

## Effect of Silicon Gel Sheeting in Nasal Injury Associated with Nasal CPAP in Preterm Infants

AYLA GÜNLEMEZ, TONGUÇ ISKEN\*, AYSE S GÖKALP, GÜLCAN TÜRKER AND ENGIN A ARISOY

From the Section of Neonatology, Department of Pediatrics; and \*Department of Plastic, Reconstructive and Aesthetic Surgery; Kocaeli University Faculty of Medicine, Kocaeli, Turkey.

### Correspondence to:

Ayla Günlemez, Cumhuriyet Mahallesi, Sahil Caddesi, Deniz Sokak 3/6, İzmit, 41100 Kocaeli, Turkey.  
aylagunlemez@yahoo.com  
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We conducted this study to investigate the efficacy of the silicon gel application on the nares in prevention of nasal injury in preterm infants ventilated with nasal continuous positive airway pressure (NCPAP). Patients ( $n=179$ ) were randomized into two groups: Group 1 ( $n=87$ ) had no silicon gel applied to nares, and in Group 2 ( $n=92$ ), the silicon gel sheeting was used on the surface of nares during ventilation with NCPAP. Nasal injury developed in 13 (14.9%) neonates in Group 1 and 4 (4.3%) newborns in Group 2 (OR:3.43; 95% CI: 1.1-10.1;  $P<0.05$ ). The incidence of columella necrosis was also significantly higher in the Group 1 (OR: 6.34; 95% CI: 0.78-51.6;  $P<0.05$ ). We conclude that the silicon gel application may reduce the incidence and the severity of nasal injury in preterm infants on nasal CPAP.

**Key Words:** Columella necrosis, Nasal Continuous Positive Airway Pressure, Nasal injury, Silicon gel sheeting, Preterm infants.

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**N**asal continuous positive airway pressure (NCPAP) is a noninvasive form of ventilation that is increasingly becoming popular as a method of respiratory support in the newborn(1). One of the complications of NCPAP application is nasal injury, ranging from edema to columella necrosis, which may occur with all types of nasal prongs and NCPAP devices(2-8).

The present study was designed to explore the potential protective effects of the silicon gel sheeting on nasal tissue during NCPAP use. We hypothesized that the use of silicon gel sheeting on nares could reduce the incidence and severity of nasal injury related to NCPAP use in premature infants.

### METHODS

This study was designed as a prospective controlled trial conducted in neonatal intensive care unit of Kocaeli University, Medical Faculty Hospital between November 2005 and July 2007. The study

protocol was approved by the hospital's Research Scientific and Ethics committee. Parental informed consent was taken from all eligible infants. Eligibility criteria were a premature infant who required NCPAP on admission or was receiving NCPAP after any other type of initial ventilation. Subjects were enrolled after they completed 24h of NCPAP. Exclusion criteria were term gestation, nasal deformities, shock and coagulation defect. SLE 2000 Ventilator Driver and Infant Nasal Cannula Assemble for CPAP were used and driver was set up according to the manufacturer's instructions (SLE Ltd, Berlin-Germany). Patients were randomized alternate day into two groups based on silicon gel sheeting application during ventilation with NCPAP. Silicon gel sheeting (Epi-Derm Silicon Gel Sheeting, 1.8 mm thick, Biodermis, Las Vegas, USA) was placed on infant's nares surface during ventilation. Nasal injuries were described as bleeding, crusting, excoriation or columella necrosis. All infants were monitored daily for the development of the injury

until they were weaned off NCPAP. The same plastic and reconstructive surgeon documented the condition of the nose systematically, in a masked manner. All patients with nasal injury were followed up for at least a month for the development of columella necrosis. Data collected included age at the onset and the duration of NCPAP ventilation, presence of nasal injury, the time interval between the initiation of NCPAP and the onset of injury (in days).

Statistical analysis was carried out using the statistical package of SPSS version 10.1 for Windows (SPSS Inc, Chicago, Illinois, USA). Data were reported as frequencies or means with standard deviations (SD). Categorical variables were compared using the chi square test and continuous variables with Student's *t* test. Logistic regression analysis was carried out to determine the significant risk factors associated with nasal injury (dependent-variable) using various potential factors (birth weight, gestational age, duration of NCPAP treatment and using silicon gel sheeting) identified as independent variables during univariate analysis.  $P < 0.05$  was considered significant.

## RESULTS

During the study period, 1084 newborns were admitted to our 27-bed tertiary care unit. A total of 179 premature infants were ventilated with NCPAP and all enrolled in the study. Of 179 infants, 87 (48.6%) received NCPAP treatment without using silicon gel (Group 1), and the remaining 92 (51.4%) were ventilated after applying the silicon gel sheeting (Group 2). There was no significant difference in the patient and ventilation characteristics between two groups (**Table I**).

Study identified a total of 17 infants who developed nasal injury related to the use of NCPAP. Incidence of nasal injury calculated to be 14.9% ( $n=13$ ) for Group 1 and 4.3% ( $n=4$ ) for Group 2 (OR: 3.43; 95% CI: 1.1-10.1;  $P < 0.05$ ). Columella necrosis occurred in 6 patients in Group 1 (6.8%) vs 1 (1.08%) patient in Group 2 (OR=6.34; 95% CI: 0.78-51.6;  $P < 0.05$ ). The time interval between the initiation of NCPAP and the onset of injury was  $12.1 \pm 3.8$  days (median: 12, range: 7-21) in all patients. The infants with nasal injury had a longer duration of NCPAP

( $19.6 \pm 10.6$  days) than the infants without nasal injury ( $4 \pm 3.3$  days). Nasal injury developed at average of  $10.8 \pm 3.1$  days in Group 1 and  $16.2 \pm 3.2$  days in Group 2 ( $P < 0.05$ ).

Logistic regression analysis showed that the main significant risk factor for the development of nasal injury was the duration of NCPAP treatment. The other risk factors were lower birthweight and gestational age ( $P < 0.001$ ). Using silicon gel sheeting was associated with lower incidence of nasal injury ( $P < 0.05$ ).

## DISCUSSION

Our study investigated a group of preterm infants receiving NCPAP with single NCPAP setup. We found that the nasal silicon shield application not only reduced the nasal injury rates significantly, but it also decreased the severity of nasal injury such as columella necrosis. Yong, *et al.*(3) compared the incidence of nasal injuries associated with the use of prongs or mask during NCPAP in VLBW infants. They classified nasal injury as redness, bleeding, crusting, excoriation, and narrowing of the passage, and found that the injury rates were 29% for the

**TABLE I** CHARACTERISTICS OF VENTILATED NEONATES

Parameters	Group 1 ( $n=87$ )	Group 2 ( $n=92$ )
Birthweight (g), mean $\pm$ SD	1752 $\pm$ 689	1776 $\pm$ 715
Birthweight, $n$ (%)		
$\leq 1000$ g	19 (21.8)	23 (25)
1001-1500g	22 (25.3)	22 (23.9)
1501-2500g	34 (39.1)	35 (38)
$\geq 2501$ g	12(13.8)	12 (13)
Gestational age (wk), mean $\pm$ SD	32.1 $\pm$ 3	32.2 $\pm$ 3.3
Mortality, $n$ (%)	5 (5.7)	4 (4.3)
Ventilation with nasal CPAP		
Age at onset (day), mean $\pm$ SD	2.7 $\pm$ 3.2	2.2 $\pm$ 3
Duration (day), mean $\pm$ SD	5.9 $\pm$ 7.4	5.1 $\pm$ 5.4
Nasal CPAP duration $\geq 7$ days	17 (19.5)	18 (19.6)
Application on admission, $n$ (%)	34 (39.1)	42 (45.7)
Application after extubation, $n$ (%)	53 (60.9)	50 (54.3)

\*  $P > 0.05$  between two groups for all characteristics.

**WHAT THIS STUDY ADDS?**

- Silicon gel application may reduce the incidence and severity of nasal injury in preterm infants on nasal CPAP.

prongs and 35% for the mask. They also found no significant difference between the two methods of application. Buettiker, *et al.*(4) reported 16 cases with nasal injury (1 severe, 8 moderate and 7 mild injury) in 40 patients on different type of NCPAP systems.

The major underlying mechanism of nasal injury related to NCPAP appears to be the pressure generated on the columella by the prongs. Etiology is similar to the pressure sores. Pressure sores are best defined as soft-tissue injury resulting from unrelieved pressure over a bony prominence(9). There is maxillary spine behind the columella and its surface is very small. NCPAP device causes the pressure on this area. Increased pressure on the columella causes diminished circulation of blood flow. This subsequently impairs tissue perfusion and leads to ischemia along with tissue damage. Persistent erythema, dermal injury, edema, induration and finally an ulcer can occur. Relieving the pressure is the key to healing and more importantly, the key to prevention. Traditionally, static devices such as gel pads and mattress overlays are used to reduce pressure and support surfaces(9-11). A silicone dressing can also be used to manage pressure ulcers(10,11). Silicon gel sheeting is a soft and flexible material. It reduces the pressure on columella, distributes pressure around the nares and reduces friction between device and skin. Silicone gel sheet can prevent trauma to the surrounding skin.

Infants during NCPAP should be closely monitored for the development of nasal injury. In addition to adequate nursing and vigilance, silicon gel sheeting can be applied to nares to reduce the incidence and the severity of nasal injury that might originate from NCPAP use in preterm infants.

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