Peak nasal inspiratory flow measurement and visual analogue scale in a large adult population

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PEAK NASAL INSPIRATORY FLOW MEASUREMENT AND VISUAL ANALOGUE SCALE IN A LARGE ADULT POPULATION

Running title: VAS and PNIF in adults. A prospective study.

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ABSTRACT

Objectives: Nasal obstruction is the most common symptom in nasal diseases. It can be evaluated objectively, i.e. by means of peak nasal inspiratory flow (PNIF) measures and/or subjectively by means of validated questionnaires. However, it has been reported that there is a lack of reliable correlation between subjective and objective measurements of nasal obstruction. The aim of the present study was to evaluate the correlation between PNIF measurements and the subjective sensation of nasal obstruction measured by means of a visual analogue scale (VAS) in a large population of consecutive rhinologic patients.

Design: prospective clinical study.

Setting: tertiary rhinological referral center.

Participants-main outcome measures: 641 consecutive subjects were enrolled. VAS and PNIF were performed to assess nasal obstruction. Nasal septal deviation was classified according to Mladina classification and its severity was assessed using three levels of severity.

Results: Although weak, there was a significant negative correlation (r = -0.13, p = 0.001) between PNIF and VAS. Dividing the population in those affected by nasal septal deviation (NSD) and those affected by chronic rhinosinusitis (CRS), a week negative correlation between PNIF and VAS was again confirmed in both groups (r=-0.208, p=0.006 for NSD and r=-0.13, p=0.04 for CRS). PNIF and VAS were also evaluated according to the grade of polyps and the type and level of septal deviation.

Conclusions: VAS and PNIF significantly correlated, although with a low degree, in a large population of rhinologic patients. PNIF, being cheap and simple to use could be a good candidate to assist clinicians dealing with 'airway' diseases in their daily clinical practice in order to provide comprehensive information on nasal function. PNIF can in fact give some important rough insights on VAS, but these measurements cannot be alternative to each other.

Key Words: VAS, PNIF, nasal obstruction, septal deviation, chronic rhinosinusitis, nasal polyps.

INTRODUCTION

Nasal obstruction is the most common symptom reported by patients affected by nasal diseases, so the measurement of nasal airflow is of considerable importance for rhinologists in the diagnosis to optimize therapeutic outcomes.[1] The objective evaluation of nasal obstruction can be assessed either with or without simultaneous pressure recordings by means of, either rhinomanometry (RM) or peak nasal flow measures. It is also possible to measure the nasal cavity cross-sectional area by means of acoustic rhinometry (AR), rhinosterometry or radiologic imaging such as computer tomography or magnetic resonance imaging.[1]

Since the last decade the importance of subjective nasal obstruction sensation measurement by means of validated questionnaires such as the Nasal Obstruction Symptom Evaluation (NOSE) and the Sino-Nasal Outcome Test (SNOT22) has been highlighted whilst visual-analogue scales (VAS)[2] offers an easy, quick, reproducible and quantifiable evaluation of patients' nasal symptoms severity[3]. However, a lack of reliable correlation between subjective and objective measurements of nasal obstruction has been reported.[4] In fact, comparing the subjective sensation of nasal airflow with objective measurement, different authors have found conflicting results, probably due to the multitude of methods used in their studies or the different study settings. The majority of these studies involved the use of RM and/or AR. Some authors observed no correlations between VAS and RM[5] or AR[6] whereas, others reported a good correlation between VAS and RM[7] in both allergic and non allergic rhinitic patients[8], in patients who had had a septoplasty[9]. In addition a clearer correlation between VAS and RM has been shown in subjects with high nasal resistance than in those with near normal nasal resistance.[10] In a study conducted on 50 patients with different grades of nasal septal deviation (NSD), VAS correlated with RM, but not with AR.[11] Interestingly, Numminen et al, comparing RM, AR, nasal peak expiratory flow and VAS in a group of 69 patients during acute viral rhinitis, concluded that these four methods support each other well in pathological noses. In fact, all these methods correlated with each other, allowing identification of sensitive intranasal changes due to nasal mucosal pathology.[12]

Peak nasal inspiratory flow (PNIF) is a cheap and quick method for the objective assessment of nasal airway obstruction, both bi- and unilaterally, and it has been shown to be reproducible in the evaluation of nasal airway obstruction.[13,14] However, not many studies have been performed to evaluate the correlation between PNIF values and the subjective sensation of nasal obstruction. The few studies conducted reported conflicting data similar to

that found with RM/AR. In particular, PNIF and VAS, in a comparative study on 64 allergic rhinitis patients and 67 healthy individuals, were not found to significantly correlate.[15] Conversely, PNIF has been demonstrated to be significantly associated with the degree of nasal obstruction measured by VAS in a group of 87 asthmatic patients[16], and in a mixed group of 78 healthy and rhinitic patients[17]. Finally, Andrews et al, studying patients affected by NSD, found no correlation between VAS and PNIF in 121 patients undergoing to septorhinoplasty.[18]A similar result was found by the same group between PNIF and VAS before and after functional endoscopic sinus surgery in chronic rhinosinusitis (CRS) patients.[19]

The aim of the present study was to evaluate the correlation between PNIF measurements and the subjective sensation of nasal obstruction measured by means of VAS in a large population of consecutive rhinologic patients.

MATERIAL AND METHODS

A population of 641 consecutive subjects who came to our Rhinology clinic, Department of Neurosciences DNS, Section of Otorhinolaryngology of Padova University, was enrolled. The age of patients ranged from 18 to 87 years, with a mean age 42±15 years. All subjects were asked to complete an anamnestic questionnaire indicating the characteristics and duration of nasal symptoms, the presence of allergies, their medication and whether they had undergone previous surgery to the nose and paranasal sinuses. Subjects younger than 18 years old were excluded. Exclusion criteria included also the inability to give informed consent, unwillingness to participate, and lack of fluency with Italian language. Patients with severe chronic obstructive pulmonary disorder, emphysema, or cystic fibrosis were also excluded. Finally, subjects affected by both CRS and NSD and those with not all data available were excluded for the present investigation.

Subjective nasal obstruction measurement

The obstruction was self-assessed by the patient using a 100 mm VAS, ranging from 0 (no nasal obstruction) to 10 (complete nasal obstruction).

Objective nasal measurements

A portable Youlten peak flow meter (Clement Clark International) was used for the PNIF measurement. Three satisfactory maximal inspirations were obtained each time at basal condition and in sitting position, although no significant differences have been observed on PNIF between standing and sitting positions[16], and the highest of the three results was then used.[14,20] PNIF was performed in all participants after at least 10 minutes of acclimatization in a room with constant temperature (between 19° and 22°) and a relative humidity of 25-35%. A complete physical examination was then performed, using anterior rhinoscopy and rigid nasal endoscopy (0 or 30 degrees), to verify the presence of NSD or signs of previous nasal trauma, CRS and/or allergy. Septal deformities were then classified using Mladina classification, which allows classifying septal deformities into seven types.[21] In this classification types I–VI are separate entities, while type VII is a combination of the type I–VI. Finally, the severity of NSD was assessed using three levels of severity (1: mild NSD with 1/3rd obstruction of the nasal cavity; 2: moderate NSD with 2/3rd obstruction of the nasal cavity; 3: NSD with complete obstruction of the nasal cavity).[22] In the presence of nasal polyps (NP), those were graded endoscopically as follow (1= NP within the middle meatus; 2=NP beyond the middle meatus; 3=NP causing massive invasion).[23]

Ethical considerations

The present investigation was conducted in accordance with the principles of 1996 Helsinki Declaration. All patients signed a written permission for clinical publication of the data. Data were examined in agreement with the Italian privacy and sensible data laws (D.Lgs 196/03) and the otolaryngology section internal regulation.

Statistical analysis

A partial correlation test was used to measure the association between PNIF and VAS for the whole group, taking into account the impact of age, with a square effect, and sex in the correlation. Moreover, the Spearman partial correlation index was preferred because of the ordinal nature of VAS.

Once divided the population with nasal obstruction symptom (VAS≥1) in two different groups, one including subjects mainly affected by NSD and the other including patients mainly affected by CRS, the same correlation test was used to measure the association between PNIF and VAS in each group. Finally, considering the patients with nasal obstruction symptom (VAS≥1) affected mainly by NSD, Kruskal-Wallis test was used to evaluate the association between the VAS score and the severity of the NSD. To evaluate difference in mean of PNIF across the groups T test was used. P-values have been calculated for all tests, and 5% was considered as the critical level of significance, moreover Holm multiple test correction was used when needed. The R: a language and environment for statistical computing (R Foundation for Statistical Computing, Vienna, Austria) was used for all analyses.

RESULTS

Of the 641 patients considered in the present study, 42 had a VAS for nasal obstruction of 0. Mean and standard deviation (SD) of PNIF and VAS values for males and females with VAS for nasal obstruction 1 are reported in Table 1.

Whether considering the whole population (641 subjects) or the population with nasal obstruction symptom (VAS≥1) (599 subjects), PNIF and VAS demonstrated a negative significant partial correlation (r=-0.13, p=0.001 for the former and r = -0.17, p=0.003 for the latter) (Figure 1 a,b). Analyzing the population with VAS≥1, we could then divide the patients according to the following two main diagnoses: NSD or CRS. This resulted in 378 subjects who were affected by CRS, and 175 patients affected by NSD. 35 patients, affected by both NSD and CRS, were excluded and not considered for the study. We found a PNIF mean value of 163.3 ± 45.9 L/min for NSD and of 174.1 ± 50.2 L/min for CRS. Although PNIF mean value is significantly lower in the group affected by NSD (p=0.006), we could demonstrate a negative significant correlation between PNIF and VAS in both groups (r=-0.208, p=0.006 for NSD and r=-0.13, p=0.04 for CRS) (Figures 2 and 3). In the CRS group, 293 patients were affected by CRS without nasal polyps (CRSsNP), while 85 had nasal polyps (CRSwNP). Although VAS scores were not significantly different between the two subgroups, PNIF mean value was higher when polyps were not present (177.4 ± 50.7 L/min) than when polyps were present (162.2 ± 46.9 L/min) (p=0.007). Considering patients with CRSwNP we had 42 patients with a grade 1, 32 patients with a grade 2 and 11 patients with a grade 3. For these groups we found mean PNIF values of 186.4 ± 42.9 L/min, 146.4 ± 39.9 L/min, and 120.0 ± 28.3 L/min, respectively for grade 1, 2 and 3. Using pairwise T test with Holm correction, we found a significant association between PNIF and the grade of polyposis (p=0.0001 and p=0.064, respectively between grade 1-2 and grade 2-3) that was particularly evident between grade 1 and grade 3 (p=0.0000) (figure 4). PNIF seems indeed decreasing

with the grade of polyposis. Conversely VAS scores did not show any correlation with the polyps grade.

The type and grade distribution of patients' NSD can be found in Table 2. Although VAS scores were not found to be different among the different NSD types, using pairwise T-test and correcting for multiplicity, PNIF values were shown to be significantly lower in the type 2 (mean value of 139.1 ± 37.5 L/min) compared to type 6 (mean value of 190. 7 ± 45.7 L/min) (p=0.035). Kruskal-Wallis test showed that VAS scores differed across the levels of severity of NSD (p=0.05), having mean values of 5.8 ± 2.7, 5.8 ± 2.3 and 6.8 ± 2.3 for levels 1,2 and 3, respectively. In particular we found a significant difference between level 2 and level 3 (p=0.03) (Figure 5). PNIF values did not differ between the different NSD severities.

DISCUSSION

The sensation of nasal obstruction is generally multifactorial as it can be determined by the intranasal anatomical status (which includes the nasal bony and cartilaginous anatomy the turbinates and the sinuses), but it can also be influenced by the autonomic nervous system and various physiological and pathological factors.[24] In addition, it is well known that its estimation can be influenced by patients' psychological circumstances or expectations so that it can be reported by patients in the absence of a genuine objective nasal obstruction.[9]

PNIF is a reliable, cheap and simple method to assess nasal airflow with an acceptable correlation with anterior active RM both in healthy and obstructed noses.[13]

VAS is a validated very simple unidimensional psychometric tool to assess nasal obstruction and, although showing high interrater and intrarater variability[18], it has been proposed to be useful in the study of rhinologic patients [25] and it is commonly administered in current practice.[26]

The subjective and objective measurements of nasal obstruction have already been investigated, before and after surgery using PNIF. Recently, a comparison between NOSE scale and PNIF measurements in the evaluation of septoplasty surgical outcome was done in 45 subjects. The authors found a significant improvement in NOSE and PNIF following nasal surgery, demonstrating a weak positive correlation between NOSE and PNIF magnitude of change.[27] However, no mention of the type and severity of the NSD was given. A similar weak but significant negative correlation was observed between PNIF and NOSE in patients undergoing septorhynoplasty.[28] A correlation between PNIF and NOSE was also found after surgery of the external nasal valve.[2] Similarly, PNIF changes have been demonstrated to strongly correlate with SNOT22 changes after functional endoscopic sinus surgery in a group of 37 patients affected by CRSsNP and CRSwNP.[18] However, the same authors did not find correlation between preoperative and post-operative PNIF and VAS obstruction scores.[18]

Strenghts of the study

In the present prospective study, a large population of consecutive rhinologic patients was considered and PNIF and VAS values were evaluated according to the main cause of nasal obstruction (NSD or CRS).

Comparisons with other studies

Our results confirmed those of a previous study conducted on 78 subjects (35 rhinitic and 43 healthy patients), in which VAS and PNIF demonstrated a negative significant correlation ($p<0.01$).[16] A similar correlation could also be identified when we divided the VAS≥1 patients into those affected by NSD or CRS. Interestingly, PNIF values were significantly lower in the group affected by NSD probably because the majority of our patients affected by CRS did not have nasal polyps (77.5%). Interestingly, VAS scores did not differ between the two subgroups of CRS patients, (with or without NP) even though

PNIF values were lower in CRSwNP patients. This could be explained by the fact that nasal obstruction sensation in CRSsNP patients may be influenced by the inflammation itself and has been shown to improve after surgery without significant objective improvement.[13]

A significant correlation between VAS and RM values in some NSD types (based on the distance between the most prominent part of the deviation and the middle part of the columella) and grades have been already found in a group of 50 patients.[11] In our study the NSD was distinguished in seven different types. Although VAS scores did not differ among them, in our population PNIF values were significantly different between type 2 and 6, with type 2 showing PNIF values lower than type 6. This result could be justified by the fact that in type 2 septal deviation, there is an obstruction of the nasal valve, while in the type 6 there are horizontal deviations not affecting the nasal valve. Intriguingly, considering the grade of severity of NSD independently from its type (types I–VII according to Mladina classification), in the present study PNIF values did not show a significant difference, probably because PNIF measurements were performed bilaterally. In a previous study, in fact, the stronger correlation between the objective measurement and the subjective sensation of nasal obstruction in NSD patients was found in the narrower side.[9] On the contrary, VAS values were shown to be higher with increasing of the septal deviation grade, independently from its type, in line with a previous smaller study where a significant VAS difference between mild (grade 2) and severe (grade 3) NSD was demonstrated.[22]

Previously a strong significant negative correlation between VAS and PNIF has been reported by Teixeira and coworkers in a mixed group of 78 healthy and rhinitic patients ($r=-0.41$; $p<0.001$).[17] In general, we found a weak correlation between objective and subjective measurement of nasal obstruction, regardless of the cause of obstruction. Similarly, Whitcroft et al, comparing PNIF and VAS in patients with CRS undergoing functional endoscopic sinus surgery, reported a weak correlation both in the whole population ($r=-0.28$) and in the

subgroup of patients with CRSsNP (r=-0.33); conversely no correlation was observed in the subgroup of patients with CRSwNP (r=-0.07).[19] Although conducted mainly on patients undergoing septorhinoplasty, other authors have found a similar weak but significant negative correlation between the objective measurement of nasal obstruction, measured by PNIF, and the subjective measurement of nasal obstruction, evaluated by NOSE. [28,29] The authors concluded that there is a limit on the use of PNIF as a diagnostic tool for nasal airway obstruction, as it does not correlate well enough with the patient experience of nasal obstruction.[28] However, the same authors stated that PNIF may provide unique and complementary information, such that PNIF, although requiring further validation for widespread adoption, should be incorporated in the clinical practice as the best currently available objective outcomes assessment tool. [28] PNIF can in fact be useful for evaluating, understanding, and improving the effects of surgical techniques and can be useful to measure individual's objective nasal airway obstruction changes following surgery. On this regard, it is important to underline that objective tests for the measurement of nasal obstruction are able to predict post-operative satisfaction, as normal values can be a marker for a poor surgical outcome.[30] Airway testing can reveal those patients in whom airflow restriction relates to obstructive symptoms and those in whom it does not. The first will have the best chances of being helped by therapy directed at enlarging the dimension of the nasal cavities, while the latter probably not.

CONCLUSIONS

In the present study VAS and PNIF, measured in a large population of rhinologic patients affected by CRS or NSD, demonstrated a significant negative correlation, although with low degree. The results of the present study suggest that these patients should be evaluated by means of both subjective and objective methods for the measurement of nasal airway as the

subjective assessment of nasal obstruction has the advantage of reporting patients' point of view, while objective measures have the advantage of being quantitative.

The correlation between VAS and PNIF found in the present study does not grant the use of just one method for the evaluation of patients complaining of nasal obstruction – without any additional information – nevertheless it can give some important insights.

PNIF, being cheap and simple to use, could be of value to assist clinicians dealing with 'airway' diseases in their daily clinical practice in order to provide comprehensive information on nasal function. Finally, given to the fact that a stronger correlation has been found between the unilateral nasal resistances, measured by rhinomanometry, and ipsilateral VAS [(31)], in future it would be interesting to study the correlation between unilateral PNIF and unilateral nasal obstruction sensation.

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FIGURE LEGENDS

Figure 1:

a) PNIF and VAS correlation in the whole population, dividing for male and female patients. The continuous line indicates the regression line. The dashed line indicates PNIF total average not considering the effect of VAS.

b) PNIF and VAS correlation in the population with nasal obstruction symptom (VAS≥1), dividing for male and female patients. The continuous line indicates the regression line. The dashed line indicates PNIF total average not considering the effect of VAS.

PNIF: peak nasal inspiratory flow

VAS: visual analogue scale

Figure 2: Regression line showing a negative significant correlation between PNIF and VAS in the group of patients with nasal septal deviation.

PNIF: peak nasal inspiratory flow

VAS: visual analogue scale

Figure 3: Regression line showing a negative significant correlation between PNIF and VAS in the group of patients with chronic rhinosinusitis.

PNIF: peak nasal inspiratory flow

VAS: visual analogue scale

Figure 4: PNIF values in relation to the grade of polyps.

PNIF: peak nasal inspiratory flow

VAS: visual analogue scale

Figure 5: VAS score variations in relation to the severity of septal deviation.

VAS: visual analogue scale

TABLES

Table 1: Mean age, PNIF and VAS results separated for males and females with nasal obstruction (VAS≥1) and older than 18 years.

PNIF: Peak Nasal Inspiratory Flow.

VAS: Visual Analogue Scale

Table 2: Distribution of the type and level of nasal septal deviations.

	Males (n=327)			**Females (n=272)**		
Variable	***Mean***	***SD***	***Range***	***Mean***	***SD***	***Range***
Age	40	14.7	18-80	42	14.9	18-87
PNIF (L/min)	180	50.1	25-350	158	45.1	50-350
VAS	6	2.3	1-10	6	2.4	1-10

	Level			***Total***
Type	***1***	***2***	***3***	
1	18 PNIF 153.3 ±46.5 VAS 5.7 ± 2.9	15 PNIF 156.0 ± 44.4 VAS 5.3 ± 2.6	6 PNIF 155.0 ± 37.8 VAS 6.8 ± 1.6	39 PNIF 154.6 ± 43.3 VAS 5.7 ± 2.6
2	1 PNIF 175.0 ± - VAS 4.0 ± -	5 PNIF 130.0 ± 18.7 VAS 6.0 ± 1.7	10 PNIF 140.0 ± 44.7 VAS 7.1 ± 2.3	16 PNIF 139.1 ± 37.5 VAS 6.6 ± 2.2
3	3 PNIF 166.7 ± 28.9 VAS 4.3 ± 0.6	10 PNIF 156.0 ± 42.5 VAS 6.2 ± 2.6	2 PNIF 180.0 ± 42.4 VAS 5.0 ± 0.0	15 PNIF 161.3 ± 38.6 VAS 5.7 ± 2.2
4	2 PNIF 200.0 ± 42.4 VAS 6.5 ± 2.1	15 PNIF 170.7 ± 45.7 VAS 5.8 ± 2.2	3 PNIF 140.0 ± 51.9 VAS 6.7 ± 1.5	20 PNIF 169.0 ± 46.4 VAS 6.0 ± 2.1
5	8 PNIF 166.9 ± 38.2 VAS 6.8 ± 1.8	25 PNIF 172.8 ± 58.9 VAS 5.4 ± 2.4	25 PNIF 165.2 ± 44.7 VAS 6.6 ± 2.6	58 PNIF 168.7 ± 49.9 VAS 6.1 ± 2.4
6	2 PNIF 205.0 ± 35.4 VAS 1.5 ± 0.7	12 PNIF 190.0 ± 49.7 VAS 6.6 ± 1.9	1 PNIF 170.0 ± (NA) VAS 7.0 ± (NA)	15 PNIF 190.667 (45.743) VAS 5.9 ± 2.5
7	2 PNIF 195.0 ± 7.1 VAS 9.0 ± 1.4	8 PNIF 145.0 ± 35.9 VAS 5.8 ± 2.3	2 PNIF 160.0 ± 0.0 VAS 9.5 ± 0.7	12 PNIF 155.8 ± 34.5 VAS 6.9 ± 2.5

Total	**36** **PNIF** **165.8 ± 42.0** **VAS** **5.8 ± 2.7**	**90** **PNIF** **165.2 ± 49.2** **VAS** **5.8 ± 2.3**	**49** **PNIF** **157.8 ± 42.6** **VAS** **6.8 ± 2.3**	**175** **PNIF** **163.3 ± 45.9** **VAS** **6.0 ± 2.4**

PNIF: Peak Nasal Inspiratory Flow (L/min)

VAS: Visual Analogue Scale