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Original article

Internal nasal dilator in patients with obstructive sleep apnea syndrome and treated with continuous positive airway pressure

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Summary. The nasal valve area has the minimal cross-sectional area of the upper airways. Obstructive sleep apnea syndrome (OSAS) is a common disorder. It has been reported that nasal obstruction may be associated with OSAS. The aim of this study was to investigate whether the use an internal nasal dilator may be able to affect respiratory pattern in a group of patients with OSAS and treated with continuous positive airway pressure (CPAP). The use of internal nasal dilator significantly reduced the pressure of CPAP (from 11.4±1.5 to 10.8±1.5; p=0.012) able to resolve apnea episodes. In conclusion, this study showed that Nas-air® is a new internal nasal dilator potentially capable to significantly improve adherence and compliance to CPAP. (www.actabiomedica.it)

Key words: nasal valve, internal nasal dilator, obstructive sleep apnea syndrome, cardiorespiratory monitoring, continuous positive airway pressure, Nas-air®

Introduction

The nasal dilators are used as a mechanical tool for reducing nasal airflow resistance (1). By lowering nasal resistance, they reduce the work of breathing and consequently the supply of oxygen into the body could increase (2). Signally, the nostril size represents a relevant limitation to the amount of air entering into the body as there is the nasal valve that accounts for relevant resistance to airflow. Nasal dilators may be external, usually strips, or internal, mechanical devices. The nasal strip is placed along the nasal valve of the nose, so it dilates the nose and allows more air to flow into the nose (3,4). On the other hand, internal dilators open up the nostrils by lifting aside the soft tissues in the nasal wings (5).

The primary effect of the nasal dilators could be either to dilate the air passage of the nose or to stiffen the nasal wall. Either mechanism would reduce nasal resistance and allow higher airflow. Stiffening the nasal wall would have its most profound effect at higher flows where the Bernoulli effect would decrease internal nasal pressures and tend to constrict nasal passage diameter. Air passage dilation would tend to decrease nasal resistance more uniformly over a range of air flows.

During breathing, there is expansion of the chest and it creates a negative intra-thoracic pressure and air is sucked into the lungs through the airways. The valve region mean cross-sectional area is 1.4 cm^2 (6). This area is smaller than the zone in the bony opening of the nose (2.0 cm^2) and in the interior part of the nose (6 cm^2). According to Pouiseuille's law, the narrowest cross-sectional area is the most important important when the pressure is calculated. Actually, increasing from 1.4 cm^2 to 2.0 cm^2, the intrathoracic negative pressure can be reduced (7). This means that it is much easier to inhale through the nose.

On the basis of this background, nasal dilators have been proposed also in patients with obstructive sleep apnea syndrome (OSAS). OSAS is a prevalent sleep disorder with significant public health outcomes (8,9). Continuous positive airway pressure (CPAP) is considered the primary medical treatment for patients with moderate to severe OSAS, as evidenced by several randomized controlled trials (10,11).

In this regard, an internal nasal dilator (Nozovent®) has been studied in 21 patients with OSAS (12). Unfortunately, most of patients had no significant improvement of polysomnographic parameters. A recent study evaluated nasal dilator strip as placebo intervention in 26 patients with severe OSAS (13). The device had no significant effect on polysomnographic issues. However, nasal dilator strips significantly improved somnolence, depressive symptoms, wake up at morning, daily activities, and quality of life. Therefore, we investigated the role of a new internal nasal dilator (Nas-air®) as add-on treatment in patients using CPAP.

Materials and Methods

The present cross-sectional study included 19 inpatients with OSAS diagnosis.

Inclusion criteria were: adult age and OSAS diagnosis according to validated criteria (14). Exclusion criteria were: anatomical clinically relevant problems (e.g. very severe septal deviation and/or turbinate hypertrophy, such as grade IV), disorders and current medications potentially able to interfere with findings.

The patients were visited and undergone otorhinolaryngological visit, including anterior rhinoscopy. During the otorhinolaryngological visit, the following parameters were considered: age, gender, body mass index (BMI); a fibro-endoscopy was also performed.

Subjective parameters were evaluated by the patients, and include perception of nasal obstruction, sleep quality, and olfaction; they were 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® (0=bad; 10=best).

Daytime sleepiness was evaluated with the Epworth Sleepiness Scale (ESS): an ESS score of ≥10 was considered excessive daytime sleepiness (15). In addition, the STOP-Bang (16), the Restorative Sleep (17) questionnaires, and Mallampati scale (18) were used.

Cardiorespiratory nocturnal monitoring was performed in all patients and was done in ambient air and spontaneous breathing using a portable 4-channel/8-track polygraph (WristOx$_2$, Nonin, the Netherlands). Oxyhemoglobin saturation, heart rate, body posture, oral-nasal air flow, snoring sounds, and thoracic and abdominal movements were recorded in detail. AHI (apnea-hypopnea index), ODI (oxygen desaturation index), TST90 (total sleep time with oxyhemoglobin saturation below 90%), SaO2-Nadir % and Restoring Sleep were calculated

All patients were treated with auto-CPAP (AirSense 10, ResMed, Italy) and evaluated for two consecutive days.

The Nas-air® (E.P.Medica, Fusignano, Italy) was given with appropriate instruction for the use, such as the internal nasal dilator should be applied into the nose at bedtime. All patients signed an informed consent to participate in the study. Patients were evaluated the first night (without any device) and the second one (with Nas-air®).

Clinical characteristics were reported as mean± standard deviation (SD) for continuous variables and as percentage for categorial variables. The normal distribution of continuous variables was verified. Continuous parameters were analyzed by Student's T-test for paired samples. Significance values assumed for $p<0.005$ All the analysis have been conducted with SPSS 21 software.

Results

The present study included 19 patients (4 females, 5 males, mean age 61±13.5 years) suffering from severe OSA with mean AHI 38.7±30.8. Mean BMI was 32.4±6.7; mean neck circumference 41.3±2.2). All patients suffered from severe OSA with mean AHI value 38.7±30.8

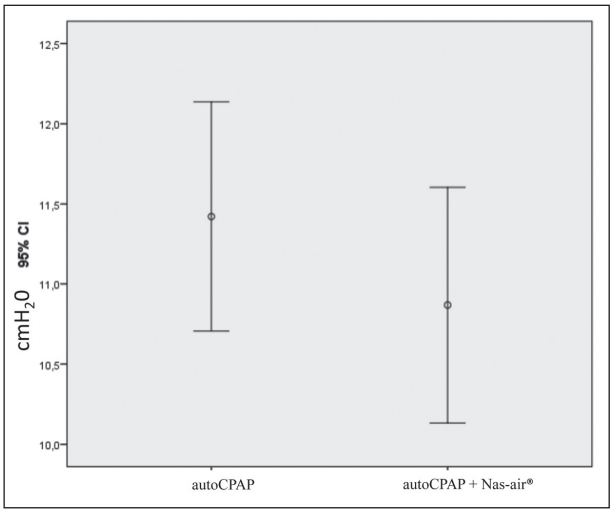

Figure 1. Operating pressure of Auto-CPAP without and with the internal nasal dilator

Notably, all patients conferred the value 10 about the liking of the internal nasal dilator.

The use of the internal nasal dilator significantly reduced the pressure of CPAP (from 11.4±1.5 to 10.8±1.5; p=0.012) able to resolve apnea episodes, as reported in Figure 1.

Discussion

Obstructive sleep apnea syndrome (OSAS) is a condition in which the upper airway becomes obstructed during sleep, so causing hypoxia, hypercarbia, disturbed sleep, and a variety of medical complications including daytime drowsiness and an increased risk of hypertension, diabetes, and cardiovascular disease (19). OSAS is highly associated with obesity and is becoming increasingly common as the obesity epidemic continues (20). Unfortunately, about 80% of patients with OSAS are unrecognized before surgery, putting them at increased risk of complications during the perioperative period (21).

Therefore, patients with OSAS represent a challenge for the doctors. In this regard, the nose may have a relevant role in OSAS patients as it accounts for about half of the total airways resistance.

Nas-air® is a new device that dilates the nasal valve so increases the nasal airflow and reduces snoring as recently reported (22).

The present study showed that Nas-air® was able to significantly reduce the CPAP pressure. The clinical relevance of this outcome could be the possibility to improve the long-term compliance and adherence to CPAP, as it might allow to reduce the mean operating pressure. Of course, further studies should be designed to confirm this hypothesis.

On the other hand, the current study has some limitations, including the open study design, the lack of follow-up, and the low number of enrolled patients. Thus, further studies should be conducted to answer these unmet needs. However, the strength of the current study was the demonstration that a single application of the device was able to significantly reduce the CPAP operating pressure.

In conclusion, this study showed that Nas-air® is a new internal nasal dilator potentially capable to significantly improve adherence and compliance to CPAP.

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