

Daniele Trevisanuto  
Nicoletta Doglioni  
Vincenzo Zanardo

## Neonatal helmet CPAP: a short-term physiological study

---

Accepted: 23 September 2005  
Published online: 9 November 2005  
© Springer-Verlag 2005

---

An author's reply to this contribution is available at <http://dx.doi.org/10.1007/s00134-005-2840-9>

---

Sir: we are grateful to Dr. Santuz and colleagues for their comments on our study. We developed the neonatal helmet CPAP to improve the patient-ventilator interface, a crucial aspect in the management of CPAP therapy. For this reason we chose to evaluate the tolerability of the patients in a short-term physiological study with a cross-over design that included within participant comparison. Therefore the suggested "more relevant clinical aspects or potential complications such as level of respiratory distress, oxygen-dependency, rate of apnoea, local damage, air leak, or need for mechanical ventilation" cannot be considered significant endpoints using this trial design. Instead, in addition to Neonatal Infant Pain Scale (NIPS), other objective physiological parameters, such as heart rate, blood pressure, oxygenation, and episodes of desaturation seemed to be ameliorate during the neonatal helmet CPAP treatment.

With regard to "the potential bias due to non-blinded scoring method which was used in this study," it is noteworthy that before the data collection three nurses were involved in determining the NIPS score interobserver variability (18%); due to these results and to organizational aspects of our Unit only the attending nurse was involved in the data collection. The use of a video recording system makes no sense due to the unmasked

characteristics of the two studied systems.

For safety reasons only 20 clinically stable patients were enrolled for this short-term physiological study. Therefore we agree with Dr. Santuz et al. that our study does preclude any definitive conclusion about the use of the neonatal helmet CPAP in preterm infants. As reported in the conclusions of the study, a much larger randomized controlled trial is needed to demonstrate the real advantages of this new device. However, it is surprising that, based on a single preliminary experience, they "speculate that conventional nasal CPAP, successfully used for apnoea of prematurity, might be more effective than the new technique."

---

D. Trevisanuto (✉) · N. Doglioni · V. Zanardo  
Pediatric Department, Medical School,  
Padua University,  
Via Giustiniani 3, 35128 Padua, Italy  
e-mail: trevo@pediatria.unipd.it  
Tel.: +39-049-8213545  
Fax: +39-049-8213502