

## Endoscopic retrograde cholangiopancreatography under moderate sedation and factors predicting need for anesthesiologist directed sedation: A county hospital experience

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### Abstract

**AIM:** To evaluate variables associated with failure of gastroenterologist directed moderate sedation (GDS) during endoscopic retrograde cholangiopancreatography (ERCP) and derive a predictive model for use of anesthesiologist directed sedation (ADS) in selected patients.

**METHODS:** With institutional review board approval, we retrospectively analyzed consecutive records of all patients who underwent ERCPs between July 1, 2009 to October 1, 2011 to identify patient related and procedure related factors which could predict failure of GDS. For patient related factors, we abstracted and analyzed

data regarding the age, gender, ethnicity, alcohol and illicit drug use habits. For procedure related factors, we abstracted data regarding initial or repeat procedures, indication for performing ERCP, the interventions performed during ERCP, and the grade of difficulty of cannulation as defined in the American Society for Gastrointestinal Endoscopy guidelines. Our outcome of interest was procedural success. If the procedure was not successful, the reasons for failure of procedures were recorded along with immediate post procedure complications. Multivariate analysis was then performed to define factors associated with failure of GDS and a model constructed to predict requirement of ADS.

**RESULTS:** Fourteen percent of patients undergoing GDS could not complete the procedure due to intolerance and 2% due to cardiovascular complications. Substance abuse, male gender, black race and alcohol use were significant predictors of failure of GDS on univariate analysis and substance abuse and higher grade of procedure remained significant on multivariate analysis. Using our predictive model where the presence of substance abuse was given 1 point and planned grade of intervention was scored from 1-3, only 12% patients with a score of 1 would require ADS due to failure of GDS, compared to 50% with a score of 3 or higher.

**CONCLUSION:** We conclude that ERCP under GDS is safe and effective for low grade procedures, and ADS should be judiciously reserved for procedures which have a higher risk of failure with moderate sedation.

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**Key words:** Cholangiopancreatography; Endoscopic retrograde/methods; Conscious sedation/utilization; Deep sedation/utilization; Adult; Endoscopy

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## INTRODUCTION

Endoscopic procedures have routinely been performed under moderate sedation administered by the gastroenterologist in the United States<sup>[1]</sup>. In recent years there has been an increasing trend towards using deep sedation or general anesthesia provided by a trained anesthesia professional. Given the high volume of endoscopic procedures and the high volume performed under anesthesia guidance, the spending on such procedures is estimated to increase into the billions of dollars over the next few years<sup>[2]</sup>. Endoscopic retrograde cholangiopancreatography (ERCP) is considered an advanced endoscopic procedure which has evolved from a diagnostic procedure to a predominantly therapeutic one of increasing duration and complexity. No guidelines specifically recommend the use of deep sedation or general anesthesia for ERCPs though the American Society of Gastrointestinal Endoscopy (ASGE) suggests considering deep sedation for increasing length or complexity of procedure<sup>[1]</sup>. Over the years, the spectrum of interventions performed during ERCPs have also increased tremendously, requiring various societies to grade the ERCP procedure into different grades of complexity (Grade 1-3 by ASGE)<sup>[3]</sup>. The more challenging and higher grade of ERCPs are now performed at tertiary centers by dedicated advanced endoscopists, while lower grade interventions are routinely performed in various community hospitals and practices.

Increasingly, high volume centers are now routinely performing ERCPs with anesthesiologist directed sedation (ADS) while moderate to low volume centers usually perform ERCPs under gastroenterologist directed moderate sedation (GDS). Anesthesia support is usually sought if prior attempts with GDS have failed.

In this era of increasing health care costs and resource limitations, it is important to establish the role of ADS in ERCP.

The objective of our study was to evaluate variables associated with failure of moderate sedation administered by gastroenterologists (GDS) during ERCP and derive a predictive model for use of ADS in selected patients.

## MATERIALS AND METHODS

The study was approved by the local institutional review board of our hospital. We retrospectively analyzed consecutive records of all patients who underwent ERCPs between July 1, 2009 to October 1, 2011 to identify patient related and procedure related factors which could

**Table 1 Endoscopic retrograde cholangiopancreatography-degree of difficulty**

Grade	Diagnostic	Therapeutic
Grade 1: standard	Deep cannulation, diagnostic sampling	Biliary sphincterotomy, stones < 10 mm, stents for leaks and low tumors.
Grade 2: advanced	Billroth II diagnostics, minor papilla cannulation	Stones > 10 mm, hilar tumor stent placement, benign biliary strictures
Grade 3: tertiary	Manometry, Whipple, Roux en Y, intraductal endoscopy	Billroth II therapeutics, intrahepatic stones, pancreatic therapies

The date was quoted by the reference of 3.

predict failure of GDS. The type of sedation use was documented as GDS which is administered with an opioid (meperidine or fentanyl) and a benzodiazepine (midazolam); or ADS which was administered as monitored anesthesia care with propofol or general anesthesia requiring intubation. If the ADS was administered after failure of GDS, it was abstracted as secondary ADS and if it was administered because the patient did not meet our institution's criteria for administration of GDS it was abstracted as elective or primary ADS. The exclusion criteria for administering GDS in our institution include patients who are American Society of Anesthesiologists (ASA) Grade 3 or more, history of anesthesia or sedation complication/difficulty, history of difficulty with tracheal intubation, compromised airway, morbid obesity, hemodynamic instability and pregnant patients. For patient related factors, we abstracted and analyzed data regarding the age, gender, ethnicity, alcohol and illicit drug use habits. For procedure related factors, we abstracted data regarding initial or repeat procedures, indication for performing ERCP, the interventions performed during ERCP, and the one word-graded difficulty of procedure as defined in the ASGE guidelines Table 1<sup>[3]</sup>.

### Outcome measures

Our outcome of interest was procedural success. A procedure was deemed successful if deep cannulation had been obtained and the objective of the procedure accomplished. If the procedure was not successful, the reasons for failure of procedures were recorded along with immediate post procedure complications. In order to limit selection bias in patients who elected for primary ADS, we compared the cannulation rates of patients receiving primary ADS to the rest of the patients.

### Statistical analysis

The results were expressed as mean plus or minus standard deviation and range. Univariate analysis was performed using logistic regression. To evaluate the association between related factors and intolerance to sedation, multivariable models were constructed that included terms to adjust for age, race, gender, alcohol and substance use and included in the final model if they

**Table 2 Patient demographics**

Demographic	n (%)
Gender	
Males	234 (48)
Females	252 (52)
Race	
Hispanic	189 (39)
Non hispanic black	179 (37)
White	91 (19)
Asian	20 (4)
Unspecified	7 (1.5)
Alcohol use	225 (46)
Other illicit substance use	79 (16)

significantly contributed to the outcome variable ( $P < 0.05$ ). From these multivariable models, odds ratios were estimated using the logistic regression. All data was analyzed using STATA version 10.1 (College Station, TX).

## RESULTS

Five hundred ninety-one ERCP procedures done in 392 patients were reviewed. One hundred and five of 591 procedures (18%) were performed electively with primary ADS and were excluded. Four hundred eighty-six procedures were included for our analysis. One hundred thirty-nine patients had more than 1 procedure during the study period. Patient demographics are presented in Table 2. Substance abuse was documented in 14% patients (24% of men, 4% of women). The mean dose of medications administered were 5.9 milligrams of midazolam, and 115 micrograms of fentanyl or 100 milligrams of meperidine. Most common indication for performing ERCP was choledocholithiasis (40%) followed by strictures (26%). The majority of procedures were Grade 1, with one fifth of the procedures Grade 2 or 3. The cannulation rates were similar in the patients with primary ADS (91%) to the rest of the patients (92%). Reasons for failure with GDS are presented in Table 3.

In our univariate analysis, substance abuse, male gender, black race and alcohol use were significant predictors of failure of GDS. However, after adjusting for substance abuse, these variables were no longer significant predictors. Hispanic race was a significant predictor for success of GDS after adjusting for substance abuse (Table 4) although most of the procedures were grade 1 procedures. ERCPs for strictures and pancreatic interventions were the most likely procedures to convert to ADS (Table 5). On multivariate analysis, substance abuse and higher grade of intervention remained the most significant predictors of need for monitored/general anesthesia (Table 6). A predictive model for requirement of monitored anesthesia for ERCP was derived. Presence of substance abuse was given 1 point and planned grade of intervention was scored from 1-3 as according to the grade of the procedure. Using this model, 12% of procedures with a score of 1, 25% with score of 2 and 50% with score of 3 or higher required monitored anesthesia.

**Table 3 Causes of endoscopic retrograde cholangiopancreatography failure with gastroenterologist directed sedation n (%)**

Cause	n (%)
Total number of patients undergoing GDS	486
Patient intolerance	68 (14)
Cardiopulmonary complications	10 (2)
Hypertension	6 (1.2)
Hypoxia, hypotension, bradycardia or tachycardia	4 (0.8)
Failure to cannulate	40 (8)
Food/contrast in lumen	8 (1.6)
Roux en Y anatomy	2 (0.4)
Esophageal bleeding on entry	1 (0.2)

GDS: Gastroenterologist directed sedation.

## DISCUSSION

Based on our analysis, most patients at moderate volume ERCP centers do not require anesthesia service use for ERCPs. Our results indicate that less than 20% of patients failed moderate sedation provided as GDS. On multivariate analysis, the most important predictors of failure of gastroenterologist directed moderate sedation included substance abuse and the grade of the procedure. Using our predictive model where the presence of substance abuse was given 1 point and planned grade of intervention was scored from 1-3 as according to the grade of the procedure, less than one in eight procedures with a score of 1 would require monitored anesthesia compared to half of patients with a score of 3 or higher.

To our knowledge, this is the first study that has attempted to define factors predicting the failure of GDS for ERCPs. Our study population is unique in that most of our low risk patients undergo GDS for ERCPs. Since anesthesia resources are limited, only those patients who meet strict criteria for monitored anesthesia based on their ASA scores or other co-morbidities are scheduled for elective anesthesia service use.

Most of the previously published studies evaluating the use of anesthesia in ERCP conclude that ERCPs with gastroenterologist directed sedation have similar cannulation and complication rates to those with ADS<sup>[4-6]</sup>. However none of these studies was designed to specifically study the factors predicting the failure of GDS.

In some studies, ADS has been associated with higher physician satisfaction and slightly higher completion rates<sup>[7,8]</sup>. These studies have been uncontrolled or limited by lack of blinding. Furthermore, routine anesthesia service use for ERCP has other limitations. Aside from increasing the cost of the procedure, it may also increase the peri-procedure time. Additionally, it may make the procedure more difficult to schedule if anesthesia support outside the operating rooms is not readily available.

Our study may have several limitations. First, as a retrospective study, we cannot be certain that our results are confirmed from chance alone (verification bias). Care was taken to a priori assess only the variable thought to be directly related to success of GDS. Further prospective studies are needed to determine if these two variables

**Table 4 Patient variables predicting failure with gastroenterologist directed sedation for endoscopic retrograde cholangiopancreatographies**

Patient variables	MS	MS failure	P value	Patient variables <sup>1</sup>	MS	MS failure	P value
Substance abuse	31	13	0.003				
Male	131	25	0.01	Male <sup>1</sup>	104	14	0.09
Female	157	12		Female <sup>1</sup>	153	10	
Race				Race <sup>1</sup>			
AA	79	22	0.001	AA	61	10	0.06
White	42	6	0.8	White	38	6	0.2
Hispanic	142	8	0.001	Hispanic	134	7	0.04
Asian	15	1	0.5	Asian	15	1	0.7
> 65 yr	37	2	0.15	> 65 yr <sup>1</sup>	33	1	0.16
≤ 65 yr	251	35		≤ 65 yr <sup>1</sup>	224	23	
Alcohol use	113	21	0.04	Alcohol use <sup>1</sup>	87	11	0.24
No alcohol use	175	16		No alcohol use <sup>1</sup>	170	13	
Bilirubin-elevated	252	44	0.03	Bilirubin-elevated <sup>1</sup>	222	34	0.45
Bilirubin-normal	146	43		Bilirubin-normal <sup>1</sup>	126	24	

<sup>1</sup>Adjusted for substance abuse. MS: Moderate sedation.**Table 5 Odds ratios for failure with gastroenterologist directed sedation by indication of the procedure**

Indication	n (%)	OR (95%CI)	Adjusted OR (95%CI) <sup>1</sup>
Gallstones/cholangitis	231 (38)	0.6 (0.4, 1.0)	0.7 (0.4, 1.3)
All strictures	125 (20)	1.5 (0.9, 2.4)	1.6 (0.9, 2.9)
Benign strictures	53 (9)	2.2 (1.2, 4.2)	2.7 (1.2, 5.7)
Suspected malignancy	72 (12)	0.9 (0.5, 1.8)	0.9 (0.4, 2.0)
Abn LFTs	36 (6)	0.6 (0.2, 1.6)	0.5 (0.12, 2.3)
Pancreatic	11 (2)	2.7 (0.8, 9.4)	3.7 (0.9, 16)
Other	7 (1)	1.8 (0.4, 9.7)	2.5 (0.5, 12.9)
Post cholecystectomy stone/leak	24 (4)	0.4 (0.1, 1.7)	0.3 (0.0, 2.0)
Exchange/incomplete	51 (8)	2.1 (1.1, 4.0)	0.9 (0.3, 2.5)
	485		

<sup>1</sup>Adjusted to substance abuse. OR: Odds ratio.

(substance use and procedure grade) can determine the likelihood of GDS success. Second, while the procedures were deemed successful, we did not identify delayed complications which may have occurred after the patient left the endoscopy unit. Third, our ERCPs are initially attempted by gastroenterology trainees and only later taken over by the supervising physician. This may increase the procedure time and lead to patient intolerance especially in patients under gastroenterologist directed moderate sedation. High dose of benzodiazepines and opioids may convert moderate sedation to deep sedation, which has been demonstrated in previous studies that advocated the use of capnography during sedation<sup>[9]</sup>. While we did not use capnography to gauge the respiratory depression, our mean doses of sedating agents used was 6 mg of midazolam and 115 mg of fentanyl suggesting a reasonably conservative approach with medication administration.

Recent data suggests an increased utilization of anesthesia services for low risk endoscopic significantly increases the cost of the procedures and may potentially affect the cost effectiveness of procedures like screening colonoscopies<sup>[2]</sup>.

Although, no cost benefit analysis have been done for

**Table 6 Multivariate analysis of predictors of failure with gastroenterologist directed sedation**

Variable	β coefficient	P value	OR (95%CI)
Grade of procedure (1-3) <sup>1</sup>	0.75	0.002	2.1 (1.3, 3.4)
Substance abuse <sup>1</sup>	1.03	0.001	2.8 (1.5, 5)
Indication			
Strictures	0.13	0.687	1.1 (0.6, 2.1)
Gallstone	-0.18	0.563	0.8 (0.5, 1.5)
Alcohol use	0.33	0.267	1.4 (0.8, 2.5)
Female gender	-0.29	0.33	0.7 (0.4, 1.3)

<sup>1</sup>Significant variables in the multivariate model.

use of anesthetist administered sedation or anesthesia for ERCPs, our study suggests that most of the ERCPs can be safely performed and completed under gastroenterologist directed sedation.

We conclude that ERCP under GDS is safe and effective for low grade procedures, and anesthesia service use should be judiciously reserved for procedures which have a higher risk of failure with moderate sedation.

## COMMENTS

### Background

In recent years there has been an increasing trend towards utilizing anesthesiologist directed sedation (ADS) in patients undergoing endoscopic procedures. Factors predicting failure of gastroenterologist directed moderate sedation (GDS) during endoscopic retrograde cholangiopancreatography (ERCP) have not been well studied.

### Research frontiers

Evaluate variables associated with failure of GDS during ERCP and derive a predictive model for use of ADS in selected patients.

### Innovations and breakthroughs

Gastroenterologist directed sedation is safe and effective for low grade ERCP procedures. Higher grade ERCPs and/or those performed in patients with substance abuse have a higher risk of failure with moderate sedation and therefore anesthesiologist directed deep sedation should be considered for these procedures. A predictive model for requirement of monitored anesthesia for ERCP was derived. Presence of substance abuse was given 1 point and planned grade of intervention was scored from 1-3 as according to the grade of the pro-



cedure. Using this model, 12% of procedures with a score of 1, 25% with score of 2 and 50% with score of 3 or higher required monitored anesthesia.

### Applications

Based on the analysis, most patients at moderate volume ERCP centers do not require anesthesia service use for ERCPs. The results indicate that less than 20% of patients failed moderate sedation provided as GDS. On multivariate analysis, the most important predictors of failure of gastroenterologist directed moderate sedation included substance abuse and the grade of the procedure. Using the predictive model where the presence of substance abuse was given 1 point and planned grade of intervention was scored from 1-3 as according to the grade of the procedure, less than one in eight procedures with a score of 1 would require monitored anesthesia compared to half of patients with a score of 3 or higher.

### Terminology

The type of sedation use was documented as GDS which is administered with an opioid (meperidine or fentanyl) and a benzodiazepine (midazolam); or ADS which may be administered as general anesthesia or intravenous anesthesia administered with propofol.

### Peer review

With this study, the authors conclude that that ERCP under GDS is safe and effective for low grade procedures, and anesthesia service use should be judiciously reserved for procedures which have a higher risk of failure with moderate sedation.

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