Inspiratory muscle training did not accelerate weaning from mechanical ventilation but did improve tidal volume and maximal respiratory pressures: a randomised trial

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Question: Does inspiratory muscle training accelerate weaning from mechanical ventilation? Does it improve respiratory muscle strength, tidal volume, and the rapid shallow breathing index? **Design**: Randomised trial with concealed allocation and intention-to-treat analysis. **Participants**: 92 patients receiving pressure support ventilation were included in the study and followed up until extubation, tracheostomy, or death. **Intervention**: The experimental group received usual care and inspiratory muscle training using a threshold device, with a load of 40% of their maximal inspiratory pressure with a regimen of 5 sets of 10 breaths, twice a day, 7 days a week. The control group received usual care only. **Outcome measures**: The primary outcome was the duration of the weaning period. The secondary outcomes were the changes in respiratory muscle strength, tidal volume, and the rapid shallow breathing index. **Results**: Although the weaning period was a mean of 8 hours shorter in the experimental group, this difference was not statistically significant (95% CI –16 to 32). Maximal inspiratory and expiratory pressures increased in the experimental group and decreased in the control group, with significant mean differences of 10 cmH_2O (95% CI 5 to 15) and 8 cmH_2O (95% CI 2 to 13), respectively. The tidal volume also increased in the experimental group and decreased in the control group (mean difference 72 ml, 95% CI 17 to 128). The rapid shallow breathing index did not differ significantly between the groups. **Conclusion**: Inspiratory muscle training did not shorten the weaning period significantly but it increased respiratory muscle strength and tidal volume. **Trial registration**: NCT00851617. **[Condessa RL, Brauner JS, Saul AL, Baptista M, Silva ACT, Vieira SRR (2013) Inspiratory muscle training did not accelerate weaning from mechanical ventilation but did improve tidal volume and maximal respiratory pressures: a randomised trial. *Journal of Physiotherapy* 59: 101–107]**

Key words: Mechanical ventilator weaning, Respiratory muscle training, Ventilator dependent, Ventilator-induced diaphragmatic dysfunction

Introduction

Most patients admitted to an intensive care unit need mechanical ventilation. The cost of managing ventilated patients is high, with high morbidity and mortality, including complications such as ventilator-induced lung injury (Vincent et al 1995) and ventilator-induced diaphragmatic dysfunction (Vassilakopoulos and Petrof 2004). Therefore, it is important to recognise patients who are ready to be weaned from mechanical ventilation and to wean them as quickly as possible (Ely et al 2001, Zeggwagh et al 1999).

Immobility, prolonged mechanical ventilation, and systemic infection and inflammation are associated with skeletal muscle dysfunction in critically ill patients (Prentice et al 2010). The disuse atrophy can result from decreased protein synthesis (Ku et al 1995) and from increased proteolysis, together with oxidative stress indicated by increased protein oxidation and lipid peroxidation (Shanely et al 2002). Respiratory muscles may be relatively less affected by these processes than peripheral muscles (Prentice et al 2010). Nevertheless, the use of mechanical ventilation may cause diaphragmatic atrophy (Levine et al 2008). With greater duration of mechanical ventilation in an animal model, the density of structurally abnormal diaphragm myofibrils increased and correlated with the reduction in the tetanic force of the diaphragm (Sasoon et al 2002). Therefore, respiratory muscle weakness may impede the weaning process (Levine et al 2008).

Inspiratory muscle training improves maximal inspiratory pressure in patients with respiratory muscle weakness and low exercise tolerance (Huang et al 2003, Martin et al 2002, Sprague and Hopkins 2003). Inspiratory muscle training can be achieved in several ways, but training with a threshold device has the advantage of a more controlled administration of the inspiratory load because it provides a specific, measurable resistance that is constant throughout each breath and is independent of respiratory rate (Martin et al 2002, Sprague and Hopkins 2003).

There are few inspiratory muscle training studies on patients receiving mechanical ventilation. Most of these studies examine tracheostomised patients receiving long-

What is already known on this topic: Inspiratory muscle weakness in mechanically ventilated patients appears to slow weaning and increase the risk of extubation failure. Systematic reviews indicate that inspiratory muscle training increases inspiratory muscle strength, but it is not yet clear whether it shortens the weaning period.

What this study adds: Inspiratory muscle training improved inspiratory muscle strength and also expiratory muscle strength and tidal volume. However, the duration of the weaning period was not significantly reduced.

term mechanical ventilation with difficult weaning. The interventions in these studies vary from spontaneous breathing via a T-tube (Aldrich and Karpel 1985, Aldrich et al 1989) to increasing the resistive load on respiratory muscles (Martin et al 2002, Sprague and Hopkins 2003, Caruso et al 2005, Cader et al 2010, Martin et al 2011, Cader et al 2012). However, inspiratory muscle training has also been achieved in intubated patients by adjusting the mechanical ventilator trigger sensitivity (Caruso et al 2005). All these studies evaluated maximal inspiratory pressure in intervals varying from once per day to once per week. In most of the studies, the training load was increased to achieve a target rating of perceived exertion (Martin et al 2002, Sprague and Hopkins 2003) or to maintain a percentage of the patient's maximal inspiratory pressure (Caruso et al 2005, Cader et al 2010, Cader et al 2012).

A systematic review recently pooled data from 150 patients from three of these studies. The studies were all randomised correctly, and group data and between-group comparisons were reported adequately, but patients, therapists, and assessors were not blinded. The pooled results showed that the training improved inspiratory muscle strength significantly, but did not show clearly whether weaning success also improved (Moodie et al 2011).

Therefore, the aim of this study was to answer the following questions:

1. Is inspiratory muscle training useful to accelerate weaning from mechanical ventilation?
2. Does inspiratory muscle training improve the strength of respiratory muscles and the values of tidal volume as well as the rapid shallow breathing index?

Method

Design

A randomised trial with concealed allocation, blinded outcome assessment, and intention-to-treat analysis was undertaken at the Intensive Care Unit of the Hospital de Clínicas de Porto Alegre, Brazil, between March 2005 and July 2007. Participants were recruited from the adult general intensive care unit. To achieve allocation, each random allocation was concealed in an opaque envelope until a patient's eligibility to participate was confirmed. The experimental group received usual care and also underwent inspiratory muscle training twice daily throughout the weaning period. The control group received usual care only. The enrolling investigators were also responsible for applying the inspiratory muscle training but were not involved in the measurement of outcomes. Other investigators, who remained blinded to treatment allocations, measured maximal inspiratory and expiratory pressures and the rapid shallow breathing index twice a day until the end of the weaning period. The weaning period was defined as from the end of controlled ventilation (ie, the commencement of pressure-support ventilation) until extubation. A daily awakening trial with a minimum level of sedation identified which patients would be transitioned from controlled mechanical ventilation to pressure-support ventilation. The time of extubation was decided by the treating physicians, who were blinded to the treatment allocations.

Participants

Patients were included in this study if they were aged 18 years or more, had undergone mechanical ventilation for more than 48 hours in a controlled mode, and were considered ready for weaning with pressure-support ventilation between 12 cmH_2O and 15 cmH_2O and positive end-expiratory pressure between 5 cmH_2O and 7 cmH_2O. They had to be haemodynamically stable without the aid of vasoactive drugs (dopamine, dobutamine or norepinephrine) or sedative agents.

This study excluded patients with hypotension (systolic blood pressure < 100 mmHg or mean blood pressure < 70 mmHg), severe intracranial disease with inadequate consciousness level (Glasgow Coma Scale ≤ 11), barotrauma, tracheostomy, or neuromuscular disease.

Intervention

In the experimental group, inspiratory muscle training began when the participants were changed from controlled to pressure-support ventilation. The patients were ventilated using one of three mechanical ventilators[a]. Before each training session, the patients were positioned in 45-deg Fowler's position and cardiorespiratory variables (respiratory rate, heart rate, systolic and diastolic blood pressures, and oxyhaemoglobin saturation) were recorded to ensure that participants did not undertake training if they were haemodynamically unstable, defined as: respiratory rate > 30 breaths/min, oxyhaemoglobin saturation < 90%, systolic blood pressure > 180 mmHg or < 90 mmHg, paradoxical breathing, agitation, tachycardia, haemoptysis, arrhythmia, or diaphoresis (Caruso et al 2005). The pressure of the endotracheal tube cuff was maintained at 30 mmHg during the training session (Lewis et al 1978).

The experimental group was trained using an inspiratory threshold device[b] with a load equal to 40% of the participant's maximal inspiratory pressure. Each training session consisted of 5 sets with 10 breaths, twice a day, seven days a week. Supplementary oxygen was added if necessary during a training session (Martin et al 2002). The training session was interrupted in the presence of haemodynamic instability, as defined above. In the event of haemodynamic instability, the participant was returned to pressure-support ventilation.

The control group did not receive inspiratory muscle training during the weaning period. Both groups received all other usual care. Regular physiotherapy intervention received by both groups included passive to active-assisted mobilisation of the limb, chest compression with quick release at end-expiration, aspiration of the endotracheal tube, and positioning.

All cardiorespiratory variables (respiratory rate, heart rate, systolic and diastolic blood pressure, and oxyhaemoglobin saturation) were recorded again one minute after the end of the protocol in both groups to identify haemodynamic instability as an adverse event. All patients were followed up until weaning was attempted, unless they died, were tracheostomised, or required controlled ventilation, before completing the weaning process.