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New Approaches to Positive Airway Pressure Treatment in Obstructive Sleep Apnea

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KEYWORDS

• Continuous positive airway pressure • Obstructive sleep apnea • Positive airway pressure
• Compliance

KEY POINTS

- Two basic modes of positive airway pressure – continuous positive airway pressure (CPAP) and autotitrating positive airway pressure (APAP) continue to be the mainstay of therapy in obstructive sleep apnea (OSA).
- Hardware improvements aimed at improving self-sufficiency of patients, and automated adjustments of delivered pressure (Autotrial mode, CPAP check mode) have been introduced.
- Patient comfort features that have been improved include new mask interfaces, improved expiratory pressure relief, heated humidifiers and heated hoses.
- Compliance monitoring has become more effective with wireless transfer of data and online provider and patient-oriented tools.

INTRODUCTION

Continuous positive airway pressure (CPAP) is a mainstay of therapy in patients with obstructive sleep apnea (OSA). Developed in early 1980s,[1] this technology has come over past decades through tremendous changes that resulted in devices that can recognize and differentiate sleep-disordered breathing events, adjust their output to these events, monitor usage, and communicate with the treatment team. This article discusses recent developments in treatment of OSA with PAP.

CONTINUOUS POSITIVE AIRWAY PRESSURE UNITS

Over the years, size and portability of the CPAP device have become key elements of patient's acceptance of therapy. The first CPAPs weighed 6.75 kg; over the years, the device's weight has decreased to 2.5 to 3 lbs, and to less than 1 lb in cases of travel devices. Mirroring the changes in size, the modern CPAP machines have become much quieter than their predecessors. The original CPAP devices were based on vortex blower technology and were so loud that they could be heard several rooms down from the bedroom.[2] Modern devices have advanced motor technology and generate noise as low as 26 dB, less than a whisper, resulting in an improved tolerance of CPAP by patients and their bed partners.

MODES OF CONTINUOUS POSITIVE AIRWAY PRESSURE DELIVERY

Two modes of PAP therapy continue to be used in treatment of patients with OSA. CPAP therapy provides the set pressure, while autotitrating PAP therapy (AutoPAP) devices utilize proprietary

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algorithms to determine presence or absence of obstruction and adjust the pressure generated by the device within the preset range. Although most patients with OSA are treated with set CPAP, AutoPAP devices are used in patients with large sleep stage- or position-related pressure requirements and when in-laboratory titration is unavailable or not effective. Use of these devices is currently not recommended in patients with congestive heart disease, significant chronic lung disease, OSA-independent hypoxemia, central sleep apnea, or in those who do not snore.[3]

AUTOTITRATING POSITIVE AIRWAY PRESSURE

AutoPAP devices use proprietary algorithms to determine the presence/absence of airway obstruction and come up with pressure to resolve it. These algorithms are typically based on the detection of small alterations of flow and pressure patterns, analyzed over a period of time.[4] Although the actual algorithms of PAP devices produced by different manufacturers are not in the public domain, they seem to result in control of airway obstruction at similar pressure and lead to similar treatment outcomes.[5,6]

Phenotypic differences exist between OSA in certain subgroups of patients. For example, female patients seem to be more sensitive to lower degrees of airway flow limitation than male patients. Clinicians now have some degree of control over the type of algorithm on some AutoPAP devices and can adjust the devices to such subtle phenotypic changes. New Resmed (San Diego, CA) devices allow to choose between a standard "autoset" and an "autoset for her" algorithm that responds faster to small degrees of flow limitation and mildly reduces the time spent with flow limitation in female patients, when compared with the standard algorithm.[7] The DeVilbiss (Somerset, PA) autoadjust algorithm allows one to customize and fine tune the device's response to apneas, hypopneas, and expiratory flow limitation; autoadjust also uniquely allows the detection of expiratory puffs (oral venting).[4]

AUTOTRIAL MODE AND AUTOMATIC PRESSURE ADJUSTMENT (CONTINUOUS POSITIVE AIRWAY PRESSURE CHECK)

AutoPAP algorithm constantly searches for the optimal pressure to maintain airway patency by increasing it in periods of obstruction and decreasing it in periods of good airway control. This, by definition, leads to periods of incomplete control of patency, which may be responsible for incomplete control of sympathetic stimulation by AutoPAP versus CPAP.[8] To address that, switching the device from the "auto" mode to the "set" mode is frequently practiced. Historically, this has been done using the 90th to 95th percentile of pressure generated by the device, based on the download of the compliance card.

This process of transitioning AutoPAP into CPAP can now be done automatically. The autotrial mode, present on Remstar Pro and Remstar Auto devices by Philips Respironics (Murrysville, PA) is equipped with a mode that allows for a smooth, remote transition from autotitrating CPAP to constant pressure CPAP. The autotrial mode, when activated, determines the pressure requirement by the patient, and, after a 30-day period, automatically activates the constant pressure CPAP, set at 90th percentile of pressure determined during the autotrial.[9]

The same Philips Respironics devices are also equipped with a mode that allows dynamic changes in PAP pressure—CPAP check. This mode is most useful on initiation of CPAP pressure or at the end of the 30-day trial of the autotrial mode, described previously. The device, set at a constant CPAP pressure, monitors the effectiveness of obstruction control, and has a capability of automatically rising or lowering the treatment pressure in 1 cmH_2O intervals (and within $\pm$ 3 cmH_2O range from the initial pressure) every 30 hours of use.[10] This allows for adjustments in treatment pressure even prior to the physician follow-up visit.

EXPIRATORY RELIEF

PAP therapy, although primarily aimed at distending the upper airway, has also some effect on the lower airway and chest distension. Physiologically, distension of the chest by CPAP increases the functional residual capacity; exhalation remains a passive event, but it takes place at the higher lung volume than without CPAP. This causes a sensation of incomplete exhalation that is uncomfortable to some CPAP users. Expiratory relief feature is a technology that has been available on CPAP machines since the early 2000s and allows dropping the pressure in the early part of exhalation and helps adjust to this sensation; it may also help with gastric distension.[11] Use of expiratory pressure relief has no effect or may improve PAP compliance, and may be better tolerated than the regular CPAP.[12–14]

How exactly the expiratory relief is produced varies between the manufacturers. Philips Respironics devices are equipped with the digital Auto-Trak system that allows for recognition and

compensation of leak, detects the onset of inspiration and expiration, and responds by triggering expiratory pressure relief (flex).[15] Philips' version of expiratory pressure relief comes in 2 variations; C-flex allows for flow-based pressure relief at 3 selectable settings, while C-flex+ offers 3 additional settings for inspiration-to-expiration transition comfort.[15] Similar technology is present on Philips' autotitrating devices (A-flex) and autotitrating bilevel devices.[16,17] Expiratory pressure relief offered on Resmed devices allows dropping of the pressure by a set amount of 1 to 3 cmH_2O, which may result in a lower mask leak than in case of C-flex.[18] Similarly, SmartFlex technology on DeVilbiss PAP devices allows one to reduce pressure in 1 cmH_2O increments during exhalation; in addition, the inspiratory and expiratory flow rounding technology (6 possible settings) allows for the smooth transition between inspiration and exhalation.[19]

Fisher Paykel (Irvine, CA) devices do not offer an expiratory pressure relief for individual breaths, but rather have SensAwake technology that drops the pressure in periods of irregular breathing associated with wakefulness. This technology lowers the mean pressure generated by the PAP device, without any significant effects on sleep architecture or measures of OSA control.[20]

MASK INTERFACES

Properly fitting and comfortable mask interface are major determinants of CPAP compliance.[21] As the decision to use a particular mask depends on the variety of factors, such as the size and shape of the face, presence of facial hair, size and shape of nostrils, presence of claustrophobia, tendency for nasal/mouth breathing, and even hairstyle, there is not a universally accepted mask interface that will fit every patient. With a multitude of available PAP masks, the old saying that "the best mask for a particular patient is the one that he/she is going to wear" continues to be true.

There has been a considerable advance in mask interfaces since the development of CPAP. Initial PAP masks were made of hard plastic, and in order to assure good fit, had to be custom-made for individual patients. Advances in plastic material technology and introduction of silicone have made them more comfortable and less expensive. Most current masks continue to have a hard plastic shell, with a silicone cuff that is typically removable. They usually come in several sizes, with clear manufacturer recommendations regarding sizing.

There are 3 main classes of PAP masks—nasal, oronasal, and nasal pillows. Comparative data suggest that oronasal masks may be associated with lower compliance with CPAP than 2 other types.[22] However, current trends in interface technology focus on assuring a wide variety of interfaces, allowing the patient to change between models and types of masks. Indeed, adjusting a poor mask fit/changing the mask is the most common intervention performed in a stable patient with OSA.[23]

Over the years, there has been a constant effort to make the interfaces smaller and the headgear less obtrusive. Although prior full-face masks were built with a forehead support plate, several new full mask interfaces (AirFit F10 by Resmed, Amara View by Philips) allow an unobstructed view, which helps in cases of claustrophobia. Also, the design of an exhalation port on current masks reduces the noise produced by escaping air and improves comfort. Finally, recent years have brought simplification of CPAP masks; most current models have a limited number of parts, which makes servicing and cleaning easier than in the case of older, more complex interfaces.

HEATED HUMIDIFICATION

Dry pressurized air may lead to nasal and oropharyngeal dryness, nasal burning or congestion, sneezing and nasal dripping and ultimately cause nocturnal mask slippage and poor compliance.[24] A humidifier unit is now a standard component of any modern CPAP system. Unlike the early inline, external humidifier systems, modern humidifiers are typically integrated with the CPAP unit. Humidity of the air leaving the humidifier chamber is controlled by the temperature of the heating plate underneath it. Patients are encouraged to adjust the level of humidity to their comfort.

HEATED TUBING

As the warm, humidified air is moved through the hose towards the patient, it is getting colder on contact with the hose. As a result, water may condensate in the tubing and the mask, and cause rainfall from the mask. A tested way of resolving this problem was a thermal insulation that was placed over the hose,[25] minimizing the temperature drop and condensation. Most modern CPAP systems are equipped with a heating wire within the hose itself that helps maintain air temperature and deliver the humidity to the patient (ClimateLine, Resmed; ThermoSmart, Fisher & Paykel; System One Heated Tube, Philips; Heated Tube, DeVilbiss; Hybernite Rainout Control System). Use of the heated tube typically results in an improved nasal patency and sleep quality.[26–28] The temperature of the heating wire is usually controlled separately

from the humidifier chamber control. Another layer of the control of humidification is an ambient humidity sensor that measures humidity in the patient's bedroom and adjusts the humidifier output to this level (H5i, Resmed; System One Humidity Control, Philips; ThermoSmart, Fisher & Paykel). This may result in a different usage of water from the humidifier chambers on different nights.[26]

In an effort to minimize the size of PAP equipment, modern humidifier units are smaller than those used in older models. This may limit the amount of water output during the night; at high humidity settings and with the long usage time, the water may be used up by the morning.

COMPLIANCE MONITORING

Compliance with CPAP remains the main barrier to successful treatment of OSA. The advent and popularization of the Internet and increasing ability to obtain, maintain, and transfer large sets of data allowed for rapid development of the technology-rich area of CPAP compliance management. Many of the mechanisms that were introduced to monitor compliance were based on common sense, and their effectiveness has not been formally tested; limited data are available to back up the measurements and interventions that have now become a common practice.

Importantly, the type and amount of data gathered by compliance systems differ between the PAP manufacturers. Also, the nomenclature of detected or calculated parameters differs among manufacturers; 4 most prevalent PAP compliance monitoring systems have different ways of measuring leak, defining a large leak, and detecting and defining apneas and hypopneas.[29] As a result the apnea–hypopnea index (AHI_{Flow}) reported by the compliance systems should not be equated by AHI as measured during sleep studies. A practicing physician needs to have a good understanding of the advantages and deficiencies of particular systems that he or she uses.[29]

Having said that, compliance monitoring is an important component of the everyday practice of sleep medicine. Early CPAP systems were not equipped with a compliance monitor at all; with time, usage hour counters were introduced and then replaced by card-based monitors, that not only registered the usage hours, but also effectiveness of treatment. This technology continues to be used in most PAP devices. Card readers are now typically built into the PAP device, although on some devices, they may have to be externally attached (DeVilbiss PAP devices, SmartLink).[30]

Modern compliance monitoring involves not only a card-based technology, with the card able to store several years' worth of data, but also wireless monitoring. This allows the management team not only to remotely follow the patient's compliance and identify problems, but also to remotely modify the CPAP settings. The new generation of Resmed devices (S10 AirSense and AirCurve) are equipped with a wireless modem that allows for a download of treatment data into a cloud-based compliance tracking system, AirView.[31] It allows for ongoing remote monitoring, and adjustments of treatment parameters. Encore Anywhere is a similar system manufactured by Philips Respironics.

Current insurance regulations require the durable medical equipment (DME) providers to monitor and supply compliance data to the insurers. Wireless technology allowed for retrieval and analysis of large sets of compliance data. U-Sleep,[32] a new monitoring system, extracts the data directly from the AirView and streamlines information on multiple patients. The DME user can set up certain threshold parameters that trigger alerts on noncompliance, lack of effectiveness, mask leakage or other parameters. Signs of usage problems or noncompliance can then be detected and intervened upon early. The software also allows one to group patients with similar types of compliance problems, making interventions on these groups easier. It is also possible to get coaching messages to the patient, based on predefined compliance data parameters, via their favorite communication channel—text message, e-mail, or phone. Finally, U-Sleep also allows patients to access their sleep data, thus promoting patient engagement.

Different technology of compliance monitoring is used in DeVilbiss PAP devices. The device generates an alphanumerical code, which, when entered into the online compliance tool, allows for generation of the compliance report for 1-, 7-, 30-, or 90-day timeframe.[4] This monitoring system requires contact between the user and the provider of the PAP device.

COMPLIANCE MONITORING BY THE PATIENT

Compliance tracking that had started as a physician and device supplier tool has been now made available for patients who are interested in monitoring their treatment. Recognition of the critical role of patient involvement in the successful implementation and continued use of CPAP has led to a rapid growth and development of this area. Higher capacity of data storage and reduced cost of data transmission resulted in the development of software applications that allow the patient to monitor the parameters that were previously only available to the clinicians. Night-to-night

feedback with the compliance monitoring system helps maintain motivation and patient's involvement in his or her own treatment.

Sleep Mapper is a mobile- and Web-based free application developed by Philips Respironics that records and reports to the patient a variety of data on daily CPAP usage.[33] Data are then transmitted via an secure digital card (manual download onto a personal computer), Bluetooth, or wireless into a mobile telephone. The application provides daily feedback, allows the patient to set compliance goals, sends the patient reminders regarding CPAP care, and offers educational video materials. Dream Mapper is a newer generation of this software, interfacing with the new generation of Philips Respironics CPAP devices, DreamStation.[34] This new line of devices was expected to be introduced on the US market in late 2015.

New generation of Resmed devices (S10 Airsense and AirCurve) is equipped with a built-in wireless modem that feeds the data into a centralized compliance system. Resmed's version of patient engagement system, MyAir, allows the patient to track the data and tailors coaching to the patient's individual needs.[35]

FUTURE DIRECTIONS OF POSITIVE AIRWAY PRESSURE TREATMENT IN OBSTRUCTIVE SLEEP APNEA

Cost of supervised, in-laboratory polysomnography and low availability of trained sleep medicine specialists have been at the root of the current trend toward less costly, home testing for OSA. Current American Academy of Sleep Medicine guidelines support use of home devices in individuals without significant cardiac or pulmonary comorbidities, and with typical clinical features of OSA. These guidelines have been quickly adopted by a number of private insurers that now only support home diagnostic testing for the majority of patients.

Cost reduction by the payers of health services has also involved the initiation of CPAP therapy. Rather than subjecting the patient to the CPAP titration study, an AutoPAP device is frequently initiated and then adjusted based on the AutoPAP efficacy data. In a recent randomized study, home-based diagnosis of OSA, followed by an AutoPAP therapy, led to a similar effectiveness of therapy, but higher compliance than a laboratory-based diagnosis and PAP titration.[36] Although economically attractive to the payer, this home diagnosis–AutoPAP route was not economically viable to the providers, if the high-quality continuity care was to be maintained.[37] It is now conceivable that much effort will be spent on incorporating new technologies in PAP delivery that allow dynamic changes in the pressure prescription, and intensive monitoring in reducing of the cost and maintaining outcomes of evaluation and treatment of OSA.

Similarly, the high cost of face-to-face contact with the patient will likely increase the role of automated, semiautomated, and remote forms of patient monitoring. Automated telephone-linked communications delivered over the phone by the computer system have been shown to increase patient's adherence to CPAP, compared with no support.[38] Increased patient engagement with therapy of OSA should, as it is the case with other chronic disease, bring an improvement in capability to self-manage one's condition.[39]

Advancements in CPAP technology and monitoring will likely affect provider involvement in routine OSA care. Because most of the need for interventions stemming from a yearly follow-up visit can either be predicted by the presence of specific, subjective complaints from the patient or the analysis of compliance data,[23] it is likely that a routine visit in an OSA patient who is doing well is not needed. This will have to be formally tested.

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