

Research Article

A STUDY ON EFFICACY OF INTRA-NASAL MIDAZOLAM SPRAY IN PEDIATRIC SEIZURE PATIENTS: A PROSPECTIVE STUDY

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ABSTRACT

An epileptic seizure is brief episodes of abnormal excessive or synchronous neuronal activity in the brain. The effect varies from uncontrolled jerking movements to momentary loss of awareness. The syndrome of recurrent and provoked seizures is termed epilepsy, but seizures can also occur in people who don't have epilepsy it may vary on the patient's genetic susceptibility

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INTRODUCTION

An epileptic seizure is brief episodes of abnormal excessive or synchronous neuronal activity in the brain. The effect varies from uncontrolled jerking movements to momentary loss of awareness. The syndrome of recurrent and provoked seizures is termed epilepsy, but seizures can also occur in people who don't have epilepsy it may vary on the patient's genetic susceptibility

Patients who experience epileptic seizures are in a situation that poses an immediate risk to health, life and therefore they require urgent intervention to prevent the worsening of the situation. Oregon et al was the first to publish on using Midazolam by administering it at a dose of 0.2 mg/kg intranasally (4). Midazolam is shown to be safe and effective in children undergoing diagnostic studies when given intranasally as an anesthetic agent (1).

Midazolam rises briskly in both, plasma and cerebrospinal fluid as readily crosses the nasal mucosa and blood brain barrier. Midazolam when given via the intranasal route can safely be used to treat seizures not only at hospitals but also at the home.(3)

Nasal Midazolam forcibly puts the epileptic activity to an end, prevents its progression and also refines the context of electroencephalogram (EEG) in children with epilepsy (1)

Recent studies have also shown that intranasal Midazolam is safe and effective in management of acute seizures in children. (1)

Intra nasal administration of therapeutic agent is a center of tremendous interest in field of therapeutics (6).

Intra nasal administration of Midazolam reaches the peak concentration at a mean of five minutes in piglets and 1.2 minutes in children (6)

When a drug is given intranasally, a fraction of it is not absorbed through the nasal cavity but it is swallowed to absorb through the gastro intestinal tract. In case of Midazolam is swallowed it is metabolized in the liver before reaching the systemic circulation (first pass metabolism) (6)

This mode of drug delivery may allow practitioner, nurse and eventually parents to administered Midazolam intranasal to children with recurrent seizures (6)

Midazolam given by intranasal route provides the more rapid onset of effect than that of oral and rectal administration (2)

Patient experiencing epileptic seizures have medical emergency and required a prompt care, rectal diazepam has emerged as the primary treatment option of the break

though seizure however rectal diazepam has slower onset of action than that of intra-nasal drug delivery(7)

All benzodiazepines share similar neuropharmacology properties including anxiety reduction, sedation, sleep inducers, anticonvulsant effect and muscle relaxation (5)

Aim: In the present study we aim to study an efficacy and therapeutic outcomes and effects of intra nasal Midazolam spray given for the treatment of febrile seizures in children's

METHODOLOGY

This is an interventional study conducted in a pediatric intensive care of princes Esra hospital after taking an ethical approval from the ethics committee of the hospital.

A total of 102 participants were enrolled in the study out of which 52 were given intra nasal Midazolam and others so were given I.Vlorazepam.

Patient came with seizure actually to the pediatric intensive care of princess Esra hospital were enrolled in the study after Obtaining the inform constant form from the parents. In case of refused of the consent by the parents that case were excluded and the seizure protocol management of the hospital is followed children with an age group from six months to 12 years are included and patients with known case of generalizedclonic tonic seizures, febrile are included where as any patient having nasal infection, nasal pathologic condition and septum deviation were excluded.

Patients with seizures enrolled in the study were stabilized with airway, breathing, circulation (ABC). And excess mucus from the mouth is cleared with suction catheter and monitored for seizure cessation, heart rate, respiratory rate and oxygen saturation levels.

Then they were given intra nasal Midazolam according to body weight as shown in below.....

Intranasal spray of Midazolam is given in a dose of 0.2mg/kg. Half dose is sprayed in each nostril as shown in table.....

In case if seizures does not respond to intranasal Midazolam and alternate drug is given intravenously after being seizures are controlled they were manage accordingly data regarding the drug, dose and patient condition is filledup by the pediatrician in a designed questioners and data was recorded in terms of yes or no replies.

Statistical methods:

Descriptive statistical analysis have been carried out using Microsoft excel spread sheet and ms word to generate graph and tables for the present study .results on continuous measurement are presented in frequencies and percentages.

RESULTS

A total of 52 patients were included in the study which comprises of 16 males and 36 females. Average age and weight are depicted in table 1.Family history of seizures was seen in just 6 of the total 52 patients. Co-morbidities associated with the patients are represented in table 2.

Thirty five patients were found to be using anti-epileptics prior to their admission into the hospital. The different anti-epileptics used and their compliance are represented in table 3.

Out of the total 52 patients, varied numbers of episodes were experienced by each patient ranging from one to five as shown in table 4. On an average, 3.06 episodes were experienced by these patients. Duration of each episode lasted in between two to five minutes (table

5) with an average duration of 2.75 minutes. Thirty one cases of convulsions were associated with fever whereas the remaining twenty one cases were caused without fever. Different types of seizures experienced by the patients are shown in table 6. Each patient was treated initially with minimum dose of Midazolam, but positive results were obtained from 75% of the patients. Remaining patients were given maximum dose, from which 6 patients were controlled. Rest of the patients was given alternate drug therapy as represented in table 4.

Table 1: Patient details

Patient Demographics	
Sex	
Male	16 patients
Female	36 patients
Age	
Average age	3.11 years
Sd	2.616
Range	8.83 years (2 months to 9 years)
Weight	
Average weight	13.36 kg
Sd	5.049

Table 2: Patient details

Co-morbidities	Patients
CP	5
HD	9
Oth	38

Table 3: Anti-epileptics history

	Drugs	No. of patients	Drug compliance
Single	Frisium	13	13
	Eptoin	10	8
	Valparin	5	5
Multiple	Eptoin/ Valparin	2	0
	Frisium/ Eptoin/ Valparin	5	5
Total		35	31

Table 4: Seizure episodes

No. of episodes	Patients
1	2
2	17
3	15
4	12
5	6
Total	52

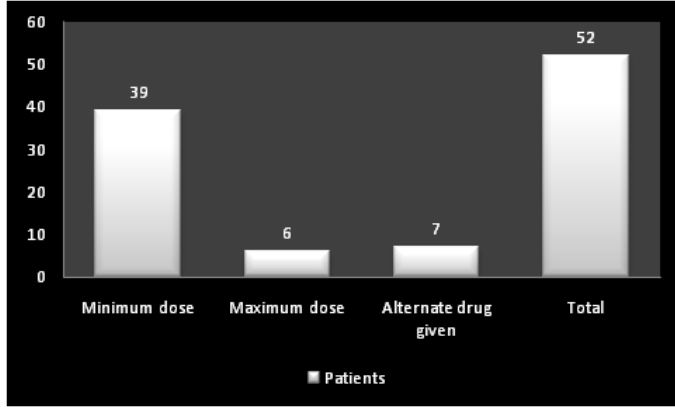
Table 5: Seizure duration

Duration in min	Patients
1	0
2	27
3	18
4	0
5	7
Total	52

Table 6: Diagnosis

Diagnosis	No. of patients
SF	20
HD	9
GCTS	8
Oth	9
Men	6
Total	52

Table 7: Treatment



REFERENCES

1) Lahat, E., Goldman, M., Barr, J., Bistrizer, T., & Berkovitch, M.. (2000). Comparison Of Intranasal Midazolam With Intravenous Diazepam For Treating Febrile Seizures In Children: Prospective Randomised Study. *BMJ: British Medical Journal*, 321(7253), 83-86.

2) Björkman S, Rigemar G, Idvall J. Pharmacokinetics of midazolam given as an intranasal spray to adult surgical patients. *Br J Anaesth.* 1997 Nov;79(5):575-80. Timothy R. Wolfe and Darren A. Braude. Intranasal Medication Delivery for Children: A Brief Review and Update. *Pediatrics* 2010 ; 126 ; 532 ; originally published online August 9, 2010 ; DOI: 10.1542/peds.2010-0616v

3) Daniel P. Wermeling. **Intranasal delivery of antiepileptic medications for treatment of seizures.** *Neurotherapeutics.* April 2009, Volume 6, Issue 2, pp 352-358

4) Riss J, Cloyd J, Gates J, Collins S. Benzodiazepines in epilepsy: pharmacology and pharmacokinetics. *Acta Neurol Scand* 2008; 118: 69-86. DOI: 10.1111/j.1600-0404.2008.01004.x

Van Stuijvenberg M, deVos S, Tjiang GC, Steyerberg EW, Derksen- Lubsen G, Moll HA. Parents' fear regarding fever and febrile seizures. *Acta Paediatr* 1999;88:618-22.

5) Janki Pancha¹, Khyati Kakkad, Prashant Kariya, Prakash Patel. Comparative Study Of Intranasal Midazolam And Intravenous Benzodiazepines In Control Of Seizures In Children. Volume 3, Issue 1, Jan - March 2013, PP 30-33.

6) Acworth JP ,Purdie D, Clark RC. Intravenous ketamine plus midazolam is superior to intranasal midazolam for emergency paediatric procedural sedation. *Emerg Med J.* 2001 Jan;18(1):39-45.

7) Ari Kupietzky, DMD, MSc Milton I. Houpt, Midazolam: a review of its use for conscious sedation of children. **Pediatric Dentistry: July/August** 1993 - Volume 15, Number 4 , 237-241.

8) Dr. Pradipta Bhakta 1 Dr. B. R. Ghosh 2 Dr. Manjushree Roy 3 Dr. Gouri Mukherjee. Clinical Investigation Evaluation Of Intranasal Midazolam For Preanesthetic Sedation In Paediatric Patients *Indian J. Anaesth.* 2007; 51 (2) : 111 - 116.

9) Mohsen Javadzadeh, MD; Kourosh Sheibani, MD; Mozghan Hashemieh, MD, and Hedyeh Saneifard, MD. Intranasal Midazolam Compared with Intravenous Diazepam in Patients Suffering from Acute Seizure: A Randomized Clinical Trial. *Iran J Pediatr* Mar 2012; Vol 22 (No 1), Pp: 1-8.

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