

# Systematic evaluation of complications related to endoscopy in a training setting: a prospective 30-day outcomes study

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**Background:** The 30-day frequency of negative outcomes after outpatient endoscopy performed by gastroenterology fellows is unknown.

**Methods:** Questionnaires were mailed to 1000 consecutive patients 30 days after endoscopy to evaluate procedure-related negative outcomes (serious and minor adverse events) and patient satisfaction. Serious adverse events were defined as follows: oversedation requiring administration of a reversal agent, and those that resulted in a physician visit, emergency department visit, admission to the hospital, or death. Minor adverse events were defined as all problems other than serious adverse events that patients related to their endoscopic procedure.

**Results:** The 30-day frequency of negative outcomes in the 869 patients who responded was 14.3%, of which 0.6% were serious and 13.7% were minor adverse events. The frequency of negative outcomes was 17.1% for EGD, 15.0% for colonoscopy, 24.4% for combined EGD and colonoscopy, and 7.8% for flexible sigmoidoscopy. One hundred percent of the serious adverse events were known to us, but only 16.0% of minor adverse events ( $p < 0.001$ ). Multiple logistic regression identified midazolam dose (OR for each 1 mg increase in dose 4.5; 95% CI [2.7, 7.3];  $p < 0.001$ ), treatment with warfarin (OR 3.0; 95% CI [1.4, 6.2];  $p = 0.003$ ), comorbid disease (OR 2.1; 95% CI [1.3, 3.4];  $p = 0.001$ ), endoscopy performed in July or August (OR 2.0; 95% CI [1.1, 3.7];  $p = 0.02$ ), and age (OR for each 1 year increase in age 1.03; 95% CI [1.01, 1.05];  $p = 0.01$ ) as independent predictors of negative outcomes. There was a significant association between negative outcomes and decreased patient satisfaction, and patients who reported negative outcomes were less likely to agree to endoscopy in the future.

**Conclusions:** Serious adverse events were rare after endoscopy performed by gastroenterology fellows. Contacting patients 30 days after outpatient endoscopy significantly improved the detection of negative outcomes. Although the majority of negative outcomes were minor, these adverse events were associated with decreased patient satisfaction. (Gastrointest Endosc 2003;57:8-16.)

The definition of an endoscopic complication and the grading of complication severity have not been standardized. An endoscopic complication can be defined as any deviation from the optimal course of a patient after endoscopy.<sup>1,2</sup> Alternatively, a complication may be defined as an adverse event that necessitates intervention.<sup>3</sup> The term negative outcome has also been used to describe complications and adverse events related to endoscopy.<sup>4,5</sup> This lack of consensus has made it difficult to accurately assess the true frequency of endoscopy-related complications. Further-

more, the majority of studies of endoscopy-related complications were case reports or retrospective reviews that relied on data from endoscopy reports and physician recall.<sup>6</sup> These studies may have incorrectly assessed the true frequency of endoscopy-related complications because of sampling/selection, confounding, and measurement biases.<sup>7</sup>

Endoscopic complications can be categorized as immediate (occurring during the procedure or before discharge from the endoscopy unit) or delayed (occurring up to 30 days after the procedure).<sup>3</sup> The frequency and spectrum of immediate complications are well described.<sup>6-13</sup> Little is known about delayed complications. Furthermore, there are currently no firmly established methods for identification and recording of delayed negative outcomes. Surgeons commonly use a period of 30 days for assessing procedure-related complications.<sup>14-16</sup> However, similar standards have not been established for endoscopy.

The 30-day frequency of negative outcomes (serious and minor adverse events) after endoscopy performed by gastroenterology fellows under the supervision of

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attending physicians is unknown. The primary aim of this study was to prospectively determine the frequency of negative outcomes within 30 days of outpatient EGD, colonoscopy, and flexible sigmoidoscopy in a training program setting. Secondary aims were to evaluate risk factors for negative outcomes and to assess whether these were associated with decreased patient satisfaction.

## PATIENTS AND METHODS

### Patient population and data collection

One thousand consecutive patients undergoing outpatient EGD, colonoscopy, combined EGD and colonoscopy, or flexible sigmoidoscopy at a Veterans Affairs hospital were enrolled in the study. All endoscopic procedures were performed by gastroenterology fellows under the direct supervision of an attending gastroenterologist. Eight fellows participated, and each procedure was supervised by 1 of 2 experienced gastroenterologists (E.J.B., E.H.W.). Endoscopy was performed by using standard diagnostic videoendoscopes; transnasal and pediatric endoscopes were not used. The study protocol was approved by the Institutional Review Board at our medical center. Written informed consent for endoscopy was obtained from all patients before the procedure. However, the need to obtain additional written informed consent for participation in the study was waived by our Institutional Review Board because the survey was performed as part of a performance improvement project.

Before endoscopy, a detailed medical history was obtained and patients underwent a complete physical examination. Data collected on each patient included the following: age, gender, race, comorbid medical conditions, daily use of aspirin or a nonsteroidal anti-inflammatory drug (NSAID), treatment with warfarin, current alcohol ingestion (ingestion of 3 or more alcoholic beverages per day), and indications for endoscopy. Comorbid illness was defined as the presence of any of the following: cardiovascular disease (congestive heart failure, angina, or myocardial infarction within the last 6 months), pulmonary disease (severe asthma or chronic obstructive pulmonary disease), renal disease (creatinine >2 mg/dL), neurologic disease (central nervous system disease with loss of independence), malignancy (except localized skin or prostate cancer), liver disease (acute hepatitis, chronic hepatitis, or cirrhosis), or infection with the human immunodeficiency virus. After each endoscopic procedure, demographic and clinical data, the indication(s) for endoscopy, endoscopic findings, dosages of medications used, and any therapeutic procedures performed were entered into a computerized database (Excel 2000, Microsoft Corp., Redmond, Wash.). In addition, the name of the fellow who performed the procedure was recorded as well as the level of fellowship training (1st, 2nd, or 3rd year).

### Definition of negative outcomes

Serious adverse events were defined as oversedation requiring the administration of a reversal agent, and those

that resulted in a physician or emergency department visit, hospitalization, or death.<sup>1,2</sup> Minor adverse events were defined as all problems, other than serious adverse events, that patients felt were related to their procedure.

### Measurement of negative outcomes and patient satisfaction

A survey to assess negative outcomes was mailed to each patient 30 days after outpatient endoscopy (Appendix). Patients were asked about symptoms that occurred within 30 days of the procedure that they felt were related to the endoscopy, including nausea or vomiting, sore throat, headache, pain at the intravenous catheter site, shortness of breath, abdominal discomfort, GI bleeding, or other problems. They were also asked whether they had seen a physician or visited the emergency department for any problems that may have been related to endoscopy, or whether they were admitted to a hospital within 30 days of the procedure.

Additionally, the survey questionnaire assesses satisfaction with the endoscopic procedure (Appendix). This portion of the survey was a modified version of the Group Health Association of America-9 survey, a well-validated instrument for measuring patient satisfaction with medical care.<sup>17</sup> This survey instrument was modified to make it applicable to measurement of patient satisfaction after endoscopy.<sup>18,19</sup> Patients were asked questions relating to their satisfaction with the endoscopic procedure, conscious sedation, their overall treatment by the doctors and support staff, courtesy of the staff, and whether they felt they were treated with respect. They were also asked about the adequacy of the information given to them after endoscopy, and whether they would have the procedure again if it were deemed necessary.

Selection of items for inclusion in the survey was based on interviews with patients undergoing outpatient endoscopy. Items were chosen on the basis of their face validity as issues pertinent to the theoretical construct of endoscopy-related negative outcomes and patient satisfaction. The negative outcomes and patient satisfaction survey instrument was pretested in the target population, which indicated that it was responsive to variation both in individual patient responses and between patients.

If the survey questionnaire was not returned within 2 weeks, the patient was contacted by telephone and the survey was administered over the telephone by trained interviewers. A minimum of 3 attempts were made to contact all patients who did not return the questionnaire.

The electronic medical record of all patients who reported serious adverse events was reviewed to determine outcomes for these individuals. Also reviewed were the electronic medical records of all patients who did not return the questionnaire and could not be contacted by telephone to determine whether they were still alive and whether they had experienced any negative outcomes within 30 days after endoscopy.

### Documentation of negative outcomes

At our medical center gastroenterology fellows routinely record all negative outcomes in computer-generated

**Table 1. Characteristics of the 869 patients who responded to the survey**

Mean age (SD), years	68.6 (10.3)
Male gender	853 (98.2%)
Race	
White	456 (52.5%)
Black	280 (32.2%)
Hispanic	122 (14.0%)
Asian/other	11 (1.3%)
Comorbid disease	362 (41.7%)
Aspirin use	393 (45.2%)
NSAID use	139 (16.0%)
Warfarin use	58 (6.7%)
Alcohol use	50 (5.8%)
Procedures performed	
EGD	140 (16.1%)
Colonoscopy	400 (46.0%)
EGD and colonoscopy	86 (9.9%)
Flexible sigmoidoscopy	243 (28.0%)
Endoscopy performed by	
1st year fellow	364 (41.9%)
2nd year fellow	333 (38.3%)
3rd year fellow	172 (19.8%)
Therapeutic endoscopic procedure	163 (18.8%)
Median (IQR) dose of medications given*	
Meperidine, mg	50.0 (0.0-50.0)
Midazolam, mg	1.0 (0.0-1.0)

IQR, Interquartile range.

\*Conscious sedation was not given for patients undergoing flexible sigmoidoscopy.

endoscopy reports, a personal procedure log, and the complications logbook of the endoscopy suite. These data were recorded at the time of the procedure if the adverse event was detected immediately, or were entered later for delayed events. The documentation of adverse events was checked by attending physicians to ensure that it was complete and accurate. Adverse events reported by patients 30 days after endoscopy were compared with those noted in the computerized patient record and logbook of complications in the endoscopy suite. The proportion of negative outcomes reported at 30 days that were known to the gastroenterology service was also calculated.

### Statistical analysis

Several analyses were performed and all were determined a priori. The 30-day frequency of negative outcomes was calculated for each type of endoscopic procedure, and data were stratified according to the level of training of the fellows (1st, 2nd, or 3rd year) who performed the procedures, the individual fellow, and time of the year during which the procedure occurred (July and August vs. other). Whether the endoscopists who performed the procedures were aware of the adverse events was determined. Risk factors for negative outcomes were evaluated. Finally, patient satisfaction was assessed and the association between negative outcomes and patient satisfaction was evaluated.

Continuous variables were compared by using the Student *t* test or the Mann-Whitney *U* test as appropriate. Data are expressed as means (SD) for those variables that were normally distributed, and medians with interquar-

tile ranges (IQR) for those with a non-Gaussian distribution. Categorical variables were compared with the chi-square with Yates correction or the Fisher exact test.

Univariate logistic regression analyses were used to identify those variables that were significantly associated with negative outcomes. Subsequently, a multivariate logistic regression model was created involving all significant variables identified in the univariate analyses. The multivariate regression analysis could then assess the independent effect of each variable in the model adjusted for the effects of each of the other variables. Odds ratios (OR) and 95% confidence intervals (CI) were calculated where appropriate.

Statistical analysis was performed by using a statistical software program (SPSS version 11.0 for Windows, SPSS Inc., Chicago, Ill.) and a two-tailed *p* value of <0.05 was considered statistically significant. As the main findings giving the significant associations of risk factors for negative outcomes were found in a multivariate setting, no correction was made for the multiple testing of data arising from the same patients. For patient satisfaction responses, no correction of *p* values are given to highlight differences; however, it should be noted that correction of significance levels for the multiple testing of those data would remove significance except where *p* < 0.001.

## RESULTS

One thousand consecutive patients undergoing outpatient endoscopy over a 9-month period (December through August) were included in this study. Of these, 869 (86.9%) were successfully contacted by mail or telephone 30 days after their procedure (Table 1). There were no significant differences between the 869 patients contacted and the 131 individuals who could not be contacted by mail or telephone (data not shown). The majority of procedures were performed by first and second year fellows. The median number of endoscopic procedures performed among the 8 fellows was 109 (IQR: 98-110).

There were 226 patients who had EGD alone or in combination with colonoscopy and 17 (7.5%) of these procedures were therapeutic (esophageal dilation, injection therapy, multipolar electrocoagulation, and band ligation). Of the 486 patients who underwent colonoscopy alone or in combination with EGD, electrosurgical snare polypectomy was performed in 147 (30.2%). A total of 425 polyps were removed in these 147 individuals; the median number removed was 3 (IQR: 1-4) and median polyp size was 8.0 mm (IQR: 7.0-15.0 mm). No therapeutic procedures were performed in patients who underwent flexible sigmoidoscopy.

### Thirty-day frequency of negative outcomes

The frequency of negative outcomes was 14.3%: 95% CI [12.0%, 16.8%]; 0.6%: 95% CI [0.2%, 1.3%] were serious adverse events and 13.7%: 95% CI

**Table 2. Incidence of minor adverse events stratified according to the type of procedure performed**

Type of complication	All procedures (n = 869)	EGD (n = 140)	Colonoscopy (n = 400)	EGD and colonoscopy (n = 86)	Flexible sigmoidoscopy (n = 243)
Abdominal discomfort	51 (5.9%)	10 (7.1%)	21 (5.3%)	8 (9.3%)	12 (4.9%)
Sore throat	41 (4.7%)	17 (12.1%)	11 (2.8%)	11 (12.8%)	2 (0.8%)
Nausea or vomiting	27 (3.1%)	3 (2.1%)	15 (3.8%)	6 (7.0%)	3 (1.2%)
Shortness of breath	27 (3.1%)	3 (2.1%)	15 (3.8%)	4 (4.7%)	5 (2.1%)
Headache	24 (2.8%)	5 (3.6%)	10 (2.5%)	2 (2.3%)	7 (2.9%)
Rectal bleeding	20 (2.3%)	1 (0.7%)	11 (2.8%)	4 (4.7%)	4 (1.6%)
Change in bowel habits	19 (2.2%)	0 (0.0%)	11 (2.8%)	4 (4.7%)	4 (1.6%)
Pain at the intravenous site	14 (1.6%)	5 (3.6%)	8 (2.0%)	1 (1.2%)	0 (0.0%)
Dizziness	13 (1.5%)	2 (1.4%)	8 (2.0%)	0 (0.0%)	3 (1.2%)
Fatigue	7 (0.8%)	2 (1.4%)	2 (0.5%)	2 (2.3%)	1 (0.4%)
Musculoskeletal pain	5 (0.6%)	1 (0.7%)	1 (0.3%)	2 (2.3%)	1 (0.4%)
Hoarseness	4 (0.5%)	2 (1.4%)	0 (0.0%)	2 (2.3%)	0 (0.0%)
Mild chest pain	3 (0.3%)	2 (1.4%)	0 (0.0%)	1 (1.2%)	0 (0.0%)
Decreased appetite	2 (0.2%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.4%)
Fever	2 (0.2%)	0 (0.0%)	1 (0.3%)	1 (1.2%)	0 (0.0%)
Rash	2 (0.2%)	1 (0.7%)	0 (0.0%)	1 (1.2%)	0 (0.0%)
Nocturia	1 (0.1%)	0 (0.0%)	0 (0.0%)	1 (1.2%)	0 (0.0%)
Nosebleed	1 (0.1%)	1 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Some patients reported more than one minor adverse event.

[11.5%, 16.2%] were minor adverse events. The frequency of negative outcomes was 16.8%: 95% CI [13.1%, 21.0%] for first year, 13.5%: 95% CI [10.0%, 17.7%] for second year, and 10.5%: 95% CI [6.3%, 16.0%] for third year fellows ( $p = 0.13$ ). The median frequency of negative outcomes among the 8 fellows was 15.4% (IQR: 11.6%-16.5%), with no significant differences among fellows ( $p = 0.58$ ). The frequency of negative outcomes differed by the month in which the procedure was performed (median 15.5%; IQR: 9.6%-17.8%), although this difference did not reach statistical significance ( $p = 0.09$ ). The frequency of negative outcomes was significantly higher early in the academic year (July and August) compared with the remainder of the study period (20.9% vs. 12.7%; OR 1.8; 95% CI [1.2, 2.8];  $p = 0.008$ ).

The frequency of negative outcomes was 17.1%: 95% CI [11.3%, 24.4%] for EGD, 15.0%: 95% CI [11.6%, 18.9%] for colonoscopy, 24.4%: 95% CI [15.8%, 34.9%] for combined EGD and colonoscopy, and 7.8%: 95% CI [4.8%, 11.9%] for flexible sigmoidoscopy. The 30-day frequency of negative outcomes for patients undergoing combined EGD and colonoscopy was significantly higher than those who had colonoscopy alone (OR 1.8; 95% CI [1.1, 3.2];  $p = 0.03$ ).

There were 5 serious adverse events including one instance each of colon perforation, oxygen desaturation requiring administration of naloxone, post-polypectomy bleeding, hospital admission for abdominal pain, and physician visit for rectal pain. No patient died within 30 days of endoscopy.

Minor adverse events occurred in 119 patients (13.7%) (Table 2), the most common being abdominal discomfort (5.9%) and sore throat (4.7%). Among the 51 patients with abdominal discomfort, 7 had abdominal pain as the indication for endoscopy. Of the 20 patients with rectal bleeding, this symptom was the indication for endoscopy in 11.

The electronic medical records of all 131 patients who could not be contacted by mail or telephone were reviewed to exclude the possibility that negative outcomes were not detected for these individuals. None visited the emergency room or a physician for adverse events related to endoscopy. In addition, none of these patients were hospitalized or died within 30 days of endoscopy.

#### Physician awareness of negative outcomes

Before contacting patients at 30 days, the gastroenterology service was significantly more likely to be aware of serious adverse events than minor adverse events (100% of serious adverse events vs. only 16.0% of minor adverse events, a difference of 84.0%: 95% CI [77.5%, 90.6%];  $p < 0.001$ ).

#### Risk factors for negative outcomes

One or more negative outcomes were reported by 124 of the 869 patients (14.3%). Because of the small number of serious adverse events ( $n = 5$ ), serious and minor adverse events were considered together in the risk factor analysis. The 124 patients who reported negative outcomes and the 745 who did not are compared in Table 3. In the univariate analysis, age,

**Table 3. Univariate analysis comparing patients with and without negative outcomes 30 days after endoscopy**

	Negative outcomes (n = 124)	No negative outcomes (n = 745)	Unadjusted OR [95% CI]	p Value
Age, y*	70.5 (11.0)	68.2 (10.2)	1.02 [1.00, 1.04]	0.02
Male gender	119 (96.0%)	734 (98.5%)	0.4 [0.1, 1.0]	0.06
Comorbid disease	66 (53.2%)	296 (39.7%)	1.7 [1.2, 2.5]	0.005
Aspirin use	61 (49.2%)	332 (44.6%)	1.2 [0.8, 1.8]	0.34
NSAID use	23 (18.5%)	116 (15.6%)	1.2 [0.8, 2.0]	0.40
Warfarin use	16 (12.9%)	42 (5.6%)	2.5 [1.3, 4.6]	0.003
Alcohol use	9 (7.3%)	41 (5.5%)	1.3 [0.6, 2.8]	0.44
Same-day EGD and colonoscopy	21 (16.9%)	65 (8.7%)	2.1 [1.3, 3.6]	0.005
Endoscopy performed by	61 (49.2%)	303 (40.7%)	1.4 [0.9, 2.1]	0.08
1st year fellow				
Therapeutic endoscopic procedure	33 (26.6%)	130 (17.4%)	1.7 [1.1, 2.7]	0.02
Median dose of medications given†				
Meperidine, mg	50.0 (50.0-75.0)	50.0 (0.0-50.0)	1.01 [1.00, 1.02]	< 0.001
Midazolam, mg	1.5 (1.0-2.0)	1.0 (0.0-1.0)	2.4 [1.8, 3.1]	< 0.001
Procedure performed in July or August	34 (27.4%)	129 (17.3%)	1.8 [1.2, 2.8]	0.008

\*Data expressed as mean (SD).

†Data expressed as median (interquartile range).

**Table 4. Independent predictors of negative outcomes 30 days after endoscopy by multivariate analysis**

	OR	95% CI	p Value
Midazolam dose*	4.5	[2.7, 7.3]	< 0.001
Warfarin use	3.0	[1.4, 6.2]	0.003
Comorbid disease	2.1	[1.3, 3.4]	0.001
Procedure performed in July or August	2.0	[1.1, 3.7]	0.02
Age†	1.03	[1.01, 1.05]	0.01

\*OR is for each 1-mg increase in dose.

†OR is for each 1-year increase in age.

comorbid disease, treatment with warfarin, same-day EGD and colonoscopy, therapeutic endoscopic procedures, dosages of meperidine and midazolam administered, and endoscopic procedure in July or August were significantly associated with negative outcomes.

A multiple logistic regression model was created by using all of the variables that were statistically significant in the univariate analysis. After adjusting for patient gender, indications for endoscopy, and individual fellow who performed the procedure, multiple logistic regression identified 5 variables that were independent predictors of negative outcomes (Table 4).

To evaluate the association between risk factors and negative outcomes, it was determined whether any of the variables in the multivariate model were significantly associated with a specific type of negative outcome. Patients who were taking warfarin were significantly more likely to experience rectal bleeding than those not undergoing anticoagulant

therapy (8.6% vs. 1.8%;  $p = 0.001$ ). No other statistically significant associations were found between variables in the multivariate model and specific types of negative outcomes.

### Patient satisfaction

There was a significant association between negative outcomes and decreased patient satisfaction for 5 of the 9 questions included in the survey instrument (Table 5). Patients who reported negative outcomes were significantly less likely to agree to have an endoscopic procedure again in the future if their doctor thought it necessary.

### DISCUSSION

This study prospectively evaluated negative outcomes (serious and minor adverse events) 30 days after outpatient endoscopy performed by gastroenterology fellows under the direct supervision of an attending gastroenterologist. Although minor adverse events occurred in 13.7% of patients, serious adverse events were uncommon (0.6%). To our knowledge, this is the first study to prospectively evaluate the frequency of negative outcomes 30 days after endoscopy performed in a training setting.

Zubarik et al.,<sup>2</sup> in a study of the frequency of negative outcomes, contacted 473 patients 30 days after outpatient EGD. The 30-day frequency of negative outcomes after EGD performed by gastroenterologists and colorectal surgeons was 18.2%, sore throat (9.5%) and abdominal discomfort (5.3%) being the adverse events most commonly reported by patients.

**Table 5. Patient satisfaction according to the presence or absence of negative outcomes 30 days after endoscopy**

	All patients (n = 869)	Proportion responding yes		p Value*
		Patients with negative outcomes (n = 124)	Patients without negative outcomes (n = 745)	
Were the doctors, nurses, and other GI staff courteous and helpful?	835 (96.1%)	116 (93.5%)	719 (96.5%)	0.12
Were you completely satisfied with the care that you received?	817 (94.0%)	105 (84.7%)	712 (95.6%)	< 0.001
Were you satisfied with the sedation you received for the procedure?†	579 (92.5%)	95 (90.5%)	484 (92.9%)	0.39
Were you satisfied with the way you were treated by the doctors and support staff?	826 (95.1%)	110 (88.7%)	716 (96.1%)	< 0.001
Did you feel that you were treated with respect?	831 (95.6%)	115 (92.7%)	716 (96.1%)	0.09
Was the procedure performed in a timely manner?	796 (91.6%)	111 (89.5%)	685 (91.9%)	0.37
Were the post-procedure instructions reviewed with you in a clear manner?	814 (93.7%)	106 (85.5%)	708 (95.0%)	< 0.001
Were all your questions answered?	784 (90.2%)	105 (84.7%)	679 (91.1%)	0.03
Would you have the procedure again if your doctor thought it was necessary?	756 (87.0%)	99 (79.8%)	657 (88.2%)	0.01

\*p Value is for comparison between patients with and those without negative outcomes.

†Only 626 patients responded to this question. The remaining 243 patients had a flexible sigmoidoscopy and did not receive sedation.

In the present study, the 30-day frequency of negative outcomes after EGD performed by gastroenterology fellows (17.1%) was similar to that reported by Zubarik et al.<sup>2</sup> The most common adverse events reported by patients in the current study were also sore throat (12.1%) and abdominal discomfort (7.1%).

In contrast to the abundance of data on immediate complications of colonoscopy, little is known about late complications of this commonly performed procedure. Zubarik et al.<sup>1</sup> prospectively studied the frequency of negative outcomes 30 days after outpatient colonoscopy. Twenty gastroenterologists and colorectal surgeons performed 1621 colonoscopies over a 1-year period; 1196 (73.8%) patients were successfully interviewed by telephone 30 days after the procedure. Negative outcomes were reported by 188 patients (15.7%) with abdominal discomfort (5.4%) and rectal bleeding (2.1%) as the most common adverse events. In the present study, the frequency of negative outcomes 30 days after outpatient colonoscopy was 15.0%, similar to that in the study of Zubarik et al.<sup>1</sup> The most common adverse events reported by patients in the present study were abdominal discomfort (5.3%), nausea or vomiting (3.8%), and shortness of breath (3.8%).

Performance of both EGD and colonoscopy at a single endoscopic session is common practice.<sup>20,21</sup> This has several potential advantages including lower cost, shorter length of hospital stay, and increased efficiency.<sup>20</sup> A study comparing same-day and alternate-day EGD and colonoscopy found the former was feasible, had an excellent diagnostic

yield, and was not associated with an increased risk of complications.<sup>20</sup> In contrast, same-day EGD and colonoscopy in the present study was associated with a higher frequency of negative outcomes (24.4%) than either EGD (17.1%) or colonoscopy (15.0%) when performed as single procedures. However, because all of our patients who had combined EGD and colonoscopy had both procedures performed on the same day, a direct comparison of negative outcomes for same-day versus different-day EGD and colonoscopy cannot be made by using data from the present study.

Contacting patients 30 days after endoscopy significantly improved the detection of endoscopy-related negative outcomes. Although all serious adverse events were known, only 16.0% of the minor adverse events were known. There are several possible reasons for this. First, it is possible that patients did not feel it necessary to contact the endoscopist who performed the procedure, thinking that it was normal to experience symptoms after endoscopy, or that these were temporary and would resolve spontaneously. Second, the endoscopist may have been contacted by the patient but did not record the adverse event because it was believed to be unrelated to the procedure. Third, it is possible that the endoscopist was contacted but failed to record the adverse event(s) in the procedure report, electronic medical record, or complications logbook, despite acknowledging that it was related to the procedure. Underreporting of negative outcomes by endoscopists has been described in previous studies.<sup>1,2,6</sup>

A better understanding of which patient-, procedure-, and endoscopist-related characteristics increase the risk of negative outcomes is essential to improvement of patient care. The present study identified midazolam dosage, treatment with warfarin, comorbid disease, endoscopy early in the academic year (July or August), and age as independent risk factors for the development of negative outcomes within 30 days of outpatient endoscopy in a training setting. The finding that higher doses of midazolam were associated with increased risk is important because this risk factor can be modified by exercising caution when sedating patients during endoscopy. An increased risk of endoscopy-related negative outcomes was noted for patients whose procedures were performed early in the academic year. Although the gastroenterology fellows, who begin training in July, were supervised by experienced gastroenterologists, the increased frequency of negative outcomes may be due to procedures that are more traumatic and longer in duration than those performed later in the academic year. These risk factors for negative outcomes within 30 days of endoscopy and strategies to reduce these risks should be evaluated in further prospective studies.

A relationship between endoscopy-related negative outcomes and patient satisfaction has not been reported. Although adverse events such as sore throat or pain at the intravenous site may seem trivial to endoscopists, patients may not agree. In the present study, there was a significant association between negative outcomes and decreased patient satisfaction. Furthermore, patients who reported negative outcomes were significantly less likely to agree to have an endoscopic procedure in the future if it was deemed necessary. Although these negative outcomes may have directly resulted in decreased patient satisfaction, it is possible that patients who were dissatisfied with their care were more likely to report adverse events compared with those who felt they received adequate care. Nonetheless, these unrecognized negative outcomes in our cohort of patients may result in poor compliance when repeat endoscopy is clinically indicated and may negatively impact quality of life, future care, resource utilization, and health care costs. Future studies to determine the impact of procedure-related negative outcomes on patient compliance with repeat endoscopy are warranted.

The present study has several limitations. First, it was conducted at a single center and the results may not be generalizable. Second, the study evaluated negative outcomes after endoscopy performed by a small number of gastroenterology fellows at different levels of training. This may result in an operator-dependent variable that influences the adverse event

rates, and a multicenter study with a large number of fellows is necessary to further evaluate negative outcomes after endoscopy in the training setting. Third, the majority of our patients were elderly men (mean age 68.6 years). Studies have shown that women and older patients are more likely to report complications after endoscopy.<sup>1,2</sup> Therefore, the current study may not accurately reflect of the true frequency of negative outcomes. Fourth, questioning patients about negative outcomes and satisfaction 30 days after the procedure may be subject to recall and response bias. Patients may forget to report adverse events that occur immediately after the procedure. However, patients are unlikely to forget serious adverse events such as postpolypectomy bleeding or colonic perforation. Harewood et al.<sup>18</sup> found that patients who did not respond to a satisfaction survey after endoscopy were significantly more satisfied when contacted by telephone than those who responded to a postal survey. These investigators concluded that this response bias may result in an underestimation of patient satisfaction after endoscopy. Fifth, the definition of negative outcomes used in the present study may differ from that used in other studies. Unfortunately, there is no standard definition of endoscopy-related negative outcomes. Sixth, the survey questionnaire used in the current study did not specify the timing of the negative outcome in relation to the procedure and cannot prove causality. Although patients were specifically asked about adverse events they felt were related to endoscopy, a control group of patients who did not undergo endoscopy was not included. Therefore, the study may have overestimated the frequency of negative outcomes because patients may have reported symptoms that were unrelated to the endoscopic procedure.

In conclusion, contacting patients 30 days after outpatient endoscopy significantly improved the detection of negative outcomes. Although the majority were minor, the importance of detecting these adverse events lies in their association with decreased patient satisfaction. The development of valid, reliable instruments for detection of delayed adverse events could improve fellowship training as well as patient care. Large, well-designed, multicenter studies of endoscopy-related negative outcomes in the training setting are needed to confirm the findings of the current study, and to determine the feasibility and cost-effectiveness of the 30-day follow-up assessment for adverse events.

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Appendix

Negative Outcomes and Patient Satisfaction Survey

You were recently seen by the Gastroenterology service and had an endoscopic procedure performed. We would like to ask you to please take a few minutes to complete the following survey.

- 1. Did you have any of the following symptoms within 30 days of your endoscopy that you felt were related to your procedure: A. Nausea or vomiting: Yes\_\_\_ No\_\_\_ B. Sore throat: Yes\_\_\_ No\_\_\_ C. Headache: Yes\_\_\_ No\_\_\_ D. Pain at the intravenous catheter site: Yes\_\_\_ No\_\_\_ E. Shortness of breath: Yes\_\_\_ No\_\_\_ F. Abdominal discomfort: Yes\_\_\_ No\_\_\_ G. Gastrointestinal bleeding: Yes\_\_\_ No\_\_\_
2. Did you have any other symptoms or problems not listed above within 30 days of your endoscopy that you felt were related to your procedure: Yes\_\_\_ No\_\_\_ If yes, please describe them in detail.
3. Did you see a physician within 30 days of your endoscopy because of symptoms or problems related to your procedure: Yes\_\_\_ No\_\_\_
4. Did you have to go to the emergency room within 30 days of your endoscopy because of symptoms or problems related to your procedure: Yes\_\_\_ No\_\_\_
5. Were you hospitalized within 30 days of your endoscopy because of symptoms or problems related to your procedure: Yes\_\_\_ No\_\_\_
6. Were the doctors, nurses, and other GI staff courteous and helpful? Yes\_\_\_ No\_\_\_
7. Were you completely satisfied with the care that you received? Yes\_\_\_ No\_\_\_
8. Were you satisfied with the sedation you received for the procedure? Yes\_\_\_ No\_\_\_ Did not receive any sedation\_\_\_
9. Were you satisfied with the way you were treated by the doctors and support staff? Yes\_\_\_ No\_\_\_
10. Did you feel that you were treated with respect? Yes\_\_\_ No\_\_\_
11. Was the procedure performed in a timely manner? Yes\_\_\_ No\_\_\_
12. Were the post-procedure instructions reviewed with you in a clear manner? Yes\_\_\_ No\_\_\_
13. Were all your questions answered? Yes\_\_\_ No\_\_\_
14. Would you have the procedure again if your doctor thought it was necessary? Yes\_\_\_ No\_\_\_

Please provide any additional comments below.

Three horizontal lines for providing additional comments.

Thank you for taking the time to complete this very important survey.