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**PAEDIATRIC PROCEDURAL SEDATION: CURRENT PRACTICE AND
CHALLENGES IN CAPE TOWN**

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DECLARATION

I, **Adrian Burger**, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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RESEARCH PROTOCOL

PAEDIATRIC PROCEDURAL SEDATION / ANALGESIA: CURRENT PRACTICE AND OBSTACLES IN THE CAPE METROPOLE

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INTRODUCTION

Children often present to the Emergency Centre (EC) with painful injuries, or conditions which require painful or upsetting interventions to diagnose or treat. Procedural sedation and analgesia (PSA) refers to the pharmacologic technique of managing the child's pain and anxiety.

The appropriate management of pain and anxiety in the EC is a significant facet of emergency care for all patients, especially in paediatric patients.¹ This is achieved partly by the administration of sedative, dissociative, or analgesic drugs which alter awareness, completely sedate the patient, reduce or eliminate pain.^{2,3,4}

PSA is an essential component of Emergency Medicine practice and is a core skill acquired in Emergency Medicine training programs. There is good evidence that proactively addressing pain and anxiety may improve quality of care and patient satisfaction by facilitating interventional procedures and minimizing patient suffering.⁵

The medication options for treating pain and anxiety in children undergoing therapeutic and diagnostic procedures in the EC has improved dramatically. The use of non-invasive monitoring devices and short-acting sedative and analgesic medications allow for safer and more effective PSA.⁶

Emergency Medicine is however a new specialty in South Africa and as it grows, so does exposure to new concepts and the development of new care protocols, such as PSA. This is often driven by Emergency Medicine trainees who are most likely to explore and apply these new concepts.

Emergency Medicine blends the pre-hospital and in-hospital clinical management in an approach that emphasizes earlier initiation of definitive treatment and pain management. With the further development of the clinical practice of Emergency Medicine in South Africa – procedures such as fracture manipulation, suturing of complex wounds and reduction of dislocations are occurring more frequently in the Emergency Centre.⁶ In South Africa these painful, distressing and invasive procedures are often performed either without adequate sedation/analgesia or are delayed unnecessarily by long emergency theatre lists. PSA is a safe, effective, and humane way to facilitate this appropriate medical care.⁷

The literature is replete with studies that emphasize the poor assessment and management of pain especially in the paediatric population group.^{8,9,10} This situation is often exacerbated by limited knowledge of procedural sedation and analgesia options^{11,12}, or delayed administration of adequate analgesia in the paediatric population.^{12,13}

It is important to distinguish the goals of PSA - pain relief, anxiolysis or both. Different medications and combinations of medications are used to achieve the desired effect. It is also important to be mindful of the possible adverse reactions and side effects associated with each medication when choosing the sedation cocktail.¹⁴ The administration of higher doses of the same medication can lead to a more profound sedative effect and increased chances of adverse events. There is also an element of inter-patient unpredictability and therefore the practitioner of PSA should have the skills and equipment to manage a level of sedation one higher than the intended level. This includes advanced cardiovascular support and airway management.¹⁵

These risks are more apparent when it comes to the paediatric population with the different anatomical, dosing and risk considerations from adults.^{11,22}

There is a perception that the government health system in South Africa has a shortage of monitoring equipment, inadequate training of EC doctors and nurses and a general shortage staff. Thus can result in an erratic application of PSA in children, and possibly poor monitoring. This situation might be similar in the private health establishments. PSA is thus often performed by practitioners with inadequate training, with no or limited patient monitoring and poor patient selection.

A training program including patient assessment, good patient selection and minimal monitoring requirements, and the use of protocols, would improve analgesia for patients, alleviate the confusion of staff and reduce the risk for the patients.^{16,17,18,19,20,21}

Definitions in PSA:¹⁵

Procedural sedation: technique of administering sedatives or dissociative agents with or without analgesics to induce a state that allows the patient to tolerate unpleasant procedures, whilst maintaining cardio-respiratory function. It is the intention of PSA to result in a depressed level of consciousness whilst allowing the patient to maintain oxygenation and airway control independently.

Moderate sedation (previously referred to as “conscious sedation)”: a drug-induced depression of consciousness during which patients respond purposefully. The drugs, doses, and techniques used are also not likely to produce a loss of protective airway reflexes.

Deep Sedation: as part of the continuum of sedation, is defined as a drug induced depression of consciousness during which patients cannot be easily aroused but respond purposefully after repeated or painful stimulation. These patients may however require assistance in maintaining airway patency and ventilatory effort.

General anaesthesia: a drug-induced loss of consciousness during which patients are not arousable, and may have an impaired cardio respiratory function requiring varying degrees of support. The patient under general anaesthesia is profoundly compromised and does not exhibit movement or autonomic nervous system responses to a standard surgical stimulus.

LITERATURE REVIEW

PSA is accepted as the standard of care in countries with a developed Emergency Medicine specialty.³

There is already an awareness of current international PSA practice through various studies, but in South Africa the only study published is a cross sectional descriptive study that surveyed current practice amongst doctors only with regard to adult PSA²³. One of the conclusions of this study was that “PSA is a known modality within the scope of adult emergency medical care in Cape Town. The private hospital sector is generally better equipped and serviced for PSA than government hospitals. The choice of drugs is generally limited to what the clinicians have always used - most use morphine and midazolam for PSA. However, there is widespread awareness of propofol as an alternative and probably superior PSA drug.” The authors also concluded that recommendations for improving PSA include “development of general protocols for PSA, training of doctors at all levels and optimization of Emergency Centre facilities and staffing.”

No similar study has been done in South Africa with reference to paediatric PSA to establish what the current state of practice is, and whether there are peculiar pitfalls and obstacles to paediatric PSA in South Africa.

Recently both the Emergency Medicine Society of South Africa (EMSSA)²⁶ and South African Society of Anaesthetists (SASA) published guidelines for PSA, but neither have assessed the

current practice and obstacles to performing paediatric PSA in the varied medical facilities in South Africa.

The literature in other countries supports the view that pain assessment in paediatric patients is poor – whether using pain scales, parent observation or clinician observation.^{8,9,10} Even when pain is recognised, there is often a delay in addressing it with adequate analgesia.^{12,13,14} These studies were either retrospective chart reviews or cross sectional studies using interviews with patients and doctors.

AIMS AND OBJECTIVES

Aim

The aim of this study is to determine the current state of practice of paediatric PSA in the EC's in the Cape Town Metropole.

Objective

A self completed questionnaire will be utilised to gather data from all fulltime doctors who work in EC's in private and public hospitals in the Cape Metropole. This will show current practice and obstacles to providing good paediatric PSA, and allow development of evidence based guidelines on paediatric PSA, as well as training and accreditation requirements.

METHODS

The study will be a questionnaire based descriptive survey. All fulltime doctors, working in EC's that accept paediatric patients, in the Cape Town Metropole, will be invited to participate in the study.

A questionnaire (Appendix 1) will be completed by each respondent. The investigator will leave the questionnaire with each doctor and ask that they complete it in private and place it in a sealed envelope for collection once completed. The questionnaire will provide information on the study and its objectives and invite the respondents to participate.

The participants in the study will have their names and the EC where they work recorded by the investigator for the purpose of keeping track of respondents, but will have a number assigned to their survey sheet, and will remain anonymous. The questionnaire consists of two parts, the first dealing with the level of experience and training of the doctor, the

workplace and their experience and practice of paediatric PSA. The second part deals with the drugs and procedures, and lastly asks what the perceived obstacles to paediatric PSA are. Data will be entered into an Excel database and analysed by simple descriptive statistics. The data captured will be held on a password protected computer.

ETHICS

Ethics approval will be obtained from the UCT Ethics Committee prior to the study commencing.

Participants and the EC's where they work will be identified by a number on the survey sheets for the purposes of keeping track of the respondents only. The details will be kept on a secure database that is password protected. No individuals nor institutions will be identifiable from the study results. No patient related information will be captured.

DISSEMINATION

The results will be disseminated to the Joint Division of Emergency Medicine of Cape Town and Stellenbosch Universities, the Western Cape Department of Health, and published in a peer reviewed journal.

WORKPLAN AND BUDGET

The timeline of the research is approximately six months from ethics approval till submission in August 2010.

Protocol Development	November 2009 – January 2010
Ethics Committee	February 2010
Sampling and data collection	February 2010 – March 2010
Analysis	July 2010
Write up and submission	August 2010

The budget for the study is minimal and will be borne by the investigator. Foreseeable costs are largely printing of survey sheets, telephonic and transport costs to administer the survey.

SUMMARY

Procedural sedation and analgesia (PSA) is the standard of care³ in many First World Emergency Centres for the management of acute procedural pain and anxiety.

There is evidence that the practice of PSA may be either ineffective or unsafe in untrained hands^{18,19,20,22} – even in countries where Emergency Medicine has been established for many years and that PSA should be only performed by trained, accredited and competent doctors, within a safe environment.²⁵

Doctors need to be able to perform this highly necessary intervention to deliver optimal care. The shortage of theatre time in South African hospitals, and high trauma load, demands solutions to definitively treat more patients in the EC.

To be consistent – there needs to be a protocol within each Emergency Centre/Healthcare Facility that delivers a reproducible, effective service to the children presenting to them. This incorporates the training, accreditation, and availability of practitioners, equipment and medication.

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APPENDICES

Appendix A - Consent

Appendix B- Questionnaire

LITERATURE REVIEW

OBJECTIVES

This section reviews and compares current policies for Paediatric Procedural Sedation and Analgesia (PPSA) as a baseline for accepted current standards of PPSA. Literature is explored for original studies that survey the practice of PPSA, identifying common themes with regard to challenges, minimum standards, and adverse events.

The primary focus is to survey the practice of PPSA within Emergency Centres (ECs) internationally, and whether there are any studies that have explored the practice of PPSA in South African ECs.

LITERATURE SEARCH STRATEGY

National and society policies and guidelines were studied. The first PPSA guideline was released by the Association of American Paediatricians (AAP)¹. The AAP and American College of Emergency Physicians (ACEP)² guidelines are included. In the United Kingdom and in Australasia, Emergency Medicine bodies have followed with their own guidelines, the evidence based National Institute of Clinical Excellence (NICE) guideline³ and the Australasian College for Emergency Medicine (ACEM) consensus⁴ guidelines. In South Africa the only two PPSA guidelines are those of the South African Society of Anaesthetists (SASA)⁵ and the Emergency Medicine Society of South Africa (EMSSA)⁶.

Recent literature was searched using Pubmed with the terms “pediatric” or “paediatric” and “procedural sedation” or “procedural sedation analgesia”. Studies that were not relevant to ECs were excluded from the results. Only surveys of PPSA were considered. For the purpose of this review, all facilities that see emergency patients will be referred to as an Emergency Centre ; this includes “Emergency Department”, “Accident and Emergency”, and “Casualty”.

QUALITY CRITERIA

National policies and guidelines are mostly consensus documents, with basic reviews of the literature supporting the statements. Only the ACEP policy presents evidence based classes of evidence ².

Evaluations of practice were undertaken either by questionnaires or by consecutive case reviews. Questionnaire based studies that actively canvassed participants had a far better response rate than those that were passively presented. Active follow up increased the return for Shavit et al who had a poor response initially⁷, whilst Seo et al ⁸ had a reasonable

institutional response, but were not clear on whether the numbers of doctors per institution were representative.

The other method employed was consecutive case studies. The numbers of patients also varied, but in this case was reflective of the case numbers that each EC sees. The two large collaborative sites accumulated 1028 cases⁹ and 2623 cases¹⁰ over a three year period, whilst this was only matched in the two large tertiary single site studies with 1727 cases¹¹ and 1244 cases¹². The smaller community or district level hospitals took around two years to gather 166 cases¹³ and 160 cases¹⁴. The power of the smaller studies was not as great as that of the larger studies, and not large enough to accurately pick up low percentage occurrences such as adverse sedations events (ADSEs).

There were also only five studies that were centred on exclusively paediatric ECs^{7,9,11,12,15}, five were in combined adult and paediatric ECs^{8,10,13,14,16}. Relevant paediatric findings were categorised and sub-analysed in the results and discussions of these studies. One study was included despite being about adult PSA, as it has country specific relevance¹⁷.

One aspect of all the studies that could skew the results is the definition of "paediatric" which differs within and between countries, and in one study the age groups were split into the authors' own defined groups⁹.

No level one study was found; this is likely in part due to the ethics of randomising pain relieving treatment.

INTERPRETATION OF LITERATURE

Emergency Medicine training produces Emergency Physicians who have acquired the skills of critical care, airway management and achieved comfort with the use of a variety of sedative and analgesic medications. These are the core skills required for the practise of PPSA².

PPSA is accepted as the standard of care¹⁸ in countries with a developed Emergency Medicine program - amongst the leaders in this are the USA, UK and Australasia, where formal policies support it. In South Africa, EM is still a comparatively fledgling specialty, but rapidly seeking to catch up with the more advanced programs overseas.

The six relevant policies identified that are used as the basis for evaluation of PPSA practice surveys are:

- i. AAP "Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures"¹

- ii. ACEP "Clinical Policy: Procedural Sedation and Analgesia in the Emergency Department"²
- iii. NICE Guideline "Sedation in children and young people"³
- iv. ANZCA consensus "Guidelines on Sedation and/or Analgesia for Diagnostic and Interventional Medical, Dental or Surgical Procedures"⁴
- v. EMSSA "Procedural Sedation in the Emergency Centre"⁵
- vi. SASA "Guideline for the safe use of procedural sedation and analgesia for diagnostic and therapeutic procedures in children"⁶

The AAP guideline seeks to unify the guidelines of the various bodies in the USA and considers adherence with the principles of their guideline will reduce morbidity in PPSA. In the USA, ACEP represents the vast majority of EM Physicians as well as Residents and Interns¹⁹. ACEP considers PPSA in other guidelines to be lacking in evidence base². ACEP regards PPSA as a part of comprehensive emergency care, improving outcome and patient satisfaction. The ACEP policy was last updated in 2004². The American Society of Anesthesiologists (ASA) has also published guidelines for sedation administered by non-anesthesiologists²⁰, and many aspects of this have been endorsed by both AAP and ACEP. The NICE guideline was updated in 2010 and notes that the increase in provision of a paediatric PPSA service outside of the traditional operating theatre is due to an increase in demand and better utilization of resources than traditional anaesthesia³. The ACEM also updated their guideline in 2010⁴, and this is a consensus of a number of societies and colleges representing Anaesthesia, EM, Surgeons, Gastroenterologists, Dentists, Intensivists and Radiologists. In South Africa, SASA released their first ever statement in 2010⁵ whilst EMSSA published their first ever guideline in 2009⁶.

All the bodies highlight that there are serious risks associated with PPSA, especially in younger or developmentally delayed patients, which can be mitigated by careful patient selection and provision of sedation¹⁻⁶. Patients should be evaluated for risk factors before the procedure¹⁻⁶. Sedationists should select and carefully administer appropriate medications, effectively monitor the patients in an appropriate setting, and be able to rescue the patient from any complications or adverse events that might occur¹⁻⁶. In older patients other techniques, such as distraction, can reduce medication needs⁵.

The definition of paediatric depends where in the world one is, and varies from 13 years²¹ to 21 years old^{1,2}. This is significant when one considers that there are certain critical issues,

like airway anatomy and drug metabolism, that are particularly relevant in younger age groups¹. It also has bearing on consent, clinical indications, drug dosages and indications, equipment required and adverse events statistics which might be skewed if applied across different geographical groups. In South Africa "paediatric" is considered to include children up to their 13th birthday.²¹

Eleven studies were identified that were recent and relevant to the evaluation of PPSA.^{7-16,18} The majority of these studies were published within the last five years in peer reviewed journals, whilst the two older studies were included as they were still relevant as they have not been repeated in the interim. See table 1.

In South Africa Hodkinson et al¹⁷ evaluated only adult procedural sedation and analgesia, but this establishes the background of PSA in South Africa when compared to the international literature. The USA, Canada and Australia have established systems that are now being surveyed with a view to refining and improving their PPSA practice, whilst Korea and South Africa are producing the first studies to establish the baseline standard of PPSA.

Objectives of PPSA

PPSA is a technique of administering sedatives or dissociative agents, with or without analgesics, to induce a state whereby the patient tolerates unpleasant procedures whilst retaining cardiorespiratory function, and retaining the ability to respond purposefully to verbal commands and or tactile stimulation³.

The patient should not experience any unnecessary anxiety, discomfort or pain, awareness or recollection^{1,4-6}. The patient's movements are limited, so as to ensure that the procedure can be completed quickly and accurately^{5,6}.

These goals should be achieved safely, using titrated, minimal dosages of as few medications as possible, and return the patient to the same pre-sedation state¹. The medications should be matched to the procedure and the goals of sedation required^{1,2}.

Common definitions

Sedation with non-dissociative medication is a continuum. It is not easy to predict how a patient will respond to the medication administered, as this depends on the drug, the dosage, additive effects of more than one drug, and the individual patient response^{2,5,6}. There are minor discrepancies with regards to the definitions of mild, conscious and moderate sedation¹⁻⁶, but the levels of sedation can be defined as:

- Dissociative - a drug induced trancelike state, where analgesia and amnesia are profound, but the patient retains airway reflexes, spontaneous respiration and cardiovascular stability but ketamine does not operate on a dose response continuum^{2,5,6}.
- Non-dissociative - propofol, opioids, benzodiazepines, etomidate and barbiturates work on a dose response continuum and therefore there is a need for careful titration⁵.
- Minimal Sedation – most define this as previously known as anxiolysis^{1,3-6} and one as conscious sedation². It is a drug induced state where the patient responds normally to verbal stimulation but that cognitive function and coordination maybe impaired, whilst ventilatory effort and cardiovascular status are stable.
- Moderate Sedation – mostly defined as previously known as conscious sedation.^{1,3-6} It is a drug induced depression of level of consciousness but the patient can respond purposefully to verbal stimulation or light touch. It is unlikely to produce a loss of protective airway reflexes, and the patient maintains cardiorespiratory function except in exceptional cases. There should be a wide margin of safety.
- Deep Sedation - all groups agree is a drug induced state where the patient can't be easily aroused, but does respond purposefully after repeated verbal and/or painful stimulation.¹⁻⁶ The patient might need assistance in maintaining a patent airway and adequate ventilation, but cardiovascular stability is usually maintained. There may be similar risks to a general anaesthetic and the sedationist must be prepared to manage this.
- General Anaesthetic - all define this as a drug induced state where the patient is not rousable, there is a loss of protective airway reflexes, respiratory depression, disturbed circulatory reflexes, and this requires an anaesthetist to be present.

A failed sedation is the failure to achieve the desired level of sedation such that the procedure is abandoned or converted to general anaesthetic⁵.

Personnel and training

Most guidelines suggest a minimum of two people present^{2,3-6} for PPSA, one to perform the sedation and monitor the patient, and the other to perform the procedure.

Patients respond differently and inadvertent deeper sedation or general anaesthesia, loss of airway, respiratory depression, cardiovascular depression and allergic reaction are risks

of PPSA. Providers should be trained and able to deal with these events, should they occur.^{4,6}

Overall the PPSA service in an EC should be supervised or overseen by an appropriately trained specialist such as an Emergency Physician², but the goal sedation level of light through to deep can be safely practiced within the boundaries of most EC doctors. Most agree that general anaesthesia is the domain of anaesthetists, and they should be summoned to assist when this level is reached inadvertently.³⁻⁵

Staffing requirements for sedation levels

The grades and qualifications of the doctors surveyed vary, as some studies focussed only on senior doctors^{7,9,15,16} whilst others focussed on a spectrum of doctors.^{8,10-14,17} The senior doctors, especially in USA and Canada, tend to predominantly perform the PPSA in paediatric ECs^{7,9,11,12,15} compared with adult or combined ECs.^{8,10,13,14,16,17} See table 2. However in South Africa, Hodkinson et al¹⁷ reported that the overwhelming majority of adult PSA was performed by junior to middle grade doctors (95.8%), with Consultants performing the minority.

Two guidelines formally set out training requirements. The NICE³ and ACEM⁴ guidelines both suggest a minimum of training required.

According to NICE the doctor should have completed a formal sedation course and have documented up-to-date evidence by keeping a log of sedations³. ACEM requires three months fulltime supervised training for PPSA, or many years of experience in the absence of formal training⁴. Credentialing, training and support should be anaesthetist led and a re-credentialing process should involve Advanced Cardiac Life Support (ACLS) and evidence of Continuing Professional Development (CPD)⁴. SASA recommends strongly that sedationists have taken a sedation course and are current with an ALS course⁵.

In two studies in community hospitals in South Africa and Canada there was some in-house training. Wentzel-Smith and Schweitzer¹³ provided in house training to their EC staff, but there was no mention of a formal credentialing process. Mensour et al¹⁴ reported active in-house training, regular CPD, and use of a standard protocol.

Any further course work might be beneficial, as Maher et al¹⁶ found an association between being current with advanced life support courses and a better knowledge of PPSA than doctors who were not current. Whether that translated into safer practice clinically was not explored though.

The advanced training and experience required for PPSA is reflected in the patterns of established EM programs where only the Consultants, Fellows and Registrars appear to be administering PPSA. In house competency assessment is required, with annual CPD to remain current.

Protocols/Clinical Practice Guidelines

Protocols were discussed in only three of the studies. Seo et al⁸ reported a guideline for PPSA in only 20% of the ECs surveyed, and Hodkinson et al¹⁷ reported only two out of the thirteen sites with a PSA protocol - but these were neither readily available nor up to date. In contrast there was a general Clinical Practice Guideline (CPG) all nine of the PREDICT sites in Australia, with most even having medication specific CPGs.¹⁵

Very little self-auditing was done, and was reported, again by one study¹⁵ where 41% of doctors and 44% of site practice this (and then mostly only when intravenous medication is administered).

Consent

All the guidelines list the need for written informed consent¹⁻⁶, as well as pre-procedural information which should be either written or verbal in nature. ACEP recognizes that implied consent might be appropriate in some circumstances where the patient can't comprehend or where the level of consciousness might be impaired². This consent should be attached to and be part of the sedation record.

Despite this there seems to be, in the five studies that addressed this issue, a poor rate of consent obtained for PPSA.^{8,11,13-15} Seo et al⁸ reported that only 40% of doctors always taking consent, whilst in Australia⁸ 21% of sedationists always take consent, 16% never take consent, and 61% only take consent when ketamine or intra-venous medications are administered.

Pre-assessment and fasting

All of the guidelines stress the importance of a proper assessment of the patient to exclude those unsuitable for PPSA, and to highlight any potential issues prior to performing PPSA.¹⁻⁶ At times it might be better to delay and consult with an anaesthetist or refer for a general anaesthetic.^{1,3-5}

The pillars of the pre-assessment are a thorough medical history (including any sedation or anaesthetic history) and a physical examination (with weight and vital signs, but focussing

on the airway, respiratory and cardiovascular systems).¹⁻⁶ Routine diagnostic tests are not indicated². The patients are graded according to the ASA scoring system. Patients that are ASA 1 and 2 are suitable for PPSA¹⁻⁶. Patients with ASA 3 or 4, younger than 2 years old, with special needs, an aspiration risk and any active illnesses are at increased risk of complications and require an anaesthetic opinion or presence first^{1,3-5}. Documentation of the findings and ASA score is required.

Aspiration is unlikely in PPSA when suitable patients are selected and the level of sedation doesn't approach a general anaesthetic². Most of the evidence of aspiration is extrapolated from general anaesthesia literature². Fasting status is contentious, with the advice ranging from "no evidence to support fasting"⁶ through to the standard anaesthetic "2-4-6" hour rule for clear fluids, breast milk and solids when moderate to deep sedation is planned⁵. Seo et al reported 85% of doctors do not consider the fasting status at all⁸, while Bell et al reported that children were more commonly not fasted for six hours and then received a dissociative agent for PPSA¹⁰. There is a body of evidence leaning towards balancing the risk of the sedation with the urgency of the procedure^{1,2}, but the reasons for continuing with PPSA need to be clearly documented. Urgent cases where the procedure cannot be postponed and where simple sedation is unsuitable might then be more suited to a general anaesthetic with rapid sequence induction and intubation.

However controversial, it might be time to liberalise the fasting times suggested in anaesthesia literature^{5,20}, and consider medication specific fasting guidelines as part of the institutional protocols. Senior EPs should be making these informed decisions based on urgency and risk.

Work area and emergency medications, equipment

The doctors performing the PPSA should be skilled to recognize and manage complications⁴, and the area for PPSA should be adequately equipped to manage emergencies.

The area for PPSA should have immediate access to facilities, personnel and equipment to manage emergencies^{5,6}. There should also be a means of summoning emergency help¹.

These aspects were not universally addressed by the studies, yet remain a concern raised by Hodkinson et al¹⁷. The only other study to evaluate this was Seo et al who noted only that airway rescue equipment was present in 77% of their ECs.

Required resuscitation and monitoring equipment

It is important that the visual observation of face and chest movements of the patient, and their response to verbal stimulus is supplemented but should never be replaced by monitoring equipment^{2,5}.

Equipment that is required for monitoring during PPSA, as well as resuscitation equipment, should be checked regularly by EC staff⁵. It should also be checked by the clinician responsible for the sedation prior to each occasion that it is used. NICE mentions that ALS resuscitation equipment should be present, but no checklist is suggested³. See table 3.

ACEP questions the clinical relevance of transient desaturations, and therefore does not insist on the empirical use of supplemental oxygen², despite the AAP recommending it for all cases¹. ACEP suggests that oxygen should be administered to patients at high risk of hypoxaemia (where high doses or multiple medications are used, or where there is significant co-morbidity) and where desaturations are stepwise or constantly below 93%². Three study sites in North America evaluated practice and reported that one site uses routine supplemental oxygen for all cases¹⁴, yet another administers it only if saturations fall below 93%¹² and a third reports only 20% routinely administer oxygen⁷.

A saturation probe that changes tone with changes in readings, and that fits properly, is needed. Oxygen saturation does not detect the adequacy of ventilation and is not a substitute for clinical assessment². Poor respiratory effort can be masked by supplemental oxygen administration², whereby saturation can be sufficient despite poor ventilatory effort, resulting in hypercarbia and a respiratory acidosis.

Capnography can detect early hypoventilation, but this has no correlation with the level of sedation and provides additional information to the clinical assessment². The role of capnography is becoming clearer, with most of the studies agreeing that it is useful in deep sedation and when the patient's breathing cannot be clinically evaluated and should be present if available^{1,3-6}. ANZCA recommends that a capnograph should be merely present in the facility⁴.

Bispectral index is promising but there is insufficient evidence to justify it for routine clinical use in the EM PSA patient population².

Required monitors based on the level of sedation

Seo et al⁸ reported poor monitoring as only a third of their ECs reported routine monitoring of the patients. Also, only half of these were monitored until recovery or discharge. They cited reasons such as not seeing a need for it, as well as a shortage of staff and equipment.

This finding was similar to Hodkinson et al¹⁷ in South Africa. The other studies didn't address this.

When an immobilisation device is used it should be checked that it is not restricting breathing or the airway, that an arm or leg is free, and the patient never left unattended. None of the studies mentioned immobilisation devices. See table 4.

PPSA Record and Documentation

The time based record should commence with the pre-assessment as a baseline, continue during the procedure and until the patient is discharged^{2,4-6}. The parameters are respiration rate and pattern, oxygen saturation, heart rate and rhythm, non-invasive blood pressure and the level of sedation. End-tidal CO₂ is recorded if its use is required^{1,3,5,6}. The frequency of the recordings is variable but some suggest every five minutes as necessary^{1,3,6}.

Further information required is the names of the staff involved, the start and end times of the procedure, medication used (dose, route, time), any adverse events and the management thereof^{1,4}.

Sedation recording varied considerably. The more developed PPSA programs used a formal sedation record^{9,12,14} or an anaesthetic chart or clinical notes^{10,11,15}. Only one of the developing programs used a sedation record¹³ while another noted very poor records¹⁷.

Three studies did not evaluate record keeping^{7,8,16}. Typically recorded parameters were age, gender, race, ASA status, medical and current history, allergies, weight, and fasting status.

The last assessment should be documented at discharge^{2,4-6}. Patients should be discharged only when they have returned to a pre-sedation status^{3,6} or are easily rousable¹, have no airway problems, normal oxygen saturation on room air and cardiovascular stability^{1,3,6}. In addition nausea and pain should be under control with no procedural/surgical problems³⁻⁶. The ability to talk and sit upright is age appropriate¹. When sedation antagonists have been used this time should be extended, as the half life of the antagonist is likely shorter than the half life of the sedation agent, and the patient might return to a sedated state and risks complications^{5,6}.

Discharge should be in the care of a responsible designated adult^{5,6}, with clear verbal and written discharge instructions^{4,6} and any prescriptions^{5,6}. The discharge must be authorised by the sedationist or another qualified practitioner^{4,5}.

Discharge criteria varied greatly. The best survey of practice was the PREDICT study¹⁵ where the discharge information was supplied pre-printed by 55.7% of the doctors, verbally in

43.6% and handwritten or typed in 15%. By contrast Seo et al⁸ reported that only 21.5% of the ECs had discharge criteria at all, and only 13.8% then had written discharge instructions.

PPSA Medications

The main medications currently advocated in the guidelines are ketamine, propofol, midazolam and fentanyl²⁻⁶. Less common are etomidate^{2,6}, nitrous oxide^{1,3,5}, sevoflurane³, chloral hydrate^{3,5} and local anaesthetics^{4,5}. Older medications like morphine and diazepam are mostly not promoted for routine PPSA.

"Ketofol" is a combination of ketamine and propofol and has become more popular for painful medical and dental procedures, but is only specifically described in the SASA guideline⁵.

Most guidelines recommend establishing intravenous access only when intravenous medication is administered or for deep sedation^{1,2,4}. They do not suggest this routinely when using intramuscular ketamine nor simple sedation techniques (inhaled nitrous oxide, or rectal, transmucosal and orally administered single agent sedation)⁵. ANZCA differs by recommending this for all levels of sedation⁴. This aspect was not addressed specifically by any studies though.

For painful procedures the medication options are nitrous oxide^{1,3,5}, ketamine^{2,3,5,6}, midazolam/fentanyl²⁻⁶, ketofol⁵ or a sedative and local anaesthetic combination^{4,5}.

Nitrous oxide and oxygen at up to 50% concentration for ASA 1 and 2 patients achieves light or moderate sedation^{1,3,5}. Ketamine is often suggested via an intra-muscular route when used as a single agent. When using a benzodiazepine and opioid, the opioid should be given first and the doses should be reduced and titrated^{2,5,6}. Safe practice further advocates that the doses of all medications should be pre-calculated and drawn up prior to the procedure commencing^{1,6}.

When painless procedures like radiological imaging are planned then chloral hydrate, sevoflurane, propofol or midazolam are appropriate³. Intranasal midazolam is not widely advocated anymore due to unpleasant side effects⁵. Chloral hydrate has a variable response and long recovery^{1,5}, yet is reported as used in almost 90% of PPSA cases, both painful and painless in one study⁸.

In the paediatric setting the off label use of medications is widely advocated, if there is good evidence in the literature supporting its use as such^{3,5}.

Adverse sedation events

With the medications used to achieve the aforementioned goals of PPSA, there is a high risk of airway obstruction, respiratory depression and hypoxia, and cardiovascular depression¹. Guidelines emphasize that adverse events can be reduced by a combination of careful patient selection, appropriate drug choices, using the lowest possible dosages of medications, titrating doses, using combinations of medications as little as possible, and closely monitoring the patient until discharge¹⁻⁶.

ADSEs in the literature over the last decade have been reported as high as 17%²² and as low as 2,3%²³. Different medications have different ADSE profiles as well²². In the surveys reviewed here variability was also demonstrated, with rates between 17.8%¹² and 0,6%⁹. Almost all the ADSEs were considered minor by the authors and easily managed with minor interventions^{9,12,13}.

ADSEs are more likely to occur when more than one agent is used, and repeated doses of the same agent are administered⁵. Most of the ADSEs occur during the sedation and initial recovery period^{2,12}, with few occurring after discharge. The most common occurrences were upper airway obstruction, desaturation, hypoventilation and vomiting¹².

Studies with reported low rates might well have not had a sufficiently powered study^{13,14}, or events might have been missed due to poor monitoring, or under reported due to definitions varying⁹. Proper documentation of PPSA is important to record these events accurately, as there might often be confusion as to what constitutes an ADSE¹².

CONCLUSION

This literature search revealed a broad global consensus on the basic definitions of PPSA, medications, monitoring equipment and sedation staff numbers for PPSA. There is recognition of the need to set standards, assess practice and make the necessary improvements that is currently not uniformly done.

National and institutional clinical practice guidelines for PPSA are required that are generic, but also include medication specific protocols. The establishment of necessary standards of training and credentialing needs to take priority especially in new EM programs.

In practice, the equipment in ECs, the monitoring of patients and the documentation of PPSA is not yet ideal. Standard sedation records should be designed specifically for and used in the EC for every sedation case. Regular institutional audits of PPSA practice should be done. Capnography is also still contentious, as is the status of fasting requirements for PPSA, and this should be specifically studied in future.

At present PPSA has been proven to be safely provided by medical professionals, mostly at a senior level and when adequately trained in sedation techniques. This hard won reputation will be damaged if the lessons of preparedness and rectifying identified deficiencies are ignored.

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TABLES

Table 1 Recent studies surveying the practice of PPSA.

Study	Population	Method
Shavit ⁷	Paediatric EC doctors on two professional websites in USA	Web based questionnaire of doctors
Seo ⁸	Adult and Paediatric ECs in teaching hospitals in Korea	Web based questionnaire of doctors
Sacchetti ⁹	Paediatric only cases in community hospital ECs in USA	Review of PPSA cases in registry
Bell ¹⁰	Adult and paediatric ECs, multiple sites in Australia	Prospective case series
Maclean ¹¹	Paediatric urban tertiary EC in USA	Retrospective case review
Pitetti ¹²	Paediatric urban tertiary EC in USA	Prospective case series
Wenzel-Smith ¹³	Adult and paediatric secondary hospital EC in South Africa	Prospective case series
Mensour ¹⁴	Adult and paediatric secondary hospital EC in Canada	Prospective case series
Borland ¹⁵	Cross sectional cohort of adult and paediatric ECs in Australia	Questionnaire of Paediatric EC doctors
Maher ¹⁶	Adult and paediatric doctors in tertiary EC in USA	Retrospective interventional study
Hodkinson ¹⁷	Adult EC doctors in South Africa	Cross sectional descriptive study

Table 2 Suggested sedation staff required as per target level of sedation.

	AAP¹	ACEP²	NICE³	ANZCA⁴	EMSSA⁵	SASA⁶
Light sedation	Not specified	No assistant	Sedationist and assistant, both BLS certified	Sedationist and assistant, one skilled in airway and resuscitation	Doctor or nurse, skilled to manage emergencies	Assistant to monitor
Moderate sedation	Sedationist advanced airway skills, assistant BLS certified	“Qualified” support person able to manage emergencies	Sedationist and assistant, one BLS and one ILS certified	Sedationist and assistant, one skilled in airway and resuscitation	Doctor or nurse, skilled to manage emergencies	Doctor to monitor and sedate
Deep sedation	Sedationist and assistant, one of them ALS certified	“Qualified” support person able to manage emergencies	Sedationist and assistant, one ILS and one ALS certified	Anaesthetist required	Doctor or nurse, skilled to manage emergencies	Doctor to monitor and sedate

Table 3 Required resuscitation equipment for PPSA.

	Equipment
Airway	Suction, airway devices, intubation equipment ^{1,2,4-6}
Breathing	High flow oxygen and mask, positive pressure device (eg. BVM) ^{1,2,4-6}
Circulation	Intravenous access and fluids ^{1,2,4-6}
Medication	ALS medication ^{1,2,4,6}
	Reversal medication ^{2,4,6}
Equipment	Monitor/Defibrillator ^{1,2,4-6}
	ECG ¹⁻⁶
	Non-invasive blood pressure ¹⁻⁶
	Saturation monitor ¹⁻⁶
	Capnograph ¹⁻⁶

Table 4 Levels of monitoring per target level of sedation in PPSA.

	Clinical Observation	Respiration and oxygen saturation	ECG	NIBP	Capnograph
Light Sedation	X ¹⁻⁶	X ^{2,4-6}	X ^{2,4,6}	X ^{2,4,6}	
Moderate Sedation	X ¹⁻⁶	X ¹⁻⁶	X ¹⁻⁶	X ¹⁻⁶	X ^{5,6*}
Deep Sedation	X ¹⁻⁶	X ¹⁻⁶	X ¹⁻⁶	X ¹⁻⁶	X ^{1*,3,4*,5,6*}

*Capnography can be used but is not a necessity unless the chest wall movement cannot be readily assessed clinically.

University of Cape Town

JOURNAL ARTICLE

PAEDIATRIC PROCEDURAL SEDATION: CURRENT PRACTICE AND CHALLENGES IN CAPE TOWN

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ABSTRACT

PURPOSE OF STUDY: A survey of the current practice of doctors working in Emergency Centres (ECs) in the Cape Town Metropole was performed to assess clinical practice and attempt to identify obstacles to practice of procedural sedation and analgesia. This is essential to establish a baseline for quality assurance purposes and improvement.

METHODS: 25 ECs in both private and government sectors in Cape Town were identified and surveys completed anonymously by full time doctors working at each EC.

RESULTS: 16 ECs agreed to be part of the study and 62 questionnaires were completed (a 64% response rate). Procedural sedation and analgesia was performed at all the participating ECs, by medical practitioners of varying experience. Doctors' awareness of unit protocols was inconsistent. Common indications are orthopaedic, radiological investigations and surgical cases. Medications used were similar, but dosages varied. Monitoring is poor compared with international standards. The obstacles reported related largely to a lack of training and the lack of formal protocols.

CONCLUSIONS: This study was the first to establish the baseline of Paediatric Procedural Sedation and Analgesia practice in a South African setting. We highlighted the lack of a formal system of training and accreditation, both for doctors and facilities, and the need for institutional and nationwide PPSA guidelines.

INTRODUCTION

Children often present to the Emergency Centre (EC) with painful injuries or conditions which require painful or upsetting interventions to diagnose or treat them. Procedural sedation and analgesia (PSA) is the technique of administering sedatives or dissociative agents, with or without analgesics, to induce a state that allows the patient to tolerate unpleasant procedures whilst maintaining cardiorespiratory function¹.

Paediatric Procedural Sedation and Analgesia (PPSA) in the EC is internationally recognised as a safe and effective means to facilitate early appropriate medical care²⁻⁵, and can alleviate waiting times for the definitive care of many conditions.

With the establishment of Emergency Medicine as a specialty in South Africa in 2008⁶, procedural interventions are increasingly being performed in ECs⁷. There are no published articles surveying South African PPSA practice^{2,7}. The findings of adult based studies might not be relevant to PPSA as children differ anatomically and physiologically from adults⁸.

Many ECs in South Africa are staffed by non-specialist doctors who practice PSA in children and adults^{2,7}. It is essential to evaluate the current practice of a spectrum of doctors in ECs to establish their training levels, their use of protocols, the indications for PPSA, the techniques used and also whether there are any challenges to safe practice. With the baseline established, areas of improvement can be addressed.

We therefore undertook a study to survey the current practice of PPSA of a spectrum of doctors in public and private ECs in Cape Town.

METHODS

A questionnaire was designed for the purpose of the survey (in the absence of any standard validated questionnaire in the literature) which reflected the various aspects of the local practice of PPSA but was itself not validated. The doctors' grade and training, practice preferences, medication and monitoring use, and any perceived challenges to performing PPSA were assessed.

Fifteen private and ten public ECs were identified that accept paediatric patients routinely, 24 hours a day, and always have a doctor on site.

The staff numbers were determined by each EC Head. Doctors were graded as senior (Consultants or Heads of Unit), middle (Registrars, Medical Officers and General Practitioners) and junior grade (Community Service Doctors and Interns).

Data were captured on a Microsoft Excel database and analysed by simple descriptive statistics. The frequency and percentage was calculated for each set of data and Fisher's exact P-values calculated.

Ethics approval was obtained from the University of Cape Town. All participants were anonymous.

RESULTS

Respondents

Full results were obtained from 16 of 25 (64%) ECs, (8 of 15 (53%) private and 8 of 10 (80%) public). The clinician response rate was similar, as 47 of 98 (46%) public doctors and 15 of 32 (47%) private doctors participated.

The majority of the doctors (54 (87%)), reported performing adult PSA. An even larger number (60 (97%)), reported performing PPSA. Of the doctors who do perform PPSA only a third performs it regularly (four or more times a month).

Two provider factors were assessed – the grade of the doctor and which sector (public or private) they work in. P-values greater than 0.05 were considered statistically insignificant. The grade of the doctor showed a trend towards influencing whether the doctor responded ($p=0.051$) to the study, but was not a statistically significant factor in whether they practiced PPSA or not ($p=0.572$). There was also no statistically significant association found between which sector the doctor works in and whether they practice PPSA ($p=0.572$).

Training and protocols

The majority of doctors (51, 82%) have no formal training; the rest had attended a sedation course. The majority (53, 85%) self-reported reasonable to competent ability in PPSA. Respondents were not universally aware of the presence of a unit protocol for PPSA: a clear protocol existed in 7/8 private ECs, but in only 3/8 public ECs; despite this, most (83%) reported that they would use one if it existed.

Procedure Indications for PPSA

Orthopaedic (fracture manipulation and joint reductions) made up the biggest grouping, followed by sedation for radiological studies, surgical procedures (laceration repair, incision and drainage of abscesses, chest drains, burn care) and lastly medical cases (general pain and anxiety, central lines, lumbar puncture) were the smallest group. See figure 1.

Medication technique

The medications used were similar across all ECs and are shown in figure 2. Nitrous oxide was not used in the ECs studied. The route of administration was dependent on the class of medication being used, although 75% preferred using the intravenous route of administration for PPSA. The dosages of the medications varied widely, with many doctors using standard fixed doses rather than a weight based dose. This led to a large variation in the medication dosages. The pattern of usage follows convenience: doctors were comfortable using those medications that they already know (77%), perceived as safe (60%), were readily available (52%), and easy to use (36%).

Patient monitoring and resuscitation equipment

Most of the doctors use some form of monitoring during PPSA, with 3(5%) never using a monitoring device. As can be seen in figure 3, the actual level of monitoring is poor, with only 19(31%) of the doctors monitoring patients on a level considered adequate by international standards^{1,10-13}. Supplemental oxygen was routinely used by 41 (66%) doctors. There was a similarity between public and private ECs with regards to the staffing for PPSA. Close to half the doctors in both sectors use a nurse as the sedation assistant. No private EC doctors use another doctor to monitor the patient, whilst 8 (17%) of the public doctors do. A similar number of doctors in both sectors (12% public and 16% private) use either a nurse or a doctor or both. One person PPSA (no assistant) was performed by 6 (12%) public doctors and 2 (16%) in private.

All respondents reported a resuscitation trolley present when performing PPSA. The contents of the trolley varied, but resuscitation equipment necessary for airway, breathing, circulation and advanced life support resuscitation was present by 86% of doctors.

Fasting

Thirty respondents (48%), applied a 4-6 hour rule of fasting prior to commencing PPSA, while 21 (34%) did not have an established fasting rule.

Challenges and obstacles

The greatest hindrances to performing PPSA, as perceived by the doctors, were the operator dependant factors, with equipment and staffing and other issues less so. These are shown in Figure 4.

DISCUSSION

Emergency Medicine training produces Emergency Physicians who have acquired the skills of critical care and airway management, and who have achieved comfort with the use of a variety of sedative and analgesic medications. These are the core skills required for the practise of PSA, and this is considered an important component of the day to day practice of emergency medicine¹⁴.

Internationally, an increasing number of procedures are moving from the operating room to the EC¹⁵. This is often reported to be sub-optimal^{16,18} and there is a lack of data on patient satisfaction after EC PSA¹⁸.

There are established international guidelines as well as an increasing body of literature examining PPSA^{8,15}. In South Africa there are only two current PSA guidelines: the Emergency Medicine Society of South Africa's (EMSSA) 2009 guideline¹² which is not paediatric specific, and the South African Society of Anaesthesiologists (SASA) 2010 paediatric specific guideline¹¹ which is not necessarily relevant to the EC.

Training and protocols

All the doctors in the private ECs practice both adult and paediatric PSA, whilst in public ECs only 72% of the doctors practice adult PSA, and 83% PPSA. This differs slightly from earlier data⁷ which reported that 60% of doctors practice PPSA in public ECs and 88% in private, which may be due to the evolution of the specialty of EM, as well as subtle differences in the study designs.

Although most respondents indicated a willingness to follow PPSA guidelines, very few protocols or care guidelines were in place at the surveyed ECs. This data is similar to that from the previous study⁷ and indicates little progress in this regard.

Minimum standards for those performing PPSA are that they should be trained in sedation, be familiar with the medication and monitors use, and at least one participant should be certified in advanced life support^{1,10-13}. Few respondents had any formal training in sedation, and a minority were current in advanced life support courses. Credentialing and training of doctors for PPSA remains limited, but the reasons for this were not explored in this study.

The lack of formalised assistance protocols is of concern, as it is regarded as standard, for all but the lightest sedation, to have one doctor administer sedation and monitor the patient while another performs the procedure^{8,9,10,13,15}. We did not assess the level of nurse

training, but a recent study found that the majority of South African nurses were not even Basic Life Support qualified¹⁹.

Procedure indications

The majority of respondents indicated performing PPSA for orthopaedic and surgical procedures, such as fracture reduction and laceration repairs. This is in line with international data, with trauma procedures dominating^{3,17}. Whilst PPSA is required for these obviously painful procedures, frequently performed minor painful interventions such as heel pricks, intravenous catheter placement and injections were not reported here. These have been noted as mostly being performed without analgesia¹⁶ and there is a need for further studies in this regard to evaluate practice and guidelines in South Africa. Patients who are anxious or those with mental illness might still be under recognized and under-treated, in keeping with international evidence¹⁶.

Medication technique

It is important to establish a specific individualised care approach with PPSA so that an appropriate drug or combination can be selected. The choice of sedation technique depends on the target level of sedation, what the procedure involves, any contraindications or side effects and patient (or parent or carer) preference⁹. In this study the nature of the procedure was seldom a factor in deciding what medication to use, and yet this is an integral part of planning for PPSA and reducing risk. This may reflect the high variability of training and specialty education within the ECs surveyed. Formalising training and credentialing for PPSA would mitigate this by entrenching more appropriate assessment and planning.

Our respondents reported using mostly ketamine, midazolam, morphine and propofol for PPSA, which is largely similar to international practice^{3,8,9,13,14,17}. But one aspect which lags behind is particularly the use of short acting opioids, nitrous oxide and sevoflurane. Knowledge of the different medications available for PPSA seemed limited as many doctors chose the same drug or combinations for all procedures. There is a measure of safety in this, in that the doctors rely on their familiarity with only one or two different medications. These medications might not have always been appropriate for each type of case though and a protocol might prove helpful.

Dosages of medications administered varied highly, and the recommended effective and safe range of medication was only rarely correctly used. There was rather a common practice of “standard” or “empiric” dose utilisation, regardless of the weight of the child.

Patient monitoring and resuscitation equipment

The common risks of PSA are inadvertent deeper sedation with loss of protective airway reflexes, respiratory depression, cardiovascular depression and allergic reactions to the medication¹⁰. These risks are higher in PPSA with different anatomical, physiological and medication characteristics from adults¹⁰. There should be adequate monitoring to detect, and equipment to manage these events.

International standards of PSA require a suitable area, equipped with resuscitation equipment and vital signs monitors⁹⁻¹³. The majority of doctors used monitors, with only 3% of respondents not using any during PPSA. The most commonly utilised monitoring equipment was pulse oximetry, but this alone is not adequate, as it has a delayed detection of a drop in oxygen saturation, and is only part of the total monitoring required.

A very low rate of respondents reported using capnography in this study. Capnography is widely recommended for early detection of hypoventilation, in addition to clinical observation and oxygen saturation, during PPSA^{1,11,12}. Cost is a factor that needs to be considered in resource poor environments, where capnography might not be readily available.

A satisfactory finding of the study is the almost universal presence of a resuscitation trolley with 90% of the doctors reporting one at hand when performing PPSA. The equipment listed as being present on the trolley is also sufficient to deal with any immediate life threatening event – oxygen, suction, airway and breathing devices, intravenous access and fluids, and resuscitation medications. The only negative finding was the poor prevalence of reversal agents for the medications being used. This is an area which can be improved upon, but it might well be a unit specific factor as there is usually access control to flumazenil, but not naloxone which is unrestricted.

Fasting

Despite some suggestions for a strict 2-4-6 hour fasting rule for PPSA¹⁰, there is a move towards more leniency in fasting requirements for PPSA in emergency medicine guidelines^{1,9,12}. This move is supported by studies^{15,20-22} which suggest that the fasting status is only a consideration, based on the sedation method planned and the urgency of the case.

Most of our surveyed group were conservative and preferred using a 6 hour period. The reasons for the fasting and type of sedation and procedure were not explored in this study, but clearly rigid application of either of the extremes is not ideal.

Challenges and obstacles

The major pitfall in the practice of PPSA was identified by the respondents as themselves - a lack of training was the biggest single factor and this was consistent across both sectors.

The other major factor was the lack of PPSA protocols. A lack of time was mostly a factor in private ECs, with nurse and doctor shortages mostly reported in public ECs. Medicolegal concerns were also a significant factor in both sectors, whilst public ECs cited a lack of senior supervision as important as well.

The minor obstacles were related to equipment being outdated or broken, but only in public ECs. According to 13% of respondents there were no obstacles to PPSA in their EC, whilst 3% felt there was no need for PPSA in their EC.

Medicolegal risk causing a reluctance to perform PPSA was probably a factor of a variety of the other obstacles that resulted in a concern that they were not adequately prepared to perform PPSA and lacked the necessary equipment and supervision to rescue an adverse event should it occur.

No respondent reported being not allowed to perform PPSA in their EC, and their clinical independence in deciding to perform PPSA or not would appear to be unchallenged by others, but mainly by their own and their ECs limitations.

LIMITATIONS

This was a small study with a limited response rate; we did not control for reporting bias and we may not have a fully representative sample. However, the hospitals which responded were representative and we believe that the results are likely to represent the best possible case scenario.

Recall bias could not be controlled for, and doctors may have misreported their training, expertise and adverse event rate.

CONCLUSIONS

This study was the first to establish the baseline of PPSA practice in a South African setting. The level of training of the doctors, the use of sedation protocols, staffing numbers, patient fasting status, medications and monitors used and the procedure indications were not

surprising, but this work provides a more evidence based assessment of PPSA practice.. The challenges identified by the respondents gave a clearer picture of their concerns, and pointed to the major deficiencies in the system that should now be addressed. The lack of a formal system of training and accreditation in PPSA, both for doctors and facilities, has been highlighted.

There is a need now for the development of a nationwide consensus PPSA guideline as well as institutional protocols. A formal training and accreditation system should be concurrently established. Regular auditing processes based on standardised sedation documentation and adverse event reporting should be followed up by revisions as further challenges are identified.

Acknowledgements This study would not have been possible without the assistance of the healthcare providers and clerks at all the hospitals studied.

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Competing interests None.

Provenance and peer review Not commissioned; externally peer reviewed.

University of Cape Town

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FIGURES

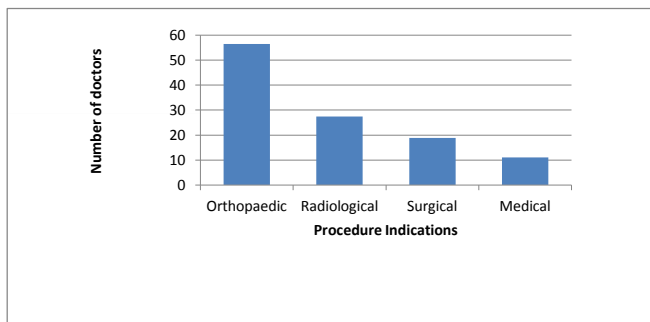


Figure 1 Common procedure indications for PPSA.

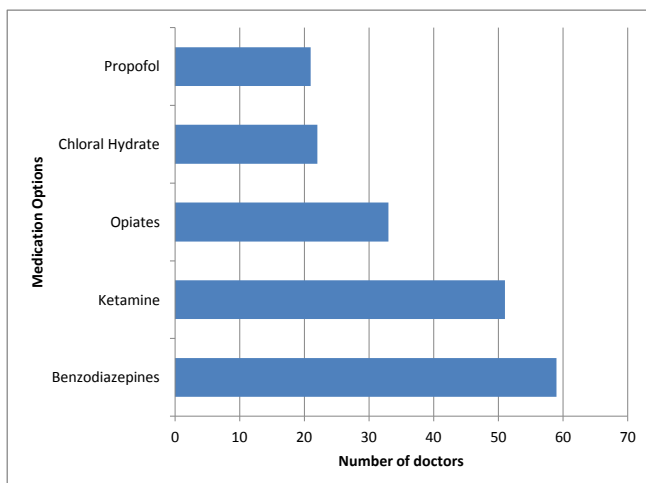


Figure 2 Frequency of use of classes of medications for PPSA.

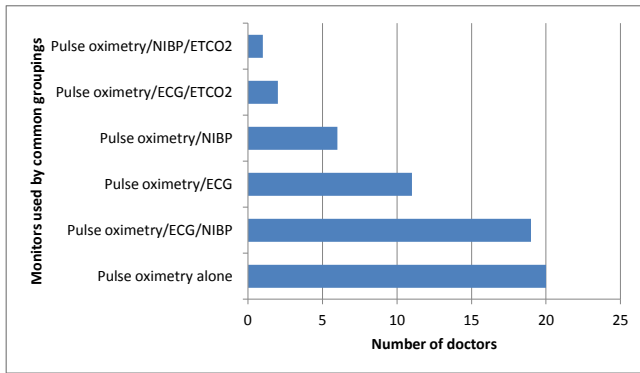


Figure 3 Frequency of use of monitors.

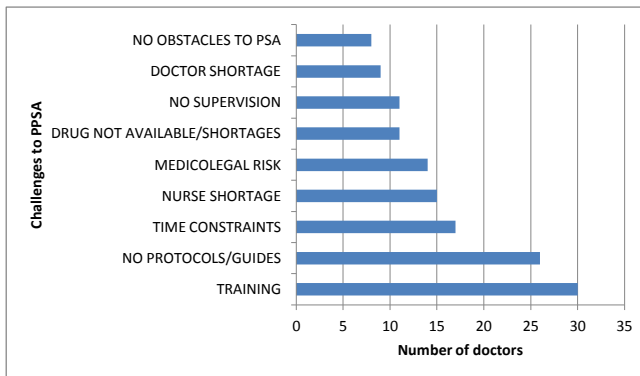


Figure 4 Obstacles to performing PPSA.

APPENDICES

APPENDIX A - CONSENT AND QUESTIONNAIRE

PAEDIATRIC PROCEDURAL SEDATION CONSENT AND QUESTIONNAIRE				
Respondent number:		EC number:		
Year of primary qualification (MBChB OR Equiv):				
Further qualifications (eg Dip PEC, sedation course):				
Primary employment (tick most appropriate):	Public		Private	
Level of Emergency Centre (EC):	1	2	3	
Position / Grade (Circle most appropriate):	Consultant CSMO	GP	PMO Intern	SMO Intern

I, _____ hereby do give my written consent to take part in this study by completing this questionnaire to the best of my knowledge accurately.

I understand that refusal to take part in this study will not prejudice me in any way.

I understand that this questionnaire forms part of the M.Med (Emergency Medicine) dissertation at UCT for Dr Adrian Burger and the findings will be disseminated by means of publication in medical journals.

I understand that all the data gathered will be kept strictly confidential and stored on a password protected computer.

Signed: _____

Date: _____

Questionnaire				
1. Experience with Procedural Sedation and Analgesia (PSA)				
(Tick the most appropriate block)				
[RARELY=<1/MONTH ; SOMETIMES=1-4/MONTH ; OFTEN=>4/MONTH]				
Do you use PSA in adults?	NEVER	RARELY	SOMETIMES	OFTEN
Do you use PSA in children?	NEVER	RARELY	SOMETIMES	OFTEN
Have you had training in PSA?	NONE	SELF	1 DAY COURSE	>1 DAY COURSE
How would you rate your competence?	POOR	REASONABLE	COMPETENT	HIGHLY CAPABLE
2. Do you have a protocol for Adult PSA in your EC?			Y	N
3. Do you have a protocol for Paediatric PSA in your EC?			Y	N
If "N" would you use PSA if a standardised protocol was available and why/why not?				
4. What do you mainly use PSA for? (circle most appropriate answer/s)				
Fracture manipulation	Joint relocation	Sutures	Wound dressing changes	
Examinations eg EUA	I&D Abscess	Acute pain/anxiety	Radiology eg CT, MRI	
Lumbar puncture	Burn care	Chest drain	Central venous line	
Other - specify				
5. What medication do you use most frequently for PSA? (circle most appropriate drug/s)			Route (IV/IM/PO/IN)	Dosage (mg/kg)
Benzodiazepines (specify which): _____				
Morphine				
Propofol				
Ketamine				
Chloral hydrate				
Other (specify which) _____				

6. What factor/s influence your drug choice/s? (circle most appropriate one/s)							
Familiarity with drug		Hospital/Unit Protocol		Cost		Ease of use	
Drug availability		Senior staff influence		Safety		Time constraints	
Type of clinical scenario							
7. Are there any medications that you would like to use but cannot?				Y		N	
If yes, please state which medications:				_____			

8. Goal pre-PSA fasting period (solid foods)							
None	1 Hour	2 Hours	3 Hours	4 hours	6 hours		
9. What monitoring devices do you use during Paediatric PSA? (circle most appropriate option/s)							
None	Pulse Oximeter	ECG					
NIBP	ETCO2/ Capnography						
10. Do you administer oxygen to the patient during PSA?				Y		N	
11. Is there another dedicated healthcare professional with you when performing PSA?				Y		N	
If yes is this person a nurse or doctor?				NURSE		DOCTOR	
12. Do you have a resuscitation trolley at hand during PSA?				Y		N	
If so, what equipment is on it (please circle):							
Oxygen		Bag valve mask		Laryngoscope and ET tubes		IV cannulae	
Reversal agents		IV fluids		Resuscitation drugs		Suction	
13. In your opinion, what are the major obstacles to using PSA for children in your daily practice? (Circle the most appropriate answer/s)							
No need for PSA		No obstacles to PSA		Training		No protocols/guides	
No supervision		Not allowed		Time constraints		Drugs not available/shortages	
Doctor shortages		Nursing shortages		Equipment broken/outdated/shortage			
Medicolegal risk		Other (specify): _____					

APPENDIX B - ETHICS APPROVAL LETTER



UNIVERSITY OF CAPE TOWN

**Health Sciences Faculty
Research Ethics Committee
Room E52-24 Grootte Schuur Hospital Old Main Building
Observatory 7925
Telephone [021] 406 6626 • Facsimile [021] 406 6411
e-mail: shoretta.thomas@uct.ac.za**

21 April 2010

REC REF: 176/2010

Dr A Burger
c/o Dr PW Hodkinson
Division of Emergency Medicine

Dear Dr Burger

PROJECT TITLE: PAEDIATRIC PROCEDURAL SEDATION/ANALGESIA: CURRENT PRACTICE AND OBSTACLES IN THE CAPE METROPOLE.

Thank you for submitting your study to the Research Ethics Committee.

It is a pleasure to inform you that the Ethics Committee has **formally approved** the above-mentioned study.

Approval is granted for one year till the 30th April 2011.

Please submit an annual progress report if the research continues beyond the expiry date. Please submit a brief summary of findings if you complete the study within the approval period so that we can close our file.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the REC. REF in all your correspondence.

Yours sincerely

PROFESSOR M. BLOCKMAN
CHAIRPERSON, HSE HUMAN ETHICS
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

S Thomas

APPENDIX C- EMERGENCY MEDICINE JOURNAL - CHECKLIST FOR AUTHORS ORIGINAL ARTICLES

For full length accounts of original research, often shorter articles are better. Additional information may be placed on the web site as a data supplement.

You also have the option to publish the abstract of your paper in your local language. If you wish to do this, please upload a Word copy of your abstract to your manuscript on Scholar One and save it as 'supplementary material'.

Abstract: 250 words

Word count: up to 3000 words

Illustrations and tables: up to 6

References: 25

Peer review: all papers are reviewed by at least one reviewer. If there is uncertainty about acceptance after review, papers are reviewed by the editors.

The manuscript must be submitted in Word. PDF format is not accepted.

The manuscript must be presented in the following order:

1. Title page.
2. Abstract (or summary for case reports) (note: references not allowed in abstracts or summaries).
3. Main text (provide appropriate headings and subheadings as in the journal. We use the following hierarchy: BOLD CAPS, bold lower case, Plain text, *Italics*).
4. Tables should be in the same format as your article (ie Word) and not another format embedded into the document. They should be placed where the table is cited and they must be cited in the main text in numerical order.
5. Acknowledgments, Competing interests, Funding.
6. Reference list.
7. Appendices should be Web only files to save space in the print journal
8. Images must be uploaded as separate files

1 Title page: The title page must contain the title of the article, full name, postal address, e-mail, telephone and fax numbers of the corresponding author, full names, departments, institutions, city and country of all co-authors, up to five keywords or phrases suitable for use in an index (it is recommended to use MeSH terms), word count - excluding title page, abstract, references, figures and tables.

2 Abstract: up to 250 words and should be subdivided into four sections: objectives; methods; results; conclusions. Sections should not be combined. Statistical values should be given (confidence intervals preferred).

3 Introduction: outline of the background and rationale of the study.

4 Methods: this section should be sufficiently detailed to permit the reader to replicate the study. Published methods should be described in brief, with appropriate citation, Statistical methods should be defined and any not in common use should be described in detail or supported by references.

5 Results: should be concise and should not contain repetition of the methods. Data in the text should not be replicated in tables or figures or vice versa. SI units should be used, except for fluid pressures, which should be in mm Hg.

6 Discussion: a clear distinction should be made between deduction and speculation.

7 Acknowledgements: where appropriate, please note these at the end of the text.

8 References: Up to 25 references can be included. Authors are responsible for the accuracy of cited references. It is vital that the references are styled correctly so that they may be hyperlinked. References must be numbered sequentially as they appear in the text. References cited in figures or tables (or in their legends and footnotes) should be numbered according to the place in the text where that table or figure is first cited. Where more than one reference is cited, separate by a comma—for example, [1, 4, 39]. For sequences of consecutive numbers, give the first and last number of the sequence separated by a hyphen—for example, [22-25]. Preparing the reference list.

References must follow the [slightly modified] Vancouver style: 12 Surname AB, Surname CD. Article title. Journal abbreviation Year; Vol:Start page–End page. Use one space only between words up to the year and then no spaces. Check journal abbreviations using PubMed. List the names and initials of all authors if there are 3 or fewer; otherwise list the first 3 and add et al.

9 Illustrations and tables: Up to 6 illustrations and tables can be supplied, each clearly numbered. Ideally, submit your figures in TIFF or EPS format. We can also accept figure files of the following types: BMP, EPI, GIF, JPEG, PDF, PNG, PNG8, PNG24, PNG32, PS, PSD, SVG, WMF. All images should be mentioned in the text in numerical order and figure legends should be listed at the end of the manuscript. Tables should be submitted in the same format as your article (Word) and not another format embedded into the document. They should appear where the table should be cited, cited in the main text and in numerical order. Tables should be self-explanatory and the data they contain must not be duplicated in the text or figures - we will request that any tables that are longer/larger than 2 pages be uploaded as web only data.