

Feasibility of Type 3 Polygraphy for Evaluating Leak Determinants in CPAP-Treated OSA Patients A Step Toward Personalized Leak Management

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Feasibility of type 3 polygraphy for evaluating leak determinants in CPAP-treated OSA patients: a step towards personalized leak management

Running head: type 3 polygraphy for evaluating leak determinants in CPAP-treated OSA patients

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38 Conflict of interest:

39 ML and JCB are employees of "AGIR à dom.", a non-profit home care provider. JCB has received 40 grants, personal fees, and non-financial support from Philips healthcare, RESMED outside the context 41 of the submitted work. JCB has also a patent with NOMICS SA. ML has received grants, personal 42 fees, and non-financial support from Air Liquide Healthcare and SEFAM outside the context of the 43 submitted work. JLP is supported by a research grant from the French National Research Agency 44 (ANR-12-TECS-0010) in the framework of the "Investissements d'avenir" program (ANR-15-IDEX-02) 45 and the "e-health and integrated care" Chair of excellence of the University Grenoble Alpes Founda-46 tion. JCB and JLP are co-inventors of a patent N # WO2016041025A1. The others authors (DN, CMS, 47 MCR, JPM, LL, EML, NM) have no conflicts to disclose linked to this work.

- 48
- 49

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51 Abbreviations list

- 52 AHI Apnea Hypopnea Index
- 53 BMI Body Mass Index
- 54 CPAP Continuous Positive Airway Pressure
- 55 ESS Epworth Sleepiness Scale
- 56 IQR Inter Quartile Range
- 57 NC Non-calculable
- 58 OR Odds Ratio
- 59 OSA Obstructive Sleep Apnea
- 60 REM Sleep Rapid Eye Movement Sleep
- 61 SD Standard Deviation
- 62 SpO2 Peripheral capillary oxygen saturation

64 Abstract65

Background: Unintentional leaks (ULs) are frequent adverse effects in CPAP-treated
patients. We previously published a novel methodology for analyzing the determinants of UL
using polysomnography. We now propose a simplified recording system using a type-3
polygraphic device (Somnolter®).

Objectives: 1) To describe individual UL determinants provided by the Somnolter® software
 in automatic-CPAP-treated OSA patients; 2) To subsequently describe the clinical consensus

of 4 physicians on how to manage each individual UL situation.

73 Methods: Somnoler® recordings performed under nasal automatic-CPAP were automatically 74 analyzed with APIOS software. For each polygraphic recording, APIOS provided the odds ratio and the confidence intervals for potential determinants of UL: mouth opening, CPAP 75 pressure, body position and mandibular oscillation. Based on these results, each of four 76 physicians was asked to choose one of four strategies: (i) increase/decrease therapeutic 77 78 pressure; (ii) change nasal mask for oro-nasal mask/chinstrap; (iii) favor a non-supine/supine 79 position; (iv) no action for individual leak management. Subsequently, a meeting was held to 80 determine a consensus choice for each individual case.

81 **Results:** 78 consecutive patients underwent home-polygraphy with Somnolter[®]. Fifty 82 recordings were analyzed (16 females; 65[57; 75]years; BMI=31.1[27.4; 35.3]kg/m²). 83 Individual diagnosis of UL was routinely feasible. The determinants of UL were heterogeneous in the population and diagnosis of UL was not feasible in 10 patients. Based 84 85 on the results from this analysis, we established consensus leak management strategies at the individual level. The average Cohen κ coefficient for the 4 raters was 0.58. Pressure 86 modification was proposed in 36% of patients, no action in 24%, installation of a facial 87 88 mask/chinstrap in 22% and positional treatment in 18%.

89 Interpretation: the use of type-3 polygraphy for characterizing leak determinants in patients 90 treated with nasal automatic-CPAP is feasible in routine practice. Leak determinants are 91 patient-specific. Inter-rater concordance for determining individual leak management 92 strategies demonstrated a "fair" level of agreement.

93

94 <u>Clinical trial registration</u>: NCT03381508

95 Key-words: sleep apnea; continuous positive airway pressure; CPAP; unintentional leak;

96 mask; leakage; home polygraphy.

97 Continuous Positive Airway Pressure (CPAP) is the first-line treatment for moderate to severe Obstructive Sleep Apnea (OSA)^{1,2}. Although adherence to CPAP 98 is crucial for improving symptoms³, more than 50% of patients discontinue or are 99 poorly adherent over the long term^{4,5}. The causes of CPAP discontinuation are 100 101 multifactorial^{6,7}, with unintentional leakage from the mouth or around the mask being 102 one of the most common side effects of CPAP-therapy contributing to nonadherence^{8,9}. However, the explanatory factors behind unintentional leaks are poorly 103 understood, and as a consequence, their management poorly established¹⁰. 104

In daily practice, when a patient is complaining of unintentional leakage, 105 106 caregivers adjust the mask, frequently shift from a nasal to an oro-nasal mask, or 107 install a chinstrap. Nevertheless, these strategies are not always effective in 108 reducing leakage or improving patient complaints¹¹, and the identification of the true determinants of leakage remains elusive¹². The potential mechanisms triggering leak 109 110 emergence are not addressed by the software embedded by manufacturers in CPAP 111 devices. Furthermore, the terminology used to report leaks varies across CPAP brands and there are no clear thresholds defining when it would be appropriate to 112 implement a leak correction process¹³. 113

114 In a recent study, we proposed a novel methodology for characterizing and 115 analyzing the overnight determinants of unintentional leakage using 116 polysomnographic recordings in OSA patients treated with automatic CPAP (i.e. the 117 OSA-auto-CPAP population)¹². We demonstrated that REM sleep, mouth opening, sleep position and pressure level were determinants of leakage. However, due the 118 size of the problem and the inaccessibility, resource use and costs associated with 119 polysomnography, we further proposed a simplified recording system using a type-3 120 121 polygraphic device (Somnolter®, Liège, Belgium).

122

Our primary objective was to describe the individual specific determinants of unintentional leaks provided by the Somnolter® device software in an OSA-auto-CPAP population using nasal masks in real life conditions. The secondary objective was to describe, based on this analysis, the clinical consensus of 4 physicians on how to manage individual leak situations.

128

129 Methods

130 First phase: data collection

A retrospective analysis of polygraphic recordings carried-out in routine care in 3 French centers (Boujan sur Libron Polyclinic, Montpellier and Grenoble University Hospitals, France) was performed. This study was approved by a local institutional review board (2017_CLER-MTP_12-03) and was registered on https://clinicaltrials.gov (NCT03381508). All participants were informed about the research objectives and were given the opportunity to oppose the use of their personal data as required per French law.

Between June 1, 2017 and December 31, 2017, consecutive adult patients 138 diagnosed with moderate to severe OSA (apnea-hypopnea index [AHI] > 15/h) who 139 140 had a type III polygraphy (with Somnolter®) for control of auto-CPAP efficacy were included. All recordings that presented the selection criteria cited above, 141 142 independently of mask type (nasal, nasal pillows and oro-nasal masks), were initially 143 selected. In order to avoid introducing a confounding factor by taking into account oronasal and nasal pillows, which are second-line interfaces, only recordings from 144 patients using nasal masks were finally analyzed. 145

146 Polygraphy was performed with the Somnolter® (Fig 1) equipped with:

- A midsagittal mandibular magnetic movement sensor to measure the
 distance in millimeters between two parallel coupled resonant circuits
 placed on the forehead and the chin¹⁴.
- A pneumotachograph measuring the patient's airflow, CPAP level, and
 leakage.
- A digital oximeter that displayed the pulse waveform (Nonin, Nonin
 Medical) and measured the arterial oxygen saturation.
- A positional sensor that recorded body position during sleep.
- 155

(See online supplement, paragraph I for further details)

Medical history, anthropometric data, the Epworth Sleepiness Score at the time of the polygraphy, smoking status, the use of a chinstrap, the use of a heated tube/humidifier, the type and model of the mask, and the initial AHI were collected from patient medical charts.

160

161 Second phase: detailed analysis of polygraphic recordings

Polygraphic recordings were analyzed with APIOS software version 2.0. This 162 version of APIOS deploys the automatic analysis of the determinants of unintentional 163 164 leaks previously developed by our team¹²: Signals from the polygraphic recording 165 are automatically computed as mean values over non-overlapping 10-s intervals 166 (mouth opening and CPAP pressure). Categorical data (sleep position), as well as 167 dichotomous data (mandibular oscillation ($\leq 0.3 \text{ vs} > 0.3, \text{ mm}$)), are also computed for intervals of 10 s. Then, each variable is analyzed for every consecutive 10-s interval. 168 Univariate conditional regression models are used to estimate the risk of leakage 169 170 during a "T-interval" using the above-mentioned variables predefined from the 171 previous interval ("T-1"). Since there are no reports of a clinically significant threshold of unintentional leakage in the literature, the presence of unintentional leakage in an interval can be classified in a dichotomous manner regarding a chosen threshold "X" in L/min (yes or no: $>/\leq$ "X" L/min).

For each polygraphic recording analyzed with APIOS, the software provided the odds ratio and the confidence intervals of the following potential determinants of unintentional leaks:

- Mouth opening (≤ median vs > median of the night)
- CPAP pressure (≤ median vs > median of the night)
- Body position (other versus supine)
- Mandibular oscillation ($\leq 0.3 \text{ vs} > 0.3, \text{ mm}$)

182 (see online supplement, paragraph II for further details)

183

184 Leakage calculation

The pressure/flow curve for intentional leaks corresponding to each mask model used was embedded into the APIOS software and used for the calculation of the unintentional leaks *(see online supplement, paragraph I for further details)*. Since there is no clear threshold of unintentional leaks defining when it would be appropriate to implement correcting interventions¹³, we ran the automatic analysis at 3 arbitrary unintentional leak thresholds: 5 l/min, 10 l/min and 20 l/min.

191

192 Third phase: clinical consensus

Based on the results provided by the automatic analysis of the determinants of unintentional leaks provided by APIOS, each of four physicians (DJ, JPM, ML, JCB) was asked to choose one of four strategies [(i) increase or decrease therapeutic pressure; (ii) change nasal mask for oro-nasal mask or add a chinstrap; (iii) favor a non-supine or supine position; (iv) no action] for individual leak
management in a blinded fashion. Although they are not completely interchangeable
in clinical practice, the switch towards an oro-nasal mask or the addition of a
chinstrap were two actions grouped together for simplicity's sake.

201 Subsequently, a meeting was held to discuss blinded results and then 202 determine a collective consensus choice from among the four strategies for each 203 individual case. **See figure 2 for methods overview.**

204

205 Statistical analysis

Data did not follow a Gaussian distribution and were summarized as medians and interquartile ranges (IQR). Qualitative parameters (characteristics and type of interface) were expressed as counts and percentages. All statistical analyses were performed with SAS enterprise guide (V.7.1).

210 To achieve the first objective, patient-specific heatmaps were created and 211 reported the crude odds ratios (OR) and 95% confidence intervals (95%CI) for 212 potential leak determinants as provided by APIOS. To achieve the second objective, the latter heatmaps were provided to the participating physicians who then 213 214 independently proposed one of the four above-listed leak management strategies. 215 Finally, kohen κ coefficients were used to measure inter-rater concordance four 216 clinical strategies and the average coefficient for all raters was calculated using the 217 Krippendorff's alpha coefficient.

218 **Sample size calculation:** considering the exploratory nature of this study that 219 use an original analysis, no previous data from which sample size could be 220 calculated were available. However, we aimed to include 50 patients who had 221 performed Somnolter® polygraphy while using nasal masks between June 1st and December 31st 2017. Considering that about 75% of patients use a nasal mask in routine care in France (sample size equivalent to previous studies comparing different types of masks^{7,12}), we estimated that at least 75 consecutive patients would need to be screened in order to analyze 50 patients treated with a nasal mask.

226

227 **Results**

Over a 6-month period, 78 consecutive adult patients underwent a home polygraphy with Somnolter® under auto-CPAP. e-Figure 6 in the online supplement depicts the study flow chart. Two recordings could not be used because of missing data related to technical problems, and 26 polygraphies were carried out using an oronasal mask. In consequence, a total of 50 home-polygraphy recordings were finally analyzed.

234

235 *Patient characteristics and treatment parameters*

Patient characteristics are presented in Table 1. All patients were parameterized with 4-14 cmH20 for auto-CPAP, as is typical of OSA-auto-CPAP populations.

239

240 *Main objective, description of unintentional leak determinants*

Figure 3 represents the determinants of unintentional leaks according to three different thresholds. Each cell represents the individual risk for (i) a given patient, for a given determinant (ii) and at (iii) a given threshold of unintentional leaks.

As an example, patient #37 should be interpreted as follows: the mouth opening above the overnight median increased the risk of leaks regardless of leak thresholds; similarly, a non-supine position also increased the risk of leaks across all thresholds. In contrast, a pressure above the overnight median pressure reduced the
risk of leaks across all leak threshold for this patient. For patient #1, a mandibular
oscillation superior to 0.3 mm (a surrogate marker of respiratory effort) increased the
risk of leaks regardless of thresholds.

In four subjects, there were inconsistencies in leak determinants across the 251 252 different leak thresholds in our analysis (subjects #2, #7, #24 and #47). For example, in subject #2 a "non-supine position" was "protective" at 5 l/min, but increased the 253 254 risk of leakage at 10 l/min; in subject # 7, mouth opening was "protective" at 10 l / min, but favored leaks at 20 I / min. Last, for 10 patients (examples # 23, 39, 40), the 255 automatic analysis was incalculable for reasons cited in the paragraph II of the online 256 257 supplement. Among those subjects, "no action" was chosen because there was no 258 evidence to support any clinical measure due to absence of data. Only 2 patients (#2 and 4) were classified as "no-action" despite calculable ORs following the consensus 259 because the analyses did not allow to choose for a particular strategy. 260

A sub analysis was also carried out using a 24 l/min threshold since the latter is a commonly used indicator in clinical practice (e-figure 7).

263

264 Secondary objective, clinical consensus for individualized leak management

Table 2 reports the Cohen κ coefficients among clinicians. The Krippendorff' alpha coefficient for all raters was 0.57. Figure 3 reports the final consensus of the 4 clinicians on individual clinical management. Pressure modification was proposed in 36% of patients, no action in 24% of patients, installation of a facial mask or a chinstrap in 22% of patients and positional treatment in 18%.

270

271 Discussion

We have demonstrated that a routine inspection with a ventilatory type III polygraph providing an individual diagnosis of unintentional leaks is routinely feasible. In this 50-patient, OSA-auto-CPAP population, the determinants of intentional leakage were heterogeneous, which highlights the importance of individualized leak management. Finally, based on the results from this analysis, we were able to establish consensus leak management strategies at the individual level.

To date, there are no data defining a tolerable unintentional leakage threshold 278 beyond which leakage correction measures should be undertaken^{13, 9}. For this rea-279 280 son, we performed the leak determinant analyses with 3 arbitrarily chosen leakage thresholds (5, 10 and 20 l/m). In addition, because leakage-related disturbances are 281 282 not correlated with the magnitude of leaks objectively reported by built-in software¹⁵, 283 it remains challenging to a priori determine an appropriate leak threshold for future analyses. One benefit, therefore, of our automatic analysis is that a clinician can rap-284 idly screen for the determining factors of leaks at different leakage thresholds in or-285 286 der to identify the most relevant one.

Overall, the risk of unintentional leakage associated with a given determinant 287 was consistent across the different leakage thresholds for a given patient. Mouth 288 opening remained the principal leak determinant (27 patients). This is consistent with 289 our previous results in which mouth opening was independently associated with the 290 presence of unintentional leakage during sleep¹². However, the interpretation of leak 291 292 determinants for a given patient appeared to be more complex when the determinants were inconsistent across different leak thresholds (as occurred for 4 patients in 293 294 our study).

Figure 3 spotlights the individual specificity of leak determinants, their great diversity and illustrates the need for a tailored, patient-by-patient, clinical approach. The difficulty resides in choosing the appropriate strategy for leak correction. For example, increasing or decreasing the therapeutic pressure with an auto-CPAP would allow the clinician to adjust the pressure window in order to modulate the median pressure. We demonstrated that the inter-rater reliability when choosing a preferred unintentional leak management strategy among experts was "moderate" with an average alpha coefficient of 0.57¹⁶. Further progress can perhaps be made in this domain.

304 Our work has two important limitations that must be taken into account: first, 305 the patients included in this retrospective study were consecutive subjects in whom the severity of complaints related to leaks was not documented. One can argue that 306 307 the leak determinants found in a population with few, weak or no specific complaints 308 are different from those of a population actively complaining about leaks, and may represent a selection bias. In addition, the fact that the study population did not spe-309 310 cifically complain about leaks may also explain why the number of non-calculable 311 ORs was high in Fig 3. Secondly, the consensus strategies indicated by the participating physicians remain "theoretical" and we don't know how much they helped pa-312 tients with the current dataset (this will of course be addressed by future studies). 313 314 Agreement on clinical decision was not ideal. This could be due to the high number 315 of non-calculable variables and the lack of thorough clinical information to help guide 316 the decision. Furthermore, generalizability to the entire OSA-auto-CPAP population 317 is compromised because only patients who used a nasal mask were analysed. Indeed, we previously demonstrated that mask type influences leak determinants,¹² 318 319 and were unwilling (for simplicity's sake) to introduce this confounding factor by tak-320 ing into account oronasal and nasal pillows, which are second-line interfaces.

322

323 Conclusion

The use of type-3 polygraphy for characterizing leak determinants in OSA 324 populations requiring automatic CPAP treatment with nasal masks is feasible in rou-325 326 tine practice. Leak determinants are heterogeneous, patient specific, and can vary with leak thresholds in certain cases. A first estimation of concordance among physi-327 cians for determining individual leak management strategies demonstrated only a 328 "fair" level of agreement, indicating room for improvement in how leak determinants 329 are interpreted. A prospective interventional trial is needed in order to validate the 330 331 clinical relevance of these individual-based clinical strategies in the management of 332 unintentional leaks.

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Guarantor statement: JCB had full access to all of the data in the study and takesresponsibility for the content of the manuscript.

337

338 Author contributions:

- 339 Conception: ML, JCB, DJ, NM, JPM.
- 340 Data Interpretation: ML, JLP, EML, DJ, JCB; NM, JPM.
- 341 Drafting the manuscript or revising it: ML, LL, JLP, EML, DJ, MCR, CMS, JCB.
- 342 Language editing: CMS.
- 343 All authors agree with manuscript results and conclusions.

344

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347

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350

352 References

- Lévy P, Kohler M, McNicholas WT, et al. Obstructive sleep apnoea syndrome.
 Nat Rev Dis Primer. 2015;1:15015. doi:10.1038/nrdp.2015.15
- Patil SP, Ayappa IA, Caples SM, Kimoff RJ, Patel SR, Harrod CG. Treatment of Adult Obstructive Sleep Apnea with Positive Airway Pressure: An American Academy of Sleep Medicine Clinical Practice Guideline. *J Clin Sleep Med JCSM Off Publ Am Acad Sleep Med*. 2019;15(2):335-343. doi:10.5664/jcsm.7640
- Weaver TE, Maislin G, Dinges DF, et al. Relationship between hours of CPAP
 use and achieving normal levels of sleepiness and daily functioning. *Sleep*.
 2007;30(6):711-719.
- Weaver TE, Grunstein RR. Adherence to continuous positive airway pressure therapy: the challenge to effective treatment. *Proc Am Thorac Soc.* 2008;5(2):173-178. doi:10.1513/pats.200708-119MG
- McEvoy RD, Antic NA, Heeley E, et al. CPAP for Prevention of Cardiovascular
 Events in Obstructive Sleep Apnea. *N Engl J Med.* 2016;375(10):919-931.
 doi:10.1056/NEJMoa1606599
- Gagnadoux F, Le Vaillant M, Goupil F, et al. Influence of marital status and employment status on long-term adherence with continuous positive airway pressure in sleep apnea patients. *PloS One*. 2011;6(8):e22503. doi:10.1371/journal.pone.0022503
- Borel JC, Tamisier R, Dias-Domingos S, et al. Type of mask may impact on
 continuous positive airway pressure adherence in apneic patients. *PloS One*.
 2013;8(5):e64382. doi:10.1371/journal.pone.0064382
- Bachour A, Hurmerinta K, Maasilta P. Mouth closing device (chinstrap) reduces mouth leak during nasal CPAP. *Sleep Med.* 2004;5(3):261-267.
 doi:10.1016/j.sleep.2003.11.004
- Valentin A, Subramanian S, Quan SF, Berry RB, Parthasarathy S. Air Leak is
 Associated with Poor Adherence to Autopap Therapy. *SLEEP*. 2011;34(06):801 806. doi:10.5665/sleep.1054
- Lebret M, Martinot J-B, Arnol N, et al. Factors Contributing to Unintentional Leak
 During CPAP Treatment: A Systematic Review. *Chest*. 2017;151(3):707-719.
 doi:10.1016/j.chest.2016.11.049
- Bachour A, Vitikainen P, Maasilta P. Rates of initial acceptance of PAP masks
 and outcomes of mask switching. *Sleep Breath*. December 2015:1-6.
 doi:10.1007/s11325-015-1292-x
- 12. Lebret M, Arnol N, Martinot J-B, et al. Determinants of Unintentional Leaks
 During CPAP Treatment in OSA. *Chest*. 2018;153(4):834-842.
 doi:10.1016/j.chest.2017.08.017
- 13. Schwab RJ, Badr SM, Epstein LJ, et al. An Official American Thoracic Society

- Statement: Continuous Positive Airway Pressure Adherence Tracking Systems.
 The Optimal Monitoring Strategies and Outcome Measures in Adults. *Am J Respir Crit Care Med.* 2013;188(5):613-620. doi:10.1164/rccm.201307-1282ST
- Senny F, Destiné J, Poirrier R. Midsagittal jaw movement analysis for the scoring of sleep apneas and hypopneas. *IEEE Trans Biomed Eng.* 2008;55(1):87-95. doi:10.1109/TBME.2007.899351
- Bachour A, Vitikainen P, Virkkula P, Maasilta P. CPAP interface: satisfaction and
 side effects. *Sleep Breath Schlaf Atm.* 2013;17(2):667-672. doi:10.1007/s11325012-0740-0
- 400 16. Landis JR, Koch GG. The measurement of observer agreement for categorical
 401 data. *Biometrics*. 1977;33(1):159-174.

402

404 Tables

405

TABLE 1. Population characteristics (n = 50)									
Demographics									
Age (yrs)	65 [57; 75]								
Gender, female n(%)	16 (32)								
BMI (kg/m²)	31.1 [27.4; 35.3]								
AHI (nb events/h) at diagnosis	37.1 [31.0; 46.7]								
Current smokers n(%)	5 (10,9) ª								
Epworth Sleepiness Scale (1-24)	11 [9; 15]								
Comorbidities									
Chronic cardiac insufficiency n(%)	15 (30.6) ^b								
Chronic respiratory insufficiency n(%)	6 (12.2) ^b								
High blood pressure n(%)	24 (50) °								
Diabetes type 1 n(%)	0 (0) ^c								
Diabetes type 2 n(%)	7 (14,6) °								
Device									
Heating humidifier n(%)	35 (70)								
Heating circuit n(%)	2 (4)								
Chinstrap n(%)	1 (2.2) ^a								
Reported side effects									
Nasal/mouth dryness, n(%)	5 (13.2) ^d								
Nasal obstruction, n(%)	15 (36.6) ^e								

AHI : Apnea-Hypopnea Index, score, BMI : Body Mass Index, CPAP: Continuous Positive Airway Pressure, ESS: Epworth Sleepiness Scale. Medians [quartile 1-quartile 3] are provided.

^aData from 4 patients were missing; ^bData from 1 patient was missing; ^cData from 2 patient were missing; ^dData from 12 patients were missing; ^edata from 9 patients were missing was missing.

406

407

	Physician 1	Physician 2	Physician 3	Physician 4
Physician 1	1			
Physician 2	0.70 [0.55-0.84]	1		
Physician 3	0.56 [0.41-0.71]	0.61 [0.46-0.76]	1	
Physician 4	0.54 [0.40-0.69]	0.47 [0.32-0.66]	0.58 [0.43-0.73]	1

Table 2 : Cohen K coefficients among all raters regarding choice of clinical leak managementstrategy.

411 Figure legends

- 412
- 413 Figure 1: polygraphic assessment with the somnolter device
- **A**. Patients' vital signs were recorded at home with the somnolter device while treated with CPAP (pneumotachograph, mandibular movement sensor, oxymetry, thoracic belts and body position sensor). **B**. Data of interest were obtained with the polygraphic device for each patient (unintentional leak flow, mandibular lowering and oscillation, CPAP pressure, body
- 418 position, respiratory flow and SpO2).
- 419
- Figure 2: Analysis of the determining factors of unintentional leaks and consensus on individual leak management (methods).
- 422 *the new version of APIOS embeds the automatic analysis of the determinants of leaks;423 †example for a given patient
- 424
- 425 Figure 3: Heat Map displaying the individualized representation of the determinants of leaks.
- 426 This figure reports the risk (OR: Odds Ratio) associated with the 4 determinants of leaks for
- 427 every patient according to three different leak thresholds. Every cell represents the individual
- risk for a given patient, for a given determinant at a given threshold of NI leaks using a color
- 429 code. Side effects reported by patients during CPAP treatment are displayed in the first two430 columns.
- 431 Green represents an OR<1. The darker it is, the closer the OR is to 0. Conversely, red 432 represents an OR>1, the darker it is, the higher the OR and therefore the risk. White cells 433 represent an OR for which the confidence interval crosses 1 (non-significant).
- 434 Mouth opening > median overnight mouth opening; CPAP pressure > median overnight 435 pressure; mandibular oscillation > 0.3 mm. NC: non-calculable, there were specific 436 conditions for which the odds ratios were non-calculable (supplemental material).



Α



	30
Non intentional leak flow	20
	10
(l/min)	0
	0
Mandibular	-3
lowering	-6
(mm)	-8
Mandibular oscillation	0.4
(mm)	
CPAP Pressure	12
	8
(cmH2O)	4
Body position	Standing Prone Left Right Supine
Respiratory flow	1-1-
SpO2	99 95 92
Belts	



STEP 1 - data collection

Collection of polygraphic recordings carried-out in routine care

STEP 2 - re-analysis with the new version of APIOS*



0 0,5 1 1,5 2,5 3

Odds ratio in 95% CI for each determining factor of unintentional leaks

STEP 3: clinical consensus on individual leak management

CPAP pressure modification



Physician 1

Switch from nasal to facial mask or chinstrap



Physician 2



Physician 3



Favoring non-dorsal or dorsal position No action

Reported side effects		Mouth opening Leak thresholds		CPAP pressure Leak thresholds		Non-supine position Leak thresholds			Mandibular oscillation Leak thresholds			-			
	Nasal obstruction	Nasal dryness	5 l/min	10 l/min	20 l/min	5 l/min	10 l/min	20 l/min	5 l/min	10 l/min	20 l/min	5 l/min	10 l/min	20 l/min	Consensus
#1										-					Increase CPAP
#2				1000	NC		NC	NC			NC			NC	No action
#3			NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action
#4				NC	NC		NC	NC	NC	NC	NC		NC	NC	No action
#5					NC			NC		1	NC			NC	Favor supine position
#6			NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action
#7			NC			NC			NC			NC			Decrease CPAP
#8	Missing data	Missing data			NC			NC			NC		Ú.	NC	Increase CPAP
#9			NC	NC	NC			NC			NC		NC	NC	Decrease CPAP
#10	D		NC	NC		NC	NC		NC	NC		NC	NC		Increase CPAP
#1	1		NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action
#12	2	4	NC	NC		NC	NC		NC	NC		NC	NC	1	Favor non-supine position
#13	3		NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action
#14	4 Missing data			NC	NC	1 - 1	NC	NC		NC	NC		NC	NC	Install facial mask or chinstrap
#1	5			NC	NC	NC	NC	NC		NC	NC		NC	NC	Install facial mask or chinstrap
#16	5				NC			NC		1.000	NC			NC	Install facial mask or chinstrap
#1	7			NC	NC		NC	NC	NC	NC	NC		NC	NC	Install facial mask or chinstrap
#18	8			1	NC			NC		NC	NC			NC	Increase CPAP
#19	9			NC	NC		NC	NC		NC	NC		NC	NC	Install facial mask or chinstrap
#20	0			-	NC			NC		S	NC			NC	Favor supine position
#2	1				NC			NC			NC			NC	Favor non-supine position
#23	2		NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action
#2	3		NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action
#24	4				NC		Pares 1	NC	10.00		NC		1.11.11.11.11	NC	Favor non-supine position
#2	5					1	1		NC	NC	NC				Decrease CPAP
#20	6				NC			NC			NC			NC	Favor non-supine position
#2	7	· · · · · · · · · · · · · · · · · · ·				4	7							1	Install facial mask or chinstran
#28	8	-										-		-	Increase CPAP
#29	9				NC		NC	NC	NC	NC	NC			NC	Decrease CPAP
#30	D				NC			NC	-		NC	NC		NC	Install facial mask or chinstran
#3	1			NC	NC		NC	NC		NC	NC		NC	NC	Favor non-supine position
#3	2 Missing data	Missing data			NC		1	NC		HE HERE	NC			NC	Favor non-supine position
#3	3		NC	NC	1	NC	NC		NC	NC		NC	NC		Increase CPAP
#34	4				NC					W				NC	Decrease CPAP
#3	5			NC	NC		NC	NC		NC	NC		NC	NC	Increase CPAP
#3	6			NC	NC		NC	NC		NC	NC		NC	NC	Favor non-sunine position
#3	7			110	110		ine.	ine				NC	NC	NC	Install facial mask or chinstran
#3	8			NC	NC		NC	NC	NC	NC	NC	110	NC	NC	Decrease CPAP
#30			NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action
# 3:	2		NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action
#4	1	Missing data		NC	NC		NC	NC	NC	NC	NC	NC	NC	NC	Increase CPAP
#4.	Missing data	Missing data	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action
#44	2 111001119 0000	Missing data	NC	NC	NC	ne	ne	NC	NC	NC	NC	inc.	110	NC	Increase CPAP
#4.	Missing data	Missing data								1		NC	NC	NC	Install facial mask or chinetran
# 41		Missing data							NC	NC	NC	ive	inc	110	Increase CPAP
#4:	Missing data	Missing data	NC		NC	NC	No. of Concession, name	NC	NC	NC	NC	NC	NC	NC	Increase CFAF
#40	7 Missing data	Missing data	NC.		NC	ne		NC	ne	INC	NC	NC	NC	NC	Install lacial fildsk of chillstrap
#4	Missing data	Missing data	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action
#42		Missing data	NC.	NC	NC		NC	NC		NC	NC	NC	NC	NC	Install facial mask or chiestern
#49	Missing data	Missing data		NC	NC			NC	NC	NC	NC	NC	NC	NC	Decrease CPAP
#50	J missing data	maaning uata			nu	1. C		ne	NC	INC.	INC.	nic.	NC	nių.	Decrease CPAP



OR>1