

New versus Conventional Helmet for Delivering Noninvasive Ventilation

A Physiologic, Crossover Randomized Study in Critically Ill Patients

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ABSTRACT

Background: The helmet is a well-tolerated interface for noninvasive ventilation, although it is associated with poor patient–ventilator interaction. A new helmet (NH) has proven to attenuate this limitation of the standard helmet (SH) in both bench study and healthy volunteers. The authors compared a NH and a SH in intensive care unit patients receiving noninvasive ventilation for prevention of postextubation respiratory failure; both helmets were also compared with the endotracheal tube in place before extubation.

Methods: Fourteen patients underwent 30-min trials in pressure support during invasive ventilation and then with a SH and a NH in a random order. The authors measured comfort, triggering delays, rates of pressurization (airway pressure–time product [PTP] of the first 300 [PTP_{300-index}] and 500 [PTP_{500-index}] ms from the onset of effort, and the first 200 ms from the onset of insufflation [PTP₂₀₀]), time of synchrony between effort and assistance ($\text{Time}_{\text{synch}}/\text{Ti}_{\text{neu}}$), respiratory drive and frequency, arterial blood gases (ABGs), and rate of asynchrony.

Results: Compared with SH, NH improved comfort (5.5 [5.0 to 6.0] vs. 8.0 [7.8 to 8.0]), respectively, $P < 0.001$), inspiratory trigger delay (0.31 [0.22 to 0.43] vs. 0.25 [0.18 to 0.31] s, $P = 0.007$), and pressurization (PTP_{300-index}: 0.8 [0.1 to 1.8] vs. 2.7 [7.1 to 10.0]%; PTP_{500-index}: 4.8 [2.5 to 9.9] vs. 27.3 [16.2 to 34.8]%; PTP₂₀₀: 13.6 [10.1 to 19.6] vs. 30.4 [24.9 to 38.4] cm H₂O/s, $P < 0.01$ for all comparisons) and $\text{Time}_{\text{synch}}/\text{Ti}_{\text{neu}}$ (0.64 [0.48 to 0.72] vs. 0.71 [0.61 to 0.81], $P = 0.007$). Respiratory drive and frequency, ABGs, and rate of asynchrony were not different between helmets. Endotracheal tube outperformed both helmets with respect to all variables, except for respiratory rate, ABGs, and asynchronies.

Conclusions: Compared with a SH, a NH improved comfort and patient–ventilator interaction. (ANESTHESIOLOGY 2016; 124:101-8)

NONINVASIVE ventilation (NIV) improves gas exchange and unloads the respiratory muscles in patients with acute respiratory failure of different etiologies.^{1,2} Depending on the several factors including the underlying disease, severity of acute respiratory failure, and associated comorbidities, the duration of NIV application varies from a few hours to several days.³ Both the performance of the interface and the patient's tolerance may affect NIV outcome.⁴⁻⁷ The helmet is a NIV interface that, compared with the oronasal mask, is better tolerated for prolonged periods and thus allows longer continuous NIV application and fewer interruptions.⁷⁻¹⁰ Unfortunately, compared with the mask, the helmet is characterized by less-efficient rates of pressurization and triggering function and worsened patient–ventilator synchrony.^{11,12}

What We Already Know about This Topic

- Mechanical ventilation using a helmet is associated with less discomfort versus commonly used interfaces (i.e., endotracheal tube, face mask). The upward displacement of the standard helmet makes the ventilator less responsive to patients' breathing effort, while armpit braces contribute to discomfort.

What This Article Tells Us That Is New

- In 14 patients, a novel helmet provided more comfort and faster responses to effort than the standard helmet, but an endotracheal tube enabled the most rapid responses.

A new helmet (NH; Castar Next, Intersurgical, Italy) was recently introduced into clinical use in Europe and Asia. A NH is characterized by an annular openable ring placed underneath

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an inflatable cushion that secures the helmet without the need for armpit braces, as opposed to the standard helmet (SH).¹³ The NH is more effective in delivering NIV by avoiding, or at least reducing to a large extent, the upward displacement of the helmet during ventilator insufflation.¹³ A NH has shown, compared with a SH, improved performance with respect to pressurization rate and triggering, both during bench study¹³ and in healthy volunteers.¹⁴ However, these encouraging results have not yet been confirmed in intensive care unit (ICU) patients. In addition, no comparison between a NH and a SH regarding patient comfort has been performed in ICU patients.

We designed this study to assess and compare a SH and a NH in patients undergoing NIV to avert the risk of postextubation respiratory failure and reintubation. Our main interest in outcomes was patient's comfort (primary endpoint) and to the following additional endpoints: triggering performance and rate of pressurization, respiratory rate and drive, arterial blood gases (ABGs), and patient-ventilator synchrony. In addition, NIV delivered with the two helmets was compared with invasive ventilation as delivered immediately before extubation through the endotracheal tube (ET).

Materials and Methods

This prospective crossover randomized controlled trial was performed from April to August 2012 in the ICU of the University Hospital "Maggiore della Carità" (Novara, Italy), in accordance with the principles outlined in the Declaration of Helsinki. The institutional ethics committee (Inter-hospital Ethical Committee, Novara, Italy) approved the study, and patient's consent was obtained according to the Italian regulations. At the time the study was conducted, trial registration was not mandatory for this type of investigations.

Patients and Protocol

Patients were eligible for the study if they were invasively ventilated for more than 48 h, were awake, and had indications to receive prophylactic NIV after extubation, being at risk of postextubation respiratory failure.¹⁵⁻¹⁷ At inclusion, midazolam and propofol had been interrupted for at least 24 and 4 h, respectively, whereas remifentanyl was administered up to $0.08 \mu\text{g}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$, if necessary.¹⁸

Patients were considered at risk of extubation failure when at least one of the following conditions was present: (1) chronic respiratory disorders, (2) chronic heart failure, (3) $\text{Paco}_2 > 45 \text{ mmHg}$ during the spontaneous breathing trial, (4) two or more comorbidities, (5) morbid obesity (body mass index $\geq 35 \text{ kg/m}^2$),¹⁹ and (6) weak cough, as assessed by an Airway Care Score values more than or equal to 8 and less than 12.¹⁵ The extubation criteria for the study protocol were those in use for clinical purposes in our ICU. Exclusion criteria were as follows: (1) age less than 18 yr, (2) pregnancy, (3) intracranial bleeding, (4) recent gastric or esophageal surgery, (5) tracheotomy, (6) active upper gastrointestinal bleeding, (7) lack of cooperation, and (8) inclusion in other research protocols.

After enrollment, a catheter for detection of electrical activity of the diaphragm (EAdi; Edi catheter, Maquet Critical Care, Sweden) was inserted, and correct positioning was assured.²⁰ Each patient underwent three 30-min trials in pressure support ventilation, first with ET and then, after extubation, with a SH (Castar R, Intersurgical) and a NH, applied according to a computer-generated random sequence. Pressure support ventilation was delivered through the Servo-I ventilator (Maquet Critical Care), set with the following ventilator settings for the entire protocol: positive end-expiratory pressure (PEEP) of $10 \text{ cm H}_2\text{O}$, inspiratory support of $10 \text{ cm H}_2\text{O}$, inspiratory flow trigger at 1 l/min , expiratory trigger at 35% of peak inspiratory flow, and the fastest rate of pressurization. Software for air leaks compensation was used during both SH and NH trials. Inspired oxygen fraction (FIO_2) was initially set to obtain pulse arterial oxygen saturation (SpO_2) ≥ 94 and $\leq 97\%$ and then maintained unmodified throughout the study period.

Predefined criteria for protocol interruption were as follows: (1) need for emergency reintubation; (2) severe acute respiratory acidosis, as defined by $\text{Paco}_2 > 55 \text{ mmHg}$ and $\text{pH} < 7.25$; (3) inability to expectorate secretions; (4) hemodynamic instability (*i.e.*, need for continuous infusion of dopamine or dobutamine more than $5 \mu\text{g}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$, norepinephrine more than $0.1 \mu\text{g}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$, or vasopressin to maintain mean arterial blood pressure more than 60 mmHg); (5) life-threatening arrhythmias or electrocardiographic signs of ischemia; or (6) loss of 2 or more points of Glasgow Coma Scale score.

Data Acquisition and Measurements

Airflow, airway pressure (Paw), and EAdi were acquired from the ventilator through a RS232 interface at a sampling rate of 100 Hz using dedicated software (NAVA Tracker version 3.0, Maquet Critical Care). Data were recorded and stored on a personal computer; the last minute of each trial was offline analyzed breath by breath, using a customized software.²⁰

The pressurization performance was assessed with the Paw-time product (PTP) of the first 200 ms computed from the onset of ventilator assistance (PTP_{200}) and with the PTP of the first 300 and 500 ms from the onset of patient effort, indexed to the ideal PTP ($\text{PTP}_{300\text{-index}}$ and $\text{PTP}_{500\text{-index}}$, respectively).^{13,21} The ideal PTP was computed considering a perfectly squared rectangle on the Paw-time tracing, having the height of the preset inspiratory pressure above PEEP, and the width of the time window considered (*i.e.*, 0.3 and 0.5 s from the onset of the inspiratory effort, assessed from the EAdi tracing, for PTP_{300} and PTP_{500} , respectively).^{13,21} The drop in Paw ($\Delta P_{\text{trigger}}$) and the PTP during the triggering phase ($\text{PTP}_{\text{trigger}}$) were computed to evaluate triggering performance.^{13,21}

Ventilator cycling rate (RR_{mcc}) and patient's neural respiratory rate (RR_{neu}) were calculated on the flow and EAdi tracings, respectively. The neural effort of the patient was

evaluated by the EAdi peak value (EAdi_{peak}).^{22,23} We calculated inspiratory (Delay_{TR-insp}) and expiratory (Delay_{TR-exp}) trigger delays²⁴ and the time of synchrony between diaphragm activity and ventilator assistance, indexed to patient's own (neural) inspiratory time (Time_{synch}/Ti_{neu}).²¹ Asynchronies (ineffective efforts, auto and double triggerings) were also assessed and expressed in absolute number and as asynchrony index (AI%), *i.e.*, the total number of asynchronous events divided by the number of triggered and not triggered breaths.²⁵

At the end of each trial, arterial blood was sampled for gas analysis. At the end of both NIV trials, patient's comfort was assessed by means of a numeric rating scale (NRS), validated and utilized for assessing pain,^{26–28} dyspnea,²⁹ and comfort/discomfort,^{30,31} asking the patient to indicate a number between 0 (worst possible) and 10 (best possible) on an ICU-adapted large print scale including number and descriptors.³¹ Before protocol initiation, all patients received a detailed explanation about the 11-point NRS, including the manner in which it was going to be administered. The scores obtained were recorded without further indications or comments.

Statistical Analysis

We considered clinically important a 50% increase of the NRS value scored by the patient to indicate his/her comfort with a NH, as opposed to a SH, and accordingly calculated a minimum of 14 patients to be necessary (α risk of 0.05 and a β risk of 0.20). Because of the relatively small number of patients, we analyzed data by nonparametric tests. Data are presented as median and interquartile range (25th to 75th percentile), unless otherwise specified. We used the Wilcoxon signed-rank test for comparison between a SH and a NH. After excluding the presence of treatment–period interaction and carryover effect, we utilized the ANOVA on ranks to compare ET with a SH and a NH; the corrected Bonferroni

post hoc test was applied, as indicated. We used the Spearman rank correlation test to determine the correlation between comfort and PTP₂₀₀, PTP_{500-index} and PTP_{300-index}, and PTPt. We always considered significant *P* values ≤ 0.05 .

Results

We enrolled 15 consecutive patients; 1 patient, however, underwent emergency reintubation because of the lack of airway patency after extubation and was then excluded from the data analysis. A second patient was reintubated 24 h after completion of the study protocol consequent to severe dyspnea and respiratory acidosis. Demographic and anthropometric characteristics of 14 patients are given in table 1. The risk of the carryover effect was ruled out for all data.

Comfort

The individual values of the comfort score for all the patients and their median and interquartile range are depicted in figure 1. Comfort was significantly improved while using a NH (8.0 [7.8 to 8.0]), as opposed to a SH (5.5 [5.0 to 6.0]) ($P < 0.001$). Not shown in the figure, the comfort score before extubation was 3.0 (2.0 to 3.7).

Pressurization and Triggering Performance

Figure 2 shows overlapped Paw tracings obtained from one representative subject, corresponding to the last mechanical insufflation with all three interfaces. Even though the rate of pressurization set on the ventilator was the same, the time to achieve the preset pressure differed between interfaces. In fact, the increase in Paw was faster with a NH (dashed line) than with a SH (dotted line), and both were slower than with ET (solid line). As depicted in figure 3, the median values with interquartile range of PTP_{300-index}, PTP_{500-index}, and PTP₂₀₀ were all improved (*i.e.*, higher) with a NH, as opposed to a SH ($P < 0.01$ for all comparisons). A NH also improved PTPt compared with a SH ($P < 0.01$). Compared

Table 1. Patients' Characteristics at ICU Admission

Patient	Gender	Age (yr)	Weight (kg)	BMI (kg/m ²)	SAPS II	Cause of ARF
1	M	68	73	25.1	68	Pancreatitis
2	F	76	76	28.4	46	Septic shock
3	F	32	45	17.2	33	Polytrauma
4	M	56	90	28.4	40	Polytrauma
5	M	63	60	20.3	30	Pneumonia
6	M	72	69	24.5	43	Congestive heart failure
7	F	78	89	29.1	49	Septic shock
8	M	72	82	26.8	36	COPD exacerbation
9	M	43	80	24.1	33	Polytrauma
10	F	65	81	26.5	30	COPD exacerbation
11	F	69	76	25.9	48	Septic shock
12	F	55	78	25.4	22	Septic shock
13	M	59	75	26.4	35	Septic shock
14	M	64	81	28.7	40	Septic shock

ARF = acute respiratory failure; BMI = body mass index; COPD = chronic obstructive pulmonary disease; ICU = intensive care unit; SAPS II = Simplified Acute Physiology Score II.

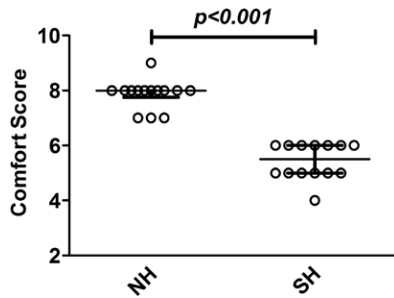


Fig. 1. Hollow circles indicate the individual scores given by the 14 patients on the Numeric Rating Scale for the two helmets. Solid lines depict median and 25th to 75th interquartile values. NH = new helmet; SH = standard helmet.

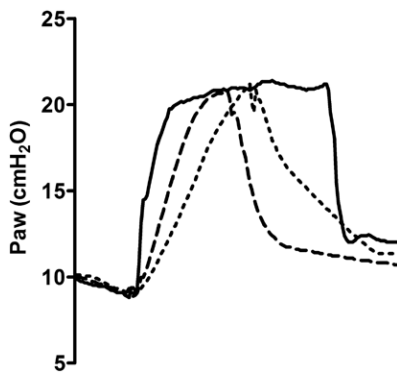


Fig. 2. Airway pressure profiles of the last mechanical breath during invasive ventilation through ET (solid line), and non-invasive ventilation with NH (dashed line), and SH (dotted line) from one representative patient. ET = endotracheal tube; NH = new helmet; Paw = airway pressure; SH = standard helmet.

with both helmets, ET was characterized by better rates of pressurization and triggering performance ($P < 0.05$ for all comparisons). Comfort was directly correlated with PTP_{200} ($\rho = 0.66$, $P < 0.001$), $PTP_{500\text{-index}}$ ($\rho = 0.60$, $P < 0.01$), and $PTP_{300\text{-index}}$ ($\rho = 0.43$, $P = 0.02$) and inversely correlated with $PTP_{\bar{t}}$ ($\rho = -0.55$, $P < 0.01$).

Breathing Pattern

As presented in table 2, RR_{mcc} ($P = 0.03$), whereas not RR_{neu} ($P = 0.13$), was higher while using a NH, compared with a SH. Moreover, $EAdi_{\text{peak}}$ was not significantly different between NH and SH ($P = 0.80$). When compared with ET, NH ($P = 0.03$), but not SH ($P = 0.65$), was characterized by a higher RR_{mcc} ; on the opposite, RR_{neu} was not different between trials ($P = 0.17$). $EAdi_{\text{peak}}$ was significantly lower with ET compared with both helmets ($P < 0.05$).

Patient–Ventilator Synchrony

As also shown in table 2, $\text{Delay}_{\text{TR-insp}}$ and $\text{Time}_{\text{synch}}/\text{Ti}_{\text{neu}}$ were improved with NH, as opposed to SH ($P = 0.007$ for both variables), whereas $\text{Delay}_{\text{TR-exp}}$ was similar between helmets ($P = 0.31$). ET assured better $\text{Delay}_{\text{TR-insp}}$ and $\text{Time}_{\text{synch}}/\text{Ti}_{\text{neu}}$, compared with both NH ($P = 0.04$ and

$P < 0.001$, respectively) and SH ($P = 0.002$ and $P < 0.001$, respectively). $\text{Delay}_{\text{TR-exp}}$ was shorter with NH, compared with ET ($P = 0.03$), whereas not different between SH and ET ($P = 0.27$).

Four patients had an $\text{AI}\% > 10\%$ during all three trials, with no significant difference among interfaces. In particular, we observed (1) 17 IEs in NH, 31 in SH, and 7 in ET; (2) 4 auto triggerings during both NH and SH and 6 in ET; and (3) 9 double triggerings in NH, 3 in SH, and 1 in ET (fig. 4).

Arterial Blood Gases

As shown in table 2, there was no difference in ABGs between NH and SH; ET was also no different with respect to both helmets.

Discussion

We found that, compared with a SH, a NH (1) improved short term (30') comfort, (2) improved patient–ventilator interaction (*i.e.*, rate of pressurization, triggering function, and $\text{Time}_{\text{synch}}/\text{Ti}_{\text{neu}}$), (3) did not affect patient respiratory rate and drive, rate of asynchrony, and ABGs. Patient–ventilator interaction was significantly better with ET compared with both helmets, with no significant difference in ABGs and rate of asynchrony. To our knowledge, this is the first comparison between two interfaces for NIV and ET during invasive ventilation.

Patient tolerance of NIV is strongly related to comfort of the interface.^{6,32} Poor tolerance is a major determinant of NIV failure leading to endotracheal intubation and its related side effects and complications.⁴ Therefore, interface comfort is an important clinical outcome variable for NIV.³² This is particularly true for the sickest patients who require NIV for a prolonged period of time.^{4,9} A recent randomized trial in hypoxemic patients comparing standard oxygen therapy with either NIV or heated and humidified high-flow oxygen therapy found the latter to be associated with an increased degree of comfort compared with NIV.³³ This may have contributed to the lower intubation rate observed in the most severely hypoxemic patients in the group treated with high-flow oxygen.³³

Comfort depends on different factors such as amount of air leaks, skin pressure sores, pressurization and triggering performance, and quality of patient–ventilator synchrony. Compared with the conventional facial masks, a SH improves patient comfort and enhances NIV tolerance,^{8,10,34} as indicated by longer time of continuous treatment and fewer interruptions,^{7–10,34} decreased NIV-related complications,^{7–10,34} and reduced rate of intubation secondary to intolerance.^{7–9,34} However, a SH has drawbacks primarily attributable to the armpit braces, which may cause pain and discomfort because of the pressure exerted on the skin of the axillary area,³⁵ and to the highly compliant soft collar, which contributes to the downward movement of the soft collar leading to an upward displacement of helmet during

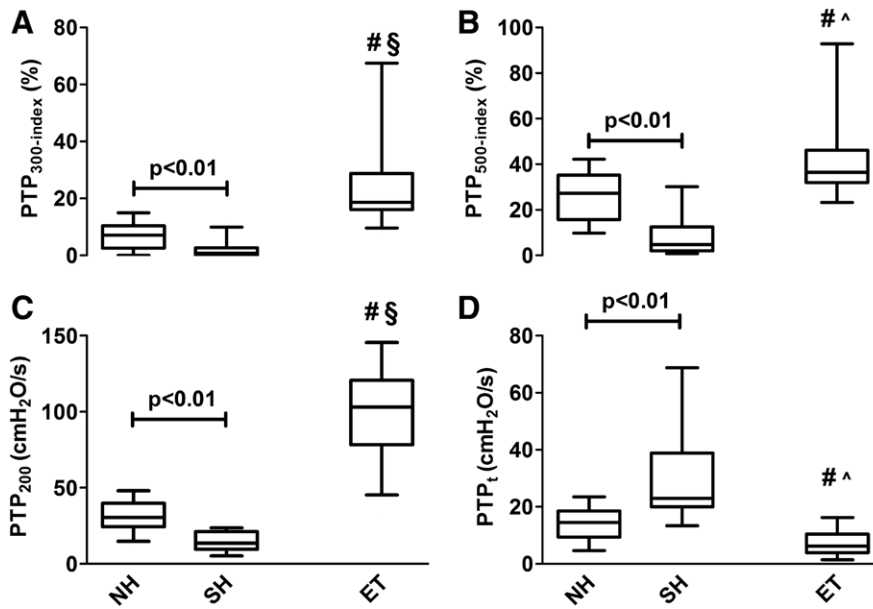


Fig. 3. PTP_{300-index} (A), PTP_{500-index} (B), PTP₂₀₀ (C), and PTPt (D) computed during NH, SH, and ET are depicted. The bottom and top of the box indicate the 25th and 75th percentile, the horizontal band near the middle of the box is the median, and the ends of the whiskers represent the 10th and 90th percentile. #*P* < 0.01 ET versus SH; \$*P* < 0.01 ET versus NH; ^*P* < 0.05 ET versus NH. ET = endotracheal tube; NH = new helmet; PTP = airway pressure–time product; PTP₂₀₀ = PTP of the first 200ms computed from the onset of ventilator assistance; PTP_{300-index} = PTP of the first 300ms from the onset of patient effort, indexed to the ideal PTP; PTP_{500-index} = PTP of the first 500ms from the onset of patient effort, indexed to the ideal PTP; PTPt = PTP during the triggering phase; SH = standard helmet.

Table 2. Arterial Blood Gases and Patient–Ventilator Interactions

	ET	NH	SH
pH	7.42 (7.40–7.46)	7.44 (7.40–7.46)	7.42 (7.40–7.43)
PaCO ₂ (mmHg)	39.5 (37.1–43.6)	38.7 (36.1–44.7)	40.1 (38.3–53.3)
PaO ₂ :FIO ₂	219 (184–240)	242 (192–269)	224(204–289)
RR _{mec} (breaths/min)	20.2 (15.7–23.8)	25.9 (19.9–26.9)*	22.1 (18.5–24.0)†
RR _{neu} (breaths/min)	19.1 (14.1–24.0)	23.8 (20.2–26.1)	21.0 (16.5–24.1)
EAdi _{peak} (μV)	5.9 (3.8–10.8)	10.7 (7.7–14.8)*	13.1 (7.1–14.7)‡
Delay _{TR-insp} (s)	0.12 (0.09–0.19)	0.25 (0.18–0.31)*	0.31 (0.22–0.43)†‡
Delay _{TR-exp} (s)	0.17 (0.15–0.24)	0.10 (0.05–0.14)*	0.13 (0.08–0.21)
Time _{synch} /Ti _{neu}	0.85 (0.77–0.90)	0.71 (0.61–0.81)*	0.64 (0.48–0.72)†‡

* *P* < 0.05 ET vs. NH. † *P* < 0.05 NH vs. SH. ‡ *P* < 0.05 ET vs. SH.

Delay_{TR-exp} = expiratory trigger delay; Delay_{TR-insp} = inspiratory trigger delay; EAdi_{peak} = EAdi peak value; ET = endotracheal tube; NH = new helmet; PaCO₂ = partial arterial pressure of carbon dioxide; PaO₂:FIO₂ = ratio between the partial arterial pressure and the inspired fraction of oxygen; RR_{mec} = ventilator cycling rate; RR_{neu} = patient’s neural respiratory rate; SH = standard helmet; Time_{synch}/Ti_{neu} = time of synchrony between inspiratory muscle activity and ventilator assistance indexed to patient’s own inspiratory time.

ventilator insufflation.¹³ An annular openable ring, placed underneath the inflatable cushion surrounding the patient’s neck, constitutes the NH securing system. By replacing the armpit braces, NH overcomes entirely the first problem; in addition, by preventing the displacement of the helmet during insufflation, which affects pressurization and triggering performances, it largely reduces the second limitation.^{13,14}

This study confirms in ICU patients the findings of previous investigations performed in bench studies¹³ and healthy volunteers,¹⁴ indicating that, compared with a SH, a NH increases the rate of pressurization and improves triggering performance with unmodified ventilator settings. Although the removal of the armpit braces likely also contributed to

the better comfort with a NH, as opposed to a SH, the enhanced pressurization and triggering performance were found to significantly correlate with the improvement in comfort achieved by a NH.

In keeping with the findings of studies comparing NIV delivery with different ventilatory modes,^{36–41} EAdi_{peak}, RR_{neu}, and ABGs were not significantly different between SH and NH and when comparing the two helmets with ET. Even more surprisingly, despite the improvement in patient–ventilator interaction with NH, compared with SH, as indicated by the significant improvement of the rates of pressurization, triggering performance, and Time_{synch}/Ti_{neu}, AI% showed overall no difference between

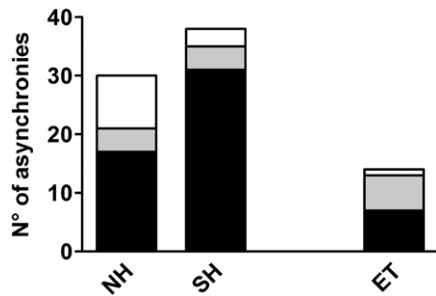


Fig. 4. Stacked bars indicating the sum of the overall asynchronies observed in all patients during noninvasive ventilation with NH and SH and during invasive ventilation. Ineffective efforts, auto triggerings, and double triggerings are separately indicated in *black*, *gray*, and *white*, respectively. ET = endotracheal tube; NH = new helmet; SH = standard helmet.

helmets. When considering separately the different asynchronous events, however, we observed that IEs were almost half with NH than with SH, whereas DTs were three times more frequent with the former, as opposed to the latter. During NIV, varying ventilator settings have a quite limited effect on IEs, which are principally reduced by containing air leaks.²⁵ Conversely, DTs depend primarily on a discrepancy between mechanical and patient's own (neural) inspiratory time, the former being shorter than the latter and is therefore dramatically influenced by the expiratory trigger threshold (*i.e.*, the percent of the peak flow rate at which the ventilator cycles off).⁴² Accordingly, varying the expiratory trigger threshold with a NH would likely reduce the rate of DTs.

Our study has some limitations deserving discussion. First, the study was designed as a physiologic comparison and did not consider clinical outcome variables. Very recently, a pilot multicenter randomized control trial enrolling patients with acute on chronic hypercapnic respiratory failure showed NH to be as effective as the oronasal mask in improving ABGs, dyspnea, and respiratory rate and showed no difference with respect to overall tolerance and need for intubation.⁴³ In hypercapnic patients with chronic obstructive pulmonary disease (COPD), compared with the oronasal mask, SH showed reduced efficacy in decreasing $Paco_2$ ⁸ and inspiratory muscles effort¹¹ and worsened patient-ventilator interaction and synchrony.¹¹ Hence, these findings by Pisani *et al.*⁴³ indirectly suggest that the physiologic benefit we observed with NH, compared with SH, translate into clinical improvement.

Second, because we powered the study to detect an improvement in comfort corresponding to a 50% increase on the NRS, 14 patients might not be sufficient to ascertain differences regarding other variables. For instance, the median value of $EAdi_{peak}$ with NH was approximately 20% lower than with SH, a difference that could achieve statistical significance when increasing the sample size.

Third, we do not consider in our comparison the oronasal mask, which is the current standard for NIV delivery.

Because of our study design, introducing a third group for comparison would have been extremely problematic. As mentioned earlier, previous investigations already separately compared the oronasal mask with either SH or NH.^{8,9,11,43} In addition, a recent study compared SH, NH, and the oronasal mask in healthy volunteers, showing that, at a PEEP level close to those used in our study, inspiratory effort and patient-ventilator interaction were significantly improved with the oronasal mask, compared with SH, whereas not with NH.¹⁴

Finally, because the evaluation of comfort was done after a relatively short period of evaluation, we cannot exclude that the improvement observed would weaken or even disappear after longer time.

In conclusion, in ICU patients receiving NIV to prevent reintubation due to postextubation respiratory failure, compared with SH, NH improved comfort, rate of pressurization, and triggering performance. This might translate in improved clinical outcome, especially for the most severe patients requiring NIV for prolonged periods of time.

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Intersurgical S.P.A. (Mirandola, Italy) provided the helmets used for the study.

Competing Interests

Drs. Olivieri and Navalesi contributed to the development of the helmet Next, whose license for patent belongs to Intersurgical S.P.A. (Mirandola, Italy) and received royalties for that invention. Dr. Navalesi received equipment and/or grants from MAQUET Critical Care (Solna, Sweden), Intersurgical S.P.A., Draeger Medical GmbH (Lubeck, Germany), Biotest (Dreieich, Germany), and Hillrom (St. Paul, Minnesota). Dr. Navalesi also received honoraria/speaking fees from MAQUET Critical Care, Covidien AG (Dublin, Ireland), Draeger Medical GmbH, Breas (Mölnlycke, Sweden), Hillrom, and Linde AG (Munich, Germany). The other authors declare no competing interests.

Reproducible Science

Full protocol available at: longhini.federico@gmail.com. Raw data available at: longhini.federico@gmail.com.

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