

**EIT Assessment of Lung Volume and Tidal Distribution:  
A Comparison of Non-Invasive Ventilation Devices**

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# **EIT Assessment of Lung Volume and Tidal Distribution: A Comparison of Non-Invasive Ventilation Devices**

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## **1.0 Background and Significance**

Mechanical ventilation is life-saving technology but it can also inadvertently induce lung injury and increase morbidity and mortality. There currently is not an easy method of assessing the impact ventilator settings have on the degree of lung inflation. Computed tomography (CT), the gold standard for visually monitoring lung function, can provide detailed regional information of the lung (Figure 1). Unfortunately, it necessitates moving critically ill patients to a special diagnostic room and involves exposure to radiation.

A technique introduced in the 1980's, electrical impedance tomography (EIT) can non-invasively provide similar monitoring of lung function. However, while CT provides information on the air content, EIT monitors ventilation-related changes of lung volume and changes of EELV. Over the past several decades EIT has moved from the research lab to commercially available devices that are used at the bedside. One such system manufactured by Draeger Medical (Lubeck, Germany) is available in Europe and Canada but is not yet FDA approved for use in the United States.<sup>1</sup> Draeger Medical has agreed to provide this system to the Adult Respiratory Care Department at the University of Michigan Health System for use in research. Our plan is to develop a series of research

protocols that build upon each other to provide us experience with the technology and insight on our practice of providing mechanical ventilation.

The EIT system consists of a 1.6-inch wide belt containing 16 electrodes, which is wrapped around the chest (Figure 2), generally at the level of the 4<sup>th</sup> - 6<sup>th</sup> rib. As an electrode pair emits a low alternating current (approximately 8 - 9 mA, depending on the frequency which can be set at 80 - 130 Hz), the resultant surface potential is measured by the remaining electrode pairs, and the impedance is determined. The adjacent electrode pair then emits a signal and the remaining pairs measure the potential. This sequence continues as the triggering of electrical emissions moves around the chest, via the belt, in a very rapid manner. One complete rotation creates voltage profiles at 16 positions of current emission, each consisting of 13 voltage measurements. The resultant 208 measurement values are reconstructed to provide one cross-sectional EIT image (Figure 3).

An exciting application for EIT is to monitor the regional and global distribution of tidal ventilation during positive pressure ventilation. Clinical studies have shown the value of EIT to quantify the effects of suctioning and ventilator disconnection<sup>2,3</sup>, during placement of double-lumen endotracheal tubes<sup>4</sup>, and to detect an incidental pneumothorax<sup>5</sup> or pulmonary edema<sup>6</sup>. Most importantly is the ability of EIT to assess lung recruitment and derecruitment<sup>7,8,9</sup> as well as to assess for alveolar overdistension<sup>9, 10</sup> in an attempt to provide a lung protective ventilation strategy.

EIT has also been applied to study the effects of various devices used to provide noninvasive ventilation. Noninvasive ventilation (NIV) is a form of mechanical ventilation which does not involve placement of and attachment to an artificial airway. Rather the ventilator is attached to the subject via a face mask or other noninvasive interface. Pelosi evaluated three devices used to provide a form of NIV, continuous positive airway pressure (CPAP), that create airway pressure using different methods (high flow CPAP, low-flow CPAP and an ICU ventilator) and detected differences in breathing pattern, end-expiratory lung volume (EELV) and airway pressures between the devices.<sup>11</sup> Andersson evaluated three CPAP systems using EIT in 14 healthy volunteers. They found different airway pressure profiles resulting in varying levels of EELV and noted that EELV increased more in ventral lung regions with increasing CPAP levels, independent of the system used, and a redistribution of tidal ventilation toward dorsal lung regions.<sup>12</sup> EIT may prove useful to optimally adjust NPPV settings to improve ventilation and oxygenation.

Our plan is to perform a study similar to that described by Andersson<sup>12</sup> as an initial project on the use of EIT.

## **2.0 Hypothesis**

We hypothesize that the distribution of ventilation and EELV in healthy adult subjects will not be different when NPPV is applied via different devices set to identical pressure settings. Also, when applying increasing NPPV pressures, the distribution of ventilation will shift from the ventral to dorsal regions and be similar between devices.

## **3.0 Subject Selection and Enrollment**

3.1 Subjects: Twenty adult healthy volunteers will be recruited for this study. They will be solicited from within the University of Michigan Health System (e.g. students, staff, and employees). No financial incentive will be provided.

3.2 Inclusion Criteria:

3.2.1 Age 18 years or older

3.3 Exclusion Criteria:

3.3.1 Use of a cardiac pacemaker, an implantable cardioverter-defibrillator (ICD) or any other active implants [electrical current may interfere with EIT signal]

## **4.0 Study Procedures**

4.1 Written informed consent will be obtained on all subjects prior to enrollment in the study and before any research procedures are performed. Subjects can withdraw from the study at any time.

4.2 Subjects will undergo testing by applying NPPV via 2 different BiPAP devices that are currently used in standard of care for patients at the University of Michigan Health System. The decision of which device to begin with will be determined by random allocation of a coin toss.

4.3 BiPAP Systems:

4.3.1 The Resironics V-60 (Phillips, Carlsbad CA) device is continuous high flow, blower type of generator.

4.3.2 The Drager V-500 (Drager Medical, Lubeck, Germany) is our primary critical care ventilator that has a specific NPPV mode.

- 4.4 EIT System: The Drager PulmoVista 500 EIT system (Drager Medical, Lubeck, Germany) consists of an electrode belt connected to the EIT monitor. Before using the system it will be reviewed and approved for use by our Biomedical Department.
- 4.5 Subjects will be placed in the supine position. This position will be maintained for the entire procedure. An electrode belt will be placed on the subject at the 5<sup>th</sup> intercostal space and connected to the EIT monitor. Prior to initiating a study session, the EIT system will be calibrated per manufacturer's instruction.
- 4.6 Each study device will be applied in the following manner:
  - 4.6.1 Four steps (series of device setting changes) will be applied, as such:
    - 4.6.1.1 A baseline will be established breathing without the NPPV mask attached
    - 4.6.1.2 Following mask attachment, a pressure support of 0 cm H<sub>2</sub>O and PEEP of 5 cm H<sub>2</sub>O will be applied, then
    - 4.6.1.3 A pressure support of 5 cm H<sub>2</sub>O and PEEP of 5 cm H<sub>2</sub>O, then
    - 4.6.1.4 A pressure support of 5 cm H<sub>2</sub>O and PEEP of 10 cm H<sub>2</sub>O.
  - 4.6.2 Each step will consist of a 5-minute stabilization period, and then readings will be taken over the next two minutes before proceeding to the next step.
  - 4.6.3 Following all four steps with the initial device, the second device will be applied and steps 1-4 repeated.
- 4.7 Primary Outcomes: Global Tidal Variation (see figures 4-6)
- 4.8 Secondary Outcomes:
  - 4.8.1 Regional Tidal Variations
  - 4.8.2 Global and Regional changes in End-Expiratory Lung Impedance (EELI)
- 4.9 Exploratory Outcomes:
  - 4.9.1 A pneumotachometer (NM3 monitor, Phillips Healthcare, Andover MA), will be placed between the mask and inspiratory hose and the following measurements obtained: respiratory rate, tidal volume, peak inspiratory

pressure, PEEP. A pulse oximeter (RAD8, Masimo, Irvine CA) will provide SpO<sub>2</sub> and heart rate.

- 4.9.2 Change in regional and global distribution in subjects with a BMI less than or greater than 25 kg/m<sup>2</sup>
- 4.9.3 Change in global and regional distribution for subjects at 0 degrees, 45 degrees, and 90 degrees' body positions.

4.10 In addition to device testing, baseline demographics such as age and gender will be recorded for each subject.

## 5.0 Statistical Analysis

A two-way ANOVA will be the first step of analysis to determine the influence of the BiPAP systems on the NPPV. Regional distribution of tidal volume will be analyzed using four ventral to dorsal regions of interest (ROI) by EIT. The relative distribution of tidal volume between regions will be displayed as a percentage. Regional change in end-expiratory lung impedance (EELI) will be similarly expressed as a percent for each ROI. These parameters will be treated as functions of each individual step outlined in 4.6, with particular attention paid to the pressure support and PEEP. Values will be presented as mean  $\pm$  standard deviation and initial comparisons will be made using paired *t*-tests against baseline. Given the factorial design of experiment, if further analysis becomes warranted, a multivariate ANOVA will be utilized to determine the time, pressure, and total tidal volume relationship to relative distribution of tidal volume within the regions of interest. Potential confounding parameters such as patient size, weight, and health status will be screened in a similar manner.

## 6.0 Risks

The total procedure should be completed within 90-120 minutes. There is minimal risk or discomfort to the subject. The electrode belt will not be applied long enough for any chafing or skin breakdown to occur. Although hyperventilation (i.e. lightheadedness, tingling in the hands) may occur as airway pressure is applied, the subject will be monitored continuously and the pressures used are relatively low compared to those used clinically or at home for sleep apnea.

## 7.0 Benefits

There will be no direct benefit to the study subjects. This research will 1) provide an opportunity to learn the EIT system in a nonclinical application on healthy volunteers

before using it in a clinical protocol, and 2) allow comparison of NPPV systems that are routinely used clinically to hopefully show equivalence in important measures.

## **8.0 Safety Monitoring/Reporting**

8.1 Due to the minimal risk of this study, only related adverse events will be reported.

- 8.1.1 Serious, related adverse events will be reported to the IRB within 7 calendar days
- 8.1.2 Non-serious, related adverse events grade 3 or higher will be reported to the IRB prior to SCR
- 8.1.3 Any serious, unanticipated problems that are related to the study and indicate risks to subjects will be reported to the IRB within 7 calendar days. Non-serious problems will be reported within 14 days.
- 8.1.4 Privacy violation or breach of confidentiality will be reported to the IRB within 7 calendar days, and to the UMHS Privacy Office within 24 hours.

## **9.0 References:**

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12. Andersson B, et al. End-expiratory lung volume and ventilation distribution with different continuous positive airway pressure systems in volunteers. *Acta Anesthesiol Scand* 2010; 55:157-164

Acknowledgement: all figures are taken from the Drager monograph by Teschner

Figure 1. CT image showing four distinct lung regions (manually colorized to highlight the distinction)

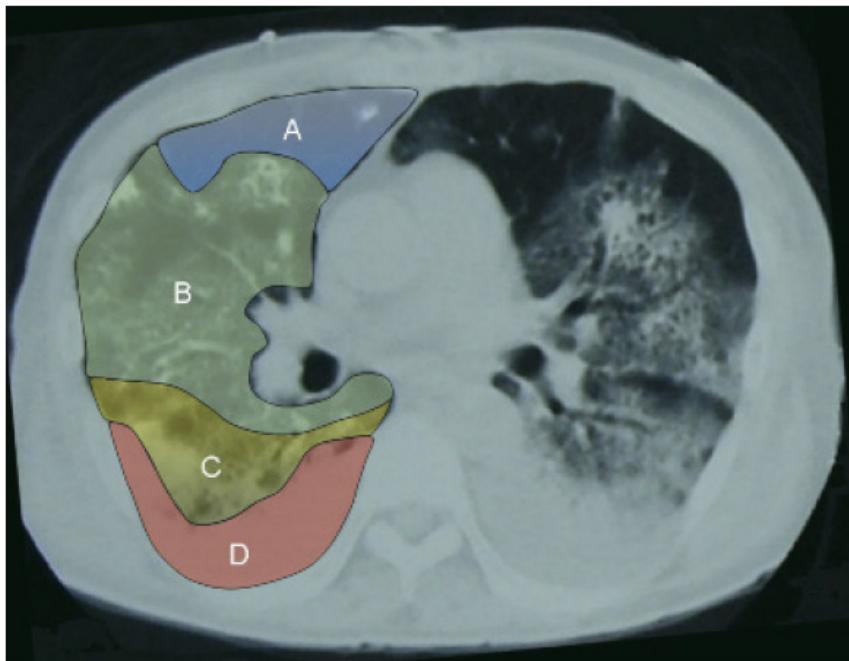


Fig. 1: CT image showing hyperinflated (A), normally aerated (B), poorly aerated (C) and non-ventilated (D) lung regions.

Figure 2. Electrode belt containing 16 electrodes wrapped around a patient's chest



Figure 3. Example of an EIT image

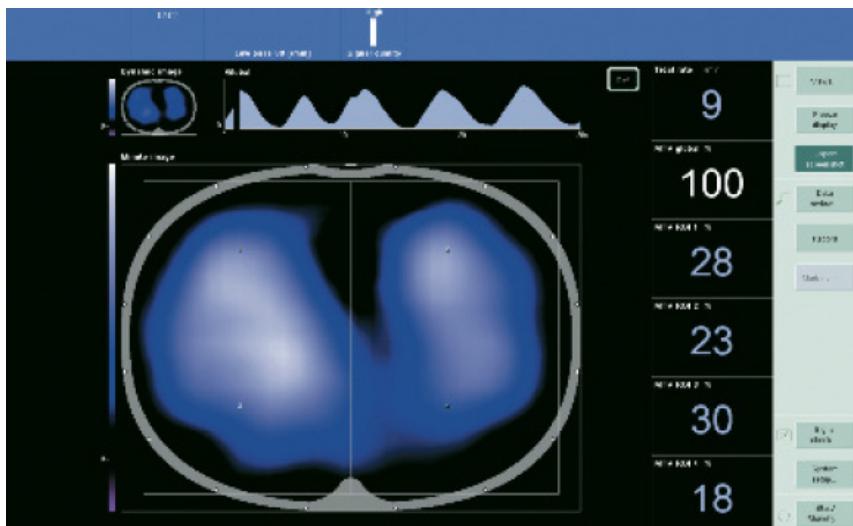


Figure 4. Main Screen

This screen depicts: 1) on the left: Dynamic Image (showing impedance changes over time) and Status Image (image used to derive waveforms and percentages) of the lungs, 2) in the center: a global impedance wave form at the top and 4 regional impedance waveforms (one for each ROI) and 3) on the right: the Tidal Rate, the global Tidal Variation (100%) and the regional Tidal variation percentages for each ROI

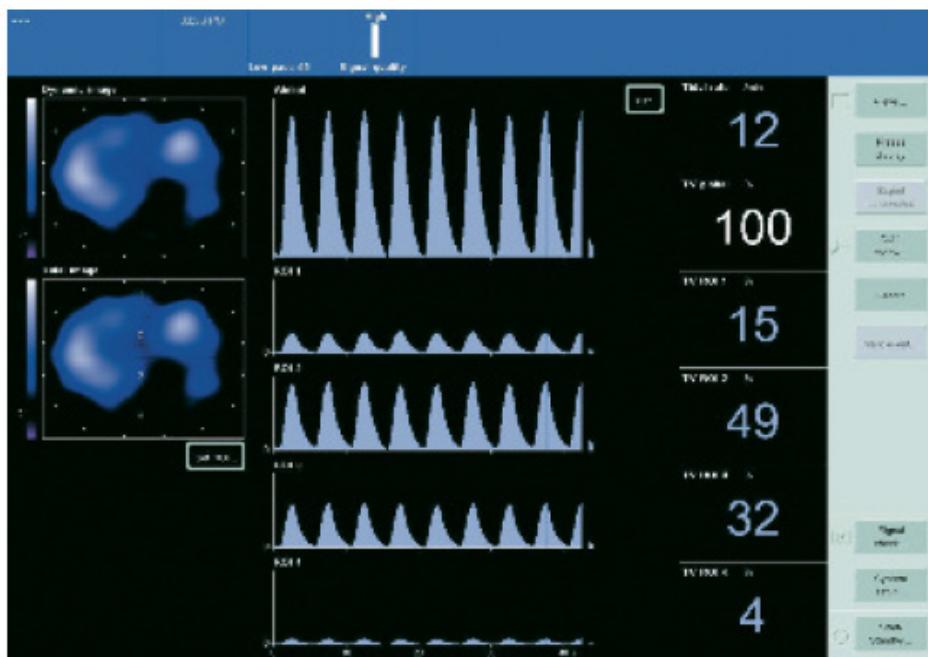


Figure 5. Trend View

Two status images are displayed (baseline and following an intervention) to graphically represent regional ventilation distribution over a time period of up to 120 minutes.

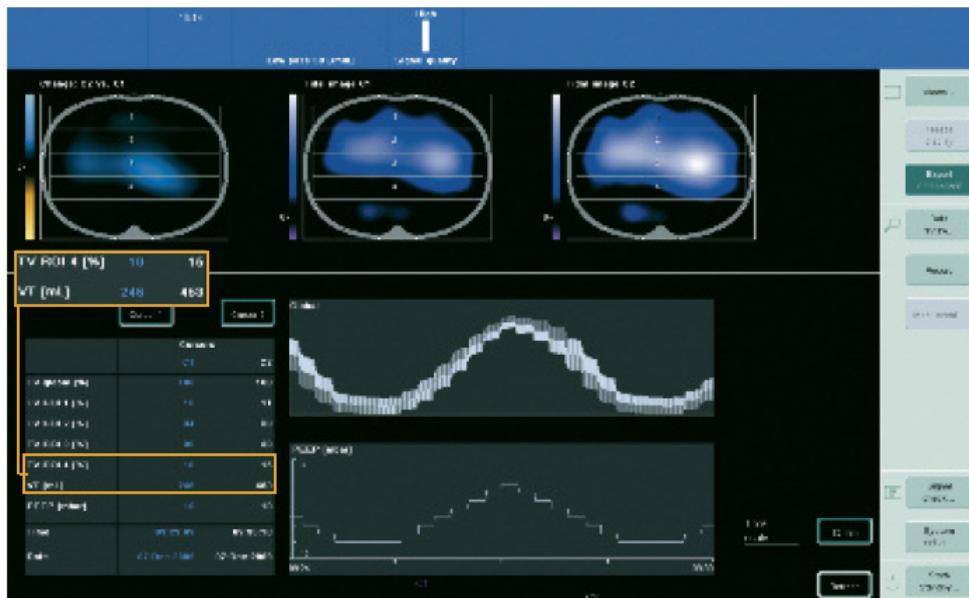


Figure 6. Delta EELV Trend View

Figure shows waveforms of the global (top center) and four regional changes in end-expiratory lung impedance. Corresponding numeric values are shown on the right.

