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Research article

Hydrocolloid versus silicone gel for the prevention of nasal injury in newborns submitted to noninvasive ventilation: A randomized clinical trial

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ABSTRACT

Purpose: To compare the effectiveness of the hydrocolloid and the silicone gel on the nasal protection of the newborns (NBs) during the use of noninvasive ventilation (NIV).

Materials and methods: Thirty-three NBs were selected. They were randomly divided into three groups of 11 NBs, according to the type of nasal protection used: hydrocolloid, thick silicone gel, and thin silicone gel. The stage of the nasal injury and need for exchanging nasal protection were assessed before the connection to the NIV and every 24 h until the physician's authorization for NIV's suspension.

Results: The mean gestational age was 32.03 ± 3.93 weeks, and the median birth weight was 1760 g (750–3535 g). The incidence of nasal injury using hydrocolloid, thick silicone gel, and a thin silicone gel group was 36.36%, 81.81%, and 72.72%, respectively ($p = 0.06$). Regarding the injury stage, there was no statistical significance between the three study groups. The hydrocolloid protection type had the best adhesion ($p = 0.03$) on the NBs' skin.

Conclusions: Although this study was conducted by local practice patterns, the results showed that the hydrocolloid could be the best choice to prevent the nasal septum base injury in the NB submitted to NIV.

1. Introduction

The NIV provides ventilatory support through a noninvasive (external) interface, replacing the invasive mechanical ventilation and their deleterious effects [1, 2, 3]. The NIV has interfaces with the NB skin, such as facial masks, nasal masks, nasopharyngeal prong, and short binasal prong [4]. The most common interface used in NB is the short binasal prong [5] which can cause nasal injuries due to the rubbing with the skin [6], causing from simple hyperemia to necrosis that destroys the columella and nasal septum [7].

Incidence of nasal injury in preterm infants receiving NIV varies from 13,2% a 50% [7], but it can reach 100 % rates [5]. Nasal injury that can be the cause of unexplained septicemia [8], is a source of discomfort for patients limiting the use of NIV in NBs [9, 10].

Hydrocolloid [11] or silicone gel dressing [12] is applied to the nasal septum base on the NB submitted to NIV to reduce the occurrence and severity of the nasal injuries. The hydrocolloid dressing consists of a hydrophobic outer layer of polyurethane film and a hydrophilic inner layer made of carboxymethylcellulose, pectin, and gelatin [13]. This dressing has been used in wound treatments of pressure ulcers to absorb exudate, transforming it into a gel [14]. The silicone gel tape, a soft and flexible material [12], is a dressing designated to prevent hypertrophic and keloid scars, besides the pressure ulcers [15]. It consists of an elastomeric membrane and a layer of adhesive composed of polydimethylsiloxane with different levels of crosslinks [16].

Although both hydrocolloid and silicone gel tape are applied to the nasal septum base of the NBs under intensive care [11, 12], prospective comparative studies showing the efficiency in the prevention of the nasal injury with these two protectors have not been found. Therefore, the present study aimed to compare the effects of hydrocolloid and silicone gel for protecting the nasal base of NBs against injuries caused by the insertion of a short binasal prong during the use of NIV, in order to find which of them is better for preventing this kind of nasal injury.

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2. Material and methods

The study was a randomized controlled clinical trial carried out in the Neonatal Intensive Care Unit (NICU) at the Waldemar Monastier Children's Hospital, Campo Largo, Paraná, Brazil, for 15 months. It followed the Consolidated Standards of Reporting Trials recommendations, was approved by the Human Research Ethics Committee at the Federal Technological University of Paraná under the number 42718915.4.0000.5547, and registered at the Brazilian Clinical Trials Registry (RBR-73xvmg).

The NBs only participated in the study after their parents or guardians have been informed of the objectives, procedures, importance of the study, and after have been signed the Informed Consent Term and the Consent Term for the Use of Image and Voice Sound.

2.1. Study population

All NBs with less than 38 weeks of gestational age in NIV during the period of the study in the NICU were eligible. The inclusion criteria had involved the following: NBs of both genders, without distinction of ethnicity or social group, requiring NIV with short binasal prong for at least 24 h. Exclusion criteria had included: NBs with choanal atresia, cleft lip, and cleft palate.

The NBs were divided into three groups, according to the type of nasal protector used: (1) hydrocolloid tape, (2) thin silicone tape (0.3 mm), and (3) thick silicone tape (0.9 mm). The sequence of nasal protection that would be used was randomly defined by a physiotherapist specialized in intensive therapy, with a strong know-how in neonatology.

The sequence defined by the physiotherapist was as follows: the first participant received hydrocolloid tape nasal protector with of approximately 0.3 mm (Group A), the second one received the silicone gel tape of 0.9 mm (Group B), and the third volunteer received silicone gel tape of 0.3 mm-thickness (Group C). This procedure was repeated until the defined end date.

If the newborn remained for less than 24 h on noninvasive ventilation, he was excluded and the next one took his place so that the number of participants was the same in the three groups.

The groups were characterized in terms of gender, gestational age, weight, and ventilatory support duration.

2.2. Intervention

All NBs had received NIV employing a mechanical ventilator (Inter Neo, Intermed, São Paulo, Brazil). The interfaces used were short binasal prongs available in the studied NICU from three different manufacturers (Inca, Ackrad Laboratories Inc, Cranford, USA; Gabisa Medical International, Sorocaba, Brazil and Fanem, São Paulo, Brazil). The prongs were sterilized and reused or new ones selected according to the availability of the material when the NIV was connected to the NB.

The NBs from Group A received the nasal protection of transparent hydrocolloid (Comfeel Plus, Coloplast do Brasil, Rio de Janeiro, Brazil). The NBs from group B gotten the thick silicone tape (Epi-Derm Silicone Gel Sheeting, Biodermis, Las Vegas, USA), and from group C received the thin adherent dressing silicone (Mepiform, Mölnlycke Health Care, Göteborg, Sweden).

In all cases, the tape was cut in the nasal base format and fixed before the installation of the NIV's equipment in order to protect nostrils, columella, and the base of the nasal septum. The NBs were placed in the supine position to fix the adhesive part. The preformed tape was replaced only in case of detachment.

Figure 1 presents the protectors cut in the nasal base format, and Figure 2 shows an NB in NIV using a short binasal prong and of the nasal protector.

All evaluations were performed before the installation of the NIV and every 24 h until the first suspension of this support. All newborns were evaluated by the same professional.

If the NBs have developed stage I nasal injury, the physiotherapists had used 0.9% physiological solution and performed circular movements in the nostrils during the usual physical treatment. For stage II nasal injury, the assistance for the stage I was the same as for stage I, but in some cases, it was possible of intercalating the NIV with an oxygen helmet. For stage III, if it was not possible to substitute NIV for other noninvasive support, the physicians have assessed the possibility of invasive mechanical ventilation.

2.3. Primary outcome

The primary outcome was the stage of nasal injury and the rate of breakdown. Nasal injuries were classified into three stages, according to Fischer *et al.* [10]: (I) intact skin with localized non-bleachable erythema; (II) partial thicknesses loss of skin exposing the dermis that presents a red crustless bed wound; and (III) full-thickness loss of skin. The clinical inspection of the skin in the columella and nasal septum base was done with the assistance of a clinical flashlight and with the NB in dorsal decubitus position without proclivity.

The photographic record was performed using a Canon PowerShot SX50 HS camera in TV mode, opening speed of 1/100, and automatic ISO. During the procedure of photos acquisition, the binasal prong was removed, and the eyes were blindfolded. Three images of each NB were taken: the first with the head centralized, the second with the head carefully turned to the right side, and the third with the head carefully turned to the left side.

2.4. Secondary outcome

As a secondary outcome, we perceived the need to exchange the nasal protector due to detachment, daily recorded, and to the injury staging; and also due to change the protective barrier to prevent the injury progression.

2.5. Statistical analysis

The data were analyzed with GraphPad Prism version 7.2 (GraphPad Software Inc., California, USA). The normality of the samples was analyzed by the Shapiro-Wilk test. Quantitative variables with a normal distribution were presented as a mean and standard deviation. Those variables found to have a non-parametric distribution are presented as a median and interquartile range. Percentage and frequencies were evaluated for categorical variables.

For statistical analysis, Pearson's chi-square test, One-way ANOVA and Kruskal-Wallis Anova were applied with Duncan and Mann-

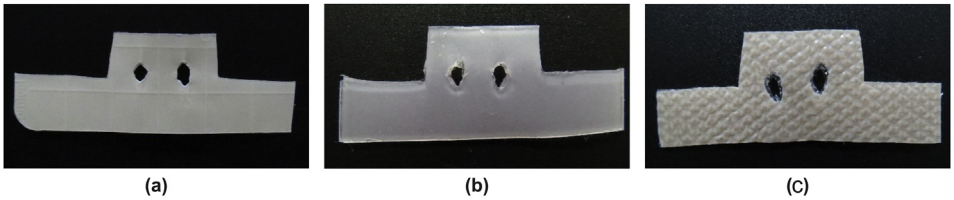

Figure 1. Tapes cut in the nasal base format to use as protectors: (a) hydrocolloid, (b) thick silicone, and (c) thin silicone.

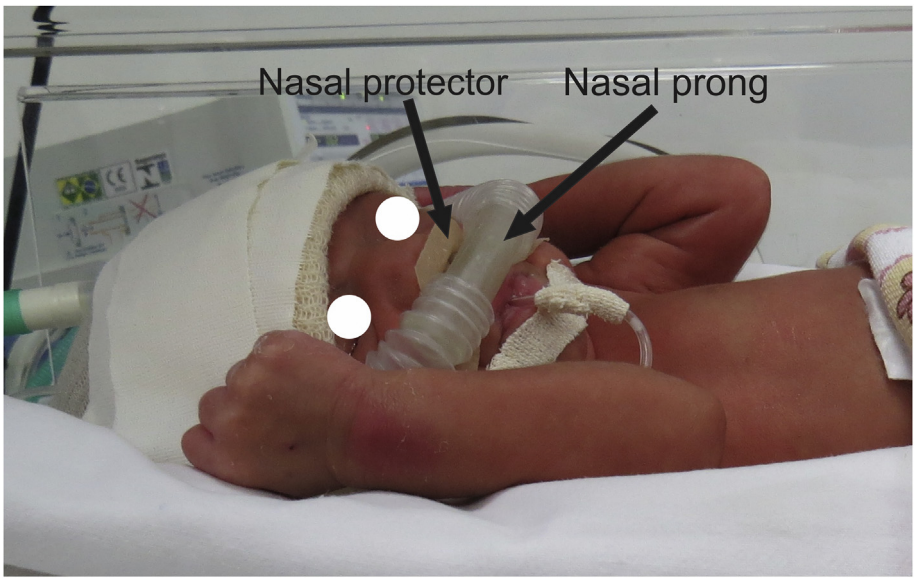

Figure 2. NB in NIV using the short binasal prong and nasal protector.

Whitney's posthoc test, respectively. The Logistic Regression model was applied to measure the influence of factors such as gestational age, birth weight, and time in NIV on the nasal injury. The relative risk was calculated to estimate the probability of injury associated with different types of protective dressings. The sample was estimated considering the significance level of 5%, type II error of 10%, lower proportion estimated at 35%, and magnitude of effect estimated at 50%, with an estimate of 10–15 cases in each group (Fleiss-Tyton-Ury Equation).

3. Results

From 05/01/2015 to 04/03/2016, 210 NBs were admitted to the NICU. Eighty-three needed NIV, 49 of them were born with less than 38 weeks of gestational age, and 16 were within the exclusion criteria as described in Figure 3.

Gender, gestational age, weight, and NIV use and length in NIV are presented in Table 1. The birth weight showed statistical significance ($p = 0.04$) between groups A and C.

The nasal injury occurred in 4 NBs (36.36%) from group A, 9 NBs (81.81%) from group B and 8 (72.72%) from group C. The stage of the nasal injury, the number of times that the material was replaced and the time until the appearance of the injury, comparing the three groups, showed a significant difference between groups A and B ($p = 0.03$) at the number of times that the material was replaced. No statistical significance was observed for the other variables (Table 2).

We have not observed significant variation between the occurrence of nasal injury and NIV time ($p = 0.31$), birth weight ($p = 0.45$) or

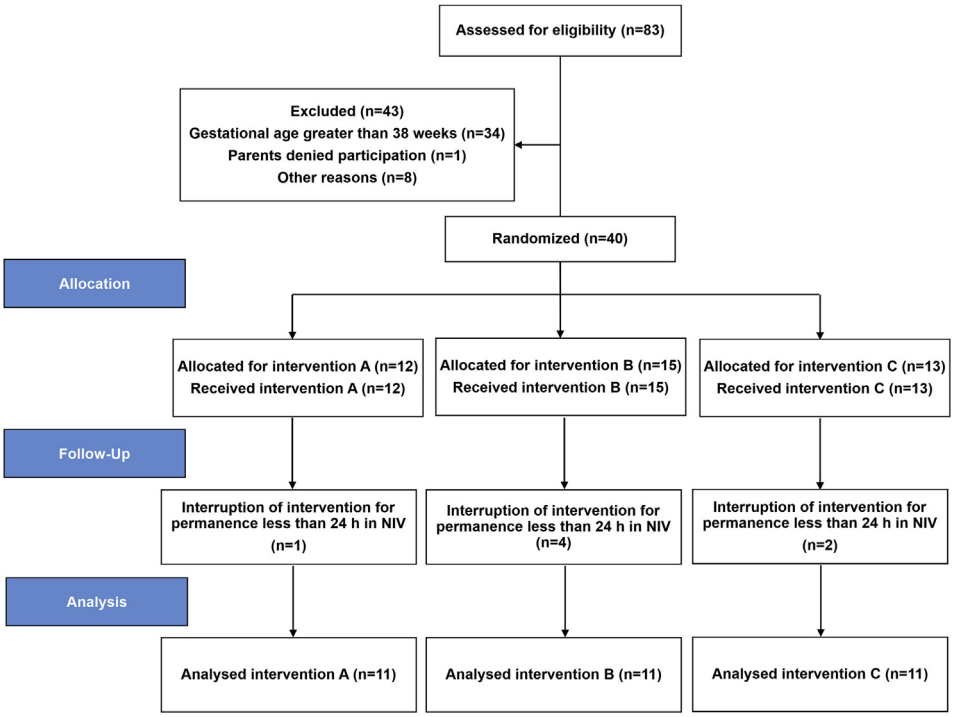

Figure 3. The selection process of the participants of the clinical trial.

Table 1. Characteristics of the NBs participants of the study.

Variable	Group A (n = 11)	Group B (n = 11)	Group C (n = 11)	*P*
Gender (male)	6 (54.55%)	4 (36.36%)	5 (45.45%)	0.69[1]
Gestacional age, mean ± SD week	33.73 ± 2.79	31.55 ± 4.48	30.82 ± 4.06	0.19[2]
Weight, mean ± SD kg	2.22 ± 0.79[A]	1.69 ± 0.85[AB]	1.37 ± 0.62[B]	0.04[2]
Length of stay in the NIV, median (min-max) h	64.50 (24.91–240.33)	69.25 (24.16–355.00)	71.08 (24.00–167.16)	0.84[3]

[A and B] indicate a comparison between groups. The weight between groups A and B and between B e C were similar, while between groups A and C presented statistical significance; NIV indicates noninvasive ventilation; SD indicates standard deviation; [1]Pearson chi-square test; [2]Student t test; [3]Kruskal-Wallis Anova.

Table 2. Differences in Severity, injury onset time and quantitative material replacement between newborns with injury in the three Groups.

Variable	Group A (n = 4)	Group B (n = 9)	Group C (n = 8)	P
Stage I injury	4 (100.00%)	5 (55.56%)	6 (75.00%)	0.25[1]
Stage II injury	0 (0.00%)	4 (44.44%)	2 (25.00%)	
Injury until 24 h	3 (75.00%)	8 (88.89%)	6 (75.00%)	0.80[1]
Injury after 24 h	1 (25.00%)	1 (11.11%)	2 (25.00%)	
Injury onset time, median (IQR)	24 (24–48)	24 (24–48)	24 (24–72)	0.70[2]
Quantitative material replacement, mean ± SD	0.00 ± 0.00[A]	3.22 ± 3.87[B]	1.50 ± 1.07[AB]	0.03[2]

[A and B] indicate comparison between the groups; IQR indicates interquartile range; SD indicates standard deviation; [1]Pearson chi-square test; [2]Kruskall-Wallis Anova.

gestational age (p = 0.14) using Univariate Logistic Regression. The risk of nasal injury was twice lower using hydrocolloid protective dressing, although with a borderline significance level (OR = 2.10, 95% CI = 0.85–5.15; p = 0.09). Figure 4 shows the images of the NBs who developed Stage I nasal injuries. In Figures 4a and 4b, it is possible to observe the presence of hyperemia characterized by redness in the basal region of the right and left nostrils in the NBs who had used hydrocolloid. The hyperemia is also seen in the region of nasal columella in one of the NBs who received the thicker silicone protector (Figure 4c). When the thinner silicone protector was used (Figure 4d), the hyperemia occurred in the region of the nasal columella and at the base of the right and left nostrils of the NBs.

Regarding Stage II injuries, Figure 5 shows the photographic images of NBs who received both thicker and thinner silicone protectors. Stage II injury with partial-thickness loss of the skin and a surface with redness bed wound in the basal region of the right nostril occurred after the use of the thicker silicone protector, shown in the Figure 5a. Figure 5b illustrates the presence of Stage II nasal injury in the left nostril after the use of the thin silicone protector.

As the physical therapists have been intercalated the NIV with an oxygen helmet, none NB had evolved to stage III.

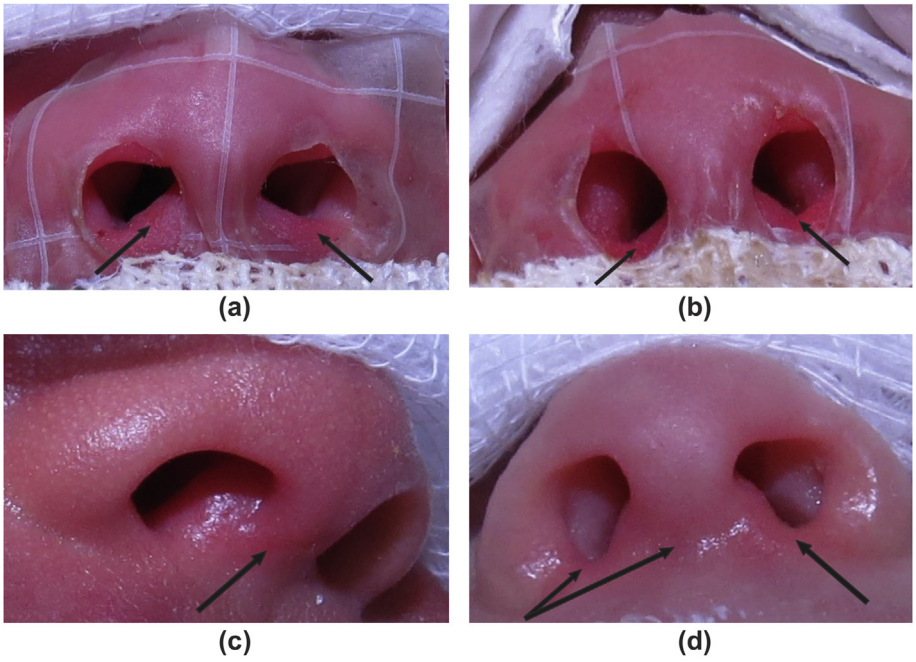

Figure 4. Stage I nasal injuries showing hyperemia regions (arrows): (a) and (b) in the basal region of the right and left nostrils of NBs from group A; (c) in the nasal columella region of a participant from group B; (d) in the base of the nasal septum and the base of the right and left nostrils of NBs from group C.

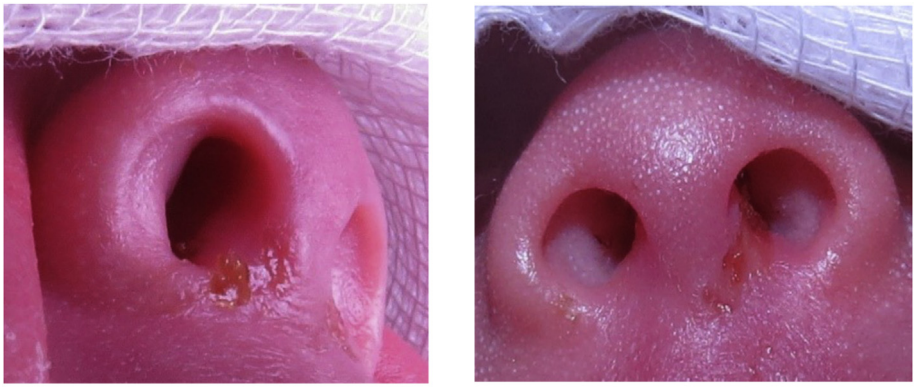

Figure 5. Stage II nasal injuries (arrows): (a) basal region of the right nostril in NB who used thicker silicone protector; (b) in the internal region and at the left nostril in NB who used thinner silicone protector.

4. Discussion

The insertion of nasal protectors such as hydrocolloid and silicone tapes is advised to prevent nasal injuries that may occur due to the contact of the newborn's skin with nasal prongs during the NIV application [11, 12]. The protectors act by reducing the friction between the surfaces [12, 17].

In the present study, the incidence of nasal injuries in NBs from the hydrocolloid group was 36.36%. This incidence was higher than the 6.06% found by Xie [11], who evaluated NBs with an average gestational age of 32.6 weeks and an average weight at birth of 1.80 kg, lower than the values from the present study. However, Xie [11] used a 1.8 mm thickness hydrocolloid. In contrast, in the present study, a 0.3 mm thickness hydrocolloid was applied because it is regularly used in the NICU, where the NBs were under care.

The isolation of nasal prong from the skin of nasal columella to prevent nasal injuries must be done, leaving the surfaces at least 2 mm far away from each other [17]. Hence, the thickness of hydrocolloid seems to influence the prevention of nasal injuries since a thicker nasal protector can reduce the friction between the prong surface and the skin of NB keeping such structures apart.

There was a high incidence of nasal injuries in the groups that have received the thicker silicone protector (81.81%) and the thinner one (72.72%). The number of injuries recorded in the present study is higher than that reported by Günlemez *et al.* [12], which had reached only 4.3% in NBs who had used silicone protector. Although both studies evaluated NBs with similar gestational ages and length in NIV, the sample sizes were different, 92 NBs in the study by Günlemez *et al.* [12] and only 11 in this study.

The difference between the incidences of the nasal injuries can also be justified by the difference between the birth weight of the participants. In the present study, the weights were smaller when compared to those of the study of Günlemez *et al* [12]. The lower the birth weight, the greater the incidence of nasal injury [18]. Besides, Günlemez *et al.* [12] have used Epi-Derm Silicone Gel Sheeting, with 1.8 mm thickness of the Biodermis, USA. In the present study, we have chosen the same material, but with thinner gel sheeting, with 0.9 mm-thickness. The difference in thickness could have provoked the lower incidence of lesions found by Günlemez *et al.* [12] since thicker protection acts as a more effective mechanical filter. It is noteworthy that in the present study, it was not found for sale in Brazil Epi-Derm Silicone Gel Sheeting of 1.8 mm-thickness. Then, we had used the material with only 0.9 mm thickness.

Displacements of the silicone protectors were observed, and this fact could be the reason for the high injury incidence because the septum and the nasal columella were exposed to the rubbing exerted by the nasal prong surface due to the movements of the NB.

The use of hydrocolloid with approximated 0.3 mm-thickness to prevent nasal injuries is routinely used in the NICU, and it was applied in the NBs from group A. The silicone protector of the group B was 0.9 mm-thickness. Because of the difference in thickness between the hydrocolloid and the silicone protector, and due to the difference in thickness could interfere with the results of the study, a third silicone protector with 0.3 mm-thickness was also used.

Since in the present study hydrocolloid performed better than silicone gel for preventing nasal injury, and as the thickness interfered with the occurrence of injury, as indicated by Xie *et al.* [11] using 1.8 mm hydrocolloid, it is recommended to use thicker hydrocolloids (1.8 mm, for example) instead of 0.3 mm as adopted in the hospital where this study was conducted.

Despite the high incidence of the injuries, most of them could be classified as Stage I. No injury had reached Stage III. Therefore, the use of nasal protector may have contributed reducing the severity of the nasal injuries. The smaller sample size can have influenced the non-occurrence of Stage III injury. Besides, it is important to consider that in this NICU the physical therapist's team was responsible for taking care of the nasal injuries with cold 0.9% physiological solution and performing circular movements in the nostrils during each physical therapy session. In the injuries stage II the treatment was intercalated the NIV with an oxygen helmet. These protective strategies could be influenced by the injuries not evolve to stage III.

With relation to the injury stage, and comparing the three groups of the nasal protectors related to the time to onset the nasal injury, no statistical significance was found. However, it was observed that the hydrocolloid group presented injuries with lower severity. The hydrocolloid was the protector that remained longer adhered to the skin and did not need to be replaced due to detachment. The better adhesion of this protector can have contributed to the prevention of more serious injuries, avoiding the nasal region from friction with the prong.

Also, there is a significant difference in birth weight among the three groups. The NBs belonged to the hydrocolloid group had presented higher weight compared to the other groups. However, applying the logistic regression, there was no significant variation between the occurrence of injury and birth weight ($p = 0.45$).

Premature birth and low birth weight are risk factors for the development of the nasal injury [9] because, in this condition, the NBs have an immature epidermal barrier and an immune system not fully developed [19]. The five layers of the epidermis are only 0.01 mm–0.05 mm thickness, 40%–60% thinner than adult skin. Besides, the stratum corneum is immature, and the junction between the dermis and the

epidermis is fragile, making the NBs more vulnerable to the development of nasal injuries [17].

Therefore, due to more susceptibility to injury of the premature and low weight NB compared to the full-term newborns weighing more than 2,500, we choose to evaluate only NB with gestational age less than 38 weeks, randomized into three groups according to the nasal protection used.

Only the difference between the replacing number of the materials exhibited a statistical significance ($p = 0.03$). The thick silicone protector (Group B) needed to be replaced more times because it detached more easily compared to Group C (thin silicone) and Group A (hydrocolloid). There was no need for substitution of the hydrocolloid protector, in the NBs had presented injuries. Therefore, because of the higher incidence of detachment, the thick silicone protector may not be adequate to protect the nasal septum and columella of the NBs during NIV.

However, considering that the junction between the epidermis and the dermis of the NB is fragile [17, 20], the use of protectors that have more effective adhesion may cause epidermal injury during removal [20]. Besides, the use of some removers can aggravate the injury, causing dryness and cracking of the skin [21] or can be toxic to the NB [22].

The thinner hydrocolloid is still used with standard protection in NBs in the NICU studied because the thicker hydrocolloid complicates the visualization of the septum, and hospital service is not able to purchase the adhesive removers due to financial factors.The analysis of the outcome of the occurrence of nasal injury had shown that the level of borderline significance found, both for the estimate of the difference in the relative frequency between the groups studied ($p = 0.06$), and for the relative risk ($p = 0.09$), maybe due to a type II error, related to the sample size. Although these results should be considered with this limitation, they indicate that the use of a hydrocolloid protective dressing can reduce the occurrence of nasal injury.

The injuries in the three groups appeared after 24 h, disagreeing with the results found by Souza *et al.* [23], who observed that the risk for the development of nasal injuries occurs only after 72 h in NIV. The authors evaluated the presence of nasal injuries in the NBs only at hospital discharge. In the present study, the NBs were evaluated before the installation of NIV and every 24 h until the medical suspension of this ventilatory support. Thus, the daily evaluation of the NBs in NIV helps the earlier detection of a nasal injury, helping the multi-professional team to make appropriate decisions to minimize the effects of the nasal injuries such as the application of cold physiological solution and massage in the nostrils of the NB.

Concerning the economic aspect, the hydrocolloid is a less expensive dressing than the silicone tape. A thin 4 × 15 cm thick silicone gel plate and a thicker silicone gel plate with a 3.6 × 15 cm size cost around five times more than an extra thin hydrocolloid plate with size 10 x 10 cm. According to the results obtained in this study, the hydrocolloid seems to be the most suitable protector to prevent nasal injuries. Moreover, considering the overall expenses with the treatment of the possible comorbidities associated with the nasal injury, the investment in the prevention of the injury is worthwhile.

One limitation of the present study was the small sample size. It is important to carry out further studies that comparatively evaluate the efficiency of these two protections in larger NB populations and to compare their different thicknesses.

5. Conclusions

The hydrocolloid tape is the most effective protector in the prevention of nasal injuries and presented a lower incidence of detachment when compared to the silicone gel tape. Besides being more effective in preventing nasal damage, hydrocolloid is a more economical dressing than silicone gel, making it a viable resource in both private and public hospitals. Also, its high adhesiveness resulted in a lower index of substitution by detachment. However, due to the high adhesiveness of the hydrocolloid, the multi-professional team needs to redouble the care during its removal to prevent damages to the skin of the NB.

The high incidence of the nasal injuries during the time in NIV warns about the need for improvements in the short binaural prongs design making them more anatomical, as well as signaling to the multi-professional team the importance of intensifying the care for NBs in NIV. The daily evaluation of the nasal region of the NBs submitted to NIV allows the multi-professional team to focus on the first signs of injury acting in time to minimize its severity. Although this study was conducted by local practice patterns, the results have shown the importance of nasal injuries evaluation and the effects of two types of adhesiveness protection, showing that the hydrocolloid tape is the best choice.

Declarations

Author contribution statement

D. Ribeiro: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper.

F. Barros, B. Fernandes, A. Nakato and P. Nohama: Conceived and designed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper.

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Competing interest statement

The authors declare no conflict of interest.

Additional information

The clinical trial described in this paper was registered at Brazilian Clinical Trials Registry under the registration number RBR-73xvmg.

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