Spontaneous breathing and work-of-breathing in mechanically ventilated children

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Primary objective: * To study differences in global lung aeration before and during spontaneous breathing during mechanical ventilationSecondary objective:* To study the work of breathing (WOB) under various pressure support (PS) levels in...

Ethical review	Not approved
Status	Will not start
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON36671

Source
ToetsingOnline

Brief title
Pediatric Work of Breathing

Condition

- Respiratory disorders NEC

Synonym
distribution of ventilation, Lung mechanics, work of breathing

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: Lung mechanics, Mechanical ventilation, Work of breathing

Outcome measures

Primary outcome

* Global lung aeration before and during spontaneous breathing during

mechanical ventilation

Secondary outcome

Work of breathing at various pressure support levels during spontaneous

breathing:

-Area of the oesophageal pressure - volume curve

-Oesophageal pressure * time product

-Oesophageal pressure * rate product

Patient comfort at various pressure support levels during spontaneous breathing

Study description

Background summary

The need for mechanical ventilation (MV) for acute or impending respiratory failure originating from (primary) lung failure is one the most common indications for children to be admitted to a paediatric intensive care unit (PICU). Recent data from the United States and Europe demonstrate that up to 64% of children admitted to the PICU are mechanically ventilated for at least 24 hrs. Despite worldwide daily use of MV in children, numerous issues remain unsolved and much of the current clinical practice is based upon anecdotal experience in combination with data originating from studies in critically ill adults. However, the respiratory system is physiologically different between small babies, children and adults implying that all data obtained from adults cannot be easily extrapolated to children.

Children are mainly ventilated in a synchronized intermittent mandatory ventilation mode (SIMV), usually in a pressure controlled (PC) fashion. This means that the inspiratory pressures that are going to be applied by the ventilator are set by the attending physician. The delivered tidal volume (Vt) depends upon the compliance and resistance of the respiratory system of the patient. The rate at which the ventilator delivers the pre-set inspiratory pressures is defined by the patient*s age and disease condition. . In addition to these machine breaths, it is possible for the patient to maintain spontaneous breathing. These breaths are supported by a pre-defined level of pressure support (PS). However, it is current clinical practice to fully ventilate the child during the early phase of the disease course; only a few days prior to discontinuation of ventilation the child is allowed to breathe spontaneously.

Studies performed in critically ill adults have shown that spontaneous breathing during mechanical ventilation significantly improves the distribution of the tidal volume and pulmonary gas exchange. In a supine patient the thorax is divided into a non-dependent lung zone (the upper half of the thorax) and a dependent lung zone (the lower half of the thorax). During mechanical ventilation the tidal volume is directed towards the non-dependent lung zones. This has two major consequences: the alveoli in the non-dependent lung zones overstretch and the alveoli in the dependent lung zones collapse. This causes significant injury to alveoli. In contrast, when adults breathe spontaneously during mechanical ventilation the tidal volume is directed towards the dependent lung zones because the posterior muscular sections of the diaphragm move more than the anterior tendon plate. Consequently, in patients in the supine position the dependent lung zones tend to be better ventilated during spontaneous breathing protecting against alveolar collapse and improving oxygenation by decreasing ventilation/perfusion mismatch.

Thus, there are strong arguments to facilitate spontaneous breathing as much as possible during mechanical ventilation. This strongly suggests that a physician should set the number of machine breaths as low as possible allowing the patient to breathe spontaneously, and to apply a sufficient level of pressure support. However, the effects of spontaneous breathing during mechanical ventilation observed in adults have to date not been explored in mechanically ventilated children. Hence, we propose that there are two main issues that need to be addressed. First, is spontaneous breathing during mechanical ventilation associated with beneficial effects similar to adults (i.e. better distribution of tidal volume and improved gas exchange)? Second, how much pressure support must be delivered by the ventilator to minimize the patient*s work of breathing?

This prospective intervention study without invasive measurements is designed to test the hypothesis that a) spontaneous breathing during mechanical ventilation is associated with improved aeration of the lung dependent zones and improved gas exchange, and b) the work of breathing during spontaneous

breathing is influenced by the level of pressure support.

Study objective

Primary objective:
* To study differences in global lung aeration before and during spontaneous breathing during mechanical ventilation

Secondary objective:
* To study the work of breathing (WOB) under various pressure support (PS) levels in spontaneously breathing mechanically ventilated children

Study design

This is a prospective intervention 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 September 1, 2011 and is completed by March 31, 2011.

Intervention

Not applicable

Study burden and risks

There are a priori no specific benefits for the patients who participate in the study as we do not know if the beneficial effects of spontaneous breathing during mechanical ventilation observed in adults also occur in mechanically ventilated children. Yet, if they do (and we expect so) then the enrolled patients will experience similar beneficial effects.
The risks associated with this study are to be considered 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
*All patients already have a nasogastric tube inserted that is capable of measuring the oesophageal pressure
*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
Nevertheless, the decrease in pressure support may induce some degree of dyspnoea as characterized by tachypnoea, nasal flaring and/or intercostal

retractions. We have therefore defined a stopping rule.

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 24hours
*weight> 3kg
*able to initiate and maintain spontaneous breathing
*stable ventilator settings, defined by the absence of need for increase of inspiratory pressures or positive end-expiratory pressure, and a FiO2 < 0.4 for at least 6 hours prior to enrollment
*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
*leakage around the endotracheal tube less then 5%, defined by the ratio of the expiratory tidal volume both to the inspiratory tidal volume measured by the ventilator

Exclusion criteria

*mechanical ventilation less than 24hours
*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-ative drugs and/or fluid challenges within 6 hours prior to enrolment
*leakage around the endotracheal tube > 5%
*admitted to the neonatal intensive care unit
*premature birth with gestational age corrected for age less than 40 weeks
*congenital or acquired neuromuscular disorders
*congenital or acquired central nervous system disorders with depressed respiratory drive
*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

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	15
Type:	Anticipated

Ethics review

Not approved

Date:	28-07-2011
Application type:	First submission

Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL33357.000.10