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General nomenclature of air leak patterns: A proposal

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ABSTRACT

Leakage is a common issue with PAP therapy and may contribute to short-term non-compliance with treatment. PAP manufacturers use different methods to estimate and report air leaks (median, mean, p90, p95, % of important air leak, time spent on major leaks), which makes the analysis and comparisons challenging. Leak intensity is a well-known parameter of major importance as it can significantly affect the performance of PAP devices. However, there is a lack of knowledge regarding another leakage parameter, namely the leakage pattern. As of now, there is no standard classification for leak patterns in real-life settings. Our objective was to develop and propose a comprehensive nomenclature for leakage patterns observed during nasal auto-PAP therapy.

We examined 50 ventilatory polygraphy recordings conducted with auto-PAP, based on data from a prior study in which the unintentional leak flow was precisely measured over time. We have categorized leaks into two main types: continuous leaks, which appear and persist for an extended period, and discontinuous leaks, which vanish more rapidly. Continuous leaks can have both abrupt or gradual apparitions and terminations. Their "shape" can be either interrupted or constant. Discontinuous leaks can have both abrupt or gradual apparitions and terminations. Due to the relatively short observation scale (less than 5 min minutes), this type of leakage is not characterized by a specific shape between apparition and termination.

This nomenclature could be a valuable tool that facilitates comparative bench tests or clinical studies. This tool could support manufacturers in developing precise algorithms for leak compensation, residual AHI estimation and the accuracy of CPAP monitoring data. Lastly, establishing a standardized approach for describing and categorizing air leakage patterns could assist clinicians in identifying device-related issues, such as patient discomfort arising from specific types of leakage.

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1. Introduction to the case

Positive Airway Pressure (PAP) is considered the first-line treatment for moderate to severe Obstructive Sleep Apnea (OSA) syndrome [1]. While the causes of PAP cessation are multifactorial [2] unintentional leakage is a common issue with PAP therapy and may contribute to short-term non-compliance with treatment [3]. PAP manufacturers use different methods to estimate and report air leaks (median, mean, p90, p95, % of important air leak, time spent on major leaks), which makes the analysis and comparisons of studies more challenging [4]. Leak intensity is a well-known parameter of major importance as it can significantly affect the performance of PAP devices [5]. However, there is a lack of knowledge regarding another leakage parameter, namely the leakage pattern. As of now, there is no standard classification for leak patterns in real-life settings, and it remains unknown whether the leakage pattern has a greater impact on the patient compared to the leakage intensity. It is crucial to note that there is no correlation between the patient's clinical assessment of leakage and the measurement of leakage by the PAP device [6].

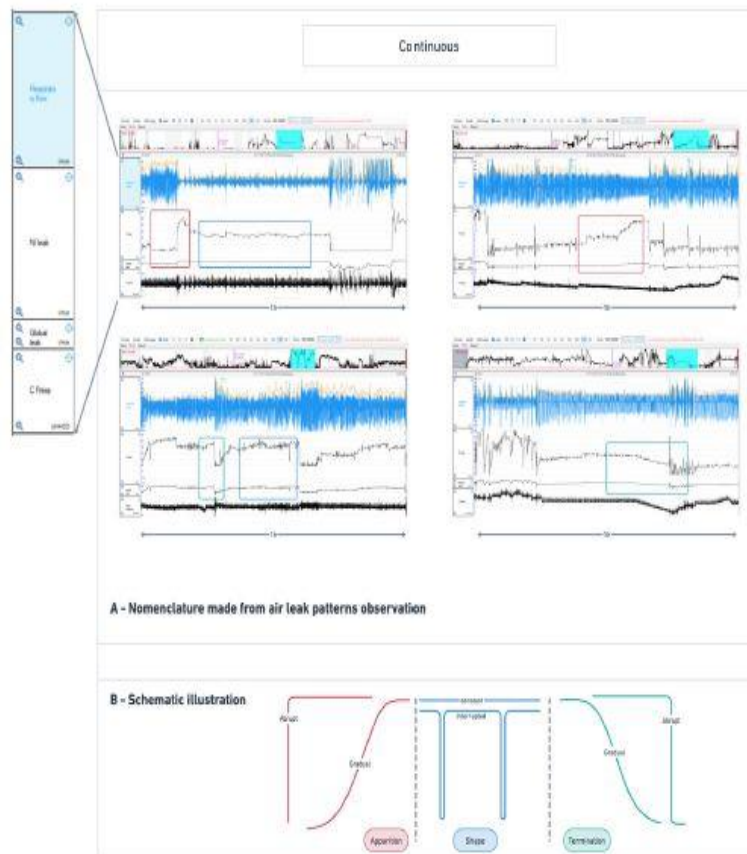


Fig. 1. Continuous leak (observation scale 1 h). In panel A, the red squares illustrate examples of leak apparitions, the blue squares represent examples of leak shapes, and the green squares depict examples of leak terminations. Panel B provides a schematic illustration of our observations from the polygraphic recordings, while Panel C shows the observation scale. Continuous leak patterns are typically observable for extended periods, often spanning hours. Within these continuous leaks, we have identified both abrupt and gradual apparitions and terminations. The "shape" of these continuous leaks can be either interrupted or constant. NI leak = non-intentional leak or unintentional leak; C Press = Continuous Positive Airway Pressure. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

2. Image analysis

Our primary objective was to establish and develop a comprehensive nomenclature for leakage patterns observed during nasal auto-PAP therapy. Following this, we intend to simulate these leakage patterns using a realistic bench model. We examined 50 ventilatory polygraphy recordings conducted with auto-PAP, totalling over 12,000 min of treatment time. Our analysis was based on data from a prior study [7], in which the unintentional leak flow was precisely measured over time for each patient's recording. However, in that previous study [7], we did not evaluate the effects of leak patterns or magnitudes on clinical outcomes, leaving this area unexplored. The nomenclature we derived from this analysis is summarized in Figs. 1 and 2.

3. Discussion

As per Baltzan et al. [8], we have categorized leaks into two main types: continuous leaks, which appear and persist for an extended period, and discontinuous leaks, which vanish more rapidly. The presence of intermittent, non-continuous leaks with irregular patterns may have different effects on the PAP device and/or the patient compared to leaks with more consistent and stable characteristics over time (i.e., continuous leaks). Moreover, our proposal introduces: i) a novel approach by identifying two major patterns of leak onset and termination, irrespective of whether it is a discontinuous or continuous leakage pattern; ii) two major leak patterns based on the shape of continuous leakage.

As CPAP telemonitoring-guided interventions continues to expand in the field of sleep apnea, it becomes essential to validate the quality of data generated by CPAP monitoring systems before incorporating them into the decision-making process. So far, sleep medicine professional societies have been unable to persuade manufacturers to standardize the way they report leakages [4]. With this general nomenclature for air leakage patterns, we aim to provide a valuable tool that facilitates comparative bench tests and clinical studies. This tool can support manufacturers in developing precise algorithms for leak compensation, residual AHI estimation and the accuracy of CPAP monitoring data. Lastly, establishing a standardized approach for describing and categorizing air leakage patterns could assist clinicians in identifying device-related issues, such as patient discomfort arising from specific types of leakage.

CRedit authorship contribution statement

Mathéo Richard and. **Dany Jaffuel** and. **Jean-Pierre Mallet** and **Marius Lebret:** manuscript preparation and review manuscript. **Raphael Gilson** and. **Maxime Patout** and. **Emeline Fresnel:** Literature search, data collection, study design, analysis of data and manuscript preparation.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Lebret Marius reports a relationship with Air Liquide Medical Systems and KerNel Biomedical that includes: employment.

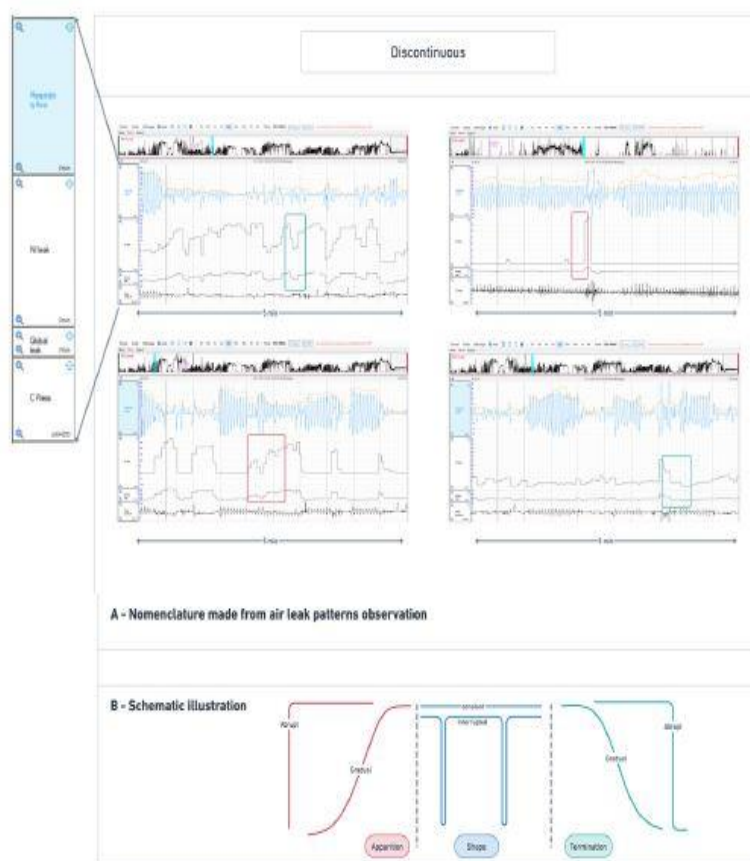


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