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Prevention of pulmonary complications after upper abdominal surgery by preoperative intensive inspiratory muscle training: a randomized controlled pilot study

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ABSTRACT

Objective: To investigate the feasibility and effects of preoperative inspiratory muscle training on the incidence of atelectasis in patients at high risk of postoperative pulmonary complications scheduled for elective abdominal aortic aneurysm surgery.

Design: Single-blind randomized controlled pilot study.

Setting: Gelderse Vallei Hospital Ede, the Netherlands.

Subjects: Twenty high-risk patients undergoing elective abdominal aortic aneurysm surgery were randomly assigned to receive preoperative inspiratory muscle training or usual care.

Main measures: Effectiveness outcome variables were atelectasis, inspiratory muscle strength and vital capacity, and feasibility outcome variables were adverse effects and patient satisfaction with inspiratory muscle training.

Results: Despite randomization, patients in the intervention group were significantly older than the patients in the control group (70 ± 6 years versus 59 ± 6 years, respectively; p=0.001). Eight patients in the control group and three in the intervention group developed atelectasis (p=0.07). The median duration of atelectasis was 0 days in the intervention group and 1.5 days in the control group (p=0.07). No adverse effects of preoperative inspiratory muscle training were observed and patients considered that inspiratory muscle training was a good preparation for surgery. Mean postoperative inspiratory pressure was 10% higher in the intervention group.

Conclusion: Preoperative inspiratory muscle training is well tolerated and appreciated and seems to reduce the incidence of atelectasis in patients scheduled for elective abdominal aortic aneurysm surgery.

INTRODUCTION

The incidence of clinically relevant postoperative pulmonary complications after upper abdominal surgery varies from 5% to 30%, depending on their definition and the type of surgery.[1-5]

Postoperative pulmonary complications are the leading cause of postoperative morbidity and mortality and increase hospital length of stay, medical consumption, and hence costs.[1,6-8] Consequently, it is imperative, both for patients and society, to prevent postoperative pulmonary complications. Physical therapy appears to be effective as postoperative treatment[9-13] and may lower the incidence of postoperative pulmonary complications when given preoperatively, as suggested and demonstrated by Weiner et al.[14] and Nomori et al.[15] in fragile, high-risk patients. Recently, Hulzebos et al.[16,17] showed preoperative physical therapy to be effective in high-risk patients who underwent a coronary artery bypass procedure. The question is whether preoperative physical therapy prevents the postoperative pulmonary complications that occur in high-risk patients after other types of surgery, such as elective upper abdominal surgery. As in thoracic surgery, but based on a distinct physiological mechanism,[18] upper abdominal surgery also induces a sharp postoperative decrease in respiratory function, a decrease which can lead to the development of postoperative pulmonary complications.[19]

The aim of this pilot study was twofold: (a) to investigate the effects of preoperative inspiratory muscle training on the incidence of atelectasis in patients at high risk of postoperative pulmonary complications scheduled for elective abdominal aortic aneurysm surgery, and (b) to assess the feasibility of preoperative inspiratory muscle training.

PATIENTS AND METHODS

Patients

Twenty high-risk patients were recruited from the surgery outpatient department of the Gelderse Vallei Hospital in Ede, the Netherlands. The primary inclusion criteria were elective surgery for aneurysm of the abdominal aorta with a scheduled delay until surgery of at least two weeks, and at least one of the following risk factors: age >65 years, smoking less than two months before surgery, chronic obstructive pulmonary disease (COPD), and overweight (body mass index (BMI) >27 kg/m^2).[20-22] Eligible patients also had to be proficient in Dutch and able to perform a valid spirometry test. Exclusion criteria were cerebrovascular disorders, immunosuppressive treatment <30 days before the operation, neuromuscular diseases, lung surgery in the medical history, cardiovascular instability, and treatment by a physical therapist within eight weeks before elective abdominal aortic aneurysm surgery. Signed informed consent forms were collected from all patients, and the protocol was approved by the medical ethics committee of the University Medical Center Utrecht and of the Gelderse Vallei Hospital, the Netherlands.

Procedure

In this single-blind randomized controlled trial, the patients were referred from the surgery outpatient department of the Gelderse Vallei hospital. After inclusion, the informed consent procedure, and evaluation of baseline characteristics, an independent research assistant randomly assigned the patients to the intervention group (n=10) or the control group (n=10) by opening a sealed and numbered envelope (Figure 5.1). The patients in the intervention and the control groups entered the study at least 2–4 weeks before surgery. After the baseline assessment, the patients in the intervention group started the intervention under the guidance of an experienced physical therapist; the patients in the control group received care as usual. All patients were seen the day before surgery, and all patients received usual postoperative care. The main postoperative outcome was atelectasis as diagnosed at the base of X-rays by a blinded radiologist.

Intervention

The intervention group took part in a training programme (six sessions, six days a week for at least two weeks before surgery) designed to increase the strength and endurance of the inspiratory muscles.[14,15] Each session consisted of 15 minutes of inspiratory muscle training; one session/week was supervised by the same physical therapist and the other five 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 Inspiratory Muscle Training; Respironics, Pittsburgh, PA, USA). 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. The subjects started breathing at a resistance equal to 20% of their maximal inspiratory pressure (MIP), measured at baseline, for 15 minutes a day.[23] The resistance was increased incrementally, based on the rate of perceived exertion (RPE) scored by the patient on the Borg Scale. If the RPE was <5, the resistance of the inspiratory threshold trainer was increased incrementally by $2cmH_2O$.

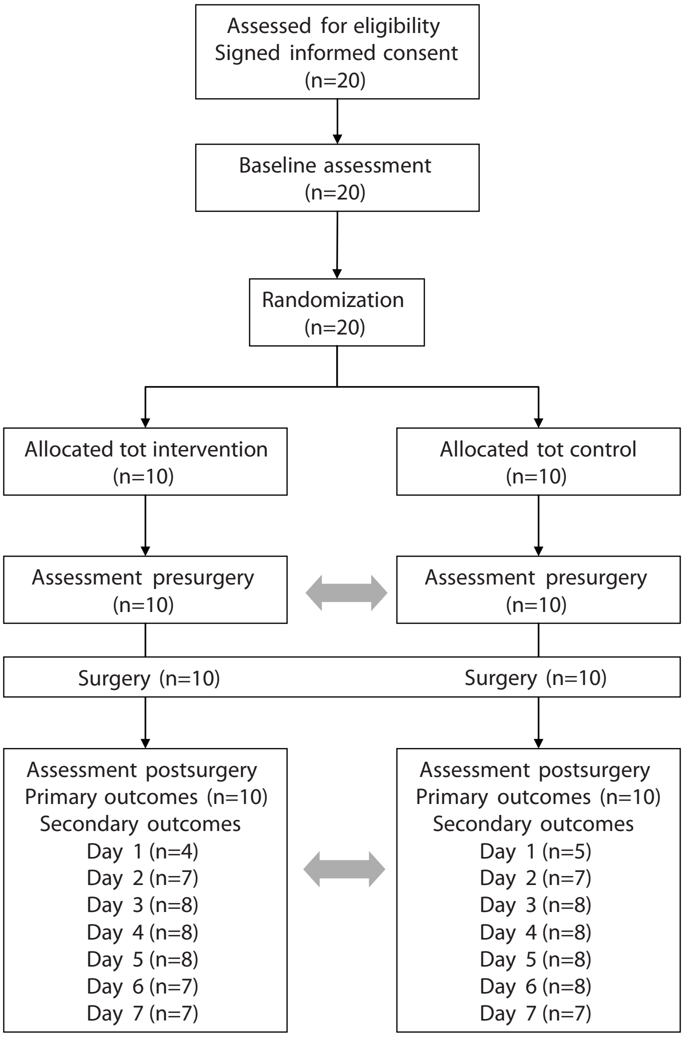

Figure 5.1 Flowchart of the study.

Usual care

In the preoperative period the control and the experimental groups received care as usual, consisting of instruction in (a) diaphragmatic breathing,[24-26] (b) deep inspirations with the aid of incentive spirometer,[1,10-13,27-29] and (c) coughing and 'forced expiration techniques' (FET).[11,13,27] The control group received this usual care one day before surgery, and the intervention group 2–3 weeks before surgery during the intervention.

Postoperative physical therapy interventions (for both groups) consisted of stimulating deep inspirations (partly with the aid of the incentive spirometer), diaphragmatic inspiration, FET and coughing. Furthermore, patients were encouraged to sit rather than lie and early mobilization was stimulated, which has a positive effect on functional residual capacity (FRC).[30]

Measurements

The main outcome measure was postoperative pulmonary complications, operationalized as atelectasis, which is considered a 'precursor' of more clinically relevant postoperative pulmonary complications.[19] A blinded radiologist evaluated radiographs of the lung base for the presence of atelectasis.

Feasibility was evaluated as the occurrence of adverse effects during testing or training and patient satisfaction. During the intervention, the participants registered adverse events in their daily diaries. Participant satisfaction was determined two weeks after discharge from hospital by means of a questionnaire (see Table 5.2).

Secondary outcome measures were postoperative respiratory function determined by MIP, inspiratory muscle endurance, and the inspiratory vital capacity (VC). Inspiratory muscle strength, expressed as MIP at residual volume, was assessed with a hand-held respiratory pressure meter (MicroMPM; MicroMedical, Rochester, UK). The MIP is thought to mainly reflect the inspiratory muscle force.[31] The respiratory muscle force tests were standardized as described in ATS/ERS Statement on Respiratory Muscle Testing.[31] The highest 1-second averages recorded in five consecutive attempts are reported. Inspiratory muscle endurance was assessed with incremental threshold loading.[32] Starting at 30% of the MIP, resistance was increased incrementally every 2 minutes by 10% of the MIP. Endurance is expressed as the highest resistance (in cmH_2O) that could be sustained for 2 minutes without interruption of inspiration. The inspiratory vital capacity (IVC) was measured with a portable spirometer (SpiroPro; Sensor Medics, Bilthoven, The Netherlands) with the patient in a sitting position, as described by the American Thoracic Society.[33] The highest values measured in three consecutive attempts are reported.

Data analysis

Data were analysed with SPSS version 10.1 statistical software (SPSS Inc., Chicago, IL, USA). All collected data were checked for completeness and normality. Intention-to-treat analyses were used to compare the preoperative outcomes and the incidence of atelectasis between the two groups. The incidence and prevalence of atelectasis was analysed with the Fisher exact test and the Mann–Whitney U-test, respectively. Patient satisfaction with inspiratory muscle training training was recorded in a frequency table. Differences in the preoperative MIP and inspiratory muscle endurance within and between the intervention and the control groups were tested with the paired and independent t-tests, respectively. Postoperative MIP and IVC were analysed by repeated measures analysis of variance with treatment as the between-subject factor.

RESULTS

The baseline characteristics of the 20 patients are listed in Table 5.1. The patients in the intervention group were significantly older than the patients in the control group (70

Table 5.1 Baseline characteristics of the patients

	Control N=10	Intervention N=10
Women / men	7/3	8/2
Age in years (SD)	59 (6)	70 (6)*
MIP in cmH_2O (SD)	83 (15)	68 (19)
IM endurance in cmH_2O (SD)	39 (10)	32 (8)
Smokers (number of patients)	6	6
COPD (number of patients)	1	1
BMI (kg/m^2)	25	26
Coughing (number of patients)	4	3
Rand 36 (physical dimension)	74 (19)	77 (20)
IVC (litres)	3.1 (1.0)	3.1 (0.7)
Surgery duration (hours)	2.9 (1)	3.3 (1.7)

* significant difference (p=0.001) between control and intervention group. MIP, maximal inspiratory pressure; IM, inspiratory muscle, COPD, chronic obstructive pulmonary disease; BMI, body mass index; IVC, inspiratory vital capacity.

± 6 years versus 59 ± 6 years, respectively; p=0.001). Two patients in the control group dropped out because they were not registered at the department of physical therapy when they were admitted to hospital and thus follow-up was not possible. Two patients in the intervention group could not be followed up during the first seven days after surgery because of acute reoperation for blood vessel occlusion in the leg. One of these two patients developed sepsis and renal insufficiency and died 35 days after surgery.

Atelectasis

Eight patients in the control group and three patients in the intervention group developed atelectasis (Fisher exact test p=0.07). Atelectasis was evident on radiographs for a median of 0 days in the intervention group and 1.5 days in the control group (Mann–Whitney U-test p=0.07).

Patient satisfaction

Eight participants in the intervention group returned the questionnaire two weeks after discharge from hospital and indicated they were motivated to complete the preoperative intervention and that it prepared them for surgery (Table 5.2). All participants reported their daily inspiratory muscle training workout in their diaries. No participants dropped out and no adverse events were reported.

Table 5.2 Patient appreciation of treatment (n=8)

	Disagree				Agree
	1	2	3	4	5
The aim of the treatment was clear to me				*	*******
I was motivated to complete treatment				**	******
The home work exercises took a lot of time	***	*	**	**	
During the exercises, the perceived exertion was high	*	*	***	**	
I exercised with pleasure				**	******
I benefited from the once-weekly supervision				**	******
I think the treatment prepared me well for the operation			*	*	******

Respiratory function

Before surgery, the mean MIP increased from 68 ± 19 cmH_2O to 72 ± 22 cmH_2O (paired t-test p=0.32) at the end of the preoperative training period in the intervention group; over the same period the mean MIP decreased from 83 ± 15 cmH_2O to 80 ± 24 cmH_2O in the control group (paired t-test p=0.60). There was no significant difference between the groups (independent t-test p=0.29). Before surgery, mean inspiratory muscle endurance increased from 32 ± 8 to 43 ± 14 cmH_2O (paired t-test p=0.05) after training in the intervention group and from 39 ± 10 to 43 ± 9 cmH_2O (paired t-test p=0.36) in the control group over the same period. There was no significant difference between the intervention and control groups (independent t-test p=0.12). ANCOVA analysis showed that the length of the training did not significantly affect the change in MIP (p=0.97) and inspiratory muscle endurance (p=0.76).

MIP and IVC values on postoperative days 1 to 7 were higher in the control group than in the intervention group (Table 5.3), but these differences were not statistically significant

Table 5.3 Mean maximal inspiratory pressure (MIP) and inspiratory vital capacity (IVC) (SD) in intervention and control groups in the first seven postoperative days

	Postoperative day						
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
MIP							
Intervention group							
Number of patients that could be measured	2	7	8	8	8	7	7
MIP	42 (1)	42 (5)	47 (6)	50 (7)	54 (10)	53 (13)	55 (14)
Control group							
Number of patients that could be measured	4	7	8	8	8	8	7
MIP	39 (8)	49 (14)	56 (17)	57 (18)	64 (21)	66 (20)	67 (16)
IVC							
Intervention group							
Number of patients that could be measured	4	8	8	8	7	6	7
IVC	1.5 (0.6)	1.5 (0.6)	1.7 (0.6)	2.1 (0.7)	2.1 (0.7)	2.1 (0.3)	2.3 (0.4)
Control group							
Number of patients that could be measured	5	6	6	6	6	6	5
IVC	1.5 (0.3)	1.8 (0.5)	2.2 (0.8)	2.3 (0.7)	2.4 (0.8)	2.6 (0.9)	2.9 (0.8)

(repeated measures analysis of variance p=0.42 and p=0.73, respectively). Because the baseline MIP was different between the two groups, the postoperative MIP was also expressed as the percentage of the MIP at baseline (Figure 5.2). When calculated in this way, the mean postoperative MIP was 10% higher in the intervention group but this difference was not statistically significant (repeated measures analysis for the first five days, p=0.36). In the intervention group, the MIP decreased on day 6 after surgery, which was when patients were discharged.

DISCUSSION

This study fits the present-day development of preventive health care methods.[34-36] In conclusion, the clinical message of this study is that (a) inspiratory muscle training is both well tolerated and appreciated by patients who have to undergo elective abdominal aortic aneurysm surgery and (b) inspiratory muscle training seems to reduce the incidence of postoperative atelectasis in this patient group. The results indicated that, after surgery, inspiratory muscle function recovered faster in the patients in the intervention group; however, this improvement appeared not to affect the postoperative inspiratory vital capacity.

Patient-centred care is a focus of many health care systems.[37] Patients evaluated the care provided by the physical therapist by completing a satisfaction questionnaire. Results

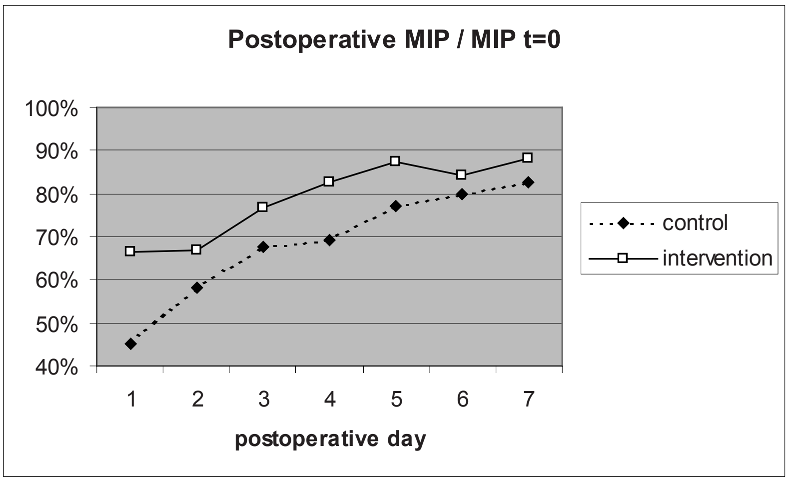

Figure 5.2 Age-corrected postoperative maximal inspiratory pressure (MIP) expressed as the percentage of the MIP measured before surgery (at the beginning of the intervention).

showed that acceptance of and compliance with inspiratory muscle training were high and there were no side-effects. The statement 'I think the treatment prepared me well for the operation' in particular received high (positive) scores.

The baseline characteristics of the two groups were not comparable, as the patients in the intervention group were significantly older than those in the control group. Because age is associated with both maximal inspiratory pressure[32,38] and the risk of a postoperative pulmonary complication,[19,39,40] we calculated individual postoperative maximal inspiratory pressure values as a percentage of the preoperative maximal inspiratory pressure; however, it is not possible to adjust the incidence of postoperative pulmonary complications for age in this way, and so the effect of preoperative inspiratory muscle training in terms of a diminished occurrence of atelectasis is probably underestimated. The inequality between the groups can be explained by the small number of patients included in the study. This also means the results should be evaluated with caution.

Despite the relatively small groups, we found a nearly significant ($p=0.07$) reduction in atelectasis in the intervention group compared with the control group. Atelectasis is considered to be a subclinical sign and may predispose a patient to more clinically relevant postoperative pulmonary complications such as pneumonia.[19] In particular, atelectasis occurring from the second postoperative day onward is considered to affect the oxygenation of blood and mucus transport.[1] Thus the lower incidence of atelectasis is relevant and is consistent with earlier results.[14,19] Although previous studies have shown inspiratory muscle training to increase inspiratory muscle strength and endurance,[23,41] the training period lasted several months whereas the preoperative training period was only 2–4 weeks. We found that preoperative inspiratory muscle training increased inspiratory muscle strength and endurance, although this effect was not statistically significant because of the small group size. Nomori et al.,[15] Weiner et al.[14] and Hulzebos et al.[17] reported significant differences in their larger studies. Indeed, all studies with large numbers of patients have found short-term preoperative inspiratory muscle training to increase inspiratory muscle strength and endurance (Table 5.4).

Studies involving more patients are needed to determine whether preoperative inspiratory muscle training has a positive effect on other postoperative complications such as pneumonia. Assuming an effect size of 0.20 (conservative estimate) and a power of 0.80, in total 196 subjects would be needed to reveal an effect on the incidence of more relevant postoperative pulmonary complications.

Table 5.4 Studies that investigated the effect of preoperative short-term inspiratory muscle training (IMT) on maximal inspiratory pressure (MIP) and inspiratory muscle (IM) endurance

Study	N	Mean age (years)	Training period (weeks)		MIP	Endurance IM
Nomori et al.[15]	50	55	Range	2-4	↑ *	↑ *
Weiner et al.[14]	84	59	Range	1-3	↑ *	-
Hulzebos et al.[16]	26	70	Range	2-4	↑	-
Hulzebos et al.[17]	251	66	Mean	4 (2–13)	↑ *	↑ *
This study	20	70	Mean	7 (2–16)	↑	↑

* Significant $p<0.05$.

Clinical messages

- Postoperative pulmonary complications are common and a major cause of morbidity and mortality after aortic aneurysm surgery.
- Preoperative insipiratory muscle training is both well tolerated and appreciated by patients and seems to reduce the incidence of postoperative atelectasis in this patient group.

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