Reducing Deep Sedation and Delirium in Acute Lung Injury Patients: A Quality Improvement Project

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Objective: Deep sedation and delirium are common in the ICU. Mechanically ventilated patients with acute lung injury are at especially high risk for deep sedation, delirium, and associated long-term physical and neuropsychiatric impairments. We undertook an ICU-wide structured quality improvement project to decrease sedation and delirium.

Design: Prospective quality improvement project in comparison with a retrospective acute lung injury control group.

Setting: Sixteen-bed medical ICU in an academic teaching hospital with pre-existing use of goal-directed sedation with daily interruption of sedative infusions.

Patients: Consecutive acute lung injury patients.

Intervention: A “4Es” framework (engage, educate, execute, evaluate) was used as part of the quality improvement process. A new sedation protocol was created and implemented, which recommends a target Richmond Agitation Sedation Scale score of 0 (alert and calm) and requires failure of intermittent sedative dosing prior to starting continuous infusions. In addition, twice-daily delirium screening using the Confusion Assessment Method for the ICU was introduced into routine practice.

Measurements and Main Results: Sedative use and delirium status in acute lung injury patients after implementation of the quality improvement project (n = 82) were compared with a historical control group (n = 120). During the quality improvement vs. control periods, use of narcotic and benzodiazepine infusions were substantially lower (median proportion of medical ICU days per patient: 33% vs. 74%, and 22% vs. 70%, respectively, both p < 0.001). Further, wakefulness increased (median Richmond Agitation Sedation Scale score per patient: −1.5 vs. −4.0, p < 0.001), and days awake and not delirious increased (median proportion of medical ICU days per patient: 19% vs. 0%, p < 0.001).

Conclusion: Through a structured quality improvement process, use of sedative infusions can be substantially decreased and days awake without delirium significantly increased, even in severely ill, mechanically ventilated patients with acute lung injury. (Crit Care Med 2013; 41:0–0)

Key Words: adult; acute lung injury; critical illness; deep sedation; delirium; respiratory distress; quality improvement

Despite the potential benefits of reduced sedative use and delirium, many critically ill patients continue to be managed without daily sedative interruptions or delirium screening (13, 22–24). These findings are due, in part, to an assumption that severely ill patients require deep sedation (25, 26), and other
barriers encountered when attempting to change practice (27–29). Consequently, many ICU patients continue to experience deep sedation and delirium (25, 27, 30–33).

Acute lung injury (ALI) patients are at especially high risk for deep sedation, delirium, and long-term physical and neuropsychiatric impairments (3, 4, 31). A review of routine clinical practice for ALI patients in our medical ICU (MICU) demonstrated frequent use of continuous sedative infusions and a high prevalence of deep sedation and delirium (34, 35). We therefore undertook an MICU-wide, structured quality improvement (QI) project to change routine medical care and reduce sedation and delirium.

METHODS
Overview of Project—New Sedation and Delirium Screening Protocols
The QI project sought to change MICU practice in two ways: 1) decrease use of continuous sedative infusions, and 2) increase awareness, recognition, prevention, and management of delirium. These changes were implemented using a new sedation protocol that is consistent with published guidelines combined with introduction of twice-daily delirium screening using Confusion Assessment Method for ICU (CAM-ICU) (36–38).

The new protocol (Fig. 1) was approved for use in April 2009. It encouraged MICU physicians to target a Richmond Agitation Sedation Scale (RASS) score of 0 (“alert and calm”) in all patients, including mechanically ventilated patients, and required failure of “as-needed” intermittent dosing before continuous infusions were used. Sedatives delivered via either continuous infusion or intermittent dosing were discontinued daily at 8 AM. Our previous protocol utilized goal-directed sedation and a modified daily interruption of fentanyl and midazolam infusions (50% reduction rather than complete interruption). An important aspect of the protocol was training bedside nurses to anticipate agitated delirium as patients awoke following discontinuation of sedatives. Although nurses

![Figure 1. New sedation strategy. Clinicians choose a Richmond Agitation Sedation Scale (RASS) target. If needed, patients then start on intermittent sedation. If initial and maintenance doses are inadequate to achieve RASS target, breakthrough dosing is allowed. If more than three breakthrough doses are administered in a 2-hr period, the intermittent sedation strategy is discontinued, and continuous infusions are started. Daily at 8 AM, all sedatives are discontinued (intermittent and continuous). Agitation is anticipated and haloperidol is suggested for treatment if the CAM-ICU is positive. If RASS is 2+ for more than 4 hr, intermittent sedation resumes. If RASS is greater than 2+, intermittent sedation resumes even if 4 hr have not passed. Continuous infusions are only re-administered if the patient again breaks through the intermittent sedative dosing.](image-url)
were initially reluctant, after training them to recognize delirium (see below), and treat it with nonpharmacologic and pharmacologic approaches, they agreed to tolerate a RASS of +2 for up to 4 hours before resuming intermittent sedation.

**QI Process: 4E’s Model**

Changes in practice were implemented using a structured QI process, using a “4Es” framework (engage, educate, execute, and evaluate (40)).

**Engaging and Educating.** The QI team was drawn from the pre-existing multidisciplinary MICU Clinical Practice Committee, including the MICU nurse educator (S.S.), pharmacist (A.R.), and physicians (D.N.H., D.M.N., R.G.B.). This group was supplemented by three non-MICU delirium experts: two psychiatrists (O.J.B., K.J.N.) and a rehabilitation neuropsychologist (P.T.).

The QI team focused on three clinician groups (day and night nursing staff, housestaff, and attending physicians) to inform them of the rationale for changing practice and importance of screening, preventing, and treating delirium. The QI team educated these groups regarding the new sedation protocol, RASS, and CAM-ICU tools, and common methods for preventing and treating delirium (41, 42).

Nurses were introduced to the sedation protocol by the MICU nurse educator and a protocol “super user” and then worked through case study examples. Training in the use of RASS and CAM-ICU tools was modeled after the process used to train the staff (nurses and nonclinicians) hired by the research team to collect data during the control period. Specifically, “super-users” were trained by a local physician expert (D.M.N.) and a nursing expert from Vanderbilt University. This training included an instructional presentation, case study examples, and a quiz.

Thereafter, super-users underwent formal quality assurance (QA) evaluations by the local expert (D.M.N.) to confirm accuracy of their RASS and CAM-ICU assessments. Super-users then performed similar QA evaluations of the remaining MICU nurses. Nurses who did not pass QA evaluations had additional one-on-one training and repeated evaluations until proficient. Correct administration of RASS and CAM-ICU became part of the ongoing MICU nursing competency evaluation process.

Housestaff were educated by two physicians from QI team (DNH and DMN) during their MICU orientation. All housestaff were provided with a “Sedation and Delirium Survival Card” that included: a) overview of RASS and CAM-ICU adapted, with permission, from an existing source (www.icudelirium.org), b) abbreviated guide to the sedation protocol, and c) strategies to prevent and treat delirium based on existing literature, such as avoiding deliriogenic medications, correcting electrolytes and other physiologic abnormalities, frequent reorientation, and using eye-glasses and hearing aids (41, 42). MICU-attending physicians were educated during grand rounds and regular meetings of MICU faculty.

**Executing.** On July 1, 2009, the old sedation protocol was removed from the electronic order entry system and replaced by the new protocol, and RASS and CAM-ICU assessments were introduced into the electronic medical record. These changes coincided with the start day for new housestaff, decreasing the number of prescribers needing to change practice. Super-users were present during day and night shifts to answer questions about the new sedation strategy, and RASS and CAM-ICU assessments. On morning rounds, bedside nurses reported each patient’s target and actual RASS score, and CAM-ICU status. This information was incorporated into medical decision making by including it in the housestaff progress note template.

**Evaluating.** After execution, the QI team continued meeting monthly to identify and resolve barriers to successful implementation. As was done for research staff during the control period, formal audit and feedback was conducted regarding the accuracy of nurse RASS and CAM-ICU assessments. Further, formal audit and feedback was conducted regarding adherence to the new sedation protocol. Nursing staff were surveyed regarding their experience with the delirium education and assessment process, which helped to anonymously identify concerns and focus additional educational efforts. Furthermore, during daily bedside rounds, the MICU pharmacist (A.R.) reviewed sedation and delirium practices and reminded clinicians regarding the sedation protocol, and delirium screening and management.

**Evaluation of the QI Project**

A formal comparison of sedative use, and sedation (RASS) and delirium (CAM-ICU) status before and after implementation of the QI project was conducted. Data for the control (before) period for the Johns Hopkins MICU was obtained from a pre-existing, multisite prospective cohort study of consecutive mechanically ventilated ALI patients conducted over a 30-month period from November 2004 to April 2007 (43). Data for the QI (after) period were prospectively collected as part of a pre-existing MICU clinical registry for the 20-month period from July 2009 to April 2011. No data were collected from May 2007 to June 2009 when the QI project was in its planning phases and the sedation protocol was being developed. During both control and QI periods, the 16-bed MICU had no changes in the type of patients referred and admitted, or staffing structure. However, an early physical medicine and rehabilitation program and efforts to improve sleep in the ICU were introduced during the QI period, as described subsequently.

**Patient Selection for Evaluation**

In both control and QI periods, consecutive mechanically ventilated ALI patients were prospectively identified using standard criteria (44). Eligibility criteria were based on those used in the cohort study which provided control group data (43) excluding patients with: a) a pre-existing illness with a life expectancy of <6 months; b) homelessness; c) pre-existing limitations on ICU care; d) unable to speak or understand English; e) more than 5 days of mechanical ventilation before ALI or transfer from another ICU with pre-existing ALI for more than 24 hours; or f) prior lung resection.

**Data Collection**

Data were collected from medical records, including patient demographics, body mass index, comorbidity (Charlson and...
Hager et al

Functional Comorbidity Indices (45, 46)), MICU admission diagnosis, and Acute Physiology and Chronic Health Evaluation (APACHE) II score (47). Sedation and delirium data collection for both the QI and control periods included daily measures of: a) continuous infusions of benzodiazepines and narcotics (7 d per wk), and b) RASS and CAM-ICU scores (5 days per week; Monday to Friday). Because RASS and CAM-ICU data collection did not routinely occur on weekends during the control period when these assessments were made by research staff, weekend assessments of RASS and CAM-ICU obtained during the QI period were excluded from this analysis to ensure comparability between the control and QI periods. Standardized patient reported (or behavioral if indicated) daily pain scores (range: 0–10, with 10 indicating greater pain) were recorded by nurses as part of routine care, and prospectively collected from the medical record for the QI period, but not available during the control period.

Statistical Analysis
Descriptive statistics were used to summarize data. For daily ICU data, the patient (rather than MICU day) was the unit of analysis to prevent a small number of patients with a long length of stay from unduly influencing the results. Stata version 10 (College Station, TX) was used for all analyses. A two-sided p value less than 0.05 was considered statistically significant. The Johns Hopkins University institutional review board approved the prospective cohort study providing the control group data and use of the MICU clinical registry database providing the QI data. Reporting of this project are in accordance with the SQUIRE guidelines for QI (48).

RESULTS

Patient Characteristics
During the 20-month QI period and the 30-month control period, a total of 82 and 120 ALI patients were included in the analysis, respectively. The QI and control groups were similar with respect to age, sex, race, body mass index, and ICU admission diagnosis (Table 1). Both groups had a similarly high median APACHE II severity of illness score of 29. During the QI versus control period, patients had better Charlson Comorbidity Index and worse Functional Comorbidity Index scores.

Medication Use, and Sedation and Delirium Status
The median proportion of MICU days per patient with narcotic and benzodiazepine infusions during the QI period was

<table>
<thead>
<tr>
<th>TABLE 1. Baseline Characteristics</th>
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<tbody>
<tr>
<td><strong>Before Quality Improvement</strong> n = 120</td>
</tr>
<tr>
<td><strong>Age, median (IQR)</strong></td>
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<tr>
<td><strong>Male, n (%)</strong></td>
</tr>
<tr>
<td><strong>Race, n (%)</strong></td>
</tr>
<tr>
<td><strong>White</strong></td>
</tr>
<tr>
<td><strong>Black</strong></td>
</tr>
<tr>
<td><strong>Other</strong></td>
</tr>
<tr>
<td><strong>Body mass indexb, median (IQR)</strong></td>
</tr>
<tr>
<td><strong>Comorbidity, median (IQR)</strong></td>
</tr>
<tr>
<td><strong>Charlson Index</strong></td>
</tr>
<tr>
<td><strong>Functional Index</strong></td>
</tr>
<tr>
<td><strong>Acute Physiology and Chronic Health Evaluation II at ICU admission, median (IQR)</strong></td>
</tr>
<tr>
<td><strong>ICU admission diagnosis, n (%)</strong></td>
</tr>
<tr>
<td><strong>Respiratory (including pneumonia)</strong></td>
</tr>
<tr>
<td><strong>Gastrointestinal</strong></td>
</tr>
<tr>
<td><strong>Sepsis, nonpulmonary source</strong></td>
</tr>
<tr>
<td><strong>Cardiovascular</strong></td>
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<tr>
<td><strong>Central nervous system</strong></td>
</tr>
<tr>
<td><strong>Other</strong></td>
</tr>
</tbody>
</table>

IQR = interquartile range.
a p values calculated using Wilcoxon rank sum test and Fisher’s exact test.
b Missing data: Two patients in “before quality improvement” and 16 in “after quality improvement”.

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Clinical Investigation

less than during the control period (33% vs. 74% and 22% vs. 70%, respectively; both $p < 0.001$; Table 2). The QI period also had a higher median RASS score per patient indicating greater wakefulness ($−1.5$ vs. $−4$, $p < 0.001$) and a greater median proportion of MICU days per patient (50% vs. 20%, $p < 0.001$) without sedation (RASS +1, 0, or −1). Similarly, coma (RASS −4 or −5) also was lower during the QI period (23% vs. 63%, $p < 0.001$), and patients were more often awake and not delirious (19% vs. 0%, $p < 0.001$). However, the median proportion of days per patient with delirium increased (38% vs. 20%, $p = 0.01$). Lastly, despite reduced use of sedative infusions and increased wakefulness, the median and interquartile range (IQR) for the average daily pain score per patient during the QI period was very low at 0.5 (0.0, 1.0).

### Compliance with RASS and CAM-ICU

The number of RASS assessments not completed during the QI and control periods were 53 (6%) and 93 (10%), respectively. For CAM-ICU assessments, the number not completed were 79 (10%) and 53 (6%), respectively.

### DISCUSSION

Using a structured QI process, we demonstrated substantial reductions in sedative infusions, increased wakefulness, and increased days awake and not delirious among mechanically ventilated ALI patients with a high severity of illness. The QI process was implemented using a previously successful 4Es model (engaging, educating, executing, and evaluating (40)). Central to this QI project was a new sedation protocol directing clinicians to target an “alert and calm” sedation goal and use of intermittent (rather than continuous) dosing of sedatives in all patients whenever feasible. These interventions supplemented our pre-existing protocol for goal-directed sedation with daily interruption of infusions. Further, twice-daily delirium screening was added to existing nursing assessments of sedation and pain. This facilitated delirium identification, prevention, and treatment.

The QI project created a substantial change. First, the median proportion of days per patient during which continuous infusions of benzodiazepines and narcotics were used was significantly reduced despite high APACHE II severity of illness scores. Second, patients achieved higher levels of wakefulness. Finally, there was a significant increase in days awake without delirium. These changes were implemented while maintaining low pain scores, providing assurance that an important unintended consequence (substantial pain) did not occur.

Despite the notable change in sedation practice and increased wakefulness, most patients were still comatose (RASS −4 or −5) or delirious for the majority of assessments. This finding likely reflects patients’ severity of illness and the impact of other less modifiable risk factors for delirium (e.g., sepsis, hypoxemia, hypercarbia, uremia, and liver failure) (49, 50).

Several factors contributed to these QI changes. First, although goal-directed sedation was used in our prior protocol, the new protocol had an explicit goal of “alert and calm” (RASS 0), which has not been a focus in earlier studies of goal-directed sedation. Consistent with a randomized trial of “no sedation” (analgesia only (14)), we demonstrated that even in patients with high severity of illness, avoidance of sedative infusions is possible for most ICU days for the majority of ALI patients.

### TABLE 2. Sedation, Delirium and Activity Status

<table>
<thead>
<tr>
<th>Sedation Status</th>
<th>Before Quality Improvement</th>
<th>After Quality Improvement</th>
<th>p*</th>
</tr>
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<tbody>
<tr>
<td>Sedative infusion (% of MICU d per patient, median (IQR))</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Narcotic</td>
<td>74 (50, 100)</td>
<td>33 (10, 65)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Benzodiazepine</td>
<td>70 (46, 94)</td>
<td>22 (0, 50)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Median RASS Score per patient, median (IQR)a</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not sedated (RASS −1, 0, +1)</td>
<td>20 (0, 50)</td>
<td>50 (20, 72)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Sedated (RASS −2, −3, −4 or −5)</td>
<td>78 (29, 100)</td>
<td>50 (21, 71)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Agitated (RASS &gt;+2)</td>
<td>0 (0, 0)</td>
<td>0 (0, 4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Delirium status (%) of MICU d per patient, median (IQR)a</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Awake and not delirious</td>
<td>0 (0, 18)</td>
<td>19 (0, 50)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Delirious</td>
<td>20 (0, 40)</td>
<td>38 (0, 60)</td>
<td>0.010</td>
</tr>
<tr>
<td>Comatose</td>
<td>65 (27, 100)</td>
<td>23 (0, 50)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

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Several factors contributed to these QI changes. First, although goal-directed sedation was used in our prior protocol, the new protocol had an explicit goal of “alert and calm” (RASS 0), which has not been a focus in earlier studies of goal-directed sedation. Consistent with a randomized trial of “no sedation” (analgesia only (14)), we demonstrated that even in patients with high severity of illness, avoidance of sedative infusions is possible for most ICU days for the majority of ALI patients.
patients. Second, because protocols alone may not be successful in changing practice, ours was developed and deployed within a structured QI process that “engaged” and “educated” all MICU clinician groups about the change in practice and included ongoing “evaluation” with audit and feedback. Moreover, the QI process utilized an interdisciplinary QI team including MICU physicians, nursing and pharmacy representatives, and delirium experts from psychiatry and rehabilitation neuropsychology. This group worked to identify and overcome barriers during planning and execution of the QI project. Third, integrating changes in sedation along with delirium screening, prevention, and treatment likely had a synergistic effect since sedation practices have a major influence on delirium (11, 51, 52).

At least two prior ICU studies have included a multidisciplinary team and new protocols to change medication use and sedation and delirium status. One study of 1,133 patients conducted in a medical–surgical ICU evaluated new protocols for analgesia, sedation, and delirium. Reduced narcotic use, less sedation-related coma, and improvements in normal cognition (i.e., absence of both delirium and subsyndromal delirium) were observed (10). This study differed from ours in evaluating a broader group of patients, including nonmechanically ventilated patients, with a lower median APACHE II score (17 vs. 29) and a higher preintervention median RASS score (0 vs. −4). A second before–after study conducted in a surgical ICU evaluated 119 trauma and surgery patients (median APACHE II score of 14) with similar goals to our QI project. This study introduced a new protocol that included routine RASS and CAM-ICU assessments, a RASS goal of −1 to +1, pain evaluation and control, and treatment of agitated delirium with nonpharmacologic interventions and haloperidol (53). Significant reductions in sedative and narcotic use were observed. The findings in these two studies and ours suggest that these results may well be generalizable to other ICUs.

It is notable that reductions in delirium have not been previously reported in the context of protocols that seek to reduce sedative administration. This is true of our study as well. Although we had an increase in the proportion of days per patient on which they were awake without delirium, we also had an increase in the proportion with delirium as more ALI patients emerged from sedative-induced coma. This is not unexpected given the hypothesized continuum of coma, delirium, and consciousness in many patients (11, 52, 54–56). Despite this increase in delirium, the combined endpoint of coma and delirium (a gross measure of brain dysfunction) was significantly reduced in the QI group. A second reason for our observed increase in delirium may be the use of deliriogenic sedative medications to manage some agitated patients as they emerged from sedative-induced coma. Although our sedation protocol encouraged risk factor modification and use of haloperidol to treat agitated delirium, anecdotaly we know that this did not always occur. As we gain greater experience and confidence in nonpharmacologic and pharmacologic approaches to preventing and managing delirium, we anticipate delirium will be further reduced.

There are potential limitations to this report. First, during the QI period, early physical medicine and rehabilitation (an ongoing program) and sleep QI (a 5-mo project) were introduced in our MICU in July 2009 and March 2010, respectively. Both interventions had the potential of reducing the duration and/or incidence of delirium (57–59). Although these efforts may have contributed to the observed increase in wakefulness without delirium (vs. control period), they did not involve any sedation-related intervention and cannot account for the substantial changes in sedative infusions and sedation status that are more clearly recognized risk factors for delirium (11). Moreover, a sensitivity analysis in which patient data obtained during the Sleep QI project (March 2010 onwards) were removed from the QI period did not materially change from the results of the original analysis.

A second potential limitation was our ability to detect delirium. Although several investigators have independently demonstrated that the CAM-ICU has a high sensitivity and specificity, the CAM-ICU in these studies was usually administered by research personnel (37, 38, 60–65). A multisite Dutch study, comparing the CAM-ICU administered by ICU nurses against three delirium experts using DSM-IV criteria, demonstrated a CAM-ICU sensitivity and specificity of 47% and 98%, respectively (66). However, bedside nurses received only 30 mins of CAM-ICU training at least 12 months prior to the study, and the CAM-ICU was not always used in medical decision making. When limited to centers that always used the CAM-ICU in clinical practice, the sensitivity increased to 71%. These findings demonstrate the importance of structured QI projects with ongoing competency evaluation, and audit and feedback (67). A separate study in three ICUs, also evaluating delirium screening by nonresearch nurses, demonstrated that when the CAM-ICU was implemented in this way it had a higher sensitivity and specificity (0.81 and 0.81, respectively) than the Dutch study, despite the CAM-ICU being introduced to the ICUs years before (68). In our study, delirium was assessed by nursing staff during the QI period and research staff during the control period. However, both groups received very similar CAM-ICU training. Further, because an increase in the median proportion of days per patient with delirium was observed during our QI period, we believe detection of delirium during the QI period was at least as good as during the control period.

A third limitation is the lack of data describing adverse effects, such as self-extubations, in our project. However, our institution independently records self-extubations through a voluntary reporting system. Review of two 6-month blocks (July–December) during the QI and control periods showed that six and 15 self-extubations were recorded, respectively. Although these data were not limited to ALI patients, they do not suggest increased rates of self-extubation consistent with previous research (7).

Lastly, there was an interphase of approximately 2 years between the control and QI periods due to the time required to create the new sedation protocol and prepare it for a new electronic order-entry system (18 mo). Further time was then needed to train a large MICU staff (nurses, faculty, and housestaff) in the use of the protocol as well as the RASS and
In conclusion, an interdisciplinary team using a structured QI process substantially changed routine practice to decrease use of continuous sedative infusions and increase days awake without delirium in mechanically ventilated ALL patients with a high severity of illness. Future work should focus on additional changes in ICU clinical care to address other modifiable risk factors for delirium.

REFERENCES

Hager et al


