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Original article

Dexmedetomidine in Contrary to Haloperidol for Controlling agitated Delirium among Spontaneously Breathing Non-Intubated Cases during The ICU Stay

Reham S. Mohamed [a], Samah B. Ebaed [b], Ahmed I. Soubih [a]

[a] Department of Critical Care Medicine , Faculty of Medicine Benha University, Egypt.

[b]Department of Clinical Pharmacology , Faculty of Medicine Benha University, Egypt.

Corresponding to: Reham S. Mohamed, Department of Critical Care Medicine , Faculty of Medicine Benha University, Egypt.

Email:

drrehamabozaied@gmail.com

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Abstract:

Background: Delirium, a common condition in ICU cases, is associated with cognitive impairment and fluctuating consciousness, contributing to higher mortality and longer hospital stays. While haloperidol has traditionally been used for treatment, its effectiveness is often limited. In contrast, dexmedetomidine (DEX), a newer sedative, has shown promise in reducing delirium duration and providing faster sedation. Evidence suggests it may be more effective than haloperidol, particularly in non-intubated cases, though more investigation is needed to confirm these findings. **Aim:** to determine the effect of early administration of DEX and haloperidol for the management of agitated delirium in spontaneously breathing non-intubated cases during the ICU stay. **Cases and methods:** In this double-blind randomized controlled investigation in Banha University Hospitals, 150 ICU cases were enrolled to investigate DEX and haloperidol efficacy in delirium and agitation management. Cases were randomized to receive DEX, haloperidol, or saline, with the primary outcomes being the attainment of a target RASS score of -3 to 0. Secondary outcomes included the occurrence of delirium, sedation requirements, safety events, and nursing care burden, with the RASS and CAM-ICU scales being used for assessment. **Results:** Baseline group demographics were similar. Group D had lower incidence of delirium, lower ICU and hospital stay, and fewer sedatives and analgesics utilized than Groups H and P without mortality differences. **Conclusion**: DEX can be an effective alternative for managing agitated delirium in non-intubated ICU cases.

Key words: Agitation, Delirium, Dexmedetomidine, Haloperidol, Sedation

Introduction

Delirium represents a prevalent complication among individuals admitted to the intensive care unit (ICU), which can manifest in both agitated and non-agitated forms. Recently, investigations have highlighted a broad spectrum in the occurrence of delirium, with reported rates varying from as low as 16% to as high as 89%. A clinical examination is required for diagnosis, which includes cognitive impairments like memory problems or disorganized thought patterns, as well as changes in consciousness like altered concentration and decreased attention [(1)].

Delirium's symptoms fluctuate over time, making it challenging to diagnose, particularly in its hypoactive (calm) form. Various assessment tools, including the Confusion Assessment Method for the ICU (CAM-ICU) and the Richmond Agitation and Sedation Scale (RASS), are routinely utilized to evaluate and monitor delirium in ICU cases. Delirium is frequently accompanied by symptoms such as hallucinations and cognitive dysfunction, which can severely impact the case's overall health. Delirium is linked to a range of adverse outcomes, including an increased risk of mortality, extended hospital stays, and a higher likelihood of developing long-term cognitive issues, such as dementia. Furthermore, the presence of delirium places a significant strain on healthcare professionals, requiring additional resources and time to manage and provide appropriate care for affected cases [(2)].

Age, smoking status, drug or alcohol abuse, extended hospitalization, surgery, benzodiazepine use, and intensive care unit stays are risk factors for delirium. For delirium prevention, non-pharmacological methods such as early mobilization, reducing the number of caregivers, and avoiding sleep disturbances are advised [(3)]. However, these methods are frequently insufficient and call for pharmacological intervention, particularly in cases of hyperactive delirium. Haloperidol, a dopamine antagonist, has been the standard for the treatment of delirium but is possibly side-effect-prone with neuroleptic malignant syndrome, dyskinesia, and oversedation. Further, its effectiveness in ICU delirium treatment has come under question with high rates of non-responsiveness at times requiring second-line therapy [(4)]

Hyperactive delirium, when coupled with restlessness and agitation, can cause dangerous side effects such as a case falling off the bed or removing life-supporting devices, necessitating control urgently in a critically ill group. Thus, delirium management, and particularly in ICUs, is a field of immense importance [(5)]. Haloperidol has historically been the primary treatment for hyperactive delirium, yet it is frequently linked to high failure rates and does not reliably reduce the duration of delirium. Despite its

widespread use, the effectiveness of haloperidol in managing this condition has been critically evaluated, as it often fails to provide consistent improvements in the length and severity of delirium episodes. Recent research suggests that dexmedetomidine (DEX), a selective α2 adrenergic agonist, is more effective than haloperidol in managing hyperactive delirium. DEX has shown a greater capacity to induce sedation more rapidly and is linked to a reduction in the overall duration of delirium in ICU cases. This has made DEX an increasingly preferred option for managing hyperactive delirium, as it not only facilitates quicker sedation but also contributes to a shorter period of delirium, potentially improving case outcomes in ICU settings [(6)].

DEX is a potential haloperidol substitute. DEX proved to be a successful treatment for delirium in intubated ICU cases and may have several advantages compared to other sedative drugs like narcotics or benzodiazepines. DEX has minimal respiratory depression, which makes it simpler to utilize in non-intubated cases. A few studies have contrasted DEX with haloperidol in non-intubated delirious individuals, and though results are promising, additional investigation needs to be done to definitively compare the two drugs within this population [(7)].

DEX's half-life (1.8-3.1 hours) is shorter than that of haloperidol (18-54 hours), and thus DEX may be infused continuously but not haloperidol, which is typically given intermittently. This difference in pharmacokinetics may make DEX easier to titrate and more rapidly acting compared to haloperidol, making DEX a better choice for hyperactive delirium sedation [(8)]. However, ICU beds are limited, and most critically ill cases are treated in ICU, where non-intubated cases are managed. High-dose sedatives are less commonly used in ICUs due to concerns about respiratory depression, and there are fewer nurses per case than in ICUs, so it is harder to control cases with hyperactive delirium [(9)]

While DEX has demonstrated effectiveness in intubated cases, its use in non-intubated ICU cases is less well explored. One study suggested that DEX was effective in non-intubated ICU cases with haloperidol-refractory hyperactive delirium, but this has not been extensively researched. We hypothesized that continuous DEX would be more effective than intermittent haloperidol in managing hyperactive delirium in non-intubated ICU cases, offering quicker sedation, and reducing the duration of delirium [(10)].

This investigation determined whether DEX reaches the desired sedation level more quickly than haloperidol, and to assess other key outcomes, including the amount of medication required for sedation maintenance, the occurrence of delirium the next day, and nursing care demands. Delirium continues to be a major public health concern, linked to long-term adverse effects such as lower survival rates, extended

ICU and hospital stays, and higher healthcare costs.

Aim of the investigation:

This investigation aimed to evaluate the impact of early administration of DEX and haloperidol in managing agitated delirium in non-intubated, spontaneously breathing cases during their ICU stay.

Cases and Methods

This study was a prospective, randomized, double-blind controlled clinical trial carried out at Banha University Hospitals. It received ethical approval from the Faculty of Medicine's ethics committee (RC 3-3-2025) at Banha University, and all participants provided written informed consent. The trial enrolled 150 adult ICU cases, aged 26 to 70 years, all classified as ASA physical status III or IV, and was conducted between August 2023 and December 2024.

Consent was proactively obtained from eligible cases or their legally authorized representatives before study enrollment, regardless of delirium status. This approach ensured participation before the onset of delirium, which could impair decision-making capacity. For cases with impaired consciousness or severe dementia, consent was obtained from a surrogate. This early consent process enabled timely administration of the investigational medications upon the emergence of hyperactive delirium.

Participants were randomly allocated to one of three groups based on a computer-generated randomization sequence: Group D received DEX (n=50), Group H received haloperidol (n=50), and Group P received normal saline (n=50).

Inclusion criteria encompassed non-intubated adults aged 20 years or older admitted to the ICU from the emergency department, without restrictions based on age or gender. Exclusion criteria included cases already on non-invasive ventilation upon ICU admission, those with a tracheostomy, prior administration of DEX or haloperidol before ICU admission, individuals diagnosed with schizophrenia or mania, cases with contraindications to the study drugs (e.g., allergy, prolonged QTc interval), pregnant or lactating women, non-Japanese speakers, and anyone deemed unsuitable by the principal investigator or their designee.

Medications were meticulously prepared and coded by the pharmacy in 50 ml syringe pumps, with dosages individualized according to case weight to maintain consistent infusion dynamics across all arms of the trial (10 ml bolus followed by 2–8 ml/h infusion). Drug administration was conducted by ICU clinicians and nursing staff, all of whom remained blinded to group allocations to preserve the integrity of the double-blind design.

In Group D, participants received DEX through continuous intravenous infusion at a rate of 0.2–0.7 µg/kg/h. If the case's RASS score was ≥+2, a loading dose of 1.0 µg/kg was

administered over a 10-minute period. In Group H, cases were administered haloperidol at an infusion rate of 0.5–2 mg/h, preceded by a 2.5 mg loading dose under the same RASS conditions. Group P served as the placebo group and received normal saline infusion at 2–8 ml/h, with a 10 ml bolus if clinically indicated.

As per the DEX administration protocol, if a case demonstrated signs of agitation (RASS ≥+1) along with a positive CAM-ICU result during the evening or overnight period (7:00 PM to 6:00 AM), a continuous infusion of DEX at 0.3–0.7 µg/kg/h was initiated. This dosage was titrated to maintain a target RASS score between -3 and 0 until 6:00 AM. In cases of pronounced agitation (RASS scores of +3 to +4), a higher loading dose of up to 6 µg/kg/h could be given. If sedation targets were not met, rescue medications—such as haloperidol—were allowed. DEX infusion could be temporarily interrupted in the event of adverse hemodynamic effects like hypotension or bradycardia.

In the haloperidol protocol (Group H), when cases met the same agitation and CAM-ICU criteria, they received a 2.5 mg dose of haloperidol either as a bolus injection, intravenous drip, or intramuscularly. If the RASS score remained above 0 after one hour, an additional 2.5 mg dose was permitted. Persistent agitation despite two doses warranted the initiation of rescue therapy, including DEX if necessary.

If RASS remained +1 or higher, additional sedatives (midazolam for RASS +1 or +2; propofol for RASS +3 or +4 or persistent agitation) were administered. Fentanyl was used to manage pain if the VAS score was ≥5. The need and total doses for these supplemental agents were recorded.

The study's primary endpoint was the proportion of cases who achieved a target RASS score between -3 and 0 within two hours of drug administration. Secondary outcomes included time to reach the target RASS, serial RASS measurements at 1, 2, 3, 4, 6, and 8 hours, total time spent within the target sedation range over 8 hours, delirium-free days during ICU stay, delirium incidence the day after intervention, length of ICU and hospital stay, frequency of rescue drug use, and safety outcomes such as oversedation, hypotension, bradycardia, need for advanced respiratory support, and other adverse events. Behavioral control measures, hazardous behaviors, and nursing workload were also assessed.

Delirium and agitation were evaluated using the RASS and CAM-ICU tools, with routine and event-triggered assessments performed by ICU nurses. Safety monitoring included predefined criteria for adverse events, and data were collected on time-intensive care tasks and behavioral interventions.

Statistical analysis

Data analysis was conducted using SPSS version 25.0 (SPSS v25Inc., Chicago, Illinois, USA). Descriptive statistics were computed for both categorical and continuous variables.

The Shapiro-Wilk test assessed data normality. Depending on the distribution, ANOVA (with Tukey's HSD), or Kruskal-Wallis (with Dunn-Bonferroni post hoc) was used for continuous variables. Chi-square or Fisher's exact test was used for categorical data. Multivariable logistic regression identified independent predictors of delirium. Time to extubate was evaluated using Kaplan-Meier survival curves. Both intention-to-treat and per-protocol analyses were performed, with statistical significance set at $p < 0.05$.

Results

The baseline characteristics of the three groups (Group D, Group H, and Group P) were similar across age, gender, and body mass index (BMI). The mean age was comparable among the groups, with no significant differences ($p = 0.596$). Gender distribution also showed no significant difference, with a similar ratio of males to females across all groups ($p = 0.664$). Regarding BMI, although there were differences between the groups, the p of 0.075 suggests that these differences were not statistically significant at the 0.05 threshold, though it is close to being significant. **Table 1**

The outcomes of delirium management across the three investigation groups (Group D, Group H, and Group P) showed significant differences in some areas. The incidence of delirium, which was the primary outcome, was significantly lower in Group D (10%) compared to Groups H (34%) and P (44%) with a p of 0.0145, indicating a statistically significant difference. Regarding the length of ICU and hospital stays, Group D had the shortest stays, with 3.1 ± 0.4 days in the ICU and 6.2 ± 0.9 days in the hospital, while Groups H and P had significantly longer stays (ICU: 6.5 ± 1.0 and 6.9 ± 1.2 days, respectively; hospital: 13.5 ± 2.0 and 15.5 ± 2.5 days, respectively), with ps less than 0.001 for both. However, there were no significant differences in mortality rates across the groups, with Group D, H, and P showing similar mortality rates (6%, 6%, and 10%, respectively) and a p of 0.856. **Table 2**

Regarding supplementary sedatives and analgesics usage, Group D used significantly lower amounts of supplementary sedatives and analgesics compared to Groups H and P. For midazolam, fewer cases in Group D received it, and the total dose was lower. The same trend was observed for propofol and fentanyl, with Group D using lower doses and fewer cases being administered these drugs. These differences were statistically significant across all three medications ($p < 0.05$), suggesting that Group D had less reliance on supplementary sedatives and analgesics than the other two groups**.** **Table 3**

Table 1: Demographic Characteristics of Investigation Groups

	Group D (N = 50)	Group H (N = 50)	Group P (N = 50)	p
Age (years)	51.1 ± 8.4	51.0 ± 8.8	49.1 ± 8.0	0.596
Gender (number)	Male/Female: 40/10	Male/Female: 36/14	Male/Female: 35/15	0.664
Body mass index (kg/m²)	25.4 ± 4.6	26.9 ± 5.1	24.3 ± 6.3	0.075

Table 2: Outcomes of Delirium Management in Investigation Groups

Outcomes	Group D (N=50)	Group H (N=50)	Group P (N=50)	p
Incidence of delirium (1ry outcome)	5 (10%)	17 (34%)	22 (44%)	0.0145
Length of ICU stay (days)	3.1 ± 0.4	6.5 ± 1.0	6.9 ± 1.2	<0.001
Length of hospital stay (days)	6.2 ± 0.9	13.5 ± 2.0	15.5 ± 2.5	<0.001
Mortality	3 (6%)	3 (6%)	5 (10%)	0.856

Table 3: Supplementary Sedatives and Analgesics Usage in Investigation Groups

Supplementary Sedatives and Analgesics	Group D (N=50)	Group H (N=50)	Group P (N=50)	p
Midazolam				
No. of cases (%)	3 (6%)	13 (26%)	18 (36%)	0.020
Total dose (mg)	5.5 ± 1.0	13.5 ± 1.9	30 ± 4.8	<0.001
Propofol				
No. of cases (%)	5 (10%)	17 (34%)	22 (44%)	0.014
Total dose (mg)	320.2 ± 88.2	680.1 ± 162.2	1151.4 ± 241.9	<0.001
Fentanyl				
No. of cases (%)	3 (6%)	13 (26%)	17 (34%)	0.035
Total dose (mcg)	100.5 ± 29.4	351.6 ± 88.2	480.1 ± 117.2	<0.001

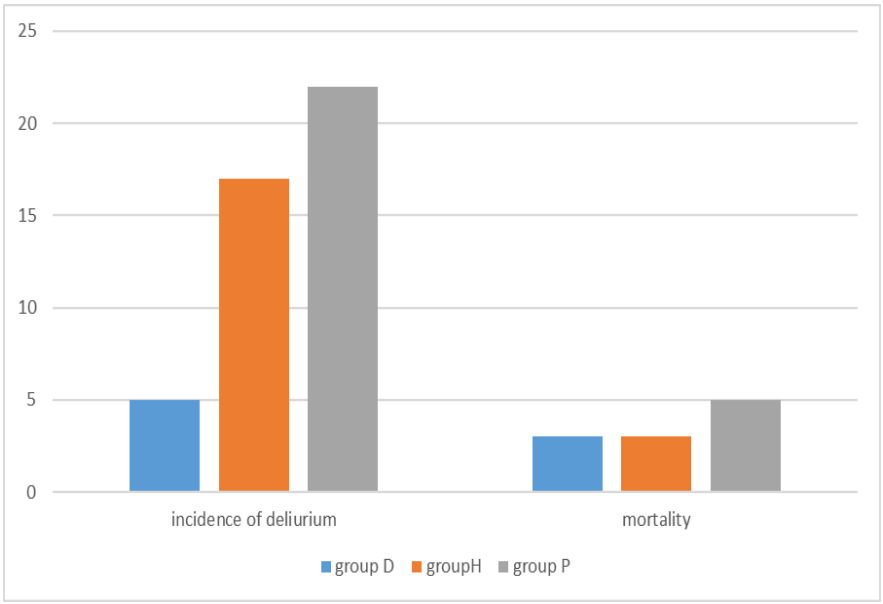

Fig1.prevalence of delirium and mortality between studied groups

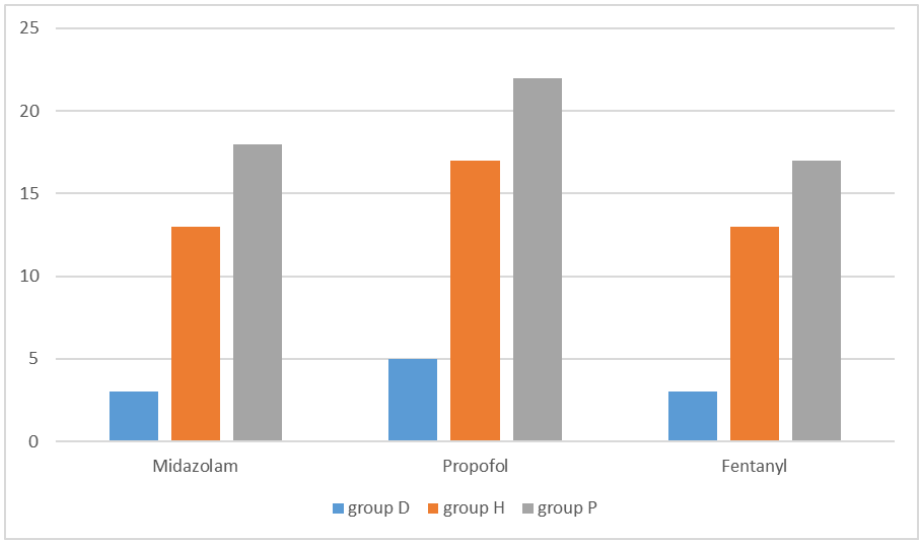

Fig2: number of cases who received supplementary sedatives and analgesics usage in investigation group.

Discussion

Delirium, a prevalent condition in ICU cases, is associated with cognitive impairment and fluctuating consciousness, contributing to higher mortality and longer hospital stays. While haloperidol has traditionally been used for treatment, its effectiveness is often limited. In contrast, DEX, a newer sedative, has shown promise in reducing delirium duration and providing faster sedation. Evidence suggests it may be more effective than haloperidol, particularly in non-intubated cases, though more investigation is warranted to verify

these findings. So, our investigation evaluated the impact of early administration of DEX and haloperidol in managing agitated delirium in non-intubated, spontaneously breathing cases during their ICU stay.

The outcomes of delirium management across our three investigation groups (Group D, Group H, and Group P) showed significant differences in some areas. The incidence of delirium, which was the primary outcome, was significantly lower in Group D (10%) compared to Groups H (34%) and P (44%) with a p of 0.0145, indicating a statistically significant difference. Regarding the length of ICU and hospital stays, Group D had the shortest stays, with 3.1 ± 0.4 days in the ICU and 6.2 ± 0.9 days in the hospital, while Groups H and P had significantly longer stays (ICU: 6.5 ± 1.0 and 6.9 ± 1.2 days, respectively; hospital: 13.5 ± 2.0 and 15.5 ± 2.5 days, respectively), with p less than 0.001 for both. However, comparable mortality rates were detected across the groups, with Group D, H, and P showing similar mortality rates (6%, 6%, and 10%, respectively) and a p of 0.856.

In agreement with our finding Carrasco and colleagues (2016)[9] conducted a study involving 132 non-intubated cases who received haloperidol during the initial titration phase. Among these, 46 cases did not respond, while 86 were classified as responders. During the comparison phase, DEX demonstrated a higher percentage of time spent within the target sedation range compared to haloperidol (92.7% vs. 59.3%). Haloperidol was associated with 10 cases of oversedation. Despite DEX having a direct cost approximately 17 times higher than haloperidol, it led to mean savings per case due to a shortened ICU stay.

Similarly, Reade and colleagues (2009) [7], in a preliminary pilot investigation, described DEX as a promising agent for managing ICU-related delirious agitation. They observed a marked decrease in ICU stay duration among cases treated with DEX, from 6.5 to 1.5 days.

According to Soltani and colleagues, (2021) [(10)] there was a significant difference between the DEX and haloperidol groups regarding the incidence of delirium and the level of agitation. Cases in the DEX group remained calmer and experienced fewer episodes of delirium compared to those in the haloperidol group.

Aligned with the present investigation, Pasin and colleagues. (2014)[(11)] from Italy examined the role of DEX in preventing and treating delirium in ICU cases. The investigation revealed a significant reduction in delirium, agitation, and confusion. Mechanically ventilated cases receiving DEX showed a lower incidence of delirium compared to controls.

Consistent with this, Bakri and colleagues [(12),] carried out a three-day clinical investigation in Egypt and concluded that DEX could be effectively used to manage post-traumatic delirium in ICU cases,

outperforming haloperidol in this context.

In 2018, Flukiger and colleague [13] carried out a comprehensive review of 28 clinical trials involving 5,141 ICU cases to assess the effectiveness of DEX in preventing and managing delirium. Consistent with the present investigation, they found that cases receiving DEX experienced a significantly lower incidence of delirium and required fewer medications for pain and agitation control compared to those in the control or haloperidol groups. However, the DEX group showed a higher incidence of bradycardia and hypotension. They concluded that DEX effectively reduces delirium among ICU cases, though they emphasized the need for broader investigations directly comparing it to haloperidol [13].

In another investigation, Nelson and colleagues (2015) [14] demonstrated that DEX indirectly mitigated delirium by enabling effective sedation and reducing the overall need for sedatives. Similarly, Louis and colleagues (2018) [15] supported the present findings by showing that DEX administration in ICU settings was associated with a reduced incidence of delirium.

In line with these observations, Abdelgalel [16] carried out a clinical trial involving 90 mechanically ventilated cases to compare the effects of haloperidol and DEX. The group receiving DEX had a lower incidence of delirium, shorter ICU stays, and fewer days on mechanical ventilation. The results suggested that DEX was more effective and efficient than haloperidol in managing and preventing delirium, aligning with the findings of the present investigation.

DEX may exert its anti-agitation effects by minimizing the use of other sedatives commonly linked to delirium [17]. In a clinical investigation involving 106 cases, DEX was shown to extend the number of days cases remained alive without experiencing delirium or coma, while also enhancing consistency in achieving target sedation levels, when compared to lorazepam [18]. However, concerns were subsequently raised, particularly regarding dose comparability [19], the economic feasibility of the drug [20] and the robustness of the outcome assessments used [21]. In a separate trial involving 375 cases, DEX was evaluated against midazolam and was found to significantly lower delirium rates and shorten the duration of mechanical ventilation [22]. Although these findings highlight its potential benefits, the widespread use of DEX as a frontline sedative remains financially unviable in many clinical settings despite its cost-effectiveness in some contexts. [23]

When analyzing the usage of additional sedatives and analgesics, Group D demonstrated a markedly reduced dependence on agents such as midazolam, propofol, and fentanyl in comparison to Groups H and P. Not only did fewer cases in Group D require these drugs, but their total administered doses were also significantly lower. These differences

reached statistical significance ($p < 0.05$), suggesting a meaningful reduction in the need for adjunctive sedation and pain control in the DEX group.

In alignment with these observations, Saber, and colleagues (2016) [24] reported a significant decrease in the requirement for supplementary sedatives and analgesics—including midazolam, propofol, and fentanyl—among cases treated with DEX. This reduced pharmacologic burden likely contributed to the observed declines in delirium incidence, intubation rates, and ICU length of stay.

Another investigation compared the early use of low-dose DEX to placebo in cases with acute respiratory failure. The study concluded that DEX did notably enhance tolerance for non-invasive ventilation (NIV), nor did it reduce the need for supplemental sedation or analgesia. However, this investigation was constrained by limited sample size and methodological factors, including the absence of an initial loading dose and gradual titration of the infusion rate [25].

Conclusion

DEX demonstrated a significant advantage over haloperidol and placebo in reducing the incidence of delirium, shortening ICU and hospital stays, and lowering the demand for additional sedative medications. Importantly, these benefits were achieved without increasing mortality, positioning DEX as a promising option for the management of agitated delirium in non-intubated ICU cases.

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