



ORIGINAL ARTICLE

Intraoperative awareness and experience with a ketamine-based anaesthesia package to support emergency and essential surgery when no anaesthetist is available

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ABSTRACT

Introduction: Five of the 7.2 billion people on earth have limited access to emergency and essential surgical procedures. The lack of safe, affordable and timely anaesthesia services are primary barriers to universal surgical coverage. The objective of this study was to assess intraoperative awareness when the ‘Every Second Matters for Emergency and Essential Surgery – Ketamine’ (ESM-Ketamine) package was used to support emergency and essential surgeries and painful procedures in rural Kenya when no anaesthetist was available.

Methods: Forty-seven consecutive adult patients that underwent an operative procedure under ESM-Ketamine at Sagam Community Hospital in Luanda, Kenya were enrolled. Participants underwent two semi-structured interviews that explored the patient’s experience with ESM-Ketamine both after the operative procedure and four to six weeks after surgery.

Results: Forty-seven participants completed the first interview and 37 (78.7%) the second interview. Thirty-seven (78.7%) cases were procedural sedations and ten were (21.3%) emergency surgeries. Intraoperative awareness occurred in nine (24.3%) participants who underwent procedural sedation and two (20%) who underwent emergency surgery. Twenty-six (55.3%) participants reported dreams during the procedure. Thirty-two (86.5%) participants considered their experience positive, and 35 (95%) would recommend a procedure supported by ketamine to a friend.

Discussion: Most patients whose painful procedures and emergency operations were supported by the ESM-Ketamine package when no anaesthetist was available reported favourable experiences.

African relevance

- In sub-Saharan Africa, the density of anaesthetists is often fewer than one per one million people.
- The ESM-Ketamine package can significantly increase access to anaesthesia services.
- Patient perceptions, expectations, and experiences with ketamine have not been assessed in this setting.
- Patients report positive experiences with the ESM-Ketamine package when no anaesthetist is available.

Introduction

Approximately five of the 7.2 billion people on earth have limited access to emergency and essential surgical procedures [1]. The lack of safe, affordable and timely anaesthesia services has been described as the “anaesthesia gap” and is one of the primary barriers to universal surgical coverage [2]. Access is especially low in resource-constrained settings where severe shortages of anaesthesia services frequently lead to surgical delays that may result in death or disability [1–3]. In sub-Saharan Africa and certain regions of Asia, the density of anaesthetists is often fewer than one per one million people [4]. In 2015, the World Health Organization recognised emergency and essential surgery and

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anaesthesia as vital components of universal health care [5]. Consequently, multiple organisations have called for a global response to address the disparities and shortfalls in the availability of anaesthesia in low- and middle-income countries (LMIC). In response to the anaesthesia gap, the authors previously designed the ‘Every Second Matters for Emergency and Essential Surgery – Ketamine’ (ESM-Ketamine) package to train non-anaesthetist providers in the administration and monitoring of ketamine anaesthesia and sedation when no anaesthetist is available [3,6].

Ketamine is an ultra-low-cost dissociative drug with analgesic, amnesic, and anaesthetic properties that has been used to support operations and painful procedures worldwide for over 50 years [3,7,8]. With proper administration of ketamine, patency of the airway is usually preserved and cardiorespiratory functions enhanced. Ketamine is commonly used for procedural sedation in high-income countries and has also been used to support emergency and essential surgeries in low-resource settings [9], even when administered by non-anaesthetists [7]. However, the use of ketamine in low-resource settings has been unregulated and disorganised [3], thus, raising concerns over patient safety and prompting development of the ESM-Ketamine package with associated research.

ESM-Ketamine is a best-evidence package that provides a novel and standardised approach to support life-saving and life-improving procedures in resource-poor settings when no anaesthetist is available. It includes a defined clinical pathway complemented by wall charts, checklists, and ESM-Ketamine kits. Over the past four and a half years, mid-level and higher (clinical officers, doctors, and nurses) non-anaesthetist providers underwent five-day training programmes on the ESM-Ketamine pathway, and thereafter supported emergency and essential operative procedures at their home facilities. To date, ESM-Ketamine has been used in more than 1500 emergency operations and painful procedures in rural Kenya, with no cases of ketamine-related deaths or disability. The ESM-Ketamine package has significantly increased access to anaesthesia services and has provided safe and effective pain control during surgery when no anaesthetist was available [3,6,10,11].

Although prior studies suggest that ESM-Ketamine is feasible, safe, and effective, the perceptions, expectations, and experiences of patients receiving ketamine when no anaesthetist is available have not been assessed. Intraoperative awareness, which occurs when a patient can recall the surroundings or an event related to the surgery while under general anaesthesia, is a uniquely important metric [12]. Intraoperative awareness is associated with decreased patient satisfaction, medicolegal consequences [12,13], and long-term psychological sequelae, such as post-traumatic stress disorder (PTSD) [14]. Intraoperative awareness during general anaesthesia has been described in 0.1–0.2% of operations while intra-procedure awareness during procedural sedation may occur in up to 25% of patients [15]. The aim of this study was to assess expectations, intraoperative awareness, and the overall experience of patients undergoing emergency and essential procedures supported by ESM-Ketamine in rural Kenya when no anaesthetist was available.

Methods

This study was conducted at a sub-district community hospital in rural Kenya between 16 January 2017 and 27 March 2017. All adult (≥ 18 years) patients who underwent any type of surgery or procedure supported by ESM-Ketamine at Sagam Community Hospital in Luanda, Kenya were eligible for inclusion. Exclusion criteria included 1) patients who did not speak Luo, Swahili, or English; 2) patients with altered mental status; 3) patients who were unable to communicate verbally; and 4) women who underwent an emergency caesarean section that resulted in stillbirth or death of the newborn (to prevent further distress). Ethical approval was obtained from the Partners Healthcare Human Research Committee (Boston, MA, USA) and the Maseno University Ethics Review Committee (Maseno, Kenya).

Patient demographics, type of procedure, ability to perform the procedure without the ESM-Ketamine package, ketamine dosage, intraoperative appearance of patients, and effects secondary to ketamine use were prospectively collected using a data collection card. Semi-structured, questionnaire-guided interviews were developed in an iterative fashion, building on validated anaesthesia assessment tools. Prior to implementation, the questionnaire was piloted and revised. Interviews were conducted on two separate occasions; the first within 24-hours after the procedure and prior to hospital discharge and the second by telephone, four to six weeks later. The interviews included 15 questions that explored the patient’s experience with the ESM-Ketamine clinical pathway and a modified Brice questionnaire to assess intraoperative awareness [16–18]. In addition to repeating the questions from the first interview, the second interview included the primary care PTSD (pc-PTSD) questionnaire [19]. Written informed consent was obtained at the initial interview in the patient’s language of preference (Luo, Swahili, or English).

The database was constructed using Excel 2015 (Microsoft, Redmond, WA, USA). Statistical analyses were conducted using RStudio version 1.0.153 (RStudio, Inc, Boston, MA, USA) [20]. Standard descriptive and frequency analyses were performed and normality for continuous variables was assessed using the Shapiro-Wilk test.

Results

Between 16 January 2017 and 27 March 2017, 72 patients who underwent a procedure or surgery supported by the ESM-Ketamine package (checklist shown in Fig. 1) met inclusion criteria, 47 (65.3%) agreed to participate in the study, and 37 (51.4%) completed the follow-up interview (Fig. 2). Thirty-seven (78.7%) participants underwent procedural sedations and ten (21.3%) emergency surgeries. Of the ten emergency surgeries, nine were Bellwether Procedures (caesarean section, laparotomy or open orthopaedic repair) [1], including two (4.2%) caesarean sections and seven (14.9%) laparotomies. Thirty-seven (78.7%) surgeries were gynaecologic and obstetric in nature. The types of procedures are shown on Table 1. The median ketamine dose was 2 mg/kg (IQR 1–3) for procedural sedations and 9 mg/kg (IQR 6–10) for emergency surgeries. The mean time to recovery, defined as the time between the last dose of ketamine and full patient orientation, was 62 min (IQR 29.75–122) and 101 min (IQR 80–152.25) for procedural sedations and emergency surgeries, respectively.

Six (16.2%) patients who underwent procedural sedation and two (20%) who underwent emergency surgery received diazepam to treat hallucinations or agitation. Atropine was administered to two (5.4%) patients with hypersalivation during their procedural sedation and to two (20%) who underwent emergency surgery. There were no ketamine-associated deaths or disabilities.

Awareness during procedural sedation occurred in nine (24.3%) participants. These nine participants reported hearing the events of the procedure, being unable to move or breathe, feeling the oxygen mask, and seeing their surroundings (Table 2). Two (20.0%) patients who underwent emergency surgery reported intraoperative awareness. In eleven (29.7%) procedural sedations and two (20%) emergency surgeries, patients reported that they heard voices but were unable to recall specific events. Intraoperative dreaming was reported by 21 (56.8%) participants who underwent procedural sedations and five (50%) who underwent emergency surgery. No significant differences were found in awareness rates between patients who reported dreaming and those who did not. One (2.3%) patient who underwent a dilation and curettage recalled 2/10 pain during the procedure but had no pain upon awakening.

During the first interview, 24 (51%) participants reported anxiety and the recovery process as the worst aspects about the procedures supported with ESM-Ketamine (Table 3). Six participants (12.8%) reported postoperative pain as the worst aspect of the overall experience. During the second interview, 31 (83.8%) participants changed their

ESM – KETAMINE™ SAFETY CHECKLIST

For emergency/essential surgery and procedural sedation

- Complete ESM-Ketamine Clinical Record
- Confirm ketamine concentration
- Confirm equipment function
 - Pulse Oximeter
 - Blood Pressure Device
 - Oxygen Source/Facemask
 - Suction
 - Bag Valve Mask
- Place IV of normal saline
- Place pulse oximeter onto the same side as the IV
- Place blood pressure cuff on arm opposite the pulse oximeter and IV
- Place oxygen on patient
- Titrate appropriate IV ketamine dosing:
 - 1) Emergency/Essential surgery:
 - 2 mg/kg initially over 30-60 seconds
 - 1-2 mg/kg every 10-15 minutes
 - 2) Procedural Sedation:
 - 1 mg/kg initially over 30-60 seconds
 - 0.25-1 mg/kg additionally as needed
- Complete ESM-Ketamine Clinical Record

Additional Potentially Useful Medications in Adults Undergoing ESM – Ketamine

- Diazepam 5 MG IM (discourage IV use! If IV, give 2.5 mg over 60 seconds x 1 only) for agitation and/or hallucinations. May repeat IM x 1
- Promethazine 25 mg IM (do not give IV!) or prochlorperazine 10 mg IV for nausea and/or vomiting, every 2 hours as needed
- Atropine 0.5 mg IV for hypersalivation x 1
- Hydralazine 5mg IV given slowly over one minute for a pregnant patient who has severe preeclampsia or eclampsia and who has high blood pressure. Dose may be repeated every 20 minutes up to 4 doses.

PLEASE NOTE:
No medications other than as stated on this card are allowed in the ESM - Ketamine clinical pathway

Version December 30, 2016

Fig. 1. ESM-Ketamine Safety Checklist (front and back).

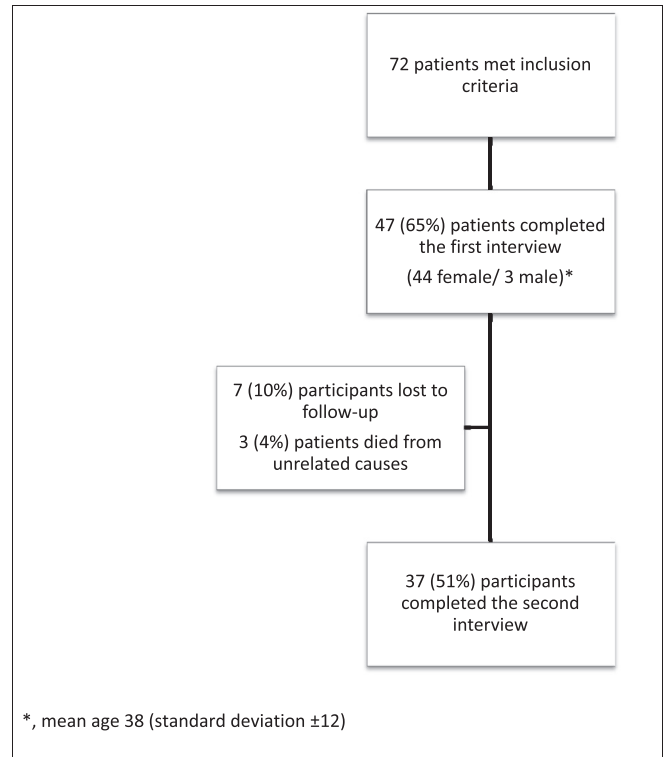


Fig. 2. Patient demographics.

Table 1
Procedures and operations supported by ESM-Ketamine.

	n	%
Gynaecological/Obstetric Surgery	39	83.0
Loop electrosurgical excision procedure (LEEP)	13	27.7
Painful biopsies	8	17.0
Laparotomies (bilateral tubal ligation, oophorectomy, hysterectomy)	5	10.6
Dilation and curettage	4	8.5
Perineal tear repair	3	6.4
Emergency caesarean section	2	4.3
Other	4	8.5
General Surgery	6	12.8
Emergency laparotomies	2	4.3
Other painful procedures	4	8.5
Orthopaedic Surgery	2	4.2
Lower limb amputation	1	2.1
Disarticulation	1	2.1
Total	47	100

opinion about the worst aspect of the surgical intervention with ESM-Ketamine when compared to the first interview. In the second interview, 12 (32.4%) participants who underwent procedural sedations reported the recovery process as the worst aspect of their experience. Four (40%) participants who underwent emergency surgery and three (8.1%) who had procedural sedations reported postoperative pain as the worst aspect of their experience. One (2.7%) interviewee reported intraoperative awareness during their procedural sedation as the worst aspect of ESM-Ketamine.

When asked during the first interview the question, “What comes to mind when you think about the procedure with ketamine,” participants reported relief (31.9%), fear (27.7%), gratitude (23.4%) and happiness (23.4%). However, during the second interview, fear was the most common (48.6%), followed by gratitude (40.5%) and pain (32.4%). There were no differences between patients who underwent procedural

Table 2
Expectations and experience of ESM-Ketamine.

	Procedural sedation (N = 37) n (%)	Emergency surgery (N = 10) n (%)
<i>What were you expecting during the procedure?</i>		
To be asleep and feel no pain	20 (54.1)	4 (40.0)
To be asleep and feel pain	3 (8.1)	2 (20.0)
To be awake and feel no pain	2 (5.4)	2 (20.0)
To be awake and feel some discomfort/pain	4 (10.8)	0 (0.0)
To be awake and feel significant pain	4 (10.8)	0 (0.0)
I don't know	4 (10.8)	2 (20.0)
<i>What do you remember between going to sleep and waking up?</i>		
Nothing/I do not remember	16 (43.2)	6 (60.0)
Hearing voices	10 (27.0)	2 (20.0)
Hearing events of procedure	4 (10.8)	1 (10.0)
Being unable to move or breathe	3 (8.1)	1 (10.0)
Other	3 (8.1)	0 (0.0)
<i>Do you recall dreaming during the procedure?</i>		
Yes. If so, was your dream:	21 (56.8)	5 (50)
Pleasant	11 (29.7)	1 (10.0)
Frightening	7 (18.9)	2 (20.0)
Neither	2 (5.4)	0 (0.0)
I do not remember	1 (2.7)	2 (20.0)
No	16 (43.2)	5 (50)

Table 3
Patient perception of ESM-Ketamine.

	First interview (N = 47) n (%)	Second interview (N = 37) n (%)
<i>What was the worst thing about the procedure?</i>		
Recovery process	12 (25.5)	13 (35.1)
Anxiety	12 (25.5)	3 (8.1)
Pain	6 (12.8)	7 (18.9)
Unable to carry out usual activities	4 (8.5)	4 (10.8)
Awareness during procedure	0 (0.0)	1 (2.7)
Other	2 (4.3)	1 (2.7)
Nothing/did not respond	11 (23.4)	14 (47.3)
<i>What comes to mind when you think about the procedure with ketamine?</i>		
Relief	15 (31.9)	10 (27.0)
Fear	13 (27.7)	18 (48.6)
Gratitude	11 (23.4)	15 (40.5)
Happiness	11 (23.4)	6 (16.2)
Pain	4 (8.5)	12 (32.4)
<i>Do you consider your experience with ketamine as anaesthesia for the procedure to be?</i>		
Positive	39 (83.0)	32 (86.5)
Negative	3 (6.4)	4 (10.8)
Both	3 (6.4)	0 (0.0)
Neither	2 (4.3)	1 (2.7)
<i>Would you recommend a procedure with ketamine to a friend?</i>		
Yes	45 (95.7)	35 (94.6)
No	2 (4.2)	2 (5.4)

sedations versus emergency surgeries. Thirty-two (86.5%) participants considered their experience with ketamine to be positive during the second interview. Similarly, 35 (94.59%) participants said they would recommend a procedure supported by the ESM-Ketamine package to a friend. All eleven people who experienced intraoperative awareness reported positive experiences with ESM-Ketamine and described they would recommend ESM-Ketamine to a friend.

Three (8.1%) of the 37 patients who completed the second interview had a positive pc-PTSD screen and were offered counseling services. All three described they would recommend the ESM-Ketamine package to a friend.

Discussion

This study suggests that the majority of patients had positive experiences with the ESM-Ketamine package when it was used in support of emergency and essential surgeries when no anaesthetist was available. Given that ketamine is a dissociative agent, we expected that rates of awareness would resemble those described for procedural sedation (25%) [12,15]. In this study, nine (24.3%) patients who underwent procedural sedation reported intraoperative awareness.

In the general population, 20 to 26% of patients who undergo procedural sedation and 22% who undergo general anaesthesia report intraoperative dreaming [21]. Controversies exist whether there is a correlation between dreaming and awareness [22,23]. Even though more than half of the participants in this study reported dreaming, only one fourth of those reported intraoperative awareness. There was no difference in awareness between those who reported dreaming and those who did not.

Although postoperative pain was commonly reported as the worst aspect of patients' experiences, ketamine does not have postoperative analgesic properties. Therefore, postoperative pain must be adequately addressed with other analgesic medications after a procedure or operation supported with ketamine. When assessing patients' opinions about the worst aspect of the procedure or operation, their answers changed significantly when asked a second time. The authors believe that this may have been influenced by the patients' experiences during the postoperative period, which may have genuinely changed their opinion about the overall experience. Nonetheless, more than 85% of surveyed patients considered their experience with ketamine positive and 95% would recommend it to a friend. Only one of the four people with negative experiences reported that they would not recommend the experience to someone else. Although several patients reported negative thoughts (pain and fear) about the procedure, it is possible that fear was directed at the fact that they needed to have an invasive medical procedure and not the experience of ketamine. In spite of this, those patients who did exhibit pain and fear still considered the overall experience to be positive and would recommend it to a friend.

Awareness rates for procedural sedation were similar to previous reports in resource-scarce environments [15,18]. However, in low-resource settings, high rates of recall are likely a reasonable tradeoff for access to life-saving surgery and pain control during painful procedures. Although evidence on intraoperative awareness in LMICs is limited and its correlation to patient satisfaction or PTSD remains unknown, anaesthesia services should have standards similar to high-income countries. While the authors strongly believe that everyone has the right to a well-trained anaesthetist who can provide high-quality care, the authors also believe that it is inexcusable to ignore the many people who are unable to access needed operative procedures due to a lack of anaesthesia services. Therefore, the authors directly support expansion of anaesthesia training programmes to decrease disparities regarding access to emergency and essential surgery. However, since training and scaling of fully trained anaesthesia providers to address the global unmet need will take many years, the ESM-Ketamine package may be able to fill this gap in the interim. The expansion of the ESM-Ketamine package will depend significantly on the voices and support from our anaesthesia colleagues.

This study has several limitations. Although rates of awareness among the ten patients who underwent emergency surgery supported by ESM-Ketamine were higher than in what is described in patients who undergo general anaesthesia in high-income countries (20% versus 0.2%) [12], the small sample size limits our interpretation of these data. This limitation warrants further research to confirm the accuracy of these results. Similarly, the modified Brice questionnaire used in this study [16] has not previously been used in a low-resource setting. Therefore, more research should be conducted on the external validity of this tool beyond high-resource settings.

Other limitations include a potential social desirability bias since

participants were interviewed by researchers stationed at the hospital where the patients received their care. Apart from response bias and cultural considerations, the sample size was modest. However, this study established a baseline for future studies on further understanding and scaling up the ESM-Ketamine package. Furthermore, the detection of intraoperative awareness may also have depended on interview technique, timing of the interview, and structure of the interview. Patients may have variably interpreted their dreams or experiences while dissociated from ketamine. Self-selection bias could have caused participants with the best experiences with ESM-Ketamine to be more inclined to participate in the study. Finally, the pc-PTSD screen has not been validated in Africa or low-resource settings [19]. Since culture influences the diagnosis and treatment of mental illness [24] and the burden of these diseases is much higher in vulnerable populations living in LMICs [25], the pc-PTSD data must be viewed with caution.

Despite the incidence of intraoperative awareness, this study suggests patient experiences were very favourable when the ESM-Ketamine package was used in support of painful procedures and operations when no anaesthetist was available. Future studies should aim for larger sample sizes, include more healthcare facilities, and further evaluate the mental health consequences.

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Conflicts of interest

The authors declare no conflicts of interest.

Dissemination of results

Results from this study were shared with staff members and trainers of the ESM-Ketamine training programme at Sagam Community Hospital in Luanda, Kenya through our weekly communications. Local staff members are authors of the manuscript and have been constantly involved in the research process.

Author contribution

Authors contributed as follow to the conception or design of the work; the acquisition, analysis, or interpretation of data for the work; and drafting the work or revising it critically for important intellectual content: SV, SS and TFB contributed 20% each; JO and GMW contributed 10% each; BDN, JI, DR and KR each contributed 5%. All authors approved the version to be published, and agreed to be accountable for all aspects of the work.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.afjem.2018.07.003>.

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