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▶ **To cite this version:**

Christophe Milési, Félicie Ferragu, Samir Jaber, Aline Rideau, Clémentine Combes, et al.. Continuous positive airway pressure ventilation with helmet in infants under 1 year. Intensive Care Medicine, 2010, 36, pp.1592-1596. 10.1007/s00134-010-1940-3 . hal-02546584

HAL Id: hal-02546584
https://hal.umontpellier.fr/hal-02546584

Submitted on 18 Apr 2020

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Abstract *Objective:* To report the feasibility of helmet use in infants between 1 and 12 months old with acute respiratory failure. *Design and setting:* Observations were made before and 2 h after helmet CPAP of 6 cm H_2O. Failure was defined as recourse to intratracheal ventilation. Patient stabilization or improvement was defined as a variation <10% or a decrease >10% in one of the following: respiratory rate, inspired oxygen fraction, or capillary partial pressure of CO_2. Tolerance was assessed by the pain and discomfort score, the systematic search for pressure sores, and the measurement of helmet humidity and noise level. *Results:* Twenty-three infants with a median age of 5 (2–8) months were included. Helmet CPAP failed in two (9%) patients. Stability or improvement occurred in 16 (70%) patients. The pain and discomfort score was stable or improved in 22 (96%). Pressure sores were found in three (13%) infants. Humidity was 98% (98–99%) and fell to 40% (39–43%) after the humidifier was stopped. The noise level in the helmet was 81 (77–94) dB-SPL. *Conclusions:* The helmet was a satisfactory interface for CPAP delivery in young infants in more than two-thirds of the cases. Pressure sores can be prevented by placing a cushion in the helmet. Caregivers need to take into account the high humidity and noise levels of this interface.

Keywords Continuous positive airway pressure · Helmet · Infant · Noninvasive ventilation

Introduction

In pediatric intensive care units (PICUs), noninvasive ventilation (NIV) failure ranges from 10 to 40% [1–3]. In infants under 1 year, the failure rate is even higher, mainly because of a misfit between the available interfaces and the infant face [4, 5]. The helmet is a potential alternative because it avoids direct facial contact. It thus has been used in pediatrics since 2004 [6–8]. However, no study has yet focused on helmet use in the critical population of very young infants.

The main objective of this study was to report the feasibility of helmet use in infants ranging in age from 1 to 12 months. For this purpose, we evaluated the failure rate and the rate of patient stabilization following the placement of a helmet providing continuous positive

airway pressure (CPAP) in young infants with acute respiratory distress. The secondary objectives were to report the side effects, the humidity, and the noise levels linked to the helmet interface.

Materials and methods

Ethical considerations

This prospective observational study was conducted in a PICU of a university hospital. Written authorization was obtained from the parents. The procedures reported are all in routine use in our PICU and did not require prior approval from the hospital ethics committee, according to French law.

Patients

All consecutive infants between 1 and 12 months requiring CPAP for acute respiratory distress (ARD) were eligible. Acute respiratory distress (ARD) was defined by the following criteria [9]: (1) dyspnea with a respiratory rate (RR) >40 breaths/min, accessory muscle use, and paradoxical abdominal respiration, (2) PCO_2 >45 mmHg, and (3) FiO_2 >0.3 to reach pulse oximetry (SpO_2) of 92–96%.

Exclusion criteria were as follows: the need for immediate intubation, rapid disease progression such as severe hypercapnia and/or hypoxia, inability to clear secretions, impaired gag or cough reflex, and recent gastric surgery.

Equipment

We used the "4-Vent Neoped" helmet (Teleflex Medical, Le Faget, France). CPAP was generated with the Elisée 150 ventilator (Resmed, Savigny, France) equipped with a two-tube circuit and a heated humidifier (Fisher and Paykel 850, Villebon, France). We placed a plateau valve (straight connector 22M–22F, Intersurgical, Fontenay sous bois, France) on the helmet expiratory port to ensure a flow >25 L/min and to limit the risk of rebreathing. As the device is not equipped with an antisuffocation valve, this helmet CPAP system was connected to a ventilator that continuously monitored pressure and flow in the helmet circuitry. FiO_2 was set to maintain SpO_2 within the target range (92–96%). The device was adjusted to deliver CPAP of +6 cm H_2O via the helmet.

Study protocol and evaluated parameters

First, we assessed the stability of the patient. If SpO_2 remained stable for 10 min, the following parameters were evaluated 5 min before and 2 h after helmet placement: RR, FiO_2, and SpO_2, recorded with an Intellivue MP70 cardioscope (Philips Medical Systems, Heerlen, The Netherlands); capillary blood gases, with a Gem Premier 3000 analyzer (Instrumentation Laboratory, Orangeburg, SC, USA); and pain and discomfort, with the French EDIN scale, which ranges from 0 to 15, with discomfort >4 [10].

We also evaluated humidity inside the helmet after 2 h, with a Thermo-Hygro-Recorder (Sanwa Tsusho, Tokyo, Japan), and the noise level in dB-SPL, with a Type 2230 sonometer (Bruël and Kjaer, Nærum, Denmark). The inspiratory flow was measured with a spirometer in the first five patients (Resmed Saime, Savigny, France).

Last, the following information was documented by the PICU nursing staff: any local complications due to the helmet, including conjunctivitis, epistaxis, vomiting, and skin irritation according to the National Pressure Ulcer Advisory Panel (NPUAP) classification [11].

Definitions

Failure was defined by the need for intubation. The criteria for intubation included at least one of the following [12]: clinical signs of extreme fatigue, severe hypoxemia ($SpO_2 < 92\%$ with $FiO_2 > 0.9$), and severe respiratory acidosis ($PCO_2 > 70$ mmHg with pH < 7.25).

Deterioration was defined as an increase >10%, stability as a variation <10%, and improvement as a decrease >10% in the respiratory parameters (RR, FiO_2, PCO_2) and EDIN score after helmet placement compared with before.

Statistical analysis

The distributions of continuous variables were tested with the Shapiro-Wilk method and not all were found to be normal. Thus, results are shown as medians and ranges and comparisons were made using nonparametric tests (Mann-Whitney and paired Wilcoxon). A P value <0.05 was considered to indicate statistical significance.

SAS software was used for all statistical analyses (Cary, NC, USA).

Results

Twenty-three patients were enrolled during 2008. Seventeen patients (74%) presented an acute exacerbation of chronic respiratory distress.

Failure occurred in two (9%) infants, both intubated for severe laryngeal stridor. Five infants (22%) did not stabilize following helmet CPAP but did not require

intubation. Nasal CPAP (Infant Flow Ventilator, EME, UK) was applied in two infants who presented an increase in PCO_2. PCO_2 decreased in one but remained at the same level in the other. Three patients presented an increase in RR, but helmet CPAP was continued because all other respiratory parameters were improved. RR decreased in two patients and remained stable in the third.

No significant difference in the baseline characteristics was observed between the 7 (30%) infants for whom the helmet failed or did not stabilize respiratory distress and the 16 (70%) infants who showed stabilized or even improved respiratory distress with the helmet (Table 1).

After 2 h of helmet CPAP, FiO_2 significantly decreased, from 0.39 (0.35–0.55) to 0.30 (0.21–0.3), $P < 0.05$, whereas SpO_2 remained stable, from 96% (95–97%) to 94% (93–96%). RR, PCO_2, FiO_2, and EDIN score either stabilized or improved in 17/23 (74%), 14/17 (82%), 23/23 (100%), and 22/23 (96%) patients, respectively. Eighteen patients were maintained continuously in the device for 12 h. FiO_2 and EDIN improved from baseline to 12 h, respectively, from 0.39 (0.35–0.55) to 0.28 (0.21–0.3), $P < 0.05$, and from 4 (2–7) to 2 (2–3), $P < 0.05$ (Fig. 1).

The humidity inside the helmet was 98% (98–99%), and the heated humidifier was therefore stopped. The humidity 1 h later was 40% (39–43%). The ambient humidity was 32% (31–36%). The noise level inside the helmet was 81 (77–94) dB-SPL and 61 (59–63) dB-SPL in the patient rooms during the same period. The inspiratory gas flow inside the helmet was 34 (30–37) L/min.

Helmet CPAP was continued for 48 (24–81) h. Pressure from the rigid frame of the helmet caused skin irritation within 24–48 h at the base of the skull in three of the first six patients, one stage 1 and two stage 2 of the NPUAP classification. From the seventh patient onward, a small cushion was placed in the helmet to prevent pressure sores, which was successful. No conjunctivitis, epistaxis, or vomiting occurred.

Discussion

Like Yanez et al. [4], we observed a rapid effect of helmet CPAP on respiratory parameters, particularly a reduction in FiO_2. Failure or deterioration also appeared quickly, within 2 h [1]. Our failure rate was comparable to that of Codazzi et al. [7] in a series of infants less than 2 years old.

It is noteworthy that PCO_2 improved in only 4 out of 17 patients, raising questions about the occurrence of CO_2 rebreathing during helmet CPAP. Significant CO_2 rebreathing has been observed in adults for fresh gas flows lower than 40 L/min. Although a 6 L hood washout probably requires lower flow than an adult hood of 12–18 L and infants under 1 year most likely produce less CO_2 than adults, the risk of rebreathing must nevertheless be kept in mind during helmet use in infants [13, 14]. Moreover, high PCO_2 would seem to be an indication for true NIV instead of CPAP. Yet NIV is difficult to achieve in young infants because of their poor mask tolerance [8], and true NIV is not possible with the helmet because of the low air flows at this age and poor helmet compliance, both of which combined prevent patient-ventilator

Table 1 Baseline characteristics of the population

	Failure or deterioration ($n = 7$)	Stability or improvement ($n = 16$)	P
Age (months)	4 (3–6)	5 (3–8)	0.32
Weight (kg)	5 (4–5)	5 (4–7)	0.47
PIM II (%)	3 (3–3)	4 (0–4)	0.5
Pathology, *n* (%)			0.48
Bronchopulmonary dysplasia	2 (29)	3 (19)	
Acute viral bronchiolitis	1 (14)	4 (25)	
UAM/congenital stridor	3 (43)	3 (19)	
Myopathy, SMA	0 (0)	3 (19)	
Patent ductus arteriosus	0 (0)	2 (13)	
Scimitar/HLH syndrome	1 (14)	1 (6)	
Respiratory rate (breath/min)	46 (41–55)	49 (43–61)	0.6
FiO_2	0.36 (0.32–0.48)	0.4 (0.33–0.5)	0.52
SpO_2	95 (93–94)	95 (94–98)	0.22
PCO_2 (mmHg)	55 (46–71)	54 (49–64)	0.75
pH	7.35 (7.34–7.37)	7.45 (7.43–7.47)	0.66
EDIN	5 (3–6)	4 (2–7)	0.86

Values are median (Q25–Q75) or absolute frequencies (percentage), P was determined with chi-squared or Mann-Whitney test. PCO_2 was measured on capillary blood gas sampling. For the distribution of pathologies, statistical testing was conducted on pathologies grouped as pulmonary, upper airway, neuromuscular, or cardiac

PIM II Pediatric Index of Mortality II, *UAM* upper airways malformation, *SMA* spinal muscular atrophy, *HLH* hypoplastic left heart, *EDIN* Newborn pain and discomfort scale

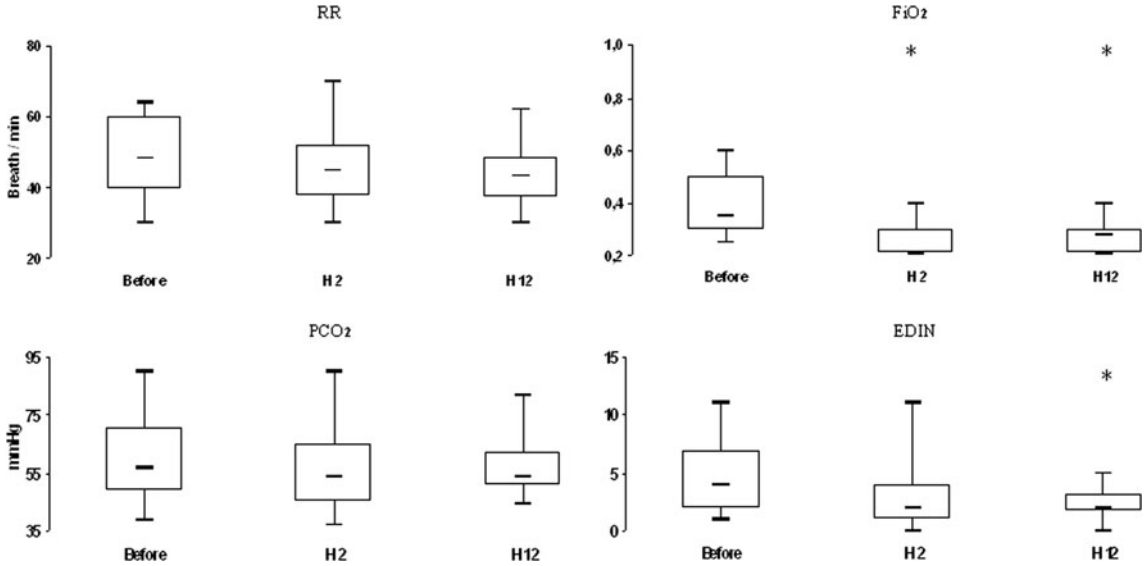


Fig. 1 Variations in respiratory parameters and EDIN score *before*, 2 h (*H 2*), and 12 h (*H 12*) after helmet CPAP. *EDIN* Newborn pain and discomfort scale, FiO_2 fractional inspired oxygen (%), PCO_2 partial pressure of carbon dioxide measured on capillary blood gas sampling (mmHg), *RR* respiratory rate (breaths per minute). $^*P < 0.05$ by paired Wilcoxon test

synchronization [2, 15]. Thus, CPAP should be considered as a therapy of last resort in infant cases of hypercapnic respiratory distress, to be implemented exclusively in the PICU with extreme care [5, 8, 16]. Furthermore, during helmet CPAP in young infants, we recommend the continuous monitoring of inspiratory flow and patient blood gases using transcutaneous measurement. In neuromuscular diseases with chronic respiratory decompensation, NIV with pressure support should be established for daily assistance as soon as tolerated.

The noise level is a disadvantage of CPAP, whatever the interface. This level is proportional to the flow and can reach 90 dB-SPL [17]. We measured the sound intensity in the helmet and not that perceived by the inner ear, which is attenuated by approximately 40 dB by the transcranial transmission of sound [18]. In any case, our measures exceeded the upper recommended limit of 45 dB-SPL [19] and suggest prudence regarding the prolonged use of helmet ventilation because of the potential long-term sensory consequences [20].

Conclusion

Our study was limited by the small number of subjects. Nevertheless, we found that the helmet interface was feasible and well tolerated in infants under 1 year needing CPAP. These results should be confirmed in a controlled study comparing the efficacy of several interfaces.

Acknowledgments We thank the nursing staff of the pediatric intensive care unit of Arnaud de Villeneuve University Hospital for their patience and cooperation, without which the study could not have been performed. We thank C. Stott-Carmeni for translating the manuscript and for editorial assistance. Last, we thank Mr. J. Noguez from the APARD association for his technical assistance.

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