**REPORT OF THE AASM CLINICAL PRACTICE REVIEW COMMITTEE**

Nonprescription Treatments of Snoring or Obstructive Sleep Apnea: an Evaluation of Products with Limited Scientific Evidence

Report of the Clinical Practice Review Committee, American Academy of Sleep Medicine

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**Purpose:** To evaluate the level of evidence regarding the safety and efficacy of nonprescription treatments used to treat snoring and obstructive sleep apnea, and form a consensus statement based on available data.

**Reviewers:** Members of the American Academy of Sleep Medicine’s Clinical Practice Review Committee.

**Methods:** A search of PubMed database using MeSH terms snore, apnea, and obstructive sleep apnea in August, 2002, including only articles published in English between 1990 and 2002 and of the World Wide Web, using Google search engine and the key words snoring and obstructive sleep apnea. Letters were sent to manufacturers of lubricant oral and nasal products requesting copies of scientific studies to support their claims.

**Results and Conclusions:** Given the paucity and quality of scientific literature regarding the nonpharmacologic treatment of snoring and obstructive sleep apnea, members of the Clinical Practice Review Committee had insufficient information to develop standards of practice recommendations. Nevertheless, substantial publicity regarding such treatments is available to the general public. Very limited data are available to support a beneficial effect of these devices on snoring and minimal evidence is available to support their use in treating obstructive sleep apnea. Studies are limited by small numbers of participants and, in some instances, inadequate design, lack of statistical analysis, and sparse use of objective measurements. Many studies do not evaluate product safety, especially over extended use. Physicians may find this information useful in counseling their patients.

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### 1.0 INTRODUCTION

STANDARD TREATMENTS FOR OBSTRUCTIVE SLEEP APNEA (OSA), INCLUDING UPPER-AIRWAY SURGERY AND THE USE OF POSITIVE-AIRWAY-PRESSURE APPLIANCES AND DENTAL APPLIANCES, HAVE EXTENSIVE SCIENTIFIC EVIDENCE THAT DETAILS THEIR SAFETY AND EFFICACY.1-4 Weight loss and positional therapy may be useful adjuncts to control snoring in some patients; their application in treating OSA is supported by limited long-term outcome data. In addition, alternative treatments, including a variety of nonprescription products, are marketed for the treatment of snoring and, less frequently, OSA.

By using nonprescription products to treat their snoring and OSA, people may gain a sense of control, avoid the time and expense associated with consulting a physician or other healthcare provider, and feel that they are using a “safe and natural” method. This final assumption, in particular, raises several concerns: 1) substances that have an effect upon a person’s state of health are inherently associated with side effects; 2) “natural” products are not necessarily non-toxic; 3) the preparation of nonprescription products lacks both standardization and review; and, most importantly, information detailing the efficacy and safety of these products is not commonly available to practitioners or the general public. Given these concerns the Clinical Practice Review Committee of the American Academy of Sleep Medicine evaluated the safety and efficacy of several nonprescription methods of treating snoring and OSA.

### 2.0 METHODS

A search of the World Wide Web was conducted using the terms snoring and OSA. A list of nonprescription treatments, including lubricant nasal and oral sprays, internal and external nasal dilators, and herbal remedies, was compiled from the results. For lubricant nasal and oral sprays and oral dietary supplements, a list was also made of manufacturers. Sixteen companies were identified, contacted by letter, and invited to provide information regarding safety and efficacy of their products; six companies responded.

Literature searches (PubMed) limited to the English language were conducted from 1990 to 2002. Additional searches using the terms external nasal dilators, internal nasal dilators, nasal lubricants, herbal treatments for snoring or OSA and individual product names were also conducted. Members of the Clinical Practice Review Committee, an American Academy of Sleep Medicine committee comprising a multidisciplinary group of clinicians, extracted the data from the search results. Committee members are comprised of pulmonary, neurology, Ear Nose and Throat surgery and pediatric specialists. A consensus of committee members was used to formulate the conclusions.

### 3.0 RESULTS

#### 3.1 MECHANICAL PRODUCTS

##### 3.1.1 External Nasal Dilator Strips

External nasal dilator strips (ENDS) mechanically pull the lateral nasal vestibule walls outward by means of 2 parallel springs enclosed in an adhesive strip. The United States Food and Drug Administration (FDA) has approved their use “...to provide temporary relief from transient causes of breathing difficulties resulting from structural abnormalities and/or transient causes of nasal congestion associated with reduced airflow.”

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Report of the AASM Clinical Practice Review Committee
3.1.1.1 Physiologic Effects of ENDS

In a number of studies, ENDs have been shown to enlarge the total cross-sectional area of the nasal airway in healthy adults by 14.2% to 25%, with up to an 8-hour duration in 1 study. The effect is most pronounced at the level of the nasal valve, the flow-limiting segment of the nasal airway located between the caudal edge of the upper lateral cartilage, the nasal septum, and the nasal floor. Increases of 16% to 35% in cross-sectional area in this region are reported. Significant increases in inspiratory nasal flow rates with ENDS have also been shown in healthy adults. Changes in nasal resistance in healthy subjects are less consistent, however, with some investigators, but not others, noting significant improvement. In patients with symptoms of nasal obstruction, the etiology of the nasal symptoms may have a particular significance in determining the response to ENDS. Roithmann et al found a greater reduction in nasal resistance, an increase in nasal mean cross-sectional area, and an improvement in subjective nasal patency, in patients with structural nasal abnormalities versus those with mucosal abnormalities. Most studies of nasal geometry, flow and resistance have shown marked intersubject variation. One proposed explanation for this variability is individual differences in lateral nasal wall compliance. Ethic differences may also account for variable response rates with the use of ENDS. Two studies found significant improvement in nasal mean cross-sectional area in Black and White subjects, although 1 study found a greater improvement in White subjects and the other in Black subjects. Reduction in nasal resistance was found in White subjects but not in Black subjects. The only report in an Asian population found an increase of 16% in total mean nasal cross-sectional area. Most studies of nasal geometry, flow and resistance with ENDS have been performed in White populations, which could increase the likelihood of a positive outcome. In others, the ethnicity of study participants was not given. All of these studies were performed during wakefulness, and caution is warranted in generalizing these improvements in nasal airflow and cross-sectional area to effects during sleep.

3.1.1.2 Efficacy and safety of ENDS for snoring and OSA

Manufacturers have proposed that ENDS are a useful treatment for snoring; five studies have been conducted and published that examined their efficacy. One study found significant reductions (p<0.001) in bedpartner ratings in subjective snoring intensity after 2 weeks of ENDS use. Changes in objective snoring measurements have been mixed. Liistro et al performed polysomnography before and after ENDS in a group of nonapneic snorers. No significant improvement in sleep parameters or snoring index was found in their series. A subgroup of patients with nasal-valve anomalies also had no significant differences. A larger series of polysomnographically recorded habitual snorers had significant improvement in maximum snoring intensity (p=0.02) and snoring index in those with baseline levels greater than 20 decibels (p=0.02) during treatment with ENDS. Subgroup analysis found significant reduction in snoring intensity and duration only in nonapneic snorers and mild snorers. The only significant changes in sleep architecture during treatment included an increased latency to Stage 2 sleep (p=0.04) and a decrease in delta and theta power (p=0.04), suggesting impaired sleep. However, subjective ratings of sleep quality improved on treatment nights. Another study suggested that the use of ENDS may decrease arousal frequency in nonapneic snorers.

The use of ENDS has been evaluated in four studies as a treatment for OSA. In their nonrandomized study of 26 patients with a history of sleep disordered breathing, Joseph et al found a small reduction in the mean apnea-hypopnea index (AHI)—from 31.7 to 26.3—which was statistically (p=0.031) but not clinically significant. However, only 4 patients (pretreatment AHI ranging from 10.3 to 16.7) had a posttreatment AHI of less than 10. Other researchers noted no significant reduction in AHI with the use of ENDS. In their study, Djupesland et al observed a significant increase (p<0.05) in AHI with the use of ENDS; patients with more severe pretreatment levels of OSA or less severe pretreatment nasal obstruction had the largest increases in AHI. No significant changes in sleep architecture were found in this series. In contrast, a randomized, double-blind, controlled study in 18 patients with upper-airway resistance syndrome showed significant improvements in 2 variables: 1) the percentage of stage 1 sleep decreased from 8.6% ± 0.8% on placebo nights to 7.1% ± 0.7% on treatment nights (p=0.03), and 2) the desaturation time, defined as the percentage of sleep time with an oxygen saturation more than 2% below the mean wake level, decreased from 12.2% ± 2.2% to 9.12% ± 1.3% (p=0.04). However, no significant change occurred in total sleep time, other sleep-stage amounts, arousal index, AHI, or sleepiness as measured by the Multiple Sleep Latency Test. Only one study evaluated tolerance of ENDS. Out of 30 habitual snorers, tolerance was rated as good or very good by 29 after the first treatment night. The only adverse effect was an urgency to sneeze after ENDS application in one subject.

3.1.1.3 ENDS-Conclusions

The use of ENDS increases nasal cross-sectional area and improves nasal airflow during wakefulness in some subjects, but the effects have not been studied during sleep and the decrease in nasal resistance varies. Efficacy may be affected by ethnicity and pretreatment nasal pathology. The clinical series that have been conducted are of limited scientific quality, have included small numbers of subjects (ranging from 9 to 35), and frequently lack placebo control.

The use of ENDS appears to be safe and may be efficacious in people with mild, nonapneic snoring, but data are inadequate to determine patient characteristics associated with favorable treatment. The limited available studies revealed not only no meaningful improvement in OSA with the use of ENDS, but also the potential worsening of disease severity with an increased AHI in some subjects. Thus, there is insufficient evidence to support the efficacy of ENDS in snoring with or without OSA.

3.1.2 Internal Nasal Dilators

Various designs of internal nasal dilators (IND) exist. One design, a plastic device placed into the nose, is held stationary by means of end tabs that contain knobs that then press against the lateral nasal vestibule walls. Another IND incorporates a flexible looped spring made of biocompatible stainless-steel wire that exerts circumferential outward pressure in the nasal vestibules. The FDA has approved the use of these devices “...to provide temporary relief from transient causes of breathing difficulties resulting from structural abnormalities and/or transient causes of nasal congestion associated with reduced airflow.”

3.1.2.1 Physiologic Effects of IND

In a brief report, Petruson published results of a study that assessed nasal airflow with the use of a plastic-type IND in 16 asymptomatic subjects, aged 25 to 60 years. Using active posterior nasal rhinometry, he found that nasal airflow increased with the use of this device from 0.68 liters per second to 0.84 liters per second. Statistical analysis was not performed. This same type of device was studied in 17 asymptomatic subjects aged 20 to 24 years before and after nasal inhalation of an α-adrenergic agonist. Nasal resistance measured by active posterior nasal rhinometry was significantly reduced by 65% ± 16% (p<0.001) and 63% ± 18% (p<0.0001) of baseline after insertion of IND and inhalation of nasal decongestant, respectively. However, combined treatment with the IND and decongestant yielded a reduction in nasal resistance to only 31% ± 10% (p<0.001) of baseline. Although this was a statistically significant change from baseline, it was also a significantly smaller change than either treatment alone. In another study, this same group of investigators reported changes in nasal resistance with this type of IND and topical nasal decongestant in 15 asymptomatic subjects aged 18 to 45 years. The use of the IND and a decongestant significantly and similarly reduced nasal resistance.
In a preliminary report of subjects with anterior nasal obstruction using the wire-spring type of IND, 12 of 15 patients reported subjective improvement in breathing. All objective measurements of nasal patency or airflow were used. Of 20 initial participants, 4 refused to try the prosthesis, and 1 did not tolerate it. A brief report by these same investigators noted reduced nasal resistance measured by anterior rhinometry in most patients but did not provide details regarding the magnitude or significance of reduction. In another report in 10 healthy subjects, the use of an IND resulted in 24.9% and 29.6% increases in peak inspiratory nasal airflow before and after application of a topical decongestant, respectively. Peak nasal flow was not significantly increased in either state.

Subjects reported in these studies were free of upper or lower respiratory complaints, though the authors did not provide the methods of assessment. The population from which participants were chosen and the methods of selection were also not detailed. None of the studies cited disclosed ethnicity of study participants. All studies were performed in subjects while awake, and changes in nasal airflow with INDs may not generalize to sleep.

3.1.2.2 Efficacy of IND for the Treatment of Snoring and OSA

All studies investigated the efficacy of a plastic-type IND in treating snoring and OSA. In an uncontrolled ambulatory study, bed-partner ratings of snoring intensity were reduced in 10 subjects, 8 men and 2 women using an IND for 5 nights (p<0.001). Subjective reduction in snoring was also found in an uncontrolled series of 42 male snorers using an IND for one month (p<0.001). This series assessed daytime tiredness rated by a 0 to 100 visual-analog scale. The mean baseline score of 58 was reduced to 43 with IND use (p<0.001). In a small series of Japanese subjects, snoring was reduced in all patients based upon subjective bed-partner reports, though no statistical analysis was performed.

Relatively few efficacy studies have used objective measures. A nonrandomized, uncontrolled report of 10 patients undergoing polysomnography to evaluate snoring showed no significant change in frequency of snoring, apnea severity, or oxygen saturation levels with IND use. A randomized, unblinded study of 11 patients used polysomnography with sound-level measurement to determine IND efficacy. None of the subjects suffered from nasal pathology except for some minor nasal septal deviation. Mean apnea index was 18 (range, 1.8 - 60) and 6.4 (range, 1.3 - 15) without and with the IND, respectively. Other determinants of sleep-disordered breathing, such as hypopnea-related and respiratory-effort-related arousals, were not assessed. No change in sleep architecture was found. A significant reduction (p=0.02) in snoring intensity, defined by the number of epochs with the level of snoring noise above 55 decibels, was found in the whole group. Yet, only 6 of the 10 subjects had more than 2 epochs with this intensity of snoring prior to treatment. No subjective improvement in daytime hypersomnolence after 10 days of home use was found. One subject was not able to tolerate use of the IND during sleep.

Hoffstein et al studied 15 subjects without nasal pathology using polysomnography with sound-level measurement. During one study night, IND was inserted in the latter portion of the night. They noted a statistically significant reduction in percentage of time with snoring but only in Stages 3 and 4 non-rapid eye movement (NREM) sleep (64% \pm 39% vs 33% \pm 43%, p<0.05). Mean AHI, oxygen saturation, and total sleep time were unchanged after IND insertion, although the number of patients with an AHI greater than 10 per hour of sleep increased from 8 to 11. This study is confounded by the significant differences in percentage of Stages 3 and 4 NREM and rapid eye movement (REM) sleep before and after IND insertion. As would be expected, slow wave sleep was reduced and REM sleep was increased in the latter portion of the night and may have affected the evaluation of the IND efficacy. Furthermore, the study design is flawed by the failure to control sleep variables during baseline and treatment periods.

No studies of long-term compliance with IND have been performed. However, the results from Hoijer et al would suggest limited compliance. Four of 11 subjects in that series opted to continue using an IND beyond the 10-day study. Additionally, in the study by Shinkawa, 3 of 18 patients dropped out over the 8-day treatment period; 60% of the remaining 15 subjects chose to continue using the IND after completion of the study.

Individual intolerance has been reported in several studies. Displacement during sleep may also be a problem. Finally, there is a potential but thus far unreported risk of mucosal ulceration and subsequent infection.

3.1.2.3 IND—Conclusions

Very limited evidence suggests that the use of an IND improves nasal resistance or airflow. All studies had small sample sizes, were not controlled, and frequently included a large degree of overlap between treatment and nontreatment variables. The available studies indicate that snoring intensity may be reduced. There are no studies reporting an improvement in OSA. Furthermore, improvement in nasal resistance, nasal airflow, or snoring intensity across ethnic groups and in nasal disease states is unknown. Thus, IND may be useful to treat snoring in some patients although long-term compliance appears to be poor. There is no evidence to support the use of IND in the treatment of OSA.

3.2 PHARMACOLOGIC PRODUCTS

3.2.1 Lubricant Nasal and Oral Products

A variety of lubricant sprays or drops are designed for use in the nose or throat. These products are advertised as a method for snoring reduction rather than a treatment for OSA or other medical conditions.

Several manufacturers have provided results of unpublished studies, which they sponsored, to evaluate individual product efficacy. One manufacturer of an orally applied lubricant reported statistically significant reductions in subjective snoring intensity and duration in 25 patients for five days of product use. Objective affirmation of product efficacy was not provided.

Another oral spray underwent a multiphase, unpublished trial of product efficacy and safety sponsored by the manufacturer. A questionnaire was given to 100 patients and their mates to establish efficacy, with 97% of the 56 respondents reporting a reduction in snoring. It is unknown how patients were selected. Next, 100 patients were contacted by phone after three weeks of product use with none reporting adverse reactions. polysomnography was performed in 20 patients in the final testing phase. The product was used only in the second half of the night, with improvement in snoring defined as any reduction in average decibel level measured by sound meter, in 97%.. The data presented in this unpublished report do not include enough detail to allow for analysis. Neither study report provided by the manufacturers included complete information regarding methodology or results to firmly establish product efficacy.

A two-week, randomized study in middle-aged, overweight adults objectively and subjectively evaluated the use of an herbal nasal spray. Although no significant differences in objectively measured snoring intensity or frequency occurred, subjective patient and bed-partner reports showed a lessening in snoring intensity in 65% of participants. Such results highlight the importance of objectively documented efficacy in such products. The Federal Trade Commission (FTC) issued a consumer alert about such products after reaching a settlement with one
manipulation over unsubstantiated claims of efficacy.37 Limited data have been published in studies concerning the efficacy of soft-tissue lubricants in snoring reduction. An intranasal phosphocholinamin preparation, derived from lecithin in a mineral oil fraction, was studied in comparison to tap-water placebo to determine if a reduction in airflow turbulence by means of soft-tissue lubrication reduced snoring.38 Using sound-meter measurements, the treatment group experienced a 25% reduction in the snoring index and a 13% reduction in the maximal decibel level. The placebo group had 1% and 9% reductions, respectively. The changes between active and placebo groups was statistically significant (p<0.05). Both the treatment and placebo groups comprised patients with moderate OSA, yet the AHI after treatment or placebo is not provided. In a placebo-controlled crossover study, Jokic et al evaluated the effectiveness of intranasally administered phosphocholinamin in 10 men with mild to moderate OSA.39 The mean baseline AHI was 17; after phosphocholinamin administration, it was 14 and after placebo administration, 24 (p<0.0003). The AHI in the treatment group was reduced only during NREM sleep. No significant change occurred in total sleep time, sleep efficiency, or sleep architecture.

3.2.1.2 Safety of Lubricant Nasal and Oral Products

Safety is based largely on unpublished reports. No published reports of adverse effects exist. One strong concern with the use of these products arises from the potential delay in appropriately diagnosing OSA because consumers may use a “quick fix” rather than seek medical attention. Consumer testimonials provided by some manufacturers mention the pretreatment presence of witnessed apneic spells during sleep, a significant symptom of OSA. In its recent settlement, the FTC required substantial disclaimers of product ineffectiveness for OSA and listing of significant symptom of OSA. The use of these products should be limited to patients with primary snoring.

3.2.2 Oral Dietary Supplements

Efficacy of oral dietary supplements is primarily based upon subjective reports; however, a single randomized, placebo-controlled study evaluated an oral product containing Nux vomica, belladonna, Ephedra vulgaris, Hydrastis canadensis, Kali bichromicum, Teucrium marum and Histaminum hydrochloricum.41 The subjects and bed partners reported that treatment resulted in a 79.5% reduction in subjective snoring, compared to a 45.6% improvement in the placebo group (p=0.0009). This latter finding emphasizes the importance of a potential placebo effect of antisnoring products.

An isolated case report describes the treatment of OSA with San’o-shashin-to, a Chinese herbal preparation of scutellariae radix, coptis rhizoma and rhei rhizoma.42 A 76-year-old, nonobese patient with a pre-treatment AHI of 18.4 was treated for an unspecified duration with various herbal remedies, including San’o-shashin-to. An AHI of 10.7 was documented by polysomnography approximately 1 month later. No additional information such as sleep staging or body position was noted, and no statistical analysis was performed. The clinical significance of this difference is uncertain given the known night-to-night variability in AHI in OSA patients.43

3.2.2.2 Safety of Oral Dietary Supplements

Safety is largely assumed based upon lack of reported adverse effects. Delay in diagnosis of OSA is a concern for these products as well. The presence of prescription substances in herbal products has been docu-

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<th>TABLE 1—TREATMENTS FOR SNORING AND OSA WITH LIMITED SCIENTIFIC EVIDENCE</th>
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<td><strong>TREATMENT</strong></td>
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<td><strong>External Nasal Dilators (ENDS)</strong></td>
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*Theoretical adverse reactions.
mented, though not specifically in antisnorning preparations.44 Some enzymes, such as amylase and cellulase, contained in these products have been associated with IgE-mediated symptoms in occupationally exposed individuals.45-47 Lower-level exposure to enzyme preparations has also been associated with hypersensitivity symptoms.48 A potential concern of allergic reactions to these products should exist, though the minimal levels of exposure are not known.

3.2.2.3 Conclusions-Oral Dietary Supplements
Extremely limited subjective data suggests a reduction in snoring with oral dietary supplements. There is no published scientific literature using objective measurements to support efficacy of dietary supplements for the treatment of snoring or OSA.

3.3 OTHER PRODUCTS

3.3.1 Magnetic Pillows and Mattresses
Magnetic therapy products have been marketed for a variety of ailments. However, a recent visit to one distributor’s web site found no mention of snoring or sleep apnea as conditions that might benefit from the use of these items.49

3.3.1.1 Effectiveness of Magnetic Pillows and Mattresses
The only paper in the scientific literature that objectively evaluated sleep apnea with polysomnography before and after treatment with magnetic pillows and mattress pad found this therapy to be ineffective for snoring and sleep apnea.49

3.3.1.2 Safety of Magnetic Pillows and Mattresses
In the one study identified, no evaluation of safety or tolerance of magnetic pillows and mattress pads was performed.

3.3.1.3 Conclusions—Magnetic Pillows and Mattresses
There is no evidence to suggest any efficacy of magnetic pillows and mattresses for the treatment of either snoring or obstructive sleep apnea.

4.0 SUMMARY
The use of complementary and alternative medicine is growing among the American public for the treatment of a variety of medical conditions, including sleep disorders. Generally, these treatments have not been submitted for rigorous scientific scrutiny and are not tightly regulated by the FDA. Nevertheless, they are often heavily promoted by their manufacturers and used by many Americans.

As summarized in the Table 1, the available data is very limited and suggests that ENDS, INDs, and nasal or oral lubricants may have a beneficial effect on snoring, but their usefulness for the treatment of OSA has not been demonstrated. Even less evidence supports the potential benefit of oral dietary supplements for the treatment of snoring. No evidence supports the use of magnetic therapy for the treatment of either snoring or OSA.

Physicians and other health care providers should be aware of this information in order to appropriately counsel their patients regarding the usefulness of complementary and alternative medicine in the treatment of snoring and OSA. This review highlights the need for further studies to ascertain the usefulness of these potential therapies to treat snoring and OSA.

5.0 REFERENCES

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