

## A prospective assessment of sedation-related adverse events and patient and endoscopist satisfaction in ERCP with anesthesiologist-administered sedation

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**Background:** Despite the increasing use of anesthesiologist-administered sedation for monitored anesthesia care (MAC) or general anesthesia in patients undergoing ERCP, limited prospective data exist on the effectiveness, safety, and cost of this approach.

**Objective:** To prospectively assess sedation-related adverse events (SRAEs), patient- and procedure-related risk factors associated with SRAEs, and endoscopist and patient satisfaction with anesthesiologist-administered sedation.

**Design:** Single-center, prospective cohort study.

**Setting:** Tertiary-care referral center.

**Patients:** A total of 528 consecutive patients undergoing ERCP.

**Interventions:** Anesthesiologist-administered MAC or general anesthesia.

**Main Outcome Measurements:** SRAEs, endoscopist and patient satisfaction.

**Results:** There were 120 intraprocedure SRAEs during 109 of the 528 ERCPs (21% of cases). Intraprocedure SRAEs included hypotension (38 events), arrhythmia (20 events), O<sub>2</sub> desaturation to less than 85% (66 events), unplanned intubation (16 events), and procedure termination (1 event). Thirty postprocedure SRAEs occurred in a total of 22 patients (4% of cases), including hypotension (5 events), endotracheal intubation (2 events), and arrhythmia (12 events). Patient-related variables associated with adverse intraprocedure events were American Society of Anesthesiologists class ( $P = .004$ ) and body mass index (kg/m<sup>2</sup>) ( $P = .02$ ). On a 10-point scale, mean endoscopist satisfaction with sedation was 9.2 (standard deviation 1.8) and patient satisfaction with sedation was 9.9 (standard deviation 0.7).

**Limitations:** The approach to sedation was not randomized.

**Conclusions:** Higher American Society of Anesthesiologists class and body mass index are associated with an increased rate of cardiac and respiratory events during ERCP. Cardiac and respiratory events are generally minor, and MAC can be considered a safe option for most ERCP patients. Despite the frequency of minor sedation-related events, procedure interruption or premature termination was rare in the setting of anesthesiologist-administered sedation. (*Gastrointest Endosc* 2011;73:710-7.)

*Abbreviations:* ASA, American Society of Anesthesiologists; BMI, body mass index; COPD, chronic obstructive pulmonary disease; GA, general anesthesia; HR, heart rate; MAC, monitored anesthesia care; OR, odds ratio; SRAE, sedation-related adverse event; VAS, visual analogue scale.

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Most routine endoscopic procedures such as upper endoscopy and colonoscopy are performed with the patient under conscious sedation administered by the gastroenterologist.<sup>1</sup> Compared with these procedures, ERCP procedures are more complex, longer, and commonly performed on patients with comorbidities. In recent years, there has been a trend toward anesthesiologist-administered sedation for endoscopic procedures.<sup>2</sup>

Advocates of anesthesiologist-administered sedation for ERCP cite 3 potential advantages. The first is procedure efficiency; the presence of an anesthesiologist may permit faster sedation and recovery times, particularly when propofol is used.<sup>3,4</sup> The second is deeper sedation; a recent retrospective study reported that use of general anesthesia (GA) was associated with a 50% decrease in sedation-related procedure failures compared to conscious sedation.<sup>5</sup> The third possible benefit is safety; anesthesiologists may provide more expertise in the immediate management of respiratory or hemodynamic compromise.<sup>6</sup>

Despite these possible advantages and the increasing use of anesthesiologist-administered sedation, there are very limited prospective data on the effectiveness, safety, and cost of this approach. ERCP is different from other surgical procedures with regard to anesthetic requirements. Compared with surgery, ERCP procedures should be less painful and do not need paralysis; however, esophageal intubation and air insufflation of the stomach and intestines can predispose patients to aspiration and vagally mediated hypotension. Therefore, outcome data from other surgical procedures may not be directly applicable to ERCPs.

The aim of our study was to prospectively assess sedation-related adverse events (SRAEs) during and after ERCP in patients undergoing anesthesiologist-administered sedation. We also sought to identify risk factors associated with SRAEs and to assess patient and endoscopist satisfaction with anesthesiologist-administered sedation.

## METHODS

### Study population

All patients who underwent ERCP at Beth Israel Deaconess Medical Center from August 2009 to December 2009 were prospectively enrolled. All ERCPs during this study period were performed with the patients under anesthesiologist-administered sedation. For the purposes of our study, GA was defined as anesthesia with endotracheal intubation, and monitored anesthesia care (MAC) was defined as all other anesthesia provided by an anesthesiologist. Choice of anesthesia approach (MAC or GA) and patient position (prone, supine, left lateral decubitus) was at the discretion of the anesthesiologist, in collaboration with the endoscopy team. Typical indications for GA

### Take-home Message

- Monitored anesthesia care is a safe and effective approach for the majority of patients.
- Higher American Society of Anesthesiologists class and body mass index are associated with an increased rate of intraprocedure cardiac and respiratory events, and these factors may help to identify patients at risk of sedation-related adverse events during ERCP.

include morbid obesity, unstable hemodynamics, or recent surgery and significant pain that might limit the ability of the patient to lie on his or her abdomen. Routine practice at our institution is to perform most ERCPs with the patient under MAC in the prone position. Patient positioning for GA is variable, but the supine position is often chosen because of practical issues related to positioning, particularly in obese patients. Patients who were already on a ventilator or in the intensive care unit were excluded from the study. The study was approved by our institutional review board.

### Data collection

Before ERCP, all patients underwent a preanesthesia assessment by a member of the anesthesiology staff. This consisted of a full history and physical examination that included height, weight, and Mallampati airway classification. An electrocardiogram was obtained in all men older than 45 years and women older than 55 years. Other testing or consultation was obtained when indicated by the history or physical examination. Each patient received an American Society of Anesthesiologists (ASA) status classification based on the completed preanesthesia evaluation.

During the ERCP procedure, an automated electronic anesthesia record was used to record all procedure details including intraprocedure vital signs, capnography, all administered medications, and anesthesia-related events or interventions.

After completion of the ERCP, patients were transferred to a dedicated recovery unit until they were ready for discharge to home or to a hospital bed. In the recovery room, heart rate (HR), respiration, blood pressure, pulse oximetry, and telemetry monitoring were recorded for all patients. Readiness for discharge from the recovery unit was determined by measuring the postanesthesia recovery score, which assigns points to key measures of activity, respiration, circulation, and consciousness.<sup>7</sup>

A dedicated study instrument was created for our study to record intraprocedure and postprocedure adverse events. The instrument was piloted before the study, and iterative improvements were made. A 10-point visual analogue scale (VAS) was used to measure endoscopy team satisfaction with sedation. The VAS scale was 10 cm wide

and marked with integers, with 0 representing unmanageable, many interruptions or terminated procedure and 10 representing excellent sedation, no interruptions. A member of the endoscopy team, the nurse or physician, recorded the VAS score at the end of each case by marking the scale. The location of the mark was measured to determine a VAS score from 0 to 10.

Outpatients were contacted by telephone 48 hours after the ERCP procedure to assess for delayed adverse events. A structured questionnaire was administered over the phone by a research coordinator to assess for delayed adverse events including bleeding, pancreatitis, and aspiration pneumonia. For patients who remained hospitalized, the inpatient nurse or physician was contacted at 48 hours via telephone. The research coordinator administered a structured inpatient questionnaire to the nurse or physician to assess for delayed adverse events including bleeding, pancreatitis, and aspiration pneumonia.

We also sought to measure patient satisfaction with sedation during the ERCP. During the routine follow-up telephone call, patients who were discharged within 24 hours of the ERCP were queried regarding their satisfaction with sedation during ERCP with a 10-point VAS. The survey also asked whether patients had any recollection or memory of endoscope intubation, endoscope removal, or other events during the ERCP.

### Definition of sedation-related events

Intraprocedure sedation-related events were defined as hypoxia ( $O_2$  saturation  $<85\%$ ) of any duration, mask ventilation, unplanned endotracheal intubation, hypotension (blood pressure  $<90$ ) requiring use of vasopressor drugs, cardiac arrhythmia (HR  $>120$  or  $<60$  beats per minute) requiring treatment, or premature termination of endoscopy caused by sedation-related events. Treatment with vasopressors occurred whenever the anesthesiologist determined that the patient's hypotension less than 90 mm Hg was clinically significant and would be inadequately treated by intravenous fluids alone. Treatment of tachycardia (HR  $>120$ ) and bradycardia (HR  $<60$ ) was at the discretion of the anesthesiologist when this was thought to be clinically significant.

Recovery room sedation-related events were defined as hypoxia ( $O_2$  saturation  $<85\%$ ), mask ventilation, unplanned endotracheal intubation, hypotension (blood pressure  $<90$ ) requiring use of vasopressor drugs, cardiac arrhythmia (HR  $>120$  or  $<60$  beats per minute) requiring treatment, use of a reversal agent, and cardiac/respiratory arrest. Aspiration pneumonia was defined as new shortness of breath or cough within 48 hours of the procedure, with chest x-ray evidence of an infiltrate and initiation of antibiotics.

### Data analysis

Proportions and 95% confidence intervals of adverse events were computed. The  $\chi^2$  test was used when com-

paring groups by using categorical variables, using Yates correction for continuity when appropriate. The Mann-Whitney  $U$  was used when comparing 2 groups by using continuous variables. Logistic regression analysis was used to assess the association between patient, procedure, and anesthesia-related variables and adverse events. Among 528 ERCPs, a total of 74 patients had more than 1 ERCP. For these patients, only the first ERCP was included in the regression analysis to exclude nonindependent observations. The  $P$  values for the univariate statistical tests are not corrected for multiple testing because those tests were taken as exploratory.

In 2007, we performed a pilot study of 200 patients focused on sedation-related complications during advanced endoscopic procedures in the setting of anesthesiologist-administered sedation (submitted for publication). The purpose of this study was to identify risk factors for adverse events and to develop a mechanism for measuring and reporting adverse events. Based on this pilot study and review of available literature, we specified the following predictor variables a priori: age, sex, comorbidities, ASA class, body mass index (BMI), ERCP procedure difficulty,<sup>8</sup> and fentanyl use. Our pilot study also demonstrated a low rate of postprocedure events and substantial variation in risk factors for intraprocedure and postprocedure adverse events. We therefore decided to use only intraprocedure adverse events as the outcome variable for regression models.

## RESULTS

During the study period, 528 ERCPs were performed on a total of 438 patients (74 patients underwent  $>1$  ERCP). The mean age of study patients was 63.7 years (standard deviation 17.3 years, range 17-93 years), and 49.6% were women. Additional baseline characteristics and procedure indications for the study population are shown in Table 1. Initial choice of anesthesia was MAC in 470 cases (89%) and GA in 58 cases (11%) (Fig. 1). A total of 466 ERCPs (88.3%) were performed with the patient in the prone position, and 446 of 466 of these procedures (96%) were performed by using MAC, with the remainder being performed by using GA. Fifty-six ERCPs (10.6%) were performed with the patient in the supine position, with 20 of 56 procedures (30%) performed with the patient under MAC. Six procedures (1%) were performed with the patient in the left lateral position, with 4 of 6 procedures (60%) performed with the patient under MAC.

The most commonly used sedative medications overall were propofol (96% of cases), midazolam (72%), ketamine (27%), and fentanyl (25%); most patients received a combination of medications. In MAC cases, sedative medication consisted of propofol (98% of cases), midazolam (73% of cases), ketamine (29% of cases), and fentanyl (19% of

**TABLE 1. Patient demographic information and procedure indications**

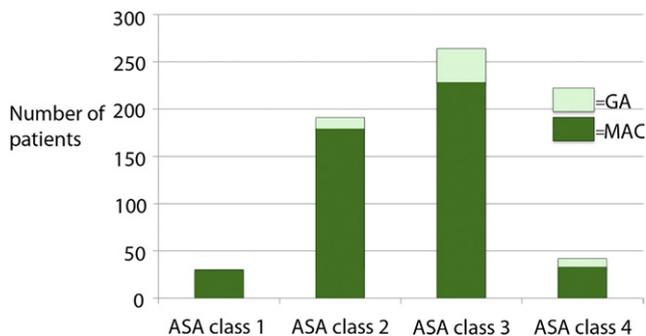
	No.	% of total patients
<b>ASA risk class</b>		
1	30	5.7
2	191	36.2
3	264	50.0
4	42	8.0
<b>Medical comorbidities</b>		
Congestive heart failure	40	7.6
Coronary artery disease	104	19.7
Hypertension	318	60.2
Asthma	54	10.2
COPD	53	10.0
GERD	309	58.5
Malignancy	126	23.9
Chronic kidney disease	42	8.0
<b>Procedure indications</b>		
Obstructive jaundice*	53	10.0
LFT abnormalities	268	50.8
Stones/sludge	220	41.7
Stricture	67	12.7
Biliary leak	28	5.3
Pancreatitis/PD stone/PD leak	57	10.8

ASA, American Society of Anesthesiologists; COPD, chronic obstructive pulmonary disease; LFT, liver function test; PD, pancreatic duct.

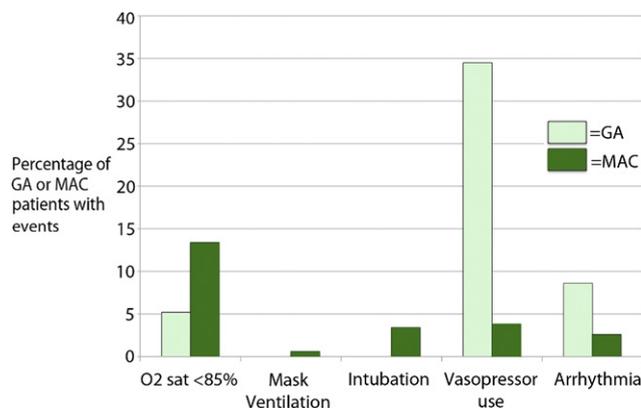
\*Without known or suspected stone.

cases). In GA cases, sedative medication consisted of propofol (79% of cases), midazolam (60% of cases), ketamine (12% of cases), and fentanyl (67% of cases).

A sphincterotomy was performed in 289 patients (54.7%), and biliary stent placement, exchange, or removal was performed in 260 patients (49.2%). Other interventions such as balloon sphincteroplasty, lithotripsy, cytology brushing, cholangioscopy, and pancreatic duct interventions occurred in 148 patients (28%). Many patients had more than 1 intervention during the ERCP. Cholangiography alone without additional procedures was performed in 46 patients (8.5%). ERCP difficulty was grade 1 in 344 patients (65.2%), grade 2 in 94 patients (17.8%), and grade 3 in 83 patients (15.7%). Biliary cannulation could not be attempted in 7 patients because of mechanical obstruction or food content proximal to the second por-



**Figure 1.** Fifty-eight percent of patients were ASA class III/IV, and 89% of patients received MAC. ASA, American Society of Anesthesiologists; MAC, monitored anesthesia care; GA, general anesthesia.



**Figure 2.** Of 528 patients, 109 (21%) had sedation-related intraprocedure events. The percentage of MAC and GA patients with specific intraprocedure events is shown. MAC, monitored anesthesia care; GA, general anesthesia.

tion of the duodenum. These procedures were not assigned an ERCP difficulty grade.

**Sedation-related events**

Intraprocedure sedation-related events occurred in 109 of 528 procedures (20.6%; 95% CI, 17.2%-24.4%) with some patients experiencing more than 1 event. Intraprocedure respiratory events included hypoxia (O<sub>2</sub> saturation <85%), 66 events (12.5%); mask ventilation, 3 events (0.6%); and unplanned endotracheal intubation, 16 events (3%). Intraprocedure cardiovascular or hemodynamic events included hypotension requiring vasopressor, 38 events (7.2%) and arrhythmia requiring treatment, 20 events (3.8%). There were no intraprocedure cardiac arrests or deaths. Procedure interruption (ie, needing to remove the duodenoscope after initial insertion or the endoscopist needing to pause mid-procedure for sedation-related events) occurred in 28 cases (5%). Procedure termination was only required in 1 procedure (<1%). Respiratory events were more common in MAC patients, whereas a higher proportion of cardiovascular events occurred in GA patients (Fig. 2).

Postprocedure sedation-related events occurred in 22 of 528 procedures (4.2%; 95% CI, 2.6%-6.2%), with some

**TABLE 2. Univariate analysis of factors associated with intraprocedure sedation-related events**

	<b>P value</b>	<b>OR</b>	<b>CI</b>
Procedure duration, min	<.0001	1.03*	1.02-1.05
ERCP difficulty grade	.91	—	—
<b>Patient characteristics</b>			
Sex, F = 1	.93	—	—
Age, y	.12	1.01†	0.99-1.02
Mallampati score	.24	—	—
BMI, kg/m <sup>2</sup>	.02	1.04‡	1.01-1.07
ASA class, I, II, III, IV	.004	1.6	1.17-2.2
<b>Medication use</b>			
Fentanyl (binary)	.004	2.05	1.3-3.3
Midazolam (binary)	.65	—	—
Propofol (binary)	.14	—	—

OR, Odds ratio; CI, confidence interval; BMI, body mass index; ASA, American Society of Anesthesiologists; SRAE, sedation-related adverse event.

\*Increase in risk of SRAEs with every 1 minute increase in procedure duration.

†Increase in risk of SRAEs with every 1 year increase in age.

‡Increase in risk of SRAEs with every 1 unit increase in kg/m<sup>2</sup>.

patients experiencing more than 1 event. Postprocedure respiratory events included hypoxia, 11 events (2.1%) and endotracheal intubation, 2 events (<1%). No patients required mask ventilation. Postprocedure cardiovascular events included hypotension requiring vasopressor, 5 events (1%) and arrhythmia requiring treatment, 12 events (2.3%). Reversal agents were not required in any patient. There were no postprocedure cardiac arrests or deaths.

A 48-hour clinical follow-up was completed for 517 of 528 of patients (98.6%). Two patients (<0.38%; 95% CI, 0.05%-1.4%) met study criteria for aspiration pneumonia (1 patient had received MAC and the other received GA). No other delayed respiratory or cardiac events were found. Of the 11 patients who could not be reached, all were outpatients; the phone numbers of 6 patients were incorrect and additional contact information was lacking, and 5 patients did not respond to follow-up telephone calls and messages.

### Regression analysis

Univariate logistic regression was performed to assess the association among prespecified predictor variables and intraprocedure adverse events (Tables 2 and 3). Procedure duration was strongly associated with adverse events; every additional minute was associated with a 3% increase in the risk of adverse events (odds ratio [OR] 1.03;  $P < .0001$ ). Because of the complex relationship between procedural duration and adverse events (longer procedures may increase the likelihood of an adverse event, and an adverse event might prolong a procedure), procedure

**TABLE 3. Univariate analysis of comorbid conditions associated with intraprocedure sedation-related events**

	<b>P value</b>	<b>OR</b>	<b>CI</b>
CAD	.38	1.27	0.74-2.18
COPD	.07	1.86	0.96-3.64
GERD	.75	1.08	0.68-1.70
Malignancy	.11	0.62	0.34-1.13
Renal insufficiency	.42	1.37	0.63-2.95

OR, odds ratio; CI, confidence interval; CAD, Coronary artery disease; COPD, chronic obstructive pulmonary disease.

duration was not considered an independent variable, and it was not included as a variable in our predictive models. Patient-related variables associated with adverse events were ASA class (OR 1.6;  $P = .004$ ), BMI (kg/m<sup>2</sup>) (OR 1.04;  $P = .02$ ), and COPD (OR 1.87;  $P = .07$ ). No association was found between other comorbidities such as coronary artery disease ( $P = .4$ ), GERD ( $P = .75$ ), malignancy ( $P = .12$ ), chronic renal failure ( $P = .4$ ), and adverse events.

Fentanyl use was associated with adverse events (OR 2.05;  $P = .004$ ). Subsequent analysis suggested that choice of anesthesia approach (GA vs MAC) may have confounded this association. The association between fentanyl and adverse events was therefore assessed separately in patients receiving GA and MAC, and no association between fentanyl

**TABLE 4. Multivariate analysis of factors associated with intraprocedure adverse events: adjusted odds ratios by logistic regression**

	Coefficient	Standard error	OR	95% CI	P value
ASA class	0.402	0.168	1.49	1.08-2.08	.017
BMI, kg/m <sup>2</sup>	0.034	0.017	1.03*	1.00-1.07	.038
COPD	0.426	0.355	1.53	0.76-3.07	.23

OR, odds ratio; CI, confidence interval; ASA, American Society of Anesthesiologists; BMI, body mass index; COPD, chronic obstructive pulmonary disease; SRAE, sedation-related adverse event.

\*Increase in risk of SRAE with every 1 unit increase in kg/m<sup>2</sup>.

and adverse events was noted. Choice of anesthesia approach (GA vs MAC) did not appear to confound the association between ASA class, BMI, and chronic obstructive pulmonary disease (COPD), and adverse events.

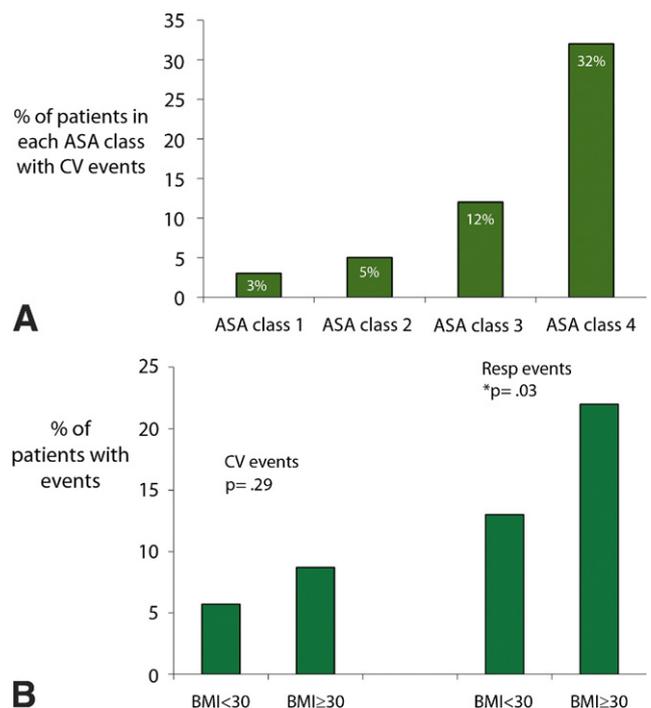
A multivariate logistic regression model was created using intraprocedure events as the outcome variable. Predictor variables with a *P* value < .1 on univariate analysis were entered into the model. On multivariate analysis, ASA class (*P* = .016) and BMI (*P* = .037) were significantly associated with adverse events, whereas COPD (*P* = .23) was no longer statistically significant (Table 4).

In post hoc analysis, we created separate multivariate regression models for intraprocedure cardiovascular events and intraprocedure respiratory events. Higher ASA class was strongly associated with cardiovascular events (OR 2.88; *P* < .0001) (Fig. 3A), but BMI was not (OR 1.03; *P* = .11). Higher BMI was strongly associated with respiratory events in patients undergoing MAC anesthesia (OR 1.08; *P* = .0006), but ASA class was not (OR 1.2; *P* = .25). Because a specific BMI threshold exists for obesity, we also modeled BMI as a binary variable (BMI < 30 [nonobese] vs BMI ≥ 30 [obese]). Figure 3B shows the association between BMI (modeled as a binary variable) and respiratory adverse events. Obese patients were almost twice as likely to experience a respiratory event compared with nonobese patients (*P* = .03).

### Endoscopy team and patient satisfaction with sedation

A 10-point VAS sedation satisfaction score was recorded for 461 of 528 (87%) procedures. The endoscopy team was very satisfied with the quality of sedation, with a mean VAS of 9.2 (standard deviation 1.8) on a 10-point scale. The mean sedation satisfaction score was higher for patients under MAC (9.3 [standard deviation 1.6]) compared with patients receiving GA 8.4 (standard deviation 0.45), but this difference was not significant (*P* = .16).

Outpatients and patients discharged within 24 hours after ERCP were queried regarding their satisfaction with sedation during the ERCP. A response was available for 238 of 260 eligible patients. In addition to the 11 patients who could not be reached by telephone, an additional 11 patients were either unable or unwilling to answer ques-



**Figure 3. A**, Higher ASA class is associated with increased proportion of cardiovascular events (*P* < .0001). ASA, American Society of Anesthesiologists. **B**, In MAC cases, obese patients had nearly double the rate of respiratory events compared with nonobese patients (*P* = .03). BMI, body mass index; CV, cardiovascular; Resp, respiratory.

tions (most commonly because of dementia or delirium). The mean satisfaction score was 9.9 (standard deviation 0.74) on a 10-point scale. Only 15 of 238 queried patients (6%) reported some memory of the ERCP procedure including endoscope intubation (6 patients), endoscope removal (5 patients), and other events during the ERCP (8 patients).

### DISCUSSION

In our study of ERCP with anesthesiologist-administered sedation, 527 of 528 procedures (>99%) were completed successfully. Eighty-nine percent of cases were performed with

patients under MAC, and 88% of cases were performed with the patient in the prone position. Sedation-related intraprocedure events occurred in 21% of cases, but most events were minor and led to transient interruption in only 5% of procedures. Recovery room sedation-related events were uncommon (4%), and clinical evidence of aspiration occurred in only 2 patients. Endoscopy team and patient satisfaction with sedation was very high for both GA and MAC. ASA class and BMI were independent predictors of sedation-related events during ERCP. Higher ASA class was predictive of both cardiovascular and respiratory events, whereas a higher BMI was predictive of only respiratory events. Longer procedure duration was also associated with adverse events, although the relationship between procedure duration and adverse events is complex, and causality could not be determined in this study.

Personal communication with leading endoscopy centers suggests that anesthesiologist-administered sedation is becoming increasingly common for ERCP and other advanced endoscopic procedures. There is evidence of a similar trend for routine upper endoscopy and colonoscopy.<sup>2</sup> For ERCP, this trend is driven by a shift away from diagnostic ERCP and toward more complicated therapeutic ERCP, as well as increasing age and comorbidities among ERCP patients. In our study population, more than half of our patients were ASA class III or IV. Despite this sick patient population, premature termination of the procedure because of sedation-related events was required in only 1 of 528 procedures. In a retrospective study of 1056 ERCPs, Raymondos et al<sup>5</sup> reported that 14% of ERCPs attempted with the patient under conscious sedation were prematurely terminated, mostly because of inadequate sedation. They also reported that it was possible to perform more interventional procedures in the same time period with the patient under general anesthesia than under conscious sedation. It is the opinion of the endoscopists who participated in this study (R.C., D.K.P., M.S.S.) that sedation with anesthesia was deeper and could be maintained longer compared with gastroenterologist-supervised conscious sedation. Satisfaction scores with sedation were extremely high for both endoscopy teams and patients. In fact, only 6% of queried patients had any recall of the ERCP procedure. Reversal agents were not required in any patient. This may reflect the ability of the anesthesia provider to immediately provide respiratory support and move to deeper anesthesia as opposed to lightening the sedation through the use of reversal agents.

Minor SRAEs were common in our study. We used a low threshold for adverse events (eg, oxygen saturation of  $\leq 85\%$  for any amount of time was categorized as hypoxia). Furthermore, continuous electronic monitoring of vital signs during the procedure allowed us to capture all changes in oxygen saturation and blood pressure. Despite this level of detail, SRAEs in our study were similar to those reported by other comparable studies of ERCPs with anesthesia. Cote et al<sup>9</sup> reported an SRAE rate of 15.5% in

patients undergoing propofol-based MAC anesthesia. Their study was different from ours in that the majority of procedures were EUS procedures and not ERCPs. In a prospective, randomized study by Paspatis et al,<sup>10</sup> an overall hypoxia rate of 15.4% was noted in patients undergoing propofol-based sedation for ERCPs. Vargo et al<sup>11</sup> reported a 23.7% rate of transient hypoxia and hypotension in patients undergoing ERCP who were randomized to the propofol arm in their study. No cardiopulmonary arrests or fatality were reported in any of these studies. Taken together, this suggests that changes in blood pressure and oxygen saturation occur often when ERCPs are performed with the patient under propofol-based MAC anesthesia, but rarely result in termination of the procedure or serious consequences.

A major limitation of our study was that we were unable to compare outcomes of anesthesiologist-administered sedation with those of conscious sedation. No studies using a similar design or definition of adverse events of patients undergoing ERCP with conscious sedation are available. Although the study was not directly comparable, Papachristou et al<sup>12</sup> reported on 3058 patients who underwent ERCP while under conscious sedation at the Mayo Clinic in Rochester, Minnesota. Overall adverse events were not reported in that study, but 4% of patients required reversal agents during or just after the procedure. In those who required reversal agents, 5% had major adverse events including cardiopulmonary arrest ( $n = 1$ ), asystolic arrest with anoxic encephalopathy and death ( $n = 1$ ), and fatal cardiopulmonary arrest ( $n = 1$ ). Older patients and those requiring promethazine or higher doses of meperidine were at risk of these adverse events. Vargo et al<sup>11</sup> reported a 16.2% rate of hypoxia, a 18.9% rate of hypotension, and a 8.1% rate of bradycardia in patients undergoing ERCP with meperidine/midazolam or propofol-based conscious sedation. No statistically significant difference was noted in adverse events between the 2 sedation approaches.

There is ongoing discussion among anesthesiology societies regarding the safety of MAC with the patient in the prone position because of concerns regarding airway safety during endoscopic procedures when access to the oropharynx is already limited. In our study, aspiration was rare, occurring in only 2 patients, and airway access was easily obtained on the rare occasion that unplanned intubation was deemed necessary during the procedure. It is the opinion of our anesthesiology group that MAC with the patient in the prone position during ERCP is safe for the majority of patients.

Large population-based studies of nonanesthesiologist-administered propofol demonstrated that nonanesthesiologists can safely administer propofol-based sedation for routine endoscopic procedures.<sup>13</sup> Although similar studies have not been conducted for advanced endoscopic procedures, the study by Vargo et al<sup>11</sup> demonstrates that in selected patients, gastroenterologist-directed propofol may be possible for ERCPs as well.

We did not analyze the cost of anesthesiologist-administered sedation during ERCP in this study. It is conceivable that anesthesiologist involvement in ERCP might be more cost-effective compared with anesthesiologist involvement in lower complexity gastroenterological procedures such as endoscopy and colonoscopy.<sup>13,14</sup> Anesthesiologist involvement clearly incurs more initial cost at the time of the procedure; however, the cost-effectiveness of this approach, taking into account ERCP completion rates and complications, has yet to be determined and merits further study. At our institution and at others, multiple anesthesiologists may provide anesthesia for ERCP. A dedicated anesthesiology team with specific expertise in endoscopic sedation may further enhance efficiency and safety.<sup>9</sup>

We sought to determine factors that may be used to identify patients who are at risk of the development of SRAEs while undergoing ERCP under anesthesia. It is conceivable that such analysis may help to develop scoring systems in the future that could be used to select patients who are at low risk of SRAES and hence appropriate for gastroenterologist-administered propofol sedation. In our study, ASA class and BMI were strong and independent predictors of adverse events. BMI was primarily associated with respiratory events. It is possible that several obese patients had sleep apnea and that a high BMI was a marker for the presence of sleep apnea, which is a well-recognized risk factor for adverse perioperative events.<sup>15</sup> Higher ASA class has been identified as a risk factor for hypoxic events during EGD and colonoscopy as well.<sup>16</sup> ASA class and BMI were also identified as independent risk factors for respiratory events during ERCP/EUS by Cote et al.<sup>9</sup> A sedation risk score that combines these variables may be especially useful in identifying patients at risk of SRAEs during ERCP.

In summary, our experience with anesthesiologist-administered sedation for ERCP demonstrates that monitored anesthesia care is a safe and effective approach for the majority of patients and that the overall safety profile for patients receiving either MAC or GA is very good. Minor SRAEs were common, but procedure interruptions and termination were rare. Additional study is warranted

to determine whether the routine use of anesthesiologists is cost-effective for ERCP.

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