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A Clinical study of the Nasal Dilator Nozovent® in Japanese Subjects

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A nasal dilator (Nozovent®) has been developed to fit in the nasal cavity and external nose of Caucasians, and beneficial effects have been confirmed. However, the ability of the device to dilate nasal valve areas of Orientals, whose external nose structure differs from that of Caucasians, has not been studied. We studied the effectiveness of the Nozovent® device in preventing snoring and sleep apnea in Japanese subjects according to the methods described by Petruson. When the Nozovent® device was worn by the eighteen subjects who experienced snoring, nine showed significant improvement, four showed good improvement, two fair improvement, and three discontinued the trial; the rate of improvement was 72.2%. The device was also seen to be effective for three patients with sleep apnea. The Nozovent® device provides a unique method for non-surgical treatment of snoring, and the effectiveness is a result of dilatation of the nasal valve area. The principle is medically sound, and is equally applicable to nasal valves of both Caucasians and Japanese who have different external nose structures.

Key Words: Nozovent®, nasal dilator, nasal valve, sleep apnea

INTRODUCTION

The importance of the nasal valve area in the nasal airflow has recently been reported (1. 2, 3, 4). Nozovent®, a device that dilates the nasal valve area, was developed in Sweden by Petruson (1988,1989)(5, 6). The Nozovent® device has been reported to prevent snoring and sleep apnea, and has been marketed primarily in the Scandinavian countries (7, 8, 9, 10). The device has been developed to fit in the nasal cavity and external nose of Caucasians, and beneficial effects have been confirmed. However, the ability of the device to dilate nasal valve areas of Orientals, whose external nose structure differs from that of Caucasians, has not been studied. We studied the effectiveness of the Nozovent® device in preventing snoring and sleep apnea in Japanese subjects according to the methods described by Petruson (5, 6).

DEVICE

As shown in Figure 1, measurements of the nasal cavity by acoustic rhinometry demonstrate that the size of the nasal cavity varies with the distance from the nasal orifice. The narrowest part of the nasal cavity is 2 to 3 cm from the nasal orifice. The Nozovent® device is designed to dilate the narrowest part of the nasal valve area.

Nozovent® is made of a medical grade plastic (Fig. 2), and is supplied as two pieces in one package. In Scandinavian countries, two sizes, large and medium, are available. We used the medium size for our study. The two oval end tabs have a long diameter of 23 mm and a short diameter of 9.5 mm, and are connected with a 48 mm long bar. The two end tabs are pressed against the skin in the lateral walls of the nasal vestibules to dilate the nasal valve, and the outside of the end tabs is covered with knobs to prevent Nozovent® from slipping out.

Figure 3 shows a Japanese subject, with a wide nasal valve area, using the Nozovent® device to dilate the nasal valve. The device is designed to effectively dilate leptorhine nasal valves, such as those of Caucasians.

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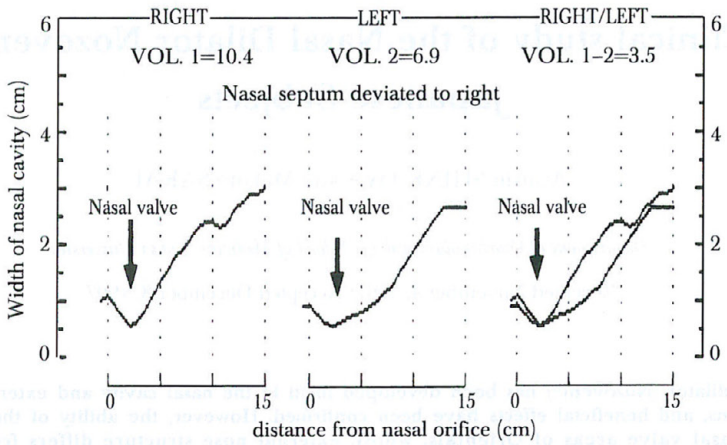

Fig. 1 Nasal cavity measurements with acoustic rhinometry

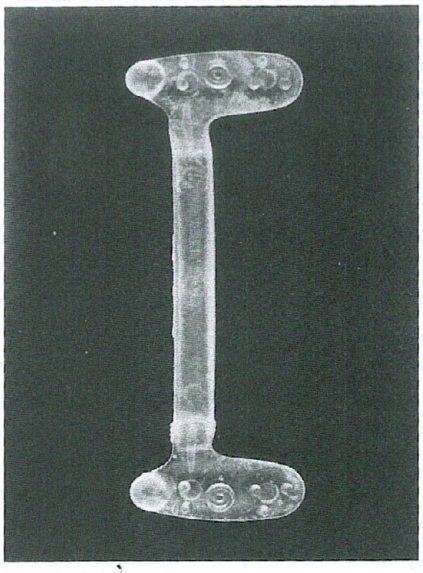

Fig. 2 Nozovent

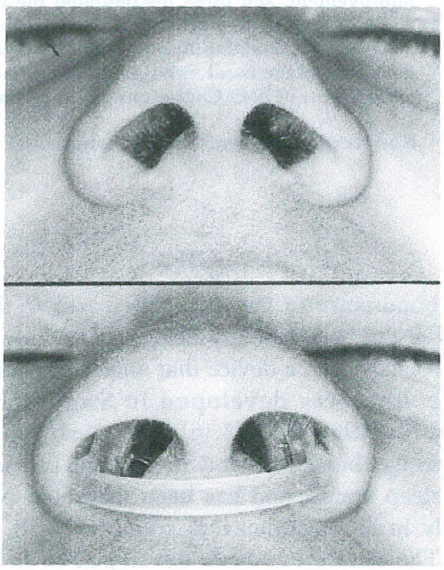

Fig. 3 Japanese subject with the Nozovent device in place

TEST SUBJECTS

Clinical trials were explained to 15 inpatients, who were identified by nurses as snorers. The subjects practiced using the Nozovent® device, and ten agreed to participate in the trial. Use of the Nozovent® device was also explained to 11 outpatients who sought medical help for snoring problems. The subjects practiced using the Nozovent® device, and the trial was explained to the subjects and their families. Eight agreed to participate. Furthermore, among the study participants two inpatients and one outpatient had sleep apnea. The subjects consisted of 12 males and six females between 20 and 60 years old with an average age of 48.

Test methods

Each subject was trained in the correct use of the Nozovent® device. Subjects were instructed to sleep with the Nozovent® device in place every other night for a total of eight nights.

Snoring score

The effect of Nozovent® was tested by scoring the degree of snoring with the following scale:

Points
3 Severe snoring: sleeping partners could not sleep.
2 Moderate snoring: sleeping partners were disturbed, but managed to sleep.
1 Slight snoring: audible during stillness.
0 No snoring.

Total scores for 4 days with and 4 days without the use of the Nozovent® device were obtained. The effect of Nozovent® was judged from the difference in the score with and without the device; i.e., significant improvement when the difference was greater than 5 points; good improvement when the difference was 3 to 5 points; fair improvement when the difference was less than 3 points, and no change in case of a zero score.

RESULTS

The results of the 18 subjects, including three subjects who discontinued the trial because of discomfort when using the Nozovent® device, are shown in Table 2. In the outpatient group, five showed significant improvement, two good improvement, and one fair improvement; the rate of improvement was 87.5%. On the other hand, of the 10 inpatients, four showed significant improvement, two good improvement, one fair improvement, and three dropped out as mentioned above. In the three subjects with sleep apnea, two showed significant improvement, and one showed good improvement. Although Nozovent® is supposed to prevent discomfort, three subjects reported insomnia and discontinued the use of Nozovent® after 1 to 2 days. Two of the three subjects were inpatients who were not aware of their snoring. The Nozovent® device fell out of the nose during sleep in five of the subjects.

Some of the representative cases are presented as follows:

Case 1 was a 56-year-old male whose snoring prevented his wife from sleeping in the same room. Examination revealed a nasal septum deviated to the right, but an x-ray examination did not show any abnormality in the paranasal sinus. The trial for Nozovent® was explained to the couple, and consent was obtained. During the 8 test days, each of the 4 days without Nozovent® scored 3 points, which meant severe snoring. While using the Nozovent® device, 3 days were with slight snoring and one day was with no snoring. The use of Nozovent® resulted in significant improvement in the subject's snoring and the couple wished to continue the use of Nozovent® after the trial.

Case 5 was a 65-year-old male inpatient, suspected of having laryngeal cancer as determined by laryngomicrosurgery. He was reported by a nurse to have been snoring. The trial for Nozovent® was explained and his consent was obtained. He scored 8 points (daily average of 2 points) and had moderate snoring on days without Nozovent®, but scored zero on the days when he used the Nozovent® device with no snoring recorded. The subject admitted to better sleeping with Nozovent®, and wished to continue the use after the trial.

Case 8 was a corpulent 40-year-old male outpatient who sought medical treatment for his snoring. His wife also indicated that he had sleep apnea. The test plans with Nozovent® were explained and his consent was obtained. No abnormalities were observed in an X-ray examination of the paranasal cavity. Scores of ten points were recorded, as shown in Figure 4, during the days without Nozovent®, and the subject's wife was able to sleep for two nights and was not able to sleep during the two other

Table 1 Clinical effects of Nozovent®

	No.	excellent	good	fair	drop-out	efficacy rate
Outpatients	8	5	2	1	0	87.5%
Inpatients	10	4	2	1	3	60.0%
total	18	9	4	2	3	72.2%

nights. The score decreased to a total of 4 points for 4 days with Nozovent®. On 2 nights with Nozovent® the wife was awakened by his snoring, and found that Nozovent® had fallen out of the subject's nose.

Case 16 was a 27-year-old female outpatient, who wished to control her snoring during a trip with a friend. The trial for Nozovent® was explained, and her mother was asked to make the required observations. The subject, however, claimed strong discomfort while wearing Nozovent®, and the results showed only slight improvement. Further, Nozovent® was reported to have fallen out quite often. Also, for reasons of appearance, the subject did not wish to continue the use of Nozovent® after the trial.

Case 18 was a 46-year-old male inpatient who had a laryngeal polyp removed under general anesthesia. There were many complaints about his severe snoring from other patients in the same room. The subject, however, did not admit to have been snoring, claimed to sleep soundly, and did not wish to participate in the Nozovent® trial.

Total snoring scores for each of the 15 subjects over four days are shown in Figure 4. Total scores for the 15 subjects on the 4 days without Nozovent® were 155 points, with an average of 2.6 points per person per night. The total with Nozovent® was 47 points, with an average 0.8 points per person per night, indicating apparent control of snoring. The results indicated that snoring in the majority of the subjects improved from a severe level, at which sleeping partners could not sleep, to a slight level, where snoring was heard only during stillness.

Among the 15 subjects, nine (60%) wished to continue the use of Nozovent® after the trial, and the device was given to them free of charge. Five subjects, including those in whom Nozovent® was effective, did not wish to continue the use of the device. They were subjects who were not bothered by their snoring or who did not admit to being a snorer.

There were five inpatients, four females and one male, who did not wish to participate in the trial. Three out of the five did not participate because they were not aware of their snoring, and two for reasons of appearance. There were also three outpatients who sought medical help for snoring, but after learning of the test plans, did not wish to participate. The three were all females who declined to participate because of the discomfort and appearance of the device when worn.

DISCUSSION

The nasal valve area is the narrowest passage in the respiratory tract according to Bachman et al.(1972)(11), causing more than 50% of the total resistance to nasal respiration. Further, results of acoustic rhinometry studies by Lenders et al.(1990)(12) and Hansen *et al.*, who cooperated in the present studies, showed

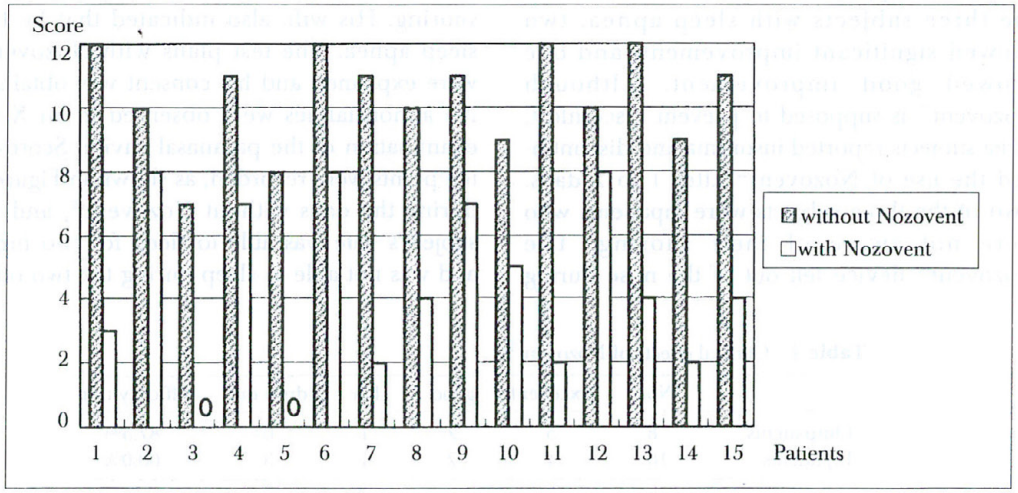

Fig. 4 Total snoring score for each of the 15 patients

that the cross-sectional area of the nasal valve is 0.7–1.0 cm^2 and is the narrowest part of the respiratory tract. Petruson (1989)(5) developed the Nozovent® device to dilate both nostrils, and the nasal airflow was reported to have increased by 24%.

Petruson (1990)(13) calculated that, when the cross sectional area of the nasal valve increased from 1 cm^2 to 1.4 cm^2, the nasal pressure decreased from 8 cm H_2O to 4 cm H_2O. It is therefore estimated that one may inhale the air with one half the negative pressure when the nasal valve is dilated by Nozovent®. Therefore, when snoring is generated by vibration of the soft palate and pharynx, snoring should be relieved with the reduced negative pressure.

The results are based on the studies with Scandinavians whose external nasal structure is different from that of Japanese. It is therefore important to study the effects of the Nozovent® device with Japanese subjects whose nasal valve area and the external nose, particularly in the nasal ala are different from that of Scandinavians. Studies were therefore conducted, with the cooperation of Petruson to evaluate the effectiveness of Nozovent® to relieve snoring in Japanese subjects.

It has been observed that snoring can be reduced, with a high success rate, when the Nozovent® device is worn. The device was also found to be effective for three patients with sleep apnea.

The Nozovent® device provides a unique method for non-surgical treatment of snoring, and the effectiveness is a result of dilatation of the nasal valve arèa, which provides the highest airway pressure in the nasal cavity. The principle is medically sound, and is equally applicable to nasal valves of both Caucasians and Japanese who have different external nose structures, the so-called "saddle nose" shown in Figure 3. Five subjects out of 18 (27%) experienced loss of the device during sleep, and the rate was considered rather high. This may be attributed to Nozovent® having been developed to fit Caucasian noses, and suggests that it may be necessary to modify the size and shape to fit to the structure of Japanese nasal ala. Such alternations could prevent the Nozovent® device from falling out during sleep, reduce discomfort, and lead to the development of a safe and effective way of controlling snoring. Studies such as those conducted by Petruson may then be developed to evaluate the usefulness against sleep apnea in Oriental subjects, and to apply the Nozovent® device to increase pulmonary function during various sports by utilizing acoustic rhinometry.

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