

## The utilization of procedural sedation and analgesia at the University Teaching Hospital of Kigali, Rwanda

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### ABSTRACT

**INTRODUCTION:** In the Emergency Department (ED), safe and effective Procedural Sedation and Analgesia (PSA) is essential. The professional performing procedural sedation has to be prepared to handle any potential adverse effects. Medications are used according to their availability and based on the physician's experience and preference. Despite the common occurrence of procedural sedation in the ED, it has not previously been studied in Rwanda.

The study aimed to describe procedural sedation and analgesia utilization and common adverse events at Rwanda's University Teaching Hospital of Kigali (UTH-K) ED.

**METHODS:** This study is a prospective observational study of procedural sedations done at UTH-K ED. The effectiveness of sedation was evaluated using the Richmond Agitation Sedation Score (RASS) during sedation. The pain scale was assessed before and after the procedure. Categorical data were analyzed for significant differences using Chi-squared (X) tests and continuous data with Mann-Whitney (MW) tests.

**RESULTS:** Two hundred fifty-one patients were recruited. Seventy-two percent (72%) of patients were male with a median age of 32 years (IQR 23 to 40). The most commonly used analgesics included morphine (78%) and tramadol (17%), with ketamine least used (1%). A common adverse event was hypoxia (36%), followed by hallucination (8%). No adverse events were observed in 47% of procedures.

**CONCLUSION:** Our study findings suggest that although sedation in our low-resource setting did not result in serious adverse outcomes for patients, there was a much higher incidence of minor adverse events (especially hypoxia) than in higher-resource settings.

**Keywords:** Procedural Sedation, Emergency Department, Adverse Events, Analgesia, Conscious Sedation

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**Received:** 23<sup>rd</sup> August 2020; **Initial decision given:** 28<sup>th</sup> April 2021; **Revised manuscript received:** 02<sup>nd</sup> August 2021; **Accepted:** 23<sup>rd</sup> November 2021.

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**Citation for this article:** A. Manirafasha; O. F. Umuhire; J. Muragizi et al. The utilization of procedural sedation and analgesia at the University Teaching Hospital of Kigali, Rwanda. Rwanda Medical Journal, Vol. 78, no. 4, p. 27-31, 2021. <https://dx.doi.org/10.4314/rmj.v78i4.4>

## INTRODUCTION

According to the American College of Emergency Physicians, procedural sedation and analgesia (PSA) is “a technique of administering sedatives or dissociative agents with or without analgesics to induce a state that allows the patient to tolerate unpleasant procedures while maintaining cardiorespiratory function. PSA is intended to result in a depressed level of consciousness that allows the patient to maintain oxygenation and airway control independently” [1]. For safe PSA, resuscitation materials and medication are needed for the rescue of patients from adverse events.

Adverse events associated with PSA have been extensively studied in high-income countries. However, monitoring resources and medications used for PSA in low-income settings are often different. Because of this, adverse events associated with PSA in a low-income setting have not been adequately studied. This study analyzes adverse events associated with PSA when more readily available medications in developing countries are used.

The emergency department (ED) is a place where procedures requiring PSA are frequently performed. PSA use must be carefully monitored, and the person performing the procedural sedation must be prepared for adverse events and competent in managing them. The patient's level of sedation may differ depending on their physiology and comorbidities. Medication choice for procedural sedation may depend on availability as well as the medical provider's experience and preference [2]. Prior research has suggested that adverse events can occur in approximately 1.4-11% of cases. Commonly reported adverse events include: hypoxia, hypotension, tachypnea, bradycardia, agitation, aspiration, laryngospasm, intubation, vomiting and apnea [3]. Severe adverse events like intubation, laryngospasm, and aspiration are rare[3].

The most common drugs used for PSA are dissociative (Ketamine), sedative/hypnotics (propofol), opioids (morphine, fentanyl), and benzodiazepines (diazepam, midazolam). Sometimes combinations of fentanyl/midazolam or ketamine/propofol can be used [2,4]. The mode of delivering medications and dosage of these drugs depends on age, weight, medical conditions, and available monitoring methods [2]. Guidelines recommend that sedation be given in the presence

of a physician and that a physical examination and history of previous medical conditions be taken before authorizing sedation [4]. For the patient in need of deep procedural sedation, close monitoring is required. This can include capnography with an experienced physician ready to provide cardiopulmonary resuscitation if necessary [1].

Our study sought to evaluate the utilization, administration and frequency of procedural sedation medication, the effectiveness of sedation, pain control before and after the procedure, and the frequency of adverse events.

## METHODS

**Study design:** Prospective observational study at the University Teaching Hospital of Kigali (UTH-K).

**Participants:** All patients above seven years were part of the study after consenting. Pregnant women were excluded.

**Definitions:** Vital signs were measured before administration of sedation and 15 minutes post-procedure. Hypoxia was reported if pulse oximetry (SpO<sub>2</sub>) was less than or equal to 90%, in which case oxygen was given immediately. Bradycardia was defined as a heart rate of less than or equal to 60 beats per minute (bpm) in adults. Hypotension was defined as a systolic blood pressure measurement of less than or equal to 90 millimeters of mercury (mmHg). Adverse events, if they occurred, were immediately addressed.

The fasting state was defined as six hours without food and three hours without clear fluids. The non-fasting state was defined as patients who have taken clear fluids within three hours prior to procedure or food within six hours. General practitioners and postgraduates in year one or two and are considered junior doctors. Senior doctors refer to postgraduates in year three or four and consultants in emergency medicine and critical care.

Success was defined as the absence of adverse events, whereas failure was defined as the occurrence of an adverse event.

**Medications:** The medications used were given in standard dosages (Morphine 0.2mg/kg, ketamine 1-2mg/kg, propofol 1-2mg/kg, Diazepam 0.1-0.2mg/Kg, midazolam 0.1-0.2mg/Kg). Ketofol was 50% ketamine and 50% propofol. As is standard practice in our setting, benzodiazepines are not routinely given before ketamine. Diazepam was

given to patients who experienced hallucinations. Fentanyl and midazolam were excluded from our study as they were not available in our setting at the time of the study

**Data collection and analysis:** A questionnaire was developed for data capturing. Data were entered into an electronic database and analyzed using Microsoft Excel 2010® software (Microsoft Corporation). Categorical data were analyzed for significant differences using chi-squared (X) tests and continuous data with Mann-Whitney (MW) tests.

**Ethical approval:** This study has been approved by the University of Rwanda College of medicine and health sciences ethical committee No 101 CMHSIRB/2019 and UTH-K Ethical committee Ref: EC/CHUK/5048/2018.

## RESULTS

In total, 251 patients were recruited. Data were not normally distributed. The majority were male at 72% (N=181). The median age was 32 years (IQR 23 to 40). The youngest patient enrolled was eight years old and the oldest was 88 years old. Ninety percent (90%) of the study population had no known comorbidities. The most common comorbidities were hypertension at 5% (N=13) and diabetes at 3% (N=7).

The analgesics used included morphine, which was used in 78% of cases (N=197), tramadol at 17%, diclofenac at 3%, ketamine at 1%, and paracetamol at 1%. The most common sedative agents used were ketamine at 68% and propofol at 26% of cases.

**Table 1: Comparison of propofol and ketamine groups**

	Total n=251		n=65		Ketamine n=173		Chi-square test p-value
	n	%	n	%	n	%	
Failure	128	51.0	35	53.8	85	49.0	0.518
Success	123	49.0	30	46.2	88	51.0	
Hypoxia (SPO2<90 on RA)	91	36.3	26	40	61	35.2	0.435
None	160	63.7	39	60	112	64.8	
Hallucination	21	8.3	3	4.6	18	10.5	0.162
None	230	91.6	62	95.4	155	89.5	
Nausea	11	4.4	3	4.6	7	4.0	0.846
None	240	95.6	62	95.4	166	96	
Male	181	72.1	48	73.8	124	71.7	0.74
Female	70	27.9	17	26.2	49	28.3	
Comorbidities	25	10	4	6.2	20	11.6	0.218
No comorbidities	226	90	61	93.8	153	88.4	
Senior (PGY3 & PGY4)	75	29.9	24	36.9	46	26.6	0.12
Junior (PGY1 & PGY2)	176	70.1	41	63.1	127	73.4	
Fasted	133	53	33	50.8	92	53.2	0.741
Not fasted	118	47	32	49.2	81	46.8	

\*Categorical data,  
p values according to Chi-square test)

The majority of our population was given Morphine and ketamine (57%), Morphine and propofol (20%), or Tramadol and Ketamine (14%).

Eighteen percent (18%) of the study population underwent a wound washout without associated fracture. Fracture wash out and immobilization accounted for 29% of procedures studied. Sixteen percent (16%) of procedures were for shoulder dislocations. Fracture reduction without washout made up 9% of cases.

Prior to procedural sedation, the median pain score was 5 (IQR 5 to 6). After the procedure, the median pain score was 2 (IQR 1 to 2). Median RASS (Richmond Agitation Sedation Score) was -2 (IQR -2 to -2).

The most common adverse events were hypoxia (36%) and hallucinations (8%). Forty-seven percent (47%) of patients did not develop any adverse events. All adverse events were minor and managed successfully. No advanced management (such as intubation) was required. Among hypoxic patients, none needed bag valve mask ventilation (BVM). Patients who hallucinated were managed with diazepam.

Patients who received propofol and those who received ketamine were compared as these made up the large majority of all sedatives used (94%). There was no significant difference in failure rates between propofol and ketamine groups (Table 1).

There was a non-significant trend towards senior doctors being more likely to use propofol than junior doctors. There were no significant changes in HR, RR, SBP and SpO<sub>2</sub> in either of the ketamine or propofol groups or overall.

Post-procedure SBP was higher in failed procedures than in successful ones. Other than this, there were no significant differences between groups.

There were non-significant trends towards pre-procedure HR higher in failures, pre-procedure pain scores lower in failures, senior doctors having more successes, and fasting patients involved in more successful procedures (Table 2).

## DISCUSSION

Very few studies addressing this issue have been performed in Africa and no similar study has been conducted in Rwanda. Two descriptive studies on procedural sedation have been done in South Africa [5,6]. This study sought to show how PSA can be done safely using widely available medications. Although we found a high (53%) incidence of minor adverse events, none required BVM or intubation. Similar to our findings, prior studies done elsewhere have shown that propofol, ketamine, morphine, fentanyl, and midazolam are safe and effective in appropriate patients and are available in most health facilities.

Propofol or ketamine was used in 94% of cases at UTH-K ED, which may reflect the easy availability of these medications. Miner et al. showed a higher rate of respiratory depression in patients in the ketamine group than the propofol group, and recovery agitation was seen more frequently in patients receiving ketamine than in those receiving propofol. That same study showed no significant difference for those medications to cause hypotension [7].

A meta-analysis of 55 articles and 9562 instances of PSA that looked at the incidence of adverse events in PSA showed that hypoxia was common (40.2 per 1000 sedations, 4%), vomiting (16.4 per 1000 sedations), and hypotension (15.2 per 1000 sedations). Severe adverse events requiring emergency medical intervention were rare, with

**Table 2: Comparison of drugs used for sedation**

	Overall		Success		Failure		Chi-square test
	n	%	n	%	n	%	
Diazepam	2	0.8	1	0.8	1	0.8	0.83
Ketamine	173	68.9	85	69.1	88	68.7	
Ketofol	7	2.8	4	3.3	3	2.3	
Propofol	65	25.9	30	24.4	35	27.3	

*\*Categorical data,  
p values according to Chi-square test)*

1.2 per thousand sedations of aspiration and 1.6 per thousand sedations of intubation [3]. Our hypoxia rate was above 30%, which is concerning in comparison to the results of this meta-analysis. Possible causes of this include the unreliability of monitoring equipment (such as battery-powered pulse oximeters) and the lack of capnography to detect a fall in a respiratory rate before hypoxia supervenes. We saw no severe adverse events, and vomiting was similarly rare (2%). In that same meta-analysis, ketamine was the leading cause of agitation and vomiting (164.1 and 170.0 per 1000 sedations, respectively). Apnea was seen more commonly with midazolam (51.4 per 1000 sedations) than any other medication [3]. We saw no apnea, and the higher percentage of hallucinations with ketamine than propofol was not significant. This is likely due to the small sample size of this study.

A priority for the department and training of residents is now to start rapid-cycle PSA quality improvement projects to identify methods to improve the quality of ED sedation and minimize adverse events.

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One limitation of our study was that pulse oximeter recordings were not consistently reported at the time of hypoxia after sedation. We did not explore the timetable under which this adverse event can arise. The sample size was not large enough to allow us to identify rarer, severe adverse events that needed aggressive management. An expanded study of at least one full year may help gain information about those severe adverse events.

## CONCLUSION

Some adverse events may be unavoidable in any setting. These data suggest that, although sedation in our low-resource setting did not result in serious adverse outcomes for patients, there was a much higher incidence of minor adverse events (especially hypoxia) than in higher-resource settings. Adequate training and preparation for severe adverse events, even if they are rare, is essential for developing sedation practice in low-resource settings.

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