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Diagnostic yield of colonoscopy to evaluate melena after a nondiagnostic EGD

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Abstract

Background—Melena can be caused by bleeding from lower GI sources. Colonoscopy is frequently used to investigate melena after a nondiagnostic EGD.

Objective—To determine the diagnostic yield and rate of therapeutic intervention during colonoscopy in patients with melena and a nondiagnostic EGD.

Design—Retrospective case-control study.

Setting—Community and academic centers over a diverse geographic area in the United States.

Patients—This study involved patients in the Clinical Outcomes Research Initiative database with a colonoscopy performed to investigate melena within 30 days of a nondiagnostic EGD for the same indication. A control group had colonoscopies performed for average-risk screening.

Main Outcome Measurements—The endoscopic finding of a suspected bleeding source defined as right-sided arteriovenous malformation, colitis, polyp 20 mm, tumor, or ulcer. Rate of therapeutic intervention during colonoscopy.

Results—Colonoscopy found a suspected bleeding source in 4.8% of patients with melena, more frequently than in the control group (odds ratio [OR] 2.17; 95% confidence interval [CI], 1.65–2.86; *P* .0001). The rate of therapeutic intervention during melena-related colonoscopy was 1.7%. Patients with melena were more likely to have a colon tumor (OR 2.87; 95% CI, 1.82–5.51; *P* . 0001) than were control patients.

Limitations—Retrospective design, conclusions being dependent on the accuracy of database input, and lack of pertinent clinical data (eg, hemoglobin).

Conclusion—The diagnostic yield of colonoscopy to investigate melena after nondiagnostic EGD is low. The need for therapeutic intervention during colonoscopy for this indication is very low. This population should undergo colonoscopy because they are at increased risk of colorectal

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cancer. Colonoscopy can potentially be performed electively in stable patients without continued bleeding.

Melena is most frequently caused by an upper GI bleeding source. However, EGD can be nondiagnostic for a source of bleeding in approximately one-fourth of cases in this patient population.[1] It has been shown that instillation of blood into the cecum can result in melena, demonstrating that lower GI bleeding sources also can cause me-lena.[2,3] Consequently, colonoscopy is frequently per-formed in patients with melena after a nondiagnostic EGD in order to rule out a lower GI source of the melena.

Previous studies on the diagnostic yield of colonoscopy in patients with melena described a relatively high rate of finding bleeding sources. These small studies found diagnostic yields of 23% to 35% for colonoscopy in this patient population.[1,4–6] Anecdotal experience suggests a much lower rate of discovering a lower GI bleeding source in patients with melena after a nondiagnostic EGD. We performed this study to describe the diagnostic yield and rate of therapeutic intervention of colonoscopy in this patient population and compare the diagnostic yield with a control population of average-risk patients having screening colonoscopies. We hypothesized that the diagnostic yield of colonoscopy in this clinical setting is lower than previously described but higher than that of average-risk screening patients and that the rate of therapeutic intervention during colonoscopy in patients with melena and a nondiagnostic EGD is low.

METHODS

We used the Clinical Outcomes Research Initiative (CORI) National Endoscopic Database to identify a population of patients with melena who underwent colonoscopy after an EGD from 2004 to 2008. The CORI database is an endoscopic database that collects data from community, academic, and Veterans Affairs settings across a broad geographic area in the United States. The composition of the endoscopic reporting sites in the CORI database has been previously described.[7] During this time period, 67 sites submitted 724,700 colonoscopy and 406,821 EGD reports. Patients with colonoscopy performed for an indication of melena who had also had an EGD performed for an indication of melena in the previous 30 days were identified. The finding of melena was defined as the stated indication of the procedure by the provider creating the endoscopic report. The paired colonoscopy reports for EGD reports that identified a potential bleeding source were excluded from further analysis. The database criteria for exclusion included an EGD finding of arteriovenous malformation (AVM), blood clot, Cameron's ulcer, Dieulafoy's lesion, esophagitis with a Los Angeles classification of C or D, Mallory-Weiss tear, polyp 20 mm, tumor, ulcer, and varices. Following these exclusion criteria, 2039 melena-related colonoscopies remained for analysis. The EGD reports paired with these reports of colonoscopies were manually review by two of the authors (J.P.E. and Z.J.) to exclude other potential upper sources of bleeding and ensure that the earlier mentioned variables had not been miscoded under alternate labels. This excluded an additional 296 colonoscopies from further analysis. Findings of the remaining 1743 colonoscopies were recorded. Missing data for any variable were recorded as "unknown." A control population of patients who had colonoscopies performed with the indication of average-risk colon cancer screening was identified during the same time period to identify a baseline rate of endoscopic findings. Suspected lower GI bleeding sources were predefined as a finding of AVM, colitis, polyp 20 mm, tumor, or ulcer in the right side of the colon. The right side of the colon location was defined as the terminal ileum and all colon locations proximal to the splenic flexure.

The sample size required for adequate power to detect a difference in the diagnostic yield of lower GI bleeding sources was estimated with the assumption that the yield of average-risk

screening colonoscopies for the earlier-mentioned suspected bleeding sources would be approximately 1%. We hypothesized that the diagnostic yield of colonoscopy in patients with melena after a nondiagnostic EGD would be 2%. From prior CORI studies, it was known that there were approximately 150,000 average-risk screening colonoscopies in the study period of interest; therefore, to have 80% power and an alpha error level of 5%, we would need 987 melena cases to detect a difference between the melena patient cases and average-risk screening controls. Univariate statistical analyses were conducted by using a chi-square test, the Fisher exact test, and a t test, as appropriate. Multivariate logistic regression models were created by including all univariate variables that were statistically significant at a cutoff of P .05. All statistical analyses were performed by using SAS version 9.2 (SAS Institute, Cary, NC). The study was conducted under the approval of the Oregon Health and Sciences University institutional review board.

RESULTS

A total of 1743 colonoscopies were performed to evaluate melena after a nondiagnostic EGD for the same indication. The demographics of the study population are presented in Table 1. The melena population included more individuals with advanced age, more men, higher American Society of Anesthesiologists (ASA) Physical Status Classification System scores, and more warfarin use than average-risk screening controls. Melena-related colonoscopies were more likely to be conducted on inpatients, have lower quality bowel preparation, and have fellow involvement than colonoscopies on controls. Colonoscopy was performed the same day as EGD in 59% of cases. The majority of same-day bidirectional endoscopy was per-formed in the outpatient setting (72%). Table 2 details the endoscopic findings on colonoscopy in the melena and control populations. All of the defined suspected bleeding sources were more prevalent in the melena population, with the exception of polyps 20 mm in the right side of the colon. The overall rate of finding a suspected lower GI bleeding source in patients with melena was 4.76% com-pared with 1.28% in the control population (*P* .0001). In addition, many other endoscopic findings with low suspicion to cause melena also were more prevalent in the melena population compared with the average-risk screening control group. This includes right-sided diverticulosis as well as left-sided AVMs, colitis, and tumors. The overall rate of any endoscopic finding was nearly double in the melena population versus the average-risk screening control group (14.2% vs. 8.5%; *P* .0001). The overall rate of endoscopic therapy in the melena population was low, with therapy being performed in 30 (1.7%) melena-related colonoscopies. Therapeutic intervention was performed on 23 AVMs, 3 colonic ulcers, 1 diverticulum, and 3 colonic lesions of uncertain etiology. Seven lesions were actively bleeding at the time of endoscopy.

Within the melena population, a multivariate logistic regression model was created to determine which variables are associated with discovery of a suspected bleeding source (Table 3). Advanced age (odds ratio [OR] 1.04 per year; *P* .0002) and ASA class IV (OR 3.62; *P* .03) were associated with a suspected bleeding source being present. There was a trend toward male sex associated with the presence of suspected bleeding sources. Variables such as warfarin use, time between EGD and colonoscopy, bowel preparation quality, and procedure setting (inpatient vs. outpatient) were not associated with finding a suspected bleeding source in the melena population.

To determine whether the defined suspected bleeding sources were found with greater frequency in the melena patient group versus average-risk screening controls, thereby suggesting that the findings did in fact represent a source of bleeding, a multivariate logistic regression model was created to control for the demographic differences in the two study groups (Table 4). This confirmed that patients with melena were approximately twice as likely (OR 2.17; *P* .0001) to have a suspected bleeding source on colonoscopy compared

with average-risk screening controls. Additionally, age, male sex, and higher ASA classification scores were associated with a suspected bleeding source finding in the entire population.

Because colon tumors were found in 1.7% of the melena population and were likely to have the highest clinical impact on patients, we created a multivariate logistic regression model to assess whether the melena population had a stronger association with colorectal cancer (right sided or left sided) than did the average-risk screening population (Table 5). This confirmed that, after controlling for other confounding variables, the melena population had a higher association with colon tumors than the average-risk screening population (OR 2.87; *P* .0001). In addition, well-described risk factors for colorectal cancer such as advanced age, male sex, and black ethnicity also were independently associated with a finding of a colon tumor. The association of melena cases and colon tumors also was seen when we created separate multivariate logistic regression models with the outcome of right-sided colon tumors (OR 2.79; 95% confidence interval [CI], 1.59–4.87; *P* .0003) and left-sided colon tumors (OR 2.53; 95% CI, 1.26–5.08; *P* .009).

DISCUSSION

This study is the largest to-date to examine the diagnostic yield of colonoscopy to investigate melena after a nondiagnostic EGD in patients from a broad geographic distribution and a variety of clinical practice settings. By using predefined suspected bleeding sources that could produce melena from the colon, we describe an overall low rate (4.8%) of locating a bleeding source on colonoscopy. In addition, the rate of therapeutic intervention during colonoscopy for bleeding was very low at 1.7%, suggesting that the majority of these procedures are diagnostic only and could be performed on an elective basis. The likelihood of finding a suspected bleeding source was higher in patients with melena and with advanced age and an ASA class of IV. We theorize that ASA class IV scores may act as a surrogate for more severe GI bleeding or the presence of non-warfarin anticoagulation such as clopidogrel related to cardiovascular morbidities. Four of the 5 predefined suspected bleeding sources were more common in the melena population than in the average-risk screening control population, suggesting that those conditions do, in fact, lead to melena in some cases. The exception was right-sided polyps ≥ 20 mm, which were equally prevalent in both groups, despite the melena population being older with a larger male predominance. This suggests that large, right-sided polyps are rarely a source of melena. A prior study that used the CORI database in an earlier time frame (2000–2002) also found no difference in the rate of masses or polyps > 9 mm between colonoscopies performed for melena versus those performed for average-risk screening.[8] Finally, after we corrected for other known risk factors for colorectal cancer, the presence of melena and a nondiagnostic EGD was independently associated with a finding of colorectal cancer, indicating that this population benefits from colonoscopy for cancer screening purposes.

Our study found a notably lower diagnostic yield in this population than did previously published reports, which describe the location of a bleeding source in the range of 23% to 35%.[1,4–6] This difference is mainly related to differing definitions of suspected bleeding sources that could produce melena. Prior studies described polyps ≥ 5 mm,[4,5] hemorrhoids,[6] or right-sided diverticula[1] as suspected sources of melena. However, we believe that small polyps are very unlikely to be a source of bleeding and that hemorrhoids or diverticula would present as hematochezia and not melena. In addition, the prior studies were all single-center with overall low numbers of patients (range 10–53), whereas our study population was obtained from multiple community and academic centers and had a much larger sample to more accurately represent the typical patient presenting with melena. Finally, the prior

studies on this subject were conducted more than 15 years ago, when the accuracy of colonoscopic findings may have been lower because of poorer quality endoscopic images.

This study has notable limitations that merit discussion. The conclusions of this study are dependent on the accuracy of the data input to the CORI database. However, our defined suspected bleeding sources have low intraobserver variability to minimize this limitation. This study is limited by the lack of data on the histology of polyps or tumors that were found on colonoscopy. The level of evidence for melena can be variable based on patient report or clinical observation. This study was dependent on melena being the stated indication for the procedure, as recorded by the provider creating the endoscopy re-port. This study is also limited by a lack of data regarding the severity of the GI bleeding in each patient, because the CORI database does not record pertinent clinical variables such as vital signs, hemoglobin levels, or need for trans-fusion, resulting in a heterogenous study population. This study made all attempts to limit analysis to colonoscopies performed to investigate melena after a nondiagnostic EGD; however, it is possible that some of the included procedures in fact had a missed upper GI bleeding source as the causative lesion. It has been described that repeat EGD can identify previously missed sources of obscure GI bleeding in 10% of cases.[9] Furthermore, ascertainment bias might result in certain findings such as AVMs and right-sided diverticulosis being more commonly recorded in patients with melena than in the healthy controls. Finally, because the ileal intubation rate was only 35% in the melena population, it is possible that the diagnostic yield of bleeding lesions on colonoscopy was falsely lowered by missed ileal sources.

As stated previously, the strengths of this study include its large sample size and the diverse geographic and practice settings from which the data were obtained. This is the first multicenter study to assess the findings on colonoscopy in this patient population. The definition used for suspected bleeding lesions is strict to avoid falsely inflating the diagnostic yield of colonoscopy in this setting. Finally, this study is the first to report the need for therapeutic intervention during colonoscopy in this clinical setting.

In conclusion, we report that the diagnostic yield of colonoscopy to investigate melena after a nondiagnostic EGD is lower than previously reported. The rate of therapeutic intervention in this population is very low; therefore, patients with melena and a nondiagnostic EGD who are stable and without evidence of ongoing bleeding may be able to safely undergo elective colonoscopy. The decision on timing of colonoscopy must be made based on an assessment of the overall clinical context. It is possible that urgent colonoscopy may provide important diagnostic information such as indirect evidence of a small bowel bleeding source. Elective colonoscopy is of benefit in this patient population because they have an increased risk for colorectal cancer.

Abbreviations

ASA	American Society of Anesthesiologists
AVM	arterio-venous malformation
CORI	Clinical Outcomes Research Initiative

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Table 1

Demographic characteristics of study population.

Variable	Level	Melena Cases (n = 1743)	Average Risk Screening Controls (n = 194,979)	p Value
Age	**<mean>**	65.6 years (SD = 15.35 years)	60.74 years (SD = 8.50 years)	<0.0001
Gender	**Male**	1022 (58.63%)	103769 (53.22%)	<0.0001
Ethnicity	**White**	1439 (82.56%)	166356 (85.32%)	<0.0001
	Black	135 (7.75%)	9887 (5.07%)	
	Hispanic	117 (6.71%)	13910 (7.13%)	
	Asian	28 (1.61%)	3511 (1.80%)	
	American Indian	18 (1.03%)	852 (0.44%)	
	Other	5 (0.29%)	321 (0.16%)	
	Unknown	1 (0.06%)	142 (0.07%)	
ASA Class	**I**	181 (10.38%)	50651 (25.98%)	<0.0001
	II	961 (55.13%)	124152 (63.67%)	
	III	454 (26.05%)	6663 (3.42%)	
	IV and V	32 (1.84%)	80 (0.04%)	
	Unknown	115 (6.60%)	13433 (6.89%)	
Warfarin Use	**Yes**	211 (12.11%)	2538 (1.30%)	<0.0001
Procedure Setting	**Inpatient**	455 (26.10%)	317 (0.16%)	<0.0001
	Outpatient	1018 (58.41%)	168355 (86.35%)	
	Unknown	270 (15.49%)	26307 (13.49%)	
Practice Type	**Community**	1235 (70.85%)	157791 (80.93%)	<0.0001
	Academic	220 (12.62%)	16264 (8.34%)	
	VA	288 (16.52%)	20924 (10.73%)	
Fellow Involvement	**Yes**	397 (22.78%)	12444 (6.38%)	<0.0001
Prep Quality	**Excellent**	367 (21.06%)	48305 (24.77%)	<0.0001
	Good	620 (35.57%)	87918 (45.09%)	
	Fair	365 (20.94%)	30182 (15.48%)	
	Poor	148 (8.49%)	7660 (3.93%)	
	Unknown	243 (13.94%)	20914 (10.73%)	
Days Between EGD and COL	**<mean>**	1.86 days (S.D. = 4.50)	N/A	N/A
Cecum Intubated (Missing = 17)	**Yes**	1641 (94.15%)	189879 (97.39%)	<0.0001
TI Intubated (Missing = 17)	**Yes**	608 (34.88%)	28106 (14.42%)	<0.0001

Table 2

Colonoscopy findings in the study population.

	Melena Cases (n = 1743)	Average Risk Controls (n = 194979)	P value
Suspected Bleeding Source	% Colonoscopies with Finding		
Colitis - Right Colon			
Crohn's Disease	3 (0.17%)	28 (0.01%)	0.0026
Infectious Colitis	1 (0.06%)	1 (0.001%)	0.0176
Ischemic Colitis	4 (0.23%)	16 (0.01%)	<0.0001
Radiation Colitis	0	0	N/A
Ulcerative Colitis	1 (0.06%)	12 (0.01%)	0.1093
Misc. Colitis	1 (0.06%)	101 (0.05%)	0.5967
Polyp ≥ 20mm - Right Colon	9 (0.52%)	1136 (0.58%)	0.7173
Tumor - Right Colon	20 (1.15%)	422 (0.22%)	<0.0001
AVM - Right Colon	43 (2.47%)	679 (0.35%)	<0.0001
Ulcer - Right Colon	4 (0.23%)	131 (0.07%)	0.0327
Any Suspected Bleeding Source	83 (4.76%)	2501 (1.28%)	<0.0001
Low Suspicion Finding	% Colonoscopies with Finding		
Diverticulosis – right colon	38 (2.18%)	2496 (1.28%)	0.0009
Polyp ≥ 20mm - Left Colon	17 (0.98%)	1126 (0.58%)	0.0296
Polyp 10–19 mm - Right Colon	47 (2.70%)	4725 (2.42%)	0.4605
Polyp 10–19 mm - Left Colon	36 (2.07%)	5221 (2.68%)	0.1145
Colitis – Left colon			
Crohn's Disease	1 (0.06%)	1 (0.001%)	0.0176
Infectious Colitis	0	3 (0.002%)	≈1.0
Ischemic Colitis	6 (0.34%)	17 (0.01%)	<0.0001
Radiation Colitis	4 (0.23%)	72 (0.04%)	0.0048
Ulcerative Colitis	0	15 (0.01%)	≈1.0
Misc. Colitis	9 (0.52%)	116 (0.06%)	<0.0001
Tumor – Left colon	9 (0.52%)	254 (0.13%)	<0.0001
AVM – Left colon	11 (0.63%)	327 (0.17%)	<0.0001
Ulcer – Left Colon	4 (0.23%)	50 (0.03%)	0.0014
Any Low Suspicion Finding	177 (10.15%)	14184 (7.27%)	<0.0001
Any Potential Bleeding Source	248 (14.23%)	16517 (8.47%)	<0.0001

Table 3

Variables associated with finding a suspected bleeding source in the melena population.*

Variable	Level	OR	95% CI	p-value
Age	**1 Year Increase**	1.036	1.017 – 1.055	0.0002
Gender	**Male**	1.556	0.963 – 2.516	0.0712
ASA Class	**I**	Reference		
	II	1.072	0.448 – 2.568	0.9409
	III	1.380	0.560 – 3.404	0.4173
	IV	3.624	1.125 – 11.681	0.0334
	Unknown	0.481	0.116 – 1.998	0.5681

* Logistic regression model created by including all variables significant in univariate analysis at a cutoff of P <.05. Model outcome is a finding of one of the defined suspected bleeding sources. Variables not significant in univariate analysis: ethnicity, warfarin use, procedure setting, practice type, fellow involvement, bowel preparation quality, time between EGD and colonoscopy.

Table 4

Variables associated with a suspected bleeding source in total study population*

Variable	Level	OR	95% CI	p-value
Study Status	**Case**	2.173	1.653 – 2.857	<0.0001
	Screening	Reference		
Age	**<1 Year Increase>**	1.045	1.041 – 1.050	<0.0001
Gender	**Male**	1.240	1.142 – 1.345	<0.0001
Ethnicity	**White**	Reference		
	Black	1.156	0.975 – 1.370	0.0957
	Hispanic	0.931	0.793 – 1.094	0.3856
	Asian	0.584	0.393 – 0.868	0.0078
	American Indian	1.698	1.073 – 2.686	0.0238
	Other	1.425	0.634 – 3.206	0.3916
	Unknown	1.423	0.452 – 4.485	0.5467
ASA Class	**I**	Reference		
	II	1.210	1.090 – 1.343	0.0004
	III	1.730	1.442 – 2.075	<0.0001
	IV or V	4.252	2.000 – 9.040	0.0002
	Unknown	1.158	0.971 – 1.381	0.1030
Warfarin Use	**Yes**	1.177	0.919 – 1.507	0.1965
Procedure Setting	**Inpatient**	1.097	0.724 – 1.662	0.6609
	Outpatient	Reference		
	Unknown	0.916	0.815 – 1.031	0.1457
Practice Type	**Community**	Reference		
	Academic	0.748	0.638 – 0.876	0.0003
	VA	1.060	0.922 – 1.217	0.4134
Fellow Involvement	**Yes**	1.028	0.867 – 1.219	0.7491

* Logistic regression model created by including all variables significant in univariate analysis at a cutoff of P <.05. Model outcome is a finding of one of the defined suspected bleeding sources. Bowel preparation quality was not significant in univariate analysis.

Table 5

Variables associated with a colon tumor in total study population.*

Variable	Level	OR	95% CI	p-value
Study Status	**Case**	2.866	1.823 – 4.506	<0.0001
	Screening	Reference		
Age	**<1 Year Increase>**	1.058	1.050 – 1.067	<0.0001
Gender	**Male**	1.311	1.123 – 1.530	<0.0001
Ethnicity	**White**	Reference		
	Black	2.149	1.660 – 2.782	<0.0001
	Hispanic	1.198	0.902 – 1.591	0.2119
	Asian	1.237	0.712 – 2.150	0.4495
	American Indian	1.455	0.542 – 3.908	0.4565
	Other**	N/A	N/A	N/A
	Unknown**	N/A	N/A	N/A
ASA Class	**I**	Reference		
	II	1.319	1.075 – 1.617	0.0078
	III	1.391	0.963 – 2.011	0.0788
	IV or V	1.491	0.200 – 11.108	0.6964
	Unknown	0.930	0.644 – 1.343	0.6987
Warfarin Use	**Yes**	0.977	0.593 – 1.610	0.9271
Procedure Setting	**Inpatient**	1.003	0.480 – 2.096	0.9935
	Outpatient	Reference		
	Unknown	1.244	1.017 – 1.522	0.0335
Practice Type	**Community**	Reference		
	Academic	0.600	0.430 – 0.836	0.0025
	VA	0.870	0.679 – 1.114	0.2700

* Logistic regression model created by including all variables significant in univariate analysis at a cutoff of P <.05. Model outcome is a finding of tumor in any location. Variables not significant in univariate analysis were fellow involvement and bowel preparation quality.

** No tumors found in the other and unknown ethnicity groups.