

Paolo Navalesi
Roberta Costa
Piero Ceriana
Annalisa Carlucci
George Prinianakis
Massimo Antonelli
Giorgio Conti
Stefano Nava

Non-invasive ventilation in chronic obstructive pulmonary disease patients: helmet versus facial mask

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P. Navalesi (✉) · P. Ceriana · A. Carlucci · S. Nava

Fondazione S. Maugeri IRCCS,
Pneumologia Riabilitativa e Terapia
Intensiva Respiratoria,
Via S. Maugeri 10, 27100 Pavia, Italy
e-mail: paolo.navalesi@fastwebnet.it
Tel.: +39-0382-592810
Fax: +39-0382-592075

R. Costa · M. Antonelli · G. Conti
Università Cattolica del Sacro Cuore,
Istituto di Anestesia e Rianimazione,
Roma, Italy

G. Prinianakis
University Hospital of Heraklion, Intensive
Care Medicine Department,
Heraklion, Greece

Abstract *Rationale:* The helmet is a new interface with the potential of increasing the success rate of non-invasive ventilation by improving tolerance. *Objectives:* To perform a physiological comparison between the helmet and the conventional facial mask in delivering non-invasive ventilation in hypercapnic patients with chronic obstructive pulmonary disease. *Methods:* Prospective, controlled, randomized study with cross-over design. In 10 patients we evaluated gas exchange, inspiratory effort, patient–ventilator synchrony and patient tolerance after 30 min of non-invasive ventilation delivered either by helmet or facial mask; both trials were preceded by periods of spontaneous unassisted breathing. *Measurements:* Arterial blood gases, inspiratory effort, duration of diaphragm contraction and ventilator assistance, effort-to-support delays (at the beginning and at the end of inspiration), number of ineffective efforts, and patient comfort. *Main*

results: Non-invasive ventilation improved gas exchange ($p < 0.05$) and inspiratory effort ($p < 0.01$) with both interfaces. The helmet, however, was less efficient than the mask in reducing inspiratory effort ($p < 0.05$) and worsened the patient–ventilator synchrony, as indicated by the longer delays to trigger on ($p < 0.05$) and cycle off ($p < 0.05$) the mechanical assistance and by the number of ineffective efforts ($p < 0.005$). Patient comfort was no different with the two interfaces. *Conclusions:* Helmet and facial mask were equally tolerated and both were effective in ameliorating gas exchange and decreasing inspiratory effort. The helmet, however, was less efficient in decreasing inspiratory effort and worsened the patient–ventilator interaction.

Keywords Non-invasive positive pressure ventilation · Respiratory insufficiency · Chronic obstructive pulmonary disease · Patient–ventilator interaction · Controlled clinical trial

Introduction

Non-invasive ventilation (NIV) provides adequate ventilatory support [1, 2, 3] and reduces the need for endotracheal intubation [4, 5, 6, 7, 8] in patients with acute respiratory failure of various etiologies and in particular in patients with chronic obstructive pulmonary disease (COPD) [4, 6, 9, 10, 11, 12].

NIV is commonly delivered via a mask secured by head-straps tightened to avoid air-leaks, the major

determinants of difficulty in patient–ventilator interaction during pressure support ventilation (PSV) [13]. Excessive tightening, however, increases patient discomfort. Both air-leaks and patient discomfort are common causes of NIV failure [14].

The helmet is a novel interface that may help to improve comfort during NIV by removing the need for sealing around the nose and mouth [15, 16]. Data from prospective non-randomized studies comparing the helmet and the facial mask suggest that the former may reduce

the rate of intubation related to intolerance, allowing for continuous delivery of NIV for longer periods of time [15, 16].

In a study evaluating COPD patients with hypercapnic acute respiratory failure, NIV improved gas exchange with both the helmet and the facial mask [16], but the helmet corrected the hypercapnia less efficiently and its clinical advantages were less evident than in hypoxemic patients [15]. The larger dead space of the helmet may increase rebreathing and could explain the higher PaCO₂ [17, 18]. The extent of this side effect, however, may not be relevant [16] as it is largely dependent on the flow rate of fresh gases, CO₂ production, respiratory mechanics, minute ventilation, and breathing pattern [17, 18]. The soft compliant wall and the elevated internal compressible volume of the helmet can interfere with triggering the ventilator assistance on and off [18, 19, 20] and further worsen the often difficult patient-ventilator interaction in COPD patients [21, 22].

We performed this physiologic randomized controlled study with cross-over design to compare helmet and facial mask in delivering NIV to hypercapnic COPD patients, with respect to gas exchange, inspiratory effort, patient-ventilator synchrony, and comfort.

Methods

The study was performed at the Fondazione S. Maugeri Hospital, Pavia. The local ethics committee approved the protocol, and signed informed consent was obtained from every patient.

Patients

We enrolled 10 consecutive hypercapnic patients with severe COPD recovering from an episode of acute exac-

erbation. Inclusion criteria were: (1) diagnosis of COPD (based on clinical history and pulmonary function tests); (2) chronic hypercapnic respiratory failure; (3) long-term NIV via nasal mask, in accordance with a predefined protocol [23], for at least 6 months; (4) recent episode of acute exacerbation (fever, leukocytosis, increase in the amount and purulence of sputum, worsening of dyspnea and gas exchange) which required medical treatment and an increase in the hours of NIV during the day. Exclusion criteria were: (1) unstable clinical conditions (i.e., need for vasopressors, metabolic acidosis, angina, life-threatening arrhythmias, need for FiO₂ ≥ 0.5, agitation and anxiety); (2) pneumonia, as assessed by X-ray; (3) inability to cooperate; (4) claustrophobia; (5) recent gastro-esophageal surgery; (6) face or neck deformities; (7) previous use of facial mask or helmet; (8) enrollment in other research protocols.

Patients' characteristics at enrollment are provided in Table 1.

Measurements

Arterial blood was withdrawn from the radial artery at the end of each trial and immediately analyzed (ABL 300 and ABL 625 Radiometer, Copenhagen, Denmark). Airflow was measured with a heated pneumotachograph (Hans-Rudolf 3700, Kansas City, KS, USA) connected to a differential pressure transducer (Honeywell, Freeport, IL, USA). The pneumotachograph was placed distally to the Y piece and proximal to the mask or mouthpiece during the mask and spontaneous breathing trials, respectively; the tidal volume was obtained by digital integration of the flow signal. With the helmet, the pneumotachograph was placed between the end of the inspiratory line and the air inlet.

Pressure at the airway opening (Pao) was assessed via a side port connected to a pressure transducer (Micro Switch, Honeywell, USA). Esophageal (Pes) and

Table 1 Patient characteristics

Sex	Age (years)	Weight (kg)	Diagnosis	PaO ₂ (mmHg)	PaCO ₂ (mmHg)	pH	FEV ₁ (l)
M	60	65	COPD	55.6	58.2	7.39	0.53
M	74	79	COPD	59.2	58.0	7.43	0.78
F	48	100	COPD, TB sequelae	64.0	50.1	7.36	0.80
F	70	65	COPD	58.0	56.9	7.35	0.48
M	80	64	COPD	52.9	58.8	7.40	0.70
M	61	71	COPD	62.8	59.5	7.38	0.78
F	73	113	COPD, Obesity	63.1	55.7	7.38	0.98
M	78	65	COPD	68.3	50.4	7.40	0.82
M	69	87	COPD	62.6	53.0	7.35	0.82
M	62	93	COPD	58.0	58.3	7.40	0.63

COPD, chronic obstructive pulmonary disease;

TB, tuberculosis; FEV₁, forced expiratory volume in 1s

gastric (P_{ga}) pressures were measured using separate balloon-tipped catheters (Microtek, Medical B.V., Zutphen, Netherlands) positioned in the mid-esophagus and in the stomach and connected to two differential pressure transducers (Micro Switch, Honeywell, USA). Esophageal and gastric balloons were filled with 0.5 and 1 ml of air, respectively. Correct positioning of the catheters was evaluated as previously described [24]. Transdiaphragmatic (P_{di}) pressure was obtained by subtracting P_{es} from P_{ga} . P_{es} was corrected for expiratory muscle activity, as previously described [25].

Patient's own (neural) respiratory rate (RR_n) and ventilator rate of cycling (RR_{vent}) were determined from P_{di} and P_{ao} swings, respectively (Fig. 1). In line with previous studies [18, 26, 27], the patient's inspiratory time (TI_p) was estimated from the P_{di} tracing as the time between the onset of the positive P_{di} swing above baseline (i.e., start of inspiratory effort) and the point where P_{di} started to fall toward baseline (Fig. 1). Likewise, the duration of the in-

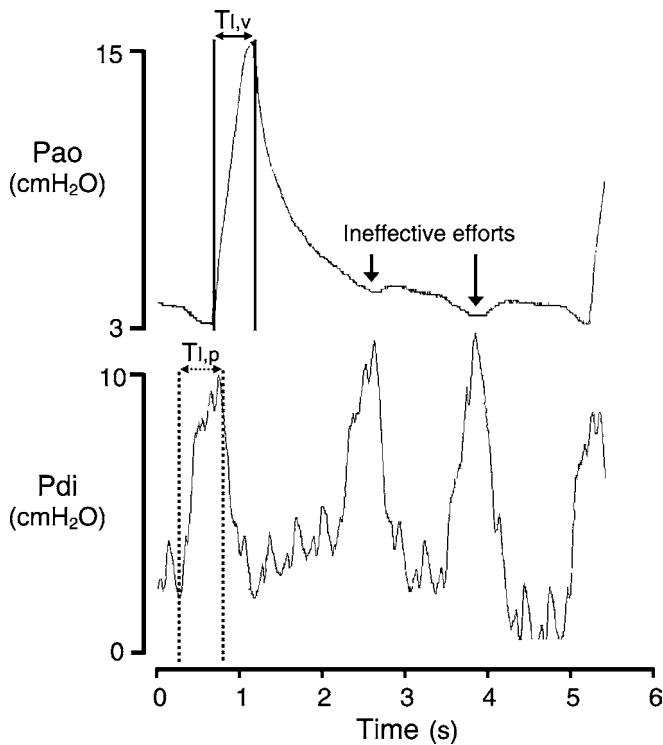


Fig. 1 Extreme impairment in patient-ventilator interaction during non-invasive ventilation by helmet. Airway opening (P_{ao}) and transdiaphragmatic (P_{di}) pressure-time tracings are shown in the upper panel and lower panel, respectively. The two solid vertical lines in the upper panel indicate onset and end of ventilator assistance, thereby delimiting its duration (TI_v). The two dotted vertical lines in the lower panel, which denote onset and end of P_{di} , demarcate patient inspiratory time (TI_p). In the first breath, TI_p and TI_v are almost completely out of phase, but the effort is able to trigger the ventilator; the two following breaths are ineffective to trigger the ventilator, as indicated by the two arrows on the P_{ao} tracing. See text for further explanation

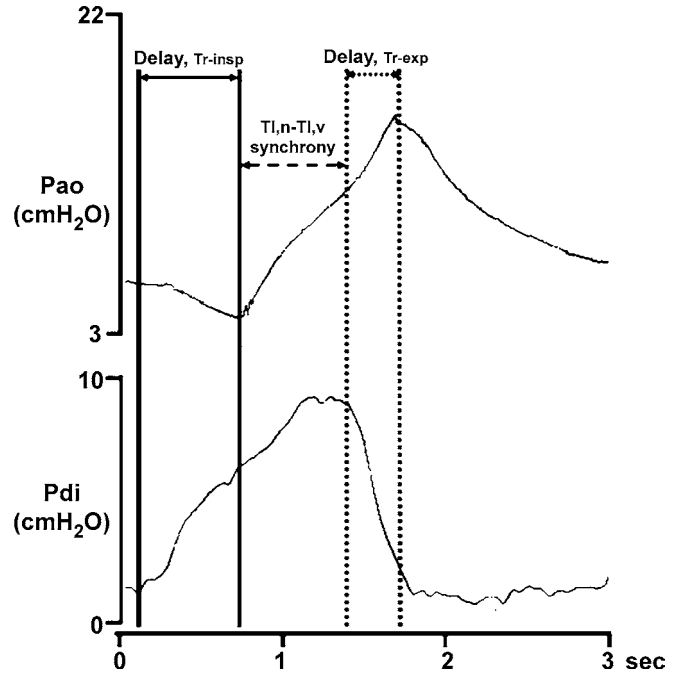


Fig. 2 Airway opening (P_{ao}) and transdiaphragmatic (P_{di}) pressure-time tracings are shown, from another subject breathing with the helmet, in the upper panel and lower panel, respectively. The two solid vertical lines denote onset of P_{di} and start of ventilator assistance; accordingly, the distance between these two lines corresponds to the effort-to-support delay at the beginning of inspiration (*Delay, Tr-insp*). The two dotted vertical lines indicate end of P_{di} and termination of ventilator support; the distance between these two lines thus corresponds to the end-inspiratory effort-to-support delay (*Delay, Tr-exp*). The distance between the second solid line and the first dotted line indicates the time during which the contracting diaphragm is supported by the ventilator ($TI_p - TI_v$ synchrony). See text for further explanation

spiratory assistance provided by the ventilator (TI_v) was calculated from the P_{ao} tracing (Fig. 1).

The inspiratory trigger delay ($Delay, TR-insp$) was calculated as the time lag between onset of inspiratory effort and start of ventilator support, while the expiratory trigger delay ($Delay, TR-exp$) was calculated as the time lag between the points at which P_{di} and P_{ao} started to fall toward baselines (Fig. 2). We also calculated the time of synchrony between muscle effort and ventilator support ($TI_p - TI_v$ synchrony) as the period in the course of inspiration during which the diaphragm was contracting and the ventilator was concurrently delivering support.

The pressure-time products of the transdiaphragmatic (PTP $_{di}$) and esophageal (PTP $_{es}$) pressure were assessed to determine the effort exerted by the diaphragm and to provide a surrogate estimate of the overall inspiratory muscle exertion, not considering the amount of effort spent to distend the chest wall, from the changes in P_{es} and P_{di} over time, respectively. The pressure-time products were

both calculated per minute, determining the area under Pdi (PTPdi/min) and Pes (PTPes/min) within a 1-min time interval, as previously described [28], and per breath (PTPdi/br and PTPes/br), dividing PTPdi/min and PTPes/min by RR_n . We also calculated the percentage of the swing in Pdi expended to trigger the ventilator (100% for the ineffective efforts) and the amount of PTPdi/min due to the ineffective efforts.

Patient comfort during NIV with the two interfaces was assessed using a five-item scale already used in previous studies [29, 30]. At the end of each run, just before ABG assessment, the patient was asked to score his comfort as follows: 1, bad; 2, quite bad; 3, acceptable; 4, quite good; 5, good.

Experimental protocol

The patients were studied in semi-recumbent position. All patients received NIV via a standard ICU ventilator (Evita 4; Dräger, Lübeck, Germany) in pressure support mode (PSV) by helmet (CaStar, NIV model, Starmed, Mirandola, Italy) and facial mask (Mirage, ResMed, Sydney, Australia), applied in random order. The size of the facial mask was chosen to be the most comfortable for the patient, while avoiding air leaks. The helmet, made of transparent latex-free polyvinyl chloride, was secured by two padded armpit braces at two hooks sited in the front and the back of a metallic ring joining the helmet with a soft-cushioned collar, which adhered to the neck allowing a sealed connection. To ensure an accurate yet comfortable seal, the helmet size was chosen according to the circumference of the neck: a small model for collar sizes of 33 cm or less, a medium one between 34 and 39 cm, and a large helmet for 39 cm and above. The helmet was connected to the ventilator by conventional respiratory circuitry joining two lateral port sites to the air inlet and outlet of the ventilator.

Inspiratory assistance of 12 cmH₂O, delivered using the highest pressurization rate, above a positive end-expiratory pressure (PEEP) of 5 cmH₂O, was used for all patients. Flow triggering was always set at 1 l/min. The two trials of NIV, delivered with the mask and the helmet, were both preceded by periods of spontaneous unassisted breathing through a mouthpiece with the nostrils closed by a nose-clip and the ventilator set in continuous positive airway pressure (CPAP) mode at 5 cmH₂O. FiO₂ was set to obtain an oxygen saturation $\geq 93\%$ and $\leq 96\%$ during the first trial of spontaneous unassisted breathing and never changed throughout the study period. All the trials lasted 30 min.

Data analysis

The last 5 min of each trial were recorded and averaged for data analysis. The signals were amplified, low-pass

filtered, digitized at 100 Hz and stored in a PC for further analysis. The results are expressed as mean \pm standard deviation (SD). Differences in arterial blood gases (ABGs), breathing frequency, patient inspiratory time, and indexes of inspiratory effort between NIV and spontaneous breathing trials were determined using the analysis of variance (ANOVA) for repeated measurements. Difference between the two interfaces with respect to all the other variables were assessed using the paired Student *t*-test. *P* values < 0.05 were considered statistically significant.

Results

All patients completed the study protocol. As shown in Fig. 3, compared with spontaneous breathing, NIV was effective in reducing PaCO₂ with both interfaces (from 55.9 ± 7.32 to 52.0 ± 7.14 mmHg, $p < 0.05$ with the helmet, and from 55.5 ± 7.77 to 51.7 ± 8.52 mmHg, $p < 0.05$, with the mask). Additionally, we observed an improvement in PaO₂ (from 60.0 ± 6.3 to 65.5 ± 7.4 mmHg, $p < 0.05$, with the helmet; from 61.4 ± 10.5 to 67.3 ± 11.1 mmHg, $p < 0.05$, with the mask).

Compared with unassisted spontaneous breathing, during NIV tidal volume was increased by 35% (from 429 ± 152 to 581 ± 167 ml; $p < 0.01$) with the mask, while it could not be determined with the helmet. As shown in Table 2, regardless of the interface, the changes in RR_p were rather small and not significant. Conversely, RR_v was lower with the helmet than with the mask ($p < 0.005$). Ineffective inspiratory efforts were not present at all when NIV was delivered by mask, while they occurred in five patients with the helmet, averaging 5.4 ± 2.1 breaths/min ($p < 0.05$). As also shown in Table 2, compared with spontaneous breathing, during NIV TI_p was significantly reduced with the mask, while not

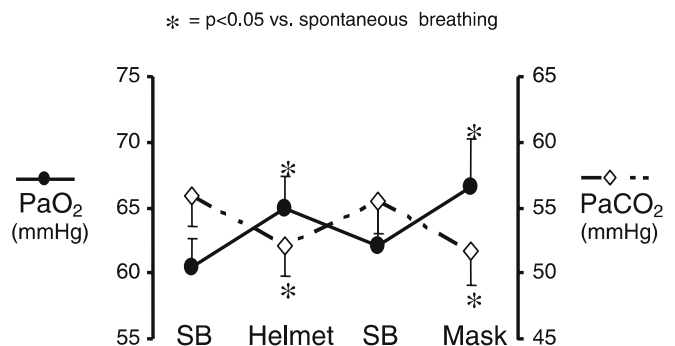


Fig. 3 Effects of non-invasive ventilation delivered either by helmet or facial mask on arterial oxygenation (PaO₂, left axis) and arterial carbon dioxide (PaCO₂, right axis). Compared with unassisted spontaneous breathing (SB), both interfaces improved gas exchange

different with the helmet. TI_v was significantly shorter with the mask than with the helmet (0.96 ± 0.31 vs 1.18 ± 0.28 s, $p < 0.05$) (Table 2). Both $Delay_{TR-insp}$ ($p < 0.01$) and $Delay_{TR-exp}$ ($p < 0.05$) were longer with the helmet than with the mask (Table 2). TI_p-TI_v synchrony, however, was not different between helmet and mask (Table 2). The time from onset of inspiratory effort to achievement of the preset inspiratory pressure was longer with the helmet than with the mask (1.09 vs 0.84 s, $p < 0.01$).

As shown in Fig. 4, compared with spontaneous breathing, NIV reduced the inspiratory effort both with helmet and mask, as indicated by the reduction in esophageal and diaphragmatic pressure swings and pressure-time products, either per breath or per minute. In particular, with respect to unassisted spontaneous breathing, NIV delivered by helmet decreased the Pdi swing by 43.5% (from 16.3 ± 7.5 to 9.2 ± 6.6 cmH₂O, $p < 0.001$), PTPdi/br by 46.1% (from 11.5 ± 5.0 to 6.2 ± 4.5 , $p < 0.001$), and PTPdi/min by 43.0% (from 254 ± 89 to 145 ± 140 , $p < 0.001$); with the mask, the Pdi swing was reduced by 51.0% (from 14.1 ± 6.5 to 6.9 ± 4.6 cmH₂O, $p < 0.001$), PTPdi/br by 64.3% (from 11.2 ± 4.4 to 4.0 ± 3.0 , $p < 0.001$), and PTPdi/min by 65.3% (from 262 ± 99 to 91 ± 69 , $p < 0.001$). PTPdi/br and PTPdi/min were significantly lower with the mask than with the helmet ($p < 0.05$ for both) (Fig. 4). The amount of diaphragmatic effort spent to trigger the ventilator accounted for 83% of the overall Pdi swing with the helmet and 31% with the mask ($p < 0.001$). During NIV delivered by the helmet, the ineffective efforts accounted for 29% of the total PTPdi/min.

As shown in Table 2, patient comfort was not different with the two interfaces.

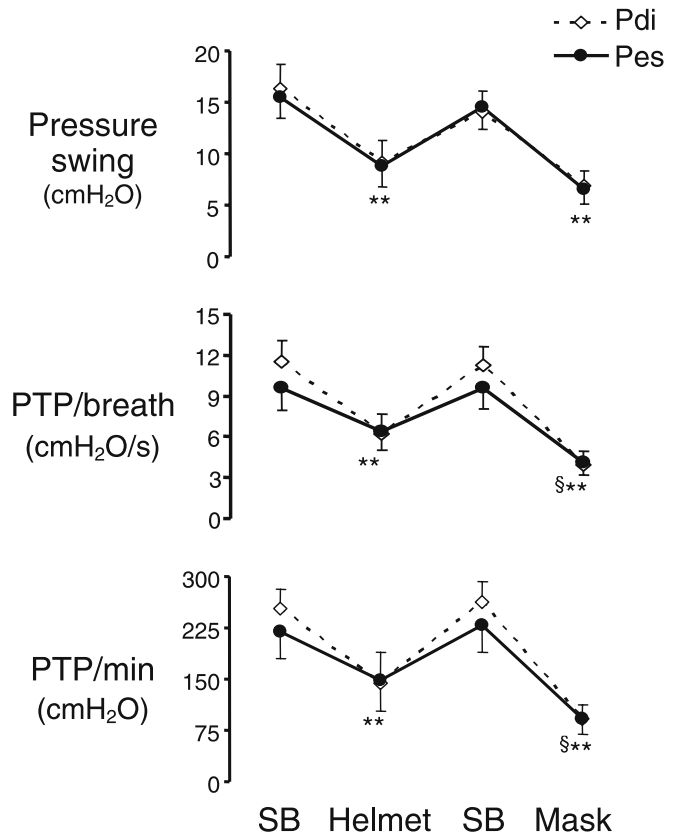


Fig. 4 Effects of non-invasive ventilation delivered either by helmet or facial mask on inspiratory effort, as indicated by pressure swing (upper panel) and pressure-time product, either per breath (PTP/ breath; middle panel) and per minute (PTP/min; lower panel), of the esophageal (Pes) and transdiaphragmatic (Pdi) pressure. Compared with unassisted spontaneous breathing (SB), both interfaces decreased the indexes of inspiratory effort. PTP/ breath and PTP/min, however, were significantly lower with the facial mask than with the helmet. ** $p < 0.001$ vs spontaneous breathing; § $p < 0.05$ vs helmet

Table 2 Respiratory rate, duration of inspiration, patient-ventilator synchrony and comfort

	Spontaneous breathing	Helmet	Spontaneous breathing	Facial mask	<i>p</i> value
RR,p (breaths/min)	22.7 ± 3.1	20.7 ± 7.5	23.5 ± 2.5	23.4 ± 4.3	ns ^a
RR,v (breaths/min)	–	16.4 ± 5.9	–	23.7 ± 4.9	$< 0.01^b$
TI,p (s)	1.04 ± 0.18	1.05 ± 0.37	1.01 ± 0.17	$0.85 \pm 0.37^*$	$< 0.01^a$
TI,v (s)	–	1.18 ± 0.28	–	0.96 ± 0.31	$< 0.01^b$
Delay,Tr-insp (s)	–	0.33 ± 0.20	–	0.17 ± 0.19	$< 0.05^b$
Delay,Tr-exp (s)	–	0.46 ± 0.22	–	0.28 ± 0.18	$< 0.05^b$
TI,p-TI,v synchrony (s)	–	0.72 ± 0.32	–	0.68 ± 0.31	0.78^b
Comfort score	–	3.0 ± 1.5	–	3.0 ± 0.8	0.99^b

RR,p, patient's own (neural) respiratory rate; RR,v, ventilator rate of cycling; TI,p, patient inspiratory time; TI,v, duration of inspiratory ventilator assistance; Delay, TR-insp, delay between onset of inspiratory effort and start of ventilator support; Delay, TR-exp, delay between the points at which Pdi and Pao start to fall toward baselines; TI,p-TI,v, time of synchrony between inspiratory muscle effort and ventilator support (see text for further explanation) ^aANOVA for repeated measurements ^bPaired *t*-test *Compared with the other three conditions

Discussion

Our study shows that NIV improves gas exchange and decreases inspiratory effort in hypercapnic COPD patients with both the helmet and the facial mask. The helmet, however, is less efficient than the mask in reducing inspiratory muscle effort and worsens patient–ventilator synchrony, as indicated by the occurrence of ineffective efforts and by longer delays between inspiratory muscle activity and support delivery, both at onset and end of inspiration.

We studied COPD patients recovering from an acute exacerbation. Although at the time of the study most of the patients had PaCO₂ values still exceeding those observed prior to the exacerbation, our patients had milder alterations of pulmonary mechanics and derangements of ABGs and breathing pattern than those of acute patients with decompensated respiratory acidosis. In chronically hypercapnic COPD patients, the effects produced by NIV on gas exchange [30, 31, 32, 33], breathing pattern [30, 31, 32, 33], patient–ventilator synchrony [32], and inspiratory effort [31, 32, 33] have been shown to be quite similar, although to a different extent, to those observed in acute patients [1, 2]. As in previous studies comparing interfaces [30, 31], we chose to investigate hypercapnic patients without decompensated respiratory acidosis; this was done to overcome the difficulties and risks of interrupting NIV to return to baseline (i.e., spontaneous breathing) and to avoid the limitation of assessing a subjective measurement, such as comfort, in patients with potential sensory impairment. Anyhow, to our knowledge, this is the first physiological study assessing inspiratory muscle effort and patient–ventilator interaction during NIV delivered by helmet in patients, rather than healthy volunteers [18, 19, 20].

NIV delivered by mask increased on average tidal volume by 33%. We could not determine the tidal volume when NIV was delivered through the helmet; however, because the changes in PaCO₂ were similar with the two interfaces and the ventilator rate of cycling (TI,v) was significantly lower with the helmet, the tidal volume was likely to be higher with the helmet than with the mask. In healthy volunteers, Chiumello et al. used optoelectronic plethysmography to overcome the problematic assessment of the volume of air actually delivered to the patient during NIV by helmet and found that the actual tidal volume was increased, compared with spontaneous breathing, by 31% and 20% with helmet and facial mask, respectively [19].

In agreement with Antonelli et al. [16], compared with spontaneous breathing, NIV decreased PaCO₂ with both helmet and mask; in contrast to Antonelli et al., however, we did not observe significant differences in PaCO₂ between the two interfaces. This may be a consequence of the difference in baseline PaCO₂ values between the two studies. The different timing of arterial blood gas assessment after NIV application (30 vs 60 min) may also have played a role. Finally, the amount of CO₂ re-breathing pro-

moted by the helmet's large internal volume is influenced by the CO₂ production [17], which is higher in severe acute patients with more frequent and intense respiratory efforts.

With respect to spontaneous breathing, both interfaces decreased inspiratory effort, but the reduction obtained was less with the helmet than with the mask. The different rate of pressurization with the two interfaces, as indicated by the longer time from onset of inspiratory effort to achievement of the preset inspiratory pressure with the helmet, as opposed to the mask, may help to explain these results.

Compared with the mask, the helmet worsened patient–ventilator synchrony: ineffective efforts occurred in five patients when NIV was delivered by helmet, but were absent in all patients with the mask. NIV by helmet was characterized by increased delays between effort and support, both at the onset and at the end of inspiration (Fig. 2). As shown in Table 2, both Delay,TR-insp and Delay,TR-exp were significantly longer with the helmet than with the mask. TI,p and TI,v, nevertheless, were also significantly longer with the helmet. As a result, the time during which the contracting inspiratory muscles were supported by the ventilator (TI,p–TI,v synchrony) was no different with the two interfaces. This finding may explain the satisfactory clinical performance of the helmet [15, 16, 34, 35, 36, 37, 38], in spite of the poor patient–ventilator interaction. It is worth remarking, however, that the fraction of TI,p actually supported by the ventilator was higher with the mask than the helmet (80% and 69%, respectively; $p < 0.05$).

As previously done [18, 26, 27], we used Pdi instead of diaphragm electrical activity to estimate onset and duration of TI,p. This approach may induce errors and is biased by limited reproducibility when compared with the measurements of TI,p obtained with diaphragm electrical activity [39]. These biases, however, are overcome by the cross-over design of the study, which offset the potential errors in estimating TI,p.

In accordance with the results of several studies performed in healthy volunteers [18, 19, 20], we found that NIV by helmet decreased inspiratory effort, but this reduction was significantly less than that obtained with the mask [18, 19]. The interaction between patient effort and ventilator support was different with the two interfaces: due to the greater Delay,TR-insp, the amount of inspiratory effort spent to trigger the ventilator was almost 3 times as great with the helmet than with the mask; in addition, as indicated by the increased Delay,TR-exp, the time of mechanical insufflation into the patient's neural expiration was significantly longer with the helmet. When NIV was delivered by helmet the ineffective efforts accounted for almost one third of the overall PTP/min, indicating that the inspiratory effort was affected by the worsened patient–ventilator interaction. As we tested only one set of inspiratory and expiratory pressures, we cannot exclude different results with other pressure settings. Also, because of technical differences

in mode of PSV delivery among ventilators, our results may differ somewhat from those obtained with other ventilators.

Patient comfort was on average no different with the two interfaces. We enrolled patients receiving long-term NIV through a nasal mask to avoid problems secondary to the lack of acquaintance with NIV, rather than to the interface used. Being already accustomed to the nasal mask might make a facial mask more acceptable than a helmet, thereby obscuring the comfort advantage that otherwise would be accrued to the helmet. Differences in patient characteristics may also contribute to explain the discrepancies, with other studies reporting a better tolerance with the helmet than with the mask [15, 16]; indeed, COPD patients on long-term NIV represent a highly selected population and our results might not be entirely applicable to naïve users during acute exacerbations. We believe, however, that most of these differences are attributable to the

trial duration, which in our study was too short for mask-related side-effects such as skin abrasion to take place.

In conclusion, NIV improved gas exchange and reduced inspiratory effort both with helmet and mask; the helmet, however, was less efficient in decreasing inspiratory effort and worsened patient-ventilator interaction. These results suggest that in COPD patients the mask is the interface of first choice; the helmet may be an alternative for patients who do not tolerate the mask or an additional tool to prevent skin breakdown when NIV is applied near-continuously for prolonged periods [5, 12, 40]. These conclusions, however, should not be unconditionally extrapolated to other populations of patients with different derangements in gas exchange and respiratory mechanics.

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References

1. Brochard L, Isabey D, Piquet J, Amaro P, Mancebo J, Messadi AA, Brun-Buisson C, Rauss A, Lemaire F, Harf A (1990) Reversal of acute exacerbations of chronic obstructive lung disease by inspiratory assistance with a face mask. *N Engl J Med* 323:1523–1530
2. Appendini L, Patessio A, Zanaboni S, Carone M, Gukov B, Donner CF, Rossi A (1994) Physiologic effects of positive end-expiratory pressure and mask pressure support during exacerbations of chronic obstructive pulmonary disease. *Am J Respir Crit Care Med* 149:1069–1076
3. L'Her E, Deye N, Lellouche F, Taille S, Demoule A, Fraticelli A, Mancebo J, Brochard L (2005) Physiologic effects of noninvasive ventilation during acute lung injury. *Am J Respir Crit Care Med* 172:1112–1118
4. Brochard L, Mancebo J, Wysocki M, Lofaso F, Conti G, Rauss A, Simonneau G, Benito S, Gasparetto A, Lemaire F, Isabey D, Harf A (1995) Noninvasive ventilation for acute exacerbations of chronic obstructive pulmonary disease. *N Engl J Med* 333:817–822
5. Antonelli M, Conti G, Rocco M, Bufi M, De Blasi RA, Vivino G, Gasparetto A, Meduri GU (1998) A comparison of noninvasive positive-pressure ventilation and conventional mechanical ventilation in patients with acute respiratory failure. *N Engl J Med* 339:429–435
6. Plant PK, Owen JL, Elliott MW (2000) Early use of non-invasive ventilation for acute exacerbations of chronic obstructive pulmonary disease on general respiratory wards: a multicentre randomised controlled trial. *Lancet* 355:1931–1935
7. Auriant I, Jallot A, Herve P, Cerrina J, Le Roy Ladurie F, Fournier JL, Lescot B, Parquin F (2001) Noninvasive ventilation reduces mortality in acute respiratory failure following lung resection. *Am J Respir Crit Care Med* 164:1231–1235
8. Hilbert G, Gruson D, Vargas F, Valentino R, Gbikpi-Benissan G, Dupon M, Reiffers J, Cardinaud JP (2001) Noninvasive ventilation in immunosuppressed patients with pulmonary infiltrates, fever, and acute respiratory failure. *N Engl J Med* 344:481–487
9. Bott J, Carroll MP, Conway JH, Klilty SEJ, Ward EM, Brown AM, Paul EA, Elliott MW, Godfrey RC, Wedzicha JA, Moxham J (1993) Randomised controlled trial of nasal ventilation in acute ventilatory failure due to chronic obstructive airways disease. *The Lancet* 341:1555–1557
10. Kramer N, Meyer TJ, Meharg J, Cece RD, Hill NS (1995) Randomized, prospective trial of noninvasive positive pressure ventilation in acute respiratory failure. *Am J Respir Crit Care Med* 151:1799–1806
11. Celikel T, Sungur M, Ceyhan B, Karakurt S (1998) Comparison of noninvasive positive pressure ventilation with standard medical therapy in hypercapnic acute respiratory failure. *Chest* 114:1636–1642
12. Conti G, Antonelli M, Navalesi P, Rocco M, Bufi M, Spadetta G, Meduri GU (2002) Noninvasive vs. conventional mechanical ventilation in patients with chronic obstructive pulmonary disease after failure of medical treatment in the ward: a randomized trial. *Intensive Care Med* 28:1701–1707
13. Calderini E, Confalonieri M, Puccio P, Francavilla N, Stella L, Gregoretti C (1999) Patient-ventilator asynchrony during noninvasive ventilation: the role of expiratory trigger. *Intensive Care Med* 25:662–667
14. Mehta S, Hill NS (2001) Noninvasive ventilation. *Am J Respir Crit Care Med* 163:540–577
15. Antonelli M, Conti G, Pelosi P, Gregoretti C, Pennisi MA, Costa R, Severgnini P, Chiaranda M, Proietti R (2002) New treatment of acute hypoxemic respiratory failure: noninvasive pressure support ventilation delivered by helmet – a pilot controlled trial. *Crit Care Med* 30:602–608

16. Antonelli M, Pennisi MA, Pelosi P, Gregoretti C, Squadrone V, Rocco M, Cecchini L, Chiumello D, Severgnini P, Proietti R, Navalesi P, Conti G (2004) Noninvasive positive pressure ventilation using a helmet in patients with acute exacerbation of chronic obstructive pulmonary disease: a feasibility study. *Anesthesiology* 100:16–24
17. Taccone P, Hess D, Caironi P, Bigatello LM (2004) Continuous positive airway pressure delivered with a “helmet”: effects on carbon dioxide rebreathing. *Crit Care Med* 32:2090–2096
18. Racca F, Appendini L, Gregoretti C, Stra E, Patessio A, Donner CF, Ranieri VM (2005) Effectiveness of mask and helmet interfaces to deliver noninvasive ventilation in a human model of resistive breathing. *J Appl Physiol* 99:1262–1271
19. Chiumello D, Pelosi P, Carlesso E, Severgnini P, Aspesi M, Gamberoni C, Antonelli M, Conti G, Chiaranda M, Gattinoni L (2003) Noninvasive positive pressure ventilation delivered by helmet vs. standard face mask. *Intensive Care Med* 29:1671–1679
20. Costa R, Navalesi P, Antonelli M, Cavaliere F, Craba A, Proietti R, Conti G (2005) Physiologic evaluation of different levels of assistance during noninvasive ventilation delivered through a helmet. *Chest* 128:2984–2990
21. Nava S, Bruschi C, Rubini F, Palo A, Iotti G, Braschi A (1995) Respiratory response and inspiratory effort during pressure support ventilation in COPD patients. *Intensive Care Med* 21:871–879
22. Appendini L, Purro A, Patessio A, Zanaboni S, Carone M, Spada E, Donner CF, Rossi A (1996) Partitioning of inspiratory muscle workload and pressure assistance in ventilator-dependent COPD patients. *Am J Respir Crit Care Med* 154:1301–1309
23. Nava S, Navalesi P (2002) Domiciliary noninvasive ventilatory support. In: Similowski T, Whitelaw WA, Derenne JP (eds) *Clinical management of chronic obstructive pulmonary disease. (Lung biology in health and disease, vol 165)* : Dekker, New York, pp 813–848
24. Baydur A, Behrakis PK, Zin WA, Jaeger M, Milic-Emili J (1982) A simple method for assessing the validity of the esophageal balloon technique. *Am Rev Respir Dis* 126:788–791
25. Lessard MR, Lofaso F, Brochard L (1995) Expiratory muscle activity increases intrinsic positive end-expiratory pressure independently of dynamic hyperinflation in mechanically ventilated patients. *Am J Respir Crit Care Med* 151:562–569
26. Barnard PA, Levine S (1986) Critique on application of diaphragmatic time-tension index to spontaneously breathing humans. *J Appl Physiol* 60:1067–1072
27. Appendini L, Purro A, Gudjonsdottir M, Baderna P, Patessio A, Zanaboni S, Donner, Claudio F, Rossi A (1999) Physiologic response of ventilator-dependent patients with chronic obstructive pulmonary disease to proportional assist ventilation and continuous positive airway pressure. *Am J Respir Crit Care Med* 159:1510–1517
28. Navalesi P, Hernandez P, Wongs A, Laporta D, Goldberg P, Gottfried SB (1996) Proportional assist ventilation in acute respiratory failure: effects on breathing pattern and inspiratory effort. *Am J Respir Crit Care Med* 154:1330–1338
29. Vitacca M, Rubini F, Foglio K, Scalvani S, Nava S, Ambrosino N (1993) Non invasive modalities of positive pressure ventilation improve the outcome of acute exacerbations in COPD patients. *Intensive Care Med* 19:450–455
30. Navalesi P, Fanfulla F, Frigerio P, Gregoretti C, Nava S (2000) Physiologic evaluation of noninvasive mechanical ventilation delivered with three types of masks in patients with chronic hypercapnic respiratory failure. *Crit Care Med* 28:1785–1790
31. Anton A, Tarrega J, Giner J, Guell R, Sanchis J (2003) Acute physiologic effects of nasal and full-face masks during noninvasive positive-pressure ventilation in patients with acute exacerbations of chronic obstructive pulmonary disease. *Respir Care* 48:922–925
32. Vitacca M, Nava S, Confalonieri M, Bianchi L, Porta R, Clini E, Ambrosino N (2000) The appropriate setting of noninvasive pressure support ventilation in stable COPD patients. *Chest* 118:1286–1293
33. Nava S, Fanfulla F, Frigerio P, Navalesi P (2001) Physiologic evaluation of 4 weeks of nocturnal nasal positive pressure ventilation in stable hypercapnic patients with chronic obstructive pulmonary disease. *Respiration* 68:573–583
34. Antonelli M, Pennisi MA, Conti G, Bello G, Maggiore SM, Michetti V, Cavaliere F, Proietti R (2003) Fiberoptic bronchoscopy during noninvasive positive pressure ventilation delivered by helmet. *Intensive Care Med* 29:126–129
35. Klein M, Weksler N, Bartal C, Gurman GM (2004) Helmet noninvasive ventilation for weaning from mechanical ventilation. *Respir Care* 49:1035–1037
36. Piastra M, Antonelli M, Caresta E, Chiaretti A, Polidori G, Conti G (2006) Noninvasive ventilation in childhood acute neuromuscular respiratory failure: a pilot study. *Respiration*, Jan 16 [Epub ahead of print]
37. Piastra M, Conti G, Caresta E, Tempera A, Chiaretti A, Polidori G, Antonelli M (2005) Noninvasive ventilation options in pediatric myasthenia gravis. *Paediatr Anaesth* 15:699–702
38. Rocco M, Dell’Utri D, Morelli A, Spadetta G, Conti G, Antonelli M, Pietropaoli P (2004) Noninvasive ventilation by helmet or face mask in immunocompromised patients: a case-control study. *Chest* 126:1508–1515
39. Parthasarathy S, Jubran A, Tobin MJ (2000) Assessment of neural inspiratory time in ventilator-supported patients. *Am J Respir Crit Care Med* 162:546–552
40. Squadrone E, Frigerio P, Fogliati C, Gregoretti C, Conti G, Antonelli M, Costa R, Baiardi P, Navalesi P (2004) Noninvasive vs invasive ventilation in COPD patients with severe acute respiratory failure deemed to require ventilatory assistance. *Intensive Care Med* 30:1303–1310