

# Risks of anesthesia or sedation outside the operating room: the role of the anesthesia care provider

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**Current Opinion in Anaesthesiology** 2010, 23:523–531

## Purpose of review

Our goal is to review the recent year's novel and relevant literature on the practice of sedation/anesthesia in the nonoperating room setting. Risk factors and outcomes were evaluated related to locations, providers, and anesthetic regimens.

## Recent findings

Administration of sedation/anesthesia for patients undergoing uncomfortable or painful interventions outside the operating room is an expanding practice involving a wide variety of practitioners. With a growing emphasis on cost, efficiency, and patient satisfaction, propofol alone or in combination with other sedatives/analgesics has become popular for procedural sedation among nonanesthesiologists. Although major adverse events are rare in this setting, potentially risky complications, such as respiratory depression and desaturation, still occur and their importance cannot be neglected. In this context, the American Society of Anesthesiologists Closed Claims and the Pediatric Sedation Research Consortium databases convey some valuable data. The bulk of reported complications are related to anesthetic drug-induced respiratory depression or airway obstruction leading to hypoxemia or hypoventilation. There are several new studies highlighting the importance of capnography in detecting impending airway or respiratory adverse events.

## Summary

The current incidence of complications associated with sedation in the nonoperating room environment remains irresolute. Although there are many studies on sedation practices in the out-of-operating room setting, high-quality studies are lacking. There are no data comparing practice outcomes between different practitioners and specialties.

## Keywords

nonanesthesiologists, outside the operating room sedation/anesthesia, risk

Curr Opin Anaesthesiol 23:523–531  
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0952-7907

## Introduction

The past few decades have witnessed an accelerated growth in the number and types of procedures performed outside the operating room. Therefore, sedation/anesthesia for diagnostic and interventional procedures has become commonplace in many settings, including radiology, gastroenterology, cardiology, pediatrics, and emergency medicine. By definition, anesthesiologists are the experts to deliver high-quality sedation services outside the operating room. However, the provision of sedation in offsite areas has clashed with the impediments imposed by the operating room logistics, cost-containment, and reimbursement issues. These obstacles have increasingly led to sedation care by nonanesthesiologists and/or trained nurses. A recent survey of 5000 physician members of the American College of Gastroenterology revealed that more than 98% of the providers in the United States routinely administer some kind of sedation

during upper and lower endoscopies [1]. Interestingly, 79% of the patients had sedation performed by nurses under the supervision of the gastroenterologist; anesthesiologists and certified registered nurse anesthetists (CRNAs) were responsible in only 29% of cases.

In addition, there is an increasing trend among nonanesthesia providers (e.g. gastroenterologists, pediatricians, emergency medicine) to use potent sedatives/hypnotics/analgesics (e.g. propofol, remifentanyl) for sedation, drugs once consecrated to the domain of anesthesiology [2–4,5\*,6]. As these drugs have a narrow therapeutic window with a rapid progression from moderate sedation to general anesthesia, there is a safety concern when they are administered by nonanesthesia providers. Therefore, this review will consider recent literature on the risk and safety of sedation/anesthesia outside the operating room, with particular focus on providers, procedural sites, and techniques.

### **Risk and safety of sedation and anesthesia outside the operating room: the anesthesiologist's perspective**

Anesthesiologists have led the patient safety movement in medicine, with a marked improvement in anesthesia safety [7]. The culture of anesthesiology focuses upon the detailed study of adverse events in order to continuously improve patient safety.

#### **Outcomes in adult patients**

Although the risks and adverse outcomes of conventional operating room and ambulatory anesthesia are well delineated [8], the opposite is true for the field of out-of-operating room anesthesia. Studies in out-of-operating room locations have focused mainly on sedation regimens for specific procedures at specific sites, organizational prerequisites [9], and patient satisfaction, but little on sedation-related morbidity and mortality [10]. In addition, many of these studies do not employ standard monitors of ventilation, are not blinded, and suffer from bias and conflicts of interest.

Extremely large cohort studies and randomized controlled trials are necessary to study sedation safety due to the low incidence of severe adverse events, but they are expensive and difficult to perform. However, the detailed analysis of closed malpractice claims is a useful technique to study rare, severe adverse outcomes. In 2009, claims from the American Society of Anesthesiologists (ASA) database were reviewed to assess patterns of injury and liability associated with anesthesia provided by anesthesiologists at out-of-operating room locations compared with anesthesia in the operating room [11]. Claims arising from anesthesia care in out-of-operating room locations had a higher proportion of death and were primarily caused by an adverse respiratory event (44%). Monitored anesthesia care (MAC) was the leading anesthetic technique, accounting for 50% of out-of-operating room claims. Respiratory depression secondary to oversedation and polypharmacy (propofol combined with other sedatives/analgesics) accounted for over a third of claims. A capnograph was employed in only a minority of claims associated with oversedation (15%), and no respiratory monitoring was used in 15% of these claims. As a consequence, substandard care, preventable by better monitoring, was implicated in the majority of claims associated with death. Although closed claims analysis suffers from various methodological deficiencies, it does point out clinically relevant findings in rare outcomes.

#### **Outcomes in pediatric patients**

Powerful data are obtained from the Pediatric Sedation Research Consortium, a large database that reports sedation-related adverse events occurring in children during out-of-operating room procedures. Their previous report

[12] comprised over 35 000 cases and included various procedure areas (e.g. radiology, oncology, gastrointestinal suite) with sedation provided by a dedicated sedation team, consisting of pediatric anesthesiologists, pediatric intensive care physicians or pediatric emergency physicians, among others. The mortality rate was zero and cardiac arrest secondary to hypoxemia occurred only once. The most commonly observed complication was of respiratory etiology. Oxygen desaturation to less than 90% for more than 30s occurred 157 times in 10 000 sedations (1 per 64) and one out of 200 sedations required some form of airway rescue, ranging from bag masking to emergency intubation.

The same group recently reported the incidence and nature of outcomes related to propofol sedation in over 49 000 pediatric patients [13<sup>••</sup>]. This is a landmark study comprising the largest set of data collected of detailed outcomes, and it should be considered as a benchmark for future studies. Although no deaths occurred, cardiopulmonary resuscitation was required twice, and there were four cases of pulmonary aspiration. As expected, the most prominent type of complication involved the airway, and affected one out of 65 sedations. One in 70 cases required interventions to rescue the airway. Contributory mechanisms involved mostly respiratory depression, airway obstruction, and apnea.

Although these data suggest that pediatric out-of-operating room sedation by well trained personnel is rarely accompanied by major mortality and morbidity, one should be cautious to make hasty deductions. Airway complications did occur, particularly in the propofol group, and in the absence of a less experienced team in airway rescue could have led to catastrophic outcomes.

### **Risk and safety of sedation and anesthesia outside the operating room: the nonanesthesiologist's perspective**

Procedural specialists outside the field of anesthesiology have published numerous studies concerning various sedation regimens and their outcomes, with particular focus on the use of propofol. Unfortunately, many intermediate adverse outcomes of respiratory depression are inadequately measured in these studies. In addition, the studies lack the power to demonstrate sedation safety to the degree expected by anesthesiologists, owing to the infrequent occurrence of death and other severe outcomes.

#### **Outcomes in gastroenterology**

The gastrointestinal suite is a leading sector in providing sedation/analgesia for diagnostic and therapeutic procedures. Many gastroenterologists regard sedation and analgesia as the sine qua non of best practice management.

Additionally, many patients, especially in the United States, demand sedation. Traditionally, moderate sedation was achieved in the gastrointestinal suite with a benzodiazepine (midazolam or diazepam) used either alone or in combination with an opioid (fentanyl or meperidine). However, in recent years sedation choices are changing, and there is a growing worldwide trend toward propofol use [1,14<sup>•</sup>]. Endoscopist-administered propofol is a highly controversial issue in both the media and the literature. Our goal is to review what is new in this field and to provide an objective view focusing on outcomes.

A recent meta-analysis extracted data from 36 randomized controlled trials (more than 3900 patients) and compared sedation and procedure-related outcomes during routine esophagogastroduodenoscopy (EGD) and colonoscopy [15]. Sedation regimens included benzodiazepines (midazolam/diazepam) alone or in combination with opioids or propofol, and propofol alone or in combination with the aforementioned drugs. The authors did not find significant differences in efficacy and safety between the different sedation regimens. The only advantage conferred by propofol was shorter recovery time. However, when interpreting the results, one should be aware of the known limitations of meta-analyses, including significant heterogeneity in study design, sedation drugs and doses, patient populations, geographic location, monitoring modalities, and definitions of adverse events. In addition, a majority of studies reviewed suffered from poor methodological quality, including the lack of blinding.

Two models have emerged for the administration of propofol by endoscopists: nurse-administered propofol sedation (NAPS) and combination propofol sedation (also referred to as gastroenterologist-directed sedation) [16]. Both models emphasize several key principles: the use of an established protocol for drug administration, a sedation team with appropriate education and training, and continuous patient assessment of clinical and physiologic parameters throughout the procedure, including end-tidal capnography.

#### *NAPS: safety and risk*

Most patients who receive NAPS undergo procedures that require deep sedation, for example EGD or colonoscopy. To be compliant, nursing personnel participate in a specialized training program conducted by an anesthesiologist; however, many programs now employ nurse-to-nurse training. Table 1 summarizes the results of these studies [5<sup>•</sup>,15,17<sup>•</sup>,18,19,20<sup>••</sup>].

In a review of more than 36 000 endoscopies performed under NAPS, the rate of clinically important adverse events (defined as an episode of apnea or other airway compromise requiring bag-mask ventilation) ranged

from approximately one event per 500 endoscopies to one per 1000. No deaths or endotracheal intubations occurred in this large cohort of patients [21]. Fatima *et al.* [18] analyzed over 800 patients and found minor sedation-related complications in 21% of upper esophageal sonographies. Five patients had O<sub>2</sub> saturations of less than 85% and required assisted ventilation. Propofol was changed to other agents in nine (1%) due to hypoxia, and one case was aborted because of prolonged apnea.

Another NAPS study [5<sup>•</sup>] compared midazolam/meperidine with propofol sedation in 150 elderly patients (half were ASA 3 or 4) undergoing interventional endoscopy. The main outcome measure was the rate of adverse cardiopulmonary events. The overall cardiopulmonary complication rate was not different in this small cohort. However, the mean decline in oxygen saturation was greater with propofol than with midazolam ( $P < 0.05$ ), as was the mean decline in blood pressure ( $P < 0.05$ ). The propofol group also showed significantly lower oxygen saturation during recovery time (8% vs. 28%;  $P < 0.01$ ). The authors concluded that NAPS is well tolerated in octogenarians for interventional endoscopy.

Serious adverse events occurred rarely in these studies and the number of individuals is small. Hence, there is inadequate power to demonstrate the safety of NAPS. Of note, doses for benzodiazepines were higher than commonly used by anesthesiologists, and untreated apnea episodes were more prolonged. Hypoventilation may have been masked due to absent end-tidal capnography and continuous oxygen administration. Few of these patients were obese, sick, or had sleep apnea. In addition, many procedures in these patients were performed in the lateral position, in which airway obstruction is less likely, and thus cannot be generalized to other types of procedures or positions.

#### *Gastroenterologist/endoscopist-directed sedation: safety and risk*

This model is based on the 'balanced anesthesia' concept, and relies on low-dose drug combinations in an effort to maximize the therapeutic actions of each drug, while minimizing the likelihood of a dose-related adverse reaction. These protocols aim to achieve moderate rather than deep sedation. Drugs used are fentanyl or meperidine, and/or midazolam, and low doses (5–15 mg) of propofol titrated to effect.

In a recent report, Rex *et al.* [19] summarized the published literature and previously unpublished cases about the safety of endoscopist-directed propofol for endoscopic procedures. More than 646 000 cases were studied; 11 cases required endotracheal intubation, 489 (0.1%) required bag-mask ventilation, and four patients died. Deaths occurred in two patients with pancreatic cancer, a

**Table 1 Selected series of administration of propofol by various providers**

Author	Year	No. of patients	ASA	Mean age	Procedure	Provider	Drug/s	Dose (total)	Complications	Comments
Schilling [5*] prospective	2009	151	3-4	86	ERCP, EUS	Nurse	Propofol vs. Midaz/meper	376 mg; 6/50 mg	SpO <sub>2</sub> <90% in 11.8% vs. 9.3%; Hypotension: 5.2% vs. 2.6%	Lower SpO <sub>2</sub> in PACU with propofol Hypotension
McQuaid [15] meta-analysis	2008	3918 (36 studies)	N/A	N/A	EGD, colonoscopy	Endoscopist	Regimens: 1. BDZ 2. BDZ + opioid 3. Propofol	Varied	SpO <sub>2</sub> <90% 18% 6% 11%	
Cote [17*] prospective case series	2010	799	6% >3	58	ERCP, EUS	Anesthesiologist	Propofol alone; Propofol combined	0.23 ± 0.10 mg/kg/min; 0.17 ± 0.11 mg/kg/min	SpO <sub>2</sub> <90%: 12.8%; Hypotension: 0.5%	Aldrete score 9; Capnography used
Fatima [18] retrospective case series	2008	806	N/A	53 ± 18	EUS	Nurse	Propofol	515 ± 266 mg	SpO <sub>2</sub> <90%: 0.7%; PPV: 4%; BMV: 1; Hypotension: 13%	27 ± 23 min recovery
Rex [19]; retrospective review	2009	646 080 (223 656 published and 422 424 unpublished cases)	N/A	N/A	EGD, colonoscopy	Endoscopist	Propofol	Varied	BMV: 489 patients (0.1%); ETT: 11 patients; Death: 4 patients	
Singh [20**] Cochrane meta-analysis	2008	267 studies	1	N/A	Colonoscopy	Endoscopist, nurse, PCS	Propofol alone; Propofol combined	Varied	SpO <sub>2</sub> , apnea, and respiratory depression comparable	Huge heterogeneity; p<0.00001

ASA, American Society of Anesthesiologists physical status; BDZ, benzodiazepine; BMV, bag – mask ventilation; EGD, esophagogastroduodenoscopy; ERCP, endoscopic retrograde cholangiography; ETT, endotracheal tube; EUS, esophageal sonographies; N/A, not available; PACU, postanesthesia care unit; PCS, patient-controlled sedation; PPV, positive-pressure ventilation.

severely handicapped patient with mental retardation, and a patient with severe cardiomyopathy. There is no mention about the proportion, duration, and magnitude of desaturation, monitoring techniques, nor oxygen administration. Many of the included studies suffered from methodological weaknesses and several authors disclosed significant conflicts of interest. However, the authors concluded that endoscopist-directed propofol has a low mortality rate and is well tolerated. The estimated cost per life-year saved was \$5.3 million, if anesthesiologists were substituted and had prevented all of the deaths.

The Cochrane group published the least biased systematic review on the subject [20\*\*]. This meta-analysis reviewed studies published between 1980 and 2007 concerning propofol sedation for colonoscopy. The primary objective was to analyze and summarize randomized controlled trials comparing the relative effectiveness, patient acceptance, and safety of propofol for colonoscopy, compared with traditional sedatives (narcotics and/or benzodiazepines). The secondary objective was to synthesize the studies comparing propofol administration by anesthesiologists with that by nonanesthesiologists, respectively. Outcome measures included sedation-related complications (cardiorespiratory: hypoxia, apnea, airway interventions, hypotension, arrhythmias) and procedure-related complications (colonic perforation, hospital readmission, and death). Of the 267 studies, only 20 met the inclusion criteria for the primary objective. In addition, there was only one small study, published as an abstract, comparing administration of propofol for general anesthesia by anesthesiologists with propofol administered by nonanesthesiologists for sedation during colonoscopy, with no difference in procedure time or patient satisfaction [22].

Although the authors of the above studies acknowledge significant methodological flaws, they conclude that propofol for sedation during colonoscopy for generally healthy individuals can lead to faster recovery and discharge times, and increased patient satisfaction without an increase in side-effects. However, large, multicenter, randomized, double-blind controlled trials and large prospective methodologically sound cohort studies need to be performed in order to provide unbiased estimates of adverse outcomes and safety.

#### **Sedation/anesthesia in the emergency department**

The emergency department (ED) has its very own sedation practice ruled by the Academy of Emergency Medicine. Although their experience with drugs such as propofol, ketamine, and various analgesics is extensive, the published data show that adverse events occur even in the most versatile settings (Table 2) [23–26]. For example, ED studies on propofol-based regimens in

adults and children observed adverse events from a low range of 1.5–3.5% to a high range of 31–33% [27], rates higher than would be acceptable under care by an anesthesia provider. One trial even reported an astounding 84% rate of complications in those receiving propofol with fentanyl [23]. In this study, 63 patients received ketofol (ketamine/propofol combination) versus propofol/fentanyl for fracture reductions or abscess drainage. Vital signs, including end-tidal capnography, were continuously monitored, but supplemental oxygen was administered only for  $SpO_2$  less than 92%. The most severe respiratory event (with potential to harm) was  $SaO_2$  less than 85% for greater than 1 min despite supplemental oxygen, and occurred in three (10%) of the patients receiving fentanyl.

Miner *et al.* [2] used propofol sedation with and without alfentanil in 145 adults for painful procedures, with capnography and bispectral index monitoring in addition to standard ED monitors. All procedures were successfully completed; however, severe respiratory depression was noted in 54 patients, 19 of whom required bag–mask ventilation. Not surprisingly, these complications were far more frequent in the propofol–alfentanil group (10% vs. 28%).

Intramuscular and intravenous ketamine is a popular sedation choice for children in the ED. A recent retrospective study on 4252 patients reported that the overall incidence of rate of respiratory adverse events was 2.4%; among the serious adverse events, apnea (10%), hypoxia (79%), hypoventilation (13%), and laryngospasm (28%) were recorded [24].

A recent retrospective chart review focused on procedural sedation/anesthesia in children less than 2 years of age [25]. Ketamine/midazolam (62%) was the most common combination used, followed by morphine/midazolam (16%). Nearly 6% of the children experienced complications, with most being considered minor (Table 2) [2,3,23–26]. One child experienced a serious adverse event in the form of apnea and bradycardia requiring intubation.

#### **Sedation/anesthesia for diagnostic and interventional radiology**

A few new articles deal with anesthesia and sedation for procedures in the radiology suite. Dexmedetomidine is increasing in popularity for imaging studies. A recent retrospective review [26] evaluated 315 children with autism undergoing sedation mostly for MRI. Although mean induction and total doses of dexmedetomidine were relatively high, adverse events were infrequent and the success of sedation was high. Ninety percent of patients received premedication with midazolam. Only one respiratory adverse event was recorded (airway

**Table 2 Selected series of nonanesthesiologist-directed administration of drugs in the emergency department or radiology**

Study and type	Year	Patient type	ASA	No. of patients	Drugs	Monitors	Complications
Miner [2]; RCT (not blinded)	2009	Adult	1	146	Premed: morphine 0.1 mg/kg, then morphine 0.05 mg/kg; Group I: propofol 1 mg/kg followed by 0.5 mg/kg every 3 min; Group II: 1.0 mg/kg/min alfentanil followed by propofol 1 mg/kg followed by 0.5 mg/kg every 3 min	Routine, bispectral index, capnography	Alfentanil group: Respiratory depression 26%; Hypotension 11%
Patel [3]; retrospective	2009	Children	1, 2, 3, 4	210	Propofol; mean induction dose: 3 mg/kg; mean maintenance dose: 5 mg/kg/min	N/A	Incidence <1%; seizure: 1 patient
Messenger [23]; RCT (double blind)	2008	Adult	1, 2	63	Group I; IV ketamine 0.3 mg/kg; IV propofol 0.5 µg/kg; Group II; IV fentanyl 1.5 µg/kg; IV propofol 0.5 µg/kg	Routine, capnography	S <sub>PO2</sub> Ketamine/propofol Fentanyl/propofol 37.5% 77.4% 6.3% 25.8% 0 9.7%
Melendez [24]; retrospective case-control	2009	Children	1, 3	102	Ketamine (IM, IV)	N/A	<92% <90% <85% Incidence=2.4%; odds ratio (95% CI) for adverse event with IM ketamine vs. IV ketamine; airway obstruction: 1.1 (1.0-1.1); apnea: 0.5 (0.1-2.3); hypoventilation: 1.2 (0.4-3.9); hypoxia: 1.3 (0.8-2.2); laryngospasm: 5.2 (2.3-11.9) Desaturation 1.7%; emesis 2.3%; apnea 1/173, inadequate sedation 5.8% Airway obstruction 0.3%; hypotension 9.5%; bradycardia 20%; agitation 0.6%
Misra [25]; retrospective	2008	Children <2 year	1	173	Ketamine/midazolam 62% of patients; morphine/midazolam 16% of patients	N/A	
Lubisch [26]; retrospective	2009	Children with autism	N/A	315	Premedication: oral midazolam or dexmedetomidine; mean induction dose: 1.4 µg/kg; mean total dose: 2.6 µg/kg	Routine, capnography	

ASA, American Society of Anesthesiologists physical status; CI, confidence interval; IM, intramuscular; IV, intravenous; N/A, not available; RCT, randomized controlled trial.

obstruction requiring a nasal airway insertion). Bradycardia and hypotension were noted in 20% and 9% of patients, respectively, but seldom required treatment.

A relatively small study (60 cases) compared the efficiency of propofol/ketamine/fentanyl with that of propofol/fentanyl in children for interventional radiology procedures [28]. Not surprisingly, the propofol/fentanyl group exhibited more desaturation events (30 vs. 10%). The addition of a low dose (0.5 mg/kg) of ketamine decreased the risk of hypoxemia and also the need for supplemental propofol for these procedures.

These relatively complex and expensive sedation protocols have been challenged by a simple regimen that used exclusively midazolam for sedation of children for diagnostic computed tomography [29]. More than 500 children were enrolled and sedated with IV midazolam 0.2 mg/kg. Seven percent of patients had decreased SpO<sub>2</sub>, which did not need airway interventions and resolved with supplemental oxygen. Agitation (0.8%) and failure to sedate (2%) occurred infrequently.

### Enhancing safety of sedation/anesthesia in out-of-operating room settings

Use of capnography for monitoring the adequacy of ventilation, anesthesia specialists in higher risk patients, and adequate training for nonanesthesia providers can enhance safety of sedation/anesthesia in out-of-operating room settings.

#### Monitoring

Earlier studies have confirmed the assumption that respiratory depression is the most prominent adverse effect of sedation/anesthesia. Therefore, monitoring for respiratory depression is essential. For this purpose, pulse oximetry is widely employed. However, pulse oximetry is far from the ideal in detecting ventilatory compromise (e.g. hypoventilation, airway obstruction, or apnea). Significant respiratory compromise can occur despite normal oxygen saturation, particularly when supplemental oxygen is administered.

According to ASA standards for monitoring during sedation, the adequacy of ventilation should be determined through continuous observation of patient respiration and/or monitoring for the presence of carbon dioxide (end-tidal capnography) exhaled by the patient [30]. Although capnography is not currently a standard requirement for sedation/anesthesia in out-of-operating room locations, its importance is supported by several recently published studies. Qadeer *et al.* [31] found that endoscopists who were blinded to capnography during moderate sedation with an opioid and benzodiazepine could not

recognize apnea lasting more than 30 s in 63% of the patients. The study concluded that capnography reduced the occurrence of severe hypoxemia by 16%, and apnea by 22%. A very similar study conducted in EDs during propofol sedation mirrors these results [32]. Capnography identified all cases of hypoxia before onset (sensitivity 100%; specificity 64%), the median time from capnographic evidence of respiratory depression to hypoxia being 60 s. The ASA has recently recommended the use of end-tidal capnography to assess adequacy of ventilation during monitored anesthesia care with propofol [33].

#### Providers

To date, there are no published data to compare outcomes of out-of-operating room anesthesia provided by anesthesiologists with those of nonanesthesiologists. However, some limited information can be gleaned from recent studies. On the basis of Cravero's report [12], pediatric anesthesiologists seem to provide safer sedation with propofol by an odds ratio of 1.38 (95% confidence interval 1.21–1.57,  $P < 0.001$ ). In a prospective cohort study, Vargo *et al.* [34] analyzed the occurrence of cardiopulmonary events for propofol sedation conducted by an anesthesiologist (MAC) compared with gastroenterologist-administered propofol during colonoscopy or upper endoscopy. The overall complication rate for more than 18 000 procedures was 11.7/1000 cases. The risks of adverse events in both procedures were lower with anesthesiologist-provided sedation for all patients undergoing colonoscopy and for ASA 1–2 patients for EGD.

In a very unique study, Coté *et al.* [17] reported the frequency of airway modifications required to be performed by CRNAs during propofol sedation for endoscopy. Airway modifications included chin lift, modified facemask ventilation, and placement of a nasal airway. The maneuver was performed as deemed necessary by the CRNA and based on direct observation and capnography. There were 154 airway modifications performed in 115 of 799 patients (14%), mostly chin lift (12%). The rate of hypoxemia (13%) and hypotension (0.5%) was comparable to other studies. No patients required bag-mask ventilation or endotracheal intubation. BMI, male sex, and ASA physical class of 3 or higher were independent predictors of airway modifications. This study underscores the importance of a trained professional who is solely responsible for maintenance of sedation and patient monitoring while using propofol.

#### Training

Anesthesiologists have always played a vital role in establishing guidelines for well tolerated sedation provided by nonanesthesiologists. However, considerable work remains in organizing sedation services and overseeing the sedation practice across departments, hospitals, and

offices. A broad interdisciplinary program should be instituted which includes didactics comprising pharmacology and side effects of commonly administered sedatives/analgesics/reversal agents; training in airway management with demonstration of skills in the simulator; monitoring techniques with emphasis on capnography; and preceptorship [35]. Given the sometimes unpredictable responses of individual patients to sedative agents, preparation and training for rescue from deeper than intended levels of sedation is necessary. In the United States, the Centers for Medicare and Medicaid Services recently revised their guidelines to require sedation and analgesia services be under the direction of the anesthesia service [35]. The anesthesia service is responsible for developing policies and procedures governing the provision of sedation/analgesia, including minimal qualifications and training procedures.

## Conclusion

Sedation and anesthesia out of the operating room is an evolving practice that involves an increasing array of medical specialties, and not just anesthesiology providers. Despite recent research and publications in this area, the comparative safety of sedation/anesthesia in the hands of anesthesiology or nonanesthesiology providers is unknown. Additional carefully designed, prospective, large scale, multiinstitutional studies are required to provide nonbiased estimates of sedation safety.

## References and recommended reading

Papers of particular interest, published within the annual period of review, have been highlighted as:

- of special interest
- of outstanding interest

Additional references related to this topic can also be found in the Current World Literature section in this issue (p. 538).

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