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Added value of technician intervention to improve mask management for apneic patients treated with long-term CPAP

Celia Vidal ^{1 2}, Fanny Bertelli ², Jean-Pierre Mallet ^{2 3 4}, Raphael Gilson ², Jean-Christian Borel ⁵, Frédéric Gagnadoux ⁶, Sarah Skinner ⁷, Arnaud Bourdin ^{2 3 4}, Nicolas Molinari ^{1 2}, Dany Jaffuel ^{8 9 10 11}

¹ IDESP, INSERM, PreMEDical INRIA, Montpellier University, CHU Montpellier, Montpellier, France.

² Groupe Adène, Montpellier, France.

³ Department of Respiratory Diseases, Montpellier University Hospital, Arnaud de Villeneuve Hospital, Montpellier, France.

⁴ PhyMedExp (INSERM U 1046, CNRS UMR9214), Montpellier University, Montpellier, France.

⁵ Centre de Pneumologie Henri Bazire, la Sure en Chartreuse, Isère, France.

⁶ Department of Respiratory and Sleep Medicine, University Hospital of Angers, Angers, France.

⁷ CHU Montpellier, Montpellier, France.

⁸ Groupe Adène, Montpellier, France. dany.jaffuel@wanadoo.fr.

⁹ Department of Respiratory Diseases, Montpellier University Hospital, Arnaud de Villeneuve Hospital, Montpellier, France. dany.jaffuel@wanadoo.fr.

¹⁰ PhyMedExp (INSERM U 1046, CNRS UMR9214), Montpellier University, Montpellier, France. dany.jaffuel@wanadoo.fr.

¹¹ Department of Respiratory Diseases, CHRU Montpellier, 371, Avenue Doyen Giraud, Montpellier Cedex 5, 34295, France. dany.jaffuel@wanadoo.fr.

Keywords:

Epworth-sleepiness-scale; Gender; Leaks; Sleep apnea; Technician.

Abstract

Purpose:

Long-term management of sleep apnea patients treated with CPAP raises questions about the cost-effectiveness of certain resources. With the growing use of remote CPAP monitoring and patient questionnaires, the importance of direct patient supervision by technicians is being challenged. To date, no real-life study has investigated the long-term additional value of a technician in evaluating common CPAP side effects compared to patient-reported side effects.

Methods:

InterfaceVent-CPAP is a prospective real-life cross-sectional study conducted in a cohort of apneic adults treated with CPAP for at least 3 months. Three common CPAP side effects (pain, erythema, and leaks) were independently assessed by the patient and the technician on visual analogue scales and diagrams, respectively. CPAP-reported leaks were also collected. Gwet's concordance coefficient was used to analyze concordance between patient and technician assessments of CPAP side effects.

Results:

1484 patients (median age 67 years (IQ₂₅₋₇₅: 60-74)) were evaluated by 32 technicians. Correlation between CPAP-reported leaks and technician-reported leaks was weak. For pain and erythema, moderate to high concordance was observed between technician and patient responses, while no concordance was found for leaks. Univariate linear regression analyses examining the effect of technician-reported areas of pain, erythema and leaks on the Epworth-Sleepiness-Scale revealed statistically significant associations between sleepiness in women and certain technician-reported areas of mask leaks and mask pain.

Conclusion:

Direct supervision of chronic apneic patients by technicians adds value in managing mask-related issues. Long-term care should include a combination of remote CPAP monitoring, patient-reported outcomes, and technician direct supervision.

Trial registration:

InterfaceVent is registered with ClinicalTrials.gov (NCT03013283). First registration date is 2016-12-23.

Abbreviations

AHI Apnea-Hypopnea-Index; BMI Body Mass Index; CPAP Continuous Positive Airway Pressure; FSS French Social Security; MRSEs Mask Related Side effects; NM Nasal Mask NPM Nasal pillow mask; ONM Oronasal Mask; PCA Principal Component Analysis; QoL Quality of Life; RES Residual Excessive Sleepiness; SAS Sleep Apnea Syndrome; VAS Visual Analogue Scales.

Introduction

The prevalence of sleep apnea syndrome (SAS) in adults over the age of 35 ranges from 5.9 to 79.2%, depending on the clinical symptoms and apnea/hypopnea scoring criteria used [1, 2]. Continuous Positive Airway Pressure (CPAP) remains the cornerstone of SAS treatment, despite major advances in alternative therapies [3–5].

Adherence is the primary goal of CPAP therapy treatment, as increased adherence enhances quality of life (QoL) [6, 7] and reduces the occurrence of major adverse cardiovascular events [8, 9]. There is evidence that the initial experience with CPAP therapy is crucial in determining future use. The patterns of adherence to CPAP therapy are established early in the treatment process and tend to persist long-term [10–12]. Consequently, interventions aimed at enhancing CPAP adherence are likely to be most effective if introduced early, as recommended [3, 4].

The long-term management of CPAP-treated patients raises questions about the cost-effectiveness of different resources. Depending on how the healthcare system is organized, in-clinic sleep technicians or homecare provider technicians are deployed to improve the quality of care. With the growing use of remote CPAP monitoring and patient questionnaires, the necessity of the direct patient supervision by a technician is being questioned [13–15]. The shift toward telemonitoring raises concerns about the diminishing role of in-person technical support. The pros and cons of implementing remote management pathways to replace in-person follow-up visits was recently reviewed [14]. Many of the historical technician tasks (collecting machine data and patient symptoms, CPAP device settings) can now be automated and managed remotely using simple telemedicine tools [16, 17]. However, the technician's presence during in-person visits enables the immediate resolution of any issues resolution, proper mask adjustments [15], and direct patient guidance—crucial aspects that remote monitoring cannot always fully replicate [14].

To date, the evidence supporting the benefits of direct patient supervision by a technician is limited. A recent prospective randomized study demonstrated that a personalized interface fitting session supervised by a sleep technician significantly improves automatic positive airway pressure (APAP) adherence at 30 days [15]. No comparable long-term study exists. To bridge this knowledge gap, we conduct an ancillary study of the InterfaceVent real-life study [18] to evaluate in long-term CPAP treated patient, the importance of direct patient supervision by the technician.

The primary objectives of the study presented here were to compare: (i) the technician's evaluation of common CPAP side effects (pain, erythema and leaks) with the patient's assessment of these side effects; (ii) the technician's evaluation of patient leaks with CPAP-reported leaks. The secondary objectives were to assess the impact of technician-reported CPAP side effects on CPAP-use, CPAP non-adherence, sleepiness, and residual excessive sleepiness (RES).

Methods

Study design and study population

This study presents an ancillary analysis of the InterfaceVent study, which was exhaustively described in a prior publication [18]. Briefly, the InterfaceVent study (ClinicalTrials.gov: NCT03013283) was a prospective, real-life, cross-sectional study conducted from February 7, 2017 to April 1, 2019 in adults undergoing at least 3 months of CPAP or non-invasive ventilation. We herein report results for SAS patients treated exclusively by CPAP. Patient inclusion was performed during a scheduled home visit by one of the 32 Apard technicians (visits were scheduled according to the visits required for reimbursement of the CPAP treatment by the French Social Security single payer system). Patients had unlimited access to 34 masks [18]. At the time of the study, no versions of the mask series specifically designed for women or men were available.

Collected data

Patient side effect evaluation: Side effect visual analogue scales (VAS; see below), the Epworth-Sleepiness-Scale and the EQ-5D-3 L questionnaire were administered during a scheduled visit, as previously described [18].

An 11-point VAS (0 (no reported side effect) to 10 (very uncomfortable side effect)) was used to assess the following side effects: patient-reported leaks, painful mask, mask injury, painful harness and harness injury. Importantly, the technician did not help patients fill out the questionnaires and the VAS.

Technician side effect evaluation: To carry out their own assessments of CPAP side effects, technicians were asked to systematically evaluate the presence of mask-related pain, erythema, and leaks during patient visits using a tool specifically designed for the study. The tool was composed of diagrams on which the technician noted the area of the face that was impacted. The diagram had 11 areas for pain and erythema and 9 areas for leaks (see Figure S1 in the supplemental material). The technicians were unaware of the patients' responses to the VAS questionnaires when they carried out their own assessments of side effects. In addition, the technicians were unaware of device-reported leaks when they conducted their own leak assessment.

Statistical analyses

Continuous data were expressed as medians with their associated quartile ranges due to non-Gaussian distributions. Qualitative parameters were expressed as numbers and percentages. Pain, erythema and leaks were evaluated using Wilcoxon-Mann-Whitney tests for quantitative data, and Chi-square tests for qualitative data. Univariate negative binomial regression analyses were used to study the number of areas of pain, erythema and leaks reported by the technicians due to the statistically significant overdispersion in the Poisson regression model. Gwet's concordance coefficient was used to analyze concordance of pain, erythema and leaks between technicians and patient responses. Univariate logistic or linear regression analyses were used to study, by gender, associations between different variables of-interest (CPAP usage, CPAP-non-adherence defined as a mean CPAP-usage for less than 4 h per day, Epworth Sleepiness-Scale and Residual Excessive Sleepiness (RES), defined as an Epworth-Sleepiness-Scale score >10) in relation to explanatory variables (areas of pain, erythema and leaks reported by technicians). All statistical analyses were performed with R (V.4.3.1).

Results

Population baseline characteristics according to technicians' evaluations of pain, erythema and leaks are summarized in Table 1. A total of 32 technicians took part in the patient evaluations, including 3 women (9.4%). A total of 1484 patients were included in the analyses (27.8% women). Patients with erythema reported by technicians (T-erythema), were more often women (38% vs. 26.6%, $p=0.003$), and patients with leaks reported by technicians (T-leaks) were more often men (76.8% vs. 70.9%, $p=0.036$). Patients with T-erythema or T-leaks were more likely to wear oronasal masks (ONM) and less likely to wear nasal cushion masks. ($p=0.032$ for erythema and $p=0.002$ for leaks, respectively). Patients with pain reported by technicians (T-pain) had more problems with mobility, self-care, usual activities and discomfort ($p=0.015$, $p=0.014$, $p=0.032$ and $p=0.009$, respectively). Patients with T-erythema had more problems with anxiety and depression ($p<0.001$). Patients with T-leaks had more recent masks model (47.2% vs. 39.5%, $p=0.012$), poorer quality of life (64.8 vs. 70, $p=0.002$), higher Epworth-Sleepiness-Scale score ($p=0.018$) and higher current AHIf flow ($p=0.013$). Patients with T-leaks had more device-reported unintentional leaks and unintentional large leaks ($p<0.001$ and $p=0.027$ respectively). CPAP side effects evaluated by technicians were related to each other. Patients with T-pain had more T-erythema (29.1% vs. 8.6%, $p<0.001$) and T-leaks (48% vs. 19.2%, $p<0.001$).

Prevalence of pain, erythema and leaks reported by the technicians according to patient gender and mask type

Table 1 suggests an effect of gender and mask type on erythema and leaks, so we analyzed the prevalence of pain, erythema and leaks reported by technicians according to gender and mask type in Fig. 1.

The prevalence of T-erythema when using nasal masks (NM) was higher in women than in men (area 4, 6.2% versus 3% ($p=0.035$), area 10, 4.1% versus 1.4% ($p=0.017$) and area 11,

4.6% versus 1.8% ($p=0.024$)). Results of univariate negative binomial regression analyses suggest that women had higher areas of T-erythema than men for NM ($p= 0.032$).

The same analyses were performed on men with or without beards/mustaches (see Table S2 and Figure S3 in the supplemental material). In this analysis, the prevalence of T-pain in NM was higher in men with beards/mustaches than in men without beards/mustaches in the mask attachment areas (area 10, 2.2% vs. 0% ($p=0.017$) and area 11, 2.2% vs. 0% ($p=0.017$)); the prevalence of T-pain and T-erythema when using ONM were higher in men with beards/mustaches than in men without beards/mustaches in the areas around the nose (areas 4 (4% vs. 0.5%; $p=0.034$) and 8 (4% vs. 0.5%; $p= 0.034$) for pain, and areas 4 (10% vs. 4.1%; $p=0.036$) and 8 (10% vs. 4.1%; $p= 0.036$), for erythema).

Table 1 Population characteristics according to technician evaluation of mask related side-effects

	Pain			Erythema			Leaks		
	No, N=1336	Yes, N=148	p-value	No, N=1326	Yes, N=158	p-value	No, N=1157	Yes, N=327	p-value
Demographics									
Age (years)	67.00 [60.00; 74.00]	69.00 [61.00; 75.25]	0.073 ^w	67.00 [61.00; 74.00]	68.00 [59.25; 74.00]	0.952 ^w	67.00 [60.00; 73.00]	69.00 [61.00; 75.00]	0.010^w
Gender, women (%)	365 (27.32)	48 (32.43)	0.188 ^c	353 (26.62)	60 (37.97)	0.003^c	337 (29.13)	76 (23.24)	0.036^c
BMI (kg/m ²)	30.85 [27.65; 35.01]	30.76 [27.21; 34.34]	0.744 ^w	30.86 [27.68; 34.98]	30.48 [26.71; 34.39]	0.323 ^w	30.82 [27.46; 35.06]	30.86 [27.77; 34.60]	0.846 ^w
Diagnostic AHI (events/h)	39.00 [31.00; 57.00]	37.00 [31.00; 53.00]	0.169 ^w	39.30 [31.00; 56.00]	36.00 [31.00; 52.45]	0.143 ^w	39.00 [31.00; 56.00]	38.00 [32.00; 56.00]	0.843 ^w
Active smokers (%)	153 (11.68)	19 (13.38)	0.551 ^c	151 (11.62)	21 (13.73)	0.447 ^c	138 (12.22)	34 (10.53)	0.405 ^c
Active workers (%)	272 (21.09)	23 (16.08)	0.160 ^c	258 (20.17)	37 (24.03)	0.264 ^c	239 (21.40)	56 (17.72)	0.154 ^c
Presence of partner (%)	942 (71.96)	108 (74.48)	0.520 ^c	945 (72.75)	105 (67.74)	0.188 ^c	802 (70.66)	248 (77.74)	0.013^c
Epworth Scale									
ESS (0–24 score)	5.00 [3.00; 8.00]	6.00 [3.00; 10.00]	0.107 ^w	5.00 [3.00; 9.00]	5.00 [3.00; 9.00]	0.527 ^w	5.00 [3.00; 8.00]	6.00 [3.00; 9.00]	0.018^w
RES (%)	209 (15.64)	31 (20.95)	0.096 ^c	220 (16.59)	20 (12.66)	0.204 ^c	182 (15.73)	58 (17.74)	0.384 ^c
EQ-5D-3 L									
Problems with mobility (%)	300 (23.44)	47 (32.64)	0.015^c	314 (24.67)	33 (21.85)	0.447 ^c	265 (23.90)	82 (26.03)	0.436 ^c
Problems with self-care (%)	70 (5.51)	15 (10.71)	0.014^c	74 (5.87)	11 (7.28)	0.491 ^c	67 (6.08)	18 (5.83)	0.868 ^c
Problems with usual activities (%)	241 (18.89)	38 (26.39)	0.032^c	250 (19.70)	29 (19.21)	0.885 ^c	207 (18.73)	72 (22.86)	0.104 ^c
Problems of pain/discomfort (%)	734 (57.21)	100 (68.49)	0.009^c	743 (58.09)	91 (60.67)	0.545 ^c	639 (57.31)	195 (62.10)	0.128 ^c
Problems of anxiety/depression (%)	497 (38.74)	66 (45.21)	0.130 ^c	484 (37.87)	79 (52.32)	<0.001^c	440 (39.32)	123 (39.68)	0.909 ^c
EQ-5D-3 L health VAS (0-100 score)	69.90 [50.50; 80.20]	66.90 [49.75; 79.90]	0.147 ^w	69.90 [50.50; 80.20]	69.80 [50.00; 80.00]	0.349 ^w	70.00 [51.03; 80.20]	64.75 [49.80; 80.00]	0.002^w
Device									
CPAP-usage (h/day)	6.75 [5.50; 7.75]	6.75 [5.79; 7.75]	0.265 ^w	6.75 [5.50; 7.75]	6.64 [5.50; 7.62]	0.612 ^w	6.75 [5.50; 7.75]	6.75 [5.50; 7.68]	0.341 ^w
Non-adherence (%)	110 (8.23)	5 (3.38)	0.036^c	107 (8.07)	8 (5.06)	0.182 ^c	88 (7.61)	27 (8.26)	0.697 ^c
Current AHI _{low} (events/h)	2.00 [1.00; 4.00]	1.80 [0.78; 3.93]	0.347 ^w	1.80 [0.90; 3.90]	2.40 [1.00; 4.25]	0.087 ^w	1.80 [0.90; 3.70]	2.40 [1.00; 4.20]	0.013^w
Treatment duration (years)	4.44 [1.94; 9.75]	4.38 [2.78; 9.66]	0.496 ^w	4.61 [2.10; 9.87]	3.63 [1.63; 7.54]	0.018^w	4.38 [2.03; 9.88]	4.57 [2.10; 9.33]	0.762 ^w
Mean pressure (cmH ₂ O)	8.20 [6.70; 10.00]	8.00 [6.63; 9.70]	0.218 ^w	8.20 [6.70; 10.00]	8.10 [6.55; 10.00]	0.910 ^w	8.00 [6.60; 10.00]	8.60 [6.80; 10.00]	0.086 ^w
90th/95th pressure (cmH ₂ O)	10.00 [8.00; 11.80]	10.00 [8.50; 11.30]	0.442 ^w	10.00 [8.00; 11.70]	10.00 [8.35; 11.90]	0.382 ^w	10.00 [8.00; 11.70]	10.00 [8.90; 11.80]	0.038^w
Fixed pressure (%)	176 (13.18)	15 (10.14)	0.294 ^c	179 (13.51)	12 (7.59)	0.036^c	158 (13.67)	33 (10.09)	0.088 ^c
Comfort mode (%)	213 (15.94)	21 (14.19)	0.579 ^c	202 (15.23)	32 (20.25)	0.102 ^c	182 (15.73)	52 (15.90)	0.940 ^c
Heated humidifier (%)	786 (58.83)	95 (64.19)	0.208 ^c	782 (58.97)	99 (62.66)	0.373 ^c	686 (59.29)	195 (59.63)	0.912 ^c
Heated breathing tube (%)	52 (3.89)	7 (4.73)	0.621 ^c	50 (3.77)	9 (5.70)	0.242 ^c	43 (3.72)	16 (4.89)	0.336 ^c
Mask									
Mask type (%)			0.527 ^c			0.032^c			0.002^c

Nasal	729 (54.57)	75 (50.68)		718 (54.15)	86 (54.43)		626 (54.11)	178 (54.43)	
Nasal pillow	232 (17.37)	25 (16.89)		240 (18.10)	17 (10.76)		219 (18.93)	38 (11.62)	
Oronasal	375 (28.07)	48 (32.43)		368 (27.75)	55 (34.81)		312 (26.97)	111 (33.94)	
Mask availability since 2013 (%)	552 (41.44)	58 (39.19)	0.597 ^c	538 (40.70)	72 (45.57)	0.239 ^c	456 (39.51)	154 (47.24)	0.012 ^c
Unintentional leaks (l/min)	2.50 [0.00; 7.50]	2.50 [0.00; 9.00]	0.645 ^{**}	2.40 [0.00; 7.50]	2.50 [0.00; 7.50]	0.685 ^{**}	2.40 [0.00; 6.00]	4.80 [0.00; 12.25]	<0.001 ^{**}
Unintentional large leaks (%)	0.10 [0.00; 0.90]	0.00 [0.00; 0.65]	0.498 ^{**}	0.10 [0.00; 0.90]	0.05 [0.00; 0.95]	0.694 ^{**}	0.10 [0.00; 0.70]	0.10 [0.00; 2.20]	0.027 ^{**}
Global leaks (l/min)	33.00 [27.25; 41.00]	33.50 [24.25; 36.75]	0.538 ^{**}	33.00 [28.00; 41.00]	29.00 [22.00; 33.60]	0.103 ^{**}	33.00 [27.00; 39.00]	35.45 [26.50; 49.00]	0.186 ^{**}
Global large leaks (%)	0.90 [0.10; 5.15]	0.55 [0.00; 1.80]	0.289 ^{**}	0.90 [0.20; 5.20]	0.15 [0.00; 0.47]	0.040 ^{**}	0.80 [0.10; 4.60]	1.05 [0.17; 9.60]	0.379 ^{**}
Technician MRSE evaluation									
Pain (%)	NA	NA	NA	105 (7.92)	43 (27.22)	<0.001 ^c	77 (6.66)	71 (21.71)	<0.001 ^c
Erythema (%)	115 (8.61)	43 (29.05)	<0.001 ^c	NA	NA	NA	101 (8.73)	57 (17.43)	<0.001 ^c
Leak (%)	256 (19.16)	71 (47.97)	<0.001 ^c	270 (20.36)	57 (36.08)	<0.001 ^c	NA	NA	NA

AHI: Apnea-Hypopnea Index; AHI_{low}: AHI reported by device; BMI: Body Mass Index; CPAP: Continuous Positive Airway Pressure; ESS: Epworth Sleepiness Scale; N=number of patients responding; Non-adherence: CPAP-usage under 4 h per day; RES: Residual Excessive Sleepiness (ESS score > 10); VAS: Visual Analogue Scale. Leaks were obtained using built-in CPAP software¹⁴. Data are reported as medians and quartiles or numbers and percentages of total as appropriate. ^{**}Wilcoxon-Mann-Whitney test; ^cChi-square test. Bold variables are statistically significant at the 5% threshold

Concordance between patient and technician evaluation of pain, erythema and leaks

Gwet's concordance coefficient was used to investigate the concordance between the patient and technician evaluations of pain, erythema and leaks. For patient response, MRSE frequencies (VAS score ≥ 1) were used. The results suggest a moderate to high concordance between technician and patient responses for pain and erythema. On the contrary, no concordance was observed between technician and patient responses for leaks (see Fig. 2). However, results did not differ between women and men. Importantly, there is no clinically significant association between technician reported and device-reported leaks (the Pearson correlation coefficient r is only 0.11 (CI 95% 0.06; 0.16), the regression coefficient is only 0.0072 (CI 95% 0.004; 0.011), see Figure S4 in the supplemental material).

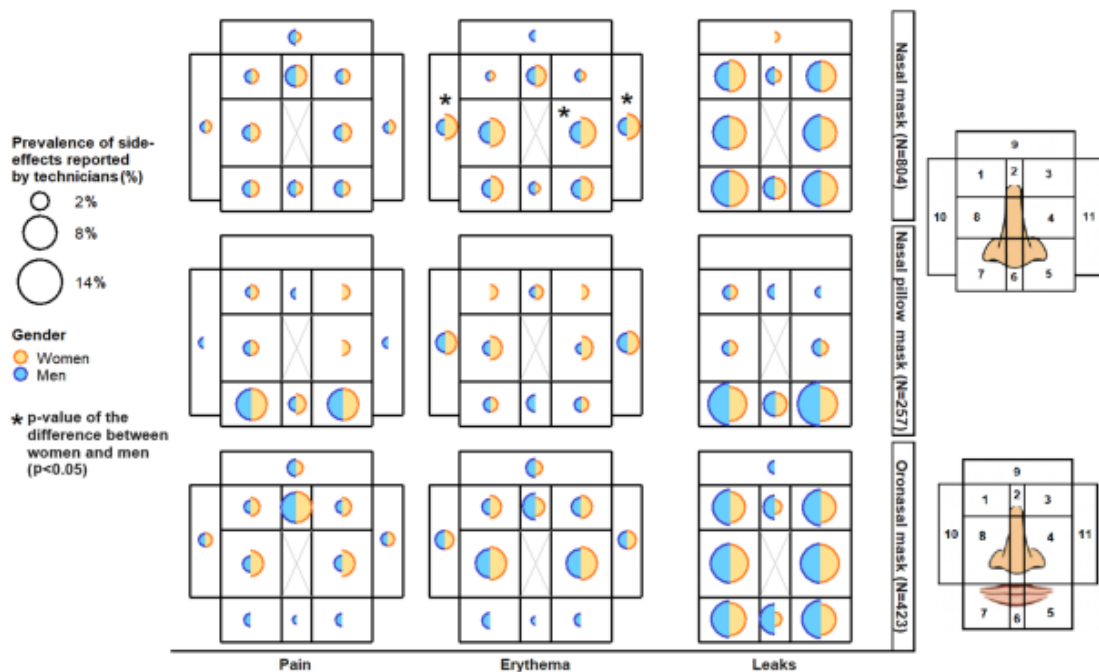


Fig. 1 Prevalence of pain, erythema and leak areas reported by technicians according to gender and mask type

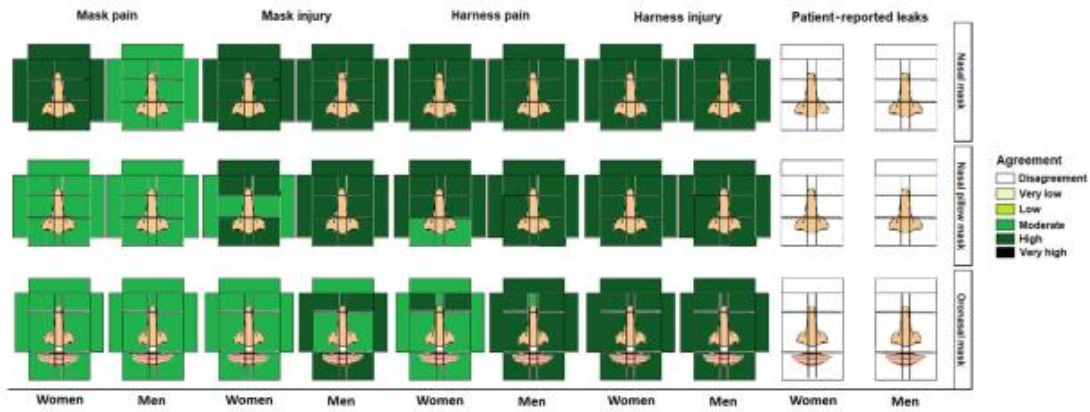


Fig. 2 Gwet's concordance coefficient between technician and patient response. *Note* injury is similar to erythema. Statistical note: a Gwet's concordance coefficient ≤ 0 indicates a disagreement, between [0; 0.2] a very low agreement, between [0.2; 0.4] a low agreement, between [0.4; 0.6] a moderate agreement, between [0.6; 0.8] a high agree-

ment and between [0.8; 1] a very high- agreement. The results suggest a moderate to high concordance between technician and patient responses for pain and erythema. On the contrary, no concordance was observed between technician and patient responses for leaks

Relationship between technician evaluation of CPAP side effects and Epworth-sleepiness-scale score, residual excessive sleepiness, CPAP-usage, CPAP-non-adherence

Tables S5 and S6 in the supplemental material, summarizes univariate logistic or linear regression analyses evaluating the impact of the technician side effect evaluation on CPAP-usage, CPAP-non-adherence, Epworth-Sleepiness Scale score and RES by gender. Explanatory variables were pain, erythema and leak areas reported by the technician.

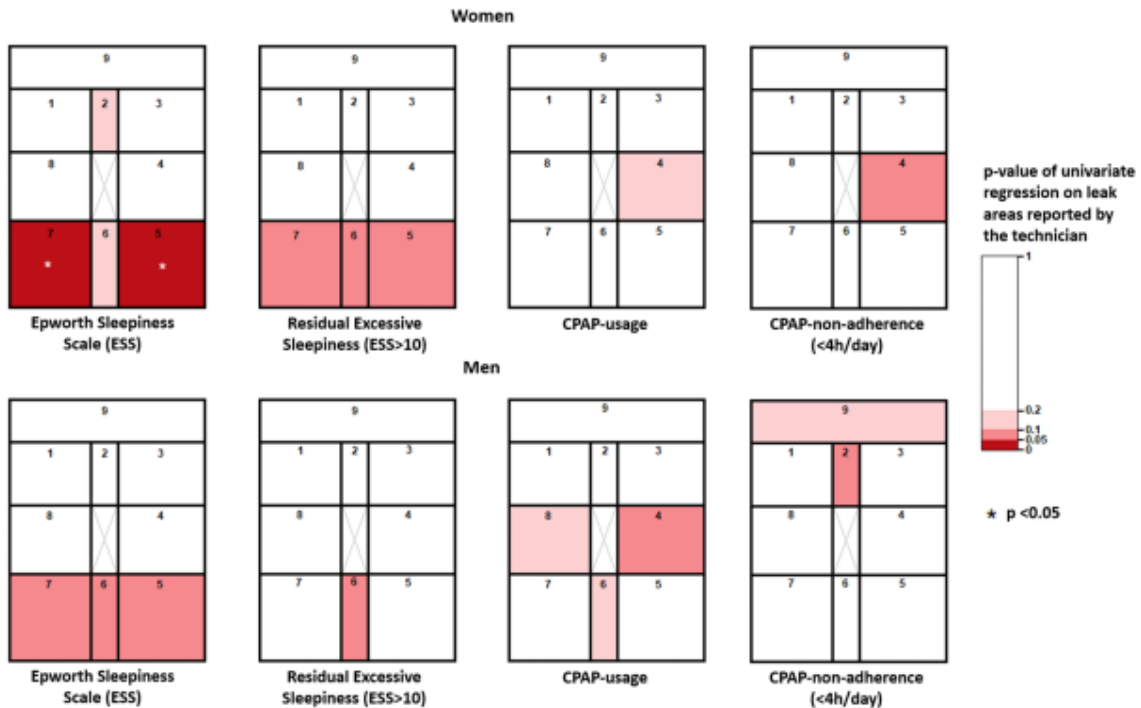


Fig. 3 p-value of univariate analyses of Epworth-Sleepiness-Scale and CPAP-usage by leaks areas according to gender. *Note* areas 5 to 7 are the areas below the mask, i.e., below the nose for the nasal and nasal pillow masks and below the mouth for the oronasal mask. Epworth-

Sleepiness-Scale was significantly associated with leaks below the mask reported by the technician (areas 5 ($p=0.025$) and 7 ($p=0.021$)) in women but not for men (area 5 ($p=0.087$), area 6 ($p=0.055$) and area 7 ($p=0.092$))

Figure 3 depicted the univariate regression analyses for leak areas reported by technicians on these variables-of-interest. Epworth-Sleepiness-Scale was significantly associated with leaks under the mask reported by the technician (areas 5 ($p=0.025$) and 7 ($p=0.021$)) in women but not for men (area 5 ($p=0.087$), area 6 ($p=0.055$) and area 7 ($p=0.092$)). For women but not men, Epworth-Sleepiness-Scale and RES were significantly associated with pain reported by the technician (areas 3, $p=0.011$ and $p=0.034$ respectively; areas 6, $p=0.008$ and $p=0.014$ respectively, see Fig. 4). No associations exist between men with or without beards/mustaches and CPAP-usage, CPAP-non-adherence, Epworth-Sleepiness-Scale scores and RES (see Table S2 in the supplemental material).

Discussion

To our knowledge, this study is the first to investigate the value of technicians for the evaluation of three common CPAP side effects: pain, erythema, and leaks, in a large cohort of real-life patients treated long-term with CPAP. Our findings describe the prevalence of technician-reported CPAP side effects based on gender as well as the added value of leak analysis performed by technicians using a simple tool, compared to patient and device assessments. Furthermore, our results indicate that in women but not in men, specific leak and pain areas identified by the technicians are associated with greater sleepiness.

Direct technician supervision versus CPAP-reported leaks and patient questionnaires

As the use of remote CPAP monitoring and patient questionnaires grows, the value and cost effectiveness of direct patient supervision by technicians for this long-term treatment has been questioned. To date, evidence supporting the benefits of direct patient supervision by a technician is sparse. A recent prospective randomized study indicated that a personalized interface fitting session overseen by a sleep technician significantly enhances APAP adherence at 30 days, particularly in the elderly and women with moderate SAS [15]. In our cohort of long-term CPAP-treated patients, the technician was shown to have potential added value compared to patient-reported side effects and device reported leaks considering that: (i) no statistically significant associations were found between technician-reported leaks and CPAP-reported leaks, nor patient-reported leaks; (ii) the technician identified specific leaks and painful areas associated with greater sleepiness in women.

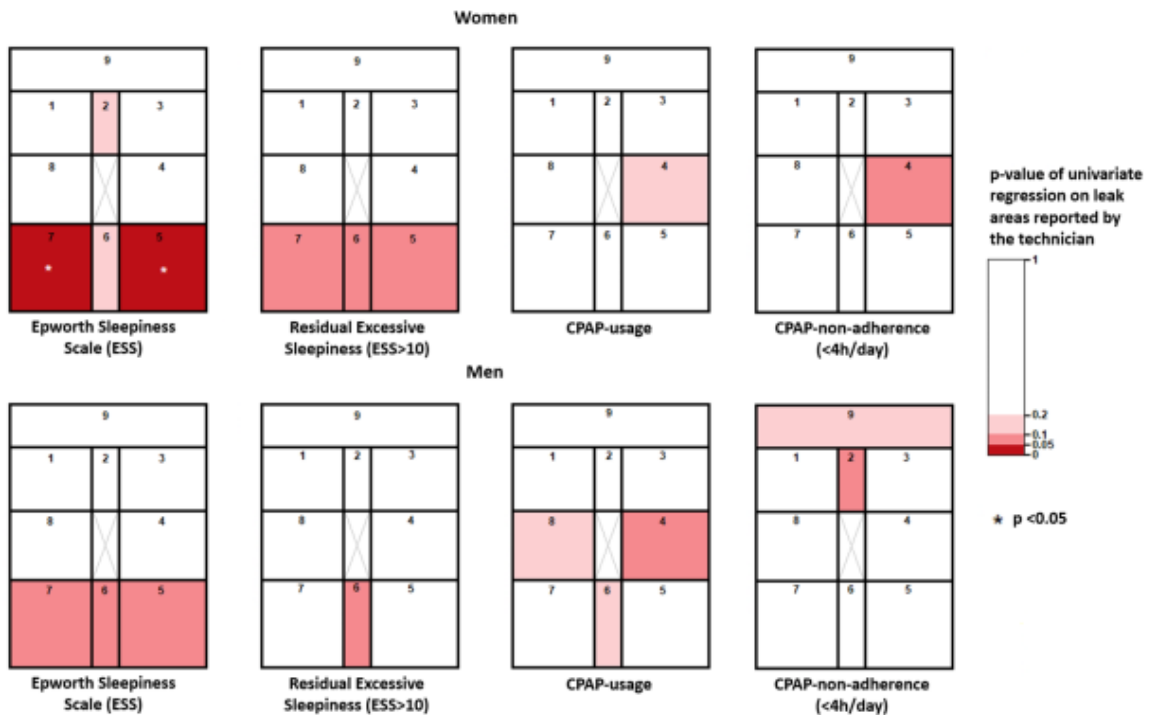


Fig. 4 p-value of univariate analyses of Epworth-Sleepiness-Scale and CPAP-usage by pains areas according to gender. *Note* areas 5 to 7 are the areas below the mask, i.e., below the nose for the nasal and nasal pillow masks and below the mouth for the oronasal mask. For women, Epworth-Sleepiness-Scale and RES were significantly associated with pain reported by the technician (areas 3, $p=0.011$ and $p=0.034$ respectively; areas 6, $p=0.008$ and $p=0.014$ respectively)

It is important for the clinician to understand that device reported leaks are not only both discordant with and of equal interest to patient-reported leaks, but also that technician reported leaks are different from patient-reported leaks and CPAP-reported leaks. As a consequence, technician reported leaks cannot be directly extrapolated from CPAP reported leaks, remotely reported during telemonitoring. This raises a critical question for clinicians regarding the optimal timing for triggering a technician visit, with cost effectiveness being a key consideration. From a personalized medicine perspective, provided that our findings are confirmed by other research teams, our data suggest that in women, subjective sleepiness may be associated with unintentional mask leaks. Looking ahead to future CPAP patient care, our findings suggest that during telemonitoring, it would be beneficial for clinicians to not only remotely assess CPAP data but also integrate targeted patient questionnaires to better evaluate the need for technician intervention. Device-reported leaks are crucial for assessing the accuracy of the AHI flow reported by the device, and its ability to maintain sufficient flow to prevent obstructive events [17]. But in the long-term, device-reported leaks are not associated with CPAP-adherence or RES, whereas patient-reported leaks are associated with RES [18].

In a previous study that was in alignment with prior findings [19], we reported that patient reported leaks are not predicted by CPAP-reported leaks [18]. Here, we demonstrate that technician-reported leaks are unrelated to both CPAP-reported and patient-reported leaks. Additionally, we found statistically significant associations between sleepiness in women and certain technician-reported areas of mask leaks and mask pain. Future studies are needed to investigate whether addressing these technician-reported areas of mask leaks and mask pain with different masks can improve sleepiness in women.

Gender differences in prevalence of technician reported CPAP side effects

Our findings indicate that gender differences exist in technician-reported CPAP side effects. In women, but not in men, specific leak and pain areas identified by the technician were associated with greater sleepiness. It is important to note that our study was conducted with unrestricted mask access (34 different masks) [18], but without any gender-specific mask series. To the best of our knowledge, there are no published studies justifying the gender-specific engineering choices of the gender series mask currently available on the market.

Furthermore, there is no published study reporting a favorable effect of gender series masks on CPAP usage or sleepiness. In the context of personalized medicine, the design of future masks should incorporate objective gender-specific considerations if masks specifically dedicated to women are to be developed. The fact that technician-reported leak areas 5 and 7 were associated with RES is of interest in the perspective of the design of future masks dedicated to women.

Our results also indicate that it could be pertinent to develop specific masks for patients with beards or mustaches.

Study limitations

Our study design has both strengths and limitations. It is important to note that our patients were undergoing long-term CPAP therapy, and therefore our findings may not be applicable to patients receiving short-term treatment.

We decided not to provide patients with a specific tool, similar to the one used by technicians, to evaluate their own pain, erythema, or leaks. Instead, we instructed them to rate their experiences using a Visual Analog Scale (VAS) ranging from 0 to 10. This decision was made to prevent patient responses from influencing the technician's evaluations. Additionally, two measures were implemented in the study protocol to minimize the impact of patient feedback on the technician's assessments: the technicians were blinded to the patients' VAS responses when conducting their own assessment of side effects, and they were also unaware of device-reported leaks when performing their own leak evaluation. We believe these measures were respected by the technician, as technician-reported leaks showed no correlation with either CPAP-reported or patient-reported leaks. However, both the technician and the patient can visually assess the red and tender skin areas, which likely explains the observed concordance in their respective assessments of pain and erythema.

To anticipate the external validity of our research, we used a simple tool to collect the technicians' assessments of common side effects such as pain, erythema and leaks. This tool can be employed by both clinic technicians and home care providers, and would also be beneficial if used by the patient. 32 technicians used this tool and did not report any problems.

A limitation of our study, due to its cross-sectional design, is that we did not assess inter- and intra-technician reproducibility and variability. Indeed, we did not plan to control for variability between technician ratings in the original study protocol. On the other hand, informing technicians of a comparison could have influenced their behavior. Future studies should address this aspect, including intra-technician variability over time.

Additionally, there was a gender imbalance among the technicians, with only 3 out of 32 being women. Our cohort represents a European population with universal healthcare coverage, ensuring that financial barriers did not limit access to care or medications. This reduces biases linked to socioeconomic disparities. However, the findings may be less generalizable to populations in healthcare systems where access to treatment is influenced by cost considerations.

In particular, no CPAP-adherence threshold was required for reimbursement, patients with poor compliance were not systematically excluded, and patients had unlimited access to 34 masks [18, 20].

One limitation of our study is the absence of a cost analysis for technician interventions. While a 2021 Spanish study estimated the cost at €19 per hour for a technician from the provider company and €24 for mask replacement [13], these costs are highly variable across countries due to differences in labor regulations, technician wages, and healthcare system structures. Additionally, the cost of masks depends on home care providers, with factors such as bulk purchasing volumes and commercial agreements influencing pricing. Future studies will include this cost-analysis in order to fully evaluate the cost-effectiveness of technician intervention.

Conclusion

In patients undergoing long-term CPAP therapy, gender differences in technician-reported side effects were observed. Additionally, discrepancies between patient-reported and technician-reported leaks were noted. Indeed, specific leak and pain areas identified by technicians were associated with increased sleepiness in women. In the context of precision medicine, our results suggest that: (i) the design of future masks should consider these gender differences, particularly if masks are developed specifically for women; (ii) direct supervision of chronic apneic patients by a technician adds potential value in mask evaluation.

Long-term care should encompass a combination of remote CPAP monitoring, patient-reported outcomes, and direct technician supervision. These data sources should be viewed as complementary rather than redundant.

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Author contributions

DJ accessed all data and takes responsibility for the integrity and accuracy of the analysis. All authors contributed to and approved the final submitted manuscript. CV: data collection, analysis, and manuscript preparation; FB: data collection; JPM: study design analysis and manuscript preparation; RG: data collection and analysis; JCB: manuscript preparation; FG: manuscript preparation; SS: manuscript preparation; AB: study design, analysis and manuscript preparation; NM: study design, data collection, analysis, and manuscript preparation; DJ: study design, analysis, and manuscript preparation.

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Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

InterfaceVent is registered with ClinicalTrials.gov (NCT03013283). The protocol complied with the Declaration of Helsinki and was reviewed and approved by an independent ethics committee (Comité de Protection des Personnes Sud Méditerranée 1; reference number RO-2016/50).

Consent for publication

Not applicable.

Competing interests

CV declares working for Adene home healthcare provider company. FB reports no conflicts of interest in relation to the present work. JPM declares grants/funds: Adene, Novartis, Chiesy, GSK, DPC-ORL; personal fees from Pulmon X. RG declares working for Adene home healthcare provider company. JCB declares consultant fees from AGIR à dom, a French Homecare provider. FG declares receipt of personal fees from AIR LIQUIDE SANTE, INSPIRE, BIOPROJET, RESMED and SEFAM; payment for presentations from BIOPROJET, CIDELEC, INSPIRE, RESMED, and SEFAM; non-financial support from ASTEN SANTE. SS reports no conflicts of interest in relation to the present work. AB declares grants/funds: Boehringer Ingelheim; personal fees: AstraZeneca, Boehringer Ingelheim, Chiesi, GlaxoSmithKline, Novartis, Sanofi-Regeneron; clinical trial investigator: Acceleron, Actelion, Galapagos, Merck Sharpe & Dohme, Nuvaira, Pulmonx, United

Therapeutic, Celltrion, Vertex. NM declares grants/funds: GlaxoSmithKline; personal fees: SanofiRegeneron. DJ reports personal fees from Lowenstein, Jazz, Bioprojet, Adene, Bastide, LVL, GSK, Astra, ALK, Boehringer Ingelheim, Sanofi, Philips Healthcare, and Resmed, personal fees and nonfinancial support from Sefam and Nomics, grants and personal fees from Novartis, outside the submitted work.

Conflict of interest statement

Declarations. Ethics approval and consent to participate: InterfaceVent is registered with ClinicalTrials.gov (NCT03013283. The protocol complied with the Declaration of Helsinki and was reviewed and approved by an independent ethics committee (Comité de Protection des Personnes Sud Méditerranée 1; reference number RO-2016/50). Consent for publication: Not applicable. Competing interests: CV declares working for Adene home healthcare provider company. FB reports no conflicts of interest in relation to the present work. JPM declares grants/funds: Adene, Novartis, Chiesy, GSK, DPC-ORL; personal fees from Pulmon X. RG declares working for Adene home healthcare provider company. JCB declares consultant fees from AGIR à dom, a French Homecare provider. FG declares receipt of personal fees from AIR LIQUIDE SANTE, INSPIRE, BIOPROJET, RESMED and SEFAM; payment for presentations from BIOPROJET, CIDELEC, INSPIRE, RESMED, and SEFAM; non-financial support from ASTEN SANTE. SS reports no conflicts of interest in relation to the present work. AB declares grants/funds: Boehringer Ingelheim; personal fees: AstraZeneca, Boehringer Ingelheim, Chiesi, GlaxoSmithKline, Novartis, Sanofi-Regeneron; clinical trial investigator: Acceleron, Actelion, Galapagos, Merck Sharpe & Dohme, Nuvaira, Pulmonx, United Therapeutic, Celltrion, Vertex. NM declares grants/funds: GlaxoSmithKline; personal fees: Sanofi-Regeneron. DJ reports personal fees from Lowenstein, Jazz, Bioprojet, Adene, Bastide, LVL, GSK, Astra, ALK, Boehringer Ingelheim, Sanofi, Philips Healthcare, and Resmed, personal fees and nonfinancial support from Sefam and Nomics, grants and personal fees from Novartis, outside the submitted work.

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Additional Files

Title:

Added value of technician intervention to improve mask management for apneic patients treated with long-term CPAP

Short title:

Technician intervention to improve mask management in long-term CPAP

Authors:

Celia Vidal, BSc(Stat)^{1,2}, Fanny Bertelli PhD², Jean-Pierre Mallet MD^{2,3,4}, Raphael Gilson², Jean-Christian Borel⁵, Frédéric Gagnadoux⁶, Sarah Skinner PhD⁷, Arnaud Bourdin MD, PhD^{2,3,4}, Nicolas Molinari PhD^{1,2}, and Dany Jaffuel MD, PhD^{2,3,4}.

Affiliations:

¹ IDESP, INSERM, PreMEDical INRIA, Montpellier University, CHU Montpellier, Montpellier, France.

² Groupe Adène, Montpellier, France.

³ Department of Respiratory Diseases, Montpellier University Hospital, Arnaud de Villeneuve Hospital, Montpellier, France.

⁴ PhyMedExp (INSERM U 1046, CNRS UMR9214), Montpellier University, Montpellier, France.

⁵ Centre de Pneumologie Henri Bazire, la Sure en Chartreuse, Isère, France.

⁶ Département de Respiratory and Sleep Medicine, University Hospital of Angers, Angers, France.

⁷ CHU Montpellier, Montpellier, France.

Corresponding author:

Jaffuel Dany, Department of Respiratory Diseases, CHRU Montpellier, 371, Avenue Doyen Giraud, 34295 Montpellier Cedex 5, France. E-mail: dany.jaffuel@wanadoo.fr

Tel: +33661533104 ; Fax : +33467316484

Figure S1. Pain Erythema Leak tool. Diagram of the areas of the patient's face observed by the technician (panel **A** for nasal and nasal pillow masks, panel **B** for oronasal masks). Note that areas 10 and 11 were not applicable for leaks

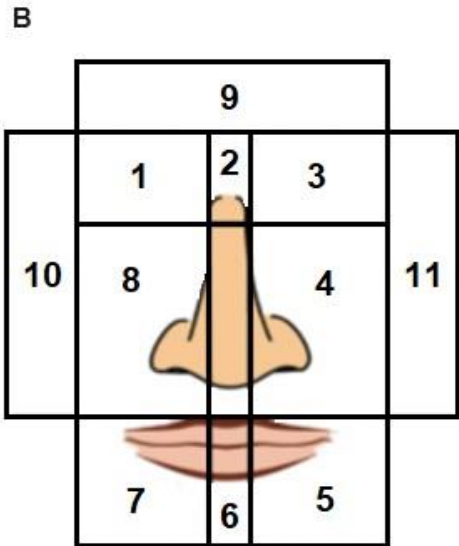
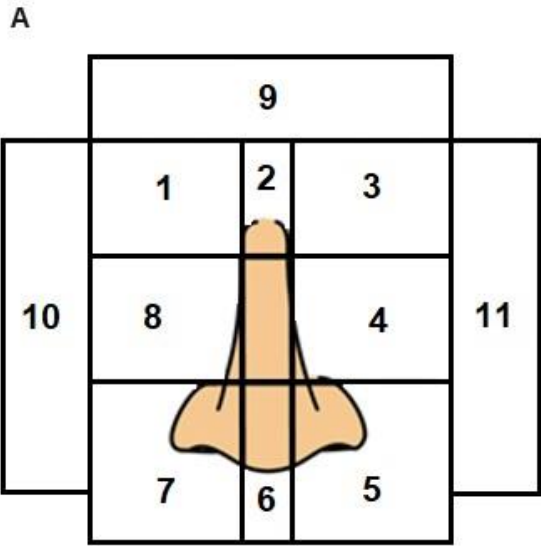


Table S2. Population characteristics according to men with and without beards/mustaches and mask type

	Whole population			Nasal mask			Nasal pillow mask			Oronasal mask		
	Men without beards/mustaches, N = 739	Men with beards/mustaches, N = 305	p-value	Men without beards/mustaches, N = 394	Men with beards/mustaches, N = 151	p-value	Men without beards/mustaches, N = 123	Men with beards/mustaches, N = 48	p-value	Men without beards/mustaches, N = 222	Men with beards/mustaches, N = 106	p-value
Demographics												
Age (years)	68.00 [61.00 ; 74.00]	66.00 [60.00 ; 72.00]	0.035^w	68.00 [62.00 ; 74.00]	65.00 [59.00 ; 71.00]	0.001^w	66.00 [59.50 ; 73.00]	69.00 [60.75 ; 74.25]	0.394 ^w	68.00 [59.25 ; 74.00]	67.50 [60.00 ; 74.00]	0.785 ^w
BMI (kg/m ²)	30.07 [27.28 ; 33.51]	31.51 [28.40 ; 35.27]	<0.001^w	29.81 [27.17 ; 33.15]	31.56 [27.96 ; 36.06]	<0.001^w	29.77 [27.11 ; 33.27]	32.06 [28.65 ; 34.18]	0.091 ^w	30.86 [27.61 ; 34.41]	31.12 [28.40 ; 34.77]	0.563 ^w
Diagnostic AHI (events/h)	40.00 [32.00 ; 56.00]	42.00 [31.00 ; 61.00]	0.106 ^w	39.00 [32.00 ; 55.00]	45.40 [33.00 ; 61.00]	0.028^w	41.00 [32.00 ; 57.00]	39.65 [29.25 ; 54.50]	0.229 ^w	40.00 [31.00 ; 57.00]	42.00 [31.00 ; 61.60]	0.367 ^w
Active smokers (%)	80 (10.91)	44 (14.57)	0.100 ^c	37 (9.46)	26 (17.45)	0.010^c	11 (9.02)	6 (12.50)	0.571 ^f	32 (14.55)	12 (11.43)	0.442 ^c
Active workers (%)	155 (21.56)	58 (19.66)	0.501 ^c	76 (19.64)	32 (21.77)	0.584 ^c	28 (23.33)	10 (21.28)	0.776 ^c	51 (24.06)	16 (15.84)	0.098 ^c
Presence of partner (%)	576 (79.12)	234 (78.52)	0.831 ^c	306 (78.26)	119 (80.41)	0.586 ^c	96 (79.34)	41 (85.42)	0.363 ^c	174 (80.56)	74 (72.55)	0.108 ^c
Epworth Scale												
ESS (0-24 score)	5.00 [3.00 ; 9.00]	6.00 [3.00 ; 9.00]	0.710 ^w	6.00 [3.00 ; 9.00]	5.00 [2.36 ; 8.00]	0.130 ^w	5.00 [2.00 ; 9.00]	6.00 [3.75 ; 8.00]	0.282 ^w	5.00 [3.00 ; 8.00]	6.00 [4.00 ; 9.00]	0.082 ^w
RES (%)	117 (15.83)	52 (17.05)	0.627 ^c	61 (15.48)	24 (15.89)	0.906 ^c	21 (17.07)	8 (16.67)	0.949 ^c	35 (15.77)	20 (18.87)	0.482 ^c
EQ-5D-3L												
Problems with mobility (%)	141 (19.80)	61 (20.89)	0.696 ^c	69 (18.21)	24 (16.67)	0.681 ^c	21 (17.80)	6 (12.77)	0.430 ^c	51 (23.72)	31 (30.69)	0.187 ^c
Problems with self-care (%)	30 (4.26)	13 (4.53)	0.851 ^c	13 (3.45)	5 (3.60)	>0.999 ^f	6 (5.04)	0 (0.00)	0.185 ^f	11 (5.29)	8 (7.92)	0.366 ^c
Problems with usual activities (%)	110 (15.49)	41 (14.14)	0.587 ^c	60 (15.92)	17 (11.89)	0.248 ^c	18 (15.25)	4 (8.51)	0.250 ^c	32 (14.88)	20 (20.00)	0.255 ^c
Problems of pain/discomfort (%)	387 (54.28)	152 (51.35)	0.396 ^c	209 (55.44)	64 (43.84)	0.017^c	64 (52.89)	23 (48.94)	0.645 ^c	114 (53.02)	65 (63.11)	0.090 ^c
Problems of anxiety/depression (%)	236 (33.15)	111 (37.50)	0.185 ^c	115 (30.42)	39 (26.90)	0.428 ^c	41 (34.75)	18 (38.30)	0.667 ^c	80 (37.04)	54 (51.92)	0.011^c
EQ-5D-3L health VAS (0-100 score)	70.50 [55.00 ; 80.40]	70.10 [50.40 ; 80.50]	0.555 ^w	71.15 [55.28 ; 80.63]	74.60 [52.40 ; 84.78]	0.494 ^w	73.80 [59.90 ; 81.60]	74.60 [52.08 ; 83.23]	0.833 ^w	70.05 [50.45 ; 80.00]	63.90 [49.55 ; 79.35]	0.078 ^w
Device												
CPAP-usage (h/day)	6.87 [5.63 ; 7.93]	6.75 [5.73 ; 7.75]	0.284 ^w	7.00 [5.84 ; 7.93]	7.00 [5.50 ; 7.82]	0.685 ^w	6.83 [5.75 ; 8.00]	6.75 [5.75 ; 7.50]	0.358 ^w	6.73 [5.35 ; 7.75]	6.49 [5.75 ; 7.50]	0.713 ^w
Non-adherence (%)	50 (6.77)	20 (6.56)	0.903 ^c	17 (4.31)	9 (5.96)	0.420 ^c	9 (7.32)	4 (8.33)	0.759 ^f	24 (10.81)	7 (6.60)	0.223 ^c
Current AHI _{flow} (events/h)	2.20 [1.00 ; 4.30]	1.80 [0.90 ; 3.90]	0.032^w	2.00 [1.00 ; 4.00]	1.65 [0.80 ; 3.48]	0.036^w	1.70 [0.90 ; 3.10]	1.20 [0.58 ; 2.63]	0.080 ^w	3.00 [1.50 ; 5.60]	2.75 [1.43 ; 4.78]	0.414 ^w
Treatment duration (years)	4.74 [2.22 ; 10.14]	5.37 [2.75 ; 10.42]	0.266 ^w	5.04 [1.60 ; 10.98]	5.32 [2.76 ; 10.47]	0.438 ^w	5.91 [3.31 ; 10.43]	8.06 [3.49 ; 11.00]	0.285 ^w	4.34 [2.32 ; 8.74]	4.08 [2.15 ; 10.00]	0.669 ^w
Mean pressure (cmH ₂ O)	8.20 [6.80 ; 10.00]	8.45 [7.00 ; 10.00]	0.326 ^w	8.00 [6.60 ; 9.80]	8.40 [7.00 ; 10.10]	0.105 ^w	7.60 [6.50 ; 8.80]	7.65 [6.65 ; 9.78]	0.370 ^w	9.45 [7.68 ; 10.90]	8.80 [7.45 ; 10.50]	0.141 ^w
90th/95th pressure (cmH ₂ O)	10.00 [8.00 ; 11.80]	10.30 [8.90 ; 11.90]	0.105 ^w	9.80 [8.00 ; 11.20]	10.30 [8.50 ; 11.90]	0.025^w	9.50 [7.90 ; 11.00]	9.60 [8.50 ; 10.90]	0.816 ^w	11.00 [9.00 ; 12.05]	10.80 [9.63 ; 11.98]	0.501 ^w
Fixed pressure (%)	109 (14.75)	36 (11.80)	0.211 ^c	61 (15.48)	15 (9.93)	0.094 ^c	13 (10.57)	11 (22.92)	0.037^c	35 (15.77)	10 (9.43)	0.119 ^c
Comfort mode (%)	117 (15.83)	48 (15.74)	0.970 ^c	69 (17.51)	21 (13.91)	0.310 ^c	19 (15.45)	9 (18.75)	0.600 ^c	29 (13.06)	18 (16.98)	0.344 ^c
Heated humidifier (%)	430 (58.19)	180 (59.02)	0.805 ^c	203 (51.52)	76 (50.33)	0.803 ^c	77 (62.60)	28 (58.33)	0.606 ^c	150 (67.57)	76 (71.70)	0.450 ^c
Heated breathing tube (%)	25 (3.38)	7 (2.30)	0.354 ^c	11 (2.79)	3 (1.99)	0.767 ^f	4 (3.25)	1 (2.08)	>0.999 ^f	10 (4.50)	3 (2.83)	0.560 ^f
Mask												
Mask availability since 2013 (%)	310 (42.12)	119 (39.14)	0.375 ^c	124 (31.63)	39 (25.83)	0.186 ^c	47 (38.21)	14 (29.79)	0.306 ^c	139 (62.90)	66 (62.26)	0.912 ^c

	Whole population			Nasal mask			Nasal pillow mask			Oronasal mask		
	Men without beards/mustaches, N = 739	Men with beards/mustaches, N = 305	p-value	Men without beards/mustaches, N = 394	Men with beards/mustaches, N = 151	p-value	Men without beards/mustaches, N = 123	Men with beards/mustaches, N = 48	p-value	Men without beards/mustaches, N = 222	Men with beards/mustaches, N = 106	p-value
Unintentional leaks (l/min)	2.40 [0.00; 7.50]	2.50 [0.00; 9.00]	0.310 ^w	2.50 [0.00; 8.40]	2.50 [0.00; 8.40]	0.801 ^w	2.50 [0.00; 8.40]	0.00 [0.00; 4.80]	0.147 ^w	0.00 [0.00; 4.80]	2.50 [0.00; 12.23]	0.012^w
Unintentional large leaks (%)	0.00 [0.00; 0.78]	0.10 [0.00; 2.20]	0.058 ^w	0.00 [0.00; 0.50]	0.10 [0.00; 0.53]	0.461 ^w	0.10 [0.00; 0.70]	0.00 [0.00; 0.15]	0.286 ^w	0.10 [0.00; 1.90]	3.00 [0.60; 9.30]	0.002^w
Global leaks (l/min)	35.00 [29.00; 42.50]	36.50 [33.00; 47.43]	0.164 ^w	32.00 [29.00; 42.25]	34.00 [32.00; 37.00]	0.551 ^w	35.50 [26.75; 39.00]	41.00 [37.00; 45.00]	0.348 ^w	36.00 [32.75; 43.00]	43.00 [37.00; 48.18]	0.194 ^w
Global large leaks (%)	0.90 [0.10; 6.30]	2.10 [0.70; 6.70]	0.276 ^w	1.25 [0.10; 5.85]	0.90 [0.20; 2.10]	0.863 ^w	0.90 [0.62; 3.97]	0.30 [0.20; 4.55]	0.385 ^w	0.50 [0.10; 6.50]	6.00 [4.90; 15.20]	0.089 ^w
Side-effects reported by technician												
Pain (%)	62 (8.39)	36 (11.80)	0.085 ^c	31 (7.87)	15 (9.93)	0.438 ^c	13 (10.57)	4 (8.33)	0.782 ^f	18 (8.11)	17 (16.04)	0.030^c
Erythema (%)	65 (8.80)	32 (10.49)	0.391 ^c	33 (8.38)	12 (7.95)	0.871 ^c	7 (5.69)	3 (6.25)	>0.999 ^f	25 (11.26)	17 (16.04)	0.226 ^c
Leak (%)	173 (23.41)	75 (24.59)	0.684 ^c	95 (24.11)	31 (20.53)	0.375 ^c	18 (14.63)	9 (18.75)	0.507 ^c	60 (27.03)	35 (33.02)	0.263 ^c

AHI: Apnea-Hypopnea Index; AHI_{flow}: AHI reported by device; BMI: Body Mass Index; CPAP: Continuous Positive Airway Pressure; ESS: Epworth Sleepiness Scale; N = number of patients responding; Non-adherence: CPAP-usage under 4 h per day; RES: Residual Excessive Sleepiness (ESS score > 10); VAS: Visual Analogue Scale. Leaks were obtained using built-in CPAP software¹⁴. Data are reported as medians and quartiles or numbers and percentages of total as appropriate.

^wWilcoxon-Mann-Whitney test; ^cChi-square test; ^fFisher exact test.

Bolds variables are statistically significant at the 5% threshold.

Figure S3. Prevalence of pain, erythema and leaks areas reported by technicians according to men with and without beards/mustaches and mask type.

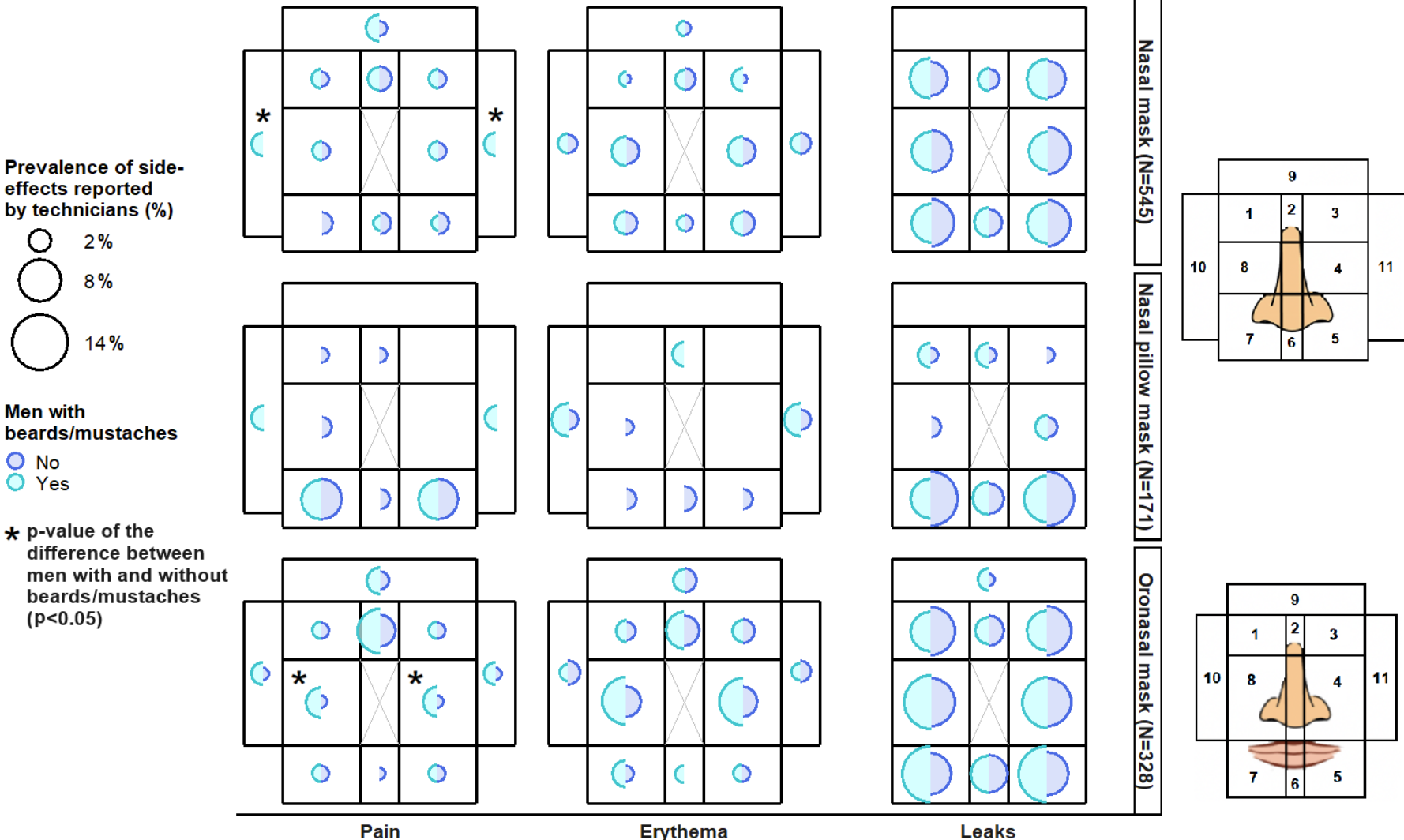
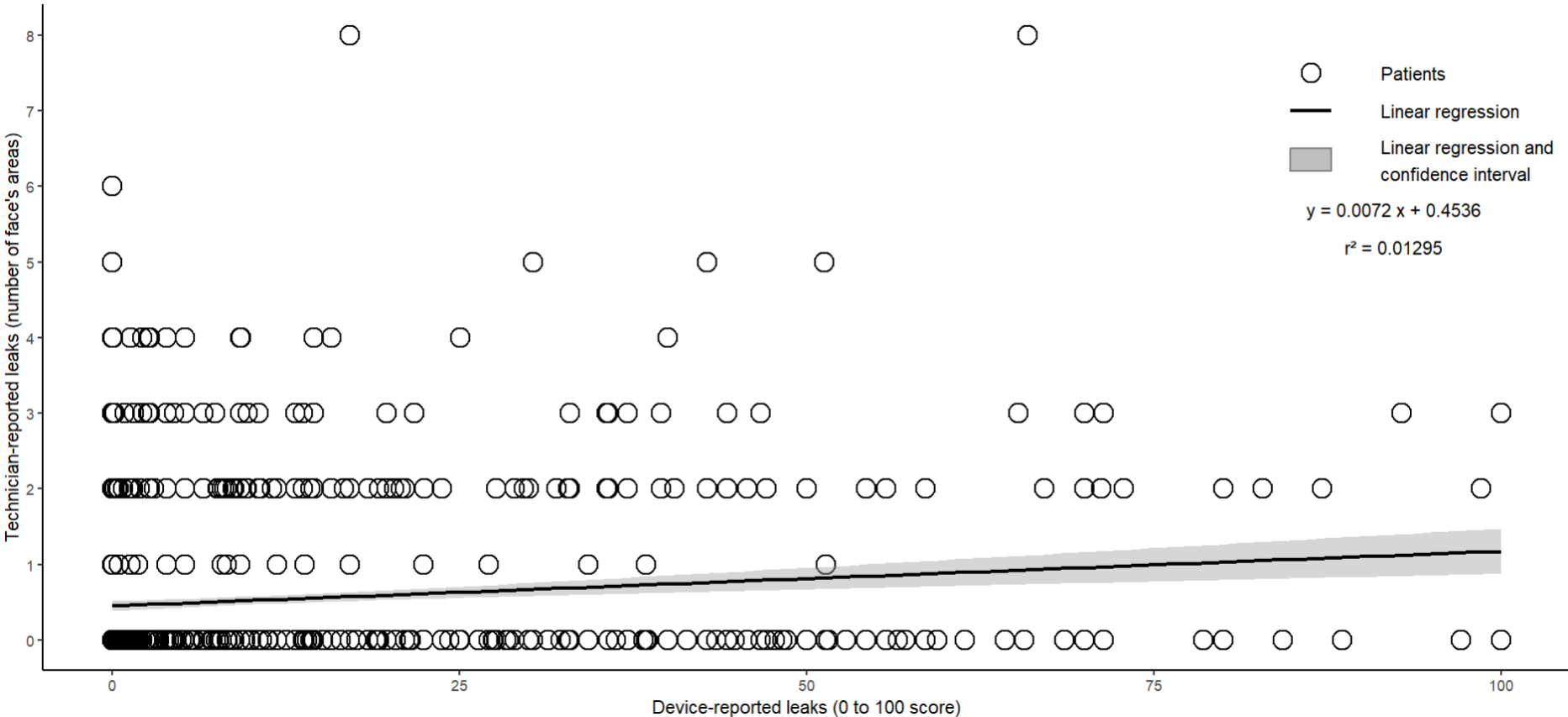


Figure S4. Relationship between technician-reported leaks and device-reported leaks: individual data and linear regression



The Pearson correlation coefficient r is 0.11 (CI 95% 0.06; 0.16) ($p < 0.001$), the regression coefficient is 0.0072 (CI 95% 0.004; 0.011) ($p < 0.001$).

Table S5. Univariate linear and logistic analyses of CPAP-usage and CPAP-non-adherence (< 4 h/day)

Variable	CPAP-usage (continuous variable)						CPAP-non-adherence (< 4 h/day)					
	Estimate	95% CI*	P-value	Estimate	95% CI*	P-value	OR [§]	95% CI*	P-value	OR [§]	95% CI*	P-value
	Women			Men			Women			Men		
Pain area 1	0.055	- 1.43, 1.54	0.94 2	0.114	- 1.04, 1.27	0.84 7	1.65 0	0.188 , 14.45	0.65 1	0.00 0	0.000 , Inf	0.98 6
Pain area 2	-0.251	- 1.27, 0.764	0.62 8	0.403	- 0.173 , 0.979	0.17 1	0.67 4	0.086 , 5.311	0.70 8	0.00 0	0.000 , Inf	0.98 2
Pain area 3	-0.029	- 1.51, 1.45	0.96 9	0.007	- 1.15, 1.16	0.99 0	1.65 0	0.188 , 14.45	0.65 1	0.00 0	0.000 , Inf	0.98 6
Pain area 4	-0.657	- 1.81, 0.495	0.26 4	-0.059	- 1.06, 0.942	0.90 8	0.90 7	0.112 , 7.325	0.92 7	2.91 5	0.626 , 13.57	0.17 3
Pain area 5	0.112	- 1.10, 1.33	0.85 6	0.378	- 0.333 , 1.09	0.29 8	1.02 3	0.125 , 8.370	0.98 3	0.00 0	0.000 , Inf	0.98 5
Pain area 6	0.597	- 1.21, 2.41	0.51 8	-0.084	- 1.09, 0.917	0.86 9	0.00 0	0.000 , Inf	0.98 5	0.00 0	0.000 , Inf	0.98 4
Pain area 7	0.344	- 0.809 , 1.50	0.55 9	0.252	- 0.475 , 0.979	0.49 7	0.90 7	0.112 , 7.325	0.92 7	0.00 0	0.000 , Inf	0.97 8
Pain area 8	0.035	- 1.12, 1.19	0.95 3	0.229	- 0.698 , 1.16	0.62 8	0.00 0	0.000 , Inf	0.98 5	2.42 4	0.532 , 11.05	0.25 3
Pain area 9	1.06	- 1.49, 3.61	0.41 6	0.055	- 0.907 , 1.02	0.91 1	0.00 0	0.000 , Inf	0.99 0	0.00 0	0.000 , Inf	0.98 3
Pain area 10	0.233	- 1.86, 2.32	0.82 7	-0.418	- 1.73, 0.889	0.53 1	0.00 0	0.000 , Inf	0.98 7	0.00 0	0.000 , Inf	0.98 1
Pain area 11	0.779	- 1.03, 2.59	0.39 9	-0.418	- 1.73, 0.889	0.53 1	0.00 0	0.000 , Inf	0.98 5	0.00 0	0.000 , Inf	0.98 1
Erythema area 1	0.467	- 1.15, 2.09	0.57 3	-0.529	- 1.84, 0.778	0.42 8	0.00 0	0.000 , Inf	0.98 9	0.00 0	0.000 , Inf	0.98 1
Erythema area 2	-0.325	- 1.48, 0.829	0.58 1	0.090	- 0.582 , 0.762	0.79 3	0.00 0	0.000 , Inf	0.98 5	0.54 3	0.073 , 4.061	0.55 2
Erythema area 3	0.467	- 1.15, 2.09	0.57 3	0.157	- 0.888 , 1.20	0.76 8	0.00 0	0.000 , Inf	0.98 9	0.00 0	0.000 , Inf	0.98 5
Erythema area 4	-0.644	- 1.38, 0.097	0.08 9	0.270	- 0.307 , 0.846	0.36 0	2.82 6	1.065 , 7.497	0.03 7	0.38 8	0.052 , 2.876	0.35 5
Erythema area 5	-0.069	- 1.22, 1.09	0.90 7	-0.277	- 1.12, 0.566	0.51 9	0.00 0	0.000 , Inf	0.98 5	0.00 0	0.000 , Inf	0.98 1
Erythema area 6	1.04	- 2.56, 4.65	0.57 1	-0.598	- 1.75, 0.556	0.31 0	0.00 0	0.000 , Inf	0.98 9	1.79 9	0.222 , 14.59	0.58 2
Erythema area 7	-0.128	- 1.23, 0	0.82 0	-0.161	- 0.981 0	0.70 0	0.00 0	0.000 , Inf	0.98 4	0.00 0	0.000 , Inf	0.98 0

		0.974										
					0.658							
Erythema area 8	-0.549	-1.31, 0.207	0.155	0.487	0.081, 1.06	0.093	2.296	0.813, 6.483	0.117	0.000	0.000, Inf	0.981
Erythema area 9	1.29	2.31, 4.90	0.482	-0.213	1.31, 0.882	0.703	0.000	0.000, Inf	0.989	0.000	0.000, Inf	0.985
Erythema area 10	-0.253	1.20, 0.695	0.601	-0.028	0.826, 0.770	0.945	1.270	0.277, 5.819	0.758	0.000	0.000, Inf	0.980
Erythema area 11	-0.121	1.04, 0.798	0.796	0.077	0.701, 0.855	0.847	1.176	0.259, 5.351	0.834	0.000	0.000, Inf	0.979
Leaks area 1	-0.069	0.827, 0.689	0.858	0.215	0.236, 0.666	0.349	0.341	0.045, 2.586	0.298	0.985	0.347, 2.798	0.978
Leaks area 2	1.09	0.997, 3.17	0.307	-0.043	0.755, 0.669	0.905	0.000	0.000, Inf	0.987	2.973	0.987, 8.949	0.053
Leaks area 3	-0.079	0.859, 0.711	0.845	0.236	0.202, 0.673	0.292	0.376	0.049, 2.860	0.344	0.918	0.324, 2.601	0.872
Leaks area 4	-0.507	1.21, 0.197	0.159	-0.323	0.704, 0.058	0.097	2.420	0.925, 6.329	0.072	1.037	0.436, 2.466	0.935
Leaks area 5	-0.104	0.758, 0.550	0.756	-0.227	0.579, 0.126	0.208	1.140	0.382, 3.407	0.814	0.845	0.357, 2.000	0.701
Leaks area 6	-0.326	1.43, 0.775	0.562	-0.390	0.910, 0.129	0.141	1.855	0.388, 8.869	0.439	0.640	0.152, 2.695	0.543
Leaks area 7	-0.150	0.786, 0.487	0.645	-0.224	0.583, 0.135	0.221	1.061	0.356, 3.156	0.916	0.884	0.373, 2.094	0.779
Leaks area 8	-0.254	0.959, 0.451	0.481	-0.317	0.713, 0.078	0.116	1.875	0.675, 5.205	0.228	0.923	0.361, 2.360	0.867
Leaks area 9	-1.28	4.89, 2.32	0.486	1.20	0.787, 3.20	0.236	0.000	0.000, Inf	0.989	7.239	0.648, 80.83	0.108

*CI = confidence interval; §OR = odds ratio. Bolds variables are statistically significant at the 5% threshold.

Table S6. Univariate linear and logistic analyses of Epworth-Sleepiness-Scale (ESS) and Residual Excessive Sleepiness (ESS > 10)

Variable	ESS (continuous variable)						Residual Excessive Sleepiness (ESS > 10)					
	Estimate	95% CI*	P-value	Estimate	95% CI*	P-value	OR§	95% CI*	P-value	OR§	95% CI*	P-value

Pain area 1	3.21	-0.427, 6.85	0.0 84	0.24 1	-2.62, 3.10	0.8 69	2.83 6	0.508, 15.82	0.2 35	0.6 29	0.078, 5.063	0.66 3
Pain area 2	-1.91	-4.40, 0.586	0.1 35	0.67 3	-0.756, 2.10	0.3 56	0.00 0	0.000, Inf	0.9 82	1.9 23	0.914, 4.047	0.08 5
Pain area 3	4.73	1.11, 8.35	0.0 11	1.47	-1.39, 4.33	0.3 13	5.78 3	1.140, 29.33	0.0 34	1.4 48	0.298, 7.029	0.64 6
Pain area 4	0.81 7	-2.02, 3.66	0.5 73	1.10	-1.38, 3.58	0.3 84	1.40 2	0.291, 6.759	0.6 74	1.6 95	0.454, 6.326	0.43 2
Pain area 5	2.16	-0.829, 5.14	0.1 58	0.94 4	-0.820, 2.71	0.2 94	2.86 7	0.698, 11.77	0.1 44	1.0 10	0.341, 2.993	0.98 5
Pain area 6	6.06	1.63, 10.5	0.0 08	- 0.07 8	-2.56, 2.40	0.9 51	17.4 5	1.785, 170.5	0.0 14	1.0 10	0.219, 4.651	0.99 0
Pain area 7	1.23	-1.61, 4.07	0.3 97	0.45 8	-1.34, 2.26	0.6 18	2.45 0	0.616, 9.739	0.2 03	1.0 65	0.358, 3.168	0.91 0
Pain area 8	- 0.82 2	-3.66, 2.02	0.5 71	0.41 6	-1.88, 2.72	0.7 23	0.61 1	0.076, 4.909	0.6 43	1.3 84	0.382, 5.012	0.62 1
Pain area 9	-2.01	-8.30, 4.28	0.5 31	- 0.78 6	-3.17, 1.60	0.5 19	0.00 0	0.000, Inf	0.9 84	0.0 00	0.000, Inf	0.97 2
Pain area 10	4.03	-1.10, 9.16	0.1 25	0.12 6	-3.11, 3.37	0.9 39	2.80 6	0.251, 31.42	0.4 02	0.8 41	0.101, 7.022	0.87 3
Pain area 11	3.03	-1.42, 7.48	0.1 83	0.12 6	-3.11, 3.37	0.9 39	1.86 6	0.191, 18.23	0.5 92	0.8 41	0.101, 7.022	0.87 3
Erythema area 1	-2.23	-6.22, 1.76	0.2 74	- 0.01 8	-3.26, 3.22	0.9 91	0.00 0	0.000, Inf	0.9 83	0.0 00	0.000, Inf	0.98 0
Erythema area 2	0.92 0	-1.92, 3.76	0.5 26	0.59 5	-1.07, 2.26	0.4 84	1.40 2	0.291, 6.759	0.6 74	1.1 52	0.431, 3.084	0.77 8
Erythema area 3	-2.23	-6.22, 1.76	0.2 74	- 0.53 0	-3.12, 2.06	0.6 89	0.00 0	0.000, Inf	0.9 83	0.0 00	0.000, Inf	0.97 5
Erythema area 4	1.27	-0.553, 3.10	0.1 72	0.26 3	-1.17, 1.69	0.7 19	1.83 4	0.702, 4.789	0.2 16	0.7 83	0.301, 2.038	0.61 6
Erythema area 5	1.84	-0.994, 4.68	0.2 04	0.13 6	-1.95, 2.22	0.8 99	1.40 2	0.291, 6.759	0.6 74	0.3 12	0.041, 2.366	0.26 0
Erythema area 6	5.01	-3.86, 13.9	0.2 69	-1.02	-3.88, 1.84	0.4 85	11 957 468	0.000, Inf	0.9 85	0.0 00	0.000, Inf	0.97 7
Erythema area 7	0.83 8	-1.87, 3.55	0.5 45	0.28 9	-1.74, 2.32	0.7 81	0.54 8	0.069, 4.359	0.5 70	0.2 93	0.039, 2.217	0.23 5
Erythema area 8	0.30 7	-1.56, 2.17	0.7 47	0.16 1	-1.25, 1.57	0.8 23	1.11 9	0.369, 3.390	0.8 43	0.7 58	0.292, 1.970	0.57 0
Erythema area 9	-3.01	-11.9, 5.87	0.5 07	- 0.06 1	-2.78, 2.65	0.9 65	0.00 0	0.000, Inf	0.9 88	0.5 59	0.070, 4.437	0.58 2
Erythema area 10	- 0.14 1	-2.48, 2.19	0.9 06	0.13 3	-1.84, 2.11	0.8 95	0.85 0	0.187, 3.861	0.8 33	0.2 77	0.037, 2.085	0.21 2
Erythema area 11	0.58 3	-1.68, 2.85	0.6 14	0.42 4	-1.50, 2.35	0.6 66	1.29 6	0.359, 4.685	0.6 92	0.2 62	0.035, 1.967	0.19 3
Leaks area 1	- 0.22 4	-2.09, 1.64	0.8 14	0.06 9	-1.05, 1.19	0.9 04	0.78 3	0.227, 2.709	0.7 00	1.0 95	0.559, 2.146	0.79 1
Leaks area 2	-3.70	-8.83, 1.44	0.1 59	0.68 8	-1.08, 2.45	0.4 45	0.00 0	0.000, Inf	0.9 87	1.3 39	0.493, 3.634	0.56 7
Leaks area 3	0.14 1	-1.80, 2.09	0.8 87	- 0.26 8	-1.35, 0.818	0.6 29	0.87 1	0.250, 3.035	0.8 28	0.8 96	0.448, 1.792	0.75 6
Leaks area 4	0.15 1	-1.59, 1.89	0.8 65	0.57 2	-0.373, 1.52	0.2 36	1.22 6	0.448, 3.354	0.6 92	1.0 26	0.574, 1.833	0.93 1
Leaks area 5	1.84	0.241, 3.44	0.0 25	0.76 2	-0.111, 1.64	0.0 87	2.26 4	0.999, 5.132	0.0 50	1.3 69	0.830, 2.256	0.21 8
Leaks area 6	1.77	-0.935, 4.48	0.2 00	1.26	-0.027, 2.55	0.0 55	3.32 2	0.943, 11.70	0.0 62	1.8 40	0.933, 3.627	0.07 8
Leaks area	1.84	0.281, 0.0	0.76	-0.125, 0.0	2.07	0.923, 0.0	1.2	0.752, 0.37				

7		3.40	21	3	1.65	92	7	4.673	77	61	2.117	9
Leaks area	-	-1.78,	0.9	0.43	-0.548,	0.3	0.92	0.308,	0.8	0.9	0.512,	0.86
8	0.04	1.70	63	3	1.42	87	1	2.751	83	48	1.755	4
Leaks area	1											
9	-1.00	-9.89,	0.8	0.84	-4.10,	0.7	0.00	0.000,	0.9	2.5	0.229,	0.44
		7.88	25	2	5.78	39	0	Inf	88	34	28.07	9

*CI = confidence interval; ^sOR = odds ratio. Bolds variables are statistically significant at the 5% threshold.

