Evaluation of the Efficacy of a Nasal Dilator in Habitual-Snorer Patients

Luigi Ferini-Strambi, M.D., Vincenza Castronovo, RPSCT,
Daniele Bizzozero, RPSCT, Alessandro Oldani, M.D.

Aim of this study was to evaluate the effects of a non-invasive external nasal dilator (Breathe Right) in a selected sample of habitual snorers without OSA. Twenty subjects have been evaluated before and after 8-night treatment by means of a portable multi-channel monitoring device (MESAM 4). Snoring percentage (a visual scoring of each 5-min epoch was performed) resulted lower in the "treatment nights" in comparison to baseline (25.7% vs 32.9%), but the difference was not statistically significant ($p<.06$). Seven subjects were arbitrarily defined as "responders" since they had a reduction > 10% of the snoring percentage in the "treatment nights". No difference was found in the clinical, ENT, cephalometric characteristics between "responders" and "non-responders". Snoring percentage variation with the nasal dilator was significantly correlated with the subjective improvement of sleep quality ($p=.02$). (Sleep and Hypnosis 1999;1:173-176)

Key words: nasal dilator, snoring

INTRODUCTION

It has been suggested that conditions associated with nasal obstruction predispose to the development of snoring and OSA (1,2). Some authors indicated that the nose accounts for approximately half of the total airway resistance to airflow (3). Nasal obstruction may contribute to an increase in snoring and sleep apnea frequency and severity (4). For this reason, nasal dilators have been proposed as a cure for snoring.

In 1905, Francis (5) proposed a nasal prosthesis to treat nasal obstruction. This appliance could be inserted into the nose dilating the region of the nasal valve. Many years later, some nasal dilators were tested and some authors reported subjective improvement in nocturnal breathing in some snorer patients or they demonstrated reduction in measured snoring frequency in slow-wave sleep (6). A type of nasal dilator that is currently used is a non-invasive external dilator ("Breathe Right", CNS, Inc., Minneapolis, MN) that is drug-free, elastic, has a small adhesive strip featuring a special backbone that mechanically improves nasal breathing by opening the nasal passages to reduce airflow resistance. Scharf et al (7) tested it in 20 light snorers using strictly subjective criteria to assess snoring. There was no statistically significant difference in snoring loudness between the baseline and the treatment nights, although the subjects reported significantly easier breathing and demonstrated reduction in sleepiness as assessed by the Stanford Sleepiness Scale.

Another recent polysomnographic study showed that "Breathe Right" nasal strip reduces the sleep fragmentation in snorers without OSA (8). A portable multichannel monitoring device (MESAM 4) permits the objective evaluation of snoring and oxygen desaturations during the night (9,10). The snoring signal recorded by MESAM 4 has been validated using spectral analysis to identify snoring (11). Thus, MESAM 4 may be useful to establish if nasal dilators are successful in reducing snoring. Aim of this study was to evaluate a sample of selected habitual snorer subjects without OSA in order to objectively test the efficacy of Breathe Right nasal strip in reducing snoring.

METHOD

Subjects

We evaluated subjects (both males and females) in good health with an age range between 30 and 65 years, referred

From the Sleep Disorders Center, University of Milano, Milano, Italy.

Address reprint requests to: Luigi Ferini Strambi, MD
Sleep Disorders Center, University of Milano
H San Raffaele Via Prinetti 29 20127 Milano, Italy
Tel: 39-2-2643.3363 Fax: 39-2-2692 1777

Accepted May 5, 1999.

to our Sleep Disorders Center for habitual snoring.

Patient Inclusion Criteria were:

1) Habitual snoring (defined, by the interview of spouses or household members, as every-night snoring) from at least one year;
2) Body Mass Index (BMI) < 30;
3) Posterior Airway Space (PAS), evaluated by cephalometry > 7;
4) Respiratory events per hour of sleep (RDI) < 10 (evaluated by a nocturnal polysomnography);

Patient Exclusion Criteria were:

1) Major medical and other concomitant medical and psychiatric disorders;
2) Alcohol consumption > 30 g/day;
3) Smoking > 5 cigarettes/day.

Study participants read, understood, and signed an informed consent containing detailed information on the study protocol.

Study Design

all subjects underwent:

1) Clinical evaluation by a physician expert in sleep disorders;
2) ENT consulting (an arbitrary scale was used to evaluate the degree of obstruction on the following sites: nose [from 0-absence of stenosis to 4-severe stenosis], oropharynx [from 0-maximum patency to 3-severe obstruction], tongue [from 0- normal tongue and normal lingual tonsil dimension to 3- macroglossia and severe hypertrophic lingual tonsil]) (12);
3) Craniofacial cephalometry to evaluate soft tissue and skeletal landmarks, according to a method previously described (12);
4) Ambulatory polysomnographic recording by means of Mesam 4, that evaluates heart rate, snoring sounds, body position and oxygen saturation throughout the night;
5) Sleep questionnaires (visual analog scales) in order to evaluate the subjective quality of sleep and the subjective quality of nocturnal respiration.

The selected patients underwent the first two nights of recording by Mesam IV (baseline nights); then, the patients were instructed to initiate the treatment with the nasal dilator. The treatment was for 8 consecutive nights and in the last two nights the patient was tested again by Mesam 4 (treatment nights). During the study the subjects did not receive any medical treatment.

Snoring percentage and RDI obtained by Mesam 4 in "baseline nights" and "treatment nights" was measured according to Bearpark et al criteria (13). A visual scoring of each 5-min epoch was performed.

Snoring percentage. A value from 0 to 9 was visually determined for each 5-min epoch to indicate the proportion of snoring: 0 indicated no snores, 9 indicated continuous repetitive snoring. An epoch of continuous repetitive respiratory disturbance with snoring terminating each episode was also scored 9. Snoring percentage was the sum of scores for all epochs/(number of epochs X9) X 100.

Respiratory disturbance index (RDI). A respiratory disturbance was scored if an episode of oxygen desaturation > 4% of the preceding baseline level, determined by visual analysis, occurred with (a) an increased HR of at least 10 beats/min, (b) a burst of snoring associated with commencement and termination of a desaturation episode, or (c) with both (a) and (b). An RDI was calculated for each subject.

Data Analysis

The primary objective of the study was to evaluate the efficacy of the nasal dilator in reducing snoring. The baseline snoring time (mean values of the first two nights) was statistically compared (Wilcoxon Test) with the data obtained after the short-term treatment (mean values of the last two nights of treatment). The same analysis was performed for RDI and Minimal SaO2.

Moreover, we evaluated the correlation between snoring percentage variation and some other parameters (nose obstruction, PAS, snoring duration in the patient's history, subjective improvement of sleep quality and nocturnal respiration) by the Spearman Test.

Table 1. MESAM results obtained in the "Baseline Nights" (Nights 1-2) and in the "Treatment Nights" (Nights 9-10).

Parameter	Baseline Nights	Treatment Nights	P*
Snoring (%)	32.9 (10.7)	25.7 (10.8)	< .06
RDI	5.6 (2.8)	5.8 (3.9)	> .06
Min SaO2 (%)	88.2 (2.5)	88.3 (2.9)	> .06

Values are Mean (SD); * Wilcoxon Test

RESULTS

Twenty patients (14 males, 6 females) have been included into the study. Mean age was 50.2 years (range 30-65), mean BMI was 25.6 (range 19.8-29.9). Table 1 shows the MESAM results obtained in the "Baseline Nights" (Nights 1-2) and in the "Treatment Nights" (Nights 9-10). Snoring percentage resulted lower in the "Treatment Nights" in comparison to baseline, but the difference was not statistically significant. The nocturnal analyzed time was not different between the two different conditions (mean – SD = 475.4 – 31.8 min vs 463.2 – 42.8 min, respectively, n.s.), as well as the percentage of time spent in supine position (mean – SD= 38.2 – 11.4 % vs 41.7 – 14.3 %, respectively, n.s.).

No difference was found in the clinical, ENT, cephalometric characteristics between 7 "responder" (we arbitrarily defined as responder the subjects with at least a 10% reduction of snoring percentage in the "Treatment Nights") and 13 "non-responder" patients (Table 2).

Table 2.Characteristics of responders* and non-responders*

	Responders*	Non-Responders	p
	(n=7)	(n=13)	
Age (yrs)	51.5 (11.6)	49.5 (10.2)	0.69
BMI	25.3 (2.8)	25.8 (3.7)	0.77
Nose Obstr.	2.4 (1.4)	2.0 (1.0)	0.43
PAS	10.5 (1.6)	10.3 (1.4)	0.71
Snoring Dur. (yrs)	8.3 (5.5)	7.3 (5.3)	0.72

* Patients with at least a 10% reduction of snoring percentage during treatment nights

In the comparison between the two experimental conditions, the percentage of the subjective improvement in sleep quality in our sample was 12.0 (range 0-30) and the percentage of subjective improvement in nocturnal respiration was 23.5 (range 0-50). Snoring percentage variation with the nasal dilator treatment was not significantly correlated with nose obstruction, PAS, snoring duration, subjective improvement of nocturnal respiration (Table 3), but a significant correlation was found with the subjective improvement of sleep quality (p= 0.02). None of the patients complained of difficulty applying the device. None of the patients dropped out of the study because of side effects.

Table 3. Correlation between snoring percentage variation and other parameters (Spearman test)

With Nose Obstruction	r= 0.239	p= 0.305
With PAS	r= 0.035	p= 0.881
With Snoring Duration	r= 0.141	p= 0.547
With Improv. Sleep Quality	r= 0.503	p= 0.020
With Improv. Nocturnal Respir.	r= 0.069	p= 0.767

DISCUSSION

The precise relationship between nasal resistance and snoring is complex (6). In snorer patients with nasal obstruction, Fairbanks found that nasal surgery reduced or eliminated snoring in 77% of the cases (14). On the other hand, some authors found no significant correlation between snoring and nasal resistance measured simultaneously during sleep in 8 snoring men (15). Our study showed that a noninvasive external nasal dilator determined a certain reduction of snoring amount, objectively measured, in 7 of the 20 investigated habitual snorers (28%).

Some authors by direct visual observation of the upper airways of snorers during sleep demonstrated that the sites of obstruction are either in the oropharynx, hypopharynx, at the level of the soft palate or at the velopharyngeal level (16,17). Nasal obstruction may further reduce inspiratory intra-airway pressure at these sites, making the walls more susceptible to collapse. In our "non-responder" snorers it is possible that even with the facilitating effect of nasal obstruction, there is sufficient sleep-induced reduction in muscle tone to increase the compliance of the pharyngeal walls, reduce the area of the pharyngeal orifice and produce partial occlusion of the pharynx.

In our total sample, the snoring amount modification was unrelated to the degree of nose obstruction, PAS and snoring duration in the patient's history. This suggests that by using the described methodology, the characteristics of snorer subjects in which the nasal dilator could be of clinical benefit may not be specified in more detail. A larger sample of subjects would be needed in this respect to come to a final conclusion.

However, in our sample the reduction of snoring amount (objectively measured) was significantly correlated with the subjective improvement of sleep quality (measured by a visual analog scale). According to Stoohs and Guilleminault some loud snorers have an increased "internal" resistive load that results in repetitive arousals from sleep (18). The use of external nasal dilators in snorers without OSA may reduce arousal frequency and sleep fragmentation, as recently demonstrated in a polysomnographic study (8), and thereby could improve sleep quality.

Our study confirmed that "Breathe Right" is a safe nasal dilator, according to the results obtained in other recent studies (19, 20). However, long-term treatment studies are necessary to confirm these observations.

REFERENCES

1. *Zwillich CW, Pickett C, Hanson FN, Weil JV. Disturbed sleep and prolonged apnea during nasal obstruction in normal men. Am Rev Respir Dis 1981;124:158-160.*

2. *McNicholas WT, Coffey M, Boyle T. Effects of nasal airflow on breathing during sleep in normal humans. Am Rev Respir Dis 1993;147:620-623.*

3. *Proctor DF. The upper airways. Nasal physiology and defense of the lungs. Am Rev Resp Dis 1977;115:117-129.*

4. *Kimmelman C. The problem of nasal obstruction. Otolaryngol Clin N Am 1989;22:253-264.*

5. *Francis A. Medical and surgical appliances: an alae nasi prop. BMJ 1905;2:1461-1463.*

6. *Hoffstein V. Snoring. Chest 1996;109:201-222.*

7. *Scharf MB, Brannen DE, McDannold M. A subjective evaluation of a nasal dilator on sleep and snoring. Ear Nose Throat J 1994;73:395-401.*

8. *Sharf MB, McDannold M, Zaretsky NT, Hux GT, Brannen DE, Berkowitz DV. Cyclic Alternating Pattern sequences in non-apneic snorers with and without nasal dilation. ENT J 1996;9:15-17.*

9. *Stoohs R, Guilleminault C. MESAM 4: An ambulatory device for the detection of patients at risk for obstructive sleep apnea syndrome. Chest 1992;101:1221-1227.*

10. *Ferini Strambi L, Zucconi M, Palazzi S, Castronovo V, Oldani A, Della Marca G, Smirne S. Snoring and nocturnal oxygen desaturations in an Italian middle-aged male population. Chest 1994;105:1759-1764.*

11. *Penzel TG, Amend G, Meinzer K, Peter JH, von Wichert P. Mesam: a heart rate and snoring recorder for detection of obstructive sleep apnea. Sleep 1990;13:175-182.*

12. *Zucconi M, Ferini Strambi L, Palazzi S, Curci C, Cucchi E, Smirne S. Craniofacial cephalometric evaluation in habitual snorers with and without obstructive sleep apnea. Otolaryngol. Head Neck Surg 1993;109:1007-1010.*

13. *Bearpark H, Elliott L, Grunstein R, Cullen S, Schneider H, Althaus W, Sullivan C. Snoring and sleep apnea: a population study in Australian men. Am J Respir Crit Care Med 1995;151:1459-1465.*

14. *Fairbanks DNF. Effect of nasal surgery on snoring. South Ed J 1985;78:268-70.*

15. *Miljeteig H, Savard P, Mateika S, Cole P, Haight J, Hoffstein V. Snoring and nasal resistance during sleep. Laryngoscope 1993;103:918-922.*

16. *Croft CB, Pringle M. Sleep nasendoscopy: technique of assessment in snoring and obstructive sleep apnea. Clin Otolaryngol 1991;16:504-509.*

17. *Morrison DL, Launois SH, Isono S, Feroah TR, Whitelaw WA, Remmers JE. Site of pharyngeal narrowing in patients with obstructive sleep apnea. Am Rev Respir Dis 1992;145:412.*

18. *Stoohs R, Guilleminault C. Snoring during NREM sleep: respiratory timing, esophageal pressure and EEG arousal. Respir Physiol 1991;85:151-167.*

19. *Turnbull GL, Rundell OH, Rayburn WF, Jones RK, Pearman CS. Managing pregnancy-related nocturnal nasal congestion: the external nasal dilator. J Reprod Med 1996;41:897-902.*

20. *Scharf MB, Berkowitz DV, McDannold M, Stover R, Brannen DE, Reyna R. Effects of an external nasal dilator on sleep and breathing patterns in newborn infants with and without congestion. J Pediatr 1996;129:804-808.*