A New Configuration for Helmet Continuous Positive Airway Pressure Allowing Tidal Volume Monitoring

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Authors' contribution:

AC: conceived the content of the study, collected the data, performed the analysis, wrote the manuscript and approved its final version.

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Continuous Positive Airway Pressure (CPAP) is a form of respiratory support which can improve oxygenation (1) limiting the risk of patient-ventilator asynchrony and delivery of high tidal volume (V_t) in spontaneous breathing patients with acute hypoxemic respiratory failure (AHRF). CPAP via helmet compared to face mask could reduce aerosolization of secretion to the environment and operators, increasing safety during viral respiratory infection outbreaks (2). Although mandatory when treating AHRF (3), V_t measurement via a helmet was previously not feasible due to its specific mechanical properties. We report the results of a bench and human study on a simple configuration for delivering helmet CPAP using a turbine-driven ventilator and accurately estimating (V_t), while limiting the unintentional leak.

We performed a bench and human study to test the hypothesis that a ventilator can accurately estimate Vt when a helmet is used in CPAP mode in a single limb configuration with an intentional leak port placed at the helmet expiratory port. We have recently demonstrated the effectiveness of this setup in bilevel mode (4).

The bench study was carried out using a lung simulator (LS - ASL 5000 Ingmar Medical, Pittsburgh, PA), in a restrictive condition (resistance 7.5 mH$_2$O/L/s, compliance 30 mL/cmH$_2$O; inspiratory muscle pressure -12 cmH$_2$O) and a modified mannequin head (Laerdal Medical AS, Stavanger, Norway). The helmet (CaStar, R Next, Intersurgical, Mirandola, Italy) inspiratory port was connected to the turbine-driven ventilator (Trilogy Evo ^{tm} Philips Respironics$^®$, Murrysville, Pa, USA) with dedicated software (version 1.03.01.00) via a single-limb circuit while the expiratory port was capped with a connector having a hole with a 5.5 mm internal diameter to allow the intentional leak (as indicated by the arrow in Figure 1). The ventilator was provided with a blender and a high oxygen pressure inlet. The setup was tested at

CPAP of 8, 10 and 12 cmH$_2$O. We avoided the unintentional leaks defined as any leak from the helmet collar in addition to the intentional leak from the expiratory port. The helmet was fixed to the mannequin head and sealed with tape. The ventilator monitoring system measured and displayed the overall leaks (intentional plus unintentional). Data were collected by the ventilator and lung simulator. Differences in V$_t$ between the ventilator and lung simulator were compared during the last 15 breaths of each trial to ensure the stability of the system (4).

After obtaining written informed consent, four healthy volunteers, 1 female, 3 males, mean age 32 ± 4 years, mean body weight 68 ± 10 kg were ventilated in CPAP 8 cmH$_2$O via a helmet (Castar, Next Intesurgical, size small or medium, Mirandola, Italy), using the same ventilator configuration used in the bench study. A mouthpiece was inserted in the volunteer's mouth and connected to a pneumotachograph (VT mobile Fluke, Germany) to measure the subject's airflow and V$_t$. A nose clip was used to avoid respiration through the nose apart from the pneumotachograph. Unintentional leaks were avoided by selecting the appropriate helmet size according to the measured size of the volunteer's neck. Data were collected by the ventilator and by the pneumotachograph. V$_t$ and respiratory rate were collected over 2 minutes. Differences in V$_t$ between the ventilator's measurement and pneumotachograph results were recorded during the last 10 breaths of each trial.

In both the bench and human studies the ventilator was set in Auto-Trak mode to avoid auto-triggering and all V$_t$ measurements were collected at body temperature and pressure, saturated water vapor (BTPS) conditions. We used two antimicrobial filters placed on the helmet ports (**Figure 1**).

Data are expressed as mean ± standard deviation (SD) or as median and interquartile range (IQR), as appropriate. Bland-Altman graphs were used to plot the differences between the V_t from the ventilator and lung simulator against the average of the two measurements. We used Prism 7 (GraphPad Software; San Diego, CA) and Microsoft Excel (version 2013; Microsoft Corporation, Redmond, CA).

Figure 2 shows the Bland-Altman plot showing the agreement between the V_t measured by the ventilator and lung simulator. The overall bias was -2.5 ml (95% Level of Agreement – LoA; -8.6 ml to 3.7). The effect of the CPAP level on the agreement seemed to be negligible since the percent differences in V_t measured by ventilator and the lung simulator were 1.3% (±0.5), 1%(±0.3) and 0% (±0.4) at 8, 10 and 12 cmH$_2$O respectively.

The amount of overall leaks (intentional plus unintentional) in the bench study was 38.7 L/min (IQR 38.5-38.9) at 8, and 43.6 L/min (IQR 43.5-43.9) at 10, 48.6 L/min (IQR 48.5-48.8) at 12 cmH$_2$O. Percent differences in V_t measured by the ventilator and the pneumotachograph for the four healthy volunteers was -2.5% (±12), -5% (±3.5), 1% (±11), -6 (±6) respectively. In the healthy volunteers, median values of overall leaks (intentional plus unintentional) were 37.7 L/min (IQR, 37.1 to 38.3).

 For the first time, we demonstrated the ability of a ventilator to estimate inspired V_t during helmet CPAP mode. ICU ventilators in pressure support modes (with or without PEEP) failed to monitor V_t accurately due to the distension of the helmet and poor estimation of the unintentional leak. The accurate measurement of V_t is clinically important to employ protective lung ventilation. Reliable monitoring of V_t during helmet CPAP can help the clinician to recognize a worsening of the patient's

respiratory drive or respiratory compliance in an early phase (3)(5). Of note, helmet CPAP can be delivered for longer periods with a lower risk of skin breakdown and with higher comfort compared to face masks. The proposed configuration also discourages additional carbon dioxide rebreathing, in comparison to helmet CPAP using two-limb ICU ventilators (6).

We did not measure aerosolization. Unintentional leaks can contaminate the environment since contain exhaled air from the patient and do not pass through the filter. They were absent during the bench study due to the designed setup and they were negligible in the human study. Thus, the overall leaks measured by the ventilator's display were reflecting only the intentional leaks. Further testing, especially related to aerosolization, is needed in clinical setting. This configuration may be eventually useful to deliver CPAP in patients with viral infections such as COVID-19 patients (7). We used a specific ventilator in our study and anticipate that results may vary with ventilators from different sources but this algorithm may be shared with other ventilator makers. We used intentional leaks from a connector having a hole with a 5.5 mm internal diameter. Although already published (4), this port has not been previously validated clinically.

One of the authors (Dr. Gregoretti) was part of an international board that participated in the manufacturing process of the EVO ventilator. Although we received help from a manufacturer expert in the development of ventilator algorithm, the authors were responsible for conception, data collection and interpretation and the writing of this manuscript.

Disclosures: Dr. Cortegiani, Dr. Accurso, Dr. Giarratano and Dr. Gregoretti declare a patent pending, in association with the University of Palermo - Italy (N°

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Figure Legends

Figure 1. Picture of the proposed helmet CPAP configuration. A mannequin head is wearing a continuous positive airway pressure (CPAP) helmet (A). The helmet inspiratory port (B) is connected to the turbine-driven ventilator (C) in intentional leak configuration via a single-limb circuit (D) with antimicrobial filter (E). The expiratory port (F) is equipped with an antimicrobial filter (G) capped with a connector having a hole of internal diameter 5.5 mm to allow the intentional leak as indicated by the arrow.

Figure 2. Bland-Altman plot of the differences (y-axis) versus average of tidal volumes (in ml – x-axis) measured by the turbine-driven ventilator and the lung simulator in the restrictive pattern conditions. Volume data are reported in ml. The different conditions of continuous positive airway pressure (CPAP) are reported in cmH_2O. X-axis: average of the two measurements; Y-axis: difference between measurements. Bias: Average of the differences between measurements. 95% Limits of agreement: ± 1.96 standard deviation of the bias.

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Figure 2