Unscheduled Procedural Sedation Multidisciplinary Delphi Consensus Guidelines, Part 2: Clinical Practice

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ABSTRACT

This is Part 2 of an update to the 2019 multidisciplinary clinical practice guidelines for unscheduled procedural sedation. Time-sensitive sedation differs in important ways from scheduled, elective procedural sedation. This document is a resource for all practitioners who perform unscheduled procedural sedation, applicable across all clinical settings and patient age groups. Part 1 addresses the underlying principles and issues relating to competencies, privileging, and quality monitoring, while Part 2 addresses clinical practice.

INTRODUCTION

Providing sedation and analgesia to facilitate the humane performance of painful and anxiety-provoking procedures is a widespread and integral practice across specialties. The safety of procedural sedation is supported by a large and robust body of literature, with serious adverse events being extremely rare.[1-15] The multidisciplinary field of procedural sedation has fostered a strong safety culture following many decades of close attention to practitioner training, patient evaluation, physiologic monitoring, and other critical safeguards.[1-13]

Please see the separate Part 1 of these guidelines for the underlying rationale and principles behind this document, and for discussions of scope, competencies, privileging, and quality improvement. Part 1 also details the methodology used for both parts of these guidelines. Part 2 addresses clinical practice. Figure 1 highlights the most notable changes in this section.

LEVELS OF SEDATION (STRONG CONSENSUS)

Figure 2 lists widely described levels of procedural sedation.[1-3,8,16,17] We discuss all levels of sedation to accommodate the wide range of unscheduled procedures and to maximize the applicability of these guidelines.

- Delphi sequential review consensus methodology with grading of the quality of the evidence
- Algorithm for risk-stratifying oral intake prior to procedural sedation
- Sedation care for of patients taking glucagon-like peptide-1 (GLP-1) receptor agonists
- Deemphasis of the role of American Society of Anesthesiologists (ASA) physical status in risk assessment
- Routine use of capnography for moderate, deep, and dissociative sedation whenever feasible

Figure 1. Notable changes in Part 2 of this update.

(Some guidelines omit deep[18] or dissociative[3,18] sedation.) We only briefly address "minimal sedation" which, by definition, carries a sufficiently low risk that monitoring devices (e.g., pulse oximetry) and other typical sedation precautions are not required,[1,3,18] and thus is outside the scope of this document.

Sedation depth

All sedatives and commonly used opioids, except ketamine can produce any sedation depth from minimal sedation to general anesthesia, depending upon dose and patient response. Patients can move up and down this sedation continuum and can transition between defined sedation states during any given procedure.[1,2]

Clinical decisions and management should focus on sedation depth and ventilatory adequacy rather than the specific drug, while recognizing that different drugs have different pharmacological properties and therapeutic windows. There is no evidentiary or pharmacological basis[1,2,8,19-21] for designating common procedural sedation agents as "intended" or "not intended" for general anesthesia, or for restricting them on this basis.[18] Likewise, there is no literature basis for hospital policies that specify that the administration of a parenteral agent, or the administration of more than one agent by any route, is by definition automatically incompatible with minimal sedation, irrespective of other factors.

Dissociative sedation is distinct from the sedation continuum

The underlying pharmacology of ketamine is fundamentally different from that of other procedural

The Sedation Continuum	Responsiveness-Based Sedation State Definitions (best to guide sedation effectiveness)	Airway & Ventilatory Focus (best to assess safety)
	Minimal sedation (anxiolysis) "A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination might be impaired, ventilatory and cardiovascular functions are unaffected."[2,17]	The airway and effective spontaneous ventilation are consistently maintained.
	Moderate sedation "A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained."[2,17]	The airway and effective spontaneous ventilation are essentially always maintained.
	Deep sedation "A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained."[2,17]	The airway may require repositioning. The ventilatory pattern may be at times slowed or irregular, but effective spontaneous ventilation is usually maintained such that assisted ventilation or other interventions are typically not required.
	General anesthesia "A drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired."[2,17]	The airway and ventilatory pattern are often impaired, and patients often require assisted ventilation or other interventions.
Ketamine		
	Dissociative sedation "A trance-like cataleptic state induced by the dissociative drug ketamine characterized by profound analgesia and amnesia, with retention of protective airway reflexes, spontaneous respirations, and cardiopulmonary stability."[1,2,8,16]	The airway may require repositioning. Effective spontaneous ventilation is essentially always maintained.

Figure 2. Common sedation state definitions, together with their corresponding airway and ventilatory focus.

sedation agents. Ketamine is a noncompetitive N-methyl-D-aspartate (NMDA) glutamate receptor antagonist and exerts its effect by "disconnecting" the thalamocortical and limbic systems, effectively dissociating the central nervous system from outside stimuli (e.g., pain, sight, sound). The resulting trancelike cataleptic state is characterized by potent analgesia, sedation, and amnesia while maintaining cardiovascular stability and preserving spontaneous respirations and protective airway reflexes.[8,22-24] Such substantial analgesia permits performance of extremely painful procedures.

Rather than displaying the dose-response continuum observed with all other procedural sedation and analgesia agents, ketamine dissociation appears at a dosing threshold of approximately 1.5 to 2 mg/kg intravenously (IV) in children and 1 to 1.5 mg/kg IV in teenagers and adults. In smaller doses, ketamine exhibits first pure analgesia (approximately 0.2 to 0.3 mg/kg IV) and then hallucinatory distortion (approximately 0.6 to 0.7 mg/kg IV)—the latter the endpoint for illicit recreational use. Once the dissociative threshold is reached, administration of additional ketamine does not enhance or deepen sedation, as would be the case with opioids, sedative-hypnotics, or inhalational agents.[8,22-24]

These unique features of ketamine do not reconcile with the traditional stages of the sedation continuum.[8,25] Dissociated patients are unable to respond to external stimuli (including repeated or painful stimulation), and thus this sedated state is inconsistent with definitions of moderate or deep sedation (Figure 2). By default, such non-responsiveness has been labeled by many as general anesthesia; however, general anesthesia, by definition, specifies an unarousable state in which airway intervention is "often required" and spontaneous ventilation is "frequently inadequate" (Figure 2). These latter elements are incompatible with the dissociative state, where airway intervention is rare and spontaneous ventilation almost always maintained.

ACEP and others have long resolved such confusion by placing dissociative sedation in its own separate category.[1,2,8,16] When others attempt to fit ketamine into one of the traditional sedation continuum states, they should recognize its technical incompatibility with any of those definitions. Ultimately, semantic debates over what to call ketamine serve little purpose.[25] It is more important to appreciate the many ways in which ketamine is fundamentally distinct pharmacologically and clinically from general anesthetic agents and other procedural sedation agents.

Ventilatory adequacy

Early procedural sedation guidelines in 1985 defined sedation levels based on patient response to verbal or tactile stimulation, as physiologic monitoring was limited to cardiac rhythm and vital signs (pulse oximetry and capnography were not yet available in the outpatient setting). While responsiveness helps target sedation depth to patient comfort, it is not a reliable safety measure, and only a crude, indirect surrogate for ventilatory adequacy and maintenance of oxygenation.[26,27] Furthermore, responsiveness poorly predicts procedural stress and recall.[28,29] Although it can provide reassurance that patients will breathe on command, focusing on responsiveness often leads to repeatedly stimulating patients to verify sedation level—counteracting the intended state of tranquility. This focus has led to irreconcilable disputes in guidelines and policy regarding sedation boundaries (e.g., distinctions between moderate and deep sedation, or between deep sedation and general anesthesia)[19-21,26,27,30] due to inherently subjective definitions. Differing interpretations of such ambiguity has long fostered unfortunate barriers to optimal patient care.[19,30,31]

Procedural sedation practice should focus on ventilatory adequacy for safety and patient responsiveness to optimize patient comfort,[26,27] assessing both throughout the sedation encounter. While cardiovascular stability remains vital, clinically significant hemodynamic alterations rarely occur in patients without serious systemic disease or acute cardiovascular compromise. In patients who maintain a stable and effective ventilatory pattern, their level of responsiveness to voice or pain is functionally irrelevant from a safety perspective. Practitioners can verify ventilatory adequacy through capnography and close, continual observation of the airway and chest wall motion. Figure 2 compares this safety focus to the traditional effectiveness focus.

PRE-SEDATION EVALUATION (STRONG CONSENSUS)

When unscheduled procedural sedation is warranted, practitioners should perform a pre-sedation assessment and patient evaluation, recognizing that urgent or emergent conditions may require streamlining this process. Many patients, particularly children, are fearful when anticipating sedation. Whenever possible, provide a calm, quiet environment, and encourage family presence and engagement.

Assess procedure

The initial assessment should determine the nature and anticipated duration of the procedure, the required level of motion control, and whether the procedure will be painful,

anxiety-provoking, or both. Some procedures, such as imaging or ocular examination, may primarily require anxiolysis, while painful procedures such as fracture reduction require both analgesia and anxiolysis.

Special circumstances such as developmental or psychiatric conditions may present safety concerns for staff, e.g., adult-sized neuroatypical patients with aggressive behaviors.[32] Certain procedures, such as upper endoscopy and bronchoscopy, carry greater risk of airway and respiratory adverse events (⊕⊕⊕⊕).[5,9,10,33-35]

Assess comfort needs

For all procedures, practitioners should assess which combination of sedation/anxiolysis and analgesia the patient requires, and determine what level of responsiveness will ensure patient comfort and procedural success while maintaining ventilatory adequacy (Figure 2).

Assess timeliness

Time is of the essence for unscheduled procedures. The ethical imperative to diminish pain, alleviate anxiety, and optimize patient comfort during procedures becomes even greater when compounded by an acute, precipitating condition. Accordingly, weighing sedation-associated risks and benefits must consider not only the underlying medical situation, procedure, and sedation, but also prioritize patient- and family-centered care.

Unlike operative anesthesia,[36] unscheduled sedation does not appear to present a higher risk of serious adverse events compared to elective sedation. In addition, serious adverse event profiles are similar during unscheduled and elective procedural sedation (⊕⊕⊕).[9,37,38] A study of 139,142 children found no significant difference in the frequency of adverse events between elective and non-elective procedures.[9] While some unscheduled procedures may be safely delayed from a pure physical health standpoint, practical considerations often make delay inadvisable. Although some clinical settings provide prompt and reliable referrals for elective scheduled procedural sedation, many do not—particularly in regions where anesthesia workforce shortages are common.[39,40] In these circumstances, delaying procedures may lead to a deterioration of the acute clinical condition, prolonged anxiety and pain for the patient, and significant distress and inconvenience for the family (e.g., lost workdays, childcare needs ⊕⊕).[41,42] These adverse consequences often disproportionately affect children and those of low socioeconomic status. For children, acute pain and anxiety have more than short-term consequences; they can also increase future sensitivity to pain and fear of healthcare settings, needles, and procedures.[43]

Multiple factors characterize unscheduled sedation and dictate its time-sensitive nature, including societal considerations (e.g., access to care, disparities of care for underserved populations), institutional constraints (e.g., lack of operating room, anesthesia, and elective sedation resources), and patient- and family-centered needs (e.g., reduction of physiologic and psychological stress). Often, carefully weighing the anticipated benefits against potential harms supports the decision to expedite the unscheduled procedure.

Assess patient history

A focused assessment of past medical history and current medications should be obtained. Children with known or suspected obstructive sleep apnea are at approximately five-times greater risk of airway and respiratory adverse events (⊕⊕).[5,9,10] Children show modestly increased risk of airway and respiratory adverse events (approximately double) with moderate to severe obesity (⊕⊕⊕),[34,35,44-46] pre-term birth (<37 gestational weeks ⊕⊕),[34,47] current or recent upper respiratory infections (⊕⊕⊕),[8,9,33,34,48] autism spectrum disorder (⊕⊕),[49] and when young (defined as <1 year old in some studies[9,35] and <2 years old in others[34,50,51] ⊕⊕⊕). Procedural sedation is generally avoided in children <6 months of age due to a presumed greater risk of airway and respiratory adverse events (⊕⊕).[9,33,52]

Adults with obesity appear at modestly greater risk of airway and respiratory adverse events (⊕⊕),[53,54] with conflicting evidence for known or suspected obstructive sleep apnea (⊕).[54-57] Although elderly adults are at greater risk of adverse events, most remain appropriate candidates for sedation (⊕⊕⊕).[58-60] Patients with moderate to severe congestive heart failure, pulmonary edema, valvular disease, and/or acute myocardial infarction present a particularly high risk, and may tolerate only minimal sedation if at all.[61]

Patients of all ages with severe underlying systemic disease are at greater risk of adverse events (⊕⊕⊕⊕).[9,33-35,50,62] This corresponds with American Society of Anesthesiologists (ASA) physical status, discussed further under "risk" below. A related potential risk factor is frailty—a decline in functioning across multiple physiological systems with increased vulnerability to stressors.[63-65] Clinicians regularly observe substantial variation in frailty among patients with otherwise similar age or with comparable underlying illness.

Prior experiences with procedural sedation or anesthesia should be queried for unexpected reactions and previous

adverse events. Current medications, pertinent allergies, and potential contraindications to specific sedatives should also be considered. There is inadequate evidence to guide the sedation care of patients with opioid use disorder; however, non-opioid sedation regimens would appear more likely to be successful (⊕).[66]

For women of childbearing potential, pregnancy status should be considered, although procedural sedation for urgent or emergent conditions often needs to proceed regardless. There is insufficient evidence to guide sedative agent selection in pregnancy (⊕).[67] Recent practice guidelines on anesthesia and sedation in breastfeeding women recommend normal breast feeding following receipt of ketamine or propofol. They also support normal breastfeeding following single doses of fentanyl or midazolam, with extra caution when babies are aged 6 weeks or less.[68]

Assess oral intake

A focused assessment of the timing and nature of recent oral intake should be obtained.

The ASA and other anesthesiology societies detail time-based fasting thresholds prior to operative anesthesia,[69-71] intended to minimize the risk of pulmonary aspiration. In many settings it is customary to extrapolate these to elective procedural sedation.[3,18] Such fasting often substantially exceeds recommended time thresholds, resulting in known adverse consequences including irritability, dehydration and hypoglycemia (⊕ ⊕ ⊕ ⊕).[5,10,72-74]

Common concerns about aspiration during procedural sedation vastly exceed actual risk (⊕ ⊕ ⊕ ⊕).[5,9,10,72,73,75,76] The combination of vomiting and loss of airway protective reflexes rarely occurs, with resultant aspiration being extraordinarily rare.[9,10] A 2017 systematic review of procedural sedation found no published reports of aspiration-associated mortality in children or healthy adults.[10] Among adults with severe systemic disease, only nine deaths were reported—eight during upper gastrointestinal endoscopy.[10] Morbidity was similarly rare—brief intubation in 1 child and 3 adults with recovery.[10] It is not surprising that the aspiration risk with procedural sedation is lower than with operative anesthesia, as its procedures are often brief, there is far less active airway manipulation, and potentially emetogenic inhalational anesthetic drugs are not routinely used.[5]

Fasting does not guarantee an empty stomach;[77-82] indeed, the duration of fasting does not predict gastric volume (⊕ ⊕ ⊕).[82,83] There is no evidence that compliance with elective fasting guidelines decreases the risk of aspiration, emesis, or other adverse events during procedural sedation (⊕ ⊕ ⊕).[5,9,10,72,73,75,76,83-87] In the largest such study of 139,140 sedations, the frequency of aspiration was no different in children who were compliant versus noncompliant with elective fasting guidelines (0.97 and 0.79 per 10,000, respectively).[9] For infants, new evidence suggests that there is no difference in gastric emptying time between breast- and formula-feeding (⊕ ⊕).[85]

For unscheduled procedural sedation, practitioners should assess the timing and nature of recent oral intake, considering this information within the context of risk factors identified during the focused history and physical examination. Evidence-based fasting recommendations from a multidisciplinary expert panel are shown in Figure 3,[5] with implementation of these guidelines noted to improve patient tolerance while maintaining safety.[88] Urgent and emergent procedures should not be delayed solely based upon fasting times. In rare cases with moderate aspiration risk factors (Figure 3), practitioners should refer for prompt anesthesia care when available. If unavailable, strongly consider dissociative sedation, as ketamine uniquely preserves protective airway reflexes.[5,8] No aspiration has been reported with ketamine as the sole agent (despite its association with vomiting and laryngospasm) except in dated reports involving compromised neonates (⊕ ⊕ ⊕).[8,10]

GLP-1 agonists

Patients taking glucagon-like peptide-1 (GLP-1) receptor agonists (e.g., semaglutide, liraglutide, tirzepatide) attract special attention due to known delays in gastric emptying.[89-96] A 2024 United States Food & Drug Administration product labeling update for these drugs notes "rare postmarketing reports of pulmonary aspiration in patients … requiring general anesthesia or deep sedation."[95] While GLP-1 agonist-associated aspiration has been reported with general anesthesia in the peer reviewed literature, no cases have been reported for deep or other levels of sedation.[97] This delayed gastric emptying may be exacerbated by active gastrointestinal symptoms, long-acting drug type (e.g., semaglutide), higher dose, escalation phase of therapy, longer duration of therapy, and poor glycemic control.[91-94]

Early pre-operative recommendations for GLP-1 agonists considered rapid sequence or awake intubation;[69,96] however, newer guidance regards the risk as low enough to induce in standard fashion for most patients (⊕).[93] In a study of 377,476 adults undergoing operative anesthesia, there was no difference in the frequency of aspiration pneumonia between those taking versus not taking GLP-1 agonists.[98] A systematic review and meta-analysis also had found no such association.[99] Given

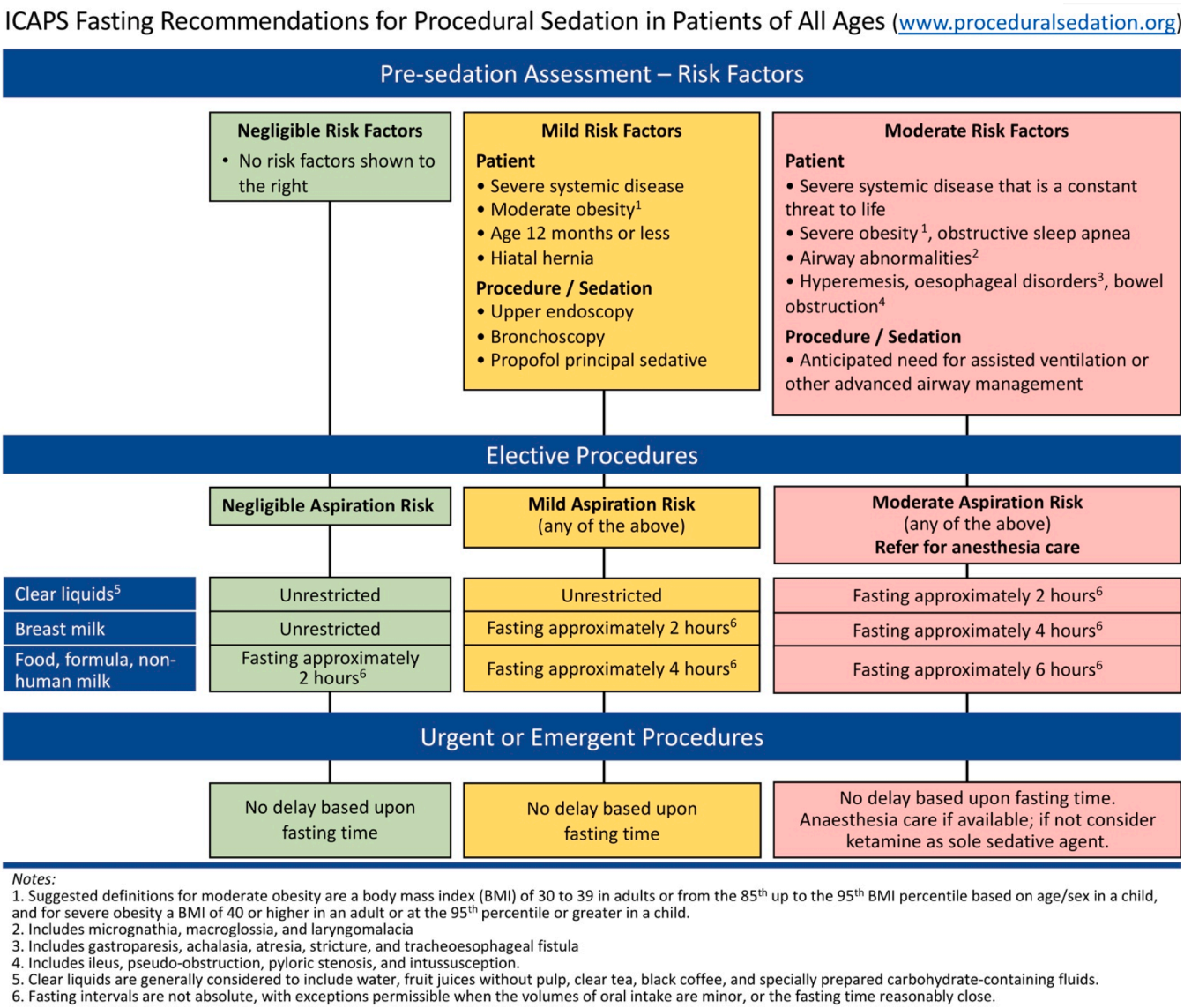

Figure 3. Evidence-based fasting recommendations for procedural sedation. Source: Anaesthesia 2020;75(3):374-85.[5] Used with permission. Full article available at: https://proceduralsedation.org/fasting/

the lower aspiration risk of procedural sedation relative to operative anesthesia, this suggests that sedation care should also proceed in usual fashion for most adult patients (⊕). There are insufficient data to advise the care of children. Should a patient requiring an unscheduled procedure be considered at higher than usual risk, consider referral for anesthesia care. If this is not an option, the use of ketamine alone appears a logical choice over other sedative regimens as it uniquely preserves protective airway reflexes.[5,8]

Assess physical exam

A focused airway, oral, and pulmonary examination should assess for anatomic or physiologic variants that might increase risk of airway or ventilatory compromise, or complicate assisted ventilation. Such risk factors include airway abnormalities (eg, micrognathia, macroglossia, laryngomalacia, tonsillar hypertrophy), short neck, or severe obesity.

The Mallampati score— a graded visual assessment of the pharynx and tonsils extrapolated from operative anesthesia— should not be required as part of the airway evaluation for procedural sedation as no evidence supports its impact on clinical outcomes.[100-103] The score poorly predicts both difficult bag mask ventilation and endotracheal intubation, is unreliably assessed, and often cannot be obtained in younger children unable to comply with the examination (⊕ ⊕ ⊕ ⊕).[100-104]

Assess risk

Following the history and physical exam, practitioners should estimate the risk for the planned sedation. Many

sedation settings apply the ASA physical status classification (Grades I-IV) for this purpose. While higher ASA scores statistically correlate with more frequent adverse events during procedural sedation,[9,33-35,50] the overall absolute increase in affected patients is minimal.[9] The ASA score was never intended for risk prediction, has poor predictive value and interrater agreement, and cannot reliably guide individual patient decisions (⊕⊕⊕).[34,105-108] Anesthesiologists recognize the limitations of this score and plan to revise it for operative anesthesia, incorporating assessment of frailty.[105,108,109] These limitations are not unique or surprising, as few scores or decision aids have been found to improve upon clinical judgment.[110-112]

Data from a 139,140-child study illustrate the limitations of the ASA physical status for procedural sedation risk stratification.[9] When comparing children with higher (>II) versus lower (I or II) ASA scores, major complications occurred in 9.10 versus 4.61 per 10,000 cases. Although this represents approximately twice the risk, the actual likelihood of a major complication remained extremely low in both groups. The absolute risk difference of 4.49 per 10,000 yields a number needed to treat of 2,227—meaning any intervention based on higher ASA scores would need to be performed 2,227 times to potentially prevent one major complication. These data provide no evidentiary justification for using ASA III versus I or II as a stipulated trigger for altered sedation planning such as requiring anesthesia consultation or care, or delaying sedation (⊕⊕⊕).

Rather than relying on the ASA physical status, sedation practitioners should apply their clinical skills and judgment to stratify potential risk based on history and physical examination findings, specific identified risk factors, and plausibly through an appraisal of patient frailty. For patients judged at unusually high risk based upon such clinical judgment, consider referral for anesthesia care when patient acuity allows, recognizing the delays required to arrange an operating room, anesthesia services, and an operating surgeon or proceduralist.

CONSENT (STRONG CONSENSUS)

Practitioners should discuss the sedation plan, its risks and benefits, and potential alternatives with patients and/or their parents, legal guardian, or health care power of attorney, as appropriate, using simple language that is easily understandable. This discussion should use their preferred language with an in-person or virtual interpreter, if needed.[113]

Appropriate consent should be obtained following local policies. Given the minimal risk presented by most sedation encounters relative to other medical procedures, such consent may be verbal rather than written in many settings. However, confirmation that informed consent was obtained should be documented.

For some urgent and emergent procedures, this process may need to be abbreviated. When patients are unable to give consent and no proxy is available, practitioners will, in certain urgent and emergent situations, need to proceed without consent.

ROOM AND SUPPLIES (STRONG CONSENSUS)

Procedural sedation must be performed in an area with oxygen, suction, physiological monitoring equipment, resuscitation medications, and age- and size-appropriate equipment for airway and ventilatory rescue (e.g., bag-valve mask, oral airway, nasal airway) and for IV access (⊕⊕⊕⊕). When using opioids or benzodiazepines, reversal agents must be readily available. Medications to treat allergic reactions and recovery nausea and vomiting should also be readily accessible.

Many practitioners prefer IV access whenever it can be readily obtained, both as a precaution to treat adverse events and to allow for additional sedative medication administration as needed. This presents little difficulty in most adults; however, it may be distressing in young children, or in older children or adults with agitation or certain neuropsychiatric disorders. To facilitate cooperation for IV placement, consider a topical anesthetic and/or behavioral strategies (see later section) to mitigate such distress.

The above being said, safe procedural sedation without IV access has been well documented when using medications such as inhaled nitrous oxide[114-116] and intranasal medications[117-120] (in proper doses, settings and patients ⊕⊕⊕). Similarly, dissociative sedation with intramuscular (IM) ketamine has been well studied without IV access and with similar safety (⊕⊕⊕⊕).[8,24,121,122] However, the expertise to initiate IV access should always be immediately available. For uncooperative patients requiring procedural sedation, one strategy is to administer ketamine IM and then, at onset of the dissociative state, establish IV access prior to the procedure.

A "time out" should occur just prior to the procedure in which the entire team verifies key details together (e.g., procedure to be performed, patient identity, sedation plan, correct anatomic site, presence of all appropriate equipment).[123] This should be performed quickly or, if necessary, skipped, in emergent situations to ensure safety while minimizing delays in providing needed care.

MONITORING (STRONG CONSENSUS)

Interactive monitoring

The sedation team must continuously assess airway patency, ventilation quality, and sedation status through direct observation and physical examination to ensure patient comfort and to anticipate, prevent, and quickly detect oversedation should it occur. This requires, wherever possible, an unobstructed view of the airway, chest, and skin. Airway and respiratory adverse events occur most frequently during induction and the immediate post-painful procedure phases, and rarely during recovery.[124]

Physiologic monitoring

The sedation team will observe and periodically document the vital signs and output of monitors. Cardiac rhythm monitoring, blood pressure assessment, capnography, and pulse oximetry with audible tone should be used routinely whenever feasible as discussed below (⊕ ⊕ ⊕ ⊕).

Cardiac monitoring allows immediate continuous assessment of heart rate and rhythm, promptly identifying clinically important bradycardia and other arrhythmias—though extremely rare during procedural sedation.

Blood pressure should be assessed prior to sedation and at appropriate intervals thereafter including—if possible and without unduly disturbing the patient—during and after procedural sedation. Blood pressure should also be assessed at the earliest evidence of potential cardiovascular compromise. Clinically important hypotension rarely occurs during procedural sedation in patients without serious systemic disease or acute cardiovascular compromise. It is more frequent in certain settings (e.g., colonoscopy with propofol[125]), warranting greater attention and more frequent measurements in those at higher risk. Patients with known or possible volume depletion should be rehydrated at the earliest time that is safe and feasible (prior to procedural sedation whenever possible) and have frequent blood pressure monitoring.

Capnography provides continuous, immediate, objective verification of ventilation quality, and is more reliable than pulse oximetry or interactive monitoring alone.[126-131] Capnography is simple, noninvasive, easy to interpret, provides the earliest warning of respiratory depression and apnea, and can reduce the risk of developing hypoxia (⊕ ⊕ ⊕ ⊕).[126-129,131-135] Normal capnography readings can quickly and unambiguously confirm ventilatory activity. Abnormal readings signal clinicians to reevaluate patients, prepare to provide ventilatory support and/or to administer a reversal agent, and avoid additional sedative doses until concerns resolve.[132] When using supplemental oxygen, capnography is the sole monitoring device to promptly identify impaired ventilation. Many capnography devices use a nasal cannula suitable for simultaneous carbon dioxide sampling and administration of supplemental oxygen.

Anxious or frightened children and uncooperative adults may not tolerate the blood pressure cuff, pulse oximetry sensor probe, or capnography cannula prior to procedural sedation. In these cases, procedural sedation may need to begin without these devices, which should then be applied at the earliest point when the patient is sufficiently sedated. Until monitoring devices can be placed, practitioners must maintain heightened focus on direct observation and physical examination to ensure patient safety.

During moderate sedation, some patients may not tolerate all components of routine monitoring. In these circumstances, practitioners should proceed with the monitoring modalities the patient can tolerate supplemented with direct observation and physical examination. As sedation takes effect, additional monitoring devices should be applied, prioritizing pulse oximetry and capnography.

BEHAVIORAL STRATEGIES TO PROMOTE PATIENT COMFORT (STRONG CONSENSUS)

Facilitating a patient's emotional well-being and preventing procedural distress throughout the sedation process is an essential component of procedural sedation and a core competency for practitioners.[136] A calm explanation of the sedation process and procedure as it is occurring is a logical way to allay fear and anxiety. Many age-specific and developmentally sensitive interventions appear to effectively manage a patient's emotional state, alleviating fear/anxiety, and mitigating pain responses (⊕ ⊕).[43,137-143] When time permits, inquiries with the patient (and, when appropriate, family or caregivers) may identify which of these strategies might best address the individual's needs, considering their age, developmental state, intellectual capacity, and baseline anxiety.

For children, practitioners should collaborate, when available, with child life specialists (North America, Europe), play therapists (United Kingdom), or individuals in similar local roles who are trained or have skills in these interventions, although sedation-specific evidence is limited (⊕ ⊕).[144-148] Distraction aids such as books, toys, and tablet computers are likely helpful. Immobilization

boards and devices for physical restraint of children should be avoided and should not substitute for behavioral interventions or, when appropriate, effective pharmacologic sedation.

SEDATIVE REGIMENS (STRONG CONSENSUS)

Sedative planning

No single sedative regimen is ideal for every patient or procedure. Sedation planning should be individualized based on clinical and logistical factors specific to each situation and patient. Agents used for unscheduled procedural sedation include, but are not limited to, ketamine, propofol, dexmedetomidine, etomidate, midazolam, remimazolam, fentanyl, and nitrous oxide. Specific recommendations for sedation indications, regimens, and doses are beyond the scope of these guidelines. We refer readers to recent systematic reviews in Supplemental Figure 1. Drug doses and concentrations should be confirmed before administration, with pediatric doses calculated using appropriate, weight-based methods (e.g., mg/kg) where applicable. For obese patients, most drug doses should be adjusted based on ideal body weight rather than actual weight.

Painful procedures

For moderate to severely painful procedures (e.g., orthopedic manipulation) fentanyl/propofol or ketamine have advantages over the combination of fentanyl and midazolam, which are well suited to mildly painful procedures.[149,150] Fentanyl and midazolam have a slower and less predictable onset, making titration more difficult, risking either undersedation with inadequate patient comfort or oversedation with respiratory depression.[151] When used for deep sedation, fentanyl and midazolam also require extended administration and recovery times, placing greater demands on bedspace, staff, and monitoring (⊕ ⊕ ⊕).[149,151] For moderate to severely painful procedures, deep or dissociative sedation can reliably ensure patient comfort and safety.[8,19,30,31,152-154]

Co-administered drugs

All sedatives can be safely and effectively used as single agents for a variety of indications. In specific patients and/or circumstances, however, second agents may be added with the intent of enhancing patient comfort and/or safety.

Adjunctive midazolam in adults, for example, modestly decreases recovery agitation with ketamine, while no similar benefit in children has been demonstrated, where recovery agitation occurs less frequently (⊕ ⊕ ⊕ ⊕).[50,155-157]

For painful procedures with IV midazolam as the principal sedative, fentanyl is commonly added to provide analgesia. While this combination enhances comfort, the close co-administration of opioids and sedatives appears to modestly increase adverse event risk (⊕ ⊕ ⊕).[6,15,158-160] Clinicians should be particularly attentive to cardiopulmonary depression when sedation occurs within approximately 30 minutes of opioid administration.[158]

Propofol also lacks analgesic properties. Many practitioners address this by pre-treating patients undergoing painful procedures with opioids to achieve substantial analgesia before sedation. An equally safe and effective alternative is "ketofol"—the co-administration of propofol with subdissociative ketamine (⊕ ⊕ ⊕ ⊕).[154,161-164] Proponents of ketofol maintain that adding ketamine ensures analgesia and adds blood pressure support, and point to conflicting evidence of enhanced sedation consistency. Critics argue that propofol alone (typically after fentanyl premedication) is equally safe and effective, and that adding ketamine unnecessarily complicates drug administration and can cause recovery agitation.[162] In contrast to operative anesthesia, the necessity of analgesia during propofol sedation has been questioned. Adult randomized controlled trials comparing propofol with or without opioids, have found no differences in reported pain, recall, or serum catecholamine levels (⊕ ⊕).[28,165]

Historically, co-administered anticholinergics were commonly advised; however, they are associated with more frequent adverse events and are no longer recommended (⊕ ⊕ ⊕).[50,166-168]

Modern procedural sedation is off-label

Current product labeling by the Food and Drug Administration (FDA), which regulates drugs in the U.S., remains incomplete and inconsistent with the extensive procedural sedation literature. As a result, essentially all medications used in modern procedural sedation practice are off-label, despite their well-established safety. Unless FDA product labeling undergoes comprehensive updates to reflect recent decades of procedural sedation advances, such labeling should not supersede the wealth of evidence from the procedural sedation-specific medical literature.

SUPPLEMENTAL OXYGEN (STRONG CONSENSUS)

The use of supplemental oxygen during procedural sedation is an area of high practice variance.[169,170] Many clinicians and settings use it routinely, while many others either do not or selectively choose to use it for specific patients or sedation regimens. It may seem intuitive that this precaution should

enhance safety, particularly in children whose oxygen reserves are more rapidly depleted than those of adults.[2]

Multiple studies have found that supplemental oxygen can decrease the frequency of hypoxemic episodes during sedation (⊕ ⊕ ⊕ ⊕);[171-177] however, these occurrences are typically transient, resolve with minimal or no intervention, and therefore manifest minimal clinical relevance. Far more important is whether oxygen impacts outcomes that matter, i.e., the more serious or consequential adverse events that require rescue interventions.[169,170] None of these studies have found reductions in the frequency or magnitude of such clinically important outcomes (⊕ ⊕).[171-177]

In the largest and most methodologically rigorous study of 85,599 pediatric sedation encounters, Li et al found no association of supplemental oxygen with a clinically important outcome—the frequency of rescue interventions for airway, respiratory, or cardiovascular adverse events.[169] Their sample predominantly used propofol and included a variety of practice settings. The study's large sample permitted them to confirm this negative outcome in multiple subgroups: high-risk children, low-risk children, ketamine-only, and pre-oxygenation only.[169] These pediatric results cannot directly inform adult care; however, given that oxygen reserves for healthy, non-obese adults are substantially greater than those in children, any potential benefit of supplemental oxygen for them would seem even less likely.[170]

Given the absence of compelling evidence that supplemental oxygen improves procedural sedation safety, its use should be considered optional and not required (⊕ ⊕). (Naturally, oxygen must always be immediately available should rescue interventions be required. Note also that this discussion does not apply to nitrous oxide, where oxygen is automatically co-administered as part of its administration.) Advocates argue that oxygen may benefit some patient subgroups who have yet to be identified, and likely causes no harm. Critics argue that it represents unnecessary staff resource utilization, cost, potential patient anxiety (particularly in children who may fear oxygen masks), and that its use renders pulse oximetry ineffective as an early warning device—potentially delaying the identification of ventilatory depression.[170] As noted in the monitoring section of these guidelines, when using supplemental oxygen, capnography is the sole monitoring device that promptly identifies impaired ventilation.

RESCUE AND REVERSAL AGENTS (STRONG CONSENSUS)

The hallmark of safe procedural sedation is the care team's ability to provide prompt and effective interventions in response to adverse events such as airway, ventilatory, or hemodynamic compromise. These "rescue interventions" may be minor and preventative (e.g., tactile stimulation or airway repositioning) or they may be more invasive (e.g., suctioning, positive pressure ventilation).

When opioids are part of the sedation regimen, the antagonist naloxone may be used to reverse opioid-induced respiratory depression and assist with rescue. Similarly, when benzodiazepines are part of the sedation regimen, the antagonist flumazenil can be administered to reverse benzodiazepine-induced oversedation, which may be associated with respiratory depression.

RECOVERY (STRONG CONSENSUS)

Following sedation, patients should be monitored until they are no longer at risk for airway obstruction or respiratory depression, they are alert and at age-appropriate baseline levels of consciousness, and they have normal or baseline vital signs.[1,2] Many institutions use specific discharge scoring scales for this purpose and practitioners should adhere to local policies. There is no literature supporting a need to establish a willingness or ability to take oral liquids.[1] If the patient is being discharged post-recovery it should be to the care of a responsible adult, with appropriate verbal and written care instructions given to the patient and their family or caregivers. Children normally capable of sitting upright unaided should be able to again do so before being transferred to a car or booster seat. If a patient is being admitted or otherwise transferred to a different care team, an appropriate hand-off should occur between practitioners prior to that transfer.

DOCUMENTATION (STRONG CONSENSUS)

Requirements will vary by setting; however, the sedation team should document the patient pre-sedation evaluation, drugs administered with their doses and timing, any adverse events and their interventions, serial assessments from interactive and physiologic monitoring, and any unusual events or outcomes. This documentation must be sufficient to permit quality reviews.

The sedation plan and patient evaluation should optimally be documented prior to sedation, in keeping with regulatory guidance developed for elective situations. However, this timing should not be maintained if documentation would delay emergent procedures. In such circumstances, documentation will appropriately occur post-procedure.

THE FUTURE (STRONG CONSENSUS)

We pose key steps for future improvement of procedural sedation clinical practice.

Outcomes research

Since patient-oriented and clinically important adverse events during procedural sedation are rare, large samples are required to study them. Further sizable studies are warranted to monitor outcomes, as changes over time occur with procedural indications, sedation regimens, and patient comorbidities. Establishing a registry to track the most significant events should be considered, similar to existing models used by the anesthesia community for malignant hyperthermia and adverse incident reporting.

Focused research is also needed to better define optimal procedural sedation strategies for populations underrepresented in typical studies, e.g., infants under 12 months, pregnant patients, obesity, the elderly, and those with severe underlying illness. Additionally, research on patient and family perspectives on sedation outcomes and experiences would help align clinician-defined best practices with patient-centered values and preferences.

Risk prediction

Given its inaccuracy and unreliability for sedation risk prediction, the ASA physical status classification should be deemphasized or discontinued.[105] Future research should identify whether this score might be refined or improved, and determine if effective risk prediction requires more than a simple, unstructured assessment of underlying health.[110]

Predicting ventilatory depression

The application of computational tools for analyzing continuous, high-resolution monitoring data – using artificial intelligence – may permit ongoing, real-time automated risk estimation. This would allow clinicians to titrate drug administration and focus interactive monitoring based on advanced risk assessments rather than traditional, cruder measures such as repeated patient stimulation.[26,27,132,178]

Fasting

There have been major changes in thinking regarding pre-sedation fasting based on observational studies and systematic literature review.[5,9,10,72] Further evaluation through large, prospective studies would be ideal to confirm these findings, with more granular detail preferred regarding the timing and nature of oral liquid and solid intake.

The focus of preventing aspiration has long been strict fasting. Newer findings, such as the absence of greater risk with incomplete fasting during unscheduled sedation,[5,9,10,72] and the lower-than-anticipated impact of GLP-1 agonists during operative anesthesia,[93,98] suggest that gastric contents may be less important than other factors, e.g., esophageal disorders, airway instrumentation and frailty. These findings have important implications for elective procedural sedation (and perhaps for operative anesthesia), warranting prospective trials of reformed fasting strategies.[179,180]

Propofol and hypotension

Although clinically important hypotension appears rare in the majority of propofol sedation studies, this is not always the case depending on the procedure and the patient population.[125] Future research should focus on blood pressure maintenance in the elderly and during propofol sedations that are not brief.

Target-controlled infusions

Target-controlled infusion technology has thus far received only preliminary study for procedural sedation. This computer-driven drug administration based on pharmacokinetic modeling smooths out the peaks and troughs of sedative drug concentrations. Theoretically, this approach might diminish hypoventilation, help ensure more consistent patient comfort, and permit the sedation practitioner to focus more closely on the patient without the distraction of repeat bolus sedative drug administration.[181-184]

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