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Not too much, not too little. Titrating flow rate to minimise inspiratory effort during helmet CPAP: A bench study

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ABSTRACT

Background: Non-invasive helmet respiratory support is suitable for several clinical conditions. Continuous-flow helmet CPAP systems equipped with HEPA filters have become popular during the recent Coronavirus pandemic. However, HEPA filters generate an overpressure above the set PEEP.

Methods: A lung simulator was used to mimic patient respiratory mechanics and effort. Compared to room air spontaneous breathing, the additional inspiratory effort attributable to helmet CPAP ($\Delta P_{\text{musHelmet}}$) was recorded at different continuous-flow rates (30-150 L/min), PEEP levels (5, 10, 12.5 cmH₂O) and respiratory rates (15, 20, 25, 30 breaths/minute), both with and without a HEPA filter at the outlet port.

Results: Helmet pressure swings during inspiration largely explained $\Delta P_{\text{musHelmet}}$ variations ($p < 0.001$, Spearman's $\rho = 0.964$). The lowest $\Delta P_{\text{musHelmet}}$ levels (0.2 [0; 0.4] cmH₂O) were frequently recorded (>70%) at a 90 L/min flow rate. Higher $\Delta P_{\text{musHelmet}}$ levels were recorded when the continuous-flow was lower than the peak inspiratory flow (3.7 [3.1; 5.6] cmH₂O, $p < 0.001$) or when a HEPA filter was used (2.7 [2.2; 3.5], $p < 0.001$). Increasing the flow rate resulted in higher overpressure levels, particularly with a HEPA filter ($p < 0.001$). Overpressure levels correlated with $\Delta P_{\text{musHelmet}}$ ($p < 0.001$, Spearman's $\rho = 0.598$).

Conclusions: Helmet pressure swings below PEEP lead to additional inspiratory efforts. The HEPA filter acts as a flow resistor, generating an overpressure leading to increased respiratory effort. The continuous-flow rate should be titrated high enough to slightly exceed the peak inspiratory flow; however, further flow increase is not recommended as it leads to an increase in overpressure and helmet pressure swings below PEEP.

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KEYWORDS

Continuous flow helmet CPAP respiratory support; circuit resistance; flow resistor; mechanical PEEP valve; inspiratory effort


Introduction

Helmets are one of the available interfaces to provide non-invasive respiratory support. Helmets were widely employed to provide either continuous positive airway pressure (CPAP) or positive pressure ventilation during the recent Coronavirus pandemic, and their use has been associated with reduced mortality.¹⁻³ During continuous-flow helmet CPAP, an air/oxygen mixture flows through the helmet removing the patient's CO₂ and exits through a positive end-expiratory pressure (PEEP) valve generating the CPAP effect at the desired PEEP level.⁴ If patient isolation is necessary, a high efficiency particulate air (HEPA) filters is placed between the helmet outlet port and the PEEP valve.⁵⁻⁷ However, the filter increases the resistance of the circuit's expiratory branch, generating a pressure above the set PEEP level valve (overpressure), which is proportional to flow.⁸

The pressure within non-invasive CPAP interfaces is not perfectly constant, but it oscillates around the set PEEP level, particularly during strong respiratory efforts.^{9,10} Pressure drops below PEEP within the helmet ($\Delta P_{\text{PressureHelmet}}$) might be associated with increased inspiratory efforts ($\Delta P_{\text{musHelmet}}$), as suggested by a recent report.¹¹ We reasoned that helmet pressure fluctuates due to (1) an insufficient continuous-flow

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as compared to the patient's inspiratory peak flow (flow deficit), leading to a transient complete closure of the PEEP valve associated with a temporary helmet volume reduction and thus a helmet pressure drop; (2) an unnecessary flow (flow excess) coupled with a relevant resistance of the expiratory limb leading to an unsteady overpressure: helmet pressure drops depend on overpressure levels drops caused by the reduction of the outflow during inspiration.

We therefore tested a bench model of spontaneous breathing during continuous-flow helmet CPAP, under different conditions of continuous-flow levels, PEEP and respiratory rate with the addition of a HEPA filter as a variant. We hypothesised that higher $\Delta\text{Pressure}_{\text{Helmet}}$ levels lead to increased $\Delta\text{P}_{\text{mus}_{\text{Helmet}}}$ levels; minimal inspiratory $\Delta\text{Pressure}_{\text{Helmet}}$ levels can be obtained by continuous-flow titration to avoid both flow deficit and flow excess, resulting in minimal $\Delta\text{P}_{\text{mus}_{\text{Helmet}}}$ levels.

Methods

Continuous-flow Helmet CPAP therapy was simulated using a standard CPAP helmet (Starmed CPAP Helmet, Intersurgical, Italy). A gas flow regulator (Flow-meter, Levate, Italy) was used to generate the continuous-flow, while fixed mechanical PEEP valves (Whisperflow Respironics, Murrysville PA, USA) were used to maintain CPAP. An active patient simulator (ASL 5000, Ingmar Medical, Pittsburgh PA, USA) reproduced spontaneous breathing. The patient simulator was connected to the head model by a 30 cm long corrugated tube. The simulated lung compliance and airway resistance were set at 50 ml/cmH₂O and 5 cmH₂O/L/s, respectively; the respiratory pattern was set at 20% inspiratory rise time, 5% inspiratory hold time, 10% inspiratory release time and 10% pause time. Pressure levels within the helmet were continuously recorded by an analog acquisition system (PowerLab, ADInstruments, Dunedin, New Zealand) and analysed with dedicated software (Labchart, ADInstruments, Dunedin, New Zealand), recording the median values of three consecutive respiratory cycles at each step (Figure 1).

The inspiratory muscle pressure (P_{mus}) needed to obtain a tidal volume of 500 ± 10 mL without the helmet was recorded at 15, 20, 25 and 30 breaths per minute to resemble spontaneous breathing without respiratory support. After wearing the helmet on the model head, P_{mus} levels were recorded for each respiratory rate at continuous-flow 30, 60, 90, 120, 150 L/min and PEEP 5, 10, 12.5 cmH₂O. Finally, a HEPA

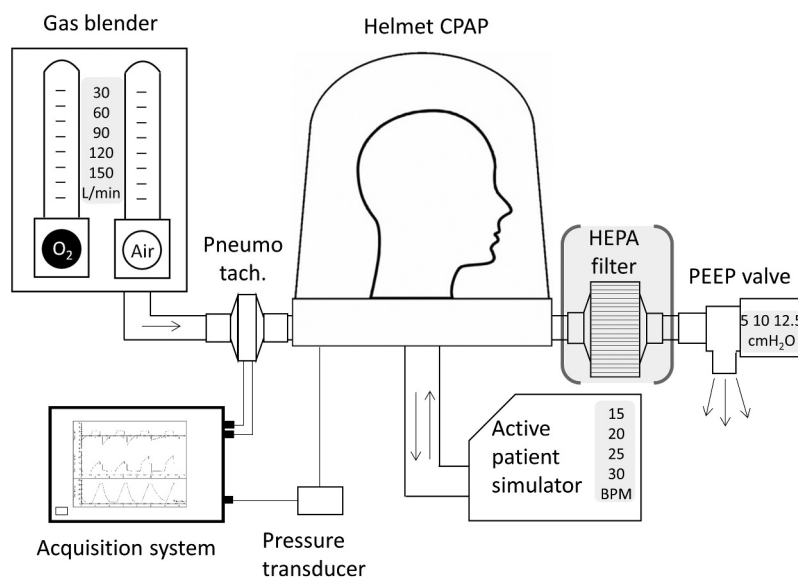


Figure 1. Schematic representation of the bench model used to simulate non-invasive helmet CPAP respiratory support. Different combinations of continuous-flow rates, PEEP levels and respiratory rates were studied while maintaining a constant tidal volume of 500 mL at the active lung simulator by inspiratory pressure titration, both with and without a HEPA filter (in light grey parentheses).

filter (Gibeck Isogard Hepa light, Teleflex, Wayne PA, USA) was connected between the helmet and the PEEP valve to increase circuit resistance and the protocol was repeated.

$\Delta P_{\text{mus}}_{\text{Helmet}}$ was defined as the difference between the P_{mus} necessary to achieve the target tidal volume under each condition and the P_{mus} measured in condition of simulated spontaneous breathing (i.e.: no helmet) at the same respiratory rate. Flow_{gap} was defined as the difference between the set continuous flow and the peak inspiratory flow generated by the simulator, with negative values indicating a flow deficit and positive values a flow excess.

$\Delta P_{\text{Pressure}}_{\text{Helmet}}$ was defined as the difference between the pressure level recorded in the helmet in the absence of respiratory activity (PEEP) and the lowest pressure reached during the inspiratory cycle. Overpressure levels were calculated as the difference between the measured PEEP level and the PEEP level recorded in the same condition at 30 L/min (Figure S1 in Supplementary material).

Statistical analysis

The Kolmogorov–Smirnov test was used to assess the variables' normality. Data are presented as median [25th and 75th percentiles] except for the Bland-Altman analysis, where mean \pm SD was used.¹² Correlations were evaluated by the Spearman's Rho correlation coefficient. Group differences were identified by the chi-squared test.

Repeated measures analyses were performed using the Generalised Estimating Equations command (GEE), considering the 12 combinations of three PEEP levels by four respiratory rates as different subjects. Depending on the analysis, the factors explored were the presence of a flow deficit condition, continuous-flow rates, and the presence of a HEPA filter leading to increased circuit resistance. IBM SPSS 28.0 was used for data analysis, while SigmaPlot 11.0 was used for graphics and post-hoc analyses.

Results

The median peak inspiratory flow was 54.5 [41.7; 66.2] L/min, resembling a patient in moderate distress. A flow deficit ($\text{Flow}_{\text{gap}} < 0$ L/min) occurred in 15 (25%) of the 60 combinations of PEEP, continuous-flow and respiratory rate: always at flow 30 L/min and in 25% of the combinations (3/12) at flow 60 L/min.

Maximum $\Delta P_{\text{Pressure}}_{\text{Helmet}}$ was 7.0 cmH₂O, occurring at 30 L/min continuous-flow; $\Delta P_{\text{Pressure}}_{\text{Helmet}}$ and $\Delta P_{\text{mus}}_{\text{Helmet}}$ levels closely correlated ($p < 0.001$, Spearman's Rho = 0.964, regression equation: $\Delta P_{\text{mus}}_{\text{Helmet}} = 1.01 * \Delta P_{\text{Pressure}}_{\text{Helmet}} - 0.24$, Figure 2). The regression coefficient close to identity and the negligible intercept indicated that helmet pressure drop and additional inspiratory effort can be considered equal. The Bland-Altman analysis showed a bias of -0.21 ± 0.4 cmH₂O (Figure S2 in Supplementary material).

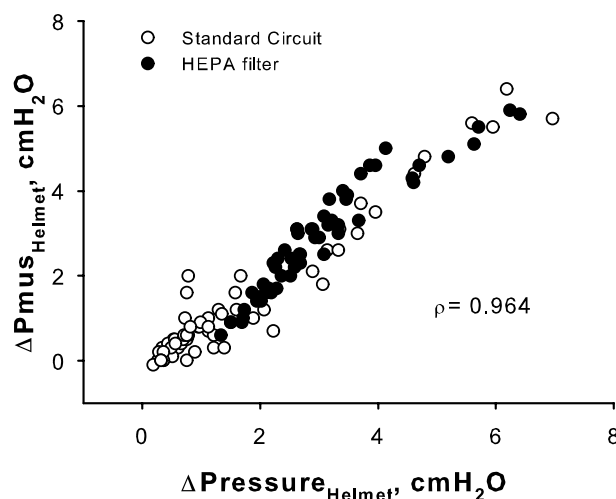


Figure 2. Helmet pressure drops lead to additional inspiratory effort. Helmet pressure drop ($\Delta P_{\text{Pressure}}_{\text{Helmet}}$) closely correlated with the additional inspiratory effort attributable to helmet CPAP respiratory support ($\Delta P_{\text{mus}}_{\text{Helmet}}$).

Standard helmet CPAP circuit (no HEPA filter)

$\Delta P_{\text{mus}_{\text{Helmet}}}$ levels were influenced by continuous-flow rates with a U-shaped trend ($p < 0.001$, Figure 3) but not by PEEP levels ($p = 0.327$). Minimal $\Delta P_{\text{mus}_{\text{Helmet}}}$ levels were often recorded (>70%) at 90 L/min ($p < 0.001$; median value 0.2 [0; 0.4] cmH₂O), corresponding to continuous-flow rates close to inspiratory peak flows ($\text{Flow}_{\text{gap}} = 27$ [22; 39] L/min).

$\Delta P_{\text{mus}_{\text{Helmet}}}$ levels were low when continuous-flow rates matched or exceeded inspiratory flows but resulted relevant in flow deficit conditions (0.8 [0.5; 1.1] vs. 3.7 [3.1; 5.6] cmH₂O, $p < 0.001$). Accordingly, $\Delta P_{\text{mus}_{\text{Helmet}}}$ levels were highest in flow deficit conditions (3.5 [2.6; 5.5] cmH₂O) and inversely correlated with Flow_{gap} ($p < 0.001$, Spearman's Rho = -0.813, Figure 4, panel A). The lowest $\Delta P_{\text{mus}_{\text{Helmet}}}$ levels were recorded when the flow rate matched the inspiratory flow; $\Delta P_{\text{mus}_{\text{Helmet}}}$ levels tended to a slight but significant increase in the case of flow excess ($p = 0.049$, Spearman's Rho = 0.295).

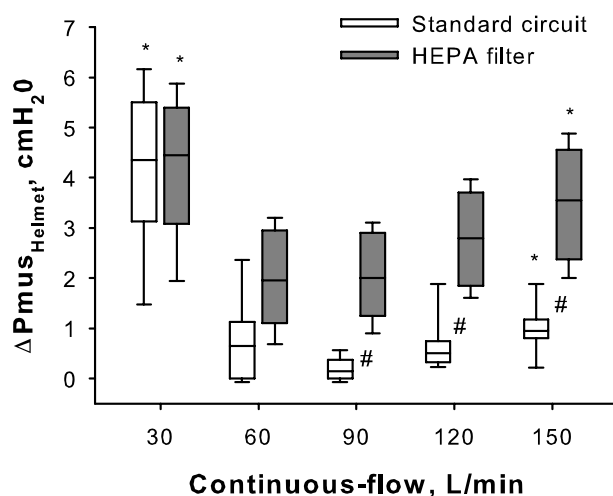


Figure 3. The additional inspiratory effort during helmet CPAP support depends on continuous-flow rate. Distribution of the additional inspiratory pressure attributable to the helmet as compared to spontaneous breathing ($\Delta P_{\text{mus}_{\text{Helmet}}}$) at different continuous-flow rates, with or without a HEPA filter at the outlet port (filled and empty boxes, respectively). Note the U-shape of the phenomenon, with minimal inspiratory efforts close to 90 L/min. $\Delta P_{\text{mus}_{\text{Helmet}}}$ levels were higher at 30 and 150 L/min as compared to 90 L/min (asterisks indicate $p < 0.05$ by Tukey Test) both with a standard circuit and after adding a HEPA filter; hashtags indicate a significant difference at the same constant-flow level comparing the standard circuit with the HEPA filter circuit.

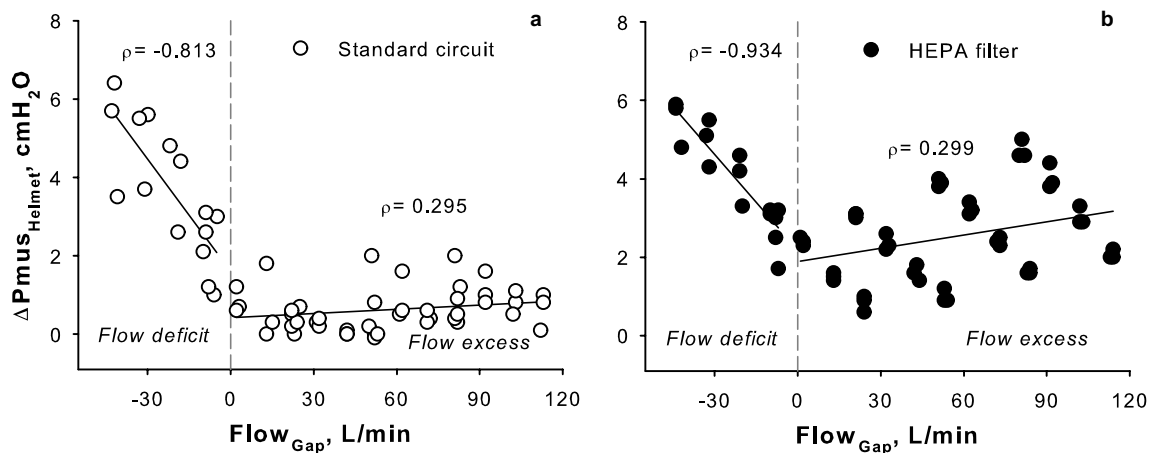


Figure 4. Additional inspiratory efforts are due to flow deficit and flow-dependent overpressure. Inspiratory effort ($\Delta P_{\text{mus}_{\text{Helmet}}}$) was increased when continuous flow was lower than the peak inspiratory flow (flow deficit). When continuous-flow was raised (flow excess) with a standard helmet circuit, $\Delta P_{\text{mus}_{\text{Helmet}}}$ ranged into clinically acceptable values (panel a). Instead, the presence of a HEPA filter at the helmet outlet port led to higher inspiratory efforts in condition of flow excess (panel b).

Using a standard circuit, overpressure levels at end expiration slightly increased with increasing flow rates ($p < 0.001$, Figure S3 on the Supplementary material, empty circles). In conditions of flow excess, $\Delta P_{\text{mus}_{\text{Helmet}}}$ correlated with overpressure levels ($p = 0.019$, Spearman's $Rho = 0.348$); however, overpressure was low (median values approximately 1 cmH₂O at 90 L/min) as well as $\Delta P_{\text{mus}_{\text{Helmet}}}$ absolute values (0.5 [0.2; 0.8] cmH₂O).

Increased circuit resistance (with HEPA filter)

When a HEPA filter was added, minimal $\Delta P_{\text{mus}_{\text{Helmet}}}$ levels were recorded either at 60 or 90 L/min (47% and 53% of the times, respectively; $p < 0.001$ by chi-squared test) and resulted higher than with the standard circuit (1.9 [1; 2.8] vs. 0.2 [0; 0.4] cmH₂O; $p < 0.001$).

In condition of flow deficit, $\Delta P_{\text{mus}_{\text{Helmet}}}$ levels did not differ as compared to the standard circuit (4.2 [3.1; 5.1] vs. 3.5 [2.6; 5.5] cmH₂O, respectively; $p = 0.204$) and correlated with flow deficit levels ($p < 0.001$, $Rho = -0.934$, Figure 4, panel B). When the flow rate was raised above the peak inspiratory flow, $\Delta P_{\text{mus}_{\text{Helmet}}}$ correlated with flow excess ($p = 0.004$, $Rho = 0.417$), showing levels higher than with a standard circuit (2.6 [2.1; 3.2] vs. 0.8 [0.5; 1.1] cmH₂O, $p < 0.001$). Similarly, $\Delta P_{\text{mus}_{\text{Helmet}}}$ levels resulted much higher with the HEPA filter than without (2.4 [1.6; 3.2] vs. 0.5 [0.2; 0.8] cmH₂O; $p < 0.001$) and positively correlated with Flow_{gap} ($p = 0.046$, $Rho = 0.299$). While $\Delta P_{\text{mus}_{\text{Helmet}}}$ did not differ among the three PEEP levels, its levels correlated with respiratory rates ($p < 0.001$, $Rho = 0.822$).

As expected, overpressure levels at end expiration were higher with the HEPA filter than without ($p < 0.001$, Figure S3 Supplementary material); overpressure progressively increased when increasing the continuous-flow levels ($p < 0.001$ for interaction between the presence of filter and flow levels), up to levels close to 9 cmH₂O at 150 L/min. Overpressure levels generated in conditions of flow excess correlated with $\Delta P_{\text{mus}_{\text{Helmet}}}$ ($p < 0.001$, Spearman's $Rho = 0.598$; regression coefficient = 0.32). Such correlation resulted even more tight when considering separately the different respiratory rates (Rho ranging from 0.781 to 0.946, Figure 5): the inspiratory load due to overpressure resulted heavier at higher respiratory rates, as indicated by the multiple regression analysis, showing a correlation between $\Delta P_{\text{mus}_{\text{Helmet}}}$ and both overpressure and respiratory rate ($p < 0.001$ for both).

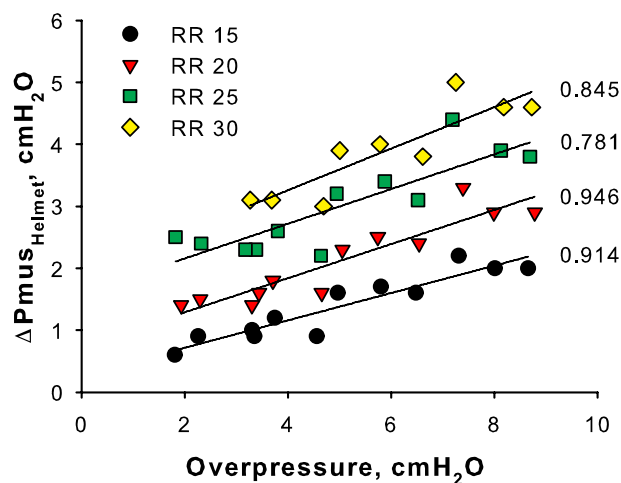


Figure 5. Overpressure leads to additional inspiratory effort, particularly at higher respiratory rates. Overpressure levels generated by the presence of a HEPA filter at the helmet outlet port correlated with increased inspiratory efforts ($\Delta P_{\text{mus}_{\text{Helmet}}}$) when continuous-flow exceeded the peak inspiratory flow ($p < 0.001$, Spearman's $Rho = 0.598$). The inspiratory load due to overpressure increased at higher respiratory rates (RR). Spearman's Rho correlation coefficients are reported for each respiratory rate.

Discussion

In a bench simulation of helmet CPAP respiratory support, we showed that helmet pressure drops correlated with additional inspiratory effort. Insufficient continuous-flow led to the highest inspiratory efforts: increasing the flow rate to match the peak inspiratory flow progressively reduced inspiratory efforts. However, once the continuous-flow exceeded the peak inspiratory flow, inspiratory efforts progressively started to increase together with overpressure, particularly when a HEPA filter was placed at the helmet outlet port.

Recently, Giosa et al. reported helmet pressure drops of 3 cmH₂O during helmet CPAP respiratory support in early COVID-19 patients.¹¹ We recorded similar pressure drops when continuous-flow rates did not match the peak inspiratory flow or when relevant overpressure was present due to increased respiratory circuit resistance. In COVID-19 patients both conditions may have occurred simultaneously: the use of a HEPA filter has been advocated to minimise ambient contamination; at the same time, the respiratory pattern characterised by hyperpnoea, associated with a preserved compliance of the respiratory system typical of early COVID-19, predisposes to a condition of flow deficit.^{13,14} In addition, we also showed that when flow rates are titrated to match the peak inspiratory flow and a standard circuit is used, helmet pressure is fairly stable despite a relevant minute ventilation.

The same authors also suggested a possible association between helmet pressure drops and increased respiratory efforts. We confirm this hypothesis, demonstrating that helmet pressure drops closely correlate with the additional inspiratory effort necessary to maintain a stable tidal volume regardless of the underlying mechanism (flow deficit or overpressure), or the configuration of the respiratory circuit (with or without a HEPA filter). However, we also showed that the additional inspiratory workload is clinically negligible when optimal helmet settings are chosen, which typically occurred at a flow level of 90 L/min without a HEPA filter. Therefore, monitoring pressure swings appears crucial to guide the optimisation of helmet respiratory support, particularly in the choice of the optimal flow level. Of note, this can be accurately and easily assessed by using a customised manometer placed on the helmet plastic bag at bedside.⁸

We showed that the flow deficit condition led to the highest respiratory load increase. The detrimental effects of a closed CPAP system fed by an insufficient flow were described many years ago in intubated patient. At that time, it appeared clear that the combination of an adequate flow and a volume reservoir could reduce the patient's inspiratory work.¹⁵ Thanks to such previous knowledge, experienced clinicians now actively prevent a flow deficit condition to provide a sufficient helmet CO₂ washout and to maintain the pressure stable within the helmet, often monitoring helmet pressure drops to identify patients requiring higher continuous-flow rates. Based on our bench data, a flow rate of 90 L/min seems to be optimal during continuous-flow helmet CPAP respiratory support, corresponding to negligible additional respiratory efforts due to the helmet interface.

We also demonstrated that the presence of overpressure increased the respiratory workload. Such supra-basal pressure was already described in CPAP systems, due to poorly performing PEEP valves or to a HEPA filter placed at the helmet outlet port.^{8,16,17} While there is sufficient knowledge about the negative effects of a helmet working with an insufficient flow level, we believe that the effects of an excessive flow coupled with increased circuit resistance are still to be acknowledged in clinical practice, notwithstanding the notion that the work of breathing is increased by expiratory circuit resistance.¹⁸ In our bench study, the increased inspiratory effort resulted dimensionally close to one-third of the measured overpressure level, reaching clinically relevant levels only when a HEPA filter was added to the expiratory circuit. When a concern of airborne contamination from the patient is not present, we suggest not using any filter due to the unavoidable increase in the patient's respiratory load associated with an increased expiratory circuit resistance. If a HEPA filter is necessary, high flow rates should be avoided: the correct balance between sufficient flow and minimal overpressure should be identified by titrating the flow rates to obtain the lowest helmet depressurisation, rarely exceeding a flow rate of 90 L/min. As a corollary, our study emphasises that the choice of the PEEP valve is crucial; PEEP valves from different manufacturers may act as flow-resistors rather than threshold-resistors, leading to clinically relevant overpressure occurring even without a HEPA filter within the circuit.^{16,17}

Based on our data, two observations may be relevant for clinical practice. First, the increased inspiratory effort due to overpressure did not depend on the set PEEP level. Therefore, the suggestion of reducing the PEEP level to revert the negative effects of overpressure is only partially true:

the total pressure is certainly reduced and lung hyperinflation may be prevented, but the additional inspiratory load does not change because the overpressure fluctuations during inspiration remain unchanged. Second, increasing the continuous-flow rate in order to minimise helmet pressure swings may not always be appropriate, especially in patients with both high respiratory rate and a high expiratory circuit resistance (i.e., HEPA filter) that produces overpressure. In such patients, the increased peak inspiratory flows due to shorter inspiratory times result in a more pronounced reduction of overpressure levels during inspiration and a corresponding increased inspiratory load. Therefore, an earlier failure of non-invasive respiratory support might occur when an excessive continuous-flow is used to treat a tachypneic patient.

The main limitation of our study is that data are collected in a bench setting with a specific equipment. The use of a lung simulator was necessary to focus on inspiratory pressure levels while maintaining a constant tidal volume with repeatable inspiratory patterns at different flow rates. Regarding the equipment, we opted for a real-life system based on low-resistance, high performance fixed mechanical PEEP valves, but different equipment may lead to markedly different results.

Conclusions

In a bench model, the additional inspiratory effort attributable to helmet CPAP respiratory support is negligible, provided that optimal continuous-flow rates and a circuit with low resistance are used. If helmet pressure drops, the inspiratory effort increases by a similar amount to maintain a stable tidal volume. When helmet pressure drops because of a continuous-flow rate lower than the peak inspiratory flow, the flow rate should be increased to reduce the inspiratory effort. Conversely, the continuous-flow should be reduced when a flow-dependent overpressure is generated by increased circuit resistance, as in the case of a HEPA filter placed at the outlet port. Minimal helmet pressure drops could be used to identify the optimal flow rate.

Disclosure statement

AC and GB are co-inventors of a patent owned by Flowmeter for a project unrelated to the present work. AC and GF are co-inventors of a patent owned by Dimar for a project unrelated to the present work. GB has relationships with Drager Medical, Getinge, and Siaretron. GF received lecture fees by Dimar. GB and GF received research funds from Dimar for a project unrelated to the present work. AL received reimbursement for congress fees from DIMAR. RF, AN, AR, ER have no competing interest to declare. ER has relationships with Draeger Medical, BURKE&BURKE and PALL outside of the present work.

Authorship

Study design: AC and GF; data acquisition: AC, RF, AN, AR and ER; analysis and interpretation of data: AC, AL, GB, ER and GF; article draft: AC, ER and GF; article critical revision for important intellectual content: RF, AN, AR, AL, GB, ER; AC, RF, AN, AR, AL, GB, ER, GF approved the final version of the article.

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