ORIGINAL PAPERS

Who should be responsible for sedation techniques in digestive endoscopy? Our point of view

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Revista Española de Enfermedades Digestivas publishes in its January 2005 issue an original paper authored by five gastroenterologists on behalf of *Sociedad Gallega de Patología Digestiva* (1). This paper reports the results of an enquiry to endoscopists carried out by this Society on sedation practices in Endoscopy Units across Galicia. In 85% of these Units, endoscopists administered sedation with varying frequency depending on the type of procedure.

An accompanying editorial asks who should be responsible for sedation techniques in digestive endoscopy. The authors' reply to this question is, literally, "*consensus exists (sic) on the fact that specialists in anesthesiology and resuscitation should perform these techniques (sedation)*" (2). The authors further claim that the practice of sedation without "*a specialist degree (in Anesthesiology and Resuscitation) may not only result in a violation of (the) 'lex artis ad hoc' – and hence in civil liability – but also in criminal liability*". And they conclude, "*Obviously in this scenario (the practice of sedation without a specialist's degree in Anesthesiology and Resuscitation), healthcare professionals (...) commit a criminal deed of*

professional intrusion, as typified in Art. 403 under the criminal law in force". These statements seriously question standard practice for many endoscopists not only in Galicia but also in the rest of the country by claiming that this standard practice is indeed punishable by criminal law.

The undersigned include 311 qualified specialist physicians from every one of the 52 provinces in the country who perform endoscopy procedures in 110 different hospitals, either private or public, including teaching hospitals from 16 different Regional Health Services within Spain. We consider these statements mistaken, based on no scientific grounds, and of potentially serious consequences. We wish to express our firm disagreement with these statements, both in form and substance.

WE DISAGREE IN FORM

1. We believe that the publication of a paper lacking so much in scientific rigor –as we shall later prove– as an Editorial in *Revista Española de Enfermedades Digestivas* bestows on it undeserved merit. We are well aware that this writing only represents its two authors' opinions, and that it is solely them who should be held responsible for what it expresses. However, the reputation and wide circulation of *Revista Española de Enfermedades Digestivas* –Official Journal of *Sociedad Española de Patología Digestiva* and *Sociedad Española de Endoscopia Digestiva*, of which many of the undersigned are members– gives a scientifically groundless personal opinion unwarranted influence.

2. Without questioning the editorialists' merits in other fields, we feel there is no lack of adequately qualified professionals in our community to editorialize on sedoanalgesia in endoscopy, be it anesthesiologists working closely with endoscopists or gastroenterologists having published original scientific papers. They might have

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provided a more realistic view on the use of sedatives and analgesics. Indeed, besides its lack of scientific rigor and inconsistency with previous literature, this Editorial is conspicuous for being out of tune with routine clinical practice. It is otherwise difficult to understand the authors' claim that certain intravenous drugs such as benzodiazepines or meperidine –most commonly used for sedation in endoscopy– should only be given by anesthesiologists. As anyone doing clinical work knows, these drugs are used by hospital physicians of different specialties on a daily basis. And this, of course, includes the non-endoscopic clinical work of gastroenterologists. Is then an anesthetist needed to administer 50 or 100 mg of i.v. meperidine to a patient with acute pancreatitis? Should we request the on-call anesthetist to take care of every agitated patient in need of some sedation?

3. We think it irresponsible, and seriously so, to pillory a great number of Spanish endoscopists by stating –in their own specialty Journal– that they are incurring in criminal liability in their daily practice just by using sedation and analgesia in endoscopic procedures without an attending anesthesiologist.

Such a gratuitous statement may obviously cause serious harm to any endoscopist facing a case in Court, even more so considering where it has been published. Although we are very well aware that this no official position of *Sociedad Española de Patología Digestiva*, *Sociedad Española de Endoscopia Digestiva*, or the Journal Editorial Board, in order to prevent wrong interpretations by the lay public, who are less familiar with the nuances of medical publishing, we would appreciate a public statement from the Directing Boards of these two Societies and some comment by the Journal Editorial Board.

WE DISAGREE IN SUBSTANCE

1. The editorialists ask who should be responsible for sedation in endoscopy. They flatly conclude that this pertains only to qualified anesthesiologists.

This statement is not in keeping with the available scientific evidence. A quick look at articles or guidelines on the topic amongst the many already published in well-respected national or international journals suffices to prove it. Some of these articles are referenced by the editorialists, in spite of the fact that sedation and analgesia as performed by the endoscopist is presented as the norm in all of them. This is flagrant inconsistency, and further shows the lack of foundation entailed by the editorialists' claim. Checking up the literature is essential to tell the difference between a legitimate controversial opinion and an assertion which not only contradicts standard practice, but also negates the value of previous literature. This assertion is thus untenable. Since this is the crux of the matter, we will examine in some detail the references provided by the authors. Here are some examples:

a. The first reference provided by the editorialists contains recommendations by the Endoscopy Committee of the British Society of Gastroenterology for standards of sedation and patient monitoring during endoscopy (3). Nowhere in these recommendations is stated that endoscopists cannot or should not perform these procedures. Furthermore, within its major recommendations, number 11 reads as follows: *"The endoscopist should ensure the well-being and clinical observation of the patient undergoing endoscopy in conjunction with another individual. This individual should be a qualified nurse trained in endoscopic techniques or another medically qualified practitioner"*. Major recommendation number 3 states: *"Staff of all grades and disciplines should be familiar with resuscitation methods and undergo periodic retraining"*. The role of nurses in patient monitoring is stated in recommendation number 5: *"A qualified nurse, trained in endoscopic techniques and adequately trained in resuscitation techniques, should monitor the patient's condition during procedures"*.

b. The Editorial's fifth reference is a pilot study on patient-maintained sedation for ERCP with a target-controlled infusion of propofol (4). The authors aim to achieve an adequate level of sedation with this new system, thus preventing the risks of oversedation with benzodiazepines and opioids, and avoiding the need for general anesthesia. The system proved safe, with no episodes of oxygen desaturation or hemodynamic compromise. The authors suggest that a prospective comparison trial with standard bolus sedation is warranted, and conclude by stating: *"However, at the present time for safety reasons, the administration of propofol in the endoscopy suite should continue to be supervised by an anesthetist or properly trained nonanesthetist physician"*.

c. The American Society for Gastrointestinal Endoscopy guidelines for conscious sedation and monitoring during gastrointestinal endoscopy (5) are the 7th reference in the Editorial. These guidelines deal with endoscopist-administered sedation. Anesthetists are only mentioned in the last paragraph, under the entry *"Deep Sedation or General Anesthesia"*, which stresses their role in selected procedures for high-risk patients. It reads as follows: *"In this situation, if the practitioner is not trained in the rescue of patients from general anesthesia, then an anesthesiologist should be consulted. The routine assistance of an anesthesiologist for average risk patients undergoing standard upper and lower endoscopic procedures is not warranted and is cost-prohibitive"*.

d. The American Society for Gastrointestinal Endoscopy guidelines for the use of deep sedation and anesthesia for gastrointestinal endoscopy (6) are referenced next in the Editorial. These guidelines apply to "deep sedation" (patient response to painful stimuli), as opposed to "conscious sedation" (response to verbal or tactile stimulation). These guidelines do not state that gastroenterologists cannot or should not administer deep sedation to patients during endoscopy. They only emphasize the

need for adequately trained personnel. Table III in these guidelines lists situations in which an anesthesiologist's assistance may be considered, as follows: "*Prolonged or therapeutic endoscopic procedure requiring deep sedation, anticipated intolerance to standard sedatives, increased risk for complication due to severe comorbidity (ASA class III or greater), increased risk for airway obstruction because of anatomic variant*".

e. An introductory statement in the guidelines for training in patient monitoring and sedation and analgesia (7), reference number 9 in the Editorial, reads as follows: "*The ability to provide sedation and analgesia safely and effectively and to ensure patients clinical stability by appropriate monitoring during gastrointestinal endoscopy are skills that endoscopic trainees must develop*".

f. In the study comparing patient-controlled sedation with propofol and alfentanil *versus* standard sedation with midazolam and meperidine (8), reference number 10 in the Editorial, the authors specifically state in the "Materials and methods" section of the paper: "*An anesthetist was not present in the procedure room*".

g. Reference number 13 in the Editorial is particularly ill-advised to claim "anesthetist-only sedation", since these are the guidelines for sedation and analgesia by non-anesthesiologists developed by the American Society of Anesthesiologists and endorsed by the American Society for Gastrointestinal Endoscopy (9). This is stated explicitly in its introduction: "*These guidelines have been designed to be applicable to procedures performed in a variety of settings (e.g., hospitals, free-standing clinics, physicians' offices) by practitioners who are not specialists in anesthesiology*". This is obviously the kind of cooperation we wish to have with our anesthesiology colleagues, with whom we have excellent personal and professional relationships in our centers. Duly accredited training courses in sedation and analgesia for gastroenterologists, jointly organized with anesthesiologists, stand as a fine example of this interdisciplinary cooperation. Such is the case with the praiseworthy pioneer initiative at *Fundación Hospital Alcorcón* in Madrid.

h. The British Society of Gastroenterology carried out an audit of upper endoscopies in the North West and East Anglia (10), which is referenced as number 14 in the Editorial. Over a 4-month period, 14,149 gastroscopies were audited in both regions. Intravenous sedation was used in 86% of cases in East Anglia, and in 84% of cases in the North West. No anesthetist was present to administer sedation, which is obvious from the paper.

i. Reference number 15 in the Editorial is eloquent in its own title (11): "*Safety of propofol administered by registered nurses with gastroenterologist supervision in 2000 endoscopic cases*". The results of this study are consistent with its title, and their authors conclude: "*Propofol can be given safely by appropriately trained nurses under supervision by endoscopists*".

In summary, there is little doubt that the literature, even that referenced by the editorialists, answers very

clearly the question of who should be responsible for sedation and analgesia regarding patients undergoing endoscopy: *a trained professional who can do it properly*. In Spain—which we all learned from recently published studies (1,12)—as well as in many other Western countries there are many gastroenterologists who can do it properly, and who are therefore not incurring any malpractice or criminal deed of professional intrusion claims, as bluntly put by the editorialists.

To conclude this section, we would also like to remind that no published study in our country has ever shown increased complication rates from endoscopist-administered sedation *versus* anesthetist-administered sedation.

2. We are not experts in law, so we can hardly discuss the editorialists' assertions regarding criminal deeds as typified under criminal law. However, as they are not legal experts either, we feel that they should have known better than making such gratuitous yet serious statements without due knowledge. Besides, the practice of Medicine is not governed by legal codes, and should rather be judged according to scientific evidence available. As we proved above, the medical literature clearly shows that sedation and analgesia administered and monitored by endoscopists is well within the standard of care (what the editorialists refer to as *lex artis ad hoc*).

3. We agree with the editorialists, and there is little controversy on this in the literature, that adequate means and training are required to practice sedation and analgesia, so that any potential complications arising from it can be dealt with efficiently. But that does not necessarily mean that a Diploma in Anesthesiology and Resuscitation is required. Again we would like to emphasize that it is anesthesiologists, and therefore colleagues of this Editorial's first author, who develop guidelines and give courses to non-anesthesiologists, and this is in sharp contrast with the bizarre ideas expressed in the Editorial itself.

Considering the above, and in view of the far-reaching consequences this matter has regarding our specialty, we think it necessary that Gastroenterology Societies in our country develop with some urgency clinical guidelines and establish requirements for those willing and able to safely practice sedation and analgesia in patients undergoing endoscopy. Sedation, of course, will never be compulsory practice for those lacking the required skills or not willing to perform it; but no grounds exist on which to forbid it to those meeting the demands to practice it. Sedation techniques should probably receive greater attention during formal endoscopic training in Spain.

Finally, we would like to take issue with the enquiry to patients (as opposed to endoscopists, such as the one reported in the paper the Editorial was meant to comment) on their preferences over who should sedate them for endoscopy. Although the editorialists obviously assume that patients should prefer anesthesiologists, that question can only be scientifically answered by a comparison study.

And their conclusions would probably only apply to the anesthetist and gastroenterologist involved in the study, since not everyone holding one same Diploma is equally skilled. For the time being, daily practice and common sense tell us that what patients demand is painless, comfortable and safe procedures. Again, endoscopist-administered sedation fulfils these demands. Many of the undersigned have first-hand experience with physician patients undergoing endoscopy –including those holding Diplomas in Anesthesiology– who are sedated to their full satisfaction by the very same gastroenterologist performing the procedure.

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