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## Sedation for Gastrointestinal Endoscopy: Practical Issues in Patient Safety and Quality Management

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See "Considerable Variability of Procedural Sedation and Analgesia Practices for Gastrointestinal Endoscopic Procedures in Europe" by Hermanus H. B. Vaessen and Johannes T. A. Knape, on page 47-55.

Due to the widespread use of screening endoscopy, the number of endoscopic procedures has increased considerably over the last decade. In recent years, advanced interventional endoscopic procedures, including endoscopic retrograde cholangiopancreatography, endoscopic ultrasonography, endoscopic submucosal dissection, and peroral endoscopic myotomy, has widely been adopted. Along with the development of lengthy and potentially uncomfortable endoscopic procedures, the rate of moderate to deep sedation has been increasing over the past few years. Sedation relieves patients' discomfort and anxiety, and consequently improves their toleration of and satisfaction with the procedure. Therefore, an adequate level of satisfactory endoscopic sedation makes endoscopic procedures safe and successful. Despite the benefits of sedation for gastrointestinal (GI) endoscopy, there are many hurdles to be overcome, including safety concerns, increasing medical costs, and quality management. Major scientific societies involved in GI endoscopy have developed curricula and guidelines based on several published studies showing that properly trained non-anesthesiologists and nurses may

effectively and safely manage sedation for endoscopic procedures.<sup>1-5</sup> However, guidelines may differ among countries, depending on their healthcare systems and legal frameworks.<sup>6</sup>

Due to its benefits—such as rapid onset of action, improved patient comfort, and shorter recovery time—in several countries, there has been a tendency toward the use of propofol in sedation in place of the traditional administration of benzodiazepine, with or without opioids.<sup>5</sup> In Korea, a study using National Health Insurance claims data reported that the number of patients who received propofol sedation for endoscopy has continuously increased from 2008 to 2012.<sup>7</sup> Due to the limited availability of anesthesiologists, propofol sedation for endoscopic procedures is widely being performed by endoscopists or trained nurses. This practice is referred to as the non-anesthesiologist administration of propofol (NAAP).<sup>8</sup> In 2010, the European Society of Gastrointestinal Endoscopy (ESGE), the European Society of Gastroenterology and Endoscopy Nurses and Associates, and the European Society of Anaesthesiology (ESA) formulated guidelines for NAAP for GI endoscopy.<sup>1</sup> However, the ESA has officially and publicly dissociated itself from the NAAP guideline after the death of Michael Jackson as a result of propofol administration without appropriate monitoring.<sup>9</sup> In Korea, public concern over the risk of propofol abuse has escalated following recent media reports of several cases of propofol abuse.<sup>7</sup> Propofol was designated as a psychoactive drug on February 1, 2011.<sup>10</sup> Although NAAP for GI endoscopy is used regularly in several countries, including Korea, its use is a matter of debate.

In this issue of *Clinical Endoscopy*, Vaessen and Knape<sup>11</sup>

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present online survey reports on the status of procedural sedation and analgesia practices for GI endoscopy from 16 countries in Europe in 2012. The survey included questions about the type of sedation technique, the sedation practitioner, patient monitoring, training, informed consent and patient satisfaction, adherence to guidelines, and complication registration. The results showed a wide range of practices for moderate to deep sedation among and within European countries. Controlled sedation care (CSC) using propofol with or without opioids was administered predominantly in 8 countries, while traditional uncontrolled sedation care (USC), using benzodiazepines with or without opioids, was predominantly used in seven countries. This range may be due to the differences in medical systems and legislation among countries. With respect to the sedation practitioners, CSC was confined to anesthesiologists in only four countries (Bulgaria, Czech Republic, Luxembourg, and Portugal). In other countries, CSC was provided by various medical personnel, including endoscopists, endoscopic assistants, endoscopic nurses, nurse anesthetists, and other health care personnel. In the survey conducted by the Korean Society of Gastrointestinal Endoscopy (KSGE), 63% of 1,332 survey respondents used propofol-based sedation, and the rate of endoscopist-directed propofol (EDP) sedation was 98.6%.<sup>12</sup> In the present study by Vaessen and Knape,<sup>11</sup> patient monitoring was abundantly applied in most countries, which potentially contributed to patient's safety. Pulse oximetry, heart rate, and non-invasive blood pressure were routinely monitored during CSC procedures in almost all countries, and electrocardiography and capnography were used in approximately half of the countries. Informed consent for sedation in both the USC group and CSC group was obtained in 65% of patients. In the current medical climate, negligent failure to inform the patient is usually regarded as a liability claim against a doctor. The ESGE guidelines suggest that informed consent should be obtained from the patient prior to the procedure.<sup>1,5</sup>

In the present survey, the rate of respondents to indicate adherence to international or domestic guidelines for moderate to deep sedation was low (25%), and the rate of the responsible sedationists taking skills training programs was also unsatisfactory. In the Korean survey, 8.9% of all respondents had not any training for sedation practices, and 45% of respondents indicated that periodic retraining on basic life support was not enforced for all medical personnel involved in sedation practices.<sup>12</sup> Untrained sedation practitioners may not be familiar with, and may not properly respond to unavoidable adverse effects of sedative drugs. A previous study showed that proper training for non-anesthesiologist sedation practitioners could significantly lower sedation-related complications during endoscopic procedures.<sup>13</sup> Academic societies

of endoscopy should develop appropriate training programs for sedation for GI endoscopy, which would include courses on basic life support, advanced cardiovascular life support, basic airway management, treatment of respiratory problems, sedation theoretical and practical courses. These societies would also encourage the completion of specialized training programs. Although the survey by Vaessen and Knape<sup>11</sup> showed considerable differences in the practice of sedation in many European countries and the importance of its quality control, the study has limitation which data from gastroenterologists were not included. Furthermore, online surveys may not reflect the real field of sedation practices in respect to quality and safety. A future survey is necessary to include the perspectives of both the sedation practitioners and patients.

A recent study, using the Korean Society of Anesthesiologists database of anesthesia-related medical disputes from July 2009 to June 2014, analyzed 105 surgical anesthesia cases.<sup>14</sup> In this study, cases related to general anesthesia were the most common (50 cases, 48%), followed by sedation cases (39 cases, 37%). Propofol-based sedation was used in 90% of sedation cases. Most sedation cases (69%) showed deviations from the appropriate standard of care (i.e., determined to be avoidable), including no pre-procedural testing, no pre-anesthetic records or anesthesia records, no intraoperative monitoring, and no oxygen supplementation. In addition, most sedation (92%) was provided simultaneously by non-anesthesiologists performing the surgical/diagnostic procedure. Further studies including the incidence of sedation-related adverse events during GI endoscopy in Korea are necessary. Currently, the Korean Medical Association is developing guidelines for propofol sedation in primary care practices and emphasizes sedation practices under supervision by trained practitioner. In 2015, the KSGE published, "A guidebook on sedation for gastrointestinal endoscopy." Several studies worldwide demonstrated that EDP sedation is a safe procedure.<sup>15</sup> Considering that EDP sedation will be increasingly used in Korea, the KSGE should make every effort in conjunction with other sedation-related societies to develop programs for quality management, anesthesiologist assistance guidelines, and other training programs (training in management of complications, airway workshop, simulation training, etc.).

#### Conflicts of Interest

The authors have no financial conflicts of interest.

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