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Original article

Internal and external nasal dilatator in patients who snore: a comparison in clinical practice

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Summary. Snoring is a common symptom. The nasal valve area has the minimal cross-sectional area of the upper airways. So, nasal dilation may significantly reduce resistance to airflow and consequently could reduce snoring. Mechanical dilators may be used: they are external or internal. Nas-air® is a new internal nasal dilator. It was compared to a nasal strip (Rinazina Breathe Right®**)** in 41 outpatients who snore in an open study conducted in clinical practice. Snoring duration, assessed by smartphone, and visual analogue scale for the perception of sleep quality were measured before and during Nas-air® or nasal strip use. A significant reduction of snoring time and an improvement of sleep quality were achieved by wearing both devices. However, Nas-air® was effective in a larger number of patients and induced a better sleep quality than nasal strip. In conclusion, the present study demonstrates that Nas-air® is an internal nasal dilator able to reduce snoring time and to improve sleep quality, and may be preferred to the nasal strip by snoring patients. (www.actabiomedica.it)

Key words: snoring, nasal valve, obstruction, internal nasal dilator, Nas-air®, external nasal dilator, nasal strip

Introduction

Snoring is a very common symptom, as it affects from 5% of females to 20% of males in young adult people (1). However, old people snore more commonly: about 40% of females and 60% of males (2). Moreover, the awareness that nasal obstruction could modify breathing during sleep and also daytime is long-standing. In fact, it is well known that nasal obstruction is associated with disturbed sleep, insomnia, and intellect and memory impairment.

About half of the total respiratory resistance to airflow passage is in the nose, so a direct relationship exists between increased nasal resistance, due to nasal obstruction, and obstructive sleep breathing (3,4). Sleep-disordered breathing can be divided in three main clusters: simple snoring, sleep apnoea syndrome, and upper airway resistance syndrome. Snoring occurs by high-frequency oscillations of the soft palate as well as the pharyngeal walls, epiglottis, and tongue. These oscillations alternately occlude and open a narrowed airway. Notably, increasing nasal patency improves snoring (5, 6).

Nasal obstruction due to nasal valve abnormalities may result from either dynamic or static problems. The normal airflow passing the nasal valve depends on the Bernoulli principle and the Poiseuille law. The Bernoulli principle states that when the flow of air increases through a fixed space, the pressure in that space decreases consequently. If the decrease in pres-

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sure overcomes the inherent rigidity of the flexible nasal sidewall, collapse can occur resulting in obstruction. Clinically, the collapse of the nasal sidewall during inspiration is termed dynamic obstruction. The Pouseille law states that the flow is inversely proportional to the fourth power of the radius, which means that small decreases in the radius of a space have dramatic impacts on the flow of air through the nose. In the clinical setting, an anatomically narrowed portion of the nasal valve is defined as a static obstruction.

The management of snoring includes careful evaluation and correction of upper airway obstruction. Septoplasty alone or associated with lateral osteotomies corrects a narrowed nasal valve creating a 2.5 times reduction in nasal respiratory resistance (2). Even in the presence of septal deviation, airflow may be improved with repair of an obstructing nasal valve. However, a potential alternative to surgical procedures may be represented by the mechanical nasal alar dilators. The nasal dilators may be classified as external and internal (3). There are some studies that explored the possibility of relieving snoring by wearing them. For these reasons, we aimed to compare a new internal nasal dilator (Nas-air®) with an external dilator (Rinazina Breathe Right®) in a group of snoring outpatients.

Materials and Methods

The present open study included 41 outpatients who snore, and was conducted in a real-world setting, such as a rhinologic clinic.

Inclusion criteria were: adult age and snoring history in the past month. Exclusion criteria were: anatomical clinically relevant problems (e.g. very severe septal deviation and/or turbinate hypertrophy, such as grade IV), obstructive sleep apnea syndrome, disorders and current medications potentially able to interfere with findings.

The outpatients were visited and undergone otorhinolaryngological visit, including anterior rhinoscopy. The Nas-air® (E.P. Medica, Fusignano, Italy) and Rinazina Breathe Right® (GSK Consumer Healthcare, Milan, Italy) were given with appropriate instruction for their use. All patients signed an informed consent to participate in the study.

Briefly, the internal nasal dilator should be applied into the nose at bedtime, whereas the nasal strip should be applied on the bridge of the nose at bedtime too. Both devices should be worn the whole night.

Snoring assessment was performed by the app "Do I Snore®" using a smartphone and recorded at home during the sleep. This app measures the time of snoring during sleeping.

Patients were instructed to measure snoring the first night (without any device), the further second (with Nas-air®) and the third night (with Rinazina Breathe Right®).

During the otorhinolaryngological visit, the following parameters were considered: age, gender, body mass index (BMI); a fibro-endoscopy was also performed.

Subjective parameters included perception of nasal obstruction, sleep quality, and olfaction. It was measured by a visual analogue scale (VAS). VAS score for nasal obstruction ranged from 0 (=completely blocked nose) to 10 (=completely patent nose); VAS score for olfaction ranged from 0 (=no smell) to 10 (=optimal smell); VAS score for quality of sleep ranged from 0 (=worst sleeping) to 10 (optimal sleeping). In addition, VAS was used for assessing the satisfaction for the Nas-air® and the nasal strip (0=bad; 10=best). These parameters were recorded by the patients at baseline, after the second night with Nas-air®, and after the third night with nasal strip.

Demographic and clinical characteristics are described using means with SDs for normally-distributed continuous data and absolute frequencies and percentages for categorical variables. Any statistically significant difference between or among mean values of each continuous variable was evaluated with the Paired t test (comparisons between two groups) or the Repeated Measures ANOVA (comparisons among three groups), followed by Bonferroni›s Multiple Comparison Test as post-hoc test, respectively. Chi-square test or Fisher's exact test, in case of expected frequencies lower than 5, was used to compare frequencies. Correlations were evaluated with Pearson correlation coefficient. Statistical significance was set at $p < 0.05$, and the analyses were performed using GraphPad Prism software, GraphPad Software Inc, CA, USA

Results

In the current study, 41 patients were enrolled: 31 males and 10 females (mean age 44.7±13.3 years). The mean BMI was 25.2 (±3.6), overweight/obese subjects were 20 (48.8%).

The application of both Nas-air® and nasal strip significantly reduced snoring time (expressed as % snoring during the nighttime) in comparison with baseline ($p<0.05$ and <0.001 respectively), but without difference between them, as reported in Figure 1.

There was a significant difference ($p<0.05$) between Nas-air® and nasal strip concerning the percentage of patients reporting a reduced snoring, as shown in Figure 2.

Nas-air® use was associated with the best perception of good sleep ($p<0.05$), as reported in Figure 3. Sleep quality VAS score significantly correlated with Nas-air® preference ($r=0.413$, $p<0.01$) and nasal strip preference ($r=0.35$, $p<0.05$).

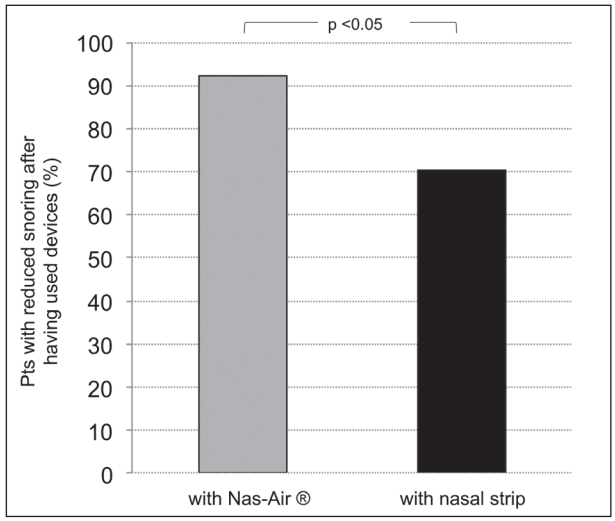

Figure 2. Percentage of patients with reduced snoring after having used both the devices

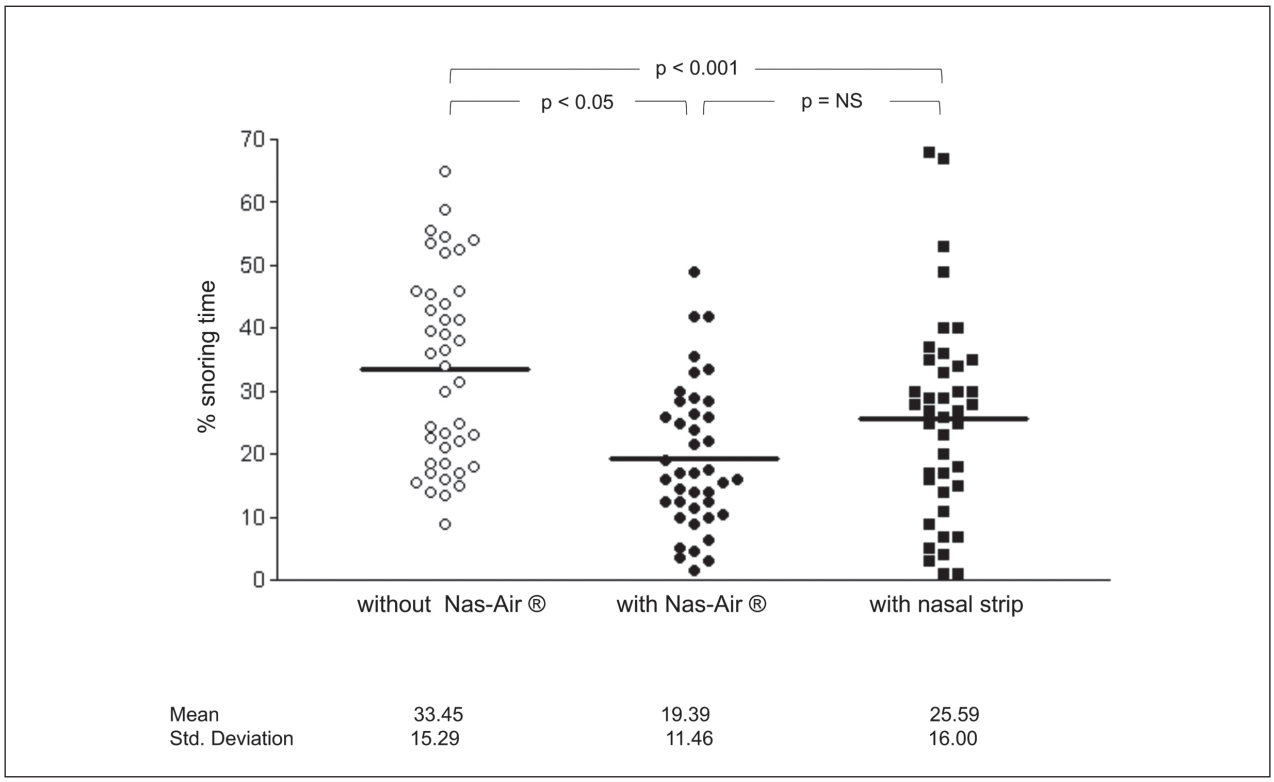

Figure 1. Snoring (expressed as % snoring time during the nighttime) during the first night (without device), the second night (with Nas-air®), and the third (with nasal strip). Horizontal bars represent mean values

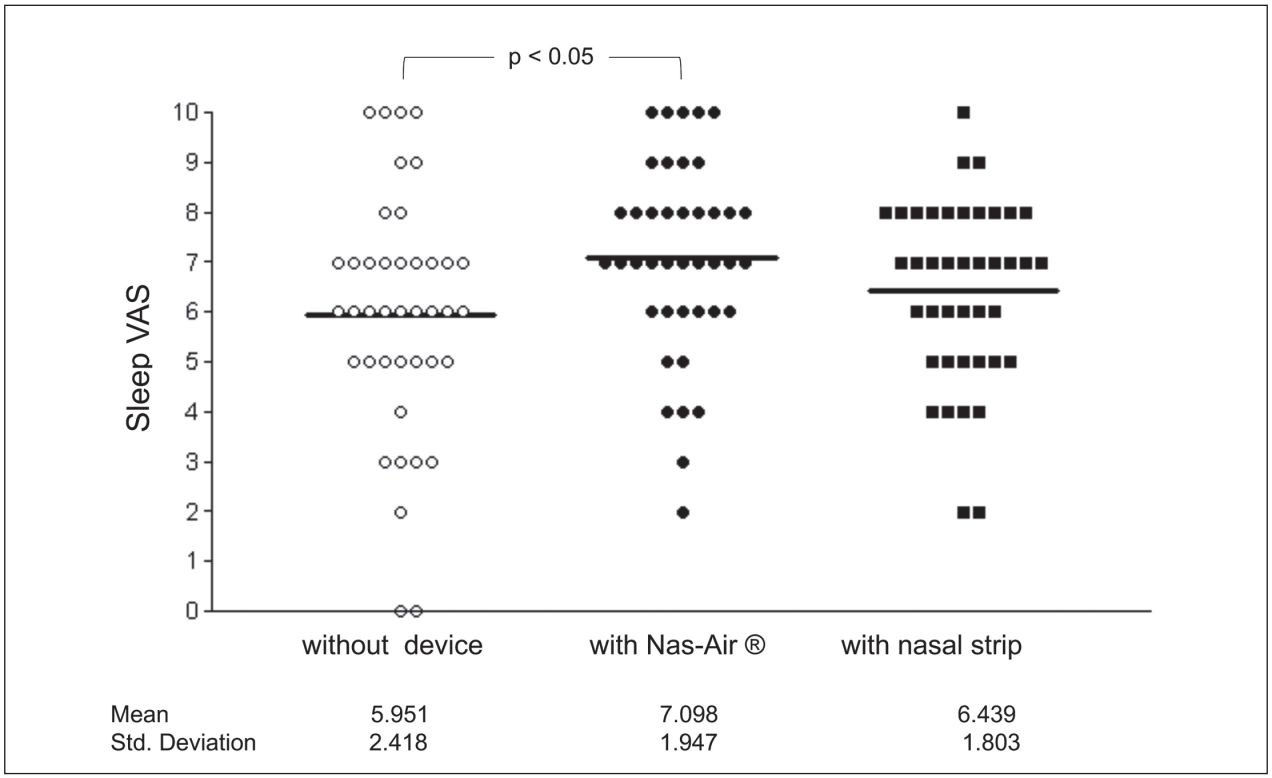

Figure 3. Sleep visual analogue scale (VAS) score during the first night (without device), the second night (with Nas-air®), and the third (with nasal strip). Horizontal bars represent mean values

Discussion

Snoring is a very disturbing symptom and affects a good social and familiar life. In fact, the snorer's partner in a relationship is the one who suffers the most from these nightly noises in the beginning. However, during the following years also the snorer becomes aware of his/her problem. So, he/she wakes himself up, gets a dry throat, and is sleepy and tired in the morning.

The nasal valve area is the narrowest passage in the respiratory tract, causing more than half of the total resistance to nasal respiration in a healthy subject. In this regard, the proportional ratio between the cross-sectional area of the nasal valve and the bony piriform aperture is about 1:1.4. The cross-sectional area surfaces vary into the nasal cavity: in the nasal valve is about 30 mm^2, in the middle of the cavity is 120 mm^2, and in the rhino-pharynx about 150 mm^2. After mechanical dilation the nasal airflow can increase up to 25%; interestingly, this change is comparable with that observed after decongestant use (3, 4).

Many disorders may result in pathologically narrow upper airways, including adeno-tonsillar enlargement, cancers, chronic rhinitis, traumatic or congenital anatomical defects and so on. In particular, nasal obstruction represents the most common cause for snoring (6). Nasal valve obstruction is the crucial point for snoring pathogenesis. Some studies investigated the role of nasal valve and its subjective and objective measurement (7, 8). However, in clinical practice the most important parameter is the snoring perception of the partner and/or of the patient.

From a therapeutic point of view, mechanical dilation of nasal valve is the best non-surgical approach in snorers (3, 4). Many dilators exist, both external and internal. Some studies investigated their efficacy and most of them were positive (9-12). Very recently, we demonstrated that a new internal dilator (Nas-air®) was able to significantly reduce the snoring time and

was well accepted by the patients (13). So, the current study compared the efficacy of Nas-air® with a nasal strip (Rinazina Breathe Right®).

Interestingly, both devices significantly reduced the snoring time, without relevant intergroup difference. However, the Nas-air® device was effective in a larger number of subjects than the nasal strip. In addition, the patients perceived the better improvement of the sleep quality during the night with Nas-air®. There was a significant relationship between the perceived improvement of sleep quality and the appreciation of the device for both dilators, even if more relevant for Nas-air®. Therefore, it is evident that the use of nasal dilators could significantly improve snoring already after the first night of use, and the Nas-air® seems to be more effective and appreciated than the nasal strip.

The findings of the present study are consistent with the previous literature that reported efficacy of nasal dilators (14, 15). However, a recent systematic review of over-the-counter nasal dilators concluded that these devices may be an alternative to surgical intervention in some patients, but the level of evidence is not optimal for many studies (6). Moreover, there is only one study that had compared external dilators to internal dilators (16).

However, this study has some limitations, including the open design, the limited number of enrolled patients, the lack of a follow-up, and the absence of validated objective parameters. Therefore, the current experience should be confirmed by further studies designed according to more robust methodology.

In conclusion, the present study demonstrates that Nas-air® is an internal nasal dilator able to reduce snoring time and to improve sleep quality, and might be preferred to the nasal strip by snoring patients.

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Conflict of interest: None to declare

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