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Clinical study on the use of Nozovent in a tertiary care setting

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Abstract

Objective: To assess the effectiveness of the Nozovent device in Pakistani subjects at Aga Khan University Hospital, Karachi and Sir Ganga Ram Hospital, Lahore from 15 January 2001 to 15 January 2002.

Methods: Sixty males and 40 females were selected by non probability purposive sampling, from OPD of ENT Department, complaining of nasal obstruction due to various reasons, e.g. vasomotor rhinitis, allergic rhinitis, congestion during pregnancy and menstruation, common cold, traumatic nose and nasal valve problem.

Results: All patients benefited subjectively but the degree of relief varied in individuals.

Conclusion: The Nozovent provides a unique method to relieve nasal obstruction with no side effects (JPMA 54:614;2004).

Introduction

The nasal valve area is the narrowest passage in the upper respiratory tract, causing more than half of the total resistance to nasal respiration in healthy subjects.¹ The proportional ratio between the cross-section area of the nasal valve and the bony piriform aperture is approximately 1:1.4.² The cross-section area on each side of the nasal valve is approximately 30 mm, in the middle of the nasal cavity 120 mm, and in the nasopharynx 150mm.

A nasal dilator Nozovent³ is a device to fit in the nasal cavity. It has two prongs and one stem. It is based on Thudiculum nasal speculum shape. The prongs fit in the nasal vestibule and stem keeps them away due to its shape and power and it causes dilatation of anterior nares. It is made of silastic, which is non-irritant and easy to wash and is reusable. Its texture maintains its elasticity for more than 6 months. It is available in three sizes; small, medium and large. Medium is the most widely used (nearly 60%), however a very few (10%) need the small, while the remainder use the large size. It is a mechanical method to keep nasal valve area dilated and is well tolerated by males and less by females due to use of "coca" in the nasal alae and also for cosmetic reasons.

Anatomic Orientation and Ethnic Variations

Migration of people and military conquests has resulted in an admixture of ethnic groups and the interaction of genetic factors. Thus, there are innumerable variations of nasal structural characteristics. Wen⁴ studied the ontogeny and phylogeny of nasal cartilages in primates and in man. He noted structural differences in the nasal cartilages of black and white individuals.

From a clinical standpoint nasal vestibules are different in Caucasians, Orientals and Negroid. Of the three major races, the variation in nasal form is greatest within the

Caucasian race. Rogers^{5,6} defined the following types of nose:

- 1. Nordic:** convex profile, narrow radix, sharp tip, and narrow nostrils and alae.
- 2. East Baltic:** less narrow than the nordic nose, less dorsal convexity, thicker alar cartilages, and broader tip.
- 3. Alpine (Central and Eastern Europe):** a more concave and foreshortened nose, and medium sized tip.
- 4. Dinaric (Balkan):** large and long nose with drooping tip.
- 5. Armenoid (Middle East):** large, convex noses with great height and length and wide tip. The large alar cartilages curve posteriorly and expose the inner aspect of the columella on profile view.
- 6. Mediterranean (Italy, Spain):** straight or convex dorsum with thin radix and tip.

The Pakistani people have nasal shape comparable to East Baltic group.

Patients and Methods

One hundred subjects were selected by non-probability purposive sampling from the out patient department of Sir Ganga Ram Hospital, Lahore. There were 60 males and 40 females, having age ranging from 18 to 75 years.

Inclusion criteria

All the patients having complaints of nasal obstruction, due to allergic rhinitis, vasomotor rhinitis, congestion during pregnancy and menstruation, common cold and traumatic nose were included in the study (Table 1).

Exclusion criteria

Patients below 18 years of age, having marked septal deviation, nasal polyposis, malignancy, vestibulitis, personality disorder and patients suffering from asthma or

deviation, nasal polyposis, malignancy, vestibulitis, personality disorder and patients suffering from asthma or chest problems were excluded from study.

All patients had complaints of mouth breathing during the phase of nasal obstruction. The nose was examined for airflow and level of obstruction. The treating physician filled a performa explaining patient's complaints and symptoms. After full assessment of the anterior nares, Nozovent was prescribed and patients were educated how to use it. Most of the patients used it at night, as the main complaint was nasal obstruction and snoring at night when they were asleep. Patients were assessed once a week during first month, twice a week for next two months and every month thereafter. After this follow up patients were advised to use the device whenever they felt nasal obstruction throughout their life. The patients were observed subjectively by scoring system, rating 0 to 100. The response was graded as Grade I; 75% -100% relief of symptoms, Grade II; 50%-75% response, Grade III; <50% response.

Results

Of the hundred subjects included in the study, 46 patients had nasal obstruction due to vasomotor rhinitis, 24 had obstruction due to allergic rhinitis, 16 patients suffered obstructed nose due to trauma, 08 had congested nose during pregnancy and menstruation, and 06 patients had nasal obstruction during frequent colds. Of these patients, 26 patients snored due to nasal obstruction. Patients were examined at follow up weekly clinics during 1st month, twice a month for 2 months and then every month for 3 months. The response was Grade I in 80 patients out of 100 (80%), Grade II in 6 patients, making 6% and Grade III in remaining 14 patients (14%) (Table 2). All male patients who were included in the study used the device (Nozovent) and benefited from Nozovent in the range of 30% to 80%. Male patients were followed regularly in the out patient

Table 1. Indications for use of Nozovent (n = 100).

Pathology	No. of patients
Vasomotor Rhinitis	46
Allergic Rhinitis	24
Traumatic / Post-op surgery	16
Congestion during pregnancy and menstruation	8
Common cold	6

Table 2. Results (n =100).

	Total	Grade I	Grade II	Grade III
Vasomotor rhinitis	46	38	0	8
Allergic rhinitis	24	18	6	0
Trauma	16	16	0	0
Congestion during pregnancy and menstruation	8	8	0	0
Common cold	6	0	0	6

department. Out of 40 females, 4 refused to use the device; one due to mild pain and other three due to the fear of dilation of their nostrils. Three more female patients had problems, because they did not want to remove the 'cocca'. Thirty seven out of 40 females used it regularly, and benefited subjectively in range of 30% to 60%. No major complications were reported, except 40 patients (40%) who complained of irritation, epiphora and sneezing during first 48 to 72 hours. Most of the patients got adapted to the Nozovent like using the wrist watch.

Patients who were diagnosed, as vasomotor rhinitis, had very good response. Thirty eight patients out of 46 got benefit upto 80% (Grade I). These patients used Nozovent for 8 -10 hours daily at night. Twenty patients reported that their airway remained patent for whole day. Six patients out of 46 had to use an anxiolytic, (Lexotanil) for one month. Twelve patients used Nozovent only for 2-3 hours daily and found that their nose remained patent the whole day.

All patients with snoring due to nasal obstruction got benefit (Grade I) except one patient who was advised to reduce weight and later had uvulopalatopharyngoplasty (UPPP).

All patients (24) with allergic rhinitis continued to use anti-histamine for six weeks. Eighteen patients with allergic rhinitis had Grade I response and 6 had Grade II response. Two patients had to use Inj. Depomedrol intramuscularly once to suppress rhinorrhoea.

Patients who had nasal airway problems due to trauma were the best candidates. All patients in our study had alar collapse and retracted collumella. These patients had to use Nozovent for a longer duration and most of the time once in 24 hours.

Six patients out of 100 used it during common cold. No doubt they got relief from nasal obstruction but complained of difficulty in using the device due to hypersensitivity and rhinorrhoea. These patients had rhinorrhoea and sneezing while using Nozovent and 5 out of 6 abandoned it. One patient who was above 50 years tolerated it well.

Discussion

Patients complaining of a blocked nose are an extremely common presentation in any ENT clinic. Nasal obstruction can be due to variety of reasons, congenital or acquired. Acquired causes are allergic rhinitis, vasomotor rhinitis, congestion during pregnancy and menstruation, trauma etc. The narrowest part of the respiratory tract is the nose. In the nose major portion of nasal airway resistance is localized to the nasal valve area.⁷ Nasal valve area is bounded: medially by the septum; superiorly and laterally by the caudal margin of the upper lateral cartilage and its fibro-adipose attachment to the piriform aperture and inferiorly by the floor of the pyriform aperture. At rest, approximately 50 - 60% of airflow resistance of the entire respiratory tract, is located in the nasal cavity.⁸ Approximately one-third of the resistance lies in the compliant nasal vestibule region and two-thirds at the level of the nasal valve area. Because the degree of obstruction to airflow is inversely and exponentially related to cross-sectional area of the nasal lumen, displacement of either wall of the valve by as little as 1 mm can result in large changes in resistance. Air flow velocity increases as diameter decreases, and turbulent flow is more likely to be present in high velocity flow. Increasing the diameter of limiting segment should therefore increase the proportion of laminar flow. Turbulent flow as we know causes generation of higher resistance. More over dynamic collapse of nasal valve occurs at higher flow rates increasing flow resistance.⁹⁻¹¹

The Francis alae nasi prop was probably the first nasal dilator used for the relief of nasal obstruction in the nasal valve area. Other internal metal devices have also been used for relief of nasal obstruction at nasal valve area.

Nosovent is a device made of medical-grade plastic. It has two prongs which when inserted in the nostrils keep them apart due to elasticity of the material. The mechanism of action of nasal dilator Nozovent is simple and is similar to the Cottle test.¹² When the nostrils are dilated with Nozovent the airflow through the nose is increased.^{13,14} This produces a significant reduction in nasal resistance to respiratory airflow.¹⁵ This improvement in airflow is comparable with that observed when nasal drops are used for decongestion of nasal mucosa in healthy subjects.¹⁶

The effect of Nozovent has been tested in normal subjects and snorers. In one study mechanical nasal dilatation caused significantly greater increase in cross sectional area of nose as compared to that achieved with nasal decongestion alone.¹⁷

We used this device in hundred subjects, 60 males and 40 females. The response was better in males up to 80% as compared to females where it was 60%. This is due to the fact that males were more compliant in using the device as

compared to females.

Most of the patients were having nasal obstruction due to vasomotor rhinitis VMR (n = 46). Nasal obstruction in VMR, allergic rhinitis and common cold is due to turbinate hypertrophy and mucosal oedema. Similarly in pregnancy and during menstruation there is nasal congestion due to mucosal oedema and turbinate hypertrophy. As the nasal airflow is increased the turbinate shrink, sinus ventilation is improved leading to decrease in consequences of mucosal oedema and hypertrophy. More over Nosovent involves no risk of side effects and drug interactions and is effective in improving nasal breathing. Therefore Nosovent is very effective in treating nasal obstruction due to turbinate hypertrophy and mucosal edema without drugs related side effects as in pregnancy.^{18,19}

Snoring is a sound made by vibrations of soft tissues in upper airway. It is caused by partial blockage of upper airway. When patient is awake sufficient muscle tone is present to keep airway open. When asleep, this muscle tone is lost and airway narrows.^{10,20} As air passes through a partially obstructed airway, its velocity increases and this produces turbulence while passing through lax tissues in the upper airway. If the nostrils are opened up with Nozovent, the air will pass more easily through the upper airways causing minimal vibration and little or no snoring. In our study 26 patients had complaints of snoring due to nasal obstruction. In these patients' nasal obstruction as well as snoring was improved with Nosovent.

Patients with narrowing of the nasal valve area were the best candidates. In our study patients with traumatic alar collapse benefited fully from nasal dilatation with Nosovent.

Mechanical dilatation of nose by Nosovent is a unique method to relieve nasal obstruction. Its use increases nasal airflow by 50%, thus improves nasal breathing, and prevents mouth breathing and its consequences. In selected cases of snoring due to nasal causes, it improves snoring. Moreover it is without risks and side effects of medications and can be used when medicinal treatment is contraindicated as in cardiovascular diseases and during pregnancy. Although females are reluctant in using it but no doubt it is an effective way to treat nasal obstruction due to various reasons.

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