

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 20/07/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/09/2009	<b>Condition category</b> 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

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **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 cmH<sub>2</sub>O lower than PEEP<sub>i</sub>, 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. SaO<sub>2</sub> 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?
<a href="#">Results article</a>	results	01/02/2007		Yes	No