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Study Of Immediate Effects Of A Rhino-Pharyngeal Clearance Strategy In Nasal BlockageAnd Middle Ear Condition In Children Under 3 Years Of Age.

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Abstract

Children up to 2 years old are at high risk of respiratory infections and nasal irrigation is often prescribed. Yet, to date there is no sufficient knowledge about its immediate effects on the nasopharynx and middle ear. Therefore, this study aimed to analyse the effect of a rhino-pharyngeal clearance intervention protocol on nasal obstruction and middle ear condition in children under 3 years of age with URTI. Randomised controlled trial in a day-care centre of Porto, including 44 children randomised to Intervention Group (IG) and Control Group (CG). Nasal auscultation and tympanometry were performed at baseline (M0) as well as after the intervention (M1), which consisted of nasal irrigation (NaCl .9%) followed by a forced nasal inspiration in the IG, and after 30 min of normal activities, in the CG. In M1 there was a lower frequency of children classified as having an obstructed nasal sound in the IG when compared to the CG (IG = 33.3%; CG = 68.4%; p = 0.042). We also observed an improvement of mean peak pressure (PP) in the IG (Left ear: M0 = 124daPa; M1 = 92daPa; p = 0.022. Right ear: M0 = 102daPa; M1 = 77daPa; p = 0.021), which was not observed in the CG (Left ear: M0 = 105daPa; M1 = 115daPa; p = 0.485. Right ear: M0 = 105daPa; M1 = 131daPa; p = 0.105). There were no significant results concerning the compliance of the tympanic membrane. The rhino-pharyngeal clearance improved the nasal obstruction and PP of the middle ear of children under 3 years of age with URTI.

Keywords: Rhinopharyngeal clearance, Nasal irrigation, Respiratory tract infections, Tympanometry.

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INTRODUCTION

The most common ailment in children is acute respiratory infections (ARI) [1]. Children are a significant risk group due to a higher exposure to viral respiratory infections and underdeveloped immunological and respiratory systems [1]. Furthermore, it is established that daycare attendance has a detrimental impact on a child's health since it exposes them to a greater risk of ARI than children who remain home [2]. Nasal discharge, coughing, nasal congestion, and indications of middle ear damage are the most typical URTI signs and symptoms. Most URTI symptoms, such as coughing and runny nose, remain for 7 days on average, although they can last for up to 2-4 weeks in certain cases [3, 4]. Since young children breathe primarily through their noses, this puts immense pressure on them. If they are unable to blow their noses to clear nasal secretions, breathing becomes difficult for them, which can disrupt their sleep, increase their risk of obstructive apnea, and make it difficult for them to feed themselves [5]. Since antibiotics, opioids, antihistamines, and decongestants are not advised for use in treating URTI in children, there is no confirmation that any of these medications are useful [6]. In order to restore nasal breathing, minimise nasal secretions and stop dissemination, an effective rhino-pharyngeal clearance may be employed [7-10].

Other advantages have also been noted, including the quicker resolution of acute nasal symptoms, particularly daytime rhinorrhea and nocturnal nasal congestion, which may explain why young children frequently undergo nasal irrigation [11, 12].

However, little is known regarding the immediate and direct effects of nasal irrigation in the middle ear and nasopharynx of children with URTI. In this study, children with URTI who were enrolled in daycare centres up to the age of 3 were evaluated for nasal obstruction and middle ear conditions. The effectiveness of a rhinopharyngeal clearing intervention model was evaluated.

MATERIAL AND METHODS

Seven private day-care centres in Ahmednagar were included for conducting a randomised controlled trial during January to March, 2016.

The Ethics committee of the DVVPF'S Hospital, Ahmednagar was approached for approval.

The procedures and objectives of the entire study was carefully explained to the parents after which a consent in the written form was taken in accordance with the Declaration of Helsinki. A form containing the correct anthropometric, social, and pathogenesis factors was also included along with the primary reports.

The following children were included:

Patients with acute URTI on the day of admission - reported by the parents, along with the presence of rhinorrhea.

Exclusion criteria were defined as: preterm child, prior history of otorhinolaryngological studies, children with any kind of allergies, asthma or with the history of insertion of grommets. Children were excluded if their ear canals were clogged with wax, or presented with a normal respiratory health condition or a normal history of events.

A blind protocol was followed with the inclusion of an audiologist and a respiratory physiotherapist. Otoscopy was followed after tympanometry. The caregivers were asked to hold their children on their laps and the procedure was performed.

Impedance audiometer MT10 calibrated on 22 November 2015 was used for the assessment of the testing protocol. The condition of the middle ear was tested and the auditory canal and its membrane were checked.

To assess the children's normal respiratory health, certain objective and subjective criterias were chosen.

Subjective parameters- nutritional intake, pyrexia, rhinorrhea

Objective parameters- dyspnea, lung morbidity, lung sounds, sputum quality and quantity.

final score is divided into three categories: mild impairment of the respiratory health condition (PRSS = 8), severe impairment of the respiratory health condition (PRSS > 16). Test-retest reliability (ICC 2.1 = 0.91) and content validity (Cronbach's alpha = 0.80) for PRSS were both very high [13].

A Littmann 3200 Electronic Stethoscope (3M Health Care®, USA) was utilised for nasal auscultation. In an upright position with respect to the nostrils, 5 cm between the nose and the stethoscope diaphragm was used to gather nasal auscultation sounds. Each sound was digitally recorded for 15 seconds using the Zargis® StethAssistTM programme. The nasal noises were then recorded and Bluetooth-transferred to a laptop computer. Following that, every sound was coded and randomly assigned according to the goals of the study by a separate, blinded researcher.

Three respiratory physiotherapists with at least three years of expertise treating paediatric nasopharyngeal obstruction served on the expert panel that examined the coded nasal sounds, classifying them as "obstructed" and "non-obstructed." In a prior study, nasal auscultation in children shown significant intra-rater (K = 0.69; K = 0.61 and K = 0.72) and inter-rater (K = 0.75) reliability [14].

Children from the Intervention Group (IG) received a standard intervention protocol from a different respiratory physiotherapist that involved nasal irrigation with an isotonic saline solution (Physiological Serum —-0.9 percent NaCl) using a low pressure device (syringe-type or unidose) with no more than 50 ml. The young patient's head was turned toward the side of the nose that needed cleaning as he or she was perched on the physiotherapist's lap, with a slight forward bend. Nasal secretions were carried along by the serum as it entered the upper nose and left through the lower nostril. In order to successfully remove the nasal secretions from both nostrils and make sure that the anterior part of the nasopharynx was unobstructed, the same process was performed as many times as necessary.

After a lengthy expiration, the child's mouth was briefly closed to trigger a quick and profound nasal inspiration in order to ensure the entire clearing of the posterior portion of the nasopharynx. This manoeuvre was modified from the Désobstruction Rhinopharyngée Rétrograde (DRR) respiratory physiotherapy technique, which is based on the Hering-Breuer deflation reflex and the active inspiratory effort caused by pulmonary deflation [15, 16].

The Control Group (CG) children carried on with their regular activities for the anticipated duration of the intervention regimen (about 30 min).

After the intervention regimen was completed in IG and after 30 minutes in CG, the usual assessment was repeated (M1).

Sample Size

Pilot testing revealed an impact size of 0.912 regarding PP of the left ear and an effect size of 0.946 regarding PP of the right ear in a sample of 10 children with URTI, with a mean age of 17.3 5.44 months and 60% male gender. A power (1 err prob) = 0.95 at a 5% level of significance was used in the sample size calculation, which indicated that a total sample size of 24 children would be required.

After reaching out to 201 parents of kids enrolled in seven daycare centres in Ahmednagar, 117 consented to take part in the study (response rate: 58.2%). A final sample of 75 children was obtained after 42 infants were eliminated because they did not match the inclusion criteria (31 had a PRSS = 8, two were pre-term births, two had chronic rhinosinusitis, three exhibited crackles in pulmonary auscultation, and four had obstructive ear wax). According to a table of random numbers, between 0 (Control Group) and 1 (Intervention Group), provided by the statistical software, the children were then divided by a blinded collaborator at random into an Intervention Group (IG) (n = 37) that underwent intervention protocol and a Control Group (CG) (n = 38) that continued normal daily activities.

Statistical Analyses

The IBM® SPSS® Statistics 22 software for Windows 8® was used for all statisticalanalyses, with a confidence interval of 95% and a significance level of 0.05.

For continuous variables, mean and standard deviation were employed, whereas relative frequency was utilised for dichotomous variables.

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Student's t-test for independent samples (continuous variables) and the Chi-square test were used to evaluate intergroup comparisons (dichotomous variables). The student's t-test for paired samples (continuous variables) and the Chi-square test (dichotomous variables) were used to analyse intra-group comparisons.

RESULTS

The data analysis only applies to the remaining 23 of the 37 children who were randomly assigned to IG because 14 of them (6 did not finish the evaluation protocol and 8 had corrupted recorded sounds) were lost to follow-up. Regarding CG, the reports from the remaining 21 children were evaluated after 17 of the 38 randomly assigned children were lost to follow-up (8 did not complete the assessment protocol and 9 had corrupted recorded sounds) (Fig. 1). Table 1 summarises the baseline sociodemographic traits and risk profile history of the children and caregivers in each group and demonstrates that there were no significant differences between the two groups.

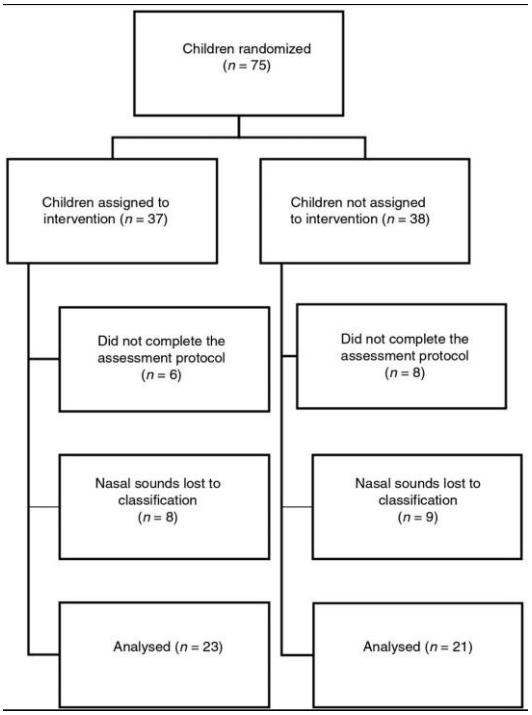

Figure 1: Diagram flow of participants.

		Control group	Intervention group	*p* value (95%)
Caregivers	Mother's age at child's birth ($X \pm SD$)	33.8 ± 4.07	32.3 ± 4.26	0.278
	Months of breastfeeding ($X \pm SD$)	6.14 ± 3.05	6.56 ± 4.08	0.675
	Higher education (%)	64.7	82.6	0.274
Household	Household >3 (%)	50.0	34.7	0.233
	Parents' respiratory diseases (%)	44.4	43.5	1.000
	House smoking (%)	27.8	17.4	0.471
Children	Male gender (%)	45.0	47.8	1.000
	Months of age ($X \pm SD$)	20.3 ± 5.92	22.6 ± 7.49	0.274
	Weight at birth (kg) ($X \pm SD$)	3.1 ± 0.53	3.2 ± 0.47	0.968
	PRSS ($X \pm SD$)	9.9 ± 1.16	10.3 ± 1.25	0.403
Day-care	Room size (m^2) ($X \pm SD$)	31.9 ± 7.93	28.4 ± 8.01	0.142
	Number of children per room ($X \pm SD$)	8.07 ± 2.22	9.33 ± 2.52	0.128

Table 1: Baseline sociodemographic characteristics and risk profile history of children and caregivers from IG and CG.

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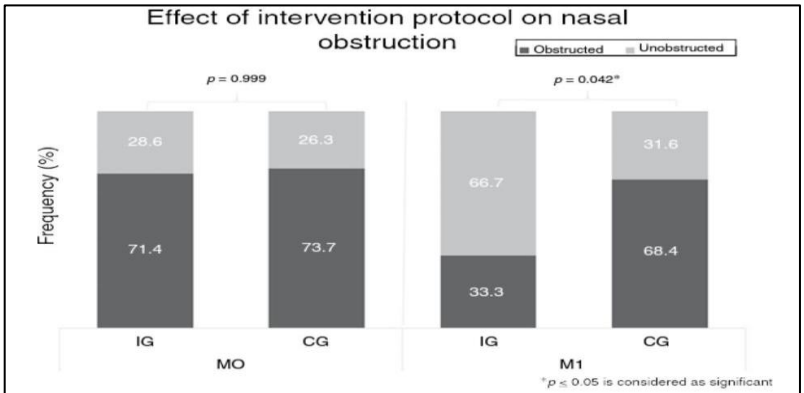

Figure 2 Effect of the rhino-pharyngeal clearance protocol on nasal obstruction of children from in IG and CG.

Significant differences between groups were found in M1 after rhino-pharyngeal clearance, with a higher percentage of children in IG being classified as having an unobstructed nasalsound (Fig. 2).

Significant differences between groups were found in M1 after rhino-pharyngeal clearance, with a higher percentage of children in IG being classified as having an unobstructed nasalsound (Fig. 2).

With the use of the intervention regimen, there were no discernible alterations in the tympanic membrane's compliance. Fig. 4 presents a summary of the findings.

DISCUSSION

This research was the first to use nasal auscultation to evaluate the direct impact of a rhino-pharyngeal clearance intervention programme in nasal blockage.Furthermore, the direct influence of nasal irrigation on children's middle ear is not well understood, therefore this study provides novel and significant evidence.

In reality, there aren't many suitable tools for evaluating nasal blockage in young children. Although acoustic rhinometry, rhinomanometry, and peak nasal inspiratory flow are effective in determining whether a nasopharyngeal obstruction is present, their use is limited due to the complexity and cost. They are also primarily used in laboratory or clinical settings, which limits their suitability in infants [17].

Therefore, nasal auscultation was employed to overcome these challenges because it is a straightforward and non-invasive process and does not require the child's cooperation, other than being relaxed and quiet. In a previous study, the psychometric properties of nasal auscultation were evaluated in comparison to other clinical assessments [14].

In terms of spectral features, it does appear that a nasally blocked sound differs from an unobstructed one. Particularly during the inspiratory phase, obstructed nasal sounds appear to be lower frequency and less intense than normal nasal sounds [14]. However, nasal flow spectrum studies need to take into account a variety of factors, including the use of suitable filters that might separate nasal sound, turbulent flow, roughness of the wall, irregular contour of the nasal cavity, collapsible segments, and other resistances. This study found significant differences across groups, with a greater frequency of children identified as having an unobstructed nasal sound following rhino-pharyngeal clearing in contrast to the control group.

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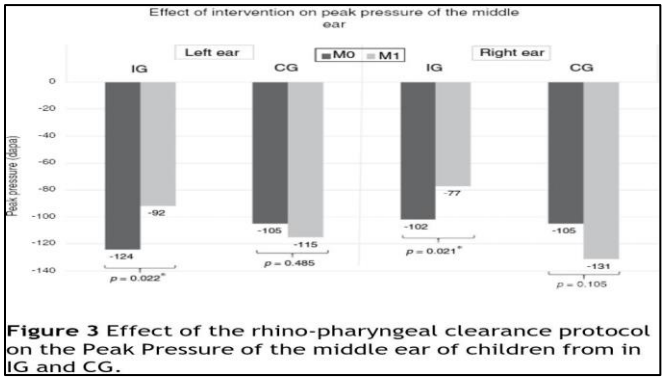

Figure 3 Effect of the rhino-pharyngeal clearance protocol on the Peak Pressure of the middle ear of children from in IG and CG.

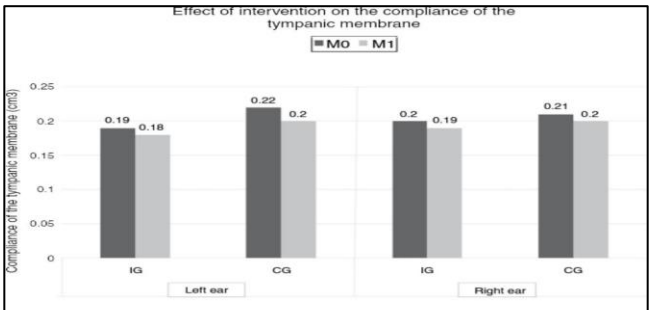

Figure 4 Effect of the rhino-pharyngeal clearance protocol the compliance of the tympanic membrane of children from IG and CG.

There is a gap in research on nasal auscultation, and little studies on pulmonary auscultation, which is regarded as a less precise measurement in children than in adults, due to its reliability being tested as low to moderate [19]. Additionally, a prior study discovered significant inter-rater reliability and high intra-rater reliability for nasal auscultation in children under the age of three [14] However, this considerable agreement in measures, either betweenexaminers or within the same examiner, demonstrates merely a strong consistency in nasal sound classification and does not indicate the accuracy of their classification. As a result, the effect of the rhino-pharyngeal clearance protocol in the middle ear condition of children with URTI was also examined, taking into consideration the relationship between nasopharyngeal blockage and Eustachian tube dysfunction [9, 10, 20].

It is well established that URTI frequently causes nasopharyngeal inflammation, resulting in blockage of the Eustachian Tube with the development of negative pressure inside the middle ear, resulting in effusion and aspiration of nasopharyngeal secretions [21-23].

This changes the conditions of the middle ear, allowing greater predisposition for Acute OtitisMedia (AOM) [21-23]. A previous study discovered a significant link between nasal sound classification and peak pressure values in middle ear of children [14]. The experts confirmed that children with "non-obstructed" nasal sounds had higher PP values than those with "obstructed" nasal sounds. So, perhaps clearing secretions from the nasopharynx could restore middle ear pressure, hence stabilising Eustachian Tube function. Our findings revealed that children who underwent the rhino-pharyngeal clearing treatment saw a rapid improvement in middle ear peak pressure (PP), which was not observed in CG. It is generally established that there is a link between middle ear pressure and nasopharyngeal blockage, as well as rhinorrhea [24, 25]. Therefore, an increase in PP immediately following the intervention programme might indicate that it was effective in lowering or eliminating nasal secretions, re-establishing nasal breathing, and improving middle ear ventilation and drainage [7, 10].

In addition, children who have low PP values during URTI and require longer to recover to a normal PP have a higher chance of developing Otitis Media with Effusion and AOM; therefore, a good improvement in PP values may also lessen the risk of AOM [26]. Although nasal irrigation reduces nasal congestion in children with URTI by clearing bacteria, allergens, and other pollutants from the nasopharynx and lowering medication use [5, 7, 11, 27, 28] it appears to have only a minimal impact on the posterior portion of the nasal cavities [29]. As a result, the inclusion of the Désobstruction Rhinopharyngée Rétrograde procedure provides the clearance of the posterior area of nasal cavities (cavum), which is the proximal end of the

Eustachian tube, hence assisting in the normalisation of PP of the middle ear [15].

Although intervention studies are needed to offer more consistent evidence on the efficacy of this procedure in babies, clinical benefits are rapid and often remarkable [15] The compliance of the tympanic membrane did not show any significant alterations immediately following the intervention treatment in this study. This might be because tympanic membrane mobility is linked to the inflammatory process of the nasopharynx, creating oedema, which reduces mobility even when PP is no longer abnormal [30]. This suggests that further treatments and/or a greater follow-up would be required to determine if compliance will return to normal levels, which is a drawback of this study. Another disadvantage is the lack of a gold standard device for measuring nasal obstruction in newborns in a community context, which restricts the validation of the intervention approach. More research is needed with larger samples, more days of intervention, and longer follow-ups to see if the changes in PP can be sustained over time and if there is any improvement in tympanic membrane compliance. It would also be interesting to investigate the clinical impact of the Rhino-pharyngeal clearance procedure on the occurrence of OME or AOM.

CONCLUSION

Children under the age of three who were receiving care at daycare facilities in Ahmednagar and had a URTI saw an immediate improvement in their nasal blockage and middle ear PP after beginning the rhino-pharyngeal clearance programme.

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