CLINICAL REVIEW

The value of auto-adjustable CPAP devices in pressure titration and treatment of patients with obstructive sleep apnea syndrome

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SUMMARY

In moderate to severe obstructive sleep apnea syndrome (OSAS), the use of Continuous Positive Airway Pressure (CPAP) is the gold standard therapy. In the last decade, new technologies such as auto-adjustable CPAP (APAP) have been promoted as having an added advantage over CPAP, because of their ability to adapt the pressure level to the patient's need at all times. This could logically result in the deliverance of lower pressures, which was hypothesized to improve patient acceptance and compliance for therapy.

Several clinical trials have been performed with APAP in different modalities, as a titration tool in attended or unattended conditions, or as a treatment device for chronic use. Comparison of these trials is challenging, since APAP technology is evolving promptly and devices differ not only in how sleep-disordered breathing is detected, but also in how the operational algorithm responds accordingly. Although the question remains whether proof has yet been delivered of the superiority of this technology over CPAP, there is a tendency to accept it as common standard practice in OSAS titration and treatment. This review will bring available evidence on this subject into perspective.

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Introduction

Obstructive sleep apnea syndrome (OSAS) is the most common organic sleep disorder, causing excessive daytime sleepiness, but is still widely unrecognised and undiagnosed. For patients with moderate to severe OSAS the administration of nasal Continuous Positive Airway Pressure (CPAP) is evidence-based standard therapy. It is widely accepted that adequate CPAP therapy has to prevent any degree of upper airway obstruction in all sleep stages and body positions, in order to restore normal sleep.[1] The method to determine this optimal CPA pressure, however, has remained an unsettled subject of debate. For years, the standard operating procedure was to perform a full polysomnography (PSG) in the sleep lab attended by a sleep technician. This manual titration is a labour-intensive and therefore expensive procedure for which an unequivocal and standardized algorithm is lacking, possibly resulting in considerable inter-technician variability. It has also

been shown that higher CPAP pressures could be required during REM sleep and in the supine sleep position.[2] Therefore, the manually determined pressure could be on average rather high, and it has been suggested that high pressures could result in discomfort and intolerance for CPAP. Anyhow, 'successful' CPAP therapy seems to be directly related to determining and delivering the 'right' pressure to the individual patient at all times.

The development of auto-adjustable CPAP devices (APAP) seemed to offer a solution to the aforementioned problems. These devices can be used for different purposes and in different modalities, most often for titration to determine the fixed CPAP level or as a treatment device for chronic use at home. They have been tested as diagnostic tools for the identification of sleep disordered breathing, but evidence has shown APAP technology to be insufficiently reliable in this perspective. Therefore, only the titration and treatment modalities will be discussed in this review.

APAP technology

APAP devices are 'intelligent' devices that monitor sleep-disordered breathing and consequently adapt the pressure level in order to obtain the ideal pressure at all times.

Currently, a wide variety of APAP devices has been commercialised, which differ considerably, not only in the methods used to detect upper airway obstruction, but also in the algorithms that

adapt the pressure accordingly. In general, the devices monitor airway vibration (snoring), airflow reduction (apnea or hypopnea), flow vs. time profile (flow limitation) or impedance with the forced oscillation technique. Most devices start at a low baseline pressure (4 cm H_2O) and gradually increase or decrease the pressure in the presence or absence of respiratory events. As a consequence, the pressure can be minimal during wakefulness, while adapting itself according to the degree of upper airway obstruction during sleep. This should allow APAP to constantly deliver the minimum effective pressure in all sleep stages and body positions, not only within one night, but also from night to night. Information about time at pressure (adherence), residual respiratory events, air leaks and pressure vs. time is available for most models.

When APAP technology was launched, it was promoted to have several advantages. An APAP titration procedure could be applied in attended conditions, allowing the sleep technologist to intervene when needed, and to titrate several patients at the same time. Moreover, performing unattended APAP titration at home reduces waiting lists in the sleep lab and realizes cost savings to a larger extent, provided that APAP devices were reliable in determining the pressure in these unattended conditions in a majority of CPAP patients. On the other hand, when using APAP for chronic treatment at home, it was suggested that the applied pressure levels could be lower, which could improve patient comfort and eventually adherence and compliance.[3,4]

APAP performances

At first, APAP was studied in a titration setting comparing it to conventional manual titration, as a tool to determine the fixed pressure level for home treatment. It was concluded that APAP titration was as effective as manual titration since it was equally efficient in lowering the apnea-hypopnea index (AHI) to acceptable levels (AHI < 10/h) in most of the patients studied.[5–13] Unsuccessful titration was reported in only a few patients, mostly due to artefacts confusing the algorithm, such as severe mask or mouth leaks. In these patients the pressure increased to inappropriately high levels due to inappropriate event detection.[13]

Another line of approach was to treat patients with auto-adjustable APAP pressures for long-term home treatment instead of a fixed CPAP pressure. Several cross-over trials confirmed that over a period of several weeks to months CPAP and APAP were equivalent in terms of respiratory control (as defined above), and impact on sleep quality (reduction in arousal index <20/h and increased slow wave and REM sleep). Similar results were also reported for clinical outcomes such as a reduction in subjective and objective measures of sleepiness or quality of life measures.[14–31]

Several studies confirmed the hypothesis that APAP tends to correct respiratory disorders with lower mean or median pressure levels than conventional (fixed) CPAP (FPAP).[5,7,9–12,14–16,25,32] In most trials, FPAP was 1–2 cm H_2O higher, but could even exceed the mean APAP by as much as 6 cm H_2O.

It was hypothesised that APAP would improve patient adherence and compliance, since lower pressure profiles would offer more patient comfort. The acceptance of CPAP therapy, on the other hand, was similar or only slightly better after APAP titration, leading to a lower dropout rate in one study[33] and a subjective preference of APAP over FPAP in others.[11,15] Compliance data derived from APAP time-loggers over variable periods (2 weeks to 8 months), confirmed at most a tendency to higher APAP usage.[11,16,19,21,22,27] Although a larger benefit in compliance was expected, previous research had already shown that pressure (in)tolerance was less important in this matter. Patient preference and compliance are mostly influenced by education and motivation by health care professionals and by treatment of side effects, more than by the characteristics of the machine itself.[34,35]

Most investigators admitted having difficulties to identify (a subgroup of) OSAS patients who would benefit more from APAP than from CPAP. It was suggested that APAP would be superior to CPAP in those patients with highly variable pressure needs, for example patients with overt sleep stage and body position dependent OSAS,[36] or in patients needing high pressure levels (>8–10 cm H_2O).[21,37] The group of Noseda et al. performed a cross-over trial specifically in patients with high within-night pressure variability and found no gain in treatment efficacy (apnea-index) or compliance with APAP compared to CPAP, only lower Epworth sleepiness scales when using APAP and a higher subjective preference for APAP.[38]

Nevertheless, the message of the first publications was overall optimistic, it was stated that APAP was safe and efficient as a titration tool as well as for home treatment for selected patients, even in unattended conditions.[15,16,22,27,28,39,40] Manual titration, regarded as the gold standard procedure, was replaced by a more pragmatic approach, and APAP was used widely in titration and treatment settings. It was even suggested that APAP technology could alleviate the need for a titration PSG.[41]

However, optimism seemed to be less appropriate when face-to-face comparison of different devices was performed. These trials showed that devices reacted differently or even inadequately to respiratory events and, above all, a considerable lack of agreement in pressure levels was found.[23,30,42–48] Also, data on compliance, patient adherence and preference, were contradictory in several trials and predicting factors for better tolerance with APAP still remained unclear.[20,49]

Considering the often contradictory and confusing results obtained by clinical studies, an alternative approach of testing the performance of APAP devices was mandatory. Bench models capable of reproducing realistic and well-defined sleep-disturbed breathing patterns were developed. This technology allows to determine whether an APAP device performs adequately in detecting respiratory events and in adapting the pressure according to its specific algorithm, and eliminates possible inter- and intra-patient variability. Bench testing, however, only confirmed that specific APAP devices respond quite differently to the same condition and display considerable differences in pressure profiles, as seen in clinical trials.[50–54]

In the last few years, several investigators focused on face-to-face comparison of three frequently used methods of determining the therapeutic CPAP pressure, being manual titration, APAP titration and prediction formulas. These formulas are calculated starting from simple numbers sorted out in multiple regression studies; body mass index, the apnea-hypopnea index (AHI) and the neck circumference are generally used. In one trial, respiratory variables and pressure levels were registered during a one night polysomnography using an APAP titration procedure compared to a fixed 'predicted' pressure (P_{pred}).[55] The conclusion was that the AHI was equally and efficiently lowered both with the use of the P_{pred} and with the APAP device, but with higher pressures in the latter.[56] Other trials compared the influence of several titration methods on clinical outcomes after treatment during several months. In a study by Masa et al. CPAP pressure was determined by manual titration, unattended APAP titration at home or P_{pred} with domiciliary adjustment when needed (in case of residual snoring or apneas).[57] After CPAP treatment for three months, the PSG variables and Epworth Sleepiness Scale showed statistically significant improvements in the three groups. The residual AHI under treatment with P_{pred} was slightly higher, but this was not translated to differences in clinical outcomes. Although the APAP group reported more side effects, compliance data and dropout rates were