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Letters to the Editor

Author's reply to the letter: *In response to the editorial "Sedation in endoscopy in 2016: is it safe sedation with propofol led by the endoscopist in complex situations?"*

Key words: Sedation. Endoscopy. Anesthesia. Adverse effects.

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Dear Editor,

We appreciate the comments made by De la Matta et al. on our recent editorial, and would like to clarify what they refer to as the *inaccuracies* it contains. We disagree with their statement that high-level-evidence conclusions cannot be obtained from Clinical Outcomes Research Initiatives (CORI) registries (1). On the contrary, CORI databases have considerable strengths. First, more than 60 clinical studies based on CORI databases have been published in high-impact factor medical journals, including *JAMA, Gastroenterology, Gastrointestinal Endoscopy, Endoscopy, Digestive Diseases and Sciences, Clinical Gastroenterology and Hepatology, Inflammatory Bowel Diseases* and others (1). Secondly, CORI registries prospectively record observational clinical data that are then analyzed retrospectively (2). Third, the total number of patients included in the National Endoscopy Database (NED) of the CORI is very large: 1,388,235 (2). Fourth, we dispute the concept that endoscopist-administered propofol sedation was only used in a *small number* of NED procedures, as 2.9% of the total number of patients with endoscopist-administered sedation (n = 1,090,221) represents 31,616 endoscopies. This large number of procedures allows us to draw highly relevant clinical conclusions through multivariate analysis (2). Fifth, the potential weakness inherent to the retrospective design of their study, as noted by the authors (2-4), is largely mitigated by the statistical methods used, multivariate logistic regression modeling with propensity score analysis. These methods allow bias reduction to make both patient groups (those with endoscopist-directed or anesthesiologist-directed sedation) comparable for the variables analyzed (4), thus affording some of the benefits of a randomized controlled trial (3). Sixth, the analysis of mortality by De la Matta et al. is biased. In fact, there is 1 death per 138,324 patients overall. During colonoscopy, this is 1/697,488 in endoscopist-directed sedation and 0/182,694 in anesthesiologist-directed sedation. During gastroscopy, mortality figures are 1/98,138 in the endoscopist-directed sedation group and 1/115,320 in the anesthesiologist-directed sedation group, a non-significant difference, as noted by Vargo et al. (2), which failed to be mentioned by De la Matta et al. in their letter.

De la Matta et al. also fail to reference some recently published studies (5-8) discussed in our editorial (9). All these recent studies similarly find an increased or at least equal risk of adverse events in anesthesiologist-directed sedation compared to endoscopist-directed sedation. We would like to mention as well another recent study, a meta-analysis published in July 2016 (10). This meta-analysis further confirms the data summarized in our editorial: propofol sedation can be safely performed in average risk patients during endoscopic procedures, with no differences whether it is administered by anesthesiologists or endoscopists. Of note, this meta-analysis also fails to detect any differences between these two groups in patients undergoing complex endoscopic procedures, such as endoscopic retrograde cholangio-pancreatography (ERCP), endoscopic ultrasound (EUS) or enteroscopy. These findings are in keeping with the data from the original study by Pérez-Cuadrado Robles et al., on which our editorial was based. Finally, another recent meta-analysis performed by anesthesiologists (11) found again that non-anesthesiologist administered propofol sedation during advanced endoscopic procedures (ERCP, EUS, etc.) is perfectly safe. The comments from these authors during their discussion of their findings mirror the ideas in our editorial. De la Matta el al. also

fail to provide any objective evidence such as meta-analyses, randomized controlled trials or prospective registries with large patient numbers in support of their opposing view to the data from the literature presented by us. Their opposing view is merely backed by guidelines or recommendations based on expert opinion, which of course they are entitled to have.

We would also like to point out to De la Matta et al. that the main reason for the increased use of propofol sedation in endoscopy in recent years is that propofol is better suited to the sedation requirements of endoscopic procedures rather than the classic combination of opioids and benzodiazepines. Legal regulations vary in different countries and dictate different practice patterns. But the use of propofol has increased at the same rate in countries where regulations allow its use by non-anesthesiologists. Propofol sedation practices, therefore, are not primarily dictated by the type of specialist who administers the drug, but by different national regulations. In countries where propofol sedation administered by qualified and trained non-anesthesiologist physicians is allowed, including Spain, Switzerland or Germany, an increased use of propofol deep sedation has also been noted. In this regard, the survey led by the Gastroenterology and Endoscopy Societies in Spain (SEED, SEPD and AEG), recently published in the journal *Endoscopy*, found a significant increase in endoscopist-administered sedations in recent years and that propofol is the most commonly used drug (12).

The final point introduced by De la Matta et al. in their letter about cost savings via endoscopist nurses revolves around national legal regulations. Under the Spanish law, endoscopy is considered to be a medical act which cannot be legally performed by nurses, either alone or supervised. However, nurses are allowed to administer propofol and to monitor sedated patients under the responsibility of a trained and qualified medical professional. A discussion about endoscopic cost reduction based on procedures being performed by paramedic or nursing personnel is purely theoretical in Spain, as it is in those countries with regulations where endoscopy, anesthesia and sedation are medical acts performed by physicians.

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