

## Comparative Study of Efficacy of Intranasal Midazolam versus Intramuscular Midazolam in Control of Acute Seizures in Children in the Age Group of 6 Months to 12 Years

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Conflict of interest: Nil

### Abstract

**Background and Aims:** Seizures in children account for up to 25% of all pediatric emergencies. Midazolam has been administered by various routes, however, there are concerns about bioavailability when the drug is administered by other routes. In our study, we are comparing the efficacy of non-intravenous routes of the midazolam administration for the control of seizures.

**Methodology:** This was a prospective simple randomized control trial conducted at a tertiary care center in India after ethical approval from October 2018 to December 2020. Children in the age group of 6 months to 12 years were enrolled. Enrolled patients were block randomized into two groups namely intranasal and intramuscular midazolam group. The time taken to abort the seizure was noted and monitoring of vital parameters was done.

**Results:** Out of the 247 enrolled patients, 123 patients received intranasal midazolam whereas 124 were treated with intramuscular midazolam. It was observed that there was no statistically significant difference in the therapeutic efficacy of midazolam used for abortion of acute seizures either through the intranasal route or intramuscular route ( $p=0.4496$ ). There was no difference in the need of a second anticonvulsant for abortion of acute seizures in both the groups and the incidence of recurrence of seizures within 60 minutes of administration of midazolam through either route.

**Conclusions:** Intranasal midazolam is equally effective as intramuscular in controlling acute seizures in pediatric patients.

**Keywords:** Intranasal Midazolam vs Intramuscular Midazolam, Pediatric Epilepsy.

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### Introduction

Seizures are caused by abnormal electrical discharges from the brain resulting in abnormal involuntary, paroxysmal, motor, sensory, autonomic or sensorial activity [1], associated with significant morbidity and mortality in the pediatric age group. Seizures increase the cerebral metabolic rate exceeding the oxygen and glucose supply to the brain leading to brain ischemia and neuronal death.[2] Thus it is important to control seizures rapidly to minimize the systemic as well as brain

damage. [3] Recently, due to its lipid solubility, 3-4 times more potency (compared to diazepam) and availability of various routes of administration like i.v., rectal, intramuscular and intranasal; use of Midazolam has increased [2]. Currently emphasis is not just on control, but also on the speed of control of acute seizures. Intranasal route assumes more relevance for its convenience in drug administration. Various separate studies of intranasal [5,6,7,8] and intramuscular [5,9,10,11,

12,13] use of Midazolam have found both the routes of administration of to be effective and safe. Hence, the purpose of our study is to compare efficacy of both the routes of administration of Midazolam in aborting acute seizure episodes in children in the age group of 6 months to 12 years presenting to the Emergency department or those developing acute seizure episodes in ward.

**Materials and Methods**

This was a simple randomised trial conducted between October 2018 to December 2020 in a tertiary care centre of Marathwada region. 247 children between age 6 months to 12 years who came in active convulsions were enrolled in the study after approval from institutional ethics committee, amongst which 123 patients received intranasal midazolam and 124 patients received

intramuscular midazolam. The patients who had hypoglycaemia, hypocalcaemia or were treated elsewhere for the present illness and referred were excluded from the study. The sample size was calculated to be 110 in each group. Enrolled patients were block randomised into 2 groups, namely intranasal and intramuscular midazolam group. The patients were given intranasal midazolam as 0.2mg/kg, and 0.2mg/kg via intramuscular route in another group. The time taken to abort an episode of seizure was measured using a stop clock by a trained health care worker. The patient was monitored for vital parameters every 15 minutes and data was collected appropriate statistical tests were used to analyse the data. If the patients require another antiepileptic, and other details including adverse effects were documented.

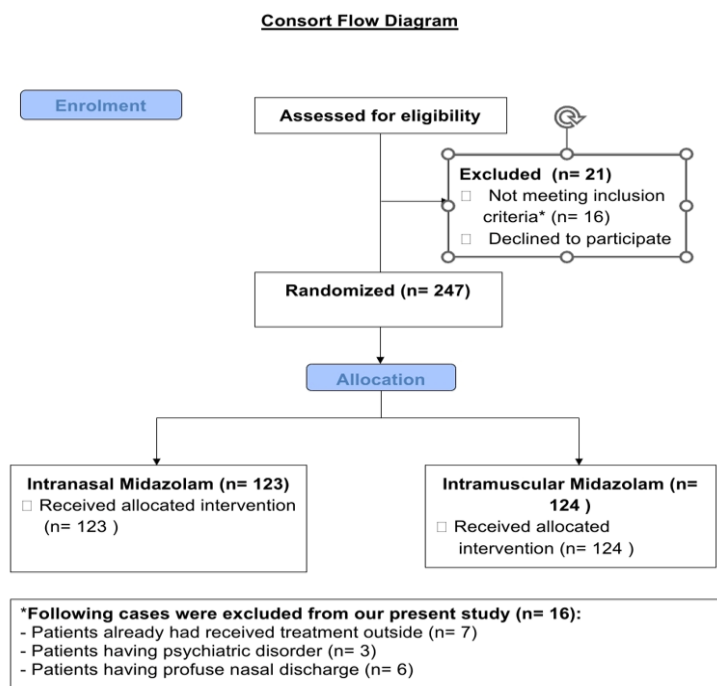


Figure 1:

Table 1: Basic demographic data and diagnosis

Result	Intranasal	Intramuscular	P value
Age			
<1year	1(0.81)	1(0.81)	0.794
1-5years	74(60.16)	78(62.90)	
6-10 years	39(31.71)	33(26.61)	
11-12 years	9(7.32)	12(9.68)	
Gender			
Male	78(63.41)	79(63.71)	0.96
Female	45(36.59)	45(36.29)	
Family history			
Yes	11(8.95)	10(8.06)	0.804
No	112(91.05)	114(91.94)	
Birth history			
Yes	12(9.76)	15(12.10)	0.555
No	111(90.24)	109(87.90)	

Developmental history			
Yes	25(20.33)	29(23.39)	
No	98(79.67)	95(76.61)	0.560
Type of Convulsion			
Focal	9(7.32)	12(9.68)	
GTCS	114(92.68)	110(88.71)	0.659
Others	0(0)	2(1.61)	
Diagnosis			
Febrile	74(60.16)	65(52.42)	
Neuroinfection	16(13.01)	22(17.74)	
Seizure disorder	30(24.39)	34(27.42)	
Other	0.3(2.44)	03(2.42)	0.389
Mean duration of symptoms before administration of drugs	12.86 min	14.77min	0.124

### Results

A total of 247 children of age group 6 months to 12 years were enrolled. Male to female ratio was 1.7:1. Most of the children were from 1-5 years (60%). The 2 groups were having similar baseline characteristics in terms of age, gender, family history, birth history, developmental history and type of convulsion as illustrated in Table 1. In this comparison, and the intranasal administration

shows a statistically significant advantage of shorter duration of administration of drug. Findings of vital parameters in two groups are as per Table No. 2. The readings of heart rate and respiratory rate did not differ statistically. The mode of administration of drug did not differ from each other in terms of treatment failure, i.e., need of second antiepileptic, or any severe side effects.

**Table 2: comparison between intranasal and intramuscular midazolam**

Result	Intranasal midazolam	Intramuscular midazolam	Significance
Mean time from arrival to administration of drug	24.69 sec	28.16 sec	<0.0001
Mean heart rate at the time of convulsions	101.7/min	102.17/min	0.152
At 15 min	95.25/min	95.62/min	0.364
At 30min	90.78/min	91.5/min	0.252
At 60 min	88.55/min	88.58/min	0.489
Mean respiratory rate			
At the time of convulsions	29.98/ min	29.03/min	0.140
At 15 min	25.56/min	25.61/min	0.462
At 30min	23.18/min	23.29/min	0.419
At 60 min	22.39/min	22.72/min	0.240
Recurrence of convulsions within 60 mins			
Yes	10(8.13)	9(7.26)	
No	113(91.87)	115(92.74)	0.797
Need of second anticonvulsant			
Yes	1(0.01)	1(0.01)	
No	122(99.98)	123(99.98)	0.995
Mean Time required from administration of drug to abortion of convulsion			
Focal	233.66 sec	201.5 sec	
GTCS	188.21 sec	191.43sec	
Median Time required from administration of drug to abortion of convulsion			
Focal	230sec	198.5sec	
GTCS	193sec	195 sec	

## Discussion

Seizure is one of the most frequently encountered emergencies in paediatrics in both developed as well as developing countries. Longer the duration of seizure, higher is the risk for neurological damage Administration<sup>20</sup> of antiepileptic drugs to control acute seizures can be a challenging task in ER. Various drugs like diazepam, lorazepam have been used. However, intranasal midazolam is being preferred to treat seizures. [20] Previous studies on use of intramuscular midazolam showed mean time to control seizures being 198 seconds. The mean time to control seizures using intranasal midazolam was 3.5± 1.8 seconds and 3.58 ± 1.68 seconds in studies done by Lahat et al. and Mahmoudian et al. In our study time required was 193 seconds and 195 seconds for intranasal and intramuscular midazolam respectively, which was comparable with previous studies.

Our study also showed that time required to administer the intranasal midazolam (24.68 sec) after arrival was shorter and statistically significant as compared to intramuscular midazolam (28.28 sec). This finding was supported by [14,15,16]

Our study have stated that there were no serious side effects like respiratory depression, bradycardia or need of mechanical ventilation which was comparable to other studies. [17,18]

We found that intranasal midazolam is as effective as intramuscular midazolam for controlling acute seizure. There is adequate literature available stating preferential use of intranasal midazolam, but very few studies have compared intramuscular and intranasal administration.

Our study had few limitations including smaller sample size, and a single centre study.

## Conclusion

The intranasal midazolam is equally effective as intramuscular in controlling acute seizures in paediatric patients with no serious side effects.

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