Testing the Performance of Positive Airway Pressure Generators
From Bench to Bedside

Kaixian Zhu, PhD[a,*], Claire Colas des Francs, MD[b], Amélie Sagniez, MSc[a], Pierre Escourrou, MD, PhD[b]

KEYWORDS

• Bench evaluations • Clinical evaluations • PAP treatment • Sleep disordered breathing

KEY POINTS

- Positive airway pressure (PAP) devices use different proprietary algorithms for sleep-disordered breathing event detection and response.
- Clinical evaluations allow measuring long-term treatment efficacy, but have limitations such as patient variability and high cost.
- Bench studies are necessary to evaluate devices in predefined conditions for understanding algorithms of detection and treatment of disordered breathing events.
- Combining results of bench tests and clinical studies is essential to improve the management of patients with PAP treatment.

INTRODUCTION

The clinician applying a positive airway pressure (PAP) treatment to a patient needs to obtain the following information:

1. Is the treatment safe for the overall condition of the patient?
2. Is the treatment efficient on the disease abnormalities?
3. Is the treatment adherence adequate for obtaining the best outcomes?
4. Is there any side effect at the interface (leaks) or inadequate patient–device interaction (such as arousals linked to the device functioning) that may impair treatment efficacy or tolerance?

Newer PAP generators can track adherence, hours of use, mask or mouth leak, and residual apnea–hypopnea index (AHI). Such data seem very useful to follow chronic disease outcomes. However, there are no standard for recording adherence data, scoring flow signals, or measuring leak, or for how clinicians should use these data.

According to the US Food and Drug Administration and the European Community regulations, PAP generators are class II devices, which may carry risks to the patient. Marketing approval for positive airway generators in the United States follows the simplified 510(k) procedure in which a device only require that clinical studies demonstrate equivalent ability to suppress sleep-disordered breathing (SDB) events in comparison with a previously approved apparatus.[1] This historical comparison may go back to devices manufactured many years before the newly sold device,

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[a] Centre Explor, Air Liquide Healthcare, 28 rue d'Arcueil, Gentilly 94250, France; [b] Sleep Disorders Center, AP-HP Antoine-Béclère Hospital, 157 rue de la Porte de Trivaux, Clamart 92140, France
* Corresponding author.
E-mail address: kaixian.zhu@gmail.com

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incorporating very different technology. The European directives also have a requirement for approving family of devices on clinical data, which may be "published and/or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated."[2]

Indeed, for these devices there is no required thorough certification process similar to what is required for any new drug. Because clinical studies are long and costly, it is common practice to introduce a new product to the market without specific clinical evaluation.

The PAP generators are in their principle, simple devices based on a blower that takes room air and generates airflow through flexible tubing at a preset pressure that is determined at the mask interface with the patient. Continuous PAP (CPAP) devices are used in most sleep apnea patients in the long term, but the settings are usually titrated during several nights at home, using an autoadjusting PAP (APAP) because manual titration in the sleep laboratory is costly and suffers long waiting lists. Because algorithms often are not disclosed, this technology is often seen as a "black box" that collects and analyses data to detect breathing abnormalities and provide a treatment supposedly adapted to the patient condition.[3]

Given that APAP are a relatively new technology, there are no generally accepted criteria for defining the optimum method of modifying the mask pressure in response to breathing events so that devices provide different results when subjected to the same breathing pattern. Therefore, the individual demonstration of their efficacy is very relevant. This evaluation cannot rely on symptoms, because controlled trials have demonstrated a noticeable placebo effect[4,5] and would require costly sleep laboratory studies. An alternative approach is the use of bench testing to challenge each device by events as close as possible to patients breathing events.

PAP usages seem to be reliably determined from device-reported compliance data, but a definitive accuracy study has not been published. The residual events (apnea or hypopnea) and leak data are not as easy to interpret and the definitions of these parameters differ among PAP manufacturers.[6]

Any observed difference in residual AHI between bench values and device-reported ones bear considerable clinical implications, because the current follow-up of patient often relies on device-reported residual AHI, which may be very different from actual patient values.[7–12]

It is the aim of this paper to describe this methodology and investigate how bench results can help clinicians in evaluating the treatment efficacy of PAP devices and the reliability of device-reported data.

BENCH TESTING OF DYNAMIC PERFORMANCE OF POSITIVE AIRWAY PRESSURE DEVICES

Pressure Stability and Effects of Leaks

PAP devices should maintain a stable positive pressure or provide a bilevel pressure in the airway during respiratory cycles with the presence of normal pressure swings from breathing and deviations in pressure caused by leaks. Therefore, these devices should offer both static and dynamic pressure stability, that is, to compensate pressure swing during each respiratory cycle. For older PAP devices, airway pressure significantly varied during the respiratory cycle, especially when the breathing flow rate was high.[13,14] Bench studies showed a higher dynamic pressure stability in bilevel PAP devices than in CPAPs owing to different technologies applied in the blowers.[13,14] Recent devices can measure the pressure loss in the patient's tubing and adjust the pressure in dynamic conditions.[15]

PAP devices can also compensate for up to a certain level of leaks.[16] **Fig. 1** shows an example of airway pressure changes of 2 CPAP devices subjected to different levels of leak. The pressure stability with leaks has significant impacts on treatment efficacy. Bench studies on APAPs demonstrated that air leaks may affect the responses of devices and cause airway pressure to significantly

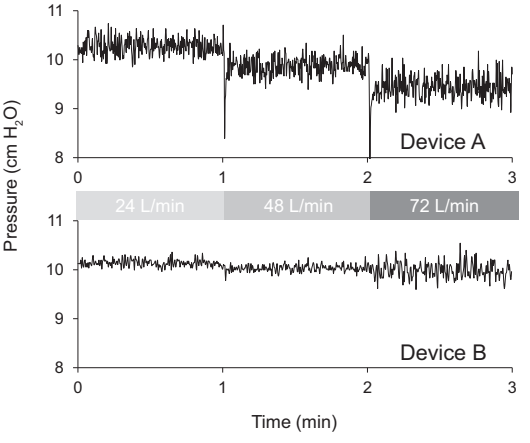

Fig. 1. Airway pressure change of 2 continuous positive airway pressure (CPAP) devices subjected to 3 levels of leak: 24, 48, and 72 L/min calibrated at 10 cm H_2O. The pressure of CPAP devices were set at 10 cm H_2O. Differences between these 2 devices are significant in pressure stability and in the capacity of leak compensation.