Absence of Benefit of Incentive Spirometry in Low-Risk Patients Undergoing Elective Cholecystectomy*

A Controlled Randomized Study

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To determine the potential benefit of incentive spirometry, which has been advocated to prevent pulmonary complications after upper-abdominal surgery, we compared a group of patients receiving incentive spirometry to another group receiving no specialized postoperative respiratory care. Forty patients in the American Society of Anesthesiologists' class 1 and 2 who were undergoing cholecystectomy (through right subcostal incision) were included in the study and were randomly allocated to one of the two groups. Patients receiving incentive spirometry were encouraged by a specialized respiratory physiotherapist to breathe deeply for five minutes hourly, 12 times daily, for three postoperative days. No statistically significant difference between the two groups was found in the radiologic evidence of postoperative pulmonary complications, arterial oxygen pressure, spirometric measurement, and clinical evaluation at the second or fourth postoperative day (or both). In particular, deterioration on the chest x-ray film at the fourth postoperative day was observed in eight of 20 patients in the group receiving incentive spirometry and in six of 20 in the control group. Our study confirms the postoperative deterioration of respiratory function after upper-abdominal surgery and demonstrates the lack of therapeutic values of incentive spirometry in these patients at low risk for pulmonary complications.

Postoperative pulmonary complications remain the most important and frequent cause of postoperative morbidity.[1] Patients with chronic obstructive pulmonary disease, obesity, advanced age, and cardiovascular diseases are highly predisposed to develop such complications.[2-5] The highest incidence of postoperative pulmonary complications occurs mainly after upper-abdominal and thoracic surgery, and the complications consist of regional or diffuse atelectasis, pulmonary embolism, and hypoxia possibly associated with infections which are related to reduced respiratory volumes and forced expiratory volume in one second (FEV_1).[6-8]

During the past two decades, in an attempt to reduce the incidence of these complications, preventive measures have been developed, such as physical measures to prevent atelectasis and to clear secretions, early use of antibiotics, early ambulation, and prophylactic treatment with heparin. In spite of routine administration of such treatments in many hospitals, no decrease in the incidence of postoperative pulmonary complications has been noted.[9] Among the different mechanical aids to pulmonary expansion which are available for the treatment of nonintubated patients, blow bottles and intermittent positive-pressure breathing (IPPB) have been mostly abandoned because they have been shown to be ineffective.[10,11] The efficiency of administration of continuous positive airway pressure (CPAP) by mask remains controversial.[1]

Since patient's collaboration and motivation are essential factors in any program of treatment, incentive spirometry has generated much enthusiasm.[12] This technique stimulates the patients to improve their inspiratory volumes by continuously visualizing their inspiratory effort; however, when compared with other techniques, the superiority of incentive spirometry has not been clearly demonstrated.[1]

The purpose of this study was to assess the potential benefit of incentive spirometry in preventing postoperative pulmonary complications after upper-abdominal surgery in patients in the American Society of Anesthesiologists' class 1 and 2,[13] when compared in a controlled and randomized fashion to a similar group of patients not receiving any form of respiratory treatment.

Materials and Methods

Forty patients in the American Society of Anesthesiologists' class 1 and 2 who were undergoing elective cholecystectomy through right subcostal incision agreed after informed consent to participate in the study, which was approved by the committee of ethics of our institution. Patients with a ratio of weight to height greater than 0.45

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were excluded from the study, as were patients over 65 years of age and those with an acute infection.

The patients were randomly assigned to one of the following two groups:

Incentive spirometry

Before surgery, these patients were trained by a respiratory physiotherapist to exercise their respiratory muscles with the help of a volumetric incentive spirometer (Inspiron) and were informed about the possible pulmonary complications after surgery. The postoperative treatment, which started on the day of surgery, was also supervised; it consisted of increasingly deep and prolonged inspirations with the incentive spirometer for five minutes hourly, at least 12 times per day for the first three postoperative days, between 8 AM and 7 PM. Each patient performed 150 to 200 inspirations daily as deeply as possible.

Control Group

These patients did not receive any respiratory treatment before or after surgery; however, they were informed that blood gas analyses and spirometric measurements would be performed in order to control the respiratory function.

The patients of both groups were mobilized on the day of surgery, and nasogastric tubes were removed on the first postoperative day. Prevention of thromboembolic complications was started on the day of surgery, and consisted of 5,000 units of heparain twice daily administered subcutaneously and was continued throughout the study.

Smoking history was taken, and preoperative clinical evaluation consisted of pulmonary auscultation in search of pulmonary hypoventilation, atelectasis, or pleural effusion. After surgery, the presence of a cough, production of sputum, and dyspnea were recorded, and the physical examination was repeated on the second and fourth postoperative days.

In all patients the following objective variables were obtained: (1) before surgery, arterial blood gas analysis on room air, determination of body temperature, white blood cell count (WBC) and differential cell count, and posteroanterior chest x-ray film in the upright position were obtained; and the forced vital capacity (FVC) and FEV_1 were determined three times using a spirometer (Vitalograph) (with the highest value considered valid); (2) on the day of surgery, the evaluation consisted only of arterial blood gas analysis in the recovery room while breathing room air; and (3) on the second and fourth postoperative days, the patients were evaluated as on the preoperative day, except for the chest x-ray film and the WBC, which were performed only on the fourth postoperative day. Chest x-ray films were evaluated blindly by two radiologists.

In the group receiving incentive spirometry, all analyses of arterial blood gas levels were performed on room air in the morning before the treatment, and pulmonary volumes were measured in the semirecumbent patient after two or three treatments. In the control group, all arterial blood gas levels and measurements of pulmonary volumes were performed in the mornings.

Preoperative, Surgical, and Postoperative Care

All patients received diazepam (5 to 10 mg) orally and meperidine (1 mg/kg of body weight) intramuscularly as preoperative medication. Antibiotics were not administered. Anesthesia was induced by thiopental (thiopentone; 4 mg/kg intravenously). Muscular relaxation was achieved with pancuronium (0.1 mg/kg intravenously). The patients were intubated, and general anesthesia was maintained with a nitrous oxide-oxygen mixture, enflurane, and fentanyl intravenously (total dose, 0.2 to 0.4 mg).

After surgery the patients were placed in the recovery room, where they received oxygen from a mask. Analgesia was provided with minor analgesics and, when necessary, with meperidine (25 mg intramuscularly) as required.

Table 1—*Physical and Clinical Characteristics of Patients in Both Groups**

Data	Incentive Spirometry	Controls
Age, yr	55 ± 15	52 ± 14
Height, cm	165.5 ± 9.0	162.8 ± 10.4
Weight, kg	65.9 ± 13.7	68.9 ± 11.6
Female-male ratio	15/5	16/4
No. of smokers (>15 pack-years)	4	4
Duration of anesthesia, min	137 ± 51	133 ± 55
Mean dosage of meperidine per patient, mg	85 ± 38	108 ± 66

*Table data are means ± SD.

Criteria for Diagnosing Pulmonary Complications

The criteria for diagnosing pulmonary complications consisted of any of the following: (1) radiologic evidence of atelectasis, alveolar infiltrate, or pleural effusion; (2) basal rales, absent breath sounds, or tubular breathing by auscultation, as well as a productive cough; and (3) evidence of elevation of body temperature above 38.5°C and increased WBC above 15,000/cu mm, associated with minimal pulmonary symptoms.

All values are given as the mean (± SD). Statistical analysis was performed with a one-way analysis of variance or unpaired *t*-test, as appropriate.

Results

The physical and clinical characteristics of the patients in the two groups were similar, as indicated in Table 1. The majority of the patients in both groups were middle-aged women. Anesthesia lasted less than three hours in the majority of patients in both groups (18 of 20 in either group). All patients received a similar dose of minor analgesics, and the number of patients, (nine in the control group and ten in the group receiving incentive spirometry) requiring meperidine and the average dose were comparable in both groups.

The changes in the chest x-ray film, WBC, and body temperature, as shown in Table 2, are comparable in

Table 2—*Roentgenographic Changes, WBC, and Axillary Temperature**

Data	Incentive Spirometry	Controls
No. of patients in group	20	20
No. with atelectasis	6	5
No. with pleural effusions	2	0
No. with alveolar infiltrate	0	1
WBC per cu mm		
Before surgery	6,458 ± 2,117	6,583 ± 1,373
4th postoperative day	6,944 ± 2,347	7,375 ± 2,170
Body temperature, °C		
Before surgery	36.5 ± 0.4	36.5 ± 0.5
2nd postoperative day	37.1 ± 0.6	37.1 ± 0.5
4th postoperative day	36.7 ± 0.4	36.7 ± 0.4

*Table data are means ± SD.

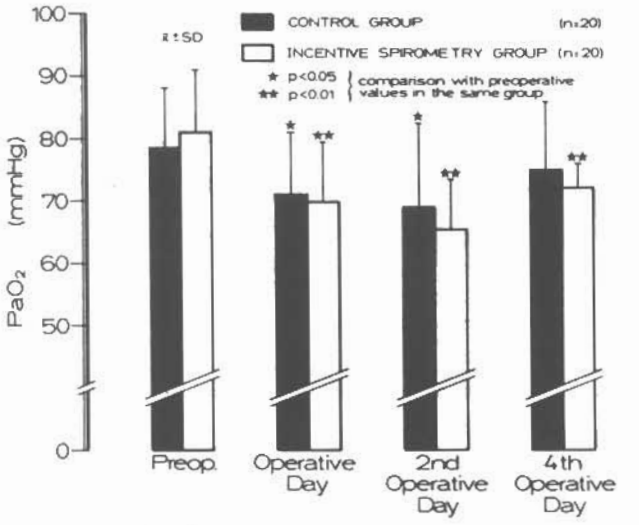

FIGURE 1. Values of PaO_2 measured before surgery and on three different postoperative days.

both groups. In no patient did body temperature exceed 38.5°C and WBC exceed 15,000/cu mm. Atelectasis was noted in six patients in the group with incentive spirometry and in five patients in the control group. In addition, pleural effusions were present in two patients in the group with incentive spirometry, and an alveolar infiltrate was seen in one patient in the control group.

Clinical evaluation revealed a similar incidence of complications: decreased basal breath sounds in three patients in the group with incentive spirometry and in three patients in the control group, as well as a productive cough in one patient in the group with incentive spirometry and decreased basal breath sounds with productive cough in one patient in the control group. In all patients, clinical complications were associated with radiologic changes, which in our study were found in eight (40 percent) of the 20

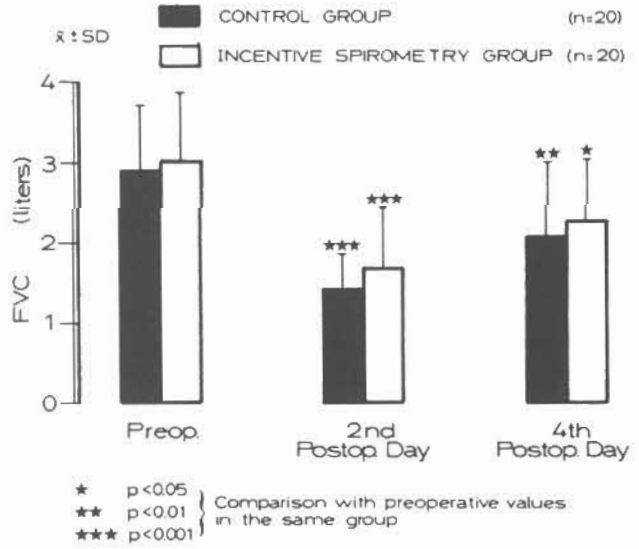

FIGURE 2. Values of FVC measured before surgery and on two different postoperative days.

patients in the group with incentive spirometry and in six (30 percent) of the 20 patients in the control group.

Figure 1 illustrates the variation in arterial oxygen pressure (PaO_2), which was similar in both groups throughout the study. In the group with incentive spirometry, PaO_2 decreased by 14 percent ($p<0.01$) on the day of surgery and by 19 percent ($p<0.01$) on the second postoperative day and returned on the fourth postoperative day to 88 percent ($p<0.01$) of the preoperative value. In the control group, PaO_2 decreased by 9 percent ($p<0.05$) on the day of surgery and by 12 percent ($p<0.05$) on the second postoperative day and returned to 95 percent of the preoperative value on the fourth postoperative day. No significant statistical difference was noted at any time between the two groups.

Figure 2 shows the variation of FVC in the patients in both groups throughout the study. On the second postoperative day the FVC decreased to 53 percent of the preoperative value ($p<0.001$) in the group receiving incentive spirometry and to 52 percent ($p<0.001$) in the control group; the FVC recovered to 76 percent of the preoperative value ($p<0.05$) in the group with incentive spirometry and to 73 percent ($p<0.01$) in the control group on the fourth postoperative day. There was no significant statistical difference between the two groups. Similar changes were observed in FEV_1 in both groups.

When all 14 patients with radiologic evidence of postoperative pulmonary complications were grouped together and compared to the 26 others, regardless of the treatment received, no statistical difference was noted in body temperature, in WBC, and PaO_2. There was also no correlation between the presence of radiologic evidence of postoperative pulmonary complications and variation of PaO_2 between the preoperative day and the fourth postoperative day.

DISCUSSION

Our study confirms the high incidence of postoperative pulmonary complications after upper-abdominal surgery, which in the literature was found to be in the range of 30 to 70 percent.[7,14-16] Our study also confirms the important decrease in PaO_2 after upper-abdominal surgery associated with the greatest measured depression in FVC which occurred on the second postoperative day, as noted in other studies.[6,8,17]

Nevertheless, comparison between the two groups revealed no significant difference in the incidence of postoperative pulmonary complications, decrease of PaO_2, in the decrease in FVC, and in changes in body temperature or WBC. Incentive spirometry was proposed on the theoretical basis of encouraging patients to breathe to total lung capacity (TLC), to sustain that inflation, and, by opening collapsed alveoli, to prevent atelectasis. Other reported advantages of incentive

spirometry include better elimination of pulmonary secretions[17] and an early detection of pulmonary disease.[18] Moreover, it has been suggested on a theoretical basis that breathing into TLC should not be particularly painful after laparotomy because abdominal muscles do not contribute to the inspiratory effect.[19] However, this is not entirely convincing, since deep excursions of the diaphragm can be painful, as clinically observed.

Studies evaluating the therapeutic value of incentive spirometry are difficult to compare with each other because of differences in the definition of postoperative pulmonary complications, groups of patients, and the design of the study.[14,16,20-24] When incentive spirometry was compared to IPPB and to resistance breathing (blow bottles) in patients undergoing upper-abdominal surgery,[23] no statistically significant differences were found in the incidence of atelectasis among the three groups. In another study, no difference in either the incidence or severity of postoperative pulmonary complications or in the postoperative course was found when the efficacy of incentive spirometry was studied as an adjunct to twice daily physical therapy.[14] On the contrary, earlier studies have shown a decrease in the incidence of postoperative pulmonary complications in patients undergoing upper-abdominal surgery who received incentive spirometry when compared to a group of patients receiving IPPB,[20] a regimen of cough and deep breathing,[16] and twice daily physical therapy.[24]

To our knowledge, only one recent study compared incentive spirometry, IPPB, and deep-breathing exercises to a control group (not treated).[22] Clinical evaluation performed on the fourth postoperative day revealed a significant decrease in postoperative pulmonary complications in these three groups when compared to the control group. No differences were noted among the three treated groups; however, in the only objective test performed (chest x-ray film performed 24 hours after surgery), no differences were noted among the four groups. No other objective data, such as PaO_2, WBC, or body temperature, are presented, and evaluation of the American Society of Anesthesiologists' class risk is not reported. We believe that both objective (PaO_2, body temperature, WBC, and chest x-ray film), as well as subjective clinical (physical examination) data are necessary to define clinically relevant postoperative pulmonary complications. In our study, clinical assessment alone is unreliable, since only 57 percent (eight) of our 14 patients with radiologic evidence of postoperative pulmonary complications had clinical signs of such complications, and all paraclinical criteria were similar, whether abnormal radiologic signs were observed or not.

In order to prevent postoperative pulmonary complications in patients undergoing upper-abdominal surgery, other investigators, comparing CPAP, incentive spirometry, and the combination of cough and deep breathing, have suggested that using CPAP may be beneficial, since after surgery the mean functional residual capacity (FRC) in patients treated with CPAP increased more rapidly than did the mean FRC of patients receiving the combination of cough and deep breathing;[21] however, there was no statistically significant difference in the postoperative increase in FRC between the group with CPAP and the group with incentive spirometry or between the groups with incentive spirometry and with combined cough and deep breathing. The incidence of atelectasis diagnosed on chest x-ray films at 72 hours was lower in the group with CPAP than in the two other groups, but not significantly. No blood gas analysis was performed.

It has been suggested that the best results in preventing postoperative pulmonary complications occur when breathing to TLC every hour with at least 100 sustained maximal inhalations per day;[24-26] this is surprising, since our patients followed a similar treatment, and our results do not support the superiority of this regimen. The absence of therapeutic value of incentive spirometry in our patients can be attributed to the fact that only low-risk patients undergoing cholecystectomy through subcostal incision were selected. They all received optimal postoperative care; nasogastric tubes were removed early, mobilization started rapidly, adequate analgesia was provided, and thromboembolic prophylaxis was carried out. Our results show that patients in the American Society of Anesthesiologists' class 1 and 2 who are undergoing upper-abdominal surgery and who receive optimal routine postoperative care do not benefit from the addition of incentive spirometry to the therapeutic arsenal. Since the subjects studied represent an important percentage of patients undergoing upper-abdominal surgery, our results suggest that respiratory therapists need not concentrate their efforts on these patients.

Our study does not exclude the benefit of incentive spirometry, but its therapeutic value should be assessed in patients at higher risk undergoing upper-abdominal surgery using different incisions, since it is accepted that subcostal incisions cause less postoperative dysfunction.[27]

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