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Rhinomanometric evaluation of the improved mechanical therapeutic nasal dilator in patients with anterior nasal obstruction*†

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SUMMARY *The effectiveness of the Improved Mechanical Therapeutic Nasal Dilator (IMTND) was evaluated rhinomanometrically in 33 patients (mean age: 26 years; range 18-68 years) with anterior nasal obstruction. Using anterior rhinomanometry the patients were observed to have a mean total resistance of 0.376 Pa/cm^3/s (range: 0.16–0.87 Pa/cm^3/s). There was a significant drop in the inspiratory nasal resistance by 26% after the insertion of the IMTND in the nostrils ($p < 0.001$). Following decongestion with 1% phenylephrine the resistance decreased by 41%. This difference was statistically significant ($p < 0.001$). Insertion of the IMTND in the decongested nostrils resulted in even higher and significant decrease in the nasal resistance by 59% ($p < 0.001$).*

Key words: rhinomanometry, nasal dilator, nasal obstruction

INTRODUCTION

Nasal obstruction is a common and distressing symptom. It is not always amenable to medical therapies or surgical procedures. The immense magnitude of the problem is evident by an estimated US$ 5.6 billion spent annually in the United States alone on remedies to relieve it (Kimmelman, 1989). Resistance to the air flow occurs mainly in the nasal valve area. In this region, the nasal passages between the free edges of the inferior turbinate and nasal septum are quite narrow. The nasal valve, main regulator of the nasal airflow, is a part of the nasal valve area. It is a triangular slit-like opening between the caudal ends of the upper lateral cartilage and septum (Kasperbauer and Kern, 1987). Nasal prostheses capable of increasing the cross-sectional area of the nasal valve have been reported in the medical literature as early as 1905 (Francis, 1905). Essentially, these devices have been used to support collapsed ala nasi in order to reduce nasal obstruction and improve cosmetic appearance (Lancer and Jones, 1986). There has been a renewed interest in mechanical nasal dilators following recent reports showing that mechanical dilation of the nasal airways during sleep can decrease both the frequency and severity of obstructed breathing events in patients with obstructed sleep apnoea (Hoijer et al., 1992). Many of the external and internal mechanical nasal dilators have been shown to be affective both subjectively and objectively (Ford and Rezakany, 1985; Petruson, 1988). However, these have been expensive to fabricate, cumbersome to use and uncomfortable for the patient. We have developed an Improved Mechanical Therapeutic Nasal Dilator (IMTND) which has been shown to facilitate breathing subjectively, is easy to use, and has a good patient's acceptance (Chaudhry and Askinazy, 1990). In this study the effectiveness of this mechanical nasal dilator has been evaluated rhinomanometrically and compared to that of a local decongestant.

MATERIAL AND METHODS

Thirty-eight patients with anterior nasal obstruction were entered into the study. Five patients could not tolerate the nasal dilator and were excluded from the study leaving 33 patients as the basis of this report. Twenty-eight patients had a deviated nasal septum, two patients had collapsed ala nasi, and the remaining three had other skeletal problems of the nose. There were 22 males and 11 females with a mean age of 26 years (range: 18–68 years).

The prosthesis

We used the Improved Mechanical Therapeutic Nasal Dilator (IMTND). The IMTND is manufactured by the Breath-With-

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EEZ Corporation of Brooklyn, New York. The device is US patented (#4759365), international patents are pending, and it is US FDA 510K market approved. It is made of biocompatible 304 stainless-steel alloy wire formed as a loop spring. This structure allows it to be flexible, collapsible and self-expanding. We used three available sizes of the device (small, medium, and large) which comfortably fitted all the patients with little or no adjustment.

Rhinomanometry technique

The anterior rhinomanometric studies were done using Rhinotest MP 500. This equipment automatically calculates resistance from the pressure flow curve. Following the recommendations of the European International Meeting on the Standardization of Rhinomanometry, the values of flow and resistance were recorded at a pressure of 150 Pa (Clement, 1980). All the patients were examined by an otolaryngologist at a date prior to the test. It was made sure that patients had not taken any antihistamine and oral or nasal decongestant at least 24 h prior to the test. In each instance the patients were acclimated to standard room temperature (21±2°C) and humidity (20%) for 15 min before the test. The patients were fully informed about the procedure during this time. In all the patients the test was performed in a systematic manner: (1) the unassisted baseline values for resistance were recorded; (2) the IMTND was inserted in each nostril and rhinomanometric studies performed for each nostril separately; and (3) to evaluate the effect of decongestion, 1% phenylephrine was sprayed into each nostril during inhalation. After 10 min, rhinomanometric tests were repeated for each nostril, first without IMTND and then with IMTND inserted into the nostrils.

The distribution of nasal resistance has been reported to be skewed towards higher values. Statistical analysis thus requires the use of non-parametric tests. We used the Wilcoxon signed-rank test for the analysis of resistance data. Accordingly, the values for resistance are presented as median (range).

RESULTS

The values obtained in the unassisted baseline state are shown in Table 1. A comparison of the IMTND assisted condition with the baseline unassisted conditions, showed a decrease in the median nasal resistance from 0.340 Pa/cm^3/s to 0.250 Pa/cm^3/s ($p < 0.001$). Expressing these values as a percentage of the baseline resistance, the median decrease in nasal resistance was 26%. The median value of nasal airway resistance after decongestion decreased from 0.340 Pa/cm^3/s to 0.200 Pa/cm^3/s, representing a 41% decrease ($p < 0.001$). After IMTND insertion in the decongested nostrils the nasal resistance decreased from 0.340 Pa/cm^3/s to 130 Pa/cm^3/s ($p < 0.001$). Compared to the baseline values, the median decrease in nasal resistance was 62% (Figure 1).

DISCUSSION

Approximately half of the total respiratory tract resistance is attributed to the nasal air flow resistance (Kasperbauer and Kern, 1987). The mean total resistance in our patients with nasal obstruction was higher than the mean total values of 0.33 Pa/cm^3/s reported for healthy subjects (Shelton and Eiser, 1992). The higher values of nasal resistance for the left nostril may represent a majority of our patients with deviated nasal septum affecting the left nostril.

Table 1. Baseline values for resistance (expressed as Pa/cm^3/s).

resistance	total	right nostril	left nostril
mean	0.376	0.677	1.244
SD	0.166	0.344	0.852
median	0.340	0.570	0.445
upper 95% c.i.*	0.317	0.555	0.942
lower 95% c.i.*	0.435	0.799	0.320

*: confidence interval

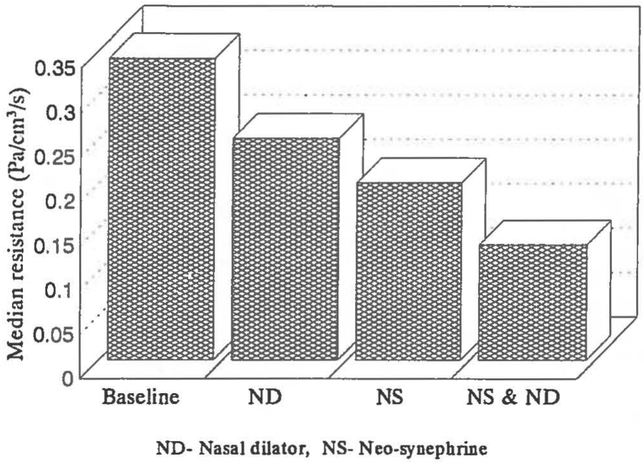

Figure 1. The effect of nasal dilator, neo-synephrine and combination of both on baseline nasal resistance.

The nasal valve area, which is the narrowest portion of the nasal passage, is the main site of resistance (Kimmelman, 1989). The resistance offered to the nasal air flow at the nasal valve depends mainly on skeletal and mucosal structures. It is to be noted that these two factors contribute to the nasal resistance separately. In order to find the nasal resistance, solely due to cartilaginous and bony structures, some authors recommend the use of vasoconstrictors to decrease the mucosal swelling (Linder-Aronson and Backstrom, 1960). Any structural deformity of the cartilaginous portion of the nasal skeleton or swelling of the mucosa can lead to nasal obstruction, particularly when the nasal valve is involved.

The preferred form of treatment for nasal obstruction of skeletal origin is surgical. In some patients alternate modes of therapy are desired due to some contra-indications to the surgery, patient's preference, or to achieve instant relief in mild obstruction. Surgical treatment for nasal obstruction has been reported to increase the nasal air flow by 33% (Gordon et al., 1989). Using a different type of nasal dilator a 24% increase in the air flow has been reported for healthy subjects (Petruson, 1988). To our knowledge the effectiveness of nasal dilators has not been compared with nasal decongestants before. However, in healthy subjects treatment with xylometazoline has been reported to increase the nasal air flow by 28% (Petruson, 1981). We achieved similar results using the IMTND and 1% phenylephrine separately in patients with nasal obstruction. The insertion of the IMTND in a decongested state resulted in a synergetic effect increasing the nasal air flow by 163%.

The IMTND increases the nasal valve area by exerting dilatory pressure internally on the nasal skeleton thus increasing the nasal angle, normally an action performed by the ala nasi. The decongestants increase this area by exerting their effect on the nasal mucosa especially on the anterior part of the inferior turbinate. As observed in this study both of these agents can significantly decrease the nasal resistance and increase the nasal airflow. An even higher decrease in the nasal resistance and increase in air flow was observed with a combination of IMTND with decongestant. This effect may have been produced by the simultaneous action of these agents on the two main contributors to the nasal resistance. A selected group of patients with nasal obstruction due to anterior nasal pathologies does not allow us to draw definitive conclusions. However, it may be speculated that the usefulness of the IMTND or nasal decongestant would depend on the aetiology of nasal obstruction. As in most of the patients there is a combination of structural and mucosal problems, the maximum benefit can be achieved by using the IMTND with a nasal decongestant. It may be concluded that the IMTND can significantly decrease the nasal resistance. A combination of the IMTND with nasal decongestant can further improve the results. Further studies are required to correlate the effectiveness of the IMTND and/or decongestant with the aetiology of the nasal obstruction.

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