Original Article

# Effect of Nasal Aspirator Use on Physiologic Parameters, Crying and Procedure Duration in Nasal Congestion in Infants: A Randomized Controlled Study

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**Abstract**
**Background:** Nasal congestion is a significant problem in babies and small children.
**Aim:** To determine the effects of nasal aspirator in nasal congestion in babies on physiologic parameters, crying and procedure duration.
**Methods:** In this study, group 1 underwent nasal aspiration with a nasal aspirator after nasal irrigation with physiologic saline, and group 2 received nasal irrigation alone. Oxygen saturation, heart rate and respiratory rate of the babies in Group 1 and Group 2 were measured, crying and procedure time were evaluated.
**Results:** Group 1 recorded lower $SaO_2$ values than group 2 immediately before the procedure, but higher values in the other stages ($p<0.01$). Heart rate values were lower in group 1, but the respiratory rate was higher in group 1 immediately before the procedure ($p<0.05$). There was no significant difference in respiratory rates between the groups in the other phases of the study ($p>0.05$). The crying time and procedure duration were longer in group 1 ($p<0.01$).
**Conclusion:** Nasal aspiration using a nasal aspirator is more effective than nasal irrigation using physiologic saline for the removal of nasal secretions and the achievement of nasal patency.

**Keywords**: infant; nasal congestion; nasal cleaning; nasal irrigation; nasal aspiration

## Introduction

Nasal congestion is a significant problem in babies and small children and can negatively affect the entire family. It is a common reason for presentations to emergency departments. The cause of nasal congestion in children can vary depending on the age of the child, but can often be attributed to foreign body aspiration and viral-origin upper respiratory tract infections (URTI) (Kyle & Carman 2013). Children experience an average of 5-6 URTIs annually (Unuvar et al., 2010). Turkish Statistics Institution data from 2019 reported an incidence of 35.9% for URTIs in children aged 0-6 years (Turkiye İstatistik Kurumu, 2019). The problems experienced by children secondary to nasal congestion include restlessness, dyspnea, colic, decreased sucking, inadequate nutrition, and insomnia (Chung, 2009). Because babies aged <6 months, in particular, are unable to breathe through the mouth, congestion increases the level of anxiety in the baby and the family, reducing the quality of life of all concerned (Casati et al., 2007; Principi & Esposito, 2017). Continued congestion increases the risk of rhinosinusitis, acute otitis media, and pneumonia (Shah & Sharieff, 2009). Nasal congestion is generally treated with adrenergic drugs and topical/oral decongestants (Eraydın, 2010; King et al., 2015). The use of decongestants in children, however, is controversial due to the associated adverse effects (Aksit, 2002; Turker et al., 2012). Nasal cleaning with 0.9% isotonic sodium chloride (physiologic saline) is suggested as an effective approach for the relief of nasal congestion in babies and children (Principi & Esposito, 2017; Uysal & Karaman 2012; Wilson, 2014).

A search of the literature on nursing interventions aimed at the relief of nasal congestion yielded no results among the nursing diagnoses of the North American Nursing Diagnosis Association (NANDA) or the nursing interventions of the Nursing Intervention Classification (NIC) (T.C. Resmi Gazete, 2011; Erdemir, 2012; Erdemir et al., 2017). In the limited studies in the literature addressing nasal congestion care, the recommended treatment is the application of physiologic saline to the nose and appropriate nasal aspiration with a bulb/nasal aspirator (Casati et al., 2007; Montanari et al., 2010). Secretions are cleaned using 0.5-1 cc physiologic saline and the congestion is relieved (Schreiber et al., 2016; Garavello et al., 2003; Kassel et al., 2010). Careful positioning involving the elevation of the head or the upper part of the bed during nasal cleaning/nasal aspiration with physiologic saline can be helpful in the clearing of secretions (Passali et al., 2015). Suggested clinical applications for the aspiration of nasal secretions included the use of an aspiration catheter fixed to a rigid aspirator for babies with nasal congestion, and other studies recommended the use of home-mixed salt water (Kyle & Carman 2013; Principi & Esposito, 2017). The present study investigates the effect of using a nasal aspirator the resolution of nasal congestion on physiologic parameters, crying, and procedure duration, in babies aged 1-12 months who presented to the pediatric emergency unit with upper respiratory tract infections.

**Research question:** Is there a difference in physiological parameters, crying and procedure time between Nasal Aspirator Aspiration Method and Serum Physiological Nose Cleaning Method in the relief of nasal congestion in infants aged 1 month to 1 year who are brought to the emergency pediatric unit due to upper respiratory tract infection?

**Hypothesis:** $\mathbf{H_1}$ There is a significant difference in oxygen saturation level, heart rate and respiratory rate between the use of a nasal aspirator and the use of only saline to clear nasal congestion in infants.

$\mathbf{H_0}$ There is no difference in oxygen saturation level, heart rate and respiratory rate between the use of a nasal aspirator and the use of only saline to clear nasal congestion in infants.

## Methods

***Study Design:*** This randomized controlled experimental design study was conducted in the pediatric emergency unit of a training and research hospital in Istanbul between May and July 2017. Included in the study were babies aged 1-12 months whose parents signed informed consent forms, who were brought to the hospital for URTI and had no factors preventing inclusion in the study (systemic disease, nasal obstruction due to foreign body or allergic rhinitis, diagnosed growth retardation and congenital atresia associated with respiratory system). None of the babies had been administered antibiotics, decongestants, or corticosteroid-group drugs before the presentation.

***Sample size and randomization:*** An initial sample-size calculation based on power could not be made because no similar study was encountered in the literature. Initially, a total of 60 babies were recruited for the study, 30 in group 1 (aspiration using a nasal aspirator following nasal cleaning with physiologic saline) and 30 in group 2 (nasal cleaning with physiologic saline), to allow the use of parametric tests for the statistical evaluation and to obtain reliable data. A computer program (https://www.randomizer.org) was used to randomize the numbers from 1 to 60, with no repeats, for the determination of the groups, and power analysis was conducted on the acquired data using the G*Power (v3.1.7) program ($\alpha$=0.05 $\beta$=0.080, $SaO_2$ measurement difference $\Delta$=2.0). At least 35 patients were determined to be required in total according to the power analysis conducted based on $SaO_2$ measurements; however, a larger number of patients was included in each group because it was a first-time study, and to account for attrition. Additional sampling of 10 patients from each group was planned, and the randomization was repeated to include the additional patients. Random numbers from 1 to 20 were assigned to each group and the number of samples was increased to 40 in each group. Consequently, a total of 80 babies were included in the final sample (group 1: n=40; group 2: n=40). Of the total 81 babies that presented to the Pediatric Emergency Unit before the randomization step, one was excluded because the parents chose not to participate. Accordingly, data were collected related to a total of 80 babies during the data collection period (Figure 1). The power of the test was calculated as 99.9% based on the results of the differences in $SaO_2$ measurements following data collection.

***Data collection tools:*** Data were collected by the principal investigator. All measurement tools were checked and prepared for use before the procedure.

***Information form.*** This form comprises 19 items garnering data on the descriptive (age and sex) and disease characteristics (e.g. umber of previous nasal congestion episodes, duration of present nasal congestion, body temperature, restlessness, cough, nasal discharge, quality and quantity of present nasal discharge) of the baby.

*Baby monitoring form.* This form gathers data on the measured values of the babies, including $SaO_2$, heart rate (HR), and respiratory rate immediately before, after, and 5 minutes after the procedure, as well as crying and procedure duration.

***Protocols for nasal cleaning with physiologic saline and aspiration with nasal aspirator.*** In the present study, protocols for aspiration using a nasal aspirator following cleaning with physiologic saline and nasal cleaning with physiologic saline were followed for groups 1 and 2, respectively, for the relief of the obstruction of accumulated secretions in the nasal cavity. Protocols were created for the procedures, and the opinions of 11 experts were obtained for the content validation of the protocols prepared, taking into account clinical experience. The final versions of the protocols were prepared after making changes based on the suggestions of the experts. The content validity indices (CVI) of the protocols for nasal cleaning with physiological saline and aspiration using a nasal aspirator were found as 0.93 and 0.98, respectively (Bulbul & Yildiz 2021).

***Nasal aspirator.*** The battery operated nasal aspirator is a home-use device, so a separate device was used for each patient. The device was used for the nasal aspiration of the babies in group 1.

***Non-invasive pulse oximeter, chronometer, physiologic saline (0.9% isotonic sodium chloride), syringe, sterile gauze, treatment tray, and examination table.*** SaO2 and HR were measured before and after the procedure in both groups using a pulse oximeter. The duration of the procedure, crying time, and respiratory rates before and after the procedure were measured using the chronometer application of a smartphone. On each day of data collection, 100 mL of 0.9% isotonic sodium chloride was opened for use in the nasal cleaning procedures of groups 1 and 2. A 5-mL syringe was used in each procedure to withdraw the physiologic saline. The syringe was prepared before the procedure by withdrawing 3-4 mL of physiologic saline, and 0.5-1 mL was inserted into the nasal cavity in each application. A pack of sterile gauzes was opened for cleaning around the nasal cavity in each patient. The treatment tray used to hold the items used in the application was cleaned using a disinfectant appropriate for the clinical setting before use. The items to be used in each procedure were placed on the tray and used following the defined procedure. The procedures were performed with the baby positioned either on the examination table or on the mother's lap.

***Study application:*** Written and verbal consent was obtained from the families of the babies who agreed to participate in the study using a consent form. The items to be used were prepared. A Patient Diagnostic Form was completed for the members of each group; the sensor probe of the pulse oximeter device was connected to the hand of the baby just before the procedure and the monitoring was begun. The respiratory rate before the procedure was measured using a chronometer and recorded together with the time of the measurement.The first chronometer was started at the start of the procedure to measure duration, and a second chronometer was started at the onset of crying to record the crying time. The nasal cleaning procedures conducted in groups 1 and 2 were performed in accordance with the developed protocols (Figure 2, Figure 3). The first chronometer was stopped when the procedure was completed and the second chronometer was stopped when the crying abated. The respiratory rate immediately after the procedure was recorded using the chronometer, along with the time of measurement.After the procedure, the information on the monitor was transferred to the computer via a USB cable. The values of measurements immediately before, after, and 5 minutes after the procedure were recorded on the Baby Monitoring Form after viewing the computer screen.

***Data assessment:*** Data were assessed using the SPSS for Windows (Version 16.0. Chicago, SPSS Inc.) and NCSS (Number Cruncher Statistical System 2007, Kaysville, Utah, USA) software packages. The assessments were based on mean, standard deviation, frequency, median, ratio, minimum and maximum values, and included Student's t-tests, Mann-Whitney U tests, Spearman's correlation analyses, repeated measures tests, Pearson Chi-square tests, Fisher-Freeman-Halton tests, and Fisher's exact tests. The significance level was set at $p<0.05$.

**Ethical approval:** Institutional approval for the study was obtained from the Public Hospitals' Association with which the hospital was affiliated (01.04.2016-1/509), and Ethics Board Approval was obtained from the Ethics Board of the hospital in which the study was performed (IRB Number:

21.06.2016/1230). The necessary permissions were obtained from the Turkish Drug and Medical Device Institution, as mentioned in the Ethics Board decision (17.04.2017/71146310-511.06-E.84002). Verbal and written consent for inclusion in the study was obtained from all parents of the babies before the procedures.

## Results

***Sample characteristics:*** The babies in groups 1 and 2 were similar in terms of their descriptive characteristics and diseases (Table 1).

***Physiologic characteristics:*** As seen in Table 2, the oxygen saturation of the two groups was different immediately before (p=0.045), after (p=0.005), and 5 minutes after the procedure (p=0.017). Binary comparisons revealed a drop of -0.80±2.50 in oxygen saturation immediately after the procedure from the value immediately before the procedure, and an increase of 2.25±1.53 was noted 5 minutes after the procedure in babies in group 1. On the other hand, oxygen saturation demonstrated a drop of -3.60±3.95 immediately after the procedure from the value immediately before the procedure, and an increase of 0.15±1.89 was noted 5 minutes after the procedure in group 2. Pairwise comparisons between the groups revealed that group 1 had a less significant drop in oxygen saturation than group 2 immediately after the procedure when compared with the value recorded immediately before the procedure, and there was a significant increase 5 minutes after the procedure when compared with immediately before the procedure (p=0.001 and p=0.001, respectively). No significant difference was identified between the measurements made 5 minutes after the procedure and immediately after the procedure (p>0.05) (Table 2).

As seen in Table 3, the heart rates recorded immediately before the procedure (p=0.468) and immediately after the procedure (p=0.230) were similar in the two groups, but different 5 minutes after the procedure (p=0.001). The babies in group 1 experienced a 5.85±8.60 drop in heart rate *5* minutes after the procedure from the values recorded before the procedure, and a decrease of 16.68±13.79 *5* minutes after the procedure when compared with the values recorded immediately after the procedure. On the other hand, an increase of 3.65±10.12 was recorded *5* minutes after the procedure in group 2 when compared with the value measured before the procedure, and a decrease of -9.05±12.35 *5* minutes after the procedure when compared with the values recorded immediately after the procedure. Intergroup binary comparisons of the recorded heart rates revealed a significant decrease *5* minutes after the procedure when compared with immediately before the procedure, and a significant decrease 5 minutes after the procedure when compared with immediately after the procedure (p=0.001 and p=0.007, respectively) (Table 3). As seen in Table 4, the respiratory rate was significantly higher in group 1 than in group 2 immediately before the procedure (p=0.017), but the heart rate immediately after the procedure and 5 minutes after the procedure were found to be similar in both groups. Binary comparisons revealed that the respiratory rate of the babies in group 1 increased by 6.28±3.97/minute after the procedure when compared with immediately before the procedure, decreased by -3.35±3.85/minute 5 minutes after the procedure when compared with just before the procedure, and by -9.63±4.82/minute *5* minutes after the procedure when compared with immediately after the procedure. In group 2 on the other hand, an 8.53±5.28 increase in respiratory rate was seen immediately after the procedure from immediately before, and a decrease of -7.75±4.88 was seen 5 minutes after the procedure from the measurement taken immediately after the procedure. Binary comparisons of the groups revealed a higher respiratory rate in group 1 than in group 2 before the procedure. The decreases recorded immediately after the procedure when compared with immediately before the procedure, and 5 minutes after the procedure when compared with immediately after the procedure, were found to be significant (p=0.001 and p=0.045, respectively) (Table 4).

***Crying time and procedure duration:*** The mean crying time of the babies in groups 1 and 2 were 60.05±16.64 seconds and 44.38±8.48 seconds, respectively. The crying time in group 1 was significantly longer than in group 2 (Z=-5.697; p=0.001). The mean duration of the procedures in group 1 and group 2 were 68.98±9.80 seconds and 43.84±6.33 seconds, respectively. A statistically significant difference was found in the procedure durations between the groups, with significantly longer mean procedure durations recorded in group 1 than in group 2 (Z=-7.535; p=0.001).

***Association between differences in physiologic parameters and crying time:*** No statistically significant associations were found between crying time and the mean $SaO_2$, and between the HR and respiratory measurement results from

immediately before the procedure, immediately after the procedurem and 5 minutes after the procedure in group 1 ($p>0.05$). A statistically significant, positive, and intermediate level (34.4%) correlation was noted between the differences in the mean $SaO_2$ measurements 5 minutes after the procedure when compared with those immediately after the procedure, and the mean crying time in group 2 ($SaO_2$ increases as crying time increases) ($r=0.344$; $p=0.030$). A statistically significant positive and intermediate level (33.7%) correlation was found between the differences in HR immediately after the procedure when compared with immediately before the procedure, and the mean crying time (HR increases as crying time increases) ($r=0.337$, $p=0.033$). No significant correlation was found between the differences in respiratory rates and crying times ($r=0.025$, $p=0.880$, $r=0.258$, $p=0.107$, $r=0.137$, $p=0.400$) (Table 5).

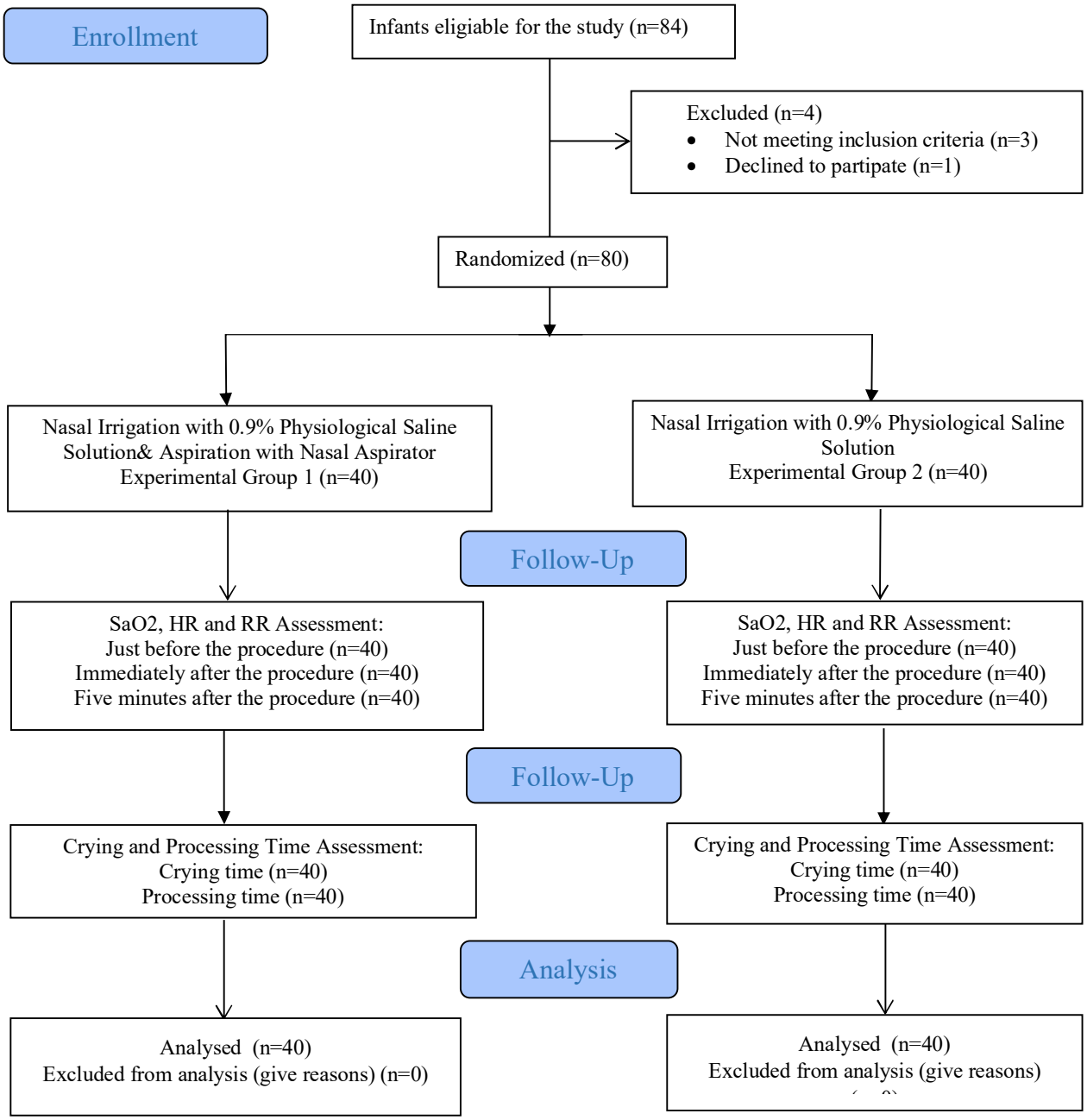


**Figure 1: CONSORT flow diagram**

**Figure 2: Aspiration Application with Battery-Operated Nasal Aspirator**

**Figure 3: Nasal Cleansing / Care by Applying Serum Physiological to Nasal Cavity**

**Table 1: Distribution and comparison of descriptive and disease characteristics by groups**

| Characteristics | | Group 1 (n = 40) | Group 2 (n = 40) | Total (n = 80) | Test Values p |
|---|---|---|---|---|---|
| **Age (day)** | *Min-Max*<br>*(Median)*<br>*Mean ± SD* | 35-302 (143)<br>155.83±85.14 | 32-340 (119)<br>142.58±96.94 | 32-340 (123)<br>149.20±90.89 | Z = - 0.943<br>[b] 0.346 |
| **Number of nasal congestion in the past** | *Min-Max*<br>*(Median)*<br>*Mean ± SD* | 0-10 (1)<br>1.9±2.88 | 0-12 (1)<br>1.85±2.7 | 0-12 (1)<br>1.87±2.77 | Z = - 0.459<br>[b] 0.646 |
| **Duration of current nasal congestion (day)** | *Min-Max*<br>*(Median)*<br>*Mean ± SD* | 1-10 (3)<br>3.5±2.31 | 1-10 (3)<br>3.38±2 | 1-10 (3)<br>3.44±2.14 | Z = - 0.083<br>[b] 0.934 |
| **Body temperature (℃)** | *Min-Max*<br>*(Median)*<br>*Mean ± SD* | 36.2-37.2 (36.7)<br>36.71± 0.25 | 36.2-37.3 (36.7)<br>36.73± 0.27 | 36.2-37.3 (36.7)<br>36.72± 0.26 | T = - 0.345<br>[a] 0.731 |
| | | **n (%)** | **n (%)** | **n (%)** | |
| **Gender** | *Girl*<br>*Boy* | 24 (60)<br>16 (40) | 16 (40)<br>24 (60) | 40 (50.0)<br>40 (50.0) | $\chi 2 = 3.200$<br>[c] 0.074 |

| | | | | | |
|---|---|---|---|---|---|
| **Discomfort (n = 66)** | | 33 (82.5) | 33 (82.5) | 66 (82.5) | $\chi^2$ = 0.000<br>[c]1.000 |
| **Cough (n = 68)** | | 33 (82.5) | 35 (87.5) | 68 (85.0) | $\chi^2$ = 0.392<br>[c]0.531 |
| **Runny nose (n = 49)** | *No*<br>*Yes* | 23 (57.5)<br>17 (42.5) | 26 (65)<br>14 (35) | 49 (61.3)<br>31 (38.7) | $\chi^2$ = 0.474<br>[c] 0.491 |
| **Characteristics of runny nose (n = 49)** | *Serous*<br>*Purulent* | 18 (78.3)<br>5 (21.7) | 19 (73.1)<br>7 (26.9) | 37 (75.5)<br>12 (24.5) | $\chi^2$ = 0.177<br>[c]0.674 |
| **Amount of runny nose (n = 49)** | *Little*<br>*Intensive* | 14 (60.9)<br>9 (39.1) | 13 (50)<br>13 (50) | 27 (55.1)<br>22 (44.9) | $\chi^2$ = 0.583<br>[c] 0.445 |

[a]*Student-t Test* [b]*Mann Whitney U Test* [c]*Pearson Chi-Square Test*
[e]*Fisher's Exact Test* [d]*Fisher Freeman Halton Test*

**Table 2: Comparison of oxygen saturation measurement values of babies**

| **Oxygen Saturation** | | **Group 1 (n = 40)** | **Group 2 (n = 40)** | **Test** | **p** |
|---|---|---|---|---|---|
| **Just before the procedure** | *Min-Max (Median)*<br>*Mean±SD* | 90-99 (95)<br>94.70±2.10 | 89-100 (96)<br>95.75±2.61 | t: - 0.982 | [a] p = 0.045 |
| **Immediately after the procedure** | *Min-Max (Median)*<br>*Mean±SD* | 89-98 (94)<br>93.90±2.22 | 87-100 (91)<br>92.15±3.10 | t: 2.904 | [a] p = 0.005 |
| **5th minute after the procedure** | *Min-Max (Median)*<br>*Mean±SD* | 93-100 (97)<br>96.95±1.89 | 90-99 (96)<br>95.90±1.96 | t: 2.437 | [a] p = 0.017 |
| | Test<br>**p** | [c]48.991<br>0.001 | [c]38.278<br>0.001 | | |
| **Just before the procedure – Immediately after the procedure** | *Difference*<br>*Test*<br>***[c]p*** | - .80±2.50<br>t: 1.468<br>0.150 | -3.60±3.95<br>t: 3.558<br>0.001 | Z: -3.635 | [b]**p** = 0.001 |
| **Just before the procedure- 5th minute after the procedure** | *Difference*<br>*Test*<br>***[c]p*** | 2.25±1.53<br>t: -3.558<br>0.001 | 0.15±1.89<br>t: 0.001<br>1.000 | Z: -5.475 | [b]**p** =0.001 |
| **Immediately after the procedure - 5th minute after the procedure** | *Difference*<br>*Test*<br>***[c]p*** | 3.05±1.91<br>t:-3.558<br>0.001 | 3.75±3.02<br>t:-3.558<br>0.001 | Z: -1.088 | [b]**p** = 0.277 |

[a]*Student-t Test* [b]*Mann Whitney U Test* [c]*Repeated Measures Test*
**p<0.05* ***p<0.01*

**Table 3: Comparison of heart rate measurement values of babies**

| Heart Rate (number / minute | | Group 1 (n = 40) | Group 2 (n = 40) | Test | p |
|---|---|---|---|---|---|
| **Just before the procedure** | *Min-Max (Median)*<br>*Mean±SD* | 123-191 (145)<br>146.38±14.16 | 112-185 (148)<br>148.70±14.36 | t:- 0.729 | [a] p = 0.468 |
| **Immediately after the procedure** | *Min-Max(Median)*<br>*Mean±SD* | 119-198 (158)<br>157.20±16.21 | 136-197 (161,5)<br>161.40±14.83 | t: -1.209 | [a] p =0.230 |
| **5th minute after the procedure** | *Min-Max (Median)*<br>*Mean±SD* | 120-184 (138.5)<br>140.53±13.03 | 115-175 (153)<br>152.35±12.57 | t: -4.132 | [a] p =0.001 |
| | *Test*<br>***p*** | [c]38.615<br>0.001 | [c]23.134<br>0.001 | | |
| **Just before the procedure – Immediately after the procedure** | *Difference*<br>*Test*<br>***p*** | 10.83±13.45<br>Z: -3.558<br>0.001 | 12.70±13.73<br>Z: -3.558<br>0.001 | Z: - 0.140 | [b]p=0.889 |
| **Just before the procedure- 5th minute after the procedure** | *Difference*<br>*Test*<br>***p*** | -5.85±8.60<br>Z: 3.558<br>0.001 | 3.65±10.12<br>Z: -1.405<br>0.084 | Z: -4.154 | [b]p=0.001 |
| **Immediately after the procedure - 5th minute after the procedure** | *Difference*<br>*Test*<br>***p*** | -16.68±13.79<br>Z: 3.558<br>0.001 | -9.05±12.35<br>Z: 3.558<br>0.001 | Z: -2.705 | [b]p=0.007 |

[a]*Student-t Test* [b]*Mann Whitney U Test* [c]*Repeated Measures Test*
***p<0.01*

**Table 4: Comparison of respiratory rate measurement values of babies**

| Respiratory Rate | | Group 1 (n = 40) | Group 2 (n = 40) | *Test* | *p* |
|---|---|---|---|---|---|
| **Just before the procedure** | *Min-Max(Median)*<br>*Mean±SD* | 34-65 (51.5)<br>50.33±7.05 | 27-68 (46.5)<br>46.03±8.70 | *t: 2.428* | [a] *p = 0.017* |
| **Immediately after the procedure** | *Min-Max (Median)*<br>*Mean±SD* | 36-68 (56)<br>56.60±6.57 | 32-72 (54)<br>54.55±9.15 | *t: 1.151* | [a] *p = 0.253* |
| **5th minute after the procedure** | *Min-Max (Median)*<br>*Mean±SD* | 32-62 (48)<br>46.98±6.89 | 28-68 (48)<br>46.80±9.16 | *t: 0.097* | [a] *p = 0.923* |
| | *Test*<br>***p*** | [c]106.383<br>0.001 | [c]79.622<br>0.001 | | |
| **Just before the procedure – Immediately after the procedure** | *Difference*<br>*Test*<br>***p*** | 6.28±3.97<br>t: -3.558<br>0.001 | 8.53±5.28<br>t: -3.558<br>0.001 | *Z: -1.580* | [b]***p*** *0.114* |
| **Just before the procedure- 5th minute after the** | *Difference*<br>*Test*<br>***p*** | -3.35±3.85<br>t: 3.558 | 0.78±3.91<br>t: - 0.453 | *Z: -4.300* | [b]***p*** *=0.001* |

| | | | | | |
|---|---|---|---|---|---|
| **procedure** | | 0.001 | 0.653 | | |
| **Immediately after the procedure - 5th minute after the procedure** | *Difference Test* [c] ***p*** | -9.63±4.82 t: 3.558 0.001 | -7.75±4.88 t: 3.558 0.001 | *Z: -1.957* | [b] ***p = 0.045*** |

[a]*Student-t Test* [b]*Mann Whitney U Test* [c]*Repeated Measures Test*
**p<0.05* ***p<0.01*

**Table 5: Distribution and comparison of crying and processing times of the groups**

| | | Group 1 (n = 40) | Group 2 (n = 40) | Total | *Z* [b] ***p*** |
|---|---|---|---|---|---|
| **Crying time (sn)** | *Min-Max (Medyan)* | 0-108.2 (60.1) | 20.4-60.9 (45.7) | 0-108.2 (50.4) | *-5.697* ***0.001***** |
| | *Ort±Ss* | 60.05±16.64 | 44.38±8.48 | 52.21±15.31 | |
| **Processing time (sn)** | *Min-Max (Medyan)* | 56.6-98.4 (65.8) | 36.9-63.7 (41.5) | 36.9-98.4 (57.6) | *-7.535* ***0.001***** |
| | *Ort±Ss* | 68.98±9.80 | 43.84±6.33 | 56.41±15.07 | |
| **Relationship between crying and processing time** | $r_s$ | 0.559 | 0.203 | 0.683 | |
| | *p* | ***0.001***** | *0.280* | ***0 .001***** | |

[b]*Mann Whitney U Test* *r: Spearman's Correlation Coefficient* ***p<0.01*

**Table 6: The Relationship between the differences in oxygen saturation, respiratory rate and respiratory rate measuring means in the groups and the crying time**

| | Crying times | | | |
|---|---|---|---|---|
| | Group 1 (n = 40) | | Group 2 (n = 40) | |
| | **r** | **p** | **r** | **p** |
| ***Oxygen saturation differences*** | | | | |
| **Just before the procedure – Immediately after the procedure** | -0.190 | 0.239 | -0.296 | 0.064 |
| **Just before the procedure- 5th minute after the procedure** | - 0.305 | 0.056 | 0.163 | 0.316 |
| **Immediately after the procedure - 5th minute after the procedure** | - 0.056 | 0.733 | 0.344 | **0.030*** |
| ***Respiratory rate differences*** | | | | |
| **Just before the procedure – Immediately after the procedure** | 0.115 | 0.478 | 0.337 | **0.033*** |
| **Just before the procedure- 5th minute after the procedure** | - 0.031 | 0.850 | 0.240 | 0.136 |

| | | | | |
|---|---|---|---|---|
| **Immediately after the procedure - 5th minute after the procedure** | - 0.133 | 0.414 | -0.206 | 0.201 |
| ***Respiratory rate differences*** | | | | |
| **Just before the procedure – Immediately after the procedure** | 0.060 | 0.712 | 0.025 | 0.880 |
| **Just before the procedure- 5th minute after the procedure** | 0.265 | 0.098 | 0.258 | 0.107 |
| **Immediately after the procedure - 5th minute after the procedure** | 0.112 | 0.491 | 0.137 | 0.400 |

*r: Spearman's Correlation Coefficient* **p<0.05*

## Discussion

There was no statistical difference in the descriptive and disease characteristics of groups 1 and 2 ($p>0.05$; Table 1). The mean age and sex distributions in the present study were similar to those recorded in the studies by Casati et al. (2007) and Montanari et al.(2010), and body temperature and discharge data were similar to those reported in the study by Casati et al.(2007).

The difference in the mean oxygen saturations recorded 5 minutes after the procedure and immediately before the procedure was significantly higher in group 1, but remained within the normal ranges in group 2 (Table 2). It was thus concluded that nasal cleaning with physiologic saline followed by aspiration using a nasal aspirator in babies led to an increase in mean oxygen saturation and a better procedural outcome, and was effective in providing comfortable respiration.

The mean HR, which was similar in the babies before the procedure, was seen to increase at similar rates immediately in the two groups after the procedure, which was attributed to the stimulant effect of the procedure. However, the mean HR in group 1 recorded 5 minutes after the procedure dropped to below the values recorded immediately before the procedure, and this was significant. A binary comparison revealed the decrease recorded 5 minutes after the procedure when compared with the value recorded immediately before and after the procedure to be significant. It was thus concluded that the 2-stage nasal cleaning method, involving nasal aspiration after nasal cleaning with physiologic saline, was more effective in decreasing HR, resulting in more comfortable babies (Table 3). The obtained results indicate that effective cleaning of the nasal cavity leads to greater respiration and improved HR.

The mean respiratory rates immediately before the procedure were significantly higher in group 1 than in group 2, but were similarly high in both groups immediately after the procedure due to the stimulant effect of the procedure, and declined to similar levels 5 minutes after the procedure. The difference in the decrease in the rates recorded 5 minutes after the procedure from immediately before and immediately after the procedure in the two groups was found to be significant in a binary comparison. It was thus concluded that the aspiration procedure using a nasal aspirator after nasal cleaning with physiologic saline in group 1 provided a significant decrease in HR and a more successful procedural outcome, and was efficacious in easing respiration. In addition, the -7.75±4.88/minute decline in the mean values 5 minutes after the procedure when compared with the mean values recorded immediately after the procedure was statistically significant, and concurred with the findings of earlier studies (Faye et al., 2010, Krishnan, 2013) (Table 4).

The methods applied in the present study are similar to those featured in earlier studies in which a 0.9% physiologic saline solution was found to be effective in softening and cleaning secretions and relieving obstructions (Principi & Esposito, 2017; Uysal & Karaman, 2012; Wilson, 2014; Schreiber et al., 2016; Garavello et al., 2003; Kassel et al., 2010) and in those recommending the use of home-made salted water (Kyle & Carman, 2013; Principi & Esposito, 2017). The present study also concurs with earlier studies in reporting the aspiration of secretions using a nasal aspirator following physiologic saline irrigation to be an effective approach to nasal cleaning (Casati et

al., 2007; Montanari et al., 2010). The positive effects of nasal aspiration following nasal cleaning with physiological saline can be attributed to the 2-phase application and the efficient clearance of the nasal passage (Casati et al., 2007; Montanari et al., 2010; Garavello et al., 2003), and the resulting significant increase in the achieved $SaO_2$ values. Secretions are removed only with the sneezing reflex and under the effect of gravity in nasal cleaning applications using only physiologic saline, whereas the removal of secretions from the nasal cavity with an aspirator following the softening of the secretions with physiologic saline leads to more positive results. It is thought that the stable vacuum power of the aspirator and the availability of appropriate tips matching the dimensions of the nose contribute to the results and lead to secretions in the nasal cavity being completely removed and a more efficient nasal cavity passage being provided, thus increasing $SaO_2$ levels.

A baby may cry for reasons other than illness (e.g., being hungry, fecal soiling, desire for affection, being cold, increased ambient temperature, stimuli such as light and noise), but crying may also indicate various life-threatening or non-life-threatening medical conditions (Baykan et al., 2017). Babies use crying to express irritation during nasal aspiration procedures involving nasal cleaning with physiologic saline, being an invasive procedure. Crying time and procedure duration were found to be significantly longer in the nasal aspiration group following nasal cleaning with physiologic saline in the present study, which may be attributed to the longer duration of the two-phase procedure in group 1, and is an expected result. Indeed, a positive (increased crying time with longer procedure duration), strong (68.3%), and statistically significant association was found between crying time and procedure duration in all cases ($r=0.683$; $r^2=0.46$; with a 46% effect of procedure duration on crying time; $p=0.001$). Although the methods used for nasal cleaning in the present study were not painful, involving such procedures as placing a syringe and aspirator in the nostrils, the physiologic saline used could cause discomfort and result in changes in the $SaO_2$, HR, respiratory rates, and crying times. A positive (greater increase in $SaO_2$ with increased crying time), moderate (34.4%), and statistically significant correlation was found between the crying time of the babies and the differences between the $SaO_2$ measurement 5 minutes after the procedure and the measurement made immediately after the procedure ($r=0.344$; $r^2=0.12$; there was a 12% effect of crying time on the difference in $SaO_2$ levels; $p=0.030$). A positive (increase in HR difference with increased crying time), moderate (33.7%), and statistically significant correlation was found between the difference in the HRs measured immediately after the procedure and immediately before the procedure ($r=0.337$; $r^2=0.11$; there was an 11% effect of crying time on the difference in HR measurements; $p=0.033$) (Table 6).

When the groups were examined in terms of crying time, it was found that the crying time of group 1 was longer than in group 2 (Table 5). However, it was observed that the increase in crying time in group 2 increased the differences in SaO2 and HR more (Table 6). This is significant because it shows that although the procedure time of group 2 was shorter than in group 1, it affected the SaO2 and HR differences more (Table 5). The procedure performed in group 1 was more effective than that in group 2. Babies were thought to be more comfortable with the prolonged procedure in group 1, and so were better able to control their HRs and respiratory rates.

### *Strengths*

Among the strengths of the study is its status as the first to evaluate these approaches to nasal cleaning and nasal aspiration in babies for the treatment of nasal congestion due to URTI considering multiple parameters. Further strengths include the group randomizations and the performance of all nasal cleaning and nasal aspiration procedures by the same researcher in accordance with the application protocols developed by the researchers.

## Conclusion and Implication for Nursing Practice

Clinical approaches involving aspiration with a nasal aspirator in addition to nasal cleaning with physiologic saline can be considered effective in the rapid normalization of oxygen saturation, HR, and respiratory rate in babies. The nasal aspirator used in the procedure cleans the secretions from the nasal cavity more efficiently in a 2-phase procedure, effectively clearing the passage of the nasal cavity, and this makes the cleansing procedure more important.

Aspiration using a nasal aspirator is a useful clinical application when used in conjunction with nasal cleaning with physiologic saline. The

clinical application of nasal cleaning protocols involving physiologic saline and aspiration with a nasal aspirator may be considered in an attempt to identify a standard application procedure. The findings of the present study can be expected to contribute to future evidence-based studies due to the limited number of studies on this subject to date.

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