Use of lung mechanics to identify the optimal level of positive end-expiratory pressure in mechanically ventilated children with acute lung injury: a pilot study

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

Summary

ID

NL-OMON44862

Source
ToetsingOnline

Brief title
Lung mechanics and volume

Condition

- Respiratory disorders NEC

Synonym
Early acute lung injury

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, Lung mechanics, Mechanical ventilation, PEEP titration

Outcome measures

Primary outcome

The main study parameter is the level and time course of the end-expiratory

lung volume.

Secondary outcome

Secondary study parameters include the level and time course of the oxygenation

index, the SpO2/FiO2 ratio, respiratory system compliance, lung compliance,

transpulmonary pressure, and alveolar dead space fraction.

Study description

Background summary

Mechanical ventilation is necessitated in children with acute lung injury to maintain gas exchange and take away increased work of breathing but is also known to induce a pulmonary inflammation aggravating the lung injury (i.e. ventilator-induced lung injury, VILI). One of the mechanisms of the ventilator is to deliver a positive end-expiratory pressure (PEEP) to maintain sufficient end-expiratory lung volume (EELV) approximating functional residual capacity (FRC) to ensure adequate oxygenation by limiting ventilation-perfusion mismatch. Also, the use of PEEP prevents the repetitive opening and closure of alveoli, which is one of the main mechanisms underlying VILI. In clinical practice, the attending physician guided by the need for supplemental oxygen sets the *optimal* level of PEEP. Alternatively, we, and many others, use an incremental * decremental PEEP titration to find the maximum end-expiratory lung volume and hence set the level of PEEP. This level is identified by the oxygenation; however, there is a poor correlation between oxygenation and the end-expiratory lung volume. As a consequence, alternative physiological

variables such as the oxygenation index (taking the level of mechanical ventilation into account), respiratory system compliance, lung compliance, transpulmonary pressure or alveolar dead space fraction are proposed as clinical surrogates for end-expiratory lung volume.

Study objective

The primary objective is to study the level and time course of the end-expiratory lung volume during the individual incremental * decremental PEEP titration; the secondary objective is to study if there is a significant association between the end-expiratory lung volume at each PEEP step during the incremental * decremental PEEP titration and the level and time course of the oxygenation index, respiratory system compliance, lung compliance, transpulmonary pressure and alveolar dead space fraction

Study design

Prospective observational study with invasive measurements

Study burden and risks

There are a priori no specific benefits for the patients who participate in the study because the techniques used for measuring the end-expiratory lung volume can only be read offline. We consider the risks associated with this non-therapeutic observational study acceptable and the burden 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. There a no specific blood sample drawings for this study. Furthermore, the maximum amount is 2.5 mL; for a 3 kg infant this would constitute as little as 1% of the circulating volume.
* The insertion of an oesophageal catheter is to be considered an invasive procedure; however, the procedure itself is comparable to inserting a nasogastric feeding tube that is routinely done in all ventilated patients to ensure nasogastric tube feeding and prevent gastric distension; the potential risk includes nasal bleeding, misplacement (either to deep or not) or * very rarely * mucosal bleeding in the oesophagus. To our best of knowledge, these complications have so far occurred very rarely in our PICU. Misplacement into the trachea is very unlikely because the endotracheal tube is already in place. Nonetheless, we will record any complication that has occurred when inserting the oesophageal catheter. Furthermore, correct position of the catheter is confirmed if the cardiac signal is present in the pressure * time curve displayed by the ventilator. If not, then the oesophageal catheter is removed. If this occurs, the oesophageal catheter is re-inserted only once. The use of additional oesophageal catheters to measure pressure in mechanically ventilated children has been approved by local IRBs (NL26857.078.09; NL24044.029.08).

Finally, the study is conducted when there is serious acute lung injury and the patient is usually deeply sedated so the procedure itself will pose little burden to the patient. Similar as for any procedure clinically required, we will measure the Comfort Score prior to insertion of the oesophageal catheter; if necessary the dosage of sedation will be adjusted. The nurse taking care of the patient will insert the catheter; he or she is fully capable of inserting such a catheter. Finally, there is negligible risk of sinusitis caused by obstruction of the ostium due to having temporarily two catheters inserted because the occurrence of sinusitis in young mechanically ventilated children is very uncommon and the study period is relatively short.
* All parameters collected in this study are displayed real-time on either the ventilator or the pulmonary function monitor; only the EIT en RIP analyses are performed off-line. For the EIT measurements 16 electrodes must be placed circumferentially around the chest. The electrodes are fully comparable with the electrodes routinely used for ECG monitoring; hence they pose minimal burden. For the RIP studies two elastic bands are placed circumferentially around the patient*s chest and abdomen. The cardiac output is measured non - invasively
* 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

* weight * 3 kg
* presence of indwelling arterial line

Exclusion criteria

* admitted to the neonatal intensive care unit
* premature birth with gestational age corrected for post-conceptional age < 40 weeks
* uncorrected congenital heart disorder
* primary pulmonary hypertension
* contra-indication for an incremental * decremental PEEP titration

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2013
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	13-11-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	07-11-2016
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	NL45347.042.13