Both Spontaneous Awakening Trials & Spontaneous Breathing Trials
KEY REFERENCES: Laying the Foundation for B (SATs & SBTs) of ABCDEF Bundle

KEY REFERENCES: Hazards of Deep Sedation (Additional Studies Laying the Foundation for B)

• Tanaka L. (Early Oversedation Outcomes) *Crit Care.* 2014;18:R156.
Session Objectives

• Review current evidence related to the hazards of deep sedation and the benefits of a coordinated SAT/SBT approach

• Describe valid and reliable sedation/agitation assessment tools

• Provide practical guidance for reliable SAT and SBT performance

• Discuss facilitators and potential barriers to successful SAT and SBT performance
Goals of ICU Sedation

• Calm
• Comfortable
• Cooperative
• Reduce anxiety and agitation
• Facilitate mechanical ventilation
• Decrease traumatic memory of ICU stay and procedures
How Do We Define “Adequate Sedation”?

• 274 patients
• Sedatives administered during 85% of 18,050 four-hour intervals
• 1 in 3 (32%) - unarousable
• 1 in 5 (22%) - no spontaneous motor activity
• Only 2.6% - thought to be over-sedated

From Canadian authors of SLEAP—

n=712
Patient-days = 3,620

“We found that nearly all patients were managed with continuous-infusion opioids and sedatives. We also found that actual practice was different from what we expected because the available clinical tools—such as protocols and assessment scales—were not necessarily applied at the bedside.”

Data collected 2008-2009.
Negative Consequences of Prolonged, Deep Sedation/Benefits of Light Sedation

- Deep sedation
  - Reduced six-month survival
  - Hospital mortality
  - Longer duration of mechanical ventilation
  - Longer ICU length of stay
  - Increased physiologic stress in terms of elevated catecholamine concentrations and/or increased oxygen consumption at lighter sedation levels BUT no clear relationship between elevation and clinical outcomes

Early Deep Sedation Longer Mechanical Ventilation and Reduced Six-Month Survival

Mental Health After Light or Deep Sedation

- 137 adults requiring mechanical ventilation-RCT
- Sedation with midazolam
  - Light: Ramsay 1-2, intermittent injection
  - Deep: Ramsay 3-4, continuous infusion
- Results
  - Primary endpoints (4 weeks after ICU discharge)
    - Trend toward more PTSD symptoms with deep sedation \( (P = 0.07) \)
    - More trouble remembering the event \( (P = 0.02) \)
    - More disturbing memories of the ICU \( (P = 0.05) \)
    - No difference in anxiety or depression scores
  - Other endpoints: light sedation patients averaged
    - 1 day shorter on mechanical ventilation \( (P = 0.03) \)
    - 1.5 days shorter length of stay \( (P = 0.03) \)

Nursing-Implemented Sedation Protocol

- **Protocol n = 162**
- **Routine n = 159**

**Median Time (days)**

- **Duration of MV**
  - Protocol: 2.3
  - Routine: 4.8
  - $P = 0.003$

- **ICU LOS**
  - Protocol: 5.7
  - Routine: 7.5
  - $P = 0.13$

- **Hospital LOS**
  - Protocol: 14
  - Routine: 20
  - $P < 0.001$

Nursing-Implemented Sedation Protocol

- Statistically shorter:
  - Duration of MV
  - ICU LOS
  - Hospital LOS

### Significant patient characteristics/metrics/outcomes

<table>
<thead>
<tr>
<th></th>
<th>Protocol</th>
<th>Control</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily midazolam, mg*</td>
<td>44 ± 31</td>
<td>92 ± 59</td>
<td>0.001</td>
</tr>
<tr>
<td>Duration midazolam, hrs**</td>
<td>3</td>
<td>5</td>
<td>0.18</td>
</tr>
<tr>
<td>Reintubated†</td>
<td>11 (6)</td>
<td>29 (13)</td>
<td>0.01</td>
</tr>
<tr>
<td>VAP diagnosis†</td>
<td>12 (6)</td>
<td>34 (15)</td>
<td>0.005</td>
</tr>
</tbody>
</table>

*Data presented in mean; ** Data presented in median
†Data presented as n (%)
Pharmacist Enforced Adherence to an ICU Sedation Guideline

• Statistically shorter:
  • Duration of MV
  • ICU LOS
  • Hospital LOS

<table>
<thead>
<tr>
<th>Significant patient characteristics/metrics/outcomes</th>
<th>RPh</th>
<th>Control</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol/drug overdose†</td>
<td>15 (19.2)</td>
<td>6 (7.7)</td>
<td>0.03</td>
</tr>
<tr>
<td>Lorazepam equivalents/vent day, mg*</td>
<td>65.2 ± 114.1</td>
<td>74.8 ± 76.1</td>
<td>0.54</td>
</tr>
<tr>
<td>Fentanyl equivalents/vent day, mcg*</td>
<td>102.5 ± 328</td>
<td>400 ± 1026</td>
<td>0.02</td>
</tr>
</tbody>
</table>

*Data presented in mean ; †Data presented as n (%)

A—Daily Sedation Interruption Decreases Duration of Mechanical Ventilation

- Hold sedation infusion until patient awake, then restart at 50% of prior dose
- “Awake” defined as any 3 of the following:
  - Open eyes in response to voice
  - Use eyes to follow investigator on request
  - Squeeze hand on request
  - Stick out tongue on request


- Length of MV 4.9 vs. 7.3 days (P=0.004)
- ICU LOS 6.4 vs. 9.9 days (P=0.02)
- Fewer diagnostic tests to assess changes in mental status
- No increase in rate of agitated-related complications or episodes of patient-initiated device removal
- No increase in PTSD or cardiac ischemia
B—Analysis of the Duration of Mechanical Ventilation After a Successful Screening Test

ABC Trial

Efficacy and safety of a paired sedation and ventilator weaning protocol for mechanically ventilated patients in intensive care (Awakening and Breathing Controlled trial): a randomised controlled trial


## ABC Trial: Main Outcomes

<table>
<thead>
<tr>
<th>Outcome*</th>
<th>SBT</th>
<th>SAT+SBT</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ventilator-free days</td>
<td>12</td>
<td>15</td>
<td>0.02</td>
</tr>
<tr>
<td>Time-to-event, days</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Successful extubation, days</td>
<td>7.0</td>
<td>5</td>
<td>0.05</td>
</tr>
<tr>
<td>ICU discharge, days</td>
<td>13</td>
<td>9</td>
<td>0.02</td>
</tr>
<tr>
<td>Hospital discharge, days</td>
<td>19</td>
<td>15</td>
<td>0.04</td>
</tr>
<tr>
<td>Death at 1 year, n (%)</td>
<td>97 (58%)</td>
<td>74 (44%)</td>
<td>0.01</td>
</tr>
<tr>
<td>Days of brain dysfunction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coma</td>
<td>3.0</td>
<td>2.0</td>
<td>0.002</td>
</tr>
<tr>
<td>Delirium</td>
<td>2.0</td>
<td>2.0</td>
<td>0.50</td>
</tr>
</tbody>
</table>

*Median, except as noted

ABC Trial: One-Year Mortality

Example QI projects using B: Wake Up and Breathe (Both SAT/SBT)
IHI’s & CDC’s Rethinking Critical Care: Implementing Change Using Bundle Approach

• Qualitative descriptions of IHI’s and CDC’s collaboratives between 2011 and 2014.

• **Conclusion:** Changing critical care practices requires an multiprofessional approach addressing cultural, psychological, and practical issues.

• **Key Take-Home Points:**
  1. Test changes on a small scale
  2. Feed back data regularly and provide ongoing education
  3. Build will through seeing the work in action

CDC’s Wake Up and Breathe Collaborative

- 20 ICUs: 12 full collaborative
- 5,164 consecutive MV days
- Opt-out SATs and SBTs
- 3x-4x increase in completion
- 35% less VAE risk/MV episode
- 65% less IVAC risk/MV episode
- 8 surveillance-only ICUs had no improvements

Klompas M. Am J Respir Crit Care Med. 2015;191:292-301.
Wake Up and Breathe in Indiana

- N=702 MICU/SICU patients
- Implemented paired SATs/SBTs
- Average RASS was 1 level more arousable ($P<0.0001$)
- Prevalence of delirium down 11% (66.7% to 55.3%, $P=0.06$)
- Combined delirium/coma down 6% ($P=0.01$)

Keystone’s ABCDE Bundle Collaborative

• 51 hospitals in Michigan’s Keystone ICU initiative
• Those implementing SATs and delirium screening were **3.5 times more likely** to exercise ventilated patients
• Incomplete or nonsequential bundle implementation yielded lower success rates
• Authors wrote, “Another layer of evidence that for the ABCDEs, the whole is greater than sum of the parts.”

Bundle Implementation Success: key findings from a meta-analysis

- 21 studies, all including process measures and 9 with clinical outcomes data
Bundle Implementation Success: key findings from a meta-analysis

• A variety of programs improved process measures
  • eg, 92% Delirium screening adherence
• Using more implementation strategies (6 or more) and integrating PAD guidelines or ABCDE bundle:
  • Statistically lower mortality and shorter ICU LOS
  • Delirium “incidence” static; delirium duration may be better metric
• Strategies targeting organizational changes in addition to provider behavior also associated with reduced mortality

Trogrlić Z. Critical Care 2015; 19:157
Sedation, Dehumanization and Maslow’s Hierarchy in Critical Care

Stop…let’s talk about this point:

“What often happens is that sedation is stopped in the morning for a brief period and then resumed later that day or during the night when the patient begins to wake up and is delirious. The physician on call or the nurses on duty either will not, cannot, or simply do not spend time dealing with an awake patient or perhaps operate under the belief that people should not be awake while receiving mechanical ventilation.”

Valid and Reliable Agitation/Sedation Assessment Tools
PAD Agitation/Sedation Assessment Recommendations

• Depth and quality of sedation should be routinely assessed in all ICU patients (1B)
• The RASS & SASS are the most valid and reliable scales for assessing quality and depth of sedation in ICU patients (B)
• Suggest using objective measures of brain function to adjunctively monitor sedation in patients receiving neuromuscular blocking agents (2B)
• Use EEG monitoring either to monitor nonconvulsive seizure activity in ICU patients at risk for seizures, or to titrate electrosuppressive medication to achieve burst suppression in ICU patients with elevated intracranial pressure (1A)

## Sedation-Agitation Scale (SAS)

<table>
<thead>
<tr>
<th>Score</th>
<th>State</th>
<th>Behaviors</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>Dangerous agitation</td>
<td>Pulls at ET tube, climbs over bedrail, strikes at staff, thrashes side to side</td>
</tr>
<tr>
<td>6</td>
<td>Very agitated</td>
<td>Does not calm despite frequent verbal reminding, requires physical restraints</td>
</tr>
<tr>
<td>5</td>
<td>Agitated</td>
<td>Anxious or mildly agitated, attempts to sit up, calms down to verbal instructions</td>
</tr>
<tr>
<td>4</td>
<td>Calm and cooperative</td>
<td>Calm, awakens easily, follows commands</td>
</tr>
<tr>
<td>3</td>
<td>Sedated</td>
<td>Difficult to arouse, awakens to verbal stimuli or gentle shaking but drifts off</td>
</tr>
<tr>
<td>2</td>
<td>Very sedated</td>
<td>Arouses to physical stimuli but does not communicate or follow commands</td>
</tr>
<tr>
<td>1</td>
<td>Unarousable</td>
<td>Minimal or no response to noxious stimuli, does not communicate or follow commands</td>
</tr>
</tbody>
</table>

Richmond Agitation Sedation Scale (RASS)

<table>
<thead>
<tr>
<th>Score</th>
<th>Descriptor</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>+4</td>
<td>Combative</td>
<td>Combative, violent, immediate danger to staff</td>
</tr>
<tr>
<td>+3</td>
<td>Very agitated</td>
<td>Pulls or removes tube(s) or catheter(s); aggressive</td>
</tr>
<tr>
<td>+2</td>
<td>Agitated</td>
<td>Frequent nonpurposeful movement, fights ventilator</td>
</tr>
<tr>
<td>+1</td>
<td>Restless</td>
<td>Anxious, apprehensive but movements not aggressive or vigorous</td>
</tr>
<tr>
<td>0</td>
<td>Alert and calm</td>
<td>Not fully alert, but has sustained awakening to voice (eye opening and contact &gt;10 seconds)</td>
</tr>
<tr>
<td>-1</td>
<td>Drowsy</td>
<td>Briefly awakens to voice (eye opening and contact &lt;10 seconds)</td>
</tr>
<tr>
<td>-2</td>
<td>Light sedation</td>
<td>Movement or eye opening to voice (but no eye contact)</td>
</tr>
<tr>
<td>-3</td>
<td>Moderate sedation</td>
<td>No response to voice, but movement or eye opening to physical stimulation</td>
</tr>
<tr>
<td>-4</td>
<td>Deep sedation</td>
<td>No response to voice or physical stimulation</td>
</tr>
<tr>
<td>-5</td>
<td>Unarousable</td>
<td></td>
</tr>
</tbody>
</table>
Facilitating Reliable Performance of SATs and SBTs
B—Related Terminology

• Spontaneous Awakening Trial (SAT)
• Daily Awakening Trial
• Daily Sedation Interruption (DSI)
• Daily Sedation Cessation
• Sedation Vacation
• Protocolized Sedation
• Spontaneous Breathing Trial (SBT)
• T-Piece Trial
• Weaning Trial
PAD Depth of Sedation Statements

• Maintaining light levels of sedation in adult ICU patients is associated with improved clinical outcomes, e.g., shorter duration of mechanical ventilation and shorter ICU lengths of stay (LOS) (B).

• Maintaining light levels of sedation increases the physiologic stress response, but is not associated with an increased incidence of myocardial ischemia (B).

• The association between depth of sedation and psychological stress in these patients remains unclear (C).

PAD Depth of Sedation Recommendations

• We recommend that sedative medications be titrated to maintain a light rather than a deep level of sedation in adult ICU patients, unless clinically contraindicated (+1B).

• We recommend that either daily sedation interruption or a light target level of sedation be routinely used in mechanically ventilated adult ICU patients (+1B).

Targeted Level of Consciousness

Choose Target RASS
Assess Actual RASS
Modify treatment so Actual = Target
Wake Up and Breathe Protocol

SAT Protocol

- SAT Safety Screen
  - every 24 hrs
  - fail
  - pass

- Perform SAT
  - fail
  - Restart sedatives at 1/2 dose

SAT Safety Screen
- No active seizures
- No alcohol withdrawal
- No agitation
- No paralytics
- No myocardial ischemia
- Normal intracranial pressure

SAT Failure
- Anxiety, agitation, or pain
- Respiratory rate > 35/min
- Oxygen saturation < 88%
- Respiratory distress
- Acute cardiac arrhythmia

ABC Study Restarting Criteria Frequency

- Agitation: 4.7%
- Tachypnea: 2.2%
- Hypoxemia: 1.4%
- Respiratory Distress: 2.8%
- Arrhythmia: 0.1%
- Myocardial Ischemia: 0%

Drug Restarting Guidelines

• Restart drug(s) at half of the previous dose

• Titrate to goal

• Consider bolus dose if rapid anxiolysis needed
  • Watch for signs of bradycardia and hypotension
SBT Protocol

SBT Safety Screen
- No agitation
- Oxygen saturation ≥ 88%
- FiO2 ≤ 50%
- PEEP ≤ 7.5 cm H2O
- No myocardial ischemia
- No vasopressor use
- Inspiratory efforts

Pass

Perform SBT

Pass

Consider extubation

Fail

Full ventilatory support

Fail

SBT Failure
- Respiratory rate > 35/min
- Respiratory rate < 8/min
- Oxygen saturation < 88%
- Respiratory distress
- Mental status change
- Acute cardiac arrhythmia

Fail

Pass
Things to Consider: Barriers

• Concern by staff
• Workload and productivity concerns
• Fear of patient discomfort and asynchrony
• Fear of inadvertent extubation
• Fear of self-extubation during decreased sedation
• Excuses: “Let’s just give it one more day.” “It’s late in the day, and we don’t have coverage tonight.”

Things to Consider: Facilitating Success

• Extubation takes a team
• Timing
• Dedicated RRT in rounds speaking up
• Ventilator LOS posted
• Extubation rates posted
• Incentives aligned around common goals
SAT/SBT Outcomes Summary

- Decreased days of mechanical ventilation
- Reduced weaning time
- Reduced reintubation rates
- Fewer days with delirium
- Decreased length of ICU stay
- Decreased length of hospital stay

All slides beyond this point will be reference only slides
The Problem

- Negative outcomes of prolonged ventilation
  - Ventilator-associated pneumonia
  - Immobility
  - Delirium
- Sedation used to relieve anxiety and agitation
  - Oversedation
  - Undersedation
  - Harmful outcomes

Bundle Synergy

Synergy of SAT and SBT

• Decreased medication accumulation
• Decreased oversedation
• Increased opportunity for effective independent breathing
Bundle Synergy

Wake Up and Breathe Protocol

• Combines SAT and SBT
• Two-step process
• Safety screen
• Trial period
*TAP = Team Administered Protocols

- Assessment: SAT, CAM-ICU, RASS, SBT
- Treatment: Most effective when implemented by nursing, respiratory therapy, and physical therapy personnel working together as an ICU team.

*Credit—Sutter Health

Barr J. Delving Into the ICU Pain, Agitation, & Delirium Care Bundle. Cynosure Health webinar, slide 17; July 26, 2012; San Francisco, CA
SAT Safety Screen
(reference safety screen)

• No active seizures
• No alcohol withdrawal being treated
• No paralytics
• No myocardial ischemia <24 hours
• No elevated Intracranial pressure
• Agitation requiring escalating sedation previous six hours
SAT Failure After:

- Anxiety, agitation or pain (restart at ½)
- Respiratory rate > 35
- $\text{SpO}_2 < 88$
- Respiratory Distress
  - Two or more signs: marked use of accessory muscles, abdominal paradox, diaphoresis, marked subjective dyspnea
- Tachycardia
- Acute myocardial arrhythmia
Survival Benefit of Linked Sedation Interruption with SBT After (refer slide 5)

- SAT plus SBT
- Usual care plus SBT

Patients alive (%)

<table>
<thead>
<tr>
<th>Days after randomization</th>
<th>Patients at risk</th>
<th>Events</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SAT plus SBT</td>
<td></td>
</tr>
<tr>
<td></td>
<td>167</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>167</td>
<td>167</td>
</tr>
<tr>
<td>60</td>
<td>110</td>
<td>97</td>
</tr>
<tr>
<td>120</td>
<td>96</td>
<td>74</td>
</tr>
<tr>
<td>180</td>
<td>92</td>
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</tr>
<tr>
<td>240</td>
<td>91</td>
<td></td>
</tr>
<tr>
<td>300</td>
<td>86</td>
<td></td>
</tr>
<tr>
<td>360</td>
<td>76</td>
<td></td>
</tr>
</tbody>
</table>

- Usual care plus SBT
- Patients at risk: 167
- Patients alive: 168
- Events: 97

Improved survival at 1 year (HR 0.68, P=0.01)

More Specific Patient Population
SAT Exclusion Criteria After

- Moribundity: Withdrawal of life support
- Hemoptysis
- Elevated ICP (>20 mm Hg)
- Open abdomen/chest
- Unsecured cerebral aneurysm
- Unstable spine
- Unusual ventilation (HFOV, VDR)
Perceived Barriers of Sedation Protocols and Daily Sedation Interruption (slide 12)

• Multidisciplinary Web-based survey—904 responders

• Reasons for lack of protocol use:
  • No physician order (35%)
  • Lack of nursing support (11%)
  • Fear of over-sedation (7%)

• Barriers for daily sedation interruption:
  • Nursing acceptance (22%)
  • Risk of device removal (19%)
  • Respiratory compromise (26%)
  • Patient discomfort (13%)

Barriers after NURSING 12

• Ostermann et al. In closely monitored clinical trials, patients were at the target level of sedation, on average, only 69% of the time.

• Guttormson et al. found that one-third of the variance in the number of patients who received sedatives was accounted for by nurses’ attitudes.

• Only 17.7% of respondents thought it was easier to care for an awake and alert patient who was receiving mechanical ventilation than to care for a similar patient who was more sedated.

How to Coordinate (blend this into 25-28, how to coordinate)

• Plan on rounds:
  • Physician champion
  • Structured rounds

• Involve respiratory and physical therapy
  • Transports
  • Mobility sessions
What to Do With Pass/Failure

• Do not re-sedate if pass
• Failure: Restart sedation at half previous dose and titrate to target
• If SBT pass, liberate
• Treat pain and discomfort
SBT

- SBT composed of two parts
  - Safety screen
  - Trial
- Ventilatory support removed
  - T-tube / CPAP +5 cm H₂O / PSV < +7 cm H₂O
  - No change in FI0₂
- Failed SBT if:
  - RR ≥ 35 or ≤ 8 breaths/min
  - SaO₂ < 88% for > 5 min
  - Abrupt change in mental status
  - Cardiac arrhythmia
  - Two or more signs of respiratory distress (accessory muscle, diaphoresis, etc.)

SBT Protocol

Step 1. Conduct Safety Screen
- NMB use
- MAP < 60 mm Hg
- FiO₂ > 50%
- PEEP > 8 cm H₂O
- Minute ventilation > 15 L/min
- Vasopressor use

FAIL

PASS

Ensure appropriate analgesia
(Pain score 0-3)
Sedation goal achieved

Step 2. Conduct 2 minute tolerance test
- CPAP=5, RR=0, No PSV
- Allow no breath for up to 60 sec

FAIL

PASS

Step 3. Conduct SBT (30-120min)
- PSV=5, PEEP=5, RR=0
- Nursing / RT perform ongoing assessment

FAIL

PASS

Record patient outcome.
Get order for liberation.

Continue mechanical ventilation at prior settings.

Place back on full support.
Notify house staff for discussion on rounds.
Team communication paper progress note integration in EMR rounds

Mechanics have little value

Secretions and cuff leak important

AFTER
Some Failure Criteria for SBT After

- RR >35 breaths/min for 5 min or more
- HR elevated >120% baseline for >5 min
- RSBI >105 greater than 5 min

- SBT Duration
  - Minimum 30 min
  - Better prognostic indicator at 120 min
What to Track for Quality SBT After

• % eligible patient SBT performed
• % pass SBT
• reasons for SBT failure
• % successful SBT liberated
• % re-intubation
• % self-extubated who are re-intubated
% Extubation after Successful SBT by Unit

Goal Setting