

Influence of respiratory efforts on b2-agonist induced bronchodilation in mechanically ventilated COPD patients

Submission date 20/07/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/07/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 25/09/2009	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Study objectives

The aim of our study was to examine the influence of controlled and assisted modes of ventilatory support on the bronchodilative effect induced by b2-agonists administered with a

metered-dose inhaler (MDI) and a spacer in a homogeneous group of patients with acute exacerbation of chronic obstructive pulmonary disease.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute exacerbation of chronic obstructive pulmonary disease

Interventions

All patients were intubated with an endotracheal tube 8-9 mm in internal diameter, sedated (propofol and remifentanyl) and initially ventilated (for 24 to 36 hours) on volume-controlled (VC) mode using settings that minimized dynamic hyperinflation. After this period, the patients were switched to flow-triggering pressure-support (PS) ventilation with the level of pressure assist adjusted to obtain a tidal volume (VT) of 7-10 ml/kg. Extrinsic positive end-expiratory pressure (PEEP) of approximately 1-2 cmH₂O lower than PEEP_i, measured on controlled mode, was applied. The threshold for triggering was set to 2 l/min. Propofol and remifentanyl infusions during VC and PS mode were titrated such as to obtain sedation levels 6 and 3 on the Ramsey scale respectively. If patients were stable on PS with adequate gas exchange, respiratory frequency less than 30 breaths/min and without clinical evidence of excessive work of breathing, all bronchodilators were withheld for 6 hours. By the end of this period patients were re-evaluated and if they had a respiratory frequency of less than 30 breaths/min, adequate gas exchange and no clinical evidence of excessive work of breathing they were prospectively randomized to receive 4 puffs of salbutamol (S, 100 µg/puff given by an MDI canister, Aerolin inhaler, GlaxoWellcome) being ventilated either on PS or VC mode. On VC mode, VT and ventilator frequency were set to values similar to these on PS. A square wave flow pattern was used and no end-inspiratory pause time was applied. No manipulation was performed on PS. After a six hour washout-period, the patients were crossed-over to receive the drug by the alternative mode of ventilation. The MDI was adapted to the inspiratory limb of the ventilator circuit using an aerosol cloud enhancer spacer (ACE, Diemolding Healthcare Division, USA), whereby the MDI flume is directed away from the patient. The spacer was placed just before the Y-ventilator connector. The canister was shaken before each series of puffs. Each actuation was performed at 20 to 30 sec intervals, immediately before initiation of airflow by the ventilator on VC or before the sudden drop in airway pressure on PS, which signaled the start of the triggering process. Arterial blood gases were measured before and 4 hours after drug administration. SaO₂ was measured continuously using a pulse oxymeter (Critikon, Tampa, FLA, USA).

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Salbutamol

Primary outcome(s)

Respiratory system mechanics (Resistance)

Key secondary outcome(s)

Heart rate, arterial blood gasses

Completion date

01/11/2003

Eligibility**Key inclusion criteria**

Patients with chronic obstructive pulmonary disease (COPD), requiring endotracheal intubation and mechanical ventilation to manage acute respiratory failure due to an acute exacerbation of chronic airflow obstruction, were studied. All patients had a previous diagnosis of COPD and met established criteria for this diagnosis.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Hemodynamically unstable

Date of first enrolment

01/03/2003

Date of final enrolment

01/11/2003

Locations**Countries of recruitment**

Greece

Study participating centre

ICU

Heraklion, Crete

Greece

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Sponsor information

Organisation

University of Crete, Medical School (Greece)

ROR

<https://ror.org/00dr28g20>

Funder(s)

Funder type

Not defined

Funder Name

None

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	01/02/2007		Yes	No