



Pilot Observational Study on the Use of Narlisim in Children Under Three Years of Age with Nasal Obstruction and a History of Acute Otitis Media

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Abstract

Nasal irrigation, by mechanically removing secretions and liquefying mucus, allows children to improve nasal breathing, with a significant impact on quality of life and reduction of comorbidities. Evidence supports its use as a safe and reasonably effective practice in managing nasal symptoms even in children under 36 months of age. In our uncontrolled observational study, we evaluated the safety profile of Narlisim, a medical device based on a hypertonic saline solution with moderately acidic pH and osmoprotective activity for nasal use, in children under 36 months of age during one month of continuous use. Despite their young age, in which allergic reactions to topical nasal applications can occur more frequently than in adults, no adverse events attributable to the use of this medical device were observed after one week (T1) or one month (T2) of treatment. Moreover, the use of Narlisim proved to be statistically effective in controlling nasal symptoms such as obstruction and rhinorrhea, and also demonstrated significant improvement in rhinoscopic findings. Given the small sample size and the study design, further controlled randomized studies with larger populations are needed to confirm our observations.

Background

In newborns and infants, breathing is defined as obligate nasal. During the first six months of life, infants breathe almost exclusively through the nose, due to the higher position of the larynx compared with older children and adults. Nasal obstruction therefore has a significant impact on the infant's breathing, with consequences for sleep quality, feeding, and, in severe cases, gas exchange. Oral breathing begins to develop after six months of age; in the presence of mucus or adenoidal hypertrophy, it may become preferred by the child, negatively affecting sleep, feeding, and, if prolonged, oral development (malocclusion, swallowing disorders, articulation issues). Nasal irrigation, by mechanically removing secretions and liquefying mucus, allows the child to regain nasal breathing, with a significant improvement in quality of life and reduction of comorbidities [1,2].

This practice is recommended by current Pediatric Guidelines as a safe and useful measure for both supportive care and prevention of upper respiratory tract infections in children [1,2]. Meta-analyses of randomized controlled trials (RCTs) conducted in children aged between 3 months and 12 years have shown that saline nasal irrigations improve nasal symptoms in acute rhinitis and reduce the need for additional treatments, with an

excellent safety profile. In children under 24 months of age, currently available trials demonstrate both symptomatic benefit and good tolerability [2-4]. Furthermore, Italian observational data in children aged between 2 and 24 months have shown a reduction in complications such as acute otitis media [5]. Overall, therefore, in children under 3 years of age, evidence supports nasal irrigation as a safe and reasonably effective practice for the management of nasal symptoms [6-8].

Narlisim is a medical device consisting of a hypertonic saline solution for nasal use, available in 2.5 cc vials and spray form. In the absence of specific RCTs conducted in children under 36 months of age, the plausibility of its efficacy is based on the shared mechanism of action and the available evidence from the class of saline nasal irrigations in infants and toddlers. Regarding safety, its use is supported by extrapolation of class evidence; moreover, studies currently available on the use of Narlisim in children over 3 years of age have demonstrated the complete safety of the product [9,10]. To investigate the safety profile of Narlisim in children under 36 months, we conducted an observational study in this age group at the Pediatric Otorhinolaryngology Service of Regina Margherita Children's Hospital (OIRM) of Turin.

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Table 1. Patients' age in months, mean and standard deviation by sex.

months												Fem m	ds	Male m	ds	m	ds
18	11	32	36	36	33	18	20	11	23	30	23	18,7	12,1	20,07	7,56	19,5	9,74
9	3	6	10	26	30	10	18	18	24	6	17						

Materials and methods

We enrolled 24 patients aged between 3 and 36 months, 10 females and 14 males, at the Pediatric ENT clinic of OIRM in Turin, all presenting with nasal obstruction and a positive history of recurrent acute otitis media. Patients were evaluated three times: at the first visit (T0), after one week (T1), and after one month (T2) of using NARLISIM (nasal irrigation with one vial per nostril, twice daily).

NARLISIM is a new nasal medical device with specific characteristics that make it "suitable also for babies" according to its safety profile [10,11] together with its well known mechanical activities [12]. Indeed NARLISIM is a nasal washing saline Hypertonic solutions with low pH that make it "mechanically useful" for children and adults [9,10].

PIROMETAXINE™, a new patented co-processate compound between Pyrrolidone Carboxylic Acid and Copper Sulphate contained in NARLISIM, has shown to add to the previous mechanical activities also the osmoprotection that could improve the osmotic balance of the nasal mucosa and an ancestral anti-infective mechanical actions [12] that, together with acidity of the solution, could create an unfavourable environment for the proliferation of virus and bacteria of the upper airways [13]. The specific profile of this medical device has shown to be useful in counteracting nasal congestion in children and in adults [9,10,14].

Aim of our observational, pilot, uncontrolled study has been to evaluate its safety (and effectiveness) in little children between 2 to 36 months of age.

At each evaluation, parents completed a Visual Analogue Scale (VAS; range 0–10) questionnaire assessing several parameters: nasal obstruction, rhinorrhea, sleep quality, feeding or breastfeeding quality, and the child's overall well-being. All patients also underwent an ENT examination, including otoscopy and rhinoscopy. The primary endpoint of the study was the tolerability of the medical device in children within this age range, while the secondary endpoint was its clinical efficacy in controlling nasal symptoms and the objective improvement of rhinoscopic and otoscopic findings.

Results

Primary Endpoint – Safety

Despite the young age, in which allergic reactions to nasal topical applications can occur more frequently than in adults, none of the evaluated children presented adverse effects attributable to the use of the medical device after one week (T1) or one month (T2) of treatment.

Secondary Endpoint – Efficacy

Narlisim use proved to be statistically significant in controlling nasal symptoms, namely obstruction and rhinorrhea. Mean VAS scores at T0 for nasal obstruction and rhinorrhea were 6.75 and 5.91, respectively. At T1, mean values were 4.13 and 4.16, while at T2 they decreased to 2.37 and 2.25, respectively. Results compared via t-Test were statistically significant.

Unpaired t test results of nasal symptoms

• Nasal Obstruction T1

Group	T0	T1
Mean	6.75	4.13
SD	1.45	1.87
SEM	0.30	0.38

P value and statistical significance: The two-tailed P value is less than 0.0001. By conventional criteria, this difference is considered to be extremely statistically significant.

Confidence interval: The mean of T0 nasal congestion minus T1 nasal congestion equals 2.63 95% confidence interval of this difference: From 1.65 to 3.60 Intermediate values used in calculations: $t = 5.4274$, $df = 46$

standard error of difference = 0.484

• Nasal Obstruction T2

Group	T0	T2
Mean	6.75	2.37
SD	1.45	1.21
SEM	0.30	0.25

P value and statistical significance: The two-tailed P value is less than 0.0001. By conventional criteria, this difference is considered to be extremely statistically significant.

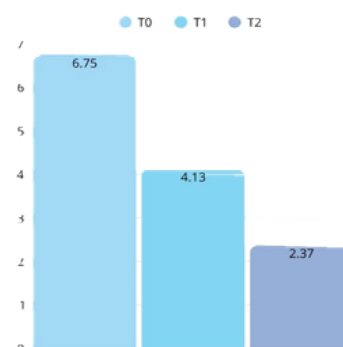
Confidence interval: The mean of Group One minus Group Two equals 4.38

95% confidence interval of this difference: From 3.60 to 5.15

Intermediate values used in calculations: $t = 11.3425$, $df = 46$

standard error of difference = 0.386

• Rhinorrhea T1

**Figure 1.** Nasal obstruction at T0, T1, T2: mean values

Group	T0	T2
Mean	5.92	4.17
SD	2.38	1.99
SEM	0.48	0.41

P value and statistical significance: The two-tailed P value equals 0.0082. By conventional criteria, this difference is considered to be very statistically significant.

Confidence interval: The mean of Group One minus Group Two equals 1.75

95% confidence interval of this difference: From 0.48 to 3.02

Intermediate values used in calculations: $t = 2.7647$, $df = 46$

standard error of difference = 0.633

• Rhinorrhea T2

Group	T0	T2
Mean	5.92	2.25
SD	2.38	1.36
SEM	0.48	0.28

P value and statistical significance: The two-tailed P value is less than 0.0001. By conventional criteria, this difference is considered to be extremely statistically significant.

Confidence interval: The mean of Group One minus Group Two equals 3.67

95% confidence interval of this difference: From 2.54 to 4.79

Intermediate values used in calculations: $t = 6.5623$, $df = 46$

standard error of difference = 0.559

No statistically significant differences were observed in the

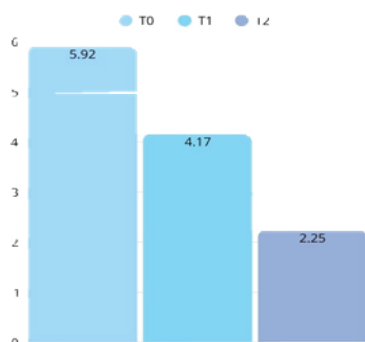


Figure 2. Rhinorrhea at T0, T1, T2: mean values

categories “general condition,” “feeding,” and “sleep quality” between T0–T1 and T0–T2. However, regarding the latter parameter, parents reported a less noisy nocturnal breathing pattern in 80% of cases.

With regard to the ENT objective findings, a statistically significant improvement in the rhinoscopic assessment (normal rhinoscopy/serous rhinorrhea/mucopurulent rhinorrhea) was observed at both T1 and T2. Conversely, no statistically significant improvements were detected in the otoscopic findings at either T1 or T2.

Unpaired t test results of ENT findings

• Rhinorrhea T1

Group	T0	T2
Mean	0.88	0.42
SD	0.45	0.65
SEM	0.09	0.16

P value and statistical significance: The two-tailed P value equals 0.0068. By conventional criteria, this difference is considered to be very statistically significant.

Confidence interval: The mean of Group One minus Group Two equals 0.46

95% confidence interval of this difference: From 0.13 to 0.78

Intermediate values used in calculations: $t = 2.8320$, $df = 46$

standard error of difference = 0.162

• Rhinorrhea T2

Group	T0	T2
Mean	0.88	0.21
SD	0.45	0.59
SEM	0.09	0.12

P value and statistical significance: The two-tailed P value is less than 0.0001. By conventional criteria, this difference is considered to be extremely statistically significant.

Confidence interval: The mean of Group One minus Group Two equals 0.67

95% confidence interval of this difference: From 0.36 to 0.97

Intermediate values used in calculations: $t = 4.4155$, $df = 46$

standard error of difference = 0.151

Conclusions

Narlisim is a medical device consisting of a hypertonic saline solution with a moderately acidic pH and osmoprotective activity for nasal use. In our study, we evaluated the safety profile of this product by observing the enrolled children over a one-month period of continuous use, without detecting any adverse events attributable to the device. Moreover, the use of Narlisim proved to be statistically effective in controlling nasal symptoms—namely nasal obstruction and rhinorrhea—and also demonstrated a significant improvement in rhinoscopic findings.

The small sample size and the observational design of the study do not allow definitive conclusions to be drawn about this medical device; further randomized controlled studies with larger sample sizes are warranted to confirm our observations.

Nevertheless, considering the well-established safety of nasal irrigation in children under 36 months of age and the exclusively mechanical mode of action of this medical device, we can affirm that nasal irrigation with Narlisim represents a safe and effective medical option for controlling nasal symptoms associated with common cold and improving rhinoscopic findings even in children below 36 months of age. Therefore, its use appears to be valuable as supportive therapy and preventive care in upper respiratory tract infections within this age group.

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