statistic significant (16% versus 35%, $P = 0.30$).

To assess the safety and tolerability, patients were asked about their sensations and feelings during and approximately 10 min after application of the nasal wash. Overall 17 in 48 participants (35%) reported nasal irritation and burning during first irrigation (28% in BHS and 43% in NSS group), but the frequency of this complaint was decreased in second and third visit. Of those who experienced an adverse effect, 1 participant (2%) reported that it was serious enough to discontinue nasal irrigation. The results are summarized in Table 4.

4. Discussion

The use of nasal irrigation is currently recommended as an adjunctive treatment modality in many sinonasal disease such as rhinosinusitis, AR and other sinonasal diseases [5,7,8]. Various studies have used different tonicities of NaCl solution. In this study we demonstrate that both BHS and NSS significantly decreased SCT in children with symptomatic AR, but the decrease in SCT was larger with BHS than NSS. The results are in line with previous studies. Cingi et al. [26] found that seawater gel nasal spray in AR significantly decreased SCT when compare to NSS. Keojampa et al. [12] and Talbot et al. [13] also found that both BHS and BNS significantly improved SCT in healthy subject, but the effect of the former was more profound.

For assessment of the clinical effectiveness, this study showed that nasal irrigation with either BHS or NSS was effective in decreasing nasal symptoms of symptomatic AR children. This effectiveness was shown both at 10 min after nasal irrigation and 1 month follow-up. The decreased in TNSS was larger with BHS than NSS. The results are in line with previous studies. Garavello et al. [19] found that BHS nasal irrigation in AR significantly decreased mean daily score, Subsequently, they reported that hypertonic saline nasal irrigation in pregnant woman with seasonal AR significant improved rhinitis score [27]. However, NSS irrigation was not included in both study. Cingi et al. [26] also found that using seawater gel nasal spray in AR patient improved TNSS and decreased lower turbinate colour rating more than NSS.

We also found statistically significant improvements in QoL at 2nd and 4th weeks follow-up. These results are also consistent with other reports following use of nasal irrigation over a short period of time [1,9,19,25,28]. The improvements of QoL were more pronounce in BHS group than NSS group. The efficacy of BHS is also supported by the significant decrease of the use of antihistamine in 2nd visit. It is in line with Garavello et al. [19,27]. Furthermore, we found that the BHS group had better compliance with irrigations than the NSS group. We conclude that the efficacy of irrigation is better in BHS group.

A limitation of our study is that we included all old and new AR patients. The old cases were receiving a variety of medications. However, we also found that BHS was more efficacious in the subgroup of 48 newly AR who receive the similar drug during study. Furthermore, this study minimized potential bias by having one investigator perform all studies on the patients, blinding both the investigator and the subject to the solution content, and observing the subjects until completion of the mucociliary clearance measurement.

In conclusion, this study supports the regular use of 1.25% BHS in the pediatric patients with AR. BHS was found to be advantageous over NSS for improvement in SCT, TNSS and QoL. BHS also showed potential to decrease use of some allergic medications. Finally, treatment with BHS was found to be safe, well tolerate, comfortable and inexpensive. These factors will likely have a positive impact on compliance. Long-term use for adjunctive therapy in AR children should be considered and studied further.

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