Journal of Physiotherapy 61 (2015) 16–20

Journal of PHYSIOTHERAPY

journal homepage: www.elsevier.com/locate/jphys

Research

The use of a modified, oscillating positive expiratory pressure device reduced fever and length of hospital stay in patients after thoracic and upper abdominal surgery: a randomised trial

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KEYWORDS

Mucus-clearance device
Postoperative pulmonary complications
Length of stay

ABSTRACT

Question: Does the use of an oscillating positive expiratory pressure (PEP) device reduce postoperative pulmonary complications in thoracic and upper abdominal surgical patients? **Design:** A multi-centre, parallel-group, randomised controlled trial with intention-to-treat analysis, blinding of some outcomes, and concealed allocation. **Participants:** A total of 203 adults after thoracic or upper abdominal surgery with general anaesthesia. **Intervention:** Participants in the experimental group used an oscillating PEP device, thrice daily for 5 postoperative days. Both the experimental and control groups received standard medical postoperative management and early mobilisation. **Outcome measures:** Fever, days of antibiotic therapy, length of hospital stay, white blood cell count, and possible adverse events were recorded for 28 days or until hospital discharge. **Results:** The 99 participants in the experimental group and 104 in the control group were well matched at baseline and there was no loss to follow-up. Fever affected a significantly lower percentage of the experimental group (22%) than the control group (42%), with a RR of 0.56 (95% CI 0.36 to 0.87, NNT 6). Similarly, length of hospital stay was significantly shorter in the experimental group, at 10.7 days (SD 8.1), than in the control group, at 13.3 days (SD 11.1); the mean difference was 2.6 days (95% CI 0.4 to 4.8). The groups did not differ significantly in the need for antibiotic therapy, white blood cell count or total expense of treatment. **Conclusion:** In adults undergoing thoracic and upper abdominal surgery, postoperative use of an oscillating PEP device resulted in fewer cases of fever and shorter hospital stay. However, antibiotic therapy and total hospital expenses were not significantly reduced by this intervention. **Trial registration:** NCT00816881. **[Zhang X-y, Wang Q, Zhang S, Tan W, Wang Z, Li J (2015) The use of a modified, oscillating positive expiratory pressure device reduced fever and length of hospital stay in patients after thoracic and upper abdominal surgery: a randomised trial. *Journal of Physiotherapy* 61: 16–20]**

Introduction

Following both thoracic and upper abdominal surgical procedures, postoperative pulmonary complications (PPCs) are frequently observed and are still a major contributor to the overall risk of surgery.[1] A recent Australian study reported that PPCs affect 13% of patients undergoing upper abdominal laparotomy.[2] Risk factors for PPCs are: duration of anaesthesia, surgical category, current smoking, respiratory comorbidity, and predicted maximal oxygen uptake.[3] Preoperative physiotherapy interventions,[4] particularly inspiratory muscle training,[5] decrease the risk of PPCs. Postoperatively, early mobilisation is recommended to minimise PPCs.[2]

Many pre-operative and post-operative physiotherapy interventions are not yet available or accepted in most hospitals in China. Postoperatively, early mobilisation is used. Currently in China, no other standardised physiotherapy and respiratory care is provided during the postoperative period. With regard to postoperative respiratory interventions, some hospitals use a traditional technique where the patients regularly blow up a balloon after the operation until mobilisation is re-established. This technique is a form of respiratory exercise that is typically used for individuals at high risk of PPCs.

Oscillating positive expiratory pressure (PEP) devices have been shown to assist mucus clearance in a number of respiratory diseases, including: cystic fibrosis,[6–9] chronic obstructive pulmonary disease,[10,11] asthma,[12] diffuse panbronchiolitis[13] and bronchiectasis.[14,15] In some of these studies, there is also some evidence that use of the oscillating PEP device may help to improve lung expansion, although the mechanism is unclear. Thoracic and upper abdominal surgical patients at risk of PPCs may benefit from an intervention that facilitates the clearance of retained secretions with a possible additional effect on lung expansion.

The hypothesis of the present study was that regular use of a hand-held oscillating PEP device might improve respiratory management in patients after thoracic or upper abdominal

http://dx.doi.org/10.1016/j.jphys.2014.11.013

surgery. Therefore, the research question for the present study was:

> In patients who have undergone thoracic or upper abdominal surgery, what is the effect of regular postoperative use of an oscillating PEP device on fever, white cell count, length of hospital stay, mortality, treatment costs and the need for antibiotics?

Method

Design

A randomised trial with intention-to-treat analysis, blinding of assessors for some outcomes, and concealed allocation was undertaken. Preoperatively, patients were informed about the study protocol and their willingness to participate was determined. Those who remained willing and eligible to participate postoperatively were enrolled and randomised by one of the study investigators. On the first postoperative day, eligible patients were randomly allocated to an experimental or control group, with each allocation removed from a sealed, consecutively numbered, opaque envelope by a research assistant. Outcomes were measured up to 28 days postoperatively or until discharge from hospital.

Before the study was registered and commenced, the principal investigators from each centre reached consensus on the study protocol. Study inspectors, who were organised and instructed by the principal investigator from Shanghai Tenth People's Hospital, conducted site visits and made phone calls to ensure study quality.

Participants, therapists and centres

Adults aged 18 to 80 years were eligible to participate if they were undergoing thoracic or upper abdominal surgery with tracheal intubation under general anaesthesia and were extubated within 24 hours postoperatively. Exclusion criteria were: inability to use the oscillating PEP device (eg, due to decreased consciousness or intellectual disability); advanced cancer; diffuse interstitial lung disease; systolic blood pressure $\geq$ 180 mmHg; diastolic blood pressure $\geq$ 110 mmHg; and severe cardiac, hepatic, renal, circulatory or endocrine dysfunction.

The investigators who administered the oscillating PEP devices and taught participants to use them were physicians or respiratory therapists. These investigators received consistent instructions in the use of the devices via the study protocol.

Three hospitals recruited participants for the present study. The co-ordinating centre was the Shanghai Tenth People's Hospital, Tongji University School of Medicine. The other centres were the Shanghai Jiangong Hospital and the Shanghai Putuo District Centre Hospital.

Interventions

Participants who were randomised to the experimental group were instructed to use an oscillating PEP device.[a] The device is required to be held in a particular position with respect to gravity. Given that the participants may have been limited in the positions that they could adopt in the early postoperative period, the device was modified by the addition of some wide-bore connector tubing used as a flexible adaptor, which was inserted between the oscillating valve and the mouthpiece, as shown in Figure 1. This allowed the participants to use the device at the required angle whilst in any body position and avoided any uncomfortable sensation of dental vibration.

Participants were instructed to take a deep breath and then to exhale through the device actively but not forcefully. The participants were also instructed to adjust the position of the device relative to gravity in order to yield the strongest feeling of thoracic vibration during exhalation through the device. The procedure was repeated for five to ten breaths over a 5-minute period, three times a day, for the first 5 postoperative days. The following schedule was recommended: after waking up in the morning, after an afternoon nap, and before going to bed in the evening. Participants were instructed to avoid having a full stomach for the breathing sessions. Participants were encouraged to cough up sputum during the breathing sessions.

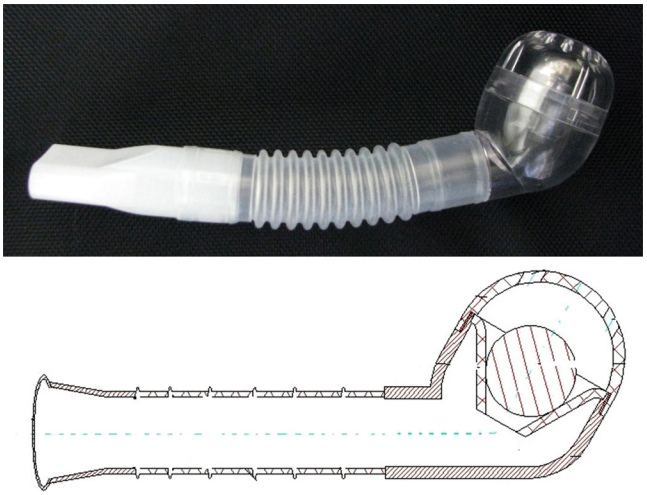

Figure 1. The oscillating PEP device was modified by the addition of a flexible adaptor inserted between the oscillating valve and the mouthpiece. This was done so that the participants could use it at the required angle while in any body position and without any uncomfortable sensation of dental vibration.

Routine medical management and early mobilisation were provided to the participants in both groups, as appropriate and according to each patient's postoperative condition. No other routine physiotherapy, such as standardised thoracic expansion exercises,[16] was administered to both groups, as this is not routinely available in the participating hospitals. Therefore, the control group had no other physiotherapy, unless a physician specifically ordered it after the development of a PPC.

Due to the unavailability of a convincing sham, the control group did not undertake sham training; therefore, the participants were unblinded.

Outcome measures

The primary outcomes were fever, antibiotic therapy and length of hospital stay. Fever was defined as a body temperature $\geq$ 38 deg Celsius. Antibiotic therapy was quantified as the number of days on intravenous antibiotics. Length of hospital stay was calculated as the number of days from admission to discharge; it was calculated as a continuous outcome, as well as being analysed after being dichotomised into those extending beyond 28 days or not.

The secondary outcomes were white cell count, abnormal chest radiograph, mortality, treatment costs and the need for mechanical ventilation. The white cell count was measured on the fifth postoperative day, and was calculated by laboratory staff who were unaware of the participants' group allocation. Radiologists, who were unaware of the participants' group allocation, decided whether there were any abnormalities on the participants' chest radiographs. Mortality and treatments costs were determined from hospital records. At discharge from hospital, participants who had used the oscillating PEP device were questioned about any adverse events associated with the device.

Data analysis

All participants completed the study as allocated, so analysis was consistent with the intention-to-treat principle. Group data