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Original Article

Comparison of Intermittent Positive Pressure Breathing and Temporary Positive Expiratory Pressure in Patients With Severe Chronic Obstructive Pulmonary Disease[☆]



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ABSTRACT

Background: Results supporting the use and the effectiveness of positive expiratory, pressure devices in chronic obstructive pulmonary disease (COPD) patients are still controversial. We have tested the hypothesis that adding TPEP or IPPB to standard pharmacological therapy may provide additional clinical benefit over, pharmacological therapy only in patients with severe COPD.

Methods: Forty-five patients were randomised in three groups: a group was treated with IPPB, a group was treated with TPEP and a group with pharmacological therapy alone (control group).

Primary outcome measures included the measurement of scale, or questionnaire concerning dyspnoea (MRC scale); dyspnoea, cough, and sputum (BCSS) and quality of life (COPD assessment test) (CAT). Secondary outcome measures were respiratory function testing, arterial blood gas analysis and haematological examinations.

Results: Patients in both the IPPB group and the TPEP group showed a significant improvement in two of three tests (MRC, CAT) compared to the control group. However, in the group comparison analysis for the same variables between the IPPB group and the TPEP group, we observed a significant improvement in the IPPB group (P<.05 for MRC and P<.01 for CAT).

The difference of action of the two techniques is evident in the results of pulmonary function testing: IPPB increases FVC, FEV1, and MIP; this reflects its capacity to increase lung volume. Also TPEP increases FVC and FEV1 (less than IPPB), and MEP, while decreasing total lung capacity and residual volume. Conclusions: The two techniques (IPPB and TPEP) improve significantly dyspnoea, quality of life tools

and lung function in patients with severe COPD. IPPB demonstrated a greater effectiveness in improving dyspnoea and quality of life tools (MRC, CAT) than TPEP.

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Comparación de la respiración con presión positiva intermitente y la presión espiratoria positiva temporal en pacientes con enfermedad pulmonar obstructiva crónica grave

RESUMEN

Presión espiratoria positiva temporal Respiración con presión positiva Enfermedad pulmonar obstructiva crónica

Escalas de valoración de disnea y calidad de vida

Antecedentes: Los resultados que respaldan el uso y la efectividad de los dispositivos de presión espiratoria positiva en pacientes con enfermedad pulmonar obstructiva (EPOC) continúan siendo objeto de controversia. Hemos evaluado la hipótesis de que la adición de la TPEP o la IPPB a un tratamiento farmacológico estándar pueda aportar un beneficio clínico adicional respecto al tratamiento farmacológico solo en los pacientes con EPOC grave.

Métodos: Un total de 45 pacientes fueron asignados aleatoriamente a los 3 grupos siguientes: un grupo fue tratado con IPPB, otro fue tratado con TPEP y un tercer grupo recibió únicamente tratamiento farmacológico (grupo de control).

Las variables de valoración principales fueron la puntuación de la escala o cuestionario relativo a la disnea (escala del MRC); la de disnea, tos y esputo (BCSS); y la de calidad de vida (test de evaluación de la

Palabras clave:

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EPOC) (CAT). Las variables de valoración secundarias fueron las pruebas de la función respiratoria, la gasometría arterial y los análisis hematológicos.

Resultados: Tanto los pacientes del grupo de IPPB como los del grupo de TPEP mostraron una mejoría significativa en 2 de las 3 evaluaciones (MRC y CAT) en comparación con el grupo de control. Sin embargo, en el análisis de comparación de los grupos para las mismas variables en el grupo de IPPB frente al grupo de TPEP observamos una mejoría significativa en el grupo de IPPB ($p \le 0.05$ para la escala del MRC y $p \le 0.01$ para el CAT).

La diferencia de efecto de las 2 técnicas se pone de manifiesto en los resultados de las pruebas de la función pulmonar: la IPPB aumenta los valores de FVC, FEV1 y MIP; esto refleja su capacidad de aumentar el volumen pulmonar. Por su parte, la TPEP aumenta la FVC y el FEV1 (en menor medida que la IPPB), pero eleva la MEP, mientras que reduce la capacidad pulmonar total y el volumen residual.

Conclusiones: Las 2 técnicas (IPPB y TPEP) mejoran significativamente la disnea, los instrumentos de valoración de la calidad de vida y la función pulmonar en los pacientes con una EPOC grave. La IPPB mostró una mayor efectividad en la mejora de los instrumentos de evaluación de la disnea y la calidad de vida (MRC y CAT) en comparación con la TPEP.

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Introduction

Chest physiotherapy by manually assisted breathing techniques is considered the gold standard for patients with chronic obstructive pulmonary diseases with normal cough reflex. In addition, positive expiratory pressure delivered by hand-held devices is considered a valid technique in the management of airway secretion and for enhancing expectoration.² Several devices producing a positive expiratory pressure have been used, for example, positive expiratory pressure (PEP) mask³ or PEP bottle⁴ and vibratory positive expiratory pressure therapy system.^{5,6} However, the results supporting the use and the effectiveness of these tools are supported by little clinical evidence. Recently a new modality to deliver a low positive expiratory pressure level during spontaneous breathing called temporary positive expiratory pressure had become available. Intermittent positive pressure breathing (IPPB) is used in clinical practice primarily to improve lung volume and to reduce the work of breathing. 17 We have tested the hypothesis that adding TPEP or IPPB to standard pharmacological therapy may provide additional clinical benefit in patients with severe to very severe COPD (Group C and D combined assessment).¹⁸

Methods

We prospectively recruited 53 patients aged 40-80 years with severe to very severe chronic obstructive pulmonary disease (FEV1<50%) (Group C and D combined COPD assessment) admitted to the Day Hospital of the Respiratory Medicine Unit of Hospital of Sestri Levante between June 2012 and November 2012. All the patients were in a stable clinical condition (free from any acute exacerbation for at least two weeks at the time of inclusion, including no change in medication). Diagnosis and severity of COPD were confirmed using the GOLD Guidelines.¹⁸ Pulmonary function testing was performed with a computerised body plethysmograph (VMAX 20 PFT Sensor Medics, Yorba Linda, CA, USA), according to the international standards. 19 The following parameters were analysed: forced vital capacity (FVC), forced expiratory volume in the first second (FEV1), forced expiratory volume in one second/vital capacity (FEV1/FVC%), total lung capacity (TLC), residual volume (RV) and lung diffusing capacity for carbon monoxide (DLCO). Inspiratory muscle strength was assessed by measuring the maximal inspiratory mouth pressure (MIP) at RV. Expiratory muscle strength was also measured as maximal expiratory mouth pressure (MEP) at TLC. The value obtained from the best of at least three efforts was used. All the measurements were obtained in upright position.⁷ Patients with history of asthma, severe cardiac arrhythmias, cancer or tracheostomy, or deemed unable to perform forced expiratory manoeuvres or to use temporary positive expiratory pressure device (TPEP) or intermittent positive pressure breathing (IPPB) were excluded. Only the patients who provided informed consent were included. Patients were considered as having dropped out of the study when clinical signs of a new exacerbation occurred.

Protocol

This was a single-blind randomised trial. A randomisation schedule was generated by a statistician not involved in the study using an online random permutation generator from http://www.randomization.com. The randomisation assignment was provided to the recruiting physicians in sealed envelopes. The patients and the investigators who carried out the study data analysis were blinded to the patients' treatment assignments.

Forty-five of the 53 patients enrolled were eligible for the study (eight were excluded: seven because of inability to perform forced expiration manoeuvre and one because of coexisting history of bronchial asthma). All the patients were being treated with association of inhaled β_2 -agonist plus corticosteroid (28-salmeterol plus fluticasone, 17-formoterol plus budesonide) and tiotropium bromide. Five patients had chronic respiratory insufficiency treated with oxygen. The randomised patients were divided into three groups (15 patients for each group): one group was treated with IPPB, one group was treated with TPEP and one group with pharmacological therapy alone (control group) (Fig. 1, flow chart).

All the eligible patients after the randomisation were instructed by a physiotherapist on the use of temporary positive expiratory pressure (TPEP) or intermittent positive pressure breathing (IPPB) for acclimatisation in a two-hour training period in the lung laboratory before definitive inclusion in the study protocol. The TPEP device (UNIKO Medical Products Research, Legnano, Italy) delivered a fixed positive pressure (1 cm $\rm H_2O$ or 0.0977 kPa) only in the expiratory phase. This increase in low pressure was created through a pulsatile flow approximately 42 Hz in frequency. 7 The TPEP therapy was delivered by a use-specific mouthpiece.

The IPPB device (ALPHA 200C, Air Liquide) delivered an inspiratory pressure that was gradually increased to the highest tolerated value (up to $40\,\mathrm{cm}$ H₂O). Respiratory rate, inspiratory flow (from 20 to $60\,\mathrm{l/min}$) and end-inspiratory trigger were set to maximise patient comfort. The IPPB therapy was also delivered by a use-specific mouthpiece.

Both treatments lasted 30 min per session and were given twice daily (morning and late afternoon). The duration of each treatment was fifteen days and the treatment was administered five days per week. The study was carried out according to the principles of the Declaration of Helsinki and approved by Institutional Ethics Committee of ASL 4 Chiavarese, Chiavari, Italy; all patients provided written informed consent before beginning the study. The study was registered as Chi CTR-TRC-12002178 at www.chictr.org.

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