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ORIGINAL ARTICLE

Deep Sedation Without Intubation for ERCP Is Appropriate in Healthier, Non-obese Patients

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Abstract
Background Providing the appropriate anesthesia for endoscopic retrograde cholangiopancreatography (ERCP) cases is challenging.
Aim The aim of our study was to prospectively assess the safety of anesthesia directed deep sedation (ADDS) in non-intubated patients compared to general endotracheal anesthesia (GET) during an ERCP.
Methods We conducted a prospective observational study in patients undergoing an ERCP. The choice of anesthetic—ADDS or GET—was made by the anesthesiologist. The pre-anesthesia assessment, intraoperative vital signs, and medications administered were collected. A standardized study instrument was used to record the number of procedure interruptions, intraprocedure and recovery room adverse events (AE).
Results A total of 393 (89.7 %) patients received ADDS (no intubation) and 45 (10.2 %) received a GET. Age and comorbidities were similar in ADDS and GET groups. BMI was higher in the GET (32.6 ± 9.5) versus in the ADDS (27.3 ± 6.1) group; $p < 0.001$. The number of ASA 2 patients was higher in the ADDS versus the GET group (38.7 versus 22.2 %; $p < 0.04$); the number of ASA 4 patients was 15.6 % of GET versus 6.6 % of the ADDS cases ($p = 0.05$). During the procedure 16 (3.7 %) ADDS patients were intubated and converted to a GET anesthetic; 4 (25 %) of the converted ADDS cases were ASA 4 versus 6.4 % of ADDS patients ($p = 0.006$). Intraprocedure events occurred in 35.6 % of GET and 25.7 % of ADDS cases, without significant complications.
Conclusion Our data suggest that the administration of anesthesia without intubation for prone ERCP cases is feasible especially in non-obese, healthier patients.

Keywords ERCP · Deep sedation · Endoscopy · General anesthesia · Respiratory complications

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Introduction

Requests for anesthesia services for gastrointestinal (GI) [1–3] procedures have risen dramatically in recent years, and are projected to continue to grow. Providing anesthesia assistance in GI suites and other remote locations is challenging on many levels including scheduling, personnel deployment, and equipment issues. Choosing the appropriate anesthetic for procedures in remote locations is paramount as they are frequently fast turnover cases in areas with limited resources for recovery and post procedure monitoring.

Prior studies have found that remote locations are associated with an increased risk of injury or death

compared to standard operating room locations. Respiratory complications in patients under monitored anesthesia care (MAC) are amongst the most commonly reported adverse events in remote locations, especially in GI suites [1, 4]. Although there are multiple studies demonstrating the safety of using propofol and sedation for GI patients undergoing upper endoscopy, colonoscopy and other GI procedures [5], only a few studies have addressed what type of anesthetic is most appropriate for more complex cases [6, 7]. In addition to patient and procedure-related considerations, the choice of anesthetic, i.e. monitored anesthesia care (MAC), deep sedation or general endotracheal (GET) anesthetic, is also influenced by the facility resources and the availability of backup personnel. In remote anesthetizing locations these latter two issues can play a key role in the decision making process.

Therapeutic endoscopic retrograde cholangiopancreatography (ERCP) is a complex endoscopic procedure performed at large referral centers and many community hospitals. ERCP is the procedure of choice for the extraction of common bile duct stones, and has reduced the need for open biliary exploration, a surgical procedure associated with high morbidity especially in the elderly patient [7, 8]. In the era of laparoscopic cholecystectomy, ERCP can also play an important role in identifying and repairing post surgical iatrogenic bile leaks. In pancreatic cancer patients, ERCP with stent placement can be critical for the palliation of obstructive jaundice [9]. Compared to regular upper endoscopy, ERCP is a longer, more complex procedure, with a substantially higher complication rate. It is important that anesthetic techniques facilitate the success of these procedures without adding to morbidity.

At our institution solo anesthesiology attendings routinely provide anesthesia for ERCP and other advanced endoscopy procedures such as endoscopic ultrasound and esophageal stent placements. Our advanced endoscopy unit is a high volume, tertiary referral center and, consequently, many patients have multiple comorbidities and have often had prior procedures or surgery. The ERCP cases are complex and preferentially performed in the prone position. We previously published a study on the rate of anesthesia-related events during ERCP and found a relatively low rate of sedation related adverse events, or premature interruption and termination of the procedure [10]. The goal of the present study was to assess and compare the feasibility of anesthesia directed deep sedation (ADDS) in non-intubated patients versus GET anesthesia in patients undergoing ERCP.

Materials and Methods

Patients referred for an ERCP in the advanced endoscopy unit at Beth Israel Deaconess Medical Center between August and December 2009 were prospectively enrolled. Patients in the intensive care unit and/or requiring mechanical ventilation prior to the procedure were excluded from the study. Institutional review board (IRB) approval was obtained, and the requirement for written informed consent was waived by the IRB.

A preoperative assessment, including a history, physical examination, review of laboratory data, and assignment of ASA classification was performed on all patients prior to the ERCP. Anesthesia and procedural consent was obtained. The anesthetic type—either GET or ADDS—and the drugs used during the procedure were decided by the solo anesthesiologist assigned to the case.

The preanesthesia information, intraoperative hemodynamic data and the medications administered were recorded using an electronic anesthesia information system (AIMS). During the procedure all patients had standard ASA monitoring including capnography. For ADDS cases, a single spray of benzocaine topical anesthesia was applied to the patient's oropharynx. Following the topical spray, ADDS patients were assisted into the 'swimmers' prone position on the fluoroscopy table. In this position a bolster is placed under the upper chest and side, raising the head and neck, which is turned to the right, the left arm is tucked under the left hip and the right leg is flexed at the knee, the right arm is generally bent with the hand level with the patients' head. This position makes the airway more accessible for suctioning and airway manipulations and relieves pressure from the abdomen. Patients receiving a GET were induced following the application of monitors and were maintained in the supine or semi-lateral position.

Following the completion of the ERCP, ADDS patients were transported to the GI recovery area and monitored by nursing until either ready for discharge as assessed using standard recovery criteria or admission to the hospital. Per hospital protocol, all GET patients were recovered in the main operating room PACU until either ready for admission or discharge.

We designed a dedicated study instrument to record intraprocedure and postprocedure adverse events [10]. The instrument was filled in by the procedure and recovery room nurses. Intraprocedure events were defined as hypoxia (oxygen saturation <85 % for any period of time), the need for mask ventilation, unplanned endotracheal intubation (conversion to GET), hypotension requiring use of vasopressors, cardiac arrhythmia requiring treatment, use of reversal agents, and cardiac arrest. Treatment of hypotension or cardiac arrhythmia occurred when clinically indicated at the discretion of the anesthesiologist. Temporary interruption of procedure or premature termination were also recorded, and similar hemodynamic events were documented in the recovery area.

Data Analysis

Preoperative and intraoperative data on each patient including demographic data, comorbidities, medications, ASA classification and intraoperative medications were extracted from the AIMS record. Adverse event data were documented using the study instrument. Statistical analysis was performed using chi-square and Fisher's exact test applied where appropriate. The chi-square test was used when comparing groups using categorical variables, employing Yates' correction for continuity when needed.

Results

A total of 528 ERCPs were performed during the study period, including 74 patients who underwent two or more procedures. Only the first procedure was considered in the statistical analysis, and the total number of procedures analyzed was 438. An ADDS anesthetic was chosen as the initial anesthetic in 393 cases (89.7 %) and GET was the initial choice in 45 cases (10.2 %). The BMI of the patients was significantly higher in the GET group at 32.6 ± 9.5 versus 27.3 ± 6.1 in the ADDS group ($p < 0.001$). There were no significant differences in patient age or other common pre-procedure comorbidities (Table 1). The number of ASA 2 patients was higher in the ADDS versus the GET group at 38.7 versus 22.2 % ($p = 0.04$), in contrast the number of ASA 4 patients was 15.6 % of GET cases versus only 6.4 % of the ADDS cases ($p = 0.05$). There was no difference in percentage of ASA 1 and 3 cases between ADDS and GET groups. The indications and technical difficulty of the ERCP were similar in both groups (Table 1). A total of 94.4 % (371) of ADDS cases were performed in the prone position versus only 4.8 % (19) of GET cases ($p < 0.001$). During the procedure 3 (6.7 %) GET patients and 59 (15 %) ADDS patients had at least one episode of oxygen desaturation to less than 85 %. Hypotension requiring a pressor (ephedrine or phenylephrine) was more common for GET patients compared to ADDS patients at 8 (17.8 %) versus 16 (4.1 %), respectively, with $p < 0.001$. Recovery room events, including hypoxia or hypotension were uncommon in both groups (Table 2).

During the procedure 16 (3.7 %) ADDS cases required intubation and the anesthetic was converted to a GET for the remainder of the procedure. The average age of 67.6 ± 19 years for the converted cases was similar to the non converted ADDS cases and the planned GET cases. The frequency of comorbidities was also similar between the groups except for COPD, which was present in 25 % (4 patients) of the converted cases compared to 10.2 % (40 patients) of the non converted ADDS cases ($p = 0.046$). Twenty-five percent of the ADDS cases that converted to a GET (4 patients) were ASA 4, compared to just 6.4 % (25 patients) of all ADDS cases ($p = 0.006$) (Table 3). A total of 87.5 % of converted cases had an episode of hypoxia and 93.8 % had either hypoxia or hypotension during the procedure. Only one case required premature termination of the ERCP due to an intraprocedure event during an ADDS anesthetic. During the study period the number of GET cases and ADDS cases was stable at approximately 10 % of GET cases per each 2-week period. The most commonly used drugs were propofol, midazolam, ketamine and fentanyl (Table 4). The average time for the cases, excluding anesthesia time, was 25 ± 14 min.

Discussion

Providing anesthesia for complex gastrointestinal cases is becoming a significant part of many anesthesia practices. The choice of anesthetic can have important ramifications on patient safety, the ability to complete painful complex procedures, and the efficiency of the operating locations. We have shown that in almost 400 non-intubated patients it was possible to complete the ERCP without GET and this was associated with a low level of significant adverse events.

Over 90 % of our ADDS patients received propofol as a continuous infusion; it is certainly not unusual for patients during a propofol anesthetic to move in and out of different levels of consciousness, from deep sedation to general anesthesia [11, 12]. It is likely that most of our ADDS patients were under general anesthesia at different points during the case. Nevertheless, our results suggest that with careful monitoring of the airway and respiration, a deep anesthetic administered by an anesthesiologist without an endotracheal tube can provide an acceptable and safe anesthetic for ERCPs for non-obese, healthy patients.

Monitored anesthesia care anesthesia or deep sedation in remote locations can be advantageous, reducing the time needed to induce the patient and discharge them at the end of the procedure. As previously reported [10], adverse events were relatively common in both sedation (25 %) and GET cases (35 %), most of these were relatively minor and did not lead to major complications. Sixteen (3.9 %) ADDS cases required conversion to a general anesthesia with intubation; however, none of these patients experienced significant complications as a result of the conversion.

In general, a review of our data on patient characteristics of intubated patients suggest that obesity and high ASA classification are important factors. In planned GET cases, 47 % of GET patients had a BMI over 30 compared to 30 % of ADDS cases ($p = 0.026$). This is not unexpected;

Table 1 Demographics and comorbidities

Demographics and comorbidities	General endotracheal anesthesia (GET) *n* (%)	Anesthesia directed deep sedation (ADDS) *n* (%)	GET versus ADDS *p* value
Number of procedures	45 (10.2)	393 (89.7)	
Demographics			
Mean age (years) ± SD	65.9 ± 17	63.4 ± 18	p = NS
% Female	44.4	53.4	p = NS
Mean BMI ± SD	32.6 ± 9.5	27.3 ± 6.1	$p < 0.001$
BMI > 30 = *n* (%)	21 (46.7)	116 (29.5)	$p = 0.026$ (Fisher's exact)
Comorbidites and ASA classification			
CHF	6 (13.3 %)	28 (7.1 %)	p = NS
CAD	10 (22.2 %)	79 (20.1 %)	p = NS
HTN	30 (66.7)	225 (57.3)	p = NS
Asthma	4 (8.9)	45 (11.5)	p = NS
COPD	5 (11.1)	40 (10.2)	p = NS
GERD	29 (64.4)	224 (57)	p = NS
Malignancy	10 (22.2)	87 (22.1)	p = NS
CKD	6 (13.3)	30 (7.6)	p = NS
ASA class 1	0	29 (7.4)	p = NS
ASA class 2	10 (22.2)	152 (38.7)	$p = 0.04$
ASA class 3	27 (60)	187 (47.6)	p = NS
ASA class 4	7 (15.6)	25 (6.4)	$p = 0.05$
Procedure indications			
Obstructive jaundice (without suspected stone)	3 (6.7)	43 (10.9)	p = NS
Liver function abnormalities	26 (57.8)	217 (55.2)	p = NS
Stones/sludge	20 (44.4)	174 (44.3)	p = NS
Stricture	3 (6.7)	43 (10.9)	p = NS
Biliary leak	3 (6.7)	19 (4.8)	p = NS
Other	32 (71.1)	288 (73.3)	p = NS

CHF congestive heart failure, *CAD* ischemic heart disease, *HTN* hypertension, *COPD* chronic obstructive pulmonary diseases, *GERD* gastrointestinal reflux, *CKD* chronic kidney disease, *ASA class* American Society of Anesthesiology physical risk status classification

obese patients have a higher incidence of sleep apnea, can be difficult to adequately sedate, and carry a higher intra-procedure risk of hypoxemia, airway obstruction, and aspiration [13]. Obesity may also have influenced the choice to convert to a GET during the procedure as 25 % of the converted ADDS cases had a BMI of over 30. A higher proportion of the GET patients were also sicker and received an ASA 4 classification; this was true for both planned GET cases and the converted ADDS cases. The other at-risk group identified for hypoxemia requiring intraprocedure intubation were patients with COPD. Twenty-five percent of the converted ADDS cases had COPD compared to only 10.2 % of planned ADDS cases ($p = 0.046$).

Some of the most significant data on the safety of MAC anesthesia in GI suites and other remote locations is derived from the ASA closed claims database [4]. Metzner et al. [1] reviewed the closed malpractice claims associated with remote locations occurring after 1990. Their data highlighted the risks associated with gastrointestinal suites—32 % of the remote claims involved the gastrointestinal suites, followed by cardiology (25 %) and the emergency department (20 %). Over-sedation leading to respiratory events were the most commonly encountered adverse events in the GI suites. A delay in recognition of deterioration and difficulty in resuscitation because of the prone position has been suggested as a contributing factor to respiratory adverse events in non intubated patients [4]. In our study we found that significant respiratory events were not common in our ADDS patients despite over 90 % being prone during the procedure. There are several reasons that could account for the apparent improvement in anesthetic outcomes. First, capnography was not routinely required during the administration of sedation at the time of

Table 2 Intraprocedure and recovery room event data

Event data	General endotracheal anesthesia (GET) *n* (%)	Anesthesia directed deep sedation (ADDS) *n* (%)	GET versus ADDS *p* value
Intraprocedure data			
Lowest O_2 sat <85 %	3 (6.7)	59 (15)	p = NS
MAP < 55 mmHg	8 (17.8)	16 (4.1)	$p = 0.001$
Arrhythmia	5 (11.1)	13 (14)	$p = 0.012$
Recovery room events			
Hypoxia	4 (8.9)	7 (1.8)	
Hypotension	3 (6.7)	6 (1.5)	
Arrhythmia	2 (4.4)	10 (2.5)	
Intubation	2 (4.4)	0	
Vasopressor	1 (2.2)	3 (0.8)	

NS not significant

Table 3 Comorbidities of converted ADDS cases

Comorbidities	ADDS converted to GET cases ($N = 16$) *n* (%)	ADDS cases versus converted ADDS cases *p* value
CHF	1 (6.3)	p = NS
CAD	3 (18.8)	p = NS
HTN	11 (68.8)	p = NS
Asthma	1 (6.3)	p = NS
COPD	4 (25)	$p = 0.046$
GERD	9 (56.3)	p = NS
Malignancy	1 (6.3)	p = NS
CKD	1 (6.3)	p = NS
BMI	29.2 ± 7	
ASA class 1	1 (6.3)	p = NS
ASA class 2	3 (18.8)	p = NS
ASA class 3	8 (50)	p = NS
ASA class 4	4 (25)	$p = 0.006$

CHF congestive heart failure, *CAD* ischemic heart disease, *HTN* hypertension, *COPD* chronic obstructive pulmonary diseases, *GERD* gastrointestinal reflux, *CKD* chronic kidney disease, *BMI* body mass index, *ASA Class* American Society of Anesthesiology physical risk status classification, *NS* not significant

the closed claims data collection, and the lack of appropriate monitoring may have contributed to the adverse outcomes described. Capnography can identify respiratory depression before the onset of hypoxemia and provides an early warning of impending significant respiratory depression [14]. The ASA guidelines for monitoring include a recommendation to use capnography in endoscopic anesthetic cases [15]. Second, there has been significant growth in the use of anesthesia in remote locations

Table 4 Intraprocedure medication usage

Sedative agent use	General endotracheal anesthesia (GET) *n* (%)	Anesthesia directed deep sedation (ADDS) *n* (%)	GET versus ADDS *p* value
Propofol use	36 (80)	384 (97.7)	$p < 0.001$
Fentanyl use	30 (66.7)	80 (20.4)	$p < 0.001$
Midazolam use	27 (60)	288 (73.3)	$p = 0.09$
Ketamine use	4 (8.9)	113 (28.8)	$p = 0.007$

since the time of data collection in these studies. This extensive experience has led to a more organized approach to remote anesthesia in many practices, including the development of dedicated GI anesthesia suites with appropriate monitoring and emergency equipment [16–18].

Common indications for utilizing anesthesia services for a GI procedure instead of nurse administered moderate sedation include a history of alcohol and substance abuse, a painful procedure, patient anxiety, the inability to complete the prior procedure and the presence of a significant comorbidities, hemodynamic and respiratory instability or an acute illness such as cholangitis [19]. For ERCP cases, which can be very challenging, few studies have addressed what is the best anesthetic choice, i.e. deep sedation or general anesthesia with intubation. Raymondos et al. [6] found that the procedure failure rate in over 1,000 ERCP cases was double in patients receiving only moderate sedation compared to general anesthesia with intubation; 14 versus 7 % ($p < 0.012$) and inadequate pain control was a major factor in their study. Our results suggest that a general anesthetic with intubation may not be necessary and that a ADDS with propofol, midazolam and small dose of ketamine as needed can provide an adequate level of sedation and analgesia for complicated ERCP cases.

At our institution we provide anesthesia services for all ERCP and advanced endoscopy cases. In general we operate 2–3 advanced GI procedure suites per day, performing between 15 and 18 cases per day, and each procedure room is staffed by a solo attending anesthesiologist. As it is recognized that regular experience by anesthesiologists in advanced GI procedures can improve personal comfort levels, reduce morbidity and enhance efficiency of the unit, all operating room anesthesiologists (approximately 55), are assigned to the GI unit on a regular basis, generally 1–2 times per month. This has provided opportunity for improved collaboration between gastroenterologists and anesthesiologists and has reduced wide variability between anesthesia providers on a day to day basis.

Limitations

This was an observational study and our data reflect the practice of a high volume advanced endoscopy unit (>1,700 ERCPs per year) with experienced endoscopists and relatively short procedures with an average of 25 min. The procedures are performed in a unit with dedicated anesthetic equipment, experienced GI nursing staff and technicians familiar with the procedures. These characteristics undoubtedly contributed to the success of an ADDS anesthetic; consequently, our results may not be generalizable to units with low volumes, prolonged procedures and less experienced endoscopists. Patients were not randomized into ADDS versus GET, and thus the individual anesthesiologist's choice or comfort level with the ERCP cases remains a significant factor. It was not possible to analyze the data by individual anesthesiologist, and selection bias towards general anesthesia especially for obese patients cannot be excluded. However during the 3-month study period the number of GET cases and ADDS cases remained at approximately 10 % of GET cases per each 2-week period. This suggests that the distribution of individual anesthesiologists did not greatly influence the type of anesthesia selected. Lastly, we did not monitor the depth of anesthesia, for example, with a BIS monitor. Thus it was not possible to compare the level of anesthesia between the two groups.

Conclusion

Anesthetic care for ERCP cases can be challenging. We have demonstrated that deep sedation anesthesia without intubation is feasible for cases performed in healthy, non-obese patients in the prone position. The choice of the "best" anesthetic for these cases is an important issue, as the ability to complete an ERCP successfully can eliminate the need for open surgery with its associated comorbidities.

Conflict of interest None.

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