The safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in children

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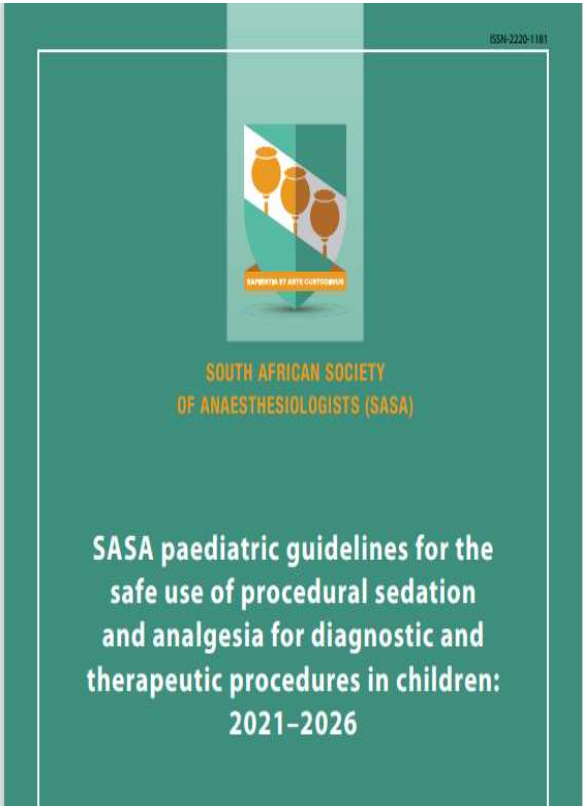
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SASA paediatric guidelines for the safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in children: 2021–2026


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Position Statement
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Managing pain and distress in children undergoing brief diagnostic and therapeutic procedures
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Practice Parameter | March 2018
Practice Guidelines for Moderate Procedural Sedation and Analgesia 2018:
A Report by the American Society of Anesthesiologists Task Force on Moderate Procedural Sedation and Analgesia, the American Association of Oral and Maxillofacial Surgeons, American College of Radiology, American Dental Association, American Society of Dentist Anesthesiologists, and Society of Interventional Radiology
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Introduction:

The performance of **diagnostic and therapeutic procedures** in children is safer and more likely to be successful when the patient does not move and when any associated pain and anxiety are effectively controlled.

Pharmacologic and nonpharmacologic interventions that consider the child's developmental status and the clinical circumstances are often required to meet these goals.

In addition, attention to the treatment of pain and anxiety associated with the child's condition is a requisite of acceptable and compassionate **patient care.**

Goals of procedural sedation and analgesia

- Maintain patient safety and welfare
- Minimize physical pain and maximize patient comfort
- Control anxiety, minimize psychological trauma, maximize amnesia
- Control behavioral movement to allow safe performance of procedures

Definition:

- The practice of procedural sedation is the administration of one or more pharmacological agents to facilitate a diagnostic or therapeutic procedure while targeting a state during which airway patency, spontaneous respiration, protective airway reflexes, and hemodynamic stability are preserved, while alleviating anxiety and pain".

- wide range of procedures may warrant sedation in children, including nonpainful imaging procedures that require no movement (MRI ,CT), mildly painful procedures (IV canulation, laceration repair), and moderately to severely painful procedures (fracture reduction, inter oseos) require analgesia as well as sedation.

CONTRAINDICATIONS AND PRECAUTIONS TO PSA

- There are no absolute contraindications.
- Relative contraindications include :
  - signs of a difficult airway
  - significant medical comorbidities (American Society of Anesthesiologists [ASA] classification III or higher).
  - severe sleep apnea
- These patients warrant consultation with a **pediatric anesthesiologist** or clinician with **similar pediatric sedation expertise**.

ASA classification

Class I – A normally healthy patient
Class II – A patient with mild systemic disease (eg, mild asthma, controlled diabetes mellitus)
Class III – A patient with severe systemic disease (eg, moderate to severe asthma, poorly controlled diabetes mellitus, pneumonia)
Class IV – A patient with severe systemic disease that is a constant threat to life (eg, severe bronchopulmonary dysplasia, advanced cardiac disease)
Class V – A moribund patient who is not expected to survive without the operation (eg, septic shock, severe trauma)

Risks to patient safety

- Although the procedure itself usually poses little risk to the child, the addition of sedation by administering sedatives, analgesics and/or dissociative agents, may add to the risk. The use of **combination** therapy may further **increase the risk** of adverse events.
- Adverse events categorized as follows, according to clinical importance:

• Lesser adverse events (i.e. a short period of oxygen desaturation)

• Standard or moderate adverse events (i.e. lowest oxygen saturation at ٧٥% or lasting longer than ٩٠ seconds)

• Critical adverse events (i.e. permanent neurological injury, admission to hospital, CPR and tracheal intubation, or death)

Definitions the depth of sedation

Analgesia

Relief of pain without intentionally producing a sedated state. Altered mental status may be a secondary effect of medications administered for analgesia.

Minimal sedation

patient responds normally to verbal commands. Cognitive function and coordination may be impaired, but ventilatory and cardiovascular function is unaffected.

Moderate sedation/analgesia

has depression of consciousness but can respond purposefully to verbal commands either alone or accompanied by light touch.
Maintains airway and adequate ventilation without intervention. Cardiovascular function is maintained.

Deep sedation/analgesia

cannot be easily aroused but responds purposefully to noxious stimulation. May require assistance to maintain airway and adequate ventilation. Cardiovascular function is usually maintained.

General anesthesia

cannot be aroused. Often requires assistance to maintain airway and positive pressure ventilation. Cardiovascular function may be impaired.

The continuum of procedural sedation and analgesia

Table I: The sedation continuum

	Minimal sedation/ anxiolysis	Moderate sedation/ analgesia	Deep sedation/ analgesia	General anaesthesia
Responsive-ness	Responds to verbal stimuli	Purposeful response to verbal or tactile stimuli	Purposeful response only after repeated or painful stimuli	Unable to rouse
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular function	Unaffected	Usually maintained	Usually maintained	May be impaired

Non-dissociative sedation

- Non-dissociative sedative drugs (including opioids, benzodiazepines, barbiturates,and propofol) operate on the sedation dose–response continuum. Higher doses provide progressively deeper levels of sedation with possible respiratory and cardiovascular compromise, central nervous system depression and unconsciousness.

- With the use of non-dissociative drugs, the key to minimizing adverse events is the careful titration of drugs until the desired effect is reached.

Dissociative sedation

- Sedation with ketamine represents an exception to the above sedation continuum, whereby increasing doses result in deeper levels of sedation and increased risk for respiratory suppression. By contrast, ketamine sedation is characterized by a trance-like cataleptic state in which the patient experiences profound analgesia and amnesia but generally retains airway protective reflexes, spontaneous respirations, and cardiopulmonary stability. Some experts call this state "dissociative sedation".

- Some practitioners believe that dissociative sedation should be part of the PSA continuum, and would fit in between moderate and deep sedation.

Sedation techniques

- PSA should always include both pharmacological and non-pharmacological strategies.

❑Non-pharmacological strategies :

psychological preparation, nutritive and non-nutritive sucking, distraction and scheduling the procedure during the child's usual nap time, *Deep breathing, Hypnosis,Music therapy*

❑Pharmacological strategies (short acting) :

Sedative hypnotic agent

Analgesic agent

❑Procedures that are not painful but require the child to remain still can usually be performed with sedation alone. Children undergoing painful procedures require analgesia as well as sedation.

Non-pharmacological strategies

Figure 5. Swaddling.

Figure 6. Distraction.

Figure 9. Cream application.

Figure 3. Sucrose administration.

Sedation techniques

SEDATIVE-HYPNOTIC AGENTS

Propofol

Dexmedetomidine

Midazolam

Short-acting barbiturates

Chloral hydrate

ketamine

Nitrous oxide

These drugs provide sedation, motion control, anxiolysis, and, to varying degrees, amnesia but (with the exception of ketamine ,dexmedetomidine,N_2O) do not provide analgesia

Chloral hydrate:

- Chloral hydrate was once the preferred sedative agent for diagnostic imaging in infants and children younger than three years of age and is efficacious for that purpose .
- small trials and observational studies indicate that chloral hydrate is inferior to other sedation options because of its delayed onset of action, prolonged effect, and high frequency of adverse effects(vomiting ,hyperactivity, respiratory depression)
- Given the availability of better alternatives, the use of chloral hydrate is no longer recommended.

Chloral hydrate:

- in many regions(USA), chloral hydrate is no longer available.
- Some countries have removed chloral hydrate from national health formularies because of potential carcinogenicity although the risk of cancer from a single dose is inconclusive
- chloral hydrate to be genotoxic, causing chromosome changes and other effects in vivo and in vitro. In addition, chloral hydrate is a reactive metabolite of trichloroethylene, a known carcinogen, and is structurally similar to other carcinogenic intermediates.
- five anatomical sites in risk of cancer , including the lung, stomach, prostate, skin melanoma and mouth floor.

Original Research Article | Published: 20 November 2012

Short-Term Chloral Hydrate Administration and Cancer in Humans

Tmirah Haselkorn, Alice S. Whittemore, Natalia Udaltsova & Gary D. Friedman

Drug Safety **29**, 67–77 (2006) | Cite this article

Potential Carcinogenicity of Chloral Hydrate–A Review

Andrew G. Salmon, Kenneth W. Kizer, Lauren Zeise, Richard J. Jackson & Martyn T. Smith

Pages 115-121 | Published online: 25 Sep 2008

Download citation https://doi.org/10.3109/15563659509000460

Abstract

Sedation techniques

ANALGESIC AGENTS:

Ketamine , Dexmedetomidine and nitrous oxide (N_2O)

Topical, local, and regional anesthesia(lidocaine,tetracaine)

Oral sucrose

Fentanyl

Simple analgesics

Sedation techniques

targeted depth of sedation and the agents used depend upon:

a) anticipated degree of pain

b) allowable amount of motion during the procedure

c) following patient factors:

Comorbidities (eg, asthma, upper respiratory tract infection)
Fasting status
Age and development level
Ability to cooperate
Degree of anxiety
Any prior problems with specific medications

Sedation techniques

- in pediatric patients, endpoints of sedation may be difficult to assess due to particular challenges of effective communication during the care of children, especially the young ones. Depending on the age and cooperation capabilities of the child, the amount of pain generated by the procedure and whether complete immobility is required, sedation endpoints in children tend to extend to the deeper end of the sedation continuum.

Sedation techniques

- This implies that with an increase in drug administration (i.e. by increasing dosage or combining different drugs), the likelihood of advancing to the next level of sedation is increased. Patients may reach a deeper-than-intended level of sedation with accompanying adverse effects. The level of sedation is also affected by drug interactions and the individual's pharmacogenetic profile.

Basic or standard sedation

- sedation induced by a **single agent** and not a combination of several agents
- **oral, transmucosal, nasal or rectal** drugs (e.g. a small dose of an oral benzodiazepine, usually midazolam)
- inhalation of nitrous oxide (N_2O) in oxygen, where the concentration of N_2O must not exceed ٥٠% in oxygen
- titrated intravenous doses of midazolam to a maximum dose of ٠٫١ mg/kg.

- Basic or standard sedation techniques can be used by operator-SPs when all the requirements for safe practice have been met (i.e. training, including supervised clinical training, an observer to monitor and help with rescue if indicated, and premises that meet the requirements for safe practice)

Advanced sedation

- any combination of drugs, administered by any route,
- any sedation administered by the intravenous route (e.g. propofol, etomidate, dexmedetomidine – with the exception of titrated doses of midazolam to a maximum of ۰/۱ mg/kg),
- any inhalational sedation (e.g. sevoflurane), with the exception of N۲O used as the sole agent in a concentration not exceeding ۵۰% in oxygen
- any infusion techniques (i.e. target-controlled infusions [TCIs])

- Advanced sedation should only be performed by SPs who have had supervised clinical training and life support training in pediatric sedation, and require the attendance of a dedicated SP and should not be performed by operator-SP

Table 2: Paediatric: Pharmacological Agents for Procedural Sedation and Analgesia

Agent (reference)	Role	Route	Age (see Appendix 6)	Initial dose - Paediatric	Maximum dose	Repeat dose	Maximum dose	Initial onset time (min)	Peak effect time (min)
Propofol (5)	Sedation/ Amnesia	IV	6months – 2 years	1mg/kg-2mg/kg*		0.5mg/kg every 3-5mins*	3mg/kg*	½ - 1	1 - 2
			> 2 years	0.5 – 1.0 mg/kg*					
Midazolam (5)	Sedation/ Amnesia	IV	6months - 5yrs	0.025-0.05mg/kg **	2mg (single dose)	Up to 0.2mg/kg after 2-5 mins	Total 6mg	1 - 2	3 - 4
			6 – 12 yrs	0.025-0.05mg/kg	2mg (single dose)	0.1mg/kg	Total 10mg		
IM Ketamine (9)	Sedation/ Amnesia/ Analgesia	IM	> 3months only	4-5mg/kg (many authorities/guidelines suggest 2-2.5mg/kg)		Half of first dose: 2-2.5mg/kg (1mg/kg if using lower dose). IM after 5-10mins		½ - 1	1 - 2
IV Ketamine (9)	Sedation/ Amnesia/ Analgesia	IV (over 30-60secs)	> 3months only	1.0mg/kg***		0.5 mg/kg IV after 5-10mins		½ - 1	1 - 2
Ketofol (ketamine and propofol) (5, 6)	Sedation/ Amnesia/ Analgesia	IV	> 6months only	0.5mg/kg propofol and ketamine				½ - 1	1-2

Table 3: Dosing schedule of midazolam

Route of administration	Dose	Recommended maximum dose ***	Time to peak effect	Duration of action
Oral	0.25–0.5 mg/kg	7.5 mg	10–30 minutes	60 minutes*
Buccal/sublingual	0.25–0.3 mg/kg	7.5 mg	10–15 minutes	20–60 minutes*
Intravenous	0.05–0.1 mg/kg to a maximum bolus of 2 mg**	3 mg	3–5 minutes	20–60 minutes*
Rectal	0.5–0.75 mg/kg		10–20 minutes	60 minutes*
Intranasal	0.2–0.3 mg/kg	7.5 mg	10–15 minutes	20–60 minutes

Table 7: Dosing schedule for bolus doses of propofol

Dose	Titration	Onset of action	Repeat dose	Duration of action
Bolus 0.5mg/kg over 3–5 minutes*	1 minute	45–90 seconds	0.5 mg/kg	5–8 minutes

Table 8: Dosing schedule for infusion of propofol for PSA

Intravenous infusion	Target controlled infusion
2–4 mg/kg/hour titrated to clinical effect	Effect site concentration 1–2 µg/ml
In elderly patients, commence infusion at 1–2 mg/kg/hour	In elderly patients, recommended effect site concentration is 0.6–0.8 µg/ml

Table 9: Dosing schedule of ketamine

Route of administration	Dose	Onset of action	Time to peak effect	Duration of action*
Oral	4–6 mg/kg as single agent, 2 mg/kg if used with other sedatives or analgesics	> 5 minutes	30 minutes**	4–6 hours
Intravenous	0.5–1 mg/kg***	1.5 minute	3–5 minutes	5–10 minutes
Intramuscular	2–4 mg/kg	2–5 minutes	20 minutes	30 minutes**
Rectal	4–6 mg/kg	> 5 minutes	30 minutes**	30–120 minutes**
Nasal	5 mg/kg	10 minutes	20 minutes	1 hour

Table 11: Dosing schedule of fentanyl

Route of administration	Dose	Onset of action	Time to peak effect	Maximum dose	Duration of action
Oral/transmucosal	5–15 µg/kg	15–30 minutes	30–45 minutes		1 hour*
Intravenous	0.25 µg/kg**	3– 6 minutes	2–3 minutes	2 µg/kg	30 minutes*

Table 16: Dosing schedule of simple analgesics

Drug	Route of administration	Dose	Time to peak effect
Paracetamol	Oral	15–20 mg/kg	15–120 minutes
	Rectal	40 mg/kg	60–240 minutes
	Intravenous	15–20 mg/kg	30 minutes
Ibuprofen	Oral	7–10 mg/kg (400–800 mg every 4 hours)	120–240 minutes
Diclofenac	Oral	1–1.5 mg/kg	30–120 minutes
Ketorolac	Intravenous	0.5–1 mg/kg (10 mg every 8 hours)	60–120 minutes
	Intranasal	0.5 mg/kg (10 mg every 8 hours)	
Parecoxib	Intravenous	40 mg	Effective within 20 minutes, duration up to 9 hours

Preparation

assessment

(Fasting status, Focused medical examination with specific attention to the airway ,American Society of Anesthesiologists classification)

Monitoring

Continuous visual observation of face, mouth, and chest wall movement when feasible
Initial and repeated measures of vital signs
Continuous measurement of heart rate and pulse oximetry
End tidal-carbon dioxide ($ETCO_2$) detection, especially when visual observation of breathing is not possible (eg, during magnetic resonance imaging)
Repeated blood pressure

Complications from sedation such as respiratory depression are most likely to occur within ٥ to ١٠ minutes after administration of intravenous medication and immediately after the procedure when stimuli associated with the procedure are removed, Thus, monitoring should be especially close during these periods.

Preparation (fasting)

If basic or standard sedation techniques are planned, fasting is recommended, but not mandatory.

If advanced techniques ,including dissociative and non-dissociative techniques, or deep sedation are planned, standard anaesthetic fasting guidelines are recommended:

- Clear fluids, apple juice: two hours
- Solid food: six hours

Preparation

Equipment

(oxygen, oxygen delivery devices, suction equipment, pediatric airway equipment, and a defibrillator are immediately available)

personnel

Administration of moderate sedation requires at least two individuals, typically an advanced practice clinician (eg, physician, physician's assistant, advanced practice registered nurse, nurse anesthetist) and an assistant (typically a registered nurse). At least one person present should have training in pediatric resuscitation and be skilled in airway management and cardiopulmonary resuscitation (CPR)

SEDATION FOR IMAGING STUDIES

- Imaging can often be performed without sedation in older cooperative children and young infants (up to six months of age) who are bundled and recently fed. Furthermore, as newer technologies decrease the image capture time for computed tomography (CT), some younger infants and many uncooperative patients can be imaged **without sedation**

older infants, toddlers, and older children with intellectual disability cannot cooperate even for brief imaging tests (CT) and warrant **sedation** to ensure accurate imaging without excessive radiation exposure.

imaging tests that are negatively impacted by motion (MRI) constitute the most common nonpainful procedures for which children undergo sedation Because imaging studies are not painful, **analgesia is not necessary.**

SEDATION FOR IMAGING STUDIES (Computed tomography)

- In urgent imaging for diagnostic purposes intravenous (IV) route is preferred (maximal efficiency, onset of action is shorter and more predictable, titration is easier, recovery is quicker

propofol, dexmedetomidine, ketamine

- In elective imaging and children without IV access

Oral or intranasal midazolam(۰/۵ mg/kg)
Intranasal dexmedetomidine(۲/۵ mcg/kg)
Intramuscular ketamine

SEDATION FOR IMAGING STUDIES (Magnetic resonance imaging)

MRI often necessitates sedation for up to **one hour**. Furthermore, machine noise and lack of patient access pose additional challenges to achieving safe and effective sedation.

We suggest using propofol or dexmedetomidine with continuous infusion permits successful completion of MRI in approximately ۹۷ to ۹۹ percent of children

propofol :۲ to ۴ mg/kg loading dose followed by an infusion at ۱۵۰ to ۲۰۰ mcg/kg/minute.

dexmedetomidine :۱ to ۳ mcg/kg loading dose (over ۱۰ minutes), followed by ۰٫۵ to ۱ mcg/kg per hour continuous infusion

Evidence from observational studies supports the combination of moderate-dose dexmedetomidine ۱ mcg/kg with low-dose propofol infusion for MRI sedation. The combination appears effective and with fewer adverse effects than propofol used alone.

SEDATION FOR OTHER NONPAINFUL PROCEDURES

- physical examination (genital examination or routine physical examination in children with intellectual disability) or other nonpainful procedures (echocardiography, electroencephalogram) can cause anxiety and lack of cooperation with the medical provider.
- nonpharmacologic interventions can permit completion of the examination or test.
- When nonpharmacologic interventions are not sufficient and mild sedation is necessary we suggest sedation with oral, sublingual, or intranasal midazolam or intranasal dexmedetomidine or intranasal ketamine and dexmedetomidine or "ketodex" (١ mg/kg ketamine and ٢ mcg/kg dexmedetomidine)
- Intravenous (IV) sedation as described for computed tomography is suggested for patients who fail midazolam or dexmedetomidine sedation by the routes described above.

SEDATION FOR PAINFUL PROCEDURES

- painful procedures including fracture reduction, laceration repair, bone marrow aspiration, central line placement, and lumbar puncture.
- chosen agents or combinations of agents must safely provide **sedation and analgesia.**
- Effective local or regional anesthesia can often lower the amount of sedative agent needed to provide adequate sedation and increase the safety of the procedure.

SEDATION FOR PAINFUL PROCEDURES (Minimally painful)

- local anesthetics can be delivered topically or by direct infiltration to diminish or abolish the pain without the need for sedation, especially when age-appropriate nonpharmacologic invention are used
- When nonpharmacologic interventions and local anesthetics are not sufficient and minimal sedation is necessary for minimally painful procedures, we suggest sedation with inhaled nitrous oxide (N_2O); oral, sublingual, or intranasal midazolam; or intranasal dexmedetomidine .Canadian Paediatric Society.pdf

SEDATION FOR PAINFUL PROCEDURES (Moderately or severely painful)

- moderately or severely painful procedures of short duration (fracture reduction, bone marrow aspiration), we suggest procedural sedation with IV ketamine, ketamine combined with propofol, or fentanyl combined with propofol rather than opioids combined with benzodiazepines (midazolam) .
- For selected procedures, effective regional anesthesia can reduce the required medication dose or eliminate the need for moderate or deep sedation altogether.