

Study compares balanced propofol sedation with conventional sedation for therapeutic GI endoscopic procedures

15 February 2011

Researchers from Korea report that, compared with conventional sedation, balanced propofol sedation (BPS) using propofol in combination with midazolam and meperidine, provided higher health care provider satisfaction, better patient cooperation, and similar adverse event profiles in patients undergoing therapeutic endoscopic procedures. This is the first prospective study of BPS in direct comparison with conventional sedation. The researchers note that this study provides further evidence to support the adoption of endoscopist-directed BPS for therapeutic endoscopy. The study appears in the February issue of *GIE: Gastrointestinal Endoscopy*, the monthly peer-reviewed scientific journal of the American Society for Gastrointestinal Endoscopy (ASGE).

Propofol [sedation](#) for gastrointestinal (GI) endoscopy has become popular worldwide. In recent years, propofol has been used safely and effectively in advanced interventional endoscopic procedures, such as endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic ultrasound (EUS), even for high risk patients. However, propofol monosedation is not risk free with interventional endoscopy, which usually entails a longer procedure time, larger doses of propofol, and potentially more frequent dose-related side effects compared with those of diagnostic endoscopies. Propofol has several disadvantages associated with its pharmacokinetic properties and therefore nonanesthesiologist-administered propofol sedation for GI endoscopy remains a highly controversial issue.

Balanced propofol sedation (BPS) combines small incremental doses of propofol with single induction doses of benzodiazepines and opioids under the direction of a physician that is not an anesthesiologist. Because BPS usually targets

moderate sedation, adequate amnesia and analgesia can be achieved with concomitant administration of benzodiazepines and opioids.

"Several prospective studies have shown that BPS can be used safely and effectively for diagnostic endoscopy under the direction of a gastroenterologist. However, there are few controlled studies of BPS with direct comparison to conventional sedation in therapeutic endoscopy," said study lead author Chang Kyun Lee, MD, PhD, Kyung Hee University School of Medicine, Kyung Hee University Hospital, Seoul, Korea. "The present study was conducted to compare the safety and efficacy of BPS, propofol in combination with midazolam and meperidine, with conventional sedation, midazolam and meperidine, in patients undergoing therapeutic GI endoscopic procedures. We found that BPS provided higher health care provider satisfaction, better patient cooperation and it had similar adverse event profiles to conventional sedation."

Methods

The study's objective was to compare the safety and efficacy of BPS (propofol in combination with midazolam and meperidine) with conventional sedation (midazolam and meperidine) in patients undergoing therapeutic endoscopic procedures. The main outcome measurements were the rates of sedation-related cardiopulmonary complications and interruption of the procedures, procedure-related times, and assessments of health care providers (endoscopists and sedation nurses) and patients.

This was a single-center, prospective, randomized, single-blinded study of 222 consecutive patients referred for therapeutic esophagogastroduodenoscopy (also called EGD or

upper endoscopy) or ERCP between July 2009 and March 2010. All endoscopic procedures were performed by five experienced endoscopists who were faculty at the hospital. Patients were randomly assigned to one of two sedation protocols (conventional group [midazolam and meperidine] vs. BPS group [propofol in combination with midazolam and meperidine]) by use of a computer-generated random sequence. Both randomization and the drugs used for sedation and analgesia were concealed from all patients, endoscopists, endoscopy nurses, and recovery-room nurses. However, the sedation nurses and research nurse were not blinded.

All sedatives and analgesics used for this study were administered by trained registered nurses who had advanced cardiac life support certification and were under endoscopist supervision. The nurses who administered the sedatives and analgesics were dedicated to drug administration and patient monitoring. The target level of sedation was moderate sedation based on the American Society for Anesthesiology (ASA) levels. All patients were continuously monitored for heart rate, blood pressure, and oxygen saturation until full recovery. At the end of the procedure, both the endoscopists and the sedation nurses completed a questionnaire. If full recovery was confirmed for patients in the inpatient setting, they also completed a questionnaire about overall satisfaction with the sedation and the procedure.

Results

The mean duration of induction, endoscopic procedures and recovery was not statistically different between the two groups. There were no significant differences between the BPS and conventional groups in the rates of cardiopulmonary complications (8.8 percent vs. 5.8 percent) and transient interruption of procedures (2.9 percent vs. zero). No patient required assisted ventilation or premature termination of a procedure. BPS provided significantly higher health care provider satisfaction compared with conventional sedation (as reported by both endoscopists and sedation nurses) and patient cooperation was significantly better in the BPS group. The sedation nurses were more satisfied with BPS

than with conventional sedation in terms of difficulty of induction and satisfaction with the procedure. Patient assessment was similar in the two study arms. However, significantly fewer patients sedated with BPS reported memory of the endoscope insertion and withdrawal than in the conventional group.

The researchers concluded that this study provides further evidence to support the adoption of endoscopist-directed BPS for therapeutic endoscopy.

In an accompanying editorial, Lawrence B. Cohen, MD, The Mount Sinai School of Medicine, New York, New York, stated that "this study provides us with additional evidence that endoscopist-directed propofol administration is safe and effective for select patients undergoing advanced endoscopic procedures. Yet, although our understanding of BPS has been expanded, questions regarding its efficacy and efficiency relative to conventional sedation remain. The pharmacologic principle underlying BPS also serves as a reminder of the important role of drug-drug interactions in the daily practice of gastroenterology."

Provided by American Society for Gastrointestinal Endoscopy

APA citation: Study compares balanced propofol sedation with conventional sedation for therapeutic GI endoscopic procedures (2011, February 15) retrieved 14 August 2022 from <https://medicalxpress.com/news/2011-02-propofol-sedation-conventional-therapeutic-gi.html>

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