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Evaluation of lung ultrasound for the prediction of lung water parameters in critically ill patients

Submission date
03/07/2019

Recruitment status
No longer recruiting

Registration date
21/07/2019

Overall study status
Completed

Last Edited
07/09/2021

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and objective:
Pulmonary edema is a well-known disorder in critically ill patients and a hallmark of acute respiratory distress syndrome (ARDS). The pathological accumulation of lung water is associated with impaired prognosis. Extravascular lung water index (EVLWI) and pulmonary vascular permeability index (PVPI) assessed by transpulmonary thermodilution (TPTD) represent the most validated parameters of lung water and alveolocapillary permeability. Numerous previous studies evaluated the high prognostic value of EVLWI and PVPI in critically ill patients. However, measurement of EVLWI and PVPI is invasive, expensive and still limited to availability of equipment.
Early, non-invasive and easily-applicable detection of lung edema is an ambitious and attractive goal. Sonographic visualizing of B-Lines - originally termed as comet-tail artefacts arising vertically from the pleural line – represents a promising and non-invasive assessment of pulmonary hydration. Although an extensive 28 sector chest scan is most commonly recommended for scoring of B-Lines, some previous studies described a positive correlation of EVLWI with simplified B-Lines scores derived from limited 4 sector or 8 sector chest scans. However, no former study evaluated the diagnostic potential of different sector scans to predict specific levels of EVLWI and PVPI in the setting of intensive care unit (ICU).
Timely and non-invasive diagnosis of pulmonary edems is of vital importance in treatment of critically ill patients. Consequently, the aim of this study is to correlate B-Lines scores derived from extensive 28 sector and 4 sector chest scan with TPTD in the setting of ICU.

Who can participate?
Critically ill patients with possibility for lung ultrasound prior to hemodynamic monitoring via transpulmonary thermodilution (TPTD). Indication for extensive hemodynamic assessment by using TPTD irrespective of the study.

What does the study involve?
Sonographic assessment in supine position at the bedside for quantification of 28 sector and 4 sector B-Lines scores prior to hemodynamic monitoring via transpulmonary thermodilution (TPTD). Documentation of clinical and laboratory parameters on the day of lung ultrasound and first TPTD-measurement.

What are possible benefits and risks of participating in the study?
The possible benefit is a thorough analysis and monitoring of pulmonary and hemodynamic parameters. There are no additional risks to participants due to the observational design of the study.

Where is the study run from?
General Intensive Care Unit R3a (2/11) of the university hospital Klinikum rechts der Isar, Technical University of Munich, Germany

When is the study starting and how long is it expected to run for?
January 2017 to May 2018

Who is funding the study?
Technical University of Munich (Germany)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Correlation of B-Lines scores derived from lung ultrasound with extravascular lung water index and pulmonary vascular permeability index: An observational study in critically ill patients.

Acronym
N/A

Study objectives
The primary aim of this study is to analyse correlations between B-Lines scores from non-invasive lung ultrasound at the bedside with lung water parameters derived from transpulmonary thermodilution (TPTD) in critically ill patients. Scoring of B-Lines is performed by an extensive 28 sector as well as simplified 4 sector chest scan.

In the following, the most important aspects addressed by this study are listed:
1. Associations of B-Lines scores derived from 28 sector and 4 sector chest scan with extravascular lung water index (EVLWI) and pulmonary vascular permeability index (PVPI).
2. Correlations of 28 sector and 4 sector B-Lines scores with further parameters of TPTD as global end-diastolic volume index (GEDVI, cardiac index (CI) and central venous pressure (CVP).
3. Correlations of 28 sector and 4 sector B-Lines scores with parameters of respiratory and ventilatory function as Howowitz-index (paO2/FiO2), Oxygenation index (OI, (mean airway pressure*FiO2/paO2), paCO2 and dynamic respiratory system compliance (Cdyn)
4. Diagnostic potential of 28 sector and 4 sector B-Lines scores to identify critically ill patients with certain levels of EVLWI and PVPI. Receiver operating characteristic curves will be performed to evaluate specific cut-offs of B-Lines scores to predict EVLWI within normal range (EVLWI < 8 mL/kg), moderate elevation of ELVWI diagnosing manifest edema (EVLWI ≥ 10 mL /kg) and severe lung edema with EVLWI ≥ 15 mL/kg. Analogously, cut-offs of B-lines scores will be evaluated for identification of critically ill patients with normal PVPI < 2 as well as for prediction of severely elevated permeability (PVPI ≥ 3)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/06/2012, the Ethics Committee of the Technical University of Munich (Ismaninger Straße 22, 81675 München; 0049 89 4140 7737; 0049 89 4140 4199; ethikkommission@mri.tum.de), ref: 5384/12.

Primary study design
Observational

Study design
Single-center observational cohort study

Study type(s)
Other

Health condition(s) or problem(s) studied
Lung water indices and respiratory function of critically ill patients

Interventions
Clinical and laboratory parameters for the calculation of APACHE II- and SOFA-score will be recorded on the day of lung ultrasound and transpulmonary thermodilation (TPTD). Ultrasound examination is done non-invasively at the bedside in supine position immediately before TPTD to assess extensive 28 sector as well as simplified 4 sector chest scan. Prints of each scanned intercostal region will be performed and a further physician of the ICU – blinded to the ultrasound procedure and results of TPTD – analyses the printed screenshots using exactly the same scoring system. Finally, the results both physicians will be averaged to the 28 sector and 4

sector B-Lines scores. Ventilator settings and respiratory profiles are recorded immediately after ultrasound and TPTD.

The intervention (Lung ultrasound for B-Lines scores) is performed at baseline just before the first hemodynamic assessment. There is no follow-up and consecutively no observation period.

Intervention Type
Other

Primary outcome(s)
B-Lines scores are correlated to lung water parameters ELVWI and PVPI at baseline just before the first hemodynamic monitoring via TPTD.

Key secondary outcome(s)
B-Lines scores are evaluated in the prediction of specific levels of EVLWI and PVPI at baseline just before the first hemodynamic monitoring via TPTD.

Completion date
30/06/2019

Eligibility

Key inclusion criteria
1. Aged 18 or older.
2. Critically ill.
3. Hemodynamic monitoring via transpulmonary thermodilution (TPTD) irrespective of the study.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
50

Key exclusion criteria
1. Visible pleural effusion at regions for sonographic chest scan.
2. Major one-sided pathologies i.e. large pleural effusion, pneumothorax, thoracic drainage, extended atelectasis, tumorous lesion or former lung resection (n=1).
3. Pulmonary vascular occlusion.

Date of first enrolment
01/01/2017

Date of final enrolment
31/05/2018

Locations

Countries of recruitment
Germany

Study participating centre
Klinikum rechts der Isar
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Sponsor information

Organisation
Technische Universität München

ROR
https://ror.org/02kkvpp62

Funder(s)

Funder type
University/education

Funder Name
Technische Universität München

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during the current study are available upon request from Ulrich Mayr (mayr.ulrich@tum.de) and Wolfgang Huber (wolfgang.huber@tum.de). The data will be available following permission from the Institutional Review Board.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/11/2020	07/09/2021	Yes	No