

CALL FOR CENTERS

Protective Ventilation with Higher versus Lower PEEP during General Anesthesia for Surgery in Obese Patients



Steering Committee

M. Gama de Abreu, T. Bluth, H. Wrigge, A. Serpa Neto, S.N.T. Hemmes, P. Severgnini, G. Cinnella, S. Jaber, J. Canet, M. Hiesmayr, K. Markstaller, J.P. Mulier, L. de Baerdemaeker, J. Sprung, M.F. Vidal Melo, J. Laffey, G. Hedenstierna, I. Matot, C. Putensen, M.J. Licker, R. Rossaint, M. Senturk, C. Gregoretti, M.W. Hollmann, I. Bobek, J. Schmitt, M.J. Schultz, P. Pelosi
for the PROBESE Investigators

ClinicalTrials.gov Identifier NCT02148692

Medical problem

Postoperative respiratory failure, particularly after surgery under general anesthesia, adds to the morbidity and mortality of surgical patients. Anesthesiologists inconsistently use positive end-expiratory pressure (PEEP) and recruitment maneuvers in the hope that this may improve oxygenation and protect against postoperative pulmonary complications (PPCs), especially in obese patients. While it is uncertain whether a strategy using higher levels of PEEP with recruitment maneuvers truly prevents PPCs in these patients, the use of higher levels of PEEP with recruitment maneuvers could compromise intra-operative hemodynamics.

Hypothesis

An intra-operative ventilation strategy using higher levels of PEEP and recruitment maneuvers, as compared to ventilation with lower levels of PEEP without recruitment maneuvers, prevents PPCs in obese patients at an intermediate-to-high risk for PPC.

Study design

International multicenter double-blinded randomized controlled trial of 748 patients

Main study parameters/endpoints

The primary endpoint is the proportion of patients with PPCs. Secondary endpoints include intra-operative complications, need for postoperative ventilatory support (invasive and/or non-invasive ventilation), unexpected ICU admission or ICU readmission, the number of hospital-free days on postoperative day 90 and 90-day survival/mortality.

Intervention

THE HIGHER PEEP LEVEL

Mechanical ventilation with protective tidal volume of 7ml/kg PBW and the level of PEEP at 12 cmH₂O with lung recruitment maneuvers performed hourly

vs.

THE LOWER PEEP LEVEL

Mechanical ventilation with protective tidal volume of 7ml/kg PBW and the level of PEEP at 4 cmH₂O without lung recruitment maneuvers

Follow up

There will be daily visits on postoperative days 1, 2, 3, 4, 5 and at discharge from hospital, as well as telephone contact at day 90.

Inclusion criteria

Obese adult patients with body mass index (BMI) ≥ 35 kg/m² at intermediate-to-high risk for PPCs¹ scheduled for open or laparoscopic surgery under general anesthesia lasting for at least 2 h.

Key exclusion criteria

- Previous lung surgery
- Persistent hemodynamic instability or intractable shock
- History of severe cardiac or chronic obstructive pulmonary disease (COPD)
- Recent immunosuppressive medication
- Invasive mechanical ventilation longer than 30 min within last 30 days
- Prevalent acute respiratory distress syndrome expected to require prolonged postoperative mechanical ventilation
- Severe pulmonary arterial hypertension
- Intracranial injury or tumor
- Neuromuscular disease
- Need for intraoperative prone or lateral decubitus position
- Need for one-lung ventilation
- Cardiac or Neurosurgery
- Planned reintubation following surgery

¹ Canet, J., Anesthesiology, 2010;113(6)

Become a co-author!

You are eligible for a co-authorship for every 12 randomized patients successfully treated according to the study protocol. Furthermore, you will be able to run your own substudy upon application to the PROBESE steering committee

