



## Is endotracheal intubation *de rigueur* for ERCP?

In this issue of *Gastrointestinal Endoscopy*, Alzanbagi et al<sup>1</sup> present a single-center randomized controlled trial comparing cardiopulmonary outcomes in American Society of Anesthesiologists (ASA) physical classification  $\leq 3$  patients receiving monitored anesthesia care (MAC) or general anesthesia (GA) for elective ERCP. The primary outcome was a composite of sedation-related adverse events including hypotension, arrhythmia, hypoxia, and hypercapnia. In addition, procedural interruption/termination by anesthesia personnel was included as a sixth component. All procedures were elective and were performed with the patient in a prone position by experienced endoscopic, nursing, and anesthesia personnel. The patients in both treatment arms were well matched in terms of demographics, comorbidities, and ERCP indications. The authors found that patients receiving MAC showed a higher rate of the composite outcome than did those who received GA (35% vs 9%,  $P < .001$ ). Procedural success and adverse events were equivalent. The authors conclude that GA for patients undergoing ERCP is safe, with fewer sedation-related adverse events when compared with those receiving MAC.

A review of the sedation administered merits further scrutiny. MAC is defined by the ASA as a service in which the anesthesia clinician continuously monitors and supports the patient's vital functions, and administers medication along the sedation continuum from anxiolysis, to sedation, to conversion to general anesthesia if required.<sup>2</sup> This means that the patients receiving MAC could have been in GA either transiently or for a prolonged interval. This is a key point because GA often results in the inability to maintain a patent airway, and cardiovascular function may also be impaired.<sup>2</sup> The targeted level of sedation in the MAC arm is not mentioned in the article; could the comparison be GA with and without intubation? This could be the case, given that propofol has no analgesic properties. Another important observation is that patients in the GA arm received sevoflurane after induction with propofol. The patients could also receive analgesics and other sedative agents at the discretion of the anesthesia team. With these observations in mind, for the remainder of this discussion and to compare the data with other studies, we will consider MAC to represent anesthesiologist-directed

sedation without elective intubation and GA to represent anesthesiologist-directed elective intubation.

There are little data comparing anesthesia-assisted ERCP with and without endotracheal intubation. Smith et al<sup>3</sup> used the Clinical Outcomes Research Initiative National Endoscopic Database (CORI-NED) to compare 10,715 patients undergoing ERCP with GA and 8395 with MAC. There are many important differences with this study compared with the study by Alzanbagi et al.<sup>1</sup> Chief among them are the lack of randomization, primarily nonquantitative cardiopulmonary outcomes, the inclusion of ASA class IV patients, and the noninclusion of patients who initially received MAC but required conversion to

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GA. Smith et al<sup>3</sup> found no significant difference in the occurrence of unplanned interventions between MAC and GA (OR, 1.04; 95% CI, 0.76–1.43). Numerically, the MAC patients had a higher rate of premature discontinuation of the procedure (23 vs 11) and sedation reversal (8 vs 2). The GA patients had numerically higher rates of intravenous (fluid/vasopressor) support (9 vs 2), unplanned hospital admission (12 vs 3), and cardiopulmonary resuscitation (CPR) and the need for CPR (6 vs 1). Again, these numbers are too small to analyze, but they emphasize the point that even with an evaluation of >19,000 patients, it is difficult to detect significant differences in serious adverse events between GA and MAC.

Cummings et al<sup>4</sup> used data from the Multicenter Perioperative Outcomes Group, a consortium of >50 centers, to analyze the incidence of sedation-related events during nonemergent ERCP with MAC or GA. The primary outcomes were the incidence of hypoxemia (defined as  $SpO_2 < 90\%$  for  $\geq 3$  minutes between anesthesia start and end times) or hypotension (defined as  $MAP < 65$  mm Hg for  $\geq 5$  minutes between anesthesia start and end times). Clearly, these outcomes would universally be interpreted as significant sedation-related adverse events. The analysis used both a superiority and a noninferiority approach with propensity scoring and sensitivity analysis. In the study, 38,830 patients were intubated and 22,905 received

anesthesia-assisted sedation without intubation. The GA group had significantly more hypotension (OR, 1.27; 95% CI, 1.19–1.35) but less hypoxemia (OR, 0.71; 95% CI, 0.63–0.80) than did those receiving MAC. Neither group was noninferior to the other on both outcomes. As in the current study, Cummings et al<sup>4</sup> found that GA was associated with longer case and anesthesia durations. The difference in numbers of patients treated with MAC was 97 in the current study and 22,905 in the study by Cummings et al.<sup>4</sup> Conversion to intubation occurred in 6.5% of MAC cases as opposed to 2% in the current study. As such, only a univariate analysis on predictors of cardiopulmonary adverse events could be performed by Alzanbagi et al.<sup>1</sup> The study by Cummings et al<sup>4</sup> did not address airway manipulation or procedural interruption and did not delve into the predictive value of minor cardiopulmonary events evolving into more serious outcomes and/or the conversion to MAC.

In summary, Alzanbagi et al<sup>1</sup> have shown that MAC is associated with a higher rate of adverse events than is GA by virtue of a compound primary outcome including cardiopulmonary events and procedural interruption. This is not surprising, inasmuch as active airway management is necessary in cases of MAC because the patients are frequently in deep sedation or GA. The question is whether the cardiopulmonary events used in the outcome are harbingers of more prolonged and serious events such as those used by Cummings et al.<sup>4</sup> We therefore can conclude the following: A standardized classification of cardiopulmonary events is needed in this research genre so that studies can be compared. Large studies are necessary to provide an appropriate analysis of the predictive value of brief cardiopulmonary events morphing into serious unanticipated outcomes. It is highly unlikely that a prospective randomized trial of the size and scope of the Smith et al<sup>3</sup> and Cummings et al<sup>4</sup>

articles will ever be performed. With respect to MAC versus GA, one size does not fit all. There is a tendency for hypoxia with MAC and hypotension with GA. Careful selection is paramount in selecting the course of anesthesia-assisted sedation for ERCP.

## DISCLOSURE

*Dr Vargo is a consultant for Boston Scientific, Docbot, and Olympus America and the recipient of research funds from Olympus America.*

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*Abbreviations: ASA, American Society of Anesthesiologists; GA, general anesthesia; MAC, monitored anesthesia care.*

## REFERENCES

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