ORIGINAL ARTICLE

Patient safety during sedation by anesthesia professionals during routine upper endoscopy and colonoscopy: an analysis of 1.38 million procedures

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Background and Aims: Sedation for GI endoscopy directed by anesthesia professionals (ADS) is used with the intention of improving throughput and patient satisfaction. However, data on its safety are sparse because of the lack of adequately powered, randomized controlled trials comparing it with endoscopist-directed sedation (EDS). This study was intended to determine whether ADS provides a safety advantage when compared with EDS for EGD and colonoscopy.

Methods: This retrospective, nonrandomized, observational cohort study used the Clinical Outcomes Research Initiative National Endoscopic Database, a network of 84 sites in the United States composed of academic, community, health maintenance organization, military, and Veterans Affairs practices. Serious adverse events (SAEs) were defined as any event requiring administration of cardiopulmonary resuscitation, hospital or emergency department admission, administration of rescue/reversal medication, emergency surgery, procedure termination because of an adverse event, intraprocedural adverse events requiring intervention, or blood transfusion.

Results: There were 1,388,235 patients in this study that included 880,182 colonoscopy procedures (21% ADS) and 508,053 EGD procedures (23% ADS) between 2002 and 2013. When compared with EDS, the propensity-adjusted SAE risk for patients receiving ADS was similar for colonoscopy (OR, .93; 95% CI, .82-1.06) but higher for EGD (OR, 1.33; 95% CI, 1.18-1.50). Additionally, with further stratification by American Society of Anesthesiologists (ASA) class, the use of ADS was associated with a higher SAE risk for ASA I/II and ASA III subjects undergoing EGD and showed no difference for either group undergoing colonoscopy. The sample size was not sufficient to make a conclusion regarding ASA IV/V patients.

Conclusions: Within the confines of the SAE definitions used, use of anesthesia professionals does not appear to bring a safety benefit to patients receiving colonoscopy and is associated with an increased SAE risk for ASA I, II, and III patients undergoing EGD. (Gastrointest Endosc 2016;■:1-8.)

Abbreviations: ADS, anesthesia-directed sedation; ASA, American Society of Anesthesiologists; CORI, Clinical Outcomes Research Initiative; EDS, endoscopist-directed sedation; NED, National Endoscopic Database; OR, odds ratio; SAE, serious adverse event.

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Sedation is an integral part of most GI endoscopic procedures performed in the United States. The goals of sedation are to improve the patient experience by reducing pain and anxiety, ultimately leading to better compliance with recommended screenings and follow-up.[1] Sedation options are primarily either endoscopists targeting minimal to moderate sedation (endoscopist-directed sedation [EDS]) or anesthesia professionals typically targeting deep sedation or general anesthesia (anesthesia-directed sedation [ADS]). Anesthesia professionals have become increasingly involved in sedation for screening colonoscopies, rising from 11% in 2001 to 53.4% in 2015.[2,3] This increase is likely because of a perceived increase in satisfaction and throughput with propofol sedation compared with narcotic/benzodiazepine-based sedation.[4] This practice is increasing overall procedural costs by approximately 20%.[2]

The Centers for Medicare & Medicaid Services recently released a ruling to ensure coverage of anesthesia services for screening colonoscopies instead of placing the burden on the patient.[5] The costs for involving anesthesia professionals are substantial.[3] An important inquiry therefore is what benefit is brought to the patient by using anesthesia professionals in regard to patient safety and the quality of the procedure.[2,6] The aim of better health care at a reduced cost has become a driving initiative that forces the health care system to ask this question.[7]

With regard to colonoscopy, several studies have addressed the method of sedation used and the effect on adenoma detection rates, a measure of quality of the procedure. One study showed no difference in the detection of polyps using moderate or deep sedation.[8] Similarly, other studies comparing propofol delivered by an anesthesiologist and endoscopist-directed midazolam/fentanyl-based sedation found no differences in the number of patients who had adenomatous polyps detected.[9,10]

Without a clear benefit in the quality of the colonoscopic examination, the increased cost for the use of ADS could potentially be justified by improved safety. An appropriately powered randomized, prospective, controlled trial would be impractical because of the rarity of significant events, but a few investigators have conducted retrospective studies. An increased rate of perforations during colonoscopies under propofol sedation and an increased risk of aspiration pneumonia with sedation delivered by anesthesia professionals have been observed.[11-13] With this landscape in mind, we examined the National Endoscopic Database (NED) created by the Clinical Outcomes Research Initiative (CORI) spanning the years 2002 to 2013 to understand what role ADS may have in improving patient safety.

METHODS

The data for this study came from the NED, a database of GI endoscopy procedure reports. The database is created and maintained by CORI, a large multicenter consortium of gastroenterology practices. From 2002 to 2013, 84 practice sites, including university medical centers, Veteran Affairs Health Care Systems, and GI private practices, contributed procedure reports to the database. Demographic, provider, and procedure data were collected in patients 18 years of age and older for all EGDs and colonoscopies over this time period. Participating sites agree to use a structured computerized report generator to produce all endoscopic reports and comply with quality-control requirements. Each site's data files are transmitted electronically to a central data repository, the NED. Data transmitted from the local site to the NED do not contain most patient identifiers and qualify as a Limited Data Set under 45 C.F.R. Section 164.514(e). The NED is reviewed by the institutional review board of the Oregon Health & Science University (eIRB no. 7331) and was most recently approved in September 2014. This study used a limited data set and was therefore exempted from further institutional review board review.

Primary outcome variable

The primary outcome variable was defined as a serious adverse event (SAE) requiring intervention. This was defined as any event requiring administration of cardiopulmonary resuscitation, hospital or emergency department admission, administration of rescue/reversal medication, emergency surgery, procedure termination because of an adverse event, intraprocedural adverse events requiring intervention, or blood transfusion.

Independent variable of interest

The independent variable of interest was the specialty of the health care provider who was directly responsible for the administration of procedural sedation, as documented in the CORI procedure report. This was defined as an anesthesia professional (ADS), such as an anesthesiologist or nurse anesthetist, or a nonanesthesia professional (EDS), specifically the endoscopist or other nonanesthesiologist procedure staff. Those sedation providers with ambiguous status (eg, "physician," "resident," and "technician") were considered to be unknown and were excluded from the analysis.

Statistical analysis

Data were analyzed using both multivariate logistic regression modeling and propensity score analyses. Analyses involving propensity scores included adjusting for propensity. All analyses were performed using SAS version 9.4 software (SAS Institute, Cary, NC).

Multivariate logistic regression model

Separate multivariate logistic regression models were created for colonoscopies and EGDs, modeling the likelihood of SAEs. Both models adjusted for patient age, gender, American Society of Anesthesiologists (ASA)