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A Comparison of Nasal Trauma in Preterm Infants Extubated to Either Heated Humidified High Flow Nasal Cannulae or Nasal Continuous Positive Airway Pressure

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Abstract

The objectives of this study were (i) to devise a nasal trauma score for preterm infants receiving non-invasive respiratory support, (ii) to compare the incidence of nasal trauma in preterm infants < 32 weeks gestation randomised to either Nasal Continuous Positive Airway Pressure (NCPAP) or Heated Humidified High Flow Nasal Cannuale (HHHFNC), in the first 7 days post extubation and (iii) to assess the effect of two different nasal dressings in those assigned to NCPAP.

We randomly assigned preterm ventilated infants to receive Vapotherm® HHHFNC or NCPAP post extubation. Infants receiving HHHFNC were treated with Sticky Whiskers® and infants receiving NCPAP received either Sticky Whiskers® or Cannualaide® nasal dressings. Bedside nursing staff scored 6 sites on each infant's nose for: erythema, bleeding or ulceration. Scores were recorded three times daily for the first 7 days post extubation. The sum of these 21 scores was used as the summary measure of nasal trauma.

The mean nasal trauma score for infants assigned HHHFNC was 2.8 (SD 5.7) compared to 11.7 for NCPAP (SD 10.4), $p<0.001$. There was no difference in mean trauma score between infants on NCPAP assigned Sticky Whiskers® 14.4 (SD 12.5) or Cannualaide® 9.5 (SD 7.3), $p=0.06$.

Conclusion: HHHFNC resulted in significantly less nasal trauma in the first 7 days post extubation than NCPAP, was most significant in infants < 28 weeks of gestation. The use of protective dressings was not associated with decreased nasal trauma for infants on NCPAP.

Keywords: Nasal trauma, NCPAP, Highflow nasal cannulae

Abbreviations:

HHHFNC Heated Humidified High Flow Nasal Cannulae

NCPAP Nasal Continuous Positive Airway Pressure

Introduction

Preterm infants are at high risk of developing pressure ulcers due to immature skin, exposure to medical devices, nutritional deficiencies and exposure to ambient humidity. Fifty per cent of pressure ulcers in neonates were reported to be associated with the use of medical equipment and devices [16]. A pressure ulcer is defined as a localised injury to the skin and/or underlying tissue as a result of pressure [14]. A number of skin assessment tools are available for adult and paediatric intensive care populations [1], however there is no standardised classification of pressure ulcers specifically for preterm infants.

The most commonly reported pressure affected area in preterm infants is the nose [6] and is associated with the use of Nasal Continuous Positive Airway Pressure (NCPAP). NCPAP facilitates extubation, but can cause nasal trauma irrespective of the device used [17]. The incidence of NCPAP associated nasal trauma in the neonatal population ranges from 15-100% [4-6,12]. Risk factors for developing nasal pressure ulcers in this population are: gestation of < 32 weeks, birth weight of <1500g and duration of NCPAP > 5 days [5]. The majority of nasal trauma resolves spontaneously when NCPAP is discontinued. However, it can lead to permanent disfigurement and long term functional sequelae [5,9,15,].

Nasal dressings are used in preterm infants receiving NCPAP with an aim of minimising nasal trauma [4,5, 7]. These may either provide a direct barrier e.g. hydrocolloid applied to the septum and/or nares, or secure the prongs to maintain a gap between the nasal septum and prongs. However, there are limited safety and efficacy data to support their use.

Heated Humidified High-Flow Nasal Cannulae (HHHFNC) are increasingly being used as an alternative to NCPAP in preterm infants despite the paucity of clinical evidence to support this practice. HHHFNC prongs are generally shorter and narrower than those used in NCPAP and do not form a seal with the nares. They are commonly perceived to cause less nasal trauma and be better tolerated when compared with NCPAP but the incidence of nasal trauma associated with their use is uncertain.

We undertook this study firstly to devise a nasal trauma score for preterm infants receiving non-invasive respiratory support and secondly to compare the incidence of nasal trauma in preterm infants <

32 weeks gestation randomised to either NCPAP or HHHFNC in the first 7 days post-extubation and assess the effect of two different protective nasal dressings in those assigned to NCPAP.
The respiratory outcomes of this trial are reported separately [3].

Methods

This is a substudy of preterm infants enrolled in a randomised controlled trial to compare HHHFNC and NCPAP post-extubation [3]. Infants were eligible for the study if they were born at < 32 weeks of gestation, required endotracheal intubation and positive pressure ventilation and were considered ready for extubation by the clinical team. Infants with suspected upper airway obstruction, congenital airway malformations or major cardiopulmonary malformations were excluded. This single centre study was approved by the Human Research Ethics Committee of the Mercy Hospital for Women, Melbourne, Australia and performed in accordance with the 1964 Declaration of Helsinki. Informed written consent was obtained from parents prior to study commencement. Infants were randomised to Vapotherm® HHHFNC with Sticky Whiskers® (Vapotherm Inc, Stevensville, MD, USA, Beevers Manufacturing & Supply, McMinville, OR, USA) or NCPAP via Hudson® binasal prongs (Hudson Respiratory Care Inc, Temecula, CA, USA) with either Sticky Whiskers® or Cannualaide® (Beevers Manufacturing & Supply, McMinville, OR, USA). A random number sequence was generated using STATA Statistical Software (Release 10.0. College Station, TX: Stata Corp, 2010), and the randomisation sequence was stratified by gestational age into <28 weeks and 28.0-31.6 weeks gestation. A variable block size was used for treatment allocation. Sequentially numbered, sealed opaque envelopes containing the treatment allocation were opened immediately prior to extubation. A clinical trials exemption number (CTN 015/2008) was obtained from the Therapeutics Goods Administration as commercially manufactured hydrocolloid protective dressings were not available in Australia at the time of this study.
A nasal trauma scoring chart was modified from Kaufman [10] (Appendix) and tested for precision . The inter-rater reliability was tested using 6 observers who independently scored the noses of 5 preterm infants. The bedside nursing staff scored 6 sites on each infant's nose for: erythema, bleeding, ulceration or skin tear. Nasal trauma scores were recorded three times daily for the first 7 days post-extubation. The sum of these 21 scores was used as the summary measure of nasal trauma.

Statistical Analysis

The sample size required to show a difference in nasal trauma between devices was difficult to estimate due to the paucity of previous data. This was therefore a convenience sample using a randomised controlled trial powered for a primary respiratory outcome. The single measures intraclass correlation coefficient was calculated to assess the reliability of the nasal trauma score. Analysis was by intention to treat. Mean values between the 2 groups were analysed by Student's paired t-test. All statistical analyses were performed using STATA Statistical Software: (Release 10.0. College Station, TX: Stata Corp, 2010).

Results

The intraclass correlation coefficient for the nasal trauma score was 0.64 (95% CI 0.26, 0.94).

We randomised 132 preterm infants < 32 weeks gestation to receive either HHHFNC (n=67) or NCPAP (n=65) post-extubation. The baseline demographic characteristics of enrolled infants were similar between groups with the exception of sex (Table 1). There were more males in the NCPAP group 41 (63%) compared to 33 (49%) of those assigned HHHFNC. The study flow chart for infants in each group is shown in Figure 1. All infants randomised to HHHFNC were allocated Sticky Whiskers®. In the NCPAP group 32 were allocated Sticky Whiskers® and 33 Cannulaide®. Seven infants assigned to HHHFNC and 8 in the NCPAP group were reintubated in the first week post-extubation for respiratory failure. Thirteen (20%) infants assigned to NCPAP (7 Sticky Whiskers® and 6 Cannulaide®) were changed to HHHFNC due to nasal trauma in the first 7 days post-extubation. These infants had a mean nasal trauma score of 22 (SD 10.1) compared to a mean score of 7.4 (SD 6.7) in those who remained on NCPAP ($p<0.001$).

There was a significant difference in the nasal trauma score between the two modes of respiratory support. The mean nasal trauma score for infants assigned HHHFNC was 2.8 (SD 5.7) compared to 11.7 for NCPAP (SD 10.4) $p<0.001$. There was no difference in mean trauma score between infants on NCPAP assigned Sticky Whiskers® 14.4 (SD 12.5) or Cannualaide® 9.5 (SD 7.3), $p=0.06$.

Discussion

This study has shown that the nasal trauma score developed specifically for preterm infants showed good inter-rater reliability with the intraclass correlation coefficient 0.64 (95% CI 0.26,0.94) indicating moderate-strong agreement between observers.

Importantly, the use of HHHFNC post-extubation was associated with significantly less nasal trauma than NCPAP. Furthermore, there was no difference in the nasal trauma score between infants assigned two different protective dressings in the NCPAP group. These findings have important implications for the care of preterm infants receiving respiratory support.

Currently, there is no nasal trauma score designed specifically for preterm infants. Fischer et al [5] reported 91% of non-blanching erythematous pressure areas resolved spontaneously and did not progress. However the same authors reported that 78% of partial thickness dermal erosions were preceded by a non-blanching erythematous phase. In the nasal trauma score developed for this study we elected to use a cumulative score in order to capture the natural history of these pressure areas as a research tool. Further development of this nasal trauma score into a clinical tool to allow clinicians to identify when nasal trauma has reached a critical threshold would be useful for the implementation and evaluation of pressure reducing strategies.

Our study identified a significant difference in the mean nasal trauma score between infants receiving HHHFNC with Sticky Whiskers® and those receiving NCPAP with either Sticky Whiskers® or Cannualaide®. The use of HHHFNC post-extubation was associated with significantly less nasal trauma than NCPAP. The smaller dimensions of HHHFNC compared to NCPAP prongs are likely to be a major factor in the reduction of nasal trauma seen in the HHHFNC group. HHHFNC are tapered from the base to the tip, they are narrower and shorter than NCPAP prongs and should not occlude more the 50% of the nares. NCPAP is however dependent upon achieving a seal between the prongs and nares so pressure effects are almost inevitable. Humidification of inspiratory gases is important for respiratory mucosal integrity. It has been the improvement of humidification systems that has allowed the development of HHHFNC. One in-vitro study reported that the humidity delivered by HHHFNC (Vapotherm®) was significantly greater than the humidity delivered during NCPAP, 83% (SD 3.1) versus 76% (SD 0.81), $p<0.001$at flows of 3-8 L/min [2]. The effect of this difference on clinical outcomes such as nasal trauma is currently unknown.

Our study also identified that there was no difference in the nasal trauma score between infants assigned two different protective dressings in the NCPAP. We elected to compare the two NCPAP

dressings firstly to allow direct comparison of HHHFNC and NCPAP using the same fixation device (Stickywhiskers®) and to evaluate the efficacy of the barrier effect of Cannulaide® for infants on NCPAP. Cannulaide® cannot be used for infants on HHHFNC as a leak between cannulae and nares must be maintained. A third NCPAP group with no protective/ fixation dressings would have been desirable but would have resulted in 3 small groups and reduced study power. Review of study centre data demonstrated there was no difference in the mean nasal trauma score between infants assigned protective dressings in this trial and the mean nasal trauma score from 53 infants without protective dressings receiving NCPAP prior to trial commencement, 11.7 (SD 10.4) and 8.4 (SD 8.9) respectively, p=0.08. This is in contrast to the findings of Gunzlemez et al., who reported a significant reduction in nasal injury when silicon gel dressings were applied [7]. Nasal dressings are used extensively in clinical practice for infants on NCPAP [4,17] but the findings of our study do not support their routine use. Safety concerns have been raised regarding their use. If infants require emergency intermittent positive pressure via resuscitation masks, the dressings can prevent an adequate mask seal and rapid removal of the adhesive dressing can also result in skin breakdown [8]. Despite the fact we have demonstrated that HHHFNC was associated with less nasal trauma than NCPAP there is likely to be a subset of the preterm population who will require the positive distending pressure that only NCPAP can provide. Protective dressings may have a role in limiting progression of nasal pressure injury in those infants who require NCPAP but this needs to be further evaluated in a large randomised controlled trial.

Damage to nasal mucosa may contribute to rates of unexplained septicaemia in the preterm population [13]. Nosocomial sepsis places a significant burden on the infant and the healthcare system. Each episode of nosocomial sepsis is estimated to cost 10 000 USD and increase the length of stay by 5.2 days [11] . The association of nasal trauma and nosocomial infection needs to be studied further in large randomised controlled trials.

We acknowledge there are limitations to this unblinded study. The sample size was calculated for a primary respiratory outcome and excluded infants who only received non-invasive respiratory support. Thirteen infants (20%) in the NCPAP group changed to HHHFNC in the first 7 days post-extubation because of nasal trauma. The nasal trauma resolved with the transition to HHHFNC. Five infants in the HHHFNC group changed to NCPAP due to apnoea and these infants accounted for the majority of the nasal trauma observed in the HHHFNC group. There was no ulceration or severe lesions seen in infants

who received HHHFNC exclusively. While these crossovers are likely to have diluted the treatment effect, the observed difference in nasal trauma between groups was clinically and statistically significant.

In conclusion, HHHFNC resulted in significantly less nasal trauma in the first 7 days post extubation than NCPAP. The use of protective dressings was not associated with decreased nasal trauma for infants on NCPAP. Further large randomised controlled trials are required to study the association between nasal trauma and nosocomial sepsis and to evaluate the role of protective nasal dressings for infants on NCPAP.

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Figure 1: Study Flowchart for infants assigned to HHHFNC or NCPAP in the first 7 days post-extubation

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295 Table 1: Baseline characteristics of infants at randomisation.

	HHHFNC N=67	**NCPAP N= 65**	
Nasal dressing	HHHFNC Sticky Whiskers® N=67	NCPAP Sticky Whiskers® N=32	NCPAP Cannulaide® N=33
Male n (%)	33 (49)	20 (63)	21 (64)
Birthweight g mean (SD)	1123 (317)	1100 (394)	1109 (361)
Completed Weeks of Gestation mean (SD)	27.9 (1.9)	27.5 (2.2)	27.8 (1.8)
Singleton n (%)	51 (76)	27 (84)	26 (79)
Antenatal Corticosteroids n (%)	59 (88)	29 (91)	29 (88)
Surfactant n (%)	66 (99)	32 (100)	32 (97)
1 min Apgar Score median (IQR 25th-75th)	5 (3-7)	5 (4-6)	6 (4-6)
5 min Apgar Score median (IQR 25th-75th)	7 (6-8)	8 (6-8)	8 (7-9)

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Appendix : Nasal Trauma Score Chart

Score																							
Date																							
Shift		AM	PM	N	AM	PM	N	AM	PM	N	AM	PM	N	AM	PM	N	AM	PM	N	AM	PM	N
Internal Nare	**L**																						
	R																						
External Nare	**L**																						
	R																						
Philtrum																							
Septum																							
Total Score																							

Score

0= normal
1= pink/red
2= bleeding/ ulcer/ scab
3= skin tear