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Original Article

J Clin Med Res. 2023;15(3):127-132

A Trial of Adding Lung Protective Strategies to Existing Enhanced Recovery After Surgery Protocols and Its Effect on Improving Postoperative Lung Function

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Abstract

Background: With this rising popularization of enhanced recovery after surgery (ERAS) protocols, it is important to ask if the current and developing pathways are fully comprehensive for the patient's perioperative experience. Many current pathways discuss aspects of care including fluid management, pain management, and anti-emetic medication regiments, but few delineate recommendations for lung protective strategies. The hypothesis was that intraoperative lung protective strategies would results in improved postoperative lung function.

Methods: One hundred patients at the Medical University of South Carolina undergoing hepatobiliary and colorectal surgeries were randomized to receive intraoperative lung protective techniques or a standard intraoperative ventilation management. Three maximum vital capacity breaths were recorded preoperatively, and postoperatively 30 min, 1 h, and 2 h after anesthesia stop time. Average maximum capacity breaths from all four data collection interactions were analyzed between both study and control cohorts.

Results: There was no significant difference in the preoperative inspiratory capacity between the control and the ERAS group (2,043.3 ± 628.4 mL vs. 2,012.2 ± 895.2 mL; P = 0.84). Additional data analysis showed no statistically significant difference between ERAS and control groups: total average of the inspiratory capacity volumes (1,253.5 ± 593.7 mL vs. 1,390.4 ± 964.9 mL; P = 0.47), preoperative oxygen saturation (97.76±2.3% vs. 98.04±1.7%; P = 0.50), the postoperative oxygen saturation (98.51±1.4% vs. 96.83±14.2%; P = 0.40), and change in inspiratory capacity (95% confidence interval (CI) (-211.2 - 366.6); P = 0.60).

Conclusions: No statistically significant difference in postoperative inspiratory capacities were seen after the implementation of intraoperative lung protective strategies. The addition of other indicators of postoperative lung function like pneumonia incidence or length of inpatient stay while receiving oxygen treatment could provide a fuller picture in future studies, but a higher power will be needed.

Keywords: Anesthesiology; ERAS; Lung; Optimization; Randomized control study; Prospective

Introduction

Enhanced recovery after surgery (ERAS) protocols are an evidence-based care improvement process for patients undergoing surgical procedures [1]. The protocols, first developed for colorectal surgeries, emphasize the importance of improving the quality of a patient's recovery process. Using a multidisciplinary approaching incorporating surgeons, anesthesia providers, and nursing staff throughout the entire perioperative period, these strategies focus on alleviating perioperative stress, maintaining euvolemia, preserving cardiac output, and maintaining oxygen and nutrient delivery to the tissues with the intent of preserving cellular function in areas of tissue injury with the need for repair [1]. The goal is an improved recovery process resulting in a decreased length of stay, reduction of cost, and a decrease in the utilization of hospital resources.

At the Medical University of South Carolina (MUSC), there are ERAS protocols in place for colorectal and hepatobiliary surgeries that focus on adequate hydration, judicious use of fluids, reduction of postoperative nausea and vomiting through the use of anti-emetic medications and avoidance of volatile anesthetics when appropriate, and multimodal pain control. However, ventilator management has not be included in the ERAS protocols and is left at the discretion of the intraoperative anesthesia team. Every year over 230 million patients in the United States require general anesthesia and mechanical ventilation while undergoing a major surgery [2]. The use of the ventilator, especially at high tidal volumes (TVs), can lead to alveolar overstretching and systemic inflammation, which leads to multi-organ dysfunction [3-5], and an increased risk for postoperative lung complications [6, 7]. This may lead

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Manuscript submitted January 18, 2023, accepted March 11, 2023

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doi: https://doi.org/10.14740/jocmr4871

to longer stays in the hospital, adverse clinical outcomes, increased use of hospital resources, and an increase in costs for the patient. For these reasons, the addition of lung protective ventilation could have a valuable role in augmenting existing ERAS protocols.

Lung protective ventilation strategies are comprised of the use of low TV, positive end-expiratory pressure (PEEP) [8], and alveoli recruitment measures [9]. Low TV alone provides no benefit due to its association with atelectasis, increased mortality, and higher postoperative complications [10]. These adverse effects are mitigated by the use of PEEP, which prevents atelectasis by increasing functional residual capacity and improving intraoperative oxygenation and driving pressure [8]. Regarding alveolar recruitment maneuvers, these techniques have been shown to decrease the frequency of atelectasis [11]. Further, alveolar recruitment maneuvers under general anesthesia result in a higher intraoperative partial pressure of oxygen in the arterial blood with improved lung compliance [12].

ERAS protocols have been implemented for a variety of surgeries including but not limited to colorectal, gynecologic, thoracic, urologic, and orthopedic surgeries [1]. The goal of this study was to standardize lung protective strategies to ensure a better recovery process for patients undergoing a wide variety of surgeries in the future. The authors hypothesize that the addition of lung protective strategies to MUSC's existing ERAS protocols will further enhance recovery by improving postoperative lung function.

Materials and Methods

This study was evaluated and approved by the Institutional Review Board of the Medical University of South Carolina (#Pro00078958). Each study participant gave written informed consent. This study was conducted in compliance with the ethical standards of the Medical University of South Carolina as well as with the Helsinki Declaration.

Participants were selected from patients scheduled for colorectal or hepatobiliary surgery. Potential subjects were excluded from study participation if less than 18 years old, pregnant, emergency surgery, or evidence of significant lung pathology by use of home oxygen or existing diagnosis such as advanced pulmonary fibrosis, lung transplantation, end-stage chronic obstructive pulmonary disease (COPD), or pulmonary hypertension. Subjects were terminated from the study for postoperative mechanical ventilation, need for postoperative bilevel positive airway pressure (BiPAP)/continuous positive airway pressure (CPAP), admission to intensive care unit (ICU), or inability to adhere to lung protective interventions due to subject intolerance.

The anesthesia care team was assigned without the knowledge of the investigational team and consisted of an attending anesthesiologist and nurse anesthetist or attending anesthesiologist and anesthesia resident. A research assistant collected preprocedure and postprocedure incentive spirometry (IS) data independent of the anesthesia care team.

Subjects were randomly assigned to intervention or control groups. Anesthesia care was guided by existing institutional ERAS protocols for colorectal or hepatobiliary surgery, respective of surgical case. For patients randomized to study intervention, anesthesia teams additionally followed five lung protective strategies: 1) pressure control ventilation-volume guaranteed (PCV-VG) ventilation mode with TVs approximately 7 mL/kg predicted body weight; 2) PEEP 7 cm H_2O; 3) recruitment breath immediately following endotracheal intubation for 30 s at 30 cm water; 4) recruitment breath every hour for 30 s at 30 cm water; 5) 40% fraction of inspired oxygen (FiO_2) or minimum FiO_2 titrated up from 40% to maintain peripheral oxygen saturation (SpO_2) > 94%.

In the intervention group, the anesthesia care team was provided an intraoperative tool to reinforce study intervention guidelines.

Each patient was educated about incentive spirometer use preprocedure, and preoperative maximum exertion inspiratory capacity breath was determined as the average of three attempts. The patients were instructed to put their lips around the funnel, inhale as deeply as they could, and then slowly and persistently exhale for as long and as hard as they could. Postprocedure, inspiratory capacity was measured at 30 min, 1 h, and 2 h after anesthesia conclusion as determined by anesthesia stop timestamp in the patient chart. Again, inspiratory capacity was measured by incentive spirometer, and the average of three attempts was used. In addition to the primary outcome of inspiratory capacity, patient data were collected on age, gender, weight, height, body mass index (BMI), O_2 saturation, average intraoperative TV, and the absence or presence of supplemental O_2 use postoperatively.

Inspiratory capacity after surgery compared to inspiratory capacity before surgery was analyzed by two-sided test of mean. Chi-square tests for homogeneity were used to compare categorical data between the two groups. A multivariate linear model assessed covariables associated with IS measurement. Covariables evaluated included age (categorized into three levels (< 50, 50 - 70, and 70+)), BMI (categorized as underweight, etc.) and preoperative O_2 saturation (continuous). Models are adjusted for statistically or clinically significant covariables. Sample size of 37 subjects in each group (n = 74) was calculated to have sufficient power (80%) at alpha = 0.05 to test the hypothesis of a difference in mean change between groups, and 50 patients in each group should give 91% power to distinguish between groups.

Results

This study initially included 100 patients, one withdrawal, resulting in 99 total patients, with a mean (± standard deviation (SD)) age of 60.2 ± 13.6 years. Eighty-two of the patients were Caucasian (82.8%), 16 were African American (16.2%), and one patient identified as other (1.0%); all 99 patients identified as non-Hispanic. By using the Centers for Disease Control and Prevention (CDC) definitions of BMI, < 18.5 kg/m^2 as underweight, 18.5 - 24.9 kg/m^2 healthy, 25 - 29.9 kg/m^2 overweight, and BMI ≥ 30 kg/m^2 as obese. The average BMI (± SD) was 27.4 ± 7.1 kg/m^2. Five patients were considered underweight (5.1%), 29 were normal weight (29.3%), 36 over-

Table 1. Demographic and Clinical Characteristics of Subjects

Characteristic	Total (n = 99)	Control (n = 50)	ERAS (n = 49)	P value
	N (%)	N (%)	N (%)	
Age	60.2 ± 13.6	59.2 ± 13.7	61.1 ± 13.5	0.50
< 30	3 (3.0)	2 (4.0)	1 (2.0)	0.90
30 - 50	18 (18.2)	9 (18.0)	9 (18.4)	
50 - 70	54 (54.5)	28 (56.0)	26 (53.1)	
70+	24 (24.2)	11 (22.0)	13 (26.5)	
Race				
White	82 (82.8)	42 (84.0)	40 (81.6)	0.53
Black	16 (16.2)	7 (14.0)	9 (18.4)	
Other	1 (1.0)	1 (2.0)	0 (0.0)	
Ethnicity				
Hispanic	0 (0.0)	0 (0.0)	0 (0.0)	
Non-Hispanic	99 (100.0)	50 (100.0)	49 (100.0)	
BMI (kg/m^2)	27.4 ± 7.1	27.2 ± 5.7	27.7 ± 8.4	0.71
Underweight (< 18.5)	5 (5.1)	2 (4.0)	3 (6.1)	0.95
Normal (≥ 18.5, < 25)	29 (29.3)	14 (28.0)	15 (30.6)	
Overweight (≥ 25, < 30)	36 (36.4)	19 (38.0)	17 (34.7)	
Obese (≥ 30)	29 (29.3)	15 (30.0)	14 (28.6)	
Preoperative IS (average)	2,028.06 ± 766.8	2,043.3 ± 628.4	2,012.2 ± 895.2	0.84
Postoperative IS 30 min (average)	1,214.74 ± 801.4	1,195.2 ± 715.0	1,233.3 ± 894.1	0.88
Postoperative IS 1 h (average)	1,352.86 ± 821.8	1,313.9 ± 618.1	1,387.3 ± 975.3	0.72
Postoperative IS 2 h (average)	1,416.66 ± 788.1	1,376.3 ± 651.2	1,454.8 ± 906.4	0.70
Postoperative IS total (average)	1,323.76 ± 803.6	1,253.5 ± 593.7	1,390.4 ± 964.9	0.47
Percent decrease from preoperative				
30 min	40.1%	41.5%	38.7%	
1 h	33.3%	35.7%	31.1%	
2 h	30.1%	32.6%	27.7%	
Total (average)	34.7%	38.7%	30.9%	
Change in IS (total-preoperative)	-789.98 ± 803.6	-829.90 ± 525.2	-752.20 ± 721.6	0.60
Preoperative O_2 saturation	97.90 ± 2.0	97.76 ± 2.3	98.04 ± 1.7	0.50
Postoperative O_2 saturation	97.68 ± 10.0	98.51 ± 1.4	96.83 ± 14.2	0.4
Average tidal volume	450.64 ± 68.4	460.50 ± 67.0	440.60 ± 69.1	0.15
Postoperative supplemental O_2				
No	17 (17.2)	9 (18.0)	8 (16.3)	0.52
Yes	16 (16.2)	7 (14.0)	9 (18.4)	
Unknown	1 (1.0)	1 (2.0)	- (0.0)	
Missing	65 (65.7)	33 (66.0)	32 (65.3)	

ERAS: enhanced recovery after surgery; BMI: body mass index; IS: incentive spirometry.

weight (36.4%), and 29 obese (29.3%) (Table 1).

The control group (n = 50, 50.5%) had a mean age of 59.2 ± 13.7 years; 42 (84%) were Caucasian, seven (14%) were African American, and one (2%) identified as other. By using a stated value of $P \leq 0.05$ to determine statistical significance, in comparison to the ERAS group (n = 49, 49.5%), there was no significant difference in the age (61.1 ± 13.5 years; P = 0.5), race (40 (81.6%) Caucasian and nine (18.4%) African American; P = 0.53), or average BMI of the patients (27.2 ± 5.7 vs. 27.7 ± 8.4 kg/m^2; P = 0.71).

Table 2. Modeling Association With Change in IS

Characteristic	Univariate association			Adjusted		P value for adjusted
Group						
ERAS	77.7	(-211.2 - 366.6)	0.60	79.1	(-220.2 - 378.5)	0.60
No ERAS		Referent			Referent	
Age						
< 50		Referent			Referent	
50 - 70	57.8	(-286.6 - 402.3)	0.75	74.6	(-278.6 - 427.9)	0.68
70+	-103.8	(-522.0 - 314.4)	0.63	-119.4	(-552.7 - 314.0)	0.59
BMI (kg/m^2)						
Underweight (< 18.5)	372.5	(-400.2 - 1,145.1)	0.35	385.8	(-408.4 - 1,180.0)	0.34
Normal (≥ 18.5, < 25)		Referent			Referent	
Overweight (≥ 25, < 30)	88.3	(-274.5 - 451.0)	0.46	91.3	(-284.9 - 467.6)	0.63
Obese (≥ 30)	-61.0	(-446.6 - 324.5)	0.27	-93.8	(-492.4 - 304.7)	0.65
Preoperative O_2 saturation	2.7	(-68.5 - 73.9)	0.94	11.7	(-62.9 - 86.3)	0.76

IS measurement for ERAS is adjusted for age, BMI and preoperative O_2 saturation. ERAS: enhanced recovery after surgery; BMI: body mass index; IS: incentive spirometry.

There was no significant difference in the preoperative inspiratory capacity between the control and the ERAS group (2,043.3 ± 628.4 mL vs. 2,012.2 ± 895.2 mL; P = 0.84). The same is said for the average postoperative inspiratory capacities at the 30 min (1,195.2 ± 715.0 mL vs. 1,233.3 ± 894.1 mL; P = 0.88), 1 h (1,313.9 ± 618.1 mL vs. 1,387.3 ± 975.3 mL; P = 0.72), and 2 h (1,376.3 ± 651.2 vs. 1,454.8 ± 906.4 mL; P = 0.70) mark after anesthesia stop time. There was also no significant difference between the total average of the inspiratory capacity volumes between the groups (1,253.5 ± 593.7 mL vs. 1,390.4 ± 964.9 mL; P = 0.47). As seen in Table 1, there was an increase in the inspiratory capacity in both groups the further from the anesthesia stop time. The ERAS group had higher TVs compared to the control group. There was a decrease from preoperative inspiratory capacity in the ERAS group compared to the control group (30.9% vs. 38.7%); however, there was no significant difference in the change in capacity while in preoperative holding (-752.20 ± 721.6 mL vs. -829.90 ± 525.2 mL; P = 0.60). No difference was found between the preoperative oxygen saturation (97.76±2.3% vs. 98.04±1.7%; P = 0.50) or the postoperative oxygen saturation (98.51±1.4% vs. 96.83±14.2%; P = 0.40) between the groups.

Inspiratory capacity increased 77.7 mL between the control and the ERAS group, however there was no significant difference (95% confidence interval (CI) (-211.2 - 366.6); P = 0.60). As seen in Table 2, there was no significant difference in the change in inspiratory capacity between those aged 50 - 70 and those above 70. Those who were older than 70 had a 103.8 mL (95% CI (-522.0 - 314.4); P = 0.63)) decrease in the change in inspiratory capacity compared to those 50 - 70 years old. When comparing different BMIs, it should be noted the obese group had a 61 mL decrease in the change in inspiratory capacity compared to the 372.5 mL increase in those classified as underweight. However, these differences were not significantly different (95% CI (-446.6 - 324.5); P = 0.27 vs. 95% CI (-400.2 - 1,145.1); P = 0.35). Compared to the preoperative IS reading, there was a 2.7% increase (95% CI (-68.5 - 73.9); P = 0.94) in inspiratory capacity. When these characteristics were adjusted for age, BMI and preoperative O_2 saturation, the P values showed that they did not confound or modify the change in inspiratory capacity.

Discussion

Our data indicate that there was not a statistically significant increase in inspiratory capacity or oxygen saturation in the intervention group over the control group with the application of lung protective strategies. Inspiratory capacity was analyzed by our investigators with the use of an incentive spirometer due to its easy access and usability, and its correlation to vital capacity (VC) and inspiratory reserve capacity (IRC) [13]. The intent of the application of lung protective strategies, more specifically the repeated administration of recruitment breaths, was to allow for more alveoli to open and to remain open longer for continued gas exchange. Further, the application continuous PEEP was intended to decrease the driving pressure of the lungs, thus leading to less strain on the lungs [14, 15] and a decrease in lung injury [16]. While both groups experienced a decrease in their postoperative incentive spirometer measurements, the decrease was less pronounced in the study patients who received the lung protective strategies, with average recorded IS measurements dropping 38.7% in control patients versus 30.9% in ERAS patients; however, this difference was not statistically significant.

The lack of statistical significance could have many possible contributing factors, including the varying nature of surgeries performed. Surgical cases were limited to colorectal and hepatobiliary procedures; however, this subset still includes a wide range, from rectal exams under anesthesia to larger cases including total colectomy and Whipple procedures. Lung complications are known to be more common in upper abdominal surgeries versus lower abdominal surgeries [17], and pulmonary dysfunction is typically more common in open versus laparoscopic cases [18] due to more incisional pain. With this in mind, an imbalance in case types between groups may inappropriately skew data in favor of the group with more benign procedures.

Another possible explanation of a lack of statistical significance between groups may simply be that many of these intervention measures have become part of standard practice for anesthesia providers. Previous studies have noted a general trend of decreasing average intraoperative TV ventilation: Hess et al [19] found a drop from 9.0 to 8.5 mL/kg ideal body weight (IBW) for adult patients between 2006 and 2010; Levin et al [20] reported a drop from 9.0 to 8.3 mL/kg IBW between 2008 and 2011; and Josephs et al [21] found a further drop in average intraoperative TV of 7.8 - 8.1 mL/kg in 2018. As the average TV utilized intraoperatively continues to decrease, it may not be surprising that studies comparing standard care to specified low-volume ventilation strategies will result in less significant outcomes.

Limitations to the study included difficulties with obtaining all data points during the post-anesthesia care unit (PACU) timeframe, specifically information regarding the use of supplemental oxygen in the immediate postoperative period, and therefore fewer conclusions can be drawn without this secondary outcome data. Specifically, finding differences in oxygenation saturation could be confounded by the application of supplemental oxygen. Further, there may have been differences in lung function not measured secondary to the difficulty in assessing other parameters of lung function (for example functional residual capacity and forced expiratory volume), which would need to be obtained by formal pulmonary function testing. Further studies examining other parameters of lung function could be conducted to seek significant differences following the application of intraoperative lung protective strategies. Some subjects needed to be withdrawn for a number of reasons, including being lost to follow-up due to discharge from the hospital, as well as postoperative complications including low blood pressure, infiltrated intravenous (IV) line, heavy sedation, pain, and longer than expected operating time. In conclusion, the addition of specific lung protective ventilation strategies to colorectal and hepatobiliary ERAS protocols did not result in a statistically significant difference in postoperative lung function as measured by inspiratory capacity.

The use of an incentive spirometer is also a factor that was initially called into question. There are multiple opportunities for error in its usage, but we did not find that to be the case. It is quite possible that it would take hundreds, if not thousands, of entries to detect a clinically significant difference in inspiratory capacity, and even then, it appears that the clinical impact of such a change would likely to be minimal.

Conclusions

No statistically significant difference in postoperative inspiratory capacities were seen after the implementation of intraoperative lung protective strategies. The likely explanation for the lack of statistically significant difference is that the control group was already implementing many of the lung eras strategies, such as lowered TV and PEEP application, at baseline.

This study demonstrates that the baseline ventilation strategies used at the Medical University of South Carolina, by the anesthesiologists, certified registered nurse anesthetists, and anesthesiology residents are evidence-based and follow the modern standard of care. The minimal threshold of lower TVs, appropriate PEEP, and reduced FiO_2 concentrations is likely universally being applied and has an outsized positive impact on lung function. Future studies might choose to try and further elucidate, which specific interventions made the greatest difference or track the ventilation strategies employed by the control group, but we believe that the three aforementioned interventions are more than enough and should be utilized routinely during all appropriate intraoperative procedures.

Acknowledgments

None to declare.

Financial Disclosure

The writeup of this clinical research paper was performed of their own volition while employed by the Medical University of South Carolina in the Department of Anesthesia and Perioperative Medicine. The authors declare that they have not received any funding, payments, goods or services that may influence their work on this publication.

Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this clinical research project.

Informed Consent

Informed consent was obtained.

Author Contributions

David A. Gutman contributed to the study design, did the literacy search, wrote up the manuscript, and performed the data gathering. Victoria Bailey wrote up the manuscript and performed the data gathering. Phillip Wilson, Andrew Fisher, Christopher A. Skorke, Carey Brewbaker, Travis Pecha, and Dulaney A. Wilson contributed to study design, did literacy search, and wrote up the manuscript. John Butler performed the data gathering.

Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Abbreviations

ERAS: enhanced recovery after surgery; MUSC: Medical University of South Carolina; PEEP: positive end-expiratory pressure; BiPAP: bilevel positive airway pressure; CPAP: continuous positive airway pressure; PC-VG: pressure control ventilation-volume guaranteed; VC: vital capacity; IRC: inspiratory reserve capacity; PACU: post-anesthesia care unit

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