Continuous Positive Airway Pressure With Helmet Versus Mask in Infants With Bronchiolitis: An RCT

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abstract

BACKGROUND: Noninvasive continuous positive airway pressure (CPAP) is usually applied with a nasal or facial mask to treat mild acute respiratory failure (ARF) in infants. A pediatric helmet has now been introduced in clinical practice to deliver CPAP. This study compared treatment failure rates during CPAP delivered by helmet or facial mask in infants with respiratory syncytial virus-induced ARF.

METHODS: In this multicenter randomized controlled trial, 30 infants with respiratory syncytial virus-induced ARF were randomized to receive CPAP by helmet (n = 17) or facial mask (n = 13). The primary endpoint was treatment failure rate (defined as due to intolerance or need for intubation). Secondary outcomes were CPAP application time, number of patients requiring sedation, and complications with each interface.

RESULTS: Compared with the facial mask, CPAP by helmet had a lower treatment failure rate due to intolerance (3/17 [17%] vs 7/13 [54%], P = .009), and fewer infants required sedation (6/17 [35%] vs 13/13 [100%], P = .023); the intubation rates were similar. In successfully treated patients, CPAP resulted in better gas exchange and breathing pattern with both interfaces. No major complications due to the interfaces occurred, but CPAP by mask had higher rates of cutaneous sores and leaks.

CONCLUSIONS: These findings confirm that CPAP delivered by helmet is better tolerated than CPAP delivered by facial mask and requires less sedation. In addition, it is safe to use and free from adverse events, even in a prolonged clinical setting.

WHAT'S KNOWN ON THIS SUBJECT: In a previous short-term physiologic randomized controlled trial, continuous positive airway pressure by helmet was feasible and efficient in improving gas exchange in pediatric acute respiratory failure due to bronchiolitis.

WHAT THIS STUDY ADDS: Continuous positive airway pressure administered by helmet reduces the rate of noninvasive respiratory support failure and provides longer application time with less sedation than a facial mask. In addition, it is safe to use and free from adverse events.

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Respiratory syncytial virus (RSV) bronchiolitis is one of most common lower respiratory tract infections in infants and is the main reason for hospitalization in developed countries.[1–5] Inflammation triggers the obstruction of small airways, resulting in reduced lung function and rapid, shallow breathing.[4] Up to 8% of infants with acute RSV bronchiolitis are admitted to a PICU needing noninvasive respiratory support (NRS) because of recurrent apnea or acute respiratory failure (ARF).[6] Continuous positive airway pressure (CPAP) is widely provided as first-line NRS by many PICU teams.[7–9] In infants, the choice of interface is crucial for NRS success. Currently, pediatric interfaces include nasal cannulas, nasal and facial mask, and pediatric helmet. Nasal cannulas are used to deliver CPAP in preterm infants, but expiratory flow limitation due to obstruction of the nostrils and prong dislodgement has been described.[10,11] Nasal and facial masks are often used for infants and older children. However, leaks around the mask may cause discomfort and make it necessary to interrupt treatment.[12–16] A pediatric helmet has been used to deliver CPAP in neonates, infants, and preschool children with ARF.[17–23] In this population, CPAP by helmet was better tolerated than a facial mask, with no major complications and less need for sedation.[21–23]

The aim of this prospective multicenter randomized controlled trial (RCT) was to compare the failure rates of helmet and facial mask CPAP in infants admitted to a PICU for RSV-related ARF.

METHODS

This prospective, nonblinded, multicenter RCT compared helmet and facial mask CPAP in infants with RSV-related ARF. The trial was approved by local institutional review boards. Written informed consent was obtained from parents/legal guardians before enrollment. The trial was conducted according to the ethical standards laid down in the 1964 Declaration of Helsinki. Consecutively admitted patients to 3 Italian PICUs (Fondazione IRCCS Ca' Granda, Ospedale Maggiore Policlinico, Milan; University Hospital "A. Gemelli," Catholic University of Sacred Heart, Rome; and Children's Hospital Vittore Buzzi, Istituti Clinici di Perfezionamento, Milan) with RSV-related ARF were followed from January 2008 to January 2010.

Inclusion criteria were (1) age 6 to 12 months; (2) diagnosis of RSV infection consistent with clinical features (history of cough, bilateral wheezing, and prolonged expiration; supporting chest x-ray findings of hyperinflation) and positive immunofluorescence test in nasopharyngeal swabs; and (3) ARF, defined by partial pressure of oxygen, arterial (Pa_{O_2}):fraction of inspired oxygen (F_{IO_2}) <300 after breathing O_2 through a Venturi mask (F_{IO_2} 0.5) for at least 15 minutes, plus 2 of the following: respiratory rate (RR) >2SD depending on age, accessory muscles recruitment, and paradoxical abdominal motion.[24]

Exclusion criteria were (1) emergency need for intubation; (2) Glasgow coma scale <12; (3) major acidosis (pH <7.25); (4) cough or gag reflex impairment; (5) upper-airway obstruction; (6) facial/gastric surgery; (7) respiratory exhaustion with impending need for intubation; (8) hemodynamic instability (defined as need for vasopressor or inotropes); or (9) enrollment in other research protocols. All patients meeting the inclusion criteria were randomized to receive helmet or facial mask CPAP as first-line intervention.

Concealed randomization was conducted centrally through a computer-generated block randomization schedule. A telephone service was available at all times for assignment of patients.

CPAP

A detailed description of the CPAP free-flow circuit has been published.[23] CPAP was maintained by a generator able to deliver gas flow up to 140 L/minute and an underwater bubbling valve. The pediatric helmet (Castar Starmed, Mirandola, Italy) has a 27-cm collar diameter and 6-L internal volume. It is made of transparent latex-free polyvinyl chloride and is secured to a soft collar that adheres to the infant's neck. The system is harnessed to the diaper for stability. One helmet port is connected to the gas source and the other to an underwater positive end expiratory pressure valve. There are two safety systems: a pressure monitoring device with overpressure safety valve (opening at circuit pressure >20 cm H_2O) and an anti-asphyxia valve (allowing room air in if pressure inside the helmet falls below 3 cmH_2O). High fresh-gas flow (>35 L/minute) was used to avoid CO_2 rebreathing.[21,23,25–27]

All patients were kept in a semirecumbent position. In all centers, a standard oronasal mask (Profile Lite Gel size XS-S, Respironics, Murrysville, PA) was used, and its size was chosen to fit the face as well as possible. It was connected to the CPAP circuit by a Y-connector. Skin lesions were prevented by using colloid dressings (DuoDERM, ConvaTec, Deeside, UK). The mask was initially placed manually then after a short time secured on the patient's face by a head cap.

A heated humidifier was used for both groups (MR730 humidifier, Fisher & Paykel, Healthcare Corp, Auckland, New Zealand). The humidification was continuous in the mask group and intermittent in the helmet group because the mixing chamber effect could result in overheating of gases and rain-out effect. The nurse in charge turned the humidifier off for short intervals when rain-out occurred inside the helmet.

After stabilization with an oxygen Venturi mask, as a first step we tested CPAP in increasing steps of 2 cm H_2O (from 4–10 cm H_2O) to obtain maximum alveolar recruitment at lowest F_{IO_2}. This approach aimed to avoid delivery of inappropriately high F_{IO_2} in the absence of optimal alveolar recruitment.

The CPAP level was chosen to obtain pulse oxygen saturation (Spo_2) ≥94% with F_{IO_2} ≤0.6. CPAP was delivered continuously in the first 24 hours until oxygenation and clinical status improved. Patients with Spo_2 ≥94%, F_{IO_2} ≤0.4, and no muscle recruitment were then weaned by reducing CPAP in steps of 2 cm H_2O, then switched to oxygen therapy at F_{IO_2} <0.4, CPAP <4 cm H_2O without signs of muscle recruitment. The protocol was interrupted in case of CPAP treatment failure, and the patient was managed at the attending physician's discretion (including noninvasive pressure support ventilation as an intermediate step before endotracheal intubation). The attending physician was not involved in the trial.

Medical treatment of infants with acute bronchiolitis remained unchanged for study purposes, per the standard hospital protocol. A nasogastric tube was placed for enteral feeding.

Endpoints and Definitions

The trial primary endpoint was treatment failure rates for the helmet and facial mask CPAP groups. Treatment failure was defined as permanent discontinuation of the CPAP trial because of intolerance to the interface and/or need for intubation. Intolerance to the interface was assessed using the objective pain scale (OPS) and COMFORT scale.[28,29] OPS is a scale designed for infants and children, containing 5 assessment categories: changes in systolic blood pressure, crying, movement, agitation, and complaints of pain. Target scores range from 1 to 4, OPS ≥4 denoting distress. The COMFORT scale is a nonintrusive tool for assessing the efficacy of pharmacologic interventions in intubated children, with high interrater agreement and internal consistency. Scores range from 1 to 40; a score between 18 and 26 indicates that the child is awake and calm, ≤17 suggests sedation, and ≥26 denotes distress.[29,30]

Patients were not sedated before enrollment. If sedation was required, an intravenous midazolam bolus of 0.1 mg/kg was delivered, followed by continuous infusion (0.1 mg/kg per hour) according to the PICU protocol. Intolerance was defined as OPS ≥4 and COMFORT ≥26 after 30 minutes of midazolam continuous infusion.

Major adverse clinical events included (1) pneumothorax, (2) hypercapnic coma, and (3) cardiac arrest. Complications related to the interface were recorded as (1) skin sores (0, no sore; 1, area of redness or change in color that did not fade within 30 minutes after pressure was removed; 2, moderate skin breakdown; 3, skin ulcer; 4, skin necrosis); (2) gastric distension, evaluated by visual inspection; or (3) eye irritation (inflammation of palpebral and/or bulbar conjunctiva over the exposed surface of the sclera), scored as 0 (not present) or 1 (present).[31]

Major leaks were defined as leaks causing depressurization in the circuit and needing interface replacement. Criteria for endotracheal intubation included (1) failure to maintain Pao_2 ≥60 mm Hg with F_{IO_2} ≤0.6; (2) clinical signs of exhaustion; (3) need to protect airways and/or manage copious tracheal secretions; and (4) hemodynamic impairment.

Measurements

Demographic data included age, gender, weight, congenital heart disease, bronchopulmonary dysplasia, airway obstruction, or any other underlying disease. After enrollment, revised Pediatric Index of Mortality (PIM2), RR, heart rate (HR), noninvasive blood pressure, and arterial blood gases were recorded at the following intervals: –T0, baseline, spontaneous breathing with oxygen therapy delivered by a Venturi mask with F_{IO_2} 0.4 (Tyco Healthcare, Mansfield, MA); T1, 1 hour after starting CPAP; and T2, spontaneous breathing (Venturi mask, F_{IO_2} 0.4) after 24 hours of CPAP, in successfully treated patients.[32]

OPS and COMFORT scores were recorded at T0 and T1. Standard F_{IO_2} of 0.4 while on oxygen therapy at T2 was chosen according to the weaning criteria to test the effect of CPAP without the risk of a sudden drop in oxygenation.

The insertion of an indwelling arterial catheter only for research purposes was judged unethical while on NRS. Arterial blood samples were collected at scheduled times. Spo_2 and electrocardiography were continuously displayed. Hours of delivered CPAP, F_{IO_2}, CPAP level, number of patients needing continuous intravenous sedation, PICU length of stay (LOS), and mortality were also recorded on the clinical data chart. Nasopharyngeal swabs were collected with nonbronchoscopic technique. The clinical diagnosis of RSV infection was confirmed with a rapid enzyme-linked immunosorbent assay.

Statistics

CPAP predicted a failure rate using the facial mask of ~50%.[20] We estimated a difference between groups of at least 30% in the primary endpoint. Given a type 1 error of 0.05 and a type 2 error of 90%, this resulted in a sample size of 30 patients per study arm. An interim analysis was conducted after enrollment of 30 patients to detect the difference in primary endpoint between groups, with normal approximation of a 2-sided α level of 0.01.

SPSS software (SPSS, Chicago, IL) was used for all analyses. Data

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distribution was determined with the Shapiro–Wilk test. Descriptive statistics were calculated for quantitative variables (median [interquartile range]) and qualitative variables (absolute frequencies and percentages). Continuous data were analyzed with the Mann–Whitney U test. Categorical data were analyzed by χ^2 or Fisher exact test.

Differences in physiologic parameters over time were compared by the Friedman Q test for repeated measures, and a post hoc analysis (Wilcoxon H test) was done if overall P was <.05. Significance was taken at $P < .05$. All statistical analyses were done by an investigator with expertise in statistics, blinded to treatment.

RESULTS

The flow chart of participants' progress is reported in Fig 1. All enrolled patients completed the trial. The study was stopped at interim analysis because the primary endpoint was achieved with high significance in favor of helmet treatment. The main baseline characteristics of the patients are presented in Table 1; there were no differences in demographic characteristics and respiratory support parameters between groups. The primary endpoint and outcome parameters are shown in Table 2.

The treatment failure rate was higher with the mask ($P = .009$) mainly because of intolerance ($P = .014$). Patients who did not tolerate the mask were all successfully switched to a helmet. Intubation rates were the same in both groups ($P = .290$). All patients were intubated within the first 24 hours because of worsening of gas exchange.

No major adverse events occurred (cardiac arrest, pneumothorax, or safety system failures). The number of days on CPAP was similar in both groups ($P = .72$), as was continuous CPAP application time in the first 24
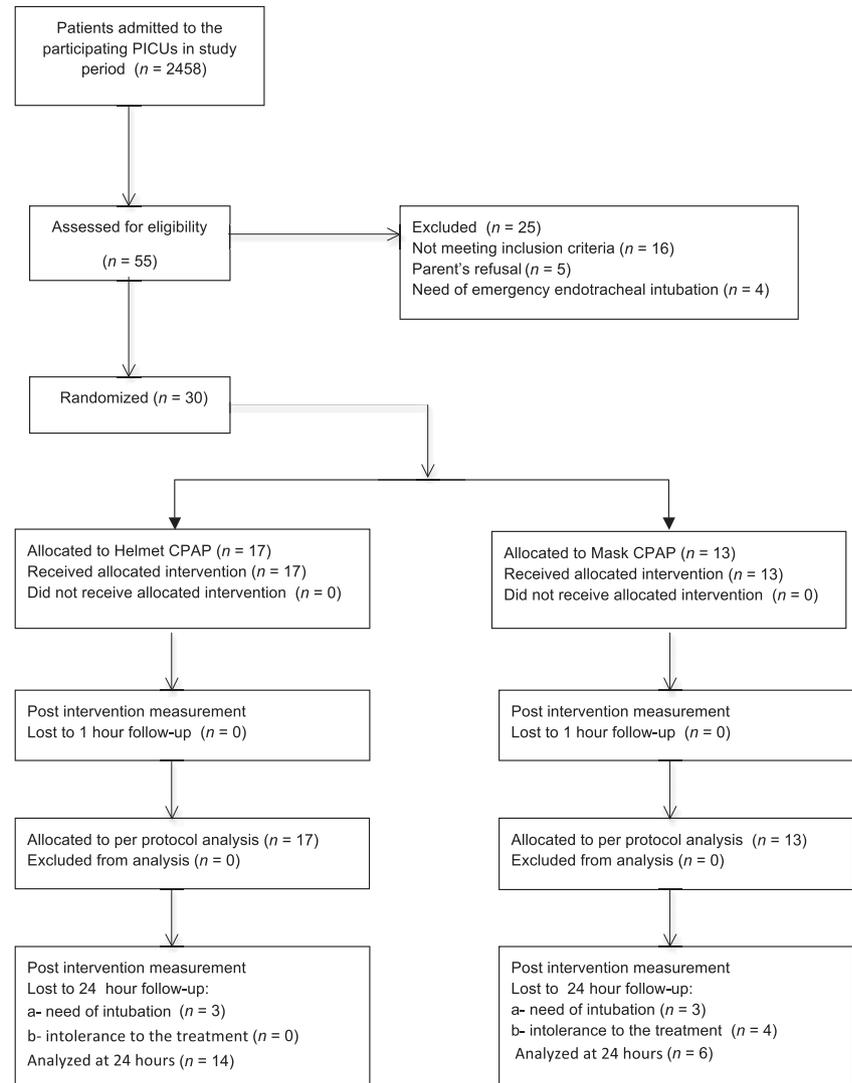
FIGURE 1
Flow diagram: progression of patients through the trial in all participating centers.

hours ($P = .091$). Total application time of CPAP during the PICU stay was longer with the helmet ($P = .004$). Air leaks, skin sores, and the need for sedation were all more frequent in the mask group ($P = .023$, .016, and .001, respectively). No differences were found between groups with respect to gastric distension, eye irritation, PICU LOS, and mortality.

Physiologic parameters are shown in Table 3. In the overall analysis PaO_2:FIO_2 increased significantly over time ($P = .001$ for helmet and $P = .006$ for mask), whereas RR ($P = .001$ and $P = .004$) and HR ($P = .002$ and $P = .016$) dropped significantly in both groups

compared with T0. Changes in pH and $PaCO_2$ were small over time and not significantly different in the 2 groups at each time point.

OPS and COMFORT scores increased significantly only during CPAP by mask compared with baseline with oxygen mask (OPS, $P = .001$; COMFORT, $P = .001$) and helmet CPAP (OPS, $P = .001$; COMFORT, $P = .001$).

DISCUSSION

These results suggest that helmet CPAP was better tolerated than facial mask CPAP, with less need for sedation. Its application in mild

TABLE 1 Baseline Characteristics of Patients

	Helmet	Mask	P
n	17	13	
Age, mo	9.2 (8 to 12)	8.2 (8 to 9)	.66
Male gender	8 (47)	6 (46)	.49
Weight, kg	8.3 (7 to 10)	7.4 (5 to 8)	.35
PIM2	4.0 (3 to 4.5)	5.0 (3 to 7)	.26
Causes of respiratory failure			
RSV-bronchiolitis	12 (70)	9 (70)	.57
RSV-bronchiolitis and coinfection	5 (30)	4 (30)	.89
Comorbidities			
Pulmonary bronchodysplasia	2 (11.7)	2 (15)	.89
Congenital heart disease	2 (11.7)	1 (7.6)	.96
Epilepsy	2 (11.7)	2 (15)	.78
Neuromuscular disease	1 (5.8)	0	.92
Previous admission for RSV	3 (17.6)	3 (23)	.88
RR, breaths per minute	60 (50 to 70)	60 (35 to 75)	.98
F_{IO_2}	0.4 (0.4 to 0.5)	0.4 (0.4 to 0.5)	.65
CPAP, kPa	0.49 (0.49–0.68)	0.49 (0.49 to 0.58)	.74
$Pa_{O_2}:F_{IO_2}$	177 (151 to 206)	163 (153 to 190)	.80
$PaCO_2$, kPa	5.5 (4.5 to 6.3)	5 (3.7 to 5.8)	.51
Arterial pH	7.38 (7.3 to 7.4)	7.37 (7.31 to 7.39)	.75
Base excess, mEq/L	0 (−1.5 to 1.2)	.15 (−0.9 to 1.2)	.44
Serum bicarbonate, mEq/L	26 (24 to 27)	24 (24 to 30)	.11
HR, beats per minute	154 (144 to 169)	135 (122 to 145)	.06
Systolic blood pressure, kPa	14.6 (12.9 to 15.9)	13.3 (11.9 to 15.9)	.51
Lactate serum, mmol/L	1.2 (1.05 to 1.35)	0.9 (0.75 to 1.05)	.48
Body temperature, °C	37.1 (36.6 to 37.6)	36.9 (36.5 to 37.6)	.93

Data are expressed as n (%) or median (interquartile range).

pediatric ARF is feasible and free from adverse events, thus allowing longer treatment than with the mask. The facial mask was prone to leaks and caused skin lesions despite the use of protective pads.

To our knowledge, this is the first RCT comparing the efficacy of CPAP by helmet and facial mask in a prolonged clinical setting. The 2 groups had similar demographic characteristics and were well matched for etiology and severity of ARF. Endpoints were clearly defined in advance, thus minimizing subjective interpretation of the data.

The main physiologic CPAP effects in infants result from airway splinting, end expiratory lung volume increase, reduced ventilation/perfusion mismatch, and respiratory pattern stabilization.[1] In infants with severe RSV bronchiolitis, CPAP reduces the esophageal pressure time product, and 6 to 7 cm H_2O CPAP was associated with the greatest muscle unloading, improvement in breathing pattern, and favorable clinical outcome.[2–4]

In this series, all infants needing NRS were <1 year old. Younger children cope less well with NRS than older ones, who are more cooperative. In young infants, the oronasal interface is the first-line choice when administering NRS, but the need for tight-fitting interfaces may lead to higher failure rates due to intolerance and the greater need for sedation.[33,34]

The helmet was reported to be efficient in delivering CPAP in a physiologic RCT in healthy adult volunteers: helmet CPAP was as effective as mask CPAP in increasing end expiratory lung volume and compensating for airway pressure oscillations without the need for a reservoir bag and without CO_2 rebreathing at high gas flow rates (>30 L/minute), regardless of the size of the helmet.[25–27] From a physiologic point of view, the more constant the pressure, the more pronounced the benefits on respiratory mechanics. Circuit depressurization can lead to interruption in CPAP delivery and alveolar collapse. A pressure monitoring system on the circuit is therefore recommended to detect loss of pressure should disconnection occur. No depressurization has been detected during treatment with a helmet, according to previous reports.[23–27]

The pediatric helmet was introduced in clinical practice to increase the infant's comfort while on CPAP. The helmet is supposed to have several advantages over nasal or whole-face masks: it allows free movement of the infant's head as well as a good interaction with the environment while maintaining a good seal without compression.[19–23] In preterm infants with mild respiratory distress, CPAP

TABLE 2 Primary Endpoint and Outcome Measures

	Helmet	Mask	P[a]
n	17	13	
Treatment failure	3 (17)	7 (54)	.009
Reasons for treatment failure			
Intolerance	0	4 (30)	.01
Intubation	3 (17)	3 (23)	.29
Major adverse events	0	0	.99
Days on CPAP	3 (2 to 4)	2 (1 to 7)	.72
CPAP delivered in the first 24 hours, h	22 (21 to 22)	16 (7 to 22)	.09
CPAP delivered during PICU stay, h[a]	28 (20 to 62)	8 (2 to 25)	.004
Patients requiring sedation	6 (35)	13 (100)	.02
Skin sores, score 1	0	8 (61)	.001
Air leaks	0	4 (30)	.01
Gastric distension	0	0	.99
Eye irritation	0	0	.99
Safety system failure events	0	0	.99
PICU LOS, d	3 (3 to 7)	5 (2.8 to 8.7)	.58
PICU mortality	0	0	.99

Data are expressed as n (%) or median (interquartile range).
[a] Mann–Whitney U test and Fisher exact t test.

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TABLE 3 Physiologic Parameters

Parameter	T0	T1	T2
Pa_{O_2}:$F_{I_{O_2}}$			
Helmet	177 (151 to 206)	209 (186 to 284)[a]	332 (229 to 418)[b]
Mask	163 (153 to 190)	204 (160 to 215)[a]	320 (266 to 476)[b]
$PaCO_2$, kPa			
Helmet	5.5 (4.6 to 6.3)	4.6 (5.1 to 6.1)	4.6 (5.1 to 5.8)
Mask	5.0 (3.7 to 5.8)	3.9 (4.5 to 5.5)	4.1 (5.1 to 6.5)
Arterial pH			
Helmet	7.38 (7.32 to 7.40)	7.4 (7.36 to 7.49)	7.42 (7.40 to 7.43)
Mask	7.37 (7.31 to 7.39)	7.43 (7.37 to 7.44)	7.41 (7.39 to 7.46)
HR, beats per minute			
Helmet	154 (144 to 169)	144 (132 to 150)[a]	133 (122 to 140)[b]
Mask	135 (122 to 145)	125 (120 to 132)[a]	115 (100 to 130)[b]
RR, breaths per minute			
Helmet	60 (50 to 70)	48 (40 to 55)[c]	40 (35 to 44)[b]
Mask	60 (35 to 75)	40 (20 to 50)[c]	40 (24 to 52)[b]
Systolic blood pressure, kPa			
Helmet	14.6 (12.9 to 15.9)	13.9 (13.1 to 14.6)	14.6 (13.3 to 14.3)
Mask	13.3 (11.9 to 15.8)	13.9 (12.9 to 14.6)	14.6 (13.2 to 14.3)
OPS			
Helmet	2 (2 to 4)	2 (1 to 2)	NA
Mask	2 (2 to 3)	5 (3 to 6)[c,d]	NA
COMFORT scale			
Helmet	20 (18 to 22)	16 (16 to 18)	NA
Mask	18 (18 to 20)	27 (24 to 28)[c,d]	NA

Data are expressed as median (interquartile range). T0, baseline; T1, CPAP treatment; T2, spontaneous breathing after 24 h in successfully treated patients (13 in helmet group, 6 in mask group); NA, not applicable. Wilcoxon post hoc analysis and significant comparisons are shown: [a] $P < .05$ T1 versus T0, [b] $P < .01$ T2 versus T0, [c] $P < .01$ T1 versus T0, [d] $P < .01$ between groups.

by helmet resulted in better tolerance and less oxygen desaturation than use of nasal prongs.[17] In preschool children with ARF of mixed etiologies, CPAP by helmet was safe and well tolerated and resulted in an early increase in oxygenation.[18] CPAP by helmet was also effective and well tolerated in hypoxemic children with parenchymal disease and in infants with RSV bronchiolitis, with less need for sedation and longer application time.[21–23]

Evaluation of comfort in infants during NRS is not standardized and, to our knowledge, no specifically designed score has yet been published. OPS is easy to apply and we chose it to reduce the risk of bias due to interobserver variability across nurses in different units.[28] To confirm the OPS results, we also used the COMFORT scale for each patient at baseline and during CPAP.[29] Both scores rose significantly from baseline with the mask and between groups, thus reinforcing the finding of greater intolerance and more need for sedation with the mask. We are aware that the 2 scores we used to evaluate distress are not validated for children on NRS, and as no specific scales are available in the literature, further studies involving a larger number of PICUs are called for to define a new pediatric NRS tolerance score.

The trial has several limitations. First, it was not blinded for treatment, since it was impossible to hide the interface from caregivers. Second, only infants with fairly mild RSV-related ARF were included, so our results cannot be applied to other patients and diseases. Third, acute bronchiolitis leading to PICU admission occurs often in babies aged 1 to 4 months.[2–5] The median age of our population was higher because in Italy younger babies are often admitted to NICUs owing to a relatively low number of PICUs.[35] Our population also had more severe parenchymal disease than the classic RSV clinical presentation; the high percentage of bacterial coinfection may explain the more severe hypoxia we found.

Other issues call for comment, too. First, suspension at interim analysis may be debatable, but the results in favor of the helmet were convincing enough to make it illogical and unreasonable to continue to treat patients with the mask. Second, new extra-small full-face masks can now be obtained to deliver NRS in PICU, but they were not available when this trial was done. Further studies are still needed to establish their efficacy and feasibility in infants and young children with ARF. Third, it is also debatable whether to routinely take arterial blood samples to evaluate gas exchange during pediatric NRS. The S/F ratio (peripheral oxygen saturation/inspired oxygen fraction) is a useful tool to monitor NRS treatment and outcome, but it had not yet been validated at the time of the trial.[36]

CONCLUSIONS

The helmet is a suitable and safe device for delivering CPAP in infants with mild RSV bronchiolitis needing NRS in a PICU. In addition, the helmet is better tolerated than the facial mask, avoiding skin lesions and allowing longer treatment.

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