J Bras Pneumol. 2022;48(1):e20210349
https://dx.doi.org/10.36416/1806-3756/e20210349

ELMO, a new helmet interface for CPAP to treat COVID-19-related acute hypoxemic respiratory failure outside the ICU: a feasibility study

Betina Santos Tomaz[1], Gabriela Carvalho Gomes[2], Juliana Arcanjo Lino[2], David Guabiraba Abitbol de Menezes[2], Jorge Barbosa Soares[2], Vasco Furtado[3], Luiz Soares Júnior[1], Maria do Socorro Quintino Farias[4], Debora Lilian Nascimento Lima[4], Eanes Delgado Barros Pereira[1], Marcelo Alcantara Holanda[1,5]

METHODS

Subjects

Inclusion criteria consisted of male or female patients ≥ 18 years of age with a confirmed diagnosis of COVID-19 by RT-PCR[(1)] who presented with hypoxemic respiratory failure (AHRF), defined as having a PaO_2/FIO_2 ratio ≤ 250 mmHg[(2)] and the following characteristics: a. the patient should be alert, oriented, and cooperative; b. the patient should need oxygen therapy via nasal cannula (NC; flow ≥ 4 L/min) or a mask with a reservoir (flow ≥ 8 L/min) and maintaining an SpO_2 ≥ 92%; c. arterial blood gas parameters up to 30 min before treatment initiation should be pH > 7.35 (no acidosis), $PaCO_2$ < 46 mmHg, and PaO_2 ≥ 60 mmHg; and d. chest X-ray or CT obtained in the last 24 h should reveal bilateral parenchymal opacities.

Exclusion criteria consisted of the following: a. diagnosis of exacerbation of asthma, COPD, pulmonary fibrosis, or other lung diseases; b. hemodynamic instability—systolic blood pressure (SBP) < 90 mmHg, mean arterial blood pressure (MAP) < 65 mmHg, or need for vasoactive drugs; c. pneumothorax or pneumomediastinum; d. signs of respiratory muscle fatigue (paradoxical breathing, accessory muscle use); e. nausea or vomiting; f. auditory canal disorder; g. use of nasoenteric or nasogastric feeding tubes; and h. imminent risk of respiratory arrest.

Study protocol

The preparation phase consisted of placing the patient in the Fowler's position (semi-seated at 45°) on the bed and asking him/her to remove any dentures and accessories (earrings, necklace, glasses), hold back his/her hair with a scrub cap, and put on hearing protectors before the application of CPAP with the ELMOcpap system. A multiparameter monitor (model DX2023 LCD; DIXTAL, São Paulo, Brazil) was set for continuous monitoring of cardiorespiratory parameters: SpO_2, RR, HR, SBP, diastolic blood pressure, and MAP.

Carbon dioxide rebreathing was assessed in the first ELMOcpap session by sidestream capnography (with a simple NC). We set a minimum total gas flow ≥ 40 L/min to avoid any CO_2 rebreathing.[(3)] We always intended to achieve undetectable inspired CO_2 (iCO_2) by capnography in all patients.

Cervical circumference was determined using a tape measure to choose the size of the ELMO silicone cervical collar (small, medium, large, or extralarge).

The ELMO interface consists of a transparent hood and a silicone seal attached to a rigid base around the neck. The airflow inlet is located at the upper left side at the back of the hood, where it connects to a heat and moisture exchanger filter and a single circuit, which is integrated into a jar with unheated distilled water connected to oxygen and compressed air flow meters (30 L/min each). At the lower right side at the front of the hood, there is an air outlet with a high-efficiency particulate air (HEPA) filter and a PEEP valve capable of offering CPAP levels from 8 to 15 cmH_2O (Figure 1).[(3)]

The ELMOcpap system was set up on the patient by two previously trained physiotherapists. CPAP level was initially adjusted by an autoclavable PEEP valve (model 28VPA—Premium PEEP Valve; Newmed, São Paulo, Brazil) at 8 cmH_2O, followed by an increase of 2 cmH_2O every two minutes according to each patient, but not exceeding 12 cmH_2O to avoid side effects.[(4)] An analog cuff pressure gauge (universal VBM model; Celmat, São Paulo, Brazil) was connected to the adapter located next to the HEPA filter in the air outlet to measure CPAP (Figure 1). The total gas flow offer (O_2 and compressed air) was adjusted to deliver 60 L/min initially,[(3,5)] and an initial FIO_2 was titrated to attain an SpO_2 ≥ 94%. FIO_2 was calculated using the following formula: FIO_2 = {[(compressed air flow × 0.21) + (O_2 flow × 1.00)]/total flow} × 100.[(6)]

CPAP application via ELMOcpap took place at least three times a day for as long as the patient tolerated it until treatment was deemed successful or unsuccessful. Weaning from the ELMOcpap system started with the reduction of FIO_2 after obtaining a consistent improvement in SpO_2 with the same previous FIO_2, until reaching approximately 0.47 (20 L/min of O_2 and 40 L/min of compressed air). Soon afterwards, total gas flow was gradually weaned down to 40 L/min every 30 min. After that, PEEP was reduced by 2 cmH_2O until reaching the lowest value of the PEEP valve. Complete discontinuation of the ELMOcpap system was carried out only when the patient was able to maintain an SpO_2 > 92-94% and an estimated PaO_2/FIO_2 ratio > 250 mmHg while on oxygen supplementation via NC at a flow < 4 L/min for at least 24 h.

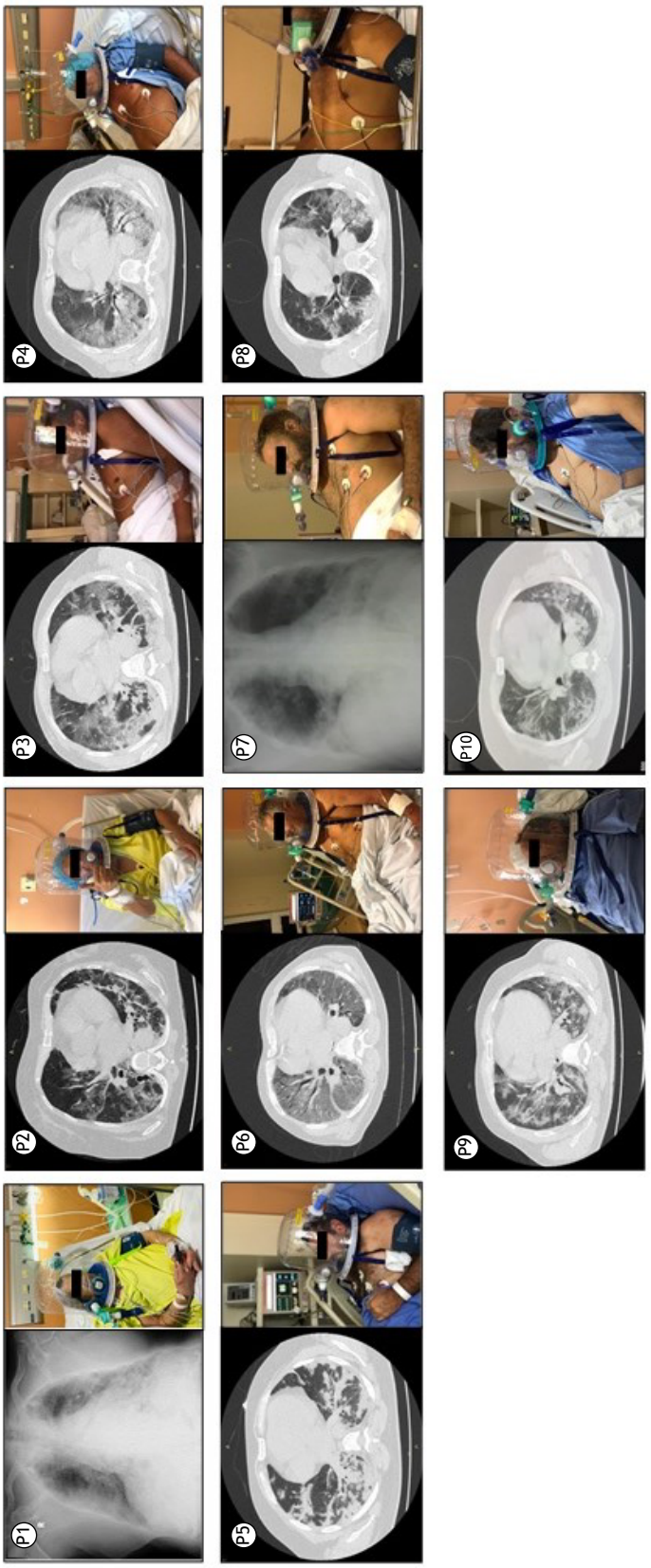

Figure S1. CT or X-ray images of the patients (P1-P10) taken within 24 h before the first ELMOcpap session and photographs of the patients during a session.

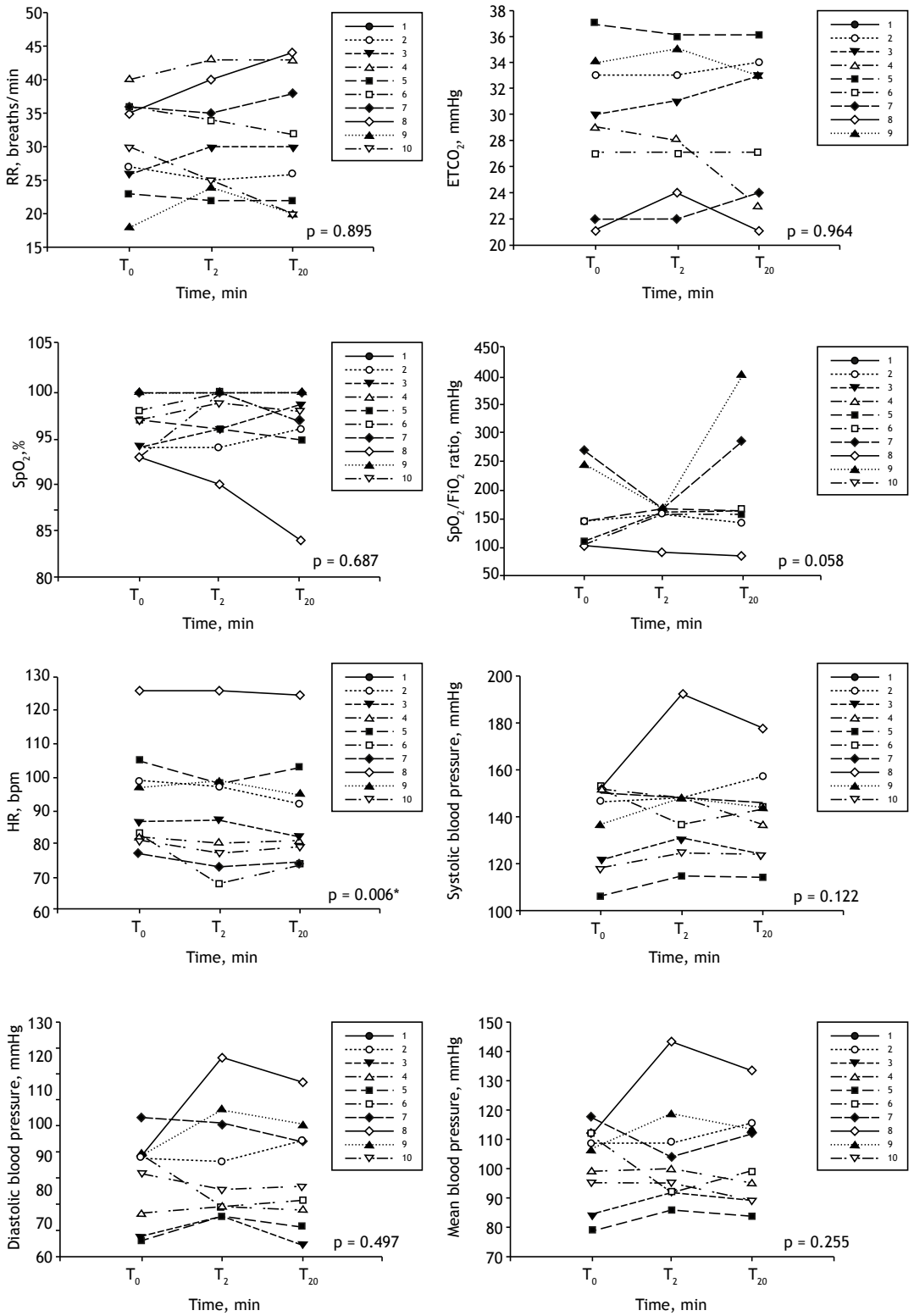

Figure S2. Cardiorespiratory variables before an ELMOcpap session (T0), as well as 2 min (T2) and 20 min (T20) after session initiation (CPAP = 10 cmH_2O and total gas flow = 60 L/min). $ETCO_2$: end-tidal carbon dioxide. *p < 0.05.

Treatment success was defined as either weaning from oxygen supplementation via ELMOcpap to that via NC at a flow ≤ 3 L/min or complete discontinuation of oxygen support. Failure was defined as the worsening of cardiorespiratory parameters (HR > 20% of baseline value, SBP > 20% of baseline value, SpO_2 < 90%,

and/or RR > 30 breaths/min) during therapy, no improvements in breathing pattern after 30 min of use, patient intolerance, or patient submitted to orotracheal intubation. Recommendation for intubation was in accordance with the hospital protocol criteria, at the discretion of the attending physician.

Data acquisition and analysis

Clinical and demographic data were collected, and the following variables were assessed: length of hospital stay, intubation during hospitalization, duration of invasive mechanical ventilation, time off invasive mechanical ventilation, and outcome (discharge or death).

Two arterial blood gas analyses were performed to assess the effects of the application of CPAP via ELMOcpap on pulmonary gas exchange: T0 (30 min before application) and T30-60min (30-60 min during therapy). FIO_2 was estimated at T0 according to the type of oxygen delivery device: NC[7] or nonrebreathing reservoir mask (between 0.600 and 0.800— being categorized as 0.646, 0.656, 0.882, and 0.906 at flows of 8 L/min, 10 L/min, 12 L/min, and 15 L/min, respectively).[8,9] The SpO_2/FIO_2 ratio was estimated overtime just before and during the ELMOcpap session, using the equation proposed by Rice et al.[10,11]

Cardiorespiratory parameters were monitored over time and measured at T0 (before the ELMOcpap session), T2 (2 min after its start), and every 20 min for the entire duration of the therapy session, as well as within 3-5 min after its interruption. Self-perception of the degree of dyspnea was assessed at the beginning and at the end of the therapy session (or opportunely) using the categorical Borg dyspnea scale (scores ranging from 0 to 10, in which 0 means no dyspnea and 10 means maximum dyspnea).[12]

The ratio of oxygen saturation as measured by the SpO_2/FIO_2 ratio to RR—$(SpO_2/FIO_2)/RR$ (i.e., the ROX index) —was calculated at the end of each session.[13] The patient was asked to evaluate the comfort of the helmet interface using a visual analog scale ranging from 0 to 10, in which 0 means very uncomfortable and 10 means very comfortable.[14]

The proof of concept for the device also considered the analysis of the total number of ELMOcpap sessions, total number of days on that therapy, total duration of sessions in min, and adverse effects.

Outcomes

The outcomes of interest were clinical and cardiorespiratory characteristics; self-perception of dyspnea and comfort before and during the sessions; FIO_2 settings; CPAP level; number of sessions; total duration of all sessions in min; total length of hospital stay; need for orotracheal intubation; duration of invasive mechanical ventilation; and final outcome (hospital discharge or death).

Statistical analysis

Given that this was a feasibility study to be carried out during the pandemic, a convenience sample of 10 patients was included.

Nonparametric tests were used in a more conservative condition due to the small sample size. The analysis of the acute effects of ELMOcpap use in terms of cardiorespiratory parameters (blood pressure, HR, RR, SpO_2, and iCO_2), self-perception of dyspnea, and arterial blood gas parameters before and during ELMOcpap sessions was performed using the Wilcoxon test, and values were described as medians [IQR]. We used the Friedman test to analyze and compare the cardiorespiratory parameters using the same time intervals for all patients. The other variables were descriptively presented. All data were tabulated and analyzed using the IBM SPSS Statistics software package, version 20.0 (IBM Corporation, Armonk, NY, USA). Statistical significance was set at 95% ($p < 0.05$).

REFERENCES

1. Vandenberg O, Martiny D, Rochas O, van Belkum A, Kozlakidis Z. Considerations for diagnostic COVID-19 tests. Nat Rev Microbiol. 2021;19(3):171-183. https://doi.org/10.1038/s41579-020-00461-z
2. ARDS Definition Task Force, Ranieri VM, Rubenfeld GD, Thompson BT, Ferguson ND, Caldwell E, et al. Acute respiratory distress syndrome: the Berlin Definition. JAMA. 2012;307(23):2526-2533. https://doi.org/10.1001/jama.2012.5669
3. Holanda MA, Tomaz BS, Menezes DGA, Lino JA, Gomes GC. ELMO 1.0: a helmet interface for CPAP and high-flow oxygen delivery. J Bras Pneumol. 2021;47(3):e20200590. https://doi.org/10.36416/1806-3756/e20200590
4. Navalesi P, Maggiore SM. Positive end-expiratory pressure. In: Tobin MJ, editor. Principles and Practice of Mechanical Ventilation, 3rd ed. New York, NY: McGraw Hill Medical; 2013. p. 253-302.
5. Lucchini A, Bambi S, Elli S, Bruno M, Dallari R, Puccio P, et al. Water content of delivered gases during Helmet Continuous Positive Airway Pressure in healthy subjects. Acta Biomed. 2019;90(11-S):65-71.
6. Chang DW. Respiratory care calculations. 3rd ed. Stamford (CT): Cengage Learning; 2011.
7. SRLF Trial Group. Hypoxemia in the ICU: prevalence, treatment, and outcome [published correction appears in Ann Intensive Care. 2019 Jan 21;9(1):10]. Ann Intensive Care. 2018;8(1):82. https://doi.org/10.1186/s13613-018-0424-4
8. Wilkins RL, Stoller JK, Scanlan CL, editors. Egan's fundamentals of respiratory care. 8th ed. St. Louis: Mosby; 2003.
9. Farias E, Rudski L, Zidulka A. Delivery of high inspired oxygen by face mask. J Crit Care. 1991;6(3):119-124. https://doi.org/10.1016/0883-9441(91)90002-B
10. Rice TW, Wheeler AP, Bernard GR, Hayden DL, Schoenfeld DA, Ware LB. Comparison of the SpO2/FIO2 ratio and the PaO2/FIO2 ratio in patients with acute lung injury or ARDS. Chest. 2007;132(2):410-417. https://doi.org/10.1378/chest.07-0617
11. Bilan N, Dastranji A, Ghalehgolab Behbahani A. Comparison of the spo2/fio2 ratio and the pao2/fio2 ratio in patients with acute lung injury or acute respiratory distress syndrome. J Cardiovasc Thorac Res. 2015;7(1):28-31. https://doi.org/10.15171/jcvtr.2014.06
12. Borg G. Borg's Perceived Exertion and Pain Scales. Champaign, IL: Human Kinetics; 1998.
13. Roca O, Messika J, Caralt B, García-de-Acilu, Sztrymf B, Ricard JD, et al. Predicting success of high-flow nasal cannula in pneumonia patients with hypoxemic respiratory failure: The utility of the ROX index. J Crit Care. 2016;35:200-205. https://doi.org/10.1016/j.jcrc.2016.05.022
14. Ueta K, Tomita T, Uchiyama A, Ohta N, Iguchi N, Goto Y, et al. Influence of humidification on comfort during noninvasive ventilation with a helmet. Respir Care. 2013;58(5):798-804. https://doi.org/10.4187/respcare.01735