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Dexmedetomidine versus Midazolam sedation and withdrawal outcomes in mechanically ventilated children: A Randomised Controlled Study

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ABSTRACT

Background: Withdrawal syndrome is a common clinical scenario in sick children receiving sedation during mechanical ventilation. Midazolam , a common sedating agent has been associated with withdrawal syndrome after discontinuation. Another sedating agent Dexmetetomidine has emerged as an alternative with advantages of decreased withdrawal related complications.
Methods: This open label RCT was conducted in Pediatric ICU of Govt. Medical College Jammu over one year. Total 106 mechanically ventilated children aged 1 month to 18 years who required sedation were randomised to receive either Dexmedetomidine or Midazolam. Withdrawal symptoms were assessed using Withdrawal Assessment Tool-1(WAT-1) in the two study groups. Assessments were done before weaning and thereafter six hourlies for 48 hrs after stopping sedation. Withdrawal syndrome was defined as WAT-1 score >3 for two consecutive occasions.
Results: Baseline demographic and clinical characteristics were comparable between the groups. Mean WAT-1 scores were significantly lower in the dexmedetomidine group throughout the weaning period. The cumulative WAT-1 score was significantly lower with dexmedetomidine than with midazolam (7.6 ± 10.8 vs. 14.9 ± 14.9; p=0.007). Withdrawal syndrome occurred in 15 patients (28.3%) receiving dexmedetomidine compared with 29 patients (54.7%) receiving midazolam (p=0.006). Reintubation rates were lower with dexmedetomidine (3.8% vs. 13.2%), although the difference was not statistically significant (p=0.148). Hypotension and bradycardia were more frequent with dexmedetomidine but were manageable and did not differ significantly between groups.
Conclusions: Dexmedetomidine was found to have significant lower incidence and severity of withdrawal syndrome compared to Midazolam in ventilated children. Despite higher frequency of cardiovascular adverse effects, Dexmedetomidine was found to be safer and effective alternative to Midazolam for sedation in Pediatric Intensive care Units.

Keywords: Dexmedetomidine, Midazolam, Withdrawal syndrome, sedation, mechanical ventilation.

INTRODUCTION

Withdrawal syndrome represents a clinically important complication among critically ill children exposed to prolonged sedation in the pediatric intensive care unit (PICU). Following abrupt discontinuation or rapid reduction of sedative medications, affected patients may develop agitation, tremors, tachycardia, diaphoresis, irritability, and, in severe cases, seizures.[1] Such manifestations can interfere with recovery, prolong intensive care requirements, and increase the need for additional therapeutic interventions. Consequently, prevention and early recognition of withdrawal syndrome have become important priorities in contemporary pediatric critical care practice.[2]

The risk of withdrawal is closely related to the duration and type of sedative therapy administered during mechanical ventilation. Midazolam remains one of the most frequently used sedative agents in pediatric intensive care because of its rapid onset of action, predictable anxiolytic effects, amnestic properties, and ease of titration.[3,4] Acting through potentiation of gamma-aminobutyric acid (GABA)-A receptor activity, midazolam provides effective sedation for a wide range of critically ill children.[5,6] However, prolonged exposure to benzodiazepines may result in physiological dependence, making withdrawal manifestations a recognized consequence of treatment discontinuation.[7]

In response to concerns regarding benzodiazepine-associated complications, alternative sedation strategies have gained increasing attention. Dexmedetomidine, a highly selective α2-adrenergic receptor agonist, has emerged as a valuable option for sedation in mechanically ventilated patients.[8] Unlike conventional sedatives, dexmedetomidine produces a state resembling natural physiological sleep with the added advantage of preserving respiratory drive .[9-12] These characteristics have contributed to its expanding role in pediatric intensive care and have raised interest regarding its potential to reduce withdrawal-related complications.

Accurate identification of withdrawal symptoms is essential for evaluating the effectiveness of different sedation strategies. The Withdrawal Assessment Tool-1 (WAT-1) is a validated and widely accepted instrument designed specifically to assess withdrawal manifestations in pediatric patients receiving prolonged sedation.[13-15] Its use allows standardized assessment of both the incidence and severity of withdrawal syndrome during the weaning process.

While minimizing withdrawal symptoms is an important goal, sedative agents must also provide adequate comfort and facilitate safe mechanical ventilation. Sedation plays a central role in reducing anxiety and distress, improving patient–ventilator synchrony, enhancing tolerance of invasive procedures, and decreasing the risk of unplanned extubation.[16,17] At the same time, maintaining an appropriate depth of sedation is essential because both under-sedation and over-sedation may adversely affect clinical outcomes.[18,19]

Given the growing use of dexmedetomidine and the continuing reliance on midazolam in pediatric intensive care units, further comparative evidence regarding withdrawal outcomes remains necessary. The present study was therefore undertaken to compare the incidence and severity of withdrawal syndrome in mechanically ventilated children receiving sedation with either dexmedetomidine or midazolam.

MATERIALS AND METHODS

This open-label randomized controlled trial was conducted in the Pediatric ICU of GMC Jammu over one year after institutional ethical approval. Mechanically ventilated children aged 1 month to 18 years requiring light-to-moderate sedation were enrolled.

Inclusion Criteria

- Mechanically ventilated patients
- Age 1 month to 18 years
- Clinical need for sedation

Exclusion Criteria

- Neuromuscular blockade beyond intubation
- Dialysis
- Trauma or burns
- Acute neurological events
- Severe hepatic impairment
- Bradycardia or advanced AV block

A total of 106 participants were randomized equally into:

- Dexmedetomidine group (0.2–1 µg/kg/hr infusion)
- Midazolam group (1–4 µg/kg/min infusion)

Randomization was performed using computer-generated block randomization with sealed opaque envelopes.

Withdrawal syndrome was assessed using the WAT-1 score in patients receiving sedation for more than 3 days. Scoring was done before weaning and every 6 hours thereafter for 48 hours after discontinuation. Withdrawal syndrome was diagnosed when WAT-1 score exceeded 3 on two consecutive assessments.

Sedation weaning followed NHS-UK guidelines based on sedation duration. Data were analyzed using SPSS version 25. A p-value <0.05 was considered statistically significant.

RESULTS

A total of 106 mechanically ventilated pediatric patients were included in the study and were equally randomized into dexmedetomidine and midazolam groups, with 53 patients in each arm. Baseline demographic characteristics including age and sex distribution were comparable between the two groups, with no statistically significant differences observed. Most patients belonged to the infant and younger pediatric age groups, and males constituted approximately 60% of the study population in both groups. This similarity ensured adequate comparability between groups and minimized demographic bias.(Table 1)

The clinical diagnoses at presentation were varied and represented the broad spectrum of illnesses encountered in the Pediatric ICU. Pneumonia was the most common diagnosis in both groups, followed by conditions such as ARDS, meningitis, septicemia, tubercular meningitis(TBM), congenital heart diseases, snake bite, and neurological illnesses. The distribution of diagnoses did not differ significantly between groups , suggesting comparable illness severity and clinical profiles.(Table 1)

The median duration of sedation was slightly shorter in the dexmedetomidine group [4 (3–6)] compared to the midazolam group [5 (4–6.5)], although the difference was not statistically significant (p=0.051). Despite the lack of statistical significance, dexmedetomidine demonstrated a tendency toward shorter sedation duration.(Table 1)

The mean duration of hospital stay was marginally shorter in the dexmedetomidine group (22.5 ± 9.7 days) compared with the midazolam group (24.2 ± 8.6 days), although this difference was not statistically significant (p=0.358).(Table 1)

Withdrawal symptoms were assessed using serial WAT-1 scores obtained every 6 hours during and after sedation weaning. Mean WAT-1 scores were consistently lower in the dexmedetomidine group at all measured intervals. At baseline, the mean WAT score was 0.7 ± 1.3 in the dexmedetomidine group compared with 1.7 ± 2.1 in the midazolam group (p=0.005). Similarly significant differences were observed at various intervals after initiation of weaning with lesser WAT-1 scores in the dexmedetomidine group. The total cumulative WAT score was significantly lower in the dexmedetomidine group (7.6 ± 10.8) than in the midazolam group (14.9 ± 14.9) (p=0.007), indicating reduced severity of withdrawal symptoms with dexmedetomidine.(Table 1)

Table 1. Baseline Demographic and Clinical Characteristics of Study Participants

Variable	Dexmedetomidine (n=53)	Midazolam (n=53)	p-value
Mean age (months)	49.8 ± 41.2	52.4 ± 39.6	0.733
Male sex, n (%)	32 (60.4%)	32 (60.4%)	1.000
Female sex, n (%)	21 (39.6%)	21 (39.6%)	1.000
Pneumonia, n (%)	10 (18.9%)	14 (26.4%)	0.576
ARDS, n (%)	7 (13.2%)	5 (9.4%)	0.538
Meningitis/TBM, n (%)	8 (15.1%)	9 (17.0%)	0.795
Septicemia, n (%)	5 (9.4%)	4 (7.5%)	0.728
Congenital heart disease, n (%)	4 (7.5%)	3 (5.7%)	0.697
Median sedation duration (days)	4 (3–6)	5 (4–6.5)	0.051
Mean hospital stay (days)	22.5 ± 9.7	24.2 ± 8.6	0.358
Baseline WAT-1 score	0.7 ± 1.3	1.7 ± 2.1	0.005*
Total cumulative WAT-1 score after 48 hours	7.6 ± 10.8	14.9 ± 14.9	0.005*

The incidence of withdrawal syndrome was also significantly lower in patients receiving dexmedetomidine. Withdrawal symptoms developed in 15 patients (28.3%) in the dexmedetomidine group compared with 29 patients (54.7%) in the midazolam group. The relative risk of withdrawal syndrome in the dexmedetomidine group was 0.52 (95% CI: 0.32–0.85), which was statistically significant (p=0.006). These findings suggest that dexmedetomidine substantially reduces the risk of withdrawal syndrome compared with midazolam.(Table 2)

Table 2. Clinical Outcomes and Adverse Events

Outcome Variable	Dexmedetomidine (n=53)	Midazolam (n=53)	p-value
Withdrawal syndrome, n (%)	15 (28.3%)	29 (54.7%)	0.006*
Relative risk of withdrawal (95% CI)	0.52 (0.32–0.85)	Reference	—
Reintubation required, n (%)	2 (3.8%)	7 (13.2%)	0.148
Relative risk of reintubation (95% CI)	0.286 (0.062–1.312)	Reference	—
Hypotension, n (%)	10 (18.9%)	8 (15.1%)	0.605
Bradycardia, n (%)	11 (20.8%)	6 (11.3%)	0.186

Reintubation rates were numerically lower in the dexmedetomidine group throughout the observation period. Overall, only 2 patients (3.8%) in the dexmedetomidine group required reintubation compared with 7 patients (13.2%) in the midazolam

group. Although this difference did not achieve statistical significance (p=0.148), the findings indicate a possible clinical advantage with dexmedetomidine regarding extubation outcomes.(Table 2)

Adverse cardiovascular events were slightly more frequent with dexmedetomidine. Hypotension occurred in 18.9% of patients receiving dexmedetomidine compared with 15.1% in the midazolam group, while bradycardia was observed in 20.8% and 11.3% of patients respectively. However, neither difference was statistically significant. These adverse effects were manageable and did not necessitate discontinuation of therapy in most patients.(Table 2)

DISCUSSION

The principal finding of the present study was the significantly lower incidence and severity of withdrawal syndrome among mechanically ventilated children receiving dexmedetomidine compared with those receiving midazolam. Patients sedated with dexmedetomidine demonstrated consistently lower WAT-1 scores throughout the weaning period and experienced withdrawal syndrome less frequently, highlighting a potential advantage of dexmedetomidine in the management of prolonged pediatric sedation.

The observed difference in withdrawal outcomes may be explained by the distinct pharmacological mechanisms of the two sedative agents. Midazolam exerts its effects through GABA receptor modulation and prolonged exposure can result in neuroadaptive changes that predispose patients to dependence and subsequent withdrawal manifestations following dose reduction or discontinuation.[3-7] Dexmedetomidine, in contrast, produces sedation through selective stimulation of central α2-adrenergic receptors and appears to be associated with a lower tendency toward physiological dependence.[8-12] These mechanistic differences may account for the reduced withdrawal burden observed in the dexmedetomidine group.

The findings of the present study are consistent with previous investigations that have reported favorable withdrawal profiles with dexmedetomidine-based sedation. Pathan et al.[20] and Bouajram et al.[21] similarly observed reduced withdrawal manifestations and improved sedation-related outcomes among patients receiving dexmedetomidine. Likewise, Mondardini et al.[22] emphasized the utility of dexmedetomidine during sedation tapering and suggested that its pharmacological characteristics may facilitate smoother transition during the weaning phase. The agreement between these studies and the present findings strengthens the evidence supporting dexmedetomidine as an effective alternative to benzodiazepine-based sedation.

Beyond statistical significance, the reduction in withdrawal symptoms observed in this study carries important clinical implications. Withdrawal syndrome may increase patient discomfort, prolong recovery, complicate ventilator weaning, and necessitate additional pharmacological treatment. Therefore, strategies that reduce withdrawal severity have the potential to improve overall quality of intensive care management. The lower cumulative WAT-1 scores observed with dexmedetomidine suggest not only a reduction in the frequency of withdrawal syndrome but also a decrease in the intensity of withdrawal manifestations among affected patients.

Although withdrawal outcomes constituted the primary focus of the present study, several secondary observations merit consideration. The duration of sedation and length of hospital stay were both numerically lower in the dexmedetomidine group, although neither difference achieved statistical significance. Similar trends have been reported by Jakob et al.[23] and Riker et al.[24], who demonstrated that dexmedetomidine may facilitate earlier liberation from mechanical ventilation through the provision of cooperative sedation with minimal respiratory depression. While the present study was not specifically powered to detect differences in these outcomes, the observed trends may nevertheless be clinically meaningful.

A lower reintubation rate was also observed among patients receiving dexmedetomidine. Although statistical significance was not reached, this finding may reflect improved patient–ventilator synchrony and preservation of respiratory function during the post-extubation period. Previous studies by Riker et al [24] and Erickson et al.[25] have similarly reported favorable extubation-related outcomes with dexmedetomidine, supporting the possibility of additional clinical benefits beyond withdrawal prevention.

Safety remains an important consideration when selecting sedative agents in critically ill children. In the present study, bradycardia and hypotension occurred more frequently among patients receiving dexmedetomidine, although these differences were not statistically significant. These observations are consistent with the established pharmacological effects of α2-adrenergic receptor agonists and have been reported previously by Jakob et al.[23], Gulla et al.[26], and Hoy et al.[27] Importantly, the cardiovascular events encountered during the study were generally mild and manageable with routine supportive measures, and rarely required interruption of therapy.

The comparability of baseline demographic characteristics and diagnostic profiles between study groups strengthens the validity of the observed findings. Similar age distribution, sex distribution, and underlying disease patterns reduced the likelihood that differences in withdrawal outcomes were attributable to baseline imbalances. The varied spectrum of clinical diagnosis in the study subjects points towards the heterogenous population usually encountered in the pediatric

ICUs. Comparable patient populations have also been reported in previous pediatric sedation studies conducted by Erickson et al.[25] and Ramachandran et al.[28] . Moreover the most common diagnosis for admission in our patients was pneumonia which is consistent with existing literature[26].

The present study has certain shortcomings. Being a single-center study, the findings may not be fully generalizable to all pediatric intensive care settings. The relatively modest sample size may have limited the ability to detect significant differences in some secondary outcomes, including reintubation rates and duration of hospitalization. In addition, the open-label design may have introduced a degree of observer bias despite the use of a validated withdrawal assessment tool. Larger multicenter randomized studies are warranted to further clarify the long-term benefits and safety profile of dexmedetomidine in pediatric critical care.

We can deduce that dexmedetomidine causes significantly lower incidence and severity of withdrawal syndrome compared with midazolam in mechanically ventilated children while providing effective sedation and maintaining an acceptable safety profile which may offer clinically meaningful advantages during the sedation weaning process. These findings support the growing role of dexmedetomidine as an alternative to benzodiazepine-based sedation in pediatric intensive care practice.

CONCLUSION

This study demonstrates that Dexmedetomidine was associated with lower incidence and severity of withdrawal syndrome compared with Midazolam in mechanically ventilated pediatric patients. Although hypotension and bradycardia were more frequent with dexmedetomidine, the differences were not statistically significant. Dexmedetomidine also showed trends toward shorter sedation duration and hospital stay. Overall, it may be a safer and more effective sedative for reducing withdrawal symptoms with appropriate cardiovascular monitoring.

Limitations

The relatively small sample size may limit the generalizability of the findings across diverse pediatric populations. The open-label design could have introduced observer and reporting bias. Variations in underlying medical conditions were not fully accounted for and may have affected withdrawal outcomes. In addition, the lack of long-term follow-up limited assessment of delayed withdrawal symptoms and other potential complications. Further large-scale blinded multicenter studies are required to validate these findings.

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