

Pressure support ventilation during general anaesthesia

Submission date 26/10/2009	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/11/2009	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 09/01/2015	Condition category Surgery	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Xavier Capdevila

Contact details
SAR A, Lapeyronie University Hospital
295 Avenue du Doyen G Giraud
Montpellier
France
34295

Additional identifiers

Protocol serial number
L94/10/04

Study information

Scientific Title
The effects of pressure support ventilation on emergence time and ventilatory function in comparison to volume controlled ventilation and spontaneous breathing: a randomised study

Study objectives

Pressure support ventilation (PSV) used with laryngeal mask airway during general anaesthesia (GA) permitted to reduce general anaesthesia emergence time and propofol consumption, compared to spontaneous breathing (SB) and controlled mechanical ventilation (CMV). An improvement in ventilatory parameters and a decrease in laryngeal mask airway (LMA) leaks were also observed with PSV.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local medical ethics committee (CPP Sud Méditerranée IV, Hôpital Lapeyronie, CHRU Montpellier) approved on the 28th October 1994 (ref: L94/10-04)

Primary study design

Interventional

Study design

Prospective randomised comparative three group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Mechanical ventilation

Interventions

SB-group: patients underwent SB throughout the ventilator circuit

CMV-group: patients underwent CMV (expiratory tidal volume: V_{Te} of 8 mL/kg, a respiratory rate (RR) of 10 breaths/min and an inspiratory/total duty cycle (T_i/T_{tot}) ratio of 1:3 with a time plateau pressure at 15% of the inspiratory time)

PSV-group: patients underwent PSV (PSV level was set to obtain a V_{Te} between 7 - 8 mL/kg and RR between 10 - 16 c/min, inspiratory trigger was fixed at -2 cm H₂O)

Ventilation was performed with zero positive end expiratory pressure in all three groups. All data were recorded at baseline (T₀: before GA induction), 10 min after GA induction (T₁), at the surgical incision (T₂), at the end of anaesthetic drugs infusion (T₃) and when the patient was totally awake (T₄). Drugs consumption during GA and duration of GA were recorded at the end of the surgical procedure. Hemodynamic (HR, MAP) and ventilatory variables (RR, V_{Ti}, V_{Te}, T_i/T_{tot}, plateau pressure, SpO₂, PetCO₂) were recorded during a 2-min stable state for each period. Peak pressure, plateau pressure and flow were measured with Capnomac Ultima at the tube opening. Airway leaks were determined by noting the difference between inspired and expired tidal volume (V_{Ti}-V_{Te}). Airway occlusion pressure (P_{0.1}) was measured at each point except in T₁, T₂ and T₃ for the CMV group. For T₀ and T₄, ventilatory variables were obtained in awake patients spontaneously breathing through the circuit via a mouth piece with a nose clip.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

1. LMA removal time, determined by repeatedly (every minute) questioning the patient
2. Emergence time, defined as the time to obtain a 10 point score on a five questions test

Key secondary outcome(s)

1. Propofol consumption
2. Ventilatory function
3. Adverse effects

Completion date

01/01/2009

Eligibility**Key inclusion criteria**

1. Patients aged 18 - 75 years, either sex
2. American Society of Anaesthesiologists (ASA) grade I - II
3. Scheduled for elective knee arthroscopic surgery under total intravenous anaesthetic (TIVA) with a LMA and mechanical ventilation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Morbidly obese patients (body mass index [BMI] greater than 35 kg/m²)
2. Chronic obstructive pulmonary disease (COPD) patients
3. Asthmatic patients
4. Less than 18 years old and more than 75 years old

Date of first enrolment

01/01/2005

Date of final enrolment

01/01/2009

Locations

Countries of recruitment

France

Study participating centre

SAR A, Lapeyronie University Hospital

Montpellier

France

34295

Sponsor information

Organisation

Lapeyronie University Hospital (France)

ROR

<https://ror.org/03xzagw65>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Lapeyronie University Hospital and Montpellier School of Medicine (France)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/12/2014		Yes	No