



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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KEY WORDS

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]

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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 panbronchiolitis¹³ 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

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 ≥ 180 mmHg; diastolic blood pressure ≥ 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.⁴ 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

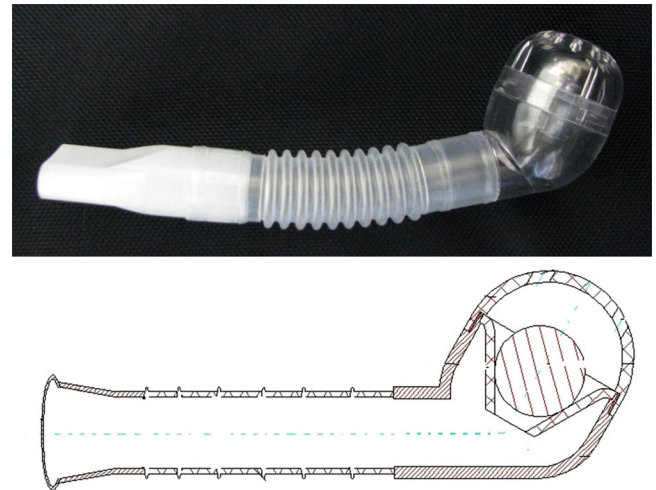


Figure 1. The oscillating PEP device was modified by the addition of a flexible adaptor inserted between the oscillating valve and the mouthpiece. This was done so that the participants could use it at the required angle while in any body position and without any uncomfortable sensation of dental vibration.

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.

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 ≥ 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

were summarised as means and SD. For continuous outcome measures, between-group comparisons used the independent-samples t-test and were reported as mean differences with 95% CI. For dichotomous outcomes, between-group comparisons used the chi-square test and were reported as relative risks with 95% CI. Significant results were also converted to 'number needed to treat'. All statistical tests were two-tailed, with an alpha level of < 0.05 considered to be statistically significant.

Results

Compliance with the study protocol

One 16 year old was enrolled, despite being below the intended age range for participants. All participants provided data for the planned outcome measures, except that a white blood cell count was unavailable for three experimental group participants and four control group participants.

Flow of participants, therapists and centres through the study

Between January 2009 and February 2010, 233 adult patients undergoing thoracic and upper abdominal surgery in the three hospitals located in Shanghai, China were screened for eligibility. Of these, 30 were excluded: 22 did not meet the eligibility criteria, six declined to participate, and informed consent was not obtained from the remaining two participants. Therefore, 203 patients were randomised – all of whom completed the study and provided data for analysis, as shown in Figure 2.

The baseline characteristics of the two groups were similar, as presented in Table 1.

Effect of intervention

The first primary outcome – the incidence of fever – was significantly reduced by the intervention. Specifically, the incidence of fever was 39% in the control group and 22% in the experimental group. This means that the experimental group had a risk of fever that was 0.56 of the risk in the control group. This 'relative risk' estimate of 0.56 was statistically significant (95% CI 0.36 to 0.87), as presented in Table 2. It also suggests that, on average, for every six patients who undertook the oscillating PEP intervention, one remained afebrile who would otherwise have experienced a fever during their first 28 postoperative days. However, this estimate of six patients, as the number needed to treat to prevent one case of fever, has some imprecision associated with it. The true 'number needed to treat' could be as low as 3 or as high as 22 patients.

The length of hospital stay was analysed in two ways: as a continuous outcome and as a dichotomous outcome. When analysed as a continuous outcome, length of stay was significantly reduced from 13.3 days (SD 8.7) in the control group to 10.7 days (SD 7.1) in the experimental group, with a mean difference of -2.6 (95% CI -4.8 to -0.4), as shown in Table 3. The risk of prolonged hospitalisation (ie, > 28 days) was 9% in the control group and 6% in the experimental group, with a RR of 0.58 (95% CI 0.20 to 1.68), as shown in Table 2.

The other primary outcomes were not significantly improved by the oscillating PEP intervention. The risk of requiring antibiotics was 95% in the control group and 93% in the experimental group, with a RR of 0.99 (95% CI 0.92 to 1.05), as shown in Table 2. The number of days spent receiving antibiotic therapy was also not significantly affected by the intervention, with a mean difference of 1.61 days less in the experimental group (95% CI -0.13 to 3.36), as presented in Table 3.

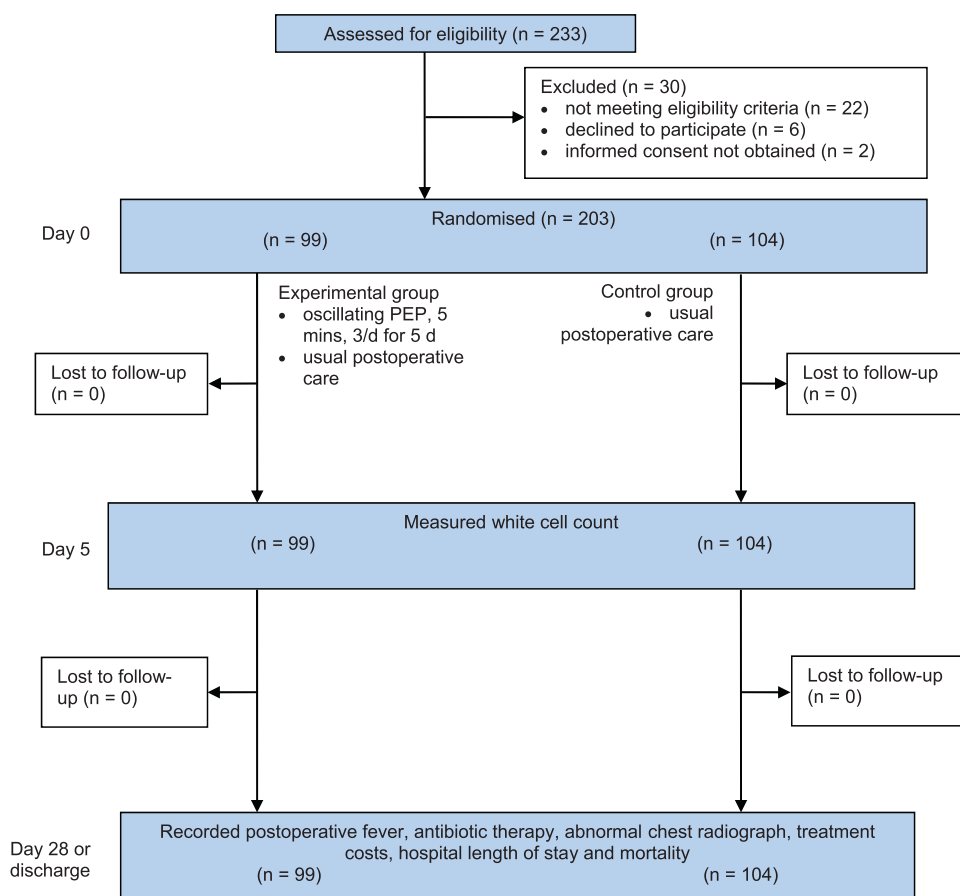


Figure 2. Flow of participants through the study.

Table 1
Characteristics of participants at baseline.

| Characteristic | Experimental group (n = 99) | Control group (n = 104) |
|--|--------------------------------|----------------------------|
| Gender (<i>male</i>), n (%) | 61 (62) | 63 (61) |
| Age (<i>yr</i>), mean (SD) | 56 (10) | 58 (12) |
| Body mass index (kg/m^2), mean (SD) | 23.5 (3.3) | 23.3 (4.2) |
| Comorbidities, n (%) | | |
| chronic cardiovascular disease | 19 (19) | 18 (17) |
| chronic respiratory disease | 1 (1) | 2 (2) |
| other | 12 (12) | 9 (9) |
| Emergency operation, n (%) | 26 (26) | 26 (25) |
| Thoracic operation, n (%) | 50 (51) | 54 (52) |
| Upper abdominal operations, n (%) | 49 (49) | 50 (48) |
| laparotomy, n (%) | 24 (24) | 25 (24) |
| laparoscopy, n (%) | 25 (25) | 25 (24) |
| Total operative time (<i>hr</i>), mean (SD) | 2.01 (1.42) | 2.15 (1.48) |
| Max body temperature on Day 1 (<i>deg C</i>), mean (SD) | 37.4 (0.5) | 37.5 (0.5) |
| White blood cell count on Day 1 ($\times 10^9/\text{L}$), mean (SD) | 9.25 (4.18) | 10.33 (4.24) |

None of the secondary outcomes was significantly affected by the oscillating PEP intervention. The white cell count on Day 5 was similar in the two groups, with a mean difference of $0.09 \times 10^9/\text{L}$. The incidence of an abnormal chest radiograph was 42% in the control group and 37% in the experimental group, with a RR of 0.90 (95% CI 0.64 to 1.27). Treatment costs were 3800 RMB cheaper in the experimental group, but this was not statistically significant (95% CI -8400 to 900), as shown in Table 3. During the course of the study, there were no deaths, and no other adverse events or reactions were reported. Individual participant data are available in Table 4 on the eAddenda.

Discussion

General anaesthesia with tracheal intubation has adverse effects on the respiratory system. These effects begin with anaesthetic induction and extend into the postoperative period. General anaesthesia reduces functional residual capacity, with an immediate and universal development of atelectasis in the dependent regions of the lung.¹⁷ Secretion retention may also occur and, when it does, it may contribute to the development of postoperative pulmonary complications. The vibrations generated by expiratory flow in the oscillating PEP device are intended to loosen and help the removal of retained airway secretions.^{18,19} The oscillating PEP device used in the present study must be set at a fixed angle relative to gravity, which is most readily achieved in a sitting position.²⁰ The modified device in the present study allowed the participants to use the device effectively in any body position and eliminated any uncomfortable vibration of the teeth. Its transparent design helped the user to find the best position for maximum vibration and comfort.²¹ As in previous studies,²² the device was well tolerated and accepted by the study participants. Adverse events or adverse reactions to the device were not reported spontaneously during the study, nor when participants were specifically questioned about this at discharge from hospital.

Table 3
Comparison of days of antibiotic therapy, white blood cell count, length of hospital stay, total expense of treatment and days of fever between groups.

| Characteristics | Exp (n = 99) Mean (SD) | Con (n = 104) Mean (SD) | Exp - Con Mean difference (95% CI) |
|--|------------------------------|-------------------------------|--|
| Length of hospital stay (<i>d</i>) | 10.7 (7.1) | 13.3 (8.7) | -2.6 (-4.8 to -0.4) |
| Antibiotic therapy (<i>d</i>) | 7.23 (5.93) | 8.85 (6.62) | 1.61 (-0.13 to 3.36) |
| White cell count on Day 5 ($\times 10^9/\text{L}$) | 7.66 (2.50) ^a | 7.76 (2.87) ^b | 0.09 (-0.67 to 0.86) |
| Total expense of treatment (RMB $\times 10\ 000$) | 2.07 (1.67) | 2.44 (1.68) | -0.38 (-0.84 to 0.09) |

Exp = experimental group, Con = control group.

^a n = 96,

^b n = 100.

Table 2
Prevalence of adverse dichotomous outcomes in the two groups and RR (95% CI).

| Outcome | Exp (n = 99) | Con (n = 104) | RR (95% CI) |
|---|-----------------|------------------|---------------------|
| Fever, n (%) | 22 (22) | 41 (39) | 0.56 (0.36 to 0.87) |
| Hospital stay more than 28 days, n (%) | 5 (5) | 9 (9) | 0.58 (0.20 to 1.68) |
| Antibiotic therapy, n (%) | 93 (93) | 99 (95) | 0.99 (0.92 to 1.05) |
| Abnormal of chest radiograph, n (%) | 37 (37) | 43 (42) | 0.90 (0.64 to 1.27) |

Exp = experimental group, Con = control group.

In the present study, some statistically significant results were observed. It is important to put these into context. The statistically significant reduction in the risk of fever was also clinically substantial, because the best estimate was that for every six patients who used the oscillating PEP, one would avoid fever who would otherwise have experienced it. However, this estimate carried some imprecision, with this estimate of six as the 'number needed to treat' having a 95% CI from 3 to 22. If 22 patients had to use the oscillating PEP to prevent one case of fever, this would not be as clinically worthwhile. Also, fever may not have been an indicator of a very severe PPC, because this result was not accompanied by significant reductions in antibiotic use or radiological abnormalities. The other statistically significant result (ie, a 2.6 day reduction in length of hospital stay) was clinically relevant to the centres in Shanghai. However, it is acknowledged that other centres have shorter lengths of hospital stay, so the potential to reduce them by 2.6 days with oscillating PEP may be limited.

The present results should also be considered in the context of other studies in this area. A previous single-centre study with a relatively small sample size indicated that incentive spirometry in addition to regular physiotherapy did not further reduce pulmonary complications or hospital stay in postoperative lung and oesophagus surgery patients.²³ Silva and colleagues reported that the addition of deep breathing exercises to physiotherapy-directed early mobilisation did not further reduce PPCs, compared with mobilisation alone.²⁴ Mackay and colleagues reported that the addition of deep breathing and coughing exercises to a physiotherapist-directed program of early mobilisation in high-risk, open abdominal surgery patients did not significantly reduce the incidence of clinically significant PPCs.²⁵ However, both of these studies had smaller sample sizes and were single-centre studies. Another study reported no reduction in PPCs from respiratory physiotherapy in elective pulmonary resection via open thoracotomy surgical patients, when compared to standard medical/nursing care.²⁶ Although the interventions in these studies had similar aims (eg, improving ventilation and reducing secretion retention) to the intervention in the present study, the results of these studies are different from the present results. However, a recent study with a larger sample size found that incentive spirometry might be a favourable intervention for patients with a high risk of developing a PPC – in particular, those with chronic

respiratory disease or a history of smoking.²⁷ Scholes and colleagues³ and Agostini and colleagues²⁸ reported risk factors that predicted PPCs, including: duration of anaesthesia, surgical category, current smoking, respiratory comorbidity, predicted maximal oxygen uptake and a body mass index over 30 kg/m². This high-risk population may benefit from physiotherapy intervention to minimise PPCs.

Currently, in most of the hospitals in China, there is no regular standardised respiratory or physiotherapy care for postoperative patients. The consensus statement²⁹ regarding pulmonary complications after thoracic surgery, which was published in 2009 by the Chinese Association of Thoracic Surgery, did not report the incidence of PPC in China and did not recommend physiotherapy for prevention. Given the favourable results from the present study, the favourable results in high-risk patients discussed above,²⁵ and evidence that physiotherapist-directed postoperative exercise decreases pain and improves shoulder function over usual care for patients following open thoracotomy, physiotherapists may have the opportunity to gain referrals for patients in this area.¹⁶

From this randomised controlled study, it can be concluded that in developing areas where physiotherapy is not standard, the use of a modified oscillating PEP device results in fewer cases of fever and reduced length of hospital stay in thoracic and upper abdominal postoperative adult patients.

Footnotes:^aFlutter[®] VRP1, Tyco Healthcare, Germany.

Addenda: Table 4 can be found online at [doi:10.1016/j.jphys.2014.11.013](https://doi.org/10.1016/j.jphys.2014.11.013).

Ethics approval: The Shanghai Tenth People's Hospital Ethics Committees approved this study. All participants gave written informed consent before data collection began.

Competing interests: None declared.

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Contributions: All authors contributed equally to this study.

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