Published in final edited form as:

Dig Dis Sci. 2010 August ; 55(8): . doi:10.1007/s10620-010-1226-1.

Does Level of Sedation Impact Detection of Advanced Neoplasia?

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Abstract

Background and Aims—Two of the foremost issues in screening colonoscopy involve delivering quality and maximizing adenoma detection rates (ADR). Little is known about the impact of deep sedation on ADR. This study aims to compare the detection of advanced lesions during screening colonoscopy performed with moderate conscious sedation (MCS) versus deep sedation (DS).

Methods—A retrospective cohort study was performed using the Clinical Outcomes Research Initiative database. Average risk screening colonoscopies performed January 2000 to December 2005 were examined for practice setting, patient demographics, and findings, including detection of a polyp >9 mm and suspected malignant lesions.

Results—A total of 104,868 colonoscopies were examined, 97% of which were performed with MCS. Univariate analysis demonstrated that more polyps of any size were detected with MCS (38 vs. 34%, $p < 0.0001$) and more advanced lesions were found with DS compared with MCS (7 vs. 6%, $p = 0.01$). When exclusively examining sites that performed DS [10% for all procedures, a more significant increase in advanced lesion detection when using DS was observed (7.5 vs. 5.7%, $p = 0.003$). When adjusted for age, gender, race/ethnicity, site, prep quality, and ASA group, DS was 25% more likely to detect an advanced lesion.

Conclusions—Our data suggest that use of DS may be associated with a higher rate of advanced lesion detection. However, this retrospective design has limitations that necessitate follow-up with prospective studies. These follow-up studies would be essential to support any change in the standard practices of sedation.

Keywords

Colonoscopy; Deep sedation; Advanced neoplasia; Propofol Polyp

Background

Colon cancer screening continues to be a priority in preventative medicine as this malignancy remains a leading cause of cancer death. In the United States, colonoscopy is the most utilized screening tool [1], with case-control and observational studies demonstrating that this procedure is associated with a decreased incidence of colorectal cancer[2–5]. The primary goals of this screening test are to identify and remove adenomas, lesions that are believed to possess malignant potential.

During an era of medicine where pay-for-performance is receiving much attention, adenoma detection rate (ADR) is recognized as an important measure of quality in screening colonoscopy. As such, recent studies have focused on this marker and have demonstrated that per-patient ADR and missed adenoma rates can be quite variable among colonoscopists,

ranging from 16 to 41% and 12 to 48%, respectively [6–8]. This variation challenges the reliability of colonoscopy and its ability to achieve the goals of a screening exam.

Recognizing the implications of these findings on the integrity of screening colonoscopy, further studies have sought to identify variables that may influence the ADR, such as bowel-preparation quality, withdrawal time, or use of advanced endoscopic imaging or techniques [9, 10, 19]. However, the level of sedation used for a procedure with respect to ADR is a variable that has been less studied. Currently, the majority of colonoscopies in the US are performed with moderate conscious sedation (MCS) using a combination of a benzodiazepine and an opioid agent. On the other hand, deep sedation (DS) has not until recently been routinely used for average-risk patients or exams but was often used as an alternative option for those who could not be safely or adequately sedated with MCS. DS is commonly achieved by using propofol, a potent drug whose favorable pharmacokinetic profile results in a short half-life with rapid recovery. As a result, DS may have advantages over MCS in regards to sedation-to-scope-insertion time and consistency of optimal patient sedation.

In this study we aimed to determine whether the use of deep sedation with or without anesthesia assistance translates to a higher-quality exam, that is, an improved detection of significant lesions. Our hypothesis was that by providing more rapid and consistent sedation, a colonoscopist would be able to dedicate more time and attention to examining the colon. Because of the absence of pathology follow-up on major databases, ADR cannot easily be derived. Therefore, to achieve our aims we identified a surrogate for ADR as the detection of “advanced neoplasia” as defined by a “polyp measuring >9 mm” and “suspected malignant tumor.” We then used the clinical outcomes research initiative (CORI) to measure any potential associations between the type of sedation used and the detection of such lesions.

Materials and Methods

Clinical Outcomes Research Initiative (CORI)

Subject data was extracted from the CORI database, which was established in 1995 to study utilization and outcomes of endoscopy in diverse practice settings. Participating sites during our study period include 72 practices sites from 26 states and are comprised of 10% academic, 80% community/HMO, and 11% VA/military sites. The data derived from these sites have been shown to be similar to the practice patterns observed in Medicare patients undergoing endoscopy [11]. These practices agree to use a standardized computerized report generator to create all endoscopic reports and comply with quality control requirements. The sites' data files are transmitted electronically to a central data repository—the National Endoscopic Database (NED). Patient and physician identifiers are removed from the data file prior to transmission to protect both patient and physician confidentiality. The data then undergoes computerized quality-control checks to identify missing fields. After quality-control checks are completed, the data from all sites is merged into the NED for analysis. As of 2009, up to 50 publications have originated from the CORI database, including numerous studies on screening colonoscopy utilization and polyp detection and characteristics among various demographic groups [12–16].

Patients and Procedures

The database was queried between the dates of January 1, 2002, to December 31, 2007 for patients undergoing colonoscopy for average-risk colon cancer screening. Incomplete or duplicate reports and those of patients younger than 18 years old were excluded. If a patient had more than one screening exam during the time period, only the first was included in the

analysis. Procedures that were performed with sedation classified as other than moderate conscious or deep sedation were also excluded. Data on patient age, gender, and American Society of Anesthesiologists (ASA) physical status classification were collected.

Further data were extracted from the procedural characteristics and endoscopic findings. Location of the procedure was categorized by the site type: community/HMO, academic, or VA center/military. Additionally, CORI has a field for level of sedation, allowing for identification of the type of sedation that was provided to the patient (anxiolysis, moderate conscious sedation, deep sedation, general anesthesia, etc.) and identifying the medical staff that administered the medications (endoscopist, nurse anesthetist, anesthesiologist, intensive care unit staff, etc.). Procedures were classified as either MCS or DS with no further stratification into who administered the sedation. Preparation quality was graded by the endoscopist and recorded as poor, fair-exam compromised, fair-adequate exam, good, and excellent.

Primary and Secondary Endpoints

The primary endpoint of this study was the presence of an advanced lesion defined as any large polyp or “suspected malignant tumor” identified during a screening colonoscopy. A large polyp was defined as “polyp >9 mm.” We used these CORI descriptions to represent our surrogate for a significant lesion, as histologic diagnosis is a feature that is not routinely reported in the CORI database. A recent study demonstrated that within this database, approximately 82% of polyps greater than 9 mm possessed adenomatous or more advanced pathology [12], further justifying our choice of proxy. Secondary endpoints included the presence of a “polyp” of any size as well as achievement of cecal intubation.

Statistical Analyses

All analyses were performed using SAS software version 9.1 (SAS Institute, Inc., Cary, NC). Comparison of demographic data was performed by using Pearson χ^2 tests. We constructed a multivariate logistic regression model with the outcome of “large polyp” and “suspected malignant tumor.” Potential covariates in the models included age, gender, race/ethnicity, ASA Class, bowel prep results and site type. Variables were retained in the model if they demonstrated statistical significance or confounding with race or ethnicity. The adjusted odds ratio (OR) of each outcome was separately calculated with 95% confidence intervals (CI).

Results

After identifying patients undergoing average-risk colon cancer screening within the time frame of interest, we identified a total of 104,868 colonoscopies (see Table 1). Of this number, 101,367 cases were performed with MCS, comprising 96.7% of the reviewed procedures. Alternatively, 3,501 (3.3%) cases were performed with DS. There was a statistically significant difference in the frequency of use of these two types of sedation among all age groups. In both groups, there was a predominance of average colon cancer screening exams performed under either type of sedation in the decades of 50–59 and 60–69 years of age, with mean age of MCS group and DS group being 61.3 and 60.8 years of age, respectively ($p = 0.0002$). When gender was evaluated, a statistically significant difference in use of MCS and DS was seen in men and women. Female gender was more likely to receive DS over MCS (49 vs. 45%), and male gender was less likely to receive DS over MCS (51 vs. 55%). However, after further analysis with exclusion of the VA population, a predominantly male population, there was no difference in level of sedation received ($p = 0.18$).

Table 1 also displays the comparison of level of sedation according to race/ethnic group (excluding cases with race/ethnic group not reported), practice site, and the ASA classification of the patient. White non-Hispanic patients comprised a majority of the study population, with greater than 85% of those receiving average-risk screening under either type of sedation being of this race. There was a statistically significant difference in type of sedation used among the race/ethnic groups ($p < 0.0001$). The majority of cases in the study population were performed in community centers, totaling 80,860 colonoscopies (77%). There was a statistically significant association between the site type and level of sedation used, with a larger proportion of community sites utilizing deep sedation.

Our unadjusted analysis of colonoscopy outcomes in relation to level of sedation is shown in Table 2. We found that, compared to all other sites, the use of DS was associated with a higher rate of advanced neoplasia, 7 vs. 6% ($p = 0.01$). We also analyzed our primary endpoint using only the data from all sites which routinely used deep sedation, defined as $>10\%$ of procedures during the time period. Again, advanced neoplasia was more likely to be found during an exam performed with deep sedation, at a rate of 7.5% compared with 5.7% ($p = 0.003$). Alternatively, when the rate of polyp detection of any size was measured, MCS yielded a higher rate of lesions (38 vs. 34%, $p < 0.0001$). There was no difference in the average number of polyps found per person between the two types of sedation. Finally, use of DS yielded an overall higher cecal intubation success rate (99 vs. 98%, $p = 0.0002$). While this was statistically significant, it is not thought to be clinically significant given small difference and overall high success rates.

Table 3 displays the multivariate analysis of our primary endpoint. When adjusted for age, race/ethnicity, gender, site, ASA category, and prep quality, the use of DS was associated with a 25% increase in the detection of advanced neoplasia (OR = 1.25, 95% CI, 1.10–1.43). In the same analysis, we found that older age (> 70 years), male gender, and black non-Hispanic race were characteristics that were also associated with a higher detection of advanced neoplasia, when controlling for other variables. In order to minimize contamination by site or endoscopist-related confounders, we also performed the same analysis on the ten sites that performed at least 10% of their procedures using DS during the time period (Table 4). The trend of more advanced neoplasia found with DS persists in this analysis (OR = 1.26, 95% CI: 1.03–1.54).

Discussion

In this retrospective cohort study we demonstrate that the use of DS was associated with a 25% higher likelihood of performing a colonoscopy that identified a polyp >9 mm or suspected malignant tumor. To our knowledge, this is the first study to evaluate the relationship between level of sedation and detection of significant lesions during screening colonoscopy. Our data originated from the CORI database, a platform that has supported numerous previous studies on endoscopy. During the study period, the sites participating in the CORI databases represented a large number of practices from over 25 states and comprised by a variety of practice types. We feel that the study population from this national database can be generalized to the US population undergoing screening colonoscopy. Additionally, our multivariate analysis indicates that older age, black non-Hispanic race, and male gender were all associated with advanced neoplasia. These are similar findings to previous population studies that evaluated the association of these variables with colorectal neoplasia [17,18], suggesting that our study population is comparable to other reported study populations and thus, representative of the general population.

These results arrive at a time when much attention is focused on quality assurance in colonoscopy. Prior studies on this subject, including those focusing on complete

colonoscopic evaluation, withdrawal time, and prep quality, have all used adenoma detection as a measure of quality in screening colonoscopy [9, 10, 19–22]. The results of such studies have highlighted the importance of high-quality colon preparations and adequate time for the inspection phase of colonoscopy. However, at this time we caution against the use of our findings as an impetus for the widespread use of deep sedation during average-risk exams. Rather, the interpretation of these findings should be considered alongside the limitations of this study and the implications of introducing DS as the mainstay of colonoscopy sedation.

First, it must be emphasized that the CORI database provides endoscopic information originating from a large number of sites, and for this reason it provides generous amounts of data that are capable of detecting small differences that will be statistically significant. In our univariate analysis, this detected difference in advanced neoplasia detection was 1%. Of a study population comprised of greater than 100,000 screening colonoscopies, we do not feel that, while statistically significant, this 1% difference is clinically meaningful. In fact, based on these findings, the number needed to screen to detect one additional advanced lesion is 141. When one takes into account a theoretical additional cost of \$1.5 billion per year spent on anesthesiology services (based on 2003 Medicare rates [23]), this amounts to a sizeable cost in exchange for a questionable gain in clinical benefit.

There are other limitations to our study. This was a retrospective study that possesses the weaknesses that are inherent to such a design. The data extracted from CORI were entered by each endoscopist who participates in the consortium but is not aware of the research projects that are derived from it. Therefore individual CORI reports may have variables that are missing or may be subject to misclassification bias. For example, race/ethnic group is entered by the endoscopist rather than the patient and therefore represents what the examiner believes the patient to be. This may be different from the actual ethnicity of the patient. While we aimed to collect all “screening” colonoscopies, it was not possible to determine if these were all index colonoscopies or if the patient was actually having an “adenoma surveillance” colonoscopy. Additionally, polyp size (≤ or >9 mm) is determined by an endoscopist’s impression of size rather than on a standard measurement, making this classification susceptible to over or underestimation. Finally, due to the limitations of CORI we did not have access to the actual histologic diagnosis of the polyps. We were therefore dependent on size alone to define our “significant” lesion, and this surrogate marker may not necessarily translate to adenoma or advanced neoplasia. However, we are able to validate the endpoint by the data provided by a prior CORI study which demonstrated that a polyp >9 mm harbored an estimated 82% chance of being an adenoma and a 30.6% chance of having advanced histology [12].

The discrepancy between overall polyp detection and advanced neoplasia detection trends with the two types of sedation deserves further discussion. Our univariate model indicates that the presence of any polyp during any exam was more likely with MCS vs. DS, with a rate of 38% compared to 34%. Alternatively, 7% of all procedures with DS yielded an advanced lesion compared to 6% with MCS. It is difficult to resolve how one method of sedation would detect more polyps of any size but fewer advanced lesions, and vice versa. One explanation may involve the lack of pathology follow-up in these “polyps.” Because it is not known which of these polyps were ultimately diagnosed as adenomas, hyperplastic polyps, lymphoid tissue, or normal colonic mucosa, it is even more difficult to discern which of these lesions were clinically significant. According to the findings by Lieberman et al. [12], the likelihood of any polyp reported in CORI of being an adenoma or advanced neoplasia was 51.6 and 7.3%, respectively. These numbers suggest that a smaller polyp may be less likely to represent a lesion of any clinical relevance. On the other hand, as noted by Chen and Rex, higher detection of non-adenomatous lesions during colonoscopy should still

correlate with a higher detection of significant lesions [24], and therefore we feel that measuring this secondary endpoint is still meaningful in this analysis.

Another possible explanation for the discrepancy is that there is actually no relationship between type of sedation and polyp detection rate but rather the difference is due to an unmeasured confounder. Because of the limitations of the database, detailed patient characteristics could not be ascertained, such as obesity, diabetes, smoking, or alcohol use. These are all factors that have been implicated in the development of colorectal neoplasia [25–30] and may also be variables associated with referral to DS. Additionally, the presence of these comorbidities may influence colonoscopist reporting behavior, in that smaller polyps may have been reported less because they were felt to have less influence a patient's overall survival. By not having these variables measured, the impact of these factors on neoplastic detection goes on unmeasured.

Finally, it is also possible that operator-dependent variables are influencing the results. This may be the case if an endoscopist who uses DS in our study routinely overestimates his/her perceived size of the polyps and/or an endoscopist using MCS routinely underestimates the size. Alternatively, the variable skill level of endoscopists who routinely use DS in this study may have contributed to a higher advanced neoplasia detection rate compared to those who used MCS. We attempted to control for some of these potential hidden confounders by exclusively analyzing the cases originating from the sites that perform >10% of all procedures with DS, and the trend seen with DS and advanced neoplasia detection persisted. However, the observational nature of this study design makes it impossible to account for all confounding variables, and this may be the core weakness of this investigation.

In summary, our study is the first to evaluate the relationship between level of sedation and detection of significant lesions during colonoscopy. Our results indicate that increased advanced neoplasia detection is associated with the use of deep sedation. However, the difference in detection rate between MCS and DS is small, and its statistical significance is the product of a large national endoscopic database that can sometimes detect negligible differences. Additionally, the association may not be due to the type of sedation used, but rather to unmeasured endoscopist variables or other confounders that are not detectable through the CORI database. Thus we anticipate that these findings will stimulate discussion, but should not prompt any changes in sedation practice. The implications of such a movement towards more widespread use of DS would invariably lead to increased costs in an already taxed health care system without any clear benefit in patient outcome. Therefore we hope our work marks the initiation of future prospective studies to evaluate all aspects of this subject, including the cost-effectiveness of broad implementation of these potential changes in patient care.

Acknowledgments

This project was supported with funding from NIDDK U01 CA 89389-01 and R33-DK61778-01. In addition, the practice network (CORI) has received support from the following entities to support the infrastructure of the practice-based network: AstraZeneca, Bard International, Pentax USA, ProVation, Endosoft, GIVEN Imaging, and Ethicon. The commercial entities had no involvement in this research. GE is the executive co-director of CORI, a nonprofit organization that receives funding from federal and industry sources. This potential conflict of interest has been reviewed and managed by the Oregon Health and Science University (OHSU) Conflict of Interest in Research Committee.

Abbreviations

ADR Adenoma detection rate

ASA	American Society of Anesthesiologists
CORI	Clinical outcomes research initiative
CI	Confidence interval
DS	Deep sedation
MCS	Moderate conscious sedation
NED	National endoscopic database
NH	Non-Hispanic
OR	Odds ratio

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Table 1

Patient and procedure characteristics

Characteristic	Moderate sedation n = 101,367 (%)	Deep sedation n = 3,501 (%)	p value
Age group			
<50	1,783(1.8)	107(3.1)	<0.0001
50–59	49,373(48.7)	1,737(49.6)	
60–69	32,149(31.7)	1,108(31.7)	
70–79	15,545(15.3)	449(12.8)	
80	2,517(2.5)	100(2.9)	
Mean age (SD)	61.3(8.7)	60.8(8.8)	0.0002
Gender			
Female	45,977(45.4)	1,713(48.9)	<0.0001
Male	55,390(54.6)	1,788(51.1)	
Excluding VA/military (n = 92,365)			
Female (n = 46,256)	44,544(50.1)	1,712(49.0)	0.18
Male (n = 46,109)	44,325(49.9)	1,784(51.0)	
Race/ethnicity (n = 104,593)			
White NH	88,094(87.1)	3,010(86.0)	<0.0001
Black NH	5,886(5.8)	69(2.0)	
Asian/PI	856(0.9)	42(1.2)	
Native American	361(0.4)	1(0.0)	
Multi-racial NH	139(0.1)	10(0.3)	
Hispanic	5,758(5.7)	367(10.5)	
Site type			
Community/HMO	77,973(76.9)	2,887(82.5)	<0.0001
Academic	10,896(10.8)	609(17.4)	
VA/military	12,498(12.3)	5(0.1)	
ASA classification			
I	31,233(32.0)	821(26.6)	<0.0001
II	62,937(64.5)	1,971(63.8)	
III	3,416(3.5)	289(9.4)	
IV	38(0.0)	10(0.3)	
Missing	3,743(3.7)	410(11.7)	

NH non-Hispanic

Table 2

Frequency of primary and secondary endpoints

Endpoint	Moderate sedation n = 101,367 (%)	Deep sedation n = 3,501 (%)	p value
Presence of advanced neoplasia	6,109(6.0)	251(7.2)	0.01
Presence of advanced neoplasia from routine ^a propofol use sites	200(n = 3,504, 5.7%)	247(n = 3,302, 7.5%)	0.003
Presence of any polyp	38,190(37.7)	1,194(34.1)	<0.0001
Average # of polyps	1.6(1.1)	1.6(1.1)	0.52
Cecal intubation rate			
No. intend to reach cecum	100,970(99.6)	3,486(99.6)	0.73
Of those, no. reach cecum	98,525(97.6)	3,436(98.6)	0.0002

^aLimited to the ten sites that performed at least 10% of their procedures using DS during the time period

Table 3

Multivariate analysis for outcome of advanced neoplasia

Characteristic	Odds ratio	95% Confidence interval
Moderate sedation	1.0 (referent)	
Deep sedation	1.25	1.10, 1.43
Age group		
<50	1.0 (referent)	
50–59	1.12	0.90, 1.39
60–69	1.61	1.29, 2.01
70	1.77	1.41, 2.21
Gender		
Female	1.0 (referent)	
Male	1.61	1.52, 1.69
Race/ethnicity		
All other race/ethnicities	1.0 (referent)	
Black non-Hispanic	1.40	1.27, 1.55
ASA classification		
I	1.0 (referent)	
II	1.25	1.18, 1.33
III/IV	1.39	1.22, 1.58
Unknown	1.27	1.11, 1.45
Site type		
Community/HMO/VA/military	1.0 (referent)	
Academic	0.75	0.69, 0.82
Prep results		
Excellent/good	1.0 (referent)	
Fair/poor	1.08	1.01, 1.15
Unknown	0.91	0.87, 1.04

Adjusted for age (categorical), site type, gender, black non-Hispanic race, ASA category, prep results

Table 4

Multivariate analysis for outcome of advanced neoplasia limited to sites with routine use of propofol

Characteristic	Odds ratio	95% Confidence interval
Moderate sedation	1.0 (referent)	
Deep sedation	1.26	1.03, 1.54
Age group		
<50	1.0 (referent)	
50–59	2.79	1.02, 7.61
60–69	4.27	1.56, 11.68
70	5.34	1.93, 14.78
Gender		
Female	1.0 (referent)	
Male	1.71	1.40, 2.10
Race/ethnicity		
All other race/ethnicities	1.0 (referent)	
Black non-Hispanic	1.02	0.58, 1.77
ASA classification		
I	1.0 (referent)	
II	1.06	0.83, 1.35
III/IV	1.02	0.64, 1.63
Unknown	0.72	0.52, 1.01
Site type		
Community/HMO/VA/military	1.0 (referent)	
Academic	1.20	0.87, 1.66
Prep results		
Excellent/good	1.0 (referent)	
Fair/poor	0.99	0.74, 1.32
Unknown	0.83	0.55, 1.25

Adjusted for age (categorical), site type, gender, black non-Hispanic race, ASA category

Limited to the ten sites that performed at least 10% of their procedures using DS during the time period