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Correlation of patient-reported outcomes of sedation and sedation assessment scores in critically ill patients

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ABSTRACT

Purpose: Patient-reported outcomes (PROs) are recommended as indicators of quality in the intensive care unit. We studied the correlation between PROs of sedation quality and a universal sedation assessment scale in critically ill patients.
Materials and methods: Twenty-nine mechanically ventilated adults admitted to a surgical/trauma or medical intensive care unit requiring continuous infusion sedation for 24 hours or more were prospectively included. Patient-reported outcomes were evaluated through sedation questionnaire 24 hours post–continuous infusion sedation. The primary outcome was the correlation of PROs with Sedation-Agitation Scale (SAS) scores.
Results: Mean (SD) SAS scores per 12-hour nursing shift for propofol (n = 179), midazolam (n = 42), and dexmedetomidine (n = 8) were 3.78 (77), 3.31 (1.1), and 2.98 (0.76), respectively. The mean score for survey questions addressing perceptions of comfort was 5.3 (1, complete comfort; 10, not comfortable at all). Of the patients, 34%, 7%, and 52% would want more, less, or the same amount of sedation, respectively, if this situation were to arise again. Patient perception of comfort correlated with the percent time at goal SAS score; $r = 0.31$ ($P < .05$).
Conclusion: Patient-reported outcomes of sedation correlate with the percentage of time spent in the goal range of scores for a universal sedation assessment scale. These findings represent initial attempts to appreciate the patient's perspective in the management and monitoring of agitation.

1. Introduction

In 2001, the Institute of Medicine named patient-centered care as 1 of the 6 fundamental aims of the US health care system [1]. Since then, health care has evolved away from a "disease-centered" model, and toward a "patient-centered" one in which patients more actively participate in their own care. In this model, patient feedback is used to both monitor the impact of specific interventions and benchmark the quality of care provided [2-4]. This shift toward patient-centered care has meant that a broader range of outcomes from the patient's perspective need to be measured, to understand the true benefits and risks of health care interventions [5,6]. These patient-reported outcomes (PROs) are highly recommended as indicators of quality even in acute care settings such as the intensive care unit (ICU) [7].

However, despite the recognized importance of acquiring PROs related to ICU practices, little is known regarding the patient's perspective of sedation therapy to manage agitation. More than 70% of critically ill patients in the ICU setting experience agitation [8]. It can originate from a multitude of sources including pain, delirium, hypotension, hypoglycemia, and withdrawal from alcohol or other drugs. Although a universal patient care goal for critical care practitioners is to maintain an "optimal" level of comfort through the use of sedatives, it is estimated that 40% to 60% of patients are mismanaged with either inadequate relief of anxiety or oversedation [9-11]. Subjective sedation scales such as the Sedation-Agitation Scale (SAS) [12] have become useful tools for critical care practitioners in determining goals for sedation therapy and are recommended as valid and reliable sedation assessment instruments for measuring quality and depth of sedation in adult ICU patients [13].

In 2005, Corbett et al [14] studied patient perceptions of short-term sedation with propofol and dexmedetomidine in 89 surgical ICU patients at a tertiary care facility. Using a numerical scale questionnaire, they found no differences in responses to pain control or the prevalence of amnesia between groups. However, compared with receiving propofol, dexmedetomidine patients expressed more discomfort ($P = .046$) during mechanical ventilation and sleeping difficulties ($P = .036$). Similar comfort levels were reported during extubation [14].

Although this study reported PROs related to sedation in ICU patients, it was limited in terms of the sedatives that were compared. In addition, it did not correlate PROs with scores from sedation assessment scales, which is in contrast to the growing literature correlating PROs of pain to pain intensity scales [15-18].

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To address these gaps in the research literature, our study investigated the correlation between PROs of sedation quality and a universal sedation assessment scale in critically ill patients receiving propofol, midazolam, or dexmedetomidine. Patient perceptions of sedation as PROs in the ICU were captured through a validated numerical questionnaire and then correlated with SAS scores. The purpose of this study was to gain insight into the risks and benefits of a common ICU practice such as sedation, using a patient-centered model. To our knowledge, there has been no published literature correlating PROs of sedation quality to sedation assessment scales.

2. Materials and methods

2.1. Study population

A prospective, single-center study was conducted, screening all patients admitted to a 22-bed surgical/trauma and 24-bed medical ICU at a tertiary care facility from February 1, 2011, to May 1, 2011. All eligible patients were surveyed to determine their level of satisfaction while on sedation therapy for mechanical ventilation in the ICU. No randomization protocols were used. Patients were considered for questionnaire administration if 18 years or older; had received mechanical ventilation; required continuous infusion midazolam, propofol, and/or dexmedetomidine for 24 hours or more while mechanically ventilated; and had been off of continuous infusion sedation for 24 hours or more. Reasons for exclusion included (1) the inability to obtain informed consent, (2) any neurologic impairment or recent severe central nervous system trauma that could potentially alter the patient's ability to reasonably complete a questionnaire, (3) known history of alcohol or drug abuse and/or withdrawal, (4) acute hepatic encephalopathy, (5) use of neuromuscular blocking agents other than for rapid sequence intubation, and (6) non–English speaking.

2.2. Questionnaire administration

This study was approved with obtainment of informed consent as required by the University of Pittsburgh Institutional Review Board. Before study commencement, investigators developed consensus regarding the administration of the questionnaire, including introductions to the patient, explanations of the study, consent provision statements, and plans to engage patients having difficulty with specific questions on the questionnaire. In addition, the initial 3 interviews were completed with all surveying investigators present to ensure consistency and minimize subjectivity.

Eligible patients were approached by a study investigator, who was a clinical pharmacist, and then were provided with an explanation of the study along with the option to participate. After informed consent, patient's perceptions of sedation were evaluated through completion of the Hewitt sedation questionnaire, [19] modified and validated for use in ICU patients [14]. The questionnaire afforded investigators the means to evaluate patient perspectives through a 1-to-10 scale and included questions regarding recall and awareness, generalized comfort level, pain level, ability to interact with health care providers and family, feelings of agitation and anxiety, perceived ease of extubation, ability to sleep or rest, and satisfaction with ICU experience. Five questions were added to the modified Hewitt questionnaire by investigators to further evaluate the patient perceptions of pain, anxiety, panic, frustration, and discomfort while mechanically ventilated (Figure). If a patient was consented but unable to complete the survey at 24-hour post–continuous infusion, repeat interviews were attempted every 24 hours until ICU discharge.

2.3. Data collection

In addition to questionnaire results, standardized data collection was used to record pertinent findings, including patient demographics, admission diagnosis, SAS assessment scores, Simplified Acute Physiology Score II (SAPS II) severity of illness scores [20], duration of mechanical ventilation, duration of sedative use, concomitant analgesia dosing and duration, and time of patient interview from the cessation of continuous infusion sedation. Hourly sedative administration rates were recorded for midazolam, propofol, and dexmedetomidine.

Because physicians changed which sedative was used for particular patients (based on preference), a within-person natural experiment occurred such that the experimental conditions consisted of midazolam vs propofol vs dexmedetomidine. Using mixed model trajectory analysis (described below), differences between the 3 sedatives were compared as if an idiographic clinical trial had been conducted [21].

2.4. Outcomes

The primary outcome was the correlation of PROs of sedation captured by the modified Hewitt questionnaire with sedation assessment scores recorded by health care professionals through the SAS. Secondary outcomes include description of sedative agents, doses, durations, and time spent at goal SAS.

2.5. Statistical analysis

Primary analysis tested the correlation of patient survey results with patient SAS scores, as evaluated by the Pearson *r* test. Secondary outcomes evaluated dose interquartile ranges (IQRs) and median durations for all sedatives and analgesia medications as well as mean SAS scores associated with each agent.

As alluded to earlier, mixed model trajectory analysis was used to test differences between the 3 sedatives within persons. Dexmedetomidine was rarely used, so analyses compared propofol vs either of the alternatives (dexmedetomidine or midazolam). Advantages of this analytic technique for testing differences within persons include its ability to account for autocorrelation with several error covariance structures available, statistical power for detecting differences in change over time (ie, between sedatives), relatively few observations per experimental condition are needed compared to alternative analytic techniques, and conservative estimates of effect size are generated [21]. Results were presented in the form of a regression equation to be easily understood by the widest readership. The outcome (Y′) was the absolute value of how far a SAS scores was from the optimal SAS range (3.0-4.0). To illustrate, a SAS score of 5.0 was scored as an outcome of $1.0 = |5.0\text{-}4.0|$ and a SAS score of 1.5 was scored as an outcome of $1.5 = |1.5\text{-}3.0|$. Outcomes were analyzed as the mean score during a 12-hour nursing shift because, for some shifts, multiple SAS ratings were made.

3. Results

3.1. Patient population

A total of 226 ICU patients were screened for inclusion over the 3-month study. Forty-four patients met initial inclusion criteria, of which 9 were unable to be successfully interviewed before ICU discharge, and 6 declined to participate. Twenty-nine ICU patients were interviewed. Demographics of these patients are shown in Table 1. Most were male surgical patients with predicted mortality rates of approximately 15% based on SAPS II scores. Respiratory failure and motor vehicle/motorcycle collisions were the most common admission diagnoses; lengths of ICU stay and days on mechanical ventilation were extensive (Table 1).