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## ORIGINAL RESEARCH ARTICLES

### Procedural sedation and analgesia: Auditing the practice at Steve Biko Academic Hospital Emergency Centre from May to October 2014



### *Sédation et analgésie d'intervention: audit de la pratique au centre des urgences de l'hôpital universitaire Steve Biko de mai à octobre 2014*

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**Introduction:** Procedural sedation and analgesia (PSA) is a vital skill for physicians working in an emergency centre (EC). For doctors working in the African setting, dealing with high patient loads and limited theatre availability, knowledge and proficiency in PSA is a highly valuable and necessary skill. The aim of this study was to audit the practice of PSA in the EC of Steve Biko Academic Hospital.

**Methods:** This was a cross-sectional descriptive audit. Procedures conducted under PSA were identified. An audit of clinical notes and interviews with staff was conducted. Data were analysed using the STAT 12 package. The results were presented as adherence statistics with reference to the PSA guidelines of the Emergency Medicine Society of South Africa (EMSSA).

**Results:** This audit indicated that documentation of informed consent prior to PSA was poor in this hospital's EC. No evidence of informed consent was found in any audited cases. Adherence to the other aspects of PSA was also fairly average (below 50% in most). The mean adherence scores for these components were as follows: pre-procedure preparation and equipment check 46.19% (95% CI 36.62–55.76), documented patient pre-evaluation 50.99% (95% CI 46.78–55.18), monitoring during procedure 39.22% (95% CI 34.68–43.75), post procedure monitoring 37.99% (95% CI 32.78–43.20), and overall documentation of procedure 40.69% (95% CI 37.85–43.52). Analysis of adherence to the guidelines between different ranks of doctors demonstrated that the registrars in EM were, in general, more compliant.

**Conclusions:** This audit identified documentation of informed consent as a major shortcoming in the practice of PSA in this EC. There is also room for improvement in most of the other aspects that were assessed. As part of the clinical audit cycle, the results of this study will be used to initiate changes to increase adherence to the guidelines.

**Introduction:** La sédation et l'analgésie d'intervention (SAI) est une compétence vitale chez les médecins travaillant en centre des urgences (CU). Pour les médecins travaillant en Afrique, gérant un grand nombre de patients et une disponibilité limitée des salles d'opération, la connaissance et la familiarisation avec la SAI est une compétence extrêmement précieuse et nécessaire. L'objectif de cette étude était d'auditer la pratique de la SAI au sein du CU de l'hôpital universitaire Steve Biko.

**Méthodes:** Il s'agissait d'un audit descriptif transversal. Les procédures effectuées dans le cadre de la SAI ont été identifiées. Un audit des notes cliniques et des entretiens avec les membres du personnel ont été réalisés. Les données ont été utilisées en utilisant le logiciel STAT 12. Les résultats ont été présentés sous forme de statistiques de respect, en référence aux directives sur la SAI de la Société sud-africaine de médecine urgentiste (Emergency Medicine Society of South Africa (EMSSA)).

**Résultats:** Cet audit a indiqué que la documentation du consentement éclairé avant la SAI était de mauvaise qualité dans le CU de cet hôpital. Aucune preuve de consentement éclairé n'a été trouvée dans aucun des cas audités. Le respect des autres aspects de la SAI était également relativement médiocre (inférieure à 50% dans la plupart des cas). Les notes de respect moyennes pour ces composantes étaient telles suit: préparation et vérification du matériel avant la procédure, 46,19% (IC à 95% 36,62–55,76), examen préliminaire documenté du patient, 50,99% (IC à 95% 46,78–55,18), suivi pendant l'intervention, 39,22% (IC à 95% 34,68–43,75), suivi suite à l'intervention, 37,99% (IC à 95% 32,78–43,20), et documentation globale de l'intervention, 40,69% (IC à 95% 37,85–43,52). L'analyse du respect des directives entre différents niveaux de médecins a montré que les registres en MU étaient généralement plus en conformité.

**Conclusions:** Cet audit a identifié le consentement éclairé comme une lacune majeure de la pratique de la SAI dans ce CU. La plupart des autres aspects évalués peuvent également être améliorés. Dans le cadre de ce cycle d'audits cliniques, les résultats de cet étude seront utilisés afin d'initier des changements visant à augmenter le respect des directives.

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## African relevance

- Knowledge and skill in procedural sedation and analgesia is useful in a resource limited setting.
- Procedures under procedural sedation and analgesia in the emergency centre may eliminate the need for theatre.
- Emergency centres should regularly audit the safety of their procedural sedation and analgesia practice.

## Introduction

Procedural sedation and analgesia (PSA) is a vital skill for any physician working in an emergency centre (EC). Previously known as conscious sedation, the term PSA is now preferred.<sup>1</sup> It is the technique of using drugs to induce a state where a patient will tolerate noxious stimuli, while maintaining his or her own cardio-respiratory function without invasive support and monitoring.<sup>2</sup> The practice of emergency medicine often requires performing painful and anxiety producing procedures. In addition to reducing the pain and anxiety associated with these procedures, PSA also frequently facilitates the successful and timely completion of the procedure.<sup>3</sup> PSA is now internationally accepted as a rapid turnaround emergency physician-led service. PSA is a core competency in emergency medicine (EM) and a daily part of EM practice.<sup>4</sup> The EC is a unique environment where patients present on an unscheduled basis, often with complicated problems. These may require urgent interventions to proceed simultaneously. Examples include fracture/dislocation reductions, complex suturing, electrical cardioversion, intercostal drain insertion as well as diagnostic procedures.

In South Africa, as in many low-resource settings, high patient loads, as well as long waiting times for theatres and specialists, are a common occurrence. This necessitates that many procedures be conducted in the emergency centre and thus, PSA has become a critical component of care in our ECs.<sup>5</sup> A study by Hodkinson et al.<sup>6</sup> published in 2009 demonstrated the many shortcomings of PSA in ECs in Cape Town. This questionnaire-based study enquired directly about the PSA practises of doctors and nursing unit managers. It was conducted in both government and private ECs. The authors postulated that the findings of their study were in all likelihood representative of the practise in ECs in the rest of South Africa. As a consequence of this study the following recommendations were made to improve PSA in ECs in South Africa:

1. Development of general protocols for PSA in ECs,
2. Training of doctors and nurses at all levels, and
3. Optimisation of EC facilities and staffing.

Shortly after this, the Emergency Medicine Society of South Africa (EMSSA) published guidelines regarding PSA in emergency centres in 2010.<sup>5,7</sup> These PSA guidelines suggest the current best practice or standard of care. Their goal is to improve the standard of PSA being conducted in South African ECs.<sup>5</sup> Important aspects of these guidelines include: pre-procedure evaluation of the patient, monitoring during and after procedure, documentation of procedure, equipment and staff required as well as types of medications recommended.<sup>7</sup>

## Methods

This was a cross-sectional descriptive study; it was conducted in the EC of Steve Biko Academic Hospital (SBAH). This tertiary academic facility provides emergency care to the residents of the greater Tshwane District, a population of approximately three million people. The number of patients treated in the EC is on average, 26,000 per annum. EC patients are selected through a triage process with a high level of acuity and hence a greater need for EC procedures. The EC serves as the referral hospital for most of Northern Gauteng and parts of Mpumalanga.

The aim of this study was to audit the practice of PSA in the EC of SBAH against the EMSSA PSA guidelines. The objectives were to assess adherence to the guidelines paying special attention to the following: informed consent, pre-evaluation of the patient, monitoring during and after the procedure, equipment and medications used, staff availability as well as the documentation of the procedure.

A clinical audit should be followed by changes designed to improve conformity with the standards and then by re-evaluation to demonstrate such improvement<sup>8</sup>; that was the goal of this study.

All PSAs conducted on adult patients for major joint/fracture reductions and intercostal drain insertions in SBAH EC by fulltime EC doctors were included. These procedures were chosen as they are the most commonly conducted under PSA in this unit. It also ensured easy identification of the files. Fulltime doctors working at this institution include registrars in emergency medicine, medical officers (MO) of varying experience as well as community service medical officers (CSMO).

Children under the age of 18 years were not considered due to difficulties in obtaining informed consent and because our audit focused on PSA in adults. Sessional doctors were not included as they were not readily available to interview and represent a small minority of doctors working in our setting.

Cases were identified on a daily basis by consulting the patient register as well as the schedule drug register. Once identified, the investigator conducted an extensive audit of the patient's notes. A data collection sheet, in the form of a tick sheet, was compiled using the EMSSA PSA guidelines as a template. The data collection sheet was broken up into a number of different components consisting of various elements (Table 1). Information recorded in the patient's notes regarding the different elements of the guidelines was marked off on the check sheet. In addition to this, an interview was conducted with the member of nursing staff who assisted in the procedure. A semi-structured interview was conducted in a private room using the same data collection sheet as a template. During this interview, elements of the PSA that may have been carried out but were not clearly documented in the notes were identified. This interview was conducted within 48 h to overcome any potential for recall bias. The study was designed to reduce the potential of the Hawthorne effect, i.e., doctors conducting PSA were not influenced by researchers directly observing or questioning them whilst performing the PSA. Data were collected over a six-month period between May and October 2014.

Data were captured on an Excel spreadsheet. Most of the data were descriptive in nature. The different components

**Table 1** Descriptions of each component of the EMSSA PSA guidelines.<sup>7</sup>

Component	Description
Pre-procedure preparation and equipment	Airway equipment (oxygen, suction, oral airways, intubation, positive pressure device), vital signs monitor, emergency medications, defibrillator, resuscitation trolley
Documented patient pre-evaluation	Medical and surgical history, allergies, vital signs, cardiorespiratory examination, airway evaluation, weight, last oral intake, ASA classification
Monitoring during procedure	NIBP, pulse oximetry, ECG, respiratory rate, capnography
Monitoring post procedure	NIBP, pulse oximetry, ECG, respiratory rate, capnography, observations 15 min for first hour, 30 min for second hour, then hourly until disposition
Summary of documentation	Date, vitals, pain score, success of procedure, start time of sedation and procedure, airway evaluation, medications used, doses and route, adverse events

EMSSA, Emergency Medicine Society of South Africa; PSA, procedural sedation and analgesia; ASA, American Society of Anesthesiology; NIBP, non-invasive blood pressure; ECG, electrocardiogram.

and their elements can be seen in [Table 1](#). For example, the 'monitoring during procedure' component consisted of five individual elements. The data collected showed how many and how often each of those individual elements was performed during that component. The data are presented as an overall mean for each component with their standard deviations and 95% confidence intervals (CI). A statistician from the Biostatistics Unit of the Medical Research Council of South Africa conducted the statistical analysis using a STAT 12 package.

The study design was approved by the MMed Protocol Committee of the University of Pretoria as well as Faculty of Health Science Research Ethics Committee of the University of Pretoria. Informed consent was collected from both doctors and nursing staff working in the EC who participated in the study. All data collected during this study will be stored for a period of 10 years in room 72442 on the 7th Floor of SBAH.

## Results

The baseline demographics of the patients and types of procedures can be seen in [Table 2](#).

Fifty-one procedures were analysed in total, 14 conducted by registrars, 33 by MOs and four by CSMOs. The majority were male patients ( $n = 40$ ) with a mean age of 38 (SD

**Table 2** Basic demographics.

Demographic	Mean (SD)
Age	38 (13.16)
Male	36 (11.82)
Female	45 (15.67)
Type of procedure	<i>n</i>
Male	40
Intercostal drain	18
Shoulder reduction	14
Elbow reduction	4
Ankle reduction	3
Hip reduction	1
Female	11
Shoulder reduction	7
Intercostal drain	4

SD, standard deviation.

13.16). There was no evidence of signed informed consent in any of the cases audited. The majority ( $n = 37$ ) of procedures were not conducted in a specific resuscitation area where access to resuscitation drugs and equipment was immediately available. Of these, none complied with the guideline of having immediate access to resuscitation drugs or equipment at the bedside. Mean overall adherence scores with their 95% confidence intervals were calculated for the important components of the EMSSA PSA guidelines ([Table 3](#)). A description of the different elements for each component can be seen in [Table 1](#).<sup>7</sup>

In over 98% of cases, more than one person was involved in the procedure with specific roles being assigned to each member of staff. However, in 73% of cases, the staff member responsible for post procedure monitoring was also responsible for multiple other patients. The most common medications used included morphine (53%), ketamine (45%), midazolam (45%) and propofol (37%). A combination of medications was used in the majority of cases with morphine/midazolam (35%) and ketamine/propofol (27%) the most commonly used combinations. There was no statistically significant difference found between the type of medications used and the rank of the doctor.

A total of 50 (98%) procedures were successful. Only nine (18%) patients were discharged and none received written discharge instructions.

There were a total of three adverse reactions noted. Descriptions of the adverse events and outcomes can be seen in [Table 4](#). Further analysis of adherence according to rank of doctor was conducted ([Fig. 1](#)).

## Discussion

This audit highlighted a significant problem with adherence to the informed consent process. None of the procedures

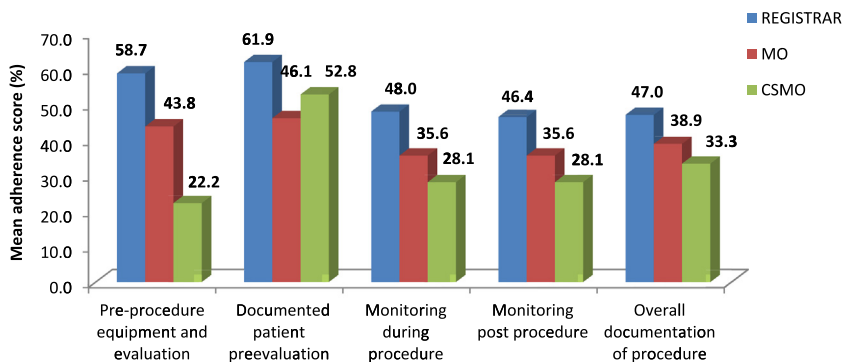
**Table 3** Mean adherence to EMSSA PSA guidelines.

EMSSA PSA guideline	Mean (95% CI)
Informed consent	0
Pre-procedure preparation and equipment	46.19 (36.62–55.76)
Documented patient pre-evaluation	50.99 (46.78–55.18)
Monitoring during procedure	39.22 (34.68–43.75)
Monitoring post procedure	37.99 (32.78–43.20)
Summary of documentation	40.69 (37.85–43.52)

EMSSA, Emergency Medicine Society of South Africa; PSA, procedural sedation and analgesia; CI, confidence interval.

**Table 4** Adverse events with corresponding treatments and outcomes.

Type of adverse event	Treatment and outcome
Hypotension	Resolution following intravenous fluids, admitted to inpatient services for continued monitoring
Hypoxia	Required supplemental oxygen, admitted for continued monitoring
Hypoventilation	Required antidote (flumazenil), discharged after complete resolution of adverse event



**Figure 1** Mean adherence score per rank of doctor.

reviewed had signed informed consent as part of the documentation. Although verbal consent may be acceptable as an alternative to formal written consent in certain emergency conditions or where the patient may be in severe pain, such consent should still be documented in the clinical notes. This was, however, not the case in any of the clinical notes assessed for this audit. It is likely that some form of verbal consent was obtained from the patient prior to the procedure but no written evidence to support such interaction could be found. In the present era of greater awareness of patients' rights, defensive medicine, and medical litigation, the existing practice could present a medico-legal risk to the staff involved. It should be mandatory that evidence of obtaining informed consent from the patient be part of the clinical notes. Ideally, a patient should sign a consent form after a discussion has taken place regarding the procedure process, possible adverse events, reasonable alternatives as well as the likelihood of success of the procedure.

Most guidelines regarding PSA suggest that unless minimal sedation is planned, all procedures should occur in a dedicated resuscitation area.<sup>7,9</sup> This ensures adequate monitoring as well as immediate access to emergency drugs and equipment should any complications arise. Monitoring after the procedure should also be conducted in a similar area until the patient meets discharge criteria. In this study, the majority of procedures were not conducted in a resuscitation area. Furthermore, none of these procedures had immediate access to the prescribed equipment or drugs available at the bedside. A resuscitation trolley and defibrillator were available in the general area but emergency drugs would have had to be fetched from the EC resuscitation area or pharmacy.

Fourteen of the 51 procedures took place in a specific resuscitation area. In these 14 cases, there was a 100% adherence to the prescribed guidelines regarding the pre-procedure preparation and equipment needed. In low-resource settings, the availability of resuscitation beds may render this part of the guideline difficult to achieve. Even in this tertiary hospital, access block due to the paucity of inpatient beds is common.

Hence, resuscitation beds are frequently unavailable. This may explain the low level of adherence to this aspect of the guidelines. However, when PSA is conducted in non-resuscitation areas, a resuscitation trolley with the necessary equipment and drugs should be at the bedside. This was not the case in many PSAs in this audit.

The rest of the cases were conducted in a non-resuscitation area. This highlights a potential risk as should any complications occur, access to staff, or obtaining equipment and medications is more difficult. Two of the three adverse events that occurred took place in a non-resuscitation area. Due to the low occurrence of adverse events, no statistical analysis could be made of the difference between adverse events occurring in resuscitation versus non-resuscitation areas.

Ideally, all procedures undergoing PSA should be conducted in a resuscitation area to allow for better monitoring, early identification of complications and prompt treatment. However, as described above, this is not always possible especially in resource-constrained areas. However, no matter where the PSA takes place, proper planning and preparation is essential and every effort should be made to have all necessary equipment in place.

Important elements of the pre-evaluation process can be seen in Table 1. Assimilation of this information helps to document patient risk, assign an 'American Society of Anesthesiology' (ASA) physical status score, determine the risk of the procedure and plan the sedative technique.<sup>7</sup> It is interesting that the most critical elements of this component were also the least well documented, in particular the weight of the patient ( $n = 0$ ), the airway assessment ( $n = 4$ ), and the time since last oral intake ( $n = 0$ ). These three aspects are important in planning the PSA procedure, especially in terms of drug selection, risk for difficult airway management and other potential complications. It is likely that the doctors took note of the above elements as these are necessary for dose calculation, etc. There was however, no documentation in the notes confirming this.

A range of sedative and analgesic medications were available to the clinicians conducting PSA in our study. The most



commonly used medications were morphine, ketamine, midazolam, and propofol. Correct dosing of medications could not be determined in this audit as the weights of the patients were not routinely documented, as mentioned above.

Appropriate monitoring of the patient during and after the procedure is an essential aspect of safe PSA. This allows the clinician to detect complications early and promptly institute appropriate measures if needed. At a minimum, non-invasive blood pressure (NIBP), pulse oximetry, electrocardiogram (ECG) as well as the respiratory rate should be monitored. According to the EMSSA guidelines, capnography is also suggested. Capnography was part of the monitoring in only two procedures. This contributed significantly to the fairly low level of adherence for this component. However, routine use of capnography in PSA is debatable. It is a level B recommendation according to the American College of Emergency Physicians, meaning such a recommendation is based on inconsistent or limited-quality patient-oriented evidence.<sup>10</sup>

Capnography helps to identify hypoventilation by detecting a rise in the end tidal carbon dioxide levels (ETCO<sub>2</sub>). Rising ETCO<sub>2</sub> is an earlier indicator of hypoventilation when compared to a decrease in oxygen saturation. This is especially true when supplemental oxygen is administered. However, there is currently not enough evidence to suggest that the use of capnography causes a reduction in the incidence of serious adverse events, i.e., neurological injury, aspiration or death.<sup>11</sup> Capnography is an expensive adjunct and is unlikely to be widely available in low-resource settings. For these reasons, monitoring other parameters such as respiratory rate is more practical.

In the setting of our study, as well as most other ECs in Africa, staff shortages are common. Although there was a second staff member available in the vast majority of the cases during the procedure, their availability for monitoring after the procedure fell to less than a third. Staff shortages and thus the inability to adequately monitor the patients post procedure contributed significantly to the low adherence scores for this component of the audit. This is another potential area where complications may be missed.

In all the cases audited, the documentation was insufficient to ascertain whether specific discharge criteria were met. Patients monitored in the resuscitation beds received more extensive post procedure monitoring since they had dedicated resuscitation room staff monitoring them. In spite of this, none of these patients received the suggested quarter-hourly observations that are required during the first hour or the half-hourly observations that are required for the second hour. Very few patients in the audit were discharged home post procedure and of these, none received written discharge instructions. This is an important aspect of appropriate patient disposition. It can easily be remedied by having instruction pamphlets readily available to give to patients on discharge.

The audit found that the majority of procedures were successful and that there was a low incidence of adverse events. The few adverse events that did occur are detailed in [Table 4](#) of the results. The incidence of minor adverse events in this study of 5.8% is in keeping with incidence rates of 5.4% in similar studies.<sup>12</sup>

Documentation of the PSA procedure should include amongst others: start and end time of sedation and procedure,

vitals, medications used as well as adverse events recorded ([Table 1](#)). The clinical notes should be accurate and concise giving a clear overall impression of all the different aspects of the sedation and procedure technique. The 'summary of documentation' component audited this aspect in particular. The overall documentation of all the procedures was found in general to be below an acceptable standard. Many elements suggested by the EMSSA guidelines that should be recorded were found not to be. This poses a potential medico-legal risk to all the staff involved in the procedure.

From [Fig. 1](#), it appears that registrars were more likely to adhere to the EMSSA guidelines than the Medical Officers. The reasons for this may include: registrars having better awareness of the EMSSA guidelines, attendance of specific PSA courses as well as exposure to PSA training during their academic programme.

This study was limited by a small sample size. This was due to the limited time frame available to do the study as well as difficulties in obtaining patient records and conducting timely interviews with the relevant staff. The study was conducted in a tertiary academic EC and may not reflect the practice in non-tertiary or non-academic emergency centres. There was the potential for recall bias as interviews were conducted with nursing staff after the procedure. By conducting timely interviews, it was attempted to reduce this bias.

## Conclusions

From our audit, it is evident that adherence to the EMSSA guidelines is fairly average and below an acceptable standard for obtaining informed consent. Notwithstanding this, a low adverse event rate was found. This reinforces the fact that PSA conducted in the EC is an inherently safe procedure.

This study was conducted in an academic tertiary centre, and most likely reflects a standard of PSA higher than that achieved in non-academic ECs, especially in the government sector. Similar audits should be conducted in such ECs to ascertain whether this is the case.

As part of the clinical audit cycle, the results of this study will be used to initiate changes to increase adherence to the guidelines. The corrective measures proposed include in-house training of all members of staff working in the EC regarding the EMSSA guidelines. Special emphasis will be placed on the following important aspects in future training: patient pre-evaluation, monitoring, and documentation. A unit-specific procedural sedation record ([Appendix 1-data supplement](#)) has been compiled to ensure recording of important details. This will be tested and refined for all PSAs performed in the EC in the future. It will also serve as a checklist for the staff involved. The sedation record will provide accurate and usable data for future studies. A follow-up audit will be conducted once training based on the audit and the existing EMSSA guidelines has been done and the new sedation record put into place.

## Conflict of interest

The authors declare no conflict of interest.

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## Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.afjem.2015.03.002>.

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