Validation of polyvinylidene fluoride nasal sensor to assess nasal obstruction in comparison with subjective technique☆

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Abstract

Objective: The aim of this study is to validate the applicability of the PolyVinylidene Fluoride (PVDF) nasal sensor to assess the nasal airflow, in healthy subjects and patients with nasal obstruction and to correlate the results with the score of Visual Analogue Scale (VAS).

Methods: PVDF nasal sensor and VAS measurements were carried out in 50 subjects (25 healthy subjects and 25 patients). The VAS score of nasal obstruction and peak-to-peak amplitude (Vp-p) of nasal cycle measured by PVDF nasal sensors were analyzed for right nostril (RN) and left nostril (LN) in both the groups. Spearman's rho correlation was calculated. The relationship between PVDF nasal sensor measurements and severity of nasal obstruction (VAS score) were assessed by ANOVA.

Results: In healthy group, the measurement of nasal airflow by PVDF nasal sensor for RN and LN were found to be 51.14 ± 5.87% and 48.85 ± 5.87%, respectively. In patient group, PVDF nasal sensor indicated lesser nasal airflow in the blocked nostrils (RN: 23.33 ± 10.54% and LN: 32.24 ± 11.54%). Moderate correlation was observed in healthy group (r = −0.710, p < 0.001 for RN and r = −0.651, p < 0.001 for LN), and moderate to strong correlation in patient group (r = −0.751, p < 0.01 for RN and r = −0.885, p < 0.0001 for LN).

Conclusion: PVDF nasal sensor method is a newly developed technique for measuring the nasal airflow. Moderate to strong correlation was observed between PVDF nasal sensor data and VAS scores for nasal obstruction. In our present study, PVDF nasal sensor technique successfully differentiated between healthy subjects and patients with nasal obstruction. Additionally, it can also assess severity of nasal obstruction in comparison with VAS. Thus, we propose that the PVDF nasal sensor technique could be used as a new diagnostic method to evaluate nasal obstruction in routine clinical practice.

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1. Introduction

The human respiration depends on the dynamics of the nasal airflow. The slight anatomical changes in the nasal cavity can affect the dynamics of the human respiration. Ideally, the right and left side of the nose in each breathing cycle should have identical airflow, resistance, and volume changes [1]. Nasal airflow entirely depends on how open/obstructed is the nasal cavity (i.e., nasal patency). Nasal airflow is inversely proportional to the nasal obstruction, i.e., the more the nasal airflow, the lesser is the nasal obstruction and vice versa. Therefore, by evaluating the nasal airflow, it is possible to assess the nasal obstruction. Nasal obstruction may be caused due to nasal anatomic abnormalities and/or mucosal disease. It is also a common symptom in patients attending the oto-rhino-laryngological (Ear, Nose and Throat; ENT) clinics affecting individuals of all age groups. Major anomalies such as septum deviations, inspiration alar collapse, nasal polyps and mucosa can be directly visualized by examining the structures of the nose by a clinician.

In general, nasal obstruction can be assessed objectively and subjectively by different methods/instruments [2]. The most commonly used instruments for the objective assessment of nasal obstruction are rhinomanometry, acoustic rhinometry, and Peak Nasal Inspiratory Flowmeter (PNIF). Rhinomanometry measures the nasal obstruction by evaluating the nasal airflow and trans-nasal pressure during respiration [3]. It uses pneumotachometer and pressure transducer to quantify the nasal resistance to the nasal airflow. It is a good research tool that is very sensitive for small measurements. Hence active rhinomanometry has been recommended by the Standardization Committee of the European Rhinologic Society [4]. A major disadvantage of the rhinomanometry is that it is expensive and is not easily portable, thus making its usage limited for routine clinical purpose. An acoustic rhinometry evaluates the cross-sectional area of nasal cavity in terms of area-distance graph by measuring echoes of sound impulses sent in the respiration tract, mainly through the nose [5]. The disadvantages of this method are, it is not only expensive, but also requires skilled operator and cannot be easily portable. PNIF evaluates the nasal airflow (in liters/minute) passing through the tube, when a subject maximally inhales air [6]. Though PNIF is inexpensive and portable as compared to its counterparts like rhinomanometry and acoustic rhinometry, it does not give unilateral measurement. PNIF measures the complete nasal airflow and requires a maximum co-operation from patients. Therefore, there is a need of instruments that are practical, cost-effective, portable, reliable, and requires minimal co-operation from patients to evaluate nasal obstruction objectively.

Other than the above mentioned objective methods, the nasal obstruction can also be measured subjectively by using Visual Analogue Scale (VAS) [7]. Basically VAS is a subjective perception or experience of patients about their nasal obstruction and it is well validated and reliable parameter [8].

In this paper, we report about a newly developed PolyVinylIliDenFluoride (PVDF) nasal sensor technique for objective measurement of nasal airflow. PVDF is a non-reactive, flexible, light weight and a bio-compatible polymer available in various thicknesses and size and has a strong piezoelectric property [9]. Piezoelectricity is the ability of the material to produce voltage whenever it is mechanically stressed/strained. PVDF is used in many biomedical applications because of its piezoelectric and pyroelectric properties [10].

In our previous study, we have successfully evaluated our newly designed and developed PVDF nasal sensor with one of the objective technique (PNIF) to assess deviated nasal septum [11]. The aim of our present work is to investigate the use of PVDF nasal sensor as a diagnostic tool to assess the nasal obstruction in comparison with the subjective technique namely, VAS.

2. Methods and materials

2.1. Subjects

The present study was conducted at M. S. Ramaiah Medical College and Hospital, Bangalore, India after obtaining necessary approval from the institutional review board. Written consent was obtained from all subjects before their participation in the study. We recruited 50 subjects and divided them into two groups. The first group was a healthy group consisting of 25 (18 male and 7 female) subjects with the age of 29 ± 8 years. The second group was a patient group consisting of 25 (20 male and 5 female) subjects with complaints of nasal obstruction with the age of 31 ± 9 years. Healthy subjects were volunteers recruited from hospital staff members and medical interns without any complaints of nasal obstruction, whereas, the patient group was recruited from the Out-Patient Department (OPD) of Ear, Nose and Throat, who consulted with a complaint of nasal obstruction. The main criterion for patients to enrol in this study was the presence of nasal obstruction without any additional nasal pathology. Prior to performing the study using PVDF nasal sensor, all crusting and nasal mucosa were removed from nasal cavity (without the use of any nasal decongestant).

2.2. PVDF nasal sensor

PVDF (supplied by Precision acoustic, UK) is a piezoelectric film that produces voltage whenever it is subjected to mechanical stress/strain. The mechanical stress/stain in this work is caused due to nasal air flow. The PVDF film with length 10 mm, width 5 mm and thickness 28 μm is firmly adhered to a plastic base in such a way that it forms a cantilever configuration leaving the other end free for deflection. The double enamelled copper wires (diameter 0.07 mm) were attached on top and bottom surfaces of the PVDF film using aluminium conducting tape. This arrangement (PVDF film in cantilever configuration with the leads attached on both the surfaces) forms the nasal sensor [12]. Two such PVDF nasal sensors were taken and attached to the flexible strings on either side of the headphone as shown in Fig. 1. PVDF nasal sensors were positioned below the right and left nostrils without disturbing the normal breathing of subjects. The pulsating air flow due to the inspired and expired air impinges on these two identical PVDF nasal sensors leading to bending strain. This bending mechanical
strain results in the voltage signal from the sensor, corresponding to breathing cycle of the respective nostrils.

2.3. Device set-up

The complete experimental set-up used for the measurement of nasal airflow consists of headphone mounted with PVDF nasal sensor, signal conditioning box, Data Acquisition card (DAQ) and a computer. The signal conditioning circuitry consists of pre-amplifier, low-pass filter and an amplifier. The output of the PVDF nasal sensor was less (30 to 40 mV_{p-p}). Therefore, a charge sensitive pre-amplifier was used to amplify the output of the PVDF nasal sensor. The frequency of the normal human respiration is known to be in the range of 0.2–0.5 Hz. Hence a second order low-pass filter with a cut-off frequency of 3Hz was designed to filter out the unwanted signals. The filtered PVDF nasal sensor signal was fed to the amplifier (with gain 10) for good amplification. Finally, the amplified output voltage signal (breathing signal) was fed to the data acquisition card (NI-6008 card), which was interfaced with the computer for recording and storing the signal for further analysis.

2.4. Visual Analogue Scale (VAS)

Detailed physical examination was performed by an otorhino-laryngologist, using a bright light source and a nasal speculum (an instrument that gently spreads open the nostril) for each subject’s right nostril (RN) and left nostril (LN). After physical examination, VAS with score 0–10 was used to evaluate the nasal obstruction experienced by the subject. Each subject answered the standardized questionnaire. Information regarding the presence or absence of the nasal obstruction as well as the side of nostril (LN or RN) where nasal obstruction is present was obtained from the subjects. Further their perception of nasal obstruction during normal breathing was marked on a score of 0–10 VAS for each nostril separately. The VAS score used in the present study is as follows,

(i) 0 corresponds to ‘no obstruction’,
(ii) 1–3 corresponds to ‘mild obstruction’,
(iii) 4–7 corresponds to ‘moderate obstruction’ and
(iv) 8–10 corresponds to ‘severe obstruction’.

2.5. Recording breathing signal using PVDF nasal sensor

A complete device setup for recording the breathing signal was kept on a table in a well-ventilated room with normal room temperature and humidity. Each subject was asked to sit on a chair in a relaxed position. Subsequently, the subject was asked to wear the headphone mounted with PVDF nasal sensors. The headphone was flexible enough to fit the same conveniently for different head sizes. A constant distance of 5 mm was maintained between each PVDF nasal sensor and nostril for all the subjects. After suitably positioning the PVDF nasal sensor, the subject was instructed to perform normal breathing. While recording the breathing signal/data, an initial signal/data for 30 seconds was truncated to avoid the possible artefacts due to wearing of head phones. The breathing signal was recorded for 2 minutes duration and stored as an ‘.lvm’ file in a computer. The average time duration taken to perform each PVDF nasal sensor measurement was about 5–6 minutes.

2.6. Analysis of breathing signal

The breathing signal recorded using the PVDF nasal sensor consists of each breathing cycle’s peak-to-peak amplitude (V_{p-p}), which directly corresponds to the magnitude of airflow from the nostril. A computer algorithm was developed using MATLAB [version 7.5.0.342 (R2007b)] software for the calculation of average peak-to-peak amplitude for the entire breathing cycle of each nostril separately.

The calculations of the percentage of nasal airflow are performed as follows,

\[
\text{Total nasal airflow} = \text{Right nostril airflow (measured in V}_{p-p}\text{)} + \text{Left nostril airflow (measured in V}_{p-p}\text{)}
\]

Right nasal airflow percentage = \[
\frac{\text{Right nostril airflow (measured in V}_{p-p}\text{)}}{\text{Total nasal airflow}} \times 100
\] (1)

Similarly,

Left nasal airflow percentage = \[
\frac{\text{Left nostril airflow (measured in V}_{p-p}\text{)}}{\text{Total nasal airflow}} \times 100
\] (2)

The percentages of right and left nasal airflow were calculated for each subject in both the groups using Eqs. 1 and 2, respectively. Finally, the average of right and left nasal airflow percentages was computed for healthy and patient group separately.
Table 1 – Breathing signal peak-to-peak amplitude measurement using PVDF nasal sensor and VAS scores of healthy and patient group.

<table>
<thead>
<tr>
<th>PVDF nasal sensor</th>
<th>Visual analog scale scores</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Peak-to-peak amplitude ($V_{p-p}$)</td>
</tr>
<tr>
<td>Healthy group</td>
<td></td>
</tr>
<tr>
<td>RN</td>
<td>0.60 ± 0.16</td>
</tr>
<tr>
<td>LN</td>
<td>0.64 ± 0.15</td>
</tr>
<tr>
<td>Patient group</td>
<td></td>
</tr>
<tr>
<td>RN</td>
<td>0.19 ± 0.11</td>
</tr>
<tr>
<td>LN</td>
<td>0.35 ± 0.14</td>
</tr>
</tbody>
</table>

2.7. Statistical analysis

The descriptive statistics such as mean ± standard deviation (SD) were calculated. A value of $p < 0.05$ was considered as statistically significant. The age of patient group was compared with healthy control group using the independent t-test. Bivariate associations between nasal parameters were analyzed using Spearman’s rho correlations. Correlations were considered as weak if $r \leq 0.4$, moderate if $0.4 < r \leq 0.8$, and strong if $r \geq 0.8$. Percentages of nasal airflow were calculated separately for each nostril (using Eqs. 1 and 2) by taking his/her total nasal airflow as a reference. The relationship between PVDF nasal sensor measurements and VAS score of severity of nasal obstruction was assessed by ANOVA using SPSS software (version 13.0 for Windows; SPSS, Inc., Chicago, IL).

3. Results

Among the subjects participated in our study, 50% had no nasal complaints while 34% ($n = 17$) had complaints in their RN and 16% ($n = 8$) had complaints in their LN. The age of healthy and patient group ranged from 22 to 56 years. The mean age of healthy and patient groups was 29 ± 8 and 31 ± 9 years respectively, which was not statistically significant ($p > 0.05$).

PVDF nasal sensor and VAS findings recorded for both the groups are shown in Table 1. All the measured results are expressed in terms of mean ± SD. In the healthy group, the mean VAS without nasal obstruction was 1.4 ± 0.95 for RN and 1.32 ± 0.85 for LN. In addition, the average peak-to-peak amplitude ($V_{p-p}$) of nasal cycle for RN and LN were 0.60 ± 0.16 $V_{p-p}$ and 0.64 ± 0.15 $V_{p-p}$ respectively, as measured by the PVDF nasal sensor. In the patient group, the mean VAS for blocked nostril was in moderate-to-severe range for RN (7.02 ± 2.26) and moderate range for LN (5.10 ± 1.85). Similarly, PVDF nasal sensor also indicated lower voltage/airflow in the blocked nostrils (0.19 ± 0.11 $V_{p-p}$ for RN and 0.35 ± 0.14 $V_{p-p}$ for LN).

Fig. 2A–C shows the sample tracing of a breathing cycle obtained from the PVDF nasal sensor for RN and LN. The signal above 0-axis represents the inspiration phase and below 0-axis represents the expiration phase. One peak-to-peak inspiration phase and expiration phase represents one complete breathing cycle. In case of healthy subjects, the peak-to-peak breathing cycle amplitude of both nostrils i.e., RN and LN were found to be similar as shown in Fig. 2A. However, for the subject having obstruction in LN, the amplitude of the breathing signal (represented in continuous line) was moderately low compared to RN signal as evident from Fig. 2B. The sample trace for the subject with severe RN obstruction (represented in dotted line) can be seen in Fig. 2C.

An increase in subjective scale (VAS) indicates a worst nasal obstruction, resulting in a lesser nasal airflow as measured using the PVDF nasal sensor. Hence, there was a negative Spearman’s rho correlation between the two methods as shown in Table 2. There was a moderate-to-strong correlation between PVDF nasal sensor and VAS, in patient group [RN: $-0.751$ ($p < 0.01$) and LN: $-0.885$ ($p < 0.0001$)] and moderate correlation in case of healthy group [RN: $-0.710$ ($p < 0.001$) and LN: $-0.651$ ($p < 0.001$)]. Fig. 3A–D shows a negative correlation between the data obtained from PVDF nasal sensor and VAS. In subjects classified according to severity of nasal obstruction (data from both RN and LN are combined for healthy and patient group), there were highly significant differences between the groups ($p < 0.001$, by ANOVA) as shown in the Fig. 4.

It is evident from the above that, both PVDF nasal sensor and VAS techniques were able to differentiate between healthy and patient groups. PVDF nasal sensor was able to measure nasal airflow in both the nostrils separately. The percentage of nasal airflow in the healthy group was 51.14 ± 5.87% for RN and 48.85 ± 5.87% for LN as shown in Fig. 5A. In the patient group, first 17 subjects suffered from RN obstruction and therefore the nasal airflow percentage for RN (23.33 ± 10.54%) was lower compared to LN (76.67 ± 2.24%). Similarly, the nasal airflow percentage for LN (32.24 ± 11.54%) was lower than RN (66.76 ± 3.68%) for 8 subjects as they had obstruction in left nostril as shown in the Fig. 5B.

4. Discussion

Nasal obstruction reported by patients in routine clinical practice is frequently used as the reliable parameter for evaluating the same. Whenever there is a significant nasal obstruction, the airflow in the corresponding nostril will be very less. Therefore it is possible to evaluate the nasal obstruction by studying the nasal airflow. Airflow through the nose follows the basic principles elaborated by Poiseuille and Reynolds [13]. The pattern of airflow may be laminar or turbulent depending upon the length and cross-sectional area of the nasal cavity [13]. The pattern of airflow shall be almost laminar at lower flow rates when there are no irregularities in the nasal cross-sectional area, whereas, it shall be a turbulent when encountered with nasal irregularities such as septum deviation, nasal polyps etc. in the nasal cross-sectional area.

The VAS used in the present study gives the quantification of the subjective sensation of nasal obstruction on a 0–10 scale. Several previous studies showed a good correlation between the subjective sensation scale VAS and objective measurements. Roithmann et al., [14] performed a nasal
patency study on 78 subjects and found good correlation between VAS and two different objective measurements: acoustic rhinometry and rhinomanometry. Fairley et al., [6] achieved a good correlation on 169 subjects by using PNIF and subjective scales. Therefore, VAS can be used as a reliable tool for the measurement of nasal obstruction [8].

The present paper discusses about the newly developed technique to measure the nasal obstruction in terms of nasal airflow. There will be a deflection in the sensor when a nasal airflow impinges on the PVDF sensor. Since PVDF is a good piezoelectric material, it provides the voltage signal proportional to sensor deflection. The presently developed PVDF nasal sensor developed is able to measure the unilateral nasal airflow. If there is no obstruction in both the nostrils, then the airflow pattern will be smooth as shown in Fig. 2(A). Fig. 2(B) shows the sample tracing of a subject with moderate nasal obstruction in LN, hence the amplitude of that signal was low compared to RN. Fig. 2(C) shows the tracing of a subject with severe RN obstruction.

The data given in Table 1 clearly indicate the ability of the PVDF nasal sensor and VAS methods to differentiate between healthy subjects and patients. In healthy group, the nasal airflow measured by PVDF nasal sensor for RN and LN were 51.14 ± 5.87% and 48.85 ± 5.87%, respectively which corresponds to breathing amplitudes of RN and LN as 0.60 ± 0.16 $V_{p-p}$ and 0.64 ± 0.15 $V_{p-p}$ respectively. Similarly, VAS score for healthy group was very less (1.4 ± 0.95 for RN and 1.32 ± 0.85 for LN). Sixteen percent of patients had problem with their LN (average VAS score = 5.10 ± 1.85) indicating that they had mild-to-moderate obstruction. Similarly, PVDF nasal sensor output was 0.35 ± 0.14 $V_{p-p}$, which was lesser than the normal breathing amplitude. The average nasal airflow percentage measured using PVDF nasal sensor for patients of LN obstruction was 32.24 ± 11.54%. Whereas thirty four percent of patients had problem with RN (average VAS score = 7.02 ±

![Image](Fig. 2 – Sample tracing of a breathing signal, recorded using the PVDF nasal sensor for 60 seconds duration of (A) healthy subject (the peak-to-peak amplitude of inspiration and expiration phases have approximately same amplitude) (B) subject with moderate left nostril block (C) subject with severe right nostril block.)

| Table 2 – Comparison of Spearman’s rho correlation co-efficient between the PVDF nasal sensor measurements and VAS score. |
|---|---|---|
| Nasal cavity | PVDF nasal sensor | Rho | p |
| Visual Analog Scale | RN a | -0.710 a | <0.001 a |
| | LN a | -0.651 a | <0.001 a |
| | RN b | -0.75 b | <0.01 b |
| | LN b | -0.885 b | <0.0001 b |

a Represent healthy group.
b Represent patient group.
2.26) indicating that they had moderate-to-severe obstruction (and PVDF nasal sensor output (0.19 ± 0.11 V_{p-p}) and also showing much lesser airflow percentage through RN (23.33 ± 10.54%) as compared to normal nasal airflow.

The previous studies reported a negative correlation between an objective and subjective technique for measuring the nasal obstruction [7,14,15]. PVDF nasal sensor is an objective technique whereas VAS is a subjective technique. An increase in VAS scoring indicates a worst subjective nasal obstruction reflecting a decreased nasal airflow as measured by the PVDF nasal sensor. In other words, there exists a good and significant negative correlation between PVDF nasal sensor measurements and VAS score (Table 2). Each individual is different from each other, so their tolerance for pain will also be different. Patients with severe obstruction in their nose could score easily on VAS scale. Hence, the correlation between PVDF nasal sensor and VAS was moderate-to-strong for patient group with high significance (p < 0.01 for RN, p < 0.0001 for LN). Patients with mild obstruction could not give uniform scoring. Therefore, there was not much difference between scores of ‘no obstruction’ and ‘mild obstruction’ by subjects on VAS scale. Hence, we found moderate correlation in healthy group (p < 0.001 for RN, p < 0.001 for LN).

Apart from assessing nasal obstruction in individual nostril, PVDF nasal sensor was also able to assess the severity of nasal obstruction in accordance with VAS as shown in Fig. 4. It is clearly evident from PVDF nasal sensor voltage output that, one can determine the severity of the nasal obstruction.

![Fig. 3](image-url) - Spearman’s rho negative correlation between the PVDF nasal sensor measurements and VAS score for (A) healthy group RN (n = 25) (B) healthy group LN (n = 25) (C) patient group RN (n = 17) and (D) patient group LN (n = 8).

![Fig. 4](image-url) - PVDF nasal sensor values of subjects classified according to severity of nasal obstruction (data from both RN and LN are combined for healthy and patient group).
obstruction qualitatively as well as quantitatively. Hence, the clinician can perform PVDF nasal sensor measurement before and after septal surgery and can further correlate the sensation of the nasal obstruction objectively.

Though there are other methods like acoustic rhinometry, and rhinomanometry to study nasal obstruction objectively, these methods are relatively expensive, require trained operator, and are not easily portable. This makes their use limited in clinical setups. PNIF method is inexpensive, portable and can evaluate the nasal airflow. However, PNIF does not provide information about individual nostril obstruction. Also, maximum patient co-operation is required. On the other hand, PVDF nasal sensor technique discussed in this paper overcomes these limitations as it is non-invasive, portable, relatively in-expensive and requires very brief time and minimal patient co-operation. The results show that this method differentiates healthy subjects from patients with the nasal obstruction. A good correlation was obtained between objective PVDF nasal sensor measurement and subjective VAS score. Additionally, the results from this study showed the ability of PVDF sensor to distinguish between severities of nasal obstruction. We propose that this new PVDF nasal sensor technique might benefit from further investigations, perhaps by recording data with greater numbers of healthy and patient populations.

Fig. 5 – The calculated nasal airflow percentage for (A) healthy group (n = 25) (B) patient group, in which first 17 subjects had obstruction in RN, whereas remaining 8 subjects had obstruction in LN.

5. Conclusion

PVDF nasal sensor is a newly developed method to assess the nasal obstruction objectively. It is a non-invasive, easily portable, relatively inexpensive and requires very brief time and minimal patient co-operation. The results show that this method differentiates healthy subjects from patients with the nasal obstruction. A good correlation was obtained between objective PVDF nasal sensor measurement and subjective VAS score. Additionally, the results from this study showed the ability of PVDF sensor to distinguish between severities of nasal obstruction. We propose that the PVDF nasal sensor is a newly developed diagnostic method to evaluate nasal airflow;
however more detailed and multi-centred studies are needed to fully access its effectiveness for future use with larger healthy and patient populations.

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