

The European Society of Anesthesiology initially endorsed the use of propofol by non-anesthesia specialists for endoscopy based on evidence review,⁴ and then withdrew the endorsement based on non-evidenced based objections from its members. The American Association of Anesthesiologists also has a history of non-evidence based positions with regard to propofol.⁵ Inevitably, the comments made by Ferreira and Riphaut will be rejected by a substantial fraction of Portuguese anesthesiologists, who in doing so will again reject available evidence.

One way to develop an evidence-based policy regarding propofol would be to remove both anesthesiologists and endoscopists from the discussion and let independent medical experts evaluate the evidence. Such an approach could eliminate bias and facilitate an evidence-based decision regarding whether, when, and under what circumstances the administration of propofol by non-anesthesia specialists is appropriate.

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Reply to the Letters to the Editor Concerning the Article: Alexandre Oliveira Ferreira, Andrea Riphaut. Propofol to Increase Colorectal Cancer Screening in Portugal. Acta Med Port 2014;27:541-42.

Resposta às Cartas ao Editor Relativas ao Artigo: Alexandre Oliveira Ferreira, Andrea Riphaut. Propofol como Forma de Aumentar o Rastreio Endoscópico do Cancro do Cólon e Reto em Portugal. Acta Med Port 2014;27:541-42.

Keywords: Colorectal Neoplasms; Hypnotics and Sedatives; Propofol; Endoscopy, Gastrointestinal; Colonoscopy.

Palavras-chave: Neoplasia Colo-Rectal; Hipnóticos e Sedativos; Propofol; Endoscopia Gastrointestinal; Colonoscopia.

Reply to the letter by Figueiredo Lima JJ:

The sedation frequency for endoscopic examinations was very low in the mid 90's in Germany and Switzerland compared to the USA and Great Britain. While up to 88% of patients were sedated in the USA and Great Britain much fewer patients, about 9%, had premedication in Germany and Switzerland. However, a current survey 'Nationwide Evaluation of Sedation in Gastrointestinal Endoscopy in Germany' shows that there is a pronounced increase in sedation frequency for endoscopic intervention of up to 88%.¹ This is most likely due, on the one hand, to the increase in interventional measures and, on the other hand, to the patients' preferences e.g. for colon carcinoma prevention.

Every patient has the right to an endoscopic examination that is as painless and as free of stress as possible. Therefore, ethically it is not justifiable to withhold sedation from patients.

In a study by Rex DK et al 65% of the patients refused to be randomized in a trial comparing colonoscopy with and without sedation. Male gender, higher education, and low anxiety are positive predictive factors for the patient's preference for unsedated colonoscopies.

Indeed, there is very robust data from nine randomized controlled trials (RCTs) that were pooled in four meta-analysis, including a Cochrane systematic review. This is the best available evidence and it clearly supports the use of propofol sedation for colonoscopy, since it not only increases patients comfort but also procedure quality as measured by cecal intubation rates. Furthermore, in the meta-analysis by Qadeer et al,² the risk of hypoxemia or hypotension during colonoscopy was actually lower with propofol than with traditional sedation 0.4 (95% CI, 0.2-0.79). None of the meta-analysis showed an increased risk for adverse events in the propofol sedation arms.

Above this, it seems that the author is unfamiliar with the developments of the last decade. Since the year 2000 an overwhelming amount of data was published, showing that sedation and especially propofol sedation performed by non-anaesthesiologists, is a safe and very cost-effective procedure. On top of the available data focusing on colonoscopy, there is even more data for upper endoscopy and ERCP/EUS.

There is also very compelling 'real life' data which include the study by Rex on the worldwide experience of propofol sedation by non-anaesthesiologists of 646080 cases.³ The incidence of endotracheal intubations, permanent neurologic injuries, and death were 11, 0, and 4, respectively. Deaths occurred in 2 patients with pancreatic cancer, a severely handicapped patient with mental retardation and a patient with severe cardiomyopathy. Mask ventilation was required in less than 1:1000 cases.

The cost effectiveness of propofol sedation by an anaesthesiologist instead of a trained team has been estimated by Cesare Hassan to be in the range of \$1.5 million/life year gained (if they had adjusted for quality the value would be even greater). This figure is considerably

over any acceptable cost-effectiveness threshold for public health policy (20-30000 sterling pounds in the UK according to NICE or 3 times the gross domestic product per capita according the World Health Organization – around 48000 euros in Portugal).

Regarding the comment by Figueiredo Lima JJ 'Face a tal insensatez e imprudência se pronunciaram 21 Sociedades Nacionais de Anestesiologia da Europa' and as we have already stated in our reply to the retraction of the ESA Board committee in *Endoscopy* 2012; 44: 302–302:

'The subject of non-anaesthesiologist administration of propofol is not new: The European Board of Anaesthesiology (EBA) already made recommendations about the use of propofol in 2007 in its Guideline for sedation and/or analgesia by non-anaesthesiology doctors. The ESGE-ESGENA and initially ESA Guideline is completely in line with the EBA Guideline. Therefore, ESA-ESGENA members expressed their astonishment, that the endorsement of the guideline was withdrawn for political reasons and not on the basis on already existing new evidence that contradicted the guideline. We understand that there are two strands of opinion in the ESA, one supporting and the other opposing the Guideline. However, it is common sense of international guideline regulations, that endorsement of a guideline should only be retracted if new evidence appears that is contradicting existing guidelines.'

However, since 2010 the guideline board of the ESA has still failed to underline their statement of guideline retraction, with evidence based arguments as the authors of the letter to the editor did.

At least five national and three international guidelines were elaborated already focusing on patient safety as a pre-condition, when performed by non-anaesthesiologists. This underlines that there is total agreement between gastroenterologists and anaesthesiologists who focus on patients' safety as the main goal. The best example is the German guideline,⁴ showing that cooperation might be an ideal option regarding guideline development and coordinating nationwide training courses. One reason that this concept might be successful is the fact that in Germany there is no reimbursement for anaesthesiologist performed propofol sedation in the ambulatory setting, while in other countries an attractive reimbursement is given. So far, more than 7000 nurses were trained so far in courses by anaesthesiologists and gastroenterologists. Both having patient's safety as main goal in their mind. Especially in the hospital setting, the capacity of anaesthesiologists is not sufficient to cover every patient for GI endoscopy with propofol as a drug that is showing more advantages than disadvantages, strictly focusing on evidence instead of politics. Therefore, alternative options (NAAP, NAPS) are increasingly recommended and performed in different countries.

Interdisciplinary cooperation according to the recommendations and contents of the European curriculum for sedation training in gastrointestinal endoscopy: position statement of the European Society of

Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA) might be the goal for further discussion, proving that monetary aspects might not be the real argument for anaesthesiologists' societies to avoid NAAP as discussed in the article by Dumonceau JM – 'NAAP: it's all about money'.⁵

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Regarding the aspects mentioned by Lobo FA and Melo AR: 'We cannot accept that the same person performing endoscopy is simultaneously administering propofol, monitoring the patient vital functions and, if necessary, managing the patient's airway; we cannot also accept the idea that a sedation educational program is the miraculous solution for nurses (endoscopy nurses? anaesthesia nurses without medical supervision?) education.'

We totally agree with this argument, therefore in current European guidelines by the ESGE-ESGENA and former ESA,¹ the guideline group clearly pointed out in concordance with other guidelines [German, American, Canadian etc]. This aspect is an absolute precondition for NAAP: 'for every endoscopy under sedation it is necessary to have one person present in addition to the endoscopist and the assisting nurse, who is not involved in the intervention and who can fulfill this task reliably. This qualified person should be able to show proof of special training and experience in monitoring patients receiving sedatives, hypnotics, and/or analgesics. In all cases when a patient has an increased risk, or when a long, complex intervention is expected, a second physician qualified in resuscitation and intensive care should be present whose only task is the sedation and monitoring of the patient.'²

The authors may argue with the open mind allegory, but they have to be cautious to avoid the brain to fall out: facing the equally shortage of digestive endoscopy in our country, are the authors agreeing with a proper training program for non-gastroenterologists professionals to perform endoscopic procedures for screening purposes?' [Lobo FA]

There are already existing concepts that other professionals for screening colonoscopy like surgeons and also trained nurses.³ However, it has been shown with big data from a large screening registry in Germany⁴ and a recently published study in The England Journal

of Medicine⁵ that having a colonoscopy performed by a gastroenterologist is associated with higher adenoma detection rates (ADR) and higher ADR is associated with a significantly decreased risk for colorectal cancer, advanced stage colorectal cancer and death from colorectal cancer.⁵ Still, what we believe that the most important aspect is working towards auditable ADR in order to provide effective screening. Not determining who is able to do it *a priori*.

Still, for the German sedation guideline,² professionals performing sedation for gastrointestinal endoscopy were invited and participated in the S3 guideline preparation on the highest level of evidence and consensus based recommendations.

The Editor of the guideline is the Endoscopy Section, commissioned by the German Society for Digestive and Metabolic Diseases ('Deutsche Gesellschaft für Verdauungs- und Stoffwechselerkrankungen e.V.', DGVS). This professional society is also in charge. Co-editors are the professional societies and organizations that participated in the preparation of this guideline:

- German Federal Association of Gastroenterologists in Private Practice ('Bundesverband Niedergelassener Gastroenterologen Deutschlands e.V.', Bng)
- Surgical Task Force for Endoscopy and Sonography of the German Society for General and Visceral Surgery ('Chirurgischen Arbeitsgemeinschaft für Endoskopie und Sonographie der Deutschen Gesellschaft für Allgemein- und Viszeralchirurgie', DGAV)
- German Crohn's Disease / Ulcerative Colitis Association ('Deutsche Morbus Crohn / Colitis ulcerosa Vereinigung e.V.', DCCV)
- German Society for Endoscopy Assistance Personnel ('Deutsche Gesellschaft für Endoskopie-Assistenzpersonal', DEGEA)
- German Society for Anesthesia and Intensive Care Medicine ('Deutsche Gesellschaft für Anästhesie und

Intensivmedizin', DGAI)

- Society for Legislation and Politics in Health Care ('Gesellschaft für Recht und Politik im Gesundheitswesen', GPRG)

'We call to the Editorial Board's attention to the serious statements done by the authors and we strongly claim the retraction of this text.' [Lobo FA]

We are more than astonished that it seems to be a common way of some anesthesiologists to call for retraction of evidence based facts, whenever they wish to and while closing their eyes to international data that has been gathered for many years. This data clearly understates NAAP or NAPS as a safe procedure under defined preconditions.

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