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Short-term effects of expiration under positive pressure in patients with acute exacerbation of chronic obstructive pulmonary disease and mild acidosis requiring non-invasive positive pressure ventilation

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Abstract *Objective:* To investigate the feasibility and the efficacy of expiration under positive pressure (PEP mask) as a chest physiotherapy in patients with exacerbation of chronic obstructive pulmonary disease (COPD) and acute hypercapnic respiratory failure (AHRF) requiring non-invasive positive pressure ventilation (NIPPV). *Design:* A prospective, randomised, controlled study. *Setting*: A respiratory intensive care unit. *Patients and interventions:* Twenty-seven patients with large amounts of bronchial secretions on clinical examination due to exacerbation of COPD and mild acidosis were randomly divided into two groups. Group A (13 patients) received PEP mask plus assisted coughing. The controls (group B, 14 patients) received assisted coughing alone. *Outcome measures*: The primary end point was to compare total sputum wet weight and to assess the feasibility of the PEP mask. Secondary outcomes were: (a) the time required for weaning patients from NIPPV, (b) treatment failure expressed as mortality within 2 months after discharge from the respiratory intensive care unit (RICU) or the need for endotracheal intubation (ETI). *Results:* The amount of sputum production at the end of physiotherapy was significantly ($p<0.01$) higher in group A (9.6±3.9 g) compared with group B (4.7±2.5 g). The total length of weaning time was significantly lower in group A (4.9±0.8 days) versus group B (7.0±0.7 days), $p<0.01$. Mortality and ETI were not significantly different in the two groups of patients (0 versus 1 and 0 versus 1, respectively). *Conclusions:* Expiration under positive pressure was effective in acutely removing secretions in patients with exacerbation of COPD and mild acidosis requiring NIPPV. In conclusion, we suggest that this chest physiotherapy technique represents a useful therapeutic option for such patients and it should often be performed in addition to NIPPV.

Keywords Chest physiotherapy · Positive expiratory pressure · Acute hypercapnic respiratory failure · Chronic obstructive pulmonary disease exacerbation · Non-invasive positive pressure ventilation · Sputum recovery

Introduction

The potential benefit of chest physiotherapy for patients with chronic obstructive pulmonary disease (COPD) has been well documented [1, 2]. These studies, however, were performed in subjects who were clinically stable. Till now, no controlled studies have assessed the role of chest physiotherapy in patients admitted to a respiratory intensive care unit (RICU) because of ventilatory insufficiency requiring non-invasive positive pressure ventila-

tion (NIPPV). Chest physiotherapy includes a variety of techniques aimed at removing bronchial secretions. Positive expiratory pressure (PEP) applied by mask (PEP mask) is well known to be effective in the short- and long-term treatment of chronic bronchitis [3, 4]. It consists of a facemask connected to a T-tube in which inspiratory and expiratory airflow are separated by a valve and a variable expiratory resistance can be applied during expiration.

Non-invasive positive pressure ventilation was developed to avoid complications associated with invasive mechanical ventilation [5, 6] and the results of the initial studies concerning NIPPV are encouraging [7, 8, 9, 10, 11]. In addition, Plant and colleagues have recently shown that early NIPPV for mildly and moderately acidotic patients with COPD leads to a reduction in the need for invasive mechanical ventilation and a reduction in in-hospital mortality [12]. However, not all patients are candidates for this mode of therapy, particularly those patients with excessive bronchial secretion [5, 13]. For this reason, in a prospective, controlled and randomised study, we compared the effects of early PEP mask plus assisted coughing versus assisted coughing alone in patients with exacerbated COPD requiring NIPPV who had large amounts of bronchial secretions on clinical examination. Our aim was to evaluate the effects of chest physiotherapy on sputum production and the feasibility of PEP mask in these patients. Moreover, we evaluated the time of ventilation and the outcomes of patients submitted to PEP therapy in addition to NIPPV, with regard to mortality and the need of ETI.

Materials and methods

Patients

Thirty consecutive hypersecretive COPD patients, admitted to the RICU between December 1998 and December 1999, were studied. The study protocol was approved by the local ethics committee. Oral informed consent was given by each patient. The American Thoracic Society (ATS) criteria were used to define COPD [14]. Every patient had been admitted to the RICU because of an episode of acute hypercapnic respiratory failure (AHRF) due to exacerbation of COPD which resulted in the patient's being affected by large amounts of bronchial secretions (clinical evaluation). In the same time period, 54 patients who did not produce significant bronchial secretions at admission were submitted to NIPPV because of AHRF. An acute exacerbation was defined on the basis of the clinical history, physical examination and chest radiograph. Throughout the study (72 h), medical treatment was standardised in all patients [15] and included nebulised salbutamol (5 mg every 4 h), nebulised ipratropium bromide (500 µg every 6 h), i.v. methylprednisolone (40 mg every day) and an antibiotic.

Study design

The study was randomised and controlled. The comprehensive PEP physiotherapy consisted of three daily sessions of 30–40 min each for the first 3 days from the beginning of NIPPV. The treatment of patients did not change during the 3 days of the study. After 1 h from the beginning of NIPPV, patients were randomly allocated to PEP mask plus assisted coughing (group A) or assisted coughing alone (group B). The treatment was performed by the specialised and trained respiratory therapist at about the same time of the day. Randomisation was performed using a computer programme (Statsoft,2325 East 13th Street, Tulsa, OK 74104).

Physiotherapy

The PEP mask consists of a facemask connected to a T-tube where inspiratory and expiratory air-flows are separated by a valve. Variable expiratory resistances can be applied into the expiratory tube as connections of different diameters, causing positive airway pressure only during expiration. In our study, the diameter of the resistor had been determined to give a PEP of 10–15 cmH_2O. Two minutes of tidal volume breathing with PEP mask were followed by assisted coughing in order to expel the mucus blocking the airways and 2 min of undisturbed breathing. This cycle was repeated 5–7 times (30–40 min). The level of pressure was measured by a manometer. Treatment was performed by patients under the supervision of a therapist while they were receiving oxygen therapy through the mask inserted into the valve.

Assisted coughing consists of compressing the trachea just above the sternal notch or huffing (after a maximal inspiration, the patient exhales several times quickly). The total time spent by therapists for patients' physiotherapy was the same in both groups (30–40 min for each session). The arterial oxygen saturation (SaO_2) was monitored continuously during treatment with a pulse oximeter (MiniOx V, MSA, Md., USA). Sputum was collected at the end of physiotherapy, and for 1 h following. Total sputum wet (saliva included) was recorded to the nearest gram with a precision balance to get the exact weight. Forced expiratory volume in one second (FEV_1) and the ratio FEV_1/vital capacity (VC) were measured before discharge from the RICU by Pony spirometer (Cosmed, Sylco, Rome, Italy).

Non-invasive mechanical ventilation

Patients were enrolled in the study on the basis of their initial arterial blood gases (ABG): pH between 7.25 and 7.35 with arterial carbon dioxide tension ($PaCO_2$) above 6.5 kPa due to the exacerbation of COPD. All patients received BiPAP (Respironics, Murraysville, USA) with a face mask ventilation plus oxygen in order to maintain SaO_2 greater than 85%. Criteria for excluding patients from NIPPV included the following: (1) pH below 7.25, (2) pneumonia, (3) systolic blood pressure (SBP) below 90 mmHg or the use of vasopressors, (4) history of unstable angina or recent (within the last 3 months) myocardial infarction, (5) inability to tolerate the mask (discomfort or pain) or (6) a facial deformity. The level of inspiratory positive airway pressure (IPAP) was adjusted to achieve the patient's comfort and set between 13 and 18 cmH_2O and expiratory positive airway pressure (EPAP) between 3 and 5 cmH_2O in order to keep SaO_2 above 90%.

Ventilatory support was delivered for 7 h each day (2 h in the morning, 2 h in the afternoon and 3 h during the night). In the remaining time, patients breathed oxygen delivered by a Venturi mask. After 3 days from the beginning of NIPPV, we evaluated the possibility of weaning patients from NIPPV. The criteria for this and the consequent discharge from RICU were defined as the ability to keep SaO_2 value above 90% for at least 70% of the night (8 h) while patients breathed oxygen at the same level of FIO_2 (28%) and respiratory rate less than 23/min; in each case, the decision was made by two expert physicians, not involved in the study, in order to avoid a bias towards longer NIPPV in those patients without PEP. To make the decision whether to perform ETI as objective as possible, we established criteria based on clinical expe-

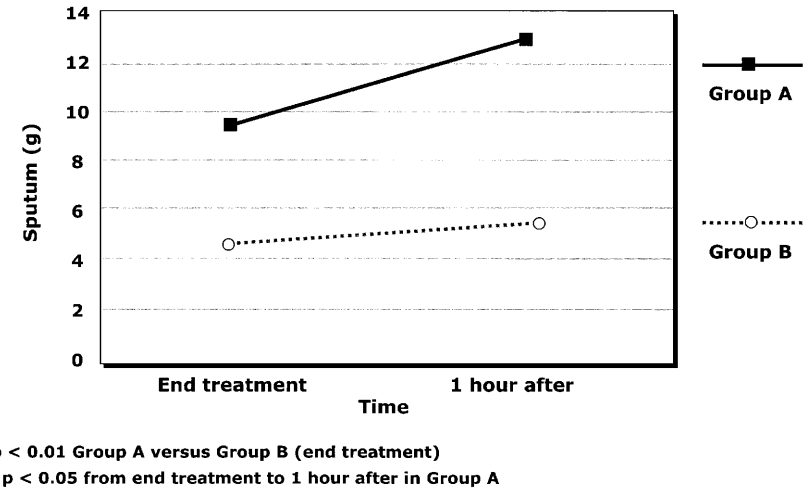

Fig. 1 Sputum production (g) in group A and group B; *p<0.01 group A versus group B (end treatment); **p<0.05 from end treatment to 1 h after in group A (see text)

rience and on reported data [7, 8, 12]. Patients were considered to have needed intubation if they met any of the following criteria within 3 days from admission: pH below 7.25 and SaO_2 lower than 85% despite NIPPV plus high flow oxygen delivered, respiratory arrest, arterial blood pressure below 70 mmHg, psychomotor agitation and altered mental status.

End points and statistics

To assess the efficacy of the PEP mask in comparison with control, the primary end point was the amount of sputum production (Fig. 1). Secondary end points were: (1) the time required to wean patients from NIPPV and (2) treatment failure in terms of mortality within 2 months after discharge from RICU or the need for ETI. Values are expressed as means (± SD). Fisher exact test was used to compare treatment failure. Two-tailed *t*-tests were used to compare the age and other normally distributed variables. A one-way analysis of variance (ANOVA) was used to compare the changes before and after physiotherapy. A p value less than 0.05 was considered statistically significant.

Results

Between December 1998 and December 1999, of the 30 patients admitted to the RICU with AHRF resulting in large amounts of bronchial secretions, 27 were enrolled in the study (Fig. 2). Three patients (10%) were not included because of worsening in pH values and impaired mental status after 1 h from the beginning of NIPPV.

The 27 patients were randomly divided into two groups. Group A (13 patients) received PEP mask plus assisted coughing; the controls (group B: 14 patients) received assisted coughing alone. The patients' details are shown in Table 1 : they were similar with respect to age, sex, ABG and APACHE II score at admission in RICU. At the end of mechanical ventilation, pH and $PaCO_2$ improved in both groups [respectively, from 7.33±0.2 to 7.43±0.9, p<0.01, and from 9.7±1.1 to 6.8±2.8 kPa, p<0.05, in group A (13 patients) and from 7.33±1.1 to

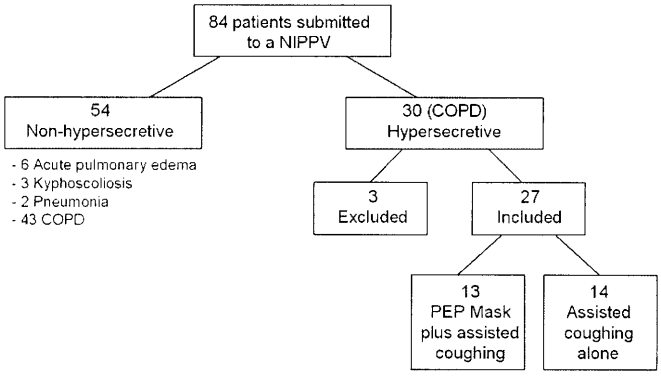

Fig. 2 Selected patient flow

Table 1 Demographic characteristics, arterial blood gases values and APACHE II score of 27 patients at admission in RICU (*APACHE II score* Acute Physiology and Chronic Health Evaluation, PaO_2 arterial oxygen tension, $PaCO_2$ arterial carbon dioxide tension, *LTOT* long-term oxygen therapy, *HMV* home mechanical ventilation, *CCP* chronic cor pulmonale, FEV_1/VC forced expiratory volume in 1 s/vital capacity (at discharge)

Variable	Group A (n=13)	Group B (n=14)	p
Mean age ± SD (years)	65±7.8	64±7.7	ns
Men, *n* (%)	8 (61)	9 (64)	ns
Mean APACHE II score ± SD	16.6±1.1	17±1.2	ns
PaO_2 ± SD (kPa)	6.9±1.3	6.8±1.4	ns
$PaCO_2$ ± SD (kPa)	9.7±1.1	9.8±1.2	ns
pH ± SD	7.33±0.2	7.33±1.1	ns
PaO_2/FIO_2 ± SD (%)	210±34	201±29	ns
LTOT, *n* (%)	13 (100)	12 (86)	ns
HMV, *n* (%)	2 (15)	2 (14)	ns
CCP, *n* (%)	10 (77)	12 (86)	ns
Co-morbidity, *n* (%)	6 (46)	6 (43)	ns
FEV_1 ± SD (m)	935±360	858±275	ns
FEV_1/VC ± SD, (%)	39±l9	38±l3	ns

Table 2 Selected outcomes variables. Values are expressed as mean ± SD (*ETI* endotracheal intubation)

Variable	Group A (n=13)	Group B (n=14)	p
Death	0	1	ns
ETI	0	1	ns
Time of weaning (days)	4.9±0.8	7.0±0.7	0.01

7.41±1.6 and from 9.8±1.2 to 7.3±2.0 kPa, $p<0.05$, in group B (13 patients: one was intubated)].

Sputum production

The results of sputum recovery (grams) are expressed as mean values (± SD), assessed during each session of the 3 days of the study. At baseline evaluation sputum production in the two groups of patients was not significantly different (2.1±2.4 g in group A and 2.6±3.8 g in group B). The amount of sputum production (Fig. 1) was significantly ($p<0.01$) higher in group A (9.6±3.9 g) compared with group B (4.7±2.5 g) at the end of treatment. One hour following, sputum had increased significantly ($p<0.05$) in group A (from 9.6±3.9 g to 13.2± 4.1 g), while no change was seen in group B (from 4.7± 2.5 g to 5.2±1.9 g). There were no significant changes in SaO_2 in either group. Only two patients (15.3%) referred to a sensation of discomfort related to the use of the PEP mask, but not so severe as to stop treatment during the period of the study.

Length of time of weaning

The total time required for weaning patients from NIPPV was 4.9±0.8 days for group A versus 7.0±0.7 days for the control group ($p<0.01$) (Table 2).

Treatment failure

Treatment failure was not significantly different among the patients receiving the PEP mask compared with the controls with regard to ETI and mortality (0 in group A versus 1 in group B) (Table 2).

Discussion

The significant improvement of sputum removal during chest physiotherapy by PEP mask in mildly acidotic patients submitted to a non-invasive ventilation because of an acute exacerbation of COPD showed that this technique is safe and useful. This is the first prospective, randomised and controlled study concerning the efficacy of a chest physiotherapy in patients admitted to the RICU requiring NIPPV. The efficacy of the PEP mask in our patients could explain the significant reduction in the ventilation time needed.

Some studies have suggested undesirable side effects of chest physiotherapy on gas exchange in COPD patients and in acutely ill patients [16, 17]. There seemed to be no beneficial effects of chest physiotherapy on the time to recovery during an acute exacerbation of COPD [18, 19] or to the resolution of pneumonia [20, 21]. By contrast, Ciesla [22] has suggested that chest physiotherapy in the intensive care unit (ICU) is useful for most of patients who are critically ill. More recently, we compared postural drainage (PD) with two different techniques in patients with acute exacerbation of chronic bronchitis without respiratory failure and showed that all the treatments used were well tolerated and effective in acutely removing secretions [23]. In general, NIPPV is not used in patients who have problems with retained secretions and this could be a reason to use ETI instead of NIPPV [5, 13].

In order to test the hypothesis of the potential role of physiotherapy during the first step of treatment of acute COPD patients needing a non-invasive modality of ventilation, we selected patients with large amounts of bronchial secretions and acute episodes of COPD exacerbation with mild hypercapnic respiratory failure (pH between 7.35 and 7.25). In our patients we used the PEP mask for the following reasons: (1) this technique is well known to be effective in patients affected by chronic bronchitis [3, 4], (2) patients were already confident with the mask because of NIPPV, (3) the positive pressure generated by the mask improves aeration to alveoli through a collateral ventilation, filling under-aerated or non-aerated segments and generating flow whereby mucus that blocks the airways is expelled, (4) PEP contributes to airway stability in patients with dynamic compression inducing airways collapse, (5) it allows patients to carry out their treatment by themselves and (6) PD, the conventionally used technique, has proved to be effective in patients with cystic fibrosis [24, 25, 26, 27], but its role in patients with chronic bronchitis is controversial.

Although there are still many unanswered questions in this area, it is important that clinicians optimise the use of available treatment options. An aggressive and early chest physiotherapy in such patients could provide adequate clearance of secretions and eliminate the need for intubation because of excessive secretions. In addition, the significant lowering of the time required for NIPPV in our patients treated with the PEP mask might involve a considerable reduction in the human and economic resources needed to ventilate COPD patients non-invasively, where the time taken by medical and paramedical personnel is very high [28].

In conclusion, our study clearly demonstrates that chest physiotherapy by PEP mask in patients with mild acidosis requiring NIPPV can produce benefits in spu-

tum clearance, and this could reduce the amount of time that the patient requires NIPPV. Moreover, we have shown that use of the PEP mask is a feasible and safe technique in acute COPD patients and we suggest that it should often be performed in addition to NIPPV. Further studies will be needed to verify the long-term effects of this treatment, particularly with respect to quality of life and cost of care.

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