

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

PALIVE

Pediatric Acute Lung Injury Mechanical Ventilation Strategies

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



Financial disclosure

- None



PALIVE 1

- Rational
- Objectives
- Methods
- Update

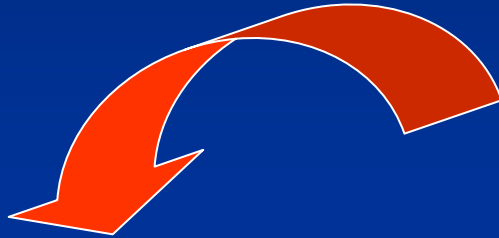
Primary disease



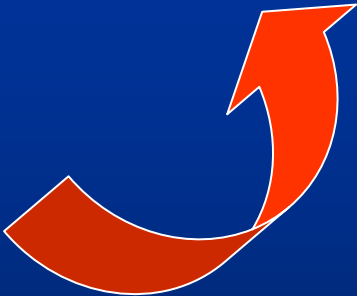
Respiratory failure



Mechanical ventilation



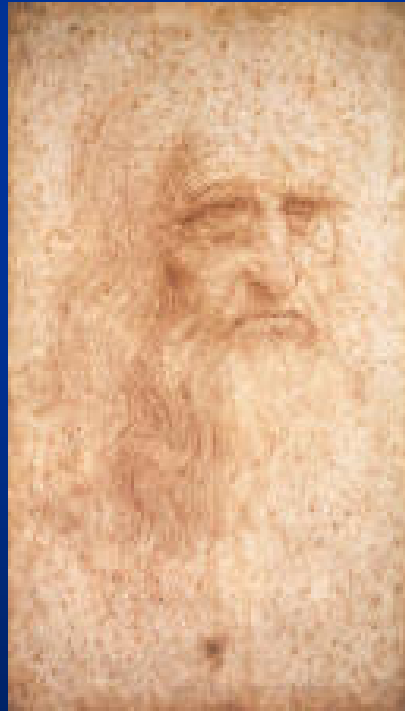
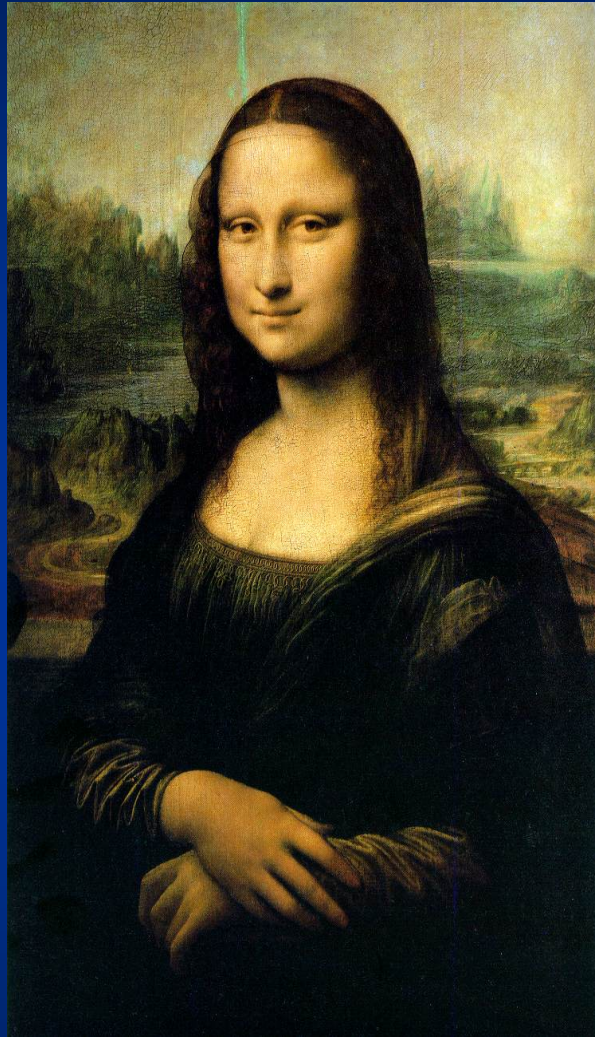
Complications of MV:
Lung atelectasia
Air leak syndrome
Lung edema .
Decrease cardiac output.
Agitation
Ventilation acquired pneumonia
Others



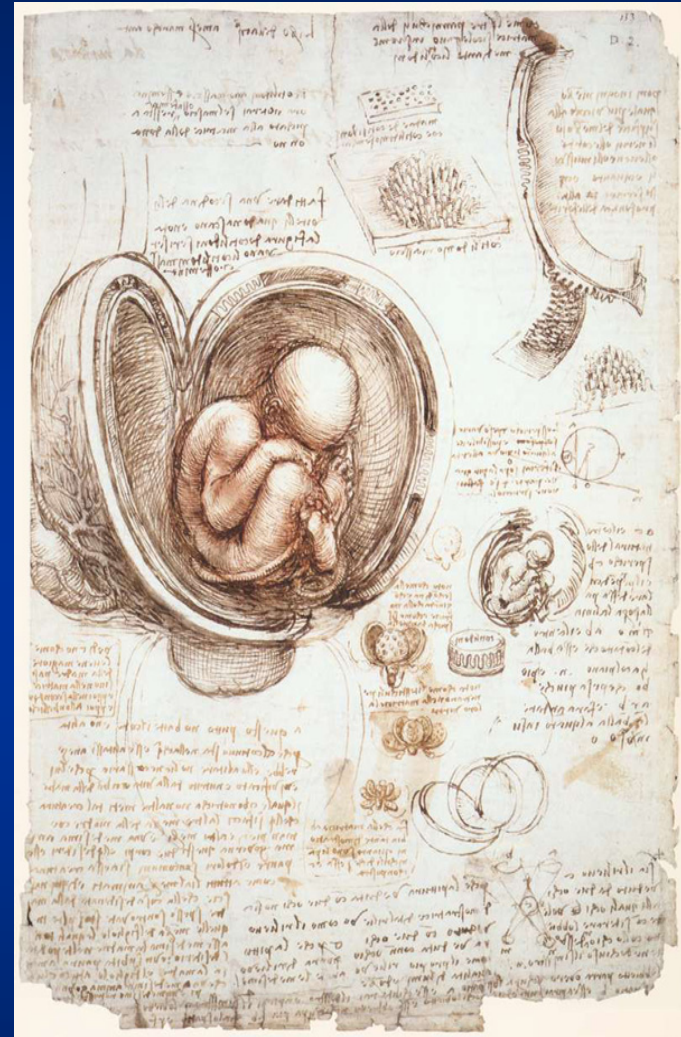
ALI and ARDS in pediatrics

- 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

Art



Science



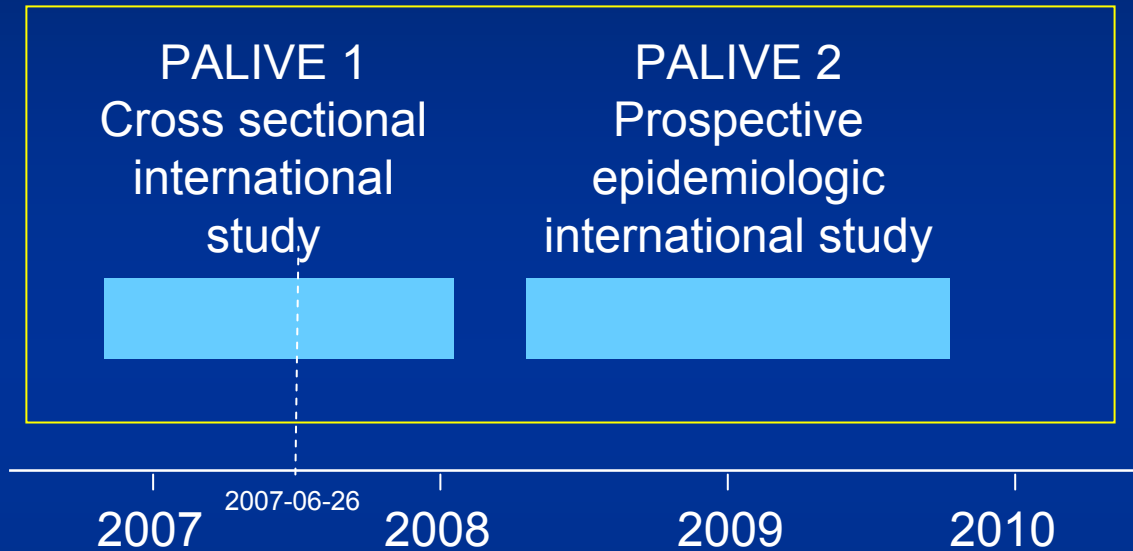
International epidemiological studies on ALI/ARDS

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& Sepsis Investigators*



PALIVE

Pediatric Acute Lung Injury Mechanical Ventilation Strategies



➡ Risk factors



MRCT



- **Executive committee:**

Philippe Jouviet, 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

Writting 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 ventilation¹
- 10% with ALI¹
- 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 Bintl, Christopher Carroll, Ira Cheifetz, Heidi Flori, Anna Lia Graciano, Philippe Jouviet, 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.

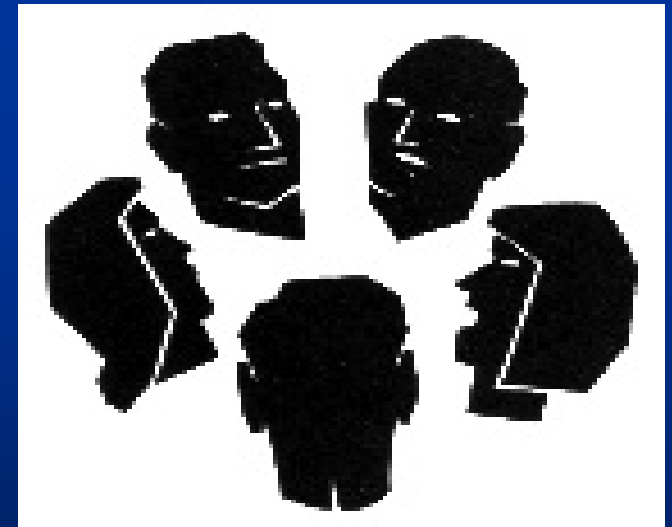
Methods



Delphi's oracle

Consensus method: Delphi process

- Item generation
3 rounds
- Item selection
3 rounds



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

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London
Vancouver
Hamilton

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Hershey (PA)
Austin (TX)
Milwaukee (WI)
Kansas City (MO)
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Lebanon (NH)
Los Angeles (CA)
Lexington (KY)
Miami (FL)
Denver (CO)
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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 Injury¹
 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:
 - $\text{PaO}_2(\text{mmHg})/\text{FiO}_2 \text{ ratio} \leq 300$ or $\text{PaO}_2(\text{kPa})/\text{FiO}_2 \leq 40$
 - If no arterial canula or no arterial blood gas:
 $\text{SpO}_2/\text{FiO}_2 \leq 320$ with $\text{SpO}_2 < 0.98$ ²

¹ Report of the American-European Consensus conference on ARDS: definitions, mechanisms, relevant outcomes, and clinical trial coordination. Consensus Committee. J Crit Care (1994); 9: 72.

² Rice T et al, American Thoracic Society 2006;3:A570.

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

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PALIVE ¹

Pediatric Acute Lung Injury
Mechanical Ventilation Strategies

User name

Password

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& Sepsis Investigators*



Executive Committee : Philippe Jouvét, Adrienne Randolph, Peter Rimensberger, Miriam Santschi, Robert C. Tasker

Screening log



Center : **CA-02** [Change]
Day : **Day #1 (09/04/2007)** [Change]
Subject : -

Logged in as : **msantschi**
23/05/2007 11:22:05 AM
[Log out]

Screening log

[Home]

At 9am on the day of the study

- | | | | |
|---|---|---------------------------------|--------------|
| 1 | Total number of patients in unit | <input type="text" value="8"/> | patients * |
| | Number of pediatric beds in the ICU | <input type="text" value="10"/> | beds ? |
| 2 | Number of patients on non-invasive mechanical ventilation | <input type="text" value="4"/> | patients * ? |
| 3 | Number of patients on invasive mechanical ventilation | <input type="text" value="2"/> | patients * ? |
| 4 | Number of patients fulfilling inclusion criteria | <input type="text" value="4"/> | patients * |
| 5 | Number of patients fulfilling inclusion criteria with at least one exclusion criteria | <input type="text" value="0"/> | patients * |

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.

- | | | | |
|---|---|--------------------------------|------------|
| 6 | Number of patients included in study (Fulfilling all inclusion criteria and no exclusion criteria) | <input type="text" value="4"/> | patients * |
| 7 | Number of patients with a vasopressure infusion (e.g. dopamine = or > 5 µg/kg/min, dobutamine, epinephrine, milrinone, vasopressine) without invasive or non invasive ventilation. | <input type="text"/> | patients ? |

[Cancel]

Save

Subject's menu



Center : **CA-02** [Change]
Day : **Day #1 (09/04/2007)** [Change]
Subject : **101** [Change]

Logged in as : **msantschi**
23/05/2007 11:28:26 AM
[Log out]

Subject's menu

[Home]

- 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**

? Legend

- Form valid and complete
- Form with warnings
- Form with missing data
- Form automatically skipped

■ Missing data

Symbol « . » indicates a missing data

Current form

Mechanical ventilation



Center : CA-02 [Change]

Day : Day #1 (09/04/2007) [Change]

Subject : 101 [Change]

Logged in as : msantschi

23/05/2007 1:42:16 PM

[Log out]

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

[Subject's menu]

6.1 Type of non-invasive mechanical ventilation

6.2 Ventilation mode

 * ?

6.3 Ventilator parameters

6.3.1	Fraction of inspired oxygen (FiO ₂)	<input type="text"/>	* (from 0.21 to 1.00) ?
6.3.2	Mandatory respiratory rate	<input type="text"/>	/ min
6.3.3	Total respiratory rate (spontaneous + mandatory)	<input type="text"/>	/ min *
6.3.4	Inspiration time	<input type="text"/>	sec ?
6.3.5	Positive end-expiratory pressure (PEEP)	<input type="text"/>	cm H ₂ O *
6.3.6	Peak Inspiratory Pressure (PIP) over PEEP	<input type="text"/>	cm H ₂ O * ?
6.3.7	Tidal volume set on ventilator (inspiratory)	<input type="text"/>	ml
6.3.8	Pressure support (AI) over PEEP	<input type="text"/>	cm H ₂ O ?
6.3.9	Mean airway pressure	<input type="text"/>	cm H ₂ O

[Cancel]

Save

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

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Peter Rimensberger

Robert C Tasker



Dr Éric Rousseau
Dany Janvier
Yvan Fortier



Contact information

<http://palive1.crc.chus.qc.ca>

palive_1@yahoo.com