

Effects of Different Mechanical Treatments on Nasal Resistance Assessed by Rhinometry*

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The goal of this study was to compare the effectiveness of three treatments aiming to reduce nasal airflow resistance (NR): an external nasal strip device (Respir+), an internal nasal mechanical dilator (Nozovent), and a topical decongestant (Pernazène). NR was estimated by active posterior rhinometry at both a 0.5 L/s flow (NR_F) and a 1 cm H₂O pressure (NR_P), under four conditions: in the basal state, with Respir+, with Nozovent, and after treatment with Pernazène. The efficacy of each treatment was assessed by the percentage changes in NR_F and NR_P (%NR_F and %NR_P, respectively). The study was performed in 15 healthy subjects. The efficacy of the treatments was significantly different, depending on whether it was evaluated by NR_F or by NR_P ($p < 0.02$), with %NR_F and %NR_P values, respectively, equal to the following: $88 \pm 20\%$ and $91 \pm 14\%$ with Respir+, $58 \pm 17\%$ and $70 \pm 13\%$ with Nozovent, and $55 \pm 29\%$ and $69 \pm 22\%$ with Pernazène. NR_F remained unchanged with Respir+, whereas it significantly decreased with Nozovent and Pernazène ($p < 0.0001$). No significant difference was observed between the effects of the two latter treatments. These results demonstrate that Nozovent, which involves no risk of side effects or drug interactions, is an effective treatment to improve nasal breathing. Nozovent might therefore be recommended as an alternative to topical decongestants, for certain subjects presenting with nasal obstruction. (CHEST 1998; 114:166-170)

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

Abbreviations: NR=nasal (airflow) resistance; NR_F=NR at 0.5 L/s flow; NR_P=NR at 1 cm H₂O transnasal pressure; PTN=transnasal pressure; V=nasal flow

The nasal passage is the largest source of flow resistance in the respiratory system, and nasal airflow resistance (NR) is responsible for about half the total work of breathing.¹ At the present time, two types of treatments aiming to reduce NR and therefore improve breathing are available. Besides the conventional pharmacologic treatments with topical vasoconstrictors, which have stood the test of time, new mechanical treatments have been proposed recently. The efficacy of vasoconstrictors, which act by reducing the turbinate section, is now well established, but their possible side effects make them difficult to use regularly. However, mechanical treatments that act by opening the nasal passages may be assumed to be used regularly without side effects. The use of such nonprescription devices is increasing, even though the efficacy of some of them appears to be based on subjective criteria. Indeed, to our knowledge, their respective effectiveness has not

always been clearly established or compared with that of topical vasoconstrictors. Consequently, it appeared interesting to perform an objective and comparative evaluation of these new mechanical nasal dilators.

The aim of the present study was (1) to evaluate the respective efficacies of two drug-free devices, one to be placed across the nose and the other inside the nose, and (2) to compare the efficacy of these two devices with that of an α -adrenergic agonist. The efficacy of each of the three different treatments was evaluated by its relative influence on NR, assessed by active posterior rhinometry at two flow levels: the 0.5 L/s flow, and the flow corresponding to a transnasal pressure of 1 cm H₂O.

MATERIALS AND METHODS

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 3-mm internal

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diameter catheter was inserted to measure pharyngeal pressure. Transnasal pressure (PTN) was measured by a differential pressure transducer (Sensym SCX 01D; Sunnival, Calif), one port of which was connected to the nasal mask and the other to the catheter. Nasal flow (\dot{V}) was sensed by a screen pneumotachograph (Jaeger Lilly; Würzburg, Germany) connected to a similar pressure transducer. Pressure and flow signals were low-passed filtered, sampled at 128 Hz for 16 s by an A-D converter, and samples were fed into a microcomputer. To determine the K_1 and K_2 Rohrer coefficients characterizing the nonlinear nasal resistance (1), PTN and \dot{V} data were analyzed by multiple linear regression analysis of PTN over \dot{V} and $\dot{V}|\dot{V}|$, according to the following equation:

$$PTN = K_1 \dot{V} + K_2 \dot{V}|\dot{V}| + P_0$$

where P_0 is a constant. NR was then calculated for a 0.5 L/s flow (NRF) and for the flow corresponding to a PTN of 1 cm H₂O (NRP). Three consecutive measurements were performed, and NR was taken as the average of the corresponding NR estimates.

Experimental Protocol

The study was performed in a group of 15 asymptomatic healthy subjects (8 male and 7 female), aged 18 to 45 years, with no upper or lower respiratory complaints, except a slight cold in two subjects.

In each subject, NR was measured under four conditions: (1) in the basal state; (2) while breathing with an external mechanical device (Respir+; Kentia Diffusion; Boulogne, France), which consists of a nasal strip with a plastic spine backed by a special adhesive, to be placed across the nose; (3) while breathing with a nasal mechanical dilator (Nozovent; Prevacure; Sté Pourret, Paris, France), which consists of a plastic bar, each extremity of which ends in a tab to be placed inside each nostril; and (4) after inhalation of two puffs of an α -adrenergic agonist consisting of a 0.05% solution of tymazoline hydrochlorate (Pernazène; Synthelabo; le Plessis-Robinson, France).

For each treatment, a 10-min stabilization period was observed prior to NR measurements. Whereas Respir+ and Nozovent were used in random order, Pernazène was always given as the last treatment, because its decongestant effect persists for variable periods of time after its administration. The effects of each treatment were assessed by the percentage changes in NRF and NRP (%NRF and %NRP, respectively).

Data Analysis

NRs were compared by analysis of variance for repeated measures, completed as necessary by modified Student's paired *t* test, and by linear regression analysis. A *p* value of <0.05 was considered to be statistically significant. Values are presented as mean \pm SD, except when otherwise indicated.

RESULTS

The K_1 and K_2 values obtained in the basal state are given in Table 1. In the basal state, no significant difference was observed between NRF and NRP (Table 1), and a highly significant correlation was found between these two estimates of NR (NRF = 1.43 NRP - 0.83, $r=0.99$, $p<0.0001$).

As illustrated in Table 1, no significant change in K_1 and K_2 was observed with Respir+, whereas

Table 1—Effects of the Different Treatments on the Parameters Characterizing NR*

	Base	Respir+	Nozovent	Pernazène
K_1 , cm H ₂ O/L/s	0.92 \pm 0.39	0.78 \pm 0.32	0.51 \pm 0.22 [†]	0.50 \pm 0.31 [†]
K_2 , cm H ₂ O/L ² /s ²	2.02 \pm 0.90	1.73 \pm 0.84	1.12 \pm 0.44 [†]	1.27 \pm 0.57 [†]
NRF, cm H ₂ O/L/s	1.87 \pm 0.71	1.61 \pm 0.60	1.03 \pm 0.34 [†]	0.98 \pm 0.48 [†]
NRP, cm H ₂ O/L/s	1.89 \pm 0.49	1.71 \pm 0.43	1.28 \pm 0.26 [†]	1.27 \pm 0.44 [†]
\dot{V}_P , L/s	0.55 \pm 0.13	0.61 \pm 0.14	0.74 \pm 0.16 [§]	0.78 \pm 0.21

*Values are mean \pm SD (n=15). K_1 and K_2 : Rohrer's coefficients characterizing NR (NR = $K_1 + K_2|\dot{V}|$); NRF and NRP: NRs calculated by active posterior rhinometry at the points of 0.5 L/s flow and of 1 cm H₂O PTN, respectively. \dot{V}_P : flow value corresponding to a 1 cm H₂O PTN.

[†]Significantly lower than the corresponding value in base ($p<0.0002$).

[‡]Significantly lower than the corresponding value in base ($p<0.0001$).

[§]Significantly higher than \dot{V}_P in base ($p<0.002$).

^{||}Significantly higher than \dot{V}_P in base ($p<0.0002$).

significant and comparable decreases in K_1 and K_2 were observed with Nozovent and Pernazène (Table 1). The efficacy of the treatments was found significantly different, depending on whether it was assessed by NRF or NRP ($p<0.02$), with %NRF and %NRP values, respectively, equal to 88 \pm 20% and 91 \pm 14% with Respir+, 58 \pm 17% and 70 \pm 13% with Nozovent, and 55 \pm 29% and 69 \pm 22% with Pernazène. The NRF parameter appeared to be more sensitive than NRP to assess the effects on NR induced by the different treatments (Table 1).

No significant effect of Respir+ on NRF could be evidenced, whereas Nozovent and Pernazène decreased NRF significantly (Fig 1 and Table 1). The decreases in NRF observed with the two latter treatments were not significantly different (Table 1). However, no significant correlation was observed between these decreases. All these results remained unchanged (Fig 2), after discarding the data for the two subjects with a cold, and for whom an increase in NR was observed in the Respir+ condition.

DISCUSSION

The efficacy of topical decongestants in reducing NR has been widely reported. By contrast, the objective efficacy of the mechanical treatments recently designed to open the nasal passages remains poorly documented,²⁻⁴ whereas the use of such treatments is becoming widespread, probably due to subjective criteria. This study was therefore initiated to quantify the respective effects on nasal resistance of two drug-free devices, namely an external nasal dilator (Respir+) and an internal nasal dilator (Nozovent), and to compare them with the effect of a topical vasoconstrictor (Pernazène).

To avoid any influence of diurnal variation on total

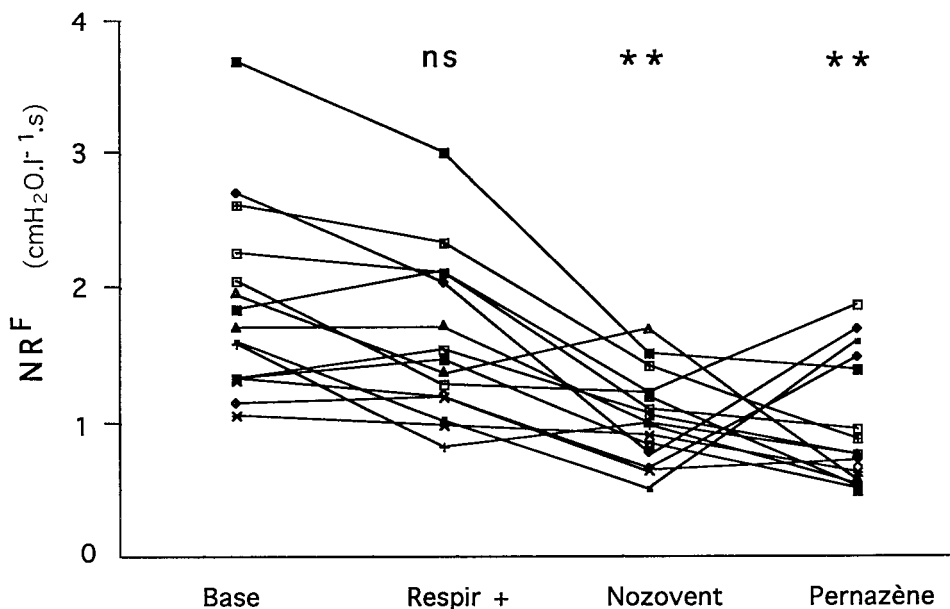


FIGURE 1. Individual changes in NR observed in the 15 subjects with the external nasal dilator Respir+, the internal nasal dilator Nozovent, and the topical vasoconstrictor Pernazène. NRF: resistance calculated by active posterior rhinometry at the point of 0.5 L/s flow. **: significantly lower than NRF in the basal condition ($p < 0.0001$).

NR,⁵ all our subjects were asked to test the three treatments at the same time of day. The duration of the stabilization period observed for each treatment prior to NR measurement was chosen on the basis of the study by Hamilton⁶ who observed that NR was always significantly decreased 10 min after topical decongestant administration.

In this study where nasal patency had to be

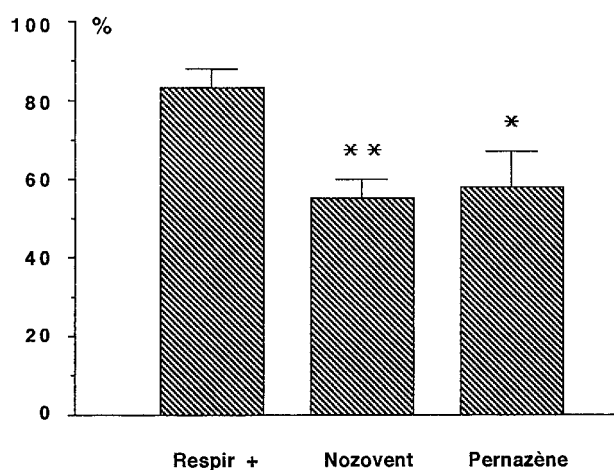


FIGURE 2. Mean changes ($n=13$) in NR observed with the external nasal dilator Respir+, the internal nasal dilator Nozovent, and the topical vasoconstrictor Pernazène. NRs are calculated by active posterior rhinometry at the point of 0.5 L/s flow, and expressed as a percentage of their corresponding basal values (%NRF). Bars indicate SE. * and **: significantly lower than %NRF with Respir+ ($p < 0.005$ and 0.0001 , respectively).

assessed in four different conditions, posterior rhinometry was preferred to anterior or postnasal rhinometry because it allows a direct and therefore rapid measurement of total NR during normal tidal breathing. However, since NR is flow dependent, a choice has to be made about the flow level at which NR is calculated. At the present time, two flow levels are often retained for NR evaluation, the 0.5 L/s flow, and the flow corresponding to a 1 cm H₂O PTN. To our knowledge, no systematic comparison of NRF and NRP has been reported so far that details their respective abilities to assess basal NR and treatment-induced changes in NR. This is why it appeared interesting to evaluate the efficacy of the three different treatments for reducing NR, using both the %NRF and %NRP indexes.

Methods

Our basal values of NRF were comparable to those calculated by other authors at the same or a similar reference flow.⁷⁻⁹ In the basal state, NRF and NRP provided comparable assessments of NR, *ie*, they were not significantly different and highly correlated. This may be explained by the fact that, on the average, the flows corresponding to a 1 cm H₂O PTN and used to calculate NRP (0.55 ± 0.13 L/s) were not significantly different from 0.5 L/s. Indeed, due to its nonlinearity, NR is likely to be markedly influenced by the flow or pressure levels retained for its calculation.^{10,11}

By contrast, the effects of the three treatments were significantly different depending on whether they were assessed by NRF or by NRP (Table 1). This may be explained as follows. NRF measures NR at a fixed flow level, and therefore reflects a resistance calculated for a constant contribution of the K_1 and K_2 Rohrer coefficients to NR, namely $(K_1 + 0.5 K_2)$. On the contrary, when NR decreases, the flow corresponding to a 1 cm H_2O PTN increases (Table 1), and NRP then reflects a resistance calculated for an enhanced contribution of the K_2 Rohrer coefficient to NR. Indeed, compared with the basal state, the theoretical flows corresponding to a 1 cm H_2O PTN were found, in our subjects, to be up to 35% higher with Respir+, 65% higher with Nozovent, and 120% higher after treatment with Pernazène, whereas no marked changes were observed in maximal nasal flow. Increases of up to 42% in mean nasal airflow corresponding to a 1.5 cm H_2O PTN were reported previously in patients with rhinitis after 2 months of treatment with nasal steroid sprays.¹² It is therefore not surprising that these methodology-induced changes in the theoretical flows used to calculate NRP made the latter parameter less sensitive than NRF for assessment of NR under treatments that improved nasal permeability. Consequently, %NRF was chosen as the index to assess treatment efficacy in the present study.

Treatments

Whatever the treatment, no complaint of either discomfort or side effects was reported by any subject. All our subjects reported a subjective improvement in ease of breathing with all three treatments, but the improvement was more marked with Nozovent and Pernazène than with Respir+. However, when examining the individual effects of the different treatments, we observed that in the two subjects with a cold, NR increased with Respir+, whereas in the other subjects, it remained unchanged or decreased. Similar discrepancies between subjective and objective evaluations of the efficacy of a treatment were reported previously for exposure to menthol vapor¹³ or for breathing through artificial noses,¹⁴ thus demonstrating that the subject's sensation may be a misleading index of his nasal patency. However, with Nozovent, NR decreased in all subjects. These contrasting results may be attributed to the fact that placing the adhesive Respir+ across the nose requires brief compression of the nostrils, which may induce a temporary increase in nasal congestion and a subsequent narrowing of the nasal passages in subjects with a cold. Therefore, to avoid any bias in the comparison of the efficacy of the different treatments, we performed a

second analysis of the data after discarding those obtained in the subjects with a cold.

When comparing the effects of the mechanical treatments in the 13 subjects without cold, Respir+ remained statistically ineffective in reducing NR. In this connection, we observed that in four of our subjects, Respir+ lowered NRF below 70%, whereas in the other nine, it left NRF roughly unchanged. Since the same care was taken for all subjects in positioning the Respir+, it is highly improbable that the lack of efficiency observed might be due to incorrect placement of the device. Contrarily to Respir+, Nozovent significantly lowered NRF to about 55% of its basal value (Fig 2). Comparable Nozovent-induced decreases in NR were reported previously in patients with respiratory sleep disorders.²⁻⁴ This difference between Respir+ and Nozovent efficacy in reducing NR is probably due to the specific design of these devices. An internal nasal dilator can indeed be expected to open the anterior nasal passages better than an external one, due to the more marked expanding force exerted in the turbinate and/or the valve region. In this connection, significant decreases in NR were also observed previously in patients with nasal obstruction who were equipped with another internal mechanical nasal dilator formed as a looped spring.¹⁵ By contrast, to our knowledge, no objective data are presently available regarding the effect of external nasal dilators on NR. Only subjective evaluations of such devices relating to sleep and snoring have been published.¹⁶

As expected, NRs were found significantly decreased after Pernazène treatment. The Pernazène-induced decreases in NRs presently observed in our normal subjects are in the range of those previously reported in patients with nasal congestion after inhalation of topical decongestants⁶ or in patients with rhinitis after administration of intranasal corticosteroid aerosol.⁹

Surprisingly, Nozovent, an internal nasal dilator, and Pernazène, a topical vasoconstrictor, resulted in comparable mean decreases in NRF in healthy subjects without upper airway complaints. Similar observations relating to another internal spring nasal dilator and a 1% phenylephrine (Neo-synephrine) nasal spray were reported previously in patients with nasal obstruction.¹⁵ Interestingly, the relative contributions of the K_1 and K_2 terms to NRF were identical with both treatments (Table 1), which suggests that the flow profiles were similar with Nozovent and Pernazène. The present results demonstrate that Nozovent, a mechanical device, is as effective as a topical decongestant treatment in improving nasal breathing. This device, which does not involve any risk of medicinal side effects or drug

interactions, might be recommended as long-term therapy for certain subjects who are concerned about pharmacologic or surgical treatments. Indeed, it must be kept in mind that, from a clinical standpoint, the means to decrease NR mainly depend on the reason for the obstruction, so that the therapy is generally tailored to the etiology of the disorder.

The fact that no significant correlation was found between %NRF with Nozovent and %NRF with Pernazène demonstrates that most subjects responded differently to each of these treatments. This could be expected since anatomy is likely to vary from one subject to another, and the two treatments increase the nasal cross-sectional area at different anatomic levels. Indeed, Nozovent acts by expanding nasal valves, whereas Pernazène acts by reducing the turbinate section via local decongestion of the nasal mucosa. This suggests that the effects of the two treatments might be additive.

In conclusion, although active posterior rhinometry is a reference method for assessing the effect of a particular treatment on nasal permeability, percentage changes in NR must be interpreted with caution, *ie*, by considering the flow level retained for NR calculation. NR corresponding to a fixed flow level appears to be a more sensitive index than NR corresponding to a fixed PTN level. With the former index, the effect of the internal nasal dilator Nozovent was evaluated as a mean decrease in NR of 45%, whereas no effect could be evidenced for Respir+. Therefore, due to its beneficial effect on NR, the noninvasive drug-free device Nozovent might be recommended as an alternative to topical decongestants for certain subjects presenting with nasal obstruction in the valve region and who are concerned about other types of treatments. Further studies evaluating patients with clinical symptoms of nasal obstruction would allow researchers to better define the physiologic and clinical effects of Nozovent.

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