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CLINICAL ARTICLE

Q1 Evaluation of a ketamine-based anesthesia package for use in emergency cesarean delivery or emergency laparotomy when no anesthetist is available

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ABSTRACT

Objective: To assess the safety of a ketamine-based rescue anesthesia package to support emergency cesarean delivery and emergency laparotomy when no anesthetist was available. **Methods:** A prospective case-series study was conducted at seven sub-county hospitals in western Kenya between December 10, 2013, and January 20, 2016. Non-anesthetist clinicians underwent 5 days of training in the Every Second Matters–Ketamine (ESM–Ketamine) program. A database captured preoperative, intraoperative, and postoperative details of all surgeries in which ESM–Ketamine was used. The primary outcome measure was the ability of ESM–Ketamine to safely support emergency operative procedures. **Results:** Non-anesthetist providers trained on ESM–Ketamine supported 83 emergency cesarean deliveries and 26 emergency laparotomies. Ketamine was administered by 10 nurse-midwives and six clinical officers. Brief oxygen desaturations (<92% for <30 s) were recorded among 5 (4.6%) of the 109 patients. Hallucinations occurred among 9 (8.3%) patients. No serious adverse events related to the use of ESM–Ketamine were recorded. **Conclusion:** The ESM–Ketamine package can be safely used by trained non-anesthetist providers to support emergency cesarean delivery and emergency laparotomy when no anesthetist is available.

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1. Introduction

Estimates published in 2015 suggest that 5.0 billion of the 7.2 billion people worldwide have limited access to both emergency and essential surgery, with a lack of anesthesia services identified as a primary barrier to such treatment [1]. Access to emergency and life-improving surgeries is lowest in severely resource-constrained settings, such as Kenya and elsewhere in Sub-Saharan Africa [1]. Several organizations, including WHO, have called for a global response to address critical shortfalls in the availability of anesthesia among low- and middle-income countries [2]. However, a systematic review [2] found that even the most ambitious expansion of anesthetist training would fall far short of closing the global anesthesia gap. Consequently, an urgent need exists for innovative solutions to the anesthesia crisis.

Maternal mortality and disability can be substantially reduced by timely access to emergency and essential surgical care, including cesarean delivery [3]. One large-scale multinational study [4] found that 100 cases of obstetric fistula and 16 800 maternal deaths might have been prevented had an additional 2.8 million cesarean deliveries been performed in 2008. The reported rate of cesarean delivery across the northern and western regions of Kenya is less than 1%, despite WHO proposing a minimum rate of 10%–15% [5,6]. An assessment of 30 health facilities in Kenya that had operating theaters and a doctor able to perform cesarean delivery indicated that 57% lacked access to anesthesia services [7]. Such shortages of anesthesia providers are a frequent challenge to performing emergency operative procedures in resource-limited settings [2].

A novel ketamine-based anesthesia program has been designed, tested, and implemented to address the crisis in anesthesia services in western Kenya [8]. The Every Second Matters–Ketamine (ESM–Ketamine) package supports the conduct of both emergency and essential surgeries at facilities with operative capability when no anesthetist is available [8]. The aim of the present study was to evaluate the safety of

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ESM-Ketamine to support emergency cesarean delivery and emergency laparotomy when implemented among non-anesthetist clinicians.

2. Materials and methods

A prospective case-series study was conducted at seven sub-county hospitals in western Kenya between December 10, 2013, and January 20, 2016. Included hospitals had a functional operating theater and perioperative nursing support, a doctor on the staff able to perform emergency cesarean delivery and other additional emergency procedures, and limited access to anesthetist services. There were otherwise no exclusion criteria. The protocol was approved by the Kenyan Ministry of Health, as well as the institutional review boards of Partners HealthCare (Massachusetts General Hospital, Boston, MA, USA) and Maseno University School of Medicine (Maseno, Kenya). Written consent was not specifically obtained for the present analysis; however, consent to use ESM-Ketamine as a rescue anesthesia had been previously added to the process by which surgical and anesthesia consent was obtained. Approval for midwives, clinical officers, and non-anesthetist doctors to become ESM-Ketamine providers was granted by the two institutional review boards stated above, the Division of Reproductive Health of the Kenyan Ministry of Health, the leaders of the participating hospitals, and the individual County Health Directors.

Development and implementation of the ESM-Ketamine program have been described in detail elsewhere [8]. Briefly, the package includes an ESM-Ketamine kit, an intensive 5-day training program for healthcare providers, wall charts, and checklists (Supplementary Material S1). Trainees for the ESM-Ketamine program were non-anesthetist healthcare providers such as nurse-midwives, clinical officers (mid-level non-physician providers), or medical officers (generalist medical doctors who had completed medical school and 1 year of an internship). They were selected by the lead administrators at each participating facility. The 5-day training course oriented providers with respect to the basic pharmacology of ketamine, contraindications (e.g. age <3 mo and psychosis), dosing schedule, patient monitoring, and essential ventilation support for both adults and newborns, including the American Academy of Pediatrics' Helping Babies Breathe program (<http://www.helpingbabiesbreathe.org>). Additional training on the use and dosing schedule of supplemental medications to control adverse effects included hydralazine for severely elevated blood pressure, diazepam for agitation or hallucinations, promethazine and prochlorperazine for nausea and vomiting, and atropine for hypersalivation. Knowledge and skills were reinforced through hands-on simulation case-based practice followed by mentored procedures in the operating theater.

The ESM-Ketamine package was used each time a life-saving or life-improving surgery was deemed necessary but an anesthetist was unavailable and safe transfer to another facility was not possible. Preoperative, intraoperative, and postoperative data were collected from both male and female patients using a structured instrument and database. All ESM-Ketamine-supported emergency cesarean deliveries and emergency laparotomies conducted within the participating facilities were extracted from the database for the present analysis.

The primary outcome measure was the ability of ESM-Ketamine to safely support these two emergency operative procedures. Other variables assessed included patient demographics and the onset of complications, including hallucinations and oxygen desaturations of less than 92%.

The database was constructed using Excel 2015 (Microsoft, Redmond, WA, USA). The data were analyzed using STATA version 13.1 (StataCorp, College Station, TX, USA). Standard descriptive and frequency analyses were performed, including Fisher exact tests for statistical significance. $P < 0.05$ was considered significant.

3. Results

Trained providers working at seven healthcare facilities in western Kenya used the ESM-Ketamine package to support 412 essential and

Table 1

Location of the emergency operative procedures included (n = 109).^a

Facility	Cesarean delivery (n = 83)	Laparotomy (n = 26)
Sagam Community Hospital	43 (51.8)	10 (38.5)
Maseno Mission Hospital	37 (44.6)	9 (34.6)
Mbita Sub-County Hospital	3 (3.6)	6 (23.1)
Yala Sub-County Hospital	0	1 (3.8)

^a Values given as number (percentage).

emergency operations when no anesthetist was available. Overall, 83 (20.1%) of these operations were emergency cesarean deliveries and 26 (6.3%) were emergency laparotomies. These 109 procedures were performed at four of the seven participating healthcare facilities (Table 1); the ESM-Ketamine package was used for other procedures at the remaining three centers. The indication for 11 (42.3%) of the emergency laparotomies was acute bowel obstruction owing to strangulated hernia; 2 (2.4%) of the emergency cesarean deliveries were characterized by uterine rupture. Among the 21 individuals who performed the included surgeries, 6 (28.6%) were obstetricians, 13 (61.9%) were medical officers, and 2 (9.5%) were family medicine physicians. They were supported by 16 ESM-Ketamine providers (10 nurse-midwives and 6 clinical officers).

The demographic characteristics of the patients who underwent emergency operative procedures are presented in Table 2. Table 3 shows the median ketamine doses used and the length of surgery. A second dose of ketamine was given to 14 (12.8%) patients, whereas 93 (85.3%) patients received three or more doses.

Brief oxygen desaturations (<92% for <30 s) were observed among 5 (4.6%) patients who underwent emergency operative procedures (Table 4). Hallucinations during recovery were observed among 9 (8.3%) patients. No serious adverse events were reported, such as deaths, prolonged desaturations (<92% for >30 s), or injuries resulting from ESM-Ketamine use. Supplemental medications included diazepam (n = 31), atropine (n = 13), and hydralazine (n = 1). None of the 109 patients received promethazine or prochlorperazine.

An audit of the first 72 of the 412 ESM-Ketamine-supported operations highlighted that 7 (9.7%) patients had experienced brief oxygen desaturations owing to lack of diligent adherence to the protocol regarding the use of supplemental oxygen and the need for slow administration of ketamine (over a period of 30–60 seconds). An emergency meeting was, therefore, held with all the trained ESM-Ketamine providers at which the operative procedures conducted to date were reviewed and the importance of precisely following the checklist reinforced. The incidence of oxygen desaturations associated with ESM-Ketamine-supported operations decreased following this meeting to 12 (2.9%) cases among the 412 ESM-Ketamine-supported operations.

Table 2

Demographic characteristics of patients who received the Every Second Matters-Ketamine package for emergency cesarean delivery or laparotomy.^a

Characteristic	Cesarean delivery (n = 83)	Laparotomy (n = 26)	Total cohort (n = 109)
Age, y	26.1 ± 5.5 (15–40)	44.7 ± 21.7 (14–80)	30.4 ± 13.8 (14–80)
10–19	8 (9.6)	3 (11.5)	11 (10.1)
20–29	48 (57.8)	6 (23.1)	54 (49.5)
30–39	26 (23.9)	2 (7.7)	28 (25.7)
≥40	1 (31.3)	14 (53.8)	15 (13.8)
Not known	0	1 (3.8)	1 (0.9)
Sex			
Female	83 (100)	14 (53.8)	97 (89.0)
Male	NA	12 (46.2)	12 (11.0)
Weight, kg			
Women	70.4 ± 11.5	62.1 ± 11.5	69.2 ± 11.8
Men	NA	55.9 ± 14.4	55.9 ± 14.4

Abbreviation: NA, not applicable.

^a Values given as mean ± SD (range), number (percentage), or mean ± SD.

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