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Incidence of nasal trauma associated with nasal prong versus nasal mask during continuous positive airway pressure therapy in very low birth weight infants: A randomised control study

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Abstract

Objective*:* To compare the incidence of nasal trauma associated with prong with that of mask during nasal continuous positive airway pressure (nCPAP) support in very low birth weight (VLBW, <1501g) infants.

Design: Randomised controlled clinical trial.

Setting: Tertiary care university hospital, Department of Paediatrics, Kuala Lumpur, Malaysia.

Methods: All VLBW infants admitted to our neonatal intensive care unit between July 2001 and December 2003 who received nCPAP through the Infant Flow Driver were randomised to use either nasal prong or mask. The nasal cavity of these infants was inspected daily during the first week and then weekly until the infants were weaned off nCPAP.

Results: Of the 89 infants recruited, 41 were randomised into the mask group and 48 into the prong group. There was no significant difference in the incidence of nasal trauma between the two groups ($p = 0.5$). In infants put on nasal mask, the primary site of trauma was at the junction between the nasal septum and the philtrum. In infants put on nasal prongs, the walls of the nasal septum were the primary sites. Logistic regression analysis showed that the duration of nCPAP was the only significant risk factor associated with development of nasal injury, after controlling for birthweight, gestational age and nasal devices used (adjusted odds ratio: 1.04; 95% C.I.: 1.01, 1.07; $p = 0.003$).

Conclusion: Irrespective of the type of nasal devices used, nasal trauma is common during nCPAP therapy and should be removed as soon as an infant does not need it.

Introduction

Nasal continuous positive airway pressure (nCPAP) is now a common mode of respiratory support used in many neonatal intensive care units for preterm infants. Several studies including a Cochrane Database of Systematic Reviews reported a reduction in the incidence of failed extubation in infants given elective nCPAP post-extubation.[1][2][3] A variety of methods of delivery of nCPAP are available. The Infant Flow Driver System (IFD; Electro Medical Equipment Ltd., Brighton, Sussex, U.K.) is commonly used worldwide. The system consists of a generator, a driver and fixation accessories. The nCPAP by the IFD is provided by application of a set of soft silicon nasal prongs to the nose of an infant or nasal mask covering the nose of an infant with appropriate strapping and fixation. Although nasal trauma has been reported by Robertson [4] using nasal prong with the IFD, there were no reported study comparing the incidence of nasal trauma caused by nasal prong with that by nasal mask. Neither was there any reported study confirming the efficacy of nasal mask CPAP in neonates. The present study aimed to compare the incidence of nasal trauma caused by nasal mask to that of nasal prong during nCPAP therapy using the IFD.

Patients and Methods

This was a randomised controlled study. All subjects were recruited prospectively upon admission to the neonatal intensive care unit (NICU), Hospital University Kebangsaan Malaysia, Kuala Lumpur, Malaysia between 1st July 2001 and 31st December 2003. This study protocol was approved by the Hospital's Research Scientific and Ethics Committee. The inclusion criteria were very low birth weight (VLBW, <1501g) infants with respiratory distress who received nCPAP via the IFD upon admission or were weaned off the ventilator and received nCPAP for continuing respiratory support. Exclusion criteria were infants who received CPAP by other methods e.g. bubble bottle or ventilator CPAP and those with tracheo-oesophageal fistula (TOF), diaphragmatic hernia, pneumothorax, nasal deformities, bilateral choanal atresia or other major malformations.

Upon admission to the NICU, an eligible infant would be assessed by a medical officer for presence of respiratory distress based on the Silverman-Andersen Retraction Score.[5] Briefly, this score is derived from the presence of 5 clinical signs (grunting, nasal flaring, sternal retraction, intercostals recession, and see-sawing movement of the abdomen and sternum) each with a maximum score of 2 and a minimum score of 0 and a total score of 10. A higher total score indicated a more severe degree of respiratory distress. During the study, any infant with a Silverman-Andersen Retraction score between 1-5 would be put on nCPAP after exclusion of choanal atresia, TOF, diaphragmatic hernia and pneumothorax. Those with Silverman-Andersen Retraction score >5 would be ventilated. Parents were then approached for informed consent to be randomised into the study. The written consent form was available in three languages (Malay, English and Chinese) for the three major ethnic groups in Malaysia. For infants who received mechanical ventilation initially and subsequently were ready for extubation to nCPAP therapy, their parents were approached for consent to enrol into the study prior to extubation. At our

unit oral intubation was practised and none of the infants enrolled into this study had nasal intubation.
Eligible infants were stratified into those treated with nCPAP on admission and those receiving nCPAP post ventilation. They were randomised to receive nCPAP using either nasal prong or nasal mask (Figure 1) based on group assignment contained in sequentially numbered sealed opaque envelopes, which had been prepared beforehand, shuffled randomly and then numbered serially.

Once randomised, the IFD would be set up according to the manufacturer's instructions. The medical officer in charge of the recruited infant would carry out an inspection of the infant's nose using overhead angle poise light prior to commencement of nCPAP. Thereafter the nose of all these infants were inspected daily by one of the investigators (S.J.C.) by the same method at the same time of the day from day 1 to day 7, and then weekly until the infants were weaned off nCPAP. The condition of an infant's nose was documented systematically and the presences of any of the 5 types of nasal trauma (redness, bleeding, crusting, excoriation and narrowing of the passages) were recorded. If S.J.C. was unsure of the type of trauma sustained in a study infant, a second opinion was sought from one of the other investigators (S.C.Y.). The intra and inter observer bias had been minimised following a similar pilot study on the incidence of nasal trauma on infants using nasal prong CPAP in our unit.

Assuming the incidence of nasal trauma was 20% in the nasal prong group, it was calculated that a sample size of 37 infants in each arm was required to detect a difference of 10% between the two groups (2-sided test) with a power of 80% at a significance level of 5%.

Statistical analysis was carried out using the statistical package SPSS version 10.1 (SPSS Inc, Chicago, Illinois, USA). Variables between the two arms of the study were compared. Categorical variables were analysed using the chi-square test (or Fisher's exact test if the expected value was less than 5). Student-t test was used for analysis of continuous variables with normal distribution and Mann Whitney U test for continuous variables with skewed distribution. Logistic regression analysis was carried out to determine the significant risk factors associated with nasal trauma (dependent variable) using various potential risk factors (i.e. duration of nCPAP therapy, types of nasal devices used, birthweight, and gestation) identified during univariate analysis (with p values of <0.05) as independent variables. P values of less than 0.05 were considered statistically significant.

Results

Two hundred and twelve VLBW infants were admitted to the NICU during the study period. Of these, 125 infants received CPAP therapy; 97 (77.6%) of them were put on IFD while the remaining 28 (22.4%) were supported with bubble-bottle CPAP due to a shortage of IFD. Of the infants who used IFD, parental consent was not obtained for 8 infants. Thus only 89 infants were enrolled with 41 randomised into the nasal mask group and 48 into the nasal prong group.

There was no significant difference in the ethnic and gender distribution between the two groups of infants ($p > 0.05$) (Table 1). Neither was there any significant difference in the proportions of infants given antenatal steroids, surfactant therapy and nasal CPAP on admission between the two groups ($p > 0.05$). There was also no significant difference in the mean birthweight, mean gestational age, mean Apgar scores at 1 and 5 minutes of life between the two groups ($p > 0.05$). However, a significantly higher proportion of infants recruited into the nasal prong group were delivered by lower segment Caesarean section ($p = 0.02$).

There was no significant difference in the duration of conventional ventilation, duration of high frequency ventilation, duration of oxygen therapy and duration of hospital stay between the two groups of infants (Table 2). There was no significant difference in the proportions of infants with nasal trauma between the two groups ($p = 0.5$). Neither was there any significant difference in the median interval between application of CPAP device and the onset of nasal trauma between the two groups. Although infants put on nasal prong received CPAP therapy for a longer duration and had nasal trauma detected at an earlier median age than infants put on nasal mask, the differences were not statistically significant ($p \geq 0.05$). Neither was there any significant difference in mortality rates between the two groups of infants.

Among the 12 infants who developed nasal trauma in the nasal mask group, six (50%) had crusting and/or excoriation on their nasal septum. Three (25%) developed narrowing of their nasal passage and two (16.7%) sustained redness in their nasal mucosa. One infant (8.3%) had three types of trauma: bleeding, crusting and excoriation. All these injuries (except for narrowing of passages) were seen at the base of the nasal septum, at the junction between the philtrum and the base of nasal septum.

Among the 17 infants who sustained nasal trauma in the nasal prong group, crusting and excoriation were seen in 10 (58.8%) infants. Redness was noted in 4 (23.5%) infants, while one (5.9%) infant had bleeding from the inside of its nostrils. Two infants had more than one injury (one infant with narrowing of passages and excoriation; and another with excoriation and bleeding from the site of injury). All these injuries (except for narrowing of passages) were seen at the medial aspect of the nostrils at the nasal septum.

Table 3 compares the clinical variables of infants who developed nasal trauma against those without trauma following nasal CPAP. Infants with nasal trauma had significantly lower mean birthweight ($p = 0.003$), and longer mean duration of CPAP therapy ($p = 0.001$) than those without trauma. Although infants with nasal trauma had lower mean gestational age than those without, the difference was not statistically significant. There was no significant difference in the proportion of infants who were put on nCPAP immediately upon admission to the NICU ($p = 0.3$). Logistic regression analysis showed that the only significant risk factor associated with the development of nasal trauma following nCPAP therapy was the duration of nCPAP (adjusted odds ratio: 1.04; 95% confidence intervals: 1.01, 1.07; $p = 0.003$) after controlling for various potential

confounders. Birthweight, gestation and types of nasal devices were not significant risk factors.

Discussion

This is the first reported randomised controlled study comparing nasal prong versus nasal mask in infants on nCPAP. Nasal masks which were used in the 1970s were abandoned in the 1980s as there was difficulty in maintaining a good seal and they tended to obstruct the nasal airways.[6][7][8] In recent years, the manufacturer of the IFD has produced soft silicon nasal masks, which can be used in place of the nasal prongs. These nasal masks are softer and fit the nasal airway better than the older generations of nasal masks of the 1970's.

In the present study, we found that although not statistically significant, the incidence of nasal trauma from nasal prong was higher than that resulting from nasal mask. In a previous case series reported by Robertson [4], the incidence of nasal trauma resulting from nasal prong with the IFD was 20% in a group of VLBW infants. That Robertson's figure is lower than that found in our study may be partly due to the fact that we included redness as a sign of trauma. We consider it important to include this mild form of trauma as this might progress to full blown trauma with prolonged use of nCPAP. In the present study, redness injury alone accounted for 16.7% (2 infants) of the trauma in the nasal mask group, and 23.5% (4 infants) of the trauma in the nasal prong group. None of our patients developed nasal septum necrosis and all 29 infants recovered fully from their nasal injuries at the time of discharge from the hospital. During the study, once trauma was detected, treatment was instituted immediately. If there was redness, excoriation or crusting, a protective dressing Duoderm® would be applied to the area to protect that injured part from worsening. This barrier protection might have helped to halt the progression of trauma in our patients as the point of maximum pressure was shielded and healing was allowed to take place.

Though the types of injuries were similar between the mask and prong groups, the sites of injuries differ between the two groups. In the nasal mask group, injuries occurred primarily at the base of the nasal septum at the junction between the nasal septum and the philtrum. This suggests that this is the area where CPAP mask exerts the highest pressure as prolonged pressure leads to impairment of tissue perfusion with resultant skin trauma. Injuries in the nasal prong group were confined primarily at the medial aspect of the nostrils on the nasal septum, thus indicating the site of maximum pressure exerted by the prongs on the nostrils. The lateral part of the infants' nostrils could expand outwards when the prongs were applied; the medial parts of the nostrils being relatively less mobile were exposed to greater persistent pressures from the prongs with resultant trauma.

Logistic regression analysis showed that the only significant risk factor associated with the development of nasal trauma following nCPAP was longer duration of CPAP therapy. The prolonged use of nCPAP exerts more pressure and if there is any area of pressure points exerted by the device, it would definitely cause trauma. This finding suggests that

monitoring of infant's nasal condition and proper application of nasal device should be meticulously carried out to minimise trauma to the delicate skin of this high-risk group of infants.

Based on the findings of this study, we recommend that nCPAP should be stopped as soon as it is no longer needed. There is a need to re-design the medial aspects of the nasal prong to be softer without compromising the efficacy of CPAP delivery system. Currently, there is no reported study to suggest which site of trauma is of greater clinical significance. However, we speculate that with constant injury to the inside of the nostril, there is greater risk of excessive production of nasal secretions leading to recurrent obstructive apnoea and potentially adverse sequelae.

In conclusion, there is no significant difference in the incidence of trauma caused by either nasal prong or nasal mask. The only significant risk factor associated with the development of nasal trauma is longer duration of CPAP therapy.

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Competing interests
none

Figure Legend

Figure 1
Silicon nasal mask (left) and nasal prong (right)

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Table 1: Comparison of demographic and basic clinical data of infants using nasal mask versus nasal prong CPAP

	Nasal mask n = 41	**Nasal prong** n = 48	**p-value**
Ethnic groups (%)			
Malay	25 (61.0)	31 (64.6)	
Chinese	9 (22.0)	10 (20.8)	0.9
Others	7 (17.0)	7 (14.6)	
Male (%)	17 (41.5)	25 (52.1)	0.3
Given antenatal steroids (%)	23 (56.1)	35 (72.9)	0.1
Delivered by LSCS	18 (43.9)	33 (68.7)	0.02*
Mean birth weight, g (SD)	1085 (232)	1105 (228)	0.7
Mean gestation, weeks (SD)	28.7 (2.3)	29.7 (2.6)	0.06
Mean Apgar score at 1 minute (SD)	6.5 (1.7)	6.3 (2.0)	0.6
Mean Apgar score at 5 minute (SD)	8.5 (0.9)	8.1 (1.7)	0.1
Given surfactant (%)	31 (75.6)	27 (56.3)	0.06
Median age when 1st dose of surfactant was given, minutes (IQR)	15.0 (13.0)	20.0 (20.0)	0.4
Received CPAP on admission (%)	8 (19.5)	12 (25.0)	0.5

LSCS= lower segment Caesarean section. SD= standard deviation; IQR= interquartile range' CPAP= continuous positive airway pressure; * denotes statistical significance

Table 2: Comparison of clinical outcome of infants using nasal mask versus nasal prong CPAP

	Nasal mask n = 41	**Nasal prong** n = 48	**p-value**
Presence of nasal trauma (%)	12 (29.3)	17 (35.4)	0.5
Median interval between application of nasal device & onset of trauma, days (IQR)	6.5 (8.7)	5.0 (2.5)	0.16
Median age of onset of trauma, days (IQR)	14.0 (18.2)	8.0 (8.0)	0.05
Mean duration of CPAP, days (SD)	22.3 (16.6)	27.7 (21.6)	0.07
Median duration of conventional ventilation, days (IQR)	4.0 (7.0)	3.5 (7.8)	0.2
Mean duration of NICU stay, days (SD)	60.2 (28.4)	56.3 (31.5)	1.0
On oxygen therapy at 28 day of life (%)	11 (26.8)	10 (20.8)	0.3
On oxygen therapy at 36 weeks of gestation (%)	4 (9.8)	7 (14.6)	0.6
Mortality (%)	3 (7.3)	5 (10.4)	0.3

SD = standard deviation; IQR = interquartile range; CPAP = continuous positive airway pressure; NICU = neonatal intensive care unit

Table 3: Comparison of potential risk factors associated with the development of nasal trauma in VLBW infants following nasal continuous positive airway pressure (nCPAP) therapy

	Nasal trauma n= 29	**No Nasal trauma** n= 60	**95% CI of difference between mean**	**p-value**
Mean birth weight, g (SD)	992 (199)	1146 (227)	55.5, 251.9	0.003*
Mean gestation, weeks (SD)	28.6 (2.2)	29.6 (2.6)	-1.3, 2.1	0.08
Mean duration of nCPAP, days (SD)	35.1 (20.0)	20.4 (17.6)	-22.9, -6.4	0.001*
Median duration of conventional ventilation, days (IQR)	5.0 (5.5)	3.0 (7.0)	-	0.1
Median duration of high frequency ventilation, days (IQR)	0 (0)	0 (0)	-	0.1
Application of nCPAP				
- On admission	4	16	-	0.3
- Post-extubation	25	44		

*: denotes statistical significant; SD = standard deviation; IQR = interquartile range; CI = confidence intervals.