Effects of a nasal ventilator restriction device on lung ventilation and gas exchange during exercise in healthy subjects

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Abstract

Introduction and objectives: A device called FeelBreathe® (FB) has been designed, developed and patented for inspiratory muscle training (IMT). In order to examine the effects of FB on lung ventilation and gas exchange during exercise, 27 trained male healthy volunteers (age: 32.5 ± 7.2 years) were measured.

Methods: Maximum static inspiratory pressure (PImax) and spirometry to determine lung capacity were measured at baseline. We continued with an incremental cycloergometer to determine the VO2 peak. Three days later, each subject performed randomly three identical submaximal cycloergometer tests at 50% between ventilatory thresholds under three different breathing conditions: a) oronasal breathing (ONB), b) nasal breathing (NB) and c) nasal breathing through the FB.

Results: FB trial showed lower minute ventilation (VE) and breathing frequency (BF) than NB, which had lower BF, but similar VE than ONB (p < 0.001). Despite this, FB had similar values of VO2, respiratory exchange ratio (RER), heart rate (HR) and peripheral capillary oxygen saturation (SpO2) compared to NB and ONB. The latter can occur partly due to increased tidal volume (VT) and expiration time (Tex) in FB until same level than NB, which were in both trials 15% and 14% respectively higher than ONB (p < 0.001). The percentage of inspiration time (Ti/Tot) was 7% greater in FB compared to NB and ONB (p < 0.001). Increased end-tidal pressure of CO2 (PET CO2) and reduced end-tidal pressure of O2 (PET O2) and fraction of O2 expiration (FEO2) were found only in FB.

Conclusions: FeelBreathe is a new nasal restriction device that stimulates the inspiratory muscles to produce a breathing pattern more efficient during exercise in well-trained humans.

Palabras clave: Dispositivo de restricción nasal. Entrenamiento de la musculatura inspiratoria. Patrón de respiración eficiente.
INTRODUCTION

Several studies have shown that specific training of respiratory muscles performed at rest causes adaptations: improved strength on respiratory muscle (1), increased fatigue resistance (2) and enhanced physical performance (3-6). Furthermore, the benefits of a specific inspiratory muscular training (IMT) are clear improvements in the quality of life of patients with cardio-pulmonary disease (7-9).

There are three methods of IMT: nontargeted inspiratory resistance trainers, targeted inspiratory resistive or threshold trainers, and nor-mocapnic hyperventilation trainers (10). Among the most frequently used devices we can find the PFlex Resistive Trainer and the PowerBreathe (11) and countless studies have shown its effectiveness (4,12-16). However, the main disadvantages of these devices are that inhalatory activity is performed by the mouth and must be used in static positions. Moreover, the inspiratory resistance devices apply a nonlinear resistance since if a person breathes slowly, only a small effort is required to produce flow, while if the person breathes faster, a larger effort is required to produce larger pressure to achieve the higher flow rate (17). Hence, new IMT devices which allow their utilization with a natural breathing by the nose and that allows its use during activities of daily tasks should be created.

Recently, a nasal ventilatory flow restriction and filtering device called FeelBreathe (18) has been designed, developed and patented to increase nasal airflow resistance (19). This device is comprised of a strip of hypoallergenic material that is placed and adhered to the nares under the nasal passages. This impairs the free entry of air through the nose by producing resistance to flow without exerting pressure on the nares or modifying their shape. It has been reported that an increased airflow resistance while breathing nasally during exercise increases the breathing effort (20), which may potentially improve the exercise tolerance (21) and energy efficiency (22).

As far as we are aware, the literature lacks reports on the use of nasal airflow restriction as a method of inspiratory muscles training during exercise. In addition, how airflow restriction during nasal inspiration could affect to the respiratory mechanics and gas exchange during exercise is still unknown.

Before investigating possible respiratory muscles adaptations in response to restricted nasal airflow, it is essential determine whether increasing resistance to airflow during nasal breathing (NB) will elicit a different physiological breathing pattern to that induced by oronasal breathing (ONB). Thus, the aim of the present study was to examine the effects of the FB in healthy subjects on lung ventilation and gas exchange during exercise compared to NB and ONB.

Our hypothesis is that the ventilatory flow restriction produced with FB device causes fatigue of the respiratory muscles after exercise and increases the efficiency of breathing during exercise.

MATERIALS AND METHODS

SUBJECTS

Twenty seven healthy amateur male cyclists (mean ± SD, age 32.5 ± 7.2 yr, height 174 ± 6.4 cm, body mass 70.2 ± 8.7 kg, and VO_{2peak} 57.0 ± 7.6 ml/kg/min) took part in this study. They habitually worked out 3-4 days per week.

Healthy active subjects have been selected to determine the nasal ventilatory flow restriction using the FeelBreathe, since they are more able to carry out the exercise without potential risk of a possible respiratory problem compared to sedentary or sick populations for this testing. It should be noted that this is a new device that has not been used so far.

The following inclusion criteria were applied: non-smokers, without known medical conditions, and without current symptoms of nasal disease, snoring, asthma or allergic rhinitis. Written informed consent was obtained from all subjects before starting the study and the protocol was approved by the University Ethics Committee and met the requirements of the Declaration of Helsinki. Trial registration at clinicaltrials.gov; Identifier: NCT01608529.

PROCEDURES

Subjects reported to the laboratory on two different days, with an interval of three days. All testing sessions were performed under similar environmental conditions (20-24 °C, 45-55% relative humidity). On the first day, different preliminary testing was performed. Subjects completed a health questionnaire and performed a resting electrocardiogram (QRS Universal ECG, QRS, Plymouth, MN, USA) and a pulmonary function tests (spirometer CPX, Cardinal Health, Hoechberg, Germany) according to criteria published by the American Thoracic Society (2002). In addition, maximal inspiratory pressure (Plmax) was measured during a maximal, static inspiratory effort (Micro RPM, Micro Medical Ltd., Chatham, Kent, UK). Plmax was recorded as the highest value averaged over 1 s from three maneuvers that varied by less than 10% (23). Plmax was measured based on three maximal reproducible respiratory efforts and the maximum achieved value was recorded.

Finally, the last test performed the first day was an incremental cycloergometer test (ERGO-Line GmbH + CoKG, mod. Jaeger ER900, Germany) described elsewhere (24). The test was preceded by a 4 min warm up period at a workload of 30 W. The initial workload was 30 W and was increased by 30 W every 1 min until volitional exhaustion (25). Heart rate response (JECG 12 Channel, Erich Jaeger, Friedberg, Germany) and respiratory gas exchange (Medical Graphics System CPX Plus Medical Graphics Corporation, Minnesota, USA) were measured every 20 s, 5 s and breath-by-breath, respectively, throughout the test. VO_{2peak} recorded was the mean of the values reached during the last 20 s before exhaustion. Gas exchange and respiratory compensation (RCT) thresholds were identified separately by 2 researchers according to the following criteria: increase in both the ventilatory equivalent for oxygen (VE·VO_{2}·^{-1}) and end-tidal partial pressure of oxygen (P_{ET O_{2}}) with no concomitant increase in the ventilatory equivalents for carbon dioxide (VE·VCO_{2}·^{-1}) for tidal volume (VT), and an increase in both VE·VO_{2}·^{-1} and VE·VCO_{2}·^{-1} and a decrease in the end-tidal partial pressure of carbon dioxide (P_{ECO_{2}}) for RCT.

On the second day, subjects underwent a submaximal cycloergometer test. This test consisted of three sets of 10 min under dif-
different breathing conditions: ONB, NB and restricted nasal breathing (FB). The order of the sets was randomized and 30 min rest periods between the sets were performed. The workload and cadence for the test were set at 50% of VO2peak (26.27) and 70-75 rpm, respectively, since they have not a high metabolic demand. In addition, subjects held the same posture (i.e., upright sitting position) to eliminate the metabolic cost impact of modifying the position.

The following variables were measured every 10 s through the test: minute ventilation (VE), breathing frequency (BF), fraction of expired oxygen (FEO2), fraction of expired carbon dioxide (FECO2), tidal volume (VT), oxygen consumption (VO2), carbon dioxide production (VCO2), respiratory exchange ratio (RER), ventilatory equivalents for oxygen (VE-VO2), ventilatory equivalents for carbon dioxide (VE-VCO2), end-tidal oxygen (PETO2), end-tidal carbon dioxide (PETCO2), inspiration time (Ti), expiration time (Tex), inspiratory time fraction (Ti/Tot), inspiratory (VTi) and expiratory (VTex) tidal volumes, heart rate (HR) and blood oxygen saturation percentage (SpO2) (Ear oximeter, Hewlett-Packard 47201A, Corvallis, OR). Immediately after each 10 min of exercise test, PImax and Borg’s perceived exertion were examined using a 1-20 scale (28).

The nasal ventilatory restriction device used in this study was the FeelBreathe (3M, Medical Specialties, Madrid, Spain). This device is available in three different sizes (i.e., small, medium and large), in the present study the medium size was used (FB-7mm). A Hans Rudolph nasal/oral, two-way and non-rebreathing face mask (model 8900, Kansas City, MO, USA) covered the subject’s mouth and nose. Care was taken to ensure the mask did not impinge on the nares during testing by removing the inner seal of the mask. For ONB, subjects were asked to breath normally (freely), while under NB and FB the subject’s mouth was closed using a mouthpiece.

STATISTICS

Each variable of gas exchange was averaged from minute 1 to minute 10 of every exercise test for statistic. To compare the evolution of ventilatory parameter during the exercise trial, the mean of the last 20 seconds of each minute was also recorded for the analysis.

The assumption of normality was verified using the Shapiro-Wilk test. The results are expressed as mean ± standard deviation (SD). An analysis of variance (ANOVA) with repeated measures was used to compare the physiological variables recorded at ONB, NB and FB. When a significant F value was found, Bonferroni’s test was applied to establish significant differences between means. Results with a p < 0.05 were considered significant. SPSS+ V.21.0 statistical software (Chicago, IL, USA) was used.

RESULTS

The descriptive variables recorded in the preliminary tests are summarized in table I. The average of gas exchange of all exercise, PImax and Borg’s scale recorded during ONB, NB and FB after submaximal cycloergometer tests are presented in table II. Figures show the tendency of each exercise trial with the significant different point marked per minute of exercise.

FB TRIAL VS. NB TRIAL

Comparing the FB trial with the NB trial, FECO2, PETO2, VE/VO2, (p < 0.01), VE (p < 0.01) and VE/VCO2 (p < 0.05) average values from minute 1 to 10 were significantly lower in FB trial (Fig. 1 A, B, C and D), while FEO2, PETCO2, Ti/Tot, Ti and Borg values were significantly higher (p < 0.001) in the FB trial than the NB trial (Fig. 2 A, B, C and D).

FB TRIAL VS. ONB TRIAL

Comparing the FB trial with the ONB trial, FECO2, PETO2, Ti/Tot, Ti, Tex, VTi, VTex, Borg (p < 0.001) and VT (p < 0.05) average values from minute 1 to 10 were significantly higher in the FB trial (Fig. 2 A, B, C and D), while FEO2, PETCO2, VE, VE/VO2, (p < 0.001) and VE/VCO2 (p < 0.05) were significantly lower (Fig. 1 A, B, C and D).

NB TRIAL VS. ONB TRIAL

Comparing the NB trial with the ONB trial, Ti, Tex, Ti/Tot, VTi, VTex (p < 0.001) and VT, FEO2, (p < 0.05) average values from minute 1 to 10 were significantly higher in the NB trial (Fig. 2 A and B), while BF, VE/VCO2, VE/VO2 values were significantly lower (p < 0.001) (Fig. 1 B, C and D).

DISCUSSION

The main finding of this study was that FeelBreathe device is a new, easy and effective tool for inspiratory muscle train-
ing, which showed an effective breathing pattern in a group of healthy physically well-trained subjects compared to the patterns elicited by NB or ONB during moderate exercise intensity. The main physiological effect of FB during exercise was a reduction of minute ventilation and breathing frequency without changes in VO₂ uptake. This is the first study that comprehensively assess the influence of restricted nasal airflow with FB on gas exchange kinetics during exercise.

### Table II. Values obtained during the submaximal cycloergometer test according to the breathing mode

<table>
<thead>
<tr>
<th>Variables</th>
<th>ONB</th>
<th>NB</th>
<th>FB</th>
</tr>
</thead>
<tbody>
<tr>
<td>BF (breaths/min)</td>
<td>20.4</td>
<td>17.1</td>
<td>15.3</td>
</tr>
<tr>
<td>Borg</td>
<td>10.5</td>
<td>10.3</td>
<td>12.1</td>
</tr>
<tr>
<td>FEO₂ (%)</td>
<td>15.4</td>
<td>15.2</td>
<td>14.8</td>
</tr>
<tr>
<td>FECO₂ (%)</td>
<td>4.5</td>
<td>4.8</td>
<td>5.1</td>
</tr>
<tr>
<td>HR (beats·min⁻¹)</td>
<td>125</td>
<td>124</td>
<td>128</td>
</tr>
<tr>
<td>PMmax post (cmH₂O)</td>
<td>140.7</td>
<td>139.6</td>
<td>145.4</td>
</tr>
<tr>
<td>Pₜ,CO₂ (mmHg)</td>
<td>43.4</td>
<td>44.0</td>
<td>46.0</td>
</tr>
<tr>
<td>Pₜ,O₂ (mmHg)</td>
<td>101.6</td>
<td>100.3</td>
<td>97.8</td>
</tr>
<tr>
<td>RER</td>
<td>0.9</td>
<td>0.9</td>
<td>0.9</td>
</tr>
<tr>
<td>SpO₂ (%)</td>
<td>97.2</td>
<td>98.2</td>
<td>97.1</td>
</tr>
<tr>
<td>Tex (s)</td>
<td>1.7</td>
<td>1.9</td>
<td>1.9</td>
</tr>
<tr>
<td>Ti/Tot (%)</td>
<td>46.2</td>
<td>47.6</td>
<td>54.5</td>
</tr>
<tr>
<td>Ti (s)</td>
<td>1.4</td>
<td>1.8</td>
<td>2.3</td>
</tr>
<tr>
<td>VCO₂ (l/min)</td>
<td>1.7</td>
<td>1.7</td>
<td>1.7</td>
</tr>
<tr>
<td>VE (l/min)</td>
<td>42.9</td>
<td>41.7</td>
<td>38.9</td>
</tr>
<tr>
<td>VE/VCO₂ (l/min)</td>
<td>23.0</td>
<td>22.0</td>
<td>20.9</td>
</tr>
<tr>
<td>VE/VO₂ (l/min)</td>
<td>21.2</td>
<td>20.1</td>
<td>18.8</td>
</tr>
<tr>
<td>VO₂ (l/min)</td>
<td>2.0</td>
<td>2.0</td>
<td>2.0</td>
</tr>
<tr>
<td>VT (l)</td>
<td>2.3</td>
<td>2.8</td>
<td>2.8</td>
</tr>
<tr>
<td>VTex (l)</td>
<td>2.2</td>
<td>2.6</td>
<td>2.7</td>
</tr>
<tr>
<td>VTI (l)</td>
<td>2.2</td>
<td>2.6</td>
<td>2.6</td>
</tr>
</tbody>
</table>

Data are presented as the mean from minute 1 to minute 10 (SD). BF: Breathing frequency; Borg: Perceived exertion post-exercise; FEO₂: Fraction of expired oxygen; FECO₂: Fraction of expired carbon dioxide; HR: Heart rate; PMmax post: Maximum static inspiratory pressure post-exercise; Pₜ,CO₂: End-tidal carbon dioxide; Pₜ,O₂: End-tidal oxygen; RER: Respiratory exchange ratio; SpO₂: Blood oxygen saturation percentage; Tex:Expiration time; Ti/Tot: Percentage time inspiration/total time breathing; Ti: Inspiration time; VCO₂: Carbon dioxide production; VE: Minute ventilation; VE/VCO₂: Ventilatory equivalents for carbon dioxide; VE/VO₂: Ventilatory equivalents for oxygen; VO₂: Oxygen uptake; VT: Tidal volume; VTex: Expiratory tidal volume; VTI: Inspiratory tidal volume; NB: Nasal breathing; FB: FeelBreathe nasal breathing; ONB: Oral nasal breathing; *p < 0.001, FB vs. ONB; *p < 0.01, FB vs. ONB; **p < 0.05, FB vs. ONB; ***p < 0.001, FB vs. ONB; ^p < 0.001, FB vs. NB; ^p < 0.01, FB vs. NB; ^p < 0.05, FB vs. NB; *p < 0.01, FB vs. NB; **p < 0.05, FB vs. NB; ***p < 0.001, NB vs. ONB; *p < 0.001, NB vs. ONB; **p < 0.05, NB vs. ONB.
It has been shown that mode of nasal breathing alters the dynamics of air flow in the upper respiratory tract and influences gas absorption compared to oronasal breathing (29,30). Using only NB during exercise is an atypical response breathing that increases the sense of respiratory effort (31), with a reduction of 35.1% in maximum ventilation and 11.6% in peak oxygen uptake (VO2peak) compared with free breathing conditions during an exercise test (20). Other authors (32) have observed that NB and the consequently increased airway resistance compared to ONB does not significantly alter VE at a given submaximal, moderate work rate. This was also observed in our study, where minute VE was similar between NB and ONB exercise (33). However, this fact could be accentuated using the FB device. In agreement, our subjects recorded higher rating of perceived exertion in FB, but not in NB, compared to ONB. Despite the above, VO2 uptake and RER in our study were similar among the three different airway resistances during moderate exercise, which could be attributed to an increased VTi and VTex both in NB as FB trials compared to ONB. The similar VT values found between NB and FB could be explained by the higher % of time for inspiration in FB trial compared to NB, and both compared to ONB, which would compensate breathing restriction.

Several authors have observed that VT is consistently greater when subjects are obliged to breathe exclusively by the oral route rather than by the normal oronasal route (34,35). However, other authors have been unable to detect any difference in breathing patterns between groups of normal subjects, and subjects with rhinitis and asthma, both at rest or during moderate exercise (36). In this latter study, subjects could freely choose the type of breathing (i.e., nasal, oronasal or oral) at all times during exercise. The respiratory pattern trends observed among subjects with rhinitis at a workload of 150 W (36) were similar to the pattern observed in the present study for FB compared to NB or ONB. Moreover, the altered breathing pattern was also probably the result of activation of neural load-compensating mechanisms at high motor centers targeted at minimizing the additional respiratory muscle work elicited by respiratory resistive loading (37).

The oxygen cost to the metabolism was the same for all trials in this study, as reflected the RER value. To get the same O2 uptake with FB, despite that minute ventilation and breathing frequency were reduced, the inspiratory muscle activation had to increase, which means higher lung volume and ventilation efficiency. In fact, two parameters related with breathing efficiency and O2 dynamics (VE/VO2 and VE/VCO2) were lower in FB trial, as it occurs in runners compared to non-runners (38). In line with this, FB trial showed lower values of fraction of expired O2 (FEPO2), while FECO2 was increased, which means a concomitant rise of oxygen utilization by the cells. Hence, FB requires deeper, slower and more O2 extraction breaths per breath, thereby causing more effective breathing pattern. Moreover, it has been recently shown that there is a large functional reserve in the muscles at the end of an incremental exercise, regardless of the inspiratory O2 pressure, since it seems that VO2 uptake is primarily dependent on convective O2 delivery and less limited by diffusion constraints (39,40).

A novel and important finding in this study was that PETCO2 was increased in the FB trial compared to NB or ONB, which suggests...
relative alveolar hypoventilation. High \( P_{\text{ET}} \text{CO}_2 \) during exercise has been characterized by high tidal volume and low respiratory rate (41), as with FB device. This respiratory pattern may belong to subjects with potential high performance, since \( P_{\text{ET}} \text{CO}_2 \) pressure has been used to estimate \( \text{PaCO}_2 \) and abnormal increases in arterial \( \text{CO}_2 \) pressure could increase haemoglobin desaturation (41). Higher \( \text{PaCO}_2 \) was associated with greater tissue and blood acidosis, which through a rightward shift on the \( \text{HbO}_2 \) saturation curve allows greater \( \text{O}_2 \) delivery to muscles (41). Another factor that supports the above is that \( P_{\text{ET}} \text{CO}_2 \) decreased with use of FB device. However, \( \text{SpO}_2 \) was similar between conditions.

External thoracic restriction has been used in healthy participants to simulate restrictive ventilator disorders (RVD), which leads to a rapid, shallow pattern of breathing sometimes associated with alveolar hyperventilation (42-45), high inspired minute ventilation and low \( P_{\text{ET}} \text{CO}_2 \), suggesting a higher level of alveolar ventilation with restriction (45). The activation of inspiratory muscles with FB could reduce these symptoms, since FB seems to improve the breathing pattern with a reduction of minute ventilation and an increment of \( P_{\text{ET}} \text{CO}_2 \) favoring a more efficient breathing.

IMT has been proved to be effective for the improvement of the quality of life in subjects with chronic heart disease (46-48), respiratory disease (13,49) or even healthy trained subjects (1,12,50). Inspiratory muscle training enhances pulmonary \( \text{O}_2 \) uptake kinetics and high-intensity exercise tolerance in humans, since it seems to increase leg blood flow to the exercising limbs (21). Indeed, several studies have reported that, after a specific training of inspiratory muscles, blood lactate concentration is reduced to a certain exercise intensity, which has been partly attributed to an improved ability of inspiratory muscles to metabolize lactate (51,52). IMT, therefore, appears to have considerable potential for exercise performance in athletes. However, the classical devices used for IMT are static and uncomfortable, since training inhalatory exercise is performed by the mouth. FB stands as a revolutionary system which allows subjects to perform daily tasks while they are training your inspiratory muscles. FB showed higher but not significant maximum static inspiratory pressure post-exercise compared to NB and ONB. These findings suggest that IMT activates the upper airway muscles and may enhance its function (53).

Our results were obtained with amateur cyclists; hence the differences in ventilatory and cardiovascular parameters may probably be even higher in other populations with lower physical capacity (sedentary people, patients with COPD, allergic rhinitis, asthma, etc.). We will focus our attention on identifying those future research directions to analyze the effects of FB on patients with either chronic obstructive pulmonary disease (COPD) or restrictive ventilatory disorders.

Despite the important findings obtained, there are some limitations in this study. The effect of FB in a maximal exercise, which could determine a totally different breathing pattern, remains unknown. Moreover, it would be interesting to measure the inspiratory muscle activation with EMG during exercise to compare the pattern with NB and ONB. In future research we will compare this new device for IMT with classic devices during a follow-up period in healthy subjects and in patients with either chronic obstructive pulmonary disease or restrictive ventilatory disorders.

**CONCLUSION**

Restriction of nasal breathing through a device such as FeelBreathe could be used for the inspiratory muscular training during moderate exercise intensity, since it clearly modifies the breathing pattern and respiratory variables. Its simple design determines its practical use for a wide range of sports modalities as well as for patients with respiratory disorders who could benefit from improved inspiratory muscle strength and efficiency oxygen delivery. Our findings provide direction for future studies designed to examine the benefits of using this device for respiratory muscle training. However, how this device can be used most efficiently and which are the most appropriate protocols and programs need to be determined in future studies.

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