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Efficacy of Buccal Midazolam in the Management of Acute Convulsion

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ABSTRACT

Introduction: Seizure is the most common neurological medical emergency in pediatric practice. Midazolam is a potent anticonvulsant and is rapidly absorbed from the rectal, nasal, and buccal mucosa. Due to lack of availability of nasal midazolam, sufficient studies and data regarding efficacy of use of buccal midazolam in resource poor country like Nepal, we are still uncomfortable with use of buccal midazolam in acute management of convulsion.
Objectives: The objective of this study was to evaluate the efficacy of buccal midazolam in controlling acute seizures in children as well as neonates attending pediatric department, neonatal intensive care unit, pediatric intensive care unit and emergency.

Methodology: It was a descriptive cross-sectional prospective study. Total of 38 patient were enrolled by nonprobability consecutive sampling. Injection midazolam was used through buccal route at a dose of 0.3-0.5 mg/kg. Data were collected using a pre-tested questionnaires'. SPSS version 25 was used for statistical analysis of the collected data using appropriate statistical tests.

Results: Among the 38-enrolled study population GTCS (generalized tonic- clonic convulsion) was the commonest form of seizure 32(84.21%). The most common cause of convulsion was simple febrile convulsion with viral fever 15(39.4%). Total 36 out of 38(94.7%), had seizure controlled within 5 minutes and only 2out of 38(5.3%) had no control of seizure with buccal midazolam. The most commonly observed side effect was sedation 31/36(86.1%) among the study population.

Conclusion: Buccal midazolam seemed effective in management of acute convulsion. Use of buccal midazolam, will save our human resources involved in IV cannulation and prompt our drug administration time leading to early cessation of seizures.

Introduction

Benzodiazepines, given via the intravenous or rectal route have generally been used as first-line drugs. Midazolam is a potent anticonvulsant, rapidly absorbed from the rectal, nasal, and buccal mucosa.[1] Buccal midazolam is one such alternative in acute convulsion. Nasal and buccal midazolam is being used as first line treatment in management of acute convulsion abroad.[2] Studies suggest that buccal midazolam is as effective as rectal diazepam at resolving seizures, if not more effective, and that buccal midazolam is probably the preferred option.[3] But due to lack of availability of nasal midazolam and data regarding efficacy of use of buccal midazolam in resource poor country like Nepal, we are still uncomfortable with use of buccal midazolam in acute management of convulsion. Nasal and buccal midazolam is being used as first line treatment in management of acute convulsion abroad. It would be a pioneer study in Nepal regarding the use of buccal midazolam for control of acute convulsion. Also in small children, IV access can be

difficult and time consuming. If we start using buccal midazolam for acute convulsion management, it will help us to save our human resources involved in IV cannulation and will prompt our drug administration time leading to early cessation of seizures in such neurological emergency. This study aims to evaluate the efficacy of buccal midazolam in controlling acute seizures in children as well as neonates attending pediatric department, neonatal intensive care unit, pediatric intensive care unit and emergency of Birat Medical College Teaching Hospital.

Methodology

It was a cross-sectional prospective study among pediatric patients and neonates admitted with acute convulsion or developed convulsion during the hospital stay. Also, in admitted patients already on anticonvulsant, seizure re-occurred were included and acute management of seizure were done by buccal midazolam. Also, patients admitted through emergency who presented with convulsion were enrolled. With permission from Head of the department and treating consultants of the department, a consensus regarding acute management of convulsion with buccal midazolam was made. The junior residents, emergency attending doctors and doctors on the floor and staffs were trained regarding the delivery of drugs. This was circulated to emergency, PICU, NICU and pediatric Ward. Injection midazolam was used with a dose of 0.3-0.5 mg/kg. For neonates and infants up to 3 months of age dose was calculated strictly based on their body weight. For ease of practice and because a child with active convulsion is difficult to weight, the following doses for buccal midazolam: 2.5 mg for children aged 3-12 months, 5 mg for 1-4 years, 7.5 mg for 5-9 years, and 10 mg for 10 years or older was used. The drug was administered by trained personnel. As soon as the decision to treat was made, buccal midazolam in the appropriate dose was drawn into a syringe. Patients received buccal midazolam by placing the syringe between their teeth and cheek, and after drug administration the cheek was gently massaged. Patients were followed up for at least 48 hours post drug administration. Data regarding particulars of the patient, type of seizure, duration of seizure, time consumed for drug administration, time since drug administration to cessation of the seizure, any adverse effects if noticed and its management were recorded from the inpatient documents and if needed was enquired from the attending doctor and nursing staffs. Data collection tool was a pre-tested questionnaire. Data were presented in tabular form edited manually. The entered data were checked, verified and analyzed by computer-based programme statistical package for social science (SPSS) for windows version 25.

Results

Among the 38-enrolled patient most of them were in the age range 1-5 years 29(76.4 %) with mean age of 2.05±0.56 years, male: female ratio of 1:1.5(Table 1). Similarly, table 2 shows the different types of seizures among the study population. GTCS (generalized tonic clonic convulsion) was the commonest form of seizure 32(84.21%) among the study population (Table 2). Similarly, table 3 shows different causes of convulsion among the study population. The most common cause of convulsion was simple febrile convulsion with viral fever 15(39.4%). Among the study population 36 out of 38(94.7%), had seizure controlled within 5 minutes and only 2out of 38(5.3%) had no control of seizure with buccal midazolam. The most common observed side effect was sedation 31 out of 36(86.1%) among the study population (Table 4).

68 (patient admitted with seizure during study period)

↓ 20 Patients received injectable antiepileptic prior to presentation in emergency and excluded

↓ 5 Patient received injectable midazolam in BMCTH emergency due to non-adherence to the departmental protocol of giving oral midazolam and were exclude

Total 43

↓ 5 Patient couldn't be enrolled because they left against medical advice

38(received buccal midazolam and were enrolled and analyzed

Table1: Flowchart of enrollment of study population

Variable	Frequency	Percentage (%)
Age		
<1 yrs.	4	10.5
1-5 yrs.	29	76.4
6-10 yrs.	4	10.5
>10 yrs	1	2.6
Mean ±SD	2.05±0.56	
Sex		
Male	14	36.8
Female	24	63.2
Male: female ratio	1:1.5	
Type of seizure		
GTCS	32	84.21
Subtle	4	10.52
Focal	2	5.26

Table 2: Demographic and clinical characteristics of the study children (n=38)

Diagnosis	Frequency	Percentage
Simple febrile convulsion with viral fever	15	39.4
Complex febrile convulsion with URTI	11	28.9
Simple febrile convulsion with UTI	2	5.2
Epilepsy	1	2.6
Hypomagnesemia	1	2.6
Meningoencephalitis	1	2.6
EONS with Perinatal asphyxia with HIE stage 2	1	2.6
LONS with meningitis	2	5.2
LONS with hypoglycemia	1	2.6
EONS with hypoglycemia	1	2.6
Neurocysticercosis	1	2.6
VitaminB12 deficiency	1	2.6

Table 3: Diagnosis of the study population who presented with convulsion

Parameters	Convulsion control group	Convulsion not controlled group
Frequency of control of convulsion	36/38(94.7%) (within 5 minutes)	2/38(5.3%) (in >5 minutes)
Adverse Effects		
Sedation	31/36(86.1%)	2/2(100%)
Respiratory depression	4/36(11.1%)	0/2
Low BP	4/36(11.1%)	0/2
Nausea and vomiting	6/36(16.6%)	1/2(50%)

Table 4: Control of convulsion and observed adverse effects among convulsion control and not controlled group

Discussion

Benzodiazepines, given via the intravenous or rectal route have generally been used as first-line drugs. Midazolam is a potent anticonvulsant and is rapidly absorbed from the rectal, nasal, and buccal mucosa.[1] Buccal midazolam is one such alternative in acute convulsion. Nasal and buccal midazolam is being used as first line treatment in management of acute convulsion abroad.[2] Studies suggest that buccal midazolam is as effective as rectal diazepam at resolving seizures, if not more effective, and that buccal midazolam is probably the preferred option.[3] But due to lack of availability of nasal midazolam and data regarding efficacy of use of buccal midazolam in resource poor country like Nepal, we are still uncomfortable with use of buccal midazolam in acute management of convulsion.

So, we aimed to see the effectiveness of buccal midazolam in controlling acute convulsion among patients admitted in pediatric ward, Pediatric intensive care unit and neonatal intensive care unit of Birat Medical College Teaching Hospital (BMCTH). No previous such studies were performed at the Pediatrics Department of BMCTH. The first and pioneer such study at BMCTH showed that among the 38 enrolled patient most of them were in the age range 1-5 years 29(76.4 %) with mean age of 2.05±0.56 years, male: female ratio of 1:1.5(Table 1). Ashrafi et al., and Mpimbaza et al., conducted similar studies to see efficacy of buccal midazolam among pediatrics patient above 3 months but in our study, we have enrolled neonates as well [1,2]. Buccal midazolam was found equally effective in control of acute convulsion with only few adverse effects among neonates as well. There are very few studies to see effectiveness of buccal midazolam in acute neonatal seizure till now. Similarly, table 2 shows the different types of seizures among the study population. GTCS (generalized tonic clonic convulsion) was the commonest form of seizure 32(84.21%) among the study population (Table 2). Ashrafi et al., Mpimbaza et al., Doose et al., and Tonekaboni et al., in similar studies found generalized tonic clonic convulsion as the most common form of seizure in pediatrics which is similar to finding in our studies.[1,2,3,4] Similarly, table 3 shows different causes of convulsion among the study population. The most common cause of convulsion was simple febrile convulsion with viral fever 15(39.4%). Mpimbaza et al., Doose et al., Tonekaboni et al., and McIntyre J also in their similar studies concluded febrile seizure is the common cause of seizure among pediatrics patients which is similar to our study. [2,3,4,5] But in study done by Mpimbaza et al., a study from Uganda, common cause of fever was malaria which is endemic for malaria but in our study common cause for febrile seizure was Viral fever. In a similar study done by Lahat Eat al., showed upper respiratory tract infection as the common cause of febrile seizure among the enrolled patients from Korea. Among the study population 36 out of 38(94.7%), had seizure controlled within 5 minutes and only 2 out of 38(5.3%) had no control of seizure with buccal midazolam. The most common observed side effect was sedation 31 out of 36(86.1%) among the study population (Table 4). Our results are comparable to previous studies. In a randomized trial reported by Scott RC et al., buccal midazolam was used to treat 40 seizures in 14 students. In their study, midazolam ceased 75% of the seizures.[7] In another study by Kutlu NO et al., the efficacy of buccal midazolam was examined in children with prolonged seizures. Nineteen children with prolonged seizure were treated with buccal midazolam with a dose of 0.3 mg/kg. Of these 19 seizures, 16 (84.2%) ceased within 10 min of buccal midazolam administration. In their study, all patients with convulsions shorter than 30 min showed a complete response (100%) and no clinically important adverse effects were seen in any patients.[8] In a randomized controlled trial reported by McIntyre J et al., the safety and efficacy of buccal midazolam versus diazepam for emergency treatment of seizures in children were studied. In their study, 219 separate episodes of seizures in 177 patients were treated. The cut-off point for seizure control was 10 min after drug administration. Therapeutic success was 56% (61 of 109) for buccal midazolam. Buccal midazolam was not associated with more adverse effects. A randomized clinical trial was performed in Ugandan children by Mpimbaza A et al. They compared buccal midazolam with rectal diazepam in the treatment of prolonged seizures in children. In their study, malaria was the most common (67.3%) underlying etiology for acute prolonged seizures. This was a single-blind trial and 330 patients were enrolled. Treatment failure occurred in 50 (30.3%) of 165 patients who received buccal midazolam.[2,5,7,8] Respiratory depression occurred infrequently. The researchers concluded that buccal midazolam was safe and effective in controlling acute convulsion in children. But when children with malaria were excluded the effectiveness of buccal midazolam was increased to 60 % and this low effectiveness could be due underlying etiology for seizure.

Similarly, Wilson MT et al., carried out a telephone survey to evaluate the effectiveness and convenience of nasal/buccal midazolam in terminating prolonged seizures in the community. In this survey, 40 families were evaluated. A total of 33/40 (83%) families who had used it found it effective and easy to use.[9] The results of our study must be interpreted in the face of certain limitations. This study was not blinded and had no control group. Doses of drugs in our study were comparable to those in previous studies. Dose calculated according to body weight so there would have been less possibility of dose related adverse effects. There were no significant differences in sedation episodes in term and preterm infants. We were able to conclude that buccal

midazolam is effective in control of acute convulsion in childrens as well as neonates. This has built up confidence among the junior doctors of pediatrics department at Birat Medical College Teaching Hospital to use buccal midazolam in acute convulsion. After this study we were able to develop a departmental protocol to use buccal midazolam for acute convulsion in pediatrics at Birat Medical College Teaching Hospital without rushing out for difficult intravenous canulation in emergency situation like convulsion.

Conclusion

Buccal midazolam seemed effective in management of acute convulsion among the study population. So, we can start using buccal midazolam for acute convulsion management in pediatric patients as well as neonates, it will help us to save our human resources involved in IV cannulation and will prompt our drug administration time leading to early cessation of seizures in such neurological emergency.

This has built up confidence among the junior doctors of pediatrics department at Birat Medical College Teaching Hospital to use buccal midazolam in acute convulsion. After this study we were able to develop a departmental protocol to use buccal midazolam for acute convulsion in pediatrics and neonates as well at Birat Medical College Teaching Hospital without rushing out for difficult intravenous canulation in emergency situation like convulsion.

Limitation of the Study

It was a single-centered, small study population, non-blinded study and no control group were all limitations in our study. As seen from the study most of the seizure are febrile seizure, there may be high chances of spontaneous resolution which we could not differentiate because we treated all the seizure episodes despite underlying pathalogy. May be another study can be conducted to see whether febrile seizure resolves on its own or not without treatment. Hence, large scale, multicenter prospective studies comparing effectiveness and ease of use of buccal midazolam with that of injectable midazolam will be needed to validate our findings.

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Conflict of Interest: None

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