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Complications Following Colonoscopy with Anesthesia Assistance: A Population-Based Analysis

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Abstract

Background—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.

Methods—Using a 5% random sample of cancer-free Medicare beneficiaries who resided in one of the regions served by a SEER registry, we identified all procedural claims for outpatient colonoscopy without polypectomy from 2000–2009. The use of deep sedation was identified by a concurrent claim for anesthesia services. Using diagnosis codes, we identified the occurrence within 30 days of the colonoscopy of hospitalizations for splenic rupture or trauma, colonic perforation, and aspiration pneumonia.

Results—We identified a total of 165,527 procedures in 100,359 patients, including 35,128 with anesthesia services (21.2%). Selected post-procedural complications were documented in 284 patients (0.17%) and included aspiration (n=173), perforation (n=101) and splenic injury (n=12). Overall complications were more common in cases with anesthesia assistance (0.22% (95% CI 0.18–0.27%)) than others (0.16% (95% CI 0.14–0.18%)) (p=0.0001), as was aspiration (0.14%, CI 0.11–18% vs. 0.10%, CI 0.08–0.12%, respectively, p=0.02). Frequencies of perforation and splenic injury were statistically similar. Other predictors of complications included age > 70, increasing Charlson comorbidity score, and performance 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—In this population-based study, although the absolute risk of complications was low, the use of anesthesia services for colonoscopy was associated with a somewhat higher frequency of complications, specifically aspiration pneumonia. Although the differences may be due in part to uncontrolled confounding, they may also reflect the impairment of normal patient responses with deep sedation.

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Introduction

Colonoscopy is currently one of the recommended screening modalities for the prevention of colorectal cancer (1, 2). Traditionally, colonoscopy procedures have been performed with conscious sedation, which involves the administration of a benzodiazpene and a narcotic. However, within the past decade there has been increasing use of propofol, a sedative agent with no analgesic properties. Although there is a precedent for both nonanesthesiologist administration of propofol and nurse administered propofol sedation (3, 4), because of its narrow therapeutic window with the potential for apnea, it has traditionally 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 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 to conscious sedation, deep sedation would be expected to blunt patient responses to painful stimuli. Thus, there is a potentially higher risk of traumatic injuries during colonoscopy, including perforation and splenic injury. In addition, because of diminished airway protective reflexes associated with deep sedation, there is a potentially higher risk of aspiration at the time of the procedure. 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. In order 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.

Materials and Methods

Data Sources

The data for the study were obtained from noncancer sample of the linked SEER-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 three 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) files, which includes all hospitalizations. Each Medicare claim contains diagnoses coded by the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM), and procedures coded according to Common Procedural Terminology, 4th Edition (CPT-4)

or 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 2000 through November 30, 2009 Medicare Carrier and Outpatient files. Patients were eligible if they were 66 years of age and 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 one year prior to and 30 days after the colonoscopy. Patients who were enrolled in Medicare sponsored managed care plans during the one-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 44388, 44389, 45378, 45380, G0105, G0121; ICD-9-CM 45.23, 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 followed from the index colonoscopy for up to 30 days after the procedure for 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 the majority of anesthesia-assisted procedures would include this agent.

Demographic characteristics, including age, gender and race, were obtained from the SUMDENOM file. Diagnosis codes according to 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 (12). We also searched the claims from one year prior to the procedure for a diagnosis of obstructive sleep apnea (ICD-9-CM 780.51, 780.53, 780.57).

We characterized the type of facility in which the colonoscopy was performed as hospital, 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 one 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-9 482.89, 482.9, 483.8, 507.0, 507.8), colonic perforation (ICD-9 540.0, 540.1, 569.4,9, 569.83) and splenic injury/ rupture (ICD-9 865.04, 865.14) or splenectomy (ICD-9 41.5, CPT-4 38100, 38101, 38115).

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 chi-square analysis.

The major outcome of interest was the occurrence of the specific complications described above 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 chi-square analysis. Because of the small numbers of individual complications and per National Cancer Institute (NCI) and Centers for Medicare and Medicaid Services (CMS) data security policy, specific subtypes of complications were not analyzed separately. In addition, multivariable logistic regression was used to determine the independent association of anesthesiology services and complication risk. We tested selected interaction terms in the model (age, comorbidty and anesthesiology services), but because they did not achieve statistical significance, they were not included in the final analysis.

In order to determine the robustness of our findings, we performed two additional analyses. First, an analysis was 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. Second, we conducted 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 (13).

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 age of the sample was 75.5 ± 6.4 years, 55% were female and 85% were Caucasian. Most patients had comorbidity scores of 0 or 1 and only 2.9% had a previous diagnosis of sleep apnea. Almost 30% were performed in an ambulatory surgery center, and the largest numbers of colonoscopies were performed in the Western US and Northeastern US.

Factors associated with anesthesia services were identified (Table 1). Anesthesia was more commonly used in African Americans compared to Caucasians 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 US having 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 more than 35% in 2009. The overall 30-day mortality was 0.29% and was similar in the anesthesia (0.32%) and nonanesthesia (0.28%) groups

(p=0.29). The overall one-year mortality was 2.68% and was also similar in the anesthesia (2.82%) and nonanesthesia (2.64%) groups (p=0.06).

In the cohort, complications including aspiration, perforation and splenic injury were recorded in 284 cases (0.17%), with 205 (0.16%, 95% CI 0.14–0.18%) in the non-anesthesia group compared to 79 (0.22%, 95% CI 0.18–0.27%) in the anesthesia group (p=0.0001). The most frequent complication was aspiration (n=173) and was greater in the anesthesia group (0.14%, CI 0.11–0.18%) than in the non-anesthesia group (0.10%, CI 0.08–0.12%, p=0.02). The incidence of perforation (n=101) and splenic injury (n=12) was statistically similar between groups. Other risk factors for post-procedure complications are shown in Table 2 and included older age, female gender, increased comorbidity and hospital based procedures. These differences were also observed in multivariable analysis. For anesthesia services, the multivariable odds ratio 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 non-anesthesia 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=0.11) or multivariate logistic regression analysis (odds ratio=1.67, 95% CI 0.83–3.33). We also performed an analysis where the proportion of colonoscopies in a given SEER region was included as an instrumental variable. The results were consistent with the primary analysis (multivariate odds ratio 1.35 for anesthesia assistance, 95% CI 1.01–1.81)

Discussion

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 of propofol administration that has been cited is the greater financial cost to the patient and health care system, which is approximately 20% higher (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 post-procedure complications was very low, there was 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 three 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-1970's through 2011 (19). With the exception of a case series where six of nine patients received propofol (20), 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-colon 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 (15–17) and was typically increased with the use of polypectomy. In two of the studies, the type of sedation was not examined separately (16, 17), but in a report that included data from an endoscopic registry, it was not predictive (15). However, in the latter study, propofol was only administered in 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 under-recognized complication of endoscopic procedures, but may actually be more frequent than perforation (21). In a large series of patients receiving monitored anesthesia care (22), the majority of whom received propofol, aspiration occurred in five of 3155 colonoscopies (0.16%), and 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 (22). 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 non-anesthesia groups. Because of potential selection bias in choice of sedation, it is possible that the increased complication rate associated with anesthesia assistance was due to comorbidity. However, we attempted to minimize this potential bias by performing 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, it is assumed that the overwhelming majority did receive propofol. Because our study design required hospitalization for a postprocedure complication, another potential limitation is underascertainment of complications. However,

we would anticipate that the overwhelming majority of the type of complications that were included in the study would have resulted in use of the healthcare 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 and thus the power to identify risk factors for specific complications was limited.

In summary, in this large sample of Medicare beneficiaries, we have 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 in both patients in whom anesthesiologist involvement was present or absent was very low, and differences may have been due in part to uncontrolled confounding based on patient severity. Nonetheless, the depth of sedation may potentially serve as an independent risk factor for adverse outcomes.

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Drs. Cooper and Kou had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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Table 1

Factors Associated with Use of Anesthesia Assistance for Colonoscopy Procedures

Characteristic	Anesthesia N (%)	No Anesthesia N (%)	P Value
Age Group			<0.0001
66–69	8598 (20.4)	29793 (79.4)	
70–74	10439 (21.3)	34251 (78.7)	
75–79	8324 (21.1)	26737 (79.2)	
80–84	5256 (22.3)	14583 (78.3)	
≥ 85	2511 (22.2)	6212 (77.4)	
Gender			0.89
Female	19392 (21.3)	61320 (78.7)	
Male	15736 (21.2)	50256 (79.1)	
Race			<0.0001
Caucasian	30075 (21.3)	94715 (78.7)	
African American	2935 (27.5)	6606 (72.0)	
Other/Unknown	2118 (15.2)	10255 (85.7)	
Procedure Year			<0.0001
2000	1251 (8.6)	13321 (91.4)	
2001	2110 (12.3)	15046 (87.7)	
2002	3022 (14.1)	18379 (85.9)	
2003	3865 (17.8)	17848 (82.2)	
2004	3928 (21.3)	14550 (78.7)	
2005	3816 (24.1)	12034 (75.9)	
2006	4193 (26.7)	11488 (73.3)	
2007	4505 (29.0)	11059 (71.1)	
2008	4470 (32.2)	9422 (67.8)	
2009	3968 (35.4)	7252 (64.6)	
Comorbidity Score			0.30
0	22687 (21.1)	84772 (78.9)	
1	11043 (21.4)	40528 (78.6)	
≥ 2	1398 (21.5)	5099 (78.5)	
Sleep Apnea			0.003
No	34038 (21.2)	126722 (78.8)	
Yes	1090 (22.9)	3677 (77.1)	
Facility Type			<0.0001
Hospital	22110 (19.1)	93888 (80.9)	
Ambulatory Surgery	12360 (26.5)	34268 (73.5)	
Other	658 (22.7)	2243 (77.3)	
Geographic Location			<0.0001
West	5436 (9.0)	54957 (91.0)	

Characteristic	Anesthesia N (%)	No Anesthesia N (%)	P Value
Southwest	696 (8.8)	7217 (91.2)	
South	6345 (18.7)	27612 (81.3)	
Midwest	7212 (27.3)	19206 (72.7)	
Northeast	15439 (41.9)	21407 (58.1)	

Table 2

Predictors of Procedural Complications in Univariate and Multivariate Analysis

Characteristic	Complication (%)	P Value	Multivariate Odds Ratio (95% CI)
Age Group		<0.0001	
66–69	0.04		Referent
70–74	0.15		3.36 (2.03–5.56)
75–79	0.17		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)
Gender		0.001	
Male	0.20		Referent
Female	0.15		0.69 (0.55–0.88)
Race		0.95	
Caucasian	0.16		Referent
African American	0.20		1.37 (0.90–2.09)
Other/Unknown	0.14		1.09 (0.72–1.64)
Procedure Year		0.37	
2000	0.23		Referent
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		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		<0.0001	
0	0.14		Referent
1	0.21		1.57 (1.21–2.03)
≥ 2	0.35		2.39 (1.53–3.74)
Facility Type		<0.0001	
Hospital	0.20		Referent
Ambulatory	0.10		0.42 (0.30–0.58)
Geographic Location		0.004	
West	0.17		Referent
Southwest	0.14		0.71 (0.47–1.06)
South	0.18		1.04 (0.73–1.48)
Midwest	0.13		0.93 (0.49–1.77)

Characteristic	Complication (%)	P Value	Multivariate Odds Ratio (95% CI)
Northeast	0.19		1.08 (0.78–1.50)
Anesthesia Services		<0.0001	
No	0.16		Referent
Yes	0.22		1.46 (1.09–1.94)