ELMO helmet for CPAP to treat COVID-19-related acute hypoxemic respiratory failure outside the ICU: aspects of/comments on its assembly and methodology

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We have read with great interest the study by Tomaz et al.,[1] which analyzes the clinical efficacy of a new model of a helmet-CPAP system, designated ELMOcpap, in COVID-19-related acute hypoxemic respiratory failure. We consider that that study published in the last issue of *Jornal Brasileiro de Pneumologia* represents a great advance regarding CPAP therapy, showing a new model of a helmet-CPAP device, and contributes to extend the use of such devices outside ICUs. However, we believe that there are some clinical and technical aspects that should be discussed.

First, Table 1[1] shows that all patients were affected by alkalosis (pH > 7.48) before starting therapy with the device, and the observed RR was not very high and not significantly different from that after its use (28.5 [24.5-34.0] vs. 26.5 [23.5-32.5] breaths/min; p = 0.866). We wonder if the authors considered the possibility of the presence of mixed alkalosis and if these data could be associated with successive helmet-CPAP setting adjustments. We think that this may also predispose patients to self-induced lung injury (P-SILI),[2] and we recommend that future studies about ELMOcpap should evaluate, by means of bench or clinical trials, data regarding V_T measurements, ELMOcpap settings, and P-SILI prevention.[3]

Second, according to Figure 1 in that study,[1] we observed that the authors have combined two humidification systems: an active humidifying jar system and a heat and moisture exchanger filter. We consider that this association could predispose to obstruction of the system by condensation, CPAP asynchrony, and, consequently, P-SILI,[2] particularly in such patients. Referring to the fact that "None of the research team members or hospital staff acquired COVID-19 during the study," it has not been stated in which way safety or diffusibility through the interface to prevent the spread of the virus was evaluated. Data about environmental air analysis would have been useful, so as to exclude that no one got infected only because the staff wore personal protective equipment and not because of interface security.

Additionally, an important aspect for a future design could be the measurement of internal helmet gas volume, the use of antiviral filters both on the inspiratory and expiratory ports, and the implementation of an anti-suffocation valve.

Lastly, we observed a great variability of total ELMOcpap therapy time, because the range of daily duration of the sessions was 60-1,230 min, and it is not clear whether defined criteria were established as a guideline, or whether the duration was dependent only on the patient; in addition, it is unclear whether other oxygen therapy options while ELMOcpap was not connected were applied. This is controversial if we consider the level of disease severity and gas exchange at admission showed in Table 2.[1] We also wonder if the authors designed the ELMOcpap device for continuous noninvasive support application outside the ICU as well, considering that they conducted the study with patients with moderate to severe ARDS, which is evident in Figure 3,[1] where we find values of Pa_{O2}/FI_{O2} < 150.

Further clinical trials are needed to evaluate some methodological and technical aspects of this new helmet-CPAP system to be used outside ICUs.

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Authors' reply

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We thank the authors for their comments and questions regarding our study entitled "ELMO, a new helmet interface for CPAP to treat COVID-19-related acute hypoxemic respiratory failure outside the ICU: a feasibility study."

Concerning the first point mentioned by the authors, we agree with the observation regarding the coexistence of metabolic alkalosis in at least 8 of the 10 patients whose arterial blood gas analysis at admission, before the use of ELMO, showed base excess values above 2.0 mEq/L. A possible cause would be the pharmacological therapy with corticosteroids routinely used in patients before their inclusion in the study. Therefore, metabolic alkalosis is not related to the sequential application of CPAP with the helmet.

The fact that some patients presented with hyperventilation in accordance with the respiratory alkalosis component is compatible with an increase in the respiratory drive, and, yes, that is possibly associated with an increase in transpulmonary pressure, a mechanism related to the occurrence of self-inflicted lung injury. In the absence of transpulmonary pressure measurement, we believe that V_T monitoring in devices such as the ELMO can identify those patients with a greater propensity to self-inflicted lung injury. The effects of the application of CPAP by helmet or another interface on V_T require investigation in clinical trials in the future, evaluating its relationship with the progression of lung injury or not. It is worth noting that, experimentally, the application of CPAP can attenuate the variation of transpulmonary pressure in ARDS.[1]

Concerning the second point, it is worth explaining the following: first, the heat and moisture exchanger filter used in the ELMO inspiratory branch serves only as a "damper" for the noise generated by the high flow of gases and not for its primary function (heat/humidity); second, the gas passage through the unheated jar was just a practical resource to offer the mixture of gases without raising their temperature. We even observed that this fact prevented condensation inside the helmet and, in volunteers, it was associated with a better sensation of comfort during the use of ELMOcpap due to the slightly cooler temperature around the head and face.[2] Because the CPAP mechanism has a continuous flow of gases, there is no occurrence of asynchrony, unlike helmets coupled to mechanical ventilators, and current trigger mechanisms are not designed for this interface.

The safety of the interface regarding the diffusibility of the virus was not the object of our study since it has already been reported in the literature[3]; the helmet interface has been considered safe and leakage is negligible when compared with face masks. The description of the absence of COVID-19 cases among researchers should not be seen as proof of this concept; however, we thought it best to report the data for recording purposes.

We agree with the idea of continuing to improve the design of the ELMO helmet on several fronts, including the improvement of anti-suffocation mechanisms, the coupling of filters in the gas inlet and outlet, the optimization of its internal volume to reduce the predisposition to CO_2 rebreathing, the monitoring of respiratory variables, such as RR, V_T, and FIO_2, as well as of intra-helmet pressure level, humidity, temperature, and others.

Given the innovation of the characteristics of that study with this type of device, our group considered that the total time of therapy would be the maximum tolerated by the patient, and, in agreement with the medical team, we alternated it with the only oxygen therapy then available (reservoir mask), because a high-flow nasal cannula was not available. The degree of comfort observed was great, and the large-scale use after the feasibility study revealed cases of continuous use of ELMOcpap for periods as long as 12-24 h (unpublished data), which is in line with other reports in the literature.

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