Supplementary Online Content

Writing Committee for the PROBESE Collaborative Group of the PROtective VEntilation Network (PROVEnet) for the Clinical Trial Network of the European Society of Anaesthesiology. Effect of intraoperative high positive end-expiratory pressure (PEEP) with recruitment maneuvers vs low PEEP on postoperative pulmonary complications in obese patients: a randomized clinical trial. *JAMA*. doi:10.1001/jama.2019.7505

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Lists of committees, investigators and study sites

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eMethods

2.1 Inclusion and exclusion criteria

Patients were included if they had a body mass index (BMI) ≥ 35 kg/m^2, were scheduled for laparoscopic or non-laparoscopic surgery expected to exceed 2h (from incision to closure) under general anesthesia, and had an intermediate to high risk of developing postoperative pulmonary complications according to the Assess Respiratory Risk in Surgical Patients in Catalonia (ARISCAT) score [1] (**Table S1**). This score predicts individual preoperative risk for postoperative pulmonary complications using 7 independent predictors, of which 4 are patient-related and 3 surgery-related predictors. An ARISCAT risk score ≥ 26 is associated with an intermediate-to-high risk for postoperative pulmonary complications.

Patients were excluded from participation if they: were aged <18 years; underwent any kind of previous lung surgery; were invasively mechanically ventilated for longer than 30 minutes within the last 30 days before surgery; or they received recent immunosuppressive medication (chemotherapy or radiation therapy up to two months prior to surgery). Further exclusion criteria comprises neurosurgical procedures and cardiac surgery, need for one-lung ventilation or planned re-intubation following surgery, need for intraoperative prone or lateral decubitus position and enrollment in another interventional study or refusal to give written informed consent. Additionally, patients showing at least one the following medical conditions are excluded: pregnancy (excluded by anamnesis and /or laboratory analysis), persistent hemodynamic instability or intractable shock (considered hemodynamically unsuitable for the study by the patient's managing physician), history of severe chronic obstructive pulmonary disease (COPD, defined as non–invasive ventilation and/or oxygen therapy at home or repeated systemic corticosteroid therapy for acute exacerbations of COPD), severe cardiac disease (defined as New York Heart Association class III or IV, acute coronary syndrome or persistent ventricular tachyarrhythmia), concurrent acute respiratory distress syndrome (according to the Berlin definition [2]) expected to require prolonged postoperative mechanical ventilation, severe pulmonary arterial hypertension (defined as systolic pulmonary artery pressure > 40 mmHg), intracranial injury or tumor or neuromuscular disease.

2.2 Description of the trial interventions

Patients underwent intraoperative lung protective mechanical ventilation with protective low tidal volume of 7 mL/kg predicted body weight (PBW), and were randomly assigned to a PEEP level of 12 cmH_2O with planned lung recruitment maneuvers performed after intubation, hourly thereafter and preceding extubation (high PEEP group), or a level of PEEP of 4 cmH_2O without planned recruitment maneuvers (low PEEP group). PEEP levels were maintained throughout the whole period of intraoperative mechanical ventilation.

2.3 Standard procedures and recommendations to anesthesiologists

To avoid interference with the trial intervention, routine elements of perioperative anesthesia care (including general anesthesia, postoperative pain management, physiotherapeutic procedures and fluid management) were performed according to each site's specific expertise and clinical routine. The following approaches were recommended (not mandatory) for anesthetic management: 1) to use inhalational isoflurane, desflurane or sevoflurane as the volatile agent, intravenous propofol, remifentanil or sufentanil, and cis-atracurium, atracurium, vecuronium, or rocuronium as required; 2) to use balanced solution of prostigmine, or

neostigmine and atropine or glycopyrrolate for reversal of muscle relaxation, guided by neuromuscular function monitoring, 3) to perform postoperative pain management in order to achieve a visual analogue scale (VAS) pain score below 3 and regional or neuraxial analgesia should be used whenever indicated, 4) to use physiotherapy by early mobilization, deep breathing exercises with and without incentive spirometry and stimulation of cough in the postoperative period, 5) to avoid hypo- and hypervolemia, 6) to use invasive measurement of arterial blood pressure whenever indicated, 7) to use appropriate prophylactic antibiotic drugs whenever indicated.
In addition, the study protocol stressed that routine intraoperative monitoring should include measurements of noninvasive blood pressure, pulse oximetry, end–tidal carbon dioxide fraction and electrocardiography. Every patient should receive at least one peripheral venous line to allow adequate fluid resuscitation during the study period. Nasogastric tubes, urinary bladder catheters and/or other intravenous catheters, as well as other, more invasive monitoring may be used according to local practice and/or guidelines. Other procedures should follow the Safe Surgery Checklist of the World Health Organization as published at www.who.int/patientsafety/safesurgery/ en/index.html.

2.4 Mechanical ventilation

Mechanical ventilation was performed with anesthesia ventilators in use in each individual site participating in the study. Patients were volume–controlled mechanically ventilated with the lowest possible FiO_2, but at least 0.4, to maintain SpO_2 of > 92%, an inspiratory to expiratory ratio (I:E) of 1:2 and a respiratory rate adjusted to normocapnia (end–tidal carbon dioxide partial pressure between 35 and 45 mmHg). It was left to the discretion of the attending anesthesiologist to use a higher FiO_2.
Tidal volume was set to 7 mL/kg PBW. The PBW was calculated according to a predefined formula: 50 + 0.91 x (centimeters of height – 152.4) for males, and 45.5 + 0.91 x (centimeters of height – 152.4) for females. Tidal volume throughout this protocol referred to the actual inspired tidal volume in the ventilator circuit.
PEEP was set according to the randomized intervention to 4 vs. 12 cmH_2O and only modified as part of the rescue strategy (in case of desaturation, see below), or at discretion of the treating physician.

2.5 Planned and unplanned recruitment maneuvers

The recruitment maneuver, as part of the high PEEP group strategy, was performed directly after induction of anesthesia, after any disconnection from the mechanical ventilator, every one hour during surgery and before extubation, in a hemodynamically stable situation as judged by the anesthesiologist. Recruitment maneuvers should also be performed as part of a rescue strategy in the low PEEP group. To obtain standardization among centers, recruitment maneuvers were performed in volume–controlled ventilation, according to the following steps:

I. Peak inspiratory pressure limit set at 55 cmH_2O
II. Tidal volume set at 7 ml/kg PBW and respiratory rate at 6 or higher breaths/min, while PEEP was 12 cmH_2O (or higher if during rescue, see below)
III. I:E at 1:1
IV. Tidal volume increased in steps of 4 mL/kg PBW until plateau pressure reached 40 – 50 cmH_2O

V. If the maximum tidal volume allowed by the anesthesia ventilator was achieved and the plateau pressure was lower than 40 cmH_2O, PEEP was increased as needed, but the maximum was 20 cmH_2O

VI. Three breaths were allowed while maintaining plateau pressure of 40 – 50 cmH_2O

VII. Respiratory rate, I:E, inspiratory pause and tidal volume were set back to pre-recruitment values, while maintaining PEEP at 12 cmH_2O (or higher if during rescue)

2.6 Rescue strategies for intraoperative hypoxemia

If $SpO_2 \leq 92\%$ developed, increase in airway resistance, presence of intrinsic PEEP, hemodynamic impairment and ventilator malfunction must have been excluded before group-specific stepwise rescue strategies could be applied (**Table S2**).

In patients receiving lower PEEP levels, rescue consisted primarily of an increase in FiO_2, whereas elevation of PEEP levels was restricted to more severe cases of hypoxemia.
In the higher PEEP group, the rescue strategy consisted of primarily increase of PEEP before FiO_2 was increased. At any rescue step, the treating physician could consider reducing PEEP if SpO_2 deteriorated further in an otherwise hemodynamic stable patient.

2.7 Protocol deviation

Anesthesiologists could deviate from the ventilation protocol at any time if concerns about patient's safety arose, or upon the surgeon's request.
PEEP could be modified according to the anesthesiologist's judgment in presence of any of the following clinical situation: 1) decrease in systolic arterial pressure below 90 mmHg unresponsive to fluids and/or vasoactive drugs, 2) need for a dosage of vasoactive drugs at the tolerance limit, 3) new arrhythmias unresponsive to the treatment suggested by the Advanced Cardiac Life Support Guidelines [3], 4) blood loss requiring massive transfusion occurred (defined as replacement of >100% blood volume in 24 hours or >50% of blood volume in 4 hours to maintain hematocrit > 21% (hemoglobin > 7 mg/dL)) or 5) any life-threatening surgical complication occurred that might benefit from changes in PEEP.

2.8 Definitions

The components of the primary endpoint, namely a composite outcome of postoperative pulmonary complications were defined as follows: 1) mild respiratory failure ($PaO_2 < 60$ mmHg or $SpO_2 < 90\%$ breathing at least 10 min of room air but responding to supplemental oxygen = 2 L/min, excluding hypoventilation), 2) moderate respiratory failure ($PaO_2 < 60$ mmHg or $SpO_2 < 90\%$ breathing at least 10 min of room air but responding only to supplemental oxygen > 2 L/min, excluding hypoventilation), 3) severe respiratory failure (need for non–invasive or invasive mechanical ventilation, excluding hypoventilation due to sedative agents), 4) ARDS, 5) bronchospasm (newly detected expiratory wheezing treated with bronchodilators), 6) new pulmonary infiltrates (chest X–ray demonstrating new mono-lateral or bilateral infiltrate without other clinical signs), 7) pulmonary infection (new or progressive radiographic infiltrate plus at least two of the following: antibiotic treatment, tympanic temperature > 38°C, leukocytosis or leucopenia (white blood cell count < 4000 cells/mm^3 or > 12000 cells/mm^3) and/or purulent secretions), 8) aspiration pneumonitis (respiratory failure after the inhalation of regurgitated gastric contents), 9) pleural effusion (chest X–ray demonstrating blunting of the costophrenic angle, loss of the sharp silhouette of the ipsilateral hemidiaphragm in upright

position, evidence of displacement of adjacent anatomical structures, or (in supine position) a hazy opacity in one hemithorax with preserved vascular shadows), 10) atelectasis (lung opacification with shift of the mediastinum, hilum, or hemidiaphragm towards the affected area, and compensatory overinflation in the adjacent non-atelectatic lung), 11) cardiopulmonary edema (clinical signs of congestion, including dyspnea, edema, rales and jugular venous distention, with the chest X–ray demonstrating increase in vascular markings and diffuse alveolar interstitial infiltrates) and 12) pneumothorax (air in the pleural space with no vascular bed surrounding the visceral pleura).

The secondary outcomes were: 1) composite of severe postoperative pulmonary complications, defined as any of the above mentioned adverse pulmonary events, except to mild respiratory failure; 2) intraoperative adverse events, e.g. hypoxemia (defined as $SpO_2 \leq 92\%$), hypotension (defined as systolic blood pressure < 90mmHg) and bradycardia (defined as heart rate < 50 bpm), 3) unexpected need for intensive care unit (ICU) admission or ICU readmission, 4) hospital-free days at follow-up day 90, 5) impaired post-operative wound healing (defined as an interruption in the timely and predictable recovery of mechanical integrity in the injured tissue) and 6) 5-day and in-hospital mortality, as well as 7) postoperative extra-pulmonary complications (PEPCs). PEPCs included systemic inflammatory response syndrome (SIRS), sepsis, severe sepsis and septic shock (all according to consensus criteria [4]), extra-pulmonary infection (wound infection or any other infection), coma (Glasgow Coma Score < 8 in the absence of therapeutic coma or sedation), acute myocardial infarction (according to universal definition of myocardial infarction [5]), acute renal failure (according to the risk, injury, failure, loss, end-stage kidney disease [RIFLE] classification system [6]), disseminated intravascular coagulation (DIC) (according to the International Society of Thrombosis and Hemostasis diagnostic scoring system for DIC [7]), gastro-intestinal failure (GIF) (defined according to the GIF-score [8]) and hepatic failure (defined as ratio of total bilirubin on postoperative day 5 to postoperative day 1 > 1.7 and ratio of international normalized ratio (INR) on postoperative day 5 to postoperative day 1 >1.0, or new presence of hepatic encephalopathy and coagulopathy (INR > 1.5) within 8 weeks after initial signs of liver injury (e.g. jaundice) without evidence for chronic liver disease)(adapted from Du et al. [9] and Wlodzimirow et al. [10]).

eTable 1. The Assess Respiratory Risk in Surgical Patients in Catalonia (ARISCAT) score

	Multivariate Analysis, OR (95% CI), n = 1624	**β Coefficient**	**Risk Score[§]**
Age, years			
≤ 50	1		
51 – 80	1.4 (0.6 - 3.3)	0.331	3
> 80	5.1 (1.9 - 13.3)	1.619	16
Preoperative SpO_2, %			
≥ 96	1		
91 – 95	2.2 (1.2 - 4.2)	0.802	8
≤ 90	10.7 (4.1 - 28.1)	2.375	24
Respiratory infection in the last month	5.5 (2.6 - 11.5)	1.698	17
Preoperative anemia (≤ 10 g/dl)	3.0 (1.4 - 6.5)	1.105	11
Surgical incision			
Peripheral	1		
Upper abdominal	4.4 (2.3 - 8.5)	1.480	15
Intrathoracic	11.4 (4.9 - 26.0)	2.431	24
Duration of surgery, hours			
≤ 2	1		
> 2 to 3	4.9 (2.4 - 10.1)	1.593	16
> 3	9.7 (4.7 - 19.9)	2.268	23
Emergency procedure	2.2 (1.04 - 4.5)	0.768	8

Legend: A risk score ≥ 26 predicts an intermediate-to-high risk for postoperative pulmonary complications). CI, confidence interval; OR, odds ratio; SpO_2, peripheral oxyhemoglobin saturation by pulse oximetry breathing air in supine position; g/dL, gram per deciliter; § The simplified risk score was the sum of each logistic regression coefficient multiplied by 10, after rounding off its value

eTable 2. Rescue strategies for intraoperative hypoxemia

	Lower PEEP			Higher PEEP		
Step	**FiO_2**	**PEEP [cmH_2O]**		**FiO_2**	**PEEP [cmH_2O]**	
1	0.5	4		0.4	14	(+RM)
2	0.6	4		0.4	16	(+RM)
3	0.7	4		0.4	18	(+RM)
4	0.8	4		0.5	18	
5	0.9	4		0.6	18	
6	1.0	4		0.7	18	
7	1.0	5		0.8	18	
8	1.0	6		0.9	18	
9	1.0	7	(+RM)	1.0	18	
10				1.0	20	(+RM)

Legend: If intraoperative hypoxemia, defined as oxygen saturation ≤ 92%, develops, sequences of interventions will be used according to group assignment. FiO_2, inspiratory fraction of oxygen; PEEP, positive end-expiratory airway pressure; RM, lung recruitment maneuver

eTable 3. Types of intraoperative IV fluids

	High PEEP n=989	Low PEEP n=987	P value
Total fluids – mL, mean (SD)	1898 (1401)	1882 (1352)	0.79
Crystalloids, No. (%)	920 (93.0)	928 (94.0)	0.37
	1838 (1306)	1841 (1298)	0.97
Synthetic colloids, No. (%)	74 (7.5)	56 (5.7)	0.10
	50 (211)	35 (171)	0.09
HES, No. (%)	45 (4.6)	32 (3.2)	0.13
	32 (178)	21 (139)	0.15
Gelatines, No. (%)	31 (3.1)	24 (2.4)	0.34
	17 (104)	13 (102)	0.38
Dextran, No. (%)	1 (0.1)	0 (0.0)	0.99
	1 (15.9)	0 (0)	0.32

PEEP, positive end-expiratory pressure; HES, hydroxyl-ethyl -starch containing solution.

eTable 4. Types of intraoperative vasoactive drugs

	High PEEP n=989	Low PEEP n=987	P value
Need for vasoactive drugs	491 (49.6)	439 (44.5)	0.02
Dopamine, No. (%)	0 (0.0)	2 (0.2)	1.00
(mg)	0.0 (0.0)	0.0 (1.5)	0.16
Norepinephrine, No. (%)	164 (16.6)	154 (15.6)	0.55
(mg)	0.3 (1.2)	0.2 (1.2)	0.36
Phenylephrine, No. (%)	232 (23.5)	190 (19.3)	0.02
(mg)	0.7 (5.5)	0.5 (4.4)	0.26
Epinephrine, No. (%)	14 (1.4)	15 (1.5)	0.85
(mg)	0.0 (0.7)	0.0 (0.7)	0.37
Use of inotropic drug			
Dobutamine, No. (%)	1 (0.1)	1 (0.1)	1.00
(mg)	0.0 (0.9)	0.0 (0.0)	0.32

PEEP, positive end-expiratory pressure.

eTable 5. Types of anesthetic, muscle paralyzing and reversal agents

	High PEEP n=989	Low PEEP n=987	P value
Volatile anesthetics, No.(%)			
Desflurane	469 (47.4)	468 (47.4)	1.00
Sevoflurane	401 (40.5)	411 (41.6)	0.62
Isoflurane	40 (4.0)	37 (3.7)	0.73
Intravenous anesthetics, No.(%)			
Propofol	927 (93.7)	911 (92.3)	0.21
Midazolam	278 (28.1)	287 (29.1)	0.63
Thiopental	37 (3.7)	40 (4.1)	0.72
Ketamine	144 (14.6)	136 (13.8)	0.62
Etomidate	7 (0.7)	7 (0.7)	1.00
Dexmedetomidine	78 (7.9)	79 (8.0)	0.92
Others	38 (3.8)	31 (3.1)	0.40
Analgesics, No.(%)			
Morphine	160 (16.2)	158 (16.0)	0.92
Alfentanil	7 (0.7)	8 (0.8)	0.79
Fentanyl	539 (54.5)	570 (57.8)	0.15
Sufentanil	239 (24.2)	208 (21.1)	0.10
Remifentanil	331 (33.5)	339 (34.3)	0.68
Lidocaine	320 (32.4)	313 (31.7)	0.76
Procaine	2 (0.2)	0 (0.0)	0.48
NSAIDS	236 (23.9)	239 (24.2)	0.85
Others	308 (31.1)	280 (28.4)	0.18
Muscle paralyzing agents, No.(%)			
Atracurium	27 (2.7)	24 (2.4)	0.68
Cis-atracurium	66 (6.7)	51 (5.2)	0.16
Mivacurium	1 (0.1)	2 (0.2)	1.00
Pancuronium	5 (0.5)	2 (0.2)	0.45
Vecuronium	47 (4.8)	48 (4.9)	0.91
Rocuronium	847 (85.6)	848 (85.9)	0.86
Succnylcholine	240 (24.3)	234 (23.7)	0.77
Others	4 (0.4)	3 (0.3)	0.71
Reversal of muscle paralysis agents, No.(%)			
Sugammadex	438 (44.3)	434 (44.0)	0.89
Cholinesterase inhibitors	290 (29.3)	295 (29.9)	0.78

PEEP, positive end-expiratory pressure.

eTable 6. Further characteristics of surgery

	High PEEP n=989	Low PEEP n=987	P value
Priority of surgery, No.(%)			
Elective	962 (97.8)	958 (97.6)	
Emergency	13 (1.3)	11 (1.1)	0.64
Urgent	9 (0.9)	13 (1.3)	
Positioning during surgery, No.(%)			
Supine	357 (36.2)	367 (37.2)	
Trendelenburg	86 (8.7)	69 (7.0)	
Reverse Trendelenburg	486 (49.3)	491 (49.8)	0.69
Lithotomy	17 (1.7)	16 (1.6)	
Seated	39 (4.0)	43 (4.4)	
Surgical wound classification, No.(%)			
Clean	514 (52.1)	525 (53.2)	
Clean-contaminated	461 (46.8)	450 (45.6)	0.46
Contaminated	10 (1.0)	7 (0.7)	
Dirty	1 (0.1)	4 (0.4)	
Intra-abdominal pressure during laparoscopy - (mmHg), mean (SD)	14.7 (3.6)	14.5 (2.1)	0.17

PEEP, positive end-expiratory pressure.

eTable 7. Assessment of postoperative pain and dyspnea

	High PEEP n=989	Low PEEP n=987	P value
VAS dyspnea – cm, mean (SD), No.			
Day 1	1.8 (1.5), 912	1.8 (1.4), 917	0.53
Day 2	1.4 (1.0), 840	1.5 (1.0), 844	0.57
Day 3	1.4 (0.9), 619	1.3 (0.8), 617	0.68
Day 4	1.3 (0.9), 461	1.3 (0.8), 459	0.79
Day 5	1.2 (0.9), 336	1.2 (0.8), 330	0.78
VAS thoracic – cm, mean (SD), No.			
Day 1	1.6 (1.3), 914	1.7 (1.4), 913	0.52
Day 2	1.3 (0.8), 838	1.4 (3.9), 841	0.34
Day 3	1.2 (0.6), 620	1.2 (0.6), 617	0.94
Day 4	1.1 (0.5), 461	1.2 (0.5), 459	0.20
Day 5	1.1 (0.4), 336	1.1 (0.5), 330	0.16
VAS abdominal rest pain – cm, mean (SD), No.			
Day 1	2.7 (1.8), 950	2.9 (1.9), 958	0.10
Day 2	2.1 (1.5), 881	2.1 (1.4), 889	0.31
Day 3	1.8 (1.3), 647	1.8 (1.2), 650	0.94
Day 4	1.6 (1.2), 469	1.6 (1.0), 475	0.75
Day 5	1.5 (1.0), 346	1.5 (1.0), 337	0.83
VAS abdominal incident pain – cm, mean (SD), No.			
Day 1	3.7 (2.4), 916	3.7 (2.3), 929	0.52
Day 2	2.8 (2.0), 837	2.9 (1.9), 857	0.51
Day 3	2.4 (1.7), 615	2.4 (1.7), 627	0.55
Day 4	2.0 (1.5), 458	2.1 (1.5), 459	0.69
Day 5	1.9 (1.4), 339	1.9 (1.5), 333	0.58

PEEP, positive end-expiratory pressure; VAS, visual analogue scale.

eTable 8. Per-protocol analysis

	High PEEP n=917	Low PEEP n=912	Effect Estimate 95% CI	P value
Primary outcome				
Postoperative pulmonary complications	186 / 917 (20.3)	209 / 912 (22.9)	0.92 (0.82 – 1.04)	0.17
Mild respiratory failure	119 / 917 (13.0)	140 / 912 (15.4)	0.90 (0.78 – 1.04)	0.15
Moderate respiratory failure	38 / 917 (4.1)	51 / 912 (5.6)	0.84 (0.66 – 1.07)	0.15
Severe respiratory failure	25 / 917 (2.7)	35 / 912 (3.8)	0.83 (0.61 – 1.11)	0.18
ARDS	3 / 917 (0.3)	1 / 912 (0.1)	1.50 (0.84 – 2.64)	0.62
Bronchospasm	11 / 917 (1.2)	10 / 912 (1.1)	1.04 (0.69 – 1.57)	0.84
New pulmonary infiltrates	14 / 917 (1.5)	14 / 912 (1.5)	0.99 (0.68 – 1.44)	0.99
Pulmonary infection	10 / 917 (1.1)	9 / 912 (1.0)	1.05 (0.68 – 1.61)	0.83
Aspiration pneumonitis	2 / 917 (0.2)	1 / 912 (0.1)	1.33 (0.59 – 2.96)	1.00
Pleural effusion	38 / 917 (4.1)	18 / 912 (2.0)	1.37 (1.14 – 1.65)	0.01
Atelectasis	38 / 917 (4.1)	50 / 912 (5.5)	0.85 (0.67 – 1.09)	0.18
Cardiopulmonary edema	15 / 917 (1.6)	7 / 912 (0.8)	1.36 (1.02 – 1.82)	0.09
Pneumothorax	1 / 917 (0.1)	2 / 912 (0.2)	0.66 (0.13 – 3.29)	0.62

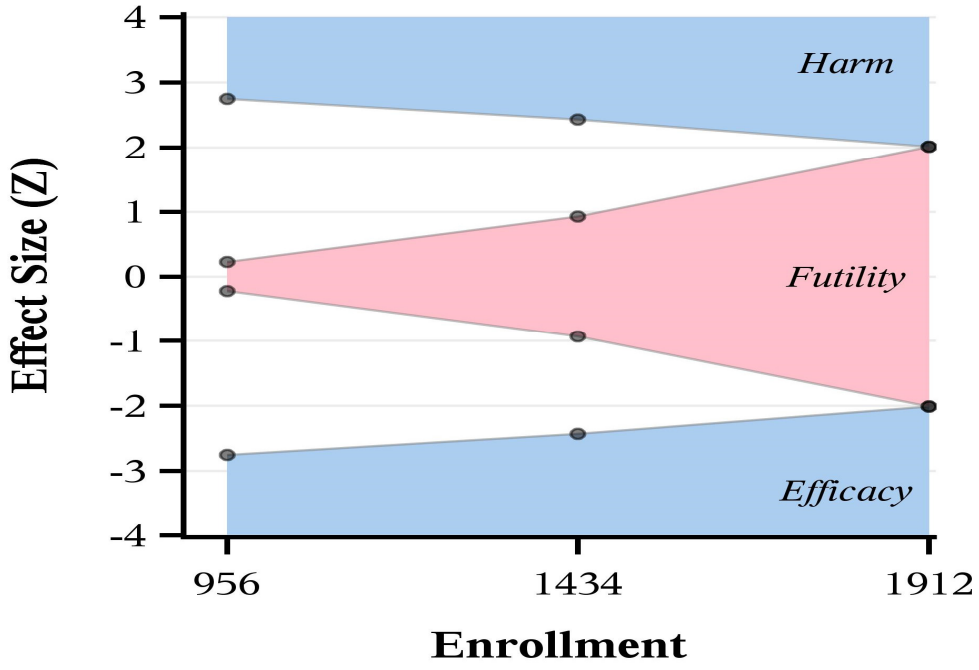
PEEP, positive end-expiratory pressure; CI, confidence interval; ARDS, acute respiratory distress syndrome.

eTable 9. Sensitivity analysis for the primary outcome

	High PEEP n=989	Low PEEP n=987	Odds ratio 95% CI	P value
Random-effect model	—	—	0.86 (0.68 – 1.08)*	0.19
Count events	0.35 (0.88)	0.38 (0.86)		
Median (IQR)	0 (0 – 0)	0 (0 – 0)	0.88 (0.72 – 1.09)£	0.25
Common effect GEE	—	—	0.93 (0.80 – 1.08)¥	0.37
Treatment-component interaction GEE	—	—	—	0.11**
Average relative effect GEE	—	—	0.99 (0.94 – 1.05)££	0.98

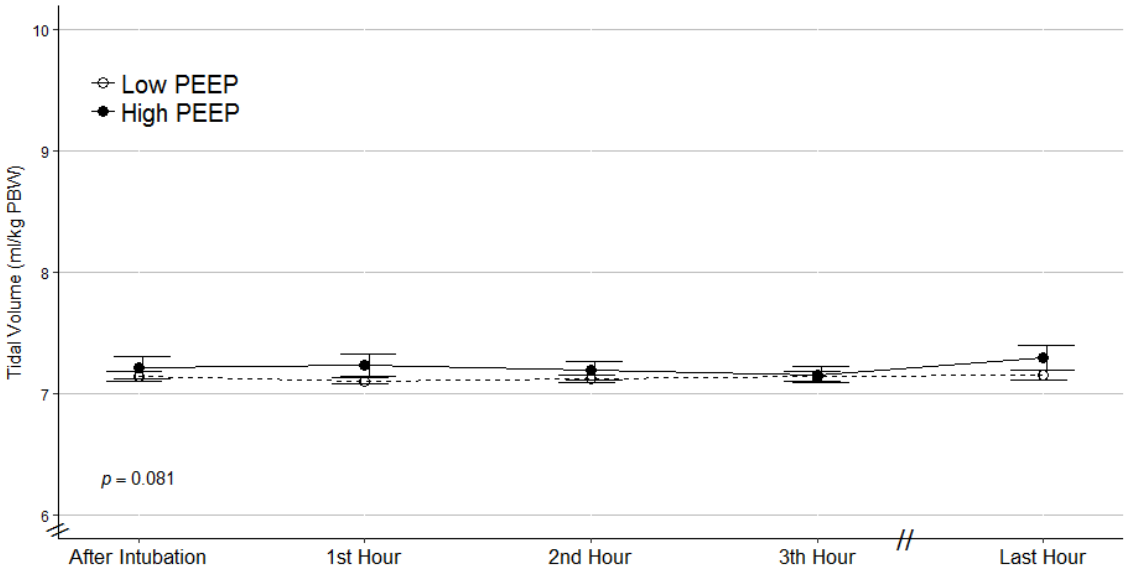
PEEP: positive end expiratory pressure; IQR: interquartile range; GEE: generalized estimating equations
* 95% confidence intervals and p values calculated in a mixed-effect model with study sites as random-effects
£ 95% confidence intervals calculated with proportional odds logistic regression and p values calculated Wilcoxon rank-sum test
¥ 95% confidence intervals and p values calculated in a common effect GEE model (estimating a single treatment effect across all 12 components)
** p value calculated in a GEE model (test whether the treatment effect differs across the 12 components)
££ p value calculated in a GEE model (estimating, then averaging, the 12 distinct treatment effects)

eFigure 1. Effect size (Z) according to the enrollment of patients in the trial



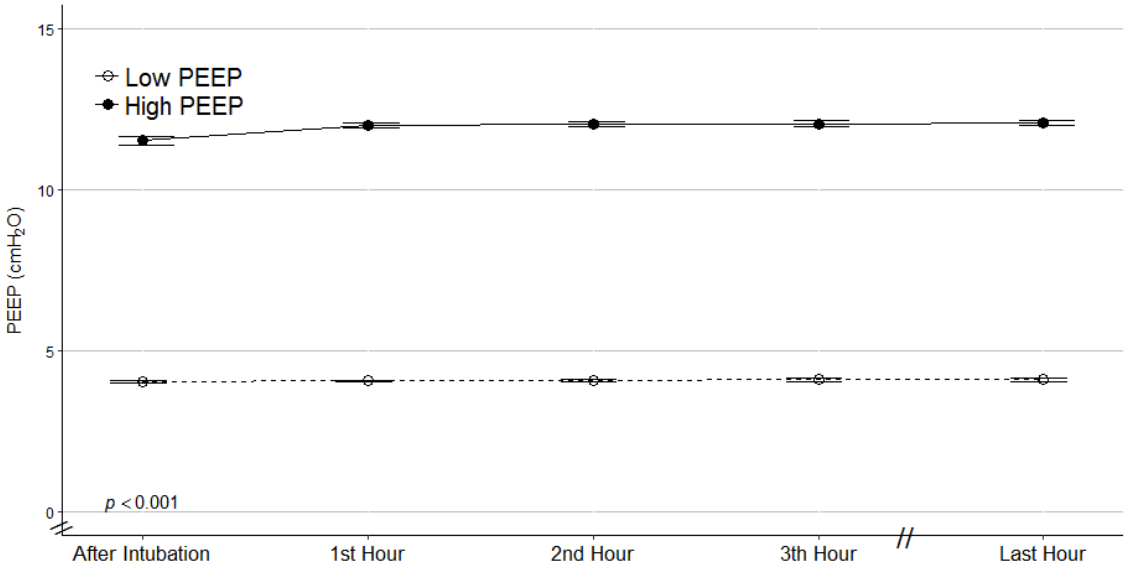
Numbers of patients enrolled in the figure do not include dropouts.

eFigure 2. Tidal volume during anesthesia



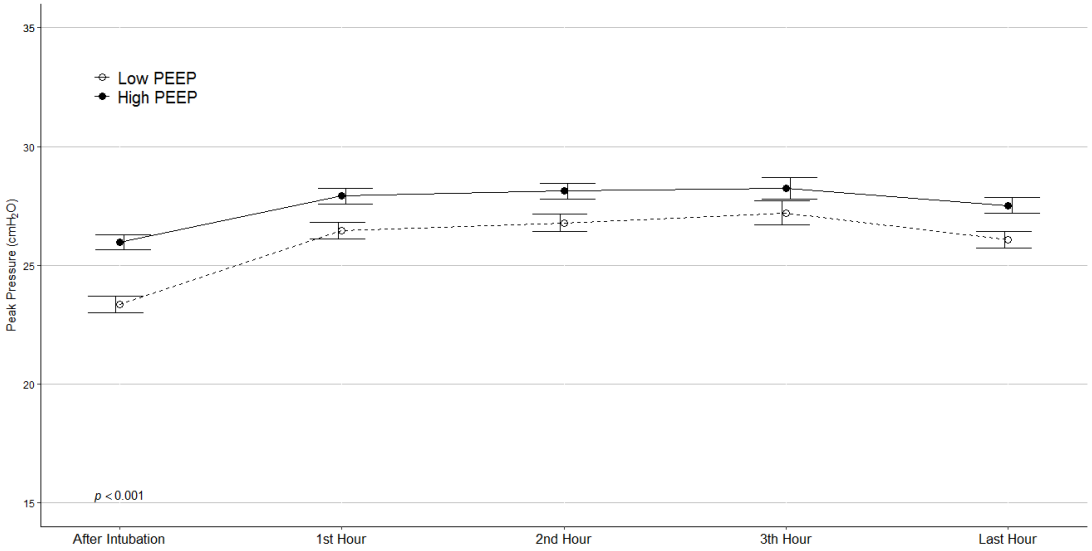
PEEP, positive end-expiratory pressure. Dots are mean and error bars are 95% confidence intervals. P-value from a time *vs.* group interaction calculated in a mixed-effect linear model.

eFigure 3. Positive end-expiratory pressure during anesthesia



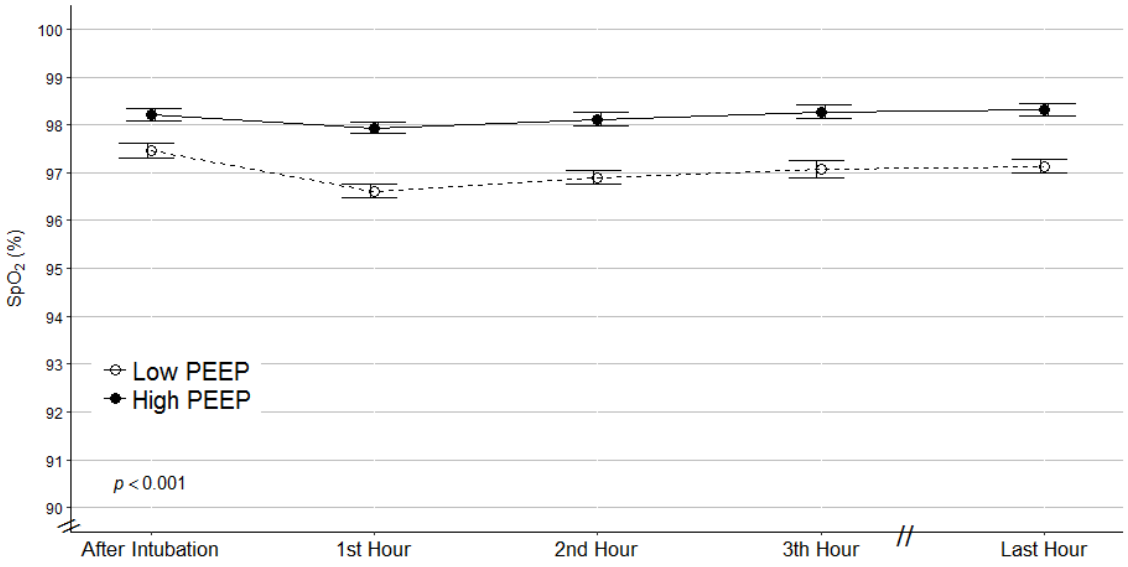
PEEP, positive end-expiratory pressure. Dots are mean and error bars are 95% confidence intervals. P-value from a time *vs.* group interaction calculated in a mixed-effect linear model.

eFigure 4. Peak pressure during anesthesia



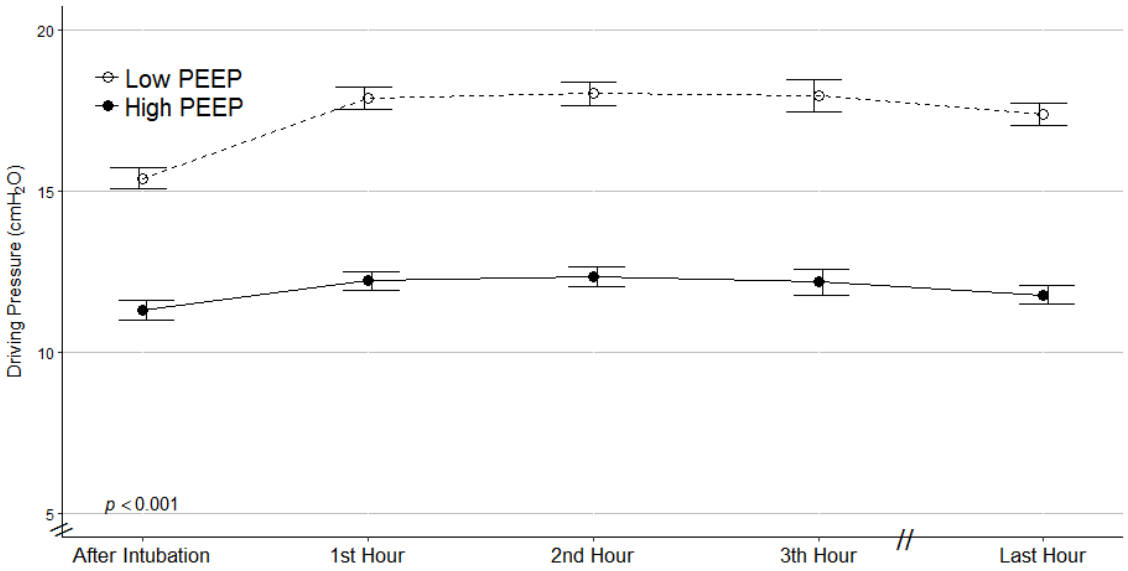
Inspiratory peak pressure values were read from the anesthesia ventilator. PEEP, positive end-expiratory pressure. Dots are mean and error bars are 95% confidence intervals. P-value from a time *vs.* group interaction calculated in a mixed-effect linear model.

eFigure 5. Peripheral oxyhemoglobin saturation during anesthesia



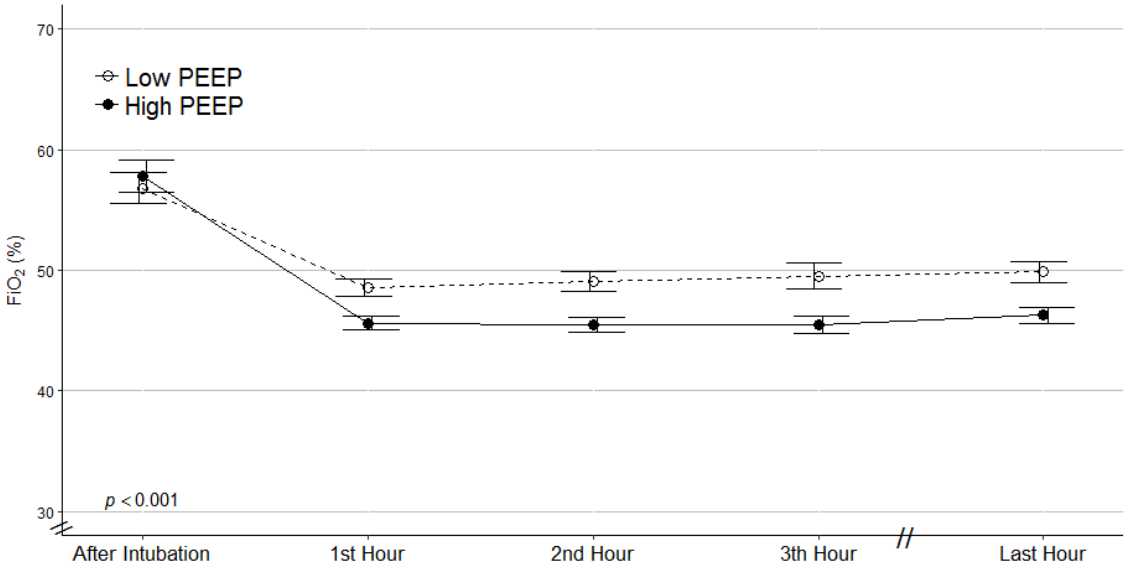
PEEP, positive end-expiratory pressure. Dots are mean and error bars are 95% confidence intervals. P-value from a time *vs.* group interaction calculated in a mixed-effect linear model.

eFigure 6. Driving pressure during anesthesia



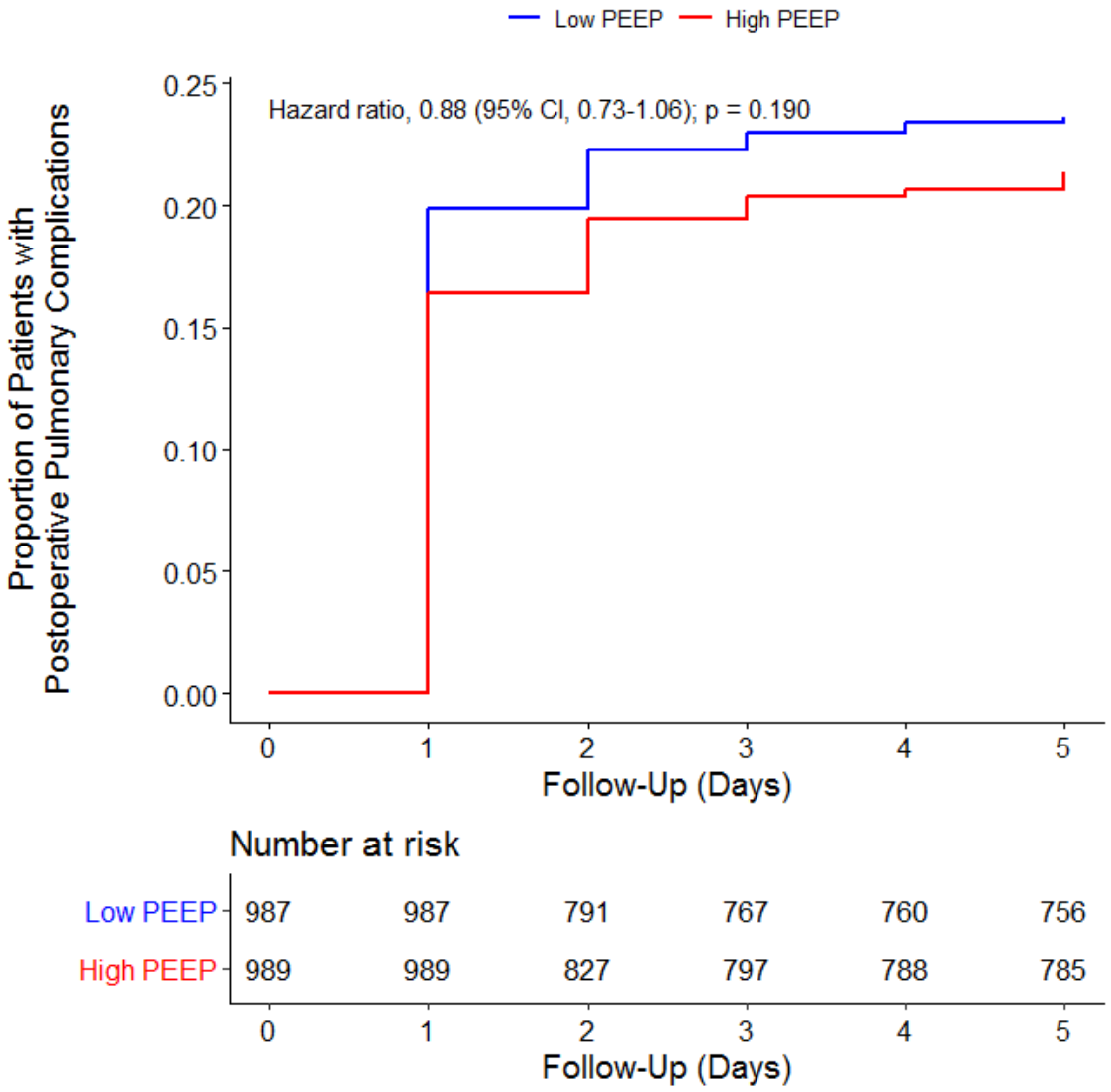
Driving pressure was calculated as airway plateau pressure minus positive end-expiratory pressure. PEEP, positive end-expiratory pressure. Dots are mean and error bars are 95% confidence intervals. P-value from a time *vs.* group interaction calculated in a mixed-effect linear model.

eFigure 7. Fraction of inspiratory oxygen during anesthesia



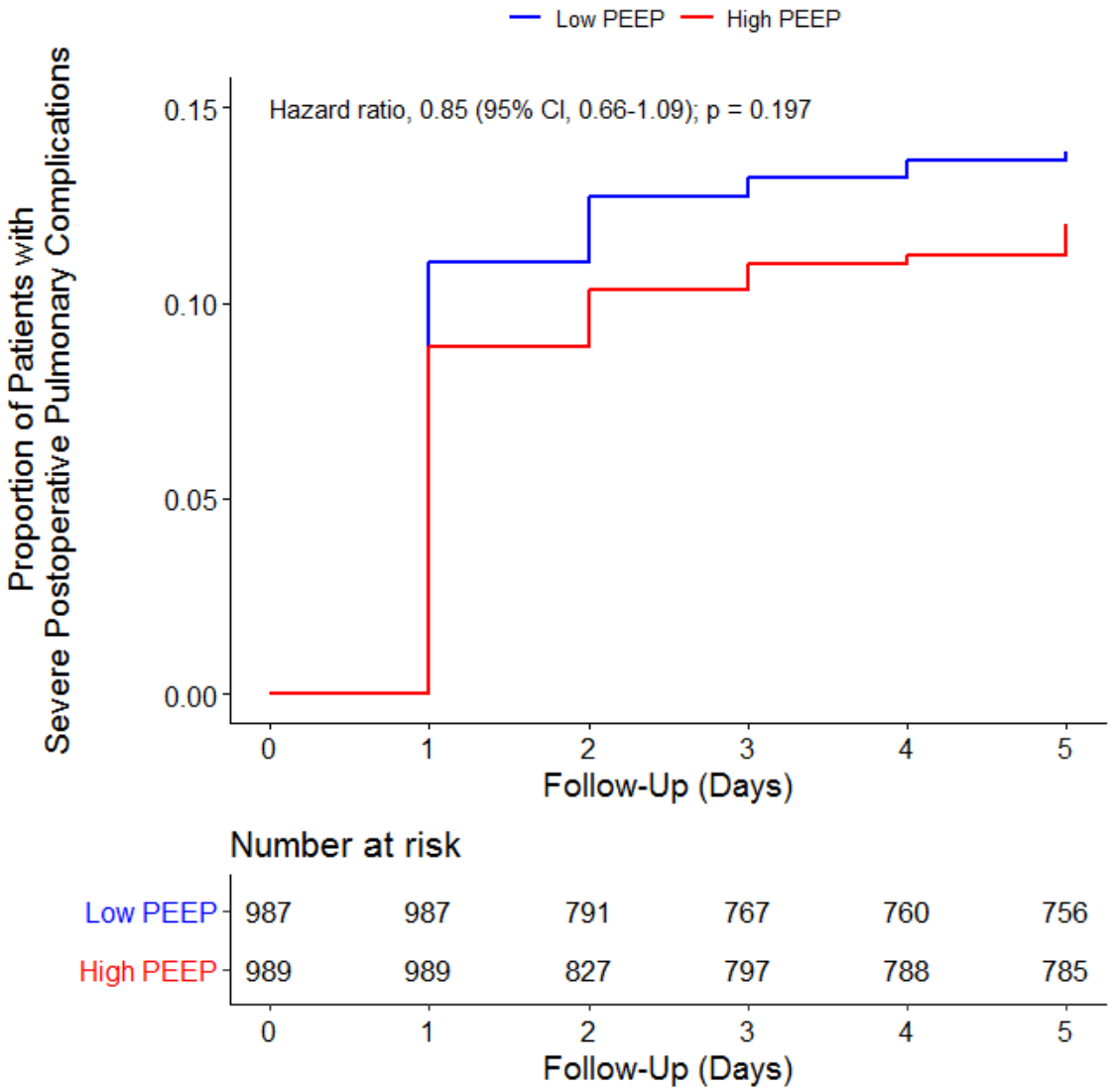
PEEP, positive end-expiratory pressure. Dots are mean and error bars are 95% confidence intervals. P-value from a time *vs.* group interaction calculated in a mixed-effect linear model.

eFigure 8. Probability of postoperative pulmonary complications in the first 5 postoperative days



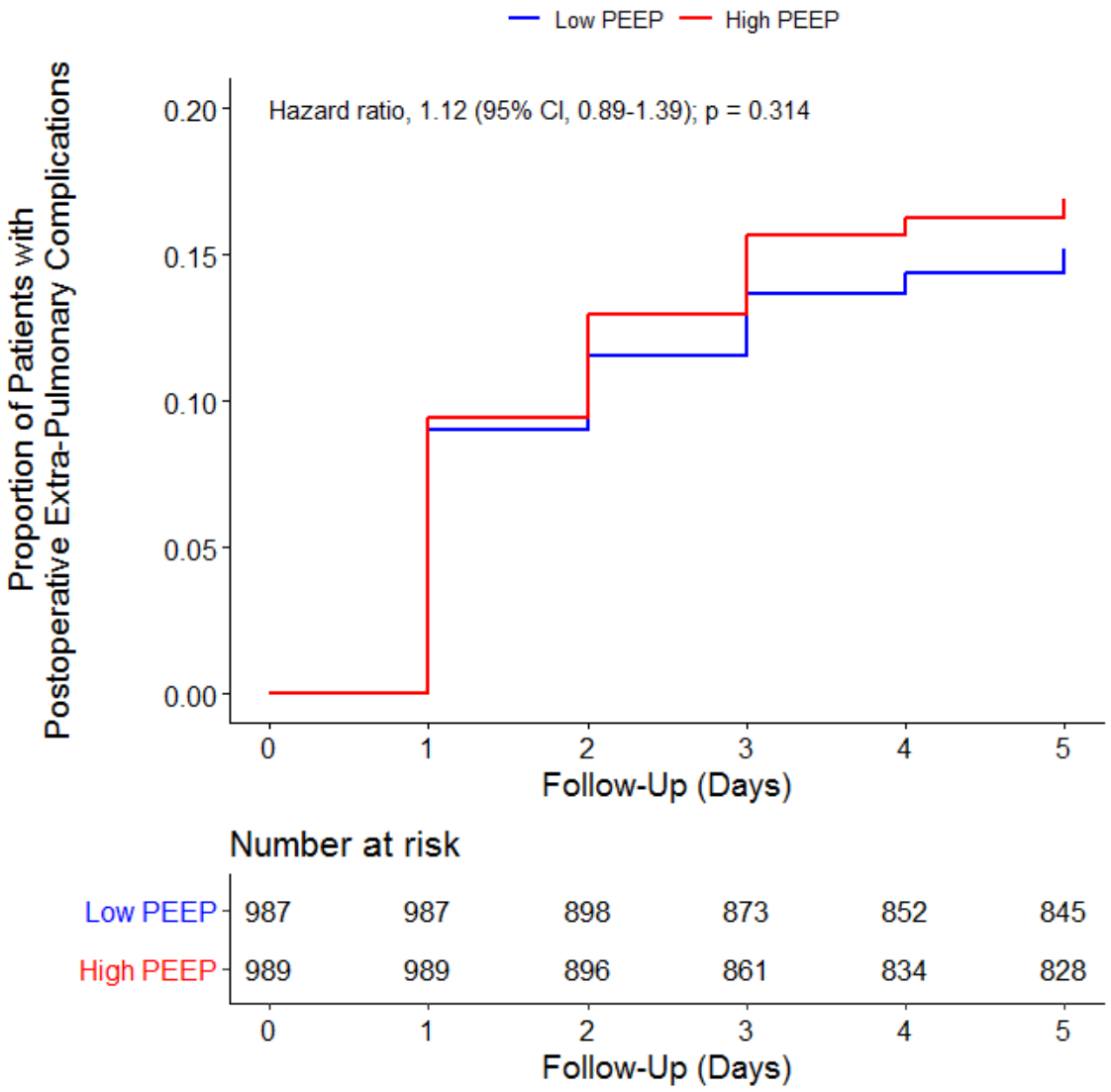
Median observation time was not computed for incidence of postoperative pulmonary complications because the maximum value observed was 0.23. With a median follow-up of 4 (2 – 5) days, the rate of postoperative pulmonary complications within the first 5 postoperative days was 21.3% in the high PEEP group and 23.6% in the low PEEP group (hazard ratio for postoperative pulmonary complications, 0.88; 95% confidence interval 0.73 to 1.06; P=0.190). P value for the Schoenfeld residuals was 0.05.

eFigure 9. Probability of severe postoperative pulmonary complications in the first 5 postoperative days



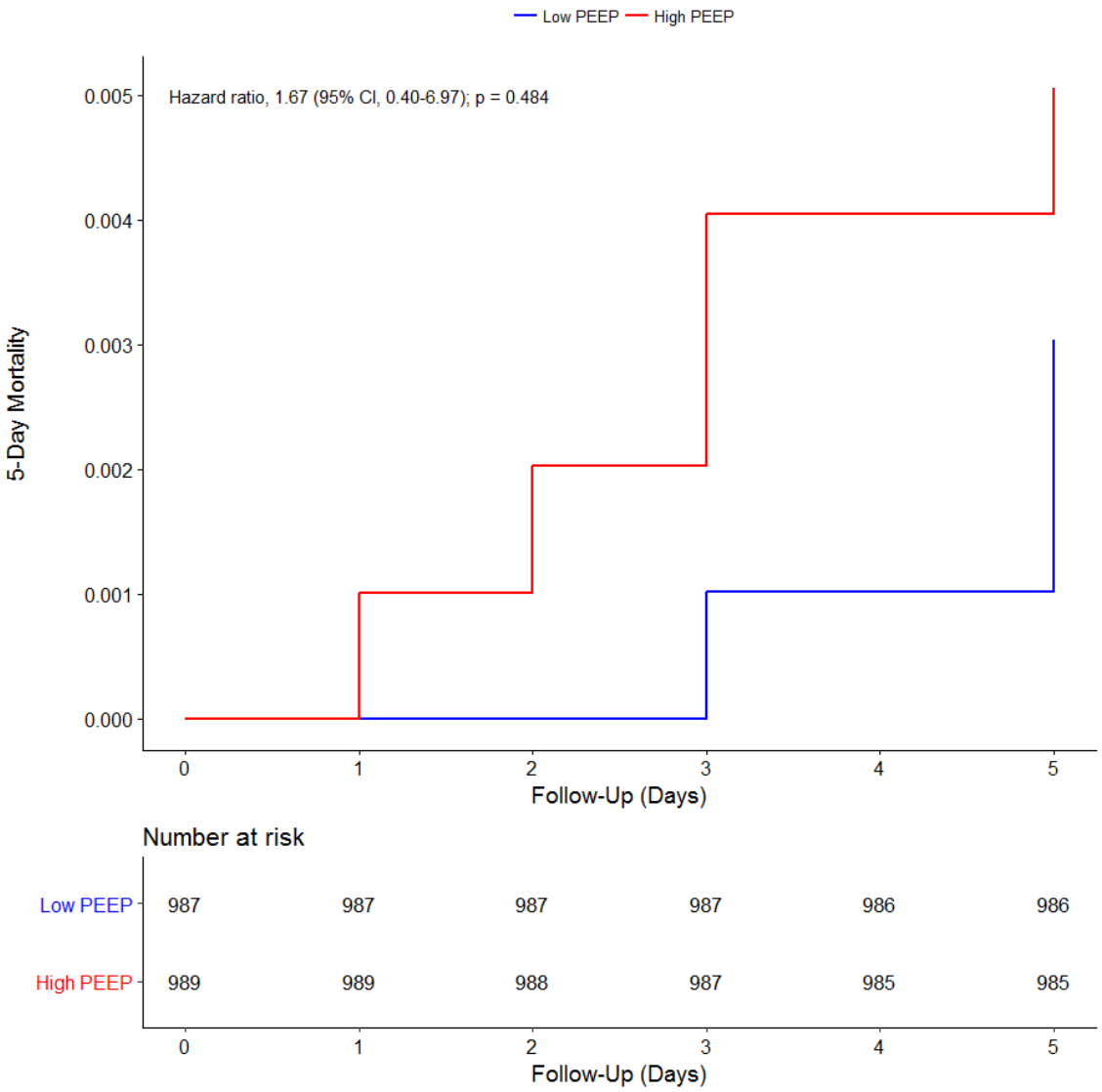
With a median follow-up of 4 (2 – 5) days, the rate of severe postoperative pulmonary complications within the first 5 postoperative days was 11.7% in the high positive end-expiratory pressure (PEEP) group and 13.6% in the low PEEP group (hazard ratio for severe postoperative pulmonary complications, 0.85; 95% confidence interval 0.66 to 1.09; P=0.197). P value for the Schoenfeld residuals was 0.28.

eFigure 10. Probability of postoperative extra-pulmonary complications in the first 5 postoperative days



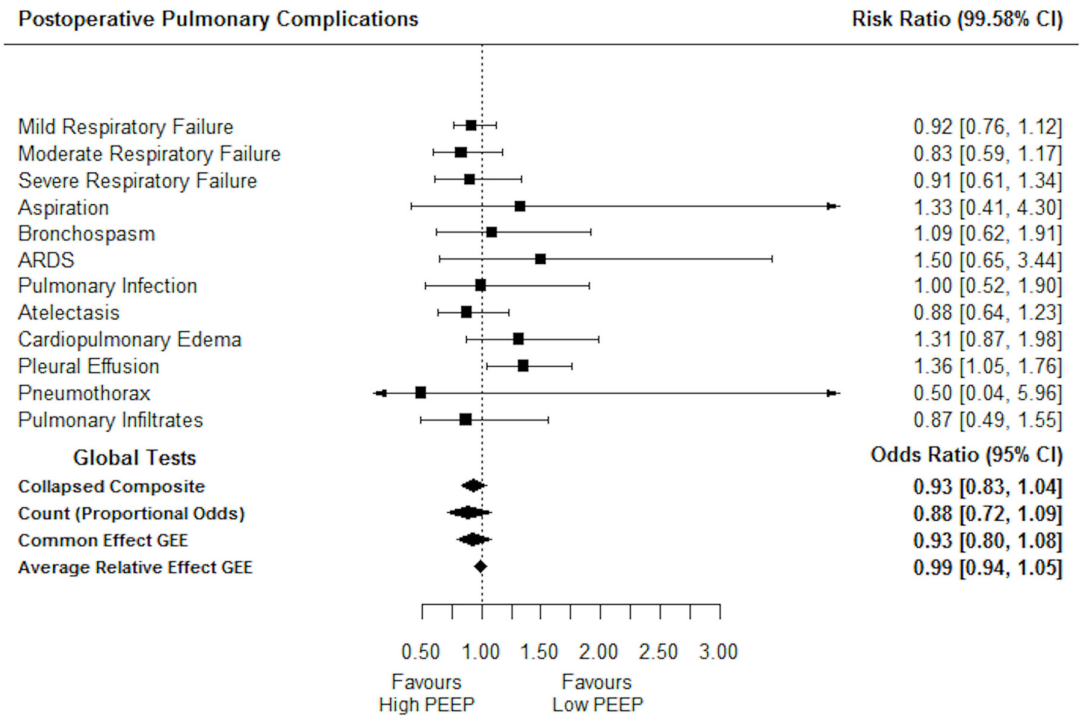
With a median follow-up of 4 (2 – 5) days, the rate of postoperative extra-pulmonary complications within the first 5 postoperative days was 16.9% in the high positive end-expiratory pressure (PEEP) group and 15.2% in the low PEEP group (hazard ratio for postoperative extra-pulmonary complications, 1.12; 95% confidence interval 0.89 to 1.39; P=0.314). P value for the Schoenfeld residuals was 0.67.

eFigure 11. Probability of death in the first 5 postoperative days



With a median follow-up of 4 (2 – 5) days, the rate of postoperative extra-pulmonary complications within the first 5 postoperative days was 0.5% in the high positive end-expiratory pressure (PEEP) group and 0.3% in the low PEEP group (hazard ratio for 5-day mortality, 1.67; 95% confidence interval 0.40 to 6.97; P=0.484). P value for the Schoenfeld residuals was 0.14.

eFigure 12. Results of the sensitivity analysis for the primary endpoint



CI, confidence interval; ARDS, acute respiratory distress syndrome; GEE, generalized estimating equations; PEEP, positive end-expiratory pressure.

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