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Early Clinical Experience in Using Helmet Continuous Positive Airway Pressure and High-Flow Nasal Cannula in Overweight and Obese Patients With Acute Hypoxemic Respiratory Failure From Coronavirus Disease 2019**To the Editor:**

In coronavirus disease 2019 (COVID-19), larger body weights are associated with respiratory dysfunction and the requirement of mechanical ventilation, particularly in younger individuals (1). Alarming, over 70% of the adult population in the United States is obese or overweight (2). Therefore, determining safe and effective ways to improve respiration and avoid intubation in this population is critical. Continuous positive airway pressure (CPAP) by a helmet interface is a form of noninvasive respiratory support (NIRS) that delivers high airway pressure to increase lung aeration and oxygenation (3). The helmet is a clear, plastic hood that is placed over the head of a patient through a flexible rubber neck seal. In acute hypoxemic respiratory failure (AHRF), NIRS delivered via a helmet has been shown to be more effective compared with standard oxygen therapy (3, 4) and to NIRS delivery via a facemask in reducing intubation rate (5). Despite being used and studied in Italy for nearly 20 years, the helmet has not been widely adopted in the United States as an early treatment for AHRF. In addition, its effectiveness compared with high-flow nasal cannula (HFNC), a more commonly used NIRS device, is unknown, particularly in obese or overweight patients.

At the start of the COVID-19 pandemic, the University of Pennsylvania Health System purchased over 250 helmets from Sea Long Medical Systems, LLC (Waxahachie, TX). Helmets were modified with a spring-loaded positive end-expiratory pressure valve. Gas flow was delivered using a Venturi gas delivery system (MaxVenturi, Maxtec, Salt Lake City, UT) with room air humidification and a minimum flow of 50 L per minute (LPM) to reduce the inspiratory carbon dioxide concentration. In patients with confirmed COVID-19 infection or who were being ruled out for infection, our institutional guidelines were developed to use NIRS when a patient had a oxygen saturation less than 92%, or increased work of breathing, despite supplemental oxygen up to 6 LPM nasal cannula and move the patient to an airborne infection

isolation room. First-line therapies for NIRS involved either the helmet or HFNC based on the preference of the treating provider and respiratory therapist.

MATERIALS AND METHODS

To evaluate our experience using helmet CPAP compared with HFNC, we conducted a retrospective review of COVID-19 patients admitted to our ICUs within two academic urban hospitals (1,012 total hospital beds). We selected patients into this cohort with a body mass index greater than or equal to 25 kg/m² who had persistent hypoxemia (oxygen saturation < 92%) and who were candidates for NIRS according to our institutional guidelines. Patients were treated with either 1) CPAP (between 5 and 10 cm H₂O) delivered with the setup described above or 2) HFNC (between 40 and 60 LPM) with a heated humidifier (MR850; Fisher and Paykel Healthcare, Auckland, New Zealand). Patients on helmet therapy were provided breaks with intervening HFNC use, as needed during daytime and during hours of sleep. FIO₂ in both treatments was titrated to maintain oxygen saturation greater than or equal to 92%. Patients were continually monitored in an ICU and intubated based on provider decision and institutional recommendations. Based on our guidelines, patients with chronic hypoxemic respiratory failure and patients with hypercapnia were not candidates for helmet CPAP. While we have used helmet CPAP in patients with do not intubate orders, we excluded them from this analysis.

We collected information on baseline patient characteristics and laboratory and clinical variables nearest to the start of NIRS treatment. Our primary endpoint was intubation within 7 days of treatment. Secondary endpoints were mortality and ICU discharge at the time of study analysis. Standardized mean differences were used to compare the distribution of characteristics prior to treatment and we used the chi-square test and logistic regression to determine the association of respiratory support with intubation. We used *p* value of less than 0.05 to indicate statistical significance.

The University of Pennsylvania Institutional Review Board approved the study under expedited review.

RESULTS

Our study cohort included 59 patients with COVID-19 AHRF admitted to an ICU; 17 (28.8%) received helmet CPAP and 42 (71.2%) received HFNC. Patients who received helmet CPAP were more likely to be younger, male, and have diabetes mellitus (Table 1). The HFNC group had higher lymphocyte counts, D-dimers, and lower oxygen saturations prior to treatment; lactate and respiratory rate were comparable between groups.

In unadjusted analysis, three patients (17.7%) who received helmet CPAP required intubation compared with 22 patients (52.4%) who received HFNC (*p* = 0.01). Adjusting for age, helmet

Key Words: acute hypoxemic respiratory failure; coronavirus disease 2019; noninvasive respiratory support

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TABLE 1. Demographic, Laboratory, and Respiratory Variables for Obese and Overweight Adults Hospitalized With Acute Hypoxemic Respiratory Failure From Coronavirus Disease 2019

Baseline Variables	Total (n = 59)	Helmet Continuous Positive Airway Pressure (n = 17)	High-Flow Nasal Cannula (n = 42)	Standardized Mean Difference
Age, yr, mean (SD)	60 (15)	56 (15)	61 (16)	0.36
Male sex, n (%)	28 (47.5)	14 (82.3)	14 (33.3)	-1.12
Black race, n (%)	39 (66.1)	12 (70.6)	27 (64.3)	-0.13
Chronic kidney disease, n (%)	17 (28.8)	4 (23.5)	13 (31.0)	0.16
Diabetes mellitus, n (%)	21 (35.6)	8 (47.1)	13 (31.0)	-0.33
Hypertension, n (%)	35 (59.3)	11 (64.7)	24 (57.1)	-0.15
Body mass index, kg/m ² , mean (SD)	35.5 (8.6)	34.8 (7.8)	35.8 (9.0)	0.12
D-dimer, µg/mL, mean (SD)	4.0 (12.4)	2.0 (3.23)	4.88 (14.7)	0.27
Lymphocyte count, 10 ³ /µL, mean (SD)	0.88 (0.52)	0.79 (0.44)	0.92 (0.55)	0.26
Lactate, mmol/L, mean (SD)	1.7 (1.2)	1.8 (1.6)	1.7 (1.0)	-0.09
Respiratory rate, mean (SD)	27 (6)	27 (5)	27 (6)	-0.02
Oxygen saturation, mean (SD)	92 (4)	94 (4)	92 (5)	-0.63
Heart rate, mean (SD)	93 (19)	89 (21)	95 (18)	0.27

CPAP was associated with a decreased odds of intubation (odds ratio, 0.17; 95% CI, 0.04–0.70; $p = 0.01$). At the time of our study analysis, 94.1% of patients in the helmet CPAP group and 81.0% of patients in the HFNC group were alive; 12.5% and 31.3% were still in the ICU, respectively.

DISCUSSION

In this letter, we have described our early experience with using helmet CPAP and HFNC in obese or overweight patients with COVID-19 AHRF. While our results show a decreased frequency of intubation with helmet CPAP compared with HFNC in this population, they are insufficient to reach definitive conclusions owing to our small sample size and residual confounding that cannot be resolved within this observational analysis. Our results have provided needed preliminary data to an upcoming pragmatic clinical trial at our institution comparing helmet CPAP to HFNC in COVID-19 AHRF (NCT04381923). For example, the majority of our patients in this study did not receive an arterial blood gas analysis prior to initiating NIRS, preventing comparison of P_{aO_2}/F_{iO_2} as a measure of AHRF severity. Other indices of oxygenation that are more identifiable and routinely recorded in a clinical setting may be needed such as the ROX index which is defined as the ratio of oxygen saturation as measured by pulse oximetry/ F_{iO_2} to respiratory rate and has been previously validated within a prior randomized controlled trial of NIRS in AHRF (6). Furthermore, the use and duration of prone position were not consistently captured in our study cohort yet may have important effects on intubation and clinical outcomes and needs to be recorded in future trials. In our practice, we have not placed patients receiving helmet CPAP in the prone position and have rather allowed prone positioning to occur during breaks with HFNC.

This is the first described experience of helmet CPAP and HFNC treatment in obese or overweight patients with COVID-19 in the United States. While we are unable to provide definitive evidence regarding the effectiveness of either intervention, our experience may inform ongoing or planned trials on NIRS in COVID-19 AHRF.

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