Epidemiologic study on mechanical ventilation management in children with Acute Lung Injury

PALIVE
Pediatric Acute Lung Injury Mechanical Ventilation Strategies

Philippe Jouvet and Miriam Santschi
CHU Sainte Justine, Montreal
On behalf of the Palive executive committee
Financial disclosure

• None
PALIVE 1

- Rational
- Objectives
- Methods
- Update
Respiratory failure

Primary disease

Complications of MV:
- Lung atelectasia
- Air leak syndrome
- Lung edema
- Decrease cardiac output
- Agitation
- Ventilation acquired pneumonia
- Others

Mechanical ventilation
ALI and ARDS in pediatrics

- Few pediatric data exists on the ventilation mode and parameters that provide the greatest benefit with the least risk to an individual patient
- Most of the pediatric knowledge comes from applications of adult literature
  - High vs. low tidal volume
  - High vs. low PEEP
  - …
- Few pediatric studies describe mechanical ventilation in children with ALI / ARDS
International epidemiological studies on ALI/ARDS
PALIVE
Pediatric Acute Lung Injury Mechanical Ventilation Strategies

PALIVE 1
Cross sectional international study

PALIVE 2
Prospective epidemiologic international study

2007 2007-06-26 2008 2009 2010

Risk factors

MRCT
Executive committee:
Philippe Jouvet, Adrienne Randolph, Peter Rimensberger, Miriam Santschi, Robert C Tasker.

Tasks:
Elaborate the research protocol
Elaborate the first draft of the case report form
Get fundings
Monitoring the research progress
Writing the reports
Primary objective

Describe mechanical ventilation strategies in ALI/ARDS in children in a large number of PICU

Secondary objectives

1. Describe current prevalence and etiologies of ALI/ARDS
2. Describe adjunctive treatments used in pediatric ALI/ARDS
3. Validate the case report form in a large PICU panel
4. Supply data for the sample size of the prospective epidemiological study
Hypothesis

There is an important variability in practice pattern in mechanical ventilation in ALI/ARDS among pediatric intensivists.
Methods

Study design:

International cross-sectional study in Pediatric Intensive Care Units on the observed practice pattern of invasive and non-invasive mechanical ventilation in children with ALI/ARDS

Repeated single day cross sectional study

Web based case report form
Sample size

- 200 patients with ALI: to include 10 patients on HFOV

- **Length of study:**
  Isolated days of study until 200 patients are included

- 70 centers
- 41% patients on mechanical ventilation\(^1\)
- 10% with ALI\(^1\)
- Mean length of MV for patients with ALI: 6.5 days
- 40 patients with ALI per day of study

4 or 5 days of study one month apart

PALIVE 1 Fundings

Informatic support for the website elaboration:
Dr Éric Rousseau
Dany Janvier
Yvan Fortier

6 000$ca for statistical analysis
• **Steering committee:**
Lutz Bindl, Christopher Carroll, Ira Cheifetz, Heidi Flori, Anna Lia Graciano, Philippe Jouvèt, Jacques Lacroix, Francis Leclerc, Laura Loftis, Christopher Newth, Adrienne Randolph, Peter Rimensberger, Robert C Tasker

• **Tasks:**
Participate to item generation and item selection of the case report form.
IRB agreement and institutional approval renewal
Supervise the activities of other committees (ex: data management, writing committee).
Supervise the expenses.
Methods

Consensus method: Delphi process

• Item generation
  3 rounds

• Item selection
  3 rounds

Jones, J. et al. BMJ 1995;311:376
e-case report form

Integration into a website

Validation of the website: one month test period
Update on PALIVE 1

Miriam Santschi
Centre Hospitalier Universitaire de Sherbrooke
Université de Sherbrooke
Québec, Canada
### Participating centers North America

<table>
<thead>
<tr>
<th>CANADA</th>
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**PALISI**

*Pediatric Acute Lung Injury & Sepsis Investigators*
## Participating centers Europe

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Inclusion criteria:

1. Child on invasive or non invasive mechanical ventilation at 9 a.m. on the day of the study
2. Diagnosis of Acute Lung Injury
   1. Onset of hypoxemia was acute
   2. Bilateral infiltrates on chest X-Ray
   3. No clinical evidence of congestive heart failure (wedge <18 mmHg, no echographic or clinical evidence of CHF)
   4. Sustained hypoxemia defined as:
      • \( \frac{\text{PaO}_2(\text{mmHg})}{\text{FiO}_2} \leq 300 \) or \( \frac{\text{PaO}_2(\text{kPa})}{\text{FiO}_2} \leq 40 \)
      • If no arterial canula or no arterial blood gas: \( \frac{\text{SpO}_2}{\text{FiO}_2} \leq 320 \) with \( \text{SpO}_2 < 0.98 \)

Exclusion criteria

1. Post conceptional age < 42 weeks
2. Age > 18 years
3. Non-corrected cyanotic congenital heart disease or evidence of extra-pulmonary right to left shunt
4. Withdrawal or withholding of active care
5. Brain death
6. Patient on ECMO
7. Already included in this study
Case report form

- Demographic data on PICU
- Demographic data on patient
- Underlying chronic disease
- Acute disease leading to intubation or non-invasive mechanical ventilation

- Punctual informations collected as close as possible to 9 am and every 6 hours for 24 h:
  - Mechanical ventilation mode (including HFOV) and parameters
  - Vital Signs
  - Lab results
  - Specific treatments (NO, prone position, surfactant, steroids, b-agonists, hemofiltration)
  - Complications of MV
Login

User name
Password
Forgot your password?

Log in

Want to know more about PALIVE 1?

An international epidemiologic study on the observed practice pattern of mechanical ventilation in children with Acute Lung Injury.

Executive Committee: Philippe Jouvet, Adrienne Randolph, Peter Rimensberger, Miriam Santschi, Robert C. Tasker
Screening log

At 9am on the day of the study

<table>
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<tr>
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<tr>
<td>1</td>
<td>Total number of patients in unit</td>
<td>8</td>
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<tr>
<td></td>
<td>Number of pediatric beds in the ICU</td>
<td>10</td>
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<tr>
<td>2</td>
<td>Number of patients on non-invasive mechanical ventilation</td>
<td>4</td>
</tr>
<tr>
<td>3</td>
<td>Number of patients on invasive mechanical ventilation</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>Number of patients fulfilling inclusion criteria</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>Number of patients fulfilling inclusion criteria with at least one exclusion criteria</td>
<td>0</td>
</tr>
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Number of subjects:
The number you will provide to the following question represents the number of subjects to be created for this day of the study.

<table>
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<tbody>
<tr>
<td>6</td>
<td>Number of patients included in study (Fulfilling all inclusion criteria and no exclusion criteria)</td>
<td>4</td>
</tr>
<tr>
<td>7</td>
<td>Number of patients with a vasopressure infusion (e.g. dopamine = or &gt; 5 µg/kg/min, dobutamine, epinephrine, milrinone, vasopressin) without invasive or non invasive ventilation.</td>
<td></td>
</tr>
</tbody>
</table>
Subject’s menu

- Visit 1 - 9 AM
  - 1 - Demographic data
  - 2 - Underlying chronic diseases
  - 3 - Acute disease
  - Type of mechanical ventilation
  - 4 - Invasive mechanical ventilation
  - 5 - Invasive mechanical ventilation parameters
  - 6 - Non-invasive mechanical ventilation
  - 7 - Vital signs / Neurological evaluation
  - 8 - Laboratory / Radiologic data
  - 9 - Specific treatments
  - 10 - Major respiratory complications
- Visit 2 - 3 PM
- Visit 3 - 9 PM
- Visit 4 - 3 AM
- Visit 5 - 9 AM
### Mechanical ventilation

#### 6 - Non-invasive mechanical ventilation - Visit 2 - 3 PM

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<tr>
<td>6.1</td>
<td>Type of non-invasive mechanical ventilation</td>
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<tr>
<td>6.2</td>
<td>Ventilation mode</td>
<td></td>
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<tr>
<td>6.3</td>
<td>Ventilator parameters</td>
<td></td>
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<tr>
<td>6.3.1</td>
<td>Fraction of inspired oxygen (FiO₂)</td>
<td>* (from 0.21 to 1.00)</td>
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<tr>
<td>6.3.2</td>
<td>Mandatory respiratory rate</td>
<td>/ min</td>
</tr>
<tr>
<td>6.3.3</td>
<td>Total respiratory rate (spontaneous + mandatory)</td>
<td>/ min *</td>
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<tr>
<td>6.3.4</td>
<td>Inspiration time</td>
<td>sec</td>
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<tr>
<td>6.3.5</td>
<td>Positive end-expiratory pressure (PEEP)</td>
<td>cm H₂O *</td>
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<tr>
<td>6.3.6</td>
<td>Peak Inspiratory Pressure (PIP) over PEEP</td>
<td>cm H₂O *</td>
</tr>
<tr>
<td>6.3.7</td>
<td>Tidal volume set on ventilator (inspiratory)</td>
<td>ml</td>
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<tr>
<td>6.3.8</td>
<td>Pressure support (AI) over PEEP</td>
<td>cm H₂O</td>
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<tr>
<td>6.3.9</td>
<td>Mean airway pressure</td>
<td>cm H₂O</td>
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[Save] [Cancel]
Study dates

June 12th, 2007
(45 patients included)

July 10th, 2007
August 7th, 2007
September 4th, 2007
October 2nd, 2007
Conclusion

• Up to now: scarce data on mechanical ventilation strategies in children with ALI / ARDS

• PALIVE 1:
  – Help better characterize actual mechanical ventilation strategies in pediatric ALI / ARDS
  – Supply data to:
    • Conduct further therapeutic or interventional studies on ALI / ARDS in pediatrics
    • Help establish pediatric guidelines for mechanical ventilation in ALI / ARDS
Acknowledgements

Steering Committee:

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