Sub-Study

Preliminary evaluation of postural reduction of peripheral oxygen saturation (SpO_2) and its association with postoperative pulmonary complications in obese patients

proposed by

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Aim

This subgroup study proposal of the PROBESE randomized controlled trial aims to assess the association of postural changes of peripheral oxygen saturation (SpO_2) with postoperative pulmonary complication (PPCs) in obese patients.

Rationale

Body position influences lung mechanics and respiratory gas exchange during both spontaneous and controlled ventilation.

Supine position contributes to a reduction of functional residual capacity (FRC), increasing the change of closing volume to fall within the breathing range. This may lead to airway closure, atelectasis formation, ventilation\perfusion mismatch and, ultimately, impaired gas exchange and oxygen desaturation [1,2]. These changes may be more pronounced in older patients, in patients with pre-existing cardiopulmonary diseases, obesity and after administration of sedatives or muscle relaxants. In obese patients these mechanisms may be more profound, after considering their possible increased airway resistance, altered lung and chest wall compliance and diaphragm displacement due to increased abdominal pressure [3-5].

The effect of position on blood gas has been previously investigated in both healthy volunteers and obese patients [6,7]. A postural drop of arterial oxygenation has been reported in the postoperative period of patients who underwent bariatric surgery. However, preoperative assessment of the role of body position on respiratory blood gas and arterial saturation led to conflicting results [8]. To our knowledge, the preoperative assessment of postural changes of SpO_2 has never been studied as a potential tool for prediction of PPCs.

Hypothesis

Patients with a pre-operative reduced cardiopulmonary function or with comorbidities may undergo a more profound reduction of SpO_2 under the *stress-test condition* of supine position. We hypothesise that the preoperative postural reduction of SpO_2 from beach chair to supine position may be associated with the incidence of PPCs in obese patients at intermediate to high risk of

PPCs (ARISCAT score ≥ 26) [9]. Preoperative postural reduction of SpO_2 may be associated with PPCs after adjustment of either lower PEEP or higher PEEP allocation of patients. Moreover, patients with a preoperative reduction of SpO_2 may be associated with an increased incidence of intraoperative respiratory complications after adjustment for type of intervention.

Proposed changes/integration in the PROBESE protocol (v2.6 PROBESE study protocol)

7.2.4. Data to be collected

- SpO_2 (10min in room air, beach chair position); %
- **SpO_2 (10min in room air, supine position), %; if SpO_2 in beach chair position ≥ 92%**

Primary endpoint

- Postoperative pulmonary complications (as defined in the PROBESE randomized trial protocol)

We will assess primary endpoint in both patients with a postural desaturation and without postural desaturation in both lower PEEP and higher PEEP level groups.

We will define postural desaturation the reduction of at least 2% of SpO_2 breathing room air when body position changes from beach chair to supine. The *postural desaturation group* will include patients with at least 2% of postural reduction of SpO_2. The *no postural desaturation group* will include patients without postural changes of SpO_2 or with a SpO_2 reduction < 2%.

Secondary endpoints

- Intraoperative complications
- Need for postoperative ventilatory support
- Unexpected need for ICU admission
- Need for hospital readmission within 30 days
- Hospital-free days at day 90
- Mortality at day 90

All the secondary endpoints will be defined as in the PROBESE randomized trial protocol.

Sample size calculation

Our substudy proposal is explorative in nature. Indeed, to our knowledge, there is no information available in the literature about the response and the meaning of the test. The aim of our substudy proposal would be to evaluate the potential association between one additional preoperative variable and PPCs. We will consider the sample of patients from centers adhering to our substudy proposal.

Data analysis plan

We will identify patients with a postural drop of SpO_2 and patients without changes in SpO_2 in both lower PEEP and higher PEEP level groups. We will define postural desaturation the reduction of at least 2% of SpO_2 breathing room air when body position changes from beach chair to supine. The *postural desaturation group* will include patients with at least 2% of postural reduction of SpO_2. The *no postural desaturation group* will include patients without postural changes of SpO_2 or with a SpO_2 reduction < 2%.

Patients' characteristics and comorbidities will be analysed according to the following groups:

	Lower PEEP level (n =)		P-value	**Higher PEEP level (n =)**		P – value
	Postural desaturation (n =)	No postural desaturation (n =)		Postural desaturation (n =)	No postural desaturation (n =)	
Age						
Weight						
Height						
Waist/Hip Ratio						
ASA score						
Cumulated ambulation score						
NYHA score						
Hearth failure						
Obstructive sleep apnea						
COPD						
Respiratory infection within the last month						
Current smoker						
Use of NIV						
Respiratory rate						
Noninvasive mean arterial pressure						
Heart rate						
SpO_2 beach chair in room air						
SpO_2 in supine position						

Table 1: Patients' characteristics

We will assess primary and secondary endpoints in both patients with a postural desaturation and without postural desaturation in both lower PEEP and higher PEEP level groups.

The following scheme illustrates the data analysis plan of primary and secondary endpoints.

	Lower PEEP level (n =)		P-value	**Higher PEEP level**		P - value
	Postural desaturation (n =)	No postural desaturation (n =)		Postural desaturation (n =)	No postural desaturation (n =)	
Postoperative polmonary complications						
Intraoperative complications						
Need for postoperative ventilatory support						
Unexpected need for ICU admission						
Need for hospital readmission within 30 days						
Hospital–free days at day 90						
Mortality at day 90						

Table 2: Study primary and secondary endpoints

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