Key messages

- Patients with breast cancer have 9% better survival at five years and 8% better survival at 10 years when cared for by specialist surgeons
- This finding is not a consequence of case mix or selective referral
- The maximum survival benefit for patients was seen in those aged 50-64 years and applied across all socioeconomic groups
- The findings could have implications for policies in cancer treatment and for purchasing cancer services

were operated on by the specialists themselves, which may indicate that training of junior staff by specialists is important.

We estimate specialist care could have improved survival over the nine year period of the study by 6·8 percentage points (specialists cared for 24·2% of the patients). This means an additional 253 patients would have survived five years in the study area, which would translate to over 850 patients in Scotland and many times that number in the United Kingdom as a whole if the same level of benefit occurred.

This study points to there being a substantial survival benefit for patients cared for by specialists. Thus we believe that future care of patients with breast cancer should be provided through specialist units. The advent of breast cancer screening has altered referral patterns but only for those between the ages of 50 and 64 years who are detected by screening. More cases of breast cancer (all ages) occur outside the screening programme than within it. Thus, the equitable provision of specialist services for patients with breast cancer presents a challenge for the health service. If our results can be reproduced in other settings the next step is to define the components of specialist care with greater precision and to relate these to outcome.

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1 Sharp L, Black RJ, Harkness EF, Finlayson AR, Muir CS. *Cancer registration statistics Scotland 1981-1990.* Edinburgh: Common Services Agency, 1993.
2 Carnon AG, Ssemwogerere A, Lamont DW, Hole DJ, Mallon EA, George WD, *et al.* Relation between socioeconomic deprivation and pathological prognostic factors in women with breast cancer. *BMJ* 1994;**309**:1054-7.
3 Bloom HJG, Richardson WW. Histological grading and prognosis in breast cancer. *Br J Cancer* 1957;**11**:359-77.
4 Carstairs V, Morris R. *Deprivation and health in Scotland.* Aberdeen: Aberdeen University Press, 1988.
5 Cox DR. Regression models and life tables. *Journal of the Royal Statistical Society* 1972;**34**:187-220.
6 Carter CL, Allen C, Henson DE. Relation of tumour size, lymph node status and survival in 24,740 breast cancer cases. *Cancer* 1989;**63**:181-7.
7 Early Breast Cancer Trialists' Collaborative Group. Systemic treatment of early breast cancer by hormonal, cytotoxic, or immune therapy. *Lancet* 1992;**339**:1-15, 71-85.
8 Junor EJ, Hole DJ, Gillis CR. Management of ovarian cancer: referral to a multidisciplinary team matters. *Br J Cancer* 1994;70:363-70.
9 Harding MJ, Paul J, Gillis CR, Kaye SB. Management of malignant teratoma. Does referral to a specialist unit matter? *Lancet* 1993;**341**:999-1002.
10 Karjalainen S. Geographical variation in cancer patient survival in Finland: chance, confounding, or effect of treatment? *J Epidemiol Community Health* 1990;**44**:210-4.
11 Basnett I, Gill M, Tobias JS. Variations in breast cancer management between a teaching and a non-teaching district. *Eur J Cancer* 1992;**28A**:1945-50.
12 King's Fund. Consensus development conference: treatment of primary breast cancer. *BMJ* 1986;**293**:946-7.
13 Sainsbury R, Haward B, Rider L, Johnston C, Round C. Influence of clinician workload and patterns of treatment on survival from breast cancer. *Lancet* 1995;**345**:1265-70.
14 Olivotto IA, Bajdik CD, Plenderleith IH, Coppin CM, Gelmon KA, Jackson SM, *et al.* Adjuvant systemic therapy and survival after breast cancer. *N Engl J Med* 1994;**330**:805-10.

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Prevention of respiratory complications after abdominal surgery: a randomised clinical trial

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Abstract

***Objective*—To evaluate the prevention of respiratory complications after abdominal surgery by a comparison of a global policy of incentive spirometry with a regimen consisting of deep breathing exercises for low risk patients and incentive spirometry plus physiotherapy for high risk patients.**

***Design*—Stratified randomised trial.**

***Setting*—General surgical service of an urban teaching hospital.**

***Patients*—456 patients undergoing abdominal surgery. Patients less than 60 years of age with an American Society of Anesthesia classification of 1 were considered to be at low risk.**

***Outcome measures*—Respiratory complications were defined as clinical features consistent with collapse or consolidation, a temperature above 38°C, plus either confirmatory chest radiology or positive results on sputum microbiology. We also recorded the time that staff devoted to prophylactic respiratory therapy.**

***Results*—There was good baseline equivalence between the groups. The incidence of respiratory complications was 15% (35/231) for patients in the incentive spirometry group and 12% (28/225) for patients in the mixed therapy group (P=0·40; 95% confidence interval −3·6% to 9·0%). It required similar amounts of staff time to provide incentive spirometry and deep breathing exercises for low risk patients. The inclusion of physiotherapy for high risk patients, however, resulted in the utilisation of an extra 30 minutes of staff time per patient.**

***Conclusions*—When the use of resources is taken into account, the most efficient regimen of prophylaxis against respiratory complications after abdominal surgery is deep breathing exercises for low risk patients and incentive spirometry for high risk patients.**

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Introduction

Chest therapy after surgery is directed towards maximal inspiration in an attempt to prevent overt atelectasis and allow for the early re-expansion of collapsed alveoli. In a previous clinical trial we demonstrated equivalence when we compared incentive spirometry with physiotherapy for patients undergoing abdominal surgery.[1] Adoption of incentive spirometry as a global method of prophylaxis, however, raises concerns that high risk patients may be receiving inadequate treatment and that important resources are being wasted on low risk patients. The objective of this trial was to evaluate the prevention of respiratory complications by comparing a global policy of incentive spirometry with a regimen consisting of deep breathing exercises for low risk patients and

incentive spirometry plus physiotherapy for high risk patients.

Patients and methods

We evaluated adults who underwent a laparotomy that included manipulation of viscera; patients who had elective operations for groin hernia were not included. The study was approved by the ethics committees for Royal Perth Hospital and the University of Western Australia. Treatment regimens were allocated at the time of admission to hospital and were based on computer generated numbers. Sealed opaque envelopes were placed within randomisation boxes on the wards. Entry of patients was monitored to ensure compliance with the randomisation procedure. Stratification into the high risk category was based on either an American Society of Anesthesia (ASA) classification >1 or an age of 60 years and over; our experience indicates that these criteria identify 88% of the patients who develop a respiratory complication after abdominal surgery.[2]

Putative risk factors were recorded to determine whether the groups were similar at baseline. The diagnosis of chronic bronchitis was based on the criteria of the Medical Research Council of the United Kingdom.[3] Patients who had smoked within eight weeks of surgery were classified as current smokers.[4] The extent of intraperitoneal sepsis at the time of surgery was recorded on a five point scale—that is, nil, confined to viscera, viscera plus free fluid, localised abscess, or free pus.[5] Anaesthesia charts were reviewed to determine the duration of anaesthesia and the American Society of Anesthesia classification.[6] In essence, the classification divides patients into five groups: healthy (class 1), mild to moderate systemic disease (class 2), severe systemic disease (class 3), severe systemic disorders that are already life threatening (class 4), and moribund (class 5). The site and length of the wound were recorded after surgery. The dosage of narcotics was expressed as the equivalent dose of pethidine.[7]

All forms of chest therapy were administered under the supervision of the attending clinicians and members of the department of physiotherapy. Table 1 details the treatment groups. Patients randomised to receive deep breathing therapy were seen once and encouraged to take 10 deep breaths each hour. Patients randomised to receive incentive spirometry were provided with a laminated information sheet and an Air_x Incentive Spirometer fitted with a one way valve (Airlife Inc, California). They were encouraged to use the incentive spirometer at least 10 times each hour by taking slow maximal inspirations and holding each breath for as long as possible. Such patients were reviewed once during the postoperative period. High risk patients in the mixed therapy group also underwent physiotherapy aimed at producing a maximal inspiratory effort at least once a day for the first three days after surgery and thereafter at a rate decided on by the attending physiotherapist. The research nurse made an independent assessment of each patient's compliance with chest therapy on a 100 mm visual linear analogue scale. On each visit the attending physiotherapist completed a sheet detailing the duration and nature of the physiotherapy. When possible, patients started respiratory therapy before surgery.

Table 1—*The treatment groups for examination of preventive therapy for respiratory complications after abdominal operation*

Risk	Incentive spirometry group	Mixed therapy group
Low risk	Incentive spirometry	Deep breathing exercises
High risk	Incentive spirometry	Incentive spirometry plus conventional chest physiotherapy

To avoid inclusion of transitory subclinical events a respiratory complication was defined as the presence of clinical features consistent with collapse or consolidation, plus an otherwise unexplained temperature above 38°C, and either positive findings on chest radiography or evidence of infection from sputum microbiology. Respiratory emboli and respiratory oedema (both cardiogenic and non-cardiogenic) were not regarded as respiratory complications for the purpose of this study. The presence of clinical signs was determined each day by the attending surgical staff. Chest radiography was done on all patients suspected of having a respiratory complication. An abnormal result on chest radiography showed atelectasis, collapse or consolidation, or pneumonic changes as judged by the attending radiologist. When a patient produced discoloured sputum samples were sent for culture. Blood gas analyses were performed at the discretion of the attending clinicians and respiratory insufficiency was defined as a $Pa0_2 < 60$ mm Hg. Decisions about the occurrence of a respiratory complication were independently checked by a clinician (JCH) who was unaware of the nature of the respiratory therapy. We also evaluated some important non-respiratory outcome events with previously established criteria.[5]

The incidence of respiratory complications was predicted to be between 10% and 15%. An overall sample size of 430 patients was estimated to be necessary to detect an absolute 10% difference in the incidence of postoperative respiratory complications by use of a two tailed comparison with a probability of a type I error of 5% and a power of 70%.[8] Data were entered onto Dbase 4 (Ashton-Tate, Torrance, California) and exported for analysis to the Complete Statistical System (Statsoft, Tulsa, Oklahoma). Statistical analysis was based on intention to treat but did not include patients who were randomised and did not subsequently undergo abdominal surgery. The proportions of patients with postoperative respiratory complications in each group were compared by using a two tailed χ^2 test, significance being defined as a probability of a type I error of less than 5%, and by declaration of the 95% confidence intervals.

Results

A total of 619 patients were considered for entry into the study. The reasons for exclusion of 143 patients from study were language problems (13), respiratory complications already present (15), and lack of consent (115). In all but 14 patients lack of consent was because of insufficient time to discuss the study with the patient. In addition, 20 patients who were randomised but did not undergo abdominal surgery were not included in the analysis. All of the patients who underwent abdominal surgery were included in the analysis.

The groups were comparable with respect to putative risk factors for a respiratory complication (table 2). As might be expected, patients classified as high risk according to age and criteria from the American Society of Anesthesia were more likely to undergo major surgery, consume more analgesics, and have cancer as the final diagnosis.

Table 3 summarises various outcome events. The overall incidence of respiratory complications was 13·8% (63/456); and 78% (49/63) of them occurred in patients classified as high risk. We did not observe any

clinically or statistically significant differences between the groups under study—that is, the incidence of respiratory complications was 15·2% (35/231) for the incentive spirometry group and 12·4% (28/225) for the mixed therapy group. No patient died as a direct result of a respiratory complication.

The administration of incentive spirometry to low risk patients occupied about the same staff time as did the supervision of deep breathing exercises (table 4). For high risk patients the addition of conventional chest physiotherapy occupied an additional 30 minutes of staff time per patient.

Discussion

All patients have some impairment of respiratory function after abdominal surgery. Areas of microatelectasis develop during anaesthesia and grow in the presence of the shallow monotonous ventilation and reduced mucociliary clearance that accompanies postoperative somnolence.[9,10] These changes occur even in the presence of good analgesia. By way of explanation, Ford *et al*[11] have emphasised that anaesthesia induces "a shift in respiratory pump activity from the diaphragm to other muscles." This temporary dysfunction of the diaphragm after abdominal surgery helps to explain the affinity of atelectasis for the bases of the lungs.[12]

There are concerns that some forms of physiotherapy are inappropriate prophylaxis. In a recent comprehensive review Stiller and Munday remarked that "there has been little conclusive research into the ability of chest physiotherapy to achieve its primary aims of improving the distribution of ventilation and increasing clearance of secretions in surgical patients."[13] It has also been suggested that physiotherapy may cause bronchospasm and short term hypoxaemia and that percussion or vibration with postural drainage should be reserved for conditions that are characterised by excessive sputum production.[14]

It is now believed that prophylaxis against postoperative respiratory complications is optimal when it is based on techniques that promote a maximal inspiratory effort. Frequent episodes of maximal inspiratory therapy, however, do not always prevent progression from microatelectasis to overt atelectasis within the bases of the lungs. In a previous clinical trial we found equivalent results when comparing chest physiotherapy, based mainly on inspiratory techniques, with incentive spirometry.[1] The overall incidence of respiratory complications was 15·5%, which suggests that neither form of treatment can completely overcome the problems associated with a "floppy" diaphragm. Chuter *et al* have presented suggestive evidence that deep breathing manoeuvres, rather than incentive spirometry, best increase diaphragmatic movement after surgery.[15,16] The precise way that incentive spirometers are used, however, is also an important consideration. It may be advantageous to do as we did and promote breath holding through the use of a one way valve.[17]

Table 2—*Characteristics of patients at baseline according to allocation of treatment groups to prevent respiratory complications after operation. Figures are numbers (percentage) unless otherwise stated*

Characteristic	Incentive spirometry —low risk (n=79)	Deep breathing —low risk (n=76)	Incentive spirometry —high risk (n=152)	Incentive spirometry plus conventional chest physiotherapy —high risk (n=149)
Male:female ratio	34:45	34:42	70:82	71:78
Median (interquartile range) age (years)	38 (29-44)	34 (29-43)	68 (62-76)	67 (58-76)
Comorbidity				
American Society of Anesthesia classification:				
1	79 (100)	76 (100)	0 (0)	0 (0)
2	0 (0)	0 (0)	94 (62)	87 (58)
3	0 (0)	0 (0)	50 (33)	50 (34)
4	0 (0)	0 (0)	8 (5)	12 (8)
Cancer	4 (5)	6 (8)	53 (35)	56 (38)
Current smoker	25 (32)	28 (37)	26 (17)	25 (17)
Chronic bronchitis	0 (0)	0 (0)	3 (2)	5 (3)
Surgery				
Median (interquartile range) duration (minutes)	90 (60-120)	90 (60-120)	105 (75-150)	120 (75-150)
Procedure:				
Hepatobiliary	22 (28)	27 (36)	39 (26)	36 (24)
Colorectal	8 (10)	10 (13)	49 (32)	55 (37)
Appendicectomy	14 (18)	11 (15)	3 (2)	1 (1)
Gastroduodenal	2 (30)	3 (4)	16 (11)	11 (7)
Cholecystectomy	24 (30)	21 (28)	19 (13)	23 (15)
Other laparotomy	8 (10)	3 (4)	22 (15)	17 (11)
Small bowel	1 (1)	1 (1)	4 (3)	6 (4)
Intraperitoneal infection:				
Nil	69 (87)	66 (87)	135 (89)	142 (95)
Viscera only	1 (1)	6 (8)	5 (3)	1 (1)
Free fluid	6 (8)	2 (3)	3 (2)	2 (1)
Free pus	2 (3)	1 (1)	5 (3)	3 (2)
Abscess	1 (1)	1 (1)	4 (3)	1 (1)
Site of incision:				
Vertical	54 (68)	50 (66)	60 (40)	66 (44)
Transverse/oblique:	25 (32)	26 (34)	92 (60)	83 (56)
Median (interquartile) length of incision (cm)	11 (4-15)	12 (5-15)	15 (12-18)	14 (10-18)
Nasogastric tube	16 (20)	13 (17)	56 (37)	58 (39)
Reoperation	3 (4)	2 (3)	7 (5)	8 (5)
Perioperative analgesia				
Intraoperative local analgesia	3 (4)	5 (7)	1 (1)	5 (3)
Epidural	5 (6)	3 (4)	27 (18)	32 (22)
Narcotic infusion	12 (15)	14 (18)	65 (43)	61 (41)
Median (interquartile range) dose of total narcotics (mg pethidine equivalents per patient receiving narcotics)	1021 (200-1166)	973 (150-1430)	1050 (200-1320)	1122 (190-1275)
Therapy with non-specific anti-inflammatory drugs	23 (29)	18 (24)	25 (16)	20 (13)

Table 3—*Incidence of outcome events in patients undergoing operation according to allocation of treatment for prevention of respiratory complications. Figures are numbers (percentage) unless otherwise stated*

Outcome event	Incentive spirometry —low risk (n=79)	Deep breathing —low risk (n=76)	Incentive spirometry —high risk (n=152)	Incentive spirometry plus conventional chest physiotherapy —high risk (n=149)
Postoperative respiratory complications*	6 (8)	8 (11)	29 (19)	20 (13)
Sputum:				
Sputum samples	2 (3)	5 (7)	12 (8)	10 (7)
Positive microbiology	0 (0)	0 (0)	3 (2)	1 (1)
Chest radiograph:				
No chest radiograph	61 (77)	54 (71)	83 (55)	71 (48)
Normal results	12 (15)	14 (18)	38 (25)	59 (40)
Segmental atelectasis	5 (6)	8 (10)	22 (15)	19 (13)
Lobar atelectasis	0 (0)	0 (0)	3 (2)	0 (0)
Whole lung atelectasis	1 (1)	0 (0)	0 (0)	0 (0)
Pneumonia	0 (0)	0 (0)	4 (3)	0 (0)
Aspiration	0 (0)	0 (0)	2 (1)	0 (0)
Respiratory failure:				
Blood gases performed	2 (3)	2 (3)	13 (9)	15 (10)
Respiratory insufficiency	1 (1)	0 (0)	3 (2)	5 (3)
Additional therapy:				
Nebuliser	0 (0)	1 (1)	20 (13)	18 (12)
Antibiotics	3 (4)	2 (3)	12 (8)	9 (6)
Endotracheal intubation	1 (1)	1 (1)	2 (1)	3 (2)
Tracheotomy	0 (0)	0 (0)	0 (0)	1 (1)
Constant positive airways pressure	0 (0)	1 (1)	3 (2)	3 (2)
Non-respiratory:				
Wound infection	1 (1)	3 (4)	9 (6)	9 (6)
Intraperitoneal infection	3 (4)	1 (1)	4 (3)	4 (3)
Intensive care admission	0 (0)	1 (1)	3 (2)	5 (3)
Median (interquartile range) length of postoperative stay (days)	5 (3-8)	5 (3-8)	9 (6-12)	9 (7-14)
Death	0 (0)	1 (1)	7 (15)	3 (2)

*Incentive spirometry group *v* mixed therapy group (deep breathing plus incentive spirometry/conventional chest physiotherapy)—χ^2=0·70; P=0·40; 95% confidence interval −3·6% to 9·0%.
Incentive spirometry (low risk) *v* deep breathing—χ^2=0·41; P=0·53; −11·7% to 5·9%.
Incentive spirometry (high risk) *v* incentive spirometry/conventional chest physiotherapy—χ^2=1·77; P=0·18; −2·6% to 14·0%.

Table 4—*Use of therapy to prevent respiratory complications after operation. Figures are medians (interquartile range)*

Detail	Incentive spirometry —low risk (n=79)	Deep breathing —low risk (n=76)	Incentive spirometry —high risk (n=152)	Incentive spirometry plus conventional chest physiotherapy —high risk (n=149)
Compliance with therapy (mm on visual linear analogue scale)	75 (70-80)	70 (65-80)	60 (50-70)	60 (50-70)
Time spent with a physiotherapist (min)	17 (10-30)	15 (10-24)	25 (15-40)	55 (30-90)

The need for prophylactic chest therapy for patients at low risk of postoperative respiratory complications is contentious. Celli *et al* compared a no treatment control group with intermittent positive pressure breathing, deep breathing exercises, and incentive spirometry in 172 patients undergoing elective surgery.[18] There were similar benefits for each of the control groups. Another study reported that deep breathing exercises were better than no treatment in patients undergoing elective upper abdominal surgery.[19] On the other hand, a small study by Schweiger *et al* suggested that healthy patients did not benefit from incentive spirometry after elective open cholecystectomy.[20] Hence, the balance of evidence suggests that any form of maximal inspiratory therapy is better than nothing, yet no particular regimen has clear superiority. Our study confirms that deep breathing exercises provide reasonable prophylaxis for low risk patients and that incentive spirometry alone is adequate prophylaxis for high risk patients. The latter finding is particularly important as previous studies have failed to evaluate the effects of providing both physiotherapy and incentive spirometry, when in fact such combined therapy is often provided in practice for patients who are thought to be at high risk for postoperative respiratory complications. It should be noted that our declared statistics are fairly conservative: concentration on atelectasis as the outcome event, with the exclusion of patients with pneumonia or overt aspiration, would have resulted in a 29/231 (12·6%) versus 28/225 (12·4%) comparison if we compared the incentive spirometry group with the mixed therapy group.

This trial also demonstrates that an American Society of Anesthesia classification >1 and an age ≥ 60 years are helpful indicators of the risk of postoperative respiratory complications. Such criteria, as well as being useful in clinical research, may play a part in clinical programmes of perioperative respiratory therapy such as those advocated by Levy *et al*[21] and Torrington *et al*.[22]

Our results also carry implications about the efficient use of resources. One of the benefits of adopting less time consuming forms of routine prophylaxis might be the diversion of resources towards those with existing respiratory problems. In a previous study we found that conventional chest physiotherapy cost $A12.19 per patient.[23] A similar cost accrued when incentive spirometers were put to use and each unit recycled on average 2·3 times. That seems to be an easy

Key messages

- Of over 450 patients who underwent abdominal surgery, 14% developed clinically important respiratory complications
- Most postoperative respiratory complications were due to atelectasis: less than 1% of the patients developed pneumonia
- An American Society of Anesthesia classification >1 and an age ≥ 60 years is a simple way of defining patients at high risk of respiratory complications and other adverse events after abdominal surgery
- A regimen consisting of deep breathing exercises (low risk patients) and incentive spirometry (high risk patients) is an efficient way of providing prophylaxis against respiratory complications after abdominal surgery

task as we were recycling the units on average 4·7 times in the absence of any specific policy. We conclude that the most efficient form of prophylactic chest therapy for patients undergoing abdominal surgery includes deep breathing exercises for low risk patients and incentive spirometry for high risk patients. In this context there is no longer a requirement on surgical wards for more intensive forms of chest physiotherapy. This information provides a platform for the rational use of services aimed at preventing postoperative respiratory complications. It will enable physiotherapists to spend a greater proportion of their time treating patients with established respiratory problems.

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1 Hall JC, Tarala R, Harris J, Tapper J, Christiansen K. Incentive spirometry versus routine chest physiotherapy for prevention of respiratory complications after abdominal surgery. *Lancet* 1991;**337**:953-6.
2 Hall JC, Tarala RA, Hall JL, Mander J. A multivariate analysis of the risk of respiratory complications after laparotomy. *Chest* 1991;**99**:923-7.
3 Medical Research Council Committee on the Aetiology of Chronic Bronchitis. Definition and classification of chronic bronchitis for clinical and epidemiological purposes. *Lancet* 1965;i:775-9.
4 Jackson CV. Preoperative respiratory evaluation. *Arch Intern Med* 1988;**148**: 2120-7.
5 Hall JC, Hall JL, Christiansen K. The role of ceftriaxone and cephamandole in patients undergoing abdominal surgery: a clinical trial. *Arch Surg* 1991;**126** 512-6.
6 Vacanti CJ, Vanhouten RJ, Hill RC. A statistical analysis of the relationship of physical status to postoperative mortality in 68,388 cases. *Anesth Analg* 1970;**49**:564-6.
7 American Pain Society. *Principles of analgesic use in the treatment of acute pain and chronic cancer pain.* Chicago: American Pain Society, 1989:10.
8 Fleiss JL. *Statistical methods for rates and proportions.* 2nd ed. New York: John Wiley, 1981:178-80.
9 Strandberg A, Tokics L, Brismar B, Lundquist H, Hedenstierna G. Constitutional factors promoting development of atelectasis during anaesthesia. *Acta Anaesthesiol Scand* 1987;**31**:21-4.
10 Jones JG. Anaesthesia and atelectasis: the role of V_{TAB} and the chest wall. *Br J Anaesth* 1987;**59**:949-53.
11 Ford GT, Rosenal TW, Clergue FC, Whitelaw WA. Respiratory physiology in upper abdominal surgery. *Clin Chest Med* 1993;**14**:237-52.
12 Dureuil B, Cantineau P, Desmonts JM. Effects of upper or lower abdominal surgery on diaphragmatic function. *Br J Anaesth* 1987;**59**:1230-5.
13 Stiller KR, Munday RM. Chest physiotherapy for the surgical patient. *Br J Surg* 1992;**79**:745-9.
14 Selsby DS. Chest physiotherapy may be harmful in some patients. *BMJ* 1989;**298**:541-2.
15 Chuter TAM, Weissman C, Starker PM, Gump FE. Effect of incentive spirometry on diaphragmatic function after surgery. *Surgery* 1989;**105**: 488-93.
16 Chuter TAM, Weissman C, Mathews DM, Starker PM. Diaphragmatic breathing maneuvers and movement of the diaphragm after cholecystectomy. *Chest* 1990;**97**:1110-4.
17 Baker WL, Lamb VJ, Marini JJ. Breath-stacking increases the depth and duration of chest expansion by incentive spirometry. *Am Rev Respir Dis* 1990;**141**:343-6.
18 Celli BR, Rodriguez KS, Snider GL. A controlled trial of intermittent positive pressure breathing, incentive spirometry, and deep breathing exercises in preventing respiratory complications after abdominal surgery. *Am Rev Resp Dis* 1984;**130**:12-5.
19 Roukema JA, Carol EJ, Prins JG. The prevention of respiratory complications after upper abdominal surgery in patients with noncompromised respiratory status. *Arch Surg* 1988;**123**:30-4.
20 Schweiger I, Gamulin Z, Forster A, Meyer P, Gemperle M, Suter PM. Absence of benefit of incentive spirometry in low-risk patients undergoing elective cholecystectomy: a controlled randomised study. *Chest* 1986;**89**: 652-6.
21 Levy PS, Rutherford HG, Shepard BM. Usefulness of preoperative screening tests in perioperative respiratory therapy. *Respir Care* 1979;**24**:701-9.
22 Torrington KG, Henderson CJ. Perioperative respiratory therapy (PORT): a program of postoperative risk assessment and individualised postoperative care. *Chest* 1988;**93**:946-51.
23 Hall JC, Tapper J, Tarala R. The cost-efficiency of incentive spirometry after abdominal surgery. *Aust NZ J Surg* 1993;**63**:356-9.

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Commentary: Mixed, or mixed up, treatment?

S J W Evans

In the past 50 years the place of the randomised clinical trial as the best method of making comparisons of treatments has come to be accepted by most investigators. The most important feature of a clinical trial is that an unbiased comparison is made between alternative treatments (including the possibility of no treatment). The central issues in carrying out a clinical trial are to remove bias from the design, conduct, and analysis of the trial and to be as precise as possible in obtaining quantitive estimates of the comparative effect of a treatment. The main features that contribute towards unbiased comparisons include randomised allocation of treatment and the concealment of that allocation from the investigator admitting a participant to the trial and making masked assessments of the effect of the treatment. An aspect of design that is also dependent on the analysis of the trial is that the number of participants is sufficient for the trials objectives to be met.

This trial illustrates several good features. In terms of internal validity, good features include that concurrent controls were used; that random allocation was used; that the method of randomisation was reasonably well described; and that the randomisation seems to have been concealed from the investigators by the use of sealed envelopes.

Some features, however, make the overall interpretation of the trial a little less clear than the authors claim. The stratification of the patients into two groups —high and low risk—which is of itself quite reasonable, leads to what is effectively two different trials. They share a control group in terms of having one "arm" with incentive spirometry. In the low risk group deep breathing exercises are the comparative arm whereas in the high risk group an entirely different procedure—physiotherapy—is additional to incentive spirometry in the intervention arm. The consequence is that the treatments being compared in the low risk and high risk groups are different. There is no reason to believe that the difference between the two arms in the low risk stratum will be in the same direction, never mind have the same magnitude of effect as the intervention in the high risk stratum. Consequently a pooling of these results is illogical and would not even occur in a meta-analysis.

There are a few other minor points at issue, some of which spring from the merging of two trials into a single design and analysis. Firstly, it is usually sensible to stratify a trial into different risk factor or prognosis groups to ensure that the intervention and control groups are as similar as possible for that prognostic factor. Hence it is important that some form of

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