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## **Preoperative exercise program for elderly patients scheduled for elective abdominal oncological surgery: a randomized controlled pilot study**

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## ABSTRACT

**Objective:** Investigation of the feasibility and preliminary effect of a preoperative short-term intensive exercise program for elderly patients scheduled for elective abdominal oncological surgery.

**Design:** Single-blind randomized controlled pilot study.

**Setting:** Ordinary hospital in the Netherlands.

**Subjects:** Forty-two elderly patients (>60 year).

**Interventions:** Patients were randomly assigned to receive a short-term intensive therapeutic exercise program to improve muscle strength, aerobic capacity, and functional activities, given in the outpatient department (intervention group; N=22), or home-based exercise advice (control group; N=20).

**Main measures:** Parameters of feasibility, preoperative functional capacity, and postoperative course.

**Results:** The intensive training program was feasible, with a high compliance and no adverse events. Respiratory muscle endurance increased in the preoperative period from  $259\pm 273$  to  $404\pm 349$  Joule in the intervention group and differed significantly from that in the control group ( $350\pm 299$  to  $305\pm 323$  Joule;  $p<0.01$ ). 'Timed up and go', Chair Rise Time, LASA Physical Activity Questionnaire, Physical Work Capacity, and Quality of Life (EORTC-C30) did not reveal significant differences between the two groups. There was no significant difference in postoperative complications and length of hospital stay between the two groups.

**Conclusion:** The intensive therapeutic exercise program was feasible and improved the respiratory function of patients due to undergo elective abdominal surgery compared to a home-based exercise advice.

## INTRODUCTION

About 35% of patients experience postoperative complications after major abdominal surgery, including 9% postoperative pulmonary complications (defined as pneumonia and respiratory failure). The overall 30-day mortality rate is 10%.<sup>1,2</sup> Preoperative physical capacity is an important predictor of the postoperative course.<sup>3-8</sup> Because the physical capacity of elderly patients is often diminished due to a lack of regular physical activity, and especially prior to surgery,<sup>9-12</sup> improvement of their functional capacity may make them better prepared for hospital admission and facilitate recovery after surgery.<sup>13</sup>

Long-term training appears to be beneficial to elderly individuals<sup>14,15</sup>; however, the time available for training before elective surgery is often limited, and especially so with oncological surgery. Little research is available about the effect of short-term training in the preoperative period. Hulzebos et al. recently showed short-term preoperative inspiratory muscle training to be effective in increasing inspiratory muscle strength and reducing the incidence of postoperative pulmonary complications in high-risk patients who underwent a coronary artery bypass procedure.<sup>16</sup> A pilot study revealed potentially similar effects in elective abdominal aortic aneurysm surgery.<sup>17</sup> The primary aim of this pilot study is to investigate the feasibility of a short-term intensive therapeutic exercise program for elderly patients (>60 years) scheduled for elective abdominal oncological surgery and its effects on muscle strength, aerobic capacity, and functional activities. A secondary objective is to investigate whether such a program affects the incidence of postoperative complications and postoperative functional recovery.

## METHODS

The study design was a single-blind pilot randomized controlled trial.

Patients were recruited from the Departments of Gastroenterology and Surgery of the Gelderse Vallei Hospital in Ede, an ordinary hospital in the Netherlands. Inclusion criteria were elective colon surgery (waiting period minimally two weeks and first surgical intervention for this pathology), age  $\geq 60$  years, and adequate cognitive functioning (a good understanding and accurate execution of instructions). Exclusion criteria were heart disease that prohibits or impedes exercise, severe systemic illness, recent embolism, thrombophlebitis, uncontrolled diabetes (fasting blood glucose of  $>400$ mg/dl), severe orthopedic conditions that prohibit or impede exercise, and wheelchair dependence.

The protocol was approved by the Medical Ethics Committees of both the University Medical Center Utrecht and the Gelderse Vallei Hospital Ede, both in the Netherlands.

All patients referred for preoperative physical therapy by the gastroenterologist or the surgeon went to the outpatient department of physical therapy, as part of the multidisciplinary preoperative work-up. Patient inclusion and exclusion criteria were checked, and patients were informed about the aims of the study and asked for their informed consent. After their functional status was evaluated (T=0), participants were randomly assigned (block randomization) using prepared envelopes, after stratification by age (60–70 years and age >70 years), to two treatment groups by two people not associated with the study. The patients allocated to the intervention group received a short-term intensive therapeutic exercise program in the outpatient department and the control group received a home-based exercise advice. The physical therapists and patients were not blinded to treatment assignment. Preoperative outcome measures (T=1) and the postoperative course (T=2) were assessed by an investigator who was unaware of the treatment allocation until after data analysis was completed.

## **Intervention**

The subjects in the intervention group trained twice a week in the outpatient department of physical therapy of the Gelderse Vallei Hospital while waiting for surgery (2–4 weeks). The patients in the intervention group were informed about the importance of their physical condition to the postoperative course and were encouraged to adhere to the training program.

Each supervised training session lasted 60 minutes and included the following elements.

- Warm-up.<sup>18</sup>
- Resistance training of the lower limb extensors (with a maximum of 1 set of 8–15 RM, consistent with 60–80% of the 1-Repetition Maximum<sup>18–21</sup>).
- Inspiratory muscle training. Patients breathed against a variable resistance (10–60% of the maximal inspiratory pressure) for about 15 minutes (240 breathing cycles).
- Aerobic training. The subject trained at a moderate intensity of exercise (to 55–75% of maximal heart rate) or perceived exertion (between 11 and 13 on the Borg scale<sup>18,20,22</sup>; Aerobic training lasted 20–30 minutes to obtain optimal benefit.<sup>18</sup>

- Training functional activities according to the patients' capabilities and interest. This is essentially according to the regimen of de Vreede et al.<sup>14</sup>
- Cooling down.<sup>18</sup>

When not training in the outpatient department, subjects followed a home-based training program. This program prescribed walking (patients received a pedometer to monitor this activity) or cycling for a minimum of 30 minutes per day.<sup>18</sup> The intensity was determined on the basis of the perceived exertion (Borg scale score between 11 and 13). Subjects were supplied with a device for inspiratory muscle training, a threshold loading device. The threshold loading device was adjusted to a resistance equal to 20% of the maximal inspiratory pressure, measured at baseline, and subjects trained with the threshold loading device for 15 minutes per day. The resistance was increased incrementally based on the perceived exertion: if perceived exertion was <13, the resistance of the inspiratory threshold trainer was increased incrementally by 10% of the maximal inspiratory pressure.

The control subjects received home-based exercise advice. They were told of the importance of their physical condition to the postoperative course and were encouraged to be active for minimally 30 minutes a day in the period prior to hospital admission. They received a pedometer to monitor their activities. Once a week the pedometers were read out in the outpatient department by the therapist.

Both groups received instruction in (a) diaphragmatic breathing, (b) deep inspirations with the aid of incentive spirometry, and (c) coughing and "forced expiration techniques".<sup>23,24</sup>

## Measurements

Demographics, preoperative risk factors, and measures of functional capacity and self-reported activities were prospectively recorded. Hand grip strength, a reliable measurement<sup>25</sup> and known to be an indicator of skeletal muscle mass and a predictor of the risk of postoperative complications,<sup>26,27</sup> was measured with a DigiMax hand force device (Mechatronics).

Feasibility was determined on the basis of (a) adherence to treatment/advice, (b) patient appreciation of the treatment/advice, recorded at the end of the preoperative period, and (c) adverse events.

Maximal aerobic capacity was determined with Physical Work Capacity 170.<sup>28</sup> Strength and power of the lower limb muscles was estimated by the chair rise time test.<sup>25,29,30</sup> MIP

reflects inspiratory muscle force and was assessed with the MicroRPM (MicroMedical).<sup>31,32</sup> Inspiratory muscle endurance was measured with the MicroRMA (Mircomedical), which calculated the total energy expended against a load. Functional mobility was measured with the Timed “Up & Go” test, a reliable and valid test of functional mobility.<sup>33</sup>

Self-reported activities were measured with the LASA Physical Activity Questionnaire, in which patients report their activities of the past 14 days.<sup>34</sup> Walking time was measured with a pedometer with a 7-day memory (New Life Styles NL1000).<sup>35</sup> Quality of life was assessed with the EORTC Quality of Life Questionnaire (EORTC QLQ-C30/version 3) designed for patients with cancer.<sup>36</sup> Fatigue was measured with the abbreviated fatigue questionnaire (AFQ).<sup>37</sup>

Postoperative complications were registered according to the hospital registration system. Data about oxygen suppletion, saturation, fever, pain medication, sputum retention, coughing, and patient mobilization were collected on a postoperative registration form. Postoperative pulmonary complications were classified as hypoxia (defined as need for additional oxygen), atelectasis (diagnosed by a radiologist), pneumonia (defined according to classification of Arozullah<sup>3</sup>), and respiratory failure (defined as need for artificial respiration).

## Data analysis

Data were analyzed with SPSS (version 15.1) statistical software (SPSS Inc. SPSS reference guide. Chicago: SPSS Inc, 1998). All collected data were checked for completeness and normality of distribution by means of the Kolmogorov-Smirnoff-test. Summary descriptive statistics were computed for the preoperative variables including frequencies, means, standard deviations, and percentages. Intention-to-treat analyses were used to compare outcomes between the two groups. Adherence to treatment in the intervention group was calculated as the percentage of scheduled visits to the outpatient department. A preoperative effect of the intervention on capacity and performance measures within and between the two groups was estimated with the paired and independent sample t-test for normal distributed data and the Wilcoxon-test and Mann-Whitney U-test for non normally distributed data, respectively. The effect of the intervention on the length of stay was estimated with an independent sample t-test for normal distributed data and Mann-Whitney U-test for non normally distributed data. Postoperative complications of the two groups were compared by means of chi-square test. The significance level for all tests was set at 0.05.

## RESULTS

The baseline characteristics of the 42 patients are listed in Table 6.1. No significant differences were found between the groups, except that more patients in the intervention group had diabetes than in the control group (57% versus 5%;  $p=0.01$ ). One patient of the intervention group decided not to have the operation, 2 weeks after inclusion.

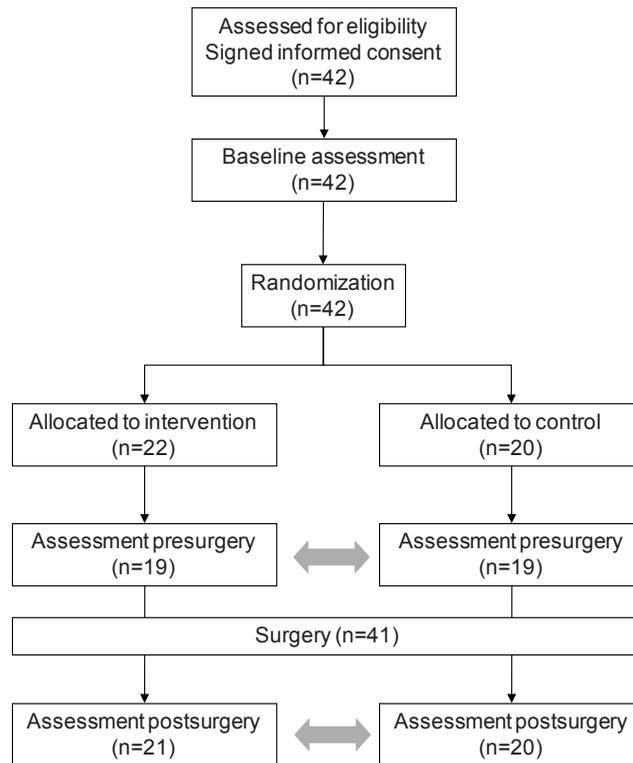
The flow chart in Figure 6.1 shows the progress of the study population. Three patients in the intervention group dropped out in the preoperative period (two patients due to the death of their spouse and one patient was unable to combine the training with daily work). One patient in the control group did not come for the second preoperative measurement for personal reasons.

**Table 6.1** Baseline characteristics of the patients

	Control N=20	Intervention N=22	p*
Age in years	68.8 (6.4)	71.1 (6.3)	0.23
Gender (m/w)	16/4	15/7	0.38
Smokers (y/n)	6/14	3/19	0.20
COPD (y/n)	3/17	3/21	0.90
Coughing (y/n)	2/18	2/20	0.92
Diabetes (y/n)	1/19	8/14	0.01
Hb women (mmol/ml)	8.6 (0.7)	6.4 (2.0)	0.04
Hb men (mmol/ml)	8.5 (0.8)	8.0 (1.6)	0.34
BMI (kg/m <sup>2</sup> )	25.7 (3.1)	26.6 (3.6)	0.40
TUG (sec)	6.4 (1.3)	8.0 (3.6)	0.07
CRT (sec)	21.6 (4.7)	26.3 (6.7)	0.12
MIP (cm H <sub>2</sub> O)	93.0 (25.4)	78.2 (32.6)	0.11
RMA Energy (Joules)	350 (299)	259 (273)	0.31
HGS (N)	430 (108)	375 (125)	0.14
LAPAQ Energy (kcal/day)	1006 (715)	782 (707)	0.31
LAPAQ Activities (min/day)	212 (110)	197 (152)	0.73
PWC (O <sub>2</sub> ml/kg/min)	31.6 (6.5)	30.3 (9.6)	0.62
AFQ	9.5 (6.2)	13.2 (7.3)	0.08
EORTC QLQ-C30 / GH	71 (20)	70 (23)	0.97
EORTC QLQ-C30 / FS	427 (52)	408 (67)	0.31
EORTC QLQ-C30 / SC	130 (89)	154 (122)	0.47
Surgery duration (minutes)	119 (57)	104 (47)	0.38

BMI, Body Mass Index; TUG, Timed Up and Go; CRT, Chair Rise Time; MIP, Maximal Inspiratory Pressure; RMA, Respiratory Muscle Analyzer; HGS, Hand Grip Strength; LAPAQ, LASA Physical Activity Questionnaire; PWC, Physical Work Capacity; AFQ, Abbreviated Fatigue Questionnaire; EORTC QLQ-C30 / GH / FS / SC, Quality of Life Questionnaires Global Health status / Functional Scale / Symptom Scale.

\* Mann-Whitney U-test (continuous variables) or Chi square test (dichotomous variables).



**Figure 6.1** Flow chart of the study population.

The mean number of training sessions in the inpatient department was  $5.1 \pm 1.9$ . The attendance at training sessions was 97% in the intervention group. The mean number of steps/day recorded by the pedometer was 4980 and 5003 for the intervention group and control group, respectively. No adverse events were reported during outpatient or home training. In total, 37 patients completed the evaluation form (see Table 6.2). Both the intervention and the control groups appreciated the assigned “treatment”, without there being a significant difference between the two groups ( $p=0.08$ ). The perceived exertion was low for the home-based training program and moderate for the intensive outpatient training program (see Table 6.2).

The intensive outpatient training program led to a significantly greater improvement in inspiratory muscle endurance than the home-based program at  $T=1$ . There were no differences in other outcome measures between the two groups (see Table 6.3).

**Table 6.2** Patient appreciation of treatment

	Disagree			Agree		p-value	
	1	2	3	4	5		
The aim of the preoperative treatment was clear to me	I II			I		p=0.54	
	C						
During the fitness test, the perceived exertion was high	I III					p=0.54	
	C		II	III		II	
In my opinion, the fitness test was useful	I I		I	II		p=0.36	
	C	II	I				
During the home-based exercises, the perceived exertion was high	I		I		III	I	p=0.91
	C		II	III	III		
In my opinion, the home-based exercise program was useful	I I			II		p=0.48	
	C	I					
During the training in the outpatient department, the perceived exertion was high	I III	II	III		I		
	C	Not applicable					
In my opinion, the training in the outpatient department was useful	I I		I	II			
	C	Not applicable					
I think the treatment prepared me well for the operation	I I			III		p=0.08	
	C	I	III				

I, Intervention group; C, Control group.

There was no significant difference in postoperative complications and length of hospital stay between the two groups at T=2 (see Table 6.4).

Based on the similar amount of moderate activity (no difference between mean number of steps) in the intervention and control group, a *post hoc* analysis over the combined dataset revealed a significant point-biserial correlation of 0.5 ( $p=0.02$ ) between the extent of activity (number of steps) and postoperative pulmonary complications. A Receiver

**Table 6.3** Differences in capacity measures between the intervention and control groups

		Baseline (T=0)	Outcome (T=1)	p-value <sup>1</sup>	Difference I-C	p-value <sup>2</sup>
TUG (sec)	I	8.0 (3.6)	7.8 (3.3)	0.29	-0.2 (0.8)	0.34
	C	6.4 (1.3)	6.6 (1.2)	0.28	0.2 (0.7)	
CRT (sec)	I	26.3 (6.7)	26.6 (6.2)	0.74	0.3 (4.1)	0.87
	C	21.6 (4.7)	21.2 (6.1)	0.81	-0.3 (4.2)	
MIP (cm H <sub>2</sub> O)	I	78 (33)	92(26)	<0.001	14 (13)	0.09
	C	93 (25)	98 (26)	0.33	5 (21)	
RMA energy (Joule)	I	259 (273)	404 (349)	<0.001	146 (160)	<0.01
	C	350 (299)	305 (323)	0.07	-44 (279)	
LAPAQ Energy (kcal/day)	I	782 (707)	980 (771)	0.05	198(541)	0.15
	C	1005 (714)	1657 (3400)	0.78	652 (3368)	
LAPAQ Activities (min/day)	I	197 (152)	236 (157)	0.11	39 (130)	0.18
	C	211 (110)	280 (399)	0.68	69 (399)	
PWC (O <sub>2</sub> ml/kg/min)	I	29.4 (9.5)	27.6 (6.5)	0.47	-1.7 (8.4)	0.16
	C	31.6 (6.5)	32.9 (6.9)	0.26	1.3 (6.4)	
AFQ	I	13.2 (7.5)	12.7 (6.6)	0.80	-0.5 (6.8)	0.91
	C	9.5 (6.2)	8.8 (4.3)	0.59	-0.7 (3.4)	
EORTC QLQ-C30 / AG	I	70 (23)	72 (19)	0.96	2 (19)	0.88
	C	71 (20)	68 (18)	0.24	-3 (13)	
EORTC QLQ-C30 / FS	I	408 (67)	413 (64)	0.43	5 (56)	0.72
	C	427(53)	425 (67)	0.98	-2 (39)	
EORTC QLQ-C30 / SC	I	154 (122)	119 (98)	0.62	-35 (125)	0.20
	C	130 (90)	155 (117)	0.18	25 (75)	

I, Intervention group; C, Control group; TUG, Timed Up and Go; CRT, Chair Rise Time; MIP, Maximal Inspiratory Pressure; RMA, Respiratory Muscle Analyzer; LAPAQ, LASA Physical Activity Questionnaire; PWC, Physical Work Capacity; AFQ, Abbreviated Fatigue Questionnaire; EORTC QLQ-C30 / GH / FS / SC, Quality of Life Questionnaires Global Health status / Functional Scale / Symptom Scale.

<sup>1</sup> Wilcoxon test.

<sup>2</sup> Mann-Whitney U-test.

operating characteristic curve (Area Under the Curve=0.79) revealed 4000 steps per day to be a clinically pragmatic and relevant cut-off point for adequate physical activity. The choice of this cut-off point was confirmed by the difference in the count of the postoperative pulmonary complications in patients with a physical activity of more than 4000 steps and those with less than 4000 steps per day(chi-square test  $p<0.01$ ; see Table 6.5).

**Table 6.4** Postoperative course

Postoperative complications	I	9 (45%)	$p=0.65$
	C	8 (38%)	
PPC*	I	5 (24%)	$p=0.93$
	C	5 (25%)	
Pneumonia	I	1 (5%)	$p=0.27$
	C	3 (15%)	
Length of stay	I	16.2 (11.5)	$p=0.31$
	C	21.6 (23.7)	

I, Intervention group; C, Control group; PPC, Postoperative complication.

\* PPC: atelectasis, hypoxia or pneumonia.

**Table 6.5** PPC related to physical activity (measured by pedometer) in both the intervention and control group

		PPC*	
		no	yes
Activity	<4000 steps per day	8	9
	>4000 steps per day	23	1

$p<0.001$ .

## DISCUSSION

The intensive therapeutic exercise program was feasible and improved the respiratory function, but did not significantly change preoperative aerobic capacity and functional capacity of patients due to undergo elective abdominal surgery compared to a home-based exercise advice. Also the postoperative course of both groups did not differ significantly.

We investigated the feasibility and effectiveness of a preoperative intensive therapeutic exercise program for elderly patients, as an aspect of preoperative care, as proposed by Craig, et al.<sup>38</sup> The patients adhered to the intensive training program and did not report discomfort or adverse effects. The patients in both groups appreciated their “treatment” (training program or advice) and felt that it prepared them well for surgery. While there was a significant improvement in inspiratory muscles function in the intensive outpatient training group, the incidence of postoperative pulmonary complications did not significantly differ from that of the control group. This is in contrast with the positive results of inspiratory muscle training achieved in patients scheduled for elective coronary artery bypass graft (CABG) or aneurysma aorta abdominalis (AAA) surgery.<sup>16,17</sup> An explanation for this difference could be that the study was underpowered and that colon surgery has a more subtle effect on diaphragm function than CABG and AAA, both procedures which are performed closer to the diaphragm.<sup>39</sup> Also the difference in mechanical ventilation time, which is of substantial influence on diaphragm function,<sup>40</sup> may explain the discrepancy. A *post hoc* sub-analysis of the data of the patients with low respiratory function (MicroRMA energy <150 Joule) indicated that these patients may benefit the most from the intervention, so that the intervention should be offered to patients with a higher risk profile.

The intervention may be more effective if it lasts longer, is of higher frequency (more training sessions per week under supervision), or is more intensive (high intensity). While the intervention improved inspiratory muscle function in the preoperative period, it did not have a significant effect on the aerobic capacity or on functional measures. The intensity of exercise was in accordance with general recommendations for elderly patients<sup>18</sup> but was probably insufficient to achieve a rapid improvement, as is required in a preoperative period of 3–4 weeks on average. Recently, a high-intensity interval training regimen led to metabolic adaptation in 2 weeks<sup>41</sup> and proved to be safe in elderly patients (aged  $75 \pm 11$  years).<sup>42</sup>

A weakness of the study could be that we did not investigate the effect of an intensive therapeutic exercise program but instead compared it with a low cost home-based exercise advice. There is a rationale for keeping patients active during the preoperative period. The diagnosis “cancer” has a tremendous impact on a person’s existence and behavior.<sup>12</sup> One item in the LASA Physical Activity Questionnaire (activities in the 2 weeks preceding admission) revealed that 60% of the patients were less active than normal. It is possible that the home-based exercise advice meets the requirement to preserve or optimize

patients' physical condition during the preoperative period. The preoperative LASA Physical Activity Questionnaire scores and the daily number of steps recorded revealed that patients in both the intervention and control groups showed a higher activity level than at baseline, at study inclusion. A *post hoc* analysis revealed an association between the moderate activity of both groups and the incidence of postoperative complications .

Another limitation of this study is the number of patients which is not powered to detect significant effects on all outcome measures.

In conclusion, we recommend that high-risk patients be included in future studies and that the exercise protocol be made more intensive.

### **Clinical messages**

- Elderly patients appreciate and can safely participate in a preoperative intensive therapeutic exercise program.
- General aerobic training parameters for elderly individuals recommended in the literature appear to be inadequate to obtain a short-term increase in physical capacity.
- A low-cost home-based exercise advice seems to have a positive effect on physical activity sufficient to preserve or optimize the physical condition of non-frail elderly individuals during the preoperative period before abdominal surgery.

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