

# **The Importance of Improved Nasal Breathing**

## **A review of the Nozovent nostril dilator**

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## Abstract

The Nozovent nostril dilator improves nasal breathing to the same degree as topical decongestants and reduces mouth dryness at night in 51% of nocturnal mouth breathers.

It does not help every snorer but reduces the snoring heard by the sleeping partner in about 50%, improves respiratory disturbance index significantly in 19% and gives less morning and daytime tiredness in 40% of snorers. The medium CPAP pressure can be significantly reduced with the dilator.

Key words: nostril dilator, Nozovent, mouth dryness, snoring, respiratory disturbance index CPAP.

It is obvious for most people that the mouth and not the nose is meant for eating and drinking; nobody uses the nose for eating. When it comes to breathing, however, it is not so obvious that the nose and not the mouth should be used. If your nose is blocked, you start to use your mouth, without bothering about the disadvantages, some of them well-known, like mouth dryness, others not, like a lack of nitric oxide in the lower airways which reduces oxygen uptake (1).

When you expand your chest and breathe in, you create a negative intrathoracic pressure and air is sucked into the lungs through the airways. The most narrow area is the anterior part of the nose, the valve region. The mean cross-sectional area is here 1.4 cm<sup>2</sup> compared with 2.0 cm<sup>2</sup> in the bony opening of the nose and 6 cm<sup>2</sup> in the interior part of the nose (2). According to Poiseuille's law of physics, it is the narrowest cross-sectional area that is important when the pressure is calculated. With an increase from 1.4 cm<sup>2</sup> to 2.0 cm<sup>2</sup>, the intrathoracic negative pressure can be reduced (3). This means that it is much easier to inhale through the nose.

### Nasal air flow

One way to open up the nostrils is by stretching the nasal wings with your fingers. You can also use a nasal strip i.e. Breathe Right<sup>®</sup> or Respic<sup>®</sup> placed superiorly to the nasal alar cartilages on either side. A built-in elastic splint pulls the nasal wings laterally and opens up the valve area. This can also be done with the Nozovent nasal dilator, which opens up the nostrils by lifting aside the soft tissues in the nasal wings. In this way, the air flow through the nose can be increased above normal, as has been shown in rhinomanometric studies.

In a study of the effectiveness of reducing nasal air flow resistance, the external Respic+ nasal strip device had no effect, while both Nozovent and a topical decongestant significantly reduced the resistance ( $p < 0.0001$ ) (4). In another study, the nasal resistance was estimated by active posterior rhinometry in 17 healthy subjects. Nozovent and a topical decongestant reduced the resistance to the same degree, but the effects were cumulative when used together (5).

In a recent study from Finland 27 healthy subjects tested the Nozovent dilator. It proved to be significantly more effective in reducing nasal resistance than the Breathe Right<sup>®</sup> nasal strip placed superiorly to the alar cartilages (6).

The air flow at 150 Pa increased significantly from an average of 0.68 l/sec to 0.88 l/sec, or by 29%, when the anterior part of the nose was dilated with Nozovent (7). A second study showed that the increase in air flow varied between 5.5% and 45% (8). When the nasal resistance in 72 patients was measured, it was found that the respiratory resistance was substantially reduced in all of them by inserting Nozovent (9).

### Mouth dryness

Of 34 patients who had a dry mouth in the morning, 28 (80%) noted less dryness and in one third of the cases there was no dryness at all, when sleeping with Nozovent (10). When 85 nights with and 85 without the device were scored by 17 patients, they noted a highly significant reduction ( $p < 0.001$ ) in dryness of the mouth after having slept with dilated nostrils (3).

In the small town of Köping, Sweden, with 19,000 inhabitants, 215 subjects tested Nozovent every other night for ten days. Every morning, they had to score how dry they were in their mouths, 0 = no dryness and 3 = severe dryness, and 51% observed less mouth dryness when the device was used (11).

## Quality of life and sleep

Utilising the subjective words "better sleep", 40 patients of 50 who gave ratings noted that they slept better when sleeping with a dilated nose. Periods of being awake during the night decreased in half the patients, as did tiredness in the morning (10).

Many snorers complain of tiredness during the day. For one month, 37 men who were heavy snorers graded their average tiredness in the morning. It was found that 15 of them (41%) were less tired when the nostril dilator was used. A significant correlation ( $p < 0.01$ ) was also found between the diminution of snoring and less tiredness (12).

In the same study, it was found that the quality of life in these middle-aged snoring men was worse than that of a population sample and at an equal level with that of patients suffering from medical conditions such as myocardial infarction and chronic obstructive lung disease (13). When the 37 snoring men slept with the nostril dilator for one month, their quality of life, measured with the Nottingham Health Profile, improved significantly ( $p = 0.001$ ). They were also significantly less tired during the day ( $p < 0.001$ ). Their female sleeping partners experienced significantly better sleep ( $p = 0.005$ ) and an improved sense of well-being in the morning ( $p = 0.006$ ) during the test period. Both were correlated with a significant reduction ( $p < 0.001$ ) in the men's snoring (14).

In quality of life questionnaires, daytime tiredness is incorporated in the mental capacity questions. The Nottingham Health Profile (NHP) includes a section about energy and, in the Psychological General Well-Being (PGWB), there is a section on vitality. It is also possible to evaluate daytime tiredness using a visual analogue scale (VAS) to show how drowsy or alert people are. After using the Nozovent nostril dilator at night for one month, NHP (energy) and the VAS value for drowsiness improved significantly ( $p < 0.001$ ), while the improvement for PGWB (vitality) was not significant ( $p = 0.06$ ). By improving nasal breathing at night, people can wake up with more energy and less drowsiness (15).

## Snoring score

For 10 nights, 10 patients used the nostril dilator every other night and the sleeping partners of the patients judged the snoring sound level every morning using a snoring score (0=no snoring; 1=slight; 2=moderate; 3=severe). The results showed a significant decrease in snoring from an average of moderate to slight, when Nozovent was used, i.e. from a barely tolerable to a tolerable noise level. On 28% of the nights, the partner heard no snoring compared with only 2% when the snorer slept without the dilator (16). When the same score was used in 18 Japanese subjects, the results indicated that the snoring of half of the subjects improved from a severe level, at which the sleeping partners could not sleep, to a slight level at which the snoring was heard only in silence, 30% of the nights were slept through without snoring (17). In a clinical study of the nostril dilator involving 62 patients in France, de Frahan found a positive effect on snoring intensity in 32 patients (unpublished data 1994).

In a study from the Medical University at Varna in Bulgaria, Marev tested 20 patients with altered nasal breathing due to deviation or hypertrophy of nasal conchaes. He used the above-mentioned snoring score and found that half the patients experienced a considerable reduction of snoring according to the sleeping partner during the nights when the nostril dilator had been used (unpublished data 1998).

In the previous mentioned article (12), the patient's sleeping partner graded the average snoring using a visual analogue scale, 0= no snoring; 100=continuous snoring before and after one month's use of Nozovent. The snoring was significantly reduced from 83 to 63 points ( $p < 0.001$ ). In half the snorers, there was a reduction of more than 10 points, 14% experienced a reduction of more than 50 points.

### Snoring noise

In three studies at sleep laboratories, the noise has been measured when sleeping with and without the nostril dilator. In the first, a sound level dosimeter with the microphone placed 50 cm above the head of the patient was used. The number of epochs of four seconds with a level of noise of more than 55 or 60 dB was significantly lower ( $p=0.02$ ) when Nozovent was used (8).

In another study, 15 obese patients slept during one night for three hours without and three hours with the dilator. The noise was measured by a sound level meter and spikes of sound intensity of more than 50 dB were perceived as snores. During slow-wave sleep, when using the dilator, a significant reduction was recorded in snores per minute of sleep ( $p<0.05$ ), in snores per minute of snoring time ( $p<0.05$ ) and in sound intensity of approximately 6 – 9 dB. In this presentation, the intensity must be regarded as the most important parameter, as a decrease of 3 dB represents a halving of the sound, 6 dB a reduction to a quarter and 9 dB to one eighth. When, for example, the level of sound goes down 10 dB from 70 dB to 60 dB, it is comparable to leaving a heavily trafficated street and listening to normal speech at a distance of one metre (18).

The snoring index in the third study was the same when 21 patients with OSA were tested before and after one month's use of the dilator (19).

### Growth hormone (GH) secretion

It is well known that GH secretion is associated with slow-wave sleep, with about 70% occurring during these periods. In a study (12), we noted that 15 of the 37 examined snoring patients were less tired in the morning when nasal breathing was improved by Nozovent and in this group we also found a significant increase in the concentration of insulin-like growth factor 1 (IGF-1) which can be used as an index of GH release. This indicates that snorers who are less tired in the morning may have more slow-wave sleep, which may increase GH secretion during the night, resulting in the elevated formation of IGF-1 (20).

### Obstructive Sleep Apnea (OSA)

The mean apnea index decreased from 18 to 6 ( $p=0.008$ ) in ten patients when the nasal dilator was tested for two nights in random order at a sleep laboratory after a training period of 10 nights at home with the dilator. The average decrease in the apnea index was 47%, ranging from 13% to 83% (8). The importance of nasal resistance in 10 male patients with severe obstructive sleep apnea syndrome (OSA) was studied with polysomnography for three nights, the first for acclimatisation, followed by nights 2 and 3 in random order without treatment (saline) or with a topical nasal vasoconstrictor and the Nozovent nostril dilator. The average fall in nasal resistance was 73%, but there was no significant decrease in the apnea hypopnea index during treatment nights. However, there was a significant decrease in the number of arousals per hour ( $p<0.04$ ) and also a significant drop in heart beats per minute from 66 to 62.8 during the night ( $p<0.01$ ) (21).

In a study of 15 significantly obese patients, eight of whom had an apnea/hypopnea index of above ten, no improvement in the index was observed when the dilator was used for half the night, while the nocturnal oxygen saturation was also the same (18).

The respiratory disturbance index (RDI) was studied in 21 patients with moderate or severe OSA, before and after one month of treatment with Nozovent. Seventeen patients were regarded as non-responders and four patients (19%) responded, i.e. there was a reduction in RDI of more than 50% or fewer than ten events per hour during treatment, down from on average of 34 before treatment. Of the 15 patients who had a bed partner, 10 reported a mild reduction, two a moderate one and two a moderate to high reduction in snoring sounds. Only one bed partner failed to observe any reduction in snoring sounds. A significant improvement ( $p=0.03$ ) in daytime sleepiness was noted when estimated according to the Epworth Sleepiness Scale (22).

### Continuous positive airway pressure (CPAP)

About half the patients treated with CPAP because of OSA develop nasal problems, i.e. dryness and congestion, and they are more frequently observed when the pressure levels are above 12 cm H<sub>2</sub>O than below 8 cm H<sub>2</sub>O. The effect of the nostril dilator was investigated in 38 patients with an RDI of more than 20 events/hour. In random order, the patients slept for one night with and one without Nozovent and the pressures were titrated and analysed with an automatic CPAP system (22).

In the whole population, the medium CPAP pressure was significantly reduced ( $p=0.023$ ). There was no significant difference in RDI. Taking 9 cm H<sub>2</sub>O as a threshold value, 20 of 38 patients required higher pressure. In this group, when Nozovent was used, the mean median pressure was reduced from 10.3 to 9.1 cm H<sub>2</sub>O ( $p<0.05$ ). None of the patients reported any sleep complaints or local side effects caused by the dilator during the study (22).

### Blood pressure

During exercise involving bicycle ergometry with the Nozovent nasal dilator, all ten men were able to cycle at maximum load without mouth breathing and there was a significantly ( $p<0.01$ ) lower increase (13 mm Hg) in the systolic blood pressure than when the dilator was not used (7). Facilitated nose breathing reduces respiratory work, which in turn lowers the systolic blood pressure during exercise. This can also be explained by the increased utilisation of nitric oxide inhaled through the nose, resulting in improved oxygen saturation.

### Nitric oxide

The first study of the importance of nasal nitric oxide was performed on four patients at a neurosurgical department. They had been mechanically ventilated for a couple of days. When nasal air was added to the inhaled air, the arterial oxygen saturation increased significantly by about 20% (23). Nitric oxide is produced in all the para-nasal sinuses (24). When it enters the nasal cavity, it is inhaled when people breathe through the nose and reaches the lower airways and the lung where it dilates the pulmonary vasculature and improves arterial oxygenation.

In a previously mentioned study at a sleep laboratory, the minimum overnight arterial oxygen saturation increased significantly from 78% to 84% ( $p=0.003$ ) the night the Nozovent nostril dilator was used (8).

The observed significant drop in heart beats during the nights when the subjects slept with the dilator, as reported by Kerr et al. (21), might be explained by improved oxygenation.

### Bronchial spasm

The mucosa in the mouth and throat has less capacity than that in the nose to warm and humidify the inhaled air. During mouth breathing, the bronchi receive somewhat colder and drier air which, in patients with asthma, has been observed to initiate bronchial spasm (25).

At an asthma centre, 15 out-patients with nocturnal asthma were selected and told to sleep every other night with the nostril dilator. Every morning, they scored the previous night. When sleeping with Nozovent, they woke up with asthma on 17 of 75 nights as compared with 32 of 75 when sleeping without it ( $p<0.01$ ). Reduced nocturnal asthma was observed by 12, less need for asthma medication at night by 7 and better sleep by 10 patients (26).

## Compliance

In order to benefit from Nozovent, it is important to breathe continuously through the nose. Many people are used to breathing through the mouth and at first continue to do so, in spite of the opportunity to breathe easily through the nose. Sometimes it takes more than a week to learn a new breathing technique.

In many studies in which Nozovent has been tested for up to ten days, the compliance has been fairly good. In one study over one month, the patients were told to increase their tolerance by using the device at least twice per day. By doing so, only five of 26 patients dropped out (19).

In another study, five of 42 patients dropped out during the first month and 15 of 42 (36%) during a test period of six months (12). When the patients in this study were asked after five years, nine of them (21%) were still using the dilator. At this time, the mean snoring score on the visual analogue scale was 74 for the nights on which the device was not used and 41 when it was used (27).

## Conclusions

In all subjects tested in an upright position, the use of the Nozovent nostril dilator has been shown to improve nasal breathing and reduce nasal resistance. No systematic tests have been performed in the supine position. The effect is equal to that of a topical decongestant in healthy subjects.

In subjects with mouth dryness due to mouth breathing during the night, at least half is helped by the dilator.

Morning tiredness is a subjective feeling experienced when the subject wakes up and it may change from day to day. After one month of continuous use of Nozovent, more than four in 10 snorers observed that they were less tired and there was also a good correlation between decreased snoring and less tiredness. Daytime tiredness also improved when tested on a visual analogue scale, as did the section on energy in a quality of life questionnaire. A significant improvement has been shown on a sleeping scale.

One common way to score snoring is to ask the sleeping partner to do it. Although it is subjective, the answer reflects the day-to-day situation and by using a four-grade scale important information can be obtained. In Nozovent studies from Sweden, Japan, France and Bulgaria, a decrease in snoring scores has been shown in about half the snorers. With the dilator, the sleeping partner heard no snoring on about one in three nights. In the three studies in which the snoring noise has been measured, one shows a decrease during the night, one does not and one only shows a decrease in slow-wave sleep. Patients with obstructive sleep apnea (OSA), presented in two studies, displayed no improvement in apnea index or apnea/hypopnea index. However, in one study, there was a significant decrease in the number of arousals when Nozovent was used.

In another study, the respiratory disturbance index, RDI, improved significantly in four of 21 patients with moderate or severe OSA, but, most interestingly, 14 of 15 bed partners reported a reduction in snoring sounds. This subjective observation may be soft data from a scientific point of view, but it is important data for the bed partner.

The most common way to treat OSA is to use CPAP. One frequent disadvantage is that pressure over 12 cm H<sub>2</sub>O produces nasal problems. In a recent study, the nostril dilator was able to reduce the pressure significantly, leading to better compliance. No side-effects have been observed with Nozovent (28).

The most striking effect of improved nasal breathing is the discovery of nitric oxide, which is produced in the para-nasal sinus, enters the nasal cavity and is inhaled when breathing through the nose to dilate the pulmonary vasculature and improve arterial oxygenation. There is a wide range of nitric oxide levels in different subjects and more research is needed to compare subjects with low levels and those with high levels.

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