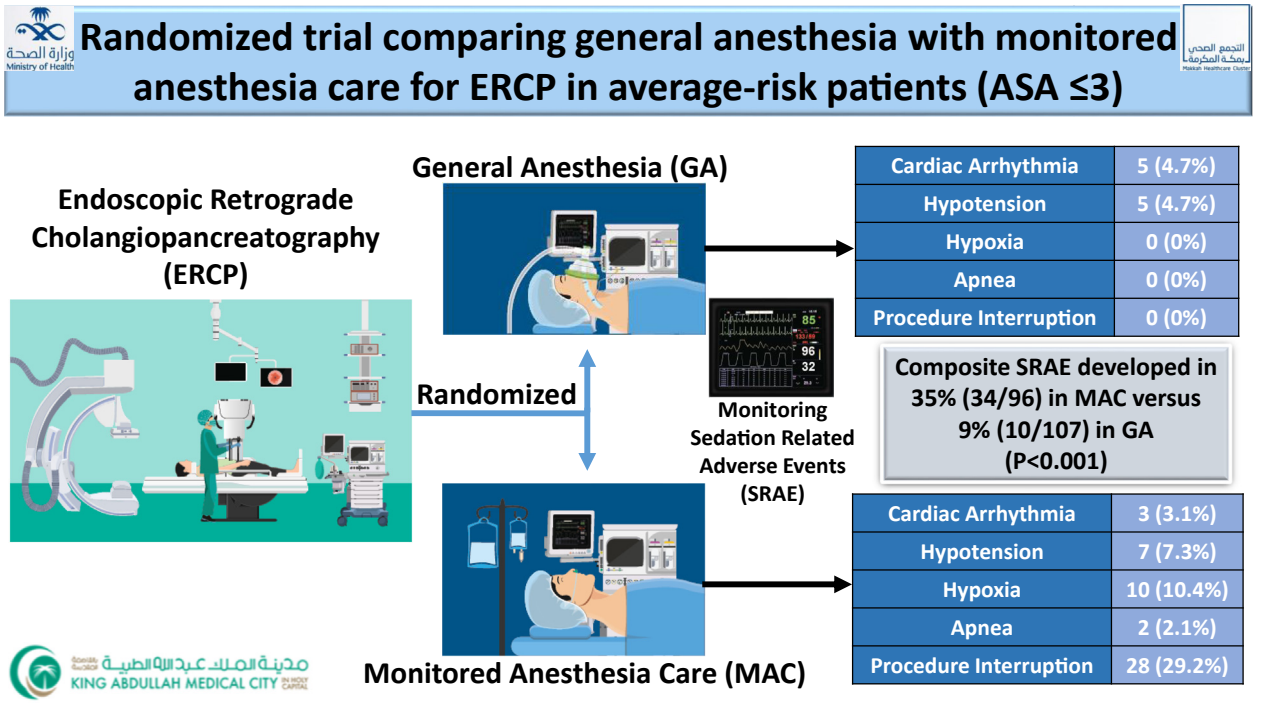
Randomized trial comparing general anesthesia with anesthesiologist-administered deep sedation for ERCP in average-risk patients (CME)

Adnan B. Alzanbagi, MD,[1] Tariq L. Jilani, MD,[2] Laeeque A. Qureshi, FCPS,[1] Ibrahim M. Ibrahim, MD,[2] Abdulaziz M. S. Tashkandi, MD,[1] Eman E. A. Elshrief, MD,[2] Mohammed S. Khan, MD,[1] Manal A. H. Abdelhalim, MD,[2] Saad A. Zahrani, MD,[1] Wafaa M. K. Mohamed, MSc,[2] Ahmed M. Nageeb, MD,[2] Belal Abbushi, MD,[2] Mohammed K. Shariff, MD[1]

Makkah, Kingdom of Saudi Arabia

GRAPHICAL ABSTRACT



Background and Aims: General anesthesia (GA) or monitored anesthesia care (MAC) is increasingly used to perform ERCP. The definitive choice between the 2 sedative types remains to be established. This study compared outcomes of GA with MAC in ERCP performed in patients at average risk for sedation-related adverse events (SRAEs).

Methods: At a tertiary referral center, patients with American Society of Anesthesiologists (ASA) class ≤III were randomly assigned to undergo ERCP with MAC or GA. The main outcome was a composite of hypotension, arrhythmia, hypoxia, hypercapnia, apnea, and procedural interruption or termination defined as SRAEs. In addition, ERCP procedural time, success, adverse events, and endoscopist and patient satisfaction were compared.

Results: Of 204 randomized, 203 patients were evaluated for SRAEs (MAC, n = 96; GA, n = 107). SRAEs developed in 35% of the MAC cohort (34/96) versus 9% in the GA cohort (10/107), which was statistically significant ($P < .001$). Mean induction time for GA was significantly longer than that for MAC (10.3 ± 10 minutes vs 6.5 ± 10.8 minutes, respectively; $P < .001$). ERCP procedure time, recovery time, cannulation time and success,

and procedure-related adverse events were not statistically different between the 2 sedative groups. The use of GA improved endoscopist and patient satisfaction ($P < .001$).

Conclusion: GA is safe with fewer SRAEs than MAC in patients with ASA scores ≤III undergoing ERCP. Apart from prolonging induction time, use of GA does not change the procedural success or ERCP-related adverse events and offers greater endoscopist and patient satisfaction. Hence, GA is a consideration in patients undergoing ERCP in this population group. (Clinical trial registration number: NCT04099693.) (Gastrointest Endosc 2022;96:983-90.)

(footnotes appear on last page of article)

ERCP is a complex endoscopic procedure with serious potential adverse events including mortality.[1] There has been a gradual increase in the number of ERCPs performed with more therapeutic interventions possible.[2] Sedation ensures an efficient, successful, and comfortable procedure.[3] Nevertheless, adverse events from sedation are the most common ERCP-related events.[1]

Although sedation is routinely used for ERCP, practices vary internationally and include endoscopist-directed sedation and anesthesiologist-assisted anesthesia. Furthermore, the practice of anesthesiologist-assisted anesthesia is divergent and differs between monitored anesthesia care (MAC) performed without endotracheal intubation and general anesthesia (GA). MAC is emerging as a preferred choice and is endorsed as an option for sedation in ERCP.[3-5] Because of questions on the safety of deep sedation, many anesthesia personnel prefer GA.[6,7] Few studies nonetheless have compared sedation-related adverse events (SRAEs) of MAC with GA for ERCP. The outcomes of observational studies are mixed, with 2 studies documenting higher cardiopulmonary events with GA use and 1 reporting it more frequently with MAC use.[8-10] The only randomized study on this topic was performed in patients at high risk for sedation and concluded that GA was associated with significantly fewer SRAEs and did not compromise ERCP procedure time or success rate when compared with MAC.[11]

Whether MAC or GA is better for ERCP in patients at average risk for sedation is unexplored. Hence, this study aimed to conduct a randomized trial comparing the safety and efficacy of MAC with GA in patients at average risk for sedation undergoing ERCP.

METHODS

Setting and patients

This study was performed in King Abdullah Medical City, Makkah, Kingdom of Saudi Arabia, a tertiary referral center for ERCP. Ethical approval was obtained from King Abdullah Medical City, Makkah Institutional Review Board, which has been accredited by the Association for the Accreditation of Human Research Protection Program, and was registered at ClinicalTrials.gov (identifier: NCT04099693).

All consecutive patients undergoing ERCP age >18 years with American Society of Anesthesiologists (ASA) class ≤III were eligible for the study. Patients who needed emergency ERCP, were ASA class ≥IV, had surgically altered upper GI anatomy, were pregnant, were suspected to have difficult intubation as assessed by an anesthesiologist based on the Mallampati score, were allergic to any anesthetic medication used in the study for sedation, or were unable to give or obtain consent were excluded.

Study design

After providing informed consent, patients were randomized on a 1:1 basis to MAC or GA. Concealed allocation was achieved using a sealed, numbered envelope that was opened in the procedure room by the endoscopy nurse who informed the study team (anesthesiologist and endoscopist) regarding the assignment.

Anesthesia and ERCP procedure

Board-certified anesthesiologists with extensive experience in endoscopic sedation administered the sedation. All participants were monitored by continuous pulse oximetry, electrocardiography, capnography, and automated sphygmomanometer every 5 minutes. Supplemental oxygen was given before sedation. For MAC, a bolus of propofol (.5-1 mg/kg) was administered followed by continuous infusion with variable doses depending on the patient's age, weight, and clinical condition to ensure a steady level of sedation. GA was administered using cisatracurium (.15 mg/kg) as a muscle relaxant and propofol (1.5-2 mg/kg) for induction. The depth of anesthesia was maintained using an inhalational anesthetic, sevoflurane, with a 50% mix of nitrous oxide and oxygen. In addition, the anesthetist used fentanyl (1-2 μg/kg) and other sedative drugs at their discretion.

Board-certified advanced endoscopists who had completed more than 500 bile duct cannulations performed all ERCP procedures. The procedures were done with the patient in a prone position using a therapeutic

duodenoscope. All patients irrespective of the type of sedation (GA or MAC) were transferred after the procedure to the endoscopy recovery area where the monitoring continued under the supervision of the anesthesiologist until assessed according to the Aldrete score[12] that they were fit for discharge.

Definitions and outcomes

The primary outcome was the proportion of patients in the 2 groups who developed the composite SRAEs defined as follows: hypotension, when systolic blood pressure dropped below 25% of the baseline measurement requiring vasopressor drugs; cardiac arrhythmia, defined as bradycardia (drop in heart rate <50 beats/min) or tachycardia (rise in heart rate >120 beats/min) requiring treatment; hypoxia, when oxygen saturation fell below 90% for any period of time; hypercapnia, when expiratory carbon dioxide increased by more than 25% from the baseline; apnea, when respiratory activity ceased for ≥10 seconds via capnography; and any interruption or termination of the ERCP procedure because of sedation. ERCP procedure interruption was further defined as any request by the anesthesiologist to pause the procedure to correct SRAEs, including any maneuvers to secure the airway. ERCP procedure termination was further defined as abandonment or deferment of the procedure because of SRAEs and/or retained gastric contents. Apart from the nasal airway, use of any airway manipulation as deemed necessary by the anesthesiologist to secure the airway was defined as an airway maneuver, including oral airway, chin lift, jaw thrust, bag and mask, and endotracheal intubation.

Secondary outcomes were sedation induction time (time from start of sedation until intubation of duodenoscope), procedure time (time from duodenoscope intubation until duodenoscope withdrawal), recovery time (time from scope withdrawal until recovery to a healthy state scoring 10 on the Aldrete system),[12] incidence of successful ERCP (technical success of achieving deep cannulation of the ducts of interest in patients with native papillae),[13] and incidence of ERCP-related adverse events (bleeding, perforation, and pancreatitis). In addition, satisfaction with the type of sedation was assessed using a 10-point visual analog scale[14] (Supplementary Fig. 1, available online at www.giejournal.org), with 1 representing the worst experience and 10 the best experience with sedation. Both the endoscopist who performed the procedure and the patient who underwent the procedure recorded their experience with sedation by placing an "X" on this scale at the time when the patient was ready for discharge. To avoid further biases, the anesthesiologist was excluded from this assessment.

Statistical analysis and sample size calculation

Data were analyzed using SPSS version 26.0 (IBM Corp, Armonk, NY, USA). Categorical data are presented as percentages and were compared using the χ^2 test. Continuous data are presented as mean ± standard deviation or as median and interquartile range and were compared between the 2 groups using the Student t test or the Mann-Whitney test, depending on their distribution type. A 2-sided alpha was set at .05 for all hypothesis tests. Multivariate logistic regression analysis was done to look for predictors of adverse events associated with sedation. After randomization, only 1 patient in the MAC arm did not receive the intervention and was excluded from the analysis. All patients randomized to the GA arm completed the study and were included in the final analysis. The analysis was thus performed per-protocol.

Previous prospective studies showed that SRAEs occurred in 24.8% of patients who had ERCP with sedation administered by an anesthesiologist.[8] To detect a reduction from this rate to 10% in the GA group with a 2-tailed alpha of .05 and beta of .20 using the χ^2 test, a total number needed was calculated to be 204.

RESULTS

Participants enrolled and assigned

Among 238 eligible patients, 204 provided informed consent and were randomized to GA (n = 107) or MAC (n = 97). One participant in the MAC group was removed from study because of the development of arrhythmia after randomization and before administration of any sedation; the remaining 203 patients completed the study and were included in the final analysis (Fig. 1). Mean patient age was 50.3 ± 19.3 year, and 53% were women (107/203). As shown in Table 1, there was no significant difference in demographics, comorbidities, and indications for ERCP between the 2 randomized groups.

Sedation-related adverse outcomes

The primary outcome of combined SRAEs in MAC (34/96 [35%]) was significantly higher compared with GA (10/107 [9%], $P < .001$). Forty-four patients experienced SRAEs, 34 in the MAC arm and 10 in the GA arm. The 34 patients in the MAC group had 50 SRAEs, with some patients experiencing more than 1 SRAE. Most MAC-related adverse events (28/50 [56%]) resulted in ERCP procedure interruptions (Table 2). All procedure interruptions were primarily because of airway manipulation; 2 were because of significant apnea requiring endotracheal intubation that led to the conversion of MAC to GA. Thirty-eight other forms of airway manipulations were carried out on the remaining 26 patients, with some requiring more than 1 maneuver to secure the airway (Table 3). Ten patients experienced hypoxia, with 9 requiring an additional airway manipulation (Table 2). None of the ERCP procedures was terminated in either group, and none was interrupted in the GA group. Two of 96 patients (2%) in the MAC group were converted to GA because of intractable apnea. Analysis by the specific type of event revealed more episodes of hypoxia (MAC vs

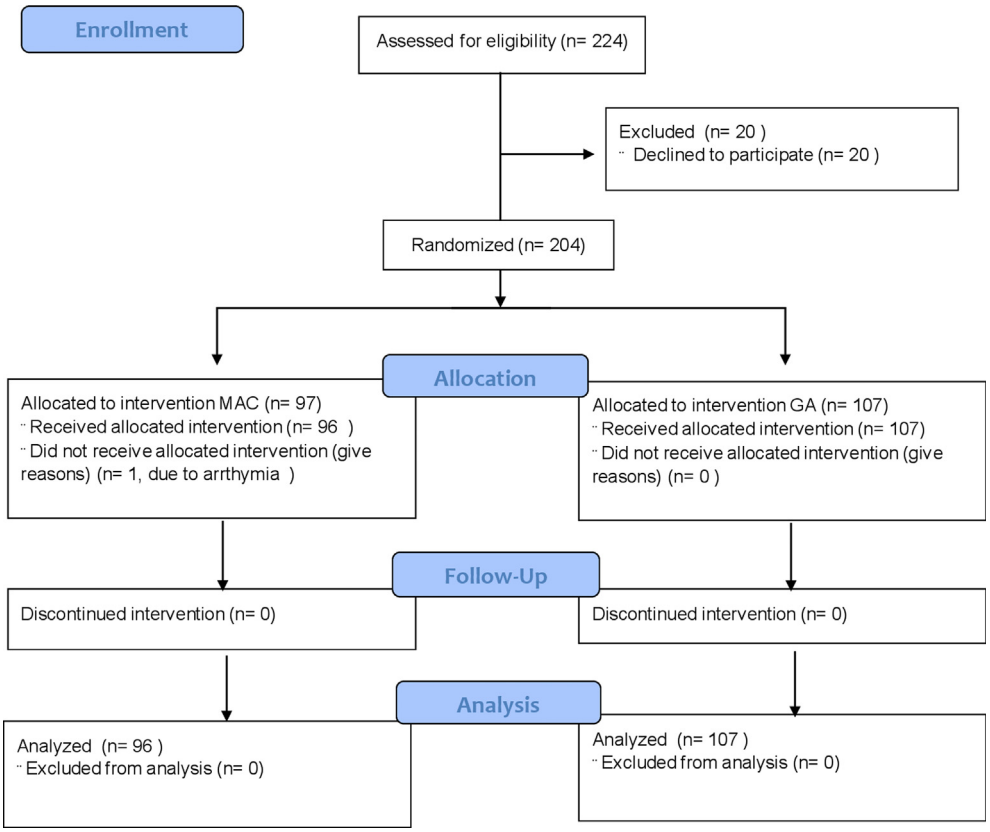


Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flow diagram. *MAC*, Monitored anesthesia care; *GA*, general anesthesia.

GA: 10 [10.4%] vs 0; $P = .001$) but no significant differences in the other SRAEs of cardiac arrhythmia, hypotension, and apnea.

Sedation and ERCP procedural efficiency

Sedation induction time was significantly longer in the GA group ($P < .001$). However, ERCP procedure time and recovery time postprocedure were similar in both groups (Table 4). In 149 patients who had a native papilla, successful bile duct cannulation (99% vs 97%) was no different between the groups, and there was no significant difference in time to bile duct cannulation. Two ERCP procedure-related bleeding events and 1 perforation in the MAC group occurred. No procedure-related adverse events were recorded in the GA group.

Patient and endoscopist satisfaction

Mean patient satisfaction with GA was greater and significantly higher than with MAC (9.6 ± .8 vs 9 ± 1.1, respectively; $P < .001$). Similarly, mean endoscopist satisfaction with GA was significantly higher than with MAC (9.6 ± 1.2 vs 8.6 ± 1.7, respectively; $P < .001$) (Table 4).

Predictors of SRAEs

To discern variables associated with SRAEs, a univariate analysis was performed. However, none of the variables, including gender, age, ASA, body mass index, comorbidity, Mallampati score, procedure indication, procedure time, or use of fentanyl, was significantly associated with SRAEs (Supplementary Table 1, available online at www.giejournal.org). In addition, we looked exclusively at cardiorespiratory adverse events related to sedation (cardiac arrhythmia, hypotension, hypoxia, and apnea), excluding procedures interruptions, to identify any association with these events. Furthermore, none of the variables discussed above was associated with cardiorespiratory adverse events (Supplementary Table 2, available online at www.giejournal.org).

On multivariate logistic regression using the abovementioned variables with SRAEs as an outcome, procedure time was significantly associated with SRAEs (odds ratio, 1.016; $P = .026$) (Supplementary Table 3, available online at www.giejournal.org). After removing procedure interruptions and focusing only on cardiorespiratory events, procedure time was no longer significant on the multivariate model (Supplementary Table 4, available online at www.giejournal.org).

TABLE 1. Baseline characteristics

Variable	Monitored anesthesia care (n = 96)	General anesthesia (n = 107)	*P* value
Gender			
Male	46 (47.9)	50 (46.7)	.866
Female	50 (52.1)	57 (53.3)	
Age			.810
18-35 y	30 (31.3)	30 (28)	
36-50 y	17 (17.7)	24 (22.4)	
51-65 y	29 (30.2)	29 (27.1)	
>65 y	20 (20.8)	24 (22.4)	
American Society of Anesthesiologists class			.823
I	36 (37.5)	43 (40.2)	
II	40 (41.7)	40 (37.4)	
III	20 (20.8)	24 (22.4)	
Body mass index			.720
≤25-34 kg/m^2	78 (81.3)	89 (83.2)	
≥35 kg/m^2	18 (18.8)	18 (16.8)	
Comorbidities			
Diabetes mellitus	18 (18.8)	19 (17.8)	.855
Hypertension	17 (17.7)	22 (20.6)	.607
Cerebrovascular accident	2 (2.1)	1 (.9)	.498
Ischemic heart disease	3 (3.1)	6 (5.6)	.391
Chronic kidney disease	1 (1)	1 (.9)	.939
Mallampati score*			.962
Class 1	9 (9.4)	11 (10.3)	
Class 2	81 (84.4)	90 (84.1)	
Class 3	6 (6.3)	6 (5.6)	
Mouth opening			.290
<3 cm	1 (1)	0 (0)	
≥3 cm	95 (99)	107 (100)	
Thromental distance			.939
<6 cm	1 (1)	1 (.9)	
≥6 cm	95 (99)	106 (99.1)	
Procedure indication			
Choledocholithiasis	63 (65.6)	61 (57)	.209
Biliary stricture	22 (22.9)	16 (15)	.187
Biliary pancreatitis	8 (8.3)	5 (4.7)	.288
Bile leak	3 (3.1)	6 (5.6)	.391
No. of patients with native papillae	74	75	.260

Values are n (%).

*Mallampati score is based on visual assessment of the space available for direct laryngoscopy to predict difficulty of endotracheal intubation. Class 1: soft palate, uvula and pillars visible; class 2: soft palate and uvula visible; class 3: only soft palate and base of uvula visible; class 4: only hard palate visible.

DISCUSSION

This randomized study shows that GA for ERCP in patients at average risk for sedation is associated with significantly fewer overall SRAEs compared with MAC (9% vs 35%, respectively; $P < .001$). Most SRAEs were because of ERCP procedure interruptions triggered by airway maneuvers to ensure a secure airway. However, this was achieved at a significantly longer sedation induction time for GA of 10.3 ± 10 minutes compared with MAC at 6.5 ± 10.8 minutes ($P < .001$). Other secondary parameters like ERCP procedural time, bile duct

TABLE 2. Sedation-related adverse outcomes

Sedation-related adverse event	Monitored anesthesia care (n = 34*)	General anesthesia (n = 10)	*P* value
Cardiac arrhythmia	3 (3.1)	5 (4.7)	.571
Hypotension	7 (7.3)	5 (4.7)	.430
Hypoxia	10 (10.4)	0 (0)	.001
Apnea	2 (2.1)	0 (0)	.133
Procedure interruption	28 (29.2)	0 (0)	<.001
Procedure termination	0 (0)	0 (0)	

Values are n (%).
*Patients had >1 sedation-related adverse event: 9 had hypoxia and procedure interruption, 2 had hypotension and procedure interruption, 2 had apnea and procedure interruption, and 3 had arrhythmia and airway manipulation.

TABLE 3. Events leading to ERCP procedure interruptions

Airway manipulation	Monitored anesthesia care (n = 28*)	General anesthesia (n = 0)	*P* value
Oral airway	7 (7.3)	0 (0)	.003
Chin lift	20 (20.8)	0 (0)	.000
Jaw thrust	8 (8.3)	0 (0)	.006
Bag mask	3 (3.1)	0 (0)	.175
Endotracheal intubation	2 (2.1)		

Values are n (%).
*Patients had >1 airway manipulation: 3 had oral airway and chin lift; 3 had chin lift and jaw thrust; and 2 had oral airway, chin lift, jaw thrust, and bag mask.

TABLE 4. Sedation and ERCP procedural efficiency and sedation satisfaction

Variable	Monitored anesthesia care (n = 96)	General anesthesia (n = 107)	*P* value
Sedation induction time, min			<.001
Mean ± SD	6.5 ± 10.8	10.3 ± 10	
Median (IQR)	5 (2-6)	8 (4-15)	
Procedure time, min			.265
Mean ± SD	31.3 ± 17.8	38 ± 35	
Median (IQR)	27 (17-45)	29 (20-50)	
Recovery time, min			.136
Mean ± SD	25.2 ± 15.8	30 ± 23	
Median (IQR)	22.5 (14.2-30)	25 (16.7-33.2)	
Time to duct cannulation, min			.165
Mean ± SD	5.9 ± 6.2	4.9 ± 5.3	
Median (IQR)	3 (2-8)	3 (2-5)	
Successful cannulation (n = 149), n/N (%)	73/74 (98.6)	73/75 (97.3)	.568
ERCP-related adverse events, n (%)			
Bleeding	2 (2.1)	0 (0)	.314
Perforation	1 (1)	0 (0)	.568
Patient satisfaction score			<.001
Mean ± SD	9 ± 1.1	9.6 ± .8	
Median (IQR)	9 (8-10)	10 (9-10)	
Physician satisfaction score			<.001
Mean ± SD	8.6 ± 1.7	9.6 ± 1.2	
Median (IQR)	9 (8-10)	10 (9-10)	

SD, Standard deviation; *IQR*, interquartile range.

cannulation time, cannulation success rate, recovery time, and ERCP-related adverse events were not markedly different between the sedative groups. Procedure time was an independent predictor of composite SRAEs only and not of cardiorespiratory adverse events. The association of procedure duration and SRAEs is intricate. Procedure complexity, cannulation difficulty, and type of therapeutic interventions lengthen the ERCP procedure, potentially aggravating adverse events.[15] Conversely, adverse events may prolong procedure duration, hence making it difficult to establish a causality relationship with certainty.

The only other randomized study that compared GA with MAC for ERCP was conducted in patients who were at high risk for sedation with ASA class ≥IV.[11] The results were similar to our study with significantly higher SRAEs in the MAC group that were primarily because of a high number of airway maneuvers carried out in these patients. In keeping with high-risk patients, the reported SRAEs and conversion rate to endotracheal intubation in the MAC group was much higher, 52% and 10%, compared with our study of 35% and 2%, respectively. Fortunately, for the most part these hypoxic adverse events were minor and could be corrected by simple airway maneuvers. Nevertheless, 2 patients did require urgent intubation, and the study was not powered to demonstrate end-organ effects of hypoxia or adverse events related to airway management. MAC resulted in 45% of patients having airway maneuvers in that study,[11] whereas only 29% needed airway maneuvers in our study. The main difference regarded procedure time, which was not different between the sedative groups, in contrast to our study where sedation induction time was markedly prolonged for GA. Substantiating the issue of prolonged induction time, a prospective study from a tertiary referral center evaluated endoscopy unit efficiency metrics and concluded ERCP with GA markedly prolonged the metrics of anesthesia induction time.[16] The efficiency of endoscopy units varies between units depending on volume, throughput, anesthesiologist experience, unit design with the flow of patients, and the way the metrics are measured.[16,17]

Three prospective, comparative, nonrandomized studies looked at the outcome of deep sedation and GA including SRAEs with more than 90% of the patient population included recording ASA class ≤III.[8,9,18] Two studies that used MAC reported higher SRAEs with GA, whereas the third study that used endoscopist-directed sedation showed no notable difference between sedative types. The conversion rate from deep sedation to GA varied from 3% to 3.7%. One study that reported on endoscopist satisfaction noted no difference between the type of sedation used, and another evaluated room utilization to be considerably shorter with moderate sedation (50.8 vs 54.5 minutes with GA, $P = .01$).[8,18] A multicenter retrospective study reported a significantly high rate of SRAEs in MAC (6%) compared with GA (.4%, $P < .001$), with 1% of cases in MAC requiring conversion to GA.[10] These studies are heterogeneous in design and patient population, making comparison difficult. The results are dissimilar to our study in that patients were not randomized and the studies were not designed to directly compare MAC with GA. The choice of sedative was at the discretion of the anesthesiologists or endoscopists, leading to higher-risk patients and difficult procedures performed with GA.

The need to achieve deep cannulation of the bile duct indirectly leads to deeper sedation requirements.[19] In addition, a systematic review and meta-analysis concluded that placing patients in the prone position results in a better technical success rate and shorter procedure duration at the cost of higher cardiopulmonary events.[20]

The main limitation to our study is the adoption of procedure interruptions as SRAEs. This is not a novel criterion and has been endorsed in other similar studies,[8,11] although the definition of procedure interruption varied. One of the predominant reasons for sedation is to ensure smooth and uninterrupted endoscopic procedures. Most of our patients who had procedure interruptions had more than 1 airway maneuver. Most cardiorespiratory adverse events that occurred in our patients also led to airway maneuvers. Multiple airway maneuvers do signify the seriousness of inadequate airway protection. Furthermore, the use of airway maneuvers was not standardized, and hence some anesthesiologists may have performed more maneuvers than others. Our study primarily focused on sedation-related patient safety and not on ERCP-related adverse events because of the need to include an extremely high number of participants to study the fortunately infrequent events. In addition, we did not followup with patients to look for delayed SRAEs like aspiration pneumonia. Thereafter, we did not look at the grade of ERCP complexity. ERCPs that are of minor complexity may be easier to perform and require shorter procedure durations with a lesser impact on SRAEs compared with higher-grade procedures.[21] In addition, being a single-center study, having dedicated anesthesiologists, monitoring patients in the same endoscopy recovery area after GA, and the cost of GA may determine its use and may influence the efficiency of sedation. Hence, our results may not apply to all endoscopy units. Nonetheless, an annual increase over the years of endoscopy sedation being provided by anesthesiologists is a growing trend.[22] Finally, randomization and blinding of anesthesiologists and endoscopists were not done because of practical reasons, which may introduce performance bias.

In conclusion, GA for ERCP is safer primarily because of high rates of airway maneuvers in MAC with better endoscopist and patient satisfaction, but this comes at the expense of prolonged induction time in patients with ASA class ≤III. However, the absolute numeric differences both for patient and endoscopist satisfaction were modest.

Procedural success, procedure time, and ERCP-related adverse events were comparable with MAC. Hence, GA for ERCP is a reasonable choice in average-risk patients in tertiary referral endoscopy units to reduce hypoxia and the need for intraprocedural airway maneuvers. Further studies with a larger sample size focusing on procedural time, ERCP-related adverse events, and cost-effectiveness are warranted to ascertain routine use of GA in average-risk patients.

ACKNOWLEDGMENTS

We thank the participants of the study for their initiative and time. We are grateful to our advanced endoscopy staff including Wafa Sandukh and Ibrahim Al-Qahtani. We thank the King Abdullah Medical City research department, especially Wedian Almwlld, Elham Bugis, and Maher Alhazmi, for their support.

REFERENCES

1. Dumonceau JM, Kapral C, Aabakken L, et al. ERCP-related adverse events: European Society of Gastrointestinal Endoscopy (ESGE) guideline. Endoscopy 2020;52:127-49.
2. Kröner PT, Bilal M, Samuel R, et al. Use of ERCP in the United States over the past decade. Endosc Int Open 2020;8:E761-9.
3. Early DS, Lightdale JR, Vargo JJ 2nd, et al. Guidelines for sedation and anesthesia in GI endoscopy. Gastrointest Endosc 2018;87:327-37.
4. Igea F, Casellas JA, González-Huix F, et al. Sedation for gastrointestinal endoscopy. Endoscopy 2014;46:720-31.
5. Smith ZL, Nickel KB, Olsen MA, et al. Type of sedation and the need for unplanned interventions during ERCP: analysis of the clinical outcomes research initiative national endoscopic database (CORI-NED). Frontline Gastroenterol 2020;11:104-10.
6. Garewal D, Vele L, Waikar P. Anaesthetic considerations for endoscopic retrograde cholangio-pancreatography procedures. Curr Opin Anaesthesiol 2013;26:475-80.
7. Metzner J, Posner KL, Domino KB. The risk and safety of anesthesia at remote locations: the US closed claims analysis. Curr Opin Anaesthesiol 2009;22:502-8.
8. Berzin TM, Sanaka S, Barnett SR, et al. A prospective assessment of sedation-related adverse events and patient and endoscopist satisfaction in ERCP with anesthesiologist-administered sedation. Gastrointest Endosc 2011;73:710-7.
9. Barnett SR, Berzin T, Sanaka S, et al. Deep sedation without intubation for ERCP is appropriate in healthier, non-obese patients. Dig Dis Sci 2013;58:3287-92.
10. Sorser SA, Fan DS, Tommolino EE, et al. Complications of ERCP in patients undergoing general anesthesia versus MAC. Dig Dis Sci 2014;59:696-7.
11. Smith ZL, Mullady DK, Lang GD, et al. A randomized controlled trial evaluating general endotracheal anesthesia versus monitored anesthesia care and the incidence of sedation-related adverse events during ERCP in high-risk patients. Gastrointest Endosc 2019;89:855-62.
12. Aldrete JA. The post-anesthesia recovery score revisited. J Clin Anesth 1995;7:89-91.
13. Adler DG, Lieb JG 2nd, Cohen J, et al. Quality indicators for ERCP. Gastrointest Endosc 2015;81:54-66.
14. Likert R. A technique for the measurement of attitudes. Arch Psychol 1932;140:5-55.
15. Mehta PP, Sanaka MR, Parsi MA, et al. Association of procedure length on outcomes and adverse events of endoscopic retrograde cholangiopancreatography. Gastroenterol Rep 2014;2:140-4.
16. Perbtani YB, Summerlee RJ, Yang D, et al. Impact of endotracheal intubation on interventional endoscopy unit efficiency metrics at a tertiary academic medical center. Am J Gastroenterol 2016;111:800-7.
17. Smith ZL, Das KK, Kushnir VM. Anesthesia-administered sedation for endoscopic retrograde cholangiopancreatography: monitored anesthesia care or general endotracheal anesthesia? Curr Opin Anaesthesiol 2019;32:531-7.
18. Akhter A, Patel R, Nelsen E, et al. Prospective comparison of moderate conscious sedation and anesthesia assistance for the performance of endoscopic retrograde cholangiopancreatography (ERCP). Can J Gastroenterol Hepatol 2021;13:8892085.
19. Patel S, Vargo JJ, Khandwala F, et al. Deep sedation occurs frequently during elective endoscopy with meperidine and midazolam. Am J Gastroenterol 2005;100:2689-95.
20. Mashiana HS, Jayaraj M, Mohan BP, et al. Comparison of outcomes for supine vs. prone position ERCP: a systematic review and meta-analysis. Endosc Int Open 2018;6:E1296-301.
21. Cotton PB, Eisen G, Romagnuolo J, et al. Grading the complexity of endoscopic procedures: results of an ASGE working party. Gastrointest Endosc 2011;73:868-74.
22. Nagrebetsky A, Gabriel RA, Dutton RP, et al. Growth of nonoperating room anesthesia care in the United States: a contemporary trends analysis. Anesth Analg 2017;124:1261-7.

Abbreviations: ASA, American Society of Anesthesiologists; GA, general anesthesia; MAC, monitored anesthesia care; SRAE, sedation-related adverse event.

DISCLOSURE: *All authors disclosed no financial relationships.*

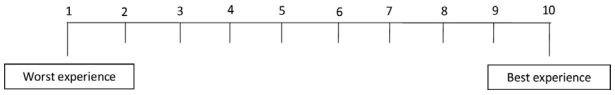
See CME section; p. 1071.

0016-5107
https://doi.org/10.1016/j.gie.2022.06.003

Received December 15, 2021. Accepted June 1, 2022.

Current affiliations: Department of Gastroenterology and Hepatology (1), Department of Anesthesia (2), King Abdullah Medical City, Makkah, Kingdom of Saudi Arabia.

Reprint requests: Mohammed Kareem Shariff, MD, King Abdullah Medical City, PO Box 57657, Makkah Al Mukaramah, Kingdom of Saudi Arabia, 21955.



Supplementary Figure 1. Visual analog scale.

SUPPLEMENTARY TABLE 1. Univariate analysis assessing predictors of sedation-related adverse events

Variable	Sedation-related adverse event (n = 44)	No sedation-related adverse event (n = 159)	*P* value
Gender			.948
Male	21 (47.7)	75 (47.2)	
Female	23 (52.3)	84 (52.8)	
Age			.613
18-35 y	12 (27.3)	48 (30.2)	
36-50 y	11 (25)	30 (18.9)	
51-65 y	14 (31.8)	44 (27.7)	
>65 y	7 (15.9)	37 (23.3)	
American Society of Anesthesiologists class			.753
I	15 (34.1)	64 (40.3)	
II	19 (43.2)	61 (38.4)	
III	10 (22.7)	34 (21.4)	
Body mass index			.930
≤25-34 kg/m^2	36 (81.8)	131 (82.4)	
≥35 kg/m^2	8 (18.2)	28 (17.6)	
Comorbidities			
Diabetes mellitus	5 (11.4)	32 (20.1)	.183
Hypertension	6 (13.6)	33 (20.8)	.289
Cerebrovascular accident	1 (2.3)	2 (1.3)	.621
Ischemic heart disease	1 (2.3)	8 (5)	.431
Chronic kidney disease	1 (2.3)	1 (.6)	.329
Mallampati score			.223
Class 1	4 (9.1)	16 (10.1)	
Class 2	35 (79.5)	136 (85.5)	
Class 3	5 (11.4)	7 (4.4)	
Procedure indication			
Choledocholithiasis	28 (63.6%	96 (60.4)	.695
Biliary stricture	8 (18.2%	30 (18.9)	.799
Pancreatitis	1 (2.3)	12 (7.5)	.206
Bile leak	0 (0)	9 (5.7)	.106
Procedure time, min			.401
Mean ± standard deviation	41.8 ± 47.6	32.9 ± 19.8	
Median (interquartile range)	30 (17.5-50)	27 (20-45)	
Fentanyl use	43 (97.7)	152 (95.6)	.453

Values are n (%) unless otherwise defined.

SUPPLEMENTARY TABLE 2. Univariate analysis assessing predictors of sedation-related cardiorespiratory events

Variable	Cardiorespiratory (n = 29)	No cardiorespiratory (n = 174)	*P* value
Gender			.491
Male	12 (41.4)	84 (48.3)	
Female	17 (58.6)	90 (51.7)	
Age			.892
18-35 y	8 (27.6)	52 (29.9)	
36-50 y	5 (17.2)	36 (20.7)	
51-65 y	10 (34.5)	48 (27.6)	
>65 y	6 (20.7)	38 (21.8)	
American Society of Anesthesiologists class			.803
I	10 (34.5)	69 (39.7)	
II	13 (44.8)	67 (38.5)	
III	6 (20.7)	38 (21.8)	
Body mass index			.653
≤25-34 kg/m^2	23 (79.3)	144 (82.8)	
≥35 kg/m^2	6 (20.7)	30 (17.2)	
Comorbidities			
Diabetes mellitus	2 (6.9)	35 (20.1)	.088
Hypertension	6 (20.7)	33 (19)	.827
Cerebrovascular accident	0 (0)	3 (1.7)	.476
Ischemic heart disease	1 (3.4)	8 (4.6)	.781
Chronic kidney disease	1 (3.4)	1 (.6)	.147
Mallampati score			.280
Class 1	1 (3.4)	19 (10.9)	
Class 2	25 (86.2)	146 (83.9)	
Class 3	3 (10.3)	9 (5.2)	
Procedure indication			
Choledocholithiasis	18 (62.1)	106 (60.9)	.906
Biliary stricture	5 (17.2)	33 (19)	.826
Pancreatitis	1 (3.4)	12 (6.9)	.483
Bile leak	0 (0)	9 (5.2)	.210
Procedure time, min			
Mean ± standard deviation	44.3 ± 56.8	33.2 ± 19.9	.673
Median (interquartile range)	30 (18-50)	28 (19.7-45)	
Fentanyl use	28 (96.6)	167 (96)	.563

Values are n (%) unless otherwise defined.

SUPPLEMENTARY TABLE 3. Independent predictors for overall adverse events

Variable	Odds ratio (95% confidence interval)	*P* value
Age	.995 (.971-1.021)	.722
Gender	1.125 (.514-2.464)	.768
Mallampati score	2.081 (.666-6.501)	.207
American Society of Anesthesiologists class	1.185 (.650-2.160)	.581
Body mass index	1.016 (.995-1.038)	.137
Diabetes mellitus	.524 (.143-1.920)	.329
Hypertension	.606 (.162-2.260)	.456
Procedure time	1.017 (1.002-1.033)	.026
Procedure indications		
Choledocholithiasis	.992 (.440-2.239)	.985
Biliary stricture	.560 (.199-1.574)	.271
Pancreatitis	.168 (.020-1.454)	.105
Bile leak	.000 (.000-.000)	.999
Fentanyl used	5.028 (.485-52.097)	.176

SUPPLEMENTARY TABLE 4. Independent predictors for overall cardiorespiratory

Variable	Odds ratio (95% confidence interval)	*P* value
Age	1.000 (.973-1.027)	.973
Gender	.751 (.308-1.828)	.528
Mallampati score	3.180 (.854-11.841)	.085
American Society of Anesthesiologists class	.941 (.474-1.871)	.863
Body mass index	1.019 (.995-1.044)	.128
Diabetes mellitus	.173 (.028-1.069)	.059
Hypertension	2.369 (.553-10.152)	.245
Procedure time	1.011 (.996-1.026)	.168
Procedure indications		
Choledocholithiasis	1.036 (.413-2.596)	.940
Biliary stricture	.689 (.207-2.296)	.544
Pancreatitis	.320 (.035-2.969)	.316
Bile leak	.000 (.000-.000)	.999
Fentanyl used	2.308 (.238-22.429)	.471