Combined Effects of a Mechanical Nasal Dilator and a Topical Decongestant on Nasal Airflow Resistance*

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The goal of this study was to compare the isolated and combined effects of two treatments being used to reduce nasal airflow resistance (NR): an internal nasal mechanical dilator (Nozovent; Prevancure; Sté Pouret, Paris, France) and a topical decongestant, fenoxazoline hydrochloride (Aturgyl; Synthelabo; Le Plessis-Robinson, France). The study was performed in 17 healthy subjects. NR was estimated by active posterior rhinometry at a 0.5 L/s flow under four conditions: in the basal state, with the internal nasal mechanical dilator, after treatment with fenoxazoline hydrochloride, and with both fenoxazoline hydrochloride and the mechanical dilator. The mean NR (± SD) decreased from 1.65 ± 0.54 cm H₂O/L/s in the basal state to 1.02 ± 0.27 cm H₂O/L/s with the mechanical dilator (p < 0.001), 1.03 ± 0.47 cm H₂O/L/s with fenoxazoline hydrochloride (p < 0.001), and 0.48 ± 0.15 cm H₂O/L/s with both the mechanical dilator and fenoxazoline hydrochloride (p < 0.001). The decreases in NR observed after using either the mechanical dilator (ΔNRn) or fenoxazoline hydrochloride (ΔNRA) were not significantly different. The decrease in NR observed with both (ΔNRn + ΔA) was not significantly different from the sum ΔNRn + ΔNRA: 1.16 ± 0.53 cm H₂O/L/s vs 1.25 ± 0.63 cm H₂O/L/s, respectively (p > 0.05). ΔNRn + ΔA strongly correlated with ΔNRn + ΔNRA: ΔNRn + ΔA = 0.80 (ΔNRn + ΔNRA) + 0.15 (r = 0.96; p < 0.0001). However, the slope of the regression line of ΔNRn + ΔA vs ΔNRn + ΔNRA was significantly lower than unity (p < 0.003). These results demonstrate that, although not totally additive, the effects of using the mechanical dilator and fenoxazoline hydrochloride are cumulative. Further studies that include patients with nasal obstruction would allow us to better evaluate the benefit of a therapy combining both treatments. (CHEST 1999; 115:1514–1518)

Key words: active posterior rhinometry; nasal airflow resistance; nasal mechanical dilator device; topical decongestant

Abbreviations: NR = nasal airflow resistance; ΔNRA = decrease in nasal airflow resistance observed after using fenoxazoline hydrochloride; ΔNRn = decrease in nasal airflow resistance observed when using the mechanical dilator; ΔNRn + ΔA = decrease in nasal airflow resistance observed when using both the mechanical dilator and fenoxazoline hydrochloride; PTN = transnasal pressure; V = nasal flow

The main sites of nasal airflow resistance (NR) are the nasal valves and the turbinates. Ordinarily, NR accounts for approximately one half of the total flow resistance of the respiratory system1,2 and is responsible for the same ratio of the total work of breathing.3 However, anatomic and physiologic factors may induce nasal obstruction and dramatically increase NR. Besides surgical therapies, two types of treatments used to reduce NR and, therefore, to improve breathing are presently available: vasoconstrictors and nasal dilators. Chemical treatments, such as vasoconstrictors, act by decreasing the nasal mucosal swelling and reducing the turbinate section, and their effectiveness in lessening NR has been widely reported.4–7 Mechanical treatments, such as nasal dilators, act by expanding ala nasi and increasing the nasal valve area, and objective decreases in NR have been reported with different internal mechanical nasal devices.9–10 As the nasal valves and turbinates are anatomically associated in series, one may ask whether the effects of a vasoconstrictor and a nasal dilator should be cumulative, especially because a previous study showed no significant correlation between the decreases in NR induced by either treatment.7

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The goal of this study, therefore, was to evaluate the isolated and combined effects of an internal nasal dilator (Nozovent; Prevacure; Sté Pouret; Paris, France) and a topical decongestant (Aturgyl; Synthelabo; Le Plessis-Robinson, France) on NR assessed by active posterior rhinometry at the 0.5 L/s flow level.

**Materials and Methods**

**Subjects**

The study was performed in a group of 17 asymptomatic healthy subjects (9 were male and 8 were female), aged 20 to 24 years, with no upper or lower respiratory complaints. Each subject gave informed consent to participate in the study. All subjects tolerated the nasal dilator well.

**NR Measurement**

NR was measured by active posterior rhinometry. The subjects breathed quietly through a rigid nasal mask with the mouth occluded by a closed mouthpiece in which a catheter with an inside diameter of 3 mm was inserted to measure pharyngeal pressure. Transnasal pressure (PTN) was measured by a differential pressure transducer (model SCX 01D; Sensym; Sunnyvale, CA) with one port connected to the nasal mask and the other to the catheter. Nasal flow (V) was measured by a screen pneumotachograph (Jaeger Lilly; Würzburg, Germany) connected to a similar pressure transducer. Pressure and flow signals were low-pass filtered and sampled at 128 Hz for 16 s by an analog to digital converter. To determine the nonlinear NR, PTN and V data were analyzed by linear regression analysis of PTN over V, according to the following equation:

\[ \text{PTN} = \text{K} \, V[V] + P_u \]  

where \( P_u \) is a constant, and \( K \) is a constant that accounts for the nonlinear flow dependence of PTN.

NR was then calculated for a flow of 0.5 L/s, as NR = 0.5 K. Three to four consecutive measurements were performed, and NR was taken as the average of the NR estimates corresponding to an \( r^2 \) value > 99%.

**Experimental Protocol**

In each subject, NR was measured under four conditions: (1) in the basal state; (2) while breathing with the nasal mechanical dilator, which consists of a plastic bar with each extremity ending in a tab to be placed inside each nostril; (3) after inhalation of two puffs of an \( \alpha \)-adrenergic agonist consisting of a 0.1% solution of fenoxazoline hydrochloride; and (4) after pretreatment with a topical decongestant while breathing with the internal nasal dilator.

For each treatment, a 10-min stabilization period was observed before NR measurements were taken. The order of the treatments was the same for all the subjects. In five subjects, NR was measured again 20 min after treatment with both the internal nasal dilator and the topical decongestant. The efficacy of each treatment was assessed by the corresponding decreases in NR when using the nasal dilator (\( \Delta \text{NRn} \)), after using fenoxazoline hydrochloride (\( \Delta \text{NRa} \)), and when using both (\( \Delta \text{NRn} + \Delta \text{NRa} \)).

**Data Analysis**

NRs were compared by one-factor analysis of variance for repeated measures, completed as necessary by modified paired \( t \) tests and by linear regression analysis. A \( p \) value < 0.05 was considered to be statistically significant. Values are given as mean ± SD, except when otherwise indicated.

**Results**

Typical PTN-V curves obtained in a representative subject at the basal state and with the different treatments are shown in Figure 1.

In the basal state, NR was 1.65 ± 0.54 cm H\(_2\)O/L/s. When breathing with the nasal dilator, NR was 65 ± 16% of its basal value \( (p < 0.001) \) with a mean \( \Delta \text{NRn} \) of 0.63 ± 0.46 cm H\(_2\)O/L/s (Figs 2 and 3). After treatment with the topical decongestant, NR was 63 ± 18% of its basal value \( (p < 0.0001) \) with a mean \( \Delta \text{NRa} \) of 0.62 ± 0.36 cm H\(_2\)O/L/s (Figs 2 and 3). No significant difference was found between \( \Delta \text{NRn} \) and \( \Delta \text{NRa} \) (Fig 3); however, no significant correlation was observed between these latter decreases. When breathing with the nasal dilator after treatment with the topical decongestant, NR was 31 ± 10% of its basal value \( (p < 0.001) \) with a mean \( \Delta \text{NRn} + \Delta \text{NRa} \) of 1.17 ± 0.51 cm H\(_2\)O/L/s (Figs 2 and 3). \( \Delta \text{NRn} + \Delta \text{NRa} \) was significantly higher than \( \Delta \text{NRn} \) and \( \Delta \text{NRa} \) \( (p < 0.0001) \).

No significant difference was found between \( \Delta \text{NRn} + \Delta \text{NRa} \) and the sum \( \Delta \text{NRn} + \Delta \text{NRa} \). As shown in Figure 4, \( \Delta \text{NRn} \) + \( \Delta \text{NRa} \) strongly correlated with the sum \( \Delta \text{NRn} + \Delta \text{NRa} \) \( (\Delta \text{NRn} + \Delta \text{NRa} = 0.80 [\Delta \text{NRn} + \Delta \text{NRa}] + 0.15; r = 0.96; p < 0.0001) \), but the slope
of the regression line of $\Delta NR_N + A$ vs $\Delta NR_N + \Delta NRA$ was significantly lower than unity ($p < 0.003$).

In the five subjects in whom additional NR measurements were performed, the NR values measured 20 min after the treatment with both the nasal dilator and the topical decongestant were not significantly different from those measured 10 min after inhalation of the topical decongestant.

**DISCUSSION**

The efficacy of topical decongestants in reducing NR has been widely reported, and vasoconstrictors actually remain the reference pharmacologic treatment for nasal obstruction. By contrast, the objective efficacy of the mechanical treatments recently designed to open the nasal passages remains less well documented.\(^6\)\(^-\)\(^10\) A recent study has demonstrated that an internal nasal dilator was as effective as treatment with a topical decongestant in improving nasal breathing but that most subjects responded differently to each of these two treatments.\(^7\) The most plausible explanation is that the two treatments act at different anatomic levels, and anatomy is likely to vary from one subject to another, which suggests that the effects of the two treatments might be cumulative. The present study was therefore initiated to compare the isolated and combined effects of an internal nasal dilator and of a topical decongestant on NR.

Active posterior rhinometry, which allows direct NR measurement during normal tidal breathing, is now used to evaluate NR. As NR is flow dependent, a choice has to be made regarding the flow or pressure level at which it is calculated. In this study, NR was calculated at the 0.5 L/s flow level, because previously it has been demonstrated a higher sensitivity of NR when calculated at a fixed flow than when calculated at a fixed PtN for assessing the effects of decongestants or nasal mechanical dilators.\(^7\)

The high $r^2$ values ($>99\%$) prove that an equation as simple as equation 1 is sufficient to accurately describe the PtN-flow relationship, at least in normal subjects. Furthermore, as demonstrated in the Appendix, equation 1 provides NR values similar to those calculated at the same flow level as the Rohrer equation, whether at the basal state or under mechanical and decongestant treatments.

To avoid the possible influence of diurnal variation on total NR,\(^11\) all our subjects were studied at the
same time of day. The order of the conditions was the same for all subjects, namely, base, nasal dilator, topical decongestant, and topical decongestant plus nasal dilator, because the decongestant effects of an α-adrenergic agonist persist for variable periods of time after its administration. The duration of the stabilization period observed for each treatment was chosen on the basis of the study by Hamilton, who observed that NR was always significantly decreased and relatively stable within the 10- to 20-min period following topical decongestant administration.

Our basal values of NR were in the range of those calculated in normal subjects at the same or a similar reference flow. The ΔNR was similar to those previously reported in patients with respiratory sleep disorders and in normal subjects, and the percentage of ΔNR was in the range of those previously reported in normal subjects and in patients with nasal congestion after inhalation of topical decongestants. As previously observed in healthy subjects without upper airway complaints, the nasal dilator and a topical vasoconstrictor resulted in comparable, but not significantly correlated, mean decreases in NR.

As illustrated by Figures 2 and 3, the combination of the nasal dilator and the topical decongestant decreased NR significantly more than either one alone. This result could be expected because the two treatments increase the nasal cross-sectional area at different anatomic levels. Indeed, the nasal dilator acts by expanding nasal valves, whereas the topical decongestant acts by reducing the turbinate section via local decongestion of the nasal mucosa. Similar results relating to an internal spring nasal dilator and a nasal decongestant were obtained previously in patients with anterior nasal obstruction by using an anterior rhinomanometric technique and by calculating resistances for each nostril separately at a 1.5 cm H₂O PTN.

The fact that no significant difference was found between ΔNR + A and the sum ΔNR + ΔNA does not allow the conclusion that the effects on NR of the nasal dilator and the topical decongestant are additive. Indeed, the flow dependence of the resistance of the nasal valves and turbinates makes it impossible to resolve total NR into the resistive components of the different nare segments. Besides, the fact that the slope of the regression line of ΔNR + A vs (ΔNR + ΔNA) is significantly lower than unity suggests that, in subjects without complaint of nasal congestion or obstruction, the effects of the nasal dilator and topical decongestant are not totally additive. This might be explained by a slight expanding effect of the nasal dilator on the turbinates and/or a slight decongestant effect of the topical decongestant in the valve region. By contrast, a time decrease of the topical decongestant effect is highly improbable because in the five subjects in whom an additional NR measurement was performed, the NR values obtained 20 min after the treatment with both the nasal dilator and the topical decongestant were similar to those previously measured 10 min after inhalation of the topical decongestant.

In conclusion, our results demonstrate the synergistic effects of a nasal dilator and a topical decongestant. Further studies that include patients with a deviated nasal septum and/or nasal congestion would allow us to better evaluate the benefit of such therapy and to correlate its effectiveness with the nasal obstruction etiology.

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APPENDIX

Let us consider the two following equations that describe the nonlinear PTN-V relationship:

\[ \text{PTN} = K_1 V + P_a \] (1)
\[ \text{PTN} = K_1 V + K_2 V^2 + P_a \] (2)

where \( K_1 \) is a constant that accounts for the linear flow dependence of PTN and \( K_2 \) is a constant that accounts for its nonlinear flow dependence. Because NR is calculated at the 0.5 L/s flow, NR derived from equation 1 is given by

\[ \text{NR}_1 = K_1/V = K/2 \] (3)

and NR derived from equation 2 is given by

\[ \text{NR}_2 = K_1 + K_2 V = K_1 + K/2 \] (4)

In our previous study, we showed that the relative contributions of the \( K_1 \) and \( K_2 \) terms to \( \text{NR}_2 \) were identical, either at the basal state or under mechanical and decongestant treatments, ie, that the \( K_1/K_2 \) ratio in each condition was about 1.2. Consequently, equation 4 reduces to

\[ \text{NR}_2 = K_2 \] (5)

Comparison of equation 5 with equation 3 shows that \( \text{NR}_2 \) and \( \text{NR}_1 \) are similar NR estimates, with \( K = 2K_2 \). This explains why comparable NR values and NR responses to mechanical or decongestant treatments are found whether NR is calculated from equation 1 or equation 2.

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