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Comment on "A new device for administration of continuous positive airway pressure in preterm infants" by Trevisanuto et al.

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Sir: we read with interest the contribution by Trevisanuto et al. [1] on the effectiveness of a new device for administering continuous positive airway pressure (CPAP) as an alternative to conventional nasal CPAP in ameliorating comfort in preterm infants needing continuous distending pressure. The data which they present are intriguing, but a few points need to be further discussed. First, the use of a "comfort scale" appears to be a surrogate end-point. To properly assess safety and efficacy of this new technique, even in a pilot study, the authors should have focused on more relevant clinical aspects or potential complications, such as level of respiratory distress, oxygen-dependency, rate of apnea, local damage, air leak, or need for mechanical ventilation.

Second, the authors reported a marked reduction in the Neonatal Infant Pain Scale (NIPS) values, i.e., a better comfort status of patients, during treatment with helmet CPAP. Given the lower level of stress imposed by this technique, one might have expected some modifications in the main physiological parameters, such as heart rate, respiratory rate, and arterial blood pressure [2]. On the other hand, none of the investigated parameters differed between the two CPAP treatments, raising doubts about potential bias due to the non-blinded scoring method used in this study. Indeed, NIPS does require a close observation of the infant, making any blinding process quite complex. Such important limitation might be partially circumvented by simultaneous NIPS measurements performed by two independent observers or by video recording.

Third, the small number of enrolled patients (powered only for the chosen end-point), the very brief duration of both CPAP treatments, and the relatively healthy status of the population studied preclude any definitive conclusion about this study. Indeed, how would this technique work in sicker infants who may require CPAP continuously for days or weeks? What are the possible effects of long-term application on abdominal distension, or in the prevention of apnea episodes?

As regards the latter point, we have had the contrary findings in a single preliminary experience. A premature infant (31weeks of post-conceptional age) treated with conventional nasal CPAP (Infant-Flow-Driver, EME) for apnea of prematurity, was shifted to helmet CPAP due to poor tolerance of nasal prongs. However, after 2 h of treatment he had to be returned to nasal CPAP for repeated episodes of apnea and arterial O_2 desaturation. Interestingly, as soon as conventional nasal CPAP was applied, the apneic episodes virtually disappeared. Of note, we report some difficulties in maintaining CPAP levels above 3 cmH_2O, despite flow

rates set as high as 15 lpm and absence of major leaks in the system. We speculate that conventional nasal CPAP, successfully used for apnea of prematurity [3], would be more effective than the new technique in these circumstances.

In summary, we congratulate the authors for their original study. Nonetheless, their conclusion that the helmet CPAP "seems to guarantee a better tolerability and at least similar improvement in oxygenation" may be misleading for the reader. We believe that larger randomized controlled studies are needed to better define the role of this new device and to verify its potential superiority over conventional CPAP by means of more appropriate end-points.

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