

ADVANCES IN ENDOSCOPY

Current Developments in Diagnostic and Therapeutic Endoscopy

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Update on Endoscopist-Administered Propofol Sedation for Endoscopic Procedures

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G&H How safe and effective is endoscopist-administered propofol sedation for endoscopic procedures?

JV Studies have shown that with proper training and patient selection, endoscopist-directed propofol sedation is safe, well tolerated, and associated with excellent patient satisfaction. A study conducted by Rex and colleagues that was published in *Gastroenterology* reviewed the worldwide experience of endoscopist-directed propofol sedation in over 646,080 patients. The authors found that endoscopist-directed propofol sedation was safe. The overall number of cases requiring mask ventilation was 489 (0.1%) of the 569,220 cases with available data. Four deaths were reported, all of which occurred in patients with advanced adverse conditions, such as metastatic malignancy or alcoholic cardiomyopathy. In addition, a systematic analysis by McQuaid and Laine examined moderate sedation for gastrointestinal endoscopy and found that propofol-administered sedation was superior to the combination of a benzodiazepine and an opioid in terms of patient satisfaction.

G&H Have any guidelines been established to regulate the use of propofol for endoscopic procedures?

JV When propofol was initially released in 1989, it was accompanied by a black box warning that limited its use

to practitioners trained in general anesthesia. Initial studies addressed the use of propofol only as an anesthetic agent. Only years later did clinicians find that propofol could also be used safely and effectively for endoscopic procedures requiring moderate sedation. It is interesting to note that a similar type of warning was placed on midazolam, which endoscopists commonly use for sedation during endoscopy.

As a result of the safety and efficacy data on non-anesthesiologist-directed propofol, the American College of Gastroenterology petitioned the US Food and Drug Administration (FDA) in 2005 to re-evaluate propofol's black box warning. Unfortunately, last year, the US FDA re-affirmed this warning. In their response to the American College of Gastroenterology, the US FDA did not cite any of the extensive safety and efficacy data, such as the more-than-646,000 patients in the world literature in whom endoscopist-directed propofol was found to be safe and effective.

G&H Have there been any other recent updates regarding propofol use?

JV Last year, the Centers for Medicare and Medicaid Services (CMS) issued a re-interpretation of anesthesia guidelines. Unfortunately, the CMS stated that propofol-directed sedation for colonoscopy was equivalent to deep sedation; subsequent clarification of this re-interpretation re-affirmed the black box warning for propofol, which limited its use to practitioners qualified to administer general anesthesia in institutions governed by CMS guidelines. This re-interpretation of CMS guidelines did not involve a re-assessment of the literature to date—particularly the literature discussed above—or involve public input.

Interestingly, the CMS listed colonoscopy as an example of deep sedation and did not mention any other endoscopic procedures by name. A study conducted by VanNatta and Rex clearly showed that propofol-mediated sedation can target moderate rather than deep sedation.

G&H It has been suggested that recent reports of propofol misuse influenced the CMS ruling in favor of anesthesiologists and certified registered nurse anesthetists. Do you agree?

JV This is an interesting question. I can only comment on this issue anecdotally. We have had concerned patients ask whether the sedative used for their procedure is the same agent that was allegedly involved in Michael Jackson's death. I think this issue needs to be clarified from a patient's standpoint. When sedation is used by qualified individuals under highly controlled circumstances with proper patient selection, it is safe and effective; unfortunately, the medication in this well-publicized incident was allegedly not administered in a monitored situation. Individuals who administer any type of medication for procedural sedation should be trained in the use of the medication as well as in appropriate physiologic monitoring and should be able to rescue the patient if there are any unexpected deeper levels of sedation. Patients should be informed of the convincing data showing that endoscopists can administer this medication with a high level of safety and efficacy to appropriate levels of sedation, and patients should also be informed that propofol-administered sedation is not akin to general anesthesia; quite the opposite, propofol can be successfully titrated to moderate sedation, as many studies have shown.

G&H What are the implications of position statements released by regulatory bodies for the use of propofol in standard endoscopic procedures (ie, esophagogastroduodenoscopy and colonoscopy) in the community?

JV Position statements can go only so far. When regulatory bodies and professional societies turn a deaf ear to the literature, it is indeed distressing. Endoscopist-directed propofol is quite common and safe in countries around the world. Patient care should not revolve around a particular medication; it should encompass the science and training that lead to the best care for all.

G&H Is it likely that the restrictions on propofol use will extend to other sedative agents?

JV Thus far, the approval of other sedative agents or propofol-associated delivery devices has not been a very

fruitful venture for gastrointestinal endoscopic procedures performed by endoscopists. The sedative agent fospropofol disodium has gone through the US FDA approval process; after reviewing data, it was decided that the agent should be used only by anesthesiologists. A computer-assisted propofol delivery device called SEDASYS was also reviewed by the US FDA. Although the subcommittee approved this device, it was ultimately not approved by the US FDA. However, last November, the US FDA decided to revisit the application for SEDASYS, and we expect this process to begin sometime this year.

G&H How does propofol sedation administered by certified registered nurse anesthetists, anesthesiologists, and endoscopists compare in terms of cost?

JV Certified registered nurse anesthetists (CRNAs) have now gained approval in 17 states to bypass the supervisory role of anesthesiologists for certain surgical procedures and to function as independent practitioners. This change is likely due to the shortage of anesthesiologists. The use of CRNAs in endoscopic procedures can certainly be helpful.

Anesthesiologist-directed sedation can be a significant source of income and has been associated with several different business models. In a business model where the anesthesiologist is a consultant, the income obviously goes to the anesthesiologist. However, there is a growing business model in which anesthesiologists are employees of gastroenterology practices, which means that their revenue stream goes to the gastroenterologist instead.

It should be emphasized that no data so far have shown a safety or efficacy advantage for anesthesiologist-administered propofol sedation in healthy patients undergoing upper endoscopy and colonoscopy. In fact, the study by Rex and associates showed that anesthesiologist-administered propofol sedation was cost-prohibitive. Cost-effective medical interventions commonly have a threshold of \$50,000 to perhaps \$100,000. Anesthesiologist-administered propofol sedation for healthy patients undergoing colonoscopy and upper endoscopy is indeed cost-ineffective, as endoscopist-administered propofol has been shown to save \$5.3 million per patient-year saved. Somehow, this cost differential will have to be covered, but regulatory bodies have yet to address this issue.

G&H What are the next steps for endoscopist-administered propofol sedation?

JV I still believe that the science of procedural sedation has convincingly shown that properly trained endoscopists and nurses can administer propofol safely and effectively

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to targeted levels of moderate sedation. As proper training and patient selection are very important, I believe that the professional societies representing gastroenterologists, gastroenterology nurses, and hopefully anesthesiologists will formulate an appropriate training program. The upcoming review of SEDASYS by the US FDA may be a watershed event, but we will have to wait for the outcome of the review. Although high regulatory hurdles must still be cleared, I remain fairly optimistic that endoscopists will ultimately be allowed to administer propofol themselves.

Suggested Reading

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