

Practice Parameters for the Use of Auto-Titrating Continuous Positive Airway Pressure Devices for Titrating Pressures and Treating Adult Patients with Obstructive Sleep Apnea Syndrome

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Summary: Continuous positive airway pressure (CPAP) is used to treat patients with the obstructive sleep apnea syndrome (OSAS). The current standard is for an attendant technician to titrate CPAP during full polysomnography to obtain a fixed single pressure. The patient uses CPAP nightly at this fixed single pressure. Recently, devices using new technology that automatically titrate positive airway pressure (APAP) have become available. Such devices continually adjust pressure, as needed, to maintain airway patency (**APAP titration**). These adjustments can be made with or without attendant technician intervention. Data obtained during APAP titration can be used to provide a fixed single pressure for subsequent treatment. Alternatively, APAP devices can be used in self-adjusting mode for treatment (**APAP treatment**). A task force of the Standards of Practice Committee of the American Academy of Sleep Medicine reviewed the available literature. Based on this review, the Standards of Practice Committee developed these practice parameters as a guide to the appropriate use of APAP. Recommendations are as follows: 1) A diagnosis of OSAS must be established by an acceptable method. 2) APAP titration and APAP treatment are not currently recommended for patients with congestive heart failure, significant lung disease (e.g., chronic obstructive pulmonary disease), daytime hypoxemia and respiratory failure from any cause, or prominent nocturnal desaturation other than from

OSA (e.g., obesity hypoventilation syndrome). In addition, patients who do not snore (either due to palate surgery or naturally) should not be titrated with an APAP device that relies on vibration or sound in the device's algorithm. 3) APAP devices are not currently recommended for split-night studies since none of the reviewed research studies examined this issue. 4) Certain APAP devices may be used during **attended titration** to identify by polysomnography a single pressure for use with standard CPAP for treatment of OSA. 5) Once an initial successful attended CPAP or APAP titration has been determined by polysomnography, certain APAP devices may be used in the self-adjusting mode for unattended treatment of patients with OSA. 6) Use of **unattended APAP** to either initially determine pressures for fixed CPAP or for self-adjusting APAP treatment in CPAP naïve patients is not currently established. 7) Patients being treated with fixed CPAP on the basis of APAP titration or being treated with APAP must be followed to determine treatment effectiveness and safety, and 8) a re-evaluation and, if necessary, a standard attended CPAP titration should be performed if symptoms do not resolve or the CPAP or APAP treatment otherwise appears to lack efficacy.

Key words: Obstructive sleep apnea; continuous positive airway pressure; CPAP; sleep-disordered breathing; auto-titrating; APAP

INTRODUCTION

AS DETAILED IN THE REVIEW PAPER,¹ OBSTRUCTIVE SLEEP APNEA SYNDROME (OSAS) AFFECTS 2%-4% OF THE ADULT POPULATION.² Continuous positive airway pressure (CPAP) is a standard treatment for patients with OSA.³⁻⁵ Standard practice requires pressure titration during laboratory polysomnography in which sleep stages and respiratory variables are recorded and monitored by a trained technician. The titration goal is to identify an optimal pressure for eliminating apnea, hypopnea, snoring, and respiratory effort related arousals (RERAs). Furthermore, the pressure must maintain airway paten-

cy in all body positions and sleep stages. In general, higher pressures are required during REM sleep and when the patient sleeps in the supine position.⁶ Attended studies allow the technician to adjust the pressure to meet changing pressure requirements produced by alterations in body position and sleep stage. Other benefits of attended titration are interventions for problems with mask fit, mask leaks, or persistent hypoxemia after airway patency is restored.⁷ Occasionally, an optimally effective pressure for all situations cannot be identified on a single night and a second attended night is necessary to properly titrate the patient. However, an optimal single pressure selected to prevent airway occlusion during supine-REM is usually higher than that necessary for the rest of the night. Using a fixed higher pressure for the entire night might be expected to increase mask leaks, mouth leaks, pressure intolerance, and possibly reduce CPAP acceptance and utilization. Optimal CPAP utilization is a substantial problem facing clinicians.⁸⁻¹⁰ Additionally, optimal pressure may

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change with time secondary to aging, sedation or alcohol consumption, weight gain or loss, and nasal congestion.

In response to such problems with standard CPAP titration and treatment, auto-titrating devices (APAP) have been developed. If an APAP device could effectively titrate a patient without attendant intervention, the need for attended laboratory CPAP titration would be reduced. This may extend CPAP availability to a wider patient group, deliver treatment in a more timely manner, and potentially reduce costs. Additionally, auto-adjustment may continuously provide the minimum effective pressure both throughout a single sleep period, as well as from night to night. Such devices have the potential to adjust to changing patient pressure needs without requiring retitration studies. Because higher pressures are only provided when needed, it is possible that the lower average nightly pressure may increase patient comfort, acceptance and utilization. Another possible use for APAP would be for titration in attended settings. This would allow a technician to attend titration of more patients than usual.

Currently, several APAP units are available.¹¹⁻¹³ What is monitored (snoring, apnea, hypopnea, airflow limitation, impedance) and the algorithms for changing pressures vary between devices. In general, pressure increases to maintain airway patency and then decreases if no events are detected over a set period of time. Some APAP units store pressure vs. time data and many can record mask leak, apnea events, and hypopnea occurrences. When transferred to a computer, this information provides both detailed and summary night by night results. The clinician can use these results to select a fixed pressure for subsequent CPAP treatment or to monitor APAP utilization and reliability in the self-titrating mode.

The purpose of this practice parameter paper is to present recommendations for using APAP to determine or provide treatment for OSA, based on the accompanying review paper. The intent here is to present the evidence for APAP's utility, not to make direct treatment recommendations. Nonetheless, we recognize this information may affect treatment decisions. The American Academy of Sleep Medicine (AASM) has previously published practice parameters for the diagnosis of OSA and the recommendations here do not modify those guidelines.¹⁴ The AASM also has previously published practice parameters on the determination of CPAP pressure for the treatment of OSA.¹⁴ The recommendations here add to those previous guidelines when APAP is used to titrate CPAP or treat OSA.

METHODS

Based on the referenced review¹ and accompanying text, the Standards of Practice Committee of the AASM, in conjunction with specialists and other interested parties, developed recommendations included in this paper. In most cases the conclusions are based on evidence from controlled studies published in peer reviewed journals. Due to overlap with other topics, references are also made to prior AASM practice parameters. It is indicated when scientific data are insufficient or inconclusive. In such cases, consensus opinion may be used to support the available evidence.

The Board of Directors of the AASM approved these recommendations. All members of the AASM Standards of Practice Committee and Board of Directors completed detailed conflict-of-interest statements and were found to have no conflicts of

interest with regard to this subject.

These practice parameters define principles of practice that should meet the needs of most patients in most situations. These guidelines should not, however, be considered inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding propriety of any specific care must be made by the physician, in light of the individual circumstances presented by the patient, available diagnostic tools, accessible treatment options, and resources.

The AASM expects these guidelines to have an impact on professional behavior, patient outcomes, and, possibly, health care costs. These practice parameters reflect the state of knowledge at the time of publication and will be reviewed, updated, and revised as new information becomes available. This parameter paper is referenced, where appropriate, by square-bracketed numbers to the relevant sections and tables in the accompanying review paper. The Standards of Practice Committee's levels of evidence (Table 1) for treatment-related evidentiary articles used to support the strength of the recommendations (Table 2) in this paper appear in the review paper's evidence.¹

BACKGROUND

A number of auto-titrating positive airway pressure devices are commercially available. They monitor different parameters to detect breathing events and utilize a variety of algorithms to determine when and how much to increase or decrease pressure. In general the devices measure one or more of the following: snoring (airway vibration), airflow reductions (apnea or hypopnea), and the flow vs. time profile (airflow limitation). Recently, devices using the forced oscillation technique to monitor impedance have been developed.¹⁵ Most devices start with a low baseline pressure (usually 3-4 cm H₂O) and then increase pressure, as needed. An absence of monitored events prompts a gradual pressure decrease. This approach provides the minimum effective pressure needed to maintain airway patency as circumstances change (e.g., body position, or appearance of REM sleep).

Mask/mouth leaks and central apnea may lead to problems using APAP devices. For leaks, units may limit pressure increases when the leak exceeds certain values or when increased blower speed does not increase mask pressure. Other units employ leak alarms to prompt the patient or staff to readjust the mask.

Central apnea during APAP treatment or titration may occur in some patients. Cheyne-Stokes type central apneas are common in patients with congestive heart failure (CHF).¹⁶ Central apnea may appear in patients with OSA and CHF during CPAP titration after the airway obstruction of OSA is treated.¹⁷ Other patients with OSA may have central apneas after arousals as they fall back to sleep or which are the result of excessive CPAP pressure.¹⁸ Attempts to identify central apnea by detecting cardiac oscillations in the airflow tracing (open airway apnea) are not reliable because the airway can close during central apnea;¹⁹ therefore, the oscillations may not appear. Another approach limits the pressure increase for apnea when snoring or airflow limitation is absent; however, the problem persists in some patients. Furthermore, many of the reviewed clinical trials excluded patients with CHF.

Auto-titrating devices can be used to determine an optimal

fixed pressure level for long term treatment with a conventional CPAP device. If used during an attended study, the technician could intervene for mask leaks, and recognize hypoxemia, requiring oxygen in addition to CPAP. Potentially the most cost-effective use for APAP would be to perform unattended titration in the home.²⁰ To succeed, in addition to an effective APAP device, unattended titration requires adequate patient education about device use and mask application.¹³ Proper mask fitting is essential prior to unattended titration. Although several studies document APAP devices' ability to titrate or treat patients, most of these studies first acclimated patients to standard CPAP before applying APAP. This makes it difficult to determine if CPAP-naïve patients would respond similarly to unattended titration and treatment.

APAP devices allow data transfer to computers. Some systems provide the percentage time at each pressure while others supply detailed pressure, leak, and sleep-disordered breathing event information. The clinician can review data and decide on an appropriate fixed pressure. Two commonly used indices are maximum pressure and pressure only rarely exceeded. The 95th percentile pressure (P_{95}) is the pressure level exceeded only 5% of the time. Most devices will graphically display the percentage of time each pressure is applied and calculate pressure statistics (such as P_{mean} , P_{95} , and P_{maximum}) over a selected time interval; this allows several days worth of data to be used for selecting an appropriate pressure. In most published studies, investigators reviewed raw data to identify high mask leak occurrences. Many devices respond to high leak with increases in pressure to a set maximum.

In addition to performing as a titration aid, APAP's other main clinical use is for treating OSA. Some have suggested that because APAP delivers the minimum effective pressure, APAP use should improve patient comfort and utilization. In addition, APAP's ability to respond to changing pressure needs (e.g., increased pressure required after weight gain or increased nasal congestion) represents a potential advantage of auto-adjusting devices compared to fixed pressure devices. However, at present APAP devices have not been shown to significantly improve utilization or functional outcome (e.g., daytime sleepiness) compared to CPAP [Table 1 of review paper].

RECOMMENDATIONS

The following are recommendations of the Standards of Practice Committee and the Board of Directors of the American Academy of Sleep Medicine. The classification of evidence was adapted from the suggestions of Sackett²¹ (Table 1). Recommendations are given as standards, guidelines, and options, as defined in Table 2.

1. A diagnosis of OSA must be established by an acceptable method. (Standard) [Table 1]

Treatment for OSA must be based on a prior diagnosis of OSA. This recommendation is based on previous AASM recommendations on indications for CPAP titration.¹⁴ In addition, the evidence for use of APAP is based on a prior diagnosis of OSA. APAP devices as reviewed for these recommendations are for treatment only. These recommendations do not address, in any way, the use of APAP for diagnostic purposes.

2. Patients with the following conditions are not currently candidates for APAP titration or treatment. (Standard) [5.5, 5.8, Table 1]:

- congestive heart failure
- lung disease such as chronic obstructive pulmonary disease
- patients expected to have nocturnal arterial oxyhemoglobin desaturation due to conditions other than OSA (e.g., obesity hypoventilation syndrome)
- patients who do not snore (either due to palate surgery or naturally) should not be titrated with an APAP device that relies on vibration or sound in the device's algorithm.

Patients with congestive heart failure and lung disease generally have been excluded from previous trials or have shown nocturnal hypoxemia in some titration studies. Titration with devices that rely on snoring as a monitoring method in patients who do not snore either naturally or because of upper airway surgery is currently discouraged.

3. APAP devices are not currently recommended for split-night titration. (Standard)

None of the reviewed studies examined APAP under conditions of an initial diagnostic period followed by a titration period in the same overnight study.

4. Certain APAP devices may be used during attended titration to identify by polysomnography, a single pressure for use with standard CPAP for treatment of OSA. (Guideline) [4.0, 5.1, 5.2, 5.3, 5.6, Table 1]

One potential use of APAP is to identify a single pressure for use with a standard CPAP device for subsequent treatment of OSA. Based on Level I and II and Grade A and B evidence, APAP devices using methods that involve snoring, apnea or hypopnea monitoring by airflow, airflow against time, or impedance by the forced oscillation technique may effectively determine a pressure to reduce sleep-disordered breathing events to the same extent as standard CPAP titration. Current Level I and II and Grade A and B evidence is specific to each device, including current software and device version. Some devices have not been fully tested in Level I and II trials.²²⁻²⁴ Caution should be exercised in selecting a particular device for use. Titration is attended in these studies so that issues such as mask fit, pressure leak, and occurrences of transient hypoxemia can be identified and properly managed.

5. Once an initial successful attended CPAP or APAP titration has been determined by polysomnography, certain APAP devices may be used in the self-adjusting mode for unattended treatment of patients with OSA. (Guideline) [4.0, 5.2, 5.3, 5.6, 5.7, Table 1]

One potential use of APAP is to treat patients with OSA on a long-term basis. Based on Level I and II and Grade A and B evidence, APAP devices using methods that involve snoring, apnea or hypopnea monitoring by airflow, airflow against time, or impedance by the forced oscillation technique may effectively

adjust pressures to reduce sleep-disordered breathing events to the same extent as standard CPAP titration. Current Level I and II and Grade A and B evidence is specific to each device, including current software and device version. Caution should be exercised in selecting a particular device for use. Since the initial CPAP or APAP titration is attended, other issues such as mask fit, mask leak, and transient hypoxemia can be identified and managed at the time of titration.

6. Use of unattended APAP to either initially determine pressures for fixed CPAP or for self-adjusting APAP treatment in CPAP-naïve patients is not currently established. (Option) [5.1, 5.7 Table 1]

Most studies used patients with previously demonstrated CPAP or APAP efficacy including reduction of AHI by polysomnography, and proper mask fit and comfort. Only a few studies used unattended APAP as a first intervention in positive pressure-naïve patients. One Level I, Grade A study²⁵ used unattended APAP titration in the sleep laboratory to determine a subsequent fixed CPAP pressure that abolished most of the obstructive events comparable to conventional attended CPAP titration. Patients were fitted and educated about the use of the mask and APAP before unattended titration. Outcome as measured by the Epworth sleepiness scale and acceptance of CPAP were similar between the two groups. Two Level IV, Grade C studies used unattended APAP to determine a single CPAP pressure in CPAP-naïve patients and then treated patients with that fixed pressure.^{26,27} Therapeutically acceptable apnea/hypopnea indices were attained.^{26,27} One Level IV, Grade C study found less consistent results in the use of APAP for unattended titration and treatment.²⁸ Moreover, based on the studies cited in the review

paper,¹ attendant interventions were necessary in a number of patients during attended APAP titration. These interventions were mostly to correct mask leaks or improve mask fit. In addition, some patients require supplemental oxygen for nocturnal hypoxemia in addition to positive airway pressure. Of note, patients who are "mouth breathers" may also fail unattended titration.

7. Patients being treated with fixed CPAP on the basis of APAP titration or being treated with APAP must be followed to determine treatment effectiveness and safety. (Standard)

Based on committee consensus and previous recommendations of the AASM,¹⁴ follow-up with assessment of resolution of OSA and symptoms is necessary. Methods may include questionnaires for sleepiness and continued snoring, follow-up polysomnograms or cardiorespiratory studies, assessment of physical conditions such as an increase in weight, and capturing information stored on the APAP or CPAP devices including time on device, time at pressure, pressure and leak profiles, and residual apneas/hypopneas (if available).

8. A re-evaluation and, if necessary, a standard attended CPAP titration should be performed if symptoms do not resolve or the CPAP or APAP treatment otherwise appears to lack efficacy. (Standard)

If a patient's symptoms such as daytime sleepiness or observations of others such as continued snoring or observed apneas continue, a clinical reevaluation should be undertaken with attention to issues such as mask fit, mask leak, use of device, weight gain, and other clinical observations. If necessary, a standard in-laboratory standard CPAP titration with polysomnography should

Table 1—AASM classification of evidence

Recommendation Grades	Evidence Levels	Study Design
A	I	Randomized, well-designed trials with low alpha and beta error*
B	II	Randomized trials with high alpha and beta error*
C	III	Nonrandomized concurrently controlled studies
C	IV	Nonrandomized historically controlled studies
C	V	Case series

ADAPTED FROM SACKETT²¹

* Alpha error refers to the probability (generally set at 95% or greater) that a significant result (e.g., p<0.05) is the correct conclusion of the study or studies. Beta error refers to the probability (generally set at 80% to 90% or greater) that a nonsignificant result (e.g., p>0.05) is the correct conclusion of the study or studies. The estimation of beta error is generally the result of a power analysis. The power analysis includes a sample size analysis which projects the size of the study population necessary to ensure that significant differences will be observed if actually present.

Table 2—AASM levels of recommendations

Term	Definition
Standard	This is a generally accepted patient-care strategy, which reflects a high degree of clinical certainty. The term standard generally implies the use of Level I Evidence, which directly addresses the clinical issue, or overwhelming Level II Evidence.
Guideline	This is a patient-care strategy, which reflects a moderate degree of clinical certainty. The term guideline implies the use of Level II Evidence or a consensus of Level III Evidence.
Option	This is a patient-care strategy, which reflects uncertain clinical use. The term option implies either inconclusive or conflicting evidence or conflicting expert opinion.

ADAPTED FROM EDDY²⁹

be performed to document or determine the efficacy of the CPAP or APAP treatment. This recommendation is based on committee consensus and previous recommendations of the AASM on CPAP titration.¹⁴

FUTURE RESEARCH

To investigate APAP's full potential, unattended titrations in CPAP-naïve patients should be conducted against standard CPAP titration in randomized controlled trials. The issues of adaptation to the full set of circumstances associated with positive airway pressure titration need to be addressed. These include mask fitting, adverse event monitoring, mask leaks, and other circumstances requiring technician interventions. This may require APAP devices to record such events for review and for machines to incorporate alarms to alert a patient if dangerous falls in arterial oxyhemoglobin levels occur. At present, the type of patient who is a candidate for unattended APAP is somewhat limited because most previous studies excluded patients with increased potential for adverse reactions. Future research should focus on safely expanding the sample to include such patients.

The role of APAP in the evaluation and treatment of OSA needs to be better defined. Criteria for including or excluding patients who can be *APAP titrated* or *APAP treated* needs considerable refining. Finally, the situations and circumstances requiring follow-up polysomnography for APAP need definition.

Whether APAP is better tolerated or will improve utilization compared to CPAP remains an open question. The comparative utility of one APAP technology compared to another also needs clarifying. It is possible that one type of patient (e.g., a mouth breather or patients with predominant RERAs) may respond better to one technology vs. another. Also, patient responses to the same type of technology may differ depending on the specific device being used. This would require comparative studies of devices with differing as well as similar technologies to be carried out to clarify whether one device can be substituted for another in a given patient. Thus, the interaction between the specific technology and patient characteristics will provide a challenge for future refinement of management of sleep-related breathing disorders.

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