

BRIEF RESEARCH REPORT

Evidence-Based Emergency Medicine

A feasibility study of low-dose ketamine for acute management of suicidal ideation

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Abstract

Objective: Mood disorders complicated by suicidal ideation (SI) frequently present to the emergency department (ED) for care. Currently, patients with SI in the ED do not typically receive targeted interventions. Ketamine may have a role in treating SI within the ED because subanesthetic doses have rapid-acting antidepressant and antisuicidal properties.

Methods: This single-arm, open-label feasibility study enrolled 14 participants from the ED with acute SI who were awaiting voluntary admission to inpatient psychiatry to receive ketamine at 0.5 mg/kg, administered intravenously. Participants were assessed post administration to evaluate feasibility of administration in the ED and short-term effectiveness. Feasibility was determined by acceptability by patients and physicians as well as tolerability and ability to recruit participants into the study. Efficacy was assessed based on changes in (1) self-reported mood and (2) suicidal ideation pre- and postinfusion of ketamine.

Results: All patients reported severe depression and active SI at baseline. No serious adverse events were reported, and acceptability was rated highly by both participants and physicians (>70%). Two hours after receiving ketamine 0.5 mg/kg, the mean SI and somatic symptom burden were decreased compared to baseline ($P < 0.001$ and $P = 0.005$, respectively), and the mean self-reported mood was increased ($P = 0.006$). Improvements in mood and decreases in suicidality persisted at 6 hours.

Conclusions: Overall, ketamine was well tolerated, considered feasible by both participants and physicians, and demonstrated short-term efficacy. There is a growing body of evidence demonstrating the feasibility of ketamine administration in the ED, and larger

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randomized trials should be conducted to establish treatment recommendations for patients with SI in the ED.

KEYWORDS

emergency service, hospital, ketamine, suicidal ideation, suicide

1 | INTRODUCTION

1.1 | Background

Patients presenting with suicidal ideation accounted for roughly 1% of all ED visits.^{1,2} Inpatient psychiatric management is the norm for many, but patients often wait hours or days in the ED before admission. ED boarding may worsen the condition for patients with mood disorders and acute SI, yet there are limited options for treatment of SI in the acute setting.^{3–7} Treating SI in the ED may improve patient outcomes and patient care.

Ketamine may have a role in treating SI within the ED. It has excellent central nervous system penetration and a rapid onset of action.⁸ Ketamine has traditionally been used at high doses as a general anesthetic, but at lower doses it is an effective mood modulator without the side effects associated with anesthetic doses.⁴ It is widely used in the ED for pain, and subanesthetic doses have a side effect profile similar to other commonly used drugs in the ED.^{9,10}

1.2 | Importance

Recent research in outpatient and inpatient psychiatric settings has demonstrated that ketamine has rapid-acting antidepressant and antisuicidal properties in patients with mood disorders.^{1,11,12} Several studies have shown promising effects of ketamine in rapidly reducing SI and moderating impulsivity and hopelessness.^{1,3,4,13} However, few studies have explored the use of ketamine for this purpose in the ED, and those that have used a lower dose of 0.2 mg/kg despite better evidence for ketamine efficacy at 0.5 mg/kg.^{9,14,15} Recent studies have provided additional support for the potential of ED-administered ketamine, but the ideal dosage and administration route have not been established because higher doses may have better efficacy but increased potential for side effects.^{16,17}

1.3 | Goal of the investigation

We conducted a prospective, open-label feasibility study that enrolled participants from the ED who were admitted to a psychiatry service for acute SI. This study evaluated (1) feasibility of ketamine administration in an ED setting with a high-risk patient population and (2) short-term effectiveness of a 0.5 mg/kg dose.

2 | METHODS

2.1 | Study design and setting

This is a single-arm, open-label feasibility study of a single dose of ketamine for patients with mood disorders and SI in the ED. The study was conducted at an academic-affiliated community hospital in Providence, RI, USA with approximately 80,000 ED visits per year. Recruitment and study follow-up were conducted between July 2019 and June 2021, and the study was registered at ClinicalTrials.gov (Identifier NCT04099771). The protocol was approved by the Lifespan Health System Institutional Review Board, and reporting is consistent with the Consolidated Standards of Reporting Trials (CONSORT) guidelines. All patients completed written informed consent.

2.2 | Selection of participants

A convenience sample of participants was recruited during hours of psychiatry coverage when a research assistant (RA) was available (7 a.m.–9 p.m., 7 days/week). Patients who met the initial eligibility screen underwent a further in-person assessment by a study RA. Participants were eligible if they were English speaking, 18–65 years of age, had active SI as determined by psychiatry staff (physician discretion), and able to provide informed consent. Additionally, only patients who were being voluntarily admitted to an inpatient service were eligible to participate so that treatment with ketamine did not influence disposition decisions in this pilot study. Participants were ineligible if they had been previously enrolled in the trial, were pregnant or breastfeeding, had a known or suspected allergy to ketamine, had used ketamine within 24 hours of presentation, required antipsychotics or other mood-altering medications for agitation, had a contraindication to ketamine per the treating ED physician (eg, uncontrolled hypertension), or were incarcerated or in police custody.

2.3 | Ketamine intervention

Before administration of the study drug, all participants completed baseline assessments: demographics, medical history, and a brief survey of recent mental health using the Center for Epidemiologic Studies Depression (CES-D) Scale.¹⁸ Each weight-based dose was individually prepared in the ED. Ketamine 0.5 mg/kg intravenous was administered over 40 minutes. This dose and rate are the most common

route of administration used in the inpatient and outpatient psychiatry literature, having been used in at least 8 different studies examining ketamine for decreasing depression and SI.^{1,3,4,8,15} All participants were placed on pulse oximetry and cardiac telemetry before administration of the study drug as per standard nursing care.

2.4 | Outcomes

This pilot study had 2 primary end points: feasibility and efficacy. Feasibility was determined primarily by acceptability of ketamine by participants and physicians, with tolerability (eg, adverse events [AEs], discontinuation of the infusion due to AEs) and ability to recruit participants into the study also considered.

The primary efficacy outcome was the change in mood and suicidal-ity scores pre infusion (baseline) and 2 hours post infusion, specifically changes in (1) self-reported mood and (2) suicidal ideation pre and post infusion of ketamine using the Immediate Mood Scaler (IMS) and the Columbia Suicide Severity Rating Scale (C-SSRS), respectively.^{19,20} Ketamine side effects were assessed pre and post infusion using the Side Effect Rating Scale for Dissociative Anesthetics (SERSDA).²¹ Participants completed the IMS, C-SSRS, and SERSDA at baseline (pre infusion), 2 and 6 hours post infusion, and daily while in the ED until inpatient disposition. Assessments were both RA- and self-administered and were completed in REDCap software.

2.5 | Analysis and sample size

Descriptive and inferential statistics were performed using R. Primary efficacy outcomes of 2-hour change in mood and suicidality were visualized graphically and compared statistically using paired *t* tests and McNemar's chi-square test with continuity correction, with an α -value of 0.05 set a priori. Although, the primary outcome of the study was feasibility of ketamine administration in an ED, the sample was also powered to detect a within-group change in mood and suicidality based upon previous literature.⁴ In prior studies, ketamine 0.5 mg/kg has resulted in significant changes in mood and suicidality with large effect sizes. Sixteen participants would have been needed to detect a 25% modest effect size (Cohen's $d = 0.73$, $\beta = 0.8$, $\alpha = 0.05$); however, recruitment was stopped early because of COVID-19-related staffing issues. In addition, new published results became available in the interim, adding to the evidence for ketamine administration in the ED and thus the decision was made to close the study early.^{16,17}

3 | RESULTS

3.1 | Characteristics of study subjects

In total, 460 patients were screened for study eligibility. The majority of patients were deemed ineligible because of physician discretion (eg, no active SI, inability to consent), or for other reasons, such as early dis-

The Bottom Line

This study of low-dose ketamine for suicidal ideation in an emergency department setting demonstrates short-term feasibility and acceptability of administration and preliminary efficacy. Larger randomized studies are needed to evaluate longer term effectiveness.

charge, non-English speaking, or required antipsychotic use. Physicians excluded patients with confirmed or suspected personality disorders to ensure that study participants' active SI was due to mood disorders. Of the 19 patients who were approached for participation, 14 consented and enrolled.

Most participants were under 40 years, there were equal numbers of men and women, and the sample was racially and ethnically diverse (Table 1). The majority of participants had a previous diag-

TABLE 1 Sample characteristics and mental health diagnoses history (n = 14)

	Mean (SD) or n (%)
Age	36.1 (13.1)
Born in the United States	13 (92.9%)
Race	
White	6 (42.9%)
African, Haitian, or Cape Verdean	3 (21.4%)
Mixed, biracial, or multiracial	3 (21.4%)
Something else or refused	2 (14.3%)
Hispanic ethnicity	4 (28.6%)
Female sex at birth	7 (50.0%)
Female gender identity	7 (50.0%)
Mental health diagnoses	
Depressive disorder	10 (71.4%)
Bipolar disorder	7 (50.0%)
Anxiety disorder	9 (64.3%)
Post-traumatic stress disorder	6 (42.9%)
Another diagnosis	2 (14.3%)
No mental health diagnosis	3 (21.4%)
Previously hospitalized for mental illness	6 (42.9%)
Self-reported health status at baseline ^a	
Good	7 (50.0%)
Fair	4 (28.6%)
Poor	3 (21.4%)
CES-D score at baseline	43.4 (4.6)

^aResponse options on the SF-12 were excellent, very good, good, fair, poor; no participants in the sample reported excellent or very good health status. Abbreviations: CES-D = Center for Epidemiologic Studies Depression Scale; SF-12, Short Form Survey-12.

TABLE 2 Follow-up data for suicidal participants receiving low-dose ketamine (n = 14)

	Baseline (n = 14)	2 hours (n = 14)		6 hours (n = 11)	
	Mean (SD)	Mean (SD)	Baseline-2 hours comparison	Mean (SD)	Baseline-6 hours comparison
SERDSA score ^a	22.1 (5.1)	16.8 (6.3)	<i>P</i> = 0.005	18.4 (7.7)	<i>P</i> = 0.09
IMS score ^b	24.7 (9.03)	40.6 (19.1)	<i>P</i> = 0.006	41.4 (18.5)	<i>P</i> = 0.007
C-SSRS severity score ^c	5 (0)	0.93 (1.5)	<i>P</i> < 0.001	1.2 (1.5)	<i>P</i> = 0.002
	n (%)	n (%)	Baseline-2 hours comparison	n (%)	Baseline-6 hours comparison
Thought about being dead	14 (100%)	3 (21.4%)	<i>P</i> = 0.003	5 (45.5%)	<i>P</i> = 0.04
Wished you were dead	13 (92.9%)	3 (21.4%)	<i>P</i> = 0.004	3 (27.3%)	<i>P</i> = 0.02
Thought about killing yourself	14 (100%)	4 (28.6%)	<i>P</i> = 0.004	4 (36.4%)	<i>P</i> = 0.02
Thought about how to kill yourself	14 (100%)	2 (50.0%)		1 (25.0%)	
Thought killing self was something you might actually do	14 (100%)	2 (50.0%)		1 (25.0%)	
Decided how/when you would kill yourself	14 (100%)	1 (25.0%)		1 (25.0%)	
Do anything to try to kill yourself or make yourself not alive anymore	12 (85.7%)	0 (0%)		0 (0%)	

^aHigher scores on the Side Effect Rating Scale for Dissociative Anesthetics (SERDSA) correspond to more severe experiences with ketamine-related side effects. Individual values for each of the 10 domains (dizziness, feeling of unreality, fatigue, hearing, headache, vision, discomfort, mood, hallucinations, and nausea) range from 1–5 (1 = none to 5 = very bothersome) and are summed to create a total score. At 2 hours, 1 participant's score could not be tabulated because of missing data.

^bHigher scores on the Immediate Mood Scaler (IMS) correspond to improved mood. Twelve domains are assessed (worthless-valuable, pessimistic-optimistic, apathetic-motivated, guilty-proud, numb-interested, withdrawn-welcoming, hopeless-hopeful, tense-relaxed, worried-untroubled, fearful-fearless, anxious-peaceful, and restless-calm). Individual values range from 1–7, with higher scores indicating closer alignment to the latter feeling, and are summed to create a total score. At 2 hours, 1 participant's score could not be tabulated because of missing data.

^cSeverity subscale of the Columbia Suicide Severity Rating Scale (C-SSRS), where 0 indicates no suicidal ideation and 5 indicates the most severe suicidal ideation.

nosis of depression and/or anxiety. Six (42.9%) participants had previously been hospitalized for mental health reasons, but notably 3 (21.4%) participants reported no previous mental health diagnoses. All participants' CES-D scores were above the cutoff values for risk of major depression.²² At baseline, all participants scored the maximum value on the severity subsection of the C-SSRS (Table 2), with 86% reporting that they had done something to try to kill themselves.¹⁹

3.2 | Feasibility results

All 14 participants received 0.5 mg/kg ketamine administered intravenously over 40 minutes. One participant stopped the infusion early because of dizziness and dysphoria. There were no serious AEs and no withdrawals before discharge from the ED. Acceptability of ketamine administration was high among both participants and physicians. When asked if they would receive ketamine again, 10 (71.4%) participants said yes, 2 (14.3%) said no, and 2 (14.3%) were unsure. Among the 13 physicians who responded, 10 (76.9%) physicians would use ketamine again in their practice, 2 (15.4%) would not, and 1 (7.7%) was unsure.

3.3 | Efficacy results and adverse events

The change in burden of somatic side effects between baseline and 2 hours was mixed across 10 symptom domains (SERDSA). Overall, the mean total physical symptom burden was significantly lower at 2 hours compared to baseline (*P* = 0.005), a difference that was attenuated at 6 hours (*P* = 0.09) (Table 2).

Two hours after ketamine administration, most participants experienced improved overall mood compared to baseline as measured by total IMS score. Figure 1 shows individual changes in mood: 7 participants improved, 5 were stable, 1 worsened, and 1 was not fully assessed. The mean total IMS score at 2 hours was significantly improved compared to baseline (*P* = 0.006), and these mood benefits persisted at 6 hours (*P* = 0.007) (Table 2). No participants had a deterioration in mood over the entire study period.

At 2 hours post-ketamine administration, the proportion of participants who had thoughts of killing themselves was significantly reduced (*P* < 0.001), and this reduction of suicidal thoughts was durable at 6-hour follow-up compared to baseline (*P* = 0.002). Among the 5 participants with daily data, 2 (40.0%) continued to endorse suicidality at 24 hours.

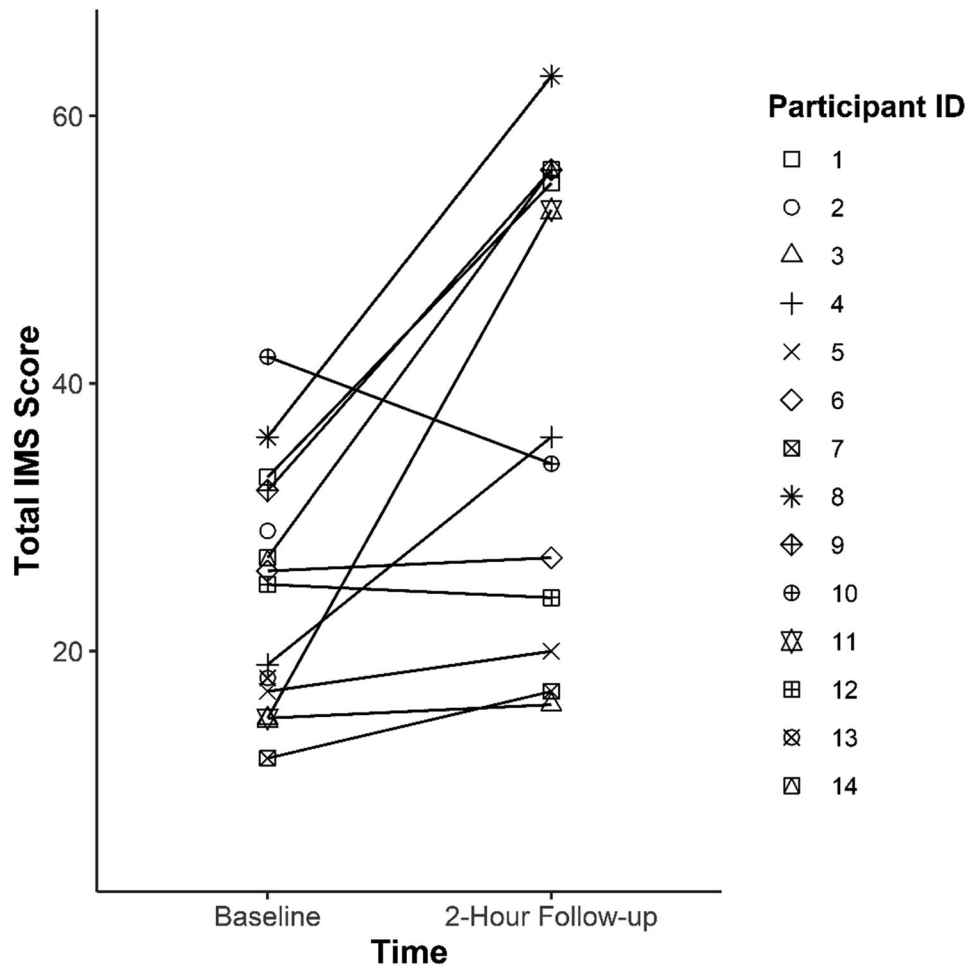


FIGURE 1 Change in total immediate mood scaler (IMS) score for each study participant pre and 2 hours post ketamine administration. Participant 2 did not complete all items of the IMS at 2 hours, so their summed score was not computed.

Although not part of study follow-up, 2 months after study participation, 1 participant completed suicide. The participant had been admitted to an inpatient psychiatric unit, started on a selective serotonin reuptake inhibitor, and discharged to outpatient follow-up in the time between the study and the event. The research team was notified through automatic electronic medical record research notifications. The study's Data Safety Monitoring Board and institutional review board reviewed the incident and determined it was not related to the study intervention.

4 | LIMITATIONS

This study has 2 major limitations: (1) the lack of a comparison group because of the primary outcome of feasibility of ketamine administration in an ED setting and (2) short follow-up time. The single-arm design of this study meant that we were unable to assess how much of the observed improvement in somatic symptoms, mood, and suicidality was due to ketamine administration versus other factors associated with being in an acute care setting. In addition, the durability of treatment effect needs to be assessed in subsequent studies that

include a comparison group. Our analysis was limited to the ED setting, but future research should follow patients receiving low-dose ketamine for days or weeks to determine how long the effects last, particularly because preliminary evidence suggests that the effect of ketamine administered at lower doses than used in this study (0.2 mg/kg intravenous or 0.4 mg/kg intranasal) may be attenuated after 24 hours.^{16,17} Longer term follow-up including a usual treatment or placebo-controlled group would help clarify the direct effect of ketamine on reducing the burden of SI.

5 | DISCUSSION

In this small open-label pilot, ketamine was tolerated, acceptable to patients and physicians, and had promising short-term efficacy. To our knowledge this is also the first study to evaluate an infusion of 0.5 mg/kg.^{9,14,16,17} These study findings add to the growing and compelling evidence on the effectiveness of ketamine for acute SI.

On average, participants had substantial and sustained improvements in mood and suicidality over 6 hours when compared to baseline. Reported side effects and physical symptoms associated with

ketamine administration actually decreased after receiving ketamine. A plausible explanation is that high somatic symptomatic burden at baseline is driven by the mood disturbance and SI and thus relieved by ketamine.^{23,24} Interestingly, treatment response was not uniform across the participants (Figure 1); roughly half the participants had marked improvements, whereas the remainder remained relatively stable over time. Future studies might further evaluate heterogeneity of treatment effect—whether there is a subgroup of patients who would particularly benefit from receiving ketamine in the ED.

One participant completed suicide 2 months after their participation in the study. Although this event was determined to be unrelated to the ketamine intervention, it underscores that we identified patients at the highest risk of suicide for inclusion in the study. It also highlights the importance of long-term follow-up for patients with acute SI, particularly because these symptoms are often chronic.²⁵ This study adds to the existing evidence that low-dose ketamine is effective for acute SI management and crisis stabilization. Currently, ketamine should not be viewed as a curative treatment in the ED, but as a bridging therapy to definitive care. Ketamine intervention should be considered a first step that assists suicidal individuals in getting connected with long-term care and ongoing supports like psychotherapy and antidepressant medications to address their underlying mood disorders.

Overall, this promising feasibility study of low-dose ketamine lays the foundation for future larger studies that further establish safety and durability of effect by following patients beyond the immediate ED period. Although this study focused on intravenous ketamine given existing evidence and clinical practice, future clinical trials might evaluate alternative routes of administration (eg, intranasal esketamine). Larger randomized trials of ketamine in the ED could establish highly needed treatment recommendations for acute care of patients with mood disorders and suicidal ideation. Specifically, before considering ketamine as a bridging therapy that allows a person to be safely discharged, it must be established that improvements in mood and SI last long enough to allow linkage to care. Once safety and durability are established, potential clinical models could involve either ketamine administration in the ED while awaiting an inpatient bed or discharge to intensive outpatient services after receipt of ketamine in the ED depending on the needs of the patient. Improving acute treatment of SI with ketamine may help patients receive more prompt treatment for their emergency, reduce the burden of SI on the health care system, and ultimately improve outcomes among this uniquely vulnerable population.

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CONFLICTS OF INTEREST

None of the study authors have any conflicts of interest.

AUTHOR CONTRIBUTIONS

Francesca L. Beaudoin and Megan Ranney were responsible for the study concept and study design. Alyssa Peachey, Jeffrey Burock, Jyllian Rogers, and Lindsey Bucci were responsible for data collection. Rachel Gaither was responsible for data analysis and manuscript drafting. All authors edited and approved the paper for submission. Francesca L. Beaudoin is responsible for the work as a whole.

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