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ORIGINAL ARTICLE

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

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ABSTRACT

Objective: To assess the feasibility of using a new helmet interface for CPAP, designated ELMO, to treat COVID-19-related acute hypoxemic respiratory failure (AHRF) outside the ICU. **Methods:** This was a proof-of-concept study involving patients with moderate to severe AHRF secondary to COVID-19 admitted to the general ward of a public hospital. The intervention consisted of applying CPAP via the ELMO interface integrated with oxygen and compressed air flow meters (30 L/min each) and a PEEP valve (CPAP levels = 8-10 cmH_2O), forming the ELMOcpap system. The patients were monitored for cardiorespiratory parameters, adverse events, and comfort. **Results:** Ten patients completed the study protocol. The ELMOcpap system was well tolerated, with no relevant adverse effects. Its use was feasible outside the ICU for a prolonged amount of time and was shown to be successful in 60% of the patients. A CPAP of 10 cmH_2O with a total gas flow of 56-60 L/min improved oxygenation after 30-to 60-min ELMOcpap sessions, allowing a significant decrease in estimated FIO_2 ($p = 0.014$) and an increase in estimated PaO_2/FIO_2 ratio ($p = 0.008$) within the first hour without CO_2 rebreathing. **Conclusions:** The use of ELMOcpap has proven to be feasible and effective in delivering high-flow CPAP to patients with COVID-19-related AHRF outside the ICU. There were no major adverse effects, and ELMO was considered comfortable. ELMOcpap sessions significantly improved oxygenation, reducing FIO_2 without CO_2 rebreathing. The overall success rate was 60% in this pilot study, and further clinical trials should be carried out in the future.

(ClinicalTrials.gov identifier: NCT04470258 [http://www.clinicaltrials.gov/])

Keywords: Pneumonia; SARS-CoV-2; COVID-19; Respiratory protective devices; Continuous positive airway pressure; Noninvasive ventilation.

INTRODUCTION

Approximately 15-20% of COVID-19 patients develop severe forms of the disease, including acute hypoxemic respiratory failure (AHRF) and ARDS. These patients need oxygen therapy and ventilatory support, which leads to an increase in the number of admissions to ICUs.[1] The mortality rate for intubated patients has remained very high, reaching up to 80% in those submitted to invasive mechanical ventilation (MV) in Brazil.[2] The increased need to use a mechanical ventilator and to be admitted to an ICU bed puts a strain on health care systems. Regions of the world with scarce resources are at a greater risk of facing a collapse in health care systems due to the high number of patients.[2,3] Brazil currently ranks third in the number of cases, and, until April 18, 2021, the country recorded 371,678 deaths from the disease.[4] Therefore, noninvasive strategies have become increasingly important to avoid intubation in these patients. On the other hand, insistence on noninvasive ventilation (NIV) may delay orotracheal intubation. This fact may worsen the outcomes of patients.[2]

The administration of CPAP through a helmet is safe and ensures minimal contamination of the environment.[5] Furthermore, it improves patient comfort[6] and oxygenation,[7,8] preventing intubation in up to 55.4% of the patients.[9,10]

In the state of Ceará, Brazil, a multidisciplinary task force developed a new helmet-type interface with complete sealing and respiratory isolation of the patient's head, which allows the application of CPAP at 8-15 cmH_2O in association

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with the supply of a gas mixture flow containing oxygen and compressed air (CA), designated ELMO (Patent no. BR 20 2020 014212 2; ANVISA 82072609001).[11] As ELMO does not require a mechanical ventilator, it can be used outside ICUs, for instance, in general wards. When tested on volunteers, the device proved to be comfortable and safe, as well as to have good usability by health care professionals. Moreover, it avoided CO_2 rebreathing as long as adequate gas flow (≥ 40L/min) was offered,[11] since this adverse effect is one of the limitations of this type of interface.[12] Figure 1 shows the components of the whole system (ELMOcpap system).

The present study aimed to assess the feasibility of and the acute cardiorespiratory response to (as well as gas exchange parameters, comfort, and adverse effects) using this new helmet device, by offering CPAP and O_2 to patients with COVID-19-related AHRF outside the ICU. The main hypothesis was that the use of ELMO is feasible in a general ward and able to improve hypoxemia with comfort and no relevant adverse effects, thereby being suitable for treating these patients outside the ICU.

METHODS

This prospective cohort study was conducted from June to November of 2020 in the general ward of the Leonardo Da Vinci Hospital, a tertiary hospital with 230 beds that has been a referral center for treating COVID-19 cases during the pandemic in the city of Fortaleza, Brazil. This study was performed in accordance with the Declaration of Helsinki. The study was approved by the Brazilian National Research Ethics Commission and registered at https://clinicaltrials.gov/ (NCT04470258). Written informed consent and authorization for use of images were obtained from all of the patients.

The study protocol and statistical analyses are described in the supplementary material.

RESULTS

Ten patients diagnosed with COVID-19-related AHRF completed the proposed study protocol (Figure 2).

Demographic, anthropometric, and clinical characteristics at baseline (i.e., at hospital admission) are shown in Table 1. Eight participants were men, and the sample was predominantly elderly—median [IQR] = 65 [42-75] years. Four participants presented with normal weight, and six were classified as overweight (n = 3) or class II obesity (n = 3). Severity scores at admission were determined using SOFA and APACHE II (medians of 2 [2-2] and 9 [5-11], respectively; Table 1).

Seven of the participants presented with at least one comorbidity, the most frequent ones being systemic arterial hypertension (in 60%) and diabetes mellitus (in 40%). The most commonly reported initial symptoms were dry cough, dyspnea, and fever (Table 1).

The median day of initiation of ELMOcpap use was day 12 [10-13] after the onset of symptoms. Half of the patients presented with a 75% lung involvement on chest CT performed within 24 h before ELMOcpap initiation (Figure S1).

Arterial blood gas and cardiorespiratory parameters

During the first hour of an ELMOcpap session, eight patients were evaluated regarding arterial blood gas and cardiorespiratory parameters. Patients 7 and 8 were not included in this analysis, because the device had to be removed. Patient 7 reported feeling dyspneic 40 min after starting therapy, and patient 8 presented a worsening of cardiorespiratory parameters, leading to the removal of the device.

Figure 3 shows the acute effects of the ELMOcpap use on arterial blood gas parameters. There was a significant improvement, defined as an increase in all oxygenation parameters (PaO_2, SaO_2, and estimated PaO_2/FIO_2) 30-60 min after starting the ELMOcpap session. This improvement made it possible to reduce

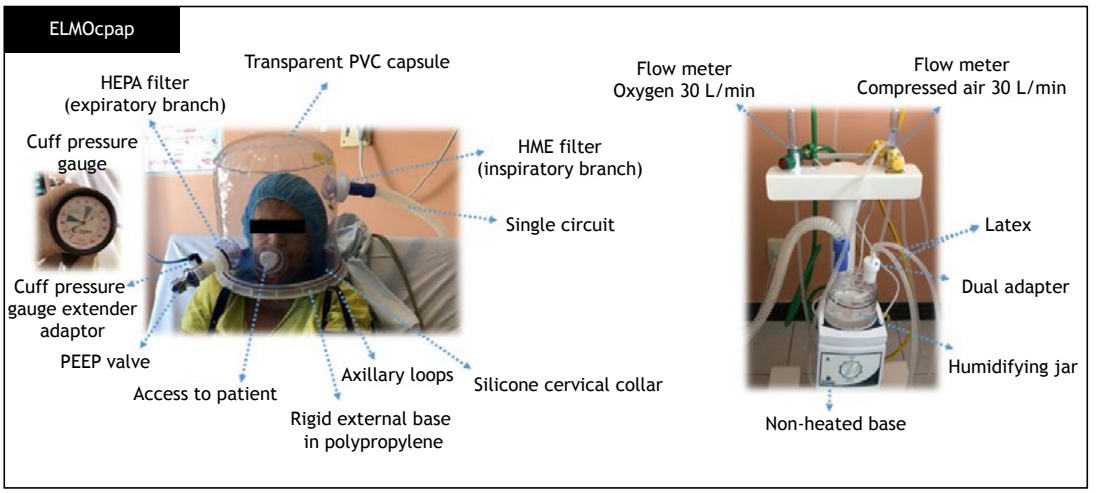

Figure 1. Images showing the components of the ELMOcpap system. HEPA: high-efficiency particulate air; and HME: heat and moisture exchanger.

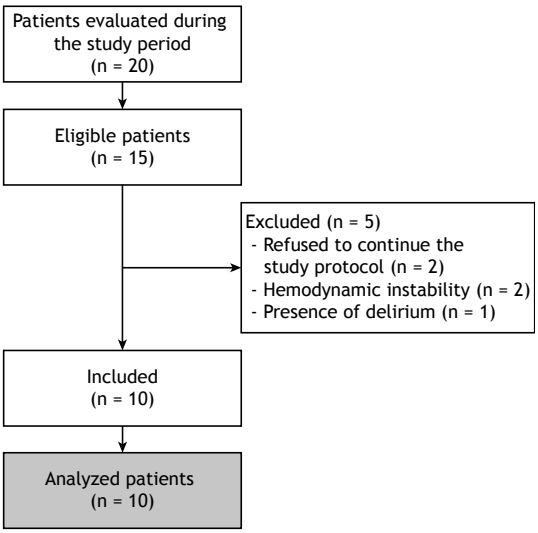

Figure 2. Flow chart of the patient selection process.

the median estimated FIO_2 (0.77 [0.65-0.89] vs. 0.60 [0.49-0.61]; p = 0.014). There was an increment of 72 [50-136] units in estimated PaO_2/FIO_2. In addition, there was a tendency toward a decrease in respiratory alkalosis, which was reflected in arterial blood pH (7.49 [7.49-7.50] vs. 7.47 [7.47-7.49]; p = 0.056; Figure 3).

As for cardiorespiratory parameters prior to and during the ELMOcpap session (30-60 min), there were significant improvements in median SpO_2/FIO_2 ratio (126.0 [105.0-147.5] vs. 164.0 [157.0-204.0]; p = 0.008) and Borg dyspnea score (4.0 [1.5-6.5] vs. 2.0 [0.5-3.5]; p = 0.054), whereas the other parameters remained stable: HR (89.0 [82.5-98.0] vs. 88.0 [76.0-97.5] bpm; p = 0.233); mean arterial pressure (97.0 [86.0-108.0] vs. 93.0 [87.5-107.0] mmHg; p = 0.641); RR (28.5 [24.5-34.0] vs. 26.5 [23.5-32.5] breaths/min; p = 0.866); end-tidal carbon dioxide ($ETCO_2$; 33 [29-37] vs. 31 [26-36] mmHg; p = 0.750); and $PaCO_2$ minus $ETCO_2$ (7 [3-8] vs. 9 [5-11] mmHg; p = 0.175). It should be noted that none of the patients experienced CO_2 rebreathing since inspired CO_2 (iCO_2) remained zero throughout the ELMOcpap session.

The absolute values for cardiorespiratory parameters before the ELMOcpap session (T0), as well as 2 min (T2) and 20 min (T20) after session initiation are shown in Figure S2. There was an improvement in oxygenation (an increase in SpO_2 and SpO_2/FIO_2 ratio and a decrease in HR [from 92 bpm to 87 bpm]; p = 0.006).

ELMOcpap utilization

All patients underwent ELMOcpap sessions, initial settings being as follows: total flow = 60 L/min (O_2 = 30 L/min and CA = 30 L/min); CPAP = 8 cmH_2O; and estimated FIO_2 = 0.60. At the end of the first session, the settings were as follows: total flow = 56 L/min (O_2 = 26 L/min and CA = 30 L/min); CPAP = 10 cmH_2O; and estimated FIO_2 = 0.58.

The rate of success rate—herein defined as either weaning from off oxygen supplementation delivered via ELMOcpap to that via nasal cannula at a flow ≤ 3 L/min via a nasal cannula or complete discontinuation of oxygen support—was 60%. Of the four patients who failed, one did not tolerate the therapy 40 min after the initiation of the first session, and three underwent orotracheal intubation in less than 24 h after the first session. Of these, two presented with delirium and refused the second session, and one showed no improvement in oxygenation during the session (PaO_2 and SpO_2 decreased by 8% and 12%, respectively, when compared with baseline values, as well as presented with worsening of dyspnea, resulting in its discontinuation after 20 min.

The median number of sessions with ELMOcpap sessions was 3.5 [1.0-11.0] for a median of 2 [1-5] days. The median daily duration of the sessions was 310 [60-1,230] min. Throughout that period, there was a gradual decrease in oxygen supplementation until complete weaning off in seven of the ten patients. The respiratory rate-oxygenation (ROX) index at the end of the first session was 6.8 [5.2-8.1]; however, this index has yet to be validated for use with the device.

The median scores assigned to the comfort provided by the interface, measured at the end of each session using a visual analog scale was 7.5 [5.0-8.8]. This score suggested that the use of ELMO was classified as moderately comfortable or very comfortable. None of the patients used any sedatives or analgesics continuously while using the interface.

The adverse effects observed with the use of ELMO are described in Table 2, all of them being considered mild by the patients. It should be noted that there were no air leaks during the sessions.

Of the ten patients, three underwent orotracheal intubation, none of which having been recommended during ELMOcpap sessions. Of these, two died, and one underwent tracheostomy and decannulation and was then discharged after being able to sustain spontaneous breathing after nearly two months of hospitalization. The median length of hospital stay for intubated patients was 24 [7-58] days, and the median number of days on and off MV was 19 [4-22] and 5 [3-36], respectively. The median length of hospital stay for patients whose therapy was considered successful was 13 [13-14] days. Eight patients were discharged after 13 [7-19] days of hospitalization.

None of the research team members or hospital staff acquired COVID-19 during the study, and all of them made rigorous use of personal protective equipment.

DISCUSSION

The present proof-of-concept study showed that the use of a new helmet device called ELMO was able to offer CPAP through a continuous flow of oxygen and CA to patients with COVID-19-related AHRF who needed oxygen supplementation outside the ICU. The use of ELMOcpap system resulted in improved oxygenation,

J Bras Pneumol. 2022;48(1):e20210349

Table 1. Baseline demographic and clinical characteristics of the patients.

Characteristic	Patient									
	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10
Age, years	76	70	71	77	42	75	37	54	60	39
Sex	F	F	M	M	M	M	M	M	M	M
Weight, kg	72	58	63	66	110	64	93	65	75	105.2
Height, cm	154	158	164	156	170	159	182	163	174	172
BMI, kg/m^2	30.2	23.2	23.4	27.1	38.0	25.7	28.0	24.9	24.7	35.6
SOFA score at study entry	2	2	2	2	2	4	2	2	2	2
APACHE II score at study entry	11	11	15	10	5	12	4	8	4	5
Smoking history	Yes	Yes	No	Yes	No	Yes	No	No	Yes	No
Comorbidities	Diabetes Obesity	Hypertension Diabetes	Hypertension Diabetes	Hypertension	Obesity	Hypertension	-	Hypertension	Hypertension Diabetes	-
Symptoms before hospital admission	Cough Dyspnea Loss of appetite Adynamia	Cough Dyspnea Fever	Dyspnea Fever	Cough Fever Loss of appetite Headache	Cough Dyspnea Fever Nausea Vomiting	Cough Dyspnea Fever Odynophagia Coryza	Cough Fever	Cough Dyspnea	Cough Dyspnea Fever Loss of appetite Myalgia	Fever Adynamia
Extension of pulmonary impairment on CT	-	> 75%	> 75%	50-75%	> 75%	50-75%	-	50-75%	> 75%	> 75%
1st arterial blood gas analysis after hospital admission										
pH	7.51	7.50	7.50	7.52	7.51	7.48	7.46	7.52	7.49	7.49
PaO_2, mmHg	51	68	68	75	167	91	60	89	74	79
$PaCO_2$, mmHg	35	33	41	35	37	34	41	34	41	39
HCO_3, mEq/L	28.5	28.5	28.5	28.5	28.5	28.5	29.2	27.8	28.5	29.7
BE, mEq/L	4.9	2.5	8.8	2.8	6.2	1.8	4.9	2.0	7.2	5.9
SaO_2, %	89	95	95	96	100	98	92	98	96	97
Lactate, mmol/L	1.4	2.0	1.3	1.5	1.1	1.8	1.3	2.0	2.0	1.4
Oxygen therapy at hospital admission	RV 8 L/min	NC 5 L/min	RV 8 L/min	RV 8 L/min	RV 10 L/min	RV 9 L/min	NC 4 L/min	RV 15 L/min	NC 6 L/min	RV 10 L/min
Laboratory findings at hospital admission										
White blood cell count/mm^3	10,780	8,351	19,340	14,630	10,730	13,610	10,870	14,950	7,931	12,900
Lymphocyte count/mm^3	757	1,338	1,355	586	537	681	1,088	1,346	795	1,419
Hemoglobin level, g/dL	11.6	13.3	12.3	13.5	13.8	14.7	13.4	13.5	14.4	13.9

Continue...▶

Table 1. Baseline demographic and clinical characteristics of the patients. (Continued...)

Characteristic	Patient									
	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10
Hematocrit, %	36.6	40.9	36.8	41.4	41.2	41.5	39.0	39.3	45.5	41.9
Band cell count/mm^3	107	83	580	0	0	136	0	149	0	0
Segmented cell count/mm^3	9,809	6,513	16,825	13,313	9,764	12,249	9,130	12,857	6,582	10,707
Platelet count/mm^3	211,500	168,200	187,000	283,000	237,800	128,500	287,500	301,900	232,500	190,000
CRP, mg/dL	27.2	3.8	20.4	7.9	11.4	3.4	14.3	5.4	4.5	5.35
Urea, mg/dL	24	29	64	43	37	44	41	63	44	35
Creatinine, mg/dL	0.3	0.5	1.4	0.9	0.7	0.7	0.6	1.1	0.7	0.7
D-dimer, µg/mL	> 20	0.42	1.38	0.7	1.28	1.32	0.74	0.73	1	1.69
Fibrinogen, mg/dL	221	-	687	-	-	-	-	-	-	-
AST, U/L	64	33	54	55	37	109	24	34	40	98
ALT, U/L	99	30	47	26	47	29	26	45	75	216
CPK, U/L	42	52	185	28	18	1,393	35	173	198	37
LDH, U/L	548	247	386	373	401	1,503	405	312	371	545
Ferritin, ng/mL	> 1,500	280	> 1,500	> 1,500	> 1,500	> 1,500	1,307	-	1,091	766
Days of symptoms preceding ELMOcpap use, n	7	13	4	13	13	10	15	17	11	11

F: female; M: male; HCO_3: bicarbonate; BE: base excess; RV: nonrebreathing reservoir mask; NC: nasal cannula; CRP: C-reactive protein (1-5 mg/dL: slight inflammation; 5-10 mg/dL: severe inflammation; > 10 mg/dL: probable bacterial infection); and CPK: creatine phosphokinase.

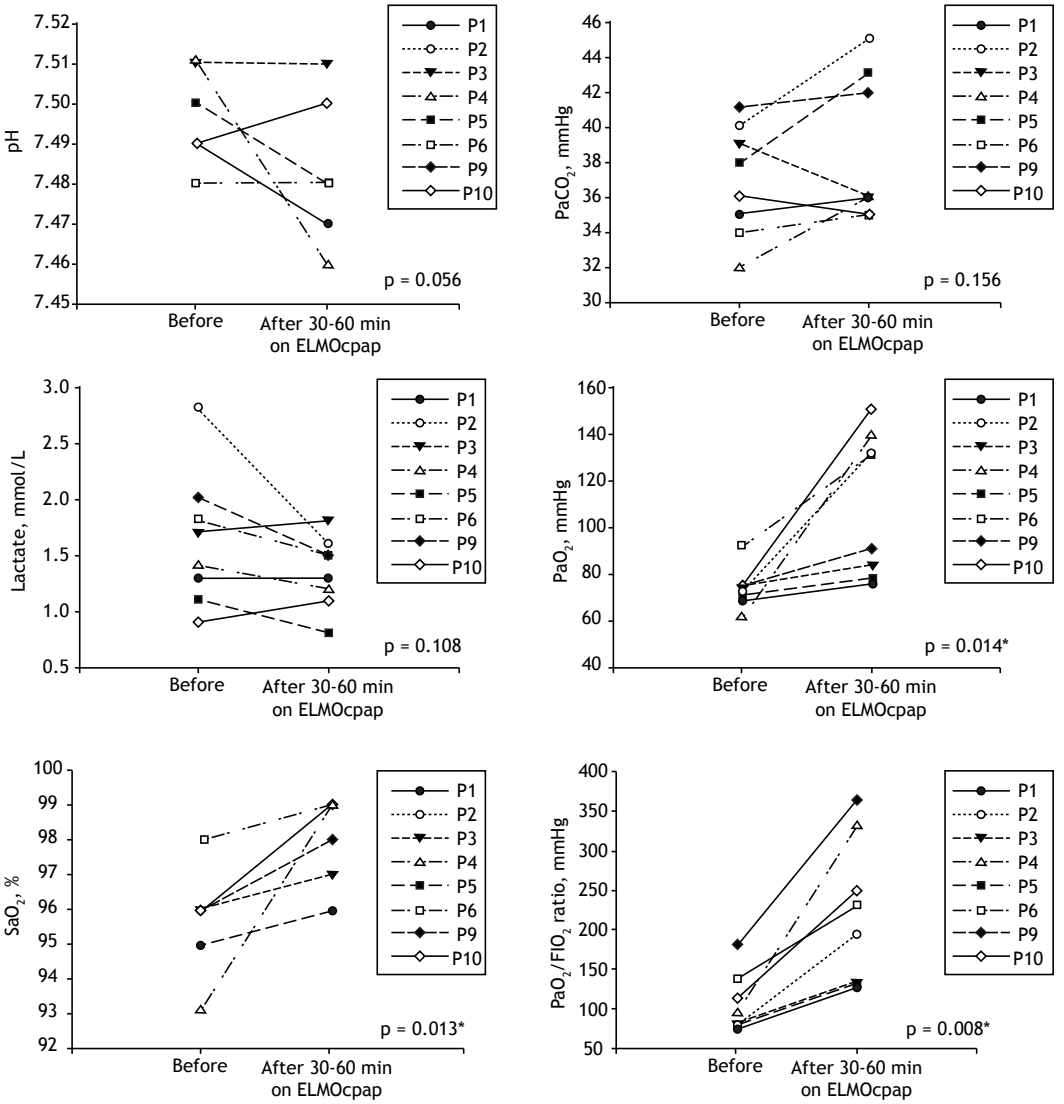

Figure 3. Arterial blood gas parameters before the first ELMOcpap session and after 30-60 min of use (CPAP = 10 cmH_2O and total gas flow = 56-60 L/min) in individual patients (P1-P6,P9,10). There were significant improvements in PaO_2, SaO_2, and estimated PaO_2/FIO_2 30-60 min after starting ELMOcpap use. These improvements made it possible to reduce median estimated FIO_2 (from 0.77 [0.65-0.89] to 0.60 [0.49-0.61]; p = 0.014). *p < 0.05.

making it possible to decrease FIO_2 without causing CO_2 rebreathing or hypercapnia. The device was well tolerated, and no relevant adverse effects were observed; its use was feasible outside the ICU for a prolonged time and was shown to be successful in 60% of the patients.

The feasibility, safety, and clinical impact of noninvasive ventilatory support in patients with COVID-19 outside the ICU were described in a prospective multicenter observational study[13] that analyzed data from 670 patients. In that study, a total of 330 patients received CPAP either via a helmet or a face mask, the helmet being used with a mean CPAP of 10.2 cmH_2O in most patients.[13] This setting is similar to the one in the present study. The researchers concluded that the use of NIV outside the ICU was feasible when performed by experienced staff and was associated with favorable outcomes, such as lower rates of endotracheal intubation and mortality. On the other hand, that use was associated with a risk of staff contamination, which was minimized when the helmet interface was used.[13] None of our research team members was infected with SARS-CoV-2 during the study period while the patients were on ELMOcpap.

The patients considered the use of the ELMOcpap system to be moderately to very comfortable. This allowed one of the patients to remain on ELMOcpap for 15 uninterrupted hours with no adverse effects. The main adverse effects reported in the literature are helmet deflation and pressure ulcers on the neck.[10]

Table 2. ELMOcpap use and patient outcomes.[a]

Variable	Patient									
	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10
Total number of sessions	2	5	11	7	17	1	1	1	2	14
CPAP level, cmH_2O	10 [10-12]	8 [8-10]	10 [8-10]	10 [10-10]	10 [8-10]	8 [8-8]	10 [8-10]	8 [8-8]	8 [8-8]	10 [10-10]
Total therapy time, min	100	440	1,230	880	1,980	60	40	20	180	2,640
ROX index within 2 h after the 1st session	6.2	5.2	5.2	7.7	8.2	5.2	7.5	1.9	16.0	13.0
VAS comfort score	5	8	7	9	9	-	3	0	10	8
Main adverse effects	-	Regurgitation	Dry mouth	Eye irritation	Cervical and armpit discomfort	-	-	-	Cough	-
Number of days of utilization	2	2	5	4	7	1	1	1	2	5
ELMOcpap use outcome[b]	Failure	Success	Success	Success	Success	Failure	Failure	Failure	Success	Success
Total length of hospital stay before first ELMOcpap session, days	0	8	4	2	4	3	3	11	1	3
Total length of hospital stay, days	7	14	13	13	19	24	7	58	5	13
Clinical course assessed just before first ELMOcpap session	Worsening	Stable	Stable	Stable	Stable	Worsening	Improving	Worsening	Improving	Stable
Orotracheal intubation after ELMOcpap use	Yes	No	No	No	No	Yes	No	Yes	No	No
Outcome	Death	Discharge	Discharge	Discharge	Discharge	Death	Discharge	Discharge	Discharge	Discharge

ROX index = $(SpO_2/FIO_2)/RR$; VAS: visual analog scale to assess comfort of the interface (zero-most uncomfortable and 10-very comfortable). [a]Values expressed in n or median [IQR]. [b]Success: weaning from off oxygen supplementation delivered via ELMOcpap to that via nasal cannula at a flow ≤ 3 L/min via a nasal cannula or complete discontinuation of oxygen support. Failure: worsening of cardiorespiratory parameters during session, no improvement in breathing pattern, or patient rejection.

In our study, none of the patients developed pressure ulcers, but a few patients reported some discomfort in the cervical region and armpits, which could be alleviated with adjustments in the positioning of the silicone cervical collar and with the symmetrical positioning of the armpit braces with the use of underarm pads.

The analysis of the acute effects on gas exchange and cardiovascular function before and during the use of ELMOcpap revealed a significant improvement in all oxygenation parameters. Similar findings were reported by Coppadoro et al.,[14] who found that the PaO_2/FIO_2 ratio doubled from 100 to 200 mmHg and that the PaO_2/FIO_2 ratio remained constantly above 150 mmHg during the first week; this was associated with a probability of recovery without intubation of 91%.[14] A similar observation was made in the first hour of ELMOcpap use, with a significant increase in the PaO_2/FIO_2 ratio from 88 to 212 mmHg. This effect can be explained by the effect of CPAP on the recruitment of swollen and/or collapsed alveoli, with immediate improvement in the ventilation/perfusion ratio.[8] The positive pressure can favor a more even distribution of perfusion, diverting blood flow from lung areas with shunt and edema towards those with a high ventilation/perfusion ratio.[15]

We identified a decrease in respiratory alkalosis, which might have resulted from a combination of effects of CPAP application that decreased ventilatory drive: improvement of hypoxemia, a potential increase in lung compliance, reduced work of breathing, and greater comfort.[16,17] A study demonstrated that RR < 24 breaths/min on helmet-delivered CPAP for a few hours were associated with greater efficacy.[14]

As for cardiovascular function, we found a decrease in HR within the first hour of CPAP application with no significant changes in systemic blood pressure. However, a decrease in blood lactate levels was found in five of eight patients. These findings indicate a decrease in global oxygen consumption and a lower demand for oxygen supply.[18,19]

None of the patients in the present study had CO_2 rebreathing. Compared with face masks, helmets, due to their larger internal volume, might facilitate CO_2 rebreathing.[20] A group of authors[12] found that such a phenomenon is associated with two factors: the amount of CO_2 produced by the patient and the amount of gas passing through the helmet. Those researchers did not recommend the use of a helmet to deliver CPAP with a mechanical ventilator, the reason being that ventilators deliver CPAP with a gas flow equal to minute ventilation in healthy subjects; in the absence of a leak, there is no additional fresh gas flow to flush CO_2 during exhalation, which is thus retained inside the helmet.[12] Thus, the delivery of a continuous flow eliminates this problem, as we could see in the present study. In fact, during the development of ELMO, we demonstrated, using capnography, the degree of CO_2 rebreathing at different gas mixture flows (30, 40, 50, and 60 L/min). Flows > 40 L/min resulted in null or negligible CO_2 rebreathing,[11] which is in accordance with previous investigations.[7,21]

The success rate described in this study is similar to the one reported in a recent retrospective observational cohort study[14] involving 306 patients that showed that treatment with helmet-delivered CPAP of 10 cmH_2O was successful in 69% of the cases, its use being feasible for several days outside the ICU. Our slightly lower rate can be explained by the severity of hypoxemia in our patients. In that study,[14] the patients had an initial median PaO_2/FIO_2 ratio of 103 [79-176] mmHg receiving standard oxygen therapy, whereas our patients presented with an initial median PaO_2/FIO_2 ratio of 88.0 [80.5-126.0] mmHg. Another study[9] found that helmet-delivered CPAP failed in up to 44% of patients with moderate to severe AHRF caused by COVID-19 pneumonia. The authors reported that 55.4% of the patients with a median PaO_2/FIO_2 ratio = 136 mmHg avoided intubation and were then successfully weaned from CPAP to oxygen therapy.[9]

The present study has some limitations, such as the lack of a control group and the small sample size. The interface was developed to deliver CPAP with a continuous flow of gases during the peak of the COVID-19 pandemic, when resources were limited and CPAP application with ICU ventilators had yet to be studied. However, this pioneering investigation conducted in Brazil received formal approval by the Brazilian National Health Surveillance Agency for the manufacturing and sale of the ELMO interface in the country.

The clinical implications are many: first, the ELMO is relatively simple to set and apply; second, it may be particularly useful as an interesting alternative to treat AHRF in situations such as during the COVID-19 pandemic, which has overwhelmed health care systems worldwide and increased the demands for ICU beds and ventilators; third, it allows longer periods of CPAP application without causing adverse effects commonly seen with the use of conventional face masks, tolerance being a well-known limitation in NIV[22]; fourth, the continuous high-flow CPAP system was efficient in preventing CO_2 rebreathing, an effect that might attenuate the increments in ventilatory demand and respiratory drive, which are important issues for patients at risk of self-inflicted lung injury and ARDS progression[23]; fifth, the material used in ELMO manufacturing allows reprocessing it up to five times, reducing hospital costs, and the silicone collar allows a good seal,[11] preventing air leaks, dissemination of contagious aerosols around the patient, and the spread of diseases among health care professionals.

The results of this pivotal study support the development of further research to assess the use of ELMO in patients with AHRF caused by COVID-19 and other similar conditions, such as pneumonia, ARDS, and acute cardiogenic pulmonary edema, as well as to determine its impact on relevant outcomes, such as intubation rates, mortality, length of hospital stay, and survival rates. In a multicenter randomized clinical trial[24] involving 109 patients with COVID-19, the

use of helmet-delivered NIV (PEEP = 10-12 cmH_2O and pressure support = 10-12 cmH_2O) for at least 48 h, eventually followed by high-flow nasal oxygen (HFNO), was compared with the use of HFNO alone. The rate of orotracheal intubation was significantly lower in the helmet group (30%) than in the HFNO group (51%); however, no significant differences were found in mortality or in the median number of days free of respiratory support within 28 days (primary outcome).[24] Clinical trials are certainly needed to access and compare different helmet interfaces; for instance, those using CPAP with continuous flow, such as ELMOcpap, in comparison with those especially adapted for full NIV with pressure support and adapted to an ICU ventilator. Furthermore, it is important to identify the patients' characteristics associated with improved physiological and clinical response to this type of respiratory therapy.[25]

In conclusion, based on the results obtained, the use of the helmet device designated ELMO is believed to be feasible and effective in delivering high-flow CPAP to patients with COVID-19-related AHRF outside the ICU. No major adverse effects were found, and the patients considered its use as comfortable. The application of CPAP using the ELMOcpap system significantly improved oxygenation, contributing to the reduction of FIO_2 and eliminating CO_2 rebreathing. The overall success rate was 60% in this pilot study, and further clinical trials should be carried out in the future.

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AUTHOR CONTRIBUTIONS

BST, GCG, JAL, and MAH: study design and drafting of the manuscript. DGAM, JBS, VF, LSJ, and the ELMO TASK FORCE: development of the ELMO device. BST, GCG, JAL, MSQF, and DLNL: data collection. BST, GCG, and JAL: guarantors of data integrity. BST, EDBP, and MAH: data analysis. All authors reviewed and approved the final manuscript.

CONFLICT OF INTEREST

None declared.

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