Clinical Study to Compare Effectiveness of Mechanical Nasal Dilators to Relieve Nasal Obstruction in Different Conditions

A IQBAL M. M ALI S MUMTAZ *T ABBAS W AHMED*
Department of ENT, Head & Neck Surgery Sir Ganga Ram Hospital, Lahore.
Correspondence to Dr. M. Mubarik Ali

Most of the patients in the ENT Department presents with Nasal symptoms. Nasal obstruction is the most common problem among these patients. Mechanical Nasal dilators are effective to manage mild to moderate Nasal airflow resistance. This study of 500 patients, was conducted at ENT Outpatient Department of Sir Ganga Ram Hospital Lahore during the period of Jan 2001 to Dec-2003. The patients were selected randomly. The effectiveness and tolerance of Breath Right compared with Nosovent. The Breath Right is better tolerated by female and sensitive male. But efficacy of Nosovent is far superior than External Nasal dilator.
Key words: Nosovent, Nasal strips, Nasal obstruction

The external nose is divided into three parts. From above downwards Nasion, Dorsum & Lobule of the nose. The inner part of the nose lined by skin is called vestibule. The subcutaneous muscles of the nose act on vestibule and contribute in facial expression.

Mink[1] introduced the term Nasal valve at the beginning of this century to designate the movable, air-flow-regulating part of the nose, corresponding to the lateral nasal cartilage. The slit like opening formed by its caudal edge laterally and the septum medially was thought to be particularly important in nasal respiration. This two-dimensional region is nowadays looked upon as the actual nasal valve[2]. The straight line connecting the posterior end of the caudal edge of the lateral nasal cartilage with the septum may be considered the posterior boundary of the valve. The broader term nasal valve area is used for the three-dimensional nasal segment that includes the septum, the caudal end of the lateral nasal cartilage, the soft tissue overlying the piriform aperture, floor of the nose and head of the inferior turbinate. The valve area is stabilized by cartilage and bone, whereas modulation is supposed to occur by nasal muscles and erectile mucosa of the nasal septum and the head of the inferior turbinate (FIG I, II).

Nasal airflow resistance present at three levels (a) Nasal vestibule (b) Nasal valve (c) Nasal turbinates (FIG III, IV). The nasal valve area is the most narrow passage in the respiratory tract, causing more than half of the total resistance to nasal respiration in healthy subjects[3]. The proportional ratio between the cross-section area of the nasal valve and the bony piriform aperture is approximately 1:1.4[4]. The cross-section area on each side of the nasal valve is approximately 30 mm^2 , in the middle of the nasal cavity 120 mm^2, and in the nasopharynx 150 mm^2. In the normal healthy subject nasal resistance is mainly determined by degree of engorgement of venous erectile tissue and activity of accessory respiratory muscles, which maintain the patency of the nostril on inspiration. Factors that increase the nasal resistance are infective rhinitis, allergic rhinitis, vasomotor rhinitis, hyperventilation, supine posture, ingestion of alcohol, aspirin, sympathetic antagonists, cold air. Factors that decrease the nasal resistance are exercise, sympatho-mimetic drugs, re-breathing, atrophic rhinitis, erect posture.

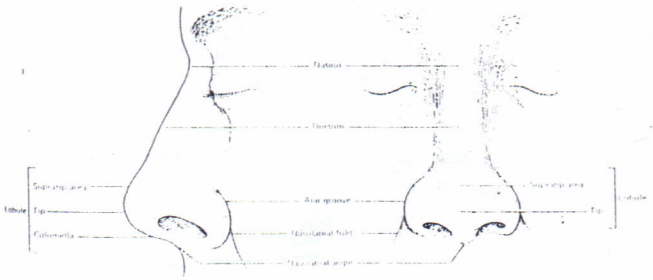

Fig. 1: External nose showing surface anatomy

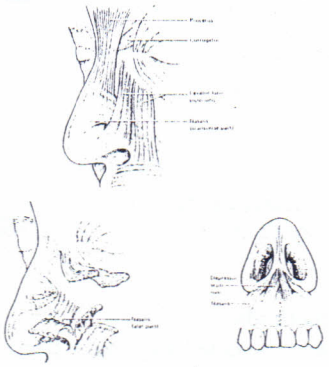

Fig. II: External musculature of the nose

Nosovent is a device to fit in the vestibule of the nasal cavity. It has two prongs and one stem. It is based on Thudiculum nasal speculum principle. The prong has to fit in the nasal vestibule and stem keep them away due to its shape and power which causes dilatation of anterior nares.

It is made of silastic, which is non- irritant and easy to wash and reusable. Its texture maintains its elasticity for more than 6 months. It is available in three sizes; small, medium and large. Medium size Nosovent is the most widely used nasal dilator (60%) however a very few (10%) need the small size, the remainder use the larger size.

The Breath Right is made to use on the nose externally. It consists of adhesive strip, which strengthen by two plastic sheaths. It is applied exactly over the nasal valve area. Due to the effect of adhesive strip on skin and muscles it pulls out the valve area and result in decrease in resistance in this narrowest site. The Nosovent can be used for six months and in long term it cost cheaper then breath right, which is for used once only.

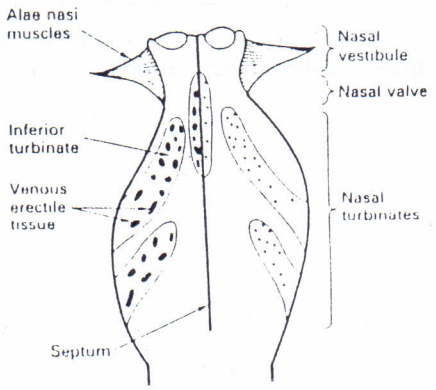

Fig. III: The nasal valve is at the level of the anterior tip of the inferior turbinate.

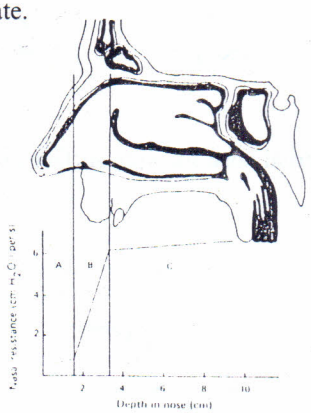

Fig. IV: Nasal resistance can be divided into the three components illustrated (A) nasal vestibule (B) Nasal valve (C) Nasal turbinate

Patients and methods

500 patients were selected randomly from the Outpatient Department of Sir Ganga Ram Hospital, Lahore during the period of Jan 2001 to Dec 2003. There were 300 males and 200 females, having age ranging from 18 to 60 years (Table I).

Inclusion criteria: All the patients having complaints of nasal obstruction due to allergic rhinitis, vasomotor rhinitis snoring, congestion during pregnancy and menstruation, were included in the study. (Table II)

Exclusion criteria: Patients below 18 years and above 60 years of age, patients with marked septal deviation, nasal polyposis, malignancy, vestibulitis, skin disease, systemic problem like Diabetes, Hypertension, personality disorders, patients having asthma or chest problems, patients having only feeling of nasal obstruction, atrophic rhinitis, post-operative cases, nasal deformity due to chronic inflammation e.g. T.B, scleroma, syphilis, patients with H/O recurrent boil nose or removing the hair of nasal vestibule (Table III).

Table 1 Age and sex of patients (n-500)

Males	300
Females	200
Age	18-60
Mean Age	34

Table II Inclusion criteria (n-500)

Nasal obstruc0tion due to:

- Allergic Rhinitis.
- Vasomotor Rhinitis.
- Nasal congestion during pregnancy and menstruation.
- Complaining of snoring.

Table III Exclusion criteria. (n-500)

- Marked deflected Nasal septum.
- Vestibulitis.
- Rhinophyma.
- Skin Allergy.
- Nasal Polyps.
- Tumour of nose and paranasal sinuses.
- Choanal atresia.
- Age below 18 and above 60 years.
- Personality disorders and Psychiatric behaviour.
- Patient refusal.
- Trauma nose or post-op nasal surgery cases.
- Chronic inflammatory lesions of nose e.g. T.B, scleroma, syphilis.
- H/O Recurrent Boil nose.

Atrophic rhinitis

After a complete history, the nose was examined for airflow and level of obstruction. Cottle test was performed for all patients. A Performa was filled to record patients symptoms and signs. After full assessment of the level of the nasal obstruction both type of the nasal dilators were given. All patients were educated how to use these dilators. Most of the patients used it at night, as the main complaint was nasal obstruction during sleep. Patients were assessed once a week during first month, fort-nightly for the next two months and every month thereafter for six months. After this follow-up patients were advised to use the device whenever they felt nasal obstruction throughout their life. The patients were observed for benefit by scoring system, rating 0 to 100. The response was graded as Grade I; 75% -100% reliefs of symptoms, Grade II; 50%-75% relief, Grade III; less than 50% relief.

Results

Out of 500 patients 300 males and 200 females were volunteered to involve in the study. These patients were presented with different pathology of nasal obstruction. The duration of nasal problems were also varies among different patients. Some female patients had nasal obstruction of short duration like during menstrual cycle. Other patient had permanent breathing problem which is more during sleep. Few patients had multiple pathology, which cause nasal obstruction like attack of nasal allergy during pregnancy.

Out of 500 subjects 40% had Allergic Rhinitis, 20% complaining of snoring, 15% had Vasomotor rhinitis, 13% had problem during pregnancy (2nd and 3rd trimester), 12% had problem during Menstrual cycle.

All the patients were advised to use both types of nasal dilators Nosovent/ Breath Right on alternate days. The patients were discussed the effectiveness and tolerance of these dilators on their first visit to hospital. The response were recorded on Performa according to the Grading system. The response was in Grade I in 70% of patients, Grade II in 20%, Grade III in 8% and no effect in 2%.

Out of 200 females 140 patients (70%) prefer Breath Right but out of 300 males 220 patients (73%) prefer to use Nosovent. Male patients preference were due to its more effectiveness. The reason is different in texture and flexibility of nasal muscles and soft tissues of male to female patients. The male patients have hard skin and strong muscles, which may not be fully pulled out by Breath Right but due to the stronger effect of Nosovent they felt more relief than the external dilators. Female have smaller size of the nose than males (Racial factor) & their skin is soft, so they tolerate Breath Right better than Nosovent. 30% of females reluctant to use Nosovent regularly due to its uneasiness or angry look of their husbands when they used Nosovent (social factor). So in our set up females are more satisfied with Breath Right than Nosovent.

Another problem with Nosovent was it may displace from its place any time at night but the Breath Right adheres to the nose whole night. Only 5% patients complain some redness on removal of Breath Right but no patient complain definite allergy or skin sensitivity.

Discussion

In this study the efficacy of two types of nasal dilators compared. The Nosovent need to apply in the vestibule of the nose. Some patients faced problems in applying it properly if it is pushed inside and touch nasal mucosa it may cause sneezing and lacrimation. Breath Right is easy to apply but to get good result it should be applied exactly at the level of the nasal valve area. The problem with external nasal dilator was in some patients loss of its power after some time. It was due to excessive sweating which loses the grip resulting loss its power. Patients who have excessive sebacious glands on the tip of the nose had some difficulty in applying Breath Right. But no complaint of skin allergy or irritation of skin area applied.

In the study of Petruson B, the ability to breath through the nose can be increased above normal by dilating the narrow nasal valve area with the plastic nasal device Nosovent. This study was conducted on 10 patients using Nosovent and sleeping partner of the patients judged the snoring sound level using snoring score. The results showed a significant decrease in snoring from moderate to slight when Nosovent was used. An increased nasal airflow is achieved with less negative intrathoracic pressure which presumably results in less opportunities for vibrations of soft palate[5].

Sakai and Shinkawa compare the effect of nasal dilators in Caucasians with Japanese in their study. Inspite of difference in shape and size of nose with different measurement of internal cut section, they found that Nosovent provide a unique method for non-surgical treatment of dilatation of nasal valve area[6].

The Petruson B also conclude that the lateral wall of the nostril is considered as the functional unit in the regulation of nasal resistance causing more than half of the total resistance. In his comparison study he measured the airflow through the nose with and without nasal dilators. In each object the mean value of 10 inspirations and 150 Pa was calculated. Before the application the mean value of the subject was 0.68 l/sec and with device 0.84 l/sec. He also concluded that the device ought to be helpful in patients with or without collapsing ala nasi during the night to increase nasal airflow when sleeping[7].

The study of Loth S et all who studied the comparison of daytime tiredness and reduced mental energy. They found a significant improvement of symptoms with the use of nasal dilators[8].

The combined effect of mechanical nasal dilators and topical decongestant on nasal airflow was studied by Lorino et all. They found that cumulative effect of the two gave better results than using one to relieve nasal symptoms[9]. In the study of Roithmann who concluded that Breath Right is an effective, non-surgical therapeutic approach in the management of nasal obstruction at the level of nasal valve area[10].

The study conducted at university of Hong Kong People's Republic of China to evaluate the effect of External nasal dilator on the dimension of nasal valve. It concludes that there is an increase in the minimal cross sectional area of the nasal airway in Orientals[11].

The recommendation of Ng BA et all after studying the effect of External nasal dilators as measured by acoustic Rhinometry was Breath Right may be used to increase the area of the nasal valve[12].

The study of Portugal et all in the objective assessment of Breath Right during exercise in adult male was improvement of airway in 21% of their subject under study, but the results of the study indicate that there is

significant improvement in all subjects. It is said that average cross sectional area of the nasal cavity that quantifies objectively the subjective impression of improved nasal breathing. In such patients where an improvement in nasal ventilation is desired, the use of the Breath Right nasal strips seems to offer a beneficial treatment[13].

In the study of Gosepath J on role of Breath Right and Respiratory Disturbance Index (RDI) in sleep related breathing disorders 19 out of 26 patients showed reduction of RDI during the second night of Polysomnography using the nasal strips indicating that nasal obstruction seems to be a predominant factor in the etiology of snoring and apnoea in these individually[14]. Lorino AM et all studies the effects of different mechanical treatments on nasal resistance assessed by rhinometry. He compared the effects of Nosovent, Breath Right and topical decongestant. No significant difference was observed between the effects of the two latter treatments. These results demonstrate that Nosovent, which involves no risk of side effects or drug interaction is an effective treatment to improve nasal breathing. Nosovent might therefore be recommended as an alternative to topical decongestants for certain subjects presenting with nasal obstruction.

The study of Griffin et all that physiological effect of Breath Right. They found that at rest Breath Right was found to significantly increase nasal valve area in all demographic groups measured. The device was also found to significantly decrease submaximal exercise perceived exertion, heart rate, ventilation and Vo_2 when compared with placebo[15].

In our study 70% female patients prefer to use Breath Right. This was due to easy to apply, stay whole night and had no social problem. The 73% male were satisfied with Nosovent. The reason was due to strong dilating effect as compared to Breath Right. Both types of dilator gave relief of nasal obstruction and patient had decrease in intensity of snoring. Due to comfortable breathing at night. Patient improve their concentration on work and have no complaint somnolence.

Conclusion

The easiness of applying Breath Right were more popular among females and sensitive males, but the Nosovent is more effective but less convenient to apply. Cost wise Nosovent is much cheaper in long term as it is reusable and work, effectively for six months. The Breath Right is disposable and cost much more to the patient than Nosovant.

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