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SPECIAL INTEREST ARTICLE

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Safe pediatric procedural sedation and analgesia by anesthesiologists for elective procedures: A clinical practice statement from the European Society for Paediatric Anaesthesiology

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Summary

The growing number of medical procedures performed in children that require cooperation of patients, lack of movement, anxiolysis or/and analgesia triggers the increased need for procedural sedation. This document presents the consensus statement of the European Society for Paediatric Anaesthesiology about the principles connected with the safe management of procedural sedation and analgesia (PSA) by anaesthesiologists for elective procedures in children. It does not aim to provide a legal statement on how and by whom PSA should be performed. The document highlights that any staff taking part in sedation of children must be appropriately trained with the required competencies and must be able to demonstrate regularly that they have maintained their knowledge, skills and clinical experience. The main goal of creating this document was to reflect the opinions of the community of the paediatric anaesthesiologists in Europe regarding how PSA for paediatric patients should be organized to make it safe.

KEYWORDS

analgesia, children, diagnostic elective procedure, procedural sedation, safety

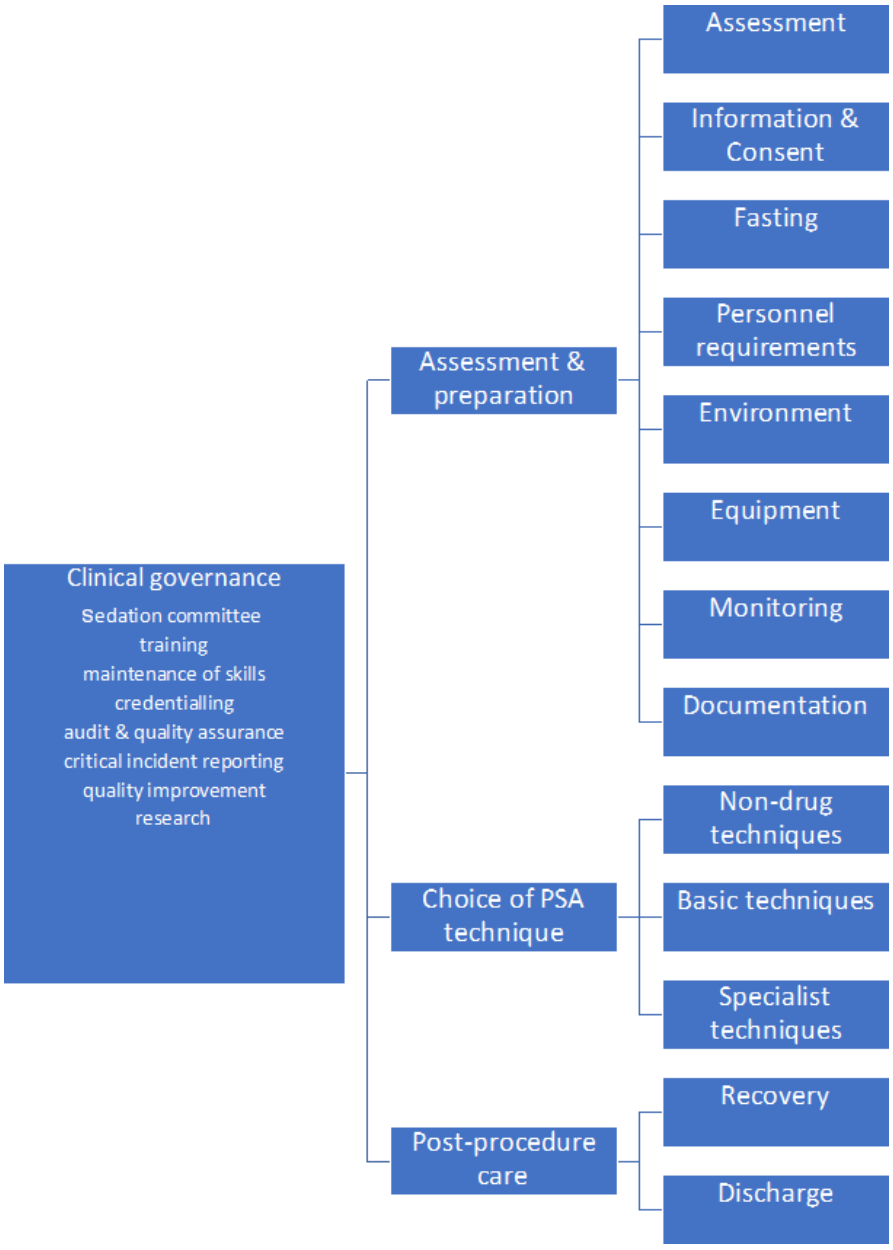

FIGURE 1 Safe pediatric procedural sedation and analgesia (PSA) care summary [Colour figure can be viewed at wileyonlinelibrary.com]

1 | INTRODUCTION

This document presents clinical practice advice from the European Society for Paediatric Anaesthesiology (ESPA) working group on the principles of safe pediatric procedural sedation and analgesia (PSA) by anesthesiologists for elective procedures from existing evidence-based guidelines and recent literature. It does not aim to provide a legal statement on how and by whom PSA should be performed but highlights that any staff taking part in sedation of children must be appropriately trained with the required competencies and must be able to demonstrate regularly that they have maintained their knowledge, skills, and clinical experience. The content of the document was posted on the ESPA website and opened for discussion for every active member of ESPA for six consecutive weeks at the end of 2018. All comments were taken into account in the final stage of preparing the document for publication. The goal of the document is to reflect the official opinion of the ESPA and of the community of the pediatric anesthesiologists in Europe on this topic. (Figure 1)

The growing number of diagnostic and therapeutic procedures performed in children that require cooperation, lack of movement, anxiolysis, fear reduction, reduced awareness, and analgesia sometimes for long periods has increased the demand for safe pediatric PSA. It is important to decide in collaboration with the child and family whether nonpharmacological techniques, local or regional anesthesia, systemic analgesia, sedation or general anesthesia (or combinations of these) are the most appropriate technique for a given child and procedure. For young children, for prolonged procedures, for painful procedures or for those with significant comorbidities or special needs general anesthesia may

be safer, quicker, less distressing, and more cost-effective. It is therefore a key principle that every child should be individually assessed for suitability for PSA. Written informed consent from the parents, and child's assent as appropriate, must cover the benefits, risks, and limits of the PSA technique proposed and alternatives, and of the diagnostic or therapeutic procedure itself. It is also vital to have a system in place for failure of PSA because sometimes the initially chosen PSA method could be inadequate for the individual needs of a patient. The environment where sedation of children is conducted must be child-friendly, child-safe, and appropriately equipped to current standards. There must be adequate systems in place for managing sedation-related emergencies and unexpected serious adverse events including staff with pediatric resuscitation training and rapid referral to a suitable critical care service. A multidisciplinary sedation committee should be created in any hospital caring for children to oversee PSA in each location or group of locations to coordinate training and continuing professional development **and finally** to ensure that standards are implemented, and outcomes audited. The pediatric sedation committee should include all care professionals involved in pediatric sedation: pediatricians, pediatric anesthesiologists, emergency care doctors and nurses, pediatric intensivists, child life specialists, and psychologists, etc Pediatric anesthesiologists should take an important role on the sedation committee and in driving quality assurance, innovation, and quality improvement. The authors of this statement intend this as an initiative for further interdisciplinary collaboration rather than to hinder sedation practice.

The National Societies or Associations of Pediatric Anesthesiology and Ministries of Health could use this document to facilitate decision-making on how PSA in children should be performed in their countries and this was the main aim of this paper.

2 | GOALS OF SAFE PEDIATRIC PSA

The main goals of safe pediatric PSA are:

- to reduce and minimize the child's fear and anxiety
- to reduce discomfort and pain connected with procedures
- to minimize psychological trauma (which may include amnesia)
- to control the child's behavior and movement for safe and successful completion of the procedure
- to protect the child's safety during the procedure and afterwards to ensure safe discharge from care[1-4]

3 | DEFINITIONS OF TARGET SEDATION STATES

Minimal sedation means a drug-induced calming of the child and reduction of fear during which the patient is conscious and responds normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are maintained.[1,5]

Moderate sedation means a drug-induced depression of consciousness during which the patient is sleepy but responds purposefully to verbal commands or light tactile stimulation. No interventions are required to maintain a patent airway. Spontaneous ventilation is adequate. Cardiovascular function is usually maintained. Reflex withdrawal from a painful stimulus is not a purposeful response.

Deep sedation is a drug-induced depression of consciousness during which the patient is asleep and cannot be easily roused but does respond to repeated or painful stimulation. The ability to maintain ventilatory function independently may be impaired. The patient may require assistance to maintain a patent airway. Spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

The individual target level of sedation depends upon the anticipated degree of pain, the allowable amount of movement during a procedure and patient factors such as comorbidities, age, ability to cooperate and degree of anxiety. As sedation targets can be difficult to achieve and maintain during a diagnostic or therapeutic procedure especially if intermittently painful, and especially in children, considerable skill and experience is required when undertaking pediatric PSA. Some techniques have a narrow margin of safety and require specialist skills, knowledge and experience (see **specialist techniques**). For many diagnostic and therapeutic procedures in younger children, deep sedation may be required. For young children, for prolonged procedures, for painful procedures or for those with significant comorbidities or special needs, general anesthesia may be safer, quicker, less distressing, and more cost-effective. In particular, failure of sedation incurs a significant cost detriment. For some procedures, the total time commitment needed to safely and successfully prepare the child, sedate the child, carry out the procedure, and recover the child may indeed be considerably longer than for a general anesthetic.

4 | ASSESSMENT AND PREPARATION FOR SAFE PEDIATRIC PSA

The assessment and preparation of a child for elective PSA should be the same as for a child undergoing general anesthesia. It is important to detect those children where caution and specialist advice is needed.[1,2]

4.1 | Assessment

The key components of assessment are:

- medical status and past medical history
- current comorbidities and surgical problems
- psychological and developmental status
- past sedation and anesthesia history including family history
- current and previous medication, nutraceuticals
- allergies
- age, weight, and height
- a focused examination of airways, lungs and heart

- details of the procedure
- in case of increased risk for complications of PSA (eg, in those with upper respiratory tract infection): urgency of the procedure
- laboratory testing if necessary

Caution and appropriate specialist advice[1,2,6,7] are needed when considering PSA in those with:

- suspected or known increased intracranial pressure
- risk of aspiration: esophageal disease, polyhandicap, duration of fasting for solids and liquids
- difficult airway due to anatomical or functional problems (hypotonia, obstructive sleep apnea)
- respiratory compromise
- ASA-PS III or greater
- young age especially infants (birth to age 1 year) including neonates (birth to age 1 month)
- severe anxiety
- autism spectrum disorder
- developmental delay

4.2 | Information and consent

Family and child should be given appropriate and sufficient information about the proposed PSA technique and the procedure for which PSA is required. This must include risks, benefits, and alternatives to PSA. Information concerning the possibility of sedation failure and what happens if sedation fails must be given. Written informed consent from parents, legal guardians, and child's assent if appropriate must be obtained and documented according to national, local, and institutional requirements.[1,2,8,9]

4.3 | Psychological preparation

The information given to the child should be appropriate for its developmental stage and a check should be made that the child has understood the procedure, what the healthcare professionals will do, what the child is expected to do, the sensations associated with the procedure and how to cope with the procedure. Parents and carers may wish to be present during procedures and they should be advised what to do that is likely to be helpful to their child.[2]

4.4 | Fasting

Elective patients may receive clear fluids up to 1 hour before PSA, breast milk up to 4 hours or milk formula or solids (light meal) up to 6 hours before PSA.[1,2,6-10] However, fasting is *not* needed for minimal sedation (anxiolysis achieved with oral midazolam or N2O used alone), during which the child will stay in verbal contact with the health professional.[2] Agents used for sedation have the potential to impair protective airway reflexes. The risk of regurgitation and pulmonary aspiration has to be considered, even if these are rare complications.

4.5 | Personnel requirements for safe pediatric PSA

The healthcare professional who is responsible for delivering and monitoring of PSA should not be the same person who performs or helps perform the procedure.[1,2]

Healthcare professionals delivering pediatric PSA should have *knowledge and understanding* of and *competency* in:

- pediatric PSA drug pharmacology
- assessment of children and young people
- monitoring of children
- recovery care of children
- pediatric PSA complications and their immediate management, including advanced pediatric life support and airway management

Healthcare professionals delivering pediatric PSA should have *practical experience* of:

- effectively delivering the chosen PSA technique to children and managing its complications
- observing clinical signs in children (eg, airway patency, breathing rate and depth, pulse, pallor and cyanosis, and depth of sedation)
- using, interpreting, and responding to monitoring equipment in children.

Pediatric PSA techniques that have a reduced margin of safety and increased risk of unintended deep sedation or anesthesia need healthcare professionals with technical pediatric skills such as the ability to relieve airway obstruction, among others to place an oral airway, nasal trumpet or supraglottic airway device, to perform bag mask ventilation to treat laryngospasm and to intubate trachea.

It is also necessary to ensure that a healthcare professional trained in delivering anesthetic agents is available to administer:

- propofol
- ketamine
- dexmedetomidine
- opioids
- drug combinations

For high-risk patients (ASA III and IV), PSA should be delivered by a pediatric anesthesiologist or intensivist. The same opinion is presented by the European Society of Anaesthesiology with regard to adult patients. [5]

Healthcare professionals delivering sedation should have documented up-to-date evidence of competency including:

- Satisfactory completion of a theoretical training course covering the principles of safe pediatric PSA practice
- A comprehensive record of practical experience of sedation

techniques including details of sedation in children performed under supervision and successful completion of work-based assessments.

Each healthcare professional and their team delivering sedation should also update their knowledge and skills through programs designed for continuing professional development.

All members of teams undertaking pediatric PSA should have basic pediatric life support skills and at least one member of the team present in the sedation area should have advanced life support skills.

4.6 | Environment

The environment for pediatric PSA should be child-friendly, child-safe and appropriately equipped with pediatric equipment which meets current standards. There must be adequate systems in place for managing sedation-related emergencies and unexpected serious adverse events including staff with pediatric resuscitation training and rapid referral to a suitable critical care service. There are different organizational options depending on the local environment. These should be defined by the local pediatric sedation committee. For example, procedures like endoscopy or painful oncology can be centralized in areas close to Operating Room structures. However, there are many procedures in remote areas for radiology, cardiac catheterization, or emergency treatment in the pediatric emergency department or wards that require special consideration. Cardiac catheterization procedures in children should always have a pediatric anesthesiologist or intensivist present. Mobile equipment may be required as well as facilities and space to treat emergency complications.

4.7 | Equipment

The following equipment needs to be available during pediatric PSA:

- pulse-oximeter
- electocardiogram (ECG)
- noninvasive blood pressure (NIBP)
- oxygen supply and delivery equipment
- capnography
- oral or nasopharyngeal airway
- face masks and other suitable supraglotic airway devices
- bag with self-inflating reservoir
- endotracheal tubes
- laryngeal masks
- laryngoscope with different pediatric blades
- suction device
- emergency medication (atropine, epinephrine, dopamine, flumazenil, naloxone, muscle relaxant, neostigmine, local anesthetics, sugammadex, calcium, glucose 10%, balanced electrolyte solution)
- intravenous catheters/lines/infusion pumps
- thermometer/active warming system
- blood gas analysis, blood glucose measurements, intraosseous needles and an appropriate defibrillator should be easily available

The majority of airway-related complications during sedation can be managed with simple manoeuvres, such as opening the airway (chin lift, jaw-thrust), suctioning, use of inserting an oral or naso-pharyngeal airway, supplemental oxygen, and/or bag-mask-ventilation. Further airway management techniques like placement of a supraglottic airway or tracheal intubation are very rarely needed. Circulatory critical events are also very rare, but the sedation team has to have the equipment for intraosseous needle placement and defibrillation immediately available.[1]

4.8 | Monitoring

The monitoring of pediatric PSA should include clinical signs of depth of sedation, respiration rate and pattern, heart rate, signs of pain, and distress. For moderate sedation, continuous pulse oximetry should also be used and the use of capnography should be strongly considered as well as ECG. For deep sedation continuous capnography, ECG, and NIBP measurement on regular time interval should be added. Inadequate spontaneous ventilation is much more likely to be detected by capnography than by pulse oximetry (See Table 1).[1,2,11,12]

4.9 | Documentation

Documentation during PSA must be a time-based record of the patient's details, assessment information, time and dosage of medication, all monitoring data, inspired gas concentration including duration of administration and details of any adverse event, its management, and outcome.

TABLE 1 Monitoring standard

Level of sedation	Moderate sedation	Deep sedation
Monitoring	Pulse oximetry	Pulse oximetry
	Heart rate	Heart rate
	Respiratory rate	ECG
	Strongly recommended:	Respiratory rate
	ECG	Blood pressure
	End-tidal carbon dioxide/ capnography	End-tidal carbon dioxide/ capnography

5 | CHOICE OF PSA TECHNIQUE

The most appropriate PSA technique depends on the following factors:

- type of procedure
- length of procedure
- target level of sedation
- contraindications for specific drugs
- known side effects of diagnostic or therapeutic procedures
- child or parent preference based on full information of risks, benefits, and alternatives
- age and level of understanding of the child

5.1 | Nondrug techniques

Nondrug strategies should be usable by all involved in pediatric PSA, supported by parental presence, to establish a relationship of thrust and mitigate preprocedural anxiety, distress and pain and to promote coping. Use of such techniques can have an important "sedation-sparing" effect and may allow a child to tolerate a procedure without the use of drugs, for example painless imaging.[2,3,14]

In children and adolescents, distraction, hypnosis, cognitive-behavioral therapy, suggestion, virtual reality, or parental coaching may be used. Adequate preprocedural information, encouragement and positive reinforcement, parental involvement in reassurance, hugging and constraining the child, and avoidance of physical restraint are all helpful to minimize psychological adverse effects.

In neonates and infants up to the age of 6 months, oral sucrose as a 12%-25% solution given 1-2 minutes in advance is effective for reducing pain-related behaviors during brief painful procedures.[3,15,16]

5.2 | Basic pediatric PSA techniques

5.2.1 | For painless imaging

For neonates and young infants, especially with modern rapid diagnostic imaging techniques, adequate imaging may be possible with good preparation and with a "feed and wrap" technique or oral sucrose,[17] thus avoiding sedatives. Some older children may be able to tolerate painless imaging for a short time if they are well prepared and are able to cooperate with skilled staff. For those children who are unable to tolerate painless imaging, consider agents with a wide margin of safety, such as midazolam should be considered. For those unable to tolerate painless imaging with either of these drugs, refer for specialist PSA or anesthesia (see below).

Ketamine or opioids should not be used for painless imaging procedures.

5.2.2 | For painful procedures

For *all* children undergoing a painful procedure, using an appropriate local anesthetic technique should be included in the management whenever possible.[2,3]

When the target level of sedation is minimal or moderate, consider inhaled 50% nitrous oxide in oxygen[2,3,18,19] or midazolam.[2,3] If these techniques are unsuitable, refer for specialist PSA or anesthesia (see below).

5.3 | Specialist pediatric PSA techniques delivered by or under the direct supervision of an anesthesiologist

5.3.1 | For painless imaging

For those unable to tolerate painless imaging with basic PSA techniques, consider dexmedetomidine,[1,20,21] clonidine or propofol [23,24] or refer for general anesthesia.[25]

For patients with painful underlying diseases, a small dose of an opioid or ketamine may be considered.

5.3.2 | For painful procedures

When basic PSA techniques are unsuitable or insufficient, ketamine [26,27] or intravenous midazolam with or without local anesthesia, fentanyl or equivalent opioid should be considered to achieve moderate sedation. Where these are unsuitable, propofol with or without fentanyl or equivalent opioid or refer for general anesthesia should be considered.[2,3]

5.3.3 | Note: Drug doses and routes of administration

For drug doses and drug information including formulations and routes of administration, consult a local or national recognized formulary or the manufacturer's product information. A useful resource is the British National Formulary for Children (BNFC) https://bnfc.nice.org.uk/.

There are also a number of pediatric drug dosage apps available, although these are often designed for emergency or critical care.

Children may find some routes of administration of drugs distressing (eg, intranasal application, rectal route) and the least distressing preferred route in a given clinical situation depends on many factors. Practitioners should be familiar with the benefits and limitations of each route of administration for each drug before embarking on PSA and must take into account the preferences of the child and parents. Consent for PSA should encompass the route of administration of drugs.

The most commonly used drugs for PSA in children with their recommended doses are presented in Table 2.

Titration according to the patient's response and taking into account the onset time of the drug(s) administered is the key for success and safety.

6 | RECOVERY AND DISCHARGE

A fully equipped recovery area should be used.[1,2]

TABLE 2 The recommended doses of drugs most commonly used for PSA in children

Drug	Dosage	Indication	Special considerations
Midazolam	0.1 mg kg^{-1} i.v. 0.4-0.5 mg kg^{-1} orally (max. 15 mg) 0.2-0.3 mg kg^{-1} intranasally (after local lidocaine application) 0.3-0.5 mg kg^{-1} rectal (max. 15 mg)	Minimal sedation	Sometimes paradoxical CNS stimulatory effect
Propofol	1-2mg kg^{-1} i.v. bolus 6-10mg kg^{-1} h^{-1} continuous i.v. infusion	Sedation (moderate or deep)	Injection pain, apnoea
(Es-)Ketamine	0.5-2.0 mg kg^{-1} i.v. bolus 0.25-1.0 mg kg^{-1} repetition 2-4 mg kg^{-1} intranasally	Dissociative Sedation (moderate and deep) and analgesia	Combination with midazolam or propofol (ketofol) for reduction of psychomimetic side effects
Clonidine	1-2 μg kg^{-1} i.v. or intranasally 2-3 μg kg^{-1} orally	Anxiolysis	Slow onset
Dexmedetomidine	1μg kg^{-1} i.v. as short infusion within 10 min 0,2-0,7μg kg^{-1} h^{-1} continuous i.v. infusion 2-3 μg kg^{-1} orally, intranasally, buccal	Sedation (moderate and deep), small analgesic effect	Slow onset, patent airway, and spontaneous respiration
Alfentanil	5-10 μg kg^{-1} i.v.	Analgesia	Apnea
Remifentanil	0.1-0.3 μg kg^{-1} min^{-1} i.v. continuous infusion	Analgesia	Apnea
Fentanyl	1-2 μg kg^{-1} i.v.	Analgesia	Apnea
Piritramid	0.05-0.1 mg kg^{-1} i.v.	Analgesia	Slower onset, in this dosage less respiratory depression
Nalbuphine	0.1-0.2 mg kg^{-1} i.v. bolus 0.3-0.4 mg kg^{-1} intranasally	Analgesia for moderate pain	Ceiling effect, no respiratory depression when used as a single sedating drug

PSA, procedural sedation and analgesia.

After the procedure, monitoring should be continued until the child:

- has a patent airway
- shows protective airway and breathing reflexes
- is hemodynamically stable
- is easily aroused[3,10]
- is back to baseline level of social interaction

Ex-preterm infants who are less than 60 weeks postconception have a higher risk of apnea and require more prolonged monitoring. These children should be monitored overnight.

Discharge criteria are:

- normal vital signs
- complete awakening of the child or young person (or return to baseline level of consciousness) with no risk of further reduced level of consciousness
- adequate control of nausea, vomiting, and pain
- no bleeding or other complications of the procedure or PSA technique.

7 | PSA QUALITY CONTROL

A standardized quality-improvement tool is recommended to identify strengths and weaknesses of PSA. This should be characterized by child-centered outcomes and should track interventions to overcome or treat adverse events. The regular assessment of sedation quality and frequency of adverse events should be performed in every center to promote a sufficient level of safety.[7] A multidisciplinary sedation committee is recommended to oversee best practice and quality improvement.

RECOMMENDED READING

- Sedation for diagnostic and therapeutic procedures outside the operating room. RF Kaplan, JP Cravero, M Yaster, CJ Cote. In: A Practice of Anesthesia for Infants and Children. Edited by CJ Cote, J Lerman & BJ Anderson. 5th Edition (2013) Chapter 47: pages 993-1013.
- Pediatric Sedation Outside of the Operating Room, A Multispeciality International Collaboration, Edited by Mason KP. 2nd Edition (2015).

ETHICAL APPROVAL

No ethics approval provided.

CONFLICT OF INTEREST

Francis Veyckemans is the current section editor of Pediatric Anesthesia and Present-President of ESPA. Neil Morton is the past

Editor in Chief of Pediatric Anesthesia and Past-President of ESPA. The other authors do not declare any conflicts of interest.

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