Respiratory Volume Monitoring to Predict & Prevent Respiratory Compromise

A presentation for HealthTrust members
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Today’s Presenters

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Speaker Disclosures

• Hans Tillmann Hein, M.D., is a Shareholder in Respiratory Motion, Inc.

• Donna Lee Armaignac, PhD, APRN, CCNS, CCRN, has no interests to disclose.

• Note: This program may contain the mention of suppliers, brands, products, services or drugs presented in a case study or comparative format using evidence-based research. Such examples are intended for educational and informational purposes and should not be perceived as an endorsement of any particular supplier, brand, product, service or drug.
Learning Objectives:

1. Recall contemporary guidelines driving new practices in respiratory monitoring
2. Discuss pathophysiologic responses that contribute to respiratory decompensation
3. Identify methods and technologies for respiratory assessment
4. Visualize respiratory volume monitoring (RVM) as a new clinical tool for respiratory assessment
5. Outline an implementation plan of respiratory solutions
Objective 1: Recall contemporary guidelines driving new practices in respiratory monitoring

“.....even admitting to the full extent the great value of the hospital improvements in recent years, a vast deal of the suffering, and some at least of the mortality, in these establishments is avoidable.”

~Florence Nightingale 1863
Respiratory Failure is One of the Largest Patient Safety Problems...
Further Exacerbated by the Growing Opioid Crisis

• Patients with respiratory compromise are 29x more likely to die vs. the rest of patients

• 30% of post-op patients have respiratory compromise

• Respiratory complication

• 3rd most rapidly increasing inpatient cost in the US

• 2nd leading avoidable patient safety issue in US

• 350,000 respiratory deaths per year

• ~1 million patients a year with 5 million extra hospital days

• Costs an average of $53,000 per patient

• Inpatient stays associated with respiratory compromise will exceed $37 billion by 2019*

• Over 60% of respiratory arrests are potentially avoidable due to delayed intervention

Continuous electronic monitoring of oxygenation and/or ventilation should be available and considered for all patients.”

“…..causes for adverse events associated with opioid use are: ...inadequate monitoring of patients on opioids.”

“Particular attention should be given to monitoring oxygenation, ventilation, circulation,…”

“OIRD has resulted in patient deaths that might have been prevented with appropriate risk assessment for adverse events as well as frequent monitoring”

“The vast majority of Respiratory Depression events (88%) occurred within 24h of surgery, and 97% were judged as preventable with better monitoring and response... particularly in the first 24 hours postoperatively.”

“Monitor all patients receiving neuraxial opioids for adequacy of ventilation (e.g., respiratory rate, depth of respiration, [assessed without disturbing a sleeping patient]), oxygenation…”

“Promoting safe opioid use by identifying high risk patients... monitoring high risk patients.”
Objective 2: Discuss pathophysiologic responses that contribute to respiratory decompensation

- Identify patients at risk.
- Identify factors leading to respiratory compromise.
Who is at Risk for Respiratory Compromise?
Respiratory Compromise and Respiratory Failure – Not Just Oxygenation...
Patients are at risk for respiratory compromise at any point during their stay.
Objective 3: Identify methods and technologies for respiratory assessment

- What parameters we monitored historically?
- What technology do you use?
- How effective are your tools?
"Closer to ideal would be a respiratory minute volume monitor, which does not yet exist as a bedside monitor."

- Richard Moon, MD, Duke, Initiatives in Safe Patient Care, 2009
• Respiratory Ventilation Monitoring (RVM)
• Monitors Minute Ventilation (MV) for non-intubated patients
• MV - Fundamental unit of breathing

Consensus – Continuous, Reliable Respiratory Monitoring is Necessary

MV = TV X RR
### How Do They Compare?

<table>
<thead>
<tr>
<th>Metric</th>
<th>Assess Ventilation</th>
<th>Quantitative</th>
<th>Continuous</th>
<th>Easy to Use</th>
<th>Early Warning</th>
<th>Low False Alarms</th>
<th>Sensitivity</th>
<th>Reliability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Gas</td>
<td>✓</td>
<td>✓</td>
<td>X</td>
<td>X</td>
<td>✓/ ×</td>
<td>×</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Respiratory Rate</td>
<td>×</td>
<td>✓</td>
<td>X</td>
<td>✓</td>
<td>×</td>
<td>×</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Capnography (extubated)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>X</td>
<td>×</td>
<td>×</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Pulse Oximetry</td>
<td>×</td>
<td>✓</td>
<td>✓</td>
<td>X</td>
<td>× ×</td>
<td>×</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Clinical Assessment</td>
<td>✓</td>
<td>×</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>×</td>
<td>Low/Mid</td>
<td>Mid</td>
</tr>
<tr>
<td>Ventilator</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>X</td>
<td>✓/ ×</td>
<td>✓</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>RVM</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>High</td>
<td>High</td>
</tr>
</tbody>
</table>
MV is the Earliest and Most Comprehensive Indicator of Change in Respiratory Status

- Low MV is on average 71 minutes earlier than low SpO₂
- Respiratory rate misses > 80% of hypoventilation
- RVM’s MV is more reliable and clinically relevant than EtCO₂ in non-intubated patients
- Hypoventilation (↓MV) is common postoperatively and with opioids

3. Mehta, J, The relationship between minute ventilation and end tidal CO₂ in intubated and spontaneously breathing patients undergoing procedural sedation. June 29, 2017: https://doi.org/10.1371/journal.pone.0180187, Massachusetts General Hospital, Harvard University, University of Texas at Houston
ECRI—Evaluated Monitors Detecting Respiratory Depression


**Evaluation Criteria**
- Timeliness
- Accuracy
- Actionable
- Real-world work flow

**Evaluation Results**

<table>
<thead>
<tr>
<th>Model</th>
<th>Overall Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>RVM</td>
<td>★★★★★</td>
</tr>
<tr>
<td>ETCO2</td>
<td>★★★</td>
</tr>
<tr>
<td>Capnography</td>
<td>★★★★</td>
</tr>
</tbody>
</table>

**Independent third party organization** that evaluates and rates medical devices

- 4 out of every 5 U.S. hospitals rely on ECRI to guide their operational and strategic decisions
- "Consumer Reports" for medical devices
- 3,000+ hospitals commissioned ECRI to evaluate respiratory monitoring devices

**Evaluation Summary**

**Requirements:**
- Pulse ox too late – not considered
- Respiratory rate insufficient – not considered
- Need connectivity to central station

**Findings for RVM:**
- Comprehensive indicator of respiratory failure
- Outperforms other devices
- Ease of use in clinical settings

www.ecri.org
Several specialty groups in the perioperative arena have developed a standard risk stratification system. Each has its own limitations.

Opioids remain the foundation of pain management.

Intermittent monitoring is inadequate.

Continuous monitoring is supported by multiple agencies in all post operative patients.

Objective 4: Visualize respiratory volume monitoring (RVM) as a New Clinical Tool for Respiratory Assessment

- What do we know?
- What are the facts?
Establishment of RVM as Earliest & Most Comprehensive Indicator of Change in Respiratory Status

Single threshold:
- 100% normal
- <40% Low MV alarm
- Non-invasive, real-time, continuous, shows trends
- Communicates objective quantifiable information
- Very few false alarms
- Remote monitoring capability

Earliest indicator: when other measurements show NO sign of respiratory depression
Minute Ventilation (MV)—Known Measurement with Long Standing Clinical Use

- MV, TV and RR used every day on ventilators, so we know what the values mean
- RVM has excellent accuracy \( \sim 90\% \)

Sources:
RVM—Supported by Clinical Evidence from Multiple Care Areas

- 30+ peer-reviewed papers, 300+ presentations, 6,000+ patients, 1 million+ data sets
- Protocols for clinical use, use across clinical environments, accuracy
- More than a decade in testing and analytical product development
- Definitive clinical information far in advance of others in the space

- PACU, general floor
- ICU
- Procedural sedation
- Endoscopy
- Orthopedics, obesity
- Obstetric
- Pediatric
- Cardiac surgery
- Pain management
- Monitoring of therapeutics
- Difficult airway
- CPAP, BiPAP, High-flow
• 259 PACU patients / joint replacement surgery – MGH observational study

• 93% of recorded SpO₂ alarms were considered false alarms

• Repeated Low MV alarms began an average of 71.4 minutes before true desaturation measured by SpO₂

• Patients with Low MV had 1 hour longer Length of Stay in the PACU compared to patients with “adequate” MV

Capnography Does Not Work Well in Non-intubated Patients

• 48 non-intubated subjects
• Sensitivity of capnography to even large changes in MV in non-intubated patients is not clinically relevant

• MV measurements change more rapidly and by a greater degree than capnography in response to respiratory changes in non-intubated patients

Pre-opioid MV, the *Only* Way to Risk Stratify Patients “At Risk” for Respiratory Depression

- 107 PACU patients s/p intraperitoneal surgical procedures
- Risk Stratification: RVM identifies patients at RISK!
- Using RR alone, 88.2% of all respiratory depression would be missed

215 patients PACU/floor

48hr observational study

7% of patients had hypoventilation during last half hour in PACU and then hypoventilation on the floor

Maximum respiratory depression not in PACU but 3-13 hours after surgery

RVM identifies patients in the PACU who went on to have significant hypoventilation on the floor
Monitoring Minute Ventilation (MV) provides indication of hypoventilation post operatively.
Low MV measurements help clinicians make objective decisions around patient care.

**Case**
- Oral opioids caused “Unsafe” hypoventilation
- TV low, with normal RR

**Take Away**
- Measuring RR alone misses >80% of hypoventilation
Adequacy of RVM during Upper Endoscopy Procedures

- 51 patients
- 9,575 respiratory epochs
- There is very weak correlation MV and the corresponding RR ($r=0.05$)
- RR alarm set at 6 bpm would miss > 82% of respiratory depression
- RR alone has only an 18.2% sensitivity – for predicting Low MV
- MV indicates respiratory performance; RR is not an adequate proxy.

Real time measurement of MV provides early, ongoing and actionable insight into patient respiratory status.

Blinded: not using RVM

- Induction Dose: Propofol
- SpO\(_2\): 95-100%
- EtCO\(_2\): 35-37mmHg

Unblinded: using RVM

- Induction Dose: Propofol
- SpO\(_2\): 96-98%
- Dose titrated based on MV

Cases

- EtCO\(_2\) & SpO\(_2\) measurements in normal range despite hypoventilation

  - When RVM data available, CRNA is able to guide propofol, opioids, sedatives to avoid hypoventilation and decrease variations in level of sedation

Take Away

- MV measurement ensures both safety and comfort
• RCT of 73 patients undergoing upper complex endoscopy (Blinded to RVM data vs using RVM data to manage patients)

• 3x LESS respiratory depression when RVM used to manage sedation compared to blinded group

Patients successfully extubated have a reproducible dip in MV post-extubation -- maximum dip at 30 min. returns to baseline after 60 min.

SpO₂ fails to report initial drop in respiration and return to baseline

Hypoventilation can be the unrecognized cause of rapid response teams or code blue events

**Patient 1**

- Usual Course
  - Usual 25% dip in MV post-extubation with return to normal in 90 min

**Patient 2**

- Hypoventilation
  - Abnormally large dip in MV post-extubation
  - Marked hypertension at change of shift
  - Patient asleep
  - Nurse treated twice with Lopressor
  - Unsafe hypoventilation
  - Hypertension likely due to hypercarbia
  - Standard bedside monitor and pulse-ox did not alert nurse
  - Arrest would have been considered cardiac in origin

Hypoventilation can be the unrecognized cause of rapid response teams or code blue events
Objective 5: Outline an implementation plan of respiratory solutions

• What do we need to address?

• How can we improve patient care based on what we’ve processed?
Prolonged Stay in PACU
(> 30-60 min after modified Aldrete criteria met)

Known OSA

- Non-compliant with PAP Tx
- Severe OSA – (AHI >30), or
- Recurrent PACU Respiratory Event (30min block)
  - $O_2$ Sat < 90% (3 episodes)
  - Bradypnea <8 breaths / min (3 episodes)
  - Apnea >10 sec (1 episode)
  - Pain sedation mismatch

Moderate OSA (AHI > 16-30), Postoperative parenteral or oral opioids required (> codeine 60 mg q4h or equivalent)

Discharge to home if minor surgery

Yes

Postoperative PAP therapy and care in a monitored bed with continuous oximetry

Yes

Suspected OSA
(>2 on STOP, 3 STOP-bang)

- Recurrent PACU Respiratory Event (30min block)
  - $O_2$ Sat < 90% (3 episodes)
  - Bradypnea <8 breaths / min (3 episodes)
  - Apnea >10 sec (1 episode)
  - Pain sedation mismatch

No

Discharge to home if minor surgery or postoperative care on the surgical ward

No

Postoperative care on surgical ward
Begin OSA MONITORING on PACU Arrival

Patient resting w/o supplemental O$_2$ + RVM Monitoring + Pain managed w/o additional opiates

Monitor for 30 minutes

Low MV Alarm
(MVpred < 40% or Apnea for 30s)

Patient monitored for > 2 hours?

YES

Consult Physician & Consider Transfer with RVM Monitoring

NO

Repeat
(Up to 4 cycles or 2 hours)

YES

NO

Clear Patient for PACU Discharge
Devices and Alarms don’t Improve Safety – A Plan Improves Safety
RVM generates actionable alarms, with a high intervention-to-false-alarm ratio. No RVM alarms provides confidence in respiratory status despite false alarms from other monitors.

Minute Ventilation (MV) – in the Perioperative setting

95% of alarms were “actionable”

Clinical Interventions:
- 72% Stimulation
- 4% Change in opioids
- 2% Change in other meds
- 3% Patient repositioning
- 3% CPAP / BiPAP
- 2% MD / RT alerted
- 2% Change in LOS
- 1% Change in level of care
- 1% Avoided intubation

RVM provides an early warning. Due to RMV alarms triggering clinical interventions there were no respiratory related negative events.
RVM had 0.01 false alarms/hour

- For a nurse with five patients, they would hear 2 false alarms per week with RVM

VERSUS:
- 200 false alarms per week with oximetry
- 2000 false alarms per week with capnography
Objective 5: Outline an implementation plan of respiratory solutions, continued

• Which clinical, financial, and operational actions need to be taken to achieve success?

• How will these changes achieve better healthcare?
RVM—Early Intervention Increases Safety & Decreases Cost of Care

<table>
<thead>
<tr>
<th>TYPE of Intervention</th>
<th>COST of Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stimulation, Repositioning, Reduce Opioid Dosing</td>
<td>Free</td>
</tr>
<tr>
<td>Opioid Reversal</td>
<td>$1,500</td>
</tr>
<tr>
<td>ICU Transfer</td>
<td>$10,000+</td>
</tr>
<tr>
<td>Complication (e.g. pneumonia)</td>
<td>$50K+</td>
</tr>
<tr>
<td>Morbidity, Mortality, $$$</td>
<td>$10M+</td>
</tr>
</tbody>
</table>

RVM—Early, Predictive & Cost Effective

Clinical Excellence that pays for itself

- Superior Patient Safety
- Standardized language for respiratory status
- Low staff burden
- Rapid financial return justifies implementation

Drive and exceed Patient Care Standards to differentiate patient care
- Manage risk and efficiency across clinical environments, across institutions in systems
- Better information for clinician feedback: guide, standardize and evaluate

National Leadership in Standard of Care Improvement

Provide Enhanced, Proactive, Preventative Clinical Care to Patients

- Better patient management: enhances Patient Experience promotes Patient Satisfaction
- Short term patient management benefits
- Long term patient satisfaction increasing:
  - Patient referral
  - Physician referral
  - Reputation of institution
RVM — “The EKG of the Lungs”
Supports Our Philosophy to Predict & Prevent Versus Recognize & Respond

- **Cardiac**
  - Diagnostics
  - Monitoring
  - Compromised Cardiac Function
  - Multiple Sites of Care
  - Advanced therapeutics
  - Closed loop (pacemakers, defibrillators, etc.)

- **Respiration Ventilation**
  - Real Time Diagnostics
  - Continuous Monitoring
  - Compromised Ventilation Function
  - Multiple Sites of Care
  - Advanced Warning
  - Therapeutic Monitoring
  - Closed loop (PCA, BiPAP)

- **RVM**
  - Fundamental unit of breathing
  - MV: Leading Indicator of Respiratory Depression
  - SpO₂, EtCO₂, RR provide false assurance and false alarms
  - Adrenergic and Non-adrenergic medications mask or falsify perfusion... limits SpO₂
  - Trend of depth and rate of ventilation
  - Enables personalized medicine
Thank you!

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Respiratory Volume Monitoring Library

Minute Ventilation Monitoring Guidelines

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   - *Kaiser Permanente Baldwin Park*

   - University of North Carolina
Assessment of obese vs. non-obese patients using RVM

• 62 PACU patients after elective joint replacement

• Obese patients have greater variability in ventilation post-op than non-obese patients

• RVM may be especially useful in obese patients