

Use of Nasal EPAP for the Treatment of Obstructive Sleep Apnea in Adult Patients: A Guide for Respiratory Therapists

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Summary

This guide is based on research and clinical practice experience regarding the use of nasal Expiratory Positive Airway Pressure (EPAP) [Provent Therapy] to treat obstructive sleep apnea (OSA). In clinical practice nasal EPAP has been used in: (1) patients with mild, moderate or severe OSA who have rejected or are non-compliant with prescribed CPAP; (2) newly diagnosed mild/moderate patients without significant co-morbidities; or (3) CPAP compliant patients looking for alternatives to current therapy or for travel. Follow-up polysomnography or portable monitoring is needed to verify efficacy. Regular follow-up is recommended to assess the patient for compliance and signs and symptoms of OSA.

1.0 Introduction

Nasal EPAP is a novel treatment of OSA (Figure 1). The device consists of a small valve attached externally to each nostril with hypoallergenic adhesive designed for single-night use. The valve acts as a one-way resistor, permitting unobstructed inspiration. During expiration, the airflow is directed through small air channels, increasing the resistance. This increased resistance

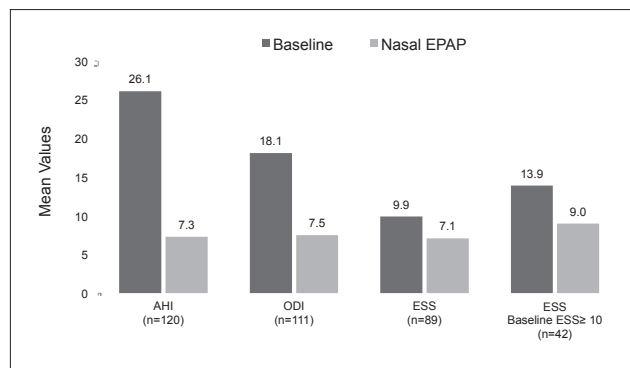


Figure 1. Nasal EPAP device. Single use valves are externally attached to each nostril and sealed with adhesive.

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during expiration creates EPAP which is maintained until the start of the next inspiration. Whereas CPAP provides positive pressure during both inspiration and expiration, EPAP only creates pressure during expiration.

The effectiveness of nasal EPAP has been validated through five published clinical trials¹⁻⁵ demonstrating statistically significant and clinically meaningful reductions in the apnea-hypopnea index, oxygen desaturation and daytime sleepiness as measured by the Epworth Sleepiness Scale (ESS). Figure 2 below presents a pooled data subgroup analysis⁶ of nasal EPAP responders from the five published studies.



(AHI reduced >50%)
p<0.001 for all groups

Figure 2. Pooled Data Subgroup Analysis of Nasal EPAP Responders

This paper is intended to provide suggested guidelines for patient selection, acclimation support and efficacy verification when using nasal EPAP for the treatment of OSA.

2.0 Methods

The guideline outlined on the next page is based on published nasal EPAP literature and clinical practice experience. While this guide outlines a recommended protocol for nasal EPAP, the treating physician is the one best suited to identify those most appropriate for EPAP therapy and to determine method of follow-up care.

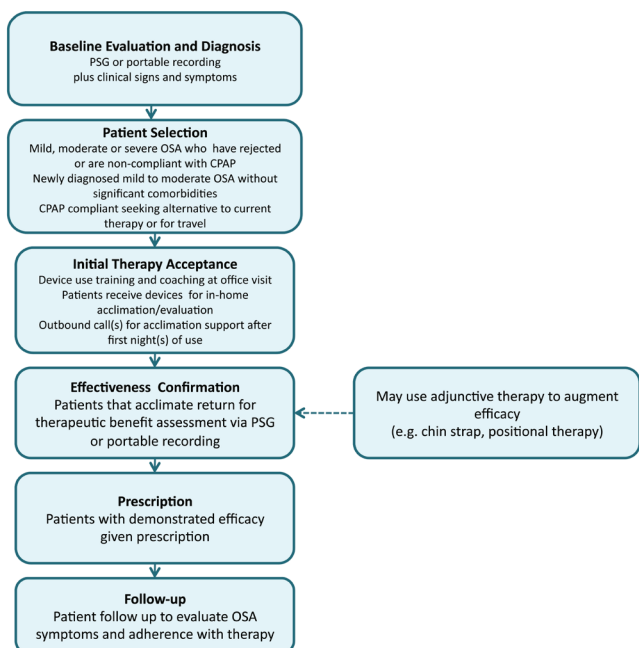


Figure 3. Suggested Guidelines for Nasal EPAP Use in OSA Patients.

Figure 3 summarizes a suggested pathway for patients considered for treatment with nasal EPAP therapy. More detailed recommendations are provided in section 3.0.

3.0 Recommendations

3.1 Diagnosis and Baseline Evaluation

An OSA diagnosis must be made and the severity of disease determined before evaluating treatment options. Either in-laboratory polysomnography (PSG)⁷ or portable recording⁸ are recommended to confirm the diagnosis.⁹ Both modalities provide objective results (AHI/RDI, ODI) that can be compared to results following the initiation of nasal EPAP treatment. The diagnostic criteria for OSA include the PSG or portable monitoring findings as well as clinical signs and symptoms.

3.2 Patient Selection

Nasal EPAP may be considered for the following patients:

1. Patients with mild, moderate or severe OSA who have rejected or are non-compliant with prescribed CPAP;
2. Newly diagnosed mild/moderate patients without significant co-morbidities; or
3. CPAP compliant patients looking for alternatives to their current therapy or for travel.

At this time, there is no data to predict which patients will be most effectively treated with nasal EPAP based on specific patient characteristics.

3.3 Initial Therapy Use and Acceptance

During an office consultation, a trained practitioner or designee should instruct each patient how to properly apply the nasal EPAP device, and refer the patient to the Instructions for Use booklet. An in-office demonstration of Provent application may be helpful.

Instruct patients to:

1. Start with a clean, dry face. Stand in front of a mirror.

2. Grasp the small tab to peel the device off the backing.



3. Align the plastic portion of the device with your nostril to ensure correct placement.



4. Drop your upper lip downward (as if shaving the mustache area).



5. Apply and press down gently on the adhesive to create a seal. Ensure there are no air leaks. Use the thumbs or fingers to completely cover the oval mesh over both nostrils and gently exhale through the nose to confirm that no air is escaping past the adhesive.



6. Repeat device application on other nostril. Breathe through the device to feel it working.

The following points should be shared with patients to set their expectations regarding acclimation:

1. The device works by making it harder to breathe out.
 - This creates pressure which keeps your airway open.
2. Breathe out through your mouth when awake and attempting to fall asleep.
 - You'll naturally breathe out through the device when you fall asleep.
3. It may take time to get used to wearing the device.
 - Give it a few days; you should feel a lot better.
4. You may take it off (if necessary).
 - If you wake up during the night and feel uncomfortable, open your mouth and try to fall back asleep. If unsuccessful, just take the device off your nose. Try to sleep with it the next night.

Follow-up with the patient after the first night(s) of device use to provide coaching and encouragement may enhance the acclimation process.

3.4 Effectiveness Confirmation

After patients acclimate to nasal EPAP during the initial evaluation period, they should undergo an assessment of effectiveness to ensure a satisfactory therapeutic benefit. It is

suggested that the same methodology used for OSA diagnosis be used for effectiveness verification in order to readily compare the outcomes. As noted in section 3.1, these verification methods include in-lab PSG or portable recording to obtain objective results.

A specially-designed nasal cannula from Ventus Medical can be used to securely attach to the nasal EPAP device to allow for standard measurement of nasal airflow via nasal pressure during a PSG or portable monitoring (Figure 4).



Figure 4. Nasal Cannula Attached to EPAP Device.

A retrospective review of clinical practice data¹⁰ suggests that adjunctive therapy such as the use of positional therapy or chin straps may augment the effectiveness of nasal EPAP. During an in-lab PSG, this can be evaluated by the technicians monitoring the sleep study.

Positional therapy may be considered when non-supine AHI values with nasal EPAP reach therapeutic levels but AHI values in the supine position are not completely therapeutic.

Chin straps may be evaluated for patients who, while wearing nasal EPAP, continuously vent through the mouth thus preventing the creation of the required nasal expiratory pressure to help keep the airway open.

3.4 Prescription and Device Use

Patients with demonstrated efficacy may be given a prescription for nasal EPAP by a licensed health care practitioner. Nasal EPAP devices are intended for a single night of use and should be discarded after wearing. Patients may use nasal EPAP as a primary therapy or some may opt to continue with CPAP and use nasal EPAP for travel. As with CPAP therapy, if nasal EPAP is used as a primary therapy, optimal therapeutic effect will be achieved only with consistent nightly use.

3.5 Follow-up

Patients should be scheduled for periodic follow-up office visits to assess patient compliance with nasal EPAP as well as to evaluate signs and symptoms of OSA.

4.0 Conclusions

This guide was developed based on the current nasal EPAP clinical literature and clinical practice experience. Nasal EPAP may be used to treat all severities of OSA and effectiveness

must be confirmed with an in-lab PSG or portable monitoring. Device use training and acclimation coaching are key elements to achieve patient acceptance of the therapy. Patient selection and effectiveness assessment with nasal EPAP are ultimately the responsibility of the prescribing physician.

5.0 References

1. Colrain IM, Brooks S, Black J. A pilot evaluation of a nasal expiratory resistance device for the treatment of obstructive sleep apnea. *J Clin Sleep Med* 2008;4:426-33.
2. Rosenthal L, Massie CA, Dolan DC, Loomas B, Kram J, Hart RW. A Multicenter, prospective study of a novel nasal EPAP device in the treatment of obstructive sleep apnea: efficacy and 30-day adherence. *J Clin Sleep Med* 2009;5:532-7.
3. Walsh JK, Griffin KS, Schweitzer PK, et al. A convenient expiratory positive airway pressure nasal device for the treatment of sleep apnea in patients non-adherent with continuous positive airway pressure. *Sleep Medicine* 2011;12:147-152.
4. Patel AV, Hwang D, Rapoport DM, et al. Predictors of response to a nasal expiratory resistor device and its potential mechanisms of action for treatment of Obstructive Sleep Apnea (OSA). *J Clin Sleep Med* 2011;7:13-22.
5. Berry, RB, Kryger, MH, Massie, CA. A novel nasal expiratory positive airway pressure (EPAP) device for the treatment of obstructive sleep apnea: a randomized controlled trial. *SLEEP* 2011;34(4):479-485.
6. Ventus Medical, Data on File.
7. Kushida CA, Littner MR, Morgenthaler TI, et al. Practice parameters for the indications for polysomnography and related procedures: an update for 2005. *SLEEP* 2005;28(4):499-521.
8. Collop NA, Anderson WM, Boehlecke B, et al. Clinical guidelines for the use of unattended portable monitors in the diagnosis of obstructive sleep apnea in adult patients. *J Clin Sleep Med* 2007;3:737-47.
9. Epstein LJ, Kristo D, Stroll PJ, et al. Clinical guidelines for the evaluation, management and long-term care of obstructive sleep apnea in adults. *J Clin Sleep Med* 2009;5(3):263-76.
10. Adams, G, Retrospective cases series analysis of a nasal expiratory positive airway pressure (EPAP) device to treat obstructive sleep apnea in a clinical practice, *SLEEP Abstract Supplement*, 2011 (34):A146.