Original Investigation

The Effect of Incentive Spirometry on Postoperative Pulmonary Function Following Laparotomy
A Randomized Clinical Trial

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IMPORTANCE Changes in pulmonary dynamics following laparotomy are well documented. Deep breathing exercises, with or without incentive spirometry, may help counteract postoperative decreased vital capacity; however, the evidence for the role of incentive spirometry in the prevention of postoperative atelectasis is inconclusive. Furthermore, data are scarce regarding the prevention of postoperative atelectasis in sub-Saharan Africa.

OBJECTIVE To determine the effect of the use of incentive spirometry on pulmonary function following exploratory laparotomy as measured by forced vital capacity (FVC).

DESIGN, SETTING, AND PARTICIPANTS This was a single-center, randomized clinical trial performed at Kamuzu Central Hospital, Lilongwe, Malawi. Study participants were adult patients who underwent exploratory laparotomy and were randomized into the intervention or control groups (standard of care) from February 1 to November 30, 2013. All patients received routine postoperative care, including instructions for deep breathing and early ambulation. We used bivariate analysis to compare outcomes between the intervention and control groups.

INTERVENTION Adult patients who underwent exploratory laparotomy participated in postoperative deep breathing exercises. Patients in the intervention group received incentive spirometers.

MAIN OUTCOMES AND MEASURES We assessed pulmonary function using a peak flow meter to measure FVC in both groups of patients. Secondary outcomes, such as hospital length of stay and mortality, were obtained from the medical records.

RESULTS A total of 150 patients were randomized (75 in each arm). The median age in the intervention and control groups was 35 years (interquartile range, 28-53 years) and 33 years (interquartile range, 23-46 years), respectively. Men predominated in both groups, and most patients underwent emergency procedures (78.7% in the intervention group and 84.0% in the control group). Mean initial FVC did not differ significantly between the intervention and control groups (0.92 and 0.90 L, respectively; $P = .82$ [95% CI, 0.52-2.29]). Although patients in the intervention group tended to have higher final FVC measurements, the change between the first and last measured FVC was not statistically significant (0.29 and 0.25 L, respectively; $P = .68$ [95% CI, 0.65-1.95]). Likewise, hospital length of stay did not differ significantly between groups. Overall postoperative mortality was 6.0%, with a higher mortality rate in the control group compared with the intervention group (10.7% and 1.3%, respectively; $P = .02$ [95% CI, 0.01-0.92]).

CONCLUSIONS AND RELEVANCE Education and provision of incentive spirometry for unmonitored patient use does not result in statistically significant improvement in pulmonary dynamics following laparotomy. We would not recommend the addition of incentive spirometry to the current standard of care in this resource-constrained environment.

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Postoperative pulmonary complications (PPC) following laparotomy are common and present a significant burden to health care systems by increasing health care costs, resource utilization, hospital length of stay, morbidity, and mortality.[1-5] The frequency of PPC after laparotomy reported in the literature varies widely, ranging from 20% to 90% for atelectasis and 9% to 40% for postoperative pneumonia.[3-16] Risk factors include older age, smoking, malnutrition, preoperative or intraoperative blood loss, emergency surgery, and upper abdominal or thoracic surgery.[2-5,8,17-19]

The functional mechanisms associated with the onset of PPC are not completely understood but likely involve a combination of decreased lung volume resulting in atelectasis and impaired mucociliary clearance.[1,4-6,17,18] Deep breathing and coughing exercises may help mobilize secretions and reexpand areas of collapsed lung postoperatively. The resultant sustained alveolar inflation and maintenance of normal functional residual capacity is thought to prevent PPC.[5]

Incentive spirometry (IS) is a breathing technique in which deep breathing exercises are performed through a device offering visual feedback in terms of inspired flow and volume. The addition of visual feedback is thought to improve breathing technique and increase patient motivation.[20] Use of IS has gained substantial popularity in high-income countries since it was first introduced by Bartlett et al[20] in 1973 and is now considered the standard of care in the postoperative period.[3,5,21] However, postoperative interventions to prevent PPC have demonstrated mixed results. Although some reviews have shown decreased incidence of PPC and length of stay in patients using IS,[9] others have found little benefit from this intervention.[5,21,22]

Data on PPC in low- and middle-income countries are scarce; however, the burden of health care–associated infections in low- and middle-income countries is high.[23,24] Limited data suggest that health care–associated infections[25] and surgical site infections[26-29] are more common in sub-Saharan Africa than in high-income countries and that patients in sub-Saharan Africa with health care–associated infections have longer lengths of stay. However, to our knowledge, no studies have reported the incidence of PPC in sub-Saharan African settings, examined the effect of PPC on mortality in this setting, or described interventions designed to reduce PPC.

Given the contradictory nature of the data in high-income settings and paucity of data in sub-Saharan Africa, we conducted a prospective randomized trial of postoperative IS in adult patients in sub-Saharan Africa who underwent laparotomy in a resource-poor setting.

Methods

Study Design

This study was a single-center, randomized clinical trial performed at Kamuzu Central Hospital in Lilongwe, Malawi. Kamuzu Central Hospital is a 600-bed tertiary care facility serving a catchment population of approximately 5 million people in central Malawi. Adult patients of both sexes and all ethnic groups who underwent laparotomy by a general surgeon at Kamuzu Central Hospital were eligible for enrollment.

A total of 150 patients were enrolled, 75 in each arm, using an intention-to-treat model (**Figure 1**). Eligible patients were identified from the operating theater log; a blinded research assistant approached patients for consent. Consenting patients were randomized into treatment or control groups using permuted block randomization in blocks of 4, 6, and 8. The randomization sequence was developed before the initiation of the trial and concealed until after enrollment. Following randomization, peak flow measurements and data analysis were not blinded. The primary surgical team treating the patients and diagnosing postoperative complications was blinded to randomization. The institutional review boards at the University of North Carolina and the Malawi National Health Sciences Review Committee approved this trial. Written informed consent was obtained from all participants.

Participants

Participants met inclusion criteria for this study if they were at least 18 years of age and underwent elective or emergency laparotomy by a general surgeon. Patients were excluded if they were younger than 18 years, if they were not general surgery patients, if they were unable or unwilling to participate, if they were admitted to the intensive care unit or high-dependency unit postoperatively, if they underwent tracheostomy or were left intubated postoperatively, or if they could not be located or recruited within 3 days of the initial operation.

Intervention

After randomization, patients in the study arm received the DISPIRO Disposable Spirometer System (Utah Medical Products Inc), in addition to deep breathing instructions. Patients in the control arm were given the standard of care only.

Measures

All patients had peak flow measurements performed on enrollment and every 2 to 3 days postoperatively. All patients received the standard postoperative pain control and instructions for deep breathing, coughing, and early ambulation. Patients in the intervention group were instructed to fully inflate the incentive spirometer every hour. Neither the research staff nor the hospital staff supervised or recorded the use of spirometers during follow-up. Peak flow measurements ended when the patient was discharged, if the patient became ineligible, or after 6 measurements if the peak flow measurements stabilized but discharge was delayed for nonpulmonary complications. Patients who became ineligible were included up to the point of withdrawal, after which time no additional peak flow measurements were taken, but final outcome and hospital length of stay were recorded from the medical record. Demographic and clinical information were obtained from the medical record and the operative log.

The primary outcome of interest of this study is change in pulmonary function, using forced vital capacity (FVC) measurements, between the patients' first and last measurements. We hypothesized that patients with incentive spirometers would have a faster return to normal FVC and baseline

pulmonary function compared with patients without spirometers. Secondary outcomes were hospital length of stay and mortality. We were unable to measure incidence of pulmonary complications due to diagnostic limitations and poor documentation. Cause of death was abstracted, when available, from the medical record. The primary surgical team was solely responsible for all postoperative diagnostic and therapeutic decision making and documentation in the medical record. No additional diagnostic tests were performed for this trial.

Statistical Analysis

The study was powered to detect a 20% difference in final FVC measurements between the intervention and control groups. We used means, medians, and percentages to describe the baseline characteristics of the study participants and bivariate analysis to assess randomization between the intervention and control groups. We used the Pearson χ^2 test to compare categorical secondary outcomes, *t* test for normally distributed continuous variables, and K-sample equality-of-means test for badly skewed continuous variables. We also performed subgroup analysis for trauma patients and patients with known or suspected cancer.

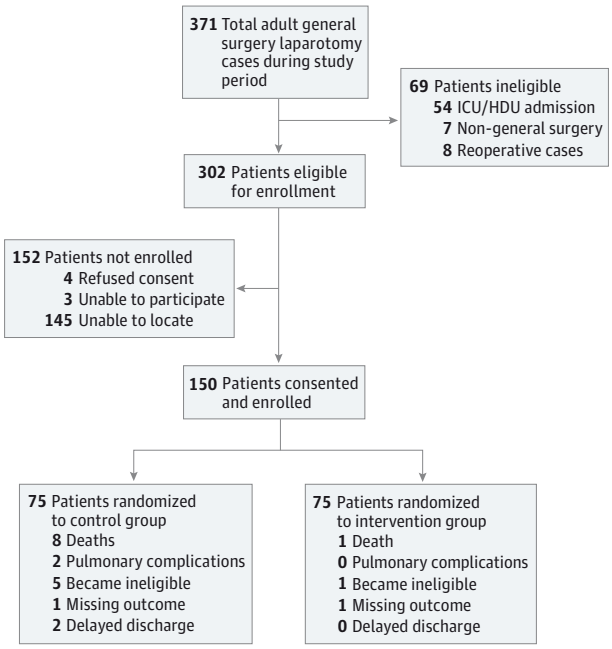
Results

A total of 371 adult exploratory laparotomy cases were performed at Kamuzu Central Hospital between February 1 and November 30, 2013. Of these, 150 patients were enrolled in the trial, and 75 patients were randomized to each arm (Figure 1). The median age in the intervention and control groups was 35 and 33 years, respectively (range, 18-78 years). Men predominated in both groups, and most patients underwent emergency procedures (78.7% in the intervention group and 84.0% in the control group). Diagnoses and procedures performed were similar between the control and intervention groups (**Table 1**). Most patients were enrolled within 2 days of exploratory laparotomy and underwent between 2 and 3 FVC measurements.

Mean initial FVC did not differ significantly between the intervention and control groups (0.92 and 0.90 L, respectively; $P = .82$ [95% CI, 0.52-2.29]). Although patients in the intervention group tended to have higher final FVC measurements, the change in FVC between initial and final measurements was not statistically different between the IS arm compared with that in the control arm (0.29 and 0.25 L, respectively; $P = .68$ [95% CI, 0.65-1.95]) (Table 1 and **Figure 2**).

Hospital length of stay did not differ significantly between groups. Pulmonary complications were rarely documented in the medical record. Two patients had documented clinical impressions of potential pulmonary complications contributing to death, although neither underwent laboratory or radiologic testing. Nine patients died, resulting in an overall postoperative mortality of 6.0%. Mortality was significantly higher in the control group compared with the IS group (10.7% and 1.3%, respectively; $P = .02$ [95% CI, 0.01-0.92]). Specific cause of death was often unknown, but the primary surgical team often attributed patient deaths to surgical complications or the underlying disease process (**Table 2**). No adverse events occurred as a result of the intervention.

Figure 1. Participant Flow



A CONSORT flow diagram illustrates the design of the randomized controlled trial comparing control vs intervention (incentive spirometry) groups. HDU indicates high-dependency unit; ICU, intensive care unit.

In our subgroup analysis, we isolated patients with known or suspected cancer. These patients were more likely to be female and older than patients without cancer, although the sex distribution did not reach statistical significance. Patients with cancer had longer hospital stays, although this factor was primarily due to a long preoperative stay before an elective procedure. The FVC measurements did not significantly differ between patients with and without cancer. Mortality for patients with cancer was 23.1% compared with 4.4% for patients without cancer (**Table 3**). Incentive spirometry did not appear to have a statistically significant effect on recovery of pulmonary function between patients with and without cancer. Hospital length of stay and mortality rate tended to be higher in the control group for patients with cancer, although the sample size was too small to detect a statistically significant difference (Table 3).

We also performed subgroup analysis for trauma patients. Trauma patients were most commonly young men. Neither recovery of pulmonary function nor secondary outcomes (hospital length of stay and mortality) were significantly different between trauma and nontrauma patients or between intervention and control groups within the trauma cohort.

Discussion

To our knowledge, this study is the only prospective randomized trial in sub-Saharan Africa to investigate the use of IS fol-

Table 1. Patient Characteristics

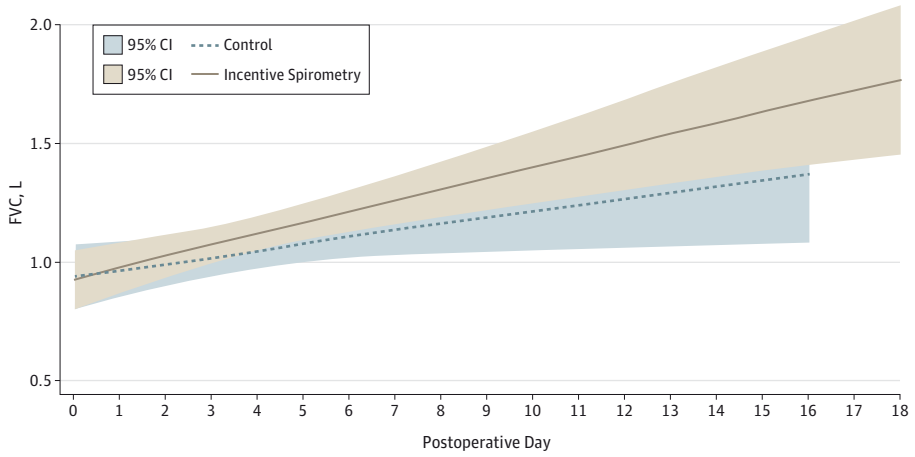
Characteristic	Spirometer (n = 75)	No Spirometer (n = 75)	*P* Value
Age, median (IQR), y	35 (28-53)	33 (23-46)	.51
Sex, No. (%)			
Male	53 (70.7)	58 (77.3)	.35
Female	22 (29.3)	17 (22.7)	
Emergency procedure, No. (%)	59 (78.7)	63 (84.0)	.40
Diagnosis, No. (%)			
Bowel obstruction	18 (24.0)	15 (20.0)	.11
Peritonitis	10 (13.3)	7 (9.3)	
Appendicitis	11 (14.7)	4 (5.3)	
Bowel perforation	0	6 (8.0)	
Perforated ulcer	1 (1.3)	3 (4.0)	
Trauma	7 (9.3)	7 (9.3)	
Hernia	6 (8.0)	8 (10.7)	
Sigmoid volvulus	11 (14.7)	12 (16.0)	
Prior colostomy	1 (1.3)	5 (6.7)	
Other	10 (13.3)	8 (10.7)	
Operative length, mean (SD), min	71.0 (26.8)	70.8 (27.8)	.96
Surgery, No. (%)			.71
Laparotomy	30 (40.0)	29 (38.7)	
Abdominal washout	1 (1.3)	2 (2.7)	
Appendectomy	10 (13.3)	4 (5.3)	
Repair perforation	2 (2.7)	4 (5.3)	
Resection			
Small intestine	4 (5.3)	5 (6.7)	
Large intestine	6 (8.0)	8 (10.7)	
Lysis of adhesions	5 (6.7)	7 (9.3)	
Mesosigmoidopexy	1 (1.3)	2 (2.7)	
Midline hernia repair	6 (8.0)	4 (5.3)	
Graham patch	2 (2.7)	1 (1.3)	
Colostomy reversal	1 (1.3)	5 (6.7)	
Derotation	2 (2.7)	1 (1.3)	
Other	5 (6.7)	3 (4.0)	
Time from admission to operation, median (IQR), d	0 (0-1)	0 (0-1)	.95
Median days to first measurement, median (IQR),d	1 (1-2)	1 (1-2)	.86
No. of measurements, mean (SD)	2 (1)	3 (1)	.48
Days between first and last measurement, median (IQR)	3 (0-6)	4 (2-6)	.74
FVC, mean (SD), L			
Initial	0.92 (0.41)	0.90 (0.46)	.82
Last	1.21 (0.60)	1.15 (0.55)	.55
Difference between first and last measured FVC, mean (SD), L	0.29 (0.64)	0.25 (0.52)	.68
Length of stay, median (IQR), d	7 (5-9)	7 (5-12)	.67
Death, No. (%)	1 (1.3)	8 (10.7)	.02

Abbreviations: FVC, forced vital capacity; IQR, interquartile range.

lowing exploratory laparotomy. Our results do not support the hypothesis that IS improves the recovery of pulmonary function or reduces hospital length of stay. Although mortality was significantly higher in the control group, the study was not adequately powered to detect a difference in mortality. In addition, based on the available medical records, we believe most of the deaths in this cohort resulted from surgical complications or the underlying disease process rather than respiratory complications.

In our subgroup analysis, we isolated trauma victims and patients with known or suspected cancer. Trauma patients were generally young, otherwise healthy men who showed no benefit from the use of IS either in recovery of pulmonary function or in length of stay. As a result, we would not recommend adding IS to the standard of care for this population. Patients with cancer, on the other hand, tended to be older and may have been more deconditioned before surgery. Previous studies have demonstrated that older patients have a higher

Figure 2. Predicted Recovery of Pulmonary Function With or Without Incentive Spirometry



Predicted forced vital capacity (FVC) values based on line of best fit for scatterplot of individual patients' recovery of pulmonary function postoperatively (P = .68). The shaded areas indicate the 95% CI for each group.

Table 2. Causes of Death

Sex/Age, y	Arm	Diagnosis	FVC Measurements, No.	FVC, L		Time to Death, d	Cause of Death
				Initial	Final		
M/19	Control	Bowel perforation	2	0.74	1.48	16	Septic shock
M/76	Control	Cecal volvulus	3	0.95	0.80	10	Wound infection, intraabdominal abscess, possible pneumonia
F/70	Control	Strangulated incisional hernia	2	0.43	0.54	9	Respiratory distress, hypovolemic shock
M/60	Control	Obstructive jaundice	2	0.95	1.56	18	Renal failure, liver failure
M/48	Control	Gastric outlet obstruction	2	0.54	0.84	42	Unknown
M/58	IS	Pancreatic mass	6	1.03	1.40	22	Readmitted for palliative care, anemia, respiratory failure
F/26	Control	Sigmoid volvulus	1	0.54	0.54	2	Unknown, watery stools prior to death
M/29	Control	Bowel perforation	1	0.94	0.94	5	Possible septic shock
F/33	Control	Peritonitis, pancreatitis	2	0.59	0.50	5	Unknown, possible seizure on POD 4

Abbreviations: FVC, forced vital capacity; IS, incentive spirometry; POD, postoperative day.

risk of PPC,[4,30] and these patients may benefit from IS more than younger patients. However, predicting risk of PPC for targeted intervention can be difficult.[4,17,31] Preoperative breathing exercises may be useful in this high-risk population, although prior studies have shown mixed results.[6,19,32]

Our data are consistent with much of the literature regarding the use of postoperative IS for prevention of PPCs. Low-risk patients have shown mixed benefit of IS following abdominal or cardiac surgery in terms of recovery of pulmonary function, prevention of PPC, or reduction in length of hospital stay.[5,21,30,33] Several studies have demonstrated that IS alone or as part of a combination respiratory program, including IS, deep breathing, oral care, and early ambulation, is effective at preventing PPC compared with no intervention.[33-36] Although some studies have demonstrated that IS may be more effective than chest physiotherapy or intermittent positive-pressure breathing,[37-40] many other studies have shown no benefit of IS compared with alternative therapies in the prevention of PPC.[21,30,33,36,37,41-43] Systematic reviews, including a recent Cochrane analysis, have concluded that IS is not effective for preventing PPC and that the routine use of IS in low-risk postoperative patients should be abandoned.[5,14,16,21,22,44-49] Despite these recommendations, IS continues to be widely used in the United States and other developed countries.[3,21,44]

We made several methodologic decisions in designing this trial that may have limited the generalizability of our results. First, we chose to measure change in FVC over time as an objective measure of pulmonary recovery. Due to diagnostic limitations, clinical impressions are not usually confirmed; therefore, estimates of the incidence of pulmonary complications were thought to be unreliable. Mortality as a secondary outcome was used as a surrogate marker of pulmonary complications.

Second, we chose to use an intention-to-treat model for this study. After teaching patients how to use the spirometer, we did not monitor or quantify IS use in any way to control for patient compliance with the treatment. In the past, studies have demonstrated that patient compliance with breathing exercises is similar with or without an IS and that even with improved com-

Table 3. Subgroup Analysis by Intervention and Known or Suspected Cancer Diagnosis

Characteristic	No Cancer (n = 137)			Cancer (n = 13)		
	Spirometer (n = 67)	No Spirometer (n = 70)	*P* Value	Spirometer (n = 8)	No Spirometer (n = 5)	*P* Value
Age, mean (SD), y	38.2 (15.1)	35.9 (15.4)	.41	53.4 (16.3)	42.2 (14.2)	.23
Sex, No. (%)						
Male	50 (74.6)	54 (77.1)	.73	3 (37.5)	4 (80.0)	.11
Female	17 (25.4)	16 (22.9)		5 (62.5)	1 (20.0)	
FVC, mean (SD), L						
Initial	0.92 (0.39)	0.90 (0.46)	.82	0.91 (0.58)	0.95 (0.49)	.92
Last	1.22 (0.61)	1.12 (0.54)	.13	1.08 (0.48)	1.56 (0.65)	.20
Difference between first and last measured FVC, mean (SD), L	0.30 (0.65)	0.22 (0.53)	.42	0.18 (0.61)	0.61 (0.21)	.21
Length of stay, mean (SD), d	9 (8)	9 (8)	.81	18 (14)	34 (10)	.05
Pulmonary complications, No. (%)	0	2 (2.9)	.21	0	0	>.99
Death, No. (%)	0	6 (8.6)	.01	1 (12.5)	2 (40.0)	.30

Abbreviation: FVC, forced vital capacity.

pliance, IS generally does not confer a significant benefit.[14,44] Furthermore, IS is primarily a patient-driven intervention and should not require assistance from a nurse or respiratory therapist. Supervising compliance would eliminate this benefit and add significantly to the cost of the intervention. In this resource-limited environment with a dearth of health care professionals, monitoring compliance is impractical.

This study has several limitations resulting from the population and resource constraints of the study setting. Most patients underwent emergency exploratory laparotomy, and hence we could not assess preoperative FVC. Although both arms were equally affected, this lack of preoperative FVC meant that we had no reference value with which to determine baseline pulmonary function. In the elective patient population, we were unable to predict when the patients would undergo surgery to obtain a preoperative measurement. A measurement obtained at admission may not have been reflective of preoperative pulmonary function, as the characteristically long preoperative hospitalization could have resulted in decreased pulmonary reserve.

Although we made every attempt to find and recruit patients as soon as possible after surgery, in some cases we were unable to obtain an initial FVC measurement until several days after surgery. This factor may have resulted in less observable improvement in FVC between the first and last measurement. Previous studies have suggested that IS may be most beneficial when begun immediately after surgery, possibly even in the post-anesthesia care unit.[39,40] To minimize this problem, we excluded patients who could not be located in the ward within 3 days of surgery, resulting in a large number of unenrolled potential patients.

Finally, our secondary outcome data were limited to mortality and length of hospital stay. We were unable to accurately record the incidence of pulmonary complications due to the limited diagnostic capabilities at Kamuzu Central Hospital. In addition, documentation in this environment is inconsistent and often incomplete. Specific causes of death are not consistently documented; however, the primary researcher (A.F.T.) reviewed the medical records of all patients who died and recorded the cause of death based on the available documentation. The surgical team documenting complications and cause of death was blinded to randomization, and documentation was equally poor in both arms.

Because of firmly held beliefs by many surgeons that IS is effective, another randomized clinical trial may not be feasible in the United States. In low- and middle-income countries where the use of IS is virtually nonexistent, we believe that evidence-based care should be pursued. Surgical patients in Malawi are different from patients in the United States, and studies from the United States may not be generalizable to our patient population. Many surgical procedures are performed urgently in Malawi, and laparoscopic surgery is unavailable at this institution. Both emergency surgery and open procedures are associated with a higher risk of PPC. However, this study suggests that IS is not an effective tool for hastening recovery of pulmonary function and thereby preventing PPC.

In this resource-poor environment, we must carefully consider the efficacy of any proposed interventions. Although the devices used in this trial are inexpensive, adopting this intervention would likely draw funds away from other areas. If IS is no more effective than deep breathing exercises without the assistance of a device, we would be better served using the available funds for more efficacious health interventions, such as preventing surgical site infections or improving timely access to surgical care.

Conclusions

The use of IS following laparotomy, as in this study without measurement of compliance, does not result in a statistically significant improvement in pulmonary function or reduced length of hospital stay. With the increasing globalization of surgical care to help attenuate the global burden of diseases treated surgically, we must continue to emphasize evidence-based medicine both at home and abroad.

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Drafting of the manuscript: Tyson, Mabedi, Charles.
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