



Appendix 6

Position Paper on Procedural Sedation: An Official Position Paper of the Canadian Anesthesiologists' Society

Introduction

A key mandate of the Canadian Anesthesiologists' Society (CAS) is to promote the provision of safe anesthesia care of the highest possible standard. Traditionally, this care has been provided in operating theatres and solely by anesthesiologists; however, practice is evolving to encompass other locations and many variations of care. Nevertheless, the requirements for assessing the patient and managing the medical intervention do not change as a function of either the provider or the location of the intervention. The purpose of this document is to describe good practices in sedation care.

Sedation is “*a state of reduced excitement or anxiety that is induced by the administration of a sedative agent*”. This condition is distinct from “general anesthesia”, which is described as “*a state of total unconsciousness resulting from anesthetic drug(s)*”, and distinct from “analgesia”, which is described as the “*reduction of or insensibility to pain without loss of consciousness*”. The provision of therapeutic sedation may make unpleasant health care procedures more acceptable to patients, but the same care can cause potentially life-threatening complications. The fundamental principle of the practice of sedation is “*primum non nocere*”, meaning “first, do no harm.”

Sedation itself does not reduce the sensation of pain. If an intervention is primarily intended to relieve pain, then additional therapeutic treatments (local, regional, or general anesthesia) must be utilized.

Definitions

The terms “conscious”, “light”, “moderate”, and “deep sedation” have become non-reproducible and difficult to interpret. Objective measures with identifiable endpoints are preferred; many practitioners feel that existing scales are inadequate because they fail to identify and separate distinct attributes of analgesia and sedation quality. An early scale by Ramsay *et al.* is easy to interpret and replicate, and it specifically defines endpoints:

The Ramsay Sedation Scale (RSS) (modified)

<i>Value</i>	<i>Description (level of sedation)</i>	<i>Test to follow:</i>
1	Awake: Patient is anxious and agitated, or restless, or both.	Observe the patient.
2	Awake: Patient is co-operative, orientated, and tranquil.	Observe the patient. Does patient make eye contact and respond to commands?
3	Awake: Patient responds to commands only.	Talk to the patient. Does patient make eye contact and respond to commands?
4	Asleep: Patient reacts with a brisk response to a light glabellar tap or a loud auditory stimulus.	Physically stimulate the patient by shaking the shoulder while speaking loudly. Does patient respond within 10 sec?
5	Asleep: Patient reacts with a sluggish response to a light glabellar tap or a loud auditory stimulus.	Physically stimulate the patient by shaking the shoulder while speaking loudly. Does patient respond after 10 sec?
6	Asleep: Patient does not respond to pain.	Use painful stimuli. No response.

Modified after Ramsay M.A., Savege T.M., Simpson B.R., Goodwin R.: Controlled sedation with alphaxalone-alphadolone. *BMJ* 1974, 2:656- 659, and van Dishoeck A.M. *et al.* Reliable assessment of sedation level in routine clinical practice by adding an instruction to the Ramsay Scale. *Eur J Cardiovasc Nurs.* 2009 Jun;8(2):125-8.

Management of Sedation

The provision of potent medications by parenteral routes is a medical act that requires the assessment of a physician. This should include the documentation of a complete history including the indications for the procedure and relevant comorbid processes, an appropriate physical examination, appropriate laboratory and radiologic investigations, and informed consent for the procedure and the anesthetic care. These cannot be delegated to paramedical personnel. General guidelines for care are the same for procedural sedation as for other forms of anesthesia as defined in the CAS Guidelines for the Practice of Anesthesia, including monitoring. Electrocardiogram monitoring may be waived in suitable patients when continuous pulse oximetry is used for minor procedures when RSS 1-3 sedation only is employed.

The following procedures must be completed prior to administering sedation:

- ensure appropriate documentation is immediately available
- review the written consent
- ensure the appropriate routine medications have been taken prior to the procedure
- review fasting status as appropriate
- ensure adequate intravenous access
- ensure the availability of appropriate supplies and equipment, including materials to manage overdose of medications or reactions to medications (e.g., anaphylaxis) and a cart for resuscitation from cardiac or respiratory emergencies
- ensure the availability of appropriately trained and accredited assistance.

Documentation must meet the standards of the health care facility and the CAS Guidelines and must be in an immediately accessible form. If an electronic health record is used, it must be

available to all team members and must have appropriate protection against technical problems, including system power outages.

The consent process must be formally documented. The patient must be given adequate explanation about the nature of the proposed treatment and its anticipated outcome as well as the significant risks involved and alternatives available. The physician most responsible for the procedure must be identified.

Generally, routine cardiac, respiratory, and other medications should be taken as usual. Specific exclusions must be specified to the patient in detail (e.g., anticoagulants, diabetic medications, psychotropic medications, etc.) and documentation should be made available.

The precise requirements for pre-procedural fasting are evolving. In general, patients provided with more profound levels of sedation (RSS 5-6) should fast in accordance with general CAS standards, namely, no lipids or solids for six hours and no clear fluids for two hours. More liberal guidelines may be appropriate for lighter levels of sedation (RSS 1-4), but they should be individualized in view of the patients' comorbidities. Some recent research, particularly in the emergency medicine literature, suggests that more liberal guidelines have not been associated with an increased incidence of regurgitation and aspiration of gastric contents. Up to now, these have been small studies, and while they frequently did not detect complications, they failed to demonstrate *safety*.

Appropriate equipment, including supplies and equipment to manage unintended oversedation and complications of medications or procedures, must be immediately available whenever intravenous medications are administered. Each facility must assess their particular circumstances to ensure that appropriate equipment is available and routinely checked and serviced.

In general, the individual performing the procedure will not be the individual administering or supervising intravenous sedation. For deeper levels of sedation (RSS 4-6), this requirement is absolute; for lighter levels, it may be appropriate to delegate monitoring of a sedated patient to an appropriately trained and certified assistant whose sole responsibility is monitoring the sedated patient. However, the responsible physician must be immediately available to intervene should such be necessary. In specific circumstances where light (RSS 1-3) sedation is administered, it may be appropriate for one anesthesiologist to supervise more than one case, provided that an appropriately trained, qualified, and accredited individual, who is approved by the health care institution, is in constant attendance with each patient receiving care. The attending anesthesiologist must assume medical responsibility for the care of all patients and must be immediately available to attend. The institution must establish the number of concurrent cases in light of the intensity and complexity of the cases and the physical status of the patients.

Medications

A variety of medications are available to provide anxiolysis, amnesia, and drowsiness, and to assist with analgesia. The ideal drug would provide all of these components; it would have a large therapeutic index and margin of safety and would achieve a fast onset and a rapid termination of effect. Unfortunately, no such drug exists, but there are a variety of available medications that the experienced practitioner can utilize, titrate, and individualize to effect to achieve good sedation/analgesia conditions while minimizing the undesirable respiratory and cardiovascular effects.

Reversal agents for benzodiazepines (flumazenil) and narcotics (naloxone) should be used with caution, inasmuch as the duration of action of these agents is much shorter than the duration of action of most of the drugs whose effects they are used to reverse. In this context, recurrence of the primary drug effect is a significant risk, and the patient must be monitored for this specific complication.

The addition of narcotic drugs to sedative agents increases the risk of respiratory depression. Acute surgical or procedural pain is uncommonly treated effectively with moderate doses of intravenous narcotics, and they are not the preferred agent for this indication. Local or regional anesthesia is effective and generally safe for this indication and is the preferred technique.

Ketamine has recently become popular for procedural sedation. It produces dose-related decreases in level of consciousness, though the “dissociative” nature of its effect may make assessment more difficult than with other agents. Ketamine will produce general anesthesia, and since there is no specific reversal agent, it must be used with caution. Although ketamine may be associated with less cardiorespiratory depression than other sedatives, airway obstruction, laryngospasm, and pulmonary aspiration may still occur with its use.

Recovery and Discharge

Post-procedural care of the sedated patient may be delegated to appropriately trained and qualified individuals once the patient has recovered to the level of RSS 2 (awake, patient cooperative, orientated, and tranquil). If the patient is to be discharged from the institution, the attending physician must be available to attend to the patient until standards for discharge have been achieved. Patients must remain in the recovery area for a minimum of 30 minutes after the last dose of intravenous sedation or analgesia is given, or for a minimum of 120 minutes after the last dose of intravenous reversal agent is given. Intravenous access must be maintained until discharge criteria are met.

Frequent notations of vital signs and details of post-procedure events or complications must be documented on the patient’s chart. As well, written guidelines for discharge from the institution must be established and documented on the patient’s chart. Instructions as to post-procedure care must be provided to the patient in written form, including wound care, management of pain and/or complications from the procedure or anesthetic, and the resumption of usual medications, diet, and activity. Patients must be accompanied on discharge by a responsible adult. Patients must be instructed to refrain from driving or operating dangerous machinery for 24 hours.

Audit

The practice of sedation outside of the operating theatre must undergo the same rigorous scrutiny as does the practice of anesthesia in the operating room. A mechanism to specifically audit procedural sedation and document critical incidents and complications must be established, and such cases must be reviewed on a regular basis.