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Research Article

Intranasal Midazolam V/S Intranasal Ketamine as Pre Medication in Paediatric Patients: A Comparative Study

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Abstract: A relaxed and calm child coming into the operating room is a welcome sight and goes a long way to help in smooth induction, maintenance and also post operative outcome. One of the methods is preanaesthetic medication in children aiming to relieve the anxiety and to calm the child. This should facilitate induction of anaesthesia without prolonging the recovery. Intranasal route to administer the premedication is accepted and easy to administer in children. The aim of our study was to evaluate & compare the efficacy of intranasal Ketamine & intranasal Midazolam as premedication in paediatric patients. Patients were randomly allocated to two groups of 30 each, receiving intranasal pre medication, group K received intranasal Ketamine (drops) 5mg/Kg with intranasal Glycopyrrolate 0.2 mg, group M received intranasal Midazolam (drops) 5mg/kg. Sedation in children was measured using Ramsay Sedation Scale. Both Midazolam and Ketamine produced rapid and adequate sedation before the child was shifted into the operating room. Quality of sedation was better with intranasal Ketamine enabling easier parental separation. We found that intranasal route is a convenient and safe route for premedication in children.
Keywords: Sedation, Intranasal Ketamine, Intranasal Midazolam

INTRODUCTION

Maternal deprivation and fasting are the major challenges in paediatric anaesthesia. This leads to anxiety and psychological trauma. Preanaesthetic medication in children should aim to relieve this anxiety and calm the child. This also should facilitate induction of anaesthesia without prolonging the recovery. It should have an acceptable non-traumatic route of administration in order not to add extra stress to the child.

The studies have shown that intranasal route is an effective way to administer premedication and sedation to children. It is relatively easy, noninvasive route. Has rapid onset of action due to rich blood supply of nasal mucosa & bypassing the first pass hepatic metabolism makes the drug highly bio-available.

Midazolam is water soluble benzodiazepine with rapid onset & short duration of action. It produces amnesia and anxiolysis. It can be administered by intranasal, intramuscular, intravenous, oral and per rectal routes. Intranasal and intravenous routes are being faster than other routes.

Ketamine is a phencyclidine derivative. It antagonizes the N-methyl D-aspartate (NMDA) receptor. It produces sedation, analgesia, preserves upper airway muscle tone & respiratory drive. It can be administered by intranasal, intramuscular, intravenous, transcutaneous, oral, per rectal routes, epidurally or intrathecally as preservative free solution. Intranasal Ketamine has onset time close to intravenous administration.

Aims and Objective

This study was undertaken to evaluate and compare the efficacy of intranasal Ketamine and intranasal Midazolam as premedication in paediatric patients and to observe the sedative and adverse effects of these drugs.

MATERIAL AND METHODS

This prospective randomized comparative clinical study was undertaken in Vani Vilas Hospital in the year 2013. Institutional ethical committee clearance and informed written consent from guardian/parents was obtained. Sixty children were randomized and allotted

to two groups of 30 each; Ketamine group and Midazolam group. This sample size was determined with a power of study at 80% & confidence interval at 95% to detect 25% difference in sedation scores between the 2 groups. Though the sample size of 23 in each group was obtained, we selected 30 patients in each group for better validation of results. Data was analysed using standard statistical analysis like student 'T' test & chi-square test.

Patients in the age group between 2 & 8years, belonging to ASA I, posted for various surgical procedures was included in the study. Patients in ASA II or more and with any co-morbidity were excluded from the study. The Ketamine group were administered intranasal Ketamine (drops) 5mg/kg with intranasal Glycopyrrolate 0.2mg, 30mins before surgery. The Midazolam group were administered intranasal Midazolam (drops) 5mg/kg, 30mins before surgery. Pulse Oximetry, Heart rate, Respiratory rate were recorded. Sedation score as per Ramsay Sedation scale (RSS) were recorded at 0, 15^{th} and 30^{th} min.

Ramsay sedation scale:

- Anxious or restless or both.
- Co-operative, oriented, and tranquil.
- Responding to commands.
- Brisk response to stimulus
- Sluggish response to stimulus.
- No response to stimulus.

RESULTS

In our study the demographic variables viz;age,weight and gender distribution are comparable in the two groups with a P value of 0.325 (Table 1). There is significant change in heart rate between the two groups from 0 to 30 mins, Midazolam group showing a reduction in heart rate of about 10% (Table 2). Saturation was maintained and comparable in both the groups (Table 3).There is a slight decrease in the respiratory rate in Midazolam group where as the Ketamine group showed no change (Table 4). Sedation achieved is comparable in both the groups (Table 5).The children were co-operative,oriented,tranquil and responding to verbal commands at the end of thirty mins in both the groups.

Table 1: Age distribution of the study population (n=60)

Age group	M group N (%)	K group N (%)	Total N (%)
2-4 years	17 (56.7)	12 (40)	29 (48.3)
5-6 years	4 (13.3)	8 (26.7)	12 (20)
7-8 years	9 (30)	10 (33.3)	19 (31.7)
Total	30 (100)	30 (100)	60 (100)

Mean age (± S.D): 4.85 (2.34) years, minimum: 2 years, maximum: 8 years; Chi square p value: 0.325

Table 2: Heart Rate

Group	Mean HR at 0 mins	Mean HR at 15 mins	Mean HR at 30 mins
Midazolam	119.37	108.63	101.40
Ketamine	100.53	111.93	114.73
Mean difference (M-K)	18.83	-3.30	-13.33
p value	<0.001	0.370	<0.001

Table 3: Saturation

Group	Mean SA at 0 mins	Mean SA at 15 mins	Mean SA at 30 mins
Midazolam	98.9	98.27	98.70
Ketamine	99.6	99.77	99.87
Mean difference (M-K)	-0.7	-1.5	-1.16
p value	0.001	<0.001	<0.001

Table 4: Respiratory rate

Group	Mean RR at 0 mins	Mean RR at 15 mins	Mean RR at 30 mins
Midazolam	22.4	19.8	18.7
Ketamine	14.3	14.4	14.9
Mean difference (M-K)	8.06	5.4	3.86
p value	<0.001	<0.001	<0.001

Table 5: Sedation score

Group	Mean SS at 0 mins	Mean SS at 15 mins	Mean SS at 30 mins
Midazolam	1.10	1.97	2.33
Ketamine	1.13	1.73	2.50
Mean difference (M-K)	-0.033	0.233	-0.167
P value	0.69	0.01	0.25

DISCUSSION

Frank Weber, Hinner Wulf *et al*. found that intranasal administration of s-ketamine and midazolam is an appropriate premedication in preschool children [1]. García-Velasco P *et al*. found that Ketamine compared with Midazolam for premedication, both by nasal route and concluded that 5mg/kg intranasal Ketamine was effective and sedation was found to be rapid [2]. Natan Weksler *et al*. Nasal Ketamine is a good alternative to injectable route of pre medication [3]. Parag Gharde, Sandeep Chauhan *et al*. Intranasal ketamine is better than intranasal Midazolam. The combination of two is better than midazolam alone but provides no benefit as compared with ketamine alone [4]. Shailendra Nath Gautham *et al*. Compared Nasal route of Midazolam Vs Ketamine and opined that the sedation parameters were comparable [5]. Namitha *et al*. Atomised midazolam at 0.3 mg/kg is safe, and achieves faster sedation and better separation scores as compared to 0.2 mg/kg [6].

Pre-operative anxiety along with fasting is highly stressful in young children. It can have long lasting adverse effect on their personality development. To reduce the stress and make the parental separation easier, it is essential to premedicate the children with anxiolytic sedatives. Administration of the premedicant by intranasal route is easy, safe and provides greater bioavailability. In our study we observed that premedication with intranasal ketamine and intranasal midazolam are both effective for the purpose of sedation. In accordance with the above studies, with respect to sedation scores, it was observed in our study that both intranasal ketamine and intranasal midazolam achieved adequate sedation and alleviation of anxiety and stress within 30 mins after administration. Parental separation was not resisted by the children. We also found that these premedicants facilitate smooth induction. The recovery is prompt and complete. However intranasal ketamine achieves better quality of sedation enabling smoother parental separation.

CONCLUSION

Premedication with intranasal ketamine and intranasal midazolam are both equally effective for the purpose of sedation. Intranasal ketamine achieved better quality of sedation enabling easier parental separation. We found that intranasal route is convenient and safe route for premedication in children. There were no side effects like excessive sedation or respiratory depression in our study the children in both the study groups, were oriented, tranquil and co-operative before shifting to the operating room.

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