

Clinical Utilisation of Respiratory Elastance (CURE) - Pilot Trials for the Optimisation of Mechanical Ventilation Settings for the Critically Ill

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Te Poari Hauora o Waitaha



Introduction – Mechanical Ventilation

- Mechanical Ventilation Therapy involves the use of an external device to support/ supplement patient breathing effort
- 60% of ICU patients are on Mechanical Ventilation
- Lung injury results in sticky and inflamed lungs units that collapse and are not available for gas exchange



Introduction – PEEP

- 'Positive End Expiratory Pressure', a ventilator setting
- Positive Pressure maintained at the end of breath to prevent alveolar collapse
- Setting PEEP too low results in insufficient support and low oxygenation
- Setting PEEP too high can result in Ventilator Induced Lung Injury (VILI)



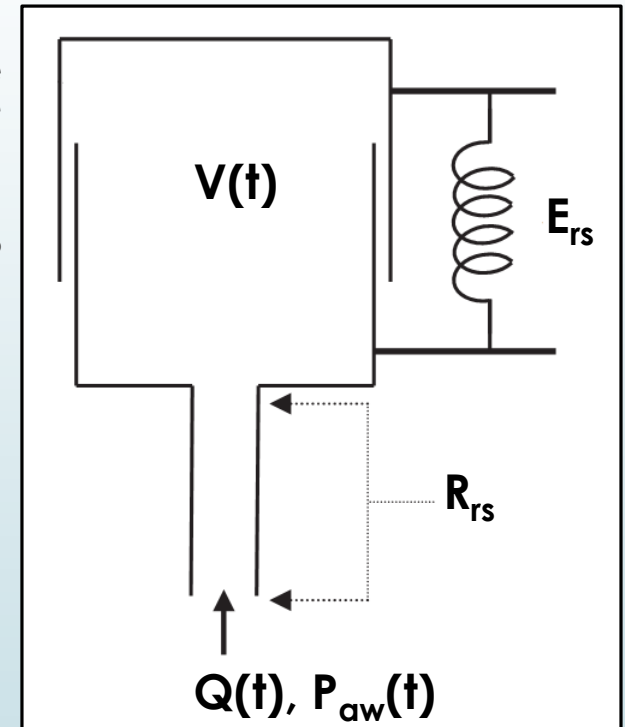


Introduction – CURE

- Patients are highly variable, and there is no practical way to directly observe the internal response of an ICU patient's lung
- Sub-optimal ventilator settings can delay recovery or even cause further injury to the patient
- Clinical Utilisation of Respiratory Elastance (CURE) is an ongoing clinical trial of software designed to determine an optimal, patient specific PEEP, in real time, at the patient bedside

Methods – CURE Soft

- CURE Soft uses pressure and flow data from the ventilator to determine respiratory elastance, a metric of the 'stiffness' of the lung
- Elastance changes with both PEEP and patient condition
- Lower elastance indicates more lung expansion for less stress generated in lung tissue, thus more oxygenation for a lowered risk of tissue damage
- A lowered respiratory elastance is thus considered to be an improvement in patient condition



Methods – Inclusion and Exclusion Criteria

Patients on MV due to respiratory failure who would not be negatively affected by the PEEP changes or use of sedatives over the course of the trial are eligible.

Inclusion

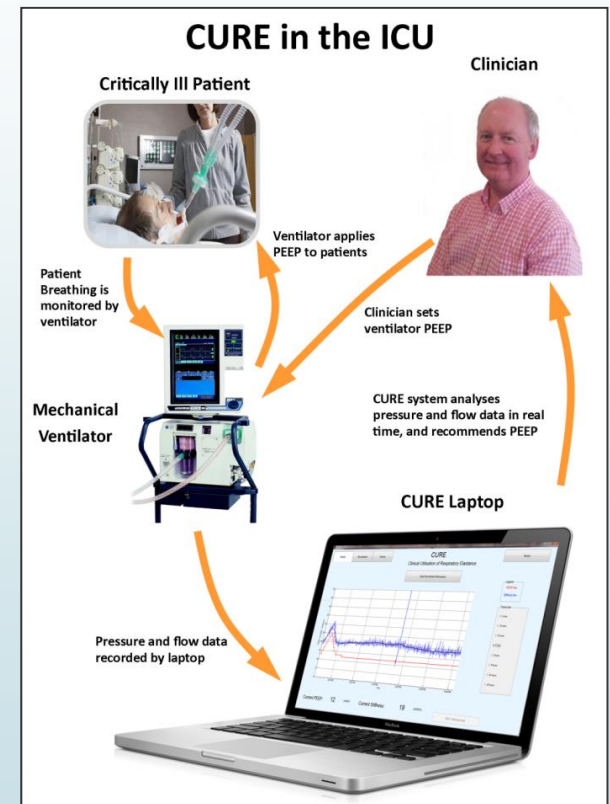
- 1) Patient on Mechanical Ventilation
- 2) Patient diagnosed with all degrees of ARDS (Partial Pressure of arterial blood gas oxygen per Fraction of Inspired Oxygen (P/F Ratio) < 300 mmHg) as per the Berlin Definition, by intensive care clinicians
- 3) Arterial line in situ.

Exclusion

- 1) Patients who are likely to be discontinued from MV within 24 hours
- 2) Patients aged < 16
- 3) Patients who are moribund and/or not expected to survive for more than 72 hours
- 4) Patients whose care could be compromised if given increased sedation and/or muscle relaxants for the purpose of assessing lung recruitment and
- 5) Lack of clinical equipoise by ICU medical staff managing the patient.

Methods – CURE Clinical Protocol

- The CURE protocol involves several recruitment maneuvers
- A recruitment maneuver is a series of short term, step-wise incremental PEEP changes which serves to re-inflate collapsed lung areas
- CURE uses these recruitment maneuvers to assess patient specific elastance at each PEEP, and recommend an optimal PEEP to the clinician
- The clinician then decides based on their experience whether to implement this recommended PEEP

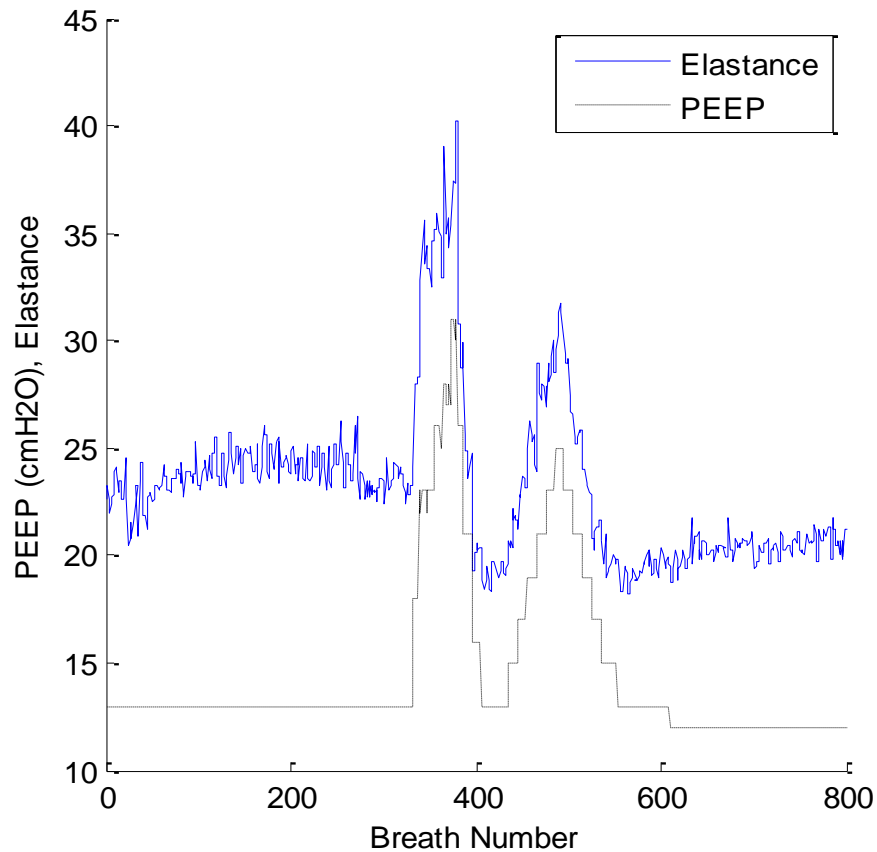


Results - Overview

- The CURE trial is still on-going, thus analysis of existing results is largely qualitative
- Two patients constituting an overall 66 hours of data and 14 recruitment maneuvers had been included in this trial at the time of publication

	Data Recorded (Hours)	Breaths Recorded (#)	RMs	PEEP Changes
Patient 1	23.1	25,412	9	3
Patient 2	42.9	48,015	5	7
Total	66.0	73,427	14	10

Results – Patient 1

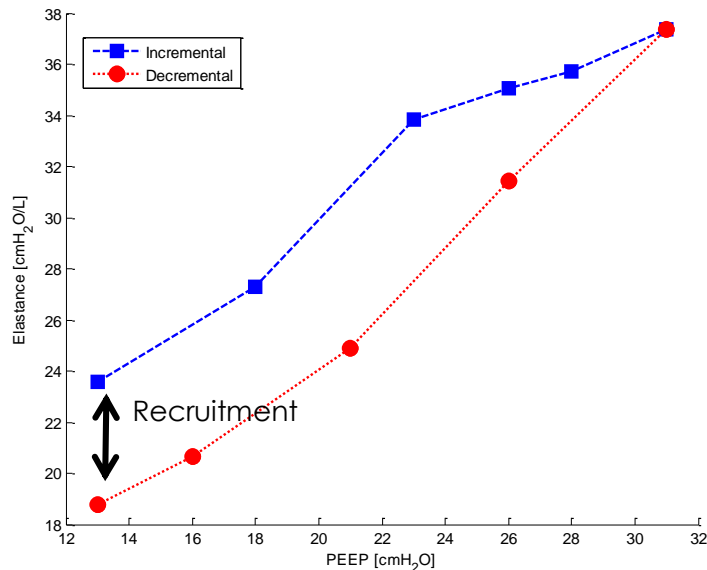


- This figure shows a section of patient one's respiratory elastance and PEEP with respect to time as determined by CURE Soft
- There are a pair of recruitment maneuvers
- The first results in a decrease in elastance, while the second does not

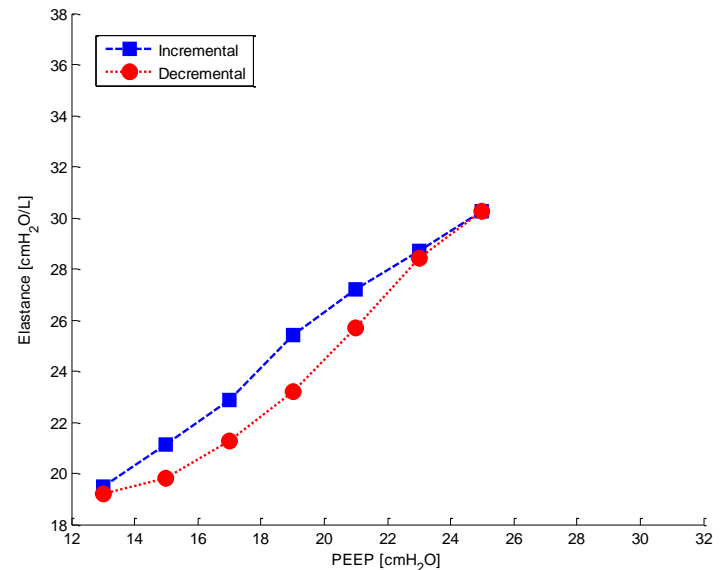
Results – Patient 1

- CURE Soft displays recruitment manoeuvres to display tracking average elastance for each PEEP level.

First recruitment maneuver.
Elastance is lower on decremental side of recruitment manoeuvre.
Recruitment has occurred

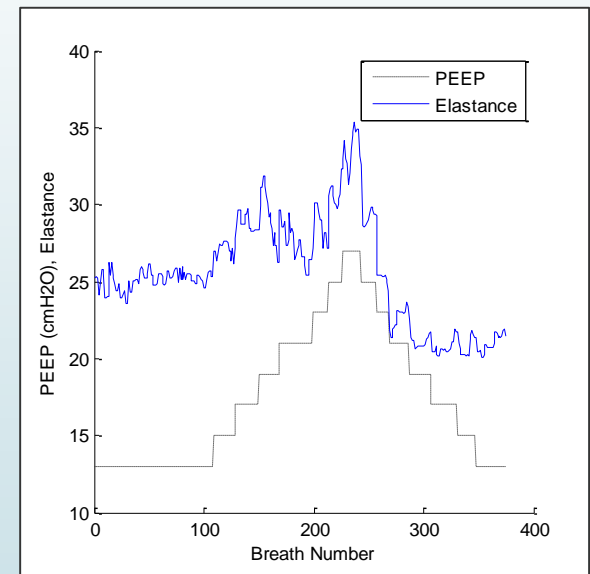


Second recruitment maneuver.
Similar elastance on both sides of the recruitment manoeuvre.
Little recruitment has occurred



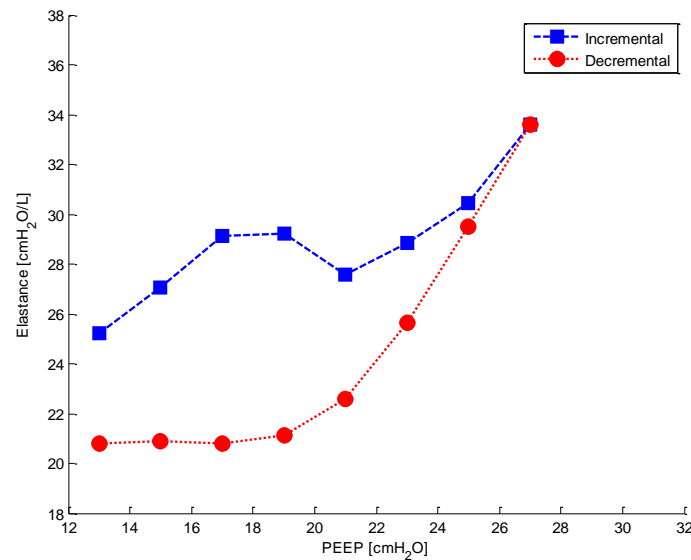
Results – Patient 2

- This figure shows a section of patient two's respiratory elastance and PEEP with respect to time as determined by CURE Soft
- There is a single recruitment maneuver
- This maneuver leads to a decrease in elastance



Results – Patient 2

- There is a sudden decrease in elastance as PEEP rises from 19 cmH₂O to 21 cmH₂O
- Suggests sudden recruitment of a large collapsed section of lung
- This matches clinical behaviour described in literature, but previously only detected using radiographic imaging methods



Results – Recruitment Maneuvers

- Below is a summary of the PEEP and elastance changes accompanying each recruitment maneuver as captured by CURE
- A successful recruitment maneuver has here been defined as a decrease in elastance of >10%
- Shows CURE has the potential to capture when lung recruitment occurs

Patient 1	RM1-2		RM3		RM4		RM5		RM6		RM7		RM8		RM9	
	B*	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A
Elastanc e	24.2	19.7	17.2	16.2	21.2	22.6	17.9	18.6	19.7	20.7	19.2	21.0	18.8	20. 3	22.5	21.0
PEEP	13 +18	12	12 +6	11	11+6	11	11 +6	11	11 +6	10	10 +6	10	10 +6	10	10 +6	10
Successf ul	Yes		No		No		No		No		No		No		No	
Patient 2	RM1		RM2		RM3		RM4		RM5		Note* RM - Recruitment manoeuvre B - Before the recruitment manoeuvre (+maximum increase in PEEP during RM) A - After the recruitment manoeuvre					
	B	A	B	A	B	A	B	A	B	A						
Elastanc e	24.4	21.8	22.7	23.5	21.7	23.3	25.7	21.3	23.6	22.2						
PEEP	13 +14	13	13+6	15	15+6	13	13+1 4	19	19+6	19						
Successf ul	Yes		No		No		Yes		No							



Why is this relevant?

- ▶ Allowing the evaluation of the success of recruitment manoeuvres provides important information to clinicians about the state of the patients lungs
- ▶ CURE Soft allows instant noninvasive feedback on the success of recruitment manoeuvres and the recruitment status of the lung at different PEEP



Conclusion

- CURE is a system designed to suggest optimal PEEP to clinicians based on real time assessment of patient specific elastance
- Initial results suggest the system is able to capture previously unavailable information about patient specific response to Mechanical Ventilation in real time
- This information has the potential to improve the reliability and ease with which clinicians make decisions about Mechanical Ventilation settings in the ICU



Future Work

- ▶ This paper presents the results from the first two patients in the pilot trial
- ▶ More patients have been included in the pilot trial over the last year to refine the clinical protocol that will be used in the randomized controlled trial
- ▶ The randomized controlled trial will be used to test the clinical impact of model based ventilation
- ▶ Since the start of the pilot trials the software has been further developed and the clinical protocol has been refined.
- ▶ The randomized control trial is expected to start within the next few months



Thanks

- Supervisors – Prof Geoff Chase
Dr Yeong Chiew
Dr Geoff Shaw
 - MV02 team – Shaun Davidson, Hamish Laing,
Richard White, Faizi Radzi
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Acknowledgement

This work was supported by EU FP7 IRSES (FP7-PEOPLE-2012-IRSES) program, project title: eTime - Engineering Technology-based Innovation in Medicine, Grant No. 318943.

