Will Computerized Mechanical Ventilation Be Superior to a Respiratory Therapist?

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Disclaimer

• All views expressed are my own opinion and not necessarily those of the Cleveland Clinic.
Disclosure

• I have affiliations with, special interests, or have conducted business with the following companies that in context with this presentation might possibly constitute a real or perceived conflict of interest:
  – Breathe Technologies
  – CareFusion
  – Covidien
  – Dräger
  – Hamilton
  – IngMar
  – Philips
Self-Driving Cars!

Self-driving Subarus on course to hit road in 2020
What is an Expert System?

- A computer program that attempts to copy human experts’ ability to give advice, to teach, and to execute intelligent tasks.
  - Hardware
  - Domain expert (human source of knowledge)
  - Knowledge base
  - Inference engine
  - Knowledge engineer (represents knowledge)
  - User interface
  - User
Expert Systems in Medicine

- **INTERNIST**
  - complex diagnosis problems general internal med
- **MYCIN**
  - diagnosis/treatment blood infections
- **ABEL**
  - acid-base and electrolyte management
- **DXPLain**
  - diagnose 2,200 diseases and 5,000 symptoms
- **Diagnosis Pro**
  - diagnosis for 11,000 diseases and 30,000 findings
Watson supercomputer goes to medical school

What can physicians teach Watson and vice versa?

- IBM's Watson supercomputer at Cleveland Clinic where it will learn to think like a physician
  - Think analytically
  - Refine its ability to create hypotheses
  - Rank its hypotheses
  - Suggest strategies for addressing the case studies
Watson supercomputer graduates medical school

IBM is offering two decision support apps based on the Jeopardy! winner

• Fed 600,000 pieces of medical evidence and two million pages of text from 42 medical journals
• Can sift through 1.5 million patient records and histories in a matter of seconds
• Can provide treatment recommendations based on prior outcomes and medical histories
• Will evaluate which treatment is most likely to succeed
• Which treatment should be authorized for payment
Current Paradigm (Human Control)
Open Loop Control (Decision Support)

Trust Me, I’m a Doctor

Information

Recommendations

Respir Care 2011;56(1):85-102
Intelligent decision support systems for mechanical ventilation

Fleur T. Tehrani\textsuperscript{a,}\textsuperscript{*}, James H. Roum\textsuperscript{b}


• 21 Decision support systems reviewed (1985-2007)
• Open loop – 16 systems
• Closed loop – 5 systems
• Technology
  – Mathematical models of physiology (simulate body)
  – Rule-based (simulate human expert decisions)
  – Fuzzy logic (simulate human brain)
What is the Evidence for Decision Support of Mechanical Ventilation?
Validation of the Better Care® system to detect ineffective efforts during expiration in mechanically ventilated patients: a pilot study


• Automated system to detect ineffective trigger efforts

• System classified events in close agreement with human experts and Edi signal
  – 92% sensitivity
  – 92% specificity
  – Kappa index 80% (high agreement with human)
Fuzzy logic advisory system for Pressure Support
- Load (power of breath) and tolerance (f and VT)
- Recommends ↑, ↓ or no change in support level

Data from 87 adults
- Compare Advisory System to physicians

No difference in recommendations
- Physicians agreed 91% of the time
Oxygenation advisor recommends appropriate positive end expiratory pressure and FIO₂ settings: retrospective validation study


• **Rule-based** expert system for respiratory failure
  – PEEP (↑, ↓ or no change )
  – FiO₂ (↑, ↓ or no change )
  – Target SpO₂ 88% to 95%
  – Target mean arterial blood pressure ≥ 65 mmHg
  – Pplt ≤ 30 cm H₂O

• **Data from 117 adults**
  – Compare Advisory System to physicians

• **No difference in recommendations**
  – Physicians agreed 92% of the time
A decision support system for suggesting ventilator settings: Retrospective evaluation in cardiac surgery patients ventilated in the ICU

- Decision support based on physiology models
  - tidal volume
  - frequency
  - FiO₂

- Data from 20 cardiac surgery patients
  - Compare Advisory System to physicians

- No difference in recommendations
  - Gas exchange results consistent with expected values
  - No difference in values predicted by model vs real
  - Advice consistent with physician decisions
    - $PIP < 23, f < 18$
Efficacy of Computerized Decision Support for Mechanical Ventilation: Results of a Prospective Multi-Center Randomized Trial


- 200 adult ARDS patients in 10 medical centers
- Randomized to computerized protocol or standard practice
- No difference
  - Survival
  - ICU length of stay
- Significantly reduced for computer protocol
  - multi-organ dysfunction score score
  - barotrauma score
- Decision support can be disseminated among sites
  - Can support standards of care and study protocols
Closed Loop Control

Supervision

Direct Control

Information

Respir Care 2011;56(1):85-102
• Demonstrated the feasibility of **closed-loop controlled propofol anesthesia** in children (cardiac surgery)

• Closed-loop system needs further and larger evaluation to establish its safety and efficacy
A Servomechanism for Automatic Regulation of Pulmonary Ventilation

Saxton, Myers. J Appl Physio 1957;11(2):326-328

• Closed loop ventilation for Iron Lung
  — Controlled iron lung to target end tidal CO₂

• No data on specific patient results
Arguments for Automation of Mechanical Ventilation

• Medical Errors
  – Up to 98,000 patients die annually due to errors
  – Equivalent to 1 plane crash per day
  – 5th most common cause of death
    ▫ More than auto accidents, breast cancer, or AIDS
Arguments for Automation of Mechanical Ventilation

• Resource Limitations
  – Nursing shortage estimated to be 800,000 in 2020
  – Duration of ventilation increases as patient-to-nurse ratio increases
  – Humans have limited capability to manage data overload
  – Protocols improve outcomes
    □ *Humans have limited ability to adhere to protocols*
Automated Closed Loop Control of Inspired Oxygen Concentration

Claure, Bancalari. Respir Care 2013;58(1):151-159

- Multiple studies (10 infants, 4 adults) compared closed loop FiO$_2$ systems to manual adjustments

- Automated systems consistently more effective
  - Reduced time spent in hyperoxia or hypoxia
  - Potential for substantial reduction of caregiver workload
  - Maximizes O$_2$ resources, reduces mission weight in combat zones (military applications)

- One commercial system (CLiO$_2$ – CareFusion)
  - Infants
  - Not yet available in USA
What’s In Our Toolbox?
Evolution of Modes of Ventilation

Advances in capabilities of modes are created by more complex targeting (feedback control) schemes

1. Set-Point
2. Dual
3. Servo
4. Bio-Variable
5. Adaptive
6. Optimal
7. Intelligent

Manual

Automatic

*Respir Care 2011;56(1):85-102*
Bio-Variable Targeting

• Operator set target
  – Mean Pressure Support
  – Pressure Variability (0% to 100% of mean PS)
  – Ventilator adjusted target
    □ Pressure = PS × randbetween(1, 1+PressVar)
Adaptive Targeting

• Operator sets certain targets
  – Example: tidal volume

• Ventilator automatically adjusts other targets
  – Example: pressure
Adaptive Pressure Targeting

• Pressure Regulated Volume Control
  – Operator set target
    - *Tidal volume*
  – Ventilator adjusted target
    - *Pressure* = \((V_{\text{target}} - V_{\text{mus}})/[C(1-e^{-t/RC})]\)
Adaptive Frequency Targeting

- Mandatory Minute Ventilation
  - Operator set target
    - *Minute ventilation*
  - Ventilator adjusted target:
    - *Mandatory breath frequency*

*Anesthesia 1977;32(2):163-169*
Optimum Targeting

- Automatic adjustment of targets to minimize or maximize some performance function
Optimal Targeting Example

• Adaptive Support Ventilation
  – Operator set parameter
    □ Patient weight
  – Ventilator adjusted targets:
    □ Inspiratory pressure
    □ Inspiratory time
    □ Frequency

J Clin Monit Comput 2008;22(6):409
Intelligent Targeting

- Automatic adjustment of targets using artificial intelligence tools
  - Mathematical models of physiologic systems
  - Rule based expert systems
  - Fuzzy logic
  - Artificial neural networks
Intelligent Targeting Example

- SmartCare
  - Operator set targets
    - *Patient weight/diagnosis*
    - *Airway size/type*
  - Ventilator adjusted targets
    - *Pressure Support*

*Int J Clin Monit Comput 1992;9(4):239*
Intelligent Targeting Example

- IntelliVent-ASV (not in USA)
  - Operator set targets
    - Patient height/sex
  - Ventilator adjusted targets
    - Minute ventilation
    - Tidal volume
    - Frequency
    - $FiO_2$
    - PEEP
  - Automatic weaning, SBT
What is the Evidence for Automated Control of Mechanical Ventilation?
Targeting Scheme: Bio-Variable
Bio-Variable Targeting in Animals

• Comparison with different modes (2002 – 2011)
  – Pressure Support
  – Pressure Support with Sighs
  – BiPAP/APRV
  – Volume Control (6 mL/kg)

• Bio-Variable Targeting:
  – Increased tidal volume variability
  – Improved oxygenation with reduced $V_D/V_T$ and PaCO$_2$
  – Reduced peak and mean airway pressure
  – Lower expression of inflammatory cytokines Improved lung recruitment and compliance
  – Enhanced clearance and/or redistribution of edema fluid
• 41 surgical patients (abdomin aortic aneurysmectomy)

• Comparison of modes
  — Volume control (10 mL/kg)
  — Bio-Variable (376 combinations \( V_T \) and frequency)

• Bio-Variable:
  — Higher \( PaO_2 \)
  — Lower \( V_D/V_T \) and \( PaCO_2 \)
  — Higher compliance
  — Lower peak airway pressure
Variable versus conventional lung protective mechanical ventilation during open abdominal surgery: study protocol for a randomized controlled trial

**Pro**tective **Var**iable Ventilation (PROVAR)

- first RCT aiming at intra- and postoperative effects of BV

**Single center enrolling 50 patients (abdominal surgery)**

**Comparison of modes**
- Volume control (8 mL/kg)
- Bio-Variable (same mean $V_T$ but 30% variability)

**Outcome variables**
- Forced vital capacity on first post-operative day
- Plasma cytokines, distribution of ventilation (EIT)
Targeting Scheme: Adaptive
Adaptive Targeting in Adults (PRVC)

• Comparison with different modes (2005 - 2012)
  – VC-CMV or PC-CMV
  – PC-IMV (BiPAP S/T)

• Adaptive Targeting:
  – Improved ventilation for obesity hypoventilation
  – Higher levels of muscle unloading vs noninvasive PS
  – Improved sleep efficiency for COPD
  – Similar duration of ventilation, mortality but fewer alarms
  – Better OI with lower mPaw post-op cardiac surgery
  – Improves oxygenation in ARF various etiologies
Adaptive Targeting in Neonates (PRVC)

- Cochrane Review 2011 (Wheeler, Klingengerg, Morley)
- Adaptive Targeting (Volume Guarantee) vs PC-IMV reduced:
  - Mortality
  - Bronchopulmonary dysplasia
  - Pneumothorax
  - Days of ventilation
  - Hypocarbia
  - Periventricular leukomalacia
  - Intraventricular hemorrhage
Targeting Scheme: Optimal
Optimal Targeting in Adults (ASV)

• Post-op cardiac surgery
  – Shorter duration of ventilation
  – Fewer human interventions and fewer alarms
  – No difference in mortality and duration of ventilation
  – Tidal volume 8-9 mL/kg

• Acute respiratory failure
  – Reduced work of breathing
  – Better patient-ventilator synchrony
  – Shorter intubation time
  – Automatic changes mimic physician decisions

• Weaning
  – Fewer human manipulations and fewer alarms
Targeting Scheme: Intelligent
Weaning children from mechanical ventilation with a computer-driven system (closed-loop protocol): A pilot study*


• Prospective single center pilot study
  – 20 children aged 1-17 years
  – Compared to historical controls managed by physicians

• SmartCare/PS
  – Duration of ventilation 5.1 vs 6.7 days (P = 0.33)
  – Successfully decreased PS in 16 patients
  – Recommended separation from vent 14 patients
    ▪ 2 failed due to agitation and went to Pressure Support
  – No serious adverse events
  – No difference in need for re-intubation or NIV
Evaluation of fully automated ventilation: a randomized controlled study in post-cardiac surgery patients


• Randomized controlled trial
  – 60 adults after cardiac surgery
  – Compared to protocolized ventilation

• SmartCare/PS
  – Time spent in predefined zones
    ▫ Optimal (90% vs 12%)
    ▫ Acceptable (10% vs 81%)
    ▫ Unacceptable (0.5 % vs 7%)
  – Fewer interventions (5 vs 148)
A randomised, controlled trial of conventional versus automated weaning from mechanical ventilation using SmartCare™/PS

Rose et al. Intensive Care Med 2008;34:1788-1795

• Randomized controlled trial
  – 102 adults in ICU
  – Compared to usual care (VC-CMV, VC-IMV, PC-IMV)

• SmartCare/PS
  – Median time to “separation potential” 20 h vs 8 h
  – Median time to successful extubation 43 h vs 40 h
  – Comparable reintubtion, sedation, NMB, NIV

• Conclusion
  – SmartCare comparable to management by experienced critical care specialty nurses using 1:2 nurse-patient ratio
Prospective randomized crossover trial
  - ASV (optimal targeting) vs IntelliVent (intelligent targeting)

IntelliVent-ASV
  - Slight reduction in minute ventilatition and $V_T$
  - Reduced Pplat (24 to 20 cm H$_2$O)
  - Reduced FiO$_2$ (0.40 to 0.30) but same oxygenation
  - Reduced peak inspiratory pressure and PEEP

Prospective observational study
  - 100 consecutive (unselected) patients
  - Ventilated from inclusion to extubation on IntelliVent-ASV

IntelliVent-ASV
  - Never needed to switch to alternative mode
  - Safely used in different lung conditions
    - Normal, COPD, ARDS, Others
  - Study generated benchmark data for lung mechanics
A prospective comparison of the efficacy and safety of fully closed-loop control ventilation (Intellivent-ASV) with conventional ASV and SIMV modes


• Prospective crossover study
  — 20 patients with pneumonia, COPD, ARDS
  — Comparison of modes (2 hours each)
    ▪ ASV, IntelliVent-ASV, VC-IMV (ARDSnet guidelines)

• IntelliVent-ASV
  — Higher PEEP (7.6 vs 5.1 vs 5.2) $P < 0.005$
  — FiO₂ lower (0.35 vs 0.41 vs 0.41) $P < 0.005$
  — Higher spontaneous rate (8.6 vs 2.9 vs 2.4) $P < 0.002$
  — No difference in hemodynamic parameters
Automated versus non-automated weaning for reducing the
duration of mechanical ventilation for critically ill adults and
children (Review)

Rose et al. Cochrane Database Syst Rev 2014 June 10

• Systematic database review (pooled targeting schemes)
  – Adaptive (MMV and AutoMode)
  – Optimal, Intelligent, (ASV, IntelliVent-ASV)
  – Servo (PAV and NAVA)

• Conclusions
  – Automated closed loop systems may result in reduced:
    ▫ Duration of weaning
    ▫ Duration of ventilation and ICU stay
  – No strong evidence for effects on mortality, hospital LOS
Will Computerized Mechanical Ventilation Be Superior to a Respiratory Therapist?
Stupid Tech Predictions

“Radio has no future” Lord Kelvin 1897

“While theoretically...television may be feasible, commercially and financially it is an impossibility” Lee DeForest, inventor of the vacuum tube 1926

“We will never make a 32-bit operating system” Bill Gates 1983

“The Internet will...in 1996 catastrophically collapse” Robert Metcalfe, inventor of Ethernet 1995
Stupid Tech Predictions

“Chess is far too complex to be definitively solved with any technology we can conceive of today.”

Gary Kasparov (World Chess Champion)

“I would have liked …a rematch in 1998 if I were better prepared, (but) it was clear then that computer superiority over humans in chess had always been just a matter of time.”

Gary Kasparov (former World Chess Champion)
My Opinion.....
RESISTANCE IS FUTILE
Computerized Mechanical Ventilation

• Will continue to develop autonomy
• Will gain momentum due to military spending
• Will gain market share as
  — Caregivers become more comfortable with technology
    (remember the resistance to computerized banking?)
  — Caregiver-to-patient ratios drop due to economics
  — Gap between technical complexity and user understanding grows
• Will eventually outperform humans as they have done in other fields
How to Avoid Obsolescence as a Human
Robert’s Rules of Survival

• **Awareness**
  – Follow the research in RC journal
  – Periodically search PubMed (other Internet sources)

• **Attention**
  – Understand current technology even if you can’t use it right now

• **Acceptance**
  – Don’t resist change (it is inevitable)
  – Integrate new technology into current practice
  – Become the resource for managing complex technology (all kinds not just ventilators)