Measuring work-of-breathing in mechanically ventilated children

Published: 06-12-2011
Last updated: 01-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON44108

Source
ToetsingOnline

Brief title
WOB and paediatric mechanical ventilation

Condition

- Respiratory disorders NEC

Synonym
Acute hypoxaemic respiratory failure, previously healthy lungs

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Children, Mechanical ventilation, Work-of-breathing

Outcome measures

Primary outcome

The level and time course of the patient work-of-breathing measured by the area under the pressure-volume curve during PS ventilation with the work-of-breathing during SIMV-PS ventilation with a lower rate of breaths per minute delivered by the ventilator.

Secondary outcome

The level and time course of surrgatoe parameters for work-of-breathing (PRP, PTP, expiratory airway resistance, imposed work of breathing), distribution of tidal volume, and level and time course of oxygenation (PaO2/FiO2 ratio) during PS ventilation with the work-of-breathing during SIMV-PS ventilation with a lower rate of breaths per minute delivered by the ventilator.

Study description

Background summary

The most common approach to weaning infants and children is gradual reduction of ventilatory support. Weaning with intermittent mandatory ventilation (IMV) or synchronized IMV (SIMV) occurs by reducing the ventilatory rate. With pressure support (PS) ventilation, the inspiratory pressure is initially set to provide the required support and then reduced gradually. PS is often combined with IMV/SIMV during weaning (SIMV-PS). Alternatively, another approach to weaning is attempted with alternating periods of complete ventilatory support and graded spontaneous breathing with assistance. This *sprinting* is performed on the theory that the respiratory muscles can be slowly trained to sustain complete spontaneous breathing. Also, theoretically this *sprinting* allows a better distribution of the tidal volume in the lung. Interestingly, both approaches are used simultaneously: the decision to use either one or both

approaches is dependent upon the preferences of the attending physician as described in many observational single center studies. Children ventilated in the PICU of the Beatrix Children*s Hospital are weaned from the mechanical ventilator using both the gradual weaning and the sprinting approach.Importantly, there is no data comparing the *sprinting* approach with more traditional approaches of weaning in children with respect to patient work-of-breathing. Work-of-breathing is defined by the physiologic work a patient has to deliver to expand the lungs and the chest wall. It can be assessed by various means:
•Bedside: tachypnoea and the presence of nasal flaring and intercostal and/or interjugular retractions indicate increased work of breathing
•Clinical surrogate parameters: the ratio of the inspiratory time to total breathing cycle time, the oesophageal pressure - rate product (PRP), oesophageal pressure - time product (PTP) and expiratory airway resistance (i.e. the difference in transpulmonary pressure and compliance, divided by flow). These clinical surrogate parameters require the presence of an oeosphageal catheter to measure the pressure. These catheters are routinely present in ventilated patients as they are used for nasogastric tube feeding; modern catheters can also measure the oesophageal pressure (i.e. double function).
•Mathematically: the area under the oesophageal pressure - volume curve. This is the classic and traditional approach to measure work of breathing. Its normal value is within the range of 0.5 - 1.0 J/L. The variable is measured by a commercially available ventilator (AVEA, CareFusion, Yorba Linda, CA, USA). To measure this parameter, an oesophageal catheter is necessary.

Study objective

The primary objective for this study is to compare the level and time course of the patient work-of-breathing during PS ventilation with the work-of-breathing during SIMV-PS ventilation with a lower rate of breaths per minute delivered by the ventilator. The secondary objectives for this study are to compare the level and time course of the PRP, PTP, imposed work of breathing and the PaO2/FiO2 ratio as well as the distribution of tidal volume in the lung during PS ventilation with the work-of-breathing during SIMV-PS ventilation with a lower rate of breaths per minute delivered by the ventilator.

Study design

This is a prospective observational study without invasive measurements in a 20 bed tertiary paediatric intensive care facility at the Beatrix Children*s Hospital/University Medical Centre Groningen. The study will start December 1, 2011 and is completed by November 30, 2012.

Study burden and risks

There are no specific benefits for the patients who participate in the study. However, the risks associated with this study are minimal, based upon the following arguments:
•Blood sample drawing is done via the already present indwelling arterial line, so that no additional venous or arterial punctures are necessary (routine clinical care)
•All patients already have a nasogastric tube inserted that is capable of measuring the oesophageal pressure (routine clinical care)
•All parameters collected in this study are real-time displayed on either the ventilator or the pulmonary function monitor; only the EIT analyses are performed off-line. For the EIT measurements 16 electrodes must be placed circumferentially around the chest. However, these electrodes are fully comparable with the electrodes routinely used for ECG monitoring; hence they pose no additional burden
•There are no invasive measurements for this study
•There is no interference with clinical management of the patients for this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

•mechanical ventilation for at least 48 hours before the start of weaning
•weight >= 3 kg
•deemed eligible for weaning by the attending physician
•stable haemodynamics, defined by the absence of need for increase in vaso-active drugs and/or fluid challenges at least 6 hours prior to enrolment

Exclusion criteria

•mechanical ventilation less than 48 hours for unplanned admissions before the start of weaning
•post-operative admission with expected duration of mechanical ventilaton less than 48 hours
•not eligible for weaning as assessed by the attending physician (usually when there are unstable ventilator settings, defined by the need for increase of inspiratory pressures or positive end-expiratory pressure, and a FiO2 > 0.6 within 6 hours prior to enrolment)
•unstable haemodynamics, defined by the need for increase in vaso-active drugs and/or fluid challenges within 6 hours prior to enrolment
•admitted to the neonatal intensive care unit
•premature birth with gestational age corrected for post-conceptional age less than 40 weeks
•congenital or acquired neuromuscular disorders
•congenital or acquired central nervous system disorders with depressed respiratory drive
•severe traumatic brain injury (i.e. Glasgow Coma Scale < 8)
•congenital or acquired damage to the phrenic nerve
•congenital or acquired paralysis of the diaphragm
•use of neuromuscular blockade prior to enrolment
•uncorrected congenital heart disorder
•chronic lung disease
•severe pulmonary hypertension

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2012
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO Date:	06-12-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	01-08-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	15-12-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL38361.042.11