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Comparison between the use of saline and seawater for nasal obstruction in children under 2 years of age with acute upper respiratory infection

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Background/aim: The effectiveness of isotonic and hypertonic saline solutions used to open the nasal passage and improve clinical symptoms was compared in children under 2 years of age admitted with the common cold.

Materials and methods: The study was performed as a randomized, prospective, and double-blind study. The study included 109 children. The children using saline (0.9%) and seawater (2.3%) as nasal drops (the patient group) and the control group (in which nasal drops were not administered) were compared. Seventy-four patients received nasal drops from package A (seawater) in single days and from package B (physiological saline) in double days.

Results: The mean age of the patients was 9.0 ± 3.9 months and the numbers of boys and girls were 65 (59.6%) and 44 (40.4%), respectively. There was no significant difference between Groups A and B in terms of nasal congestion ($P > 0.05$). However, a significant difference was found between the control group and Groups A and B ($P < 0.05$).

Conclusion: Relief was seen in nasal congestion, weakness, sleep quality, and nutrition with the use of both saline and seawater in children with the common cold. Seawater or saline drops may be added to standard treatment protocols.

Key words: Child, common cold, nasal saline, nasal drop, seawater

1. Introduction

The common cold is an acute and self-limiting viral infection of the upper respiratory tract. Varying degrees of sneezing, nasal congestion, rhinorrhea, sore throat, cough, mild fever, headache, and weakness are seen (1–3). The treatment of the common cold is supportive. Plenty of fluid intake and opening of the nasal passage with saline or hypertonic solution are recommended (2).

Paranasal sinus mucosa is a continuation of the mucosa of the nasal cavity. Therefore, the infection of this region is usually seen as rhinosinusitis. The mucociliary activity decreases in rhinosinusitis. It has long been argued that nasal irrigation had a place in the treatment. Nasal irrigation is used in rhinosinusitis and allergic rhinitis (4).

Mucociliary plaque in the respiratory tract is protective against infection entering by inhaled air. Reduction in mucociliary activity causes various respiratory diseases. According to the accepted hypothesis, it is said that nasal irrigation increases the mucociliary clearance and reduces nasal edema and inflammatory mediators (5). At the same time, it is known that irrigation cleans dust and secretions and makes the mucus more fluid; irrigation is performed with isotonic or hypertonic saline (4).

It is reported that nasal irrigation with saline solution performs mechanical cleaning by increasing the mucociliary clearance; in addition to increasing the mucociliary activity, hypertonic serum reduces edema and suppresses inflammation (6–8).

Besides the benefits of hypertonic solutions used for nasal washes, studies have also reported side effects of these solutions. It has been stated that hypertonic solutions cause nasal congestion, rhinorrhea, and pain by increasing histamine and substance P release. It was reported that the side effects increased with increasing the concentration of the nasal wash solution (9,10). In contrast, another study reported that there was no adverse effect in children with allergic rhinitis using hypertonic saline (3%) (11).

The studies conducted so far investigated the effectiveness and the side effects of nasal irrigation in children with allergic rhinitis or rhinosinusitis. There are very few studies in the literature related to the use of physiological serum in upper respiratory tract infections

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and influenza (12,13). It is not known whether the use of physiological serum or seawater is more effective in viral upper respiratory tract infection. In the present study, we aimed to investigate whether there is a difference between the use of seawater and saline in terms of the relief of nasal congestion-associated symptoms in children with acute upper respiratory tract infections.

2. Materials and methods

In this study 109 children under the age of 2 who were admitted to Turgut Özal University School of Medicine general pediatric outpatient clinic between 17 September 2012 and 16 November 2012 and diagnosed with acute upper respiratory tract infection were evaluated. The patient group consisted of children using saline (0.9% isotonic saline) and seawater (2.3% hypertonic saline) as nasal drops; the control group included children who were not given nasal drops. The results of both groups were compared.

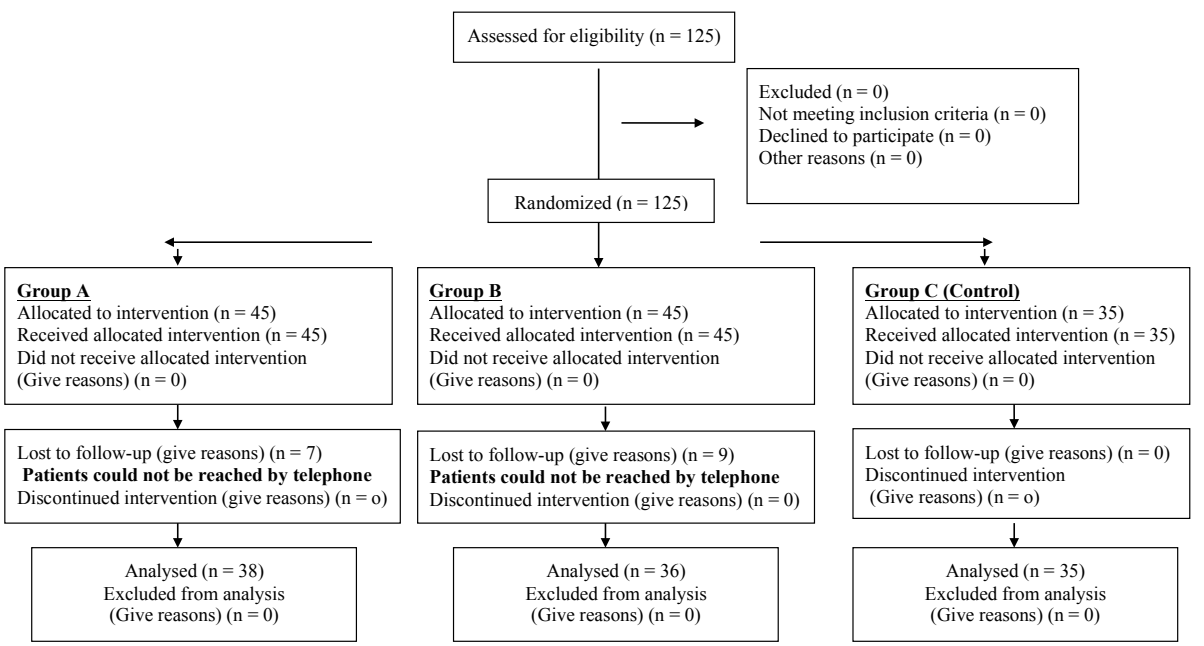
The study was planned as a randomized, prospective, and double-blind study. It was approved by the ethics committee of Turgut Özal University (B 30 2 FTH 0 20 00 00/1093/2012). The families of the patients participating in the study were informed and written consent was obtained. Children with chronic diseases and other serious infections were excluded from the study.

In this study, 38 of 74 patients admitted to the clinic received nasal drops from package A (Group A: seawater) in single days; the other 36 patients received nasal drops from package B (Group B: physiological saline) in double days. Cleaning with nasal aspirator or nasal pumps after instillation of drops in the nose was suggested for Groups A and B. No drops or devices were recommended for the control group (n = 35). While the study was being planned, the A and B boxes were prepared equally, including 45 vials in each of them. However, 7 patients from Group A and 9 patients from Group B could not be reached by telephone, and these patients did not come for check-ups. These 16 patients, who could not be reached for these reasons, were excluded from the study, as shown in the study flow diagram in Table 1.

Three boxes of nasal drops, including 5 vials in each box, were given to the patients in their first admission and 3 vials were recommended to be used each day. Enough drops were given for 5 days. Group A and Group B were treated exactly the same, and we did not provide any treatment to the control group. All the groups (A, B, and control) were examined on days 1 and 7 and rung on days 3 and 5. We planned to recall and examine the patients in the presence of circumstances necessitating intervention other than the standard findings asked in the questionairre. However, we did not observe a different cause other than the patients' complaints.

On days 3 and 5 after the initiation of treatment, the families were contacted by phone. As it was planned, the contributions of "TK, MNÇ, DB, MKK, and TT" were in the conception and design of the study, or the acquisition of data, or analysis and interpretation of data (call the patients' families and/or answer the families' call). The telephone numbers of the doctors above were given to the

Table 1. Study flow diagram.



families. If there was no problem, the doctors phoned the families on days 3 and 5. However, if there was a problem on days other than these days (3 and 5), the families called the doctors. The calls by the families only included questions about the parents' concerns about their children and so these calls did not affect the conclusion of the study. The participants were called in for a check-up on day 7.

If we did not reach the participants by phone the first time, we tried again three times at different times of the day. When we were not able to reach them the third time, we excluded these participants from the study.

As mentioned above, the authors who made the calls were experienced medical doctors. They did not know to which group the patient had been allocated and neither did the families (double-blind study).

We always asked the same questions in the first application, the check-up (day 7), and over the phone (days 3 and 5), and we have added in the "study form" the exact wording of the questions.

In the first application, on the phone (days 3 and 5), and the check-up (day 7), the families were asked about several parameters including nasal congestion, rhinorrhea, nasal bleeding, weakness, sleep patterns, cough, whether nutrition was affected, and whether there was a history of usage of nasal pump or aspirator. The answers given were evaluated as no symptoms: 0, mild symptoms: 1, moderate symptoms: 2, and severe symptoms: 3.

2.1. Statistical analysis

Descriptive statistics were summarized as counts and percentages for categorical variables, and as medians, minimums, and maximums for continuous variables. Repeated measures were determined by repeated measures ANOVA, followed by Bonferroni's post-hoc test. Chi-square test was applied to compare the data between the groups. All the data were analyzed using SPSS for Windows 20 (SPSS Inc, Chicago, IL, USA). $P < 0.05$ was considered significant. Sample size estimates were calculated using G*Power. (Considering an effect size d of 0.5 and alpha error probability of 0.05, the power calculated by G*Power (Universität Düsseldorf) was 78%).

3. Results

The mean age of the patients was 9.0 ± 3.9 months (with a range of 2–17 months), and the numbers of boys and girls were 65 (59.6%) and 44 (40.4%), respectively. In Group A there were 22 boys (57.9%) and 16 girls (42.1%). In Group B there were 25 boys (69.4%) and 11 girls (30.6%). In the control group there were 18 boys (51.4%) and 17 girls (48.6%).

There was no significant difference between Groups A and B in terms of nasal congestion ($P > 0.05$). However, a significant difference was found between the control group and Groups A and B ($P < 0.001$). As the days passed, the nasal congestion in Groups A and B lessened, and a significant difference was found when compared with the control group (Figure 1).

Similarly, there was no significant difference between Groups A and B in terms of weakness, but significant differences were also found between the control group and Groups A and B ($P < 0.05$) (Figure 2).

There was no significant difference between Groups A and B in terms of rhinorrhea, but significant differences were found between the control group and Groups A and B ($P < 0.05$) (Figure 3). There was no significant difference between the control group and Groups A and B in terms of nasal bleeding ($P > 0.05$, for each) (Figure 4).

There was no significant difference between Groups A and B in terms of sleep quality ($P > 0.05$). However, a significant difference for this variable was found between the control group and Groups A and B ($P < 0.001$). Every day sleep quality was found to be slightly increased in Groups A and B (Figure 5).

There was no significant difference between Groups A and B in terms of diet ($P > 0.05$). A significant difference for this variable was found between the control group and Groups A and B ($P < 0.001$). However, changes were not seen from day 5 (Figure 6).

There was no significant difference between box A and box B in the usage of nasal pump and nasal aspirator to clean the nose. However, a significant difference for this variable was found between the control group and Groups A and B ($P < 0.001$) (Figure 7).

There was no significant difference between the groups in terms of cough ($P > 0.05$) (Figure 8).

Distributions of the parameters in Groups A and B and the control group at 0, 3, 5, and 7 days are shown in Tables 2, 3, and 4, respectively.

Comparison between the study groups for all variables (nasal congestion, weakness, etc.) is provided in Table 5.

4. Discussion

Children are mostly affected by nasal congestion in upper respiratory tract infections. Treatment of acute upper respiratory tract infections is supportive, including the intake of food and plenty of fluids and opening of the nasal passage. In upper respiratory tract infections, nasal secretions become more dense and mucopurulent; therefore, this situation secondarily affects the mucociliary transport. When mucus debris is aspirated or rehydrated with a few drops of saline, it is seen that transport starts again (14). It has been emphasized in many studies that nasal irrigation is useful in seasonal allergic rhinitis, acute sinusitis, and chronic sinusitis (11,15–17). In another study it was shown that using nasal saline and nasal corticosteroid together was more effective and economical than using nasal saline alone or nasal steroid alone (18).

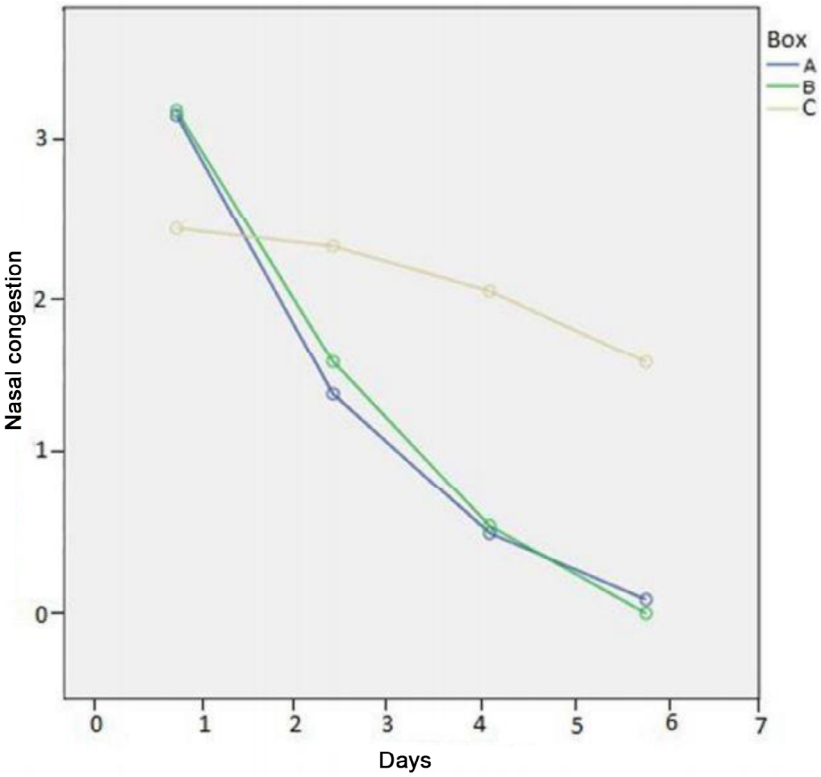


Figure 1. Nasal congestion in Group A, Group B, and the control group 63 × 45 mm (300 × 300 DPI).

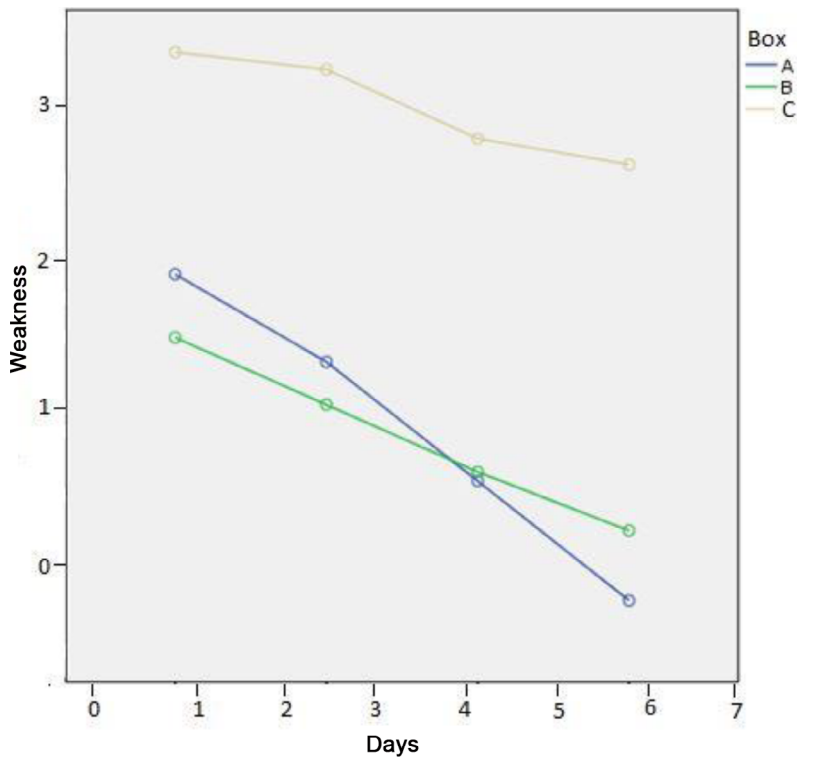


Figure 2. Weakness in Group A, Group B, and the control group 54 × 47 mm (300 × 300 DPI).

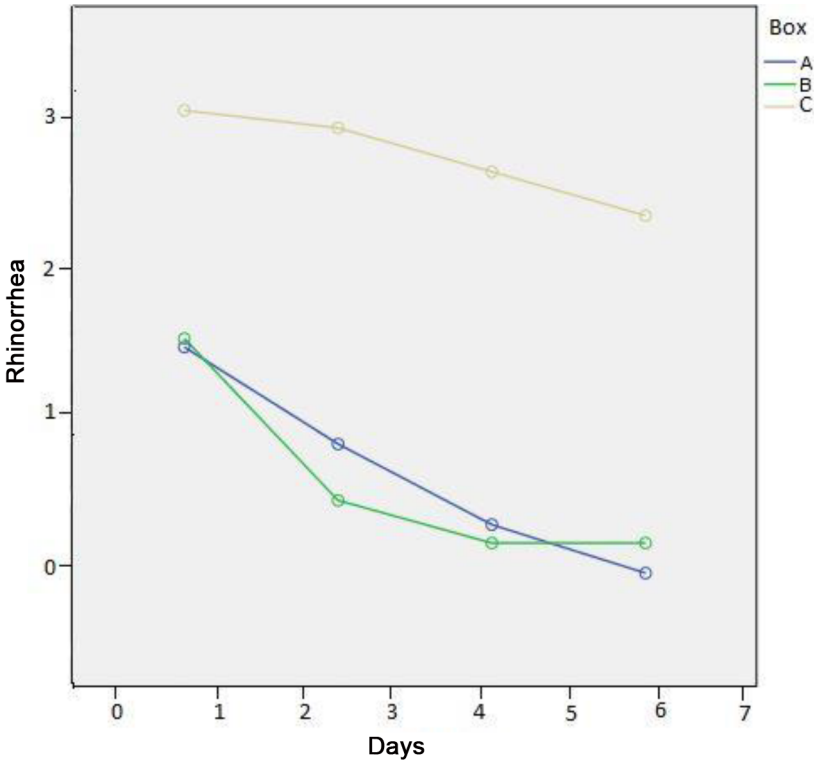


Figure 3. Rhinorrhea in Group A, Group B, and the control group 54 × 42 mm (300 × 300 DPI).

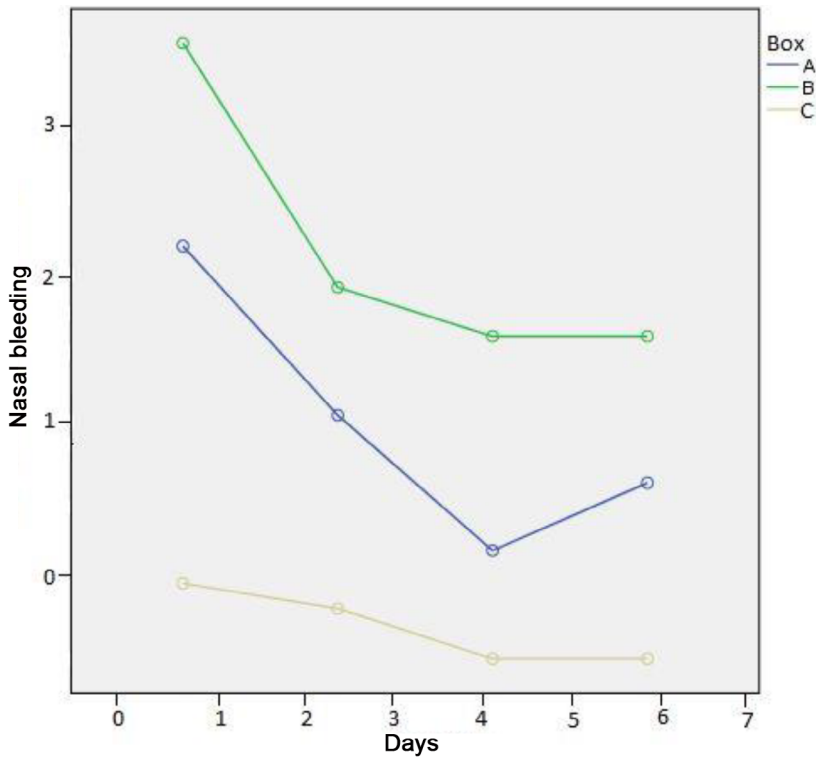


Figure 4. Nasal bleeding in Group A, Group B, and the control group 54 × 42 mm (300 × 300 DPI).

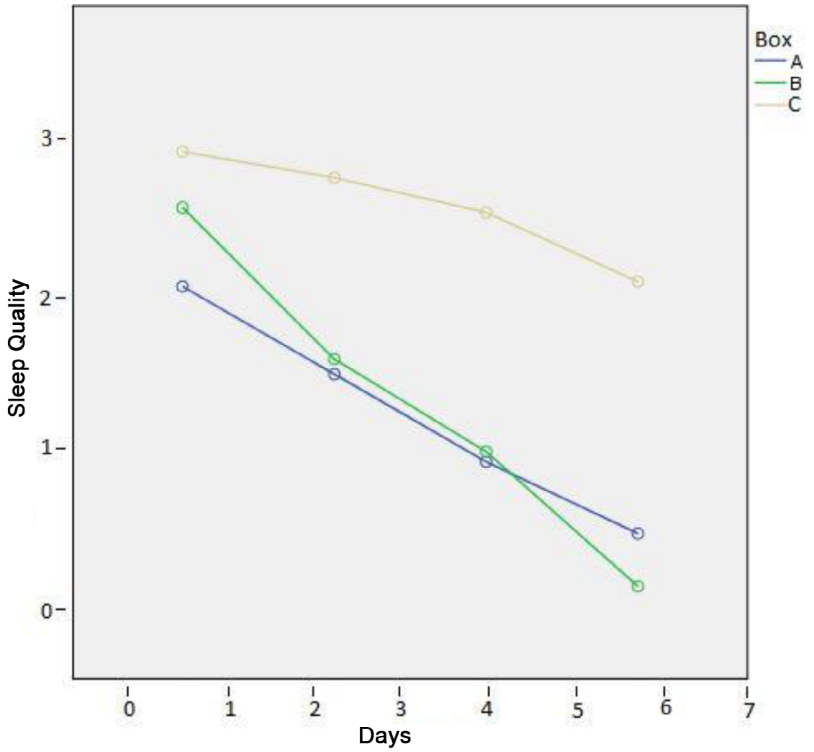


Figure 5. Sleep quality in Group A, Group B, and the control group 54 × 42 mm (300 × 300 DPI).

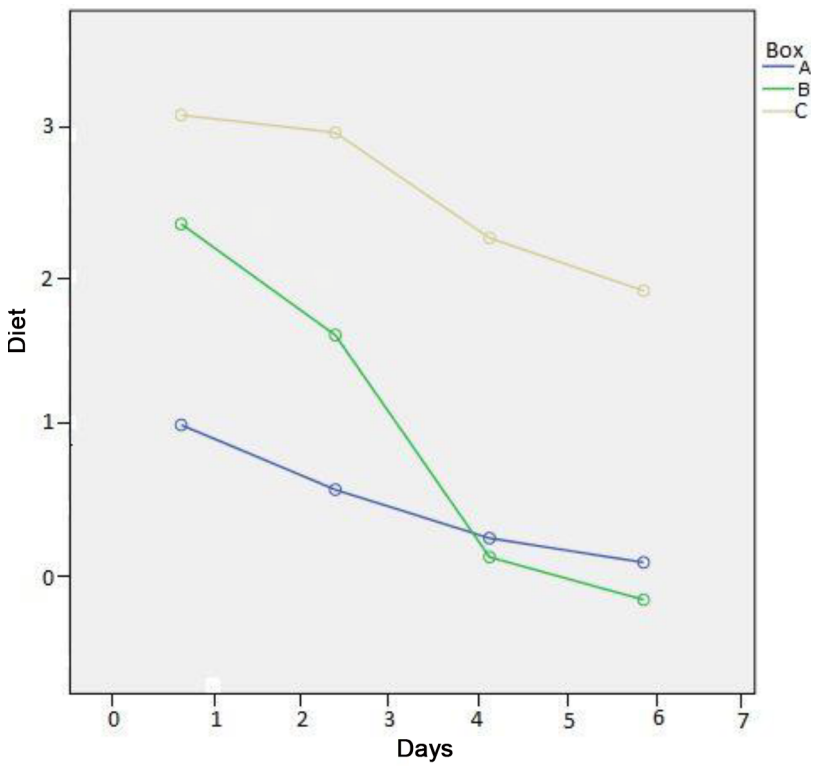


Figure 6. Diet in Group A, Group B, and the control group 54 × 42 mm (300 × 300 DPI).

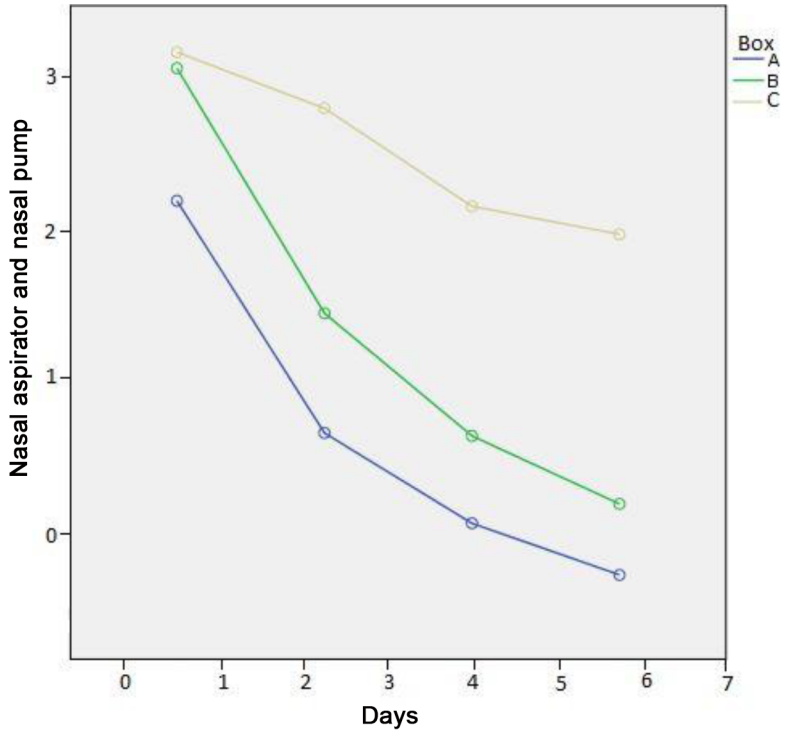


Figure 7. Use of nasal aspirator and nasal pump in Group A, Group B, and the control group 54 × 42 mm (300 × 300 DPI).

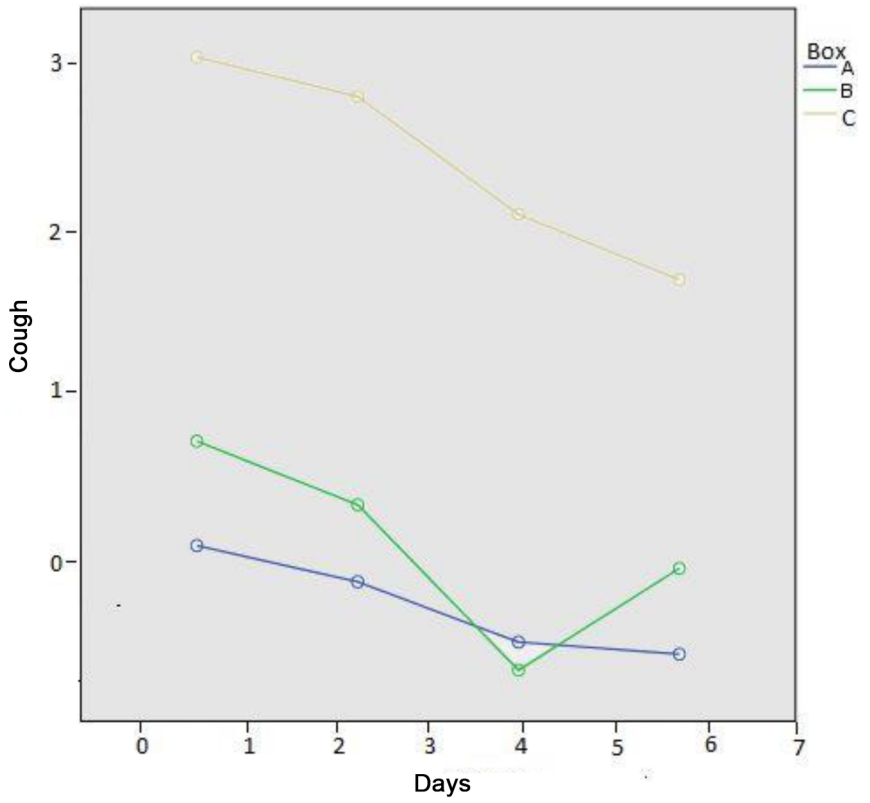


Figure 8. Cough in Group A, Group B, and the control group 54 × 42 mm (300 × 300 DPI).

Table 2. Distributions of the parameters of Group A (n = 38) at 0, 3, 5, and 7 days.

Days	0	3	5	7
Parameters	n (%)	n (%)	n (%)	n (%)
Nasal congestion	38 (100)	26 (68)	14 (37)	8 (21)
Weakness	28 (74)	21 (55)	14 (37)	9 (24)
Rhinorrhea	30 (79)	26 (68)	20 (53)	15 (39)
Nasal bleeding	1 (3)	0	0	0
Sleep quality*	30 (79)	27 (71)	19 (50)	13 (34)
Diet**	21 (55)	16 (42)	13 (34)	11 (29)
Cough	33 (87)	30 (79)	18 (47)	8 (21)
Nasal pump and aspirator***	5 (13)	19 (50)	19 (50)	19 (50)

*Deterioration in sleep quality; **Deterioration in appetite;
***Use of nasal pump and aspirator.

Table 3. Distributions of the parameters of Group B (n = 36) at 0, 3, 5, and 7 days.

Days	0	3	5	7
Parameters	n (%)	n (%)	n (%)	n (%)
Nasal congestion	36 (100)	24 (67)	12 (33)	6 (17)
Weakness	29 (81)	24 (67)	15 (42)	8 (22)
Rhinorrhea	25 (69)	20 (56)	15 (42)	13 (36)
Nasal bleeding	2 (6)	1 (3)	0	0
Sleep quality*	31 (86)	30 (89)	18 (50)	6 (17)
Diet**	31 (86)	29 (81)	10 (28)	7 (19)
Cough	25 (69)	26 (72)	21 (58)	14 (39)
Nasal pump and aspirator***	6 (17)	7 (19)	7 (19)	7 (19)

*Deterioration in sleep quality; **Deterioration in appetite;
***Use of nasal pump and aspirator.

Our results were in parallel with these studies and it was observed that physiological saline and seawater had equal efficiency to relieve nasal congestion; moreover, nasal congestion was relieved earlier in the treated groups than in the control (untreated) group. The thickened mucus was removed from the ambient and the nasal mucosa was moistened with nasal drops. In addition, more effective cleaning of the nose with a pump or aspirator and the reduction of symptoms were significant.

Šlapak et al. (13) showed that washing the noses of children between 6 and 10 years of age with acute upper respiratory tract infection with saline cured the nasal symptoms and reduced the recurrence of common cold. In that study, a group of patients were given standard therapy (antipyretics, nasal decongestants, mucolytics, and/or systemic antibiotics) and nasal saline wash was not recommended. In one group, nasal wash with saline was added to this standard treatment. Those who were enrolled in the study were followed up for 12 weeks. At the end of this process, earlier remission of symptoms and recurrence prevention were found in the group treated with nasal saline (13). In our study, patients aged 0 to 2 years did not receive any treatment except isotonic and hypertonic nasal drops. No nasal drops were recommended for the control group. Patients were followed for 7 days and the comparison was made among three groups. The symptoms of the groups that used nasal drops were lighter and were relieved sooner. Some researchers have argued that nasal wash was not effective on the common cold (19).

The uses of buffered hypertonic saline and buffered normal saline were compared in children with allergic rhinitis previously. It was found that buffered hypertonic saline was more advantageous in reducing complaints compared with normal saline, as it was well tolerated, safe,

Table 4. Distributions of the parameters of Group C (n = 35) at 0, 3, 5, and 7 days.

Days	0	3	5	7
Parameters	n (%)	n (%)	n (%)	n (%)
Nasal congestion	35 (100)	34 (97)	30 (86)	26 (74)
Weakness	34 (97)	31 (89)	27 (77)	26 (74)
Rhinorrhea	35 (100)	35 (100)	35 (100)	33 (94)
Nasal bleeding	1 (3)	0	0	0
Sleep quality*	33 (94)	34 (97)	34 (97)	31 (89)
Diet**	35 (100)	35 (100)	32 (91)	31 (89)
Cough	35 (100)	35 (100)	35 (100)	35 (100)
Nasal pump and aspirator***	10 (29)	10 (29)	10 (29)	10 (29)

*Deterioration in sleep quality; **Deterioration in appetite; ***Use of nasal pump and aspirator.

Table 5. Comparison between study groups for all variables (nasal congestion, weakness, etc.).

				95% Confidence interval for difference	
Group		Mean difference ± std. error	p	Lower bound	Upper bound
A*	B	–0.024 ± 0.114	>0.05	–0.301	0.252
	C	–0.413 ± 0.115	**0.001**	**–0.692**	**–0.134**
B**	A	0.024 ± 0.114	>0.05	–0.252	0.301
	C	–0.388 ± 0.116	**0.003**	**–0.671**	**–0.106**
C***	A	0.413 ± 0.115	**0.001**	**0.134**	**0.692**
	B	0.388 ± 0.116	**0.003**	**0.106**	**0.671**

*Group A (seawater); **Group B (physiological saline); ***Control group. Values in bold are significant.

and cheap (20). Significant difference in the reduction of complaints in our study was not observed between seawater and physiological saline. The most important difference between this study and the previously mentioned one is the content of the patient groups. Patients with allergic rhinitis were included in that study and patients with acute upper respiratory tract infection were included in our study. Hypertonic solutions may become more effective by reducing edema due to the predominance of mucosal edema in allergic rhinitis. The difference in the washing effect of the two solutions may not be seen due to the predominance of increase in secretion in the pathophysiology of acute upper respiratory tract infection.

Washing with hypertonic saline, particularly in allergic rhinitis, indicated an increase in the level of leukotriene C4 (21). Garavello et al. (11) also supported this study by saying that nasal wash with hypertonic saline relieved seasonal allergic rhinitis. Ural et al. (4) emphasized in their study that nasal irrigation was simple, cheap, and effective in the treatment of sinonasal pathology and reduced the use of antibiotics. They reported that hypertonic saline increased mucociliary clearance in patients with chronic sinusitis only, but hypertonic irrigation was not superior to saline irrigation in patients with allergic rhinitis (4). It was seen in our study that the effects of using seawater and physiological saline were similar in acute upper respiratory tract infections.

Changes in cell structure and mucus secretion were analyzed in nasal epithelial cells caused by pure water, hypertonic (0.3%), isotonic (0.9%), and hypertonic (3%) solutions in another in vitro study. As a result, it was reported that pure water, hypotonic, and hypertonic solutions increased mucus secretions and damaged the cells, but isotonic solutions did not cause any change in the mucous secretion and cell structure (22). In another study, it was emphasized that hypertonic saline, given as inhaler, increased mucus secretion (23). It has also been reported in a review published in 2007 that nasal irrigation reduced the use of antibiotics and had very few side effects. These side effects are nasal itching and nausea. Serious side

effects have not been reported (24). It has also been shown in a study conducted by Jeffe et al. (25) that nasal irrigation with saline was cheap and had minimal side effects.

In conclusion, we found relief with the use of both physiological saline and seawater in the following parameters: nasal congestion, weakness, nutrition, and sleep quality. Opening the nasal passage with the aid of a simple device was highly effective in relieving symptoms regardless of which solution was used. The significant differences found between the control group and Groups A and B have shown that washing the nose with physiological saline or seawater in order to clear the nose in acute upper respiratory tract infections has utility in the improvement of symptoms. Seawater or saline drops may be added to standard treatment protocols.

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