

## **CLINICAL STUDY OF NOZOVENT ON 62 PATIENTS IN FRANCE**

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### **INTRODUCTION**

Nozovent is a nasal device made of medicinal plastic, designed by a Swedish ENT-specialist in Gothenburg. The principle is that the nostrils are dilated. The narrowest passage in the upper respiratory airway accounts for more than half of the total respiratory resistance.

When the nostrils are widened the inspiratory airflow is improved by approx. 24 %.

### **PATIENTS AND METHODS**

The study was carried out by 8 ENT-doctors in various districts in France from June until November 1991. A pre-therapeutic report was kept for each patient containing information about snoring intensity and history, connected symptoms (nasal stuffiness, dryness of mouth, morning fatigue, memory deficiency), ease of wakening, factors impairing airflow and examination procedures (nostrils and nasal cavity anatomy, clarity of speech and dental alignment) were noted.

Each of the patients filled in a report form after ten consecutive nights when they had used Nozovent. The form contained information as to snoring intensity, dryness of mouth (on a scale of 1 to 3 where 1 = no difference; 2 = reduction and 3 = considerable reduction), nasal stuffiness and an estimation of tolerance towards the device. Each patient used Nozovent for ten nights.

The studies were carried out on 62 patients of whom 52 were men and 10 were women. The average age was 44, ranging from 21 to 68. 9 patients were awaiting surgery of the palate (UPPP).

### **THE RESULTS**

The primary criteria for evaluation was, of course, snoring intensity. Other criteria included dryness of mouth and the importance of nasal blockage. In practice it was found that these three criteria often corresponded in direct proportion to each other.

Of the 62 patients

- 7 experienced a considerable reduction in snoring intensity (approx. 11,25 %)
- 25 experienced a reduction in snoring intensity (approx. 40,25 %)
- 30 failed to experience any improvement.

Snoring was reduced to a greater or lesser extent in 32 patients through the application of the device.

Dryness of the mouth was reduced in 18 patients.

Nasal stuffiness was considerably reduced in 24 patients, of whom 20 experienced a reduction in snoring intensity in relation to this (the patients showed a deviation of the nasal septum and/or hypertrophy of the nasal turbinates).

It should be noted that two patients in whom studies could not be evaluated due to colds, showed a clear improvement in respiration through their noses and quality of sleep when Nozovent was applied.

#### ANALYSIS OF POSITIVE RESULTS (32 PATIENTS)

In our study no significant differences have been shown relating to the age of the patient contra the effectivity of the nasal device.

Snoring intensity was very considerable or considerable in 21 patients.

Snoring intensity was moderate in the other 11 patients.

During the course of examination 22 patients showed nasal septal deviation and/or enlargement of the conchae nasales and snoring intensity was reduced in these patients by the nasal dilator. The cause of decreased nasal airflow is logically affected by Nozovent.

On the other hand, this associated result could not be verified, since the dilator could reduce snoring intensity in patients who did not have any nasal breathing problems (10 cases).

#### TOLERANCE

9 patients did not tolerate Nozovent and were taken off the study immediately. Amongst these, 2 patients felt uncomfortable and were taken off the study after their snoring intensity had been reduced.

#### FAILURES

This concerns 30 patients out of 62 tested. Beside the nine patients who could not tolerate to use the device another frequent cause for failure was that Nozovent in 11 patients fell out during the night. The reasons for this are:

- the device is not positioned properly. It is very essential to explain for the patient how the dilator is introduced in two steps – first in the upper part of the nostrils and then the lower part of the device is lifted into the nostrils and fixed against the nasal floor. If this is not done the device will fall out quickly
- unrestful sleep and continuous movements in bed

- the openings of the nostrils are too small, the medium size can not be positioned. It would be desirable to have a smaller size of the device for these patients.

The remaining 9 failures were spontaneous, not relevant to any objective etiology.

### CONCLUSION

Nozovent was tested on 62 patients and was found to have a positive effect on snoring intensity in 32 patients. The effect was more apparent in patients experiencing difficulty with nasal breathing (septal deviation, enlargement of conchae nasales). The causes of failure were primarily dependent on intolerance and that the dilator failed to remain in place. Naturally, in the true sense, Nozovent can not be classified as a curative treatment for snoring, but the excellent quality of the results obtained and the safety level enjoyed by this application can be considered to be of interest:

- in snoring patients with nasal breathing problems
- as a therapeutic test in order to evaluate nasal influence upon snoring intensity
- as treatment before operations
- in patients who refuse to undergo operation or have a contra indication to the operation

Due to the difficulty in calculation of snoring intensity both before and during this study it would be interesting to complement a study of Nozovent with a registration of sleep quality and nasal manometric measurements in order to establish SaO<sub>2</sub>, desaturation index and objectively calculate the sleep quality of the patients.