Randomised clinical trial of physiotherapy after open abdominal surgery in high risk patients

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Postoperative physiotherapy has been shown to reduce the incidence of postoperative pulmonary complications after open abdominal surgery. This study aimed to determine if the addition of deep breathing exercises and secretion clearing techniques to a standardised physiotherapist-directed program of early mobilisation improved clinical outcomes in patients undergoing open abdominal surgery. Fifty-six patients undergoing open abdominal surgery, at high risk of developing postoperative pulmonary complications, were randomised before operation to an early mobilisation-only group or an early mobilisation-plus-deep breathing and coughing group. Mobility duration, frequency and intensity of breathing interventions were quantified for both groups. All outcomes were assessed by a blinded outcomes researcher using a standardised outcomes measurement tool developed specifically for this population. Outcomes included incidence of clinically significant postoperative pulmonary complications, fever, length of stay, and restoration of mobility. There were no significant differences between groups in mean age, anaesthetic time, perioperative morbidity, or postoperative mobility. Outcome data were available for 89% of enrolled subjects. Overall incidence of postoperative pulmonary complications was 16%. The incidence of postoperative pulmonary complications in the non-deep breathing and coughing group was 14%, and the incidence of postoperative pulmonary complications in the deep breathing and coughing group was 17%, (absolute risk reduction -3%, 95% C1 -22 to 19%). There was no significant difference between groups in the incidence of fever, physiotherapist time, or the number of treatments. This study suggests that, in this clinical setting, the addition of deep breathing and coughing exercises to a physiotherapist-directed program of early mobilisation does not significantly reduce the incidence of clinically significant postoperative pulmonary complications in high risk open abdominal surgery subjects.
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Introduction

Physiotherapy treatment for patients after open abdominal surgery consists of a variety of interventions intended to improve cardiopulmonary and/or physical function and reduce the incidence of postoperative pulmonary complications. These interventions may include lung expansion exercises, secretion clearance techniques, limb exercises, progressive mobilisation programs, and other techniques. The incidence of clinically significant postoperative pulmonary complications after open abdominal surgery has been shown to be as high as 53 per cent in NSW hospitals (Mackay and Ellis 2002).

The incidence of postoperative pulmonary complications has been shown to be lower in open abdominal surgery patients who receive physiotherapy compared to those who receive none (Celli et al 1984, Chumillas et al 1998, Moran et al 1983, Olsen et al 1997). This effect has been attributed to the application of various forms of lung expansion and secretion clearance techniques. However, it is not known whether it is the lung expansion and coughing exercises, or the patient's change in position and assisted early mobilisation that accompanies these interventions, or indeed, a combination of both, which is responsible for the decrease in incidence of postoperative pulmonary complications. Therefore, this study aimed to investigate whether the addition of deep breathing and coughing exercises (DB&C) to a standardised program of early mobilisation for all patients conferred any significant benefit in reducing the incidence of clinically significant postoperative pulmonary complications after open abdominal surgery in high risk patients.

Method

Subjects To be eligible for inclusion subjects had to have surgery planned which involved manipulation of the viscera via a single upper, or combined upper and lower, midline open abdominal incision, and be classified as at high risk of developing postoperative pulmonary complications. High risk patients were those under 59 years with a history of cigarette smoking, pulmonary disease, heart disease, cancer, renal and/or liver disease, an American Society of Anaesthesiologists (ASA) (Vacanti et al 1970) score > 2 or obese (body mass index > 27 kg/m^2), plus any patient having the same surgery aged 59 years and over (Arozullah et al 2001, Brooks-Brunn 1997, Hall et al 1991). Patients undergoing repairs of abdominal aortic aneurysms were excluded due to differences in the postoperative management. Patients who were unable to understand English were provided with a translator, employed by the hospital, who explained the study to the patient in the patient's own language.

The flow of subjects through the study is shown in Figure 1. All eligible patients admitted between 5 May 2001 and 28 February 2003 through the preadmission clinic at Westmead hospital were assessed, with 58 meeting entry criteria. Two of

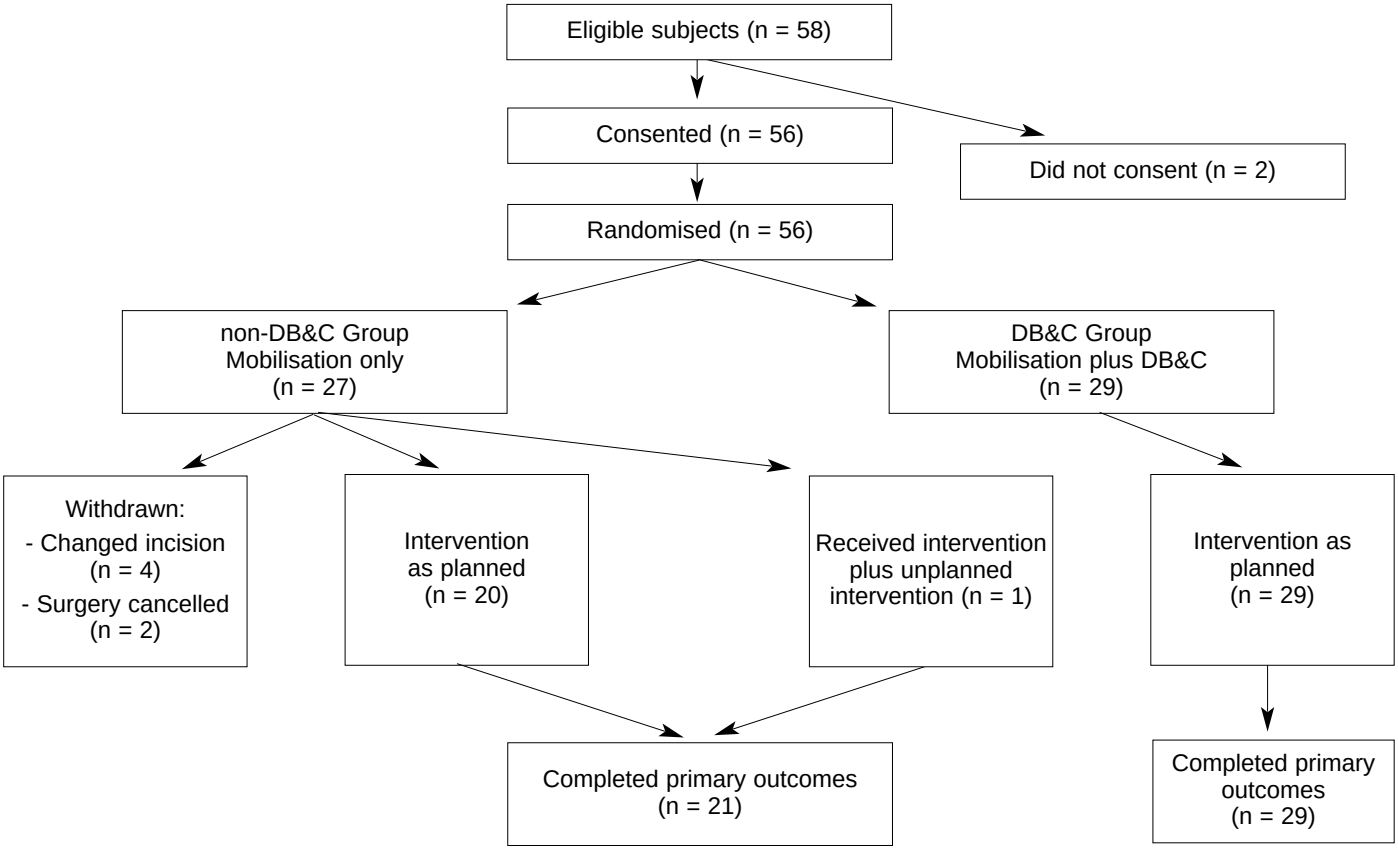

Figure 1. Flow of subjects through the study.

these subjects did not consent, one of whom spoke no English and her family did not consent, the other had undergone multiple previous open abdominal procedures and did not wish to participate. There were no other differences between these two subjects and those who consented. All other subjects gave written and informed consent. A total of 56 subjects were randomised to one of two treatment groups using a random numbers table and concealed allocation prior to the initial contact. Two subjects from non-DB&C group had their surgery cancelled for reasons unrelated to the study. One subject in this group was given deep breathing exercises by a physiotherapist in error Day 1 after surgery. This subject remained in this group and analysis was conducted by intention to treat. Two subjects had combined abdominal and thoracic incisions, and another two subjects had only laparascopic procedures (despite having been scheduled for an open procedure) necessitating their subsequent exclusion from the study. Ethical approval was granted by the Human Research Ethics Committee of Western Sydney Area Health Service and the chairperson of the Department of Surgery.

Intervention groups Subjects in the non-DB&C Group participated in a standardised program of early mobilisation designed to maximise the rate of restoration of mobility and improve pulmonary ventilation. The program was implemented and supervised by the ward physiotherapist. Provided that subjects were awake (or drowsy but easily woken), had stable blood pressure and heart rate, no dyspnoea at rest and less than 8/10 pain, the following goals were attempted in order during each treatment session:

- Sit out of bed
- Walk 5 m with assistance
- Walk 15 m with assistance
- Walk 30 m with assistance
- Walk 30 m without assistance.

Subjects were encouraged to achieve one or more goals during each treatment, and were encouraged to walk at a speed where they were taking deeper breaths than at rest, at an intensity of at least 6/10 according to the Borg 10 point scale of perceived exertion (Klinger et al 2001, Ryujin et al 1997). This was intended to challenge the respiratory system sufficiently to produce an increase in minute ventilation (Orfanos et al 1999). Subjects were permitted to also attempt the goals with the nursing staff and with visitors. Subjects were encouraged to perform active ankle planter flexion and dorsiflexion exercises, at least 20 times every waking hour, whilst in bed.

DB&C Group subjects received exactly the same program of early mobilisation and leg exercises as that described for the non-DB&C Group *with the addition of coached lateral basal expansion exercises and sputum clearance techniques*, referred to as deep breathing and coughing (DB&C) exercises. The DB&C exercises consisted of at least three coached lateral basal expansion manoeuvres (deep breaths) followed by a cough, huff, or forced expiratory manoeuvre. Instruction and supervision from the physiotherapist focused on bilateral basal expansion, avoiding upper chest and

Table 1. Criteria for a clinically significant pulmonary complication.

A postoperative pulmonary complication is deemed to have occurred if three or more of the following respiratory signs occur within the same day, in the first 14 days after surgery:

- Auscultation changes (decreased breath sounds, crackles, wheezes, bronchial breathing) that were additional to those found prior to surgery.
- Temperature over 38 degrees Celsius.
- Chest X-ray changes consistent with collapse, consolidation, or atelectasis.
- Increase in amount and/or changed colour of sputum produced, compared to what the patient reports is usual for them.

(Modified from: Brooks-Brunn 1997, Hall et al 1996)

shoulder elevation, and maximising expansion of the lower chest diameters during inspiration, with a three second end-inspiratory hold, followed by relaxed expiration. This was done with the subject in sitting with the physiotherapist providing bilateral proprioceptive feedback with the hands on the lower ribs. This cycle was repeated at least twice during each treatment. Patients were also encouraged to practise these DB&C exercises every waking hour by themselves.

All the above interventions were administered by the ward physiotherapists three times daily on postoperative Days 1 and 2, twice daily on Days 3 and 4, then daily until the patient was independently mobile and had a clear chest assessment for three consecutive days. A clear chest was defined as no auscultation or chest radiograph changes, normal temperature, and no sputum. All assessments were carried out by the ward physiotherapists at least once daily. Any subject in either group who showed signs of developing clinically significant postoperative pulmonary complications commenced chest physiotherapy techniques as appropriate for their condition and as determined by the ward physiotherapist.

Measurements A standardised validated outcome measurement tool, the Abdominal surgery Physiotherapy Outcomes Data Sheet (APODS) was used to collate data for all subjects in this study (Mackay and Ellis 2002). All outcomes were assessed by the first author, a physiotherapist, who was blind to group allocation and had no contact with any subjects in the study. All data, with the exception of intervention details, were obtained via an independent audit of each subject's medical records after discharge from hospital. Physiotherapy interventions were documented on a separate sheet kept by the ward physiotherapist until the researcher had completed the outcome measures, to ensure that the researcher remained blind to allocation.

Preoperative assessments, conducted by the physiotherapist, medical officer, and anaesthetist, included previous medical, surgical and anaesthetic history, previous pulmonary disease, age, sex, language spoken at home, preoperative cardiovascular fitness, smoking history, height and weight, and ASA score (Vacanti et al 1970). Cognitive function was assessed by the physiotherapist and recorded as either alert and orientated or difficulty learning new skills. Preoperative mobility was recorded as independently mobile over at least 30 metres, mobility limited mainly by shortness of breath, mobility limited mainly by musculoskeletal impairments, or mobility limited by other causes. Preoperative chest radiographs were done at the discretion of the admitting medical staff. Subjects were classified as ex-smokers if they had ceased smoking more than eight weeks prior to surgery and had a history of smoking of 20 years or less. 'Smokers' included current smokers plus those who had ceased smoking but had a history of smoking greater than 20 pack-years.

Pulmonary function tests, consisting of forced expiratory volume in one second (FEV_1) and forced vital capacity (FVC) were conducted using American Thoracic Society criteria (ATS 1979) with a Vitalograph (bellows-type) spirometer (model R). These values were expressed as a percentage of predicted values for each subject's age and height using prediction formulae (West 1982) as a measure of preoperative pulmonary function. These measures were not repeated postoperatively as the decrease in FEV_1 and FVC in open abdominal surgery patients after surgery is already well-documented (Chummilas et al 1998, Olsen et al 1997).

Type of anaesthetic, route of administration, and medications used were obtained from the anaesthetic operation records. The length of anaesthetic was taken from the anaesthetist's record of vital signs showing induction and reversal of anaesthesia. Type of surgical incision and operative details were taken from the surgeon's operation report. Amount of intraperitoneal pus in the operative field was classified by the surgeon according to criteria used at Westmead hospital: clean, clean-contaminated, contaminated, or dirty.

The incidence of postoperative pulmonary complications was assessed daily according to the criteria in Table 1, a definition similar to that used in previous studies of postoperative pulmonary complications incidence in open abdominal surgery (Brooks-Brunn 1997, Chumillas et al 1998, Hall et al 1996, Olsen et al 1997). The definition of postoperative pulmonary complications in these earlier studies is yet to be validated, and in some cases includes 'physician diagnosis' as a definition of postoperative pulmonary complications. For these reasons our definition included only those criteria that could be assessed objectively. Chest auscultation findings and sputum production were recorded at least once daily in the medical record by the treating physiotherapists and medical officers. Oral temperature was taken as the highest temperature on each postoperative day in the nursing observation records. Chest X-ray findings were reported by a radiographer who was blinded to allocation, study aims and objectives. Chest X-rays were ordered by the medical staff only if patients had adverse respiratory signs or symptoms.

The mobility indicators used were: (1) first day sitting out of bed, (2) first day walking (with or without assistance, including walking on the spot), and (3) first day able to walk 30 m without assistance of another person (with or without a walking aid). Total distance walked, perceived exertion and time spent sitting out of bed were documented daily by the treating physiotherapist on a separate chart.

Physiotherapy staff time and number of treatments were taken from the Allied Health Information System (AHIS 1993) version 2.00 and cross-checked for accuracy with the treatment record sheets. Any discrepancies were clarified by the ward physiotherapist. Staff time was measured as individual patient attributable (IPA) time (NAHCC 1996). Length of stay was calculated from the first day admitted (which was the day of surgery for all subjects) to day of separation from the hospital. Type and days of use of antibiotics and analgesia were taken from the medication

Table 2. Preoperative characteristics of subjects in non-DB&C and DB&C Groups.

	non-DB&C Group n = 21	DB&C Group n = 29
Mean age ± SD, range (years)	69 ± 15, 29–91	63 ± 13, 30–85
Mean FEV_1 (l)	1.79 ± 0.79	2.24 ± 1.01
*Mean FEV_1 % predicted	0.79 ± 0.28	0.88 ± 0.34
*Mean FVC % predicted	0.84 ± 0.22	0.84 ± 0.29
Male	10 (47)	15 (52)
Language English	19 (90)	28 (97)
Non-smoker	12 (57)	17 (59)
Life-long non-smoker	8 (38)	13 (45)
History of CAL	5 (24)	7 (24)
Other pulmonary disease	6 (29)	7 (24)
Chest X-ray changes	4 (19) n = 9	4 (14) n = 11
Obese	7 (33)	7 (24)
Cardiac disease	9 (43)	11 (38)
Liver disease	4 (19)	4 (14)
Renal disease	2 (10)	4 (14)
History of cancer	12 (57)	16 (55)
Musculoskeletal problems	7 (33)	10 (35)
Stroke/TIA	1 (5)	2 (7)
Diabetic	4 (19)	5 (17)
Mobility		
Independently mobile over 30 m	20 (95)	24 (83)
Mobility limited by SOB	1 (4)	4 (14)
Mobility limited by MSI	0 (0)	1 (3)
Mobility limited by other causes	0 (0)	0 (0)
Cognitive function		
Alert and orientated	18 (86)	28 (97)
Difficulty learning new skills	3 (14)	1 (3)

Values are absolute numbers per group with percentages unless otherwise stated. *FEV_1 and FVC as percentage of predicted value for age and height. Obese: Body mass index (BMI) 29 kg/m^2 or above. CAL: chronic airway limitation. TIA: transient ischaemic attack. SOB: shortness of breath. MSI: musculoskeletal impairment. See text for definition of 'Smoker'.

Table 3. Perioperative characteristics of the subjects in non-DB&C and DB&C Groups

	non-DB&C Group n = 21	DB&C Group n = 29
Mean anaesthetic time ± SD, range (hours)	3.7 ± 1.5, 1.8–7.8	3.7 ± 1.2, 1.3–6.5
ASA score		
1	1 (5)	4 (14)
2	11 (52)	12 (41)
3	8 (38)	13 (45)
4	1 (5)	0 (0)
Type of operation		
Anterior resection/ Sigmoid colectomy	8 (38)	11 (38)
Right or left hemicolectomy	4 (19)	3 (10)
Small bowel resection/ Whipples	2 (10)	2 (7)
Oesophagectomy/ gastrectomy	3 (14)	3 (10)
Liver resection	1 (5)	5 (17)
Abdominoperineal resection	1 (5)	2 (7)
Other	2 (10)	3 (10)
Surgeon		
A	11 (52)	13 (45)
B	2 (10)	5 (17)
C	3 (14)	3 (10)
D	1 (5)	4 (14)
E	2 (10)	1 (3)
F	2 (10)	1 (3)
G	0 (0)	1 (3)
H	0 (0)	1 (3)
Operative field		
Clean	14 (67)	16 (55)
Clean-contaminated	4 (19)	10 (35)
Contaminated	3 (14)	3 (10)

Values are absolute subject numbers with percentages in parentheses unless otherwise stated.

charts. Any medications prescribed by medical officers but not taken by the subjects were not recorded. All subjects received titrated general anaesthesia using propofol, rocuronium bromide, and midazolam. Number of days of supplemental oxygen and use of nasogastric tube were taken from the physiotherapy and nursing notes. Any complications, in addition to respiratory complications, were also documented on the APODS during the medical record audit.

Statistical analyses A power analysis prior to this trial revealed a total subject number of 50 (25 in each group) would provide an 80% chance of detecting a large effect size in the difference in the proportions of each sample (Cohen 1992), at the 0.05 level of significance using a two-sided test. The primary outcome measure in this study was the proportion of postoperative pulmonary complications. Earlier studies had demonstrated large physiotherapeutic treatment effects of deep breathing exercises in high risk subjects in physiotherapy treatment groups compared to non-treatment groups (Olsen et al 1997). Therefore we anticipated a large treatment effect when designing this study. Fifty-eight subjects were considered to be sufficient in case of data loss or dropouts.

Differences between preoperative data and postoperative outcomes of the two groups were tested using Student t-tests for differences between means of continuous data and chi square tests for nominal data. Skewed data such as length of stay (LOS) are presented as medians ± interquartile ranges (IQR). Analyses were conducted on an intention to treat basis.

Table 4. Total intervention 'dosage' during postoperative Days 1 to 5.

	non-DB&C Group n = 21	DB&C Group n=29	Difference between means (95% CI)	*p*
SOOB (hours)	16.2 ± 6.5 6–30	15.6 ± 5.5 3–26	0.6 (-2.8 to 4.02)	0.71
Distance walked (m)	568 ± 615 130–2304	370 ± 200 100–932	198 (-47.1 to 443.1)	0.11
Number of deep breaths	1.9 ± 8.7 0–40	100.8 ± 37.8 14–161	-98.9 (-115.84 to -81.96)	*$p < 0.001$
Number of coughs	0.7 ± 2.4 0–10	32.0 ± 9.9 9–48	-31.3 (-35.8 to -26.9)	*$p < 0.001$
Number of huffs/FETs	0.7 ± 2.4 0–10	33.9 ± 16.0 6–81	-33.2 (-40.3 to -26.1)	*$p < 0.001$

Interventions expressed as mean ± SD, range. *$p < 0.05$ statistically significant. SOOB: time spent sitting out of bed. FET: forced expiratory technique.

Results

The 50 subjects who completed the study had an average age of 66 years (range 29 to 91, SD 14) with exactly half being female. There were no clinically or statistically significant differences between the two intervention groups in any demographic, preoperative, or perioperative characteristic as shown in Tables 2 and 3. The DB&C Group had a slightly larger proportion of life-long non-smokers but this difference was not statistically significant. The non-DB&C Group had a slightly higher mean age, a higher proportion of subjects with cardiac disease, more obesity, and poorer cognition, although none of these differences reached statistical significance.

Sixty-nine per cent of all subjects had epidural analgesia consisting of bupivacaine 0.125% and fentanyl citrate 2.5 mcg/ml. Seventy-eight per cent of all subjects took oxycodone, an oral narcotic, once intravenous analgesia was withdrawn. A significantly ($p < 0.01$) higher proportion of subjects in the non-DB&C Group (86%) took paracetamol compared to the DB&C Group (48%). There were no statistically significant differences between groups for use of other analgesia including intravenous narcotic patient-controlled analgesia (PCA), narcotic epidural, patient-controlled epidural analgesia, oral oxycodone, tramadol, nonsteroidal anti-inflammatories, and subcutaneous morphine. Nasogastric tubes were used for only eight subjects in the non-DB&C Group (38%) and 13 subjects in the DB&C Group (45%). There was no significant difference between groups in the mean number of days of use of nasogastric tubes (non-DB&C Group mean 4.8 ± 3.24 SD days, DB&C Group mean 3.9 ± 2.5 SD days).

To ensure equivalence in the 'dosage' or amount of early mobilisation given to each group, the hours of sitting out of bed and the distance walked over the first five postoperative days were compared (Table 4). The 95% confidence intervals indicate group equivalence in the amount of early mobility interventions. There were three subjects in the non-DB&C Group who walked over 1000 m in their first five postoperative days, which skewed the data slightly, resulting in a slightly higher (but not significant) mean for the non-DB&C Group compared to the DB&C Group. The mean exertion for subjects in non-DB&C Group, using the Borg scale out of 10, was 5.6 ± 1.4, range 3 to 8, during the first five postoperative days. This was comparable to the mean exertion of subjects in the DB&C Group over the first five days: 5.2 ± 1.7, range 2 to 8.

Statistically and clinically significant differences were found in the amount of lateral basal expansion and secretion clearance interventions between the two groups (Table 4). One subject in the non-DB&C Group did some deep breathing exercises in error, therefore the 'dosage' of chest physiotherapy was not zero in this group, as might be expected in ideal trial conditions. This subject did not develop a postoperative pulmonary complication. The three subjects from the non-DB&C Group who developed postoperative pulmonary complications commenced DB&C exercises at the discretion of their physiotherapist according to the study protocol. These additional interventions have not been included in Table 4. No subject received any other physiotherapy treatments other than those mentioned above.

Incidence of postoperative pulmonary complications The overall incidence of postoperative pulmonary complications in this study was 16%. Three subjects in the non-DB&C Group (14%) and five subjects in DB&C Group (17%) developed clinically significant postoperative pulmonary complications (absolute risk reduction -3.0%, 95% CI -0.22 to 0.19%). These eight subjects who developed postoperative pulmonary complications commenced additional chest physiotherapy techniques at the discretion of their therapist as per the trial protocol and continued in the trial. Exclusion of the data from one non-DB&C Group subject who performed DB&C exercises in error alters the incidence of postoperative pulmonary complications in non-DB&C Group to 15%, which was still not significantly different to the DB&C Group's incidence of 17%. The clinical profiles of each subject who developed a postoperative pulmonary complication are summarised in Appendix 1 (posted as an e-addendum on the journal website). The only common factor in these patients was the relatively high proportion of smokers (six of the eight subjects), a well-known risk factor

Table 5. Clinical outcomes.

Outcome	non-DB&C Group n = 21	DB&C Group n = 29	Difference between means or proportions (95% CI)	*p
Respiratory measures				
Post-operative pulmonary complications	3 (14)	5 (17)	-0.03 (-0.22 to 0.19)	0.62
Fever (38ºC or higher)	4 (19)	10 (34)	-0.15 (-0.37 to 0.10)	0.89
Mobility indicators				
1. 1st day sat out of bed, mean ±SD, range, in postoperative days	1.3 ± 0.7, 1-3	1.4 ± 0.7, 1-4	-0.1 (-0.50 to 0.30)	0.68
2. 1st postoperative walk, mean ±SD, range, in postoperative days	1.8 ± 1.5, 1-7	1.9 ± 0.9, 1-5	-0.1 (-0.78 to 0.58)	0.99
3. 1st day able to walk 30 m independently, mean ± SD, range, in postoperative days	6.1 ± 2.8, 3-12	5.6 ± 3.1, 1-17	0.5 (-1.22 to 2.22)	0.56
No. of subjects who met indicator #3 by day 5	11 (52)	14 (48)	0.04 (-0.22 to 0.30)	0.61
Length of stay				
Median length of stay in days ± IQR	13 ± 5.5	10 ± 3.0	n/a	
Mean length of stay ± SD, range in days	13.3 ± 4.5 5-23	10.4 ± 3.0, 6-21	2.9 (0.77 to 5.03)	*0.008
Use of additional resources				
Subjects with NG tubes	8 (38)	13 (45)	-0.07 (-0.31 to 0.20)	0.69
Subjects admitted to ICU	3 (14)	2 (7)	0.07 (-0.10 to 0.28)	0.78
Subjects requiring mechanical ventilation	2 (10)	2 (7)	0.03 (-0.14 to 0.23)	0.65
Mean ICU patient days	2.0 (n = 3)	2.5 (n = 2)	n/a	
Mean days of mechanical ventilation	2.0 (n = 2)	0.75 (n = 2)	n/a	
Subjects requiring > 5 days of oxygen	10 (48)	7 (24)	0.23 (-0.03 to 0.47)	0.96
Subjects with complications other than pulmonary	10 (48)	7 (24)	0.23 (-0.03 to 0.47)	0.96

Values are absolute subject numbers with percentages in parentheses unless otherwise stated. IQR: interquartile range. ICU: Intensive care unit. *$p < 0.05$ statistically significant

for postoperative pulmonary complications. Five of these eight subjects had postoperative pulmonary complications diagnosed on two or more consecutive days. Clinically significant postoperative pulmonary complications were most frequently diagnosed on postoperative day three, although two subjects did not develop any signs of significant postoperative pulmonary complications until Day 4. The incidence of postoperative pulmonary complications peaked at postoperative Days 3 (four subjects) and 5 (three subjects).

The incidence of postoperative pulmonary complications and fever (body temperature 38 degrees Celsius or higher at any time) in each group during the first 14 postoperative days is shown in Table 5. The incidence of postoperative pulmonary complications and fever in the DB&C Group was higher than in the non-DB&C Group, however these differences were not statistically significant. The contribution of each of the four adverse respiratory signs to the overall respiratory status of patients during the postoperative period is shown in Figure 2. This figure shows the percentage of subjects who had auscultation changes, sputum changes, temperature changes and/or chest X-ray changes on each of postoperative Days 0 (day of surgery) through to 7. The most commonly occurring adverse respiratory sign was pulmonary auscultation changes, occurring in over 60% of all subjects on postoperative Days 1, 2, and 3. A body temperature of 38 degrees Celsius or higher was the least common respiratory sign, occurring in less than 10% of subjects on any one postoperative day, despite being measured at least twice daily. A total of 14 subjects (four in the non-DB&C Group and 10 in the DB&C Group) developed a fever in the first 14 postoperative days. The breakdown and distribution between the two groups of auscultation findings, sputum, temperature, and chest X-ray changes across the postoperative period was virtually identical for the two groups.

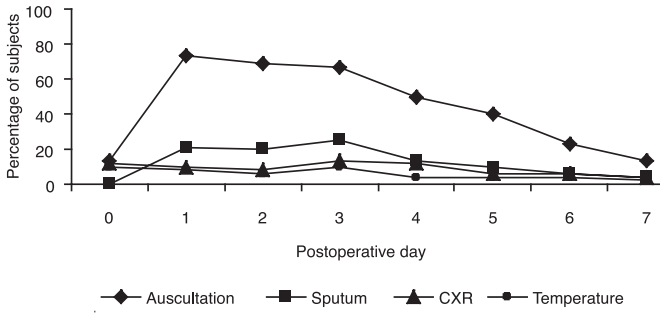

Figure 2. Percentage of subjects who exhibit the four respiratory signs by postoperative day.

Mobility and resource utilisation outcomes There were no significant differences in the rate of restoration of mobility between groups as measured by the mean of each of the three indicators, sitting out of bed, first day walked, and first day independent, as shown in Table 5. Overall median length of stay of the 52 subjects was 10.5 ± 4.0 (IQR) days, range 5 to 23 days. The mean length of stay was significantly longer in the non-DB&C Group compared to the DB&C Group. The raw data were examined for possible sources of this difference in length of stay. A significantly higher proportion of non-DB&C Group patients ($p < 0.0001$) had other (non-respiratory) complications, such as wound infections and gastrointestinal complications, which impacted upon their length of stay (see Table 6, provided as an addendum on the journal website). The clinical profiles of those patients who had a length of stay greater than 16 days are shown in Appendix 2 (provided as an addendum on the journal website). One subject in the DB&C group developed congestive heart failure, subsequently had a myocardial infarction, and died on day five. This reduced the mean length of stay in this group. Omission of these outlying cases results in a mean ± SD (95% CI) length of stay for the non-DB&C Group of 11.4 ± 2.8 (9.9 to 12.9) days and for the DB&C Group of 10.5 ± 3.0 (9.4 to 11.7) days, with no significant difference between the two.

The mean (SD) number of actual physiotherapy treatments on postoperative Days 1 to 4, consecutively, was 2.9 ± 0.3, 2.9 ± 0.3, 2.0 ± 0.2, and 1.9 ± 0.3. This was close to the planned treatment frequency of three treatments on Days 1 and 2, and two treatments Days 3 and 4. The mean amount of Individual Patient Attributable time, the number of treatments per subject, and the other types of interventions for each group is given in Table 7 (provided as an e-addendum on the journal website). Significantly more subjects used an incentive spirometer in the DB&C Group, the group that was already doing coached DB&C exercises. One subject in the non-DB&C Group was given an incentive spirometer by a nurse in error, but was told not to use it by the physiotherapist and received no instruction on its use from nursing or physiotherapy staff. There was no statistically or clinically significant difference between the groups in utilisation of other postoperative resources.

Other complications Just over a third (34%) of all subjects developed complications (other than postoperative pulmonary complications) that had the potential to impact upon length of stay. The types and frequency of these other postoperative complications are shown in Table 6 (provided as an e-addendum on the journal website). The most common complication was confusion, followed by wound infection, vomiting and/or diarrhoea, pulmonary oedema/congestive heart failure, and atrial fibrillation. The non-DB&C Group had a significantly larger proportion of subjects who had wound infections.

Discussion

This study found that, in this clinical setting, the addition of coached lateral basal expansion and secretion clearance techniques to a targeted program of physiotherapist-directed early mobilisation conferred no additional benefit in reducing the incidence of postoperative pulmonary complications after open abdominal surgery in high risk subjects. The comparatively low incidence of postoperative pulmonary complications in both groups (13% in the non-DB&C Group and 17% in the DB&C group) was unexpected, considering the 53% incidence in a previous study of 90 high risk subjects using the same criteria for postoperative pulmonary complications, across three different hospitals (Mackay 2003). The low postoperative pulmonary complications incidence of the non-DB&C Group was even more remarkable considering that the DB&C Group had a slightly *lower* risk profile for postoperative pulmonary complications on almost every measure of perioperative morbidity, although these differences did not reach statistical significance.

A decade ago, Dean (1994) commented that 'most studies [evaluating conventional chest physiotherapy] are confounded by the physiologic effects of body positioning and mobilisation' and advocated the use of changing body position and mobilisation as a primary treatment intervention. Since then, this investigation is the first to control for the possible treatment effect of early mobilisation and the effect of physiotherapist attention on subject outcome by having both study groups receive the early mobilisation intervention, rather than having a no-intervention 'control' group such as in previous studies (Chumillas et al 1998, Olsen et al 1997).

This study was significant in that, unlike previous randomised trials of physiotherapy after open abdominal surgery, it documented the actual type and dosage of physiotherapy interventions and used a sample of subjects from the population of open abdominal surgery patients who are most likely to benefit from physiotherapy, that is, those identified as high risk of developing postoperative pulmonary complications. Previous studies have involved a mix of low, medium, and high risk subjects (Hall et al 1996, Olsen et al 1997). This study also used blinded assessment of postoperative pulmonary complications outcome rather than the more subjective 'physician assessment' for postoperative pulmonary complications diagnosis in earlier studies (Brooks-Brunn 1995, Hall et al 1996).

The targeted program of early mobilisation was designed to have a respiratory effect and was implemented by physiotherapists, and is therefore likely to have influenced the incidence of postoperative pulmonary complications in this patient group. Additional factors which may have contributed to the low postoperative pulmonary complications incidence are the type of early postoperative analgesia and the physiotherapist 'treatment effect'. The use of patient-controlled epidural analgesia, and oral analgesia such as tramadol and oxycodone, have been closely associated with improved respiratory function, better postoperative mobility and improved pain relief, compared to earlier forms of

analgesia such as intravenous opioids (Carli et al 2002, Peyton et al 2003, Tarkkila et al 1997, Webb 2002). The use of regional anaesthesia and analgesia have also been shown to significantly reduce or inhibit the neuroendocrine stress response which affects cardiovascular, immune and coagulation function after surgery (Wu and Fleisher 2000) thus influencing surgical outcomes. The effect of physiotherapist involvement with all subjects in this trial may have also had a positive influence on the incidence of postoperative pulmonary complications in both groups. Preoperative physiotherapy assessment alone has already been shown to be effective in reducing the incidence of postoperative pulmonary complications to clinically acceptable levels in open abdominal surgery patients (Castillo and Haas 1985, Denehy et al 1999). Whilst no preoperative 'treatment' was given to subjects in this current trial, such as instruction regarding DB&C, there may still have been a 'treatment effect' either due to the attention that all subjects received or the knowledge that they were in a research trial.

The incidence of postoperative pulmonary complications in DB&C Group (17%) is only slightly higher than the postoperative pulmonary complications incidence for high risk subjects in the 'intervention' groups of previous studies, that is, 8% in Chummilas et al (1998), 13% in Hall et al (1996) and 15% in Olsen et al (1997). This is most likely to be due to the perioperative profiles of the subjects in this study. The subjects in this current study had a mean age 13 years older than those in Olsen et al (1997), and had a significantly longer anaesthetic time and higher proportion of smokers than in Hall et al (1996). In addition, all subjects in this current study had midline incisions, whilst just over 58% of the high risk subjects in the Hall et al (1996) study had transverse or oblique, rather than midline, incisions. Types of incision were not documented in Olsen et al (1997). Transverse incisions result in significantly less postoperative pain, less hypoxeamia and fewer pulmonary complications (Grancharov and Rosenberg 2001). Considering these differences, we might reasonably expect an even higher incidence of postoperative pulmonary complications than that obtained in the current study. The main finding of the current study was that the non-DB&C Group obtained equally good results, with an incidence of postoperative pulmonary complications of 14%. This may not be surprising in the light of Dean's comments as discussed above.

Both groups in the current study were found to be equivalent in all aspects with the exception of the proportion of subjects who took paracetamol. This was significantly higher in the non-DB&C Group (86%) than in the DB&C Group (48%, $p < 0.01$). This discrepancy in the use of paracetamol is, however, unlikely to have affected the development of postoperative pulmonary complications for two reasons. First, oral paracetamol is prescribed after postoperative Day 4, or even later, whereas most postoperative pulmonary complications develop from Days 0 to 4. Second, all but one of the eight subjects in this study who developed postoperative pulmonary complications took paracetamol in addition to other analgesic medication. The one subject who had no record of taking paracetamol had seven days with a narcotic epidural, followed by six days of oral oxycodone, then subcutaneous morphine injections, instead of paracetamol.

The resultant mobility 'dosage' in this study may have been underestimated, as the recorded interventions did not include mobility assistance from nursing staff. In addition, we assumed that the nursing staff were unlikely to 'coach' patients to mobilise at the intensity that the physiotherapists were aiming for, that is, 6 out of 10 on the Borg scale. The consequence of this is that, in the application of these results to clinical practice, it may be prudent to view the mobilisation dosages as minimum goals. The actual amount of early mobilisation was relatively small, consisting of only a mean of three hours sitting out of bed per day and approximately 75 to 100 m walked per day, at an intensity of at least 5 out of 10 on the Borg scale. These goals may be considered easily achievable by most patients. The relative benefits of coached early mobilisation versus nurse-initiated ambulation are yet to be studied.

In some trial subjects the attending medical officers insisted on their patients having an incentive spirometer. For the one subject in the non-DB&C Group who received an incentive spirometer, it is unlikely that this would have had any effect on development of postoperative pulmonary complications, as a number of previous studies have shown that incentive spirometry, whether supervised or unsupervised, has no effect in preventing the development of postoperative pulmonary complications after open abdominal surgery (Overend et al 2001, Ricksten et al 1986, Schwieger et al 1986).

It is possible that outcomes achieved in a clinical setting may be less optimal than those produced by a clinical trial for a number of reasons, including scarcity of resources and/or physiotherapy access to preoperative clinics. A survey of physiotherapy services across 37 NSW hospitals which conduct open abdominal surgery showed that 46% of hospitals did not routinely conduct preoperative assessments on open abdominal surgery patients (Mackay 2003). This may mean that some patients may be missing out on a highly effective part of physiotherapy. Considerable differences in anaesthetic practices and analgesia prescription in this group of patients also exist between hospitals in NSW (Mackay 2003), and is therefore also likely to influence respiratory outcomes.

Further research is required to determine if similar results can be obtained with less physiotherapy mobilisation input, or, if clinical outcomes can be improved by intensifying the distance, time, and/or exertion of early mobility interventions. A study comparing preoperative assessment with no preoperative assessment, with all subjects receiving a global policy of coached early mobilisation would also be a useful investigation. Such a study would require a non-physiotherapist to obtain consent from subjects prior to surgery to control for the possible treatment of the physiotherapist's visit. A comparison of coached early mobilisation provided by physiotherapists with standard early mobilisation provided by nursing staff might also clarify any differences between outcomes obtained from nursing compared to physiotherapy input. Further studies are needed investigating the efficacy of various physiotherapy interventions (including coached lateral basal expansion, CPAP, and mobilisation) in improving the rate of resolution of clinically significant postoperative pulmonary complications after they have developed.

In conclusion, the addition of DB&C exercises to a physiotherapist-directed program of early mobilisation does

not significantly reduce the incidence of clinically significant postoperative pulmonary complications in high risk open abdominal surgery subjects. These results were obtained in a clinical setting where patient-controlled epidural analgesia was used extensively and the standardised early mobilisation program was implemented and monitored by the physiotherapists.

Note Additional data (Tables 6 and 7, and Appendices 1 and 2) are available as e-addenda on the journal website at <www.physiotherapy.asn.au/AJP>.

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