Prospective Validation of Sedation Scale Scores That Identify Light Sedation: A Pilot Study

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Background Intensive care unit (ICU) sedation guidelines recommend targeting a light sedation level, but light sedation has no accepted definition, and inconsistent levels have been proposed.
Objective To determine Sedation-Agitation Scale and Richmond Agitation-Sedation Scale scores that best describe patients' ability to follow voice commands.
Methods This prospective, observational pilot study enrolled a convenience sample of ICU patients receiving mechanical ventilation. Pairs of trained investigators evaluated scores on the Sedation-Agitation Scale and Richmond Agitation-Sedation Scale and ability to follow commands before and up to 2 hours after sedation lightening in a blind, independent, simultaneous fashion. Positive predictive values (PPVs) and likelihood ratios (LRs) of Sedation-Agitation Scale and Richmond Agitation-Sedation Scale scores associated with light sedation (ability to follow at least 3 commands) were calculated.
Results Ninety-six assessments (50 before and 46 after lightening of sedation) were performed in medical ICU patients. Scores best associated with ability to follow at least 3 commands were Sedation-Agitation Scale score of 4 (PPV, 0.88; 95% CI, 0.70-0.98; LR, 14.0) and Richmond Agitation-Sedation Scale score of –1 (PPV, 0.81; 95% CI, 0.61-0.93; LR, 10.7), superior to previously recommended thresholds of Sedation-Agitation Scale score of 3 (PPV, 0.62; 95% CI, 0.48-0.75; LR, 3.1) and Richmond Agitation-Sedation Scale score of –3 (PPV, 0.52; 95% CI, 0.39-0.64; LR, 2.0).
Conclusions The level of sedation most associated with the ability to follow commands appears higher than previously recommended. Further study is needed regarding the effects of sedation level on ICU patients' ability to follow commands and assessment of delirium, pain, and patient preferences. (*American Journal of Critical Care.* 2022;31:202-208)

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Comfort and sedation are central components of patient care in the intensive care unit (ICU). Two practice guidelines published in the past 10 years provided evidence-based recommendations for adult ICU sedation.[1,2] Both guidelines recommended avoiding oversedation and targeting light sedation for adult ICU patients.

The 2013 pain, agitation, and delirium (PAD) guidelines[1] defined light sedation as the ability to follow 3 commands according to studies identifying the benefits of sedation interruption.[3-5] The 2018 guidelines for the prevention and management of pain, agitation/sedation, delirium, immobility, and sleep disruption made similar recommendations favoring light sedation but also noted that no accepted definition of light sedation exists and called for further study into sedation level and its potential relationship to the ability to evaluate pain, delirium, and sleep.[2]

Numerous methods have been developed to assess sedation. Two agitation and sedation assessment tools subjected to rigorous psychometric analyses are recommended for monitoring the depth of ICU sedation[1,6]: the Sedation-Agitation Scale (SAS), developed[7] in 1994 and revised and validated[8] in 1999, and the Richmond Agitation-Sedation Scale (RASS), developed[9] in 2002 and revised[10] in 2003 (Table 1). Although the SAS and RASS both evaluate depth of sedation, they differ in several important ways. The SAS evaluates the ability to communicate and follow simple commands after verbal or physical stimuli, and the RASS assesses movement, eye opening, and duration of eye contact following verbal or physical stimulation.

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Although the developers defined the deeper limit of light sedation[8,9] as a SAS score of 3 and a RASS score of −2, differing thresholds have been proposed. For the RASS, values of −1, −2, and most commonly −3 have been suggested,[2,4,5,10-14] making it difficult to know what the lower limit of light sedation really is. These varying thresholds for SAS and RASS scores are not based on comparative evaluative trials. In addition to the uncertainties involving accurate description of sedation levels, the degree of wakefulness needed to accurately report pain or identify delirium remains unproven, and no consensus has been defined regarding the SAS or RASS score that correctly identifies light sedation per the 2013 PAD guideline definition of following commands.[1,2] In this pilot study, we sought to determine the SAS and RASS scores associated with light sedation, as proposed in the 2013 PAD guidelines, and to determine the accuracy of various SAS and RASS scores for identifying this light level of sedation.

> No accepted definition of light sedation exists—we need further study into sedation level and its relationship to pain, delirium, and sleep.

Methods

We enrolled a convenience sample of medical ICU patients receiving sedation and mechanical ventilation between June 2016 and May 2017 in our 42-bed multidisciplinary ICU in a 600-bed teaching hospital. Patients were excluded if they were not eligible for sedation lightening per the bedside nurse because of unstable hemodynamics, elevated intracranial pressure, a planned invasive procedure that day, or suspected withdrawal from alcohol or another substance. This study was approved as an observational human research study by the institutional review board at our medical center, with waiver of informed consent per federal guidelines.

Screening and Data Collection

Pairs of trained investigators simultaneously and independently assessed patients' ability to obey

Table 1
Sedation-Agitation Scale and Richmond Agitation-Sedation Scale

Score	Scale	Description
		Sedation-Agitation Scale
7	Dangerous agitation	Pulls at endotracheal tube, tries to remove catheters, climbs over bed rail, strikes at staff, thrashes side to side
6	Very agitated	Does not calm despite frequent verbal reminding of limits, requires physical restraints, bites endotracheal tube
5	Agitated	Anxious or mildly agitated, attempts to sit up, calms down to verbal instructions
4	Calm and cooperative	Calm, awakens easily, follows commands
3	Sedated	Difficult to arouse, awakens to verbal stimuli or gentle shaking but drifts off again, follows simple commands
2	Very sedated	Arouses to physical stimuli but does not communicate or follow commands, may move spontaneously
1	Unarousable	Minimal or no response to noxious stimuli, does not communicate or follow commands
		Richmond Agitation-Sedation Scale
+4	Combative	Overtly combative, violent, immediate danger to staff
+3	Very agitated	Pulls or removes tube(s) or catheter(s), aggressive
+2	Agitated	Frequent nonpurposeful movement, fights ventilator
+1	Restless	Anxious but movements not aggressive or vigorous
0	Alert and calm	
–1	Drowsy	Not fully alert but has sustained awakening (eye opening/eye contact) to voice (>10 seconds)
–2	Light sedation	Briefly awakens with eye contact to voice (<10 seconds)
–3	Moderate sedation	Has movement or eye opening to voice (but no eye contact)
–4	Deep sedation	No response to voice but has movement or eye opening to physical stimulation
–5	Unarousable	No response to voice or physical stimulation

4 specific commands and evaluated all elements necessary to score the SAS and RASS just before lightening continuous sedative medication and again before resuming sedative medication up to 2 hours later.

We defined light sedation as the ability to follow 3 of 4 voice commands.

The evaluators included 2 critical care physicians, 2 critical care pharmacists, and a fourth-year medical student. All evaluators were trained in a didactic session reviewing the 2 sedation scales and 4 voice commands (open or close eyes for 3 seconds, show 2 fingers, wiggle toes, and squeeze and release evaluator's hand), adapted from the 2013 PAD guidelines[1] and sedation interruption studies.[3-5] The evaluators practiced with several patients until agreement was reached.

During data collection, 1 evaluator conducted the assessment sessions while the other evaluator observed patient responses and timed eye contact. Immediately following each patient evaluation, the eye contact duration was reported and the investigators independently recorded the SAS score, the RASS score, and the number of commands the patient followed. If resumption of sedation was required before the end of the 2-hour lightening period, the evaluators attempted to complete the assessments before the resumption. Sedation could be resumed for patient or staff safety even if the second evaluations had not been completed. Evaluators were not blinded to their own initial assessment when they performed the follow-up assessment after sedation lightening, but they remained blinded to the other evaluator's assessment scores. We defined light sedation as the ability to follow 3 of the 4 voice commands. We collected baseline demographics, admitting diagnosis, continuous infusion sedative and analgesic medications and doses, Sequential Organ Failure Assessment score, and first 24-hour ICU Acute Physiology and Chronic Health Evaluation IV score.

Statistical Analysis

Patient demographic and medication data were described using means and SDs for normally distributed continuous variables, frequencies and percentages for categorical variables, and medians and interquartile ranges (IQRs) for ordinal and nonnormal continuous variables. The positive predictive value

(PPV) was chosen as the primary statistic variable, calculated as true positive divided by (true positive + false positive). For example, if 23 patients with a SAS score of 4 or above followed commands and 3 patients did not: 23/(23+3) = 0.88. Sensitivity, specificity, positive likelihood ratio (LR), and area under the receiver operating characteristic curve were also calculated for each SAS and RASS score, using light sedation (defined as following at least 3 commands) as the reference standard outcome. All data analyses were performed using R, version 1.2.1335 (R Foundation for Statistical Computing).

Results

A total of 96 SAS, RASS, and command-following assessments were done with 25 medical ICU patients. These assessments included 25 paired assessments by 2 evaluators during sedation and 23 paired assessments by 2 evaluators during sedation lightening. In 2 patients, sedation was restarted before their repeat assessments could be performed. As shown in Table 2, patients' mean (SD) age was 59 (12) years, 36% were female, the median (interquartile range) Sequential Organ Failure Assessment score was 8 (5-9), and respiratory failure and infections were the most common reasons for admission.

Sedation and Analgesia

At the time of the baseline assessments before sedation lightening, 9 of 25 patients (36%) were receiving infusions of both an opioid and a sedative, 6 (24%) were receiving analgosedation with an opioid infusion alone, 5 (20%) were receiving an infusion of an α_2 agonist with sedative and analgesic-sparing properties (including 3 with an accompanying opioid infusion), 4 (16%) were receiving a sedative infusion with intermittent opioid doses, and 1 (4%) was receiving no continuous opioid or sedative infusion. At the time of assessments after sedation lightening, 5 of 23 patients (22%) were receiving an α_2 agonist infusion at lower doses (3 with an opioid infusion), 5 (22%) were receiving infusions of both an opioid and a sedative agent, 1 (4%) was receiving a sedative alone, 2 (9%) were receiving an opioid alone, and 10 (43%) were receiving no continuous opioid or sedative infusion (Table 3).

Scale Evaluation for Light Sedation

Data on patients' ability to follow at least 3 commands at each SAS and RASS score are shown in Table 4 and the Figure. Of the 96 assessments in 25 patients, three or more commands were followed 33 times (34%). As indicated by the highest PPV for each sedation scale, a SAS score of 4 best predicted light sedation and ability to follow at least 3 commands (PPV = 0.88, as compared with PPV = 0.62 for a SAS score of 3). A RASS score of −1 best predicted light sedation (PPV = 0.81, as compared with PPV = 0.52 for a RASS score of −3 or PPV = 0.73 for a RASS score

Table 2
Demographic data for 25 patients in the study

Characteristic	Value
Age, mean (SD), y	59 (12)
Female sex, No. (%)	9 (36)
SOFA score, median (IQR)	8 (5-9)
Mechanical ventilation, No. (%)	24 (96)
APACHE IV score, mean (SD)	59 (20)
Total No. of patient assessments[a]	96
Admitting diagnosis	
Respiratory failure	9
Septic shock	2
Endocarditis	2
Bacteremia	2
Wound or abscess	2
Encephalopathy	2
Cardiac arrest	2
Overdose	1
Pancreatitis	1
Angioedema	1
Hepatic failure	1

Abbreviations: APACHE, Acute Physiology and Chronic Health Evaluation; SOFA, Sequential Organ Failure Assessment.

[a] An assessment included the Sedation-Agitation Scale, the Richmond Agitation-Sedation Scale, and response to 4 commands, assessed by 1 evaluator at 1 time point. Two evaluators assessed 25 patients before sedation lightening. Two evaluators reassessed 23 patients after sedation lightening; 2 patients did not receive reassessments before sedative medication was restarted.

Table 3
Continuous infusion medications for sedation and analgesia

Sedative/analgesic	No. (%) of patients	Infusion rate, mean (SD)
Before sedation lightening (n=25)		
Fentanyl	11 (44)	55 (24) μg/h
Hydromorphone	7 (28)	1.5 (1.2) mg/h
Propofol	9 (36)	29 (7) μg/kg/min
Dexmedetomidine	5 (20)	0.68 (0.4) μg/kg/h
Midazolam	4 (16)	3.75 (2.3) mg/h
During sedation lightening (n=23)		
Fentanyl	5 (22)	42.6 (21.7) μg/h
Hydromorphone	5 (22)	1.1 (0.7) mg/h
Propofol	5 (22)	19 (3.7) μg/kg/min
Dexmedetomidine	5 (22)	0.5 (0.5) μg/kg/h
Midazolam	1 (4)	7 mg/h

Table 4
Distribution of light sedation (defined as ability to follow at least 3 of 4 voice commands) by Sedation-Agitation Scale and Richmond Agitation-Sedation Scale scores

Score on scale	Follows 3 commands: No	Follows 3 commands: Yes	Positive predictive value (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)	Positive likelihood ratio
Sedation-Agitation Scale						
1	20	0	0.34 (0.25-0.45)	1.00 (0.89-1.00)	0.00 (0.00-0.06)	1.0
2	23	0	0.43 (0.32-0.55)	1.00 (0.89-1.00)	0.32 (0.21-0.45)	1.5
3	17	10	0.62 (0.48-0.75)	1.00 (0.89-1.00)	0.68 (0.55-0.79)	3.1
4	1	19	0.88 (0.70-0.98)	0.70 (0.51-0.84)	0.95 (0.87-0.99)	14.0
5	2	4	0.67 (0.22-0.96)	0.12 (0.03-0.28)	0.97 (0.89-1.00)	0.12
Richmond Agitation-Sedation Scale						
–5	13	0	0.34 (0.25-0.45)	1.00 (0.89-1.00)	0.00 (0.00-0.06)	1.0
–4	18	0	0.40 (0.29-0.51)	1.00 (0.89-1.00)	0.21 (0.11-0.33)	1.3
–3	21	3	0.52 (0.39-0.64)	1.00 (0.89-1.00)	0.50 (0.37-0.63)	2.0
–2	6	9	0.73 (0.57-0.86)	0.91 (0.76-0.98)	0.83 (0.71-0.91)	5.4
–1	1	10	0.81 (0.61-0.93)	0.64 (0.45-0.80)	0.94 (0.85-0.98)	10.7
0	0	9	0.73 (0.45-0.92)	0.33 (0.18-0.52)	0.93 (0.84-0.98)	0.4
1	2	2	0.33 (0.04-0.78)	0.06 (0.01-0.20)	0.94 (0.85-0.98)	0.1
2	2	0	0.00 (0.00-0.84)	0.00 (0.00-0.11)	0.97 (0.89-1.00)	0.0

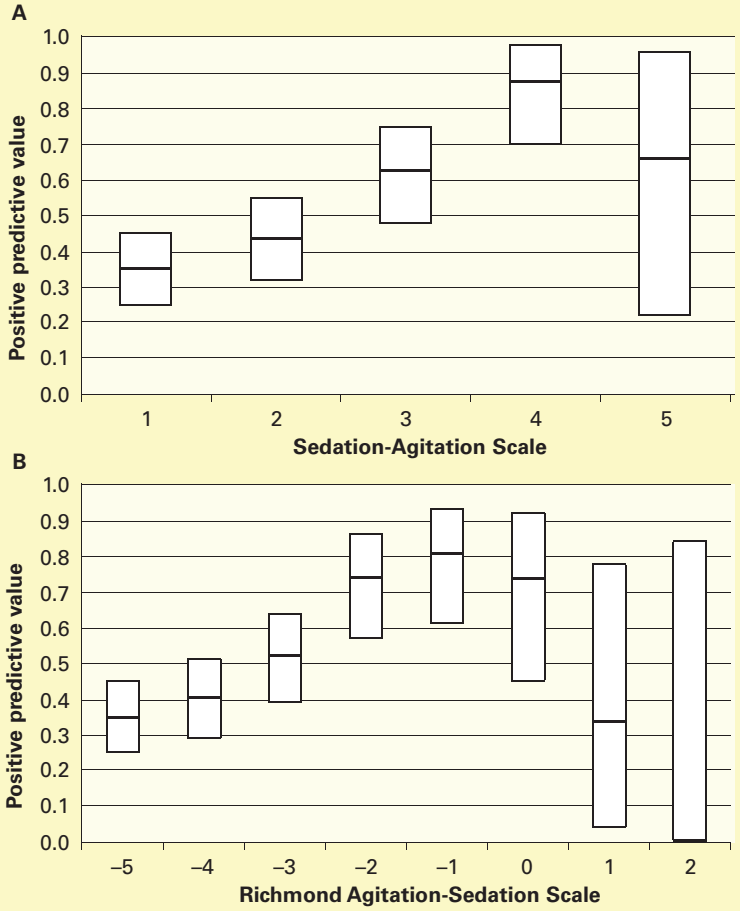

Figure Positive predictive values for Sedation-Agitation Scale scores (A) and Richmond Agitation-Sedation Scale scores (B) associated with light sedation (defined as ability to follow at least 3 commands). Positive predictive value is presented as value (bold central bar) and 95% CI.

of –2). The LRs identified the same sedation scale thresholds for the SAS (LR = 14.0 for a SAS score of 4, as compared with LR = 3.1 for a SAS score of 3) and the RASS (LR = 10.7 for a RASS score of –1, as compared with LR = 2.0 for a RASS score of –3). The area under the receiver operating characteristic curve to predict light sedation was 0.92 (95% CI, 0.87-0.97) for the SAS and 0.89 (95% CI, 0.83-0.96) for the RASS.

Discussion

Many assumptions have been made through the years regarding the level of sedation that corresponds to light sedation. Sedation assessment tools use different criteria to assess patients, and the designers incorporated their ideas and biases when creating the scales, empirically defining specific scores as light sedation. Both the 2013 and 2018 sedation guidelines identified that no clear consensus exists on how to define light versus deep sedation. In this study, we tested 2 validated and recommended ICU sedation scales,[1,6] the SAS and the RASS, defining light sedation as the ability to follow 3 commands as proposed in 2013.[1-5] Perhaps surprisingly, a SAS score of 4 and a RASS score of –1 predicted the ability to follow commands better than the conventionally recommended thresholds, a SAS score of 3 and a RASS score of –3. The implications of this study reach beyond the depth of sedation titration and extend to the level of sedation or wakefulness that is needed for accurate delirium assessment (when failure to follow commands is interpreted as delirium), accuracy of pain self-report, and perhaps even informed consent for procedures or research and critical discussions about goals of care.

These data are important because light sedation has been associated with improved clinical outcomes,[15-20] yet intermittent sedation is associated with greater recall of serious discomfort[21] and 43% of former ICU patients stated that they would prefer to receive more sedation if in the ICU again.[22] Additional uncertainty was revealed by a recent American Association of Critical-Care Nurses survey, in which 50% of nurses agreed that patients were oversedated if they were not following commands but 52% felt that patients were undersedated if they were spontaneously moving their trunk and legs.[23] Additionally, 2 recent randomized clinical trials used different definitions of light sedation (RASS score ranges of 0 to −2 or of −2 to −3).[24,25] A consistent and better understanding of what light sedation really means may help us better target sedation levels associated with better results.

Although sensitivity and PPV both assess the relationship between a screening test and a reference standard test, they do so differently. Sensitivity assesses only patients who attain positive results on the reference test and reports how many were positive on the screening test; PPV includes all patients with positive results on the screening test and reports how many were positive on the reference test. Applied to our question, sensitivity assesses how many patients who followed 3 commands (light sedation) had scores at or above the SAS or RASS threshold, and PPV assesses how many patients who had scores at or above the SAS or RASS threshold actually followed commands. When we assess patients at the bedside with a sedation scale, it is often the latter question we are trying to answer. Similarly, the LR identifies the probability that patients who can follow 3 commands will score at or above a sedation threshold as compared with those who cannot follow commands. Our LRs of 14.0 for a SAS score of 4 and of 10.7 for a RASS score of −1 are considered strong evidence.[26]

This study has several limitations that should be acknowledged. The data were collected using an observational approach from a small sample of patients in a medical ICU in a single center; this increases the chance for bias. Since predictive values change as the prevalence of the condition being tested changes, our results are most applicable to a cohort similar to ours in which 34% of patients overall were able to follow at least 3 commands. We also did not change or manipulate sedation dosing for research purposes, which would have allowed measurement of within-patient variability. Additionally, patients in this ICU had a range of diagnoses, including acute respiratory distress syndrome and sepsis. These diagnoses may increase the rate of encephalopathy, potentially confounding the data. The greatest challenge is understanding when failure to follow commands reflects the effects of sedation, is a component of delirium, or results from a combination of sedation effects and delirium. We did not assess delirium as part of this study, but future research should prospectively evaluate whether ability to follow commands at specific sedation levels applies to delirium or pain assessments. Finally, different drugs have varying types and durations of effect depending on drug class, intensity of dosing, pharmacokinetics, pharmacodynamics, and patient-specific factors.

The primary findings of our study demonstrate that a SAS score of 4 and a RASS score of −1 best satisfy criteria for light sedation as defined by the 2013 PAD guidelines. These thresholds for following commands are higher than those commonly proposed to assess pain or delirium. Patients exhibiting SAS and RASS scores at or above these thresholds may better cooperate with their caregivers, participate in their care, and respond accurately when pain, delirium, or patient preferences are being assessed. A recent review recommended a lighter sedation target of RASS scores ranging from +1 to −1, which would fit with our finding that patients with scores in this range are able to cooperate with commands.[27] If validated, these findings have major implications because they represent a shift in titration targets using these sedation scales and may affect how delirium and pain are assessed (for instance, by requiring a SAS score of 4 or a RASS score of −1 to reliably assess delirium). Whether our findings translate to improved outcomes remains to be tested, and further research in different settings with larger populations is needed.

A consistent and better understanding of what light sedation really means may help us better target sedation levels associated with better results.

Conclusions

Patients who meet criteria for light sedation, defined as ability to follow 3 commands, have higher SAS and RASS score thresholds than are commonly recommended. In our pilot study, a SAS score of 4 and a RASS score of −1 appear most strongly associated with the ability to follow multiple commands; our results require further validation.

FINANCIAL DISCLOSURES
None reported.

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1. Describe the potential differences in how a patient may respond to commands at a RASS of –3 or a RASS of –1 as sedation is reduced.
2. Prioritize the recognition of a patient's ability to follow 3 out of 4 commands during a sedation reduction maneuver.
3. Utilize the evidence suggested in clinical guideline recommendations to assess light sedation.

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