IAPA SEDATION/ ANALGESIA ADVISORY FOR INDIAN CHILDREN

(Statements do not supersede instructions of concerned anesthesiologist /Sedation Team) (For a quick recap, please read the Infographics poster on this topic)

Dr. Indu Sen, Dr. Anudeep Jafra, Dr. Neerja Bhardwaj, Dr. Nandini Dave

Introduction

Sedation/analgesia is practiced in various locations outside operating rooms for diagnostic and therapeutic procedures (*Table 1*). Pediatric patients, especially neonates and infants have a narrow margin of safety, and are vulnerable to the effects of sedative and anesthetic drugs when not used in a rational manner. They have a myriad of emotions ranging from worry, fear, anxiety in an unfamiliar environment, which is sometimes noisy and they are expected to keep still or hold breath. A child's ability to control his/her behavior depends upon his/her chronological age, as well as cognitive and emotional development.^{1,2}

Over several decades, sedation/ analgesia has been practiced by non-anesthesiologists who get busy in the conduct of procedure. This is a matter of significant concern as there are multiple challenges in various out-of-operating room locations. These include unfamiliar environment, space constraints, poor access to the child, use of contrast, loud noise and risk of ferromagnetic materials in MRI as well and remote monitoring of the patient. Incidence of inadequate sedation was 13.1% and failure rate of optimum image acquisition in pediatric patients ranges from 1-20%.^{3,4} Also, there are published reports of deaths related to dental sedation.⁵ Subsequently, the National Institute of Health (NIH) and the American Academy of Pediatrics (AAP) laid down guidelines to cope up with these challenges, and the need for uniform guidelines across all remote locations was realized. In 2018, international organizations functioning in remote areas along with American Society of Anesthesiologists Task Force jointly drafted Practice Guidelines for Moderate Procedural Sedation and Analgesia. It has been recommended that administration of medications, should be only under the supervision of specially trained medical personnel who can recognize and manage adverse events. Furthermore, rational use of these agents and their route of administration should be based upon individual child's needs, urgency and type of procedure. It has been stated that 'The sedation provider must have skills to manage compromised airway, perform high quality resuscitation and rescue patients from inadvertent general anesthesia. ⁶Emphasis was also placed upon the need for institution specific protocols for procedural sedation. The Pediatric Sedation Advisory by the Indian Association of Paediatric Anaesthesiologists is an effort to ensure safety of children during and after procedures performed under sedation and analgesia in non-operating room locations. These guidelines are also useful for anesthesiologists who may be called for rescue purposes when a child has been sedated by a non-anesthesiologist.

This sedation advisory includes the following:

- I. Appropriate infrastructure and manpower.
- II. Patient evaluation and written informed consent.
- III. Preprocedural fasting ,premedication, monitoring and peri-procedural care.
- IV. Post-procedural care, safe discharge, and follow up plan.

I. Appropriate infrastructure and manpower.

Infrastructure

It should be ensured that well-defined areas are available for the following:

- The location where the child and care giver should report on arrival to hospital.
- Where the child can be evaluated and examined prior to the procedure.
- Where the child can be monitored following premedication and intravenous access.
- Location of the recovery area following sedation/ intervention, where the child can be monitored. This area should have ready access to the pediatric emergency/ICU where patient can be shifted to if escalation of care is required.

Manpower

Qualified medical personnel dedicated for solely providing sedation and monitoring the child in a remote location should be available to ensure the safe and prompt execution of services. This team must be trained in Basic and Pediatric Advanced Life Support and familiar with these locations. It is desirable that team is not only trained in pediatric resuscitation and airway management, but also have adequate experience to handle adverse events in these resource limited areas. A back-up rescue plan should also be available if sedation fails or the child deteriorates during or after the procedure.

II Pre-Procedural Assessment and written informed consent.

This requires detailed evaluation of all children, similar to a preoperative assessment. This evaluation should be done before the child is given an appointment. Children with syndromic manifestations, compromised airways, cardiac anomalies, neurological disorders etc. should be investigated in detail for associated problems and their sequel. A printed proforma helps ensure a complete evaluation and to minimize omissions due to human error. Appropriate fasting instructions should be given to avoid last day cancellations. Its important to know that care provider has complete knowledge of child's history.

This will help in identification and documentation of "**red flags**" ie high-risk patients who may not tolerate or are likely to deteriorate during or after the procedure in a remote location. These children should be admitted for safe conduct of sedation and analgesia.^{1,2,7}

- Conjoint Twins
- Children with craniofacial abnormalities
- Compromised airway

- Acute respiratory distress
- Uncorrected or severe cardiac anomalies
- Serious neuromuscular disorders
- Allergic predisposition
- Children with special healthcare needs (cognitively challenged)
- High risk of pulmonary aspiration/ regurgitation
- Previous failed sedation

All these children should be examined in detail for the associated problems, and a management strategy should be planned with the help of the referring physician and interventionist. Children with any of the above problems, require a trained anesthesiologist and a well-equipped setup for providing sedation/anesthesia.

Written Informed Consent

A valid informed written consent given by a care taker in the language he/she understands, should be obtained and this should include:

- Explanation of the sedation technique and its risks.
- Description of benefits of sedation and other alternatives.
- An offer to answer queries.
- Possibility of refusal by the parent/caretaker.
- In children more than eight years assent s hould also be taken.

III. Pre-Procedural Fasting, Premedication, Monitoring, Peri-procedural care

Standard Fasting guidelines as recommended by the IAPA should be followed.⁸

- Recommendations; 2 hours for clear liquids, 4 hours for breast milk, 6 hours for solids.
- Precise fasting status should be confirmed on arrival and the time of finishing the last feed documented.
- Ensure that the procedure is performed at the scheduled time. Avoid undue delays which prolong the fasting period and can increase irritability, uncooperative behavior and dissatisfaction.
- If delay in the procedure is unavoidable, clear non-aerated fluid or juice may be administered two hours prior to the expected time of the procedure.
- In breast fed babies, if the mother is on any sedative medications, a record should be made about the drug and timing of sedative medications administered to her. Caution is needed because many of these medications are secreted in milk.

Premedication

All children must be re-evaluated on the day of procedure by medical practitioner involved in the care. The psychological behavior of child needs to be understood. It may be possible to perform the procedure under appropriate sedative premedication alone. Sedative premedication can be administered to children from aged 9 months to 5 years, to minimize separation anxiety.^{9,10,11} The

need for carefully titrated medications taking into consideration the pros and cons of each agent requires expertise. Sedative premedication in children older than 5 years, should be reserved for cognitively challenged or uncooperative children. Older children may be counselled regarding the need to lie still for the diagnostic non-painful procedures. If the procedure demands complete immobility and cooperation in older children, pharmacological sedation in appropriate doses, under adequate monitoring is indicated.^{12,13,14} Parental presence during the procedure is debatable. If the child feels secure in the presence of a parent or caregiver and the location of the intervention permits, one care giver may be allowed to stay with the child.

A child with an anticipated difficult airway requiring any interventional procedure, should be intubated and extubated by an expert either in the OR setting or pediatric high dependency unit where difficult airway cart and monitoring facilities are available.

Equipment

Trained personnel should be present during the entire peri procedural duration to clinically monitor the child. Age appropriate equipment for airway management, resuscitation, emergency drugs and antidotes to drugs used, should be readily available. Certain remote locations like the MRI suite, demands for specialized MRI compatible monitoring and resuscitation equipment. It is desirable that equipment and resuscitation carts and labelled drugs similar to those available in the operating room be available in these locations to enhance prompt actions in emergency situations. Resuscitation carts should be checked regularly, using a check list (*Table 2*).

Monitoring

The IAPA 2016 monitoring guidelines can be followed.¹⁵ These include continuous monitoring of:

- Oxygenation using pulse oximeter with an audible alarm
- Respiration using capnography (via a facemask or nasal cannula)¹⁶
- Heart rate, preferably with an ECG monitor
- Intermittent measurement of blood pressure

• Although not mandatory, BIS (Bi-Spectral Index) monitoring if available is useful in titrating dosages of anesthetic agents to targeted level of sedation in these children.

Assessment of pain and level of sedation

It's important to know the nature of the procedure and associated intensity of pain. Age appropriate pain assessment criteria should be followed. Verbal rating scale either by caregivers or older children can be recorded. Whenever possible VAS being more accurate should be preferred.

Level of sedation should be continually monitored to maintain a moderate level of sedation. Clinical assessment requires repeated stimulation and this may not be practical. Different scales have been used *e.g.*, the Ramsay Sedation Scale (*Table 4*), University of Michigan Sedation Scale UMSS, OASS etc.^{17,18,19} None of these however, ensure complete immobility for children of all age groups.²⁰ However Ramsay Sedation Scale is easy to follow and has been widely used. Once the child becomes

sedated or drowsy, oxygen supplementation with FiO₂ of 0.24- 0.40 or higher should be administered to maintain the $SpO_2 > 94\%$.

Drugs for Sedative Premedication

Medications need to be carefully selected depending upon the age and behavior of the child, associated morbidities, positioning required, type of procedure, need for immobility *e.g.*, short duration high-speed diagnostic imaging, requires minimal to moderate sedation with immobility for a brief period. Painful procedures require a deeper level of sedation and analgesia. Various sedatives-hypnotics, analgesics, and/or dissociative agents have been used to relieve anxiety and pain. The most widely used medications are listed in *Table 3*. Some of the common side effects noted with these drugs are mentioned below:

Benzodiazepines (Midazolam) antegrade amnesia and may cause respiratory depression.

Propofol: Due to its favorable pharmacokinetic properties of rapid onset and recovery, the absence of nausea, vomiting and emergence phenomenon, propofol has been commonly used. Propofol does not have specific analgesic properties, necessitating supplementation with opioids (*e.g.*, fentanyl) or non-opioid analgesics.

Ketamine: A dissociative sedative analgesic, it can be used alone or in combination with propofol ("**ketofol**"). Ketamine mitigates propofol-induced hypotension and propofol mitigates ketamineinduced vomiting and recovery agitation. 'Ketofol' exhibits synergistic properties of smooth sedation, reduced total dose of propofol and obviates the need for opioid use. However it should be used only by the medical personnel trained to manage airway and hemodynamics.

Alpha 2 agonists (clonidine, dexmedetomidine): These drugs provide analgesia besides sedation and reduce the requirement of other anesthetic agents by 30%. Dexmedetomidine has reduced bioavailability after oral administration and onset of action is slow compared to benzodiazepines and hypnotic agents. Therefore, the intranasal route has been suggested for better bioavailability and when intravenous access is not present.

Routes of Administration

Oral route:

For anxious but cooperative children, oral midazolam (0.5 mg/kg; maximum dose 20 mg) may be mixed with juice, honey or paracetamol syrup (15-20 mg/kg). The time to maximal effect of oral midazolam is 20-25 minutes. Combinations of midazolam and ketamine or midazolam and clonidine has been used for more anxious children. Combination therapy mandates 30-50% reduction in dose of each agent to avoid over sedation.

Intranasal route:

Alpha 2 agonists (clonidine $2-4 \mu g/kg$ or dexmedetomidine $1-2 \mu g/kg$) may be used for uncooperative children who refuse oral medications. However, these drugs have maximal effect after 40-45minutes. **Intravenous route (IV):**

If an IV cannula is in place, IV sedative premedication can be administered titrated to effect.

Intramuscular route (IM):

IM premedication should be avoided unless absolutely necessary. In extreme scenario, a stunning dose of IM ketamine 5mg/kg (Ketamine Dart) may be given.

Non-sedative Premedication

Some children may require use of glycolytic agents, local anesthetics and antibiotic prophylaxis. For children at high risk for aspiration prophylaxis, ranitidine 2mg/kg and metoclopramide 0.2 mg/kg may be required. Anti-epileptics need to be continued in children who are already taking these medications.

Behavior Modification Strategies

Play therapy and various distraction methods are alternative to traditional sedation in pediatric patients. However, additional studies, with adequate sample size are needed to find out the benefits and adverse effects of this modality, as well as its impact on the overall procedure length.

Special Scenarios

Imaging procedures in the Radiology and Nuclear Medicine suites

With the advent of newer technology, routine scanning time has been reduced considerably and children need to be quiet for a short period. However, certain three-dimensional reconstruction studies for the airway, lungs or cardiac structures pose unique challenges. In such scenarios, additional help should always be available. Whenever, there is a doubt about securing the airway, the safest practice is to induce the child in the nearest operating room and then transport the child for the scanning using appropriate monitoring facilities. Certain oral contrast studies demand the procedure to be done within 1-2 hours after the intake of contrast media. The volume which is administered ranges from 60-300 mL, leading to violation of fasting guidelines. To maintain the accuracy of the evaluation, use of prokinetic agents is not recommended. The risk-benefit ratio needs be established and the search for alternate safe diagnostic tools should be made. If unavoidable, caretakers need to be informed about the possible consequences and appropriate backup ventilatory care should be arranged.

The choice of anesthetic agents and airway devices depends upon the duration and frequency of procedure. These patients need to be fully awake at the time of extubation.

Certain SPECT scan studies demand for administration of radio labelled technetium 99 and more than one exposure to study the pharmacodynamics of the drug. Overall drug dosages need careful titration by using the combination of agents and target controlled drug delivery devices. Besides, routine monitoring, certain investigations like MRI, radiation oncology, and interventional radiology require intermittent remote video monitoring of the patient.

Dental sedation

Dental procedures are challenging because they are painful procedures which demand for sharing the airway and prosthetic appliances can further complicate the management. Sometimes, children can

be distracted but may demonstrate uncooperative behavior due to acute situational anxiety during the procedure. There is a need for continuous monitoring and facility to handle unexpected emergencies like vomiting, aspiration, local anesthetic toxicity or latex allergy. A common protocol in collaboration with the dental surgeon should be made to manage complications (*Table 6*).

IV. Post-procedural care, safe discharge, follow up plan.

At the completion of procedure, all children should be monitored in a well-equipped recovery area, until they are no longer at risk for cardio respiratory depression and their vital signs are stable. The recovery location should have the following basic equipment:

- Suction apparatus
- An oxygen source to provide more than 90% oxygen
- Bag-valve-mask device for positive pressure ventilation
- Monitoring should be continued till the discharge criteria are met;
- Age appropriate pain and recovery scores can be used. (*Table 4*).
- Attendants should be provided with a list of warning signs and actions to be taken.
- Clear documentation should be maintained with regard to the of patients' status, vitals at the time of discharge and the parent or caregivers signature taken at the time of discharge.
- Appropriate instructions should be given to a reliable adult, regarding diet, medication and assessment of activity level in the next 24 hours.
- Emergency contact number and address should be provided where care providers can report if some unexpected adverse event occurs.
- Children who required repeat doses of medications or reversal agents (*e.g.*, naloxone, flumazenil) should preferably be admitted and monitored overnight in the hospital.
- Designate an ICE(In Case of Emergency) area for day care patients where 24 hours care is available (Table 5).
- A satisfaction score of services provided can be taken to find out ways to improve patient care.

Key Points

- NORA locations demands for thorough patient evaluation, meticulous planning, experienced team, a well equipped setup & multidisciplinary approach.
- Choice and route of sedative agent depend upon age, procedural requirement & day care facilities.
- Supplement with non –pharmacological behavioural modification strategies and other procedure specific medications/antibiotic prophylaxis should be used.
- Practice guidelines/algorithms are useful tools, but in actual scenarios, judgement and vigilance of attending team plays a vital role.

Titrating sedative agents will remain an art, supplemented with monitors this is practiced with more confidence.

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Dental Suite	Dental restorations, extractions
Diagnostic Radiology	CT scan, MRI scan, Nuclear scans
Radiotherapy Unit	Brachytherapy, External Beam Radiation
Gastroenterology	Upper GI Endoscopy, Colonoscopy
Burn-care Unit	Dressing, wound suturing
Otolaryngology	Pediatric Myringotomy and Tympanostomy
Interventional Radiology	Embolization/Angioplasty/Thrombolysis/ Radio frequency
	ablation/ Transjugular Intrahepatic Portosystemic Shunt (TIPS)
Cardiac Catheterization lab	Diagnostic & therapeutic interventions
Pulmonology Suite	Flexible bronchoscopic procedures

Table 1: Procedural sedation and analgesia in various locations

Table 2: Equipment Check List for Remote Locations

S	Suction (functioning suction apparatus with all sizes of suction catheters)
Ο	Oxygen (ensure continuous supply of oxygen, pipeline + O _{2 cylinders]}
A	AirwayEquipment(oropharyngeal airways, laryngeal mask airways, laryngoscopes, endotracheal tubes, stylets
Р	Pharmacy adrenaline, atropine, antihistamine, pheniramine (Avil), steroids, dextrose and flumazenil
М	Monitoring (Heart rate, SpO ₂ , EtCO ₂ , temperature, Blood Pressure, ECG)
E	Equipment (Defibrillator with pediatric paddles, emergency light, emergency contact numbers (local institute code blue numbers)

Table 3: Ramsay Sedation Scale

Patient anxious, agitated or restless	1
Patient co-operative, oriented and tranquil	2
Patient asleep, responds to commands only	3
Patient asleep, responds to gentle shaking, light glabellar tap, loud auditory stimulus	4
Patient asleep, responds to noxious stimuli such as firm nail bed pressure	5
Patient asleep, has no response to firm nail-bed pressure, other noxious stimuli	6
Acceptable sedation 2, 3 or 4	
Excessive sedation 5 or 6	

Activity	Score
Able to move 4 extremities voluntarily or on command	2
Able to move 2 extremities voluntarily or on command	1
Able to move 0 extremities voluntarily or on command	0
Respiration	
Able to breathe deeply and cough freely	2
Dyspnea or limited breathing	1
Apneic	0
Consciousness	
Fully awake	2
Arousable on calling	1
Not responding	0
Circulation	
$B/P \pm 20\%$ of preanesthetic level	2
$B/P \pm 20\%$ to 50% of preanesthetic level	1
$B/P \pm 50\%$ of preanesthetic level	0
Color	
Normal	2
Pale, dusky, blotchy, jaundiced, other Cyanotic	1
Cyanotic	0
Maximum Score	10

Table 4: Aldrete Score for discharge from the hospital

Table 5: Procedural Sedation Complications

Pain	Procedural pain, underlying disease
Delayed awakening	Prolonged drug action, hypoxia, hypercarbia, hypovolemia
Agitation	Hypoxia, hypercarbia, full bladder, emergence reactions
Nausea /vomiting	Sedative agents, premature oral feeds, previous history, disease process
Dysrhythmias	Hypoxia, pain, hypovolemia, vagal stimulation, opioids.
Desaturation	Laryngospasm, airway obstruction, over sedation, aspiration.

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With technological innovations complexity of procedures an THIS ADVISORY IS AN EFFORT TO EN	I demand for se SURE SAFE	dation services to facilitate TY OF CHILDREN DU	diagnosis and RING AND	perform interventions AFTER PROCED	In high risk patients I URES PERFORM	us increased. This is the matter of conce IED UNDER SEDATION AND A	am-childre	n have narrow margin of safety and complications do occur. A IN NON-OPERATING ROOM LOCATIONS.
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RED FLAGS: identify patients who may not tolerate/ deteriorate during or after procedure.	Description	dol/Midazolam/Xetamine (e edetomidine IN/ intranasal	ither alone or or Oral Clonid	In combination) Ine .	Patient asleep, hi	as no response to firm nail-bed	9	Kav nointe
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Investigate for associated problems, their sequel and chaik o safe management strategy.	nta	Adduct Hang for 6 months 5 yes in 10 mg for age >6 yes	charges		Pain	Procedural pain		 Choice and route of sedative agent depend upon age, procedural requirement & day care facilities
	PHENCYCLID	NE DEBUNDTNES	Name of Street, Street	Contraction of the local data	Delayed	Prolonged drug action, hypoxia, hyperca	arbia and	
IAM Fasting Guidelines 2023 www.iapaindia.com/guide-lines. Clear liquids 2 Hours	Itmi serve served served under 2	Oral 0-5 20-50 Maria transmussid 4-1 20-50 Intransmussid 9-6 15-50	territors tradices	Increased safestion, (Anti-Safegoper Inspired Allingen/Shcopmidan 0.00.mg/kg)	awakening Agitation	hypowolemia Hypoxa, hypercarbia, full bladder, parad	footcal	 Supplement with non -pharmacological behavioural modification strategies and other procedure specific medications/antibiotic prophylaxis should be used.
Breast milk 4 Hours		midzalam 6 img/kg bense	_	the state		reactions, emergence reactions		Received as defending of functions are not as a first the second second
Infant formula/Other milk 6 Hours accels a	ALPHA 2 AGC	N :0.25-0.5 N :0.25-0.5			Nausea Vomiting	Sedative agents, premature oral feeds		 Practice guidelines/agonitims are useru tool, put in actual scenarios, judgement and vigilance of attending team plays a vital role.
	Concretion of the	Association and the second	Section and analysis	Physician and American Ame American American Americ American American Ameri	Tachycardia Bradycardia	Pain, hypovolemia Vagal stimulation, opioids and hypoxia		the state of a state of a state of the state
ENSURE FASTING but AVOID PROLONGED FASTING DU TO DELAY IN PROCEDURE Clear fluid/juice up to 2 hours prior to expected procedure	Condition	atraveou bola prog/kg one 10 min 3-3.2-3 mg/kg one 10 min cell 1-4 mg/kg N folai breg/kg 3-0.3 mg/kg/h	transfer of the second		Hypotta	Laryngospasm, airway obstruction, over sedation, aspiration		unreaung secontive agents war remain on or ur, supplemented with monitors this is practiced with more confidence.