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Feasibility of preoperative inspiratory muscle training in patients undergoing coronary artery bypass surgery with a high risk of postoperative pulmonary complications: a randomized controlled pilot study

Erik HJ Hulzebos Section Rehabilitation, Department of Neurology and Neurosurgery, Rudolf Magnus Institute of Neuroscience, University Medical Center Utrecht, **Nico LU van Meeteren** Section Rehabilitation, Department of Neurology and Neurosurgery, Rudolf Magnus Institute of Neuroscience, University Medical Center Utrecht and Department of Physiotherapy-Research, Academy of Health Sciences Utrecht, **Bram JWM van den Buijs** Section Rehabilitation, Department of Neurology and Neurosurgery, Rudolf Magnus Institute of Neuroscience, University Medical Centre Utrecht, **Rob A de Bie** Physiotherapy-Research, Department of Epidemiology, Maastricht University, Maastricht, **A Brutel de la Rivière** Department of Thorax Surgery, Onze Lieve Vrouwe Gasthuis, Amsterdam and **Paul JM Helders** Department of Paediatric Physical Therapy, University Medical Centre and Children's Hospital Utrecht and Department of Physiotherapy-Research, Academy of Health Sciences Utrecht, The Netherlands

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Objective: To determine in a pilot study the feasibility and effects of preoperative inspiratory muscle training in patients at high risk of postoperative pulmonary complications who were scheduled for coronary artery bypass graft surgery.
Design: Single-blind, randomized controlled pilot study.
Setting: University Medical Centre Utrecht, the Netherlands.
Subjects: Twenty-six patients at high risk of postoperative pulmonary complications were selected.
Intervention: The intervention group ($N = 14$) received 2–4 weeks of preoperative inspiratory muscle training on top of the usual care received by the patients in the control group.
Main measures: Primary outcome variables of feasibility were the occurrence of adverse events, and patient satisfaction and motivation**.** Secondary outcome variables were postoperative pulmonary complications and length of hospital stay.
Results: The feasibility of inspiratory muscle training was good and no adverse events were observed. Treatment satisfaction and motivation, scored on 10-point scales, were 7.9 ($\pm$0.7) and 8.2 ($\pm$1.0), respectively. Postoperative atelectasis occurred in significantly fewer patients in the intervention group than in the control group ($\chi^2_{DF1} = 3.85$; $P = 0.05$): Length of hospital stay was 7.93 ($\pm$1.94) days in the intervention group and 9.92 ($\pm$5.78) days in the control group ($P = 0.24$).

Address for correspondence: Erik Hulzebos, Department of Paediatric Physical Therapy and Exercise Physiology, University Medical Centre and Children's Hospital. Room KM 02.056, PO Box 85090, 3508 AB Utrecht, The Netherlands.
e-mail: h.hulzebos@umcutrecht.nl.

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Conclusion: Inspiratory muscle training for 2–4 weeks before coronary artery bypass graft surgery was well tolerated by patients at risk of postoperative pulmonary complications and prevented the occurrence of atelectasis in these patients. A larger randomized clinical trial is warranted.

Introduction

Patients undergoing coronary artery bypass graft surgery are at risk of postoperative pulmonary complications, which lead to increased postoperative morbidity and mortality.[1,2] The probability of such complications ranges from 5% to 73%, depending on the definition of postoperative pulmonary complications and the diagnostic techniques used.[2,3] The presence of pre-existing pulmonary conditions, age, smoking, obesity and diabetes significantly increases the risk of postoperative pulmonary complications.[4]

Although considerable effort is taken to prevent these complications, there is no consensus on the most appropriate or effective therapy. Indeed, controversy exists about the possible overuse and abuse of many of the therapeutic modalities commonly used for prevention and treatment.[5,6] A few studies have demonstrated that preoperative physical therapy has advantages over postoperative care in patients undergoing cardiac surgery.[7–10] However, research has failed to show indisputably that these interventions reduce the incidence of postoperative pulmonary complications.

Only a few studies have investigated the role of the respiratory muscles *after* coronary artery bypass graft surgery. These studies showed that respiratory muscle function was diminished after surgery and that unilateral or bilateral phrenic nerve paralysis frequently developed, both of which may lead to respiratory muscle dysfunction and respiratory failure.[11–15] Dysfunction of the respiratory muscles due to surgery may also lead to a reduction in the vital capacity (VC), tidal volume (VT), and total lung capacity (TLC), and hence to insufficient cough.[11] This may cause atelectasis in the basal lung segments and a decrease in functional residual capacity (FRC), which, in turn, will affect the gas exchange properties of the lung by increasing the ventilation/perfusion (V/Q) mismatch.[16] Indeed, it has been hypothesized that respiratory muscle weakness is associated with a higher rate of postoperative pulmonary complications, and that preoperative inspiratory muscle training can help to prevent these ventilatory impairments.[10] Consequently, we started a line of research (1) to develop a preoperative risk model to identify those patients at high risk of developing postoperative pulmonary complications after undergoing coronary artery bypass graft surgery,[17] (2) to develop an appropriate preoperative intervention (this pilot study), and (3) to demonstrate the (cost-) effectiveness of this intervention in a randomized clinical trial.

Before embarking on a proper randomized controlled trial, we first performed this pilot study to test the feasibility of the approach and to help clarify decisions about operational definitions and procedures.[18] The aims of the pilot study reported here were to evaluate the feasibility and effectiveness of inspiratory muscle training on inspiratory muscle strength in patients at increased risk of developing postoperative pulmonary complications after coronary artery bypass graft surgery. Effectiveness was evaluated in terms of the incidence of postoperative pulmonary complications and the length of hospital stay.

Method

Study population

Forty patients, all candidates for elective coronary artery bypass graft surgery, were recruited and evaluated from October to December 2002. Inclusion criteria were age >18 years, elective surgery and written informed consent. Exclusion criteria were a history of a cerebrovascular accident, use of immunosuppressive medication 30 days before surgery, the presence of a neuromuscular disorder, previous pulmonary surgery, cardiovascular instability or the existence of an aneurysm.

Of these 40 patients, only those at high risk of developing a postoperative pulmonary complication were selected, using a six-factor risk model.[17] The risk factors in this model are age ≥ 70 years,

productive cough, history of smoking, diabetes mellitus, inspiratory vital capacity $< 75\%$ of predicted, and maximal expiratory pressure $< 75\%$ of predicted. The risk factors are weighted and patients with a risk score ≥ -1 are classified as being at high risk of developing a postoperative pulmonary complication.[17] Twenty-six of the 40 patients were considered to be at high risk; the other 14 patients, with a low risk of developing a postoperative pulmonary complication, were not included in the current study (Table 1).

Design

In this single-blind, randomized controlled pilot study, patients at high risk of developing postoperative pulmonary complications were randomly assigned, using a computer-generated randomized block design, to either the intervention or the control group (Figure 1). The intervention group received inspiratory muscle training for 2–4 weeks before surgery (depending on the actual date of surgery) additional to care as usual (e.g. patient education about early mobilization, and coughing with wound support, one day before surgery). The control group received care as usual. All measurements were taken by an experienced physical therapist (EH) who was blinded for the group allocation of the patients. The training was provided by a second experienced physical therapist (BvdB). The Institutional Review Board of the University Medical Centre Utrecht approved this pilot study.

Table 1 Clinical characteristics of patients

	Intervention group ($N = 14$)	Control group ($N = 12$)
Score on the 'Hulzebos risk model' (SD)	1.64 (1.91)	1.92 (2.15)
Sex, *n* (%)		
Male	7 (50%)	6 (50%)
Female	7 (50%)	6 (50%)
Age in years (SD)	70.14 (9.86)	70.50 (10.10)
Body mass index (SD)	26.13 (2.93)	28.32 (3.47)
History of cigarette smoking, *n* (%)	4 (29%)	3 (25%)
Coughing, *n* (%)	4 (29%)	3 (25%)
Presence of comorbid conditions, *n* (%)		
History of COPD	6 (43%)	2 (17%)
Diabetes mellitus	2 (14%)	3 (25%)
SAS 1–2	12 (85%)	11 (92%)
SAS 3–4	2 (15%)	1 (8%)
Lung function tests in % predicted (SD):		
FEV_1	81.93 (20.00)	80.83 (20.20)
IVC	88.57 (15.97)	84.00 (18.60)
FEV_1/IVC	93.07 (11.12)	98.25 (12.98)
$P_i$max	64.60 (15.79)	66.80 (26.31)
Duration of surgery (min)	250 (84.93)	265 (53.40)
Length of hospital stay (days)	7.93 (1.94)	9.92 (5.78)

Values are means ± standard deviation (SD).
Score on the Hulzebos risk model: -4 up to -2 points = low risk, -1 up to 10 points = high risk. FEV_1, forced expiration volume in 1 s; IVC, inspiratory vital capacity; $P_i$max, maximal inspiratory pressure; COPD, chronic obstructive pulmonary disease; SAS, specific activity scale.

Intervention

Subjects in the intervention group trained daily at home, seven times a week, for at least two weeks before surgery. Each training session consisted of 20 min of inspiratory muscle training. One session a week was supervised by the same physical therapist (EH); the other six sessions were unsupervised. The subjects were instructed to keep a daily diary during the study and were trained to use an inspiratory threshold-loading device (Threshold IMT; PT Medical, Leek, the Netherlands). With this device, patients inspire against a threshold load whereas expiration is unimpeded. The inspiratory load is calibrated in cmH_2O and can be increased as required.[19,20] The subjects started breathing at a resistance equal to 30% of their maximal inspiratory pressure ($P_i$max), measured at baseline, for 20 min per day.[21] The resistance was increased incrementally based on the rate of perceived exertion (RPE) scored on the Borg scale.[22] If the RPE was < 5, the resistance of the inspiratory threshold trainer was increased incrementally by 2 cmH_2O.

Primary outcome measures

Variables to test the primary outcome measure, feasibility, included the occurrence of adverse effects during testing or training, participant satisfaction and motivation, compliance with therapy, and adequate use of the diary. During the intervention, the participants registered compliance and adverse events in programme diaries. Participant satisfaction and motivation were determined after the intervention by means of

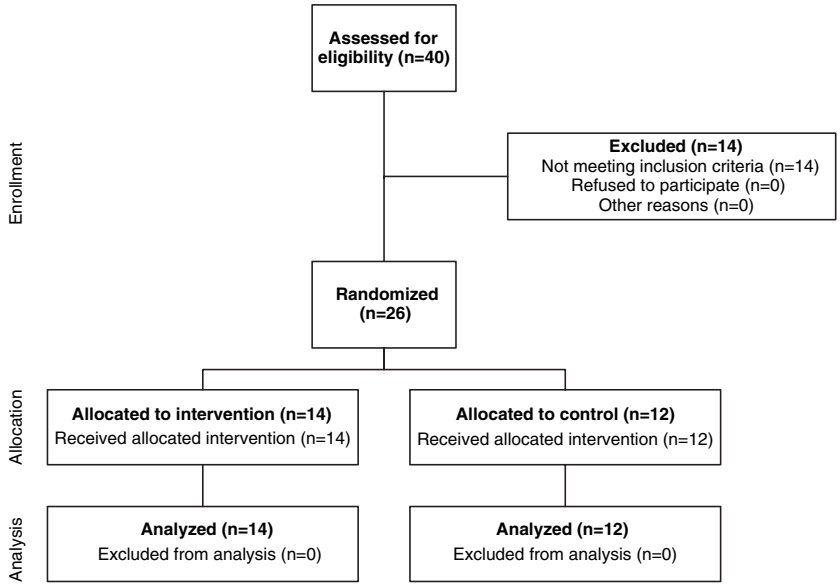

Figure 1 Study design.

an anonymously completed questionnaire (see Appendix).

To assess the cardiovascular stress of training, heart rate and blood pressure were recorded in five randomly selected patients just before, during (at 3-min intervals), and immediately after the training session, using the Nonin 2120 non-invasive blood pressure (NIBP) measurement device (PT Medical, Leek, the Netherlands). According to the manufacturer, the accuracy of the NIBP instrument is ± 3 mmHg with a standard deviation of 8 mmHg (http:/www.micromedical.co.uk/products).

To assess the effectiveness of inspiratory muscle training, inspiratory muscle strength, expressed as $P_i$max at residual volume, was measured with a hand-held pressure gauge (Micro Medical MPM; PT Medical, Leek, the Netherlands) as previously described by Black and Hyatt.[23] The $P_i$max is thought to mainly reflect the force of the diaphragm and is a useful variable to measure when respiratory muscle weakness is thought to cause a low lung volume or hypoventilation.[24–26] The respiratory muscle force test was standardized as described by Clanton and Diaz.[26] Normal values for $P_i$max were calculated from regression equations according to age and sex.[23,25] Eight measurements were recorded, with the criterion that the two highest values should not vary by more than 10%.[27] The highest values obtained after 1 s of maximum effort are reported.

Secondary outcome measures

The secondary outcome measure, effectiveness, was evaluated as the incidence of postoperative pulmonary complications and length of hospital stay. Lung function and functional status were assessed at baseline and one day before surgery by the same experienced examiner (BvdB), who was blinded for group assignment.

Postoperative pulmonary complications

Postoperative pulmonary complications were defined according to clinical (symptoms and physical examinations) and radiological criteria such as bronchitis, atelectasis and pneumonia (Table 2).[35] When there were only radiological alterations without clinical symptoms, the complications were considered to be subclinical.

Lung function tests

Forced vital capacity (FVC), forced expiratory volume in 1 s (FEV_1), and inspiratory vital capacity (IVC) were measured by spirometry (Micro-Loop; PT Medical, Leek, the Netherlands). Measurements were recorded with the patient in

Table 2 Definition of postoperative pulmonary complications[35]

Bronchitis	Chest X-ray: negative Temperature of $<37.5^{\circ}C$ Auscultation: rales Sputum abundant and clear
Atelectasis	Chest X-ray: collapse, diaphragmatic elevation Temperature of $<38^{\circ}C$ Auscultation: diminished or abolished vesicular murmur
Pneumonia	Chest X-ray: consolidation, pleurisy Temperature of $>38^{\circ}C$ (≥ 4 days) Auscultation: rales Sputum abundant and purulent

a sitting position, as described by the American Thoracic Society.[28] The highest IVC, FVC and FEV_1 measurements recorded in five consecutive attempts were used. Predicted values were calculated from regression equations according to age, height and sex.[29,30]

Functional status

Preoperative cardiac functional class was assessed by means of self-reported data for the performance of well-defined daily activities (e.g. walking, climbing stairs, bicycling, taking a shower, dressing), scored with the Specific Activity Scale (SAS).[31–33]

Rating of perceived exertion

The rating of perceived exertion (RPE) scale, or the Borg scale, is a category scale (CR-10) used in the assessment of inter- and intra-individual differences.[34]

Statistical analysis

Data were analysed with SPSS (version 12.0.2) statistical software (SPSS Inc., Chicago, IL, USA). Data were checked for completeness and for outliers, and the patient diaries were used to determine adverse events and compliance with inspiratory muscle training. Intention-to-treat analyses were used to compare outcomes between both groups. The Shapiro–Wilk goodness-of-fit test was used to check whether data were normally distributed. Summary descriptive statistics, including frequencies, means and standard deviations, were computed for the preoperative and perioperative variables. Descriptive assessments, not statistical analyses, were made of the primary outcome measures because only the intervention group completed the satisfaction questionnaire.

Paired sample *t*-test was used to compare inspiratory muscle strength and lung function at baseline and one day before the operation within the intervention and control groups. The independent-sample *t*-test was used to compare the inspiratory muscle strength and lung function at baseline and one day before the operation between the intervention and control groups, with significance set at $P = 0.05$. Effect size was determined as follows: Effect size = [mean inspiratory muscle strength score 1 day before the operation − mean inspiratory muscle strength baseline score]/pooled standard deviation. The analysis of the incidence of postoperative pulmonary complications according to whether or not inspiratory muscle training had been provided was carried out by the χ^2 test.

Results

Participants

Of 40 consecutive patients who were scheduled for elective coronary artery bypass graft surgery, 26 patients (65%) met the criteria for being at high risk of postoperative pulmonary complications, as assessed with the six-factor risk model.[17] The baseline characteristics of these 26 patients (13 men and 13 women), their risk model scores and perioperative data are given in Table 1. The patients were randomly assigned using a computer-generated randomized block design (block of four people) to the intervention group ($n = 14$) or the control group ($n = 12$). The mean (SD) age of the intervention group was 70.1 (9.9) years and that of the control group 70.5 (10.1) years. There were no statistical significance differences in perioperative baseline scores for body mass index, history of cigarette smoking, coughing, specific activity scale, history of chronic obstructive pulmonary disease, diabetes mellitus, pulmonary lung function, inspiratory muscle strength ($P_i$max), duration of surgery and length of hospital stay between the two groups.

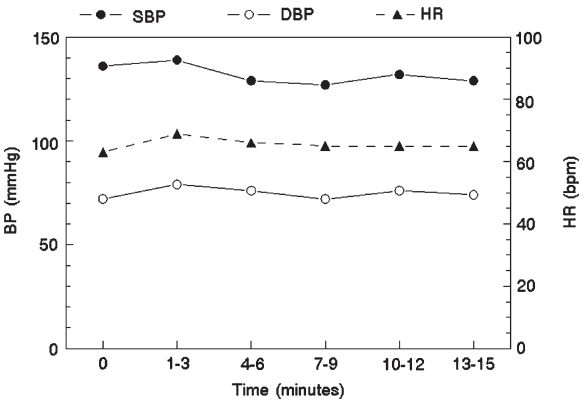

Figure 2 Mean heart rate and blood pressure response ($N = 5$) during a respiratory training session. SBP, systolic blood pressure; DBP, diastolic bood pressure; HR, heart rate.

Primary outcomes

The feasibility of the intervention was good. All participants reported their daily inspiratory muscle workout in the programme diaries and the rating of perceived exertion on the Borg scale. No participants dropped out and no adverse events were reported. No cardiovascular complications or side effects occurred during any testing or training session. The cardiovascular load during inspiratory muscle training was minimal because the mean heart rate and mean blood pressure did not increase in the five randomly selected 'test' patients during a 15-min inspiratory muscle training session (Figure 2). All participants in the intervention group returned the questionnaire–the mean (SD) scores for satisfaction and motivation on a 10-point scale were 7.9 (0.7) and 8.2 (1.0), respectively (see Appendix).

In the control group, the mean (SD) inspiratory muscle strength increased by 15% from 66.8 (26.3) cmH_2O to 76.83 (27.9) cmH_2O ($P = 0.18$) (Table 3a). In the intervention group, the inspiratory muscle strength increased by 36%, from 64.6 (15.8) cmH_2O at baseline to 87.6 (29.1) cmH_2O at the end of the training period and one day before surgery ($P = 0.001$) (Table 3b). The effect size (ES) between the intervention group and control group one day before surgery was medium (ES = 0.38; 95% confidence interval (CI) −0.39 to 1.15). During the training period, the participants increased the inspiratory threshold load without a greater perceived exertion (Figure 3). Only one patient could not increase her inspiratory threshold load because of dyspnoea (RPE = 6–7): this patient trained two weeks with a constant workload of 30% $P_i$max for 20 min.

Secondary outcomes

Lung function (IVC, FVC and FEV_1) remained almost unchanged at the end of the training period and before operation in both groups (Table 3a,b).

In addition to the postoperative pulmonary complications, one patient in the control group and one patient in the intervention group developed pneumonia. The postoperative X-rays revealed alterations in 19 of the 26 (73%) cases. Eleven (six patients in the intervention group and five patients in the control group) of the pathological images (e.g. pleural effusion), however, were of no clinical significance. However, segmental atelectasis was seen in six patients in the control group and in two patients in the intervention group and this was statistical significantly ($\chi^2_{DF1} = 3.85$; $P = 0.05$).

Table 3a Pulmonary functions at baseline and one day before surgery in the control group

Pulmonary function tests (SD)	Control group ($N = 12$)		Paired *t*-test significance (2-tailed)	95% CI
	Baseline	Pre-op		
FEV_1 % predicted	80.8 (20.2)	80.9 (20.3)	0.97	−5.23 to 5.06
IVC % predicted	84.0 (18.6)	87.4 (17.8)	0.20	−8.95 to 2.12
FEV_1/IVC % predicted	98.3 (12.9)	94.7 (17.6)	0.21	−2.40 to 9.56
$P_i$max cmH_2O	−66.8 (26.3)	−76.8 (27.9)	0.18	−25.40 to 5.36

FEV_1, forced expiration volume in 1 s; IVC, inspiratory vital capacity; $P_i$max, maximal inspiratory pressure; SD, standard deviation; CI, confidence interval of the difference; pre-op, preoperative.

Table 3b Pulmonary functions at baseline and one day before surgery in the intervention group

Pulmonary function tests (SD)	Intervention group ($N = 14$)		Paired *t*-test significance (2-tailed)	95% CI
	Baseline	Pre-op		
FEV_1 % predicted	81.9 (20.0)	80.7 (20.6)	0.13	−0.93 to 6.16
IVC % predicted	88.6 (16.0)	87.3 (18.1)	0.45	−2.30 to 4.91
FEV_1/IVC % predicted	93.1 (11.1)	93.0 (9.6)	0.38	−2.31 to 5.70
$P_i$max cmH_2O	−64.6 (15.8)	−87.6 (29.1)	*0.00	−32.18 to −11.13

FEV_1, forced expiration volume in 1 s; IVC, inspiratory vital capacity; $P_i$max, maximal inspiratory pressure; SD, standard deviation; CI, confidence interval of the difference; Pre-op, preoperative.
*$P < 0.05$.

Discussion

Inspiratory muscle training for 2–4 weeks before coronary artery bypass graft surgery seems feasible as it is well tolerated and appreciated by patients who are at high risk of developing postoperative pulmonary complications. Moreover, inspiratory muscle training significantly improves inspiratory muscle strength (increase of 36%) in the preoperative period and seems to prevent postoperative atelectasis.

Although there was no statistically significant difference in inspiratory muscle strength between the control group and the intervention group, the difference in effect sizes between the two groups suggests that a significant effect may be detected if more patients at high risk of developing postoperative pulmonary complications are studied. The increase in the inspiratory muscle strength after inspiratory muscle training is in line with the results of the study of Weiner *et al.*, which involved patients at lower risk of developing postoperative pulmonary complications,[10] and with the results of studies involving healthy people.[36–38] Lötters *et al.* had previously demonstrated that patients with inspiratory muscle weakness ($P_i$max ≤ 60 cmH_2O) benefited more from inspiratory muscle training than patients without inspiratory muscle weakness.[20] Although it could be argued that the length of the training period, which in our pilot study was on average three weeks, with a minimum of two weeks, was too short. Weiner *et al.*[10] and Nomori *et al.*[39] have demonstrated that inspiratory muscle training for two weeks before surgery increased inspiratory muscle strength. The 16% improvement in inspiratory muscle strength seen in the control group in our study suggests that the measurement technique when applied repeatedly also has an effect, which might be attributed to neuropsychological adaptations, in this case, the respiratory muscles during the test manoeuvres.[40]

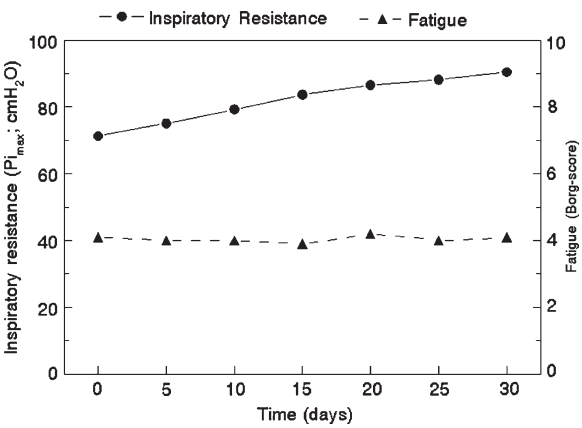

Figure 3 Mean Borg score and inspiratory resistance during the training period ($N = 14$).

It is well known that dysfunction of the respiratory muscles due to surgery may lead to a reduction in vital capacity, tidal volume and total lung capacity and, thus, insufficient cough.[11] This may cause atelectasis in the basal lung segments and a decrease in functional residual capacity which, in turn, affects gas exchange properties of the lung by increasing the ventilation/perfusion mismatch.[16] This may be further aggravated by hypoventilation due to several factors including sedation, pain and increased mechanical load. As a result, hypoxia may ensue, with a detrimental effect on the condition of the patient. In addition, atelectasis may be a risk factor for pulmonary infections, which have

Clinical messages

- Inspiratory muscle training is feasible, safe and well tolerated by patients at high risk of developing postoperative pulmonary complications.
- Preoperative inspiratory muscle training significantly improves inspiratory muscle strength and seems to have an prophylactic effect against postoperative pulmonary complications.

significant morbidity and mortality in this patient population.[41] The preoperative inspiratory muscle training in this study is meant to improve respiratory function after surgery, and thereby to reduce the incidence of postoperative pulmonary complications such as atelectasis and the more serious events such as pneumonia and bronchitis. The significantly lower incidence of atelectasis in the intervention group in this small study with relatively low statistical power was unexpected but demonstrates the potential effectiveness of inspiratory muscle training in reducing postoperative pulmonary complications. It is possible that inspiratory muscle training shortens the stay in hospital as fewer patients develop atelectasis. In this study, the stay in hospital was on average two days shorter in the intervention group, a difference that was clinically relevant but not statistically significant ($P = 0.24$) and may have been caused by chance. A larger study should shed light on this matter.

One of the main benefits of a pilot trial is that practical problems (such as participant instructions or registration of performance in a personal file) and methodological issues (such as randomization and measurements) can be identified and resolved.[18] The satisfaction questionnaire provided insight into how patients at high risk of postoperative pulmonary complications experienced the intervention and made it possible to optimize the inspiratory muscle-training programme. The good results obtained in this pilot study, in terms of effectiveness, acceptance and compliance, and the lack of side effects warrant further study of the inspiratory muscle training programme in a larger randomized clinical trial. Before starting such a trial, we decided to adapt the inspiratory muscle training programme slightly on the basis of recent publications by Davids *et al.*,[42] who reported on variability as a component of training, and Eastwood *et al.*,[43] who reported on motor learning matters in inspiratory loading. Accordingly, in our next study patients will be instructed to train in a number of different body positions and motions, that is, in both the supine and prone position, seated as well as standing, and also while walking or, if tolerated by the patient climbing stairs, etc. We also intend to ask patients during preoperative inspiratory muscle training to image the postoperative conditions,[44] in order to increase the carry-over and sustain the preoperative training effects postoperatively.

The results obtained in this pilot study justify a larger randomized clinical trial. Such a study is currently in progress.

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Competing interests

None declared.

Contributors

Erik HJ Hulzebos: writing the paper, initiating the study, designing the study.
Nico LU van Meeteren: writing the paper, initiating the study, guarantor, monitoring progress.
Bram JWM van den Buijs: initiating the study, designing the study.
Rob A de Bie: deciding on the analytic strategy,
Brutel de la Rivière: monitoring progress.
Paul JM Helders: monitoring progress.

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Appendix – Patient evaluation of the inspiratory muscle training (IMT) programme

1) What is your overall opinion of the exercise programme?	
Fairly good	0 (0%)
Good	11 (79%)
Very good	3 (21%)
2) How would you qualify the intensity of the inspiratory muscle training?	
Light	2 (14%)
Ideal	10 (72%)
Heavy	2 (14%)
3) How would you qualify the duration of the intervention?	
Short	0 (0%)
Ideal	11 (79%)
To long	3 (21%)
4) How would you qualify the supervision given by the physical therapist?	
Not so good	0 (0%)
Good	4 (29%)
Very good	10 (71%)
5) How motivated were you?	
Considered quitting	0 (0%)
Motivated	2 (14%)
Very motivated	12 (86%)
6) Did you experience an exercise effect?	
Yes	12 (86%)
I don't known	2 (14%)
No	0 (0%)
7) How would you qualify the overall organization?	
Bad	0 (0%)
Good	5 (36%)
Very good	9 (64%)
8) Would you participate again in a preoperative IMT programme?	
Yes	12 (86%)
No	2 (14%)
9) How would you rate the IMT programme on a scale from 1 to 10 (1 = very bad, 10 = excellent)? (mean ± SD)	8.3 (±1.3)
10) How would you rate your satisfaction of the IMT programme on a scale from 1 to 10 (1 = very bad, 10 = excellent)? (mean ± SD)	7.9 (±0.7)
11) How would you rate your motivation for preoperative IMT on a scale from 1 to 10 (1 = very bad, 10 = excellent)? (mean ± SD)	8.2 (±1.0)