Sedation and Analgesia in the Interventional Radiology Department

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Administration of sedation and analgesia in the interventional radiology suite is often necessary during painful diagnostic and therapeutic procedures. Although sedative and analgesic agents are generally safe, catastrophic complications related to their use can occur, often as a result of incorrect drug administration or inadequate patient monitoring. The incidence of adverse outcomes related to provision of sedation and analgesia can be reduced with improved understanding of the pharmacology of these medications, by providing adequate monitoring to sedated patients, by recognizing patients who are at increased risk of experiencing an adverse drug reaction, and by early and appropriate management of complications.

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Abbreviations: ASA = American Society of Anesthesiologists, BZD = benzodiazepine, CNS = central nervous system, IR = interventional radiology

analgesia, they are usually not avail-

able to attend all IR cases, and the re-

sponsibility of medication administra-

tion and patient care often falls on the

INVASIVE diagnostic and therapeutic procedures performed in the interventional radiology (IR) suite can be painful and anxiety provoking (1-5), rendering patients unable to follow breathing and movement instructions and potentially increasing the risk of cardiovascular complications (6,7). To calm patient anxiety, reduce unwanted movements, and alleviate patient discomfort, it may be necessary to provide pharmacologic sedation and analgesia. Proper use of these agents improves patient satisfaction, reduces procedure times, and stabilizes hemodynamic status, but incorrect drug administration or inadequate patient monitoring can precipitate disastrous complications (8-10).

Although anesthesiologists are best equipped to administer sedation and

interventionalist. The provision of sedation and analgesia by properly trained nonanesthesiologists is thought to be safe (11–15), provided that proper methods of drug administration and patient monitoring are adhered to. The purpose of this article is to review the topic of sedation and analgesia as it applies to the IR area by discussing the medications available for the provision of sedation and analgesia, describing the proper care of sedated patients, and outlining the management of a number of potential complications of sedation and analgesia. The patient care recommendations included in this review are primarily derived from practice guidelines outlined by the American Society of Anesthesiologists (ASA) task force on sedation and analgesia by nonanesthesiologists (12) and other guidelines published in the anesthesia and medical literature (12,14,16).

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DEFINITIONS

Sedation refers to the use of pharmacologic and nonpharmacologic means to depress the central nervous system (CNS) and reduce patient anxiety and irritability. Proper sedation achieves anxiolysis (a state of diminished apprehension) and, in some circumstances, amnesia (a loss of memory of events during the procedure) (12). The stages of sedation have been categorized in an attempt to define targeted endpoints for drug administration (Table 1). Although these categories are useful to guide therapy, the depth of sedation is not easily divided into discrete stages but rather refers to a therapeutic continuum with infinite points ranging from minimal anxiolysis to coma (Table 2).

Moderate sedation/analgesia is a depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. The patient maintains airway patency and spontaneous ventilation, and cardiovascular function is usually maintained. Moderate sedation provides sufficient anxiolysis and control of unwanted movement for most IR cases, and respiratory compromise is rare. This level of sedation is therefore an appropriate target for cases that are not supervised by an anesthesiologist.

Deep sedation/analgesia is a depression of consciousness during which patients cannot be easily aroused but respond purposefully after repeated or painful stimulation. The ability to independently maintain a patent airway and ventilatory function may be impaired. Cardiovascular

Table 1
Definition of General Anesthesia and Levels of Sedation/Analgesia

	Responsiveness	Airway	Spontaneous Ventilation	Cardiovascular Function
Minimal sedation (anxiolysis)	Normal response to verbal stimulation	Unaffected	Unaffected	Unaffected
Moderate sedation/analgesia ("conscious sedation")	Purposeful response to verbal or tactile stimulation	No intervention required	Adequate	Usually maintained
Deep sedation/analgesia	Purposeful response after repeated or painful stimulation	Intervention may be required	May be inadequate	Usually maintained
General anesthesia	Unarousable even with painful stimulus	Intervention often required	Frequently inadequate	May be impaired

Note.—Adapted from Practice guidelines for sedation and analgesia by non-anesthesiologists. Anesthesiology 2002; 96:1004–1017. Used with permission.

function is usually maintained. The intentional induction of deep sedation by nonanesthesiologists is discouraged because of the significant incidence of airway and respiratory compromise.

The term conscious sedation continues to be used in both the anesthesia and nonanesthesia literature. However, this term is no longer included in the ASA standards (12), and its use is discouraged because it is imprecise and potentially misleading (17–19).

Analgesia is defined as relief of pain without intentional production of an altered mental state such as sedation (20). Analgesia can be targeted to the site of drug administration (local anesthesia) or can have a systemic effect (eg, intravenous opioids).

GOALS OF SEDATION AND ANALGESIA

Surveys of practice patterns of sedation and analgesic use in IR departments in Europe and North America reveal that procedural medication delivery patterns are highly variable, with different levels and methods of sedation being used for similar procedures in different institutions (21–23). The use of sedation and systemic analgesia during routine diagnostic angiography was common in these surveys, despite the fact that most patients undergoing angiography experience only mild discomfort (4). Lang et al (3) reported that decisions regarding the use of sedatives and analgesics during IR procedures were primarily determined by habits and

Table 2 The Sedation Continuum

Alert-anxious

Alert-calm (anxiolysis)

Drowsy but clear mentation (sedation)

Eyes open, speech slurred

Eyes closed but answers questions appropriately

Opens eyes to voice, is confused Oxygen desaturation on room air

Opens eyes to pain, responds purposefully

Eyes closed, moans and withdraws from pain

Moans to pain, nonspecific motor response to pain CO₂ retention

Oxygen desaturation on 2 L O_2

No response to pain Bradypnea, poor gag reflex

Apnea, hypotension
Death

Note.—Adapted from reference 13. Used with permission.

philosophies of the institution and that neither patient anxiety and pain scores nor physician decisions affected drug utilization. These papers illustrate the importance of developing an approach to medication administration that focuses on the needs of the individual patient, in which requirements for sedation and analgesia are determined on a case-by-case basis by the pain tolerance and anxiety level of the patient and by the level of discomfort that is expected during the procedure.

For all IR cases, it is recommended that a desired endpoint for sedation be decided on before medication is given, and medications should be administered incrementally until this endpoint is achieved. Medication should be administered in an attempt to achieve the following goals:

- To provide adequate analgesia, sedation, anxiolysis, and amnesia during the performance of painful diagnostic or therapeutic procedures
- To control unwanted motor behavior that inhibits the performance of diagnostic procedures or image-guided interventions,
- 3. To rapidly return the patient to a state of consciousness,
- To minimize the risks of adverse events related to the provision of sedation and analgesia.

Drug Class	Drug	Effects	Incremental Dose*	Onset (min)	Duration (min)
Hypnotics	Midazolam	Sedation, anxiolysis, amnesia, motion control, no analgesia	1.0 mg	2	45-60
	Diazepam	Sedation, anxiolysis	1.0–2.0 mg	2-3	6 h
	Propofol	Anesthetic, sedation	25–75 μg/kg/min infusion	60 s	3-5
	Ketamine	Analgesia, dissociation, amnesia, motion control	5–10 mg, repeat every 10 min with ½ dose	1–2	Dissociation: 15, recovery: 60
Analgesics	Fentanyl	Analgesia	25 μg/dose, repeat every 3 min to desired effect	2–3	30-60
	Sufentanil	Analgesia	2 μg/dose	2-3	15
	Remifentanil	Analgesia	$0.1-0.2 \mu g/kg/min$	3-5	5–7
	Morphine	Analgesia	2 mg/dose	3-10	3–4 h
Miscellaneous	Nitrous oxide	Anxiolysis, analgesia, sedation, amnesia	Preset mixture, self-administered	1–2	<5 min after discontinuatio
Reversal agents	Naloxone	Opioid reversal	40 μg/dose, repeat every 2 min as required to maximum of 2 mg	2	20-40
	Flumazenil	Benzodiazepine antagonist	200 μg/dose, repeat every 1 min to maximum of 1 mg	12	30-60

MEDICATIONS

The most commonly used medications for the administration of sedation and analgesia are summarized in Table 3.

Hypnotics and Sedative Drugs

Benzodiazepines.—Benzodiazepines (BZDs) act on γ -aminobutyric acid receptor sites, causing a dose-related CNS depression. They cause anxiolysis, antegrade amnesia, and hypnosis and have an anticonvulsant effect. They have no analgesic effect. In excessive doses, general anesthesia may be induced. In susceptible patients, particularly the elderly and those with chronic obstructive airway disease, respiratory depression and apnea may occur at lower doses (24,25).

Midazolam (Sabex, Boucherville, Canada) is a short-acting BZD. It is usually given intravenously but may be used orally. Onset of effect is within 2 minutes, lasting between 45 and 60 minutes. The short-acting sedative effect with rapid recovery, low risk of respiratory depression, and antegrade amnesic effects associated with midazolam makes it the favored sedative agent used by nonanesthesiologists to achieve moderate sedation for radiology procedures (26). It should be given in 1-mg increments

to the desired response. Although this agent is relatively safe, more than 80 deaths have occurred after midazolam use in patients undergoing a variety of medical and surgical procedures. These were mainly respiratory in nature, and in 57% of cases, an opioid had also been used (10).

Diazepam (Sabex) is a mediumacting BZD that may be given orally, intramuscularly, rectally, or intravenously. In an aqueous solution, it causes pain on injection and thrombophlebitis. A lipid emulsion preparation is therefore preferable if diazepam is to be given intravenously. It has a predictable onset of action in 2–3 minutes if given in 1- to 2-mg increments. Its duration of effect is at least 6 hours with a hangover effect due to its active metabolite desmethvldiazepam. Diazepam is not as well suited as midazolam for use as a sedative because of less pronounced amnesic effects, long duration of effect, and long hangover effect.

Lorazepam (Ativan; Sabex) is a long-acting BZD that may be given orally, sublingually, intramuscularly, or intravenously. It is usually given orally or sublingually in a 0.5- to 1.0-mg dose. Its onset of effect is as long as 60–90 minutes, and it has a variable duration of effect with a prolonged amnesic effect. Because of

its slow onset and prolonged effect, it is not suitable as a titratable agent for sedation. Machinery should not be operated for 48 hours after administration of this drug.

Other Hypnotic Drugs.—Propofol (Abbott Laboratories, Saint-Laurent, Canada) is an intravenous general anesthetic induction agent that is often used for monitored anesthetic care by anesthesiologists. It is administered by continuous infusion or in a 10- to 20-mg bolus. Onset of action is 60 seconds, lasting 3–5 minutes. There has been substantial investigation into the use of propofol as a sedative agent for patients undergoing endoscopic and IR procedures. Many of these articles claim that propofol has a favorable side effect profile and improved sedative effects compared with the use of intravenous midazolam and opioids (5,27-30). However, even in relatively low sedative doses, propofol can unpredictably cause a loss of airway reflexes. Propofol can rapidly cause apnea in excessive doses, and in larger boluses, dystonic reactions may occur with patients withdrawing from painful stimuli. It also causes significant hemodynamic depression in susceptible patients. For these reasons, current guidelines recommend that propofol only be used under the supervision of an anesthesiologist (12).

Ketamine (Ketalar; Parke-Davis, Amprior, Canada) is an intravenous general anesthetic induction agent that has intense analgesic properties. It is given in 5- to 10-mg increments. Its onset of effect is 1-2 minutes, lasting 45-60 minutes. It causes dose-related hallucinations and dissociative symptoms, more commonly women. Ketamine can cause involuntary muscle movement, potentially limiting its suitability in IR procedures. Hemodynamic stability and cerebral blood flow are maintained. Ketamine is more commonly used in pediatric patients (31,32). It is recommended that ketamine be used under the supervision of an anesthesiologist

Analgesics

Analgesics.—Nonsteroidal Simple antiinflammatory drugs. This broad category of pharmacologic agents includes salicylates (eg, aspirin), propionic acid derivatives (eg, ibuprofen, naproxen, ketoprofen), fenamates (eg, diclofenac), and indoles (eg, indomethacin). All these agents have analgesic, antipyretic, and antiinflammatory effects resulting from inhibition of cyclooxygenase activity. Nonsalicylate compounds are favored as oral analgesic agents due to a more favorable side effect profile. These agents should not be used in patients with active peptic ulcer disease or gastrointestinal bleeding or those with a history of bronchospastic reactivity to these agents. Renal toxicity can occur with the use of these agents, and they should be used only with great caution in patients with dehydration, on diuretic therapy, with liver disease, or with diminished renal function.

Acetaminophen has analgesic and antipyretic properties with minimal antiinflammatory effects. It is used as an oral analgesic agent alone or in combination with other analgesic agents, particularly opioids. The analgesic mechanism of acetaminophen is not well understood but is thought to be through inhibition of prostaglandin synthetase in the CNS. Acetaminophen has very limited side effects in therapeutic doses and is typically administered orally in 325- to

1,000-mg doses every 4–6 hours, with a maximal 24-hour total dose of 4,000 mg.

Opioids.—Opioid analgesics bind opioid receptors distributed widely throughout the CNS. They are potent analgesics and have a sedative effect but may cause dysphoria, nausea, vomiting, and respiratory depression. These adverse effects limit their use to painful procedures in which analgesia is required for the duration of the procedure. To avoid respiratory depression, incremental doses are advisable. Opioids act synergistically with BZDs and decrease BZD dose requirements to achieve a given level of sedation (10,33). As a result of the potential respiratory complications associated with their use, the administration of opioids by nonanesthesiologists is discouraged in some institutions.

Fentanyl (fentanyl citrate; Sabex) is a short-acting opioid. It is given in 25-µg increments, and its onset of effect is 2-3 minutes with a 30- to 60minute duration of analgesic effect. Given in larger doses, it may cause dizziness and apnea. Small doses (25–50 μ g) may reduce the required doses of concomitant sedative agents. Fentanyl is favored over other opioids by most physicians for short painful procedures because of its rapid onset and suitable duration of effect. The respiratory depressant effect of fentanyl lasts as long as 4 hours longer than its analgesic effect. Therefore, susceptible patients need to be monitored carefully postprocedure.

Sufentanil (Sufenta; Janssen-Ortho, Toronto, Canada) is a short-acting opioid that is eight to 10 times more potent than fentanyl with a similar onset of effect. For use in a moderately sedated patient, sufentanil should be given in 2-µg increments. Incremental dosing necessitates dilution of the medication preparation. Sufentanil is more lipid soluble than fentanyl and may cause more drowsiness, even in lower doses.

Remifentanil (Ultiva; Abbott Laboratories, Vaughan, Canada) is a new opioid with a rapid onset of 1–2 minutes and a short duration of action (5–7 minutes). It is administered by an infusion titrated to desired effect. Apnea is common at inappropriate infusion rates, and an anesthesiolo-

gist should supervise use of this agent (12). Postprocedure nausea is common.

Morphine (morphine sulfate; Abbott Laboratories, Toronto, Canada) is a long-acting opiate that is sedative, anxiolytic, and analgesic. Its onset of effect is 3–10 minutes if given intravenously and is given in 2-mg increments. It has an analgesic effect of 3–4 hours. Because of its longer duration of action, it is less suitable than fentanyl as a titratable and reversible sedative/analgesic agent. Morphine often causes dysphoria and nausea.

Miscellaneous

Nitrous oxide (VitalAire, Vancouver, Canada) was first used in clinical practice in 1844. It is a colorless, inorganic natural gas. It has a good analgesic effect and in low concentrations leads to dissociation. In higher doses, disinhibition may occur. It is administered in 50% oxygen through a mask. Its onset is 1–2 minutes, and its effect is terminated within minutes of removing the mask. It may be useful for short-duration procedures but must be used in well-ventilated rooms to avoid operator effects.

Local Anesthetic Drugs

Local anesthetics reversibly depress impulse transmission in nerves with subsequent anesthesia and motor block to a specific area. Sufficient infiltration with local anesthesia may markedly reduce sedation and analgesic requirements but does not entirely obviate these medications in most situations (34).

Lidocaine (Xylocaine; Astra-Zeneca Canada, Mississauga, Canada) is an amide local anesthetic agent with a rapid onset and a medium duration of action. It is available in an injectable form in solutions of 0.5%-5% and as a topical gel. Onset of action is 2-5 minutes, and the duration of anesthesia is approximately 1 hour without epinephrine and 2 to 3 hours with solutions containing epinephrine. The maximal safe single dose is 300 mg (3 mg/kg) without epinephrine and 500 mg (7 mg/kg) with the addition of epinephrine. CNS toxicity is dose limiting. Lidocaine is acidic and can cause pain at injection. Adding 1 mL 8.4% sodium bicarbonate solution to 9 mL lidocaine immediately before injection can reduce this pain.

Abbott Bupivacaine (Marcaine; Laboratories, Mississauga, Canada) is an amide local anesthetic with a slower onset of action and longer duration of effect than lidocaine. It is available in an injectable form in solutions of 0.25%-0.75%. Onset of action is 5-10 minutes, making it a less desirable drug for local infiltration in IR procedures. Its duration of effect is 3-4 hours and longer with epinephrine, making it a suitable agent for postoperative pain relief. The maximal safe dose is 150 mg without epinephrine and 225 mg with the addition of epinephrine. Bupivacaine is a highly cardiotoxic drug with a long half-life, and intravenous administration needs to be scrupulously avoided.

Local infiltration with a mixture of 2% lidocaine and 0.25% bupivacaine results in a rapid onset block with a long duration of effect, and this combination of properties is often desirable for IR procedures with significant postoperative discomfort. Because these drugs share the same metabolic pathway, care needs to be taken not to approach a cumulative toxic dose.

Reversal Agents

These agents should be given judiciously in increments, waiting at least 1-2 minutes between each dose. Rapid or overzealous reversal can precipitate an anxiety response as well as an antalgesic response. Caution is required because the sedative effects of the drugs used may outlast the reversal effect of these agents.

The use of reversal agents should be reserved for instances in which patients have inadvertently been sedated more deeply than was intended or in patients experiencing a complication of sedation and analgesia. Most patients should not need any reversal if sedative agents have been used

appropriately.

Naloxone (Sabex) is an opioid antagonist that reverses both the respiratory and analgesic effects of opioids. Drug administration should be titrated in 0.04-mg increments to the desired effect to minimize the reversal of the analgesia effect. Because its duration of effect is <90 minutes, which is considerably shorter than that of some

opiates, repeated doses may need to be given.

Flumazenil (Anexate; Hoffmann-La Roche, Mississauga, Canada) is a competitive antagonist at the y-aminobutyric acid/BZD receptor. The dose for reversal is 0.01 mg/kg and should be given in increments of 0.1-0.2 mg in adults. Its duration of effect is 15-140 minutes, and patients may become resedated after this period, particularly if longer acting BZDs are used. If flumazenil has been used, patients must be monitored for 2 hours after the procedure to ensure that they do not become resedated after reversal effects wear off. Some patients may experience intense agitation on reversal of BZD activity. This drug should be used with caution in any patient on long-term BZD treatment.

NONPHARMACOLOGIC ADJUNCTS FOR SEDATION

Nonpharmacologic methods of analgesia and sedation such as hypnosis and anodyne imagery have been successfully used in the IR department (35-38). They have been shown to significantly reduce drug requirements, and hypnosis has been shown to be a cost-effective method of delivering care to IR patients (39). Although the training of staff in techniques of hypnosis is reported to be relatively simple, the practice of nonpharmacologic methods of sedation and analgesia has yet to become widespread.

SUGGESTIONS FOR ADMINISTRATION OF SEDATION AND ANALGESIA

Many different medications are available for the induction of moderate sedation during IR procedures, and the drug or drug combination used in an institution will often vary depending on operator preference and experience. Some principles of drug administration may help to ensure safe and effective use of these agents:

- 1. Sedative drugs should be easily titrated to the desired clinical effect and should have a predictable onset and duration of effect with a rapid recovery
- 2. Întravenous drug administration is favored because it results in a more reliable rate of

- onset and a more predictable rate of absorption.
- 3. Each drug should be given in increments.
- 4. Appropriate time needs to be given to allow the drug effect to be evaluated before giving the next incremental dose or a different drug.
- 5. Drug combinations need to be used prudently and according to required effect and patient response.
- 6. Repeated increments need to be given throughout the procedure to maintain an adequate level of patient comfort.

For all patients in whom pain is anticipated during the procedure or in the recovery period, preemptive analgesia should be administered. Preemptive analgesia is based on the premise that the initiation of antiinflammatory and analgesic agents before the initiation of the procedure reduces peripheral nociception and decreases postoperative analgesic requirements (40). All patients undergoing painful procedures should receive acetaminophen (1 g orally) and a nonsteroidal antiinflammatory drug (eg, 50 mg diclofenac sodium, 500 mg naproxen orally or rectally) 30-60 minutes before the anticipated time of initiating the procedure. Skin infiltration with local anesthesia is part of the practice of preemptive analgesia (41), and liberal use of these drugs with a combination of long- and short-acting agents is recommended.

Effective, moderate sedation can be achieved with the administration of a short-acting BDZ, either alone or combined with an opioid agent. In the authors' opinion, midazolam should be administered intravenously in 1-mg increments until a desired level of sedation and anxiolysis is achieved. Fentanyl can also be used in small (25 μ g) increments to potentiate the sedative effects of midazolam and to provide systemic analgesia. Larger doses of opioids may be necessary during particularly painful procedures such as hepatobiliary interventions or uterine fibroid embolizations.

SKILLS AND TRAINING OF PERSONNEL

All personnel responsible for the administration of sedation and analgesia and the monitoring of sedated patients both during and after the procedure must be capable of recognizing and acting on complications of oversedation. They must have knowledge of the pharmacology of the drugs that they are administering and be familiar with available antagonists (12). Personnel should be capable of maintaining airway patency and assisting ventilation. It is recommended that an individual with advanced cardiac life support skills be immediately available in cases in which moderate or deep sedation is administered.

During IR procedures, two qualified individuals must be present to ensure adequate care of a sedated patient. The interventional radiologist is responsible for overseeing drug administration and ensuring patient safety. A second designated individual, usually a nurse or a respiratory technologist, must be present during the procedure to monitor the patient for adverse drug reactions, to assess the response to medications, and to acquire and record vital signs. During moderate sedation, this individual may assist with minor interruptible tasks provided that adequate monitoring of the patient's level of sedation is maintained (12). During deep sedation, whether intentional or accidental, this designated individual should have no other responsibilities besides monitoring the patient and providing assistance with ventilation as needed.

EQUIPMENT AND SETTING

Appropriate sedative and analgesic agents and their relevant reversal agents should be immediately available in the IR area. An oxygen source, suction equipment, nasal cannulae, appropriately sized oral airways, and a bag-valve mask should be in the procedure room. IR suites should be equipped with a cardiac monitor, an automatic blood pressure cuff, and a pulse oximeter. Appropriate emergency equipment must be immediately available. All IR departments should be equipped with a cardiac monitor/defibrillator, a laryngoscope, age-appropriate cuffed endotracheal tubes, and standard resuscitation

The primary goal of administration of sedation is anxiolysis, and care should be taken to provide a treatment

Table 4 ASA Physical Status Classification

- I. Healthy patient
- II. Mild systemic disease: no functional limitation
- III. Severe systemic disease: definite functional limitation
- IV. Severe systemic disease that is a constant threat to life
- V. Moribund patient not expected to live without the operation

environment that minimizes patient anxiety. Patients who undergo procedures while awake are exposed to a number of anxiety-provoking auditory and visual stimuli. It has been demonstrated that modifying these stimuli by providing music and limiting ambient noise may reduce analgesic and sedative requirements (42,43), although the literature is not unanimous in this regard (44).

PREPROCEDURE PATIENT PREPARATION

Patients should be evaluated with a medical history and physical examination to determine the degree of physiologic reserve of the CNS and cardiovascular and respiratory systems and to assess for the likelihood of the patient experiencing an adverse reaction to sedation. Details of medication use, drug allergies, time of last oral intake, abnormalities of major organ systems, and alcohol or substance abuse should be elicited. The physical examination should include assessment of vital signs, level of consciousness, weight, and evaluation of airway. The patient's ASA status should be determined (Table 4).

Preprocedure fasting may decrease the risk of aspiration of gastric contents, a rare but potentially fatal complication of deep sedation and general anesthesia. Although the duration of fasting required before administration sedation remains controversial (12,45), the ASA has recommended 6 hours of no oral intake for solids and 2 hours for clear liquids. In emergent situations in which preprocedure fasting is not practical, care should be taken to protect against aspiration by limiting the depth of sedation, delaying the procedure, or arranging for endotracheal intubation.

Medications intended to decrease the risk and consequences of aspiration include prokinetic agents such as metoclopramide (Reglan; A.H. Robbins, Richmond, VA) (10 mg intravenous) to increase gastric motility and promote emptying, and histamine H2 receptor antagonists such as ranitidine (Zantac; Glaxo, Research Triangle Park, NC) (50 mg intravenous) to decrease the pH of gastric contents (46). The use of these drugs should be considered in patients who are at high risk of reflux (eg, obese, pregnant, emergency nonfasting, or a history of hiatal hernia or scleroderma) or who have a depressed level of consciousness before the procedure (eg, previous stroke, head injury, intoxication).

Patients who are taking nothing by mouth for prolonged periods may become dehydrated and consequently are at higher risk of contrast material-induced nephropathy when undergoing image-guided interventions. Those considered at risk of contrast material nephropathy should be hydrated with 0.45% saline at 1.0–1.5 mL/kg per hour from the onset of the nothing by mouth status (47).

PATIENT CONSENT

A discussion of the risks and benefits of receiving sedation and analgesia should be included during acquisition of informed consent. Estimates of the incidence of adverse events and fatalities related to sedation and analgesia are highly variable. However, the overall risk of significant adverse effects is thought to be low. A review of patients who underwent endoscopy after sedation with BZDs and supplemental narcotics reported the incidence of serious cardiopulmonary complications and death as 5.4 and 0.3 per 1,000, respectively (33), and a study of deaths associated with dental procedures estimated the fatality rate as one per 152,000 (48).

PROCEDURE MONITORING AND PATIENT CARE

All patients receiving moderate sedation should receive supplemental oxygen, either through nasal prongs or a mask, and should have adequate intravenous access throughout the procedure and until the patient is no longer at risk of cardiopulmonary de-

Table 5 Sedation Scale (Ramsey Scale)				
Score	Description			
0	None, patient maintains wakefulness			
1	Mild, occasionally drowsy			
2	Moderate, frequently drowsy, easy to arouse			
3	Severe, somnolent, difficult to arouse			
S	Sleeping			

pression (12). All results of patient monitoring, including vital signs, depth of sedation, dose, route, and response to medications, must be documented in the patients' chart. Patients must be continuously monitored to assess the depth of sedation and to recognize complications of oversedation, including respiratory depression, airway compromise, and cardiovascular instability. Assessment of the depth of sedation is greatly simplified by the use of a scoring system such as the Ramsey scale (Table 5).

Vital signs (blood pressure, pulse, respiratory rate), should be recorded before and immediately after any drug administration and should be monitored and recorded at 5-minute intervals until the patient has reached a stable level of sedation. Throughout the procedure and in the immediate recovery period, vital signs should be recorded every 15 minutes. Electrocardiographic monitoring should be used for all patients undergoing deep sedation. It should also be used during moderate sedation for patients with significant cardiovascular disease (12).

All patients undergoing sedation/ analgesia should be monitored by pulse oximetry with appropriate alarms (12). However, monitoring oxygenation by pulse oximetry is not a substitute for monitoring ventilatory function. Deeply sedated patients can hypoventilate and become significantly hypercapnic without becoming hypoxic if they are given supplemental oxygen (49). End-tidal CO2 monitoring allows visual monitoring of the respiratory rate and may detect respiratory depression sooner than pulse oximetry (50). Although CO₂ monitoring requires specialized monitoring equipment, it can be performed on patients wearing an oxygen mask. Patients receiving anxiolysis or moderate sedation are at low risk of respiratory depression, but monitoring of exhaled CO_2 should be considered for all patients receiving deep sedation (12).

POST-SEDATION CARE

Patients continue to be at significant risk of developing complications related to sedation and analgesia after their procedure. Continued observation, monitoring, and predetermined discharge criteria are therefore thought to decrease the likelihood of adverse outcomes after moderate and deep sedation (12). Postprocedure monitoring should be done in an appropriately staffed and equipped area until the patients are at their baseline level of consciousness.

Oxygenation should be monitored until patients are not at risk of hypoxemia. If fentanyl is used as the analgesic agent, most patients are at minimal risk of hypoxemia within 60 minutes of the last dose. Other opioid analgesics may require longer periods of observation. Level of consciousness and vital signs should be assessed and recorded at regular intervals until discharge criteria are met.

Discharge timing for patients undergoing IR procedures are usually determined by the recovery period of the procedure. However, some criteria pertaining to sedation and analgesia must be met before discharge. The following discharge criteria are recommended by the ASA (12):

- Patients should have returned to their baseline level of consciousness.
- 2. Vital signs are stable and within acceptable limits.
- Sufficient time (as long as 2 hours) should have elapsed after the administration of reversal agents (naloxone, flumazenil) to ensure that patients do not become resedated after reversal agents have worn off.
- 4. Outpatients should be discharged in the presence of a responsible adult who will accompany them home and be able to report any postprocedure complications. Patients must be instructed not to drive.
- 5. Outpatients and their escorts should be provided with writ-

ten instructions regarding diet, medications, activities, and a phone number to call in case of emergency.

HIGH-RISK PATIENTS

Obese Patients

Sedated obese patients are at increased risk of gastroesophageal reflux, upper airway obstruction, and oversedation (51,52). The risk of reflux may be reduced by strict adherence to fasting requirements and preprocedure treatment with an oral H2 antagonist and metoclopramide. Upper airway obstruction can occur in obese patients at lighter levels of sedation, and therefore patients should be carefully monitored for this complication. Obese patients are more susceptible to the respiratory depressant effects of sedative agents, and drug doses should be based on an estimated lean body mass not total body mass. Incremental dosing and waiting for effect are crucial.

Patients with Chronic Obstructive Pulmonary Disease

Patients with chronic obstructive pulmonary disease are at substantial risk of respiratory adverse events resulting from the administration of sedation and analgesia. Supine positioning of these patients impairs chest muscle wall function, further reducing functional residual capacity and impeding adequate oxygenation. Patients with severe chronic obstructive pulmonary disease already have a blunted ventilatory response to CO₂, and excessive sedatives and opiates will further compromise this response, predisposing patients to severe respiratory depression with excessive sedation.

Supplemental oxygen must be provided to all patients with chronic obstructive pulmonary disease. All prescribed bronchodilatory medications should be given before the procedure. Attempts should be made to limit the use of opiates and sedative agents where possible. Adequate local anesthesia can substantially reduce sedative and analgesic requirements. Incremental dosing and intense patient monitoring are necessary.

Patients with Coronary Artery Disease

Coexistent coronary artery disease is frequently present in patients undergoing IR procedures, particularly for peripheral vascular or renovascular disease. Inadequate sedation can increase the risk of an acute cardiac event in these patients as a result of increased cardiac demand. Similarly, excessive sedation or respiratory suppression can also precipitate cardiac complications by inducing hypotension or hypoxemia.

Ideally, proper sedation and analgesia in the patient with coronary artery disease will reduce or maintain myocardial oxygen requirements and optimize myocardial perfusion and oxygenation. All routine cardiac medparticularly beta-blocker ications, therapy, should be taken on the day of the procedure. Supplemental oxygenation must be provided. Adequate analgesia and anxiolysis must be provided to minimize the stress response to the procedure. Adverse reactions to sedation and analgesia, particularly airway obstruction, hypoxia, and hypotension, must be immediately recognized and corrected.

Patients with Chronic Renal Failure

Most medications (or their metabolites) used for sedation and analgesia are secreted renally, and patients with chronic renal failure receiving these medications will be predisposed to overdose or to prolonged effect. Longer acting opioids such as meperidine and morphine should not be used in these patients, but shorter acting agents such as fentanyl are thought to be safe. Patients with chronic renal failure have an exaggerated response to BZDs, and smaller doses of these medications with incremental dosing should be used. In the authors' institution, dialysis-dependent CRF patients undergo dialysis on the day of the image-guided procedure to correct fluid balance. Because drugs and metabolites are protein bound, hemodialysis is ineffective in removing these substances from the circulation.

Patients with Drug Addiction

Dose requirements in the drug-dependent patient are often unpredictable, and drug tolerance is often encountered. Drug-seeking behavior can be difficult to distinguish from analgesic requirements. Drug-dependent patients should take all prescribed replacement medications (eg, methadone) on the day of their procedure. Adequate local anesthesia will limit systemic analgesic requirements. A short-acting BZD can be used in this patient group with incremental dosing. Severe withdrawal symptoms can be experienced with reversal agents, and therefore these agents should be used with great caution, and only when absolutely necessary.

Elderly Patients

In addition to being associated with a higher incidence of concomitant illness, increased age is an independent risk factor for adverse effects of sedation and analgesia. In elderly patients, sedatives and analgesics elicit a longer lasting and more pronounced effect because of changes in bioavailability and reduction in drug metabolism (24,25). Generally, elderly patients need lower doses on a milligram-perkilogram basis. Once again, conservative incremental dosing should be used in this patient population, and medication requirements should be minimized with the liberal use of local anesthetics.

Pediatric Patients

A complete discussion of the topic of pediatric sedation and analgesia is beyond the scope of this paper, and the interested reader is referred to a current review article dedicated to this topic (14). In general terms, children tend to require higher doses by weight to achieve a given endpoint and have narrower safety margins than adult patients. Respiratory depression and airway obstruction are the most common causes of adverse reaction in pediatric patients, and children 1–5 years of age are most at risk. Currently, most agents that are used for sedation and analgesia in adults are not approved by the U.S. Food and Drug Administration for use in pediatric patients.

WHEN TO ASK AN ANESTHETIST TO ATTEND

ASA guidelines recommend that an anesthesiologist be in attendance for all cases in which deep sedation or general anesthesia is the intended level of sedation. It is also recommended that for procedures on patients of ASA level 3, 4, or 5 during which any more than minimal sedation is to be administered, consideration should be given to seeking the consultation of an anesthesiologist regarding patient care (12).

The frequency with which an anesthesiologist attends IR procedures for other cases is in part determined by institutional habit, anesthesiologist availability, and the comfort level and experience of the interventional radiologist. The radiologist must recognize that some subgroups of patients, such as those previously outlined, are at higher risk of adverse drug reactions and should proceed with sedation only if his/her knowledge and experience justifies doing so.

MANAGEMENT OF ADVERSE REACTIONS TO SEDATION

Excessive Sedation

For most procedures performed without anesthesiology assistance, moderate sedation is the target level of sedation (Table 1), and if a deeper level of sedation is encountered, this should be considered an adverse event. Oversedation is not in and of itself dangerous to the patient. However, risks of airway compromise, hypoventilation, and hemodynamic instability increase significantly with the induction of deep sedation, and a properly trained individual with no other responsibilities must be assigned to monitor deeply sedated patients.

Desaturation

The most common cause of desaturation in sedated patients is airway obstruction. Relaxation of the pharyngeal muscles and loss of muscle tone allows the tongue to fall back and obstruct the upper airway. This is more common at lower levels of sedation in those with sleep apnea and obesity. Snoring, grunting, or complete absence of breath sounds may be ob-

served followed by a gradual decline in oximetry values. Airway obstruction is usually effectively managed with a jaw thrust to support the airway and to arouse the patient. An oral or nasal airway is useful in the oversedated patient to maintain an obstructed airway. Vomiting patients must be rolled onto their side and suction provided to clear the upper airway. Supplemental oxygen therapy delivered by a nonrebreather mask is recommended in all patients with desaturation.

Hypoventilation

Hypoventilation occurs when the normal regulatory balance in the respiratory center is compromised and the ventilatory response to hypoxemia and hypercapnia is blunted. Apneic patients should be encouraged or stimulated to breathe deeply. Suitably trained personnel must be available to support the airway in these patients. Supplemental oxygenation should be provided by a nonrebreather mask, and pharmacologic reversal of the causative agent may be needed. Consideration should be given to insertion of an endotracheal tube if apnea is persistent.

Hypotension

If patients are found to be hypotensive or bradycardic, it should be determined whether the instability is a result of a complication related to the procedure or a result of oversedation. Procedure-related causes of hypotension include hemorrhage, sepsis, dehydration, vasovagal reactions, and anaphylactic reaction to iodinated contrast material. These complications should be immediately recognized and managed appropriately.

Hemodynamic instability resulting from sedation is occasionally encountered in deeply sedated patients, particularly in patients with limited cardiopulmonary reserve. Oxygen should be administered to all hypotensive patients at 10 L/min by a nonrebreathing mask. An intravenous fluid bolus should be delivered while the patient is being assessed. Reversal of excessive medication should be undertaken judiciously. An early call for assistance is prudent because the pa-

tient's condition may rapidly deteriorate without aggressive resuscitation.

Administration of vasopressive agents such as ephedrine (ephedrine sulfate; Sabex) (2.5–5-mg intravenous increments) may be used in combination with adequate fluid management in the management of hypotension. However, potential benefits of pharmacologic intervention in hypotension must be weighed against the risks of overcorrection with potential cardiac and cerebrovascular consequences. If the use of this class of drug is being considered, more experienced assistance should be requested at the same time.

CONCLUSION

The provision of adequate sedation and analgesia to patients undergoing invasive diagnostic or therapeutic procedures in the IR department improves patient satisfaction and facilitates optimal patient care by reducing unwanted movement and stabilizing hemodynamic status. The administration of sedation and analgesia is associated with a significant risk of adverse effects, particularly respiratory compromise. However, knowledge of sedative and analgesic agents and their proper use, careful monitoring of sedated patients during and after interventional procedures, and adequate training of support personnel to recognize and act on complications minimize the risk of permanent injury to the patient.

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Revised 2015 (Resolution 23)*

ACR-SIR PRACTICE PARAMETER FOR SEDATION/ANALGESIA

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care¹. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner in light of all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of this document is to assist practitioners in achieving this objective.

Sedation/Analgesia / 1

^{1 &}lt;u>Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing,</u> N.W.2d (Iowa 2013) Iowa Supreme Court refuses to find that the ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, <u>Stanley v. McCarver</u>, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

This practice parameter was revised collaboratively by the American College of Radiology (ACR) and the Society of Interventional Radiology (SIR) to assist physicians in the safe administration of sedation/analgesia and monitoring of patients receiving sedation/analgesia outside the operating room. Sedation/analgesia allows patients to better tolerate diagnostic imaging and image-guided procedures by relieving anxiety, discomfort, or pain. It facilitates and may optimize diagnostic imaging, image-guided interventions, and radiation oncology procedures that require patient cooperation.

II. SCOPE

The monitoring practice parameters in this guidance document apply to patients who receive minimal sedation beyond anxiolysis, or moderate sedation. Patients receiving a single anxiolytic agent in appropriate doses do not require monitoring [1].

The administration of deep sedation/analgesia requires a greater level of skill and experience and more intensive monitoring than is described here. Deep sedation is within the scope of practice of qualified interventional radiologists but is outside the scope of this document.

Special consideration should be given to patients undergoing sedation in a magnetic resonance imaging (MRI) environment. Relevant issues are addressed by the American Society of Anesthesiologist (ASA) Practice Advisory on Anesthetic Care for Magnetic Resonance Imaging [2].

III. DEFINITIONS

Sedation is a dynamic continuum ranging from minimal sedation/anxiolysis to general anesthesia. Minimal sedation or anxiolysis is defined by the Joint Commission and the ASA as "a drug-induced state during which the patient responds normally to verbal commands." The ASA states further that "although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected" [1].

Moderate sedation/analgesia is a minimally depressed level of consciousness induced by the administration of pharmacologic agents in which the patient retains a continuous and independent ability to maintain protective reflexes and a patent airway and to be aroused by physical or verbal stimulation. Planned levels of sedation/analgesia beyond moderate sedation are outside the scope of this document.

IV. OUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

Sedation/analgesia may be administered by a physician, or by a nurse or licensed independent practitioner under the supervision of a physician. Appropriately trained medical personnel should be immediately available to treat any sedation-related adverse event.

A. Supervising Physician

The supervising physician should maintain the following:

- 1. Sufficient knowledge of preprocedural workup, patient monitoring equipment, medications and their reversal agents, and postsedation management
- 2. Appropriate continuing education in accordance with the <u>ACR Practice Parameter for Continuing Medical Education (CME)</u> [3]
- 3. Current Basic Life Support (BLS) certification. For pediatric sedation, have Pediatric Advanced Life Support (PALS) certification [4]. For adult sedation, have Advanced Cardiac Life Support (ACLS) certification or have an individual with ACLS certification or institutionally approved alternative (e.g., Advanced Radiology Life Support) available with a response time of less than 5 minutes [1].

4. Privileges to perform sedation at their health care institution

B. Health Professional Responsible for Monitoring the Patient

There must be a physician, licensed independent practitioner, or nurse other than the practitioner performing the procedure present to monitor the patient during sedation/analgesia. This individual may administer the medications used for sedation/analgesia and may assist with minor, interruptible tasks during the procedure.

This professional should:

- 1. Be a physician, licensed independent practitioner, or nurse authorized by the facility, whose primary job is to monitor the patient.
- 2. Be appropriately privileged by the institution
- 3. Have current certification in ACLS or institutionally approved alternative (e.g., Advanced Radiology Life Support). If children are being sedated, certification in PALS is needed as well
- 4. Be knowledgeable in the use, side effects, and complications of the sedative agent(s) and reversal agents to be administered
- 5. Be knowledgeable and experienced in monitoring vital signs, using pulse oximetry, and cardiac monitoring, including the recognition of cardiac dysrhythmias and treating associated complications.
- 6. Meet the credentialing requirements of the facility

V. PATIENT SELECTION

Patients who are ASA class I or II qualify for sedation/analgesia outside the operating room; ie, by personnel other than anesthesiologists (See Appendix A.). Patients who are ASA class III or IV may require additional consideration. When the patient's history and comorbidities, current condition, and expected goals and objectives of sedation, either before or during the procedure, exceed the experience or resources of nonanesthesiology sedation personnel, there should be a low threshold for consultation with an experienced anesthesiologist.

These practice parameters specifically exclude the following:

- 1. Patients whose sedation is managed by the anesthesiology or critical care service
- 2. Patients on mechanical ventilation
- 3. Patients who are ASA class V; such patients should not be sedated by nonanesthesiologists

VI. RISK FACTORS

All patients referred for sedation should be appropriately screened by a physician, registered nurse, nurse practitioner, physician's assistant, or other appropriately trained individual for the presence of risk factors that may increase the likelihood of an adverse effect. If risk factors are present, consultation with an anesthesiologist may be considered.

Positive-pressure ventilation, with or without endotracheal intubation, may be necessary if respiratory compromise develops during sedation/analgesia. This may be more difficult in patients with airway abnormality. Some airway abnormalities may increase the likelihood of airway obstruction during spontaneous ventilation (See Appendix B.).

Additional risk factors include, but are not limited to, the following:

- · Recent catastrophic event, ICU admission, surgery, or interventions
- Sedation or anesthesia within 24 to 48 hours of the planned sedation

- Septicemia
- Polypharmacy and polyintravenous therapy
- Lung disease
- Respiratory impairment
- Cardiovascular disease
- Critical aortic stenosis
- Congestive heart failure
- Congenital heart disease
- · Hemodynamic instability
- Neuromuscular and metabolic diseases
- Symptomatic brain stem dysfunction
- Apnea or hypotonia
- Liver failure
- Restricted hepatic and renal clearance
- Symptomatic gastroesophageal reflux or poor gastric emptying

VII. PATIENT EVALUATION AND MANAGEMENT

Sedation as described in this practice parameter should be performed in accordance with ASA guidelines, as described below [1].

Adult patients and legal guardians providing consent should be informed of and agree to the administration of sedation/analgesia before the procedure begins. Minor patients should be informed of the procedure and provide their assent as appropriate. The requirement for written informed consent should follow facility policies and procedures and state and local laws and regulations.

A. Patient Preparation Before Sedation

Hospital guidelines for preprocedure fasting should be followed. A suggested pediatric fasting protocol is given in Appendix C.

B. Evaluation Before Sedation

- 1. Electrocardiogram tracings and relevant laboratory values, when appropriate, should be available for review.
- 2. A focused history and physical examination should be performed and recorded. It should include the patient's previous experience with sedation/analgesia, current medical problems, current medications, drug allergies, and any significant comorbidities. A physician, nurse practitioner, or physician assistant should perform the presedation evaluation.
- 3. Prior to initiating sedation, an assessment of recent oral intake, recent illness, pulmonary status (including upper airway), cardiac status, baseline vital signs, level of consciousness, pulse oximetry, capnography (if available), and electrocardiogram (when applicable) should be performed and recorded.
- 4. For all outpatient procedures, the person responsible for accompanying the patient after discharge and who will be receiving postprocedure instructions must be clearly identified and contact information obtained.

C. Management During Sedation

Qualitative clinical signs such as chest excursion and auscultation of breath sounds are useful. During moderate or deep sedation the adequacy of ventilation should be evaluated by continual observation of qualitative clinical signs and monitoring for the presence of exhaled carbon dioxide unless precluded or invalidated by the nature of the patient, procedure, or equipment [5].

- 1. Intravenous access must be maintained.
- 2. Homeothermia should be preserved.
- 3. Patients should be protected from pressure-related and position-related injuries.
- 4. All patients should be continuously monitored throughout the procedure by physiologic measurements that should be recorded (at least every 5 minutes). These measurements include, but are not limited to, level of consciousness, respiratory rate, pulse oximetry, blood pressure (as indicated), heart rate, and cardiac rhythm. The types of measurements taken should comply with facility policies.
- 5. Supplemental oxygen with size-appropriate equipment should be immediately available and administered as needed.
- 6. Suction should be immediately available.
- 7. A defibrillator with backup emergency power and an emergency cart, including equipment for intubation and ventilation, should be immediately available.
- 8. The route, dosage, and time of all sedation and reversal agents should be documented on the sedation record by the health professional responsible for monitoring the patient.
- 9. Drug antagonists and intravenous fluids should be immediately available; their use should be based on the clinical circumstances.
- 10. For pediatric patients, intravenous sedative/analgesic drugs should be given based on the patient's weight in incremental doses that are titrated to the desired endpoints of sedation and analgesia. Weight-based dosing should operate within the maximum dose limit guidelines for each medication. For all patients, sufficient time must elapse between doses to allow the effect of each dose to be assessed before subsequent drug administration. When drugs are administered by nonintravenous routes (eg, oral, rectal, intramuscular, inhaled), allowance should be made for the time required for drug absorption before supplementation is considered.
- 11. In adult patients, intravenous sedative/analgesic drugs are given in incremental doses that are titrated to the desired endpoints of sedation and analgesia. In smaller adults, weight-based dosing may be considered.
- 12. Combinations of sedative and analgesic agents should be administered as appropriate for the procedure being performed and the medical condition of the patient. Ideally, each component should be administered individually to achieve the desired effect (eg, additional analgesic medication to relieve pain, additional sedative medication to decrease awareness or anxiety). The combinations of sedative and analgesic agents may potentiate respiratory depression. This underscores the need to dose each agent appropriately, as well as the need to monitor respiratory function.

D. Recovery Following Sedation

- 1. The patient must recover in an area where continuous monitoring and resuscitative equipment (eg, suction, oxygen) are immediately available. A code cart must be immediately available. Monitoring should include, but is not limited to, the level of consciousness, respiratory rate, pulse oximetry, blood pressure, and heart rate and rhythm, and should comply with facility requirements.
- 2. Levels of consciousness and vital signs must be monitored at intervals consistent with recovery status until all return to presedation levels. A patient may not leave the recovery area without accompanying monitoring personnel until vital signs and level of consciousness are at acceptable levels as determined by facility policy.
- 3. If intravenous access is used during the procedure it should be maintained until the patient is ready for discharge.
- 4. If use of reversal agents was required, the level of consciousness and vital signs should return to acceptable levels for a period of 2 hours from the time of administration of the reversal agent before monitoring ends. (Use of reversal agents may be associated with relapse into a deeper level of sedation than intended after successful rescue, and repeated doses may be required.)

- 5. The monitoring personnel will notify a supervising physician (who should remain available until recovery is complete) of any significant change in the patient's clinical status.
- 6. Qualified monitoring personnel (as described in section IV) must be immediately available to the patient from the initiation of sedation until the patient has adequately recovered or has been turned over to the appropriate personnel delivering recovery care.

VIII. SEDATION-RELATED DOCUMENTATION

Adequate documentation of all aspects of patient evaluation and monitoring is essential for high-quality patient care. This documentation should include, but is not limited to, the following:

- 1. Presedation assessment
- 2. Dose, route, site, and time of administered drugs must be part of the permanent medical record.
- 3. Patient's response to medication and the procedure
- 4. Inspired concentrations of medical gases, such as oxygen and nitrous oxide, their rate and duration, and method of administration
- 5. Physiological data from monitoring
- 6. Any rescue interventions, including ventilatory support, or use of reversal agents, and the patient's response
- 7. Any significant adverse reactions and their management

Reporting should be in accordance with the <u>ACR-SIR Practice Parameter for the Reporting and Archiving of Interventional Radiology Procedures</u> [6].

IX DISCHARGE CRITERIA

- A. The patient should not be discharged until vital signs, level of consciousness, and motor function have returned to the patient's preprocedure baseline, as determined by the health care professional responsible for monitoring the patient, and dependent on the patient's destination. Recovery according a standardized scoring system (such as the Aldrete score) should be documented [7,8].
- B. When discharge is to home, discharge instructions must be given to the patient or accompanying responsible adult. The discharge instructions should include, but not necessarily be limited to, the following:
 - 1. Physician contact information, including after-hours contact information, in the event of postprocedure problems
 - 2. Advice against driving or operating machinery for a minimum of 12 hours
 - 3. Advice against alcohol intake for 24 hours
 - 4. Advice regarding diet and activity
 - 5. Advice regarding follow-up
 - 6. The patient should be advised of possible sedation-related adverse effects and when to seek medical attention

X. EQUIPMENT

Facility policies for monitoring and evaluating the function of all equipment should be followed. Any location where sedation is administered and recovery from sedation is provided must have equipment and drugs for emergency resuscitation readily available [2]. It is critical that a complete range of sizes of emergency and monitoring equipment be available in the immediate area, for all ages and sizes of patients treated at the facility. The equipment should include the following:

1. Oxygen supply from a portable or fixed source, with a backup oxygen supply

- 2. Airway maintenance and oxygen delivery equipment appropriate to patient age and size, including nasal cannulae, face masks, and oral airways and resuscitation equipment (eg, an Ambu bag, laryngoscopes, ventilation masks, and endotracheal tubes). A mask capable of delivering 100% oxygen is necessary (eg, a nonrebreather mask).
- 3. Suction apparatus capable of producing continuous suction at a negative pressure of 150 mm Hg that is regularly checked for adequacy according to facility policies. Suction catheters appropriate for patients' airways must be available.
- 4. Appropriate emergency medications and equipment, including a defibrillator, must be immediately available to treat adverse reactions associated with administered medications. The equipment and medications should be monitored according to facility policies. The equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population. Equipment function should be checked on a regular basis, according to facility policies. Equipment checks should be documented in accordance with facility policies.

5. Monitors

- a. Pulse oximeter with probes appropriate for the patient's size. Pulse oximeter should have both visual and audible outputs.
- b. Blood-pressure measuring device with cuffs appropriate for the patient's size
- c. Multilead electrocardiographic monitors as appropriate for the patient's medical history
- d. A means of monitoring ventilation, either visually or through a device
- e. Capnography (if available)
- 6. A stethoscope
- 7. A telephone
- 8. An emergency light source, such as a flashlight
- 9. Emergency electrical power (or battery backup) for all electrical equipment listed above

For sedation performed in the MR suite, special equipment requirements apply, as indicated in the <u>Practice Advisory on Anesthetic Care for Magnetic Resonance Imaging: An Updated Report by the American Society of Anesthesiologists Task Force on Anesthetic Care for Magnetic Resonance Imaging.</u>

XI. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR website (http://www.acr.org/guidelines).

A record should be kept for all patients receiving sedation, indicating sedation failure and adverse effects (eg, vomiting, hypoxic events, resuscitation, and 24-hour follow-up when possible) and possible explanations for adverse outcomes. Patient care areas using sedation and analgesia should have policies and procedures for reporting complications encountered during sedation and analgesia to the quality assurance committee.

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APPENDIX A

American Society of Anesthesiologists (ASA) Physical Status Classification

A normal healthy patient Class I

A patient with mild systemic disease Class II

A patient with severe systemic disease Class III

A patient with severe systemic disease that is a constant threat to life Class IV Class V A moribund patient who is not expected to survive without the operation

A declared brain-dead patient whose organs are being removed for donor purposes Class VI

APPENDIX B

Factors that may be associated with difficulty in airway management include, but are not limited to, the following:

- Previous problems with anesthesia or sedation
- Stridor
- Snoring or apnea
- Dysmorphic facial features (eg, Pierre Robin syndrome, trisomy 21)
- Craniocervical abnormalities

- Significant obesity (especially involving the neck and facial structures)
- Short neck, limited neck extension, neck mass
- Tracheal deviation
- Small mouth, protruding incisors, loose or capped teeth, high-arched palate
- Macroglossia
- Tonsillar hypertrophy
- Nonvisible uvula
- Micrognathia
- Retrognathia
- Trismus

APPENDIX C

Suggested Fasting Protocol

Check the ASA guideline for updated information; reorganize variability

	Solids and Nonclear Liquids**	Clear Liquids
Children <6 months	4 to 6 hr	2 hr
Children 6 to 36 months 6 hr		2 to 4 hr
Children >36 months	6 to 8 hr	2 to 4 hr

^{**}This includes milk, formula, and breast milk (high fat content may delay gastric emptying).

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