Deep sedation for endoscopy not administered by anesthesiologists: The position of an endoscopist in 2011

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Translation from Spanish to English by T.A. Zuur and The Language Workshop

Received: 02-05-11
Accepted: 06-06-11

Abstract

Deep sedation with propofol for gastrointestinal endoscopy, administered by endoscopists or trained nurses (NAAP - Non-anesthesiologist administration of propofol for GI endoscopy) is positioned to be the best strategy for endoscopic sedation in most patients undergoing this procedure.

The overwhelming medical evidence for its use, with more than six hundred thousand cases reported and millions made in the world, together with the extensive legal and ethical debates for over a decade of its increasing use, finished with the initial fears about the adequacy of endoscopist and trained nurses to perform it, and that this practice had illegal or unethical medical elements that could compromise the labor of the endoscopist in case of any complications.

With the increasingly widespread use and published evidence in its favor, there are few endoscopists and anesthesiologists with bias and conflict of interest, and they exist due to the lack of knowledge of evidence. Fortunately, the most important anesthesiologists associations in the world today are actively supporting the dissemination of its use and training to endoscopists and nurses who practice it.

The discussion now is whether under the new circumstances, it is ethical and good medical procedure that endoscopic procedures are performed without adequate sedation, behavior that even now could be considered inhumane and cruel.

Key words

Sedation, endoscopy, propofol.

INTRODUCTION

Among the objectives of the use of sedation for endoscopic procedures are decreasing anxiety, pain, nausea and cardiovascular stress, and increasing the patient's tolerance of the procedure. These measures allow the doctor to perform better, and they facilitate the conduct of future examinations upon a fearful patient. More recently, there has been an effort to replace many surgical procedures which use anesthesia and have higher morbidity rates and costs with less morbid endoscopic procedures performed under moderate or deep sedation. This search has also facilitated the development of new and increasingly complex endoscopic procedures which do not use anesthesia.

The use of sedation with propofol for endoscopic procedures has increased greatly over the last decade. Its pharmacokinetic profile is more favorable than that of the combination of benzodiazepines and opiates, especially when there is a need for deep sedation (1).

Propofol (2, 6-diisopropilphenol) is a sedative and anesthetic phenol derivative that acts by facilitating the action of gamma-Aminobutyric acid (GABA) in the brain. Because of its high lipid solubility it rapidly crosses the blood brain barrier making its action almost instantaneous

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(30 seconds). Its half life is only 1.8 to 4.1 minutes, and patients' recovery periods are short because it is rapidly metabolized, and because it has no cumulative sedative or anesthetic effects even after prolonged infusion. In addition, it lacks active metabolites and has a rapid hepatic dilution rate even in patients with liver failure. Hence no adjustment in patients with renal failure is required. Under propofol sedation, patients sleep pleasantly so that undergoing endoscopic procedures is more satisfactory for them. The result is that patients are grateful to the clinical staff, endoscopic procedures are shorter, and the results of almost all endoscopic procedures are better than with traditional sedation or general anesthesia.

Among the risks associated with propofol use are depressed respiration, sometimes to the point of apnea, decreased peripheral vascular resistance and decreased heart rates. Nevertheless, because of its short half-life, in practice these risks have not translated into serious complications. Propofol has been used for over 10 years. Accumulated evidence about its use includes more than six hundred thousand cases reported in the largest review of literature. So far there have been no clearly demonstrated cases of mortalities resulting from its use for sedation in gastrointestinal endoscopy. It is contraindicated in the first trimester of pregnancy, for use on infants and for use with patients in the ASA IV and ASA V classifications of the American Society of Anesthesiologists.

DEEP SEDATION BY NON-ANESTHESIOLOGISTS: THE EVIDENCE

The most recent and most serious consensus on the administration of propofol by non-anesthesiologists for sedation during diagnostic and therapeutic endoscopic procedures (2) reviewed all the evidence accumulated over more than a decade of propofol use for sedation in endoscopy by non anesthesiologists (Non-anesthesiologist administered propofol (NAAP)) for GI endoscopy. The editorial group included the European Society of Anesthesiology (ESA), the European Society of Gastrointestinal Endoscopy (ESGE) and the European Society of Gastrointestinal Nurses and Associates (ESGENA). The study is a critical review and meta-analysis of controlled clinical trials which measured levels of evidence and drew up recommendations based on the evidence. This review considered all publications related to ethical discussions in the world and their conclusions regarding medical legal responsibility that have been discussed for over a decade all over the world and for which there are already clear conclusions. This consensus has the strength of having been made by people who work in socialized health systems whose sole interest is the best and most cost-effective patient care and health systems. This is in contrast to the consensus in the United States where controversy has been fueled by financial conflicts of interest between different professional medical associations rather than by scientific or ethical considerations, similar to what has happened in Latin America.

As seen in this serious review of all accumulated evidence, the discussion no longer centers on whether someone other than the anesthesiologist can administer propofol for sedation in endoscopic procedures, but rather centers on three other main issues. The first is whether or not patients rated by the American Society of Anesthesiologists as ASA risk III may now be sedated with propofol by non-anesthesiologists as has been previously clearly accepted for categories ASA I and ASA II patients. Second, the conversation is now about how endoscopists and nurses who perform this activity should be trained. The third question now being debated is whether or not the endoscopy room requires a third person dedicated exclusively to administering, and as seems to be the trend of the latest evidence and publications, can this be done for short diagnostic procedures (endoscopy and colonoscopy) by only two people (the endoscopist and an assistant who aids in both endoscopic procedures and in sedation with propofol).

In the following section I will transcribe the most relevant conclusions from the appropriate, judicious and impartial European Consensus of 2010 which includes and also expands upon and clarifies the findings of the review of evidence conducted and published in the consensus by the American Society for Gastrointestinal Endoscopy (ASGE) and in 2009 (3). In addition, I will include with the level of evidence and the recommendations made for each conclusion, and I will add some feedback regarding this practice in our environment based on our experience of almost ten years of routinely administrating propofol for deep sedation for diagnostic and therapeutic endoscopic procedures in the Department of Gastroenterology and Digestive Endoscopy of the Hospital Central de la Policia which is done by nurses and endoscopists. Part of this has already been published (4).

1. *"Compared with traditional sedation, propofol-based sedation presents similar rates of adverse effects, provides higher post-procedure patient satisfaction for most endoscopic procedures, decreases time to sedation, and decreases recovery time (and may therefore decrease discharge time compared with traditional sedation). Propofol-based sedation may also increase the quality of endoscopic examination. There are no cost-effectiveness data directly comparing specifically NAAP with traditional sedation or monitored anaesthesia care for gastrointestinal endoscopy. (Evidence level 1+.)"*

This has been demonstrated primarily for Esophagogastroduodenoscopy (EGD) and endoscopic retrograde cholangiopancreatography (ERCP). Three meta-analyses showed no differences in rates of hypoxemia or hypotension between traditional deep sedation and deep sedation using propofol. They even showed that colonoscopy has less cardiopulmonary complications with propofol than with traditional sedation (5, 6). NAAP is more cost effective and more efficient than standard sedation. The use of sedation administered by anesthesiologists for healthy low-risk patients undergoing gastrointestinal endoscopy is extremely expensive, even in rich countries. Moreover, it has never shown higher levels of patient safety or effectiveness of the procedures. A recently published review of the safety record of NAAP (7), which included a total of 646,080 NAAP cases (223,656 published and 422,424 unpublished) found only 489 patients who required mask ventilation for short periods of time (0.1% of the 569,220 cases with this data available), 11 patients who required endotracheal intubation, and 2 patients who had transient neurological disorders without long-term sequelae. Four deaths occurred, but they were probably not related to sedation as they occurred during follow-up upper gastrointestinal endoscopies in patients with significant comorbidities who had been considered high-risk cases for sedation. These mortalities are difficult to compare with the mortalities of similar patients related to propofol sedation for endoscopy because none of the 4 deaths reported could be directly linked to sedation. In this large series, there were no mortalities among patients sedated with propofol for colonoscopy nor among in patients with American Society of Anesthesiologists (ASA) class I or II classifications. The most optimistic series in the published literature on mortality due to anesthesia among low risk patients places the rate at 1 in 400,000 patients. This was not a systematic review, but a publication of an anesthesiologist's perspective on sedation by non-anesthesiologists (8). If we assume that, theoretically, all complications and deaths could be avoided by administration of propofol by anesthesiologists, the economic cost for this series of cases would have been $US 5.3 million, a prohibitive sum for health care systems in developed countries where resources are used rationally, and far more prohibitive for our bankrupt health care system. In any case this assumption is false for two reasons. In the first place anesthesiologists are in extremely high demand all over the world. In the second place, after more than a decade of constantly growing and increasingly better organized use, with many millions of cases worldwide, there has not been a single case of a lawsuit against an endoscopist or nurse related to sedation with propofol for gastrointestinal endoscopy anywhere in the world. The Cochrane Collaboration, whose meta-analyses are highly valued in the medical world, assessed sedation with propofol for colonoscopy (9) in a metaanalysis and found that, compared with traditional sedation with benzodiazepines and opioids, propofol sedation provided more satisfaction for patients, faster recovery times, and had no side effects. Its most important conclusion was that there were no differences in safety or risks between the administration of propofol by anesthesiologists and propofol administered by non-anesthesiologists (endoscopists and nurses).

2. *"NAAP performed by endoscopists and endoscopy nurses should not take place without appropriate training, and self-training in NAAP is strongly discouraged. (Evidence level 2++, Recommendation grade A.")*

Recently, NAAP-specific courses and courses on other forms of sedation in endoscopy have begun to be included in residency programs in endoscopy. This will guarantee that, prior to graduation as endoscopists, specialists will have the specific training required by law (10).

3. *"Digestive endoscopists and registered nurses are adequate candidates for NAAP training courses. Previous experience in intensive care medicine is desirable for the physician who is responsible for NAAP. We recommend that training courses for NAAP include a theoretical and a practical part, each part being followed by an examination to document successful training. NAAP training courses should teach techniques of basic life support (BLS) to all participants and advanced cardiac life support (ACLS) to caregivers who will practice in locations where an ACLS provider is not immediately available. (Evidence level 4, Recommendation grade D.)"*

The European Society of Anesthesiology (ESA) recommends that endoscopists performing NAAP should be trained in advanced cardiac life support including training in endotracheal intubation. The majority of internists and surgeons are already being trained in this procedure during residency. The ESA recommends that nursing staff performing NAAP be trained only for in basic life support given the rarity of the need for intubation. In both cases the ESA recommends supplementing this training with knowledge of the peculiarities of propofol. In Colombia this type of training in sedation is regularly organized through courses give by, among others, the department of gastroenterology at the Hospital de la Policía. Recently the Colombian Society of Endoscopy began offering these courses with the support of the Colombian Society of Anesthesiology. These courses, following global recommendations, include a theoretical component and a practical component. The theoretical component covers pharmacology, pharma-

cokinetics, interaction of sedatives, analgesics and their antidotes; principles of sedation and patient monitoring including ECG monitoring analysis, different types of sedation and peri-patient care proceedings relating to sedation, monitoring, recovery, hospitalization criteria, management of complications, documentation, and legal aspects such as delegation and informed consent. The practical component covers basic management of the air ducts; use of different tubes for ventilation such as the Guedel airway tube and the laryngeal mask; treatment of acute respiratory problems; and BLS and ACLS, including the use of defibrillators, for nurses and endoscopists.

4. *"Higher categories of the American Society of Anaesthesiology (ASA) physical status classification system and some endoscopic procedures are associated with a higher incidence of complications after endoscopy. Higher Mallampati's classes are associated with more difficult airway management. We recommend that these risk factors are assessed before each NAAP procedure by reviewing patient past medical history, performing a focused physical examination, and assessing type and anticipated complexity of the endoscopic procedure. (Evidence level 2+, Recommendation grade C.)"*

It should always be noted that the biggest risks for complications are extremely poor physical condition (ASA IV or V), morbid obesity and disorders of the neck according to the Mallampati classification. Among neck disorders we should highlight an oral opening of less than 3 cm. Two additional groups of patients, young children and pregnant women, are considered at high risk because they cannot be sedated within the usual parameters. Recently it has been found that men, who have more normal cervical fat than do women, have higher incidences of obstruction of the air ducts than do women. This is similar to what occurs with sleep apnea, but does not imply that male patients cannot be candidates for NAAP (11).

5. *"In the presence of patient-related risk factors for complications, the primary involvement of an anaesthesiologist during endoscopy is suggested. These factors include ASA category ≥3, a Mallampati's class of 3 or other conditions at risk for airway obstruction (e.g. pharyngolaryngeal tumors), patients who chronically receive significant amounts of pain medications or in cases of anticipated long-lasting procedure. (Evidence level 4, Recommendation grade D.)"*

Publications of anesthesiologists have reported that ASA category III significantly increases the risk of complications above those of ASA I and II patients (12). Although many anesthesiologists have criticized NAAP for ASA III patients, there are reviews of NAAP that report no increases in complications (13).

6. *"In the vast majority of NAAP studies, propofol was administered by a person who had patient sedation as his/her sole task (Evidence level 1++). It is recommended that patients be continuously monitored by a person dedicated to NAAP (Recommendation grade A)."*

Recently there has been a tendency to change this recommendation. There are currently more than 28,000 publications about diagnostic endoscopic procedures with NAAP, in which only the endoscopists and nurses are involved. In addition to supporting NAAP, they also support low complexity endoscopic procedures by showing that they have very low risks of complications (14-16). Possibly in the future, this will become the primary recommendation for endoscopic sedation of low risk and short duration (diagnostic endoscopies and colonoscopies).

7. *"There is no evidence that quick availability of a life support team is required for propofol administration. We do not recommend compulsory availability of a life support team if propofol is administered in the presence of a person trained in ACLS. (Evidence level 2+ Recommendation grade C.)"*

It is understood that the person skilled in Advanced Cardiac Life Support (or Advanced Cardiovascular Life Support - ACLS) may be the same endoscopist who performs the procedure.

Anesthesiologists have expressed the opinion that the development of computerized ACLS systems of sedation control will facilitate the development of NAAP in the future in particular by facilitating monitoring of sedation levels. In recent years the initial enthusiasm for the control of sedation using the bispectral index to analyze electroencephalography has diminished. Now computer systems that evaluate muscle tone and other indicators to define the level of sedation and adjust propofol dosage have been developed. Nevertheless, additional studies are needed to provide clear universal recommendations (17-19).

8. *"Hypoxemia and hypotension are the most frequent adverse effects of propofol and develop during NAAP in 5%–10% of patients. Measures to be taken in case of complications should be established in a check-list that is updated and tested at regular intervals. If a patient proves difficult to sedate adequately for the examination purpose, endoscopy termination and referral to an anaesthesiologist should be considered (Evidence level 4, Recommendation grade D)."*

When hypoxemia develops during an endoscopic procedure, the infusion of sedatives should be discontinued, the oxygen supply should be increased, the air passages should be kept open using the jaw thrust technique, and if necessary the patient should be ventilated using a mask. If the patient does not respond adequately to these measures, the endoscopic procedure should be discontinued and the emergency protocol should be initiated following ACLS guidelines. In the case of hypotension these include IV administration of fluids with electrolytes alone, or if needed with catecholamines, and when needed for bradycardia with atropine.

9. *"The endoscopist bears the ultimate medicolegal responsibility to ensure proper personal training of the endoscopy staff involved in NAAP. (Evidence level 4.)"*

The information provided should include the pros and cons of sedation, alternatives to sedation including the option of no sedation, potential complications after the procedure, risks related to management, using computers and equipment in which psychomotor functions are essential, alcohol and drugs, decision-making, legal implications following the procedure and the risk of amnesia. It must remembered that there are also clear risks if the patient is not sedated. It has been shown that cardiac patients who are not sedated often develop tachycardia, arrhythmias and other electrocardiographic abnormalities. In addition, unsedated patients may cause disruption of diagnostic testing or treatment which can increase costs and risks by causing repetition of procedures. Also, extended or therapeutic procedures are much more difficult for a doctor to perform in the absence of sedation, especially if the patient has nausea, pain, anxiety, agitation or intense peristalsis. Without sedation the risks are greater and morbidity and mortality rates are higher for biliary procedures, They are nearly impossible to perform conveniently, rapidly and safely in the absence of good sedation.

MEDICAL ETHICS AND LEGAL ISSUES

A special topic which must be reviewed is the set of conclusions of the discussions around the world regarding the ethical and medical-legal aspects of the administration of propofol by non-anesthesiologists for deep sedation in diagnostic and therapeutic gastrointestinal endoscopy (NAAP) (20-25).

To date this discussion has only been theoretical because there has been no discussion in courts which could serve as legal reference points. After more than a decade of uninterrupted use, no endoscopist or nurse has been tried or convicted in any case related to NAAP in Colombia or elsewhere in the world. When faced with an injury or adverse effect, the law seeks to determine whether the duty of health care personnel to care for patients has been violated, and if this was the cause of the damage. Medicine and patient care are doctors' duties, but their results are not. The duty of doctors and health workers (in this case nurses) is to do their best within the accepted best standards of medical practice, experience and knowledge accumulated throughout the world experience. This currently includes NAAP which not only has the support of strong global evidence of being a good medical practice, but is also currently the most commonly recommended method. Medical personnel have the duty to do their best for the patient, regardless of the outcome. These results may occasionally be adverse for exceptional reasons arising from the patient or because of an imperfection, and therefore unintentional human error by doctors and/or nurses. Medical personnel must always demonstrate to the law, and for us Colombian law, that they acted without negligence, incompetence or carelessness, i.e. that they accomplished protocols that met the criteria for inclusion and exclusion and that they have the knowledge and proper training required, and that they did not work against common sense.

As stated above, the entire endoscopy team should always seek to meet the inclusion criteria (ASA I-III), there should be support available for handling emergencies and maintaining the level of sedation sought (deep sedation in the case of propofol). The team should always follow the protocols and guidelines, and each institution must continuously update these and retrain their staff as they are updated. Protocols and guidelines should always be in accordance with the internationally most accepted medical evidence. Fortunately for patients this includes NAAP. Medical institutions should conduct periodic retraining of personnel involved in NAAP.

To meet legal requirements, it is important that institutions are able to demonstrate all of the above which means mandatory documentation of the entire process. This should include assessment of proper implementation of protocols. In most countries including Colombia, written documentation of the procedure is required. This must include an explanation of the specific risks to the patient related to sedation and clear acceptance of these by patients or their guardians. The Act requires the patient to accept and authorize the execution of the procedure with the understanding of its possible results which, depending on the type and complexity of the procedure, might include the risk of death. Hopefully, this risk will minimized to the utmost by the good work of the medical team. Nevertheless, there is absolute certainty that such risks exist even with the best medical team working under the best possible conditions.

We also should remember that sedation with drugs other than propofol was traditionally accepted, although it is now known to be slightly riskier than sedation with propofol by non-anesthesiologists. The law and the medical profession has accepts sedation by dentists for certain procedures for decades. Even now this is practiced worldwide without the controversy generated by the use of NAAP for endoscopy, even though endoscopy treats more patients, and therefore generates more economic interests. During electroshock therapy psychiatrists use Pentothal as an anesthetic and suxamethonium chloride (INN) as a muscle relaxant safely, effectively and without complications. Most endoscopists using propofol for NAAP would panic if they had to manage these medications and administer them for sedation, yet for more than 40 years they have been managed without any problems by psychiatrists who are specialists in one of the less interventionist fields among the medical specialties.

CONCLUSIONS

Some anesthesiologists, mainly Americans, initially opposed the administration of propofol by non-anesthesiologists for sedation in gastrointestinal endoscopic procedures. They based their opposition on three main arguments.

- First, propofol is a potent drug with no antidote. Patients under its effect can rapidly move from moderate to deep sedation and from there to the level of anesthesia thus exposing them to high risks of sustained hypoxemia and as a consequence of hypoxia-related sequelae complications such as brain damage and even death. The most compelling evidence is provided by a decade of use and more than six hundred thousand reported cases which show that this danger is not true. Administration is safer than it was ever thought it would be, and every new insight has been easy to adjust to. In fact, deep sedation with NAAP has never been shown to produce neurological damage or death. As a result, the European Society of Anesthesiologists (free of prejudice resulting from the conflict of economic interests among professional associations) now accepts, endorses and strongly recommends the use of NAAP. It supports the process of training and supporting non-anesthesiology personnel because the accumulated medical evidence is so clear and strong it has annihilated any earlier criticism about NAAP. It is clear that NAAP the use now and in the future will grow since it is the most cost effective, ethical and appropriate method for sedation within the field of gastrointestinal endoscopy. Criticism of NAAP by anesthesiologists who equated sedation using propofol with general anesthesia and its risks, and held that all deep sedation should be considered as potential anesthesia, and therefore should only be done by anesthesiologists, has also been forcefully quashed. Recently, the death of the singer Michael Jackson led to an attempt to revive the debate, but it is now clear that the accident in this case had nothing to do with NAAP as an endoscopic sedation technique. The singer received a propofol infusion together with many other parenteral and oral sedatives, plus additional boluses of propofol. Moreover, monitoring was neglected for periods of more than 15 minutes. The risk in Jackson´s case is clearly not comparable to NAAP (26).
- Second, although in 1988 the FDA said of the original medical package that it was a drug "for exclusive use by anesthesiologists," it has been almost a quarter century since then, and it is now clear that everything has changed in both the field of anesthesia and the field of endoscopy. Now there is evidence that this contraindication is no longer applicable to NAAP.
- The third argument was based on issues of the laws covering medical practice. It was an attempt to create a climate of fear about possible complications in the event that the endoscopist was unaware of the law and medical evidence. Intimidated and fearful, the endoscopist would desist from attempting this practice and call the anesthesiologist for sedation of patients. In practice, this was impossible in rich and developed countries because anesthesiologists are not only very expensive, but their participation in gastroenterology procedures was not the most cost-effective for more civilized health systems. For Colombia, a poor country with a bankrupt health system, with the government's current debt to Fosyga above three billion pesos, this is an even greater imperative. Our system must find the most cost-effective alternative. On the other hand, we cannot deprive our patients of the possibility of humane treatment which avoids pain and distress: this is our duty as doctors. It is all the better, if we can do this cheaply and affordably, and in a manner accepted by world opinion. Moreover, now endoscopic sedation using propofol administered by adequately trained endoscopists and nursing staff as well as by anesthesiologists is accepted not only by the medical profession, but by the law. Its success has been demonstrated not only in Colombia, but in every part of the world. The proof of this success is found in the absence of the expected multimillion dollar lawsuits and complications which have never materialized here or anywhere else. Now, no law will ever ban something which has been done so successfully for over ten years.

Medical evidence from around the world has positively reinforced NAAP. Evidence of this is the fact that one of the most important and objective societies of anesthesiolo-

gists in the world, the European Society of Anesthesiology, broadly supports this activity. After evaluating the legal arguments and ethical issues that arose during more than a decade, the legal and ethical concerns that existed have been overturned. This society has also been assisting gastrointestinal endoscopy and nursing associations in the organization of training and monitoring of this activity. Apparently, this is also happening in Colombia with the onset of support by the Colombian Society of Anesthesiologists, the Colombian Society of Endoscopy and the Colombian Society of Gastroenterology in the labor of educating endoscopy personnel, and not anesthesiology staff, in sedation.

In recent publications by anesthesiologists, the critics limit themselves criticisms of style and to saying that, if in any series, noninvasive capnography is not routinely used, you cannot demonstrate that hypoventilation did not occur. In theory, although never in practice, patients could be at risk. In clinics and endoscopic procedure rooms where patients are cared for in Bogota, anesthesiologists who perform sedation for endoscopy with propofol do not use noninvasive capnography to monitor sedation. The European review of the evidence, which underlies this article, did not find any clear evidence of a need for its use. All health staff members who sedate patients for endoscopy with propofol, including endoscopists, nurses and anesthesiologists, must do so within the highest standards for quality of care as in any other medical procedure.

I recently heard a lecture in Bogotá by an anesthesiologist who accepted, albeit with some reservations, that nurses and endoscopists may administer propofol sedation. The lecturer simultaneously criticized NAAP studies for the reasons already mentioned including the lack of capnography. However, I noticed that the bulk of his criticism generated an atmosphere and climate of fear of legal consequences. They were supported by three studies about which I will point out some fundamental issues that the anesthesiologist did not highlight in his speech.

The first is the collection of studies already mentioned in this article which shows that only four deaths have occurred over the course of more than 600,000 acts of NAAP, and that none of these deaths were due to the administration of propofol. They were instead due to the intrinsic severity patients' conditions. None of these cases ended in lawsuits. The doctor criticized the methodology of that study and therefore the information about the safety of administration of propofol by non-anesthesiologists. This series, which combined approximately 250,000 retrospective cases with over 400,000 prospective cases, documented convincing results: only four deaths, only 11 cases of need for intubation and a total absence of cases of permanent neurologic sequelae events. This can leave no doubt. I consider it to be a very important series which collects most of the information published about real serious NAAP risks.

The second study, undertaken by anesthesiologists (27), sought to determine risk factors for cardiopulmonary events in the administration of propofol for endoscopy and colonoscopy. It compared sedation administered by non-anesthesiologists with sedation administered by anesthesiologists and reported that the cardiopulmonary incidence events was 11.7 per thousand procedures. For ASA I and II patients the incidence was lower for procedures performed by anesthesiologists than for those performed by non-anesthesiologists. However, this series included cardiovascular risks which can skew the results. One example is that saturation levels below 95% at any time during the procedure were considered adverse events. This cannot be taken too literally, since at Bogotá's altitude many patients begin the procedure with a saturation level that would be reported as an adverse effect in this study even before administration of the drug. What this doctor did not say is that this study found that there were no differences in cardiopulmonary risks or adverse events for severely ill patients (ASA III, IV and V) between administration and management by anesthesiologists or that by nurses or endoscopists. It should also be mentioned that this series did not include a single death or adverse neurologic event. Consequently, I think the doctor overestimated the risks in his lecture.

The third study (28) is a report of the lawsuits against anesthesiologists because of deaths and neurological damage resulting from administration of anesthesia or sedation within and outside of operating rooms (including endoscopy rooms). The study included cases in which anesthesiologists generally used mixtures of drugs, including propofol. The doctor understood this as if only propofol was being used in patients undergoing endoscopic procedures. This study showed that mortality is higher outside of surgical operating rooms than within them. One of its conclusions was that mortality was associated with inappropriate failures by anesthesiologists to appropriately monitor patients including some undergoing endoscopic procedures such as, colonoscopies or ERCPs. This study looked at management of sedation and anesthesia performed by anesthesiologists. As of this writing, the available databases have reported no cases of reported deaths related to NAAP and not one reported case of a lawsuit against an endoscopist or nurse related to complications arising from the use of propofol. Nevertheless, as shown by the study in question, mortalities have been demonstrated in cases in which anesthesiologists have administered propofol mixed with other drugs during endoscopic procedures.

This obliges us to raise the hypothesis that non-anesthesiologist administered propofol may be safer than propofol sedation administered by anesthesiologists.

Anesthesiologists mostly work in operating rooms and administer general anesthesia. Since it is not common for them to work outside of operating rooms, endoscopy sedation is exceptional for them and they in fact may have very little experience in this procedure.

As has been shown, the literature that the anesthesiologist used to support criticism of NAAP did not really support, although the anesthesiologist may be biased for reasons outside the purely scientific world.

Finally, I will discuss some of the recommendations he issued for sedation in endoscopy that reflect the group of anesthesiologists in our country that do not quite agree with propofol sedation by non-anesthesiologists. Based upon my experience and an extensive literature review, I do not agree with some of his recommendations. Below are his recommendations, with my comments.

1. Sedation should be performed by someone other than the person in charge of the endoscopic procedure. This recommendation, although it is accepted in the literature, is undergoing reassessment for short diagnostic endoscopic procedures. These include the majority of endoscopic procedures which are diagnostic endoscopies and colonoscopies. Here I must point out that while management of sedation is performed by the endoscopist, direct control and administration is performed by the nursing staff.
2. That training for the practice of NAAP must take place both in hospitals and in nonhospital settings.
3. The training should be supported by scientific societies, but run by the Society of Anesthesiology. I disagree with this point because nurses need a BLS course, but endoscopists need ACLS course (if they have not already been trained for it during their rotation in intensive care and resuscitation). Traditionally, in our country and around the world, training in BLS and ACLS have been given mostly to cardiologists and internists, and to a lesser extent to pulmonologists, internists, intensive care physicians and emergency care physicians. Although it is desirable for the Society of Anesthesiology as well as the Society of Cardiology and Pulmonology to support this training, I think it is sufficient that gastroenterological internists and surgeons who have training in intensive care, and almost all do, can conduct this training within the societies related to endoscopy. In my service we conduct a training course in BLS for nurses who work with sedation using propofol. The course is supported by emergency physicians, internists, cardiologists and gastroenterologists and has had with very good results. Believing that anesthesiologists are the only experts in resuscitation would disqualify internists, surgeons, cardiologists, pulmonologists, emergency physicians, intensive care physicians and other specialists who are both interested and well trained in resuscitation.
4. Mild to moderate sedation should be used. Although this is what is sought with traditional sedation with benzodiazepines and opiates, it has already been demonstrated above that this is riskier than sedation with propofol. Hence, I disagree with this recommendation, too. With propofol deep sedation is achieved and the patient falls asleep and has no verbal response (which defines deep sedation). I think we should end the confusion of the concept of moderate sedation with propofol, which does not really exist in practice. This article and all of the literature speak of propofol for NAAP, meaning deep sedation.
5. NAAP should be administered only for ASA I and II patients as recommended. Nevertheless, as shown above, there are also many reports of safe administration in ASA III and higher patients.
6. Use of single drug treatment. I agree. The literature shows that there are fewer complications with single drug treatment, especially when propofol is used.
7. Electrocardiographic monitoring, or better yet capnography, should be used when propofol is administered. I disagree. What defines the need for echocardiography is the greater complexity of the patient (ASA III or higher) and long duration of a procedure with great complexity. No evidence in the literature has shown that low-risk ASA I and II patients undergoing sedation with propofol for short procedures with no other risk factors present need routine use of continuous electrocardiography. The same is true for non-invasive capnography which, as the European consensus reviewed above made clear, is not required on a regular basis except for patients at high risk of hypoventilation. These patients are by definition at high risk and unusual candidates for NAAP. Nevertheless, anesthesiologists continue to insist on this.
8. That a defibrillator should be available nearby. This is true, but it does not necessarily have to be in the endoscopy unit.
9. That an anesthesiologist must be available less than 5 minutes away. Although this is desirable, the consensus statement only required having someone trained in ACLS, and it is understood that this can be the same endoscopist.

My final thought is, "Why, in spite of such favorable evidence, don't all endoscopists use sedation today?" Clearly in the past endoscopists had doubts about patients sedated with propofol. Although endoscopists tried to do their best work for their patients and profession, they might have thought their use of sedation would be criticized and

punished by the medical profession and the law. Ten years of evidence should have crushed these concepts. How can anyone justify not using sedation for all procedures, even for the simplest of them such as diagnostic esophagogastroduodenoscopy which causes serious discomfort and unpleasantness for the vast majority of patients? Any casual observer who witnesses an endoscopic procedure without sedation will consider it to be an inhuman, nasty and cruel act, perhaps rightly so.

Currently my view is that not sedating all patients for endoscopic procedures is medical malpractice which eventually should be punished by the medical profession and the law. When the patient is not sedated we cannot guarantee the best performance and unnecessary suffering is caused. Indeed, when we now have all the means, evidence, and the legal and moral support, we have the duty to do this.

We should quickly end the lack of knowledge of law and medical evidence in regards to this issue. That ignorance keeps alive prejudices and conflicts of interests of some anesthesiologists and nurse endoscopists and allows suffering and mistreatment of many patients in Colombia and other parts of the world to continue as they undergo endoscopic procedures cruelly without adequate sedation.

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