

Computer-Assisted Personalized Sedation (CAPS): A Disruptive Innovation in Sedation Practice

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Sedasys[®] is a propofol delivery system designed for the provision of moderate sedation in healthy patients undergoing routine endoscopic procedures by gastroenterologist lead endoscopy teams. Sedasys[®] is the first FDA approved device in a category known generically as Computer-Assisted Personalized Sedation (CAPS). It can be viewed as part of a general trend aimed at increasing the sophistication of sedation practice by non-anesthesia professionals through the development of new sedative agents, alternative propofol formulations, and novel delivery systems.¹⁻⁵ The CAPS development process has played out against the backdrop of controversy associated with propofol administration by non-anesthesia professionals.⁶⁻⁹

Basic Concept

Viewed schematically, CAPS is a propofol infusion device and a sophisticated monitoring package that are linked together by a smart alarm system that can interrupt or constrain drug delivery when unfavorable trends in patient physiology develop.¹⁰ The propofol infusion scheme, while not a true target controlled infusion (TCI) system, is intended to emulate a TCI-like dosage regimen, including automated calculation of loading doses and brief infusion interruptions based on pharmacokinetic principles. The propofol dosages are based on the assumption that fentanyl is also administered, taking advantage of the synergistic pharmacodynamic interaction between propofol and opioids.¹¹ Importantly, the propofol dosage strategy incorporated into CAPS is compliant with the original propofol labeling for sedation and is by infusion only (no boluses).

In addition to non-invasive arterial blood pressure, pulse oximetry and electrocardiogram monitoring, the CAPS monitoring package also incorporates capnography and an automated responsiveness monitor.¹² The patient's level of sedation is automatically assessed in terms of responsiveness to both verbal and tactile stimulation; the automated responsiveness system is intended to detect with confidence the loss of the conscious response (e.g., loss of response to "shout and shake"), a clinical event that must be identified reliably in order to prevent significant periods of deep sedation or general anesthesia.

The smart alarm system continuously monitors patient well-being and constrains drug delivery when the monitoring signals indicate the development of untoward changes in patient physiology, including apnea or hypoxemia. The smart alarm system also includes a variety of clinician "advisories" that convey important information to the practitioner but do not reduce or stop propofol delivery.

The CAPS system was developed with the rapid throughput environment of the gastrointestinal endoscopy suite in mind. Given the low doses of propofol infused, patients are expected to recovery very quickly.¹³ The CAPS system is comprised of a base unit and a bedside unit. The bedside unit is a basic monitoring module that can be attached to the patient throughout the peri-procedure period, thus providing a means of

monitoring the patient before and after the procedure without the need to remove and attach repeatedly new monitoring equipment.

Clinical Application

The CAPS clinical development program has focused on gastrointestinal endoscopy patient populations, although with further study the system could conceivably be applied to other patient groups requiring procedural sedation. The system targets healthy, adult patients undergoing routine gastrointestinal endoscopy procedures.¹⁴

A large, randomized trial, considered a “pivotal” trial in terms of the regulatory process, confirmed the findings of a smaller preliminary trial,¹⁰ demonstrating that CAPS can safely produce moderate sedation for gastrointestinal endoscopic procedures with high levels of patient and physician satisfaction.¹⁵ The CAPS group was superior to the current standard of care group (i.e., midazolam and opioid) in terms of the area under the oxygen desaturation curve (i.e., AUC_{Desat}), the pivotal trial’s primary endpoint. Another important finding of the pivotal study was that the CAPS system successfully achieved and maintained the clinical state of moderate sedation using propofol dosages known to be associated with sedation (and not general anesthesia). Episodes of deeper-than-intended sedation were rarely encountered in the study and were not associated with respiratory or cardiovascular complications in the CAPS group. The CAPS group also recovered more quickly than the current standard of care group.

Implications for Sedation Practice

CAPS will surely be viewed as a “disruptive innovation” in the sedation arena; references to CAPS in the popular press have already confirmed this reality.¹⁶ Elements of the “propofol controversy” (i.e., Who is qualified to administer propofol and under what circumstances?) include political considerations, regulatory questions, reimbursement issues, and work force challenges. Concerns regarding what training is appropriate are also a prominent part of the discussion. The advent of CAPS introduces additional complexity into the “propofol” controversy but also presents some intriguing opportunities for collaboration between disciplines in helping to make procedural sedation safer and better for all patients.

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