

## Endoscopy and sedation: an inseparable binomial for the gastroenterologist

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### ABSTRACT

The development of endoscopy and its increasing demand among the population have led to a growing need for propofol-based sedation techniques. Benefit is indisputable for both patients and endoscopists, but some aspects require considering the “who” and “how” of sedation as related to safety and health care costs.

Propofol is first-choice in endoscopy for the European Society of Gastrointestinal Endoscopy because of its fast onset of action and short half-life, and many reports exist on its safety when used by gastroenterologists rather than anesthesiologists.

In this issue of REED several originals support the efficiency and safety of propofol even for complex, high-risk, or protracted procedures such as endoscopic retrograde cholangiopancreatography (ERCP) and enteroscopy. Propofol may be safely and effectively administered by a team with specific skills acquired through education and using a specific procedure. However, difficulties arise in real-world clinical practice that preclude such training, which in Spain should be included in the MIR (*médico interno residente*) specialization program curriculum. The Comisión Nacional de Digestivo (Spanish National Commission on Digestive Diseases), sensitive to this training gap, has included in their latest version of the MIR program (under assessment) four additional competences, with number 145 (training in deep sedation) being most relevant here. In addition, the Spanish Society of Gastrointestinal Endoscopy (SEED) has invested significant efforts in sedation training, with over 50 courses on sedation for endoscopists and nurses. Continuing education and training in this field (for instance, refresher courses on advanced cardiopulmonary resuscitation) should be a goal for all endoscopy units. Because of the diversity found among hospitals, with single or multiple endoscopy rooms, efforts should be made to persuade those in charge of gastroenterology and anesthesiology departments to establish the necessary care circuits in order to guarantee patient safety by developing accurate protocols and promoting consensus among the scientific societies involved (Spanish Society for Digestive Diseases [SEPD], SEED and Spanish Society of Anaesthesiology, Resuscitation and Pain Management [SEDAR]) and their respective national commissions.

**Key words:** Sedation. Propofol. Drug safety. Endoscopy.

The development of multiple advanced diagnosis techniques, generalization of colorectal cancer screening programs, availability of endoscopic therapy for various conditions, and growing patient demands have all led to an exponential increase in sedation needs at endoscopy units, overwhelming at times the ability of anesthesiology and gastroenterology departments to respond adequately (1).

Overall, the benefit of sedation is indisputable both from the viewpoint of patient tolerability and endoscopist satisfaction with a higher-quality procedure. However, sedation requires carefully considering some aspects, including how it should be administered and who should provide it during endoscopic procedures, which have remained a source of significant debate for the last decade. A key aspect to consider is patient safety, followed by increase in health care costs. Obviously, the incorporation of anesthesiologists to endoscopy units results in higher endoscopy costs, hence wondering whether an anesthetist is required for all sedations performed at an endoscopy unit seems a rational thing to do. And any concerns should be approached from a patient safety perspective.

Historically, benzodiazepines (midazolam) have been most commonly used, either alone or in association with opiates (pethidine, fentanyl). While this regimen remains standard in some Spanish centers, and is still recommended by societies such as the American Society for Gastrointestinal Endoscopy (ASGE), it is now being supplanted by propofol-based sedation (propofol alone or in combination with the above-mentioned drugs), which is considered as first-choice by other societies such as the European Society of Gastrointestinal Endoscopy (ESGE) (2,3). This is because propofol exhibits “almost” all the characteristics that are deemed desirable in this setting: rapid onset of action, short half-life, and metabolism scarcely effected by renal or liver dysfunction. The one, non-negligible drawback of this drug

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is its narrow therapeutic window, with overdosing resulting in hypoventilation and apnea. This adverse effect is shared by benzodiazepines and opiates, but antidotes capable of immediate reversal are available for these compounds (flumazenil and naloxone, respectively). Despite this potential risk of propofol, abundant reports on the safety of its use by trained professionals during endoscopy are available in the literature. We highlight three studies because of their high number of procedures assessed: a meta-analysis published in 2013, a US registration study reported in 2016, and a meta-analysis from 2017, all of which conclude that propofol sedation by the endoscopist is safe, with no increase in cardiorespiratory or other complications when compared to sedation by an anesthesiologist (4-6). In the present issue of REED, additional scientific evidence is provided supporting the fact that gastroenterologist-guided propofol sedation during endoscopy is both efficient and safe (7-12). In this respect, the work by Maestro-Antolín et al. on 33,195 procedures shows that, in their hands, sedation as administered by a trained endoscopist is safe, effective, and efficient (7). The second paper assesses the efficacy and safety of conscious sedation in a small number of patients undergoing colonoscopy, and obtains a similar result (8). In the third paper (9), which reports on 661 patients undergoing complex, high-risk procedures such as ERCP, the authors conclude that sedation is safe when performed by trained gastroenterologists, although, as expected, with more complications as compared to other endoscopic procedures; complications are associated with ASA  $\geq$  III, older age, high body mass index (BMI), and prolonged procedure duration. Similarly, sedation for a protracted, labor-intensive procedure such as enteroscopy is also safe in the hands of a gastroenterologist (10). However, in the present issue of REED not only is gastroenterologist-administered sedation shown to be safe. López-Muñoz et al. audit their results in a praiseworthy quality program, and show that propofol may be safely and effectively administered by a team with specific competences acquired in a training program and using a specific procedure (11). Finally, other authoring team headed by Julián-Gómez designed and carried out a clinical trial comparing different sedation schemes (12).

As has been seen, the scientific literature dealing with the safety of endoscopy sedation both by anesthesiologists and non-anesthesiologists (endoscopists, specialist nurses) is rife, and recommendations are available on the training needs of providers other than anesthesiologists. However, training difficulties are manifold in real-world practice. It is a relevant fact that this competence, so much needed at present, was not included in the gastroenterology curriculum established within the MIR program in Spain, hence we lack formal education on this subject matter. Although the efforts of the Spanish Society of Gastrointestinal Endoscopy (SEED) should be commended, with over 50 courses on propofol-based sedation for endoscopists and nurses, their courses have limitations, including their voluntary attendance and lack of exposure to serious adverse effects given their low incidence. The Comisión Nacional de Digestivo (Spanish National Commission on Digestive Diseases), sensitive to this deficiency in resident physician training, has developed a new gastroenterology curriculum (currently under evaluation) that includes four sedation competences future specialists will have to accredit: knowledge of the various classifications of sedation risk (competence 142); practical use of the drugs indicated for endoscopic sedation,

including propofol, midazolam, fentanyl, and others (competence 143); and knowledge of both basic and advanced cardiopulmonary resuscitation techniques, and the ability to recognize and manage sedation-related complications (competence 144). Finally, the Comisión Nacional (Spanish National Commission on Digestive Diseases), suggests a competence (competence number 145) referring to training in deep sedation, an aspect that will be developed once the new program has seen the light of day. Furthermore, other training modalities such as clinical simulation may be extraordinarily useful for the teaching of endoscopic sedation. Clinical simulation is a widely used tool in educational itineraries for specialties such as anesthesiology or intensive medicine, and to a far lesser extent for clinical specialties such as ours. It allows training in procedures such as advanced airway management, addressing serious and/or uncommon clinical scenarios, and coordination of health care teams in complex predicaments, always within a safe context and in association with subsequent reflective analysis. Experiencing these training activities has yielded highly satisfactory results in a number of services, including ours, among all sorts of professionals (gastroenterologists, anesthesiologists, nurses, nursing assistants). This kind of instruments also has its place in the newer MIR training program. Continuing education or training in this setting (for example, refresher courses on advanced cardiopulmonary resuscitation) should be regarded as a goal in all endoscopy units.

A final point on safety is the need for adequate data collection regarding endoscopic sedation, as well as other endoscopic procedures, in order to allow self-assessments and audits, as only in this way shall we be able to confirm our adherence to quality standards in terms of patient satisfaction and safety, or otherwise to detect deviations to be addressed. Variables necessary to establish a sedation level include age, BMI, ASA grade, and Mallampati classification, as well as patient comorbidity and type of endoscopic procedure. In our view, multidisciplinary care protocols need to be developed that explicitly include these aspects. During a procedure and over the recovery period sedation should be documented according to standard protocols in every hospital.

Patients undergoing sedation should be cared for and monitored by trained health care professionals. As gastroenterologists we are no doubt prepared to sedate or guide sedation for our patients. However, there is also no doubt that getting rid of our anesthesiologist colleagues in endoscopy units would be a serious error. As the ASGE, ESGE, and SEED point out in their respective clinical guidelines, complex patients and procedures may occur (with increasing frequency in both cases) where the presence of an anesthesiologist is advisable (2,3,13). Because of the diversity found among hospitals, where endoscopy rooms may be single or multiple, efforts should be locally invested so that the people in charge of gastroenterology and anesthesiology departments implement the necessary care circuits to guarantee patient safety by developing accurate protocols. However, we are certain that the problem will not be definitely solved until consensus is reached among the scientific societies involved (Spanish Society for Digestive Diseases [SEPD], SEED and Spanish Society of Anaesthesiology, Resuscitation and Pain Management [SEDAR]) and their respective national commissions. A few months ago

our national commission made an offer that remains valid to the Comisión Nacional de Anestesiología y Reanimación (Spanish National Commission on Anaesthesiology and Resuscitation). This effort will likely improve our preparedness and, most importantly, our patients' safety.

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