Emergency Medicine Society of South Africa

PRACTICE GUIDELINE
EM013

PROCEDURAL SEDATION IN THE EMERGENCY CENTRE

Expertise in Procedural Sedation is a core competency in Emergency Medicine internationally. This guideline sets out the standard for the routine, safe use of Procedural Sedation by clinical staff in Emergency Centres.

Excluding the cover page, this guideline is 16 pages long.

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PROCEDURAL SEDATION DEFINITION*

Procedural sedation refers to a technique of administering sedatives or dissociative agents, with or without analgesics, to induce a state that allows patients to tolerate unpleasant procedures while maintaining cardiorespiratory function and retaining the ability to respond purposefully to verbal commands and/or tactile stimulation. This technique is appropriate for both adult and paediatric patients.

LEVELS OF SEDATION*

Minimal sedation (anxiolysis) is a drug-induced state during which patients respond normally to verbal commands. Cognitive function and co-ordination may be impaired but ventilatory and cardiovascular systems are unaffected.

Moderate sedation (previously referred to as conscious sedation) is a drug-induced depression of consciousness during which patients respond purposefully to verbal or light tactile stimulation. The techniques and drugs (in the doses used) are not likely to produce loss of protective airway reflexes.

Deep sedation is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully after repeated or painful stimulation. These patients may require assistance in maintaining a patent airway and they may need ventilatory support.

General anaesthesia refers to a state of drug-induced loss of consciousness during which patients are not rousable and may have impaired cardiorespiratory function requiring varying degrees of support.

Dissociative sedation is a trancelike cataleptic state characterised by profound analgesia and amnesia with retention of protective airway reflexes, spontaneous respirations and cardiopulmonary stability. Ketamine is the only approved dissociative agent.

(*)From the American College of Emergency Physicians Clinical Policy on Procedural Sedation and Analgesia in the Emergency Department, Ann Emerg Med. 2005;45:177-196

Progression from one stage to the next is a continuum, and it is often difficult to predict how a patient will respond to a specific sedative agent. It is essential that practitioners possess the skills necessary to rescue a patient from one level deeper than the desired level of sedation.

Recommendations in this guideline are not intended to represent the only diagnostic and management options that emergency practitioners can apply. The individual physician's judgement is of utmost importance. However, procedural sedation is the recognised and validated standard of practice for painful and intimidating procedures.

SCOPE OF PRACTICE GUIDELINE

This Practice Guideline:

- applies to the administration of dissociative agents, sedative agents or sedative and analgesic agents together.
- does NOT apply to:
    - administration of agents to facilitate airway management or tracheal intubation
    - patients who have already undergone tracheal intubation and ventilation
- refers to the use of moderate sedation and analgesia, and deep sedation and analgesia, in order to facilitate diagnostic or therapeutic procedures.
- refers to the use of sedative, analgesic and dissociative agents in the Emergency Centre.
- refers to adult and paediatric patients.

OBJECTIVES OF PROCEDURAL SEDATION

- To provide adequate analgesia, anxiolysis, sedation and amnesia during the performance of painful diagnostic or therapeutic procedures.
- To minimise variations in patients' cardiovascular and respiratory physiological parameters.
- To maintain the patient's protective airway reflexes.

CONTRAINDICATIONS TO PROCEDURAL SEDATION

Contraindications include:

- Lack of personnel experienced in airway management or interpretation of monitoring equipment.
- Lack of appropriate monitoring equipment, or inability to monitor patient during procedure.
- Lack of resuscitation and airway management equipment.
- Children under the age of two years should not receive procedural sedation unless under the care of an emergency physician experienced in paediatric emergency medicine.
- Allergy or sensitivity to the prescribed medication (Refer to the listed contraindications to specific medications as described in the latest edition of the SAMF).

Relative contraindications include:

- facial, dental or airway abnormalities which would preclude tracheal intubation.
- patients at high risk of vomiting and aspiration
- haemodynamically or neurologically unstable patients.

PATIENT EVALUATION

Obtain a history and perform a physical examination to identify medical illnesses, medications, allergies and anatomic features that may affect procedural sedation and airway management.

The time and nature of last oral intake must be documented.

The medical history and formal physical examination to be performed prior to administering sedation is to include the following:

- Health and risk assessment history including allergies, current medications, current health problems, previous hospitalisations, previous sedation and anaesthetic history.
- Vital signs and weight.
- Mental health status.
- Assessment of airway opening and patency.
- The airway should also be assessed for potential difficulties to bag-mask ventilate as well as difficult laryngoscopy.
- Respiratory status.
- Cardiovascular status.
- NPO status.
- Developmental status (in paediatric cases).

As part of the consent process, staff members must clearly explain the proposed treatment or procedure. The explanation should include the following:

- Potential benefits and drawbacks
- Any possible adverse affects of treatment
- Any significant/reasonable alternatives
- The likelihood of success.

Informed consent for sedation and the procedure is to be obtained by documentation on a formal consent form.

Patients at high risk for complications due to Procedural Sedation include individuals with:

- Upper airway obstruction (stridor when awake).
- Sleep apnoea or significant snoring.
- Mandibular hypoplasia, craniofacial abnormalities or history of difficult airway during anaesthesia or sedation.
- Active vomiting, delayed gastric emptying.
- Significant gastro-oesophageal reflux, particularly with history of aspiration.
- Pre-existing significant neurologic dysfunction or depressed level of consciousness.
- Hypovolaemia, cardiac disease or other potential for alteration in perfusion.

- Pneumonia, reactive airway disease or other disorder of gas exchange or pulmonary mechanics.
- History of sedation failure.
- Multiple trauma.
- Head trauma.
- Patients who have ingested a central nervous system depressant such as alcohol.

Sedation techniques with higher risk for complications include:

- Deep sedation, regardless of intended depth or drugs administered.
- Non-elective sedation.
- Combination drug therapy, particularly opioids and hypnotics.
- Medications administered in large doses instead of titrated to effect.
- Use of opioids for sedation instead of analgesia.

The planned sedation process will be developed based on the assessment information including patient risk documentation, assignment of an ASA physical status score, risk of procedure and risk of planned sedative techniques. Patients with ASA classification of IV and V should NOT be considered for procedural sedation.

American Society of Anesthesiology patient classification status

ASA I

Normal healthy patient

ASA II

Patient with mild systemic disease; no functional limitation
eg smoker with well-controlled Hypertension

ASA III

Patient with severe systemic disease; definite functional impairment
eg Diabetes and angina with relatively stable disease, but requiring therapy

ASA IV

Patient with severe systemic disease that is a constant threat to life
eg Patients have dyspnoea on mild exertion and chest pain

ASA V

Unstable moribund patient who is not expected to survive 24 hours with or without the operation

ASA VI

Brain-dead patient whose organs are removed for donation to another

E

Emergency operation of any type - added to any of the 6 above categories
(eg ASA II E)

PRE-PROCEDURE PREPARATION AND EQUIPMENT

The procedure should be performed in a clinical environment where monitoring can occur and where access to resuscitative drugs and equipment is immediately available. The relevant reversal agents must also be available.

The following equipment should be present (refer to EMSSA Practice Guideline EM006):

- Oxygen and delivery devices (nasal, cannula and face mask)
- Suction and suction catheters
- Resuscitation trolley and defibrillator and intubation equipment
- Vital signs monitor (including BP, cardiac monitor and saturation)
- Positive pressure breathing device
- Appropriate size oral airways
- ACLS medications

Intravenous access must be established and maintained, except when using an intramuscular technique for the administration of Ketamine in children.

FASTING BEFORE PROCEDURAL SEDATION

There is no evidence to show that patients need to be fasted, and recent food intake is not a contra-indication. The risks and benefits for performing procedural sedation on each patient need to be carefully considered in choosing the timing and target level of sedation.

STAFF

Sedation and performance of a procedure requires at least 2 appropriately qualified staff (a doctor and a nurse or two doctors): one to perform the procedure, and one to be solely responsible for the administration of medication, monitoring and documentation.

Observation and monitoring should be done from the start of sedation until discharge criteria have been met.

The staff responsible for administering the IV analgesia and sedation should be trained in the recognition of complications associated with IV sedation. Personnel providing procedural sedation and analgesia must have an understanding of the drugs administered, the ability to monitor the patient's response to the medications given and the skills necessary to intervene in managing all potential complications.

MONITORING AND DOCUMENTATION

Assessment of the patient should be done at baseline and every five minutes once the first analgesia/sedation dose has been administered. The following should be documented:

- Vital signs (BP, HR, RR)
- ECG rhythm
- Oxygen saturation
- Airway patency
- Use of supplemental oxygen or not
- Level of consciousness
- Pain
- Medications given including route, dose and person administering.

Capnometry can be considered to provide additional information regarding the early identification of hypoventilation but is not an essential requirement of procedural sedation.

Documentation should include the date and time of start of sedation, start of procedure and time of conclusion of post-procedure care. Adverse events which should be recorded include apnoea or airway obstruction requiring intervention, vomiting, aspiration, over sedation and inadequate sedation or sedation failure or need for reversal agents.

DRUGS ADMINISTERED

Ketamine, midazolam, fentanyl, propofol and etomidate can all safely be administered for procedural sedation and analgesia in the Emergency Centre. Morphine can be safely used as an analgesic adjunct.

Medication doses must be calculated, drawn up and labelled prior to commencement of the procedure. Appropriate antagonists must be available and only used if absolutely necessary. Antagonists should not be given directly after the procedure in order to "reverse" the patient's sedation and analgesia.

Drugs should be given slowly and in small incremental doses. Analgesic agents should generally be administered before sedative agents, as oversedation may result if analgesic medications are given after sedation. The therapeutic affect should be assessed before the next incremental dose is determined and the patient should be observed for the following:

- Decrease in oxygen saturation.
- Ability to maintain patent airway.
- Appropriate response to physical stimulation and/or verbal command.
- Significant changes in vital signs.

Adjust doses according to patient's age, level of debilitation, drug combinations, patient tolerance, pulmonary reserve, previous narcotic usage and length of procedure.

POST-PROCEDURE CARE AND DISCHARGE CRITERIA

The patient should not be left alone at any stage, but a trained staff member should remain with the patient until discharge. Post-procedure assessments should be documented:

- every fifteen minutes for 1 hour
- then every thirty minutes for 1 hour
- then hourly or until discharge criteria have been met.

If the patient receives a reversal agent, then they should be observed post-procedure for a minimum of 1.5 additional hours.

The following criteria need to be fulfilled before the patient can be discharged:

- Vital signs, level of consciousness, cardiovascular and respiratory status have returned to pre-sedation levels.
- A responsible, designated adult is able to accompany patient and transport is available.
- The patient/caregiver has received appropriate verbal and written discharge instructions.
- Discharge forms are completed and discharge medication has been dispensed.
- Pain is adequately controlled.
- Nausea/vomiting is controlled.
- Oxygen saturation is at pre-intervention status.
- No signs or symptoms that may jeopardize the safety of recovery (i.e. Bleeding, swelling, extreme pain, dizziness etc.)
- Follow-up for extended care has been provided.
- For children: age appropriate responses are present.

All patients **MAY NOT DRIVE** back home in the subsequent 12 – 24 hours following discharge. The same precaution would apply to patients who have to operate heavy machinery the same day.

Patients with special handicaps including the Blind with or without a guide dog; the Deaf & Mute; patients with Mental illness and/or mental handicap: All these may need extra precautions on discharge under the discretion of the attending doctor.

APPENDIX A

APPENDIX OF MEDICATIONS AND DOSAGES

DRUG	ADULT DOSING (>45kg)*	PAEDIATRIC DOSING	ONSET	SPECIAL CONSIDERATIONS & REVERSAL AGENT	PRECAUTIONS (P) / CONTRAINDICATIONS (C) / SIDE EFFECTS (S)
ETOMIDATE (Hypnomidate) Sedative	**Initial dose:** 0.1-0.2mg/kg slow IV push over 30-60 seconds	Under 10 years, no dose established. Over 10 years, as for adults.	**Onset:** <1 min **Duration:** 3-5 min **Metabolised:** Liver **Excreted:** Kidney	No reversal agent	**P**-Category C in pregnancy, increased CNS depressant effect with alcohol **C**-Porphyria **S**-Commonly causes myoclonus, pain upon injection -Adrenal suppression (typically no clinical significance) -Nausea / Vomiting -Lowers seizure threshold - Minimal effect on haemodynamics -No release of histamine -No analgesic properties

* Patients with higher tolerance may receive higher doses at the discretion of the physician.

DRUG	ADULT DOSING (>45kg)*	PAEDIATRIC DOSING	ONSET	SPECIAL CONSIDERATIONS & REVERSAL AGENT	PRECAUTIONS (P) / CONTRAINDICATIONS (C) / SIDE EFFECTS (S)
FENTANYL (Sublimaze) Analgesic Sedative effects	**Initial Dose:** 1-2 mcg/kg slow IV push (over 1-2 min); may repeat dose after 30 min. **Usual Maximum:** 100mcg within 30 min. **IV Dose Rate:** Administer slowly. Wait 5 minutes to evaluate effect. Maintain level with 25-50% of initial IV dose.	**Initial dose :** 1mcg/kg.	**Onset:** 1-2 min. **Peak:** 3-5 min. **Duration:** 30-60 min. **Metabolised:** liver **Excreted:** kidney	Reduce dose by 1/4 to 1/3 when used with other CNS depressing drugs or in the elderly or debilitated. Muscle rigidity from high doses may prevent adequate chest wall expansion and respirations. This is reversed with neuromuscular blockers or naloxone, but patient must be artificially ventilated **NALOXONE**	**P**-elderly/debilitated -bradyarrhythmias -head injury -resp. disease **C**-hypersensitivity **S**-CNS/resp. depression -hypotension -muscle rigidity -bradycardia -N/V -pruritus -seizures

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DRUG	ADULT DOSING (>45kg)*	PAEDIATRIC DOSING	ONSET	SPECIAL CONSIDERATIONS & REVERSAL AGENT	PRECAUTIONS (P) / CONTRAINDICATIONS (C) / SIDE EFFECTS (S)
FLUMAZENIL (Anexate) Reversal of Benzodiazepines	Reversal of benzodiazepine induced sedation. **Onset:** 1-2 min. **Peak effect:** 6-10 min. High Risk people may be necessary to increase interval between doses to over one minute.	**Initial dose:** 0.2mg IV over 15 sec. Wait 45 sec, additional 0.2mg. doses at one minute intervals until maximum of 4 additional doses have been given. Maximum cumulative dose is 1.0 mg. Repeat above in 20 min. if needed No more than 3 mg in one hour.	No manufacturer published data.	Can precipitate seizures in those with seizures controlled by benzodiazepines, with tricyclic depression overdose, and with high risk for seizures.	**P** –resedation, monitor for resedation, respiratory depression for up to 120 min. Resedation least likely in low dose sedation, (eg<10mg Midazolam) **C**-hypersensitivity -tricyclic antidepressant overdose -benzodiazepine dependency **S** –visual disturbances, diaphoresis, seizures, arrhythmias

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DRUG	ADULT DOSING (>45kg)*	PAEDIATRIC DOSING	ONSET	SPECIAL CONSIDERATIONS & REVERSAL AGENT	PRECAUTIONS (P) / CONTRAINDICATIONS (C) / SIDE EFFECTS (S)
KETAMINE Analgesic Dissociative agent	**Initial dose:** 1 – 2mg/kg IVI **IV dose rate:** Give slowly over one minute.	**IV**: 0 .5-1 (2) mg/kg maximum dose 100mg **IM**: 4mg/kg (range 3-5mg/kg) maximum dose 50mg/kg (IM preferred Route) **Oral**: 4-5mg/kg **Different formulations** available: 10mg/ml, 50mg/ml, 100mg/ml	**Onset:** 30 sec – 1 min. IV 3-4(5) min. IM **Duration:** 5- 15min. IV 12-25 min. IM **Full Recovery:** 30-120 min **Initial IV dose over 60 sec.** (rapid administration may cause respiratory depression) **Metabolism**: liver **Excretion:** kidney	Atropine should NOT be given routinely as it has been shown to be associated with a higher incidence of respiratory complications. Barbituates and Ketamine should not be injected using the same syringe	**C**-history of Cardiovascular disease or hypertension -active pulmonary infection or disease -age 3 months of less -Head injury not a contraindication to ketamine -Glaucoma or acute globe injury not a contraindication to ketamine -Psychosis -Conditions with intracranial hypertension -Seizure or CNS disorders -History of airway instability, tracheal surgery or stenosis **S**-nystagmus,resp. depression, hypersalivation, laryngospasm, non-purposeful movements, emesis, ↑ HR,B/P, ICP -"Emergence reaction" -unpleasant dreams/hallucinations (most common in females>age 10)

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MIDAZOLAM (Dormicum) Anxiolytic Sedative Amnesic Skeletal muscle relaxant Anti-convulsant	**Initial dose:** 0.02-0.1 mg/kg IV initially; if further sedation is required, may repeat with 25% of initial dose after 3-5 min; not to exceed 2.5 mg/dose (1.5 mg for elderly persons) and 5 mg cumulative dose (3.5 mg for elderly persons) **Usual max:** Average adult<60 years 5mg within 30 min. Elderly adult >60 years 3.5 mg within 30 min. **IV Dose rate:** 1mg over 1 min. Wait 2 min. after each increment to fully evaluate effects. Maintain level with 25% of initial IV dose.	**IV:** Intravenous: 0.05-0.1 mg/kg IV 3 min before procedure; not to exceed a total cumulative dose of 0.4 mg/kg or 6 mg **Oral**: 0.5-0.75mg/kg	**Onset:** 1 ½-5 min. **Peak:** 10-15 min. **Duration:** 60-90 min. **Metabolised:** liver **Excreted:** kidney Recovery is dose dependent, usually 1-2 hrs.	Reduce dose by 1/3 to 1/2 when used with other CNS depressing drugs or in the elderly or debilitated. Manufacturer recommends not more than 1.5 mg over at least two minutes in patients with decreased pulmonary reserves. **FLUMAZENIL** (Anexate)	**P**-elderly/debilitated **C**-hypersensitivity, - acute narrow angle glaucoma **S**-CNS/respiratory depression -hypotension -agitation -Nausea/Vomiting - hiccups

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DRUG	ADULT DOSING (>45kg)*	PAEDIATRIC DOSING	ONSET	SPECIAL CONSIDERATIONS & REVERSAL AGENT	PRECAUTIONS (P) / CONTRAINDICATIONS (C) / SIDE EFFECTS (S)
MORPHINE Analgesic Sedative effects Used as analgesic adjunct in procedural sedation, not as sole agent	**Initial Dose:** 0.05-0.1mg/kg slowly 2.5mg.- elderly/debilitated 5-10 mg. –healthy adult **Usual Maximum:** 10 mg within 30 min. **IV Dose Rate:** Administer slowly. Wait 5 min. to evaluate effects	0.05-0.1mg/kg slowly	**Onset:** 1 min. **Peak:** 15 min. **Duration:** 2-4 hrs. **Metabolised:** liver **Excreted:** kidney	Reduce dose by 1/3 to 1/2 when given with other CNS depressing drugs or in the elderly or debilitated **NALOXONE** (Narcan)	**P**-elderly/debilitated -respiratory conditions -seizure disorders -head injury **C**-hypersensitivity **S**-CNS/respiratory depression -hypotension -Nausea/Vomiting -dizziness

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DRUG	ADULT DOSING (>45kg)*	PAEDIATRIC DOSING	ONSET	SPECIAL CONSIDERATIONS & REVERSAL AGENT	PRECAUTIONS (P) / CONTRAINDICATIONS (C) / SIDE EFFECTS (S)
NALOXONE Reversal of narcotics	0.4mg. –2mg. IV May repeat as needed in 2-3 minute intervals prn	0.01mg/kg every 2-3 min. May repeat as needed. If does not produce desired outcome, a subsequent dose of 0.1mg/kg may be administered. Alternate option infusion at 0.4mg/hour	**Onset:** 1-2 min.	Can precipitate ventricular tachycardia and fibrillation in those with cardiovascular disease or receiving potentially cardiotoxic drugs. Monitor for resedation.	**P** –cardiovascular disease **C**-hypersensitivity -narcotic dependency **S**-Nausea/Vomiting, - sweating -tachycardia, hypertension -pulmonary oedema

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PROPOFOL (Diprivan) Non analgesic Sedative	**Initial dose**: 1mg/kg bolus IV Manually "top-up" doses with boluses at half the initial dose.	**Initial dose:** 0.5-1mg/kg over 20-30 seconds or continuous infusion starting at 100-150mcg/kg/min followed by maintenance infusion of 25-75 mcg/kg/min **(Infusions should only be used by those experienced at using them)**	**Onset**: <1 min **Duration**: 5-10mins **Metabolised**: liver **Excreted:** kidney	No reversal agent	**P-** Avoid bolus dosing and use smaller infusion doses in elderly/debilitated patients -May cause hypotension in 3-10% of adult patients and 17% of paediatric patients. **C**- Patients with soybean and egg hypersensitivity. -Caution in elderly and hypovolaemic patients (consider fluid bolus in hypovolaemic patients pre-injection of propofol) **S**- Painful injection. This is improved by mixing the drug with a small amount (0.25 mg/kg) of intravenous lignoocaine

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