Complications Following Colonoscopy With Anesthesia Assistance

A Population-Based Analysis

Gregory S. Cooper, MD; Tzuyung D. Kou, PhD; Douglas K. Rex, MD

Importance: Deep sedation for endoscopic procedures has become an increasingly used option but, because of impairment in patient response, this technique also has the potential for a greater likelihood of adverse events. The incidence of these complications has not been well studied at a population level.

Design: Population-based study.

Setting and Participants: Using a 5% random sample of cancer-free Medicare beneficiaries who resided in one of the regions served by a SEER (Surveillance, Epidemiology, and End Results) registry, we identified all procedural claims for outpatient colonoscopy without polypectomy from January 1, 2000, through November 30, 2009.

Intervention: Colonoscopy without polypectomy, with or without the use of deep sedation (identified by a concurrent claim for anesthesia services).

Main Outcome Measures: The occurrence of hospitalizations for splenic rupture or trauma, colonic perforation, and aspiration pneumonia within 30 days of the colonoscopy.

Results: We identified a total of 165 527 procedures in 100 359 patients, including 35 128 procedures with anesthesia services (21.2%). Selected postprocedure complications were documented after 284 procedures (0.17%) and included aspiration (n=173), perforation (n=101), and splenic injury (n=12). (Some patients had >1 complication.) Overall complications were more common in cases with anesthesia assistance (0.22% [95% CI, 0.18%-0.27%]) than in others (0.16% [0.14%-0.18%]) ($P<.001$), as was aspiration (0.14% [0.11%-0.18%] vs 0.10% [0.08%-0.12%], respectively; $P=.02$). Frequencies of perforation and splenic injury were statistically similar. Other predictors of complications included age greater than 70 years, increasing comorbidity, and performance of the procedure in a hospital setting. In multivariate analysis, use of anesthesia services was associated with an increased complication risk (odds ratio, 1.46 [95% CI, 1.09-1.94]).

Conclusions and Relevance: Although the absolute risk of complications is low, the use of anesthesia services for colonoscopy is associated with a somewhat higher frequency of complications, specifically, aspiration pneumonia. The differences may result in part from uncontrolled confounding, but they may also reflect the impairment of normal patient responses with the use of deep sedation.

COLONOSCOPY IS CURRENTLY one of the recommended screening modalities for the prevention of colorectal cancer.[1,2] Colonoscopy procedures traditionally have been performed with conscious sedation, which involves the administration of a benzodiazepine and a narcotic. However, within the past decade, there has been increasing use of propofol, a sedative agent with no analgesic properties. Although a precedent exists for both nonanesthesiologist administration of propofol and nurse-administered propofol sedation,[3,4] because of its narrow therapeutic window with the potential for apnea, propofol typically has been administered by anesthesiology personnel.

Studies that have included physician surveys[5] and health claims data[6-9] have documented an increasing use of propofol and/or anesthesiology services in colonoscopy practice. These studies have reported a marked rise in the use of anesthesiology assistance over time, increasing from 11% in 2000 to 23.4% in 2006 in a Medicare cohort[7] and from

Author Affiliations: Division of Gastroenterology, University Hospitals Case Medical Center (Dr Cooper), and Case Comprehensive Cancer Center, Case Western Reserve University (Drs Cooper and Kou), Cleveland, Ohio; and Division of Gastroenterology, Indiana University, Indianapolis (Dr Rex).

13.6% in 2003 to 35.5% in 2009 in commercially insured individuals.[8]

Despite the known advantages of propofol use, population-based studies have not considered the potential adverse events associated with administration. Specifically, compared with conscious sedation, deep sedation would be expected to blunt patient responses to painful stimuli. Thus, a potentially higher risk of traumatic injuries during colonoscopy exists, including perforation and splenic injury. Because of diminished airway protective reflexes associated with deep sedation, a potentially higher risk of aspiration at the time of the procedure also exists. However, to our knowledge, the frequency of these complications has not been compared with conscious sedation at a population level.

We therefore conducted the present study in a large population-based sample of Medicare beneficiaries undergoing outpatient colonoscopy. To minimize confounding by procedural interventions, such as polypectomy, the study was limited to diagnostic colonoscopies. We hypothesized that, although infrequent, the potential risk of sedation-associated adverse events would be higher with the use of deep sedation.

METHODS

DATA SOURCES

The data for the study were obtained from a noncancer sample of the linked SEER (Surveillance, Epidemiology, and End Results) Program–Medicare database.[10,11] The files consist of a 5% random sample of Medicare beneficiaries without cancer who reside in one of the geographic areas contained in the SEER registries. The SEER Program currently captures approximately 26% of the US population.

Medicare claims are contained in 3 different files: the Carrier file, which includes provider claims; the Outpatient file, which includes claims from institutional outpatient providers; and the Medicare Provider Analysis and Review (MEDPAR) file, which includes all hospitalizations. Each Medicare claim contains diagnoses coded by the *International Classification of Diseases, Ninth Revision, Clinical Modification* (*ICD-9-CM*) and procedures coded according to the fourth edition of *Common Procedural Terminology* (*CPT-4*)[12] or the *ICD-9-CM*. In addition to Medicare claims, the Summarized Denominator (SUMDENOM) file contains demographic, enrollment, and entitlement information for all patients in the database.

PATIENTS AND MEASURES

The cohort of patients undergoing outpatient diagnostic colonoscopy was identified using the January 1, 2000, through November 30, 2009, Medicare Carrier and Outpatient files. Patients were eligible if they were 66 years or older (to allow measurement of comorbidities during the year prior to the colonoscopy procedure) and were receiving Medicare benefits through Part A and Part B for at least 1 year prior to and 30 days after the colonoscopy. Patients who were enrolled in Medicare-sponsored managed care plans during the 1-year period prior to and 30-day period after the colonoscopy were also excluded because of the high likelihood of incomplete claims.

All claims for diagnostic colonoscopy were identified by procedure codes (*CPT-4* codes 44388, 44389, 45378, 45380, G0105, and G0121 and *ICD-9-CM* codes 45.23 and 45.25). These codes were selected to minimize the likelihood that procedural interventions, such as snare polypectomy or control of hemorrhage, would independently increase the risk of traumatic injury. Patients were monitored from the index colonoscopy for up to 30 days after the procedure for the occurrence of specific complications and up to 1 year for death.

Consistent with previous studies,[6-8] we identified anesthesiology involvement with colonoscopy by the *CPT-4* code 00810, anesthesia assistance with endoscopic procedure distal to the duodenum, occurring on the same date as the colonoscopy of interest. Although this approach does not specifically identify the use of propofol, it is presumed that most anesthesia-assisted procedures would include this agent.

Demographic characteristics, including age, sex, and race, were obtained from the SUMDENOM file. Diagnosis codes according to *ICD-9-CM* during the 365-day to 30-day interval (total, 11 months) prior to the index colonoscopy were searched to derive a previously validated, weighted comorbidity index.[13] We also searched the claims from 1 year before the procedure for a diagnosis of obstructive sleep apnea (*ICD-9-CM* codes 780.51, 780.53, and 780.57).

We characterized the type of facility in which the colonoscopy was performed as a hospital, an ambulatory surgery center, or other/unknown. Geographic regions were divided into Northeast, South, Midwest, Southwest, and West.

The major outcome of interest was the occurrence of 1 or more prespecified complications requiring hospitalization within 30 days of the colonoscopy. The MEDPAR and Carrier files were searched for the following codes: aspiration pneumonia (*ICD-9-CM* codes 507.0 and 507.8), colonic perforation (*ICD-9-CM* codes 540.0, 540.1, 569.49, and 569.83), and splenic injury/rupture (*ICD-9-CM* codes 865.04 and 865.14) or splenectomy (*ICD-9-CM* code 41.5 and *CPT-4* codes 38100, 38101, and 38115).

STATISTICAL ANALYSIS

In the initial analysis, we identified patient and provider characteristics associated with the use of anesthesia services. The frequencies across subgroups were compared using χ^2 analysis.

The major outcome of interest was the occurrence of the specific complications within 30 days of the index procedure. The frequency of procedural complications was calculated by dividing the number of procedures with a complication by the number of total procedures. We also identified patient, facility, and geographic factors associated with the occurrence of complications and compared the frequencies with χ^2 analysis. Because of the small numbers of individual complications and per National Cancer Institute and Centers for Medicare & Medicaid Services data security policy, specific subtypes of complications were not analyzed separately. In addition, multivariate logistic regression was used to determine the independent association of anesthesiology services and complication risk. We tested selected interaction terms in the model (age, comorbidity, and anesthesiology services) but, because they did not achieve statistical significance, they were not included in the final analysis.

To determine the robustness of our findings, we performed 2 additional analyses. The first was an analysis performed among patients undergoing colonoscopy at ambulatory surgery centers, recognizing that such patients may have lower severity of illness than those treated in an outpatient hospital setting. The second was a multivariate logistic regression analysis that included an instrumental variable consisting of the proportion of eligible patients undergoing procedures with anesthesia assistance in their specific SEER registry.[14]

Table 1. Factors Associated With the Use of Anesthesia Assistance for Colonoscopy Procedures

Characteristic	No. (%)[a]		P Value
	Anesthesia (n = 35 128)	No Anesthesia (n = 130 399)	
Age group, y			
66-69	8598 (20.4)	29 793 (79.4)	
70-74	10 439 (21.3)	34 251 (78.7)	
75-79	8324 (21.1)	26 737 (79.2)	<.001
80-84	5256 (22.3)	14 583 (78.3)	
≥85	2511 (22.2)	6212 (77.4)	
Sex			
Female	19 392 (21.3)	61 320 (78.7)	.89
Male	15 736 (21.2)	50 256 (79.1)	
Race			
White	30 075 (21.3)	94 715 (78.7)	
African American	2935 (27.5)	6606 (72.0)	<.001
Other/unknown	2118 (15.2)	10 255 (85.7)	
Procedure, y			
2000	1251 (8.6)	13 321 (91.4)	
2001	2110 (12.3)	15 046 (87.7)	
2002	3022 (14.1)	18 379 (85.9)	
2003	3865 (17.8)	17 848 (82.2)	
2004	3928 (21.3)	14 550 (78.7)	
2005	3816 (24.1)	12 034 (75.9)	<.001
2006	4193 (26.7)	11 488 (73.3)	
2007	4505 (28.9)	11 059 (71.1)	
2008	4470 (32.2)	9422 (67.8)	
2009	3968 (35.4)	7252 (64.6)	
Comorbidity score			
0	22 687 (21.1)	84 772 (78.9)	
1	11 043 (21.4)	40 528 (78.6)	.30
≥2	1398 (21.5)	5099 (78.5)	
Sleep apnea			
No	34 038 (21.2)	126 722 (78.8)	.003
Yes	1090 (22.9)	3677 (77.1)	
Facility type			
Hospital	22 110 (19.1)	93 888 (80.9)	
Ambulatory surgery	12 360 (26.5)	34 268 (73.5)	<.001
Other	658 (22.7)	2243 (77.3)	
Geographic location			
West	5436 (9.0)	54 957 (91.0)	
Southwest	696 (8.8)	7217 (91.2)	
South	6345 (18.7)	27 612 (81.3)	<.001
Midwest	7212 (27.3)	19 206 (72.7)	
Northeast	15 439 (41.9)	21 407 (58.1)	

[a] Percentages are based on row totals; however, percentages may vary because of missing data. Some patients underwent more than 1 procedure.

RESULTS

From the database, we identified a total of 165 527 examinations in 100 359 patients who met the entry and exclusion criteria. This included 130 399 colonoscopies (78.8%) performed without anesthesia assistance and 35 128 (21.2%) with anesthesia assistance. Demographics of the patient population and associations with anesthesia assistance are shown in **Table 1**. The mean (SD) age of the sample was 75.5 (6.4) years, 55.0% were female, and 85.1% were white. Most patients had comorbidity scores of 0 or 1, and only 2.9% had a previous diagnosis of sleep apnea. Almost 30% of the colonoscopies were performed in an ambulatory surgery center, and the largest numbers were performed in the Western and Northeastern United States.

Factors associated with anesthesia services were identified (Table 1). Anesthesia was more commonly used in African Americans compared with whites and other racial groups. Anesthesia was also more likely to be included in procedures that were performed in ambulatory surgery centers. We also observed significant geographic variation, with more than 40% of procedures in the Northeastern United States including anesthesia services compared to 9% or less in the Southwest or West. The proportion of colonoscopies with anesthesia also increased from 8.6% in 2000 to 35.4% in 2009. The overall 30-day mortality was 0.29% and was similar in the anesthesia (0.32%) and nonanesthesia (0.28%) groups (P = .29). The overall 1-year mortality was 2.68% and was similar in the anesthesia (2.82%) and nonanesthesia (2.64%) groups (P = .06).

Table 2. Predictors of Procedural Complications in Univariate and Multivariate Analysis

Characteristic	Complication, %	P Value	Multivariate OR (95% CI)
Age group, y			
66-69	0.04		1 [Reference]
70-74	0.15		3.36 (2.03-5.56)
75-79	0.17	<.001	3.63 (2.18-6.05)
80-84	0.28		5.97 (3.58-9.97)
≥85	0.50		10.41 (6.18-17.54)
Sex			
Male	0.20		1 [Reference]
Female	0.15	.001	0.69 (0.55-0.88)
Race			
White	0.16		1 [Reference]
African American	0.20	.95	1.37 (0.90-2.09)
Other/unknown	0.14		1.09 (0.72-1.64)
Procedure, y			
2000	0.23		1 [Reference]
2001	0.17		0.58 (0.35-0.96)
2002	0.14		0.47 (0.28-0.77)
2003	0.11		0.40 (0.24-0.67)
2004	0.17		0.62 (0.38-1.01)
2005	0.16	.37	0.58 (0.34-0.98)
2006	0.14		0.52 (0.30-0.89)
2007	0.18		0.68 (0.41-1.13)
2008	0.19		0.88 (0.52-1.48)
2009	0.30		1.35 (0.82-2.20)
Comorbidity score			
0	0.14		1 [Reference]
1	0.21	<.001	1.57 (1.21-2.03)
≥2	0.35		2.39 (1.53-3.74)
Facility type			
Hospital	0.20		1 [Reference]
Ambulatory	0.10	<.001	0.42 (0.30-0.58)
Geographic location			
West	0.17		1 [Reference]
Southwest	0.14		0.71 (0.47-1.06)
South	0.18	.004	1.04 (0.73-1.48)
Midwest	0.13		0.93 (0.49-1.77)
Northeast	0.19		1.08 (0.78-1.50)
Anesthesia services			
No	0.16		1 [Reference]
Yes	0.22	<.001	1.46 (1.09-1.94)

Abbreviation: OR, odds ratio.

In the cohort, aspiration, perforation, and splenic injury were the complications recorded in 284 cases (0.17%), with 205 (0.16%; 95% CI, 0.14%-0.18%) in the nonanesthesia group compared with 79 (0.22%; 0.18%-0.27%) in the anesthesia group (*P* < .001). The most frequent complication was aspiration (n = 173), with greater frequency in the anesthesia group (0.14%; 95% CI, 0.11%-0.18%) than in the nonanesthesia group (0.10%; 0.08%-0.12%; *P* = .02). The incidence of perforation (n = 101) and splenic injury (n = 12) was statistically similar between groups. Other risk factors for postprocedure complications are shown in **Table 2** and included older age, male sex, increased comorbidity, and hospital-based procedures. These differences were also observed in multivariate analysis. For anesthesia services, the multivariate odds ratio (OR) for occurrence of complications was 1.46 (95% CI, 1.09-1.94).

In a secondary analysis of procedures performed in an ambulatory surgery center as opposed to a hospital outpatient setting, there were fewer total complications

(n = 46), with 29 in the nonanesthesia group (0.08%) and 17 in the anesthesia group (0.14%). However, because of the smaller frequency of adverse events, the differences did not achieve statistical significance in unadjusted (*P* = .11) or multivariate logistic regression (OR, 1.67; 95% CI, 0.83-3.33) analysis. We also performed an analysis in which the proportion of colonoscopies in a given SEER region was included as an instrumental variable. The results were consistent with the primary analysis (multivariate OR, 1.35 for anesthesia assistance; 95% CI, 1.01-1.81)

COMMENT

In recent years, administration of propofol for the performance of colonoscopy has increased.[7,8] Whereas patients with complex medical problems and a known intolerance to conscious sedation are probably more appropriate for anesthesia involvement in procedures,

much of the observed variation in the use of anesthesia presumably relates to physician discretion. In patients without clear medical indications for deep sedation, the potential advantages of propofol include the rapid onset of sedation, faster recovery time, and improved patient and provider satisfaction. The major disadvantage cited is the greater financial cost to the patient and health care system, which is approximately 20% higher than costs without anesthesia assistance.[7,8]

In this analysis, which included a large population-based sample of colonoscopies, we report a somewhat higher complication risk with anesthesia involvement. Although the absolute incidence of postprocedure complications was very low, we found an almost 50% increased adjusted risk in procedures that were associated with anesthesia services. Based on the estimated number of colonoscopies in the entire Medicare population in 2009, this difference of 0.06% would extrapolate to a net annual increase of 518 (95% CI, 432-604) complications.

We identified and studied 3 complications that we consider potentially increased in patients undergoing deeper levels of sedation. Splenic injury has been described in multiple case reports, with the most recent estimate of 93 reported cases from the mid-1970s through 2011.[15] With the exception of a case series in which 6 of 9 patients received propofol,[16] the type of sedation has not been previously described as a risk factor. Presumably, deeper levels of sedation could allow creation of complex loops in the colonoscope, which might not be tolerated by patients with moderate levels of sedation and which may stress the attachments between the spleen and colon. In a related potential mechanism, the use of deep sedation might prevent the patient from expressing pain associated with stress on splenic-colonic attachments that would serve as a warning to the endoscopist to change insertion tactics. However, we did not demonstrate a statistically significant increase in splenic injury in patients undergoing deep sedation.

The incidence of perforation in large samples has ranged from 0.19 to 0.9 per 1000 colonoscopies[17-19] and was typically increased with the use of polypectomy. In 2 of the studies, the type of sedation was not examined separately[18,19]; in a report that included data from an endoscopic registry, it was not predictive.[17] However, in the latter study, propofol was administered in only 1.3% of procedures. As with splenic injury, we hypothesize that deep sedation may predispose to this complication if colonoscopists continue to push the instrument forward when fixed resistance is palpated and the patient is unable to perceive pain that would warn the endoscopist to stop insertion. Analogous to splenic injury, however, we did not demonstrate a statistically increased risk of perforation in diagnostic colonoscopies.

Aspiration is a relatively underrecognized complication of endoscopic procedures but may be more frequent than perforation.[20] In a large series of patients receiving monitored anesthesia care,[21] most of whom received propofol, aspiration occurred in 5 of 3155 colonoscopies (0.16%) and in 0.10% of all procedures. In a recently published study that used coughing during procedures as a surrogate measure of microaspiration, the use of propofol for sedation was associated with an increased risk of cough.[21] We found that anesthesia services were associated with an increased risk of aspiration, and an increased risk of aspiration was the main factor accounting for the overall increase in the complications we identified in patients undergoing colonoscopy with anesthesia services.

We recognize several potential limitations of the study. First, because the study was a nonrandomized observational study, we could not completely adjust for potential differences in case mix between the anesthesia and nonanesthesia groups. Because of potential selection bias in the choice of sedation, the increased complication rate associated with anesthesia assistance may have resulted from comorbidity. However, we attempted to minimize this potential bias by performing a secondary analysis using instrumental variables and in patients treated only in ambulatory surgical centers, and the results were consistent. Second, as in previous analyses,[6-8] we used claims for anesthesia services as a proxy for propofol administration. Although we could not obtain medical records to verify what medications a patient received, one can assume that the overwhelming majority received propofol. Because our study design required hospitalization for a postprocedure complication, another potential limitation is underascertainment of complications. However, we anticipate that the overwhelming majority of the type of complications included in the study would have resulted in use of the health care system. We also could not validate the occurrence of the complication and whether the complication directly resulted from the procedure. Finally, despite the large total sample size, the number of patients with individual complications was low; thus, the power to identify risk factors for specific complications was limited.

In summary, in this large sample of Medicare beneficiaries, we identified the use of anesthesiology services for colonoscopy as one of the risk factors for complications, specifically aspiration pneumonia. The absolute risk for these complications was low in colonoscopies with as well as those without anesthesiologist involvement, and differences may have resulted in part from uncontrolled confounding based on patient severity. Nonetheless, the depth of sedation may serve as an independent risk factor for adverse outcomes.

Correspondence: Gregory S. Cooper, MD, Division of Gastroenterology, University Hospitals Case Medical Center, 11100 Euclid Ave, Cleveland, OH 44106 (gregory.cooper@uhhospitals.org).

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INVITED COMMENTARY

Anesthesia for Colonoscopy

Too Much of a Good Thing?

Anesthesia services to provide sedation for endoscopic procedures are increasing in prevalence.[1,2] The drivers of use are many, including the desire for improved procedural tolerance and patient satisfaction[3]; however, economic factors may influence physicians' practice to use anesthesia.[1,4] The tremendous geographic variation in anesthesia use supports the latter, especially since the geographic differences fall largely along reimbursement lines.[2,4,5] By far the most common reason to use anesthesia services is to administer propofol, a sedative without analgesic properties. Endoscopic procedures that use propofol have reduced procedural and recovery times, which improve procedure throughput and increase the efficiency of endoscopy units.[3]

The study by Cooper and coauthors[6] examines the potential clinical downsides of propofol use as sedation for colonoscopy. These investigators explored whether clinical adverse events leading to hospitalization within 30 days could be ascribed to propofol use. The complications examined in this study included aspiration pneumonia, colonic perforation, and splenic injury. Aspiration could result because sedated patients are unable to protect their airway during the procedure and the immediate postprocedure period. The risk for perforation could be increased by reducing the patient's pain re-