The new agreement of the international RIGA consensus conference on nasal airway function tests*

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Abstract

The report reflects an agreement based on the consensus conference of the International Standardization Committee on the Objective Assessment of the Nasal Airway in Riga, 2nd Nov. 2016.

The aim of the conference was to address the existing nasal airway function tests and to take into account physical, mathematical and technical correctness as a base of international standardization as well as the requirements of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Rhinomanometry, acoustic rhinometry, peak nasal inspiratory flow, Odiosoft-Rhino, optical rhinometry, 24-h measurements, computational fluid dynamics, nasometry and the mirrow test were evaluated for important diagnostic criteria, which are the precision of the equipment including calibration and the software applied; validity with sensitivity, specificity, positive and negative predictive values, reliability with intra-individual and inter-individual reproducibility and responsiveness in clinical studies. For rhinomanometry, the logarithmic effective resistance was set as the parameter of high diagnostic relevance. In acoustic rhinometry, the area of interest for the minimal cross-sectional area will need further standardization. Peak nasal inspiratory flow is a reproducible and fast test, which showed a high range of mean values in different studies. The state of the art with computational fluid dynamics for the simulation of the airway still depends on high performance computing hardware and will – after standardization of the software and both the software and hardware for imaging protocols – certainly deliver a better understanding of the nasal airway flux.

Key words: nasal cavity, nasal mucosa, nasal septum, physiology, diagnosis

Abbreviations and symbols

AAR: active anterior rhinomanometry; AR: acoustic rhinometry; BCE: before the Common Era; CFD: computational fluid dynamics; COSMIN: Consensus-based Standards for the selection of health Measurement Instruments; EEG: electro-encephalogram; FSO: full signal output; FEV1: forced expiratory volume during the first second; GBI: Glasgow Benefit Inventory; GHSI: Glasgow Health Status Inventory; h: hour; Hz: Hertz; ISCO-ANA: International Standardization Committee on the Objective Assessment of the Nasal Airway; LBM: Lattice-Boltzmann methods; lg: logarithm; mCSA: minimal cross-sectional area; NCV: nasal cavity volume; NOSE: nasal obstruction symptom evaluation score; OR: Odiosoft-rhino; Pa: Pascal; PEF: peak expiratory flow; PNIF: peak nasal inspiratory flow; RANS: Reynolds-averaging Navier-Stokes approach; Reff: effective resistance; ReffEx: effective resistance during exhalation; ReffIn: effective resistance during inhalation; REM: rapid eye movements; RANS: Reynolds-averaged Navier-Stokes approach; $\dot{V}$: volume flux; ΔP: pressure difference; 4PR: Four-phases rhinomanometry

Introduction

The consensus conference dealt with the validity of objective measurements of the nasal airway. Participants included members of the International Standardization Committee on the Objective Assessment of the Nasal Airway (ISCOANA) and experts from Austria, Germany, Greece, Italy, Norway, Latvia and Ukraine, representing physics, mathematics, statistics, fluid dynamics, biotechnology and clinical rhinology. The consensus conference to update nasal function tests was necessary because some of the diagnostic procedures currently in use in rhinology no longer fulfil the requirements of quality management for medical devices. In addition, recent studies critically evaluating techniques for nasal airway assessment have not addressed technical progress in this field in recent years and the resulting experimental work, which has a great impact on daily practice [1]. The experiments of Wong and Eccles are not fully representative, because the artificial resistance units did not resemble the elasticity of the human nose, which includes skin, cartilage, connective tissue, mucosa and mucociliary epithelia. The elasticity of the nasal vestibule and the nasal cavity has an impact on nasal obstruction in all four different breathing phases [2]. All medical devices must comply with regulations concerning general state-of-the-art techniques and information technology. Furthermore, nasal airway function tests should be used with consideration of the extensive information obtained by means of computational fluid dynamics (CFD) methods, which is the most important upcoming method for the detailed topical analysis of the airflow in selected regions of interest in the upper airway. However, the basis of every nasal airway assessment is the synthesis of anamnesis, anterior rhinoscopy, endoscopic anterior rhinoscopy, endoscopy and posterior rhinoscopy or transnasal flexible endoscopy of the epipharynx.

It was necessary to achieve an agreement on the accuracy of rhinomanometric measurements in the first part of the conference and, in the second part, to consider the strength of evidence and measuring conditions of other methods such as acoustic rhinometry (AR), peak nasal inspiratory flow (PNIF), optical rhinometry, mirror test and 24h-measurements as tools in practice and research. The experience of nasal obstruction is one of the most common issues in rhinology as summarised recently in an editorial [3].

Part I: Update on standard recommendations for rhinomanometry

Moderator: Klaus Vogt

Speakers: Klaus Vogt/Germany and Latvia; Alina Nechyporenko/Ukraine, Franz Peters/Germany; Andreas Lintermann/Germany

Updated Standard for Rhinomanometry 2016 (Riga Standard)

In the systematic discussion of the previous standard for rhinomanometry, three issues were presented in detail because of their relationship to accurate measurements or evaluation with rhinomanometry: first, information on loops in the pressure-volume flow diagram of rhinomanometry obtained with extended model experiments [4]; secondly, the relationship between CFD and rhinomanometry [5]; and thirdly, the derivation of the hydrodynamic resistance coefficient [6, 7].

The standard recommendations determined during this meeting are an update to the 1984 recommendations of the ISCOANA [8] and the 2005 "Consensus report on acoustic rhinometry and rhinomanometry", including the addendum to that report [9]. The recommendations concern active anterior rhinomanometry (AAR) and active posterior rhinomanometry (APR) with the restrictions for APR outlined below.

A. Specifications for flow and pressure measurement channels.

The flow and pressure measurement channels should provide linearity within a range of +/- 1200 cm^3/s for flow and 1200 Pa for differential pressure. The response time for both channels shall provide a reliable measurement up to 80 Hz with a maximal error of 2% of the FSO. The temperature and humidity ranges that allow accurate measurement should be specified. If mass flow meters are used for flow measurements, the software must allow for adjustment of the flow channel according to the altitude above sea level.

Comment: Mass flow meters, used in anaesthesiology and intensive care, are highly accurate and sensitive sensors designed to measure breathing. They do not require the tubal connections necessary in pneumotachography. Because the density of air depends on the environmental pressure, mass flow meters must be adjusted according to altitude above sea level.

B. Calibration intervals.

The first calibration of the rhinomanometer must be carried out by the producer. Recalibration intervals must be specified in the user's manual.

Comment: The recalibration interval depends primarily on the type of sensor. While modern solid-state sensors do not need recalibration except after unexpected events, repair or changes in location (altitude above level sea), older devices do need calibration control at fixed intervals. Rhinomanometer calibration must be documented before and after studies as well as when rhinomanometer use has a medico-legal impact. Therefore, a simple calibration control device should be included with the necessary accessories.

C. Fixation of the pressure tube.

Fixation of the pressure tube should not affect the shape of the nasal entrance and should not restrict its motility during measurement. Therefore, adhesive tape remains the standard for fixation. Other types of connection should be checked against tape fixation [8, 9]. The tightness of the tape must be checked prior to measurement by closing the contralateral nostril with a lateral finger press, by blocking the silicone pressure tube, and by asking the patient to close the lips and to both inhale and exhale. Rarely, it is impossible to fix the pressure tube in an air-tight manner. In this case, fatty skin or make-up has to be cleaned and/or a few millimetre of the moustache or beard has to be shaved next to the nostrils.

Comment: This recommendation from 1984 remains very important and determines the initial accuracy of rhinomanometric measurements. However, producers of rhinomanometers and accessories sell nasal olives or sponge devices, which are popular among medical assistants because of their ease of use. Nasal olives and other sealing devices not only distort the closed nostril but also alter the contralateral airflow. This distortion exceeds by far the effects of decongestants or allergens. Thus, the results obtained are inaccurate and useless for functional diagnostics.

D. Mask.

The mask must be transparent, to allow visualization of oral tightness, must be clean according to hygienic standards, and must be adaptable to a bacterial filter to minimize the risk of contamination. The mask must fit the patient's face without disturbing the functional anatomy of the anterior nose.

Comment: Generally, full-face masks (respiratory protective masks) or anaesthesiology masks can be used. The investigator must evaluate possible distortion of the midface, especially in the case of children. Racial differences must be considered. When using full-face masks, the dead-space or mask volume is higher. This extra volume may influence measurements if the resistance of the device including the bacterial filter is high.

E. Measurement conditions.

Ingestion of alcoholic beverages is not allowed 16 h prior to measurement. This applies to all objective measurements. When in doubt, a blood sample must be taken to verify that the alcohol level is below 0.1 mg/g (alternative 0.1 ‰)[10]. All objective measurements must be made under standardized indoor measurement conditions. The indoor temperature must be between 18 and 35 degrees Celsius and the humidity must be at least 30%. The period of adaptation depends on the ratio between outdoor and indoor temperature. A minimum time period of 10 min is recommended for acclimatization to indoor room temperature and humidity in the waiting room. The patient should be
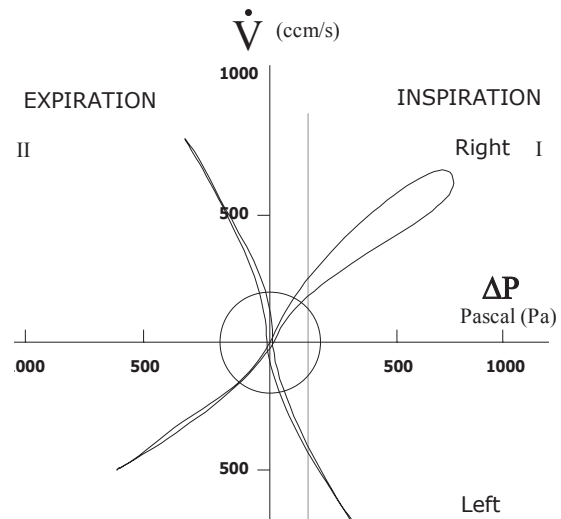

Figure 1. Graph of rhinomanometric measurements. Pressure difference of 150 Pa indicated by light gray line. (Figure from Rhinology Supplement 21).

seated comfortably during recording.

Comment: Reference data ("normal" values, classifications of obstruction) should be obtained under these conditions [11-13]. Physical effort rapidly diminishes nasal resistance. Airway resistance is markedly elevated in the supine position. Nasal resistance is lower during growth; the influence of age between 6 and 15 years can be estimated by correlation with anthropometric data.

F. Graphical information.

The relationship between pressure difference ΔP and volume flux $\dot{V}$ is depicted in Figure 1 (Consensus report 2005, Figure 36). The lengths of the x-axis and y-axis must provide all information in the physiological range of 1000 cm³/s and 1000 Pa. "Radius 2" as part of the polar coordinate system of Broms can be depicted as additional information [14]. The flow at 150 Pa can be indicated by a dashed line. A proportional dynamic extension of the range can be implemented, if the standard range does not depict the full range of the actual measurement.

To better understand time-dependent changes and to identify measurement errors separately for each measurement channel, it is useful to add an additional graph depicting the timeline of flux and pressure difference (Figure 2).

Comment: Nearly all modern rhinomanometers depict more or less expressed loops instead of a simple bent line. Loops as technical errors are excluded in rhinomanometers with short response times as defined above. The physical background of loops has been extensively described in model experiments with numerical calculations [4]. Asymmetric loops provide important additional visual information indicating the influence of elastic compartments such as the nasal valve and the soft palate (Starling resistor).
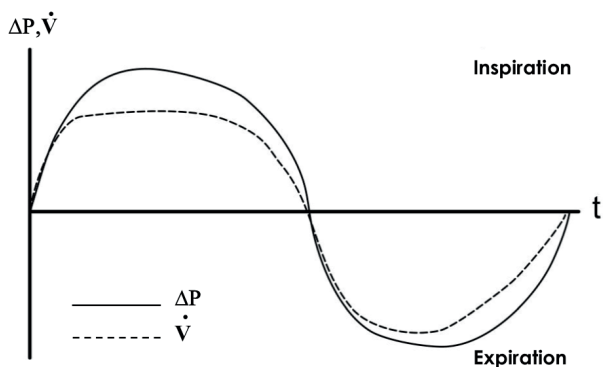
Figure 2. Timeline of pressure difference ΔP and volume flux $\dot{V}$

If the rhinomanometric graph does not show loops at all, the software is not in agreement with the basic norm of software in medical products (ISO 14971, IEC 62304) because the averaging procedure is erroneous.

The physical units agree with the SI system and the Council Directive 89/617 of the European Union.

The additional graphs of the timelines of volume flux and pressure difference provide information about correct measurements of both channels or errors resulting from these measurements and contribute to a better understanding of loops caused by elastic compartments of the nasal channel. "Flow limitations", as described in sleep medicine, are better visualized in the two-channel timeline.

G. Numerical information.

The basic numerical information shall be the effective resistance of the entire breath (Reff) and the effective resistance during inspiration (ReffIn) and expiration (ReffEx). For clinical purposes the values shall be expressed as common logarithmic values LReff, LReffIn and LReffEx, where LReff = lg (Reff), LReffIn = lg (ReffIn) and LReffEx = lg (ReffEx). For easier practical use, clinical data should be given as LReff = lg(10Reff), LReffin = lg (10ReffIn) etc.

Derivation of effective resistance:
Effective resistance is an important term in electricity, where voltage is generally measured as "effective voltage", which is the root mean square (RMS) of voltage. In rhinomanometry effective resistance is calculated as

$$W_{eff} = \sqrt{\frac{1}{T}\int_0^T w^2 dt}$$

where w is the value Δ P or $\dot{V}$

$$R_{eff} = \frac{\Delta P_{eff}}{\dot{V}_{eff}} [Pas/ccm]$$

where ΔP_{eff} and $\dot{V}_{eff}$ are the effective pressure loss and volume flux over the complete respiratory cycle.

Comments: As described in the standard recommendation of 1984, the calculation of resistance at 150 Pa is not correct, because this point of a breathing curve is in the accelerating or decelerating region of the curve, where the pressure/volume flux relationship is non-linear. The resistance differs and depends on the pressure at any point of the breathing wave. Furthermore, a pressure of 150 Pa is frequently not reached in normal unstrained breathing cycles. With state-of-the-art sensor techniques and information technology it is not necessary to use estimations, because exact measurement results can be used as the basis for diagnostic parameters. Applying resistance at 150 Pa or replacing this value with resistance at another point (75 Pa for example) leads to erroneous results and is not in agreement with the normative conditions mentioned above. In summary, the nasal resistance in classical AAR is calculated on one single volume value at one fixed pressure at 150 Pa (alternative 75 Pa) whereas the nasal resistance in 4PR is calculated on the area under the curve of hundreds of resistances continuously recorded during inspiration and expiration along the entire breathing cycle. Effective resistance is closely related to "surface under tracing" as described by Naito et al. [15].

Many studies have shown that rhinomanometric one-point measurements and linear effective resistance are only weakly or not at all correlated with the feeling of nasal obstruction[16]. *Extended contradictory clinical studies have shown that according to the Weber–Fechner law the logarithmic effective resistance and logarithmic vertex resistance correlate significantly with subjective scores as measured on a visual analogue scale* [11, 16].

Based on 36,500 active anterior rhinomanometry measurements and 10,030 measurements of calculated total resistance, a clinical classification for nasal obstruction in increments of 20% is now available for Caucasian noses (Table 1).

Additional numerical parameters:

Additional parameters can be included in the rhinomanometer software, if the derivation or algorithms of the parameters are published and reproducible by anyone on demand. The clinical meaning and relevance of new parameters must be validated in clinical studies. The parameters listed in Table 2 are presently in use.

Comments:

1. *The flow at 150 Pa should remain available to allow comparison of new measurement results with the results of older rhinomanometers. The flow sum of both sides at 150 Pa and the side quotient (lateralization percentage) are correct parameters for the evaluation of total nasal airflow* [17].

2. *The calculation of total nasal resistance with the equation for parallel electric resistors is estimated, because of the unknown role of the nasopharynx. However, this calculation is more reliable than the measurements of posterior rhinomanometry because that method is limited by the cooperation of the*

Table 1. Classification of nasal obstruction according to active anterior rhinomanometry in 36,500 measurements.

Class		Unilateral Resistance		Total Resistance	
		Untreated	after de-congestion	Untreated	after de-congestion
1	0–19%	<0.71	<0.63	<=0.42	<=0.36
2	20–39%	0.71–0.89	0.63–0.78	0.42 - 0.57	0.36 - 0.47
3	40–59%	0.89–1.08	0.78–0.94	0.57 - 0.70	0.48 - 0.59
4	60–79%	1.09–1.35	0.94–1.18	0.70 - 0.90	0.59 - 0.76
5	80–100%	>1.35	>1.18	> 0.90	> 0.76

The classification is valid for LReff, LReffin, LReffex, LVRin, LVRex, where LReff = lg10Reff etc. Class 1 represents noses without any obstruction while class 5 corresponds to total functional blockage [12].

patient.

3. *Vertex resistance and logarithmic vertex resistance. The vertex resistance is defined as the resistance measured at the highest point of the flow curve during quiet breathing. This part of the curve is characterized by a steady airflow and is important for further correlations with CFD. Vertex resistance and effective resistance in normal breathing are statistically strongly correlated. They differ in inspiration in case of the onset of nasal valve activity. Vertex resistance and peak flow resistance have been confirmed as reliable parameters in early studies of rhinomanometry [14]. Neither vertex resistance nor peak flow resistance in rhinomanometry is related to or comparable with PNIF.*

4. *The hydrodynamic resistance coefficient may be considered as a new classification of nasal obstruction, independent of racial differences in nasal shape, for the investigation of different nasal activities (calm breathing, breathing during physical exertion, influence of nasal cycle)[6, 18]. The hydrodynamic resistance coefficient is a dimensionless coefficient, which takes into account laminar and turbulent regimes of flow. Hydrodynamic resistance coefficient and vertex resistance are highly correlated.*

5. *With resistometry both resistance and hydraulic diameter were shown to distinguish healthy from rhinologic patients in a prospective cohort study. Reference values were determined and published [19]. The clinical value of this information has been demonstrated in a prospective case series with a 1-year follow-up [20, 21]. The calculation of linear resistance at 250 cm³/s is physically incorrect because there is no linear relationship between pressure and volume flux at this point.*

6. *Calculation of breathing performance as $\Delta P\dot{V}$ and the calculation of breathing work may provide additional physiological information [22]. The clinical impact of this information is*

limited because performance and work depend on the depth of a breath [57].

Part II: Diagnostic strength of nasal airway function tests

Moderator: Gregor Bachmann-Harildstad/Norway

Speakers: Klaus-Dieter Wernecke/Germany; Mara Argale, Krista Kaulina, Rudolf Viksne/Latvia; E.G. Wuestenberg/Germany; Gregor Bachmann-Harildstad/Norway; Klaus Vogt/Latvia and Germany

In an introductory lecture Klaus-Dieter Wernecke summarised the importance of applying the criteria for evidence-based medicine to critically evaluate the diagnostic power of current diagnostic methods. Within this context it is necessary to determine the validity of information obtained with each method and the application of this information to clinical problems and decision-making related to the care of individual patients.
The criteria for diagnostic power are:
*   Reproducibility (reliability) and responsiveness under physiological and pathophysiolgical conditions (reliability refers to both interrater agreement as to whether the criteria that define a disorder occur in a patient population, and to the consistency with which any particular diagnosis is made over time)
*   Diagnostic validity as measured by sensitivity, specificity, positive and negative predictive values as well as overall accuracy (validity refers to the accuracy with which the mentioned criteria define and differentiate a disease from other diseases)
*   These definitions include in particular:
    *   Precision and accuracy of measurements as given by technical equipment and/or software details (evaluating gauge repeatability and reproducibility)
    *   Intra-individual variability
    *   Inter-individual variability
    *   Arguable agreement with other methods of measuring
    *   Comparability under different clinical conditions
Appropriate statistical procedures for evaluation with these criteria have been shown in the examples.

1) Active anterior rhinomanometry (AAR).
The topic was extensively discussed in the first session. Increased diagnostic power has been achieved in recent years with the analysis of comprehensive clinical data after correction of obsolete calculations and the introduction of new parameters (4PR). A classification of obstruction in Caucasian noses is available; corrections for noses during growth will be published soon. By choosing correct parameters, a direct relation to CFD measu-

Table 2. Additional parameters in rhinomanometry.

Parameter	Author	Calculation	Additional information	Validation
Flow at 150 Pa	ISOANA [8,9]		Comparison with references	Yes
Flow sum at 150 Pa	ISOANA [8,9]	$\dot{V}_{right} + \dot{V}_{left}$	Total nasal airflow	Yes
Lateralization percentage	Postema et al. [17]	$\dot{V}_{right} / \dot{V}_{left}$	Lateralization	Yes
Calculated total resistance	ISOANA [8,9]	$R_{Tot} = R_{right} * R_{left} / (R_{right} + R_{left})$ for R = Reff, LReff, ReffIn, LReffIn, ReffEx, LReffEx	Total nasal resistance	Yes
Nasal breathing performance	Eichler [22]	$P_N = \Delta P \dot{V}$	Alternative parameter	No
Polynomial model	Rohrer	$\Delta P = k_1 \dot{V} + k_2 \dot{V}^2$ where k_1 = linear coefficient, k_2 = quadratic coefficient	Curve adaption	No
Vertex resistance (VR), Logarithmic Vertex Resistance (LVR)	Vogt et al. [11]	$\Delta P / \dot{V}$ at maximum flow (inspiration, expiration)	Resistance at steady flow (inspiration, expiration)	Yes
Radius 2	Broms [14]	Angle in a polar coordinate system for pressure and flow	Comparative parameter	Yes
Hydrodynamic resistance coefficient (HRC)	Garyuk, Nechyporenko [6,7]	$\zeta = \dfrac{A}{Re} + B$, where $A = k_1 \dfrac{4S^2}{P\rho\upsilon}$, $B = k_2 \dfrac{2S^2}{\rho}$ $Re = \dfrac{V_{av} d_{eq}}{\upsilon} = \dfrac{\dot{V} d_{eq}}{S\upsilon} = \dfrac{4\dot{V}}{P\upsilon}$ S: cross-sectional area of nostril; P: perimeter of nostril, deq: diameter of nostril; υ: kinematic coefficient of air viscosity; ρ: air density; k_1, k_2: coefficients from Rohrer's equation (k_1: coefficient of the laminar flow; k_2: coefficient of the turbulent flow); Re: Reynolds number	New classification possible	No
Resistance in resistometry	Mlynski, Löw [19]	$R = \Delta P / \dot{V}$ at 250 ml/s	Comparison with references	Yes
Hydraulic diameter	Mlynski, Löw [19]	$d_h = 2 \sqrt[4]{\dfrac{8 \dot{V} \eta l}{\Delta P \pi}}$ η = viscosity, l = length of nasal cavity	Measure for the width of the nasal flow channel during laminar flow	Yes
Flow at beginning of nasal valve collapse	Beule, Mlynski, Gogniashwili [20]	Difference between calculated R and measured R > 5%	Discrimination between physiological and pathological valve collapse	Yes
Flow at pure turbulence	Mlynski, Löw [19]	Flow at exponent n = 1.8 in the equation $R = \Delta P / \dot{V}^n$ as a function of breathing flow velocity $n(\dot{V}) = \dfrac{d \ln(\Delta P)}{d \ln(\dot{V})} = \dfrac{d \Delta P}{d \dot{V}} \cdot \dfrac{\dot{V}}{\Delta P}$	Information on transition of laminar to turbulent flow behavior with increasing flow velocity	Yes

rements can be achieved. As a tool for objective measurement of nasal resistance in nasal provocation tests, AAR was chosen in most studies so far [23].

The correlation between objective and subjective measures on the nasal airway is still a complex issue and many studies did not find a significant correlation [24].

However, the first study following consensus-based standards for the selection of health measurement instruments (COSMIN) concluded, that the Glasgow health status inventory (GHSI), the Glasgow benefit inventory (GBI), PNIF and 4-P AAR all scored appropriately on content validity and reliability and only the GHSI scored well on responsiveness [25].

2) Peak nasal inspiratory flow.
Peak nasal inspiratory flow can be measured by the Youlten peak flow meter. This is a portable, passive, light and re-usable device, connected to a sterilized face mask.

Described for the first time by Benson in 1971, the correlation between PNIF and both AAR and PEF has been shown already in 1991 [26]. Recent studies have compared PNIF with AAR using statistical correlation tests with the confirmation that a significant correlation exists [27]. The reproducibility has been shown in several studies [28-30] and its application in functional rhinosurgery resulted in a diagnostic accuracy of 0.72 at a cut-off of 2000 ml/s (120 L/min)[31].

Measurements of bilateral PNIF revealed mean values between

80.8 and 174 L/min in different populations, and it does depend not only on sex but also on age, height and lung function [32]. Interestingly, in about 90% of individuals the sum of right-sided PNIF and left-sided PNIF exceeds the value of simultaneous bilateral PNIF; in approximately 10% of individuals the opposite is true. This finding might correlate with ala nasi insufficiency. Occasionally, either right-sided or left-sided PNIF exceeds the value of simultaneous bilateral PNIF. The only variable that significantly correlates to unilateral PNIF values is height, shown in a modified PNIF value model [33]. The PNIF values do not depend on the body mass index [34] as the nasal cavity does not contain fat cells. The influence of lung function and the missing information about nasal valve function and the role of the nasopharynx are essential disadvantages of this method. The PNIF value increases by 0.3 L/min per % increase in FEV1 (% predicted in spirometry), as published in a study on patients with nasal obstruction and asthma [35].

A. Specifications

The flow is measured as volume/time and the device should cover a range of at least 30 to 350 L/min. For the residual volume method, two measurements are taken in the seated or upright position [36] with maximum transnasal inhalation and closed lips, starting from the end of a full expiration. Two measurements are performed each bilaterally and unilaterally, both before and after decongestion, yielding 12 values. The best value from each of the six measurement conditions is recorded. Closure of the contralateral side for unilateral PNIF is performed using a flexible air-tight tape. The seal has to be checked prior to each measurement by blocking the contralateral side and asking the patient to inhale. Blockage of one nasal cavity with cotton wool inside the vestibule is contraindicated because of anatomical changes in the contralateral side and the risk of suffocation.

B. Calibration

Peak nasal inspiratory meters are currently not calibrated at fixed intervals when in use. This may result in inaccurate values because of material breakdown over time. A PNIF meter must be replaced after three years or after 50,000 measurements. Otherwise, it must be recalibrated by the manufacturer or at a national metrology service every second year with the results and the method of calibration communicated to the hospital administration.

C. Mask

For the mask, see the hygienic requirements for rhinomanometry. The device and the mask must be autoclavable. A bacterial filter is not suitable, as it would not allow for comparison with normal peak flow values. Unintentional exhalation or blowing the nose during an attempt to obtain the first PNIF measurement might contaminate not only the mask but also the measuring device.

The impact of mask tightness in males with a beard has not been clarified for PNIF measurement so far.

D. Recommendation

Peak nasal inspiratory flow may be used as a fast test and should be supplemented by AR and/or AAR in cases of discrepancy between the symptoms and objective findings. Research about intra- and inter-individual variability is ongoing.

3. Acoustic rhinometry.

Acoustic rhinometry is a rapid method of determining morphologic changes in the nasal airways. It is based on the reflection of ultrasound waves, directed into the nasal cavity.

A. Specifications

Important parameters are the minimal cross-sectional area (mCSA) at different "notches" or spaces and the nasal cavity volume (NCV). The NCV is defined as the space between the opening plane of the device and a parallel plane at a defined distance from the opening plane. For this measurement, either a fixed distance or the distance to the mCSA is applied. Mlynski in 2015 stated, that the mCSA1 is the narrowest part between 0 and 3 cm from the external ostium and the mCSA2 between 3 and 5,2 cm respectively (personal communication). Garcia et al. [39] in 2016 pointed out that AR measurements are affected by several factors: the position of the sound tube and possible leakage at the nostril, the inconsistency in user operation and the overestimation of mCSAs in the posterior nose due to sound leakage into the sinuses. Dynamic changes at the nasal valve during inhalation and exhalation are not represented. When using diagnostic methods designed for morphologic evaluation to obtain functional information, the key question is the relationship between rhinometric parameters and functional airway resistance. A significant correlation between PNIF and AR was found at the mCSA2 and mCSA3 except for the nasal vestibule space at $0 - 3 \ cm^3$ of the NCV [37]. In one study on responsiveness, the subjective 11-year satisfaction correlated with AR improvement 3 months after septoplasty in pre-decongestion mCSA1, mCSA2 and mCSA3, using distances of 0–2.2, 2.21–5.4 and 0–5.4 cm, respectively [38]. It could be shown that for low mCSA values a power correlation does exist between mCSA and airway resistance as measured with CFD [39]. The law of Hagen–Poiseuille is also valid for irregular cross-sectional areas. The inter-examiner variation with AR has not yet been quantified.

B. Calibration

The first calibration of the acoustic rhinometer has to be carried out by the producer. Recalibration must be repeated before each measurement.

C. Hygiene

The end pieces of the device must follow hygiene standards and must fit to the configuration of the nostril anatomy on each side. For recalibration, the patient closes the tip of the end piece with a thumb.

D. Recommendation

We feel the definition of the mCSA in AR needs further attention and agreement. Either a fixed distance will be defined, which probably will depend on age and ethnic conditions, or the individual distances will be used. Until a common consensus is achieved, it is of importance to describe in detail the chosen definition of the mCSA in each study. The popularity of AR varies widely in different countries. Whereas in Germany AR is used at some research facilities, in Norway the screening diagnostic approach for nasal airway assessment combines AR and PNIF.

4. Odiosoft-rhino.

Odiosoft-rhino (OR) is the acoustical analysis of the sound produced by nasal breathing [40]. The system consists of a computer program, microphone, a sound card and a computer.

A. Specifications

The method is an indirect determination/estimation of nasal resistance using a microphone 1 cm next to the nares. A correlation of OR with the results of AAR and VAS has been shown for frequencies between 2 and 4 kHz [41]. The clinical data on the method are limited.

B. Calibration

A calibration for OR is not specified so far.

C. Hygiene

As the microphone is not exposed directly to the nasal airflow, the hygienic prerequisites include a clean microphone and tape, not necessarily sterilised.

D. Recommendation

The advantage of the method lies in the hardware which is not expensive and it does not take more than a few minutes to apply the equipment. Studies on the reproducibility have not been published so far and the responsiveness has not been confirmed by other groups.

5. Optical rhinometry.

The method is not primarily intended to analyse nasal air flow, but rather uses emission or transmission spectroscopy to evaluate mucosal oedema as indicated by changes in blood flow and light absorption with high reproducibility [42]. Intra-individual variability is independent of patient cooperation. Absolute data or norm values are not available for inter-individual variability

or comparability; presently, only relative measurements are possible. No patients have to be excluded with this method because it is possible to assess patients with polyps or septum perforation. The test is therefore suitable for nasal provocation tests and has shown promising diagnostic value [43].

6. 24h-measurements.

The nasal cycle has been studied for more than half a century [44]. It remains an open question whether the nasal cycle reflects a central function and/or follows simple gravity conditions [45]. Initial data indicate that nasal air flow lateralization relates to the sleep stage with REM phases, measured by EEG [46]. Semi-quantitative measurements of nasal breathing have long been a substantial part of polygraphy and polysomnography. The technical principles of these methods are thermistor measurements or pressure measurements; the latter are preferred in sleep medicine [47]. Extended information about the role of the nose during sleep can be obtained by using divided cannulas connected to pressure sensors, thus allowing the separate measurement of left and right nasal passages. The role of body position on nasal breathing can be visualized as well in increased nasal resistance in the supine position and side differences in nasal breathing. The form of the recorded breathing waves can themselves hint at a so-called "inspiratory flow limitation". Similar curves are produced in AAR when the nasal valve is active or the soft palate is retracted by nasal breathing.
Particular information about the nose has to be seen generally in the framework of polysomnography and should be supplemented by rhinomanometry and endoscopy in case of pathological findings.
Analysis of long-term measurements must be separated from the influence of physical exertion or body position, which also influences cyclic changes in nasal blood supply.

7. Computational fluid dynamics.

The development of CFD methods, which can be included in the daily work of an ENT surgeon, is one of the most promising and challenging tasks for the future of upper and lower airway diagnosis. The analysis is based on CT- or MR-imaging data [48]. As such, this method requires patient exposure to radiation, unless CT has been performed for other indications. Casey et al. reported on the middle nasal cavity area as a key space with a high correlation for subjective nasal obstruction measured by VAS and nasal obstruction symptom evaluation score (NOSE) [49]. By means of extraction algorithms the three-dimensional surface of the airway, i.e., the interface between air and tissue, is reconstructed from the corresponding CT data [50]. This surface consists of a set of triangles forming a watertight volume of the region of interest. It serves as a basis to construct a computational mesh for the simulation. This mesh is necessary to approximately solve the governing equations of fluid mechanics, i.e.,

the Navier-Stokes equations (conservation of mass, momentum, and energy), in their discrete form on computers. Lattice-Boltzmann methods (LBM) operating on hierarchical Cartesian meshes [51] have shown to be efficient for the computation of the flow in the nasal cavity [5, 48, 50, 52-54]. They allow for effective parallelization, easy boundary treatment, and accurate simulation of respiratory flows. The application of adaptive outflow conditions at geometry outlets placed at the pharynx at inspiration in conjuction with second-order accurate no-slip wall-boundary conditions and Saint-Venant-Wanzel inflow conditions at the nostrils allows an in-solve adjustment of the Reynolds number [50], or in other words, an adaptation of the ratio on inertial to viscous forces. Eitel et al. [50] and Lintermann et al. [5, 52, 53] have shown detailed studies of the nasal airflow using this method and classify nasal cavities by the total pressure loss, wall-shear stress, heating capability, and heat transfer.

While the feasibility of CFD methods is obvious, the transfer to daily practice is closely related to the development of high-performance small computers and standard programs allowing the use of CFD at a reasonable price.

That is, accuracy, which is defined by the mesh resolution and the simulation and modelling method, comes at a defined computational cost. High resolution simulations are currently only viable by employing high-performance computing (HPC) hardware. For this reason, many approaches follow a model such as The Reynolds-averaging Navier-Stokes (RANS) approach. Such RANS computations are computationally cheaper than directly solving the Navier-Stokes equations without using any modelling approach. However, the error introduced by such models is not easily quantifiable and their application stays questionable since the assumption of turbulent flow, a prerequisite of turbulence models, is not necessarily true for nasal cavity flows.

In the end it needs to be stated that to the best of the author's knowledge, no simulation tool has made its way into daily clinical practice so far, at least any which is capable of finding a reasonable balance between computational costs, high accuracy, and user-friendlyness.

Two further tests should be mentioned as suitable for limited indications:

8. Mirror test.

This functional assessment is the oldest rhinological test. It is performed with a clean, smooth, preferably cooled surface of at least 5 × 7 cm, placed under both nostrils to determine the size of the fogged area produced by each nostril during exhalation. Made out of metal, it is autoclavable. The method was extensively described by Hendrik Zwaardemaker from Utrecht and a modified device has been in use since 1901, known as Glatzel–Spiegel in Germany. The first documented use of this test appears on a stone wall in southern Italy illustrating its application as a tool to examine a dying woman, dated about 320 BCE. The test is far older than any published medical report on printed paper [55].

The mirror test is a simple, non-invasive (not even touching the patient asleep), non-irradiating, inexpensive and a very fast bedside test, and is recommended for the objective assessment of the nasal passage in newborns and premature babies. The test rules out unilateral or bilateral choanal atresia with a self-evident positive predictive value when combined with a diagnostic nasogastric tube in cases of doubt. Published studies on a diagnostic value are not known. The device's non-invasive character and price per patient are definitely superior to all other nasal function tests for this patient group. One may guess that the test most probably will remain in use for the next 2000 years.

9. Nasometry.

The aim of nasometry is the determination of the cause of nasality in speech rather than evaluation of the nasal airway.

Finally, job shift is a reality in the medical profession. Methods such as the mirror test, PNIF, AR, AAR, 24-h measure may altogether be delegated to trained medical assistants. For reasons of effectiveness this is not to avoid to some extent. However, not only the capability but also the possibility to perform these tests on demand should stay in the hands of the rhinologist. The advantage of having the surgeon herself or himself perform the appropriate test is that the process of important verbal and non-verbal communication will continue and that may support shared decision-making in a worldwide constantly increase of multiple possible choices for therapies and surgeries. It was proposed that 'cure' and 'care' are inseparable. Gulbrandsen et al. pointed out that careful curating should foster autonomous capacity, but is not always possible because of lack of familiarity with the information available and exchanged, or with the patient when providers are exchanged. The performance of an objective assessment of the nasal airway should not be underestimated as an element for a reliable relation, especially for the professional care in complex cases [56].

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Authorship contribution

KV and G B-H, are the authors of this conference report. The

Conflict of interest

The authors declare no conflicts of interest.

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