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Early nasal injury resulting from the use of nasal prongs in preterm infants with very low birth weight: a pilot study

Lesão nasal precoce pelo uso da pronga nasal em recém-nascidos prematuros de muito baixo peso: estudo piloto

ABSTRACT

Objective: To analyze the incidence of early-onset nasal injury in infants with very low birth weight and indication for noninvasive ventilation via nasal prongs.

Methods: A prospective case series of infants with gestational age <37 weeks, weight <1.500 g and postnatal age <29 days. The patients were evaluated three times daily from the installation of nasal prongs to the 3rd day of use. The patients' clinical conditions and the device's characteristics and its application were analyzed. The initial analysis was descriptive, indicating the prevalence of nasal injury and factors associated with it. Categorical data were analyzed using the chi-squared test or Fisher's exact test, and numerical data were analyzed using the t-test or the Mann-Whitney test.

Results: Eighteen infants were included; 12 (with a gestational age

of 29.8±3.1 weeks, birth weight of 1.070±194 g and a Score for Neonatal Acute Physiology - Perinatal Extension (SNAPPE) of 15.4±17.5) developed nasal injuries (injury group), and 6 (with a gestational age of 28.0±1.9 weeks, weight of 1.003±317 g and SNAPPE of 26.2±7.5) showed no nasal injury (uninjured group). The injury group subjects were more often male (75% versus 17%), and their injuries appeared after an average of 18 hours, predominantly during the night (75%).

Conclusion: The incidence of nasal injury in preterm infants who experienced noninvasive ventilation via nasal prongs was high, and a study of associated factors may be planned based on this pilot.

Keywords: Preterm infants; Very low birth weight infants; Risk factors; Interactive ventilatory support

INTRODUCTION

Infants, especially preterm infants hospitalized in intensive care units, often develop respiratory distress. For several years, preterm infants with respiratory distress were preferentially submitted to mechanical ventilation using an endotracheal tube to minimize their distress. (1-3) Currently, noninvasive ventilation (NIV) and continuous positive airway pressure (CPAP) have been adopted as first-choice methods for preterm infants' respiratory care. (4) A prong mask or a similar device functions as the patient/ventilator interface in both methods, replacing the endotracheal prostheses (1,5,6) and aiming to reduce the work of breathing, incidence of extubation failures (7) and frequency of apneas, (8) thus minimizing lung injury. (4,9,10)

Nasal or oronasal masks are the interfaces most commonly used to apply NIV in children and adults. Nasal prongs attached to a device generating nasal continuous positive airway pressure (NCPAP) have been used in infants since 1975. The prongs are made of a lightweight and flexible material, have good adaptability to the anatomical and physiological characteristics of infants and are widely used because they are the best interface for infants who require ventilatory support. (12)

Despite the benefits offered by nasal prongs, their use is not without risks because prolonged and incorrect application may cause skin and mucous membrane lesions in the region of the nostrils and nasal septum. Such injuries may appear as persistent redness in the nasal region (Grade I) worsening into superficial ulceration (Grade II) until necrosis and loss of nasal tissue occurs (Grade III). (13) The prevalence of nasal injury resulting from the use of prongs may reach approximately 50% and appears to be facilitated by several factors, including lower gestational age and birth weight, in addition to prolonged length of CPAP use. (12,13) Aside from prematurity, the causes for nasal injuries are poorly studied, although prolonged use of nasal prongs may lead to the exertion of higher pressure on the airways, resulting in an increased risk for injury. Those findings indicate that therapy must be meticulously monitored to fully prevent nasal injuries, which in turn will result in better treatment efficacy. (14)

The present study aimed to evaluate the incidence of early nasal injury resulting from the use of noninvasive mechanical ventilation in a prospective case series of preterm infants with very low birth weight, given the lack of studies on the incidence and factors associated with injuries resulting from the use of noninvasive mechanical ventilation via nasal prongs in the literature and the importance of the topic in terms of establishing treatment efficacy.

METHODS

This case series study was conducted prospectively and included all infants with gestational age <37 weeks, birth weight <1,500g and postnatal age <29 days who were hospitalized in the Neonatal Intensive Care Unit of *Hospital São Paulo*, *Universidade Federal de São Paulo*, who required noninvasive mechanical ventilation through nasal prongs as the initial ventilatory support or during weaning for a minimum of 6 hours and whose

parents and/or guardians freely signed an informed consent form. The study was approved by the Ethics Committee of the Universidade Federal de São Paulo. Each patient was monitored until his or her 3rd day of NIV via nasal prongs.

The maternal and neonatal demographic data and data regarding the indication for NIV were collected at study entry, and the patient's condition was classified as recurrent apnea, postextubation or respiratory discomfort. Recurrent apnea was noted when the NIV resulted from the occurrence of more than two episodes of apnea and/or bradycardia within a 6-hour period. The postextubation indication was noted when the NIV was indicated as a preventive measure to reduce the work of breathing, regardless of the presence or absence of signs of distress at the time of extubation. Conversely, signs of respiratory distress were noted when the NIV was indicated to correct persistent tachypnea (respiratory rate [RR] >70rpm) and/or respiratory distress with increased expansions and contractions of the rib cage and/or use of accessory muscles.

A layer of colloid material is routinely placed in the region of the nasal septum and wings before the prongs are installed in the unit. The fixation is performed using adhesive elastic bandage, and it is installed after placing the colloid to minimize the inadvertent movement of the prongs. The brand of prong use was chosen according to the availability of suitable size for each infant, that is, according to the patient's weight. Three different brands (A, B, C) were available in the unit at the time the study was conducted. The following differences between brands may be highlighted: Brand B prongs had cannulae with a smaller diameter (7.5 FR) than the others and a tapered shape. Conversely, Brand A and C prongs had cylindrical cannulae. The prongs of all brands were manufactured with silicon to minimize the pressure on the nasal septum and, consequently, the nasal lesions.

Data concerning the conditions of the neonatal unit (the number of infants per room and number of infants undergoing NIV and invasive ventilation per room) and staff number (the presence and number of physical therapists during the study period and the number of people present on the nursing staff) were collected three times daily at night (collection at 7 am), in the morning (collection at 1 pm) and in the evening (collection at 7 pm). The infants' nostrils were inspected to evaluate the presence of skin alterations during the above-defined

periods (night, morning and afternoon) and were classified according to Fischer et al. (13) as Grade I (presence of persistent hyperemia), Grade II (superficial ulceration) or Grade III (necrosis and tissue loss).

A convenience sample was studied because this was a pilot study. The descriptive analysis was performed to characterize the study sample using the mean and standard deviation or median and minimum and maximum values for numeric variables, which were compared using the *t*-test or the Mann-Whitney test depending on the data distribution and the number and frequency of categorical variables and using the chi-squared test for comparison. The significance level p<0.05 was considered for all exploratory tests.

RESULTS

Eighteen preterm infants met the inclusion criteria during the period from September 2011 to April 2012, and no parents refused to participate in the study during that period. The infants included in the study were born with a mean gestational age of 28.9±2.2 weeks and a birth weight of 992.5±247.8g. Ten (55.5%) were male, and 15 (83.4%) appropriate for gestacional age. Apgar scores at the 1st and 5th minutes of life were 5±2 and 8±1 on average, respectively, and Score for Neonatal Acute Physiology - Perinatal Extension (SNAPPE-II) scores were 15±14. The 18 patients were kept under NIV for a median time of 6 days, ranging from 4 to 10 days.

Twelve (67%) of the infants monitored in the study developed some degree of injury (injury group) until the 3rd day NIV use via nasal prongs. There were no differences in birth and neonatal conditions between groups except in terms of the injury group's lower severity and greater predominance of males (Table 1).

The most frequent indication for NIV use was the presence of respiratory distress (39%), with no differences between groups. The distribution of information and the period of NIV via nasal prongs are shown in table 2. Regarding the prong brands used, 8 of 10 infants who used brand C had some grade of nasal injury. Six other patients used Brand A prongs, including three from the injury group. The last two infants received Brand B prongs, and one of the infants (50%) developed a nasal injury. There were no statistically significant differences between groups regarding the brand used and the injury incidence (p=0.407).

 Table 1 - Neonatal characteristics and perinatal conditions in the groups with and without nasal injury

Neonatal characteristics	Group with nasal injury (N=12)	Group without nasal injury (N=6)	p value
Gestational age (weeks)	28.0 ± 1.9	29.8 ± 3.1	0.066
Birth weight (grams)	962±318	1.070 ± 194	0.122
Cesarean birth	9 (75)	3 (50)	0.344
Male	9 (75)	1 (17)	0.043
SGA	2 (22)	1 (17)	0.529
Apgar 1st minute	6±2	5±2	0.682
Apgar 5 th minute	8±1	8±1	0.633
Antenatal corticosteroids	5 (43)	1 (17)	0.600
PPV in the delivery room	9 (75)	5 (83)	1.000
El in the delivery room	6 (50)	3 (50)	1.000
SNAPPE-II	11±14	26±7	0.010

SGA - small for gestational age; PPV - positive pressure ventilation; EI - endotracheal intubation; SNAPPE-II - Score for Neonatal Acute Physiology - Perinatal Extension - severity index upon admission measured at 12 to 24 hours of life. The results are expressed as number (%) or mean±standard deviation.

Table 2 - Main indications for the use of noninvasive ventilation via nasal prongs in the groups with and without nasal injury

	Group with nasal injury (N=12)	Group without nasal injury (N=6)	p value
Indication of NIV			0.341
Respiratory distress	7 (58)	2 (33)	
Apnea	3 (25)	1 (17)	
Postextubation	2 (17)	3 (50)	
Period of nasal prong installation			0.235
Morning	6 (50)	1 (17)	
Evening	5 (42)	5 (83)	
Night	1 (8)	0	

NIV - noninvasive ventilation. The results are expressed as number (%).

The onset of nasal injury occurred on average 18 hours after the device was installed, with the lowest period of use as 6 hours and the longest period of use as approximately 72 hours. The onset of injury occurred predominantly during the night (8/12 patients; p<0.001), when there were no physical therapy team available in the unit. Regarding the nasal injury severity of the 12 affected patients, Grade I injury occurred in 10 (82%), Grade II occurred in 1 (9%), and Grade III occurred in 1 (9%) infant.

The mean time of NIV use was 7 ± 5 days in the group with nasal injury and 5 ± 4 days in the uninjured group (p=0.477), noting that the present study evaluated the injury incidence during the first three days of NIV. On

average, during the study period, there were 5.4±0.5, 5.1±1.0 and 5.5±0.5 infants under intensive care during the morning, evening and night periods, respectively. On average, invasive ventilation and NIV were required by 0.4±0.5 and 1.5±0.7 of those infants in the morning, 0.6±0.9 and 1.4±0.5 infants in the evening and 0.5±0.3 and 1.3±0.5 infants at night. There were 2.5, 2.7 and 2.0 nursing staff members (nurses or nursing technicians) caring for these patients in intensive care during the morning, evening and night periods, respectively. Two physical therapists were available at the time of the study in the neonatal unit as a whole during the morning and evening periods, and none were available at night. Twenty-four beds were occupied, on average.

DISCUSSION

The use of more gentle ventilatory support systems has been advocated in recent years in all age groups and in different types of disease. ⁽¹⁵⁾ In preterm infants, that recommendation is becoming more common given the disorders that result from the use of invasive devices for mechanical ventilation. However, the use of noninvasive devices is not without complications, as noted in the present study, which indicates a high incidence (67%) of nasal injury with the use of nasal prongs for NIV in preterm infants.

In a previous study conducted from 2002 to 2007 in a Neonatal Unit in Lausanne, Switzerland, the authors evaluated 989 infants with a birth weight of 2.142±840g and a gestational age of 34±4 weeks and found a nasal injury incidence of 42%, including 371 (88%) mild, 46 (11%) moderate and 3 (0.7%) serious injuries. (13) The incidence reported by those authors was lower than that found in the present study. One of the possible reasons for the high nasal injury index may have been the actual study design, in addition to sample characteristics and issues related to human resources for neonatal care. Observations three times a day imply more frequent observations and, consequently, more accurate detection of problems. In other studies, the observation of the infants' skin conditions occurred once a day(13,16,17) or even at a single cross-section, (12) complicating the detection of the moment of injury onset. However, it should be noted that the incidence observed in that pilot project cannot be generalized given the reduced external validity of the study.

Preterm infants are known to have an immature

epidermal barrier and an immune system that is not fully developed, (18) which would facilitate the occurrence of cutaneous and mucosal lesions in cases of compression of a specific area. (17) Therefore, preterm infants unsurprisingly show a greater frequency of nasal injury compared with term infants or children in other age groups. Indeed, reports show that older children quietly accept NIV with minor complications related to gas demand but not to the presence of nasal prongs. (19) In the present study, the mean gestational age of the infants was less than 30 weeks, typical of extremely preterm infants and therefore associated with a high risk of skin lesions. Indeed, Fischer et al. (13) reported that infants with a gestational age <32 weeks are 2.48 (95% confidence interval [95% CI]: 1.59-3.86) times more likely to develop nasal injury when using CPAP with nasal prongs compared with infants with an older gestational age. Thus, rigorous monitoring and a constant interface for NIV with the immediate correction of potential problems may help prevent nasal injury in more immature patients.

Apparently, according to the clinical severity assessment of the infants (SNAPPE-II), (20) the children from the uninjured group had a more serious clinical condition than the children from the injury group did. Patients with tend to have more severe comorbidities and respiratory disease, complicating the disease's clinical course and increasing the need for invasive interventions, including endotracheal intubation, which may limit the time of exposure to nasal prongs and, consequently, the injury associated with them. However, the small number of patients evaluated complicates that analysis, and only a larger sample will enable us to ascertain whether infants with lower initial severity are indeed more prone to nasal injury during NIV support.

The successful therapeutic use of NIV is linked to proper patient selection, good patient adaptation to the interface and, especially, the team treating the patient. (21) Training and collective involvement to optimize the resources used are keys to good NIV performance. In the present study, the nasal injuries noticeably occurred most frequently during the night, when the physical therapy team was absent from the unit and there were fewer nurses/nursing technicians available. Thus, there is an accumulation of functions for the working team that reduces the surveillance of patients using NIV devices. Constant observation may improve the positioning of

the nasal prongs and the infants' position, among other factors that could reduce the skin lesions.

Furthermore, the involvement of professionals in that matter is critical to the improvement of care for those infants. Constant training and analysis of patient evolution is required for such purposes to intervene early in the detection of problems related to the use of NIV. Some studies(12,13,16) show that the prolonged time of use of nasal prongs increases the risk of nasal injury. However, in the present study, extremely short times were noted before the occurrence of nasal injury in 60% of the patients analyzed. The patients developed injuries within an average of 18 hours of use, enabling us to infer that care and constant vigilance greatly affect the onset of injuries and that evaluations of the improvement of the quality of care for infants should include nasal injury triggered by the use of prongs for NIV as an indicator.

Another factor possibly associated with the onset of nasal injuries is linked to the manufacturing brand of the device, which, in turn, is related to the quality of the material and the prong design (for example, the distance between the nasal catheter insertion and the catheter's length). There were no statistically significant differences between the children with nasal injuries and those without, although chemical and physical structures of the materials used in the nasal prongs have not been analyzed. Furthermore, it should be noted once again that the sample power was very limited, with a high likelihood of incurring in a Type II error.

Accordingly, the present study must continue towards evaluating whether the mode of interface setting was associated with the presence of the lesion. Establishing the best method for setting the prong and the most appropriate size for the prongs and caps is a challenge for the health professionals who care for these infants.

The small sample power stands out among the study limitations, as previously mentioned, and caution should be taken when interpreting and generalizing the results. Furthermore, although this is an observational and prospective study, the sample limitation⁽²²⁾ precluded a deeper inferential analysis. Accordingly, the results reported herein should be useful for planning other studies in this field.

CONCLUSION

Although this was a pilot study, the clinical problem was detected so frequently that an intervention to reduce the incidence of nasal injury in preterm infants undergoing NIV and further study to understand the key risk factors associated with such injury is a priority for the quality of neonatal care.

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RESUMO

Objetivo: Analisar, em recém-nascidos de muito baixo peso e com indicação de ventilação não invasiva via pronga nasal, a incidência do aparecimento precoce de lesão nasal.

Métodos: Série de casos prospectiva de nascidos com idade gestacional <37 semanas, peso <1.500g e idade pós-natal <29 dias. Os pacientes foram avaliados desde a instalação da pronga nasal até o 3º dia de uso, três vezes ao dia. Foram analisadas as condições clínicas dos pacientes, características do dispositivo e de sua aplicação. A análise inicial foi descritiva, verificando-se a prevalência de lesão nasal bem como os fatores a ela associados. Os dados categóricos foram analisados por qui-quadrado ou exato de Fisher e os dados numéricos, por teste t ou Mann-Whitney.

Resultados: Dezoito recém-nascidos foram incluídos, dos quais 12 (idade gestacional de 29,8±3,1 semanas, peso ao

nascer de 1.070±194g e Score for Neonatal Acute Phisiology - Perinatal Extension (SNAPPE) de 15,4±17,5) evoluíram com lesão nasal (Grupo Lesão) e 6 (idade gestacional de 28,0±1,9 semanas, peso de 1.003±317g e SNAPPE de 26,2±7,5) não apresentaram lesão nasal (Grupo Sem Lesão). No Grupo Lesão, houve maior frequência do gênero masculino (75% *versus* 17%), a lesão apareceu em média após 18 horas e predominantemente no período noturno (75%).

Conclusão: A incidência de lesão nasal em prematuros submetidos à ventilação não invasiva via pronga nasal foi elevada, sendo possível planejar estudo dos fatores associados, com base neste piloto.

Descritores: Prematuro; Recém-nascido de muito baixo peso; Fatores de risco; Suporte ventilatório interativo

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