Comparison of oronasal and nasal masks in home mechanical ventilation: an observational cohort and bench study

Emeline Fresnel [1,16], Christian Caillard [2,3,16], Marius Lebret [1,4,5], Léa Razakamanantsoa [6,7], Adrien Kerfourn [1], Johan Dupuis[8], Jean-François Muir [9], Elodie Lhuillier [10], Kinan El Husseini [11,12], Thomas Similowski [7,13], Antoine Cuvelier [2,14] and Maxime Patout [7,15]

[1]Kernel Biomedical, Rouen, France. [2]Normandie University, UNIRouen, EA3830-GRHV, Institute for Research and Innovation in Biomedicine (IRIB), Rouen, France. [3]Medical and Surgical Intensive Care Unit, Elbeuf-Louviers-Val de Reuil Intercommunal Hospital, Saint-Aubin-Lès-Elbeuf, France. [4]Université Paris-Saclay, UVSQ, Erphan UR20201, Paris-Saclay University, Versailles, France. [5]Vent'Lab, Angers University Hospital, University of Angers, Angers, France. [6]AP-HP, Groupe Hospitalier Universitaire APHP-Sorbonne Université, site Pitié-Salpêtrière, Service de Pneumologie (Département R3S), Paris, France. [7]Sorbonne Université, INSERM, UMRS1158 Neurophysiologie Respiratoire Expérimentale et Clinique, Paris, France. [8]Asten Santé, Isneauville, France. [9]ADIR Association, Rouen, France. [10]Hôpital des Courses, Maisons Laffitte, France. [11]Service de Pneumologie A, Hôpital Bichat, FHU APOLLO, AP-HP, Paris, France. [12]INSERM UMRS1152 Physiopathologie et Épidémiologie des Maladies Respiratoires, Université Paris-Cité, Paris, France. [13]AP-HP, Groupe Hospitalier Universitaire APHP-Sorbonne Université, site Pitié-Salpêtrière, Département R3S, Paris, France. [14]Service de Pneumologie, Soins Intensifs Respiratoires, CHU de Rouen, Rouen, France. [15]AP-HP, Groupe Hospitalier Universitaire APHP-Sorbonne Université, site Pitié-Salpêtrière, Service des Pathologies du Sommeil (Département R3S), Paris, France. [16]These authors contributed equally to this work.

Corresponding author: Maxime Patout (Maxime.patout@aphp.fr)

Shareable abstract (@ERSpublications)
Mask-related side-effects are highly prevalent in patients treated with home non-invasive ventilation and are associated with poorer outcomes. Nasal masks are associated with a lower rate of side-effects and should be preferred as a first-line interface. https://bit.ly/4dh3OFB

Cite this article as: Fresnel E, Caillard C, Lebret M, *et al*. Comparison of oronasal and nasal masks in home mechanical ventilation: an observational cohort and bench study. *Eur Respir J* 2025; 65: 2302010 [DOI: 10.1183/13993003.02010-2023].

This article has an editorial commentary: https://doi.org/10.1183/13993003.02007-2024

Received: 11 Nov 2023
Accepted: 14 Sept 2024

Abstract

Background In patients with chronic respiratory failure, home non-invasive ventilation (NIV) is delivered through oronasal or nasal masks. Masks are a cornerstone for NIV success but can be associated with side-effects. However, the type, frequency and consequences of these side-effects are unknown. Here, we aimed to study the prevalence, nature and impact of mask-related adverse events in a cohort of stable patients. We then investigated differences between oronasal and nasal masks both in our cohort and in a bench study.

Methods This was a prospective observational cohort including patients established on long-term NIV admitted for their elective review. Data regarding mask-related side-effects were assessed using a structured questionnaire. Our bench study was performed using a three-dimensional printed head connected to an artificial lung.

Results 800 patients were included, of whom 84% had an oronasal mask. Moderate to very severe mask-related side-effects occurred in 47% of patients and severe to very severe side-effects occurred in 18% of patients. Side-effects were associated with poorer daytime arterial partial pressure of carbon dioxide ($p=0.005$), poorer subjective sleep quality ($p=0.003$) and poorer quality of life ($p<0.001$). Mask-related side-effects were more frequently reported with the use of oronasal masks compared to nasal masks ($p=0.023$). Our bench study showed that nasal masks were more stable than oronasal masks ($p<0.001$).

Conclusions Mask-related side-effects are frequent and associated with poorer outcomes. Our data suggest that nasal masks may have a better tolerance profile and should be used as a first-line interface.

Introduction

Home non-invasive ventilation (NIV) has become a cornerstone of the management of chronic alveolar hypoventilation, whether caused by COPD [1], morbid obesity [2] or a neuromuscular deficiency [3]. Home NIV can be administered through oronasal or nasal masks. Each type of mask has advantages and inconveniencies. Oronasal masks allow high-intensity NIV [4] with limited amounts of leak and are

mainly used in acute respiratory failure [5, 6]. However, they can be uncomfortable, cause claustrophobia, and hinder verbal communication and feeding [7]. Moreover, the pressure they exert on the lower jaw promotes obstructive apnoeic events [8]. Nasal masks are smaller and lighter, and are mainly used in sleep disordered breathing [9]. They are considered more comfortable and less oppressive by patients with obstructive sleep apnoea (OSA) [10]. However, they can generate mouth leaks that favour patient–ventilator asynchronies which can compromise the efficacy of ventilatory support [5]. Despite these differences, oronasal and nasal masks have not formally been compared in the home NIV setting aside from two crossover trials that failed to show any difference between oronasal and nasal masks in patients with neuromuscular disorders and COPD regarding their primary outcomes (mean nocturnal oxygen saturation and sleep efficiency, respectively) [11, 12]. Therefore, there is no documented reason for the predominance of oronasal mask prescription that is observed in clinical practice [13, 14].

Based on data describing a high frequency of NIV-related side-effects 2 months after home NIV initiation [15] and based on the notion that most of these side-effects are mask related [16], we aimed to study the prevalence, nature and impact of mask-related adverse events. We hypothesised that nasal masks would be associated with fewer side-effects than oronasal masks. To test this hypothesis, we assessed the prevalence of mask-related side-effects by conducting a prospective observational cohort study in patients established on long-term NIV. In a complementary manner, and to elucidate some of the clinical observations made, we designed and conducted a bench study of oronasal and nasal masks. This study specifically aimed to measure the oronasal pressure exerted by each type of mask and to determine the impact of mask type on ventilator performance.

Methods

Cohort study

The clinical study was approved by the ethics committee of Rouen University Hospital, Rouen, France (approval number: E2020-09). All consecutive patients admitted for NIV elective review between April 2017 and November 2019 in Rouen University Hospital were prospectively included in the study, except when mask type was not recorded. We only considered the first elective review of patients who attended multiple elective reviews after the study was initiated. NIV initiation was decided prior to inclusion in the study by experienced respiratory physicians. All commercially available masks in all sizes were available in the respiratory department where NIV was initiated. The type of mask (oronasal or nasal), its model and its size were decided by an experienced respiratory physician according to patients' characteristics and patients' comfort. All masks were tried in the hospital setting before being used at home.

Elective review assessments included physical examination, arterial blood gas (ABG) determination during unsupported breathing, ABG determination after 1 h of NIV, analysis of data downloaded from the ventilator built-in software, the French version of the Severe Respiratory Insufficiency (SRI) Questionnaire (maximal score: 100) [17, 18], sleepiness (Epworth Sleepiness Scale; maximal score: 24) and the Pittsburgh Sleep Quality Index (PSQI) (maximal score: 28) [19]. 11 NIV-related side-effects were systematically recorded: eye redness, rhinorrhoea, mouth dryness, hoarseness, abdominal bloating, mask-related pain, mask straps-related pain, pressure sores, noticeable leaks, deventilation dyspnoea (*i.e.* severe dyspnoea occurring immediately after cessation of NIV) and patient–ventilator asynchrony as perceived by the patient. Each side-effect severity was graded on a 0–4 scale as: absent (0), mild (1), moderate (2), severe (3) and very severe (4) (maximal NIV side-effect score: 44). Among this list, the five side-effects considered specifically attributable to the masks (rather than to NIV in general) were: eye redness, noticeable leaks, mask-related pain, mask straps-related pain and oronasal pressure sores (maximal mask-related side-effect score: 20). Conversely, the non-mask-related side-effect score maximal total was 24 (more details are provided in the supplementary material). Management and timing for next follow-up was decided by a respiratory physician with expertise in the management of home NIV.

Bench study

The bench study was conducted using a realistic three-dimensional (3D) printed head model using custom silicon to mimic skin texture containing eight force sensors, on which the tested masks (seven vented oronasal masks and three vented nasal masks; see supplementary material) were fitted. The 3D printed head was connected to an artificial lung (ASL 5000 breathing simulator; IngNar Medical, Pittsburgh, PA, USA) (figure 1) as previously described [20, 21]. A linear differential pressure transducer was used to measure mask pressure. Data were digitalised at 200 Hz with a 10 Hz filter (Biopac Systems, Goleta, CA, USA). Optimal mask fitting was determined by progressively tightening mask straps to minimise leaks while keeping the surface pressure as low as possible. Mask contact pressure and leaks were then evaluated

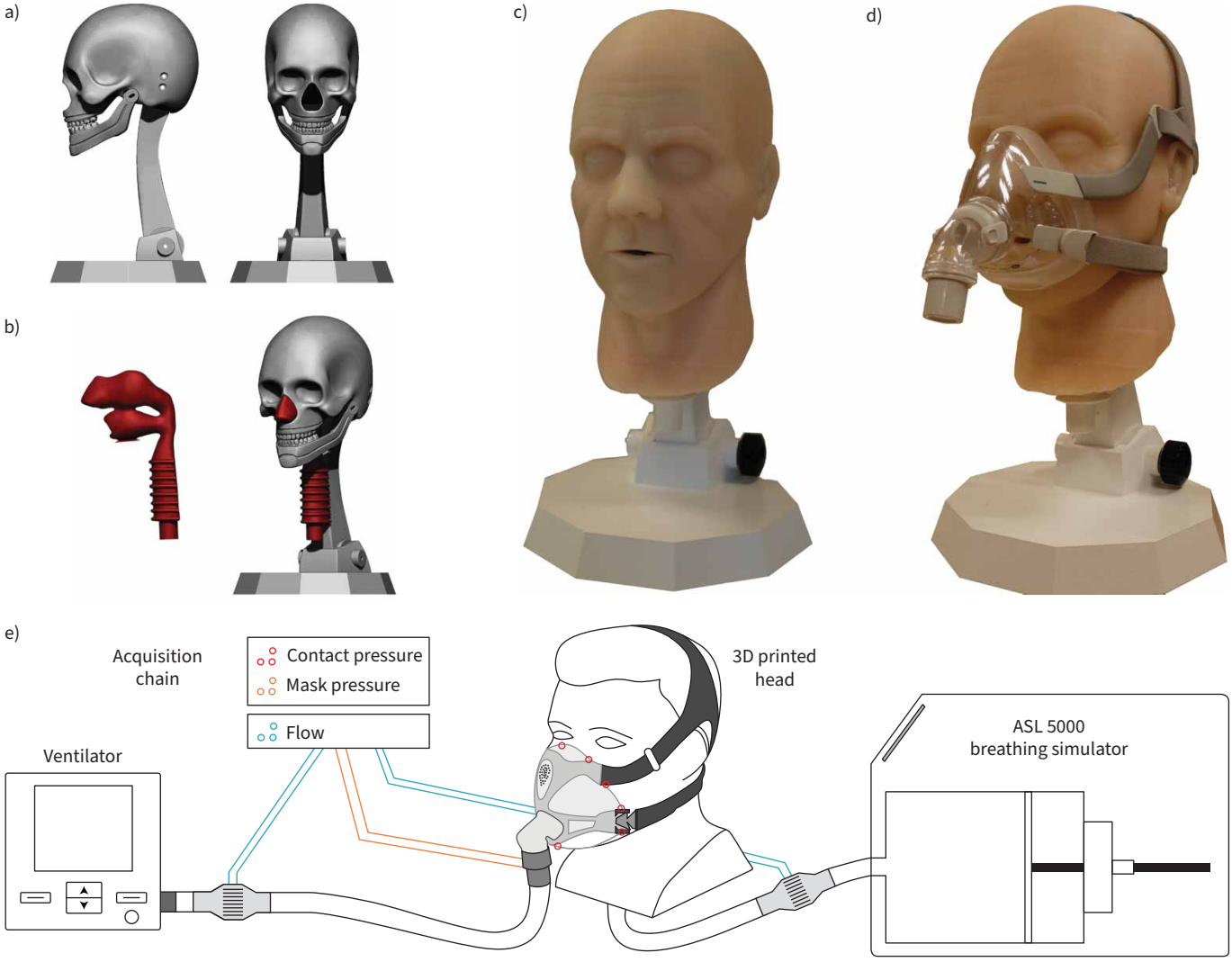

FIGURE 1 Realistic three-dimensional (3D) printed head model: a) 3D model of the skull and mandible structure (profile and front) with its pedestal, b) 3D model of the airway alone and when included in the skull, c) 3D printed head model covered with silicon skin and d) 3D printed head model fitted with an AirFit F20 size M mask (ResMed). e) Bench test setup.

under two different lung mechanics conditions: 1) restrictive (compliance 30 $mL \cdot cmH_2O^{-1}$, inspiratory resistance 8 $cmH_2O \cdot s \cdot L^{-1}$, expiratory resistance 5 $cmH_2O \cdot s \cdot L^{-1}$) and 2) obstructive (compliance 50 $mL \cdot cmH_2O^{-1}$, inspiratory resistance 20 $cmH_2O \cdot s \cdot L^{-1}$ expiratory resistance 25 $cmH_2O \cdot s \cdot L^{-1}$). During each simulation, respiratory rate ranged from 12 to 20 $breaths \cdot min^{-1}$ and inspiratory effort ($P_{0.1}$) was set at 2.5, 3.0 and 3.5 cmH_2O for each breathing frequency. Each simulation was conducted with three different ventilators: Trilogy 100 (Philips Respironics, Murrysville, PA, USA), Vivo 50 (Breas, Mölnlycke, Sweden) and Astral 150 (ResMed, San Diego, CA, USA) in spontaneous mode set with a positive expiratory pressure of 5 cmH_2O and a positive inspiratory pressure of 20 and 35 cmH_2O (the higher level of positive inspiratory pressure was used to simulate maximal delivered pressure according to real-life data; detailed settings for each ventilator and for each lung mechanics condition can be found in the supplementary material). We evaluated the following variables: mean total leak ($L \cdot min^{-1}$), mean contact pressure (mmHg), differential inspiratory–expiratory contact pressure (mmHg), mask movement (cm), inspiratory flow preceding ventilator triggering ($L \cdot min^{-1}$), inspiratory effort required to trigger the ventilator (cmH_2O), triggering delay (ms), maximal inspiratory pressure (cmH_2O), tidal volume (mL) and work of breathing (mJ) (a detailed computation of variables is described in the supplementary material). Simulated patient–ventilator asynchronies were analysed according to the framework established by the SomnoNIV working group of the French "Société de Pneumologie de Langue Française" [22] and expressed as a percentage of asynchronised cycles over the total number of cycles.

Statistical analysis

Continuous data are presented as mean and standard deviation when normally distributed and as median and interquartile range when not. They are compared using the t-test or Mann–Whitney test according to data distribution. Categorical data are presented as frequency counts and percentages. They are compared using the Chi-squared test. Correlations were determined using Spearman's test. Comparisons were considered significant for p-values <0.05. Analyses were performed using SPSS version 26.0 (IBM, Armonk, NY, USA).

Results

Study population

Between April 2017 and November 2019, 2314 elective reviews of patients established on home NIV were performed in 816 patients. Of those, 16 (2%) were not included as the type of interface used could not be retrieved. Out of the 800 patients in the cohort, 676 patients (84%) used oronasal masks and 124 (16%) used nasal masks (figure 2). Patients' characteristics are described in table 1 (detailed ventilator settings are provided in the supplementary material).

NIV-related side-effects: prevalence and consequences

In the cohort, the NIV-related side-effect total score was 5 (3–8). Patients reported side-effects in 3 (2–5) types of side-effects regardless of their severity (figure 3). 375 (47%) patients reported at least two moderate to very severe side-effects in two different side-effects and 211 (26%) patients reported at least one severe to very severe side-effect (the distribution of side-effects is presented in the supplementary material). Mask-related side-effects accounted for 46% (25–60%) of the total side-effect score. Patients with a total NIV-related side-effect score ⩾5 had poorer control of daytime arterial partial pressure of carbon dioxide (P_{aCO_2}) (6.2 (5.7–7.0) *versus* 5.8 (5.3–6.4) kPa; p<0.001), poorer health-related quality of life (SRI Questionnaire 52 (41–65) *versus* 64 (53–77); p<0.001), poorer subjective quality of sleep (PSQI 5 (4–11) *versus* 5 (3–8); p<0.001) but similar daily use of NIV (7.3 (5.0–9.0) *versus* 7.7 (5.5–9.2) $h \cdot day^{-1}$; p=0.250).

Mask-related side-effects: prevalence

The overall prevalence of moderate to very severe (grade ⩾2 out of 4) mask-related side-effects was 47%. Moderate to very severe mask-related side-effects were more frequent in patients with oronasal masks than in patients with nasal masks (49% *versus* 38%; p=0.023) (figure 4). The overall prevalence of severe to very severe (grade ⩾3 out of 4) mask-related side-effects was 18%. Severe to very severe mask-related side-effects were also more frequent in patients with oronasal masks than in patients with nasal masks (20% *versus* 8%; p=0.006). Nasal masks were more frequently used in patients with OSA (29%) and neuromuscular diseases (24%) compared to patients with COPD (11%), patients with COPD and OSA

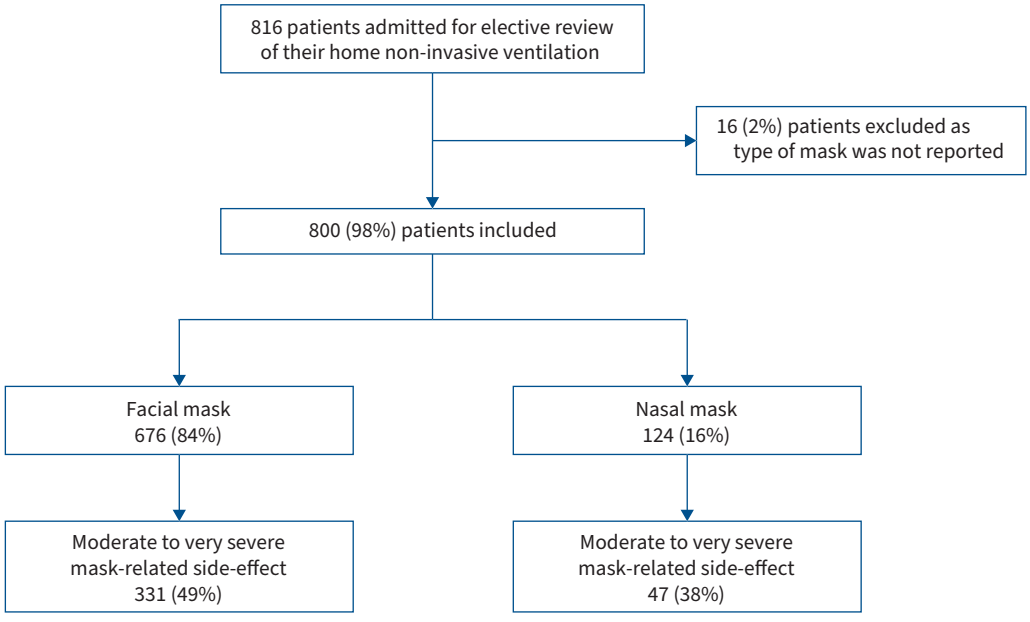

FIGURE 2 Study flowchart.

TABLE 1 Characteristics of the cohort population

Patients	800
Male	392 (49)
Age (years)	64±15
Body mass index (kg·m^{-2}) (n=779)	33±11
Comorbidities	
Hypertension	469 (59)
Diabetes	246 (31)
Dyslipidaemia	300 (38)
Ischaemic heart disease	121 (15)
Smoking history	
Non-smoker	307 (38)
Active smoker	151 (19)
Former smoker	342 (43)
Smoking pack-years (n=488)	40±28
Respiratory symptoms	
Dyspnoea ⩾3 mMRC scale (n=782)	385 (48)
Underlying disease justifying NIV initiation	
COPD	180 (23)
COPD associated with sleep apnoea	147 (18)
Isolated obesity hypoventilation syndrome	35 (4)
Obesity hypoventilation syndrome with obstructive sleep apnoea	202 (25)
Obstructive sleep apnoea	14 (2)
Amyotrophic lateral sclerosis	59 (7)
Slowly progressive neuromuscular disease[#]	110 (14)
Chest wall disease[¶]	53 (7)
Chronic respiratory failure history	
NIV initiation during elective admission	451 (56)
Time since installation (days)	367 (89–1659)
Baseline apnoea–hypopnoea index (events·h^{-1}) (n=582)	21 (8–42)
Admission for acute respiratory failure within 12 months	135 (17)
Patient-centred outcomes[+]	
Severe Respiratory Insufficiency Questionnaire (n=710)	57.8 (45.2–70.9)
Epworth Sleepiness Scale (n=665)	4 (2–8)
Pittsburgh Sleep Quality Index (n=691)	6 (4–10)
NIV side-effect score	5 (3–8)
Arterial blood gases	
Unsupported breathing (n=793)	
pH	7.39 (7.37–7.42)
P_{aCO_2} (kPa)	6.1 (5.5–6.7)
P_{aO_2} (kPa)	10.0 (8.9–11.2)
After 1 h NIV (n=775)	
pH	7.43 (7.40–7.46)
P_{aCO_2} (kPa)	5.4 (4.7–6.2)
P_{aO_2} (kPa)	11.3 (9.9–13.0)

Data are presented as n, n (%), mean±SD or median (interquartile range). mMRC: modified Medical Research Council; NIV: non-invasive ventilation; P_{aCO_2}: arterial partial pressure of carbon dioxide; P_{aO_2}: arterial partial pressure of oxygen. [#]: slowly progressive neuromuscular disease group included patients with myotonic dystrophy, Duchenne's disease or diaphragm palsy; [¶]: chest wall disease group included patients with kyphoscoliosis or post-polio syndrome; [+]: maximal scores: Severe Respiratory Insufficiency Questionnaire 100, Epworth Sleepiness Scale 24, Pittsburgh Sleep Quality Index 28, NIV side-effect score 44.

(14%) or patients with obesity hypoventilation syndrome (OHS) (11%). The incidence of moderate to very severe mask-related side-effects did not differ between groups (p=0.345).

Mask-related side-effects: consequences

Patients with moderate to very severe mask-related side-effects had poorer control of daytime P_{aCO_2} (6.12 (5.7–6.8) *versus* 5.9 (5.4–6.6) kPa; p=0.005), poorer subjective sleep quality (PSQI 7 (4–11) *versus* 6 (3–9); p=0.003) and poorer quality of life (SRI questionnaire 54.6 (41.8–67.4) *versus* 59.8 (49.3–74.6); p<0.001); adherence to NIV was similar in both groups (figure 5). Patients with moderate to very severe mask-related side-effects were more likely to have a level of leaks above the abnormal threshold (rate ratio 1.13, 95% CI 1.01–1.27; p=0.0421).

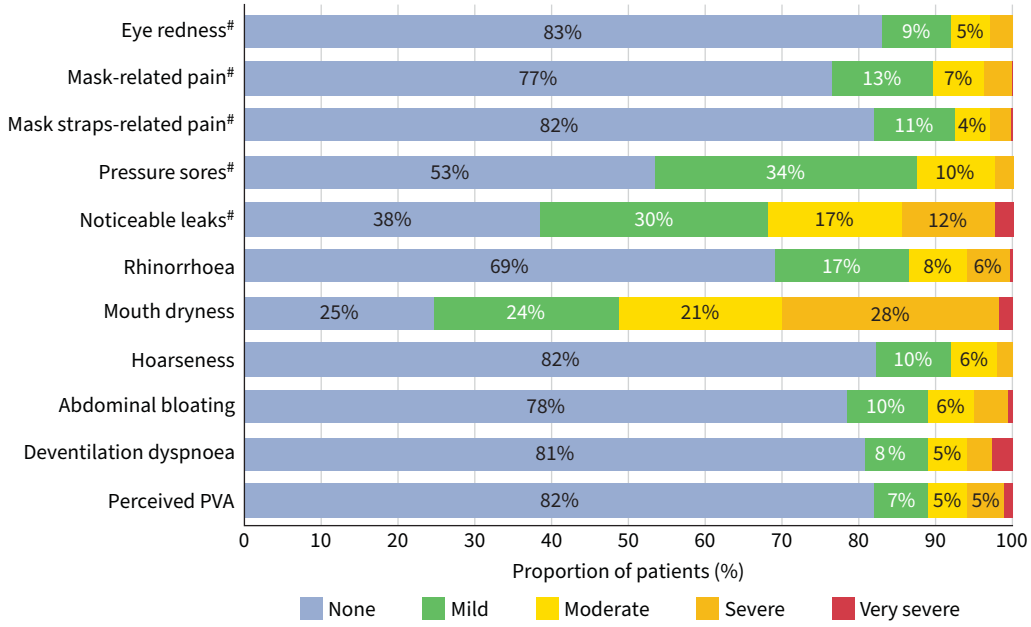

FIGURE 3 Incidence of non-invasive ventilation-related side-effects according to type of side-effect and its severity. #: mask-related side-effect. PVA: patient–ventilator asynchrony.

Patients with mask-related side-effects were more likely to have a change in their respiratory management following their elective review than those without side-effects (rate ratio 1.37, 95% CI 1.18–1.58; p<0.001).

Mask-related side-effects: impact of mask type

Patients with an oronasal mask had lower control of daytime P_{aCO_2} (6.1 (5.6–6.8) *versus* 5.9 (5.2–6.5) kPa; p=0.007) compared to those with a nasal mask. Patients with an oronasal mask reported a higher overall side-effects score than those with a nasal mask (5 (3–9) *versus* 4 (2–7); p=0.008). This difference was driven by the mask-related side-effects score: 2 (1–4) for patients with oronasal masks *versus* 1 (0–3) (p<0.001), as no difference was seen in the non-mask-related side-effects score (p=0.174). No difference was seen in health-related quality of life (p=0.245), quality of sleep (p=0.945) nor adherence (p=0.693) between patients with oronasal masks and those with nasal masks.

Bench study

Nasal masks were significantly more stable than oronasal masks on our bench model (p<0.001), at the expense of an increased inspiratory effort required to trigger the ventilator (p=0.015) and a lower maximal inspiratory pressure (p=0.015). The rate of asynchrony was lower with nasal masks (table 2 and figure 6).

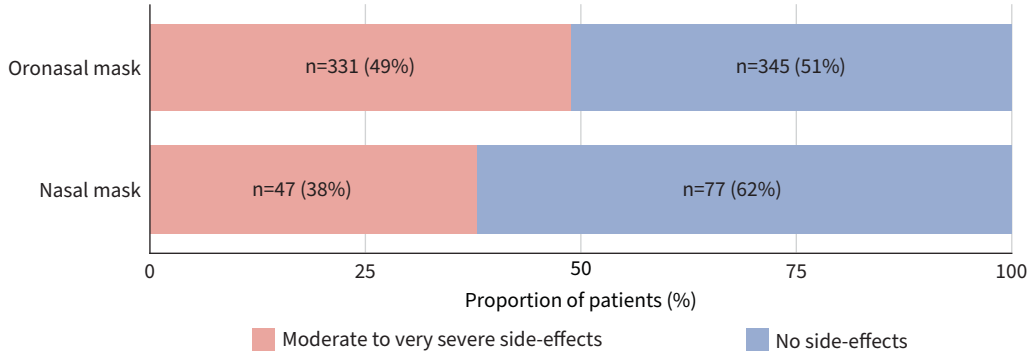

FIGURE 4 Frequency of mask-related side-effects according to type of mask (p=0.023).

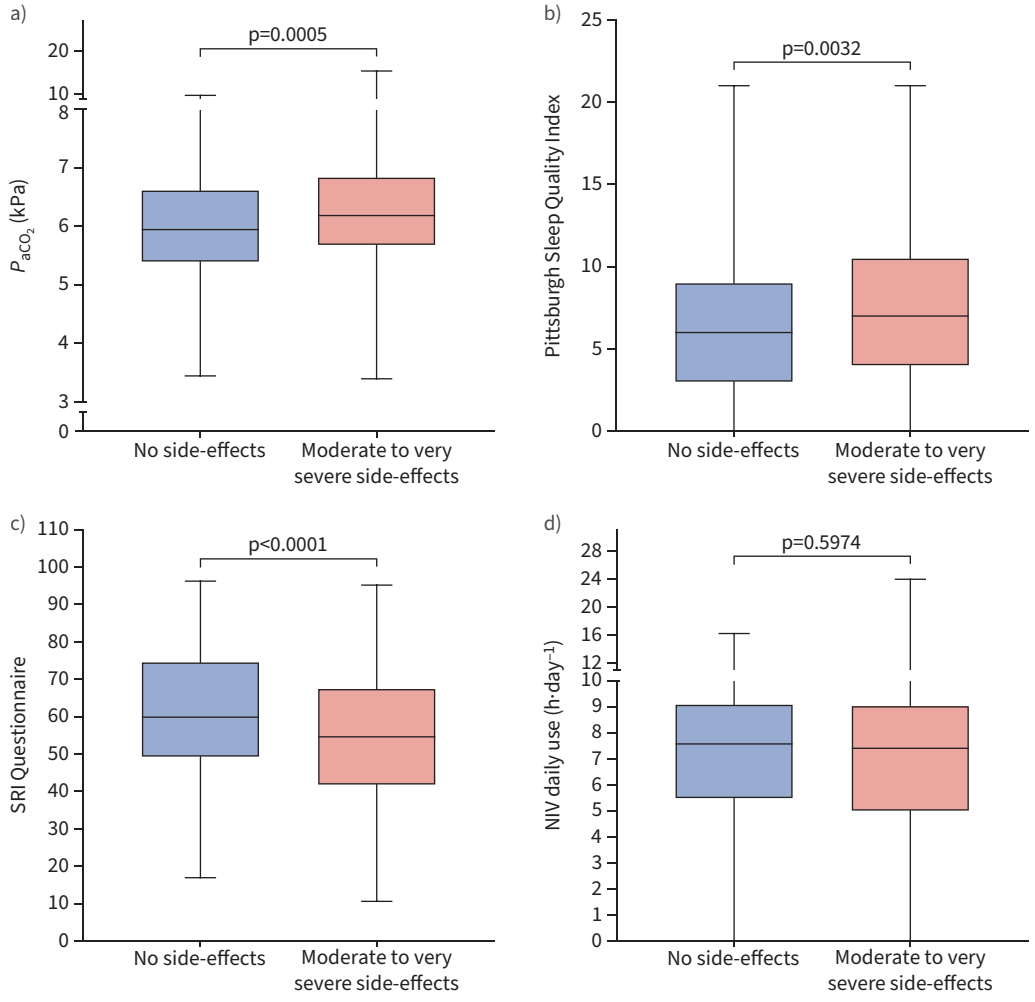

FIGURE 5 Comparison of patients with moderate to very severe mask-related side-effects to those without: a) daytime arterial partial pressure of carbon dioxide (P_{aCO_2}), b) subjective sleep quality assessed by the Pittsburgh Sleep Quality Index (maximal score: 28), c) Severe Respiratory Insufficiency (SRI) Questionnaire (maximal score: 100) and d) daily use of non-invasive ventilation (NIV). Box-and-whisker plots present median and interquartile range (boxes) with minimum–maximum range (whiskers).

TABLE 2 Results from bench test experiments regarding the pressure applied on the model's skin, movements of the mask and leaks with a comparison between oronasal and nasal masks

	Oronasal masks	Nasal masks	p-value
Mean contact pressure (mmHg)	45.0±2.5	43.8±3.6	0.207
Inspiratory–expiratory contact pressure differential (mmHg)	3.6±2.0	2.8±2.3	0.040
Mean nasal contact pressure (mmHg)	44.4 (42.2–46.1)	32.3 (31.8–34.1)	<0.001
Mask movement (mm)	2.03 (1.94–2.27)	0.24 (0.02–0.07)	<0.001
Mean leaks (L·min^{-1})	41.16±4.25	34.46±3.27	<0.001
Maximal inspiratory pressure delivered by the ventilator (cmH_2O)	24.6 (19.5–34.0)	24.2 (18.8–32.2)	<0.001
Patient work of breathing (mJ)	−6.13 (−3.35– −14.6)	−9.37 (−3.89– −23.75)	0.204
Inspiratory flow preceding trigger of the ventilator (L·min^{-1})	8.84±4.71	9.42±4.85	0.067
Inspiratory effort required to trigger the ventilator (cmH_2O)	−4.98±1.91	−5.29±1.93	0.015
Triggering delay (ms)	171 (120–256)	199 (136–307)	0.064
Tidal volume generated to the artificial lung (mL)	820±238	812±209	0.592
Simulated patient–ventilator asynchrony (%)	2.1 (0.4–18.1)	0.2 (0.1–8.1)	0.012

Data are presented as mean±SD or median (interquartile range), unless otherwise stated.

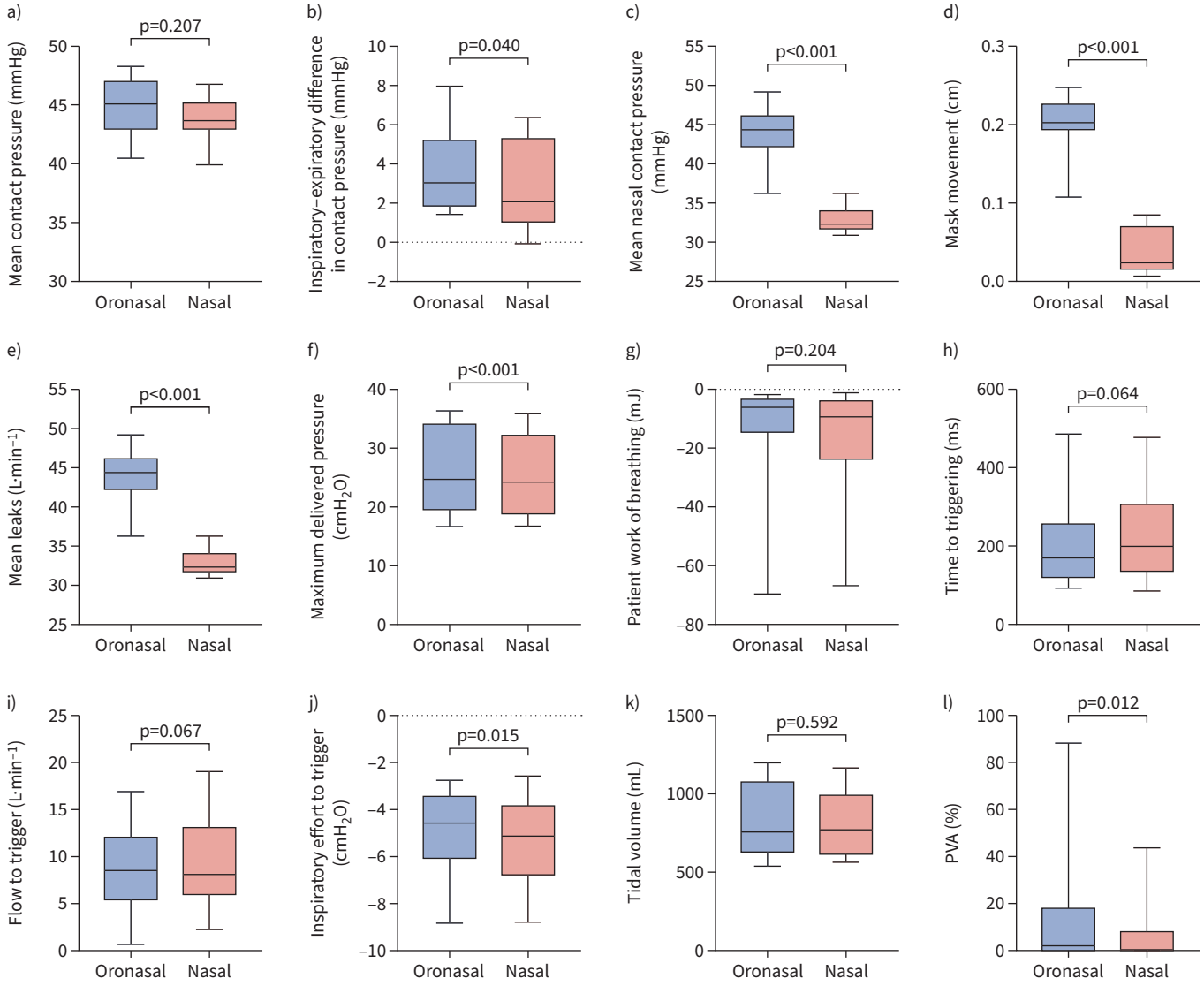

FIGURE 6 Results from the bench study: a) mean contact pressure, b) inspiratory–expiratory contact pressure differential, c) mean nasal contact pressure, d) mask movement, e) mean leaks, f) maximal inspiratory pressure delivered by the ventilator, g) patient work of breathing, h) triggering delay, i) inspiratory flow preceding trigger of the ventilator, j) inspiratory effort required to trigger the ventilator, k) tidal volume generated to the artificial lung and l) simulated patient–ventilator asynchrony (PVA). Box-and-whisker plots present median and interquartile range (boxes) with minimum–maximum range (whiskers).

Oronasal masks predominantly applied their contact pressure on the lower mandible compared to the rest of the face (60% (52–67%) *versus* 40% (33–48%); p<0.001). By definition, nasal masks applied no contact pressure to the lower mandible. We observed a correlation between the maximal inspiratory pressure and the level of total leaks (ρ=0.592, 95% CI 0.427–0.718) when analysing all masks together (p<0.001). Detailed performance data of each tested mask are available in the supplementary material.

Discussion

This large prospective observational study confirms that oronasal masks are more frequently prescribed to patients receiving home NIV [4, 13, 14]. The proportion of patients with oronasal masks in our study population, namely 84%, compares with previous reports [13, 14]. This is the first large-scale prospective study documenting the prevalence of NIV-related side-effects. Among the patients, 82% reported side-effects, with mask-related complications being particularly common; 47% of these patients described moderate to very severe issues. This study also shows that in addition to being frequent, mask-related side-effects are also clinically relevant in view of their association with poorer control of hypoventilation,

worse quality of life and worse sleep quality. Importantly, our findings suggest that nasal masks may be better tolerated than oronasal masks. The corresponding clinical results are corroborated by the bench study, which shows that nasal masks are more stable than oronasal masks and are associated with a lower level of leaks and a lower rate of asynchronies.

Studies addressing home NIV tolerance in general, and the specific issue of mask-related side-effects in particular, are rare. A study by Ribeiro *et al.* [16] of 235 patients comparing the efficacy and tolerance of home NIV according to its mode of initiation (in-hospital *versus* domiciliary) reported, as do we, a very high frequency of side-effects. In their study, 46% of the patients reported mask-related pressure sores and 41% reported leaks. In spite of this high side-effects frequency (which did not differ according to the mode of NIV initiation), patients considered their experience of NIV as positive, with perceived benefits overcoming the negative impact of side-effects. Although the methodology used to identify side-effects differs between the two studies, the proportion of significant side-effects that we report is similar to the proportion reported by Ribeiro *et al.* [16]. Indeed, 48% of the patients in our cohort experienced moderate to very severe side-effects and 18% reported severe to very severe side-effects. Nevertheless, and of concern with respect to the favourable benefits/drawbacks balance described by Ribeiro *et al.* [16] in a qualitative manner, we found that mask-related side-effects were associated with poorer control of hypoventilation ($p<0.01$) as well as poorer quality of life ($p<0.01$) and poorer sleep quality ($p<0.01$). Hence, to maximise the chances of obtaining optimal home NIV results regarding both classical and emerging outcomes [23], our data suggest that mask-related side-effects should be systematically assessed either using a dedicated questionnaire [15] or a generic NIV questionnaire [24], bearing in mind that such a questionnaire does not assess all mask-related side-effects. Such assessment appears crucial when NIV is ineffective, either from a gas exchange or from a quality of life/sleep point of view.

In addition to a higher rate of mask-related side-effects, we have shown that 60% of the contact pressure generated by oronasal masks on our 3D printed head was applied on the lower mandible. This is in line with clinical data published on patients with lone OSA for whom the use of oronasal masks is associated with a higher level of obstructive events [25]. As 45% of our study population with chronic respiratory failure also had comorbid OSA and given the obesity pandemic [26], the use of oronasal masks may have a deleterious impact on upper airway management. These data further suggest that nasal masks should be considered as a first-line interface in patients with chronic alveolar hypoventilation, in a manner similar to what is done in patients with OSA [27].

As highlighted by our results, the choice of a NIV interface should not be overlooked and requires time. Choosing an adequate interface is particularly important from the patient's perspective. The choice of interface should consider the patient's morphology (facial and dental aspects), the anxiety related to having a mask on the face, the patient's communication needs and abilities, the patient's ability to close the mouth, and the level of pressure needed. Hence, even if our findings suggest trying a nasal interface first, an individualised approach is needed for each patient as well as close follow-up. To facilitate such follow-up, remote monitoring may be useful to provide data on the level of leaks and trigger an early intervention [28, 29]. If studies have yet failed to show a benefit of telemonitoring in reducing leaks, this may be because they did not include a more holistic approach assessing all NIV-related side-effects [30].

Our study has limitations. We acknowledge that its observational design restricts its interpretation. In particular, this prevents us from implying causation between mask-related side-effects and suboptimal NIV results. Some degree of under-reporting of NIV side-effects cannot be ruled out because most of the patients were long-term home NIV users and some may have become used to some of the side-effects. Yet, if anything, such a bias would have led to underestimation of an already high prevalence of mask-related side-effects. Another limitation lies in the fact that we did not longitudinally evaluate the dynamics of mask-related side-effects and of NIV benefits. We only used the first NIV elective review undergone by a given patient for our analysis, thus we cannot exclude that both tolerance and efficiency could have improved or worsened over time. Our study also included patients with OHS and OSA. Some of these patients could probably have been treated with continuous positive airway pressure [31] and may then have reported fewer side-effects with such treatment. We did not evidence any difference regarding NIV use between patients reporting or not reporting side-effects. This might stem from perceived benefits being sufficient for the patients to overcome the side-effect-related inconveniences. Our study was not designed to assess the impact of side-effects on NIV management. However, the physicians in charge of the patients were more likely to adjust ventilation settings and modalities in the presence of side-effects. This suggests that these side-effects were considered clinically relevant. Our study also has strengths. To the best of our knowledge it is the first study of this size on the topic, and the first to use a dedicated, structured and comprehensive side-effects questionnaire. In part for this reason, the number of missing data

is minimal. Most importantly, our clinical results favouring nasal masks over oronasal masks in terms of side-effects are corroborated by our experimental bench results. Indeed, we have shown that nasal masks were associated with lower leaks in our bench test. Leaks are a major contributor to NIV side-effects and alter sleep quality in home NIV users [32]. However, leaks can occur because of mouth opening during sleep in patients treated with nasal masks. In that case, a chin strap may be used to secure mouth closure in patients with neuromuscular diseases or those who cannot maintain their mouth closed while being treated [33]. As our bench test was based on only one morphology, our findings regarding the performance of the masks may differ in patients with a different morphology. Another limitation of our study is the fact that our bench results are not directly comparable to the clinical data as the settings used in the bench test were different from those seen in the cohort.

Several explanations can be proposed to explain the predominance of oronasal masks over nasal masks for home NIV in clinical practice. These include lack of data from clinical trials, all conducted with face masks [14, 34]; carry-over from acute respiratory failure-related NIV initiation [13]; and ease of fitting an oronasal mask when the time to spend with the patient is limited, particularly in the presence of suspected mouth leaks, *e.g.* during home NIV initiation [34–36]. However, the clinical preference for oronasal masks does not derive from the results of specifically designed studies. Indeed, no difference in terms of efficacy or adherence was seen between the use of oronasal or nasal masks in two crossover trials [11, 12] nor in a large systematic review and meta-analysis on individual participant data [14].

Conclusions

From our results, we submit that nasal masks can be used as a first-line interface in patients established on home NIV (as is the case in patients treated for OSA) and should be tried instead of facial masks in patients who report important mask-related side-effects. Upholding these positions will require prospective randomised multicentre studies in patients under home NIV.

Acknowledgements: The authors would like to thank the following respiratory registrars at CHU de Rouen (Rouen, France): Edouard Dantoing, Grégoire Jolly, Timothée Lambert, Raphael Lukaszewicz, Jasmine Sutter, Elise Godeau, Marielle de Marchi, Mathilde Le Brun, Hugo Couturier, Julien Maris, Diane Gervereau, Gwenaëlle Maclaud, Samuel Dolidon, Julien Pierchon, Antoine Grégoire, Justine Dampierre, Juliette Da Cunha, Guillaume Rousseau, Pierre Demontrond and Robin Thevenin, as they were involved in the clinical review of patients established on home NIV. The authors would like to thank Remi Dubian (medical student) who showed a remarkable involvement in the unit, and Elise Artaud-Macari, Catherine Viacroze, Luis Carlos Molano, Daniel Benhamou and Florence Portier (CHU de Rouen) for their participation as the senior physicians of some of the patients included. The authors would like to thank Capucine Morelot and Jesus Gonzalez (Sorbonne Université, Paris, France) for their advice and their expertise. The authors would like to thank all the nurses, physiotherapist, healthcare workers and secretaries that worked in the home NIV unit at CHU de Rouen.

Ethics approval: This study was approved by the ethics committee of Rouen University Hospital, Rouen, France (approval number: E2020-09).

Author contributions: E. Fresnel, C. Caillard and M. Patout made substantial contributions to the conception and design of the work, to the acquisition, analysis and interpretation of data for the work, and drafted the work and revised it critically for important intellectual content. L. Razakamanantsoa, A. Kerfourn, E. Lhuillier, J. Dupois, J-F. Muir, K. El Husseini, A. Cuvelier, M. Lebret and T. Similowski made substantial contributions to the analysis and interpretation of data for the work, and revised the manuscript critically for important intellectual content. C. Caillard, E. Fresnel, L. Razakamanantsoa, A. Kerfourn, J. Dupois, J-F. Muir, E. Lhuillier, K. El Husseini, A. Cuvelier, M. Patout, M. Lebret and T. Similowski gave final approval of the version submitted for publication, and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflicts of interest: E. Fresnel reports support for the present study from ADIR Association, grants from ADIR Association and Adène Groupe, a leadership role as CEO of Kernel Biomedical, and is employed as a research engineer by Kernel Biomedical. C. Caillard reports support for the present study from Asten Santé and Kernel Biomedical, and support for attending meetings from Asten Santé and SOS Oxygène. M. Lebret reports grants from ADIR Association and Aden scientific fund, support for attending meetings from Air Liquide Medical Systems and Kernel Biomedical, and is a part-time employee of Air Liquide Medical Systems (medical affairs department) and part-time employee of Kernel Biomedical (research engineer). L. Razakamanantsoa reports support for attending meetings from Asten Santé and ASV Santé. A. Kerfourn reports support for the present study from ADIR Association, grants from ADIR Association and Adène Groupe, leadership role as CEO of Kernel Biomedical, and is

employed as a research engineer by Kernel Biomedical. J. Dupuis is an employee of Asten Santé. J-F. Muir receives a salary from ADIR Association as President. E. Lhuillier reports support for attending meetings from Asten Santé. T. Similowski reports consultancy fees from AstraZeneca, Chiesi, KPL consulting, Lungpacer Inc. and OSO-AI, payment or honoraria for lectures, presentations, manuscript writing or educational events from Chiesi and Vitalaire, patents planned, issued or pending (WO2008006963A3, WO2012004534A1, WO2013164462A1), and stock (or stock options) with Austral Dx and Hephai. M. Patout reports grants from Fisher & Paykel, ResMed and Asten Santé, consultancy fees from Philips Respironics, Air Liquide Medical, ResMed, Asten Santé and GSK, payment or honoraria for lectures, presentations, manuscript writing or educational events from Philips Respironics, Asten Santé, ResMed, Air Liquide Medical, SOS Oxygène, Antadir, Chiesi, Jazz Pharmaceutical, Loewenstein, Fisher & Paykel, Bastide Medical, Orkyn and Elivie, support for attending meetings from Asten Santé and Vitalaire, participation on a data safety monitoring board or advisory board with ResMed, Philips Respironics and Asten Santé, stock (or stock options) with Kernel Biomedical, and receipt of equipment, materials, drugs, medical writing, gifts or other services from Philips Respironics, ResMed and Fisher & Paykel. The remaining authors have no potential conflicts of interest to disclose.

Support statement: A research grant provided by ADIR Association was used for the bench study. Mask and ventilators were kindly lent by Asten Santé (Isneauville, France). No further funding was required.

References

1 Ergan B, Oczkowski S, Rochwerg B, *et al.* European Respiratory Society guidelines on long-term home non-invasive ventilation for management of COPD. *Eur Respir J* 2019; 54: 1901003.
2 Mokhlesi B, Masa JF, Brozek JL, *et al.* Evaluation and management of obesity hypoventilation syndrome. An official American Thoracic Society clinical practice guideline. *Am J Respir Crit Care Med* 2019; 200: e6–e24.
3 Bourke SC, Tomlinson M, Williams TL, *et al.* Effects of non-invasive ventilation on survival and quality of life in patients with amyotrophic lateral sclerosis: a randomised controlled trial. *Lancet Neurol* 2006; 5: 140–147.
4 Callegari J, Magnet FS, Taubner S, *et al.* Interfaces and ventilator settings for long-term noninvasive ventilation in COPD patients. *Int J Chron Obstruct Pulmon Dis* 2017; 12: 1883–1889.
5 Girault C, Briel A, Benichou J, *et al.* Interface strategy during noninvasive positive pressure ventilation for hypercapnic acute respiratory failure. *Crit Care Med* 2009; 37: 124–131.
6 Lemyze M, Mallat J, Vangrunderbeek N, *et al.* Under-the-nose *versus* over-the-nose face mask to prevent facial pressure sores during face mask-delivered noninvasive ventilation for acute hypercapnic respiratory failure: a randomized controlled trial. *Crit Care Med* 2023; 51: 1177–1184.
7 Iosifyan M, Schmidt M, Hurbault A, *et al.* "I had the feeling that I was trapped": a bedside qualitative study of cognitive and affective attitudes toward noninvasive ventilation in patients with acute respiratory failure. *Ann Intensive Care* 2019; 9: 134.
8 Genta PR, Kaminska M, Edwards BA, *et al.* The importance of mask selection on continuous positive airway pressure outcomes for obstructive sleep apnea. An official American Thoracic Society workshop report. *Ann Am Thorac Soc* 2020; 17: 1177–1185.
9 Chen LY, Chen YH, Hu SW, *et al.* In search of a better CPAP interface: a network meta-analysis comparing nasal masks, nasal pillows and oronasal masks. *J Sleep Res* 2022; 31: e13686.
10 Rowland S, Aiyappan V, Hennessy C, *et al.* Comparing the efficacy, mask leak, patient adherence, and patient preference of three different CPAP interfaces to treat moderate-severe obstructive sleep apnea. *J Clin Sleep Med* 2018; 14: 101–108.
11 Leotard A, Lebret M, Daabek N, *et al.* Impact of interface type on noninvasive ventilation efficacy in patients with neuromuscular disease: a randomized cross-over trial. *Arch Bronconeumol* 2021; 57: 273–280.
12 Majorski DS, Callegari JC, Schwarz SB, *et al.* Oronasal *versus* nasal masks for non-invasive ventilation in COPD: a randomized crossover trial. *Int J Chron Obstruct Pulmon Dis* 2021; 16: 771–781.
13 Patout M, Lhuillier E, Kaltsakas G, *et al.* Long-term survival following initiation of home non-invasive ventilation: a European study. *Thorax* 2020; 75: 965–973.
14 Lebret M, Leotard A, Pepin JL, *et al.* Nasal *versus* oronasal masks for home non-invasive ventilation in patients with chronic hypercapnia: a systematic review and individual participant data meta-analysis. *Thorax* 2021; 76: 1108–1116.
15 Jolly G, Razakamanantsoa L, Fresnel E, *et al.* Defining successful non-invasive ventilation initiation: data from a real-life cohort. *Respirology* 2021; 26: 1067–1075.
16 Ribeiro C, Jacome C, Oliveira P, *et al.* Patients experience regarding home mechanical ventilation in an outpatient setting. *Chron Respir Dis* 2022; 19: 14799731221137082.
17 Windisch W, Freidel K, Schucher B, *et al.* The Severe Respiratory Insufficiency (SRI) Questionnaire: a specific measure of health-related quality of life in patients receiving home mechanical ventilation. *J Clin Epidemiol* 2003; 56: 752–759.
18 Cuvelier A, Lamia B, Molano LC, *et al.* Traduction française et adaptation culturelle du questionnaire SRI. Questionnaire de qualité de vie liée à la santé des patients insuffisants respiratoires chroniques traités par

ventilation à domicile. [The French translation and cultural adaptation of the SRI questionnaire. A questionnaire to assess health-related quality of life in patients with chronic respiratory failure and domiciliary ventilation.] *Rev Mal Respir* 2012; 29: 705–713.

19 Buysse DJ, Reynolds CF 3rd, Monk TH, *et al.* The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. *Psychiatry Res* 1989; 28: 193–213.

20 Patout M, Fresnel E, Lujan M, *et al.* Recommended approaches to minimize aerosol dispersion of SARS-CoV-2 during noninvasive ventilatory support can cause ventilator performance deterioration: a benchmark comparative study. *Chest* 2021; 160: 175–186.

21 Rabec C, Fresnel E, Retory Y, *et al.* Addition of bacterial filter alters positive airway pressure and non-invasive ventilation performances. *Eur Respir J* 2022; 59: 2102636.

22 Gonzalez-Bermejo J, Janssens JP, Rabec C, *et al.* Framework for patient-ventilator asynchrony during long-term non-invasive ventilation. *Thorax* 2019; 74: 715–717.

23 Patout M, Razakamanantsoa L, D'Cruz R, *et al.* Cognitive function in patients with chronic respiratory failure: effect of treatment with home noninvasive ventilation. *Am J Respir Crit Care Med* 2023; 208: 900–903.

24 Dupuis-Lozeron E, Gex G, Pasquina P, *et al.* Development and validation of a simple tool for the assessment of home noninvasive ventilation: the S^3-NIV questionnaire. *Eur Respir J* 2018; 52: 1801182.

25 Andrade RGS, Viana FM, Nascimento JA, *et al.* Nasal *vs* oronasal CPAP for OSA treatment: a meta-analysis. *Chest* 2018; 153: 665–674.

26 The GBD 2015 Obesity Collaborators. Health effects of overweight and obesity in 195 countries over 25 years. *N Engl J Med* 2017; 377: 13–27.

27 Patil SP, Ayappa IA, Caples SM, *et al.* Treatment of adult obstructive sleep apnea with positive airway pressure: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med* 2019; 15: 335–343.

28 Reginault T, Bouteleux B, Wibart P, *et al.* At-home noninvasive ventilation initiation with telemonitoring in amyotrophic lateral sclerosis patients: a retrospective study. *ERJ Open Res* 2023; 9: 00438-2022.

29 Borel JC, Palot A, Patout M. Technological advances in home non-invasive ventilation monitoring: reliability of data and effect on patient outcomes. *Respirology* 2019; 24: 1143–1151.

30 Pontier-Marchandise S, Texereau J, Prigent A, *et al.* Home NIV treatment quality in patients with chronic respiratory failure having participated to the French nationwide telemonitoring experimental program (the TELVENT study). *Respir Med Res* 2023; 84: 101028.

31 Masa JF, Mokhlesi B, Benítez I, *et al.* Long-term clinical effectiveness of continuous positive airway pressure therapy *versus* non-invasive ventilation therapy in patients with obesity hypoventilation syndrome: a multicentre, open-label, randomised controlled trial. *Lancet* 2019; 393: 1721–1732.

32 Sutter J, Cuvelier A, Lukaszewicz R, *et al.* Poor sleep quality and nocturnal home noninvasive ventilation: prevalence, risk factors and impact. *Pulmonology* 2023; 29: 546–549.

33 Georges M, Perez T, Rabec C, *et al.* Proposals from a French expert panel for respiratory care in ALS patients. *Respir Med Res* 2022; 81: 100901.

34 Murphy PB, Patout M, Arbane G, *et al.* Cost-effectiveness of outpatient *versus* inpatient non-invasive ventilation setup in obesity hypoventilation syndrome: the OPIP trial. *Thorax* 2023; 78: 24–31.

35 Duiverman ML, Vonk JM, Bladder G, *et al.* Home initiation of chronic non-invasive ventilation in COPD patients with chronic hypercapnic respiratory failure: a randomised controlled trial. *Thorax* 2020; 75: 244–252.

36 van den Biggelaar RJM, Hazenberg A, Cobben NAM, *et al.* A randomized trial of initiation of chronic noninvasive mechanical ventilation at home *vs* in-hospital in patients with neuromuscular disease and thoracic cage disorder: the Dutch Homerun trial. *Chest* 2020; 158: 2493–2501.