Physiologic Evaluation of Different Levels of Assistance During Noninvasive Ventilation Delivered Through a Helmet*

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Objective: To evaluate the effects of various levels of pressure support (PS) during noninvasive ventilation delivered through a helmet on breathing pattern, inspiratory effort, CO₂ rebreathing, and comfort.

Design: Physiologic study.

Setting: University-affiliated hospital.

Patients and participants: Eight healthy volunteers.

Interventions: Volunteers received ventilation through a helmet with four different PS/positive end-expiratory pressure combinations (5/5 cm H₂O, 10/5 cm H₂O, 15/5 cm H₂O, and 10/10 cm H₂O) applied in random order.

Measurements and results: The ventilatory respiratory rate, esophageal respiratory rate (RRpes), airway pressure, esophageal pressure tracings, esophageal swing, and pressure-time product (PTP) [PTP per breath, PTP per minute, and PTP per liter] were evaluated. We also measured the partial pressure of inspired CO₂ (PiCO₂) at the airway opening, mean partial pressure of expired CO₂ (PeCO₂), CO₂ production (V˙CO₂), minute ventilation (V˙E) delivered to the helmet (V˙Eh), and the true inspired V˙E. By subtracting V˙E from V˙Eh, we obtained the V˙E washing the helmet (V˙Ewh). A visual analog scale (from 0 to 10) was used to evaluate comfort. Compared to spontaneous breathing, different levels of PS progressively increased tidal volume (VT) and decreased RRpes, reducing inspiratory effort. The increased levels of assistance did not produce significant changes in PiCO₂, end-tidal CO₂, and V˙CO₂. PeCO₂ had a slight decrease when increasing the level of PS from 5 to 10 cm H₂O (p < 0.05). Despite the presence of constant values of V˙E, the increase of PS produced an increase in V˙Ewh, without significant differences comparing 10 cm H₂O and 15 cm H₂O of PS. The subjects had a slight but not significant increase in discomfort by augmenting the level of assistance. At the highest level of PS (15 cm H₂O), the discomfort was significantly higher (p < 0.001) than at the other levels of assistance.

Conclusion: In volunteers, the helmet is efficient in ventilation, allowing a VT increase and RRpes reduction. A significant discomfort was present only at the highest level of assistance; however, it did not affect patient/ventilator interaction.

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Key words: CO₂ rebreathing; helmet; mechanical ventilation; noninvasive ventilation; positive end-expiratory pressure

Abbreviations: CPAP = continuous positive airway pressure; NIV = noninvasive ventilation; PeCO₂ = partial pressure of expired CO₂; PEEP = positive end-expiratory pressure; Pes = esophageal pressure; PiCO₂ = partial pressure of inspired CO₂; PS = pressure support; PSV = pressure support ventilation; PTP = pressure-time product; RRvent = ventilatory respiratory rate; RRpes = esophageal respiratory rate; VAS = visual analog scale; V˙CO₂ = CO₂ production; V˙E = minute ventilation; V˙Eh = minute ventilation delivered to the helmet; V˙Ewh = minute ventilation washing the helmet; VT = tidal volume

Noninvasive ventilation (NIV) reduces the need for endotracheal intubation,1–5 decreases the frequency of infections,6–7 and may improve the survival rate of patients with acute respiratory failure.1–5 A considerable effort has been made in the last 5 years to improve devices and tolerance.8–12

The choice of the interface is one of the crucial issues affecting NIV outcome.11–12 New interfaces have been introduced with the aim of improving patient comfort. The helmet is one of the newest interfaces that can reduce several side effects of NIV—skin necrosis, conjunctivitis, eyes irritation, and gastric distension13–15—and improve tolerance in both adult and pediatric patients.16 Despite these
advantages, the helmet has specific drawbacks, primarily related to its large volume and to its highly compliant soft collar. Inspiratory pressure dissipation may increase the time lag between inspiratory effort and ventilatory assistance, with a further impairment of ventilator functioning. Moreover, due to its large volume, a certain amount of CO₂ rebreathing may be present. Some authors have proposed that during continuous positive airway pressure (CPAP), CO₂ rebreathing depends on interface volume, CO₂ production (VCO₂), and the flow of gases flushing through the helmet. It has been recently demonstrated that in normal subjects receiving NIV, the CO₂ concentration was slightly higher with the helmet than with the mask.

However, most studies analyzed helmet effects only during CPAP, or by applying a single level of pressure support (PS) and positive end-expiratory pressure (PEEP), while the effects of incremental PS and PEEP both on pressurization time and impairment of ventilator functioning were never investigated. The aim of the present physiologic study was to evaluate breathing pattern, inspiratory effort, CO₂ rebreathing, and comfort in healthy volunteers receiving NIV with a helmet at various levels of PS and PEEP.

**Materials and Methods**

The protocol was approved by our institutional review board, and written informed consent was obtained from each subject. NIV was delivered through a helmet equipped with a soft inner inflatable cushion for dead space reduction (CaStar Starmed; Starmed; Mirandola, Italy) [Fig 1] using an ICU ventilator (EVITA 4; Dräger Medical; Lübeck, Germany) set in PS ventilation (PSV) mode. The fraction of inspired oxygen was set at 0.21, and the inspiratory trigger threshold was set at 2 L/min, checking the absence of the autotriggering phenomena.

**Study Protocol**

We studied eight white, healthy volunteers, naïve to NIV, in a semirecumbent position and in a quiet environment. The subjects (two women and six men; age range, 24 to 28 years; mean, 25.38 ± 1.30 years [± SD]) were all nonsmokers and had a body mass index ranging from 18 to 24.6 kg/m² (mean, 22.9 ± 2.9 kg/m²). Before initiating the study, a latex balloon-tipped catheter was placed in the middle third of the esophagus, and its proper positioning was checked by an occlusion test. After 20 min of spontaneous unassisted breathing, all of the subjects underwent five NIV trials (20-h each), applied in random order, with four different PS/PEEP combinations (5/5 cm H₂O, 10/5 cm H₂O, 15/5 cm H₂O, and 10/10 cm H₂O). The third trial (PS/PEEP at 10/5 cm H₂O) was performed twice, with and without the cushion inflated. The other trials were carried out leaving the cushion deflated.

**Equipment**

The airflow delivered by the ventilator to the helmet during the inspiratory phase was measured with a pneumotachograph (Fleisch No. 2; Metabo; Epalinges, Switzerland) positioned at the distal end of the inspiratory limb of the circuit (Fig 2). The airway pressure at the inspiratory limb of the circuit was measured by a pressure transducer with a differential pressure of ±1 cm H₂O (Digima Clic-1, ICU-Lab System; KleisTEK Engineering; Bari, Italy) placed distally to the pneumotachograph. Esophageal pressure (Pes) was measured by an esophageal catheter connected to a pressure transducer (Digima Clic-1, ICU-Lab System; KleisTEK Engineering). The signals were amplified, low-pass filtered, digitized at 100 Hz, and stored in a personal computer for further analysis. The last 5 min of each trial were averaged and used for further data analysis (ICU Lab 2.1; KleisTEK Engineering).

The airflow at the mouth and the partial pressure of inspired CO₂ (PICO₂) were measured at the airway opening using a small mouthpiece, including a flow and a capnographic sensor (CO₂SMO Plus model S100; Novametrix Medical Systems; Wallingford, CT). This device was positioned under the helmet soft cushion, before initiating the study, and held in the mouth by the subjects during the last 5 min of each trial. The presence of air leaks was carefully avoided by sealing the collar to the neck with Parafilm (Pechiney Plastic Packaging; Neenah, WI). The obtained measurements were analyzed by dedicated software (Analysis Plus; Novametrix Medical Systems). The tidal volume (VT) at the mouth was calculated integrating the airflow at the mouth over time. In addition, we measured the mean partial pressure of expired CO₂ (PETO₂) from a 2-L reservoir bag placed proximal to the expiratory port of the ventilator, at the end of the expiratory limb of the circuit, by means of a three-way connector (Fig 1). At the distal end of the reservoir bag, a stopcock was mounted to sample, after 20-h equilibration, the exhaled gases for measurements of the PETO₂ into the system (Stat-profile Ultra; NovoBioMedical; Waltham, MA).

The esophageal respiratory rate (RRpes) and the number of
breaths delivered by the ventilator per minute (ventilatory respiratory rate [RRvent]) were assessed by the number of Pes and airway pressure swings in a minute, respectively. The presence of patient/ventilator asynchrony was defined as the presence of wasted efforts or autocycling. The magnitude of the inspiratory muscle effort was estimated from the tidal excursions of Pes and by measuring the area under Pes (i.e., the pressure-time product [PTP] per breath). PTP per minute was calculated by multiplying esophageal PTP per breath and RRpes, while PTP per liter was defined as the ratio between PTP per minute and Ve. The inspiratory delay was calculated as the time lag between the beginning of the inspiratory effort and ventilator assistance, while the pressurization time was defined as the time necessary to achieve the preset level of PS. The difference between the minute ventilation (Ve) delivered to the helmet (V˙ e h) [measured on the inspiratory limb of the helmet] and subject Ve (measured at the airway opening) represented the Ve washing the helmet (V˙ e wh). V˙ co2 was determined automatically by the Novametrix system according to the following equation:

\[
V\dot{c}O_2 = V\dot{E}CO_2 - V\dot{E}CO_2 = (F\dot{E}CO_2 \times V\dot{e}) - (F\dot{I}CO_2 \times V\dot{i}),
\]

To evaluate comfort during NIV, we administered at the end of each trial a visual analog scale (VAS), where 0 indicated the best comfort and 10 indicated the worst comfort.

**Statistical Analysis**

Data are expressed as mean ± SD. The analysis of variance for repeated measures was used to detect significant differences between the different experimental conditions. When significant differences were detected, post hoc analysis was performed using the Tukey test; p ≤ 0.05 was considered significant.

**RESULTS**

All the subjects completed the study protocol. In comparison to spontaneous breathing, during helmet NIV, RRpes was reduced by 7% during PS/PEEP at 5/5 cm H2O (p = 0.086), by 13.1% during PS/PEEP at 10/5 cm H2O (both with and without an inflated cushion) [p = 0.023 and p = 0.015, respectively], by 28% during PS/PEEP at 15/5 cm H2O (p = 0.000003), and by 5.2% during PS/PEEP at 10/10 cm H2O (p = 0.12) [Table 1].

No significant differences were found between RRvent and RRpes, which were similar during the whole study period (Table 1). In comparison with unassisted breathing, with increasing levels of assistance, we observed an increase in Vt measured at the mouth by 49.8% with PS/PEEP at 5/5 cm H2O (p = 0.0054), by 48.8% with PS/PEEP at 10/5 cm H2O (deflated cushion) [p = 0.0069], by 56% with PS/PEEP at 10/5 cm H2O (inflated cushion) [p = 0.013], by 84.4% with PS/PEEP at 15/5 cm H2O (p = 0.00028), and by 30% with PS/PEEP at 10/10 cm H2O (p = 0.05) [Table 1]. Subject Ve did not significantly change during the whole study period, as shown in Table 1.

Data related to inspiratory effort are shown in Table 2. Compared to the spontaneous breathing period, the lowest level of PS/PEEP decreased tidal excursions of Pes by 25.2% (p = 0.096), while this value was significantly reduced by 34% (p = 0.031) during PS/PEEP at 10/5 cm H2O (inflated cushion) and by 37.6% during PS/PEEP at 10/10 cm H2O (p = 0.022). PTP per liter significantly decreased by 48% during PS/PEEP at 5/5 cm H2O (p = 0.049), by 52% during PS/PEEP at 10/5 cm H2O as well as during PS/PEEP at 15/5 cm H2O (p = 0.025 and p = 0.027, respectively).
Table 1—Breathing Pattern and CO₂ Values During Different Helmet NIV Trials Compared to Spontaneous Breathing*

<table>
<thead>
<tr>
<th>Variables</th>
<th>Spontaneous Breathing</th>
<th>PS/PEEP at 5/5 cm H₂O</th>
<th>PS/PEEP at 10/5 cm H₂O</th>
<th>PS/PEEP at 15/5 cm H₂O</th>
<th>PS/PEEP at 10/10 cm H₂O</th>
</tr>
</thead>
<tbody>
<tr>
<td>RR(respirations/min)</td>
<td>14.2 ± 1.3</td>
<td>13.2 ± 1.5</td>
<td>12.4 ± 2.1†</td>
<td>12.4 ± 1.8‡</td>
<td>10.2 ± 1.1†</td>
</tr>
<tr>
<td>RW (additional breaths)</td>
<td>Not measured</td>
<td>1 ± 1.2</td>
<td>0.7 ± 1.4</td>
<td>0.9 ± 0.9</td>
<td>0.6 ± 0.7</td>
</tr>
<tr>
<td>VT (mL)</td>
<td>605.56 ± 221.68</td>
<td>907.41 ± 188.03‡</td>
<td>901.63 ± 199.52‡</td>
<td>945.25 ± 317.71‡</td>
<td>1116.88 ± 238.63‡</td>
</tr>
<tr>
<td>VE (L/min)</td>
<td>8.5 ± 3.1</td>
<td>12.1 ± 3.2</td>
<td>11.1 ± 3.2</td>
<td>11.4 ± 3.8</td>
<td>11.4 ± 2.6</td>
</tr>
<tr>
<td>Vth (L/min)</td>
<td>Not measured</td>
<td>29.5 ± 14.7</td>
<td>36.5 ± 14.5</td>
<td>25.2 ± 4.6</td>
<td>38.5 ± 5.9</td>
</tr>
<tr>
<td>Vveh (L/min)</td>
<td>Not measured</td>
<td>17.4 ± 14.1</td>
<td>25.3 ± 15.48‡</td>
<td>13.77 ± 7.60</td>
<td>27.1 ± 7.14‡</td>
</tr>
<tr>
<td>End-tidal CO₂ (mm Hg)</td>
<td>39 ± 3</td>
<td>39 ± 8</td>
<td>36 ± 7</td>
<td>34 ± 5</td>
<td>34 ± 6</td>
</tr>
<tr>
<td>PeCO₂ (mm Hg)</td>
<td>Not measured</td>
<td>10.5 ± 1.3</td>
<td>8.7 ± 1.5†</td>
<td>9.2 ± 1.5</td>
<td>9.7 ± 1.4</td>
</tr>
<tr>
<td>PICO₂ (mm Hg)</td>
<td>Not measured</td>
<td>6.5 ± 5.1</td>
<td>5.2 ± 3.1</td>
<td>5.7 ± 3.9</td>
<td>5.5 ± 2.5</td>
</tr>
<tr>
<td>VCO₂ (mm Hg)</td>
<td>Not measured</td>
<td>153 ± 26</td>
<td>191 ± 89</td>
<td>184 ± 89</td>
<td>198 ± 50</td>
</tr>
<tr>
<td>VAS</td>
<td>Not measured</td>
<td>2 ± 0.75</td>
<td>2.37 ± 0.51</td>
<td>2.37 ± 0.74</td>
<td>5.62 ± 1.06‡</td>
</tr>
</tbody>
</table>

*Data are presented as mean ± SD.
†p ≤ 0.05.
‡p ≤ 0.01.

and by 54% during both PS/PEEP at 10/5 cm H₂O (with inflated cushion) and PS/PEEP at 10/10 cm H₂O (p = 0.019 and p = 0.018, respectively).

The analysis of patient/ventilator interaction showed the absence of wasted efforts and autocyling phenomena over the study period. Increased levels of assistance did not affect the inspiratory delay and the pressurization time (Table 2).

The analysis of CO₂ rebreathing did not show a significant reduction in PICO₂ nor a significant modification in end-tidal CO₂ by increasing the level of assistance (Fig 3), and the different levels of PS did not significantly change the VCO₂ as well. Incremental levels of PS from 5 to 10 cm H₂O decreased PeCO₂ from 10.48 ± 1.34 to 8.73 ± 1.47 mm Hg (p < 0.05), while a further increase in the level of assistance did not produce other changes (Table 1). As shown in Figure 4, Vveh significantly increased when the level of assistance was increased from 5 to 10 cm H₂O (p = 0.0087). Interestingly, the reduction in the helmet dead space by inflating the cushion or by increasing helmet pressurization (high PEEP) reduced Veh despite constant values of subject Vë.

All subjects were asked to evaluate the comfort using a VAS from 0 (best comfort) to 10 (worst comfort) at the end of each trial. Our results showed that a low level of PS (5 to 10 cm H₂O) allowed optimal comfort even at high PEEP (10 cm H₂O). Conversely, the highest level of PS (15 cm H₂O), both with low and high PEEP (5 cm H₂O and 10 cm H₂O) increased discomfort, significantly increasing the VAS from 2 ± 0.75 to 5.62 ± 1.06 (p < 0.001).

**DISCUSSION**

The main finding of the present study is that increasing levels of assistance in healthy volunteers receiving PS ventilation through a helmet signifi-

Table 2—Inspiratory Delay, Pressurization Time, and Inspiratory Effort During Different Levels of PS and PEEP*

<table>
<thead>
<tr>
<th>Variables</th>
<th>Spontaneous Breathing</th>
<th>PS/PEEP at 5/5 cm H₂O</th>
<th>PS/PEEP at 10/5 cm H₂O</th>
<th>PS/PEEP at 15/5 cm H₂O</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inspiratory delay</td>
<td>Not measured</td>
<td>0.29 ± 0.072</td>
<td>0.270 ± 0.123</td>
<td>0.264 ± 0.071</td>
</tr>
<tr>
<td>Pressurization time</td>
<td>Not measured</td>
<td>1.240 ± 0.110</td>
<td>1.166 ± 0.061</td>
<td>1.156 ± 0.055</td>
</tr>
<tr>
<td>Tidal excursion of Peps</td>
<td>7.25 ± 3.42</td>
<td>5.42 ± 1.63</td>
<td>5.34 ± 1.19</td>
<td>4.78 ± 0.62‡</td>
</tr>
<tr>
<td>PTP/breath, cm H₂O/s</td>
<td>14.55 ± 10.31</td>
<td>12.23 ± 4.92</td>
<td>11.05 ± 5.76</td>
<td>9.61 ± 2.32</td>
</tr>
<tr>
<td>PTP/min, cm H₂O/s/min</td>
<td>204.4 ± 133.5</td>
<td>161.7 ± 65.0</td>
<td>133.4 ± 36.7</td>
<td>118.4 ± 28.9†</td>
</tr>
<tr>
<td>PTP/L, cm H₂O/L</td>
<td>0.027 ± 0.018</td>
<td>0.014 ± 0.006‡</td>
<td>0.013 ± 0.004‡</td>
<td>0.012 ± 0.005‡</td>
</tr>
</tbody>
</table>

*Data are presented as mean ± SD.
†p ≤ 0.05.
cantly reduced RRpes, with a significant increase in VT. Increasing levels of assistance produced a significant reduction in tidal excursions of Pes only during PS/PEEP at 10/5 cm H2O with the cushion inflated and PS/PEEP at 10/10 cm H2O, while, compared to spontaneous breathing, ventilatory support produced a significant decrease of PTP per liter regardless of the PS/PEEP combination applied.

NIV delivered through a helmet has been shown to be an interesting alternative to the conventional facemask, increasing patient tolerance and reducing the most common side effects of the mask. Despite the good efficiency and tolerability, the use of the helmet is still controversial. This is mainly related to the increased dead space and the occurrence of patient/ventilator asynchrony.

In a study comparing helmet CPAP and mask CPAP, Patroniti and colleagues found that both interfaces were effective in increasing the end-expiratory lung volume, but high gas flows (40 to 60 L/min) were required with the helmet to maintain a low PiCO2. Taccone and colleagues obtained similar results, finding that CO2 rebreathing during helmet CPAP was related to VCO2 production and fresh gas flows. In that study, the authors recommended avoiding the use of the helmet with ventilator CPAP, showing that only a continuous high gas flow made CO2 rebreathing clinically irrelevant. Recently, Chiumello and colleagues compared the helmet to the mask in a group of healthy subjects receiving free-flow CPAP and a fixed level of PS/PEEP. Their results showed that both interfaces...
reduced the work of breathing in comparison to spontaneous breathing, but during PS the mask was more efficient than the helmet⁹; these authors hypothesized that the pressure delivered by the ventilator was partially spent to pressurize the large inner volume of the helmet, interfering with patient/machine interaction, with a lower level of assistance in the initial phase of the breathing effort.

Different from studies that evaluated the helmet efficacy during free-flow CPAP or PSV with a single level of PS and PEEP, we investigated the effects of different levels of PS and PEEP on inspiratory effort, patient/ventilator interaction, CO₂ rebreathing, and comfort. In order to eliminate any possible bias, all of our healthy individuals never experienced the helmet or PSV before the study. The slight reduction in tidal excursions of Pes that we observed can probably be explained by the normal respiratory drive, respiratory muscle function, and respiratory mechanics of our volunteers, for whom high levels of assistance were probably excessive and poorly tolerated, as demonstrated by the VAS analysis. High levels of PS, more than high levels of PEEP, were considered by the volunteers to be “uncomfortable and difficult to overwhelm.” Despite the high degree of discomfort, all of the volunteers kept synchrony with the ventilator, as shown by the inspiratory delay that did not significantly change for the whole course of the study, as well as by the absence of wasted efforts or autocycling phenomena.

A possible explanation is that the subjects maintained synchrony with the ventilator by increasing inspiratory and probably expiratory efforts at increasing levels of assistance. Consequently, their respiratory muscles were less unloaded and this produced a net increase in subject discomfort.

The increase of PS levels did not change PICO₂, end-tidal CO₂, and VCO₂ during the study. A slight but significant PICO₂ decrease was observed only with PS/PEEP at 10/5 cm H₂O.

In the present study, PICO₂ values were similar to those observed by Taccone et al.¹⁸ and Patroniti et al.¹⁹ who used CPAP with flow rates from 30 to 60 L/min. In our study, Veh delivered to the system was lower (< 40 L/min) and Vehw was from 13 to 27 L/min. This more efficient CO₂ washout is probably related to the phasic administration of inspiratory flow during PSV.

Different from our expectations, helmet pressurization produced by inflating the cushion or increasing the PEEP level caused a decrease in Vehw, despite the significant reduction in inspiratory effort, seriously questioning its clinical utility. Finally, the helmet was well tolerated with 5 cm H₂O and 10 cm H₂O of PS, and a significant discomfort was observed only with PS at 15 cm H₂O.

In conclusion, our study demonstrates that the helmet is effective in reducing the inspiratory effort and is efficient in providing ventilation to healthy volunteers, without relevant CO₂ rebreathing. It is worth remembering that the results of the present study were achieved in healthy volunteers. The generalization of the present data to patients with acute respiratory failure remains to be proven.

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