

Comparison of SAT and SBT Conduct During the ABC Trial and PILOT Trial

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Abstract

Background: Implementation of the “B” element—both spontaneous awakening trials (SATs) and spontaneous breathing trials (SBTs)—of the ABCDEF bundle improves the outcomes for mechanically ventilated patients. In 2021, the Pragmatic Investigation of optimal Oxygen Targets (PILOT) trial investigating optimal oxygenation targets in patients on mechanical ventilation was completed.

Objectives: To compare SAT and SBT conduct between a randomized controlled trial and current clinical care.

Methods: The 2008 Awakening and Breathing Controlled (ABC) Trial (2003-2006) randomized mechanically ventilated patients to paired SATs and SBTs versus sedation per usual care plus SBTs. The PILOT trial (2018-2021) enrolled patients years later where SAT + SBT conduct was observed. We compared SAT and SBT conduct in ABC’s interventional group (SAT + SBT; n = 167, 1140 patient days) to that in PILOT (n = 2083, 8355 patient days).

Results: Spontaneous awakening trial safety screens were done in all 1140 ABC patient-days on sedation and/or analgesia and in 3889 of 4228 (92%) in PILOT. Spontaneous awakening trial safety screens were passed in 939 of 1140 (82%) instances in ABC versus only 1897 of 3889 (49%) in PILOT. Interestingly, SAT was performed in ≥95% of passed SAT safety screens in both trials and was passed in 837 of 895 (94%) in ABC versus 1145 of 1867 (61%) in PILOT. SBT safety screens were performed in all 983 ABC instances and 8031 of 8370 (96%) in PILOT. SBT safety screens were passed in 647 of 983 (66%) in ABC versus 4475 of 8031 (56%) in PILOT. Spontaneous breathing trial was performed in ≥93% of passed SBT safety screens in both trials and was passed in 319 of 603 (53%) in ABC versus 3337 of 4454 (75%) in PILOT.

Conclusion: This study compared SAT/SBT conduction in an ideal setting to real-world practice, 13 years later. Performance of SAT/SBT safety screens, SATs, and SBTs between a definitive clinical trial (ABC) as compared to current clinical care (PILOT) remained high.

Keywords

spontaneous awakening trials, spontaneous breathing trials, sedation, analgesia, mechanical ventilation

Introduction

At any given time, around 30% of patients admitted to an intensive care unit (ICU) are mechanically ventilated.¹ Many of these patients receive analgesics or sedatives for comfort or safety.^{2,3} Targeting light sedation and limiting the time on ventilator have each been correlated with decreased rates of delirium, reduced mortality rate, hospital and ICU length of stay, and shortened time to extubation.⁴⁻⁹

The ABCDEF bundle stands for A: Assess, Prevent, and Manage Pain, B: Both Spontaneous Awakening Trials (SATs) and Spontaneous Breathing Trials (SBTs), C: Choice of analgesia and sedation, D: Delirium: Assess, Prevent, and Manage, E: Early mobility and Exercise, and F: Family engagement and empowerment.¹⁰ Implementation of the “B” component aims to liberate patients from sedation and mechanical ventilation in a timely, patient-driven manner. Combined with the other components of the bundle, these strategies reduce and/or

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prevent complications including hospital death, delirium, coma, readmission to the ICU, transfer to a facility, use of restraints, and cost in critically ill patients.^{11,12}

In the Awakening and Breathing Coordination (ABC) Trial, which was published in 2008,¹³ pairing daily SATs with SBTs in the intervention group resulted in patients spending more time liberated from mechanical ventilation, decreased ICU and hospital length of stay, and improved 1-year survival. Since then, the 2013 Pain, Agitation, and Delirium (PAD) and 2018 Guidelines for the Prevention and Management of Pain, Agitation/Sedation, Delirium, Immobility, and Sleep Disruption in Adult Patients in the ICU (PADIS) both recommend light levels of sedation and use of nonbenzodiazepine sedation strategies.² Given that these guidelines were published after the ABC Trial, the performance and success rates of SATs and SBTs may have changed over time. Whether the implementation of the “B” component in the ABCDEF bundle is still being done currently in medical intensive care units (MICUs) at an academic medical center with a diverse patient population has not been studied, to our knowledge. Thus, investigating the rate of SAT and SBT conductance in current clinical care may indicate if our clinical practice includes bundle adherence.

We conducted this study to compare SAT and SBT conduct in the ABC Trial with use in current real-world practice, as observed in the Pragmatic Investigation of optimal Oxygen Targets (PILOT) trial, which compared different arterial oxygen saturation (SpO₂) targets mechanically ventilated ICU patients and was published in 2022.¹⁴

Methods

This study was a secondary analysis of data collected during the ABC Trial and the PILOT study. This secondary analysis was approved by the Vanderbilt University Institutional Review Board (#212382).

Awakening and Breathing Coordination and PILOT Trials

The ABC Trial was a randomized controlled trial conducted in four tertiary medical centers in the United States. The trial randomized 336 mechanically ventilated adults in MICUs to daily SATs coordinated with SBTs (intervention group; $n = 167$, 1140 patient instances) versus SBTs plus sedation via usual care (control group).

The PILOT study was a randomized controlled trial that enrolled 2541 mechanically ventilated adults in a MICU at a single academic medical center. There was an institutional protocol implemented in the ICU to include the whole ABCDEF Bundle.¹⁰ The letter B (SAT/STB) of the Bundle was modeled after the ABC Study's protocol.¹³

Population

Inclusion criteria for the current secondary analysis included (1) age 18 years or older; (2) admission to a MICU from 2003 to 2006 in the ABC Trial or admission to a MICU from 2018 to

2021 in the PILOT trial; and (3) receiving mechanical ventilation.

Exclusion criteria for the ABC Trial included (1) admission after cardiopulmonary arrest; (2) continuous mechanical ventilation for 2 weeks or longer prior to enrollment; (3) moribund state (ie, death was perceived to be imminent); (4) withdrawal of life support; (5) profound neurological deficits (eg, large stroke or severe dementia); or (6) current enrollment in another trial. Exclusion criteria for the PILOT trial included (1) pregnant women or (2) prisoners.

Data Collection

During the ABC Trial, the study personnel collected data on passing/failing the safety screen and trial conduct of SATs and SBTs. During the PILOT trial, the MICU pharmacist collected these data each day. The MICU pharmacist at this institution plays a tremendous role in leading the effort for protocol implementation and maintenance along with teamwork with physicians, advanced practice providers, nurses, respiratory therapists (RTs), and physical therapists.

During both ABC and PILOT trials, if patients passed the SAT safety screen, then the SAT trial was conducted and involved cessation of all sedatives and analgesics used for sedation. Analgesics needed for active pain were continued. In the ABC Trial, patients passed the SAT if they opened their eyes to verbal stimuli or tolerated sedative interruption for 4 or more hours. In the PILOT trial, patients passed the SAT if they had a RASS of 0 to -2 and were able to follow simple commands.¹⁵

For ABC intervention group (SAT + SBT), when a patient passed the SAT safety screen, the SAT, and the SBT safety screen, then an SBT was performed. If a patient was not receiving sedation, the SAT safety screen and SAT were considered to be passed. Unlike ABC, not all patients in the PILOT study who underwent a SBT were on sedation. Thus, in the PILOT study, passing SAT safety screen and SAT trial was not a prerequisite to SBT safety screen and SBT conduction.

Statistical Analysis

Categorical data are reported as numbers and percentages and analyzed using Chi-square tests. Continuous data are reported as medians and interquartile range. Statistical analyses were performed with Microsoft Excel 2016 and IBM SPSS Statistics, version 29.

Results

Population

Baseline characteristics including age, sex, and diagnosis on ICU admission in both studies were similar other than the PILOT study having more patients admitted with sepsis/septic shock, hepatic failure, renal failure, asthma, COPD, and altered mental status (Table 1).

Table 1. Baseline Characteristics.

	ABC interventional group (n = 167)	PILOT trial (n = 2083)
Age	60 (48, 71)	58 (46, 67)
Sex (male) ^a	90 (54)	1144 (55)
Diagnosis on admission to intensive care ^b		
Sepsis/septic shock	23 (14)	690 (33)
Acute respiratory distress syndrome	23 (14)	214 (10)
Congestive heart failure/heart failure with reduced ejection fraction (<45%)/Cardiogenic shock	11 (7)	137 (7)
Acute myocardial infarction (STEMI and NSTEMI)/arrhythmia	11 (7)	334 (16)
Coronary artery disease	NA	385 (19)
End-stage renal disease on renal replacement therapy	NA	109 (5)
Cardiac arrest	NA	199 (10)
Pneumonia, hemoptysis, or pulmonary embolism	37 (22)	604 (29)
Airway protection/Upper airway obstruction	8 (5)	NA
Chronic obstructive pulmonary disease/asthma (including exacerbations)	17 (10)	505 (25)
Altered mental status	18 (11)	1410 (68)
Gastrointestinal bleeding	1 (1)	209 (10)
Cirrhosis/hepatic failure (liver encephalopathy) or renal failure (all 3 acute kidney injury stages)	9 (5)	1386 (67)
Other ^c	27 (16)	657 (33)

Abbreviations: ABC, Awakening and Breathing Controlled; NA, not available; NSTEMI, non-ST segment elevation myocardial infarction; PILOT, Pragmatic Investigation of optimal Oxygen Targets; STEMI, ST-segment elevation myocardial infarction.

Values are medians (interquartile range) for continuous variables and count (percentages) for categorical variables.

^aCategorized sex in the PILOT trial was missing for 17 patients.

^bIt is possible that some patients may have had more than one diagnosis. In the PILOT trial, 18 to 23 patients did not have diagnosis confirmation documented.

^cIncluding alcohol withdrawal, aspiration pneumonitis, cardiogenic pulmonary edema, elevated intracranial pressure, hemorrhagic shock, internal bleeding (nongastrointestinal), intracranial hemorrhage, ischemic stroke, malignancy, metabolic disarray, overdose, status epilepticus, surgical anastomosis, and traumatic brain injury. Not all of the "other" diagnoses were documented in both studies.

Spontaneous Awakening Trial Safety Screen and SAT

During the ABC Trial, SAT safety screens were done during all 1140 of 1140 (100%) patient-days on mechanical ventilation. During the PILOT Trial, SAT safety screens were done during 3889 of 4228 (92%) patient-days. Of the SAT safety screens performed, 939 of 1140 (82%) were passed during ABC, whereas 1897 of 3889 (49%) were passed in PILOT ($P < .001$). A SAT was performed after 895 of 939 (95%) of the passed SAT safety screens in ABC and after 1867 of 1897 (98%) of the passed SAT safety screens in PILOT. In ABC, 837 of 895 (94%) SATs were passed and in PILOT, 1145 of 1867 (61%) SATs were passed ($P < .001$).

Spontaneous Awakening Trial Failure Reasons

The proportion of SAT safety screen failure reasons was similar between ABC and PILOT other than agitation that was higher in the PILOT Trial. In addition, hypoxemia and "other" categories were not considered as failure reasons in the ABC Trial. The PILOT Trial SATs had higher proportions of tachypnea and anxiety, agitation, and pain considered as failure reasons, than the ABC study (Table 2).

Spontaneous Breathing Trial Safety Screen and SBT

During the ABC Trial, 155 of 167 (93%) patients in the intervention group underwent a total of 983 SBT safety screens.

In the PILOT trial, 2083 of 2541 (82%) patients underwent a total of 8031 SBT safety screens. Spontaneous breathing trial safety screens were passed on 647 of 983 (66%) patient-days in ABC and in 4475 of 8031 (56%) in PILOT ($P < .001$).

Spontaneous breathing trials were performed after 603 of 647 (93%) passed safety screens in the ABC Trial and after 4454 of 4475 (99%) in PILOT. Of these SBTs, 319 of 603 (53%) were passed during ABC and 3337 of 4454 (75%) were passed in PILOT ($P < .001$).

Spontaneous Breathing Trial Failure Reasons

The ABC Trial had higher proportions of "high FiO₂, and high PEEP requirement," "vasopressor receipt," and "other" as failure reasons for SBT safety screen; however, not all of the "other" SBT safety screen failure reasons were documented in the ABC interventional trial (Table 2). The SBT failure reasons were also comparable other than the ABC intervention group having higher proportions of tachypnea, signs of respiratory distress, and hypoxemia compared to PILOT study SBTs (Table 2).

Discussion

This study conducted a comparative analysis of the processes of SATs and SBTs as employed in the original trial that investigated SATs and SBTs, and the same as applied in routine

Table 2. Results of the Spontaneous Awakening Trials and Spontaneous Breathing Trials.

	ABC interventional group (n = 167)	PILOT trial (n = 2083)	P value
SAT safety screen	N = 161	N = 2083	
Total patient-days	1140	3889	<.001
Passed	939 (82)	1897 (49)	<.001
Failed ^a	201 (18)	1992 (51)	<.001
Reasons for failure			
Active seizures/Alcohol withdrawal	11 (1)	26 (1)	.5
Agitation	151 (11)	790 (20)	<.001
Hypoxemia	NA	752 (19)	NA
Myocardial ischemia	18 (1)	2 (0)	-
Paralytics	26 (2)	59 (2)	.167
Other ^b	3 (1)	360 (9)	.1
SAT			
Total patient-instances ^c	895	1867	<.001
Passed	837 (94)	1145 (61)	<.001
Failed ^a	58 (7)	722 (39)	<.001
Reasons for failure			
Anxiety, agitation, or pain	42 (5)	438 (24)	<.001
Signs of respiratory distress	25 (3)	21 (1)	.25
Tachypnea	20 (2)	156 (8)	.022
Hypoxemia	12 (1)	99 (5)	.167
Dysrhythmia/Cardiac arrhythmia	1 (0)	5 (0)	-
Other ^d	NA	8 (0)	NA
SBT safety screen	N = 155	N = 2083	
Total patient-days	983	8031	<.001
Passed	647 (66)	4475 (56)	<.001
Failed ^a	336 (34)	3556 (44)	<.001
Reasons for failure			
Agitation	54 (5)	83 (1)	.167
High FiO ₂ requirement	187 (19)	609 (8)	<.001
High PEEP requirement	158 (16)	692 (9)	<.001
Hypoxemia	21 (2)	172 (2)	.33
Insufficient inspiratory effort	25 (3)	262 (3)	.1
Vasopressor receipt	103 (10)	589 (7)	<.001
Other ^e	19 (2)	1597 (20)	.004
SBT			
Total patient-instances ^c	603	4454	<.001
Passed	319 (53)	3337 (75)	<.001
Failed ^a	284 (47)	1117 (25)	<.001
Reasons for failure			
Tachypnea	221 (37)	544 (12)	<.001
Signs of respiratory distress	125 (37)	36 (1)	.026
Hypoxemia	33 (6)	292 (7)	<.001
Abrupt change in mental status	13 (2)	11 (0)	-
Bradypnea	8 (1)	31 (1)	1.0
Dysrhythmia/Cardiac arrhythmia	15 (3)	8 (0)	-
Other ^f	NA	216 (5)	NA

Abbreviations: ABC, Awakening and Breathing Controlled; FiO₂, fraction of inspired oxygen; PEEP, positive end-expiratory pressure; PILOT, Pragmatic Investigation of optimal Oxygen Targets; SAT, spontaneous awakening trial; SBT, spontaneous breathing trial.

Values are medians (interquartile range) for continuous variables and count (percentages) for categorical variables.

^aIt is possible that some patients may have had more than one failure reason. In the PILOT trial, 15 patient-instances had missing SAT safety failure reasons, 10 had missing SAT trial failure reasons, 10 had missing SBT safety failure reasons, and 12 had missing SBT trial failure reasons.

^bIncluding airway edema, analgesia, anaphylaxis, bradycardia, breathstacking, code, comfort care, contraindicated, deep sedation due to high peak pressures, elevated intracranial pressure, extracorporeal membrane oxygenation, flolan, going to procedure, hemodynamically unstable, high peak pressures, new or recent intubation, no cuff leak, pain, procedure, retropharyngeal abscess, Richmond Agitation Sedation Scale of -4 or -5, tachypnea, trach placement, unsafe airway, and vent dyschrony. Not all of the "other" SAT safety screen failure reasons were documented in the ABC interventional trial.

^cIn the ABC trial, from the 939 patient-instances that passed SAT safety screen, 43 were not followed by SAT and from the 647 patient-instances that passed SBT safety screen, 44 were not followed by SBT. While in the PILOT trial, from the 1897 patient-instances that passed SAT safety screen, 30 did not have a SAT trial performed and from the 4475 patient-instances that passed SBT safety screen, 21 did not have a SBT trial performed.

^dIncluding comfort care, Glasgow Coma Scale, hypotensive, procedure, Richmond Agitation Sedation Scale of -5, and seizures.

^eIncluding acid/base, actively withdrawing, anaphylaxis, angioedema, aspirating, bleeding, bradycardia, coded, comfort care, concern for rebleed, continuous renal replacement therapy, expired, extracorporeal membrane oxygenation, flolan, going to or in procedure, hemoptysis, high peak pressures, low Glasgow Coma Scale, low minute ventilation, low tidal volume, mechanical ventilation >10, new intubation, no cuff leak, off study, on transplant, paralyzed, Richmond Agitation Sedation Scale of -5, secretion, seizures, tachypnea, terminally extubated, too much going on, too sedated, trach, transferred, vent dependent and waiting for swelling to decrease. Not all of the "other" SBT safety screen failure reasons were documented in the ABC interventional trial.

^fIncluding acid/base, agitation, anxiety, apnea, aspiration, bradycardia, catatonia like symptoms, decreased minute ventilation, decreased tidal volumes, high minute ventilation, high peak pressures, hypertension, in procedure, no cuff leak, no respiratory effort, reintubated, respiratory rate, too sedated, tracheostomy, triggered backup mode, vasopressors, vent dependent, vomiting, and weakness.

clinical care within the same ICU during a pragmatic clinical trial. The results revealed that the safety screens for SATs and SBTs were implemented on more than 90% of patient-days, and that an overwhelming 93% of passed SAT and SBT safety screens subsequently underwent an SAT and an SBT, respectively. Intriguingly, only 53% of SBTs achieved pass status during the original ABC Trial, while an impressive 75% of SBTs achieved this during the PILOT. These disparities could potentially be attributable to variations in eligibility criteria or adherence to the intervention in a trial in which systematic performance of an SAT and SBT was the primary intervention compared to routine clinical care performed during a pragmatic clinical trial. Additionally, there might be unexplored avenues in clinical care to more rigorously adopt the SAT procedure as proven effective in a randomized trial. Importantly, the data suggest that the implementation of the “B” component (SBT) within the ABCDEF bundle is still actively undertaken in a diverse MICU at an academic medical center, affirming its fundamental role in the bundle’s ability to decrease mortality rates.

The 2013 PAD guidelines recommended using daily awakening trials, targeting light levels of sedation, and using nonbenzodiazepine sedatives instead of benzodiazepines when sedating mechanically ventilated critically ill adults to improve short-term outcomes.^{7,13,16–19} The updated 2018 PADIS guidelines reinforce these recommendations and also suggest the use of propofol or dexmedetomidine.² More recently, the ICU Liberation Collaborative, which included more than 15 000 adults, found that implementation of the ABCDEF bundle, including both daily SATs and daily SBTs, was associated with a lower probability of hospital death, next day mechanical ventilation, coma, delirium, use of physical restraints, ICU readmission, and discharge to a facility.¹¹

Published in 2008, the ABC Trial showed that paired SATs and SBTs decrease time to extubation, days spent in ICU and hospital, and 1-year mortality, compared with usual care.¹³ Published in 2012, the Daily Sedative Interruption in Critically Ill Patients Being Managed With a Sedation Protocol randomized trial compared an SAT protocol with a light sedation protocol and found no differences in duration of mechanical ventilation, delirium incidence, and ICU/hospital lengths of stay.²⁰ The SAT group, however, received larger boluses and overall doses of benzodiazepines and opioids than the control group, highlighting that SATs are only effective if they result in less sedative exposure.²⁰

Importance of SAT and SBT performance is well-established; however, working on strategies for ensuring their consistent daily execution and long-term sustainability is still needed as many ICUs are still not consistently performing them. This could be due to reasons such as lack of acceptance, culture, and safety concerns such as fear of the patient being agitated or possible self-extubation.²¹ One option to overcome this barrier might be interprofessional education designed to create a shared mental model within the ICU team regarding the positive outcomes from paired SATs and SBTs evident from several randomized trials that have safely implemented

both SAT and SBTs.^{11,22–28} Moreover, existing literature cites successful utility in leveraging the diverse skills within their ICU teams such as physician-led and nursing-led initiatives^{22,24,29} that have enhanced SAT and SBT protocol compliance. Additionally, a pharmacist-led quality improvement (QI) initiative may be an excellent strategy in collaborative with an interprofessional team comprised of physicians, advanced practice providers, nurses, RTs, and physical therapists that can be implemented as the pharmacist is consistently present in the ICU. This comprehensive QI initiative recently performed encompassed pharmacist-led educational modules, active discussions during daily interdisciplinary rounds, and proper execution of SATs and SBTs.¹⁵ The pharmacist verified SAT safety criteria were met, managed sedation protocols with nurses, and collaborated with physicians to deliver intermittent analgesia when indicated. Additionally, the pharmacist worked closely with RT to align SAT with SBT protocols. Finally, to sustain protocol adherence, formal educational sessions were conducted for newly inducted nurses in the MICU. Although previous research has not always shown alignment of reported and actual execution of daily SATs in ICUs, this pharmacist-led QI initiative indicated that consistent reminders and real-time feedback to nurses and RTs significantly improved SAT and SBT compliance rates.¹⁵

A recent large secondary analysis of 68 ICUs in the US investigated the factors associated with SAT/STB conduct in routine clinical practice.³⁰ The results indicated that significant pain, deep sedation/coma, less frequent level of arousal assessments, and the use of a benzodiazepine, ketamine, or antipsychotic medications were associated with failure to conduct an SAT the next day. Patients that were in deep sedation/coma, less routine delirium and level of arousal assessments done, and the use of benzodiazepines or ketamine were associated with increased conduct of an SBT the next day. Not only were the benefits of incorporating daily SATs and SBTs evident in MICUs but also in other ICU settings such as burn ICUs.³¹ More recently, the ABCDEF bundle, which includes SAT+STB performance, was shown to be successful in cardiac, surgical, and neuroscience units.¹¹

Our study has several strengths. To our knowledge, our study is the first published comparative evaluation of SAT and SBT conduct in MICU patients before and after publication of the 2018 PADIS guidelines (2008 vs 2021). Comparing the change in SAT and SBT conduct and focusing on failure reasons is pivotal for informing not only what changes have been made in clinical practice over the past 12 to 13 years but also why difference in performance and conduction may differ between clinical trial versus routine clinical care.

Our study also has a few noted limitations. The ABC Trial was a randomized trial during which SATs+STBs were conducted per protocol by research staff. Thus, these data do not reflect real-world use of SATs+STBs prior to the 2018 PADIS guidelines. However, this study provides helpful information by comparing performance and conduction during a controlled clinical trial to routine clinical practice. In the PILOT trial, we did not document which sedatives/analgesics

the patients were receiving. This would have allowed us to investigate if the administration of sedatives aligned with the 2018 PADIS guidelines. However, current practice in the MICU is to use nonbenzodiazepine sedation except rare cases when deep sedation is needed and propofol is clinically contraindicated. The coauthors on this paper are critical care leaders that have impacted the ICU clinical practice throughout the years and there is a possibility of confounding bias. However, implementation of the complete ABCDEF bundle (including SAT/STB) is already part of our institutional protocol implemented in the ICU during current clinical practice.

Conclusion

This study compared SAT + STB conduct in an ideal setting with that in a real-world practice setting years apart. Performance of SAT and STB safety screens, SATs, and STBs remains high in current clinical care (PILOT) many years after the definitive clinical trial (ABC) as both SAT and STB performance was completed in more than 90% of cases in both trials. Opportunities for more rigorous implementation in clinical care include optimization of anxiety, agitation, and analgesia and interprofessional education to maximize SAT safe screen and trial performance and conduction. Enhancing SAT and STB safety screen performance and conduct is an important component of the ABCDEF bundle to decrease delirium, optimize patient recovery, and improve outcomes in critically ill adult patients.

Declaration of Conflicting Interests

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