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Conscious Sedation for Upper Endoscopy in the Gastric Bypass Patient: Prevalence of Cardiopulmonary Adverse Events and Predictors of Sedation Requirement

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Abstract

Background—Safety of conscious sedation for performing esophagoduodenoscopy (EGD) in obese and Roux-en-Y gastric bypass (RYGB) patients remains controversial. Additionally, it has been suggested that patients with higher body mass index (BMI) require higher sedation doses, imparting greater risk.

Aim—The aim of this study is to assess the prevalence of sedation-related adverse events and the independent predictors of sedation requirements in RYGB patients.

Methods—This study is a retrospective database review of RYGB patients who underwent EGD under conscious sedation. Database analysis was performed and linear regression applied to identify significant predictors of sedation requirement. Primary outcomes are sedation-related adverse events and predictors of sedation requirement.

Results—Data on 1,385 consecutive procedures (diagnostic 967; therapeutic 418) performed under conscious sedation were analyzed. Unplanned events were reported in 1.6 %, with 0.6 % being cardiopulmonary in nature and 0.7 % requiring early termination. Multivariable linear regression revealed procedural time was the only significant predictor of fentanyl (standardized β 0.34; P value < 0.001) and midazolam (standardized β 0.30; P value < 0.001) doses. Post-RYGB BMI was not significantly associated with the dose of fentanyl (standardized β 0.08; P value 0.29) or midazolam administered (standardized β 0.01; P value 0.88).

Conclusions—Upper endoscopy can be safely performed in RYGB patients under conscious sedation with a similar cardiopulmonary risk profile to that of standard EGD. The non-

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cardiopulmonary adverse events were procedure-specific and unrelated to sedation. Procedure length, and not absolute BMI, was the only predictor of sedation requirement in this patient population.

Keywords

Endoscopic sedation; Conscious sedation; Gastric bypass; Cardiopulmonary adverse events

Introduction

Roux-en-Y gastric bypass (RYGB) is a commonly performed weight loss surgery [1]. Despite its efficacy, RYGB is associated with a number of early and late adverse events, including bleeding, anastomotic leaks, wound infection (early adverse events), stenosis, gastrogastic fistulae, gastrojejunal stricture, weight regain, and marginal ulcerations (late adverse events) [2]. Managing RYGB patients often requires esophagoduodenoscopy (EGD) as part of the diagnostic and therapeutic algorithms [2, 3].

Sedation is an integral component of any endoscopic examination. In general, conscious sedation remains the method of choice for diagnostic and uncomplicated therapeutic EGD [4, 5]. Conscious sedation, or moderate sedation, allows patients to tolerate uncomfortable procedures while maintaining adequate cardiopulmonary function and ability to respond purposefully to verbal commands or tactile stimuli [4]. This sedation method is generally chosen in standard EGD because it is well studied and reported to be safe with an adverse event rate of 0.3–0.6 % [7, 8]. In comparison, the approach to endoscopic sedation in obese and post-gastric bypass patients is based mainly on expert opinion [6]. It is common that gastric bypass patients require anesthesia consultation for any endoscopic procedure, merely because they have a history of bariatric surgery. This practice is not evidence-based and may subject this patient population to unnecessary testing and longer procedure wait times. Additionally, it remains unclear whether RYGB patients with higher body mass index (BMI) require higher sedation doses, imparting greater procedure risk.

The aim of this study is to assess the prevalence of cardiopulmonary adverse events in this patient population undergoing upper endoscopy under conscious sedation. Additionally, the study evaluates independent predictors of sedation requirements.

Methods

Study Population

All consecutive patients with history of RYGB who underwent EGD under conscious sedation from 2005 to 2010 were included. The study was approved by the Institutional Review Board. In our study, conscious sedation was defined as sedation that required the use of an opiate and/or benzodiazepine. EGDs that were performed under anesthesiologist-administered sedation, such as monitored anesthesia care or general anesthesia, were excluded.

Data Collection

All procedural notes of the patients who were included in the study were reviewed. The ProVation MD System (ProVation Medical Inc, Minneapolis, MN) is used to generate all endoscopy notes in our unit. The system operates by a series of drop-down menu. American Society of Anesthesia (ASA) class, Mallampati score, patient tolerability, medication doses, and complications status are mandatory fields and must be completed before signing the note.

Data on patient demographics, BMI, ASA class, Mallampati score, comorbidities, time from bariatric surgery, indications, procedure details, history of chronic opioids and benzodiazepine uses, and type and dose of conscious sedation were collected. History of chronic opioids and benzodiazepine use were defined as being on opioids and benzodiazepine for greater than or equal to 3 consecutive months, respectively. Endoscopy and anesthesia reports were reviewed to obtain intra-procedural vital signs, all administered medications, sedation-related events during the procedure or recovery period, and any interventions.

Definition of Sedation-Related Events

Sedation-related events included cardiopulmonary events, which were defined as clinically significant hypoxemia requiring temporary removal of the endoscope. Transient hypoxemia that did not require endoscope withdrawal may not have been adequately captured and was not reported. Additionally, cardiopulmonary events included hypotension (systolic blood pressure < 90 mmHg), cardiac arrhythmia (heart rate > 120 or < 60 beats per minute) requiring treatment, or premature termination of endoscopy.

Statistical Analysis

Multivariable linear regression was used to identify significant clinical and procedural predictors of sedation requirements during EGD. In the regression analysis, only the first upper endoscopy for patients having undergone more than one procedure was included to maintain sample independency. All procedures included in the model were diagnostic (non-therapeutic) in nature to minimize confounding. However, all procedures were included to determine adverse event rate. Potential predictors and confounders included in the multivariate linear regression model were defined prior to the analysis based on the clinical judgment and included patient age, BMI, ASA class, Mallampati score, history of obstructive sleep apnea, time from surgery, procedure tolerability, previous opioids use, previous benzodiazepine use, and procedure time. Statistical significance was set at a two-sided *P* value of .05 or less. Statistical modeling was performed using SAS version 9.2 software (SAS Institute, Cary, NC).

Results

Clinical Characteristics

During the study period, 519 RYGB patients underwent a total of 1,385 EGDs under conscious sedation. Additionally, 53 cases were performed under monitored anesthesia care and 302 cases were performed under general anesthesia. The majority of procedures (83 %)

that required anesthesiologist-administered sedation were highly therapeutic in nature (endoscopic retrograde cholangiopancreatography, endoscopic ultrasound, and endoscopic suturing). The remaining 17 % were performed with anesthesia support upon patient request or if they were considered to be poor candidates for conscious sedation due to other comorbidities or prior sedation history. This represented roughly 3 % of all RYGB endoscopies.

Clinical characteristics of these patients are shown in Table 1. At the time of procedure, 268 (19.4 %) patients had a history of chronic opioid use and 114 (8.2 %) a history of chronic benzodiazepine use.

Procedures

The mean procedural time was 20 min (SD = 9). This was defined as the time from the initiation of IV sedation to endoscope removal. The majority of procedures (967, 69.9 %) were diagnostic EGD with or without biopsy, and the remaining 418 procedures (30.1 %) were basic therapeutic endoscopies (Table 2). Indications for diagnostic procedures included but were not limited to abnormal weight regain/rule out fistula (54.4 %), abdominal pain/follow-up for ulcers (27 %), and nausea/vomiting (7.4 %). Indications for therapeutic procedures included dilated anastomosis (for Transoral Outlet Reduction), foreign body, stricture, stomal ulceration, polyp, and gastrogastic fistula, in addition to the symptoms that prompted diagnostic EGDs as mentioned above (Table 2). Ulcer treatment included clipping, epinephrine injection, and fibrin glue application.

Clinical Outcome

Out of 1,385 reviewed procedures, 22 adverse events (1.6 %) were reported. The types of adverse events are listed in Table 3. Ten out of those 22 events required unplanned early termination as summarized in Table 4. The remaining 1,375 (99.3 %) procedures were completed successfully. Clinical characteristics of the patients who developed adverse events are shown in Table 5.

Predictors of Sedation Doses

The mean fentanyl and midazolam doses were 131 µg (SD = 43) and 5 mg (SD = 2), respectively. The procedures that involved adverse events required higher sedation doses than those with no adverse events (Table 6).

Procedural time was the only significant independent predictor of fentanyl and midazolam dosages ($P < 0.0001$, $P < 0.0001$, respectively). Patient age, BMI, ASA class, Mallampati score, history of OSA, time from surgery, procedure tolerability, previous opioids use, and previous benzodiazepine use were not significant predictors of sedation doses (Tables 7, 8).

Discussion

Conscious sedation has been shown to have several benefits over monitored anesthesia care (MAC) and general anesthesia for simple endoscopic procedures in the general population [9, 10]. In contrast, there are no large studies addressing cardiopulmonary events in the

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Table 1

Clinical characteristics of RYGB patients

Characteristics	
Age, y, mean (SD *)	46.3 (10.3)
Gender, <i>n</i> (%)	
Male	56 (10.8)
Female	463 (89.2)
Time from RYGB, y, median (range)	4 (0.003–38)
BMI, mean (SD)	35.1 (7.7)
ASA score, median (range)	2 (1–3)
Mallampati score, median (range)	2 (1–3)
History of obstructive sleep apnea, <i>n</i> (%)	92 (17.7 %)

Range is presented as the 25th and 75th interquartile range

* SD standard deviation

Table 2

Breakdown of 1,385 EGD procedures by indications

Indication	<i>n</i>	%
Diagnostic	967	69.9
EGD	854	61.7
EGD with biopsy	113	8.2
Therapeutic	418	30.1
Sclerotherapy for weight regain	291	21
Foreign body removal	79	5.7
Stricture dilatation	23	1.7
Ulcer treatment	12	0.9
Polyp removal	8	0.6
Fistula closure	5	0.4

Table 3

Adverse events and unplanned interventions

Adverse events	N (%)	Unplanned interventions	N
Total adverse events	22 (1.6)		
Hemorrhage/ bleeding	10	Clipping	5
		Epinephrine injection	2
		Transfusion	1
		Early termination	2
Inadequate sedation	6	Early termination	4
Hypoxemia	3	Scope removal/repositioning	1
		Bag ventilation	1
		Flumazenil administration	1
		Early termination *	2
Hypertension	2	Early termination	1
Bowel perforation	1	Hospital admission **	1

* Two out of three hypoxemia prompted early termination after unplanned interventions were applied (bag ventilation in one case and flumazenil administration in the other)

** Patient re-presented and was admitted for bowel perforation on post-procedural day 1

Table 4

Causes of early termination

Characteristics	
Early termination, no. of procedures (%)	10 (0.7)
Inadequate sedation	4
Hemorrhage/bleeding	2
Hypoxemia	3
Hypertension	1
Successful completion, no. of procedures (%)	1,375 (99.3)

Table 5

Clinical characteristics of patients who developed complications

Characteristics	
Age, y, mean (SD)	47 (11.6)
Gender, <i>n</i> (%)	
Male	2 (9.1)
Female	20 (90.9)
BMI, mean (SD)	52.1 (11.4)
ASA score, median (range)	2 (2–2)
Mallampati score, median (range)	2 (1–2)
History of obstructive sleep apnea, <i>n</i> (%)	2 (9.1)
Fentanyl dose (µg), mean (range)	157 (75–200)
Midazolam dose (mg), mean (range)	3 (1–8)

Table 6

Sedation doses in procedures with and without adverse events

	Fentanyl dose (µg)	Midazolam dose (mg)
Procedures with adverse events (<i>n</i> = 22)	158 ± 32	6 ± 1
Procedures with no adverse events (<i>n</i> = 1,363)	130 ± 43	5 ± 2
<i>P</i> value	0.0024	0.019

Table 7

Linear regression on predictors of fentanyl doses

Predictors of fentanyl dose	Standardized β	<i>P</i> value
Age	−0.11	0.1
Years from surgery	0.11	0.1
BMI	0.06	0.44
ASA score	0.04	0.69
Mallampati score	0.06	0.49
Obstructive sleep apnea	−0.12	0.09
Procedural tolerability	0.06	0.34
Previous opiates use	−0.12	0.08
% Excess body weight loss after RYGB	−0.01	0.88
Procedural time	0.34	<0.0001

Table 8

Linear regression on predictors of midazolam doses

Predictors of midazolam dose	Standardized β	<i>P</i> value
Age	−0.14	0.058
Years from surgery	0.10	0.16
BMI	0.003	0.97
ASA score	0.04	0.64
Mallampati score	0.07	0.48
Obstructive sleep apnea	−0.10	0.15
Procedural tolerability	0.045	0.51
Previous benzodiazepines use	0.025	0.71
% Excess body weight loss after RYGB	−0.09	0.29
Procedural time	0.31	<0.0001