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Haloperidol versus Ketamine for Managing Acute Agitation in the Emergency Department: A Randomized Clinical Trial

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ABSTRACT

Objective: The primary outcome was the management of acute agitation, as measured by the Richmond Agitation-Sedation Scale (RASS). Secondary outcomes included the incidence of adverse effects and the time to onset of the therapeutic effect.
Methods: This randomized clinical trial was conducted between March 2021 and March 2022. Participants were recruited from patients presenting with acute agitation who required pharmacological intervention at Emam Reza and Shahid Hasheminejad hospitals (Mashhad, Iran). Eligible participants were adults aged 18 to 65 years. Using a block randomization method with a block size of four, patients were assigned to receive either 5 mg of intravenous (IV) haloperidol or 2 mg/Kg of IV ketamine. Data were analyzed using SPSS software (version 22).
Results: A total of 120 participants were randomized. The majority were male, comprising 43 (73%) in the haloperidol group and 45 (75%) in the ketamine group. The mean age was 45.42±16.65 in the ketamine group and 48.28±16.75 years in the haloperidol group (p=0.34). In the haloperidol group, the mean admission RASS score was 1.73±0.75, which decreased to 0.07±1.25 post-intervention. In the ketamine group, the mean admission RASS score was 1.58±0.61, which improved to -0.92±1.19 following treatment.
Conclusion: Ketamine demonstrated a faster onset of action in managing acute agitation than haloperidol. These findings suggested that ketamine might represent a viable first-line therapeutic option for acutely agitated patients, particularly in clinical scenarios where rapid symptom control is critical.

Keywords: Emergence delirium, Psychomotor agitation, Ketamine, Haloperidol, Emergency.

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Introduction

Agitation and delirium are acute disturbances of mental state that necessitate a systematic management approach in the Emergency Department (ED) to ensure the safety of the patient, staff, and others, while simultaneously addressing the underlying etiology [1, 2]. The effective control of agitation in the ED is crucial for both patient safety and the overall functioning of the healthcare facility

[3-5]. Agitated patients may pose a significant risk to themselves or others; therefore, effective management is essential to mitigate the potential for violent outbursts and to maintain a secure environment [6]. Furthermore, controlling agitation enables healthcare providers to diagnose and treat underlying medical conditions more accurately [7]. Calm patients are more likely to cooperate with medical evaluations and interventions, which subsequently leads to improved clinical outcomes [4, 8]. Thus, effective management strategies benefit not only the individual patient but also contribute to a safer and more efficient healthcare environment [9]. These strategies encompass both non-pharmacological and pharmacological interventions [10].

Common pharmacological interventions for agitation include benzodiazepines, antipsychotics, and ketamine [11]. Among antipsychotic agents, haloperidol is frequently employed for agitation management, particularly in acute care settings, such as ED or psychiatric units [12]. Its rapid onset of action and efficacy in controlling severe symptoms make it a valuable option in emergency psychiatric care [13, 14]. However, close monitoring for adverse effects is essential, and treatment must be adjusted as needed to ensure safety and efficacy [15]. The administration of haloperidol for agitation should always adhere to established institutional protocols and clinical guidelines [11].

Ketamine is increasingly utilized for the management of acute agitation, particularly in emergency and psychiatric settings [16]. Its rapid onset of action and unique mechanism of action make it a suitable option for patients requiring immediate intervention [17]. Nevertheless, careful monitoring is crucial due to potential adverse effects and the imperative to ensure safety [16].

Given these considerations, the present study was designed to compare the efficacy of haloperidol versus ketamine in controlling acute agitation in the ED setting. The primary outcome was the management of acute agitation, as measured by the Richmond Agitation-Sedation Scale (RASS). The secondary outcomes included the incidence of adverse effects and the time to onset of the therapeutic effect of the administered medication.

Materials and Methods

This randomized clinical trial was conducted on agitated patients in the ED who were candidates for pharmacological intervention at Hasheminejad and Emam Reza hospitals (Mashhad, Iran). The study was carried out at these two academic centers, which had an average annual patient volume of 150,000, between March 2021 and March 2022.

The study enrolled patients aged between 18 to 65 years presenting with acute agitation that required pharmacological intervention. The exclusion criteria included patients who improved with non-pharmacological measures, RASS score of ≤1, a known sensitivity to ketamine or haloperidol, underlying conditions predisposing to hypertension and its complications (e.g., history of aortic dissection or myocardial infarction), a prolonged QT interval on electrocardiogram (ECG), pregnancy or lactation, and treatment with benzodiazepines and neuroleptics within the past 24 hours.

A total of 120 participants were randomly allocated to two groups: one receiving haloperidol and the other receiving ketamine. The haloperidol group received 5 mg intravenously (IV), and the ketamine group received a dose of 2 mg/Kg IV. Both agents were diluted in 10 mL of normal saline (0.9%). The injections were administered by a nurse who was blinded to the contents of the syringe.

The level of agitation was assessed using the RASS score. Vital signs, including systolic blood pressure, heart rate, and RASS scores, were recorded at baseline (upon entry) and 20 minutes post-administration. Adverse effects were defined as the occurrence of dysrhythmia, requirement for intubation for airway management, hypertension (defined as a >20% increase in blood pressure from age-adjusted baseline), and tachycardia (defined as a >20% increase in heart rate from age-adjusted baseline).

Block randomization was performed using Random Allocation Software (version 2.0.0), with a block size of four. Each block comprised two participants allocated to the haloperidol group and two to the ketamine group. The research secretary, who was not involved in the study's execution, enrolled the participants. A research nurse, responsible for drug administration, was blinded to group assignments through the use of sequentially numbered, opaque, sealed envelopes that concealed the treatment codes. The study was triple-blind; blinding was maintained for patients, investigators, and healthcare providers throughout the trial.

The sample size was calculated based on the effect size observed in a prior study by Heidari *et al.,* [18], which compared the mean time to sedation between the haloperidol and ketamine groups.

$\text{Mean}_{\text{Ketamine}}=7.73$, $\text{SD}_{K}=4.71$

$\text{Mean}_{\text{Haloperidol}}=11.42$, $\text{SD}_{H}=7.20$

$\alpha=0.05$, $\beta=80\%-1$, Attrition=5%

N=120, n1=60, n2=60

$$n=\frac{(Z_{(1-\alpha/2)}+Z_{(1-\beta)})^2(sd_1^2+sd_2^2)}{d^2}$$

Data were analyzed using SPSS software (version 22; IBM Corporation, Armonk, NY, USA). Categorical variables were expressed as frequencies and percentages. Continuous variables were expressed as mean±SD, if normally distributed, and median and interquartile range (IQR), if non-normally distributed. The Normality of distribution was assessed using the Kolmogorov-Smirnov test.

Inter-group comparisons were performed using the Chi-square tests (or Fisher's exact test, if applicable) for categorical variables. The independent samples t-tests were used for normally distributed continuous variables, and the Mann-Whitney *U* tests were employed for non-normally distributed variables. A two-sided *p*-value of less than 0.05 was considered statistically significant for all analyses. For this study, hypertension was defined as a systolic blood pressure ≥140 mmHg, a diastolic blood pressure>100 mmHg, or a mean arterial pressure (MAP) increase exceeding 30% from baseline. Acute agitation was defined as a RASS score of ≥+1. A reduction of one point on the RASS score was considered a clinically significant response to treatment.

Results

A total of 120 participants were randomly assigned to either the ketamine group (n=60) or the haloperidol group (n=60), as illustrated in Figure 1. The majority of the participants in both groups were male, comprising 43 (73%) in the haloperidol group and 45 (75%) in the ketamine group. The mean age was 45.42±16.65 years in the ketamine group and 48.28±16.75 years in the haloperidol group. No statistically significant differences were observed in demographic characteristics between the two groups (*p*>0.05, Table 1). In the haloperidol group, the mean baseline RASS score was 1.73±0.75, which decreased significantly to 0.07±1.25 post-intervention (*p*<0.001). Similarly, in the ketamine group, the mean RASS score decreased significantly from 1.58±0.61 to -0.92±1.19 (*p*<0.001). The mean reduction in the RASS score was significantly higher in the ketamine group than in the haloperidol group (2.50±1.33 vs 1.66±1.20, respectively; *p*<0.001) (Table 2, Figure 2).

The mean±SD time to achieve adequate sedation was significantly longer in the haloperidol group (19.67±13.95 minutes) than in the ketamine group (9.38±5.67 minutes; *p*<0.001) (Table 3).

In terms of medication requirements, 20% (n=12) of the participants in the haloperidol group required repeated doses, compared to 13.3% (n=8) in the ketamine group. However, this difference was not statistically significant (*p*=0.46) (Table 3). As presented in Table 3, non-significant decreases in both systolic blood pressure (*p*=0.15) and heart rate (*p*=0.74) were observed in the haloperidol group following treatment. In contrast, the ketamine group exhibited non-significant elevations in heart rate (*p*=0.8) and systolic blood pressure (*p*=0.24).

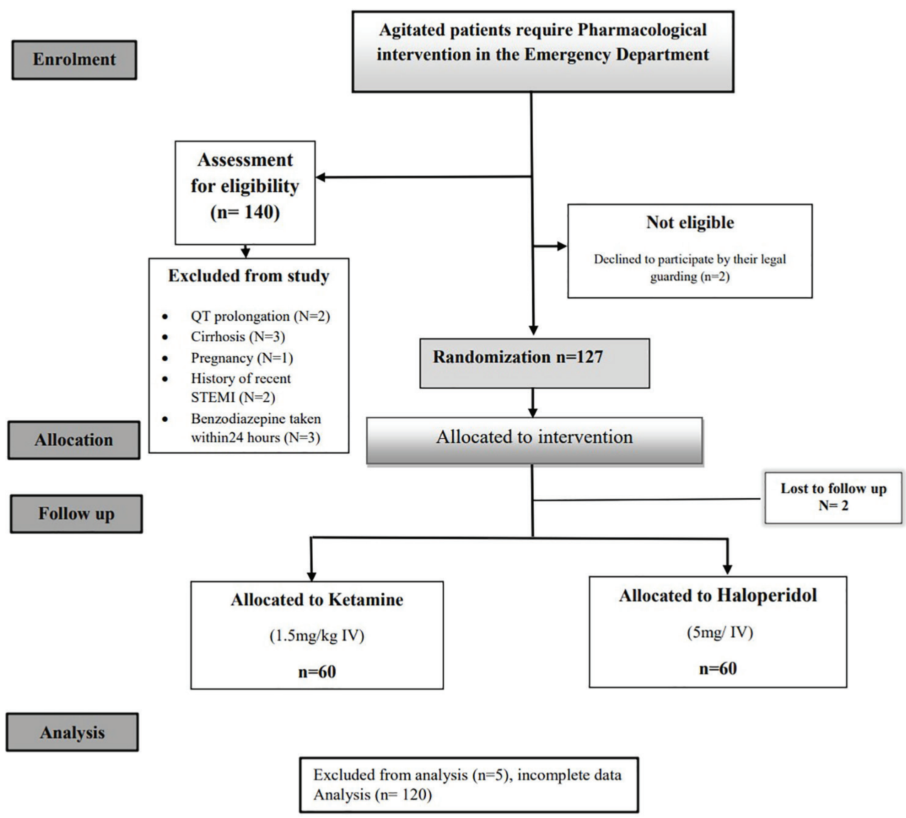

Fig. 1. 120 participants were randomly assigned to either the ketamine group (n=60) or the haloperidol group (n=60).

Table 1. Demographic and vital signs information of participants in the two groups.

		Haloperidol group (n=60)	Ketamine group (n=60)	*p* value
Age (mean±SD)		45.42±16.65	48.28±16.75	0.34*
Sex n (%)	Male	43(73)	45(75)	0.83#
	Female	17(28)	15(25)	

*Student's t-test; # Chi-squared test; SD: standard deviation

Table 2. RASS score before and after intervention in two study groups.

Variables		Haloperidol group (n=60)	Ketamine group (n=60)	*p* value*
Primary RASS	Mean±SD	1.73±0.75	1.58±0.61	0.34
Secondary RASS	Mean±SD	0.07±1.20	-0.92±1.19	<0.001
RASS changes (Mean difference±SD)		-1.66±1.20	-2.5±1.33	<0.001
p value **		<0.001	<0.001	-

*Mann–Whitney U test; **Wilcoxon Test; SD: Standard deviation

Table 3. Clinical information before and after intervention in the two studied groups

Variables		Haloperidol group (n=60)	Ketamine group (n=60)	*p* value
Systolic Blood Pressure (Mean ±SD)	Before intervention	133.78±13.6	131.68±12.82	0.39*
	After intervention	126.82±14.01	133.73±12.64	<0.001*
	Mean difference (95% CI)	-6.96 (-10.25,-3.67)	2.05 (-1.59, 5.69)	<0.001*
	p value**	<0.001	0.13	-
Heart Rate (Mean±SD)	Before intervention	80.68±13.17	76.9±13.32	0.12*
	After intervention	77.58+14.46	80.83+15.45	0.28*
	Mean difference (95% CI)	-3.1(-4.81,-1.38)	3.93(1.89,5.97)	<0.001*
	p value**	<0.001	0.01	-
Time to maximum effect (minutes)	Mean±SD	19.67±13.95	9.83±5.97	<0.001*
	Median (IQR) (Min-Max)	15(20) (5-60)	10(9) (5-30)	
	Mean difference (95% CI)	9.83 (5.96, 13.68)		
Repeat dose n (%)		12(20)	8(13.3)	0.46#
Intubation: n (%)		5(8)	4(6)	0.72#

*Mann–Whitney U test; # Chi-squared test; **Wilcoxon test; IQR: Interquartile range; SD: Standard deviation; CI: Confidence interval

Consequently, post-intervention blood pressure was significantly higher in the ketamine group than in the haloperidol group ($p<0.001$).

Regarding airway management, 4 (6%) patients in the ketamine group and 5 (8%) patients in the haloperidol group required intubation. There was no statistically significant difference between the two groups concerning the need for intubation ($p=0.72$) (Table 3). Patients were followed until discharge. No extrapyramidal side effects were observed in the haloperidol group.

Discussion

The effective management of patient agitation in the hospital setting is crucial for ensuring safety, facilitating timely medical interventions, optimizing resource utilization, enhancing patient experience, and fulfilling legal and ethical obligations [10, 11, 14]. The implementation of evidence-based strategies for agitation management can significantly improve outcomes for both patients and healthcare providers [15]. This study compared the efficacy of haloperidol and ketamine in controlling agitation in the ED setting.

The findings of the present study indicated that both pharmacological agents were effective for sedation. However, a statistically significant difference was observed in the time required to achieve sedation, with the ketamine group demonstrating a more rapid onset of sedation than the haloperidol group.

In 2018, Heidari *et al.,* conducted a study and compared the effects of intramuscular (IM) ketamine to IM haloperidol for agitated patients in the ED. Their findings demonstrated a significantly shorter mean time to achieve adequate sedation, as defined by an Agitation Management Scale Score (AMSS) of less than 1, in the ketamine group compared to the haloperidol group [18]. While the present study also indicated that ketamine provided effective sedation more rapidly than haloperidol, the overall time to sedation was longer in both of our groups than the findings reported by Heidari *et al.* This discrepancy might be attributed to differences in the methods of drug administration and the agitation scales used (AMSS vs. RASS). Nevertheless, both studies demonstrated a significant difference between the two intervention groups. In the study by Heidari *et al.*, 13.3% of the patients in the ketamine group and 6.7% in the haloperidol group required intubation.

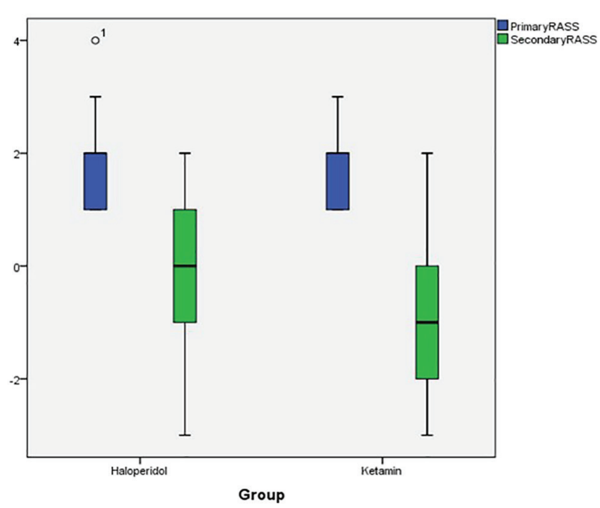

Fig. 2. The diagram shows the pre- and post-intervention RASS score distributions in haloperidol and ketamine groups.

However, our study found no significant difference in intubation rates, a finding that might reflect variations in the patients' underlying health conditions.

Cole *et al.,* conducted a prospective study in 2016 on agitation control in hospital settings and reported that IM ketamine was significantly more effective than IM haloperidol in reducing the time to achieve adequate sedation. The median time to adequate sedation was 5 minutes for ketamine and 12 minutes for haloperidol [19]. Furthermore, their study noted a higher incidence of additional sedation requirements with midazolam among patients in the haloperidol group. Our findings were in agreement with those of Cole *et al.;* however, differences in methodology, such as routes of administration and midazolam use, were noted. In the present study, the requirement for additional doses of sedative medication did not differ significantly between the two groups, a finding that might be influenced by variations in patient age, route of administration, medical history, and underlying conditions contributing to agitation. In both investigations, ketamine demonstrated a more rapid onset of action than haloperidol, representing a significant advantage for its utilization in the ED settings, where prompt symptom control was essential to facilitate improved patient management and the investigation of underlying etiologies. It is important to highlight that these two studies were conducted in different contexts; Cole and colleagues carried out their research in a prehospital setting, whereas the present study was conducted within the ED of a hospital.

In 2023, Hosseini Doost *et al.,* examined the comparative effectiveness of ketamine and haloperidol in preventing delirium among ICU patients [20]. Their findings indicated a higher rate of successful sedation in the ketamine group (86.4%) than the haloperidol group (36.4%), with no significant difference in physician satisfaction between the two groups [20]. In that investigation, ketamine was administered intravenously, while haloperidol was given intramuscularly. The results corroborated those of our research, which also demonstrated a greater level of sedation in the ketamine group than the haloperidol group. Riedel *et al.,* explored the differences in sedation effects among ketamine, haloperidol, and benzodiazepines in agitated patients [21]. Their results indicated that patients receiving ketamine as a first-line treatment for agitation experienced significantly better sedation outcomes than those receiving haloperidol or benzodiazepines [21]. Additionally, patients treated with ketamine exhibited similar rates of drug re-administration, changes in vital signs, and adverse drug reactions to those receiving haloperidol and benzodiazepines [21]. These findings were consistent with our research regarding the efficacy of ketamine in managing agitation. However, Riedel's study exhibited several methodological differences from our research. Specifically, their investigation focused on three pharmacological agents—ketamine, haloperidol, and benzodiazepines—for managing acute agitation, whereas the present study evaluated ketamine and haloperidol. Furthermore, Riedel *et al.,* concluded that ketamine had a more rapid onset of action than haloperidol and midazolam in controlling agitation among ED patients. A key methodological distinction was that the present study employed a triple-blind, randomized clinical trial design, while Riedel's research was prospective and observational. This difference in study design was one of the key strengths of the present research.

Given the increasing prevalence of agitated patients presenting to EDs and the time constraints for intervention, it is imperative to establish protocols for the effective management of agitation without compromising care for other patients. This study aimed to compare the efficacy of haloperidol and ketamine for achieving sedation in agitated patients. The findings indicated that ketamine demonstrated a faster onset of action, reduced agitation levels more rapidly than haloperidol. This rapid response is particularly critical in emergency settings, where timely intervention is essential for patient safety and comfort. Although both agents are associated with adverse effects, the safety profile of ketamine warrants further investigation to establish its long-term viability as a treatment in this context.

Future research should focus on larger, multicenter trials to validate these findings and to explore optimal dosing strategies and safety considerations associated with ketamine use in diverse patient populations. Ultimately, the adoption of ketamine as a standard treatment for acute agitation could enhance patient outcomes and improve the overall efficiency of emergency care services.

These significant findings suggested that ketamine should be considered a first-line treatment option for acute agitation, due to its expedited therapeutic effect.

This study had several limitations, including a restricted sample size and its conduct across only two hospitals. Multicenter studies would likely yield more generalizable results. Additionally, certain patients were excluded due to non-cooperation or absolute contraindications to either haloperidol or ketamine, a challenge that was also noted in previous studies. Future research could investigate these interventions in ICUs, pre-hospital settings, and other hospital wards to provide more comprehensive data and support the development of practical clinical guidelines.

Declaration

Ethical approval and consent to participate: Ethical approval for this study was obtained from the Organizational Ethics Committee of Mashhad University of Medical Sciences (IR.MUMS. IRH. REC.1402.062), and the trial was registered as a clinical study under registration number IRCT20230612058465N1.

Consent for publication: On behalf of all coauthors, I, the corresponding author, hereby grant the journal exclusive publication rights to this work.

Conflict of Interest: The authors declared that there was no conflict of interest.

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Authors' Contribution: SMS: Acquisition of the data; AM: Analysis and interpretation of the data, and drafting of the manuscript; BRK: Critical revision of the manuscript for important intellectual content; EVM: Drafting of the manuscript and critical revision of the manuscript for important intellectual content and supervision. All the authors

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Data availability: The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request for academic and research purposes.

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