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Original Contributions

UTILITY OF PROCEDURAL SEDATION AS A MARKER FOR QUALITY ASSURANCE IN EMERGENCY MEDICINE

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☐ **Abstract—Background: The Joint Commission requires health care organizations to monitor and evaluate procedural sedation. However, the utility of mandatory review of procedural sedation in evaluating health care quality is unknown. Objective: To determine whether procedural sedation is a useful marker for evaluating error in the emergency department (ED). Methods: We prospectively collected data for patients presenting to an urban, tertiary care, academic medical center ED between October 2013 and June 2015. We used an automated, electronic tracking system to identify patients who underwent procedural sedation. We randomly assigned cases to physician reviewers. Reviewers used a structured tool to determine the presence of error and adverse events. If a reviewer felt that the case had an error or adverse event, it was referred to a quality assurance (QA) committee, which made a final determination as to whether or not an error or adverse event occurred. Results: There were 166 cases of procedural sedation reviewed. Two errors were identified, for an error rate of 1.2% (95% confidence interval [CI] 0.003–0.043). Both errors occurred during the use of propofol to facilitate upper gastrointestinal endoscopy. Neither error resulted in an adverse event. One adverse event was identified that was unrelated to physician error (0.6%; 95% CI 0.001–0.033). Conclusion: Routine review of procedural sedation performed in the ED offers little advantage over existing QA markers. Directed review of high-risk cases, such as those involving endoscopy or other longer-duration procedures, may be more useful. Future studies focusing quality review on projected high-risk sedation cases may establish more valuable markers for QA review.** © 2016 Elsevier Inc.

☐ **Keywords—procedural sedation; quality assurance; error; adverse event; conscious sedation**

INTRODUCTION

Preventable error is known to be a significant cause of morbidity and mortality in all fields of medicine. Landmark studies from the 1990s found that nearly 4% of hospitalized patients suffered disabling complications from treatment, two-thirds of which were attributable to provider error (1,2). Since the publication of these studies, national awareness and scrutiny of medical errors has increased, as have efforts to reduce the occurrence of errors and adverse events. Yet, appropriate markers and identifiers of error have not been determined.

In an effort to help curb medical error, the Joint Commission has required health care organizations to demonstrate adherence to a multitude of patient safety standards. One such standard applies to the use of procedural sedation and mandates that use of sedation be consistently "monitored and evaluated" (3). Precisely how procedural sedation should be monitored and evaluated is not described. Our emergency department (ED), like many others, conducts a formal quality assurance (QA) review of each instance of procedural sedation. However, the utility of this review is unknown.

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The purpose of this study is to determine whether procedural sedation is a useful marker for evaluating error in the ED.

MATERIALS AND METHODS

Study Design and Setting

We conducted a prospective, cohort study of consecutive patients presenting to an urban, tertiary care academic medical center ED with an annual volume of 57,000 patients between October 2013 and June 2015. Institutional Review Board approval was waived.

Selection of Participants

All patients presenting to the ED during the study period were eligible for inclusion. We used an automated, electronic tracking system to prospectively identify all patients who underwent procedural sedation as documented in the electronic medical record. Procedural sedation included patients undergoing both moderate sedation and deep sedation.

Moderate sedation was defined as drug-induced (fentanyl, midazolam, or ketamine) depression of consciousness where patients can respond purposefully to verbal commands alone or with light tactile stimulation. Interventions are not required to maintain an airway and spontaneous ventilation is adequate.

Deep sedation was defined as drug-induced (etomidate and propofol) loss of consciousness during which patients are not easily aroused but can respond purposefully after repeated stimulation. The ability to independently maintain ventilatory function can be impaired, and patients may require assistance in maintaining a patent airway.

Data Collection and Processing

Physician reviewers who were not involved with the patients' care were randomly assigned to independently review each case in which procedural sedation was performed. Reviewers used an eight-point Likert scale to determine whether errors were made and whether adverse events occurred. If a reviewer felt that the case had a possible error or adverse event, it was referred to a 20-member QA committee comprised of ED physicians, nurses, and ancillary staff. The committee made a final determination as to whether or not an error or adverse event occurred. The result of this discussion was entered into the QA database (4). After the study period, data were extracted from the QA database and entered into a Microsoft Excel 2003 (Microsoft Corporation, Redmond, WA) worksheet. Rates of error and adverse events were then determined. Results are reported as percentages with 95% confidence intervals.

RESULTS

There were 166 cases of procedural sedation identified and reviewed. Deep sedation (propofol, etomidate) was performed 141 times (85.0%). Moderate sedation with fentanyl and midazolam was performed 14 times (8.4%), and moderate dissociative sedation with ketamine was performed 11 times (6.6%). These 166 cases represented 9.0% of all cases reviewed by our QA committee during this period. Two errors were identified, for an error rate of 1.2% (95% confidence interval [CI] 0.003–0.043). One patient suffered an adverse event (0.6%; 95% CI 0.001–0.033). This adverse event was not caused by provider error.

Both errors occurred during the use of propofol to facilitate upper gastrointestinal (GI) endoscopy. Neither resulted in an adverse event. In other words, both cases were considered "near misses." In the first case, a patient presented with hematemesis. Endoscopy was performed under deep sedation with propofol. This was complicated by further large-volume hematemesis. The procedure was aborted, and the patient was intubated. Postintubation, endoscopy was repeated and Mallory-Weiss tears were injected and clipped. The patient was admitted to the intensive care unit (ICU) and recovered. Attempting endoscopy without first intubating the patient was determined to be an error. In the second case, upper GI endoscopy was performed under deep sedation with propofol to remove an impacted food bolus. The patient required intubation during a difficult and prolonged procedure due to persistent hypoxia and the expected duration of the procedure. Post intubation, the food bolus was removed, and the patient was ultimately extubated in the ED. After extubation, the patient was febrile and tachycardic and was treated for aspiration pneumonia. As the patient did not aspirate during the initial preintubation attempt at endoscopy, the aspiration was thought to have occurred prior to endoscopy. He was discharged from the hospital after a brief admission. In this case, attempting endoscopy without first intubating the patient was deemed an error. Additionally, the dose of propofol was felt to be excessive (>2 mg/kg in <3 min).

The single adverse event occurred during a shoulder reduction performed under deep sedation with propofol. A Bankart fracture, which was not present on the initial films, was noted on the postreduction x-ray studies. No error was attributed to the involved practitioners, as this is a well-described complication of reduction regardless of use or type of sedation.