



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

Marius Lebret, Dany Jaffuel, Carey M. Suehs, Jean-Pierre Mallet, Loïc Lambert, Marie-Caroline Rotty, Jean-Louis Pépin, Eric Matzner-Lober, Nicolas Molinari, Jean-Christian Borel

► To cite this version:

Marius Lebret, Dany Jaffuel, Carey M. Suehs, Jean-Pierre Mallet, Loïc Lambert, et al.. Feasibility of Type 3 Polygraphy for Evaluating Leak Determinants in CPAP-Treated OSA Patients A Step Toward Personalized Leak Management. Chest, 2020, 158, pp.2165 - 2171. 10.1016/j.chest.2020.05.593 . hal-03493439

HAL Id: hal-03493439

<https://hal.science/hal-03493439>

Submitted on 7 Nov 2022

HAL is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers.

L'archive ouverte pluridisciplinaire **HAL**, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d'enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.



Distributed under a Creative Commons Attribution - NonCommercial 4.0 International License

Word count, text: 2374
Word count, abstract: 300

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

Marius Lebret, PT, PhD^{1,2}, Dany Jaffuel, MD, PhD^{3,4,5}, Carey M. Suehs, PhD⁴, Jean-Pierre Mallet, MD⁴, Loïc Lambert, MSc⁶, Marie-Caroline Rotty, PhD^{3,7}, Jean-Louis Pépin, MD, PhD^{1,8}, Eric Matzner-Lober, PhD⁹, Nicolas Molinari, MD, PhD⁷, and Jean-Christian Borel, PT, PhD^{1,2,8}

1 Univ. Grenoble Alpes, Inserm, CHU Grenoble Alpes, HP2, 38000 Grenoble, France

2 AGIR à dom. Association, Meylan, France

3 APARD, groupe Adène, Montpellier, France

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

5 Pulmonary Disorders and Respiratory Sleep Disorders Unit, Polyclinic Saint-Privat, Boujan sur Libron, France

6 Nomics-SA, Liège Belgique

7 IMAG, CNRS, Montpellier University, Montpellier University Hospital, Montpellier, France

8 Sleep Laboratory, Thorax and vessels division Grenoble Alpes University Hospital

9 CREST UMR 9194, ENSAE formation continue, 91120 Palaiseau, France

Corresponding author:

Marius Lebret

Agir à dom.

36 Chemin du Vieux Chêne,

38244 Meylan

France

GSM: +33618561003

e-mail: mariuslebret@gmail.com

Conflict of interest:

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

Funding information: none

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

63

Abstract

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.

Methods: Somnolter® recordings performed under nasal automatic-CPAP were automatically 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 pressure, body position and mandibular oscillation. Based on these results, each of four physicians was asked to choose one of four strategies: (i) increase/decrease therapeutic pressure; (ii) change nasal mask for oro-nasal mask/chinstrap; (iii) favor a non-supine/supine position; (iv) no action for individual leak management. Subsequently, a meeting was held to determine a consensus choice for each individual case.

Results: 78 consecutive patients underwent home-polygraphy with Somnolter®. Fifty recordings were analyzed (16 females; 65[57; 75]years; BMI=31.1[27.4; 35.3]kg/m²). 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 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 modification was proposed in 36% of patients, no action in 24%, installation of a facial mask/chinstrap in 22% and positional treatment in 18%.

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

Clinical trial registration: NCT03381508

Key-words: sleep apnea; continuous positive airway pressure; CPAP; unintentional leak; mask; leakage; home polygraphy.

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

In daily practice, when a patient is complaining of unintentional leakage, caregivers adjust the mask, frequently shift from a nasal to an oro-nasal mask, or install a chinstrap. Nevertheless, these strategies are not always effective in reducing leakage or improving patient complaints¹¹, and the identification of the true determinants of leakage remains elusive¹². The potential mechanisms triggering leak emergence are not addressed by the software embedded by manufacturers in CPAP 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 implement a leak correction process¹³.

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

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.

Methods

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 diagnosed with moderate to severe OSA (apnea-hypopnea index [AHI] > 15/h) who had a type III polygraphy (with Somnolter®) for control of auto-CPAP efficacy were included. All recordings that presented the selection criteria cited above, independently of mask type (nasal, nasal pillows and oro-nasal masks), were initially 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 patients using nasal masks were finally analyzed.

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.

(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.

Second phase: detailed analysis of polygraphic recordings

Polygraphic recordings were analyzed with APIOS software version 2.0. This version of APIOS deploys the automatic analysis of the determinants of unintentional leaks previously developed by our team¹²: Signals from the polygraphic recording are automatically computed as mean values over non-overlapping 10-s intervals (mouth opening and CPAP pressure). Categorical data (sleep position), as well as dichotomous data (mandibular oscillation (≤ 0.3 vs > 0.3 , mm)), are also computed for intervals of 10 s. Then, each variable is analyzed for every consecutive 10-s interval. Univariate conditional regression models are used to estimate the risk of leakage during a "T-interval" using the above-mentioned variables predefined from the 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: \geq “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 (\leq median vs $>$ median of the night)
- CPAP pressure (\leq median vs $>$ median of the night)
- Body position (other versus supine)
- Mandibular oscillation (≤ 0.3 vs > 0.3 , mm)

(see online supplement, paragraph II for further details)

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.

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.

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

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).

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

Sample size calculation: considering the exploratory nature of this study that use an original analysis, no previous data from which sample size could be calculated were available. However, we aimed to include 50 patients who had 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.

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.

Patient characteristics and treatment parameters

Patient characteristics are presented in Table 1. All patients were parameterized with 4-14 cmH₂O for auto-CPAP, as is typical of OSA-auto-CPAP populations.

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 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 risk of leakage at 10 l/min; in subject # 7, mouth opening was "protective" at 10 l / min, but favored leaks at 20 l / min. Last, for 10 patients (examples # 23, 39, 40), the automatic analysis was incalculable for reasons cited in the paragraph II of the online supplement. Among those subjects, "no action" was chosen because there was no 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 because the analyses did not allow to choose for a particular strategy.

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).

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%.

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 beyond which leakage correction measures should be undertaken^{13, 9}. For this reason, 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 not correlated with the magnitude of leaks objectively reported by built-in software¹⁵, 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 rapidly screen for the determining factors of leaks at different leakage thresholds in order to identify the most relevant one.

Overall, the risk of unintentional leakage associated with a given determinant was consistent across the different leakage thresholds for a given patient. Mouth opening remained the principal leak determinant (27 patients). This is consistent with our previous results in which mouth opening was independently associated with the presence of unintentional leakage during sleep¹². However, the interpretation of leak 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 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.

Our work has two important limitations that must be taken into account: first, 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 the leak determinants found in a population with few, weak or no specific complaints 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 specifically complain about leaks may also explain why the number of non-calculable 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 patients with the current dataset (this will of course be addressed by future studies). Agreement on clinical decision was not ideal. This could be due to the high number of non-calculable variables and the lack of thorough clinical information to help guide the decision. Furthermore, generalizability to the entire OSA-auto-CPAP population is compromised because only patients who used a nasal mask were analysed. Indeed, we previously demonstrated that mask type influences leak determinants,¹² and were unwilling (for simplicity’s sake) to introduce this confounding factor by taking into account oronasal and nasal pillows, which are second-line interfaces.

322
323
324
325
326
327
328
329
330
331
332
333

Conclusion

The use of type-3 polygraphy for characterizing leak determinants in OSA populations requiring automatic CPAP treatment with nasal masks is feasible in routine practice. Leak determinants are heterogeneous, patient specific, and can vary with leak thresholds in certain cases. A first estimation of concordance among physicians for determining individual leak management strategies demonstrated only a “fair” level of agreement, indicating room for improvement in how leak determinants are interpreted. A prospective interventional trial is needed in order to validate the clinical relevance of these individual-based clinical strategies in the management of unintentional leaks.

334 **ACKNOWLEDGMENTS**

335 **Guarantor statement:** JCB had full access to all of the data in the study and takes
336 responsibility 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

345 **Financial/nonfinancial disclosures:** The study was funded by “AGIRadom”, a French non-
346 profit home care provider.

347

348 **Role of the sponsors:** The sponsors had no role in study performance, analysis or
349 interpretation (beyond financial support).

350

351

352 **References**

- 353 1. Lévy P, Kohler M, McNicholas WT, et al. Obstructive sleep apnoea syndrome.
354 *Nat Rev Dis Primer*. 2015;1:15015. doi:10.1038/nrdp.2015.15
- 355 2. Patil SP, Ayappa IA, Caples SM, Kimoff RJ, Patel SR, Harrod CG. Treatment of
356 Adult Obstructive Sleep Apnea with Positive Airway Pressure: An American
357 Academy of Sleep Medicine Clinical Practice Guideline. *J Clin Sleep Med JCSM*
358 *Off Publ Am Acad Sleep Med*. 2019;15(2):335-343. doi:10.5664/jcsm.7640
- 359 3. Weaver TE, Maislin G, Dinges DF, et al. Relationship between hours of CPAP
360 use and achieving normal levels of sleepiness and daily functioning. *Sleep*.
361 2007;30(6):711-719.
- 362 4. Weaver TE, Grunstein RR. Adherence to continuous positive airway pressure
363 therapy: the challenge to effective treatment. *Proc Am Thorac Soc*.
364 2008;5(2):173-178. doi:10.1513/pats.200708-119MG
- 365 5. McEvoy RD, Antic NA, Heeley E, et al. CPAP for Prevention of Cardiovascular
366 Events in Obstructive Sleep Apnea. *N Engl J Med*. 2016;375(10):919-931.
367 doi:10.1056/NEJMoa1606599
- 368 6. Gagnadoux F, Le Vaillant M, Goupil F, et al. Influence of marital status and
369 employment status on long-term adherence with continuous positive airway
370 pressure in sleep apnea patients. *PloS One*. 2011;6(8):e22503.
371 doi:10.1371/journal.pone.0022503
- 372 7. Borel JC, Tamisier R, Dias-Domingos S, et al. Type of mask may impact on
373 continuous positive airway pressure adherence in apneic patients. *PloS One*.
374 2013;8(5):e64382. doi:10.1371/journal.pone.0064382
- 375 8. Bachour A, Hurmerinta K, Maasilta P. Mouth closing device (chinstrap) reduces
376 mouth leak during nasal CPAP. *Sleep Med*. 2004;5(3):261-267.
377 doi:10.1016/j.sleep.2003.11.004
- 378 9. Valentin A, Subramanian S, Quan SF, Berry RB, Parthasarathy S. Air Leak is
379 Associated with Poor Adherence to Autopap Therapy. *SLEEP*. 2011;34(06):801-
380 806. doi:10.5665/sleep.1054
- 381 10. Lebrete M, Martinot J-B, Arnol N, et al. Factors Contributing to Unintentional Leak
382 During CPAP Treatment: A Systematic Review. *Chest*. 2017;151(3):707-719.
383 doi:10.1016/j.chest.2016.11.049
- 384 11. Bachour A, Vitikainen P, Maasilta P. Rates of initial acceptance of PAP masks
385 and outcomes of mask switching. *Sleep Breath*. December 2015:1-6.
386 doi:10.1007/s11325-015-1292-x
- 387 12. Lebrete M, Arnol N, Martinot J-B, et al. Determinants of Unintentional Leaks
388 During CPAP Treatment in OSA. *Chest*. 2018;153(4):834-842.
389 doi:10.1016/j.chest.2017.08.017
- 390 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

14. 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
15. 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/s11325-
012-0740-0
16. Landis JR, Koch GG. The measurement of observer agreement for categorical
data. *Biometrics.* 1977;33(1):159-174.

404 Tables
405

TABLE 1. Population characteristics (n = 50)

Demographics

Age (yrs)	65 [57; 75]
Gender, female n(%)	16 (32)
BMI (kg/m ²)	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) ^c
Diabetes type 1 n(%)	0 (0) ^c
Diabetes type 2 n(%)	7 (14,6) ^c

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

408 Table 2 : Cohen K coefficients among all raters regarding choice of clinical leak management
409 strategy.
410

Figure legends

Figure 1: polygraphic assesment 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 position, respiratory flow and SpO₂).

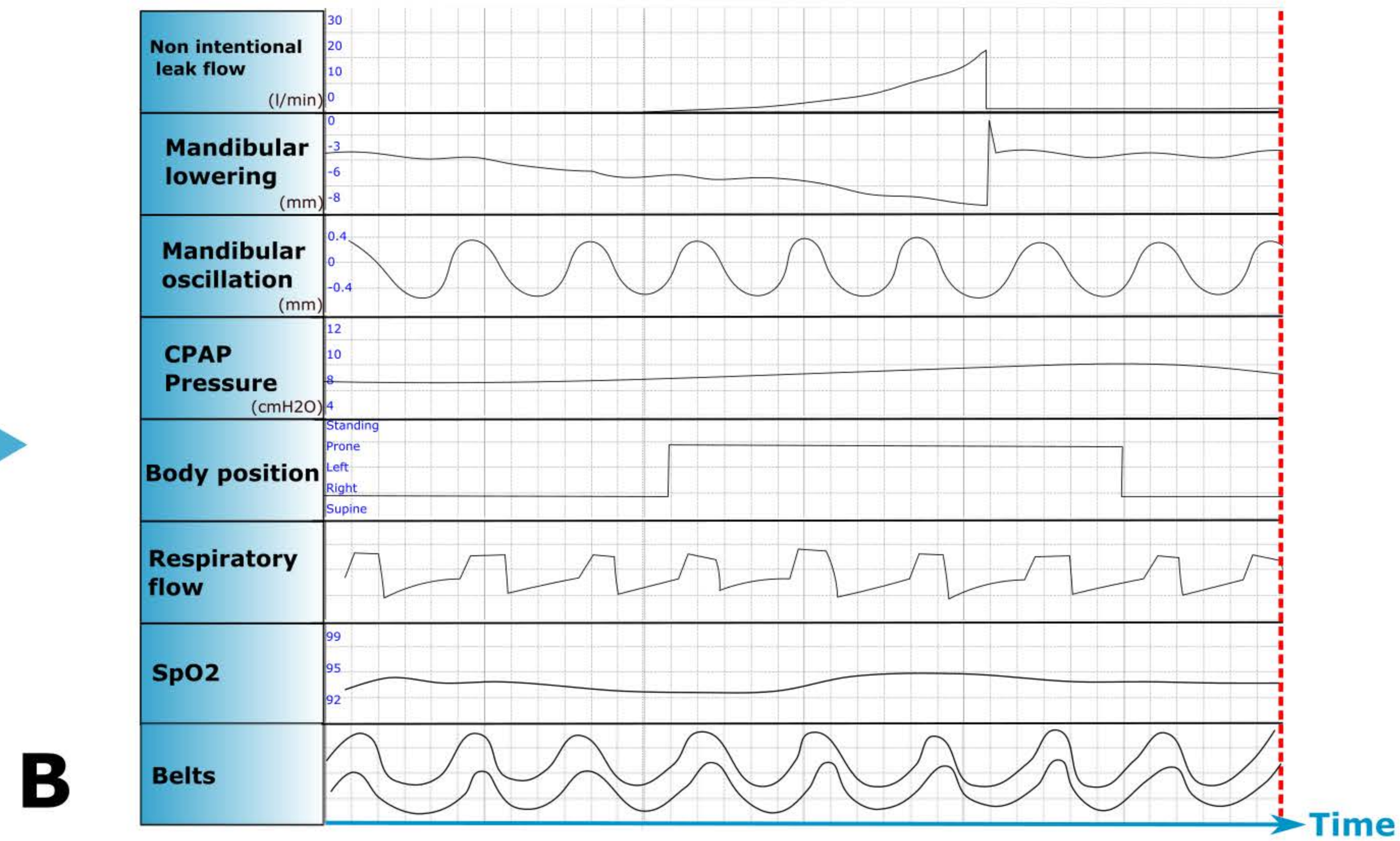
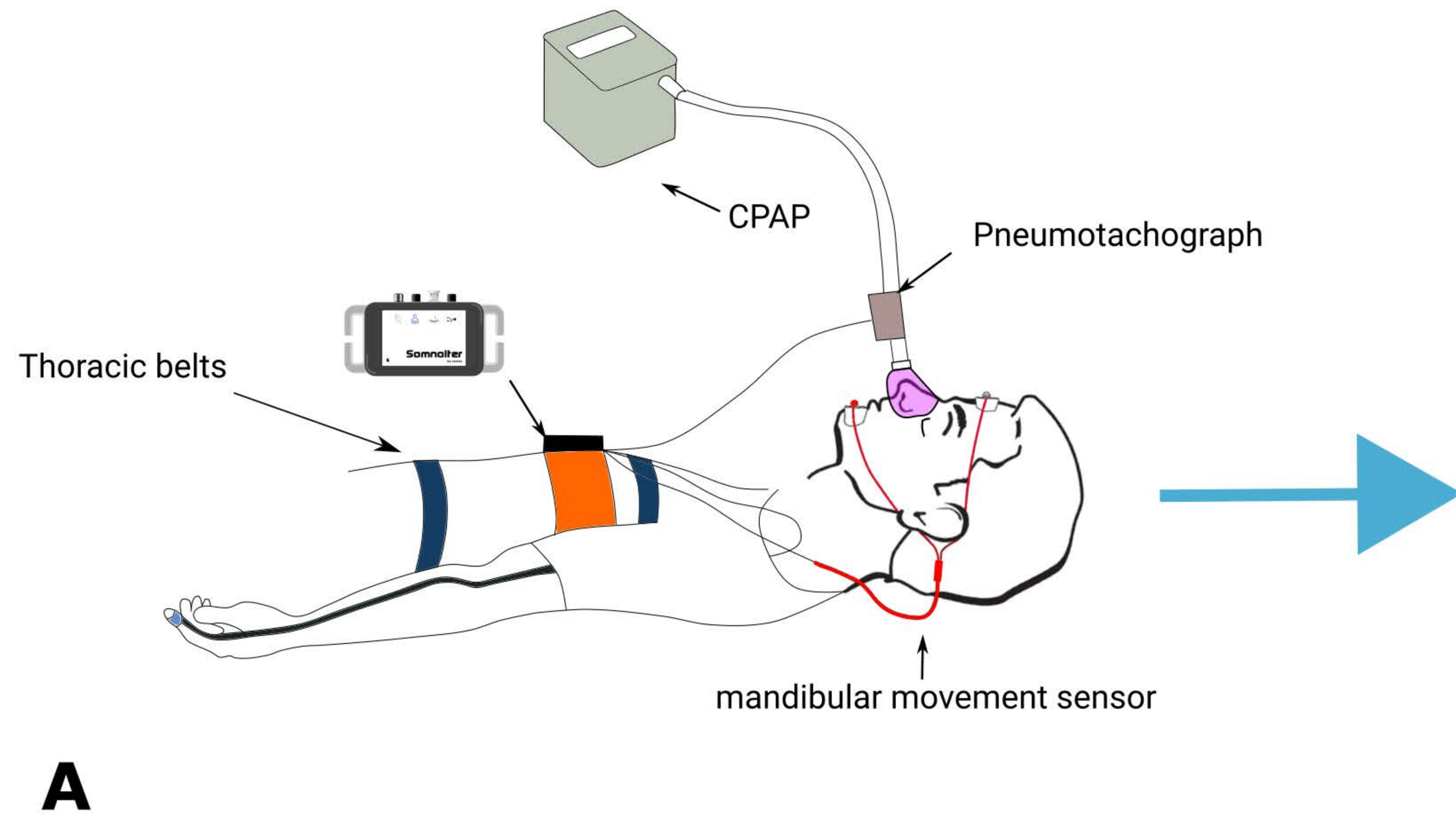
Figure 2: Analysis of the determining factors of unintentional leaks and consensus on individual leak management (methods).

*the new version of APIOS embeds the automatic analysis of the determinants of leaks;
†example for a given patient

Figure 3: Heat Map displaying the individualized representation of the determinants of leaks. This figure reports the risk (OR: Odds Ratio) associated with the 4 determinants of leaks for 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 code. Side effects reported by patients during CPAP treatment are displayed in the first two columns.

Green represents an OR<1. The darker it is, the closer the OR is to 0. Conversely, red represents an OR>1, the darker it is, the higher the OR and therefore the risk. White cells represent an OR for which the confidence interval crosses 1 (non-significant).

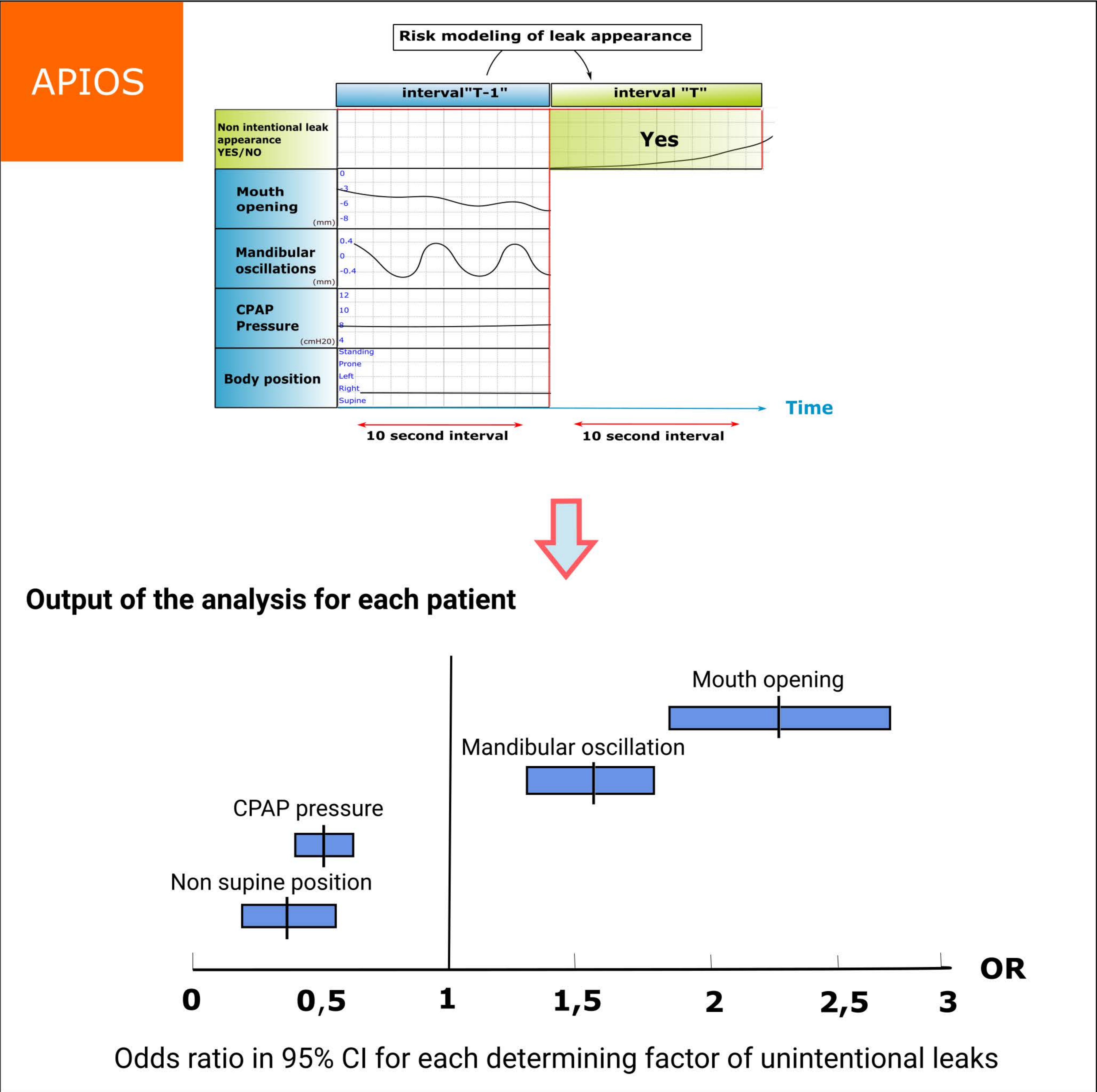
Mouth opening > median overnight mouth opening; CPAP pressure > median overnight pressure; mandibular oscillation > 0.3 mm. NC: non-calculable, there were specific conditions for which the odds ratios were non-calculable (supplemental material).



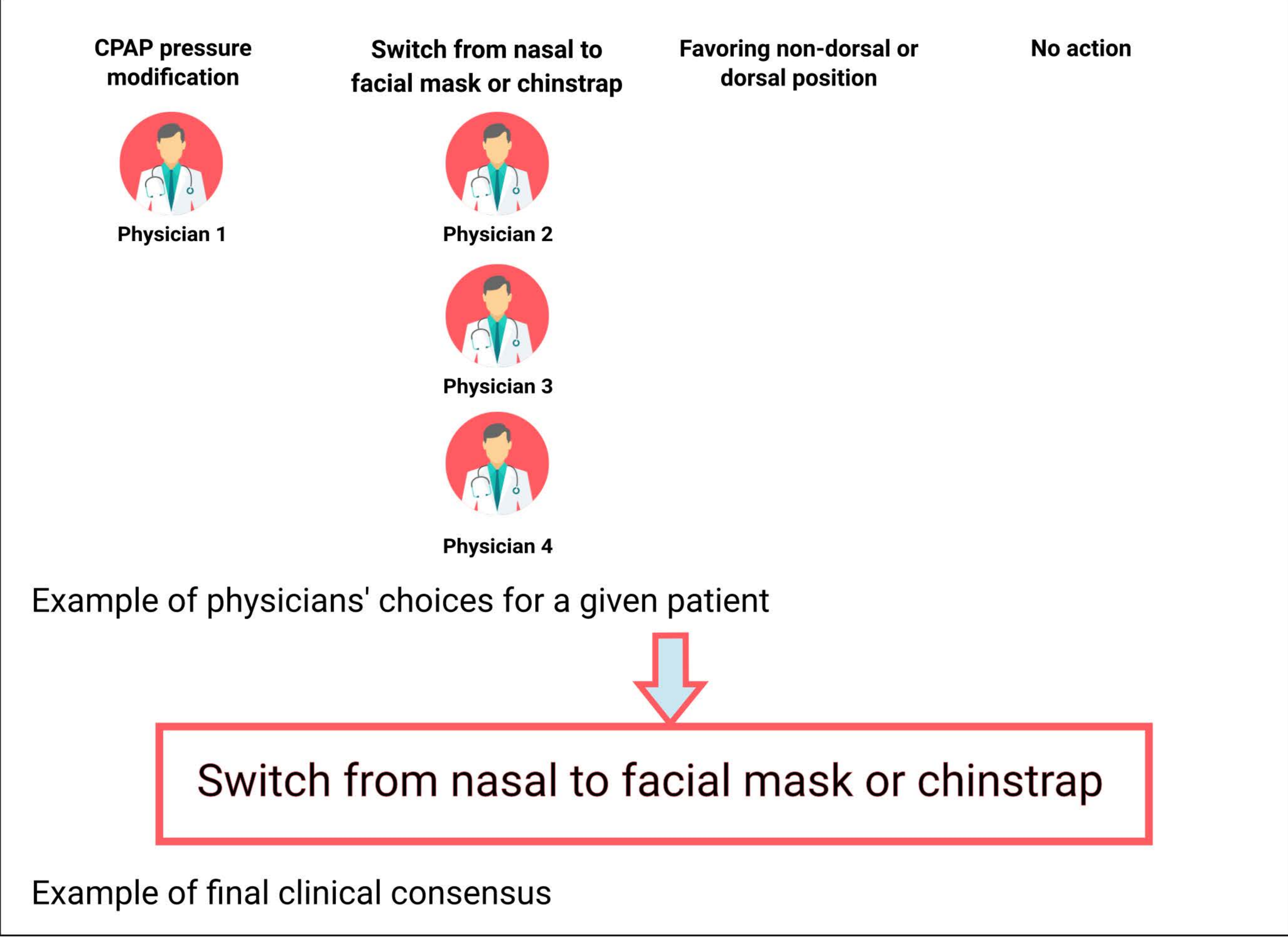
STEP 1 - data collection

Collection of polygraphic recordings carried-out in routine care

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



STEP 3: clinical consensus on individual leak management



	Reported side effects		Mouth opening			CPAP pressure			Non-supine position			Mandibular oscillation			Consensus
			Leak thresholds			Leak thresholds			Leak thresholds			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	
#1															Increase CPAP
#2					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			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			NC	Increase CPAP
#9			NC	NC	NC			NC			NC		NC	NC	Decrease CPAP
#10			NC	NC		NC	NC		NC	NC		NC	NC		Increase CPAP
#11			NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action
#12			NC	NC		NC	NC		NC	NC		NC	NC		Favor non-supine position
#13			NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action
#14	Missing data			NC	NC		NC	NC		NC	NC		NC	NC	Install facial mask or chinstrap
#15				NC	NC	NC	NC	NC		NC	NC		NC	NC	Install facial mask or chinstrap
#16					NC			NC			NC			NC	Install facial mask or chinstrap
#17				NC	NC		NC	NC	NC	NC	NC		NC	NC	Install facial mask or chinstrap
#18					NC			NC		NC	NC			NC	Increase CPAP
#19				NC	NC		NC	NC		NC	NC		NC	NC	Install facial mask or chinstrap
#20					NC			NC			NC			NC	Favor supine position
#21					NC			NC			NC			NC	Favor non-supine position
#22			NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action
#23			NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action
#24					NC			NC			NC			NC	Favor non-supine position
#25									NC	NC	NC				Decrease CPAP
#26					NC			NC			NC			NC	Favor non-supine position
#27															Install facial mask or chinstrap
#28															Increase CPAP
#29					NC		NC	NC	NC	NC	NC			NC	Decrease CPAP
#30					NC			NC			NC	NC		NC	Install facial mask or chinstrap
#31				NC	NC		NC	NC		NC	NC		NC	NC	Favor non-supine position
#32	Missing data	Missing data			NC			NC			NC			NC	Favor non-supine position
#33			NC	NC		NC	NC		NC	NC		NC	NC		Increase CPAP
#34					NC									NC	Decrease CPAP
#35				NC	NC		NC	NC		NC	NC		NC	NC	Increase CPAP
#36				NC	NC		NC	NC		NC	NC		NC	NC	Favor non-supine position
#37												NC	NC	NC	Install facial mask or chinstrap
#38				NC	NC		NC	NC	NC	NC	NC		NC	NC	Decrease CPAP
#39			NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action
#40			NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action
#41		Missing data		NC	NC		NC	NC	NC	NC	NC	NC	NC	NC	Increase CPAP
#42	Missing data	Missing data	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action
#43		Missing data			NC			NC	NC	NC	NC			NC	Increase CPAP
#44	Missing data	Missing data										NC	NC	NC	Install facial mask or chinstrap
#45		Missing data							NC	NC	NC				Increase CPAP
#46	Missing data	Missing data	NC		NC	NC		NC	NC	NC	NC	NC	NC	NC	Install facial mask or chinstrap
#47	Missing data	Missing data			NC			NC			NC			NC	Increase CPAP
#48	Missing data	Missing data	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	No action
#49		Missing data		NC	NC		NC	NC		NC	NC	NC	NC	NC	Install facial mask or chinstrap
#50	Missing data	Missing data			NC			NC	NC	NC	NC	NC	NC	NC	Decrease CPAP

