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Noninvasive Continuous Positive Airway Pressure in Acute Respiratory Failure: Helmet Versus Facial Mask

WHAT'S KNOWN ON THIS SUBJECT: nCPAP is used to treat mild ARF in infants and children. A new pediatric helmet was recently introduced in clinical practice that offers an alternative to the conventional facial mask for delivery of nCPAP to treat ARF.

WHAT THIS STUDY ADDS: In this randomized study, the pediatric helmet was compared with a facial mask for delivery of nCPAP in infants with mild ARF. Helmet delivery could be applied for a longer time and patients required less sedation, had improved oxygenation, and were free of adverse events.

abstract

OBJECTIVE: Noninvasive continuous positive airway pressure (nCPAP) is applied through different interfaces to treat mild acute respiratory failure (ARF) in infants. Recently a new pediatric helmet was introduced in clinical practice to deliver nCPAP. The objective of this study was to compare the feasibility of the delivery of nCPAP by the pediatric helmet with delivery by a conventional facial mask in infants with ARF.

PATIENTS AND METHODS: We conducted a single-center physiologic, randomized, controlled study with a crossover design on 20 consecutive infants with ARF. All patients received nCPAP by helmet and facial mask in random order for 90 minutes. In infants in both trials, nCPAP treatment was preceded by periods of unassisted spontaneous breathing through a Venturi mask. The primary end point was the feasibility of nCPAP administered with the 2 interfaces (helmet and facial mask). Feasibility was evaluated by the number of trial failures defined as the occurrence of 1 of the following: intolerance to the interface; persistent air leak; gas-exchange derangement; or major adverse events. nCPAP application time, number of patients who required sedation, and the type of complications with each interface were also recorded. The secondary end point was gas-exchange improvement.

RESULTS: Feasibility of nCPAP delivery was enhanced by the helmet compared with the mask, as indicated by a lower number of trial failures ($P < .001$), less patient intolerance ($P < .001$), longer application time ($P < .001$), and reduced need for patient sedation ($P < .001$). For both delivery methods, no major patient complications occurred.

CONCLUSIONS: The results of this current study revealed that the helmet is a feasible alternative to the facial mask for delivery of nCPAP to infants with mild ARF. *Pediatrics* 2010;126:e330–e336

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KEY WORDS

noninvasive continuous positive airway pressure, acute respiratory failure, infants, helmet

ABBREVIATIONS

nCPAP—noninvasive continuous positive airway pressure
ARF—acute respiratory failure
FIO_2—fraction of inspired oxygen
$tcPO_2$—transcutaneous oxygen pressure
$tcPCO_2$—transcutaneous carbon dioxide pressure
SB—spontaneous breathing

Drs Chidini, Calderini, and Pelosi were involved in the design of the study and preparation of the manuscript. Dr Cesana was involved in the statistical analysis, and Drs Gandini and Prandi participated directly in the collection of the data.

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Noninvasive continuous positive airway pressure (nCPAP) is used in care of children with hypoxemic acute respiratory failure (ARF). nCPAP results in alveolar recruitment, inflation of collapsed alveoli, and reduction of intrapulmonary shunt.[1] The choice of interface for application of nCPAP is a crucial issue. Preterm infants and neonates are nose breathers, and nCPAP is usually administered via nasal cannulas or nasal prongs. Infants are mostly mouth breathers, and for these patients a facial mask is usually the interface of choice. However, air leaks around the mask often occur, whereas a tight-fitting mask leads to patient discomfort and treatment interruption.[2,3] A nasal mask is better tolerated, but mouth opening by the patient reduces nCPAP efficacy by decreasing the mean applied airway pressure.[4,5] Thus, improving tolerance to the nCPAP interface may facilitate more effective application. A new pediatric helmet for delivery of nCPAP has been introduced in clinical practice. Preliminary data from neonates, infants, and children have shown that the helmet has several advantages including increased comfort and decreased cutaneous lesions and air leaks.[6–10] The aim of this physiologic, randomized, controlled study with crossover design was to investigate feasibility of nCPAP delivered by helmet compared with conventional facial mask in infants with mild ARF.

PATIENTS AND METHODS

Study Design

We conducted a single-center physiologic, randomized, controlled study with a crossover design. Study participants were consecutively enrolled infants with ARF admitted to a 6-bed PICU of a tertiary children's hospital (Fondazione IRCCS Ca' Granda, Ospedale Maggiore Policlinico, Milan, Italy) from January 2007 to June 2008. The ethics committee approved the protocol, and informed consent for each patient was obtained from at least 1 parent or a legal guardian before enrollment. Patient inclusion criteria were age between 1 and 24 months and clinical suspicion of pulmonary infection (bacterial and/or viral) defined as the presence of infiltrates visible on chest radiograph plus the presence at least 1 of 3 clinical variables: fever (body temperature $>$ 38 C°); leukocytosis/leukopenia and purulent secretions accompanied by abnormal breath sounds[11,12]; and the simultaneous presence of transcutaneous oxygen pressure/fraction of inspired oxygen ($tcPo_2/FIo_2$) $\leq$300 mm Hg after breathing O_2 through a Venturi mask for at least 15 minutes, respiratory rate higher than maximum value of physiologic range for age,[13] and active contraction of respiratory muscles or paradoxical abdominal motion. Exclusion criteria were Glasgow Coma Scale score of $<$13, hypercapnia ($tcPco_2 > 55$ mm Hg), status asthmaticus, impairment of cough or gag reflex, upper-airway obstruction, failure of any other organs, recent facial/gastric surgery, recurrent apnea, hemodynamic instability, uncorrected cyanotic congenital heart disease or pulmonary vascular anomalies, and enrollment in other research protocols.

Experimental Protocol

Infants were studied while they were in a semirecumbent position. We used sealed envelopes to randomly assign the infants to 1 of 2 treatment sequences: 1 sequence with helmet first and mask after and the second sequence with the treatments performed in the reverse order. Thus, 10 infants received first a 90-minute nCPAP trial by helmet, and 10 infants received a 90-minute nCPAP trial by mask. Furthermore, to evaluate time effects, after each treatment we allowed a 30-minute washout period of unassisted spontaneous breathing (SB) with O_2 therapy delivered by a Venturi mask (Tyco Health Care, Mansfield, MA). FIo_2 was set to maintain a peripheral oxygen saturation of 93% to 96% while infants were on SB and kept constant throughout the study period. CPAP was set at 5 cm H_2O.

End Points

The primary end point was feasibility of nCPAP evaluated by the number of trial failures with the 2 interfaces. The secondary end point was gas-exchange improvement. In addition, we evaluated the duration of trials, number of patients needing sedation, and type of complications with each interface.

Definitions

Trial failure was defined as interruption of an nCPAP trial attributable to at least 1 of the following: persistent air leak, deterioration in gas exchange, patient intolerance, or major adverse patient event (hemodynamic instability, pneumothorax, hypercapnic coma, and cardiac arrest). If 1 of the mentioned criteria was present during an nCPAP trial, the physician stopped the protocol and clinical treatment was performed according to clinical judgment. Tolerance to the interface was assessed by use of the COMFORT scale.[14] The COMFORT scale is a nonintrusive tool for assessing efficacy of pharmacologic interventions used to reduce distress in pediatric patients receiving ventilation. This assessment method has been shown to have high interrater agreement and high internal consistency. Target scores range from 1 to 26; a score of 26 indicates that the child is awake and calm, a score of $<$17 suggests deep sedation, and a score $>$26 denotes distress. To determine the interobserver variability of the COMFORT scale when it was used to assess our study patients, 2 senior nurses who simultaneously and

independently observed the patients for a 2-minute period scored 20 procedures. Agreement between observers was analyzed by linearly weighted Cohen's κ; κ values of <0.4 indicated poor agreement, values of 0.4 to 0.75, fair-to-good agreement, and values of >0.75, excellent agreement. Patients were not sedated before the study. If sedation was required to improve tolerance of the procedure, patients were administered a maximum of 2 boluses of 0.01 mg/kg of intravenous midazolam. Persistent air leak was defined as the presence of leaks around the interface that affected circuit pressurization <3 cm H_2O despite repeated positioning of the interface by nurses. Gas-exchange deterioration was defined as a reduction in $tcPo_2/FIo_2$ of ≥ 50 points below the baseline and/or an increase in $tcPco_2$ of ≥ 10 mm Hg. Cutaneous sores were scored as 0 (no sore), 1 (area redness or change in color that did not fade within 30 minutes after pressure was removed), 2 (moderate skin breakdown), 3 (skin ulcer), or 4 (skin necrosis).[15] Gastric distension was evaluated by clinical visual inspection. Eye irritation was defined as presence of inflammation of palpebral and/or bulbar conjunctiva covering the exposed surface of sclera and was scored as 0 (not present) or 1 (present).

Equipment

The pediatric helmet (Castar Starmed, Mirandola, Italy) had a collar diameter of 27 cm and a volume of 6 L. It was made of transparent latex-free polyvinyl chloride and was secured to a soft collar that adhered to the child's neck. The system was linked by 2 braces to a diaper. One port of the helmet was connected to a fresh gas source and the other to an underwater positive end-expiratory pressure valve. An overpressure safety device (20 cm H_2O) was present on the inspiratory line. High fresh-gas flow (>40 L/min) was used to avoid subjecting the infants to CO_2 rebreathing. The helmet could be removed quickly in case of emergency. An antiasphyxia valve was present to prevent suffocation and could be easily removed to facilitate nursing and suctioning (Fig 1). Tracheal and oral suction were performed via an opening in the surface of the helmet. A high-compliance reservoir balloon (15 L) was inserted in the inspiratory line of the circuit to minimize pressure swings. The facial mask (Respironics, Murrysville, PA) was chosen to provide optimal fit to the contour of the face and was connected to the previously described nCPAP circuit via a Y connector. Prevention of skin lesions was achieved by application of colloid dressings (DuoDERM [ConvaTec, Deeside, UK]). The mask was initially applied manually, and after a short period of adaptation it was secured on the patient's face by a head cap. Pressure, FIo_2, and temperature were measured on the inspiratory line and displayed (Sensor OPT [Starmed, Mirandola, Italy]). During nCPAP delivered with the helmet no active humidification was applied, whereas during nCPAP delivered with the mask inspired gases were humidified with a hot-water humidifier (MR730 [Fisher & Paykel Health Care Corporation, Auckland, New Zealand]).

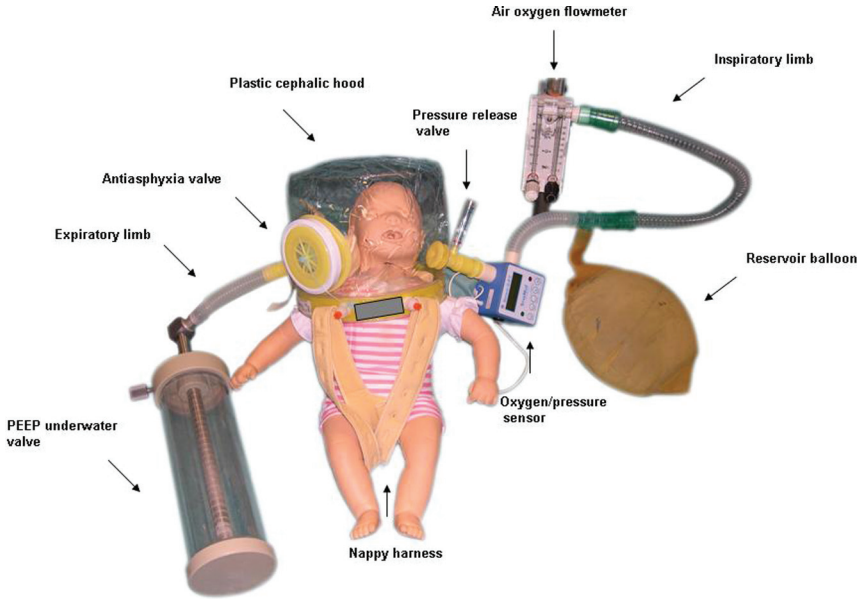

FIGURE 1
The circuit used to deliver nCPAP with the helmet. PEEP indicates positive end-expiratory pressure.

Measurements

We evaluated gas exchange by measuring $tcPo_2$ and $tcPco_2$ with a $tcPo_2/tcPco_2$ monitor (Infinity Kappa XLT [Drager, Lubeck, Germany]). We assumed that $tcPo_2$ was related to arterial O_2 pressure with a variability of 10% lower than arterial value as reported by Weaver et al.[16] We considered $tcPo_2$ in relation to FIo_2 as an index of oxygenation. Sensors were calibrated and then applied to the patient's chest. To compute $tcPo_2/FIo_2$, an in vitro determination of delivered FIo_2 was obtained by an independent O_2 analyzer, with respect to the Venturi O_2 mask and nCPAP systems. The FIo_2 delivered by different Venturi connectors (Tyco Health Care) was found to be accurate for a wide range of O_2 concentrations. During nCPAP, calibration of the O_2 analyzer showed that nCPAP delivery with a mask provided 0.8% more O_2 than delivery with a helmet. All patients

were continuously monitored for peripheral O_2 saturation, respiratory rate, and electrocardiographic activity. All measurements were recorded in the last 5 minutes of each trial or before trial interruption. Arterial blood pressure was measured at 10-minute intervals. Respiratory effort was evaluated by using a respiratory-effort score that ranged from 0 (best) to 12 (worst).[17] Nasopharyngeal and/or tracheal secretions were collected by use of a nonbronchoscopic blind technique. Viral infection was detected by enzyme-linked immunoadsorbent assay. The lung-injury score was calculated by use of chest radiography at the time of admission.[18]

Criteria for Endotracheal Intubation

Criteria for administering endotracheal intubation to study patients were $tcPO_2/FIO_2 < 100$ mm Hg with $FIO_2 \geq 0.6$ and $tcPCO_2 > 65$ mm Hg; clinical signs of exhaustion (active contraction of muscles of respiration with paradoxical abdominal and thoracic motion); need for endotracheal intubation to protect airways/remove secretions; and hemodynamic instability.

Data Analysis

The SPSS package (SPSS Inc, Chicago, IL) was used for all analyses. Descriptive statistics were calculated for quantitative variables (mean ± SD, range, and median with 95% confidence interval) and for qualitative variables (absolute and percent frequencies). The analysis of quantitative variables was conducted by means of an analysis of covariance for repeated measures (the 2 final values after each treatment) with changing covariates (the 2 baseline values before each treatment). This model allowed us to test the carryover effect, the treatment effect, and the period effect according to a 2-period–2-treatment crossover design. A repeated-measurements analysis of variance that included measured values obtained at the end of treatment was used for application time and COMFORT score. The carryover effect was tested at a statistical significance of $P = .10$. Qualitative variables were analyzed by means of McNemar's test. Assuming a proportion of discordant response to helmet and mask treatment ranging from 0.50 to 0.70, a sample size of 20 patients allowed us to demonstrate with a power of 0.80 an odds ratio ranging from 5.0 to 10.0 with McNemar's test conducted at a significance level of .05 (2-tailed). In addition, a sample size of 20 patients allowed us to demonstrate with a power of 0.80 an effect size of ~0.67 with a paired Student's t test conducted at a significance level of .05 (2-tailed) between the 2 treatment groups for quantitative variables, a difference of 0.67 times the variability of the investigated phenomenon.

RESULTS

During the study period 58 infants with hypoxemic ARF were admitted to the PICU. Twenty-three were excluded before randomization because of hypercapnia ($n = 10$), status asthmaticus ($n = 4$), upper-airway obstruction ($n = 4$), and uncorrected cyanotic heart disease ($n = 4$). Thirty-five were assessed to protocol eligibility, but 8 were lost because of parents' refusal and 4 because of failure to collect $tcPO_2/tcPCO_2$ data. Twenty-three were allocated to randomization, but in 3 patients data on physiological variables were not collected because of technical reasons. For these patients no treatment-failure end point was considered in the intention-to-treat analysis; for the remaining end points, data from 20 patients were analyzed.

Characteristics of population randomization are shown in Table 1. No major complications occurred throughout the study period. Outcome parameters are shown in Table 2.

TABLE 1 Patient Characteristics

Characteristic	Value
Male/female	12/8
Age, mo	8 (3–10.9)
Weight, kg	8 (5–11)
Pediatric Index of Mortality 2	4 (4–5.9)
$TcPO_2$, mm Hg	60 (55–69)
$TcPO_2/FIO_2$, mm Hg	180 (150–198)
$TcPCO_2$, mm Hg	45 (38–48)
Respiratory rate, breaths per min	67 (57–71)
Respiratory-effort score	8 (5–8)
Lung-injury score	1 (1–2)
Heart rate, beats per min	142 (131–160)
Systolic blood pressure, mm Hg	105 (82–120)
Causes of acute respiratory failure, *n* (%)	
Bacterial pneumonia	13 (65)
Respiratory syncytial virus pneumonia and/or bronchiolitis	7 (35)

Data are expressed as median (95% confidence interval) or *n* (%).

No differences at baseline were detected between helmet and mask for FIO_2 (0.45 with helmet vs 0.48 with mask; $P = .552$) and CPAP level (5 ± 0.5 cm H_2O with helmet vs 5.1 ± 0.6 cm H_2O with mask; $P = .570$). Linear weighted Cohen's κ value for the total COMFORT scale was 0.67. Results of intention-to-treat analysis indicated that nCPAP by mask resulted in a higher number of trial failures before the time end point: 16 of 23 (69%) compared with 4 of 23 (17%) with a helmet ($P = .014$). In particular, the 12 discordant results were all failures for the mask compared with treatment success for the helmet. Thirteen of 23 (56%) mask-treated patients failed the nCPAP trial because of intolerance compared with 1 of 23 (4%) helmet-treated patients ($P = .0001$). Per-protocol analysis results showed that 16 of 20 (80%) patients treated with the mask failed the nCPAP trial compared with 4 of 20 (20%) treated with the helmet ($P = .0002$). Intolerance of nCPAP was the leading cause of trial failure, and it occurred in 13 of 20

TABLE 2 Outcome Variables

Variable	SB	Helmet	SB	Mask	P^a
No. of trial failure, *n* (%)	—	4 (20)	—	16 (80)	.0002
Causes of trial failure					
Intolerance, COMFORT score > 26, *n* (%)	—	1 (5)	—	13 (65)	.0005
Air leaks, *n* (%)	—	3 (15)	—	3 (15)	.683
Deterioration in gas exchange, *n* (%)	—	0	—	0	.99
Major adverse events, *n* (%)	—	0	—	0	.99
COMFORT score, median (95% CI)	21.5 (18–23)	23.5 (22–26)	21 (18–24)	30 (27–34)	.0011
Application time, median (95% CI), min	—	84 (76–92)	—	15 (12–36)	.0001
Patients needing sedation, *n* (%)	—	4 (20)	—	12 (60)	.004
Cutaneous sores, level 1, *n* (%)	—	0	—	9 (45)	.009
Gastric distension, *n* (%)	—	2 (10)	—	3 (15)	.96
Eye irritation, *n* (%)	—	0	—	0	.99

CI indicates confidence interval.

[a] *P* value between interfaces and ANOVA and McNemar's test (see text).

(65%) patients with the mask versus 1 of 20 (5%) with the helmet ($P = .0005$). In addition, 3 infants with the helmet and 3 with the mask failed because of leaks ($P = .683$). nCPAP application time was markedly longer with the helmet than with the mask ($P = .0001$). Twelve of 20 (60%) patients required sedation with the mask compared with only 4 of 20 (20%) with the helmet ($P = .004$). Despite the lower application time, area redness over cutaneous pressure points occurred early and more frequently with the mask ($P = .009$), whereas no difference between mask and helmet was detected for gastric distension ($P = .96$) and eye irritation ($P = .99$). The effect of nCPAP on gas exchange and physiologic parameters is shown in Fig 2. nCPAP with both interfaces increased tcP_{O_2}/FI_{O_2} compared with previous SB (helmet: $P = .0008$; mask: $P = .0002$). Moreover, nCPAP by helmet significantly improved oxygenation compared with the mask ($P = .001$). The mean differences in tcP_{O_2}/FI_{O_2} with nCPAP versus SB were: 98 mm Hg with helmet and 87 mm Hg with mask. Conversely, with both interfaces tcP_{CO_2} did not change over time. nCPAP by helmet also produced a significant decreases in respiratory rate and respiratory effort score compared with the mask ($P = .0007$ and .0014, respectively) and with SB ($P = .0005$ and .0003, respectively). Systolic blood pressure and heart rate were lower with the helmet than with the mask ($P = .0006$ and .0122, respectively).

DISCUSSION

To our knowledge, this is the first randomized study to compare the feasibility of nCPAP delivered by helmet or facial mask in a population of infants with mild hypoxemic ARF. We found that the helmet enhanced the feasibility of nCPAP, as indicated by lower number of treatment failures, better

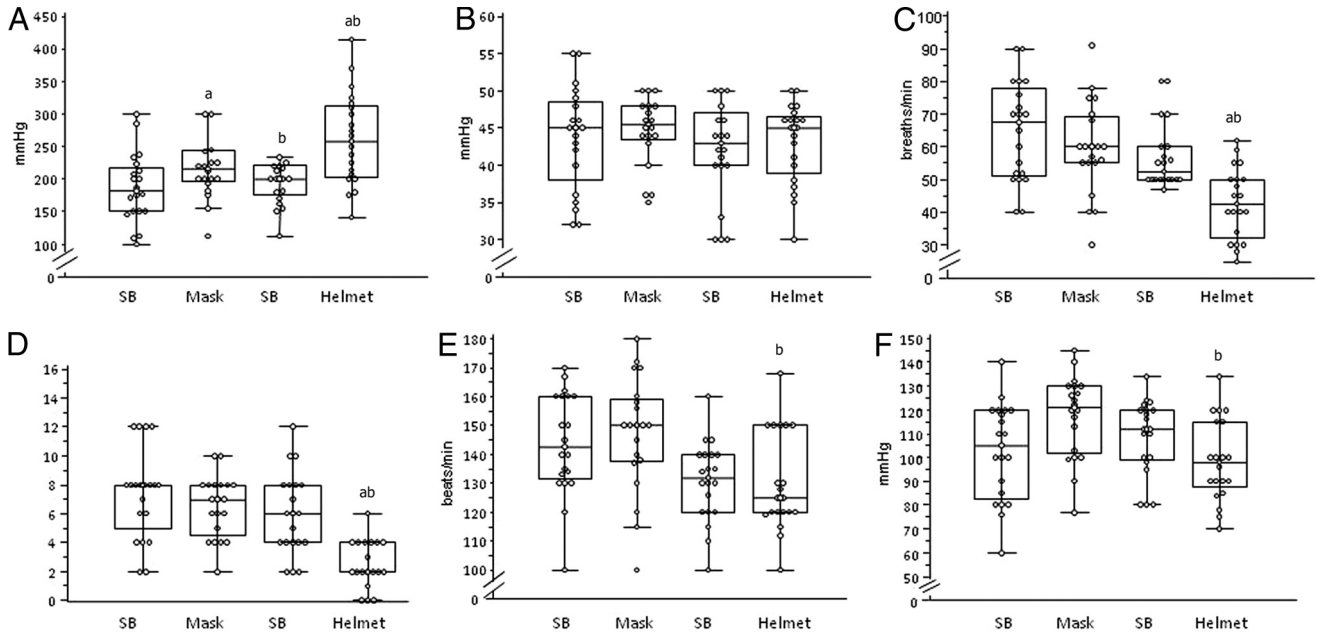

FIGURE 2

Boxplots of physiological parameters during unassisted spontaneous breathing (SB) and nCPAP at high flow delivered by mask or helmet with whiskers from the first to the third interquartile range. The patients were randomly assigned to 2 treatment sequences: 1 with the helmet first and the mask afterward and the second sequence with the treatment in the reverse order. Thus, 10 patients received treatment with the helmet first and 10 with the mask first. Data are represented in reverse order according to treatment sequence. A, tcP_{O_2}/FI_{O_2}; B, tcP_{CO_2}; C, respiratory rate; D, respiratory effort score; E, heart rate; F, systolic blood pressure. [a] $P < .001$ compared with previous unassisted SB; [b] $P < .001$ between interfaces; analysis of covariance for repeated measures.

tolerance, longer application time, and less requirement for sedation. Noninvasive respiratory support is increasingly used in the care of infants with ARF,[1,6,7,10,19] and results of a recent randomized, controlled trial indicated that noninvasive respiratory support seems to reduce the intubation rate.[20] The beneficial effects of nCPAP result from splinting of the airways, enhancement of lung expansion, prevention of alveolar collapse, reduction of ventilation/perfusion mismatch, and stabilization of respiratory pattern.[21] The appropriate performance of the nCPAP interface, which is usually a nasal cannula or nasal and facial mask, plays a crucial role in the success of nCPAP.[3,4] Nasal cannulas and nasal masks are easy to use and keep in place but are highly flow resistive and associated with mucosal bleeding and excess of nasal obstruction with increased work of breathing.[22–24] Nasal masks are associated with air leaks caused by patient mouth-opening, which lead to interruption of respiratory treatment.[4,5] Facial masks have the advantage of limiting oral leaks, but patient discomfort from tight-fitting masks may lead to increased numbers of failures.[3] In an attempt to increase the comfort of infants undergoing nCPAP, a pediatric helmet was recently introduced in clinical practice.[6–10] The helmet has advantages over nasal or whole-face masks, because it allows the infant free movement of the head and interaction with environment while maintaining a good seal without compression of the face. Several researchers have investigated the efficacy and tolerability of the helmet in nonrandomized, controlled studies. Trevisanuto et al[6] used a rigid helmet to deliver nCPAP to preterm infants for mild respiratory distress. Tolerability was enhanced, and fewer episodes of desaturation occurred with the helmet compared with nasal prongs. Codazzi et al[7] demonstrated tolerability and safety of nCPAP delivered by helmet in a population of preschool children with ARF of mixed etiologies. Piastra et al[8] used the helmet in 4 hypoxemic children with acute leukemia and found an improvement in oxygenation without any complications. Afterward, the same authors reported tolerance, effectiveness in improving gas exchange, and safety of the device in children with adult respiratory distress syndrome who received pressure-support ventilation via facial mask versus a helmet.[9] In a recently published prospective matched-control study in hypoxemic infants, Chidini et al[10] demonstrated that nCPAP by helmet was safe and better tolerated than nCPAP by facial mask. Our study results confirmed that nCPAP by helmet resulted in enhanced feasibility and longer application time compared with a mask, mainly because of greater tolerance. Indeed, despite a short time of application and assistance provided by well-trained nurses, the facial mask produced early cutaneous sores over the nasal bridge. The absence of pressure points on the face with the helmet is undoubtedly an advantage. Results of other reported studies revealed a lower percentage of intolerance to the facial mask.[9,25] However, patients included in these studies were older (9–10 years vs 8 months), and for this age group more possibilities to use different interfaces are available.

Some precautions must be kept in mind when the helmet is used, particularly the risk of CO_2 rebreathing. Taccone et al[26] demonstrated that hypercapnia occurred when nCPAP was delivered by a ventilator but not when a continuous high-flow system was used. Moreover, the CO_2 concentration within the helmet did not depend on its volume but, rather, on the patient's CO_2 production and the fresh-gas flow rate. Another risk is the ability of nCPAP delivered by helmet to maintain alveolar recruitment. In a physiologic study on healthy subjects, Patroniti et al[27] found that nCPAP by helmet and mask was equally effective in increasing lung volume as well as minimizing respiratory airway pressure oscillations. In another study, however, Patroniti et al[28] also showed that although a safety valve proved effective in limiting CO_2 rebreathing, it did not protect patients from the risk of hypoxia related to decreases in F_{IO_2} and loss of positive end-expiratory pressure. Thus, dedicated monitoring and alarm systems as well as a strict clinical control are mandatory for safe use of nCPAP by helmet, even in PICU settings.

Our study has several limitations. First, it is a short-term physiologic study, which did not include the investigation of possible long-term clinical consequences and complications of nCPAP application. Second, it is possible that some observable carryover effects of the first intervention occurred in the second, but the results of the statistical test for the carryover effect at $P = .10$ were not statistically significant. Moreover, because of the high variability between interfaces of important outcomes such as tolerance and improvement in oxygenation in our study patients, an additional investigation with ~130 patients in each treatment group is necessary to demonstrate an effect size of 0.35 times the phenomenon variability in a long-term randomized, controlled trial on parallel groups. Third, we used tcP_{O_2} to estimate arterial O_2 pressure. However, a recent study[16] revealed a strong correlation between arterial O_2 pressure and tcP_{O_2}, with a variability of 10% lower than the arterial value. Fourth, the study was not blinded for practical issues.

CONCLUSIONS

The results of our study have revealed that nCPAP by helmet com-

pared with facial mask can be applied for longer times and that patients undergoing helmet nCPAP delivery required less sedation to achieve a good tolerance than patients undergoing mask delivery. With the use of the helmet, patients also had improved oxygenation and were free of adverse events related to the device.

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