Introduction

Sedation and analgesia are frequently administered to patients in non-operating room settings to relieve the pain, discomfort and anxiety associated with diagnostic and/or therapeutic procedures. Sedation and analgesia are often necessary to minimize patient movement so that procedures can be performed safely and successfully in the most expedient fashion. Clinicians who participate in procedures that require the use of sedation and analgesic techniques must possess a thorough understanding of the essential elements of the process so that the benefits to the patient are maximized while risks are minimized. Optimal dosages of sedative and analgesic agents must be carefully determined based upon patient characteristics and procedure requirements to avoid the deleterious consequences of cardiac or respiratory depression (i.e. hypoxic brain damage, cardiac arrest, or death).

This course is designed to provide reinforcement of recognized standards for administering moderate sedation and analgesia in non-operating room settings and to review current guidelines for managing and monitoring sedated patients in such settings. Completion of this course work does not confer or constitute a credential to administer sedation and analgesia to patients. All non-anesthesiology professionals should consult with the authority that issues their credentials and privileges regarding the specific requirements for becoming approved to administer moderate sedation and analgesia in their practice. At a minimum, practitioners who administer moderate sedation and analgesia must have formal practical training under the guidance of a qualified experienced professional and possess ACLS and/or PALS certification. Practitioners must be able to immediately manage a compromised airway or depressed cardiovascular function and rescue patients from inadvertent or unexpected deep sedation or general anesthesia.

ELEMENT 1: PHYSIOLOGICAL EFFECTS OF MODERATE SEDATION AND ANALGESIA – THE CONTINUUM OF SEDATION

Introduction

Sedative and analgesic effects occur along a continuum. Moderate sedation carries the potential for cardiac and respiratory complications especially in patients with risk factors and/or co-morbidities. To reduce the risk of hypoxic brain damage, cardiac arrest, or death, medical professionals who administer analgesic and sedative agents must assure that the patient is appropriately monitored and that symptoms of distress are rapidly recognized and corrected .

Upon completion of this element, the practitioner will be able to:

- Describe in detail the four levels of sedation with emphasis on cardiac, respiratory and cognitive components.
- Define the goal of moderate sedation and analgesia.

What are the four levels of sedation and analgesia?

Moderate sedation and analgesia (formerly known as "conscious sedation") describes a drug-induced state of consciousness that occurs along a dose-related continuum. To define this continuum, four levels of sedation and analgesia have been established.

1. Minimal sedation (anxiolysis)

   Minimal sedation (anxiolysis) is a drug-induced state during which patients respond normally and promptly to verbal commands. Although cognitive function and coordination may be slightly impaired, ventilatory and cardiovascular functions are minimally affected (i.e heart rate or blood pressure may decline slightly). This level of sedation is generally experienced by patients receiving anxiolytic or analgesic drugs administered for pain relief, anxiety, or insomnia.

2. Moderate sedation and analgesia

   Moderate sedation and analgesia is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either spontaneously or when touched lightly. (Reflex withdrawal from a painful stimulus is not considered a purposeful response.) No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

3. Deep sedation and analgesia

   Deep sedation and analgesia is 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. Deep sedation and analgesia should only be administered by an anesthesiologist.

4. General Anesthesia

General anesthesia is a drug-induced loss of consciousness during which patients are unarousable, even by painful stimulation. The ability to independently maintain ventilatory function is impaired and patients usually require assistance in maintaining a patent airway. Because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function, positive pressure ventilation may be required. Cardiovascular function may be impaired. General anesthesia should only be administered by an anesthesiologist.

Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation / Analgesia

	Minimal Sedation (Anxiolysis)	**Moderate Sedation / Analgesia ("formerly Conscious Sedation")**	**Deep Sedation / Analgesia**	**General Anesthesia**
Responsiveness and Consciousness	Normal response to verbal stimulation. Impaired cognition and coordination.	Purposeful* response to verbal or tactile stimulation. Depression of consciousness.	Purposeful* response following repeated or painful stimulation. Depression of consciousness.	Unarousable, even with painful stimulus.
Airway	No intervention required	No intervention required	Intervention may be required	Intervention often required
Spontaneous Ventilation	Adequate	Adequate	May be inadequate	Frequently inadequate
Cardiovascular Function	Maintained	Usually maintained	Usually maintained	May be impaired

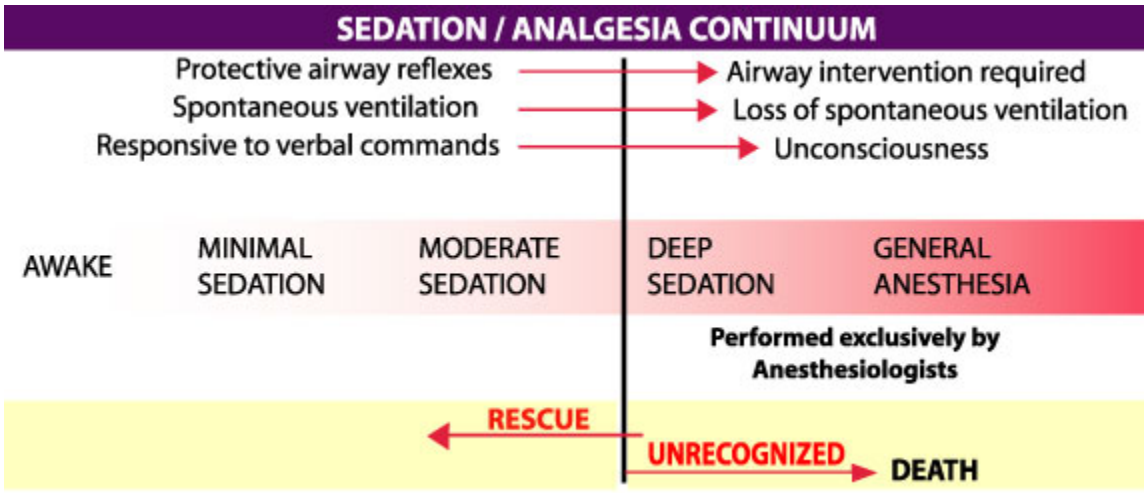
**Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.*

What is the goal of moderate sedation and analgesia?

The goal of moderate sedation is to provide pain relief, reduce anxiety, diminish recall and enhance cooperation in patients undergoing diagnostic or therapeutic procedures, with minimum risk to patient safety. Patient and procedural characteristics are carefully examined to determine appropriate dosages of analgesic and sedative agents so that the patient is maintained at - and does not progress beyond - the second level in the sedation continuum.

In practice, it is not always possible to predict how a specific patient will respond to sedative and analgesic medications. Therefore, practitioners must be able to rescue patients if the level of sedation becomes deeper than initially intended - i.e., the patient progresses to the third or fourth level of the continuum. As such, professionals administering moderate sedation and analgesia

must be equipped with the knowledge, skills and resources necessary to manage any patient who develops a compromised airway, becomes hypoxemic or hypoventilates.



ELEMENT 2: PRE-PROCEDURE PATIENT ASSESSMENT AND PREPARATION

Pre-procedure evaluation and management of all patients is one of the most important parts of the process of delivering safe and effective sedation and analgesia in settings outside of the operating room. This element will discuss important components of the patient history and physical; examination of the patient's airway; fasting or NPO guidelines; and the American Society of Anesthesiologists (ASA) Physical Status Score.

Upon completion of this element, the practitioner will be able to:

- List the important parts of a pre-procedure history and physical.
- Explain the components of a proper airway assessment.
- Discuss standards for pre-procedure fasting.
- Describe criteria for assignment of an ASA Physical Status Score.

What are appropriate pre-procedure practices?

Prior to the administration of moderate sedation/analgesia, the practitioner should:

- Perform and document a medical history.
- Perform and document a physical examination.
- Review results of appropriate laboratory tests.
- Assign an American Society of Anesthesiologists (A.S.A.) Physical Status Score.
- Obtain informed consent for moderate sedation/analgesia after explaining the risks and benefits and offering alternatives.
- Perform an airway examination including Mallampati classification, documentation of dentition and assessment of neck motion.
- Verify appropriate pre-procedure fasting.
- Assure that an appropriate patient escort is available for outpatients.
- Document a complete plan for moderate sedation and analgesia.

What should be included in the pre-procedure history and physical?

Clinicians administering sedation and analgesia should focus on aspects of the patient's medical history and physical attributes that are most likely to impact the outcome of sedation and analgesia. It is essential to remember that drug requirements and metabolism are decreased with increasing age. The patient assessment should identify:

- any abnormality of a major organ system.
- height, weight and body mass index (BMI).
- the presence or suspected presence of obstructive sleep apnea. (Most cases are NOT laboratory diagnosed.)
- previous adverse experience with sedation and analgesia, including regional and general anesthesia.
- drug allergies

- current medications including herbal preparations. (Many herbal preparations have interactions with sedative and analgesic drugs. Moreover, most patients do not consider herbs as medications and thus, unless specifically asked, may not tell the physician of their use.)
- tobacco, alcohol or substance use or abuse.
- time and nature of last oral intake.
- vital signs.
- physical characteristics of the airway.
- pertinent laboratory work, as indicated – e.g., hematocrit, EKG, etc.
- ASA physical status class.

How can a practitioner make a proper assessment of the patient's airway?

Sedatives and analgesics tend to impair airway reflexes in proportion to the degree of sedation and analgesia achieved. It is ***NOT UNCOMMON*** for patients to progress to a level of sedation deeper than intended. When this occurs, patients with certain pre-existing conditions are especially predisposed to airway obstruction. These conditions include:

- A past history of airway obstruction during moderate sedation or anesthesia
- Stridor, snoring, or sleep apnea
- Advanced rheumatoid arthritis
- Chromosomal abnormality (e.g. trisomy 21)
- Patients with dentures that have been removed for the procedure

Furthermore, in circumstances where an obstructed patient is unresponsive to simple airway maneuvers, intubation may be required. Intubation may be difficult in patients with certain medical conditions including but not limited to:

- Significant obesity involving neck and facial structures.
- Short neck; limited neck extension; neck mass; cervical spine abnormality; tracheal deviation.
- Protruding incisors; loose or capped teeth; dental appliances; high arched palate; macroglossia; tonsillar hypertrophy, non-visible uvula.
- Jaw abnormalities such as micrognathia, retrognathia, trismus or significant malocclusion.
- Limited voluntary mouth opening i.e., less than two fingerbreadths.
- Past history of difficult airway and/or intubation.

It is important for a practitioner to be aware of such conditions to most effectively determine and tailor the dose of anesthetic agents and (as with all patients) be ready to manage the airway should obstruction occur.

A technique for airway examination, developed by S. Rao Mallampati, M.D., is used by anesthesiologists to assist in identifying patients with potentially problematic airways. Known as the *Mallampati Classification System*, it enables practitioners to categorize a patient airway and

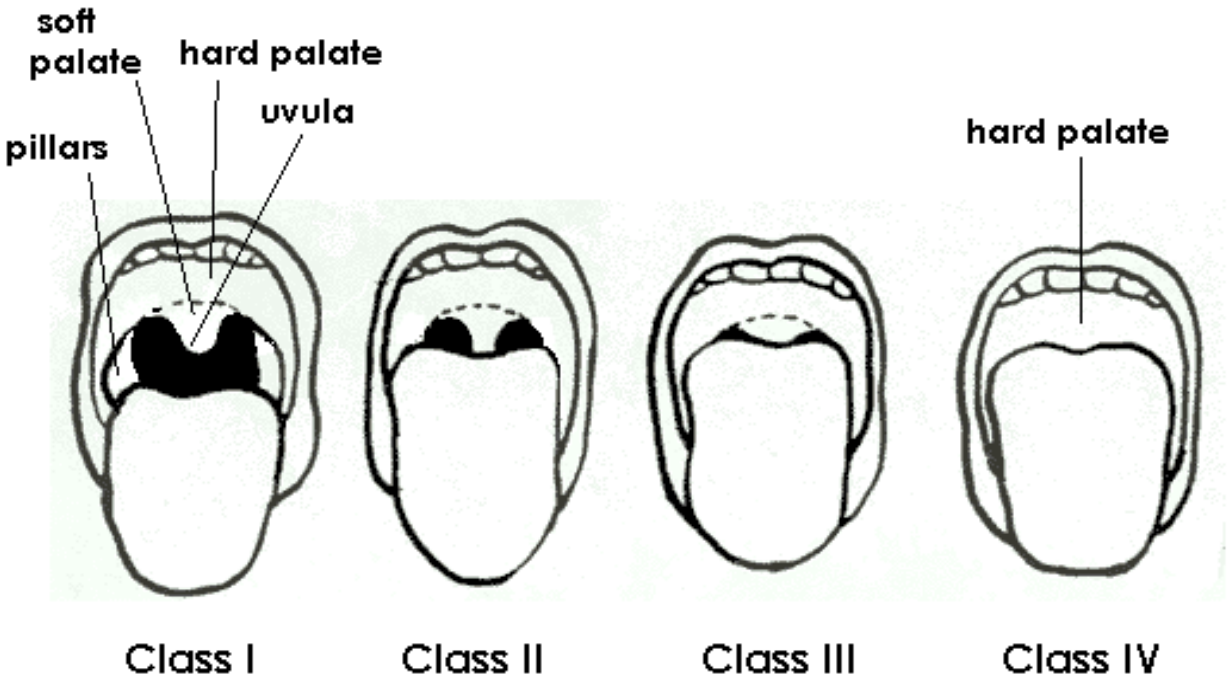
predict the degree of difficulty of endotracheal intubation should it be required. As the Mallampati class number increases, the difficulty of endotracheal intubation increases.

The Mallampati classification method should always be combined with an assessment of the aforementioned clinical features to achieve a greater predictive value of difficult intubation. The Mallampati classification ONLY provides an indicator of difficulty.

Performing a pre-sedation airway assessment using the Mallampati Classification System

To begin the exam, the patient should be seated upright with the head in a neutral position. The tongue is protruded maximally without phonation.

The oral cavity is examined and classified as follows:



Mallampati Class I	**tonsillar pillars easily visualized**
Mallampati Class II	**entire uvula visualized**
Mallampati Class III	**only the base of the uvula visualized**
Mallampati Class IV	**only the bony palate visualized**

What are the current recommendations for pre-procedure fasting?

Pre-procedure fasting is recommended to decrease the risk of aspiration during moderate sedation. Patients undergoing sedation for **elective** procedures should not drink fluids or eat solid foods for a sufficient period of time to allow for gastric emptying prior to their procedures. In urgent or emergent situations, the potential for pulmonary aspiration of gastric contents must be considered in determining (1) the target level of sedation, (2) whether the procedure should be delayed or (3) whether the trachea should be protected by intubation. The practitioner's clinical judgment should be the basis for determining whether intubation is required.

The American Society of Anesthesiologists recommends the following fasting guidelines for healthy patients who will be undergoing elective procedures, which require moderate sedation and analgesia. These recommendations apply to healthy patients of all ages and may require modification for patients with conditions that might affect gastric emptying or fluid volume (e.g. women in labor or diabetics) and patients in whom airway management might be difficult.

Summary of American Society of Anesthesiologists Guidelines for Preoperative Fasting

Ingested Material	Minimum Fasting Period (in hours)	Notes
Clear liquids	**2**	Examples of clear liquids include water, fruit juices without pulp (e.g., apple juice, grape juice), carbonated beverages, clear tea, and black coffee. These liquids should not include alcohol. The volume of liquid ingested is less important than the type of liquid ingested.
Breast milk	**4**	
Infant formula	**6**	
Non-clear liquids	**6**	Examples of non-clear liquids include fruit juices with pulp (e.g., orange juice), and coffee with milk, cream, or additives.
Non-human milk	**6**	Since non-human milk is similar to solids in gastric emptying time, the amount ingested must be considered when determining an appropriate fasting period.
Light meal	**6**	A light meal typically consists of toast without butter and clear liquids. Meals that include fried or fatty foods or meat may prolong gastric emptying time. Both the amount and type of foods ingested must be considered when determining an appropriate fasting period.
Fatty foods, meat	**8**	

Patients at increased risk for aspiration or patients with impaired gastrointestinal motility (e.g., diabetes, pregnancy, obesity, history of reflux or other gastrointestinal dysfunction, anticipated airway difficulty) should have nothing by mouth for at least 8 hours. In emergency situations, the practitioner must weigh the benefits of a shorter *NPO* period with the risks of aspiration and document this in the medical record.

What are the criteria for assignment of the American Society of Anesthesiology (ASA) Physical Status Score?

The pre-procedure assessment includes the determination and documentation of the ASA Physical Status Score. The following chart represents the current ASA classifications.

ASA SCORE	CRITERIA	ADULT EXAMPLES	PEDIATRIC EXAMPLES
ASA 1	Healthy patient without systemic disturbance.		
ASA 2	A patient with mild or well-controlled systemic disease with no functional limitations.	well-controlled asthma, diabetes mellitus or hypertension, stable angina	well-controlled asthma or seizure disorder; repaired ASD/VSD
ASA 3	A patient with severe systemic disturbance that results in definite functional limitations.	poorly controlled hypertension; diabetes mellitus with vascular complications; angina pectoris; pulmonary disease that limits activity	poorly controlled asthma, gastroesophageal reflux disease, sleep apnea, congenital cardiac defect without heart failure
ASA 4	A patient with severe systemic disturbance that is life-threatening with or without planned procedure.	congestive heart failure; advanced pulmonary, unstable angina pectoris; renal or hepatic dysfunction	pulmonary hypertension; congenital cardiac defect with heart failure
ASA 5	Moribund patient not expected to survive with or without the planned procedure.	ruptured abdominal aneurysm; pulmonary embolus; head injury with increased intracranial pressure	head injury with increased intracranial pressure, congenital diaphragmatic hernia on extracorporeal membrane oxygenation
E	Any patient for whom the procedure is emergent.		

To assure a safe and effective outcome, non-anesthesiologists in ambulatory settings should consult with appropriate medical specialists prior to administration of sedation to patients with significant underlying conditions. The choice of specialists depends on the nature of the underlying condition and the urgency of the situation. Non-anesthesiologists should strongly consider the services of an experienced anesthesiologist when planning to administer moderate sedation and analgesia to severely compromised or medically unstable patients or patients with any of the following characteristics:

- anticipated difficult airway, e.g. a Mallampati class IV airway, or other uncertainty about the airway
- severe obstructive pulmonary disease
- significant coronary artery disease, or congestive heart failure
- a history of problems with sedation

What other practices are useful in preparation of the patient for sedation and analgesia?

As part of the consent process, the physician should discuss with the patient or guardian the risks, benefits and alternatives of sedation and analgesia and important details about the planned procedure and sedative effects. If the procedure is expected to be painful, it is useful to establish a system by which the patient can signal when experiencing pain.

A plan for delivering moderate sedation should be formulated and documented prior to the procedure. Before any medications are administered, a positive identification of the patient must be made and documented; and the intended procedure and operative site should be verbally affirmed by the patient and documented. This is commonly referred to as “time out”. The procedure should not be initiated until all concerns are addressed.

ELEMENT 3: MONITORING AND MANAGEMENT OF PATIENTS RECEIVING MODERATE SEDATION AND ANALGESIA

Medical professionals who administer moderate sedation and analgesia outside of the operating room must monitor and document the mental and physiological status of the patient at all times. Accomplishing this task requires appropriate personnel and equipment, as well as the means necessary to manage adverse reactions and complications.

The following element discusses recommended peri-procedure practices for non-anesthesiologists administering moderate sedation and analgesia to patients during diagnostic and therapeutic procedures.

Upon completion of this element, the practitioner will be able to:

- List appropriate competencies for the physician directing sedation and the health care professional designated to monitor the effects.
- Describe methods for assessing a patient's level of consciousness.
- Describe means to monitor ventilation, oxygenation and hemodynamic function of patients undergoing moderate sedation and analgesia.
- Explain specific maneuvers for treating patients who become hypoxic during sedation.
- Discuss the use of supplemental oxygen and maintenance intravenous access during the sedation process.
- Identify equipment and supplies that should be available during administration of moderate sedation and analgesia.

What are appropriate competencies for professional staff involved in the administration of moderate sedation and analgesia?

The safety of the patient is contingent upon the availability of professional staff with validated skill to assure proper execution and maintenance of the sedation process. Whenever moderate sedation is administered in a non-operating room setting, there must be a physician responsible for directing the administration of the pharmaceutical agents and another qualified health professional to monitor the patient such as a physician, registered nurse, nurse practitioner, physician assistant, dentist, or surgeon's assistant. The person who is monitoring the patient for the effects of sedation and analgesia must NEVER be the same person who is performing the diagnostic or therapeutic procedure. The directing physician and the patient monitor must possess competencies in line with the tasks that they are expected to perform.

Physician Directing Moderate Sedation/Analgesia:

A physician, who has been granted the clinical privilege to administer moderate sedation and analgesia, should at a minimum:

- successfully complete a basic training course in Moderate Sedation and Analgesia
- possess certification in ACLS for adults and PALS for pediatric emergencies
- undergo a formal evaluation of practical skill whereby the professional repeatedly demonstrates competence to:

- assess whether or not a patient is an appropriate candidate for moderate sedation/analgesia
- safely administer drugs to achieve the desired level of sedation/analgesia
- monitor patients to maintain them at the desired level of sedation/analgesia
- detect and manage a compromised airway
- ensure adequate oxygenation and ventilation
- rescue a patient from deep sedation should it occur

The physician who is directing the administration of moderate sedation and analgesia must:

- perform and document the medical history and physical exam
- review appropriate laboratory data
- obtain and document informed consent
- document a proposed plan for moderate sedation and analgesia
- order medications to be administered for moderate sedation and analgesia
- determine appropriate interval for monitoring vital signs during the entire moderate sedation and analgesia process
- determine need for oxygen administration
- determine need for intravenous access
- verify discharge readiness
- remain on the premises post-procedure until the risk of cardio-respiratory depression is no longer present

Physicians who are directing the administration controlled substances for the purposes of moderate sedation and analgesia must comply with their institutional policy for maintaining a formal record of all controlled substances and provide a secure area for storage. The following principles apply:

- Controlled substances should be stored in a locked cabinet or lock-box. Breakaway locks are not permissible.
- Policies and written procedures should clearly define personnel who are authorized to access controlled substances.
- Inventory of controlled substances should be counted and documented at appropriate intervals.
- Controlled substances that are given for sedation and analgesia must be fully documented including name of patient and exact dosages administered.
- Unused portions of controlled substances must be 'discarded' according to facility policy and fully documented including exact amount of medication that was unused. Some facilities require that unused portions be returned to the pharmacy for inspection and validation.

Patient Monitor:

The health professional that is monitoring the patient during the sedation process should possess the following qualifications:

- familiarity with the effects of the drugs used for moderate sedation and analgesia
- competence to monitor required parameters
- ability to recognize abnormalities in the required parameters and intervene as indicated

Specific responsibilities include the following:

- measurement and recording of vital signs, oxygen saturation and level of consciousness during moderate sedation and analgesia and during recovery
- documentation of medications and dosages administered, drug reactions and interventions
- delivery of medications ordered by the directing physician

What equipment must be available in areas designated to give moderate sedation/analgesia?

Prior to sedating the patient, the practitioner must ensure that all equipment necessary to monitor and rescue the patient is available and functioning.

The following equipment must be available whenever moderate sedation and analgesia are administered:

- monitors capable of measuring oxygenation, blood pressure, heart rate and temperature
- suction device with Yankauer tip suction catheter
- bag/mask ventilation and O_2 source - all age appropriate
- oral airways, supraglottic airway, laryngoscope, blade, endotracheal tubes - all age appropriate
- cardiac arrest cart with standard emergency medications
- defibrillator
- intravenous supplies
- telephone numbers for emergency assistance

What are the essential components of the monitoring process for patients receiving moderate sedation?

The patient's level of consciousness, responsiveness, respiratory rate, oxygen saturation, blood pressure and heart rate should all be assessed and recorded at a frequency appropriate for the type and amount of medication being administered, the length of the procedure, and the general condition of the patient. The ability to monitor temperature prior to the procedure and at any time during the procedure should be available. Furthermore, the practitioner must document medications administered with dose, time, route of administration; and drug reactions, untoward events, and interventions.

At a minimum, an assessment should be performed (1) before the procedure begins; (2) every five minutes beginning with the first dose (3) during initial recovery; and (4) prior to discharge.

How is the patient's level of consciousness monitored?

During procedures performed with sedation and analgesia, the patient's ability to respond to verbal commands serves as an indication of the level of consciousness and correlates with the patient's ability to maintain proper ventilation. Monitoring of the patient's response to verbal commands should be routine during moderate sedation, except in circumstances where patients are unable to respond appropriately (e.g., young children, mentally impaired or uncooperative patients) or where eliciting movement could be detrimental for the patient. During procedures where a verbal response is not possible (e.g., oral surgery, upper endoscopy), asking the patient to give a "thumbs up" or other indication of consciousness is an acceptable substitute.

If a patient progresses to a state of deep sedation, a more profound stimulus should be employed to monitor the patient's status. Purposeful response that occurs only when a painful or repeated stimulus is applied indicates that a patient is in a state of deep sedation (level three on the sedation continuum). Lack of response or mere reflex withdrawal from painful stimuli indicates that a patient has progressed to a state of general anesthesia (level four).

How are ventilation, oxygenation and hemodynamic variables monitored?

Proper monitoring of ventilatory function involves observation and auscultation of the airway and chest, and documentation of the respiratory rate. In circumstances where the patient is at a considerable distance from the care giver (e.g., during MRI procedures), exhaled carbon dioxide monitoring is indicated. Side stream capnography may be attached to the oxygen cannula.

All patients undergoing moderate sedation and analgesia should be monitored by pulse oximetry with appropriate alarms. A variable pitch "beep" provides a continuous audible indication of the oxygen saturation reading. Desaturation is generally accompanied by a lowering of pitch in the audible indicator. Early detection of hypoxemia through the use of oximetry decreases the likelihood of adverse outcomes such as cardiac arrest and death.

Ventilation and oxygenation are separate though related physiological processes. The monitoring of oxygenation by pulse oximetry is <u>not</u> a substitute for continuous monitoring of ventilatory function by auscultation and observation. There may be a lag time, depending on the patient's physical characteristics, between the onset of hypoventilation and a change in oxygen saturation.

Electrocardiography (using a cardiac monitor) should be continuous throughout the entire process of administering moderate sedation.

Blood pressure should be determined before medications are administered. Once sedation and analgesia are established, blood pressure should be measured at 5-minute intervals during the

procedure. If standard arm monitoring interferes with the procedure, blood pressure may be recorded from the wrist or leg. Automated non-invasive blood pressure monitors that are equipped with alarms are useful for frequent monitoring of blood pressure.

The following vital signs and parameters should be documented on an appropriate flow sheet every 5 minutes:

- Respiratory rate
- Blood pressure
- Heart rate and EKG reading
- Level of consciousness and responsiveness
- Oxygen saturation
- Exhaled carbon dioxide. Continuous monitoring of expired CO2 is a standard during administration of all types of anesthesia in the operating room. Monitoring of exhaled carbon dioxide concentration although not a standard at this time may be considered for use in cases where the monitoring practitioner is separated from the patient, for example during MRI.

What are the requirements regarding oxygen administration and intravenous access during administration of moderate sedation and analgesia?

Supplemental oxygen reduces the frequency of hypoxemia and should be strongly considered for all patients receiving moderate sedation and analgesia. In patients receiving intravenous medications for sedation and analgesia, vascular access should be maintained throughout the procedure and continued until the patient is no longer at risk for cardio-respiratory depression. If an intravenous line becomes infiltrated, clotted or accidentally dislodged, an individual with the skills to establish intravenous access must be immediately available to re-establish vascular access.

What are the potential complications of sedation and how should they be managed?

Oxygen desaturation, airway obstruction, and depression of respiratory drive

Mild hypoxemia that results from airway obstruction and /or depression of the respiratory drive is probably the most common complication arising from administration of sedation. The patient's oxygen saturation may drop into the mid to low 90's with an associated deterioration of responsiveness and level of consciousness.

The practitioner should first address this problem by:

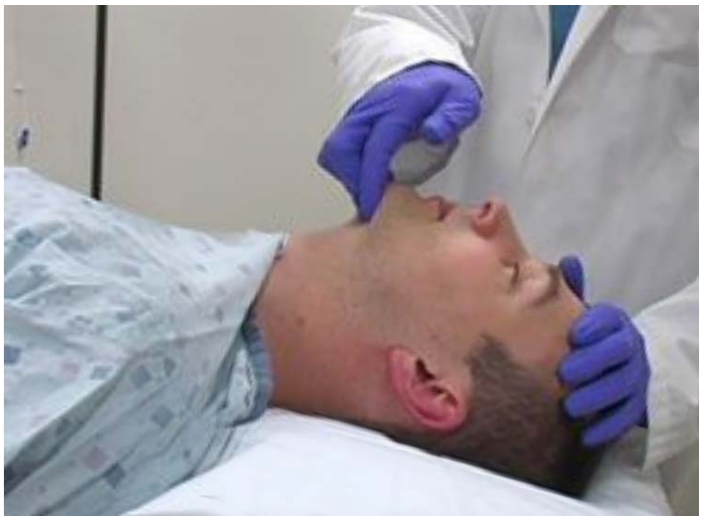
(1) checking that the oxygen is turned on, attached and flowing through the nasal cannula;
(2) asking the patient to take a deep breath and tapping (gentle stimulation), the patient if necessary;

(3) performing a simple chin lift / head tilt to stimulate the patient and clear an airway obstruction that may be caused by the tongue falling back in the mouth.

If these efforts are unsuccessful at correcting respiratory depression, a jaw thrust may be performed. If still unresolved, more aggressive strategies should be employed such as placing an oral or nasal airway and / or positive pressure ventilation (bag-valve mask), placement of a supraglottic device (e.g. laryngeal mask airway) or endotracheal intubation.

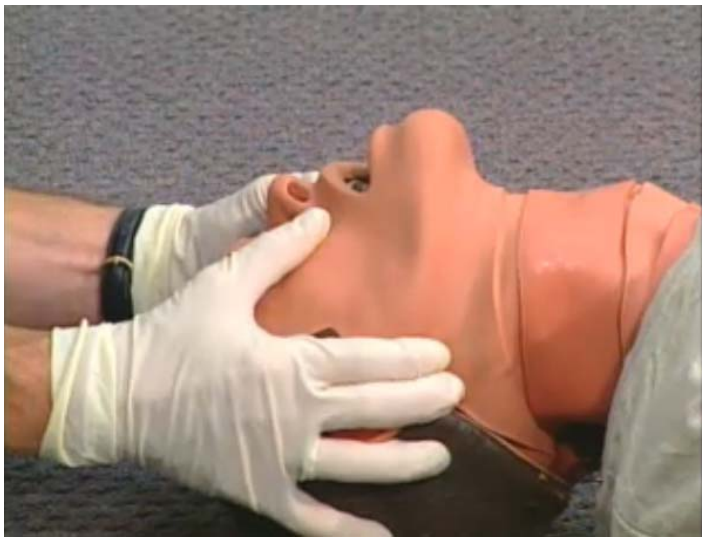
Performing a chin lift/ head tilt

Using one hand, apply downward pressure to the patient's forehead. With the other hand, use the tips of the index and middle fingers to lift the mandible at the mentum. This action improves airway patency by lifting the tongue away from the posterior pharynx.



Performing a jaw thrust

Position the 4th and 5th digits of each hand underneath and behind the angle of the patient's mandible. While maintaining stabilization of the patient's head and neck, push each side of the patient's mandible forward, or anterior, until the lower jaw is extended.



Methods of oxygen delivery

Nasal Cannula

The nasal cannula is the first choice for delivering supplemental oxygen during moderate sedation. The concentration of oxygen delivery varies according to the oxygen flow rate approximately as follows:

1 l/min – 24%
2 l/min – 28%
4 l/min – 36%
6 l/min – 44%

The nasal cannula delivers oxygen at a rate of 2 - 6 liters per minute, at concentrations of 24 - 44%. In general, it is well-tolerated and useful when delivery of low oxygen concentrations is desired. At higher concentrations, patients may complain of the drying effect. In patients with severe chronic obstructive pulmonary disease (COPD), hypercarbia may not stimulate breathing especially during moderate sedation. In these patients, careful attention must be given to safely deliver a low oxygen concentration while avoiding depression of the respiratory drive.

Oxygen Mask

An oxygen mask may be used to deliver higher oxygen concentrations.

Three basic styles of oxygen mask are available:

- the simple mask
- the non-rebreathing mask, and
- the venturi mask.

The simple mask has a number of small vents on each side and can deliver up to 50% oxygen. There is a large variability in actual inspired oxygen concentration due to entrainment of room air.

The non-rebreathing mask uses flutter valves on each side to prevent entrainment of room air, and uses a reservoir bag to hold a supply of 100% oxygen. This device can deliver a maximum inspired oxygen concentration of 90%.

The venturi mask is similar to the basic mask but allows relatively fixed amounts of supplemental oxygen in concentrations ranging from 24% to 40%.

Bag-valve mask (also known as the "Ambu-Bag")

A self-inflating resuscitation bag allows manual positive pressure ventilation to a patient who has stopped breathing spontaneously. With an attached oxygen reservoir and a flow rate of 10-15 L/min, an FiO2 of up to 90% may be delivered. The mask must fit properly so that potential air leaks are prevented and adequate ventilation is maintained. Some bags have one-way expiratory valves to prevent the entry of room air; these allow for delivery of greater than 90% oxygen to ventilated and spontaneously breathing patients. Bags lacking this feature deliver a high concentration of oxygen during positive pressure ventilation but only deliver 30% oxygen during spontaneous breaths. The provider must understand how to adjust the flow rates and valves to allow good positive pressure ventilation. Self-inflating bags are often supplied with "pop-off" valves which must be closed to achieve positive pressure ventilation.

Bag-valve mask ventilation requires a good seal around the face and a patent airway. Adjuncts such as oral and nasal airways may be necessary to relieve airway obstruction and assure consistent patency.

The masks come in many sizes, including newborn, infant, child, and adult (small, medium, and large). Choosing the appropriate size helps to create a good seal and, therefore, aids effective ventilation.

Techniques for Bag-valve mask ventiliation

Before initiating bag-valve mask ventilation, the airway must be opened by using a head-tilt chin-lift maneuver, jaw thrust or an oral or nasal airway.

One person – one hand technique

Select a mask that covers the mouth and nose without extending over the chin and position it on the patient's face prior to attaching the bag. Hold the mask firmly in place using the non-dominant hand. Create a "C" shape with the thumb and index finger over the top of the mask and apply gentle downward pressure. Hook the remaining fingers around the mandible and lift it upward toward the mask, creating an "E".





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Two person – two hand technique



A two-hand technique can be used when a second person is available to ventilate the patient by compressing the bag. Two opposing semicircles are created with the thumb and index finger of each hand forming a ring around the mask connector. While holding the mask on the patient's face, the mandible is lifted up by the remaining digits.



An alternative maneuver requires placing both thumbs in opposition on the mask connector using the thenar eminences to hold the mask on the patient's face. The remaining fingers wrap around the mandible and lift it upward while pushing downward on the mask with gentle pressure.

With the bag-valve mask technique, the patient can be ventilated at a volume of 6 – 7 mL/kg per breathe (approximately 500 mL for an average adult). In the oversedated patient with stable cardiovascular dynamics, ventilation should be at a rate of 10-12 breaths per minute giving each breath over 1 second. During cardiopulmonary resuscitation (CPR), 2 breaths should be delivered after each series of 30 chest compressions until an advanced airway is placed. Ventilation is then continued at a rate of 8-10 breaths per minute.

If the patient has intrinsic respiratory drive, the patient's breaths should be assisted. In a patient with tachypnea, every few breaths should be augmented.

The risk of gastric distension can be reduced by ventilating at low pressure and low volume; and by maintaining cricoid pressure. This pressure is intended to compress the esophagus and reduce the risk of aspiration. However, it does not completely protect against regurgitation, especially in cases of prolonged ventilation or poor technique. Care must be taken to avoid excessive pressure, which can result in compression of the trachea.

The adequacy of ventilation is assessed by observing chest rise, improvement of color, and oxygen saturation. The operator must also watch for air leak and increasing gastric distention.

Endotracheal Intubation

The definitive means of emergently securing an airway in the non-breathing patient is by endotracheal intubation. A correctly placed endotracheal tube with an inflated cuff allows precise control of ventilation and offers protection from aspiration of stomach contents. Endotracheal intubation should only be used after other less invasive measures to support ventilation have failed.

When ventilation and oxygenation are compromised, further doses of sedative agents should be avoided until the patient's condition improves. The physician performing the procedure should be kept advised of the patient's condition at all times.

In most situations, the measures presented here will successfully reverse hypoventilation. In the event the patient's respiration and oxygenation fail to improve, more aggressive action is required. During periods of uncertainty or decline, a rapid decisive response is required.

Scrupulous attention to oxygen saturation is essential to performing safe and effective patient sedation, as hypoxia can lead to cerebral damage, myocardial infarction, arrhythmias and other serious complications.

Cardiac Complications and Hypotension

Hypotension may occur due to vasodilation secondary to sedative agents. Such episodes are usually self limiting, but will require treatment if they become severe or persistent. Appropriate treatment options include a fluid bolus; briefly placing the patient in a head down position (Trendelenburg); or administering a small dose of a short acting vasoconstricting medication.

Hypotension may also arise from bradycardia, myocardial dysfunction, or arrhythmia. This situation is critical and requires immediate attention. When hypotension occurs, it should not be assumed that it is secondary to sedatives and more serious causes should be ruled out FIRST. It may be advisable to stop the procedure while the cause of the hypotension is identified and treated.

Practitioners should keep in mind that vigilance and contact with the patient are paramount. Many complications can be avoided with good communication among the caregivers involved in the procedure and with the patient. All personnel involved should be encouraged to call attention to early signs of potential problems.

What other special considerations are required prior to the administration of moderate sedation and analgesia?

Infection Control Considerations

Standard precautions must be utilized in the care of all patients. Other isolation procedures should be utilized as required by an individual patient (e.g., respiratory precautions for airborne infections or contact isolation for antibiotic resistant pathogens). Needleless injection systems should be used whenever possible.

Safe injection practices

Several outbreaks of Hepatitis B virus (HBV) and Hepatitis C virus (HCV) have resulted from administration of sedation using unsafe injection practices. Investigation of these outbreaks revealed that practitioners were reinserting used needles into a multiple-dose vial or solution container (e.g., saline bag) or using a single needle/syringe to administer intravenous medication to multiple patients.

Medications should never be administered from a single syringe to multiple patients, even if the needle or cannula on the syringe is changed.

Needles, cannulae and syringes are sterile, single-use items and should never be reused for another patient or to access a medication or solution that might be used for a subsequent patient. Fluid infusion and administration sets (i.e., intravenous bags, tubing and connectors) should be used for one patient only and disposed appropriately after use.

Single-dose vials should be used for parenteral medications for a single patient whenever possible. If multidose vials must be used, both the needle or cannula and syringe used to access the multidose vial must be sterile. Multidose vials must not be kept in the immediate patient treatment area and always discarded if sterility is compromised or questionable. Bags or bottles of intravenous solution must not be used as a common source of supply for multiple patients.

ELEMENT 4: PHARMACOLOGY OF ANALGESICS, SEDATIVES AND ANTAGONISTS USED FOR MODERATE SEDATION AND ANALGESIA OF ADULT AND PEDIATRIC PATIENTS

Health care providers who are responsible for patients receiving moderate sedation and analgesia should understand the pharmacology, dosing considerations and associated complications of the agents that are administered, as well as the role of pharmacologic antagonists for opioids and benzodiazepines. The appropriate choice of agents and techniques for sedation/analgesia depends upon the experience and preference of the practitioner, requirements or constraints imposed by factors associated with the patient or procedure, and the likelihood of producing a deeper level of sedation than anticipated. Furthermore, institutions often have a limited formulary of sedatives and analgesics for use by non-anesthesiologists.

Specific dosing instructions will not be provided for the pharmaceutical agents that are described in this element. Unlike other drugs and medications, sedatives and analgesics that are used to achieve the second level of the continuum of sedation are titrated to effect. This titration greatly depends on patient and procedure characteristics and the experience of the provider. Hospitals and health care institutions that grant sedation privileges to non-anesthesiologists generally provide a practical training program and also provide guidelines for dosing that have been created by their anesthesiology staff based on experience with the population served.

Because it is not always possible to predict how a specific patient will respond to sedative and analgesic medications, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended. Propofol will not be discussed in this element as it is NOT recommended for use by non-anesthesiologists because of the known high risk of inadvertent deep sedation associated with this agent.

Upon completion of this element, the practitioner will be able to:

- Discuss basic principles which apply to the administration of analgesics and sedatives used for moderate sedation and analgesia.
- List analgesics commonly used for moderate sedation and analgesia of adult and pediatric patients and describe the indications, dosing considerations and potential side effects for each of them.
- List sedatives commonly used for moderate sedation and analgesia of adult and pediatric patients and describe the indications, dosing considerations and potential side effects for each of them.
- List the available antagonists used for reversal of sedative and analgesic agents and describe the indications, dosing considerations and potential side effects for each of them for adult and pediatric patients.
- Discuss patient and procedural factors that impact dosing.

What important principles apply to the administration of pharmaceutical agents used for moderate sedation and analgesia?

A provider should choose appropriate analgesic and sedative agents after careful consideration of the following factors:

- patient-related factors such as age, BMI, ASA class, fasting state, airway characteristics and history of medication reactions
- the desired effect of the anesthetic agent - motion control, anxiolysis, sedation, analgesia, amnesia
- procedural characteristics such as duration, anticipated pain, patient position.

Procedure-related characteristics

The following procedure-related characteristics are likely to play a role in the choice of analgesic and sedative agents selected by the provider.

1. ***Duration of the procedure.*** The duration of action of the analgesic and/or sedative agent should correlate to the anticipated length of time for the procedure. For example, there is no need to administer a sedative medication that lasts for several hours to a patient undergoing a procedure that takes several minutes. If the duration of action is shorter than the procedure, the provider must possess knowledge of further dosing.

2. ***Pain as a side effect of the procedure.*** Sedatives commonly used for moderate sedation have no analgesic component. Therefore, a moderately sedated patient will likely respond to a painful stimulus. For very painful procedures, sedatives will only provide adequate movement control if a state of deep or general anesthesia is achieved – a level that is inappropriate to the skill of a non-anesthesiologist. Analgesic medications, such as fentanyl, provide powerful pain control for procedures while not offering the same sedative potency.

3. ***Position required for the procedure.*** The positioning of the patient during a procedure may inhibit access to the airway or increase the likelihood of airway obstruction. Flexing the head during a procedure (e.g. a child undergoing a lumbar puncture or a scan) can increase the likelihood of an obstruction especially if the patient progresses to a level of deep sedation.

4. ***Lack of patient cooperation during a procedure because of anxiety or psychological stress.*** Thought should always be given to how a procedure could be accomplished without medication through the use of emotional support and/or distraction techniques (e.g., music, television, DVD). Sedation may be required for procedures that are not particularly painful and do not require a great deal of movement control but are psychologically and emotionally distressful to the patient.

5. ***Availability of rescue resources.*** The location in which the sedation is taking place must be equipped with the personnel and equipment necessary to fully rescue a patient

from unexpected apnea. Sedation should NEVER be administered if emergency personnel are not immediately available. Emergency response systems should be clearly defined and tested on a regular basis. Mobile phones should not be relied upon as a means of communication since they may not receive signals in screened radiology areas and are not permitted inside MRI units.

General rules

The following general rules apply to the administration of moderate sedation and analgesia in non-operating room settings by non-anesthesiologists.

1. Dosages of anesthetic agents should be determined according to the clinical situation and the practitioner's experience with the agents.

Many of the clinical effects of medications administered to achieve analgesia and sedation are dose and age-related and must be assessed for each patient. Drugs are most commonly administered intravenously but may be available in preparations that can be administered orally, transmucosally (intranasal, rectal), by intramuscular injection or by inhalation. Modes of administration other than the intravenous route often result in unreliable serum levels and are generally less used.

Pharmaceutical agents that are available for moderate sedation and analgesia have the following properties:

- Sedative: decreases activity, moderates excitement and calms the patient.
- Hypnotic: produces drowsiness and facilitates the onset and maintenance of sleep.
- Analgesic: relieves pain by altering perception of nociceptive stimuli.
- Anxiolytic: relieves apprehension and fear due to an anticipated act or illness.
- Amnesic (antegrade): affects memory incorporation such that the patient is unable to recall events following delivery of the drug.

The dose of any sedative or analgesic should be **REDUCED** in the following circumstances:

- when used with other sedatives or narcotic/opioid analgesics. Combinations of sedatives and opioid analgesics may increase the likelihood of adverse outcomes including ventilatory depression and hypoxemia by potentiation.
- in neonates, the elderly, or debilitated patients.
- when the patient has severe major organ disease (cardiac, pulmonary, cerebral, hepatic or renal).
- in psychiatric patients receiving psychotropic medications.
- in obese patients most drugs are dosed based on lean body mass rather than actual weight.

2. All agents should be slowly titrated with careful attention to the time to peak effect.

All drug administration must be individualized to the patient by TITRATION IN SMALL INCREMENTS SLOWLY, waiting an appropriate amount of time between doses to fully evaluate response, before considering an additional dose. The interval of time between doses should be determined according to the time to peak effect for the agent being administered. Patients with cardiac disease or the elderly may have slower circulation times and a longer period may elapse until onset of peak effect.

Oral, transmucosal, and intramuscular routes are often more convenient, less invasive, and especially useful for children for whom intravenous access is difficult. However, they are less reliable for timely dose titration leading to variability in onset of action, peak effect and duration of action.

3. Practitioners administering moderate sedation and analgesia must be fully qualified to monitor and manage adverse reactions.

Considerable judgment in the administration of these drugs is required for their safe and effective use. All agents have been reported to have adverse effects, even at the recommended doses, and caution must be exercised at all times. A sedative or analgesic agent must never be used for a patient with known intolerance or allergy to the drug.

4. Patient characteristics must be carefully and completely assessed before selecting sedative or analgesic agents.

A focused medical history and complete physical examination should be performed for every patient for whom sedation and / or analgesia may be required. In addition, the following categories of patients merit special consideration:

- *The pregnant patient*: Analgesics and anesthetics administered to pregnant patients should have minimal transmission to the fetus; minimal effects on protective reflexes of the mother; little or no direct effects on the fetus; and little or no respiratory depression. There is a major potential for difficulties in airway management because of the normal physiological changes of pregnancy especially during the third trimester. Pregnant patients are also at increased risk for rapid desaturation secondary to a decrease in pulmonary reserve.

- *The pediatric patient*: Drugs administered to pediatric patients should have minimal effects on the cardiovascular and respiratory systems and minimal effects on protective reflexes. Medications should not diminish heart rate in infants as cardiac output depends on heart rate to a greater extent than in adults and older children. In infants and children, the drug half-life may differ from adults for physiological reasons (e.g., altered metabolism and/or excretion), resulting in a longer or shorter duration of action. Young

children also have a higher metabolic rate than adults, resulting in a risk of rapid desaturation.

- *The patient with a disorder of the cardiovascular system*: Analgesics and anesthetics administered to patients with cardiovascular disorders should not be arrhythmogenic, and should not cause hypotension or hypertension. In addition, the drugs should not cause myocardial depression or increase the work of the heart by increasing heart rate.

- *The patient with hepatic disease*: For patients with compromised liver function, drug degradation should result in inactive and non-toxic metabolites which are not metabolized by the liver or excreted by the biliary tract. Drugs should have a short elimination half-life and have minimal or no effect on blood pressure to reduce the possibility of further liver compromise secondary to hypotension and reduced blood flow.

- *The substance abuser (drugs and/or alcohol)*: Patients with substance abuse problems may demonstrate a cross-tolerance to sedatives and analgesics. Enzyme induction may alter drug metabolism and therefore decrease the duration of action of the drug. Acute use (i.e., within twenty-four hours) may enhance the effects of drugs utilized for moderate sedation, including effects on the cardiovascular and/or respiratory systems.

- *The psychiatric patient receiving psychotropic drugs*: Drugs administered to psychiatric patients should have minimal or controlled interaction with psychotropic drugs. Almost all psychotropic drugs have an additive effect when combined with drugs utilized for moderate sedation. Hypotension may occur with the combination of major tranquilizers and drugs used for moderate sedation.

- *The obese patient*: With obese patients, the volume of medication distribution is altered and drugs that bind to fat will require increased dosages. Obese patients are more likely to have airway management problems and also have decreased pulmonary reserves leading to a higher risk of rapid desaturation.

ANALGESICS

What analgesics are commonly used in the management of peri-procedure pain in adult and pediatric patients?

For adult and pediatric patients, the following analgesics are appropriate for the management of peri-procedure pain:

- fentanyl citrate
- morphine sulfate

What are the indications, dosage considerations and potential side effects of these analgesics?

Fentanyl citrate

Fentanyl citrate is a short-acting narcotic/opioid analgesic used for management of peri-procedure pain. There is no amnesic effect.

Fentanyl can be effectively used for analgesia during painful procedures. For this purpose, it is usually administered SLOWLY through an infusing intravenous line. As with all intravenous agents, dosages should always be carefully titrated to achieve the desired anesthetic effect starting at the lower end of the range of recommended dosage. Individual dosages may vary when drugs are used in combination, especially when benzodiazepines are used in combination with opioids.

The onset of action of fentanyl is almost immediate when the drug is given intravenously; however, the maximal analgesic and respiratory depressant effect may not be noted for several minutes. The time to peak effect is 3 - 5 minutes. Additional doses of fentanyl should not be administered without waiting a minimum of 5 minutes between doses to fully evaluate the effects of the drug. The duration of action is 30 – 60 minutes.

Side effects of fentanyl include:

- Hypoventilation and apnea, which may be potentiated by other CNS depressants (such as midazolam or diazepam) and are reversible by naloxone (Narcan™).
- Muscle rigidity, especially with rapid administration.
- Bradycardia and hypotension.
- Nausea/vomiting.

Morphine sulfate

Morphine sulfate is a long-acting narcotic/opioid analgesic used for management of peri-procedure pain. There is no amnesic effect.

The onset of action for morphine is slow relative to fentanyl, making it a less desirable drug for acute procedural pain. Similarly, morphine's clinical effect is prolonged, typically 2 to 4 hours. Consequently morphine is much better for postoperative pain or chronic pain management. Morphine may have some advantages for prolonged painful procedures.

For painful procedures, morphine may be administered SLOWLY through an infusing intravenous line. As with all intravenous agents, dosages should always be carefully titrated to achieve the desired anesthetic effect starting at the lower end of the range of recommended dosage. The onset to peak effect is 5 - 10 minutes with duration up to 2 – 4 hours. Additional doses of morphine should not be administered without waiting a minimum of 10-15 minutes between doses to fully evaluate the effects of the drug. The duration of action is 2 – 4 hours.

Side effects of morphine include:

- Hypoventilation and apnea, which may be potentiated by other CNS depressants (such as midazolam or diazepam), and are reversible by naloxone.
- Hypotension and tachycardia or bradycardia.
- Nausea/vomiting.

Why is Meperidine (Demerol) NOT RECOMMENDED as an analgesic?

Meperidine, although tolerated by many patients, yields metabolites that are pharmacologically active and have undesirable side effects including CNS stimulation. Toxic interaction with medications such as MAO inhibitors may occur. Demerol has also been reported to cause a toxic fatal interaction with cocaine.

SEDATIVES

What sedatives are commonly used for moderate sedation in adult and pediatric patients?

- midazolam hydrochloride
- diazepam

These agents are used for sedation, anxiety reduction, and amnesia before and during a procedure. They do NOT produce an analgesic effect.

What are the indications, dosage considerations and potential side effects of sedatives that are used for adult and pediatric patients?

Midazolam hydrochloride

Midazolam hydrochloride is a short-acting benzodiazepine that has anxiolytic, amnestic, sedative, hypnotic, anticonvulsant, and muscle relaxant properties. There is no analgesic effect.

The time to peak effect for midazolam is 2 – 3 minutes when administered intravenously. The duration of action is 30 – 60 minutes. Intravenous midazolam is commonly used for procedural sedation and is preferred to diazepam because the time to peak effect is brief and the duration of action is shorter. As with all intravenous agents, dosages should always be carefully titrated to achieve the desired anesthetic effect starting at the lower end of the range of recommended dosage. An initial dose can be administered SLOWLY into an infusing intravenous line. Additional doses of midazolam should not be administered without waiting a minimum of 3-5 minutes between doses to fully evaluate the effects of the drug.

Midazolam should be used with great care in elderly patients, especially those over 80 years of age, who require SIGNIFICANTLY lower dosages of midazolam to achieve moderate sedation.

Midazolam is also available in preparations that can be delivered through intramuscular, oral, intranasal and rectal routes. This is sometimes useful with children in whom intravenous access may be difficult. Children may complain of a bitter taste or a burning sensation if inhaled. Administration of midazolam through these methods can lead to unreliable serum concentrations and unpredictable clinical results. Careful and prolonged monitoring is required to assess the effectiveness of the sedation and to monitor for signs of respiratory depression. Despite the rapid metabolism of midazolam, effects may linger for many hours, especially if other drugs have been used in combination and thus patients should be advised against driving or making important decisions for 24 hours.

Side effects of midazolam include:

- Hypoventilation and apnea is greatly potentiated by narcotic/opioid analgesics (such as fentanyl and morphine), alcohol and other CNS depressants. These adverse effects most often occur with rapid injection and are reversible with flumazenil. There should be continuous vigilance for signs of respiratory depression.

- Vertigo, dizziness.
- Agitation, combativeness and restlessness, especially in the elderly and in patients in pain.

Diazepam

Diazepam is a long-acting benzodiazepine with anxiolytic, amnestic, sedative, hypnotic, anticonvulsant, and muscle relaxant properties. There is no analgesic effect.

Diazepam should be avoided in confused or agitated patients. Furthermore, with adult patients, the duration of action for diazepam increases with age and may be as long as 48 hours in patients over 80 years of age. In children, midazolam is usually preferred over diazepam because of its shorter duration of action and multiple routes of administration.

The time to peak effect for diazepam is 3 – 5 minutes when administered intravenously. The duration of action is very variable. As with all intravenous agents, dosages should always be carefully titrated to achieve the desired anesthetic effect starting at the lower end of the range of recommended dosage. An initial dose can be administered SLOWLY into an infusing intravenous line. Additional doses of diazepam should not be administered without waiting a minimum of 5-10 minutes between doses to fully evaluate the effects of the drug.

Side effects associated with diazepam include:

- Hypoventilation and apnea, which may be potentiated by narcotic/opioid analgesics (such as fentanyl and morphine), alcohol and other CNS depressants. These adverse effects occur most frequently with rapid injection and are reversible with flumazenil.
- Vertigo, dizziness.
- Pain on injection.

Chloral hydrate

Chloral hydrate is a hypnotic agent with slow onset and long duration that is generally used for pediatric patients undergoing diagnostic imaging studies. There is no analgesic effect.

Chloral hydrate is formulated for oral and rectal administration. Rectal administration is not recommended because of erratic absorption of the drug. Oral administration of the drug produces most reliable clinical results in children under the age of 3 years. The effects of the drug are unpredictable in children over the age of 3 years. Chloral hydrate is NOT reversible with flumazenil or naloxone.

When administered orally, the average time to peak sedation is approximately 30 minutes but can be as much as 60 minutes. The duration of action is 1 – 2 hours.

Side effects or chloral hydrate include:

- motor imbalance may persist for several hours following administration.
- hypoventilation and apnea, which may be potentiated by narcotic/opioid analgesics (such as fentanyl or morphine) and other CNS depressants.
- respiratory depression and oxygen desaturation especially in children with airway pathology, such as bronchiolitis or sleep apnea.

Pentobarbital

Pentobarbital is a barbiturate sedative-hypnotic with slow onset and long duration that is sometimes used for pediatric patients undergoing diagnostic imaging studies. It produces profound sedation, hypnosis, amnesia, and anticonvulsant activity. There is no analgesic effect.

Pentobarbital is contraindicated in pediatric patients with porphyria. Pentobarbital is NOT reversible with flumazenil or naloxone.

The time to peak effect for pentobarbitol is 3 – 5 minutes when administered intravenously. The duration of action is 45 – 60 minutes. As with all intravenous agents, dosages should always be carefully titrated to achieve the desired anesthetic effect starting at the lower end of the range of recommended dosage. An initial dose can be administered SLOWLY into an infusing intravenous line. Additional doses of diazepam should not be administered without waiting a minimum of 5-10 minutes between doses to fully evaluate the effects of the drug.

Side effects include hypoventilation and apnea, potentiated by narcotic/opioid analgesics (such as fentanyl or morphine) and other CNS depressants.

Ketamine

Ketamine provides both a dissociative state of hypnosis and analgesia. It has rapid onset and relatively rapid offset. Ketamine has sympathomimetic action that preserves cardiac function and has minimal effect on respiration.

Ketamine is not routinely used for moderate sedation of adults. This medication should only be administered by practitioners experienced with its unique effects. In many institutions, ketamine is restricted for use by non-anesthesiologists. Ketamine is contraindicated for infants younger than 3 months; and in patients with established psychosis, known or suspected cardiovascular disease, active pulmonary infection, or those who have sustained head injury with loss of consciousness or altered mental status, or emesis; procedures involving stimulation of the posterior pharynx; patients with CNS masses, abnormalities or hydrocephalus, glaucoma, acute globe injury, porphyria, thyroid disorders or those receiving thyroid medication.

At very low dose, ketamine produces analgesia and sedation. When the critical dosage threshold is reached, the characteristic dissociative state abruptly appears. This dissociation has no observable level of depth and the goal of titration is to maintain this state. Both intravenous and intra-muscular routes are considered equally effective in achieving sedation.

The intravenous dose should be administered over a period of 60 seconds. More rapid administration may result in respiratory depression or apnea and enhanced pressor response.

For intravenous administration, the time to peak effect is usually 1 minute with a duration of dissociation lasting 15 minutes and recovery at 60 minutes. For intramuscular administration, the time to peak effect is usually 3 – 5 minutes with dissociation lasting 15 – 30 minutes and recovery at 90 – 150 minutes. Prolonged recovery time may occur if barbiturates and/or narcotics are used concurrently with ketamine. Ketamine is NOT reversible with flumazenil or naloxone.

Side effects of ketamine include:

- hypersalivation
- hypertension, tachycardia
- increased intracranial pressure, CNS excitement, dysphoria.
- diplopia, nystagmus, elevation in intraocular pressure measurement
- unpleasant recovery reactions including hallucinations

ANTAGONISTS

What antagonists are used for reversal of serious adverse effects of opioid analgesics and benzodiazepine sedatives?

- Naloxone for reversal of opioids.
- Flumazenil for reversal of benzodiazepines.
- There are NO antagonists for chloral hydrate, pentobarbital, or ketamine.

Antagonists are **NOT RECOMMENDED** for routine use as their implementation implies overdose. They should NEVER be used as substitutes for careful monitoring, or the cautious titration of opioids or benzodiazepines to a desired effect.

Prior to (or concomitant with) pharmacological reversal, patients who become hypoxemic during sedation and analgesia should:

(1) be encouraged or stimulated to breathe deeply;
(2) receive supplemental oxygen; and
(3) receive positive pressure ventilation if spontaneous ventilation is inadequate.

What are the indications, appropriate dosage and potential side effects of these antagonists?

Naloxone

Naloxone is a narcotic/opioid antagonist used for reversal of respiratory depression and hypotension caused by narcotic/opioid analgesics (e.g., fentanyl, morphine).

An initial dose of naloxone is given by RAPID IV push. Peak effect occurs within 1 – 2 minutes. Additional doses may be administered after waiting sufficient time to fully evaluate effect.

Naloxone must be used with special care in patients with cardiac disease or known tolerance to opioids, and should be given in small incremental doses. A larger than necessary dose of naloxone may result in a significant reversal of analgesia and an increase in blood pressure.

Naloxone has a duration of action of 30 – 60 minutes which is a shorter duration than most narcotics/opioids. As a result, re-sedation may occur necessitating re-administration of naloxone. All patients must be observed for up to two hours following the last dose of the antagonist.

Side effects of naloxone include:

- Abrupt reversal may result in pain, leading to tachycardia, myocardial ischemia and pulmonary edema, especially in elderly patients.

- Too rapid reversal may induce nausea, vomiting, sweating or circulatory distress, and pulmonary edema.
- Production of withdrawal symptoms (tremors, nausea, vomiting, excitement, sweating, hypertension) in patients chronically receiving narcotic/opioid analgesics.

Flumazenil

Flumazenil is a benzodiazepine antagonist used for reversal of sedative and respiratory depressant effects of benzodiazepines (midazolam or diazepam).

Flumazenil is contraindicated in patients taking benzodiazepines for control of a potentially life-threatening condition, such as seizures. Flumazenil should be used with special care in patients taking benzodiazepines regularly for chronic conditions and patients requiring medications that lower the seizure threshold (e.g., cyclosporin, cyclic antidepressants, propoxyphene, theophylline, isoniazid, lithium). Rapid reversal can produce withdrawal symptoms.

Flumazenil has a shorter duration of action than some benzodiazepines. Re-administration of flumazenil may be necessary after 20 minutes. All patients must be observed for up to two hours following the last dose of the antagonist.

Side effects include:

- Seizures, especially in patients with seizure disorders or at high risk for seizures
- Blurred vision
- Dizziness
- Dysrhythmias
- Excitement, agitation, anxiety, confusion
- Inconsistent and incomplete reversal of amnesia
- Withdrawal symptoms (tremors, sweating, hypertension, abdominal discomfort, seizures) in patients taking benzodiazepines regularly for chronic conditions

ELEMENT 5: POST-PROCEDURE MANAGEMENT AND DISCHARGE OF PATIENTS WHO RECEIVED MODERATE SEDATION AND ANALGESIA

When moderate sedation and analgesia are delivered in non-operating room settings, specific procedures must be established for monitoring and management of recovering patients and determining each patient's readiness for discharge. This element discusses post-procedure practices.

Upon completion, the practitioner will be able to:

- Discuss basic principles in post-procedure care.
- Explain when it is appropriate to discharge a patient.

What are the basic principles for post-procedure care?

All patients must be cared for in an area appropriate to the sedation technique employed. During the recovery period, patients must be medically supervised by a physician and monitored by a nurse or other qualified individual who is trained to evaluate the patient's condition and recognize complications. Comprehensive mental and physiological monitoring continues until discharge criteria are met.

Level of consciousness, vital signs and oxygenation should be monitored and recorded at regular intervals. The duration and frequency of patient monitoring depends on the level of sedation achieved, the overall condition of the patient, and the specific intervention which required administration of sedation and analgesia. Oxygenation should be monitored until patients are no longer at risk for respiratory depression.

The patient recovery area must be equipped with monitoring and resuscitation equipment. A qualified health care practitioner must be immediately available to manage any complications that arise (e.g., establish a patent airway and provide positive pressure ventilation) and be able to call for assistance.

When is it appropriate to discharge a patient?

To further ensure the safety of the patient, providers who administer sedation and analgesia must establish a set of criteria that accurately measure the patient's recovery process and provide a specific threshold indicative of the patient's readiness for discharge. The following criteria generally describe the physical condition of a patient ready to be discharged:

- Awake or restored to the baseline level of consciousness.
- Breathing spontaneously with no respiratory distress.
- Oxygen saturation is at an acceptable level for the patient and type of procedure performed (i.e. returned to baseline in room air).
- Hemodynamically stable.
- Bleeding, pain, nausea and vomiting are controlled.

In ambulatory settings, the following criteria must also be met prior to discharging the patient home:

- Patient is ambulating appropriate for age and medical condition.
- A responsible adult escort is available to accompany the patient.
- Verbal and written post-procedure instructions are given.

Most facilities use a scoring system such as that shown in Figure 2. An acceptable post-sedation discharge score indicates that the patient has returned to the baseline condition and can be discharged. The directing physician should write a discharge order or note that indicates established criteria have been met and the patient is ready for discharge. Some facilities have standing orders whereby a nurse is authorized to perform an assessment of pre-determined discharge criteria (established by an anesthesiologist) are discharge the patient if the criteria are met.

If a patient in recovery required reversal agents (naloxone, flumazenil) at the end or during the procedure, sufficient time for observation should follow the last dose of reversal agent to ensure that the patent does not become re-sedated. As previously discussed, the duration of action for sedatives may be longer than the duration of action of the reversal agents.

Figure 2. Utilizing a Discharge Score

SAMPLE DISCHARGE SCORING SYSTEM					
If category is Non-Applicable, check appropriate box and assign a score of "2"			ON ADMISSION	IMMEDIATE POST-PROCEDURE	ON DISCHARGE
Able to move all extremities (age appropriate) or baseline Some weakness in extremities Unable to move extremities	2 1 0	**ACTIVITY**			
Able to breathe deeply and cough freely Dyspnea, limited breathing or tachypnea Apneic or on mechanical ventilator	2 1 0	**RESPIRATION**			
BP = 20% of pre-anesthetic level BP = 29% to 49% of pre-anesthetic level BP = 50% of pre-anesthetic level	2 1 0	**CIRCULATION**			
Fully awake Arousable on calling Not responding	2 1 0	**CONSCIOUSNESS**			
Able to maintain O2 Sat > 92% on room air Needs O2 inhalation to maintain O2 Sat > 90% O2 Sat < 90% even with O2 supplement	2 1 0	**OXYGEN SATURATION**			
Pain free Mild pain handled by oral medication Severe pain requiring parenteral medication	2 1 0	**PAIN**			
Minimal Moderate, requiring treatment Severe, requiring treatment	2 1 0	**NAUSEA / VOMITING**			
Discharge Criteria Recovery Score must be <u>greater than 12 with no score less than 1 in any individual category.</u>		Total score =			

Patients in ambulatory care settings must be discharged in the presence of a responsible adult who will escort them home and accept responsibility for reporting any post-procedure complications. Patients frequently do not remember information told to them during the post-procedure period. Verbal instructions must be reinforced in writing and/or given to a responsible companion. Patient instructions should include information regarding post-procedure diet, medications, activities, and a phone number to call in case of emergency.

Conclusion

Production of a state of moderate sedation and analgesia is essential to successfully complete many therapeutic and diagnostic examinations and procedures. Careful application of monitoring and the ability to respond quickly and appropriately to adverse changes and the knowledge of available drugs, their effects and correct application can make almost all of these patient encounters stress and pain free and above all, safe.