

Monitoring equipment for endoscopy

The American Society for Gastrointestinal Endoscopy (ASGE) Technology Committee provides reviews of existing, new, or emerging endoscopic technologies that have an impact on the practice of GI endoscopy. Evidence-based methodology is used, with a MEDLINE literature search to identify pertinent clinical studies on the topic and a MAUDE (U.S. Food and Drug Administration Center for Devices and Radiological Health) database search to identify the reported adverse events of a given technology. Both are supplemented by accessing the "related articles" feature of PubMed and by scrutinizing pertinent references cited by the identified studies. Controlled clinical trials are emphasized, but in many cases, data from randomized, controlled trials are lacking. In such cases, large case series, preliminary clinical studies, and expert opinions are used. Technical data are gathered from traditional and Web-based publications, proprietary publications, and informal communications with pertinent vendors. Technology Status Evaluation Reports are drafted by 1 or 2 members of the ASGE Technology Committee, reviewed and edited by the committee as a whole, and approved by the Governing Board of the ASGE. When financial guidance is indicated, the most recent coding data and list prices at the time of publication are provided. For this review, the MEDLINE database was searched through January 2012 for articles related to monitoring equipment for endoscopy. Technology Status Evaluation Reports are scientific reviews provided solely for educational and informational purposes. Technology Status Evaluation Reports are not rules and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment or payment for such treatment.

BACKGROUND

All patients receiving sedation to facilitate endoscopic procedures should have monitoring of cardiorespiratory parameters before, during, and after administration of sedation/analgesia.¹ Electronic monitoring may detect early signs of patient distress and is an adjunct to continuous clinical assessment. Commonly used monitoring

equipment for patients undergoing endoscopic procedures includes pulse oximetry, single-lead continuous electrocardiographic (ECG) monitoring, and automated blood pressure monitoring. With the increased use of propofol to facilitate endoscopy in recent years, less familiar monitoring devices have been introduced, including end-tidal CO₂ and level of consciousness monitors. Given a recent change in the American Society of Anesthesiologists (ASA) guidelines,² recommending CO₂ monitoring for patients undergoing both moderate and deep sedation, familiarity with capnography may become necessary.

This report discusses monitoring equipment for endoscopy and updates a previously published ASGE Technology Status Evaluation Report.³

TECHNOLOGY UNDER REVIEW

Pulse oximeters

These devices use transcutaneous measurement of light wavelengths to calculate arterial oxygen saturation. Pulse oximetry exploits the fact that oxygenated and deoxygenated blood (oxyhemoglobin and reduced hemoglobin) have differing absorption of light spectra. Pulse oximeters consist of a probe (usually for the finger or the ear) with 2 light-emitting diodes, each emitting at a different frequency, and a photodetector. The light-emitting diodes sequentially emit at their respective wavelengths, typically 660 nm (red) and 940 nm (infrared). Oxyhemoglobin absorbs preferentially at a red wavelength and reduced hemoglobin absorbs in the infrared. A microprocessor converts these absorption measurements into oxygen saturation estimates based on correlation data obtained in healthy human volunteers.⁴ Spurious oxygen saturation readings can occur if there are significant amounts of other hemoglobin species (eg, methemoglobin and carboxyhemoglobin) because of partial overlap of their absorption spectra with oxyhemoglobin. Recently developed multi-wavelength oximeters are now commercially available that sample a broader absorption spectrum, allowing differentiation of these hemoglobin species.⁵ The majority of pulse oximeters use transmission spectrophotometry, meaning that the light is transmitted through the patient's tissue to the photodetector. Reflectance pulse oximetry, where the light bounces off the skin back to the photodetector, has the advantage that sensors can be placed on the forehead, an advantage in low circulation states and in burn units.⁶ They are rarely used for procedural monitoring. Photoplethysmography is the technology used by the

pulse oximeter that provides the pulse waveform.⁷ The pulse waveform has subtle variations that are caused by respiratory movements that result in changes of the venous return. Algorithms exist that can extract this information and convert it into a respiratory rate.⁸

Pulse oximetry measures oxygenation rather than ventilation, and decreases in oxygenation saturation lag behind decreases in ventilation. Pulse oximetry cannot detect hypercarbia, an early warning sign of hypoventilation. Earlier literature warned against possible false readings with painted fingernails or false (acrylic) nails. More recent studies with newer equipment indicate that painted or false nails do not generally change the oximeter measurements, at least not to a clinically significant extent, and the previously recommended 90-degree rotation of the probe is not usually required.^{9,10}

A decreasing pitch of the pulse synchronous beat is commonly used to denote decreasing oxygen saturations. An international standard released in 2005 provides guidelines on how to make auditory alarms on medical electrical equipment more recognizable and distinguishable.¹¹ The suggested use of melodies to distinguish different sources has, however, been criticized and not widely adopted.¹²

In routine practice with stable patients, fingertip pulse plethysmography is more convenient than earlobe pulse plethysmography. However, it has been noted that fingertip pulse plethysmography is more sensitive to sympathetic control of peripheral circulation, whereas earlobe pulse plethysmography is relatively immune to the local vasoconstrictive effects of the sympathetic system. In addition, the strength of respiratory variations may increase with central hypovolemia, and the effect on plethysmography waveform variability is 10 times stronger in the ear compared with the finger.¹³ For these reasons, it may be preferable to place the pulse oximeter on an earlobe in a bleeding patient who is not yet fully resuscitated.

Automated sphygmomanometers

These devices intermittently measure and continuously display the patient's blood pressure. The oscillometric method is the most commonly used technique for automatic blood pressure determination. In this method, the cuff initially is inflated above the systolic blood pressure. During deflation, a sensor located in the monitor detects air-pressure fluctuations in the cuff. These pressure fluctuations correspond to arterial volume changes that occur because of pulsatile flow of blood. The pressure at which the oscillations peak is proportional to the mean arterial pressure.¹⁴ From the increasing and decreasing magnitudes of these oscillations, the device uses algorithms to calculate the systolic and diastolic pressures. In addition to displaying the blood pressure, most devices calculate and display the pulse rate.

ECG monitors

ECG monitors provide a continuous single-lead ECG display and can be used in conjunction with pulse oximeters and blood pressure monitors to provide real-time information regarding a patient's cardiac status. Various combinations of ECG monitors, pulse oximeters, and automatic sphygmomanometers are available as compact single units. Available options include rate and arrhythmia alarms, filters to prevent loss of waveform during electrocautery, printout capabilities, and integration with electronic medical records systems.³

Capnography

Capnography refers to monitoring of CO₂ levels. Increased CO₂ levels denote hypoventilation and are an early warning sign for subsequent hypoxemia. Both transcutaneous and end-tidal CO₂ monitoring are available. End-tidal CO₂ is accomplished by the continuous sampling of CO₂ at the level of a specially modified nasal cannula prong or a specialized bite block. It is possible to measure CO₂ tension transcutaneously. However, the 2011 American Society of Anesthesiologists Standards for Basic Anesthetic Monitoring specifically mention "expired carbon dioxide," referring to end-tidal capnography.²

CO₂ absorbs infrared light at a maximum of 4300 nm. Capnography uses infrared spectroscopy to continuously track the absorption peak of CO₂ to calculate its concentration. There are 2 types of capnography. Mainstream (nondiverting) capnography is performed in a closed circuit where expired CO₂ is not exposed to the atmosphere (eg, via an endotracheal tube). It can also be performed in the sidestream (diverting capnography) via a specialized nasal cannula or specialized bite block. This method is most often used for endoscopy, but it may be less reliable than nondiverting capnography because it does not measure the actual end-tidal CO₂ (normal 35-45 mm Hg) but reflects a mixture of exhaled and fresh ambient air.¹⁵ Clinicians need to be aware of the multitude of artifacts that can arise from different components of the system.¹⁶

Level of consciousness monitoring

Level of consciousness monitors, also known as anesthesia effect or brain function monitors, use electroencephalography as the fundamental signal that is processed to estimate level of awareness. They were originally promoted to reduce "anesthesia awareness" in paralyzed patients, but clinical studies have had variable results.¹⁷ Whether level of consciousness monitors are effective in reducing anesthetic requirements and consumption is the topic of ongoing research.¹⁸ There are many different algorithms, such as entropy analysis, patient state index, Narcotrend index, and SNAP index. By far, the best known is the bispectral index (BIS). BIS monitoring of sedation uses a complex mathematical evaluation of relevant, descriptive electroencephalographic (EEG) parameters of the

frontal cortex corresponding to various levels of sedation. By using a specialized analysis of EEG signals, BIS translates sedation depth into a numeric scale. BIS monitoring has also been evaluated for procedural sedation, especially in the emergency department.^{19,20}

Ease of use

Monitors such as pulse oximeters, ECG monitors, and automated sphygmomanometers are in widespread use and are part of basic sedation practice. The use of less familiar equipment (eg, capnography, level of consciousness monitors) requires additional training. Although monitors have become more capable, their sophistication is often not fully exploited. The sheer proliferation of the number of audible alarms contributes to the cognitive load for health care providers. Two new issues of clinical interest are integration with electronic medical record systems and alarm fatigue.

Integration with electronic medical records systems

Despite the increasingly widespread use of electronic medical record systems, nurses and anesthesia providers still frequently manually enter the readings of the various monitors into the electronic medical records. Anesthesia information management systems automatically integrate documentation of the physiologic parameters into the anesthesia report. A 2008 survey found that nearly half of academic anesthesiology departments had or were in the process of installing an anesthesia information management system.²¹ Many electronic medical records vendors now offer automated incorporation of patient monitoring data into the electronic medical records.²²

Alarm fatigue

Alarm fatigue refers to failure to acknowledge some monitor alarms. The increased number of alarms, many of which may not be clinically relevant, contributes to this phenomenon. The magnitude and pervasiveness of alarm fatigue have been widely recognized and have resulted in a joint conference sponsored by the U.S. Food and Drug Administration, American College of Engineering, the Association for the Advancement of Medical Instrumentation, the ECRI Institute (formerly the Emergency Care Research Institute) and the Joint Commission called "The Medical Device Alarms Summit (2011)." One intensive care unit study found that 40% of all alarms did not correctly describe the patient condition and could be classified as technically false; only 15% of all alarms were considered clinically relevant.²³ Some possible solutions to the alarm fatigue problem have been published and may include adjustment of monitor alarm defaults, careful assessment and customization of monitor alarm parameter limits and levels, and implementation of an interdisciplinary monitor policy.²⁴

On the technology side, manufacturers are developing algorithms that can reduce clinically insignificant alarms.²⁵

Outcomes and comparative data

Many of the monitoring devices currently used for sedation were introduced in the 1960s and 1970s and became standard of care despite a lack of rigorous controlled studies. Randomized trials comparing endoscopy with sedation performed with or without electronic monitoring equipment are unlikely to be completed.

Pulse oximetry

There are few studies evaluating the use of pulse oximetry during endoscopy. A large Cochrane review found no evidence that the use of pulse oximetry in the perioperative setting affects patient outcomes.²⁵

Automatic sphygmomanometers

Although the reproducibility of measurements with oscillometric devices within a subject is good, blood pressure measurements may differ in the same patient with different device models, essentially because diastolic and systolic blood pressures are calculated by using proprietary algorithms. Although manual blood pressure determination is only made when the Korotkoff sounds are clearly distinguishable, an automatic sphygmomanometer will also attempt to obtain a blood pressure when the patient is moving or shivering, which may lead to inaccurate results. Other research has shown that oscillometric systolic blood pressures tend to be lower in the elderly or critically ill overweight patients.²⁶

The error in blood pressure measurement with any device is larger when the cuff is too small relative to the patient's arm circumference than when it is too large.²⁷ Atrial fibrillation may cause erroneous automated sphygmomanometer readings.^{28,29}

ECG monitoring

Although ECG monitoring is part of standard endoscopic practice, there are currently no known studies assessing its value in the procedural setting.

Capnography

Hypoxemia, especially when supplemental oxygen is being given, does not occur until after ventilation has become inadequate or has stopped. The American Society of Anesthesiologists recently modified their Standards for Basic Anesthesia Monitoring to include a requirement for capnography in moderate or deep sedation.² The ASGE, American Gastroenterological Association, and American College of Gastroenterology have published a joint statement opposing the universal adoption of capnography for moderate sedation: "Universal adoption of capnography for moderate sedation in adults undergoing upper endoscopy and colonos-

copy has not been shown to improve patient safety or clinical outcomes and significantly increases costs for moderate sedation.³⁰

A recent meta-analysis of 5 fairly heterogeneous studies comparing procedural sedation (including deep sedation) with oximetry alone versus oximetry combined with capnography showed that cases of respiratory depression (the only reported outcome) were 17.6 times more likely to be detected if monitored by capnography than cases not monitored by capnography (95% confidence interval, 2.5-122.1; $P < .004$).³¹ However, this meta-analysis included only 1 study involving endoscopy patients. These patients were undergoing complex upper endoscopy including ERCP.³² One trial of patients undergoing EUS or ERCP reported statistically fewer hypoxemic and apnea events with use of capnography versus oximetry alone.³³ There are no studies that have investigated the use of capnography during moderate sedation for *routine* GI endoscopy in adults. All of the reported data for the use of capnography during GI endoscopy reside either in the pediatric endoscopic literature or are derived from studies involving patients undergoing advanced endoscopy procedures in which deep sedation was targeted.³⁰

Capnography during endoscopy in an unintubated patient is by necessity sidestream capnography, which entrains ambient air into the analysis chamber and is, therefore, not designed to detect hypercarbia. The main functions of sidestream capnography are to monitor the respiratory rate and detect apnea. Regular breathing is often disturbed by moving, sneezing, coughing, or changes between nose and mouth ventilation. This can cause artifacts or difficulty in interpretation of data acquired with end-tidal sidestream capnography.³⁴

The Multisociety Sedation Curriculum for Gastrointestinal Endoscopy recommends that real-time interpretations of capnographic waveforms be taught in endoscopy units where capnography is used.³⁵ Training in other settings will not provide the relevant experience. There is currently no standardized program for training in this technology.

Consciousness monitoring

Experience with EEG-based consciousness monitoring in endoscopic sedation is scant. A review of 3 randomized trials in which EEG monitoring was compared with clinical assessment during endoscopy showed no relevant clinical benefit.³⁶ During longer lasting interventional endoscopic procedures, a significant propofol-sparing effect of EEG monitoring was noted. However, this propofol-sparing effect was not observed in 2 recent randomized, controlled trials of patients undergoing endoscopic mucosal dissection³⁷ or ERCP.³⁸ The ERCP trial, however, showed that BIS monitoring was accompanied by faster recovery of patients as reflected by shorter times to eye opening, first verbal response, and leaving the procedure room. No significant differences were seen in total rates of cardiopulmonary adverse events, mean propofol doses, or qual-

ity of sedation.³⁸ Another study showed that BIS monitoring did not reliably discriminate between moderate and deep sedation compared with observed alertness as measured by the Modified Observer's Assessment of Alertness and Sedation Score.³⁹

Safety

Skin avulsion and nerve palsy have occurred with malfunctioning sphygmomanometers.³ These adverse events, observed in earlier device development, prompted manufacturers to decrease the duration of cuff inflation. Patients who take anticoagulants or have very atrophic skin with little subcutaneous fat may be at increased risk even today.⁴⁰

Direct safety risks to patients and personnel originating from the other monitoring devices are few and anecdotal. In the past, incidents occurred when electrode lead wires, which should have been attached to the patient cables connected to ECG or home apnea monitors, were instead plugged into energized detachable power line cord plugs.⁴¹ In 1995, standards for ECG cables were released that made such hazardous connections impossible.

Human error, such as improper use of monitors and errors caused by alarm fatigue, is a frequent root cause of device-related serious adverse events.⁴²

Financial

Monitoring devices of varying complexity (single-function units vs combined-function units) are available from commercial manufacturers and vendors. Prices range considerably, depending on the complexity and sophistication of the device. The price range of multiparameter monitors that include blood pressure, electrocardiography, oximetry, and capnography is typically between \$5000 and \$6000. Sophisticated stand-alone capnographs that also incorporate oximetry with download capabilities designed for sleep labs are in the \$3000 to \$4000 range. Stand-alone capnographs suitable for endoscopy labs cost approximately \$2000 to \$3000. Recurring costs include staff training and the cost of the disposable components of the equipment.

AREAS FOR FUTURE RESEARCH

Integration of physiologic monitoring records into endoscopy information management systems can now be performed. This provides the potential for studies on sedation outcomes involving large numbers of patients.

Alarm fatigue is an important safety issue, and further research into ways to reduce this problem is warranted. With the increasing sophistication of monitors, ease of use may be decreasing, resulting in human error and potential for safety issues. Research into making devices more user-friendly is also desirable. Finally, with the recent change in recommendations regarding the use of capnography,² large randomized trials evaluating its utility in patients

undergoing routine endoscopic procedures with moderate sedation are essential.

SUMMARY

A wide range of monitoring equipment is available to support the use of sedation with GI endoscopy. Although direct benefit is unproven, many of these devices have become standard operating equipment. Electronic monitoring should supplement attentive clinical monitoring but is not a substitute for it. With the proliferation of infusion pumps, monitors, and other devices that are able to sound alarms, desensitization and alarm fatigue may occur. The use of capnography has been proposed for moderate sedation, but its utility in routine endoscopic procedures remains unproven.

DISCLOSURE

All authors disclosed no financial relationships relevant to this publication.

Abbreviations: BIS, bispectral index; ECG, electrocardiographic; EEG, electroencephalographic.

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Prepared by:

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