

Sleep quality in critically ill patients on proportional assist ventilation with load-adjustable gain factors (PAV+) vs pressure support (PS)

Submission date 22/10/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 11/11/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 11/11/2009	Condition category Respiratory	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Study information

Scientific Title

Sleep quality in critically ill patients on proportional assist ventilation with load-adjustable gain factors (PAV+) vs pressure support (PS) - a randomised controlled cross-over trial

Study objectives

Previous studies have repeatedly reported sleep disruption in intensive care unit (ICU) patients with reduced nocturnal sleep efficiency and reduced slow wave and rapid eye movement sleep. Critical illness itself, the ICU environment, medications, and patient-ventilator interactions may all be contributing factors to altered sleep architecture. Alteration of sleep quality and quantity can have significant adverse consequences prolonging mechanical ventilation and ICU stay.

Proportional assist ventilation (PAV) is a mode of support during which the ventilator pressure is proportional to instantaneous flow and volume and hence to pressure generated by the respiratory muscles. The necessity of regular measurements of respiratory system mechanics imposes a major obstacle on the use of this mode. A software has been developed (PAV+) which automatically adjusts the flow assist (cmH₂O/L/sec) and volume assist (cmH₂O/L) such as to represent always constant fractions of the measured values of resistance and elastance of the respiratory system⁶ by applying a 300 msec pause maneuver at random intervals at the end of selected inspirations. It was recently shown that these brief end-inspiratory occlusions do not affect sleep quality or sedation requirements in a selected group of critically ill patients.

Parthasarathy and Tobin observed greater sleep fragmentation in critically ill patients during pressure support (PS) than during assist-volume control ventilation with backup rate. Numerous studies have shown that compared to PS, PAV improves the synchrony between patient and ventilator and may thus decrease sleep disruption and improve sleep quality. The aim of this study will be to compare sleep quality under constant conditions in critically ill patients ventilated with PAV+ and PS.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee, University Hospital of Heraklion Crete, approved on 12/12/2006 (ref: 13449)

Study design

Randomised controlled crossover trial

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Sleep quality in critically ill patients on mechanical ventilation

Interventions

Patients will be connected to an ICU ventilator (Puritan-Bennett® 840), able to ventilate them with PS and PAV. Polysomnography will be performed in each patient as previously described for 24 hours starting 10 PM in single rooms in the intensive care unit with the window blinds closed. During the study day patients will be ventilated randomly either on pressure support or on PAV+ mode. The pressure support at which the patient was ventilated before the study will serve as baseline pressure support. With PAV+ the percentage of unloading will be set such as to achieve a mean inspiratory airway pressure similar to that with baseline pressure support. In the 24-h study period patients will be ventilated for six 4-h periods (10PM-2AM, 2AM-6AM, 6AM-10AM, 10AM-2PM, 2PM-6PM, 6PM-10PM), three 4-h periods with PS, and three with PAV+. Each patient

will be initially randomised to receive 4 hours of either PS or PAV+ followed by alternating 4-h periods of PS and PAV+.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Effect of PAV and PS in sleep quality.

Key secondary outcome(s)

Patient - ventilator interaction during sleep. Flow (V), volume (V), airway pressure (Paw), end-tidal CO₂ (PETCO₂), the motion of the rib cage and abdomen, inspiratory (TI) and expiratory (TE) time, total respiratory cycle time (TTOT) and peak inspiratory airway pressure (Pawpeak) will be measured on a breath-by-breath basis, while coefficient of variation of tidal volume (VT) and TTOT will be calculated.

Completion date

30/03/2010

Eligibility

Key inclusion criteria

Critically ill patients (>18 years old, both males and females) who are receiving mechanical ventilation for at least 48 hours will be studied. At the time of the study all patients will be haemodynamically stable and ventilated on PS through cuffed endotracheal or tracheostomy tubes with anticipated further mechanical ventilation of at least 24-h duration. All patients must achieve a score of 0 on the Richmond Agitation Sedation Scale (RASS) either with or without intravenous (IV) propofol.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Anticipated ICU stay <24 h
2. Premorbid diseases that could confuse interpretation of sleep monitoring including central

- nervous system (CNS) diseases and sleep disorders
3. Haemodynamic instability (BP <90 mmHg despite therapy)
 4. Glasgow Coma Scale <11 and acute physiology score >13
 5. General anesthetic, drug overdose, or alcohol intoxication within the preceding 24 h

Date of first enrolment

25/10/2009

Date of final enrolment

30/03/2010

Locations

Countries of recruitment

Greece

Study participating centre

Intensive Care Unit

Heraklion

Greece

71110

Sponsor information

Organisation

Cretan Critical Care Society (Greece)

Funder(s)

Funder type

Research organisation

Funder Name

Cretan Critical Care Society (Greece)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration