Comparison between a national and a foreign manovacuometer for nasal inspiratory pressure measurement

Comparação entre o manovacuômetro nacional e o importado para medida da pressão inspiratória nasal

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Abstract

Background: The measurement of nasal inspiratory pressure, known as the sniff test, was developed as a new test of inspiratory muscle strength, mainly used in neuromuscular conditions. The test is easy to be performed and noninvasive. Despite the clinical importance of assessment of nasal inspiratory pressure a national equipment is not available to assess it. Objectives: To compare a national with a foreign manovacuometer in assessing the nasal inspiratory pressure (sniff test) in healthy subjects. Methods: 18 subjects were evaluated (age 21.44±2.8 years, BMI 23.4±2.5 kg/m², FVC 102.1±10.3% pred, FEV₁ 98.4±1% pred). We performed two measures of nasal inspiratory pressure using two different manovacuometer: a national and a foreign. All subjects performed the tests at the same time of day, in different days being the order of the testes established randomly. It was used the paired t test, Pearson correlation and the Bland-Altman plots for statistical analysis considering a 5% significance level. Results: The averages observed for the two measures of nasal pressures were 125±42.4 cmH₂O for the foreign equipment, and 131.7±28.7 cmH₂O for the national equipment. The Pearson correlation showed significant correlation between the means with a coefficient of r=0.63. The t test showed no significant differences between both measurements (p>0,05). The BIAS±SD found in Bland-Altman plot analysis was 7 cmH₂O with limits of agreement between -57.5 cmH₂O and 71.5 cmH₂O. Conclusion: The results suggest that the national electronic device is feasible and safe to the sniff test measurement in healthy subjects.

Key words: respiratory muscle strength; respiratory muscle training; respiratory pressure; nasal inspiratory pressure.

Resumo

Contextualização: A medida da pressão inspiratória nasal, conhecida como *sniff* teste, desenvolvida como um novo teste de força muscular inspiratória, utilizada principalmente em doenças neuromusculares, é de fácil realização e não invasiva. Apesar da importância clínica da avaliação da pressão inspiratória nasal, não existe um instrumento nacional disponível para realizá-la. *Objetivos*: Comparar os manovacuômetros eletrônicos nacional e importado para a avaliação da pressão inspiratória nasal em pessoas saudáveis. *Métodos*: Foram avaliados 18 voluntários saudáveis (idade 21,4±2,8 anos, IMC 23,4±2,5 Kg/m², CVF 102,1±10,3%pred, VEF₁ 98,4±1%pred) por meio de duas medidas de pressão inspiratória nasal em dois equipamentos diferentes: um nacional e outro importado. Todos os sujeitos realizaram a manobra no mesmo horário do dia, em dias ocasionais, sendo a ordem determinada aleatoriamente. Para análise estatística, foi utilizado o teste *t* pareado, a correlação de Pearson e o Bland-Altman com nível de significância de 5%. *Resultados*: As médias encontradas durante as duas medidas das pressões nasais foram de 125±42,4 cmH₂O para o aparelho importado e de 131,7±28,7 cmH₂O para o nacional. A análise de Pearson demonstrou uma correlação significativa entre as médias, com um coeficiente r=0,63. Os valores médios não apresentaram diferenças significativas pelo teste *t* pareado (p>0,05). Na análise de Bland-Altman, encontrou-se um BIAS igual a 7 cmH₂O, desvio-padrão de 32,9 cmH₂O para o DP e um intervalo de confiança de -57,5 cmH₂O até 71,5 cmH₂O. *Conclusão*: Os resultados encontrados sugerem que o manovacuômetro eletrônico nacional é viável e seguro para realização do *sniff* teste em sujeitos saudáveis.

Palavras-chave: força do músculo respiratório; treinamento dos músculos respiratórios; pressão respiratória; pressão inspiratória nasal.

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Introduction :::.

The respiratory muscle weakness is an important clinical problem, can be acute or chronic and it is a potentially treatable condition¹. Clinically, respiratory muscle weakness is related to hypercapnia, respiratory infections and ineffective cough, which predispose the development of atelectasis and respiratory failure¹⁻⁴. In neuromuscular diseases, disorders of respiratory muscles are associated with the onset of respiratory failure¹⁻⁴.

The clinical importance of respiratory muscles assessment with a variety of tests was proposed in previous studies^{5,6}. Strength of these muscles can be assessed by means of static or dynamic measures. The more traditional static measures for respiratory muscle strength assessment are the maximal respiratory pressures (MIP, maximal inspiratory pressure and MEP, maximal expiratory pressure)^{7,8}. Although the MIP measurement is simple, it depends on collaboration and coordination of the patient, which can lead to inaccurate assessments and, hence, an incorrect diagnosis⁹. Some authors suggest that the use of a single test may not be sufficient to identify the inspiratory muscle dysfunction. Therefore, the combination of several tests would improve accuracy of inspiratory muscle weakness diagnosis⁵.

A recently developed alternative is the nasal inspiratory pressure assessment or sniff test¹⁰. The test represents the MIP achieved through an inspiration from functional residual capacity (FRC) transmitted by a connection through the nasal cavity¹¹. In this test, the type of activation of respiratory muscles, the patient/equipment interface, learning and performance are simpler than the MIP^{12,13}. Clinically, the sniff test was considered by some authors a complementary assessment method for the diagnosis of inspiratory muscle weakness when associated with the MEP measure^{5,9}.

Commercially, there is only one equipment of electronic manovacuometry for sniff test assessment. Since it is a foreign equipment, the costs are high, and the use of this measure that have a great clinical importance in the Cardiopulmonary Physical Therapy area becomes, often, unfeasible. In the national market, the electronic manovacuometer equipment, similar to the foreign, was developed for respiratory muscle strength assessment and it is available commercially. However, the feasibility of this equipment for the evaluation of sniff test has not yet been performed. The aim of this study was to compare the measure of nasal inspiratory pressure in healthy subjects between two electronic manovacuometers: a national and a foreign.

Methods

This study was conducted in accordance with the resolution 196/96 of the National Health Council. All procedures in which the subjects were tested were approved by the Ethics Committee of the University Hospital Onofre Lopes, Universidade Federal do Rio Grande do Norte (UFRN), Natal (RN), Brazil, according to the protocol 238/08, and subjects signed the consent form to participate in the study.

Subjects

A sample of physical therapy students was recruited from the UFRN where the study was conducted. All the subjects participated voluntarily. Students without prior knowledge of the used technique, nonsmokers, students without cardiopulmonary diseases, asthmatics without exacerbation of symptoms, subjects without nasal septal deviation and/or chronic rhinitis diagnosed by specialists, students without previous history of surgery in the nasal cavity and without forced vital capacity (FVC), forced expiratory volume in one second (FEV $_1$) and FEV $_1$ /FVC ratio below the normal limits (<80% of predicted values) were included. Those students who had nasal congestion during the study period and who were using medications that could influence the assessments results were excluded.

Procedures

Prior to the beginning of sniff test assessments, all subjects were assessed by otorhinolaryngologist to exclude from the sample those with nasal septal deviation or rhinitis. This measure was adopted to ensure that the results of the sniff test were reliable, although it is not necessary in daily clinical practice. Assessments conducted by otorhinolaryngologist consisted of anamnesis and anterior rhinoscopy with nasal speculum, following a protocol published previously¹⁴.

At the beginning of the physical therapy assessment procedures, subjects were asked about the habits of life (general health, physical exercise practice and use of medication) and vital signs were measured (blood pressure, body temperature, heart rate, respiratory rate). Anthropometric and spirometric measurements were performed by two assessors previously trained for such procedures.

The subjects underwent sniff test assessments using two different equipments: the national MVD300® (Globalmed, Brazil) and the foreign MicroRPM® (Micromedical, UK). All measurements were performed at the same time of day, on different days, being the order of use of equipments determined randomly by individual sortition.

Variables analyzed

Anthropometric characteristics: anthropometric assessment was performed to characterize the sample by measuring the body weight and the height of the subject in a WELMY® - model R-110 scale (WELMY, Santa Barbara d'Oeste, Brazil).

Spirometry: spirometry was used to characterize the sample in a healthy spirometry point of view, following the technical procedures and criteria for acceptability of the Brazilian Society of Pneumology and Tisiology¹⁵. Subjects were instructed in detail about the procedures to be performed during spirometry assessment. Tests were implemented with subjects sitting in a comfortable chair and a nose clip was used. Subjects were instructed to breathe through a disposable cardboard mouthpiece placed between the teeth, carefully observed by the assessor to avoid air leaks during spirometric maneuvers. Subjects were asked to achieve maximal inspiration, near total lung capacity (TLC), followed by a maximal expiration, close to residual volume (RV). A maximum of eight tests in each subject were performed and the best three were considered, being the variability between them less than 5% or 200 milliliters. FEV, FVC and FEV,/FVC ratio in their absolute and relative values were analyzed. FEV₁/FVC ratio was obtained by comparison with normal curve for all spirometric variables and with reference values16. The equipment used was the DATOSPIR 120 (SibelMed Barcelona, Spain) spirometer conected to a computer and it was calibrated daily.

Nasal Inspiratory Pressure: two sniff test measures were performed in two electronic manovacuometer equipments: a measure in the foreign equipment MicroRPM® (SNIP,) and a measure in the national equipment MVD300® (SNIP₂). Although equipments have the same electronic mechanism, MicroRPM® equipment has a selection switch for option MIP/MEP and another selection option for SNIP. The foreign equipment has four nasal plugs of polyethylene in a cylindrical shape with a convex external edge to connect to the nasal orifice. For each subject, the nasal plug that best suited the size of the nasal orifice was chosen. In relation to its size, the bases vary from 1.1 to 1.9 cm in height, thickness ranges from 3.1 to 4.5 cm and there is an internal orifice of 0.5 cm. The extension is made of silicone and measures 68 cm. The equipment MVD300[®] has two connection options, one for MIP assessment and other for MEP assessment. The maneuver to obtain the SNIP was held at the connection option of MIP assessment, option able to capture the negative pressure generated by the test. The equipment has a silicone extension of 60 cm and was used for sniff assessment with a silicone nasal plug similar to the foreign plug, with conical shape, with base and height of 2.2 cm and an orifice of 0.5 mm of internal diameter for pressure transmission.

Sniff test assessments were performed following the standard methodological description9-11,17 and reference values previously reported for the English population⁹ were used, since there are no values described and standardized for the Brazilian population. The test was performed by placing a nasal plug in one of the nostrils, no preference for right or left, keeping the contralateral nostril without occlusion. Then the subjects were asked to maintain a normal breathing and at the end of relaxed expiration, identified as FRC, the mouth should be closed and then a maximum inspiratory effort was performed. At this time the pressure generated was transmitted from the nostril connected to the nasal plug to the manovacuometer by the silicone extension. During the maneuver, the subjects were verbally encouraged. The maneuver was performed ten times, the interval between them was 60 seconds and at the end of ten maneuvers, the highest value was used, considering it as the subject's nasal inspiratory pressure 10,11,17. To perform the sniff test with the equipment MVD300®, the nasal plug was connected on one end of the extension (place where the mouthpiece would be connected), while the other end was connected to the manovacuometer in the connection of MIP assessment.

Statistical analysis

To calculate the sample size, 95% reliability power and standard deviation, previously published by Uldry and Fitting⁹, of 29.5 cm $\rm H_2O$ were used, considering a maximum difference between 14-18 cm $\rm H_2O$ due to lack of previous results on minimum or maximum established differences. This calculation indicated a sample of 10 to 17 subjects.

The normality of variables was tested by Kolmogorov-Smirnov test. The paired t test was conducted to assess the differences between SNIP, SNIP, measures, which are the values obtained in the national and foreign equipment, respectively. To assess the correlation between means performed on both equipments, SNIP, SNIP, simple correlation analysis was used by using the Pearson correlation coefficient (r)18. The Bland-Altman plots analysis, the mean of differences (BIAS) was assessed, which establishes how close clinically important discrepancies between the two used equipments were and which limits of agreement determines the differences between the two equipments located in the 95% confidence interval^{19,20}. For statistical analysis, SPSS 15.0 (SPSS, Chicago, IL, USA) and GraphPad Prism® 4 (GraphPad Software Inc.) softwares were used. The level of significance was set at p<0.05 with a two-tailed approach.

Results::..

A total of 26 subjects accepted the invitation to participate in this study, but only 18 healthy subjects, aged between 18 and 35 years, of both gender, were included. Eight subjects were excluded, two due to nasal septal deviation, one was in a period of asthma attack, four were athletes and one because he already have knowledge of assessment techniques used in the study. The sample consisted of nine male subjects and nine female subjects. The distribution of variables was considered normal. The sample consisted of young subjects, with spirometric values close to those considered healthy, $FEV_1/FVC\% \ge 90\%$, $FVC \ge 80\%$ predicted, as shown in Table 1.

Table 2 shows the mean reference value of the sniff test of the sample, mean±standard deviation of the values found in each manovacuometer when performing nasal inspiratory pressure and the percentage of means in relation to reference values for the healthy population. In the same table, values of paired t test (p>0.05, 95% CI= -23.4 to 9.4) are described, in which no significant differences were found between the values obtained from different equipments.

Table 1. Anthropometric and spirometric characteristics of the sample.

	Male	Female	Total	
	iviale	remale	Total	
Subjects	09	09	18	
Age (years)	20.9±1.4	22.0±3.8	21.4±2.8	
BMI (Kg/m²)	24.8±1.9	22.0±2.3	23.4±2.5	
FVC (% pred.)	93.9±8.5	93.5±11.7	93.8±9.9	
FEV ₁ (% pred.)	91.9±10.0	98.1±13.6	95±12	
FEV ₁ / FVC (% pred.)	86.1±1.2	90.4±0.7	88.3±2.4	

BMI=Body Mass Index; FVC= Forced Vital Capacity; FEV_1 =Forced Expiratory Volume in the first second; FEV_1 / FVC = FEV_2 / FVC ratio.

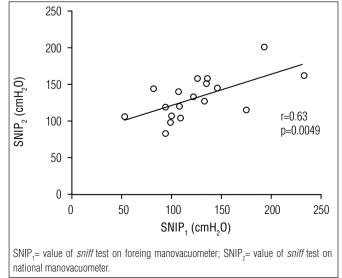


Figure 1. Pearson's Correlation between the sniff values in both equipment.

The results of the Pearson correlation analysis (r) showed a significant correlation between measures with an r=0.63 (p=0.0049, 95% CI=0.23 to 0.85 and R²=0.39), as shown in Figure 1. Statistical graphical analysis performed by the Bland-Altman plots between SNIP $_{\rm 1}$ and SNIP $_{\rm 2}$ measures, represented in Figure 2, shows a BIAS = 7 cmH $_{\rm 2}$ O, a standard deviation of 32.9 cmH $_{\rm 2}$ O for SD and a confidence interval from -57.5 cmH $_{\rm 2}$ O to 71.5 cmH $_{\rm 2}$ O were found.

Discussion :::.

This study was conducted to assess the feasibility of sniff test assessment using a national electronic manovacuometer. No significant differences were found between the mean results of sniff test in both equipments, weak limits of agreement between measurements were found, while the differences mean found was lower than the measure coefficient of variation. The sniff test assessment performed with the national manovacuometer proved to be feasible and safe.

Through analysis of the results, some implications can be suggested. First, the possibility of easy access to the nasal inspiratory pressure assessment with a low cost equipment

Table 2. Comparison between the foreign and national manovacuometer.

	Mean RV Sniff	Mean SMIP		Mean SNIP ₂		Paired t test*
	(cmH_20)	(cmH ₂ 0)	(%)	(cm H ₂ 0)	(%)	p value
Male	118±0.6	146.3±46.4	124	141.5±29.2	120	0.70
Female	90±0.8	103.1±25.0	114	121.9±26.0	135	0.58
All	104±20.3	124.7±42.4	119	131.7±28.7	126	0.38

RV= reference values; $SNIP_1 = sniff$ test developed on the foreign manovacuometer; $SNIP_2 = sniff$ test developed on the national manovacuometer; * Paired t test between absolute values of $SNIP_1$ and $SNIP_2$.

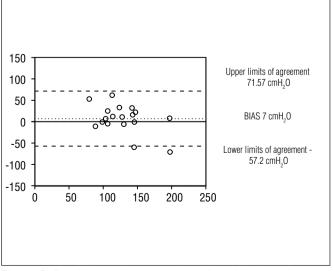


Figure 2. Bland-Altman plot among the sniff test in both equipments.

compared to the foreign one. Secondly, the origin of the equipment is national and it is standardized by the National Institute of Metrology, Standardization and Industrial Quality, and its marketing, acquisition and maintenance are carried out more easily in Brazil. Currently, the foreign equipment used for sniff test assessment is the only world-wide commercially available for this type of assessment, fact that hampers it access due to the costs of the equipment, importation and maintenance.

The nasal inspiratory pressure measured by the sniff test stared to be used in the 90's9, when the reference values for the British population were established. But only in the last decade, the parameters and clinical information about the importance of the test in the follow-up and in the assessment of inspiratory muscle strength^{17,21-23} were demonstrated in some publications, especially in patients with restrictive diseases of the chest cavity of musculoskeletal origin and with neuromuscular diseases.

In a recent study, Maillard et al.22 demonstrated that the sniff test shows a similar reproducibility to the values reported for MIP in healthy subjects with a coefficient of variation of 6%. Thus, the study by Luo et al.23, also with healthy subjects, showed that the sniff test demonstrates similar levels of reproducibility to the values reported for the transdiaphragmatic pressure with a coefficient of variation of 11%. Both results reinforced the hypothesis that the sniff test is considered a reliable test that largely reflects the strength of the diaphragm muscle. Physiologically, during its performance, there is a strong neuromuscular activation of diaphragm and scalene muscles 12,13. This contraction, due to the characteristics of the test, occurs rapidly and it is considered a ballistic muscle contraction, rather than sustained isometric contraction of the inspiratory muscles, as occurs in the MIP maneuver assessment. The maneuver performance is simpler than MIP, since there

is less need for coordination between the end of expiration and fitting with the mouthpiece⁹. Despite some similarities between maneuvers to obtain MIP and the sniff test, the limits of agreement between them are large, indicating that these measures are not interchangeable and therefore are considered complementary for inspiratory muscle strength assessment^{24,25}.

Findings in this study showed no significant difference between the means assessed by both equipments. The results of the correlation between means in both equipments should be interpreted with caution because, in the Bland-Altman plots analysis, the range found within the limits of agreement was extensive, although the BIAS, or mean of differences between the assessed measures, showed to be close to zero, below the values of variability found in other studies (6-11%)²¹⁻²³ and below the coefficient of reproducibility of 23-32 cmH₂O, observed by Maillard et al.²².

The study has some potential limitations such as the absence of a retest for the sniff test measures, which can be minimized by the number of maneuvers performed, ten trials, in each assessment to obtain the measure. Another potential limitation is the wide range of limits of agreement found in the Bland-Altman plots analysis. Due to the characteristics of the sniff test, which is dependent on effort, possibly the low performance of four subjects may have contributed to raising the standard deviation of differences, as well as the limits of agreement.

Conclusion :::.

The sniff test assessment conducted by the national electronic manovacuometer was found to be a feasible and safe measurement. These results can help to spread the technique of nasal inspiratory pressure assessment.

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