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Original Research Article

Comparative study of the effects of intranasal midazolam with intranasal dexmedetomidine as premedication in paediatric anaesthesia

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ABSTRACT

Background: Premedication in children is more acceptable with the intranasal route. In this study, we evaluated the efficacy of intranasal dexmedetomidine as premedication in paediatric surgeries as compared to intranasal midazolam.
Methods: This study was conducted in 60 patients of 6 to 12 years posted for tonsillectomy surgeries. Patients were randomly allocated into Group 1 and 2. Patient in group 1 (30) received 0.2mg/kg of intranasal midazolam as nasal drop using 1ml insulin syringe and similarly group 2 (30) received 1µg/kg of intranasal dexmedetomidine as nasal drops using 1ml insulin syringe. Sedation score, Anxiolysis score, pre oxygenation mask holding response score, post-operative agitation scores were evaluated.
Results: In our study, we observed that 76.7% of children in dexmedetomidine group attained better sedation compared to 46.7% in midazolam group. Anxiolytic effect in Group 1 (83.3%) was slightly better than in Group 2 (80%). 90% of the patients in dexmedetomidine group allowed easy pre oxygenation compared to 80% in midazolam group. Venipuncture response was better with dexmedetomidine group (86.7%) compared to midazolam group (73.3%). Postoperative agitation response in both the groups was same. The fall in HR, SBP was more with dexmedetomidine and there was no significant change in DBP in both the groups.
Conclusions: From our study, we concluded that premedication with intranasal dexmedetomidine is more effective than intra nasal midazolam in providing sedation. Both the drugs are effective in providing anxiolysis and better inducing condition. Therefore, intranasal dexmedetomidine is more efficacious than intranasal midazolam as premedication in children.

Keywords: Anaesthesia, Dexmedetomidine, Intranasal, Midazolam, Paediatric, Premedication

INTRODUCTION

Pre-anaesthetic medication in paediatric patients is a challenge for anaesthesiologists. Surgery and anaesthesia induce considerable emotional stress upon children.[1] The consequences of this stress remain in the child's psyche for long time even after the hospital experience has passed.[2] A distressed child is at risk for potentially hazardous psychological and physiologic sequel. The age of the child, family characteristics, illness and hospital stay all contribute to the degree of distress. The sympathetic, parasympathetic, and endocrine systems are stimulated by preoperative anxiety, which raises blood pressure, heart rate, and cardiac excitability. Children aged two to five years are especially vulnerable to these problems, since their understanding is limited.

A peaceful separation of the child from the parent is the definition of successful premedication. Premedication

helps to alleviate the stress and fear of treatment as well as to ease child-parent separation and promote a smooth induction of anaesthesia.[3-6]

For paediatric patients, tonsillectomy (with or without an adenoidectomy) is one of the most common surgical operations done. The goals of pre-anaesthetic medication for children include allaying anxiety and facilitating smooth induction of anaesthesia and preventing postoperative psychological sequel.[7]

The premedication should have few side effects and be palatable, acceptable, fast acting, and dependable. Children have been premedicated with a variety of medications. There is no single premedication with all the ideal characteristics. The commonly used premedication drugs in children are benzodiazepines like midazolam, opioids like fentanyl and sufentanil, phencyclidine derivative like ketamine, short acting barbiturates like pentobarbital. Opioid premedication can result in unpleasant dysphoria and increased incidence of preoperative and postoperative vomiting and significant respiratory depression. Ketamine is most likely to prolong recovery and delay discharge from the post-anaesthesia room. The barbiturates Group 1rugs like pentobarbital produces a prolonged effect as the metabolism of this drug is very slow. Also, the barbiturates have no analgesic properties and when these drugs are given to children who have pain, they may develop restlessness, excitation and irrational behaviour.[8]

Midazolam, a γ-amino-butyric acid (GABA) receptor inhibitor is a commonly used sedative drug for premedication in children. It provides effective sedation, anxiolysis, and varying degree of antero-grade amnesia. Oral, rectal, intravenous, intramuscular and sublingual routes for pre medication have been tried. However, each route has its own disadvantages. The intramuscular route is painful. Unpredictable absorption and pain for the child are linked to rectal administration. Oral route has got low bioavailability due to high first pass metabolism and also bitter taste which is a disadvantage in children. In sublingual route, the drug must be held under the tongue for at least thirty seconds**,** which requires co-operation and is difficult to achieve in children. Owing to high vascularity in nasal mucosa, pre-anaesthetic medication administered nasally has rapid and reliable onset of action. A recent evidence based clinical update has shown that intranasal midazolam 0.2 mg/kg is effective in reducing both separation and induction anxiety in children, with minimal effect on recovery time.[9]

Clonidine, an α 2-agonist, has been suggested as another option for premedication in children and previous studies have shown it to be equally as effective as midazolam. Premedication with clonidine (α2-agonist), applied via various routes has exhibited superior sedative effects and decreased the incidence of agitation at emergence, and achieved more effective early postoperative analgesia, compared to midazolam.[10,11]

A more recent α 2-agonist with a shorter half-life and a more focused effect on the α 2-adrenoceptor is dexmedetomidine.[12] It has a bioavailability of 81.8% (72.6-92.1%) when administered via the nasal mucosa.

The objective of the study was to compare the effects of intranasal dexmedetomidine with that of midazolam regarding degree of sedation, ease of parental separation, response to venipuncture, response to pre-oxygenation mask holding and post-operative agitation. Studies to compare the sedative effects of midazolam and dexmedetomidine administered intra nasally as pre-anaesthetic medication have been scarcely done and hence, we sought to do the study.[13-15]

METHODS

This study was conducted in 60 children undergoing elective tonsillectomy surgeries under general anaesthesia in Department of Anaesthesiology, Kempegowda Institute of Medical Sciences, Bangalore after getting approval from the institution's ethical committee. The study was conducted in two study groups (30 each) of ASA 1 and 2 children of either sex, between 4-10 years of age undergoing tonsillectomy between December 2014 to April 2016. Patients with rhino- pharyngitis, history of allergy to study drugs, chronic illness and congenital heart diseases, cardio-respiratory problems and hepatic and renal diseases were excluded from the study.

Sample size

Total 60 patients were randomized to two groups of 30 each to receive one of the following as premedication: 1) GROUP 1 (n=30) received 0.2mg/kg of intranasal midazolam, 2) GROUP 2 (n=30) -received 1µg/kg of intranasal dexmedetomidine

Procedure

Preoperatively all patients' parents were explained in detail about the premedication, the anaesthetic procedure and informed written consent was obtained. A detailed pre anaesthetic evaluation was done and appropriate laboratory and radiological investigation were done. All patients were kept NPO for a period of 8hours prior to surgery. The children were randomly allocated to one of two groups by a computer-generated table of random numbers. In the preoperative holding area, routine monitors (NIBP, ECG, SpO_2) were connected and baseline parameters were recorded.

All the children received intranasal medication 30 minutes before induction of anaesthesia. Patient in group 1 (30) received 0.2mg/kg of midazolam administered intra nasally as nasal drop using 1ml insulin syringe attached to intranasal atomizer spray and similarly group 2 (30) received 1µg/kg of dexmedetomidine using 1ml insulin syringe attached to atomizer spray. Sedation status was assessed by a blinded observer every 15 minutes

with a six- point sedation scale and the level of anxiety was evaluated every 15 minutes using a four- point scale. After 30 minutes of intranasal drug admission, patients were shifted to operating room. Child's response to venipuncture and pre-oxygenation mask holding were scored. Post-operative agitation was scored with a three-point scale.

RESULTS

Table 1 presents the baseline characteristics of patients before the initiation of treatment, categorized into two groups: Group 1 and Group 2. The variables examined include sex, age, and weight, with corresponding values provided for each group. The distribution of males and females is similar between the two groups, and the p value of 0.787 suggests that there is no statistical significance. The average age in both groups is quite close, and the p value of 0.729 indicates that there is no significance. The mean weight in both groups is similar, and the p value of 0.928 suggests that there is no statistical significance.

Table 1: Baseline characteristics of patients in before initiation of treatment.

Variables		Group 1 (%)	Group 2 (%)	P value
Sex	Male	10 (33.3)	11 (36.7)	0.787
	Female	20 (66.7)	19 (63.6)	
Age (in years)		7.2±1.9	7.1±1.9	0.729
Weight		20.4±5.7	20.5±5.8	0.928

Table 2 provides a comprehensive comparison of hemodynamic, intraoperative, and postoperative data between Group 1 and Group 2. The variables examined include heart rate, systolic blood pressure, diastolic blood pressure, and oxygen saturation (SpO2%) at various time points throughout the surgical process.

For heart rate, no statistically significant differences were observed between Group 1 and Group 2 at any of the measured time points, including preoperative, 15 minutes, 30 minutes, induction, and postoperative (after 10 minutes). Systolic blood pressure in Group 1 and Group 2 showed no significant differences preoperatively, at 15 minutes, at 30 minutes, and postoperatively (after 10 minutes). However, a statistically significant difference ($p = 0.046$) was observed at the time of induction. Group 2 had a lower systolic blood pressure compared to Group 1 at this specific point.

No significant differences in diastolic blood pressure were found between Group 1 and Group 2 at any of the measured time points, including preoperative, 15 minutes, 30 minutes, induction, and postoperative (after 10 minutes). Oxygen saturation (SpO2%) demonstrated no significant differences between Group 1 and Group 2 at any of the measured time points.

Table 2: Comparison of hemodynamic, intra operative and post-operative data.

Variables	Group 1	Group 2	P value
Heart rate			
Pre op	105.8±8.7	106.5±12.9	0.797
At 15 minutes	102.7±8.6	102.7±11.7	1.000
At 30 minutes	98.8±8.0	101.7±12.1	0.276
Induction	100.2±8.6	103.03±12.5	0.307
Post operative (after 10 min)	106.5±10.7	107.2±11.4	0.826
Systolic blood pressure			
Pre op	111.3±8.7	106.3±12.9	0.080
At 15 minutes	109.8±8.5	104.7±11.5	0.056
At 30 minutes	106.1±8.6	103.8±11.7	0.388
Induction	108.0±7.8	105.3±11.3	0.279
Post operative (after 10 min)	112.7±6.6	108.1±10.6	0.046*
Diastolic blood pressure			
Pre op	71.2±8.0	69.1±9.1	0.354
At 15 minutes	71.2±7.5	67.5±8.8	0.088
At 30 minutes	68.7±8.8	67.9±9.8	0.740
Induction	70.2±7.6	68.8±8.6	0.517
Post operative (after 10 min)	73.1±6.1	70.0±8.7	0.118
SpO2%			
Pre op	98.8±0.5	98.8±0.5	0.795
At 15 minutes	98.7±0.6	987±0.6	0.831
At 30 minutes	98.6±0.7	98.6±0.7	0.713
Induction	98.6±0.7	98.7±0.5	0.671
Post operative (after 10 min)	98.8±0.4	98.9±0.3	0.286

*Significant at the 0.05 level (2-tailed)

Table 3 presents a comparison of sedation score, agitation score, and adverse effects between Group 1 and Group 2, focusing on various time points and quality scores. Notably, at 15 minutes, Group 2 exhibited a significantly higher sedation score than Group 1, with a greater proportion of patients experiencing deeper sedation levels (4 and 5). Similarly, Group 1 had a higher anxiolysis score of 2 at 15 minutes compared to Group 2, where most patients had an anxiolysis score of 1. These differences were statistically significant, suggesting variations in the sedative and anxiolytic effects of the treatments at this early stage of the procedure. However, by the 30-minute mark, the sedation and anxiolysis scores converged, with no significant differences between the groups. Additionally, no significant differences were observed in venipuncture score, mask induction score, and agitation score at any time point, indicating comparable experiences during these aspects of the intervention. Table 4, Figure 1 and 2 presents the results of Receiver Operating Characteristic (ROC) curve analysis comparing the performance of dexmedetomidine and midazolam in influencing various physiological parameters, including heart rate, systolic blood pressure,

diastolic blood pressure, and oxygen saturation (SPO2). The Area Under the Curve (AUC) is used as a metric to assess the discriminatory power of each drug, with standard errors (SE) and p-values providing additional insights into the reliability of these measures. For dexmedetomidine, the AUC values range from 0.553 to 0.714 across the different physiological parameters, with statistically significant AUC values observed for heart rate and systolic blood pressure. Conversely, Midazolam exhibits lower AUC values ranging from 0.541 to 0.603, indicating a comparatively weaker discriminatory ability. Notably, the AUC values for dexmedetomidine are generally higher, suggesting a potentially more effective impact on the monitored physiological parameters compared to midazolam. These findings from the ROC analysis provide quantitative evidence of the differential effects of dexmedetomidine and midazolam on the physiological responses under consideration.

Table 3: Comparison of sedation score, agitation score and adverse effects.

Quality score		Group 1	Group 2	p value
Sedation score				
At 15 minutes	2	0 (0.0)	6 (20)	0.000*
	3	0 (0.0)	15 (50)	
	4	5 (16.7)	7 (23.3)	
	5	25 (83.3)	27 (90.0)	
At 30 minutes	2	23 (76.7)	14 (46.7)	0.050*
	3	6 (20.0)	13 (43.3)	
	4	1 (3.3)	3 (10.0)	
Anxiolysis score				
At 15 minutes	1	0 (0.0)	19 (63.3)	0.000*
	2	28 (93.3)	11 (36.7)	
	3	2 (6.7)	0 (0.0)	
At 30 minutes	1	25 (83.3)	24 (80.0)	0.739
	2	5 (16.7)	6 (20.0)	
Venipuncture score				
0		26 (86.7)	22 (73.3)	0.197
1		4 (13.3)	8 (26.7)	
Pre oxygenation mask holding score				
1		27 (90.0)	24 (80.0)	0.472
2		3 (10.0)	6 (20.0)	
Agitation score				
At 10 minutes	1	25 (83.3)	25 (83.3)	1.000
	2	5 (16.7)	5 (16.7)	
	3	0(0.0)	0(0.0)	

Note: ** Significant at the 0.01 level (2-tailed); * Significant at the 0.05 level (2-tailed)

Figure 1 and Figure 2 depict Receiver Operating Characteristic (ROC) curves for the evaluation of hemodynamic and recovery responses during the administration of dexmedetomidine and midazolam, respectively. These curves serve as graphical representations of the trade-off between sensitivity and specificity, providing a visual tool to assess the performance of each drug in influencing physiological parameters and recovery outcomes. The position of the ROC curve relative to the diagonal line (representing random chance) indicates the discriminatory power of the drugs. A curve closer to the upper-left corner signifies higher sensitivity and specificity, indicating a more effective impact on the measured responses. The comparison between Figure 1 and Figure 2 allows for a visual assessment of the relative efficacy of dexmedetomidine and midazolam in influencing hemodynamic parameters and recovery responses. The area under the ROC curve (AUC) provides a quantitative measure of this discriminatory power, with a larger AUC indicating better overall performance. Analyzing the shapes and positions of these curves can offer valuable insights into the drugs' effectiveness and guide clinical decision-making regarding their use in specific medical scenarios.

Table 4: ROC curve analysis for dexmedetomidine vs midazolam.

Variables	AUC	SE	p value	95% CL	
				LB	UB
Dexmedetomidine					
Heart rate	0.700	0.070	0.008	0.563	0.837
Systolic blood pressure	0.714	0.068	0.004	0.581	0.848
Diastolic blood pressure	0.610	0.073	0.143	0.467	0.753
SpO_2	0.553	0.075	0.478	0.407	0.700
Midazolam					
Heart rate	0.603	0.074	0.169	0.458	0.749
Systolic blood pressure	0.574	0.075	0.326	0.427	0.721
Diastolic blood pressure	0.541	0.075	0.589	0.393	0.688
SpO_2	0.585	0.074	0.258	0.440	0.730

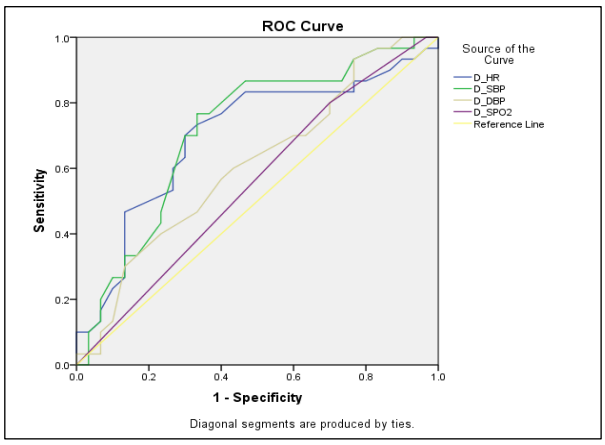

Figure 1: Receiver operating characteristic curve of hemodynamic and recovery responses during dexmedetomidine.

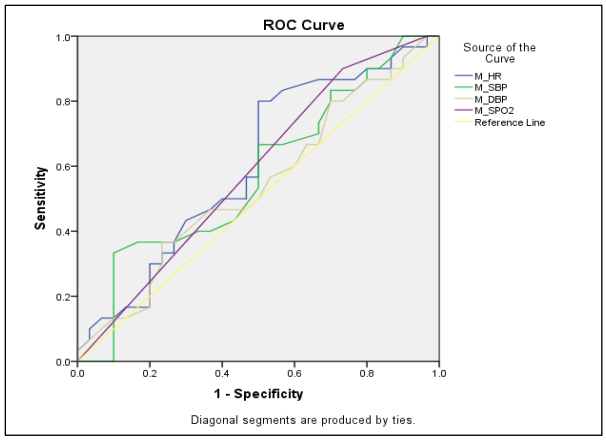

Figure 2: Receiver operating characteristic curve of hemodynamic and recovery responses during midazolam.

DISCUSSION

In our study, we compared effects of intranasal dexmedetomidine vs intranasal midazolam on mask induction and satisfactory sedation upon separation from parents in children undergoing tonsillectomy with or without adenoidectomy. It was found that both are equally effective in terms of providing satisfactory sedation during mask induction. Premedication with 1µg/kg of intranasal dexmedetomidine was superior to 0.2 mg/kg of intranasal midazolam in providing sedation and decreasing anxiety at the time of induction.

An ideal pre anaesthetic medication should ease separation from parents and facilitate the patient's acceptance of the face mask during the induction of anaesthesia.

The most popular premedication medication is midazolam. The major problem with intranasal midazolam in everyday practice is the unpleasant burning sensation it produces in the nasal cavity. However, it has been reported that intranasal administration of midazolam is better tolerated by children than its oral administration.

Walbergh et al conducted study comparing the plasma concentration of midazolam in children following intranasal and intravenous midazolam. They concluded that intranasal midazolam rapidly achieved sedative plasma concentration.[16]

Malinovsky et al studied the effect of intranasal, rectal and oral route on plasma midazolam concentration after premedication in children. 0.2 mg/kg dose of intranasal midazolam was used in the study. They observed that adequate sedation occurred within 10 min with intranasal midazolam.[17]

Intranasal midazolam offers the significant advantage of being a fast-acting drug. In our study, satisfactory sedation and anxiolysis for intranasal midazolam is obtained within 15 min.

The site of action of dexmedetomidine in the central nervous system is primarily in the locus ceruleus. It induces electroencephalogram activity similar to natural sleep.[18,19] Dexmedetomidine has anxiolytic, sedation analgesic and sympatholytic properties. As a result, it is a helpful addition to premedication, particularly for individuals who are prone to preoperative anxiety.

Yuen et al studied the sedative and analgesic effect of intranasal dexmedetomidine and concluded that intranasal route is effective, well tolerated and convenient for the administration of dexmedetomidine. Another study on volunteers has reported that intranasal 1 and 1.5 µg/kg doses of dexmedetomidine have similar effects.[18]

Talon et al preferred high doses of intranasal dexmedetomidine (such as 2 µg/kg) for preoperative premedication in children with burns, and they preferred higher doses as their patient group was also experiencing the pain and stress associated with burns.[20]

Considering previous studies, we decided the use of 1 µg/kg intranasal dexmedetomidine will be optimium for our studies.

Yuen et al studied the time of onset of action for intranasal dexmedetomidine and concluded it as about 25 min. As the timing of the onset of the effect of both agents used in our study differed, we took the preoperative sedation time to be 30 min for our study.

Study by Eren et al showed dexmedetomidine produced better and longer sedation compared to midazolam. In this investigation, we observed that 76.7% of children in dexmedetomidine group attained a sedation score of 2 compared to 46.7% in midazolam group.[21]

Akin et al conducted study to compare dexmedetomidine and midazolam. They observed that both the drugs produced equally effective anxiolysis, in our study, anxiolysis effect from parental separation is effective in both groups with intranasal dexmedetomidine (83.3%) slightly better than intranasal midazolam (80%).[22]

In our study, 90% of the patients in dexmedetomidine group allowed preoxygenation with mask holding without signs of distress compared to 80% in midazolam group. Cooperation to venipuncture is better with intranasal dexmedetomidine group (86.7%) compared with that of intranasal midazolam group (73.3%).

Hemodynamic parameters

A modest reduction in BP and HR is produced by α2-agonists. Clonidine as well as dexmedetomidine decrease the mean BP and HR before and during surgery. In addition, 0.5 and 1µg/kg of intranasal dexmedetomidine preoperatively reduced HR and BP in healthy children

during the first hour after the administration of the drug. However, these effects were clinically insignificant, and no intervention was required.[23]

In our study, reduction in heart rate with intranasal dexmedetomidine was strongly significant (p<0.001) at 30 min and strongly significant (p<0.001) during induction. With intranasal midazolam, it was strongly significant (p<0.001) at 30 min and moderately significant (p=0.011) during induction.

In our study, reduction in systolic blood pressure with intranasal dexmedetomidine was strongly significant (p<0.001) at 30 min and strongly significant (p=0.003) during induction. With intranasal midazolam, fall in SBP was moderately significant (p=0.014) at 30 min and insignificant (p=0.275) during induction.

In our study, reduction in diastolic blood pressure with intranasal dexmedetomidine was strongly significant (p=0.006) at 30 min and insignificant (p=0.209) during induction. With intranasal midazolam, it was insignificant (p=0.114) at 30 min and insignificant (p=0.683) during induction.

Post-operative agitation

In our study, postoperative agitation score in both the groups had better score and there is no statistical significance.

There were no differences between the groups with regard to the adverse effects of the drugs in question during the premedication period, emergence from anaesthesia, or follow-up care. There was no difference in the incidence of postoperative nausea and vomiting and discharge time between the dexmedetomidine and midazolam study groups.

The major limitation of this study was the timing of the drug administration, since peak onset of both the drug varied.

CONCLUSION

From our study we conclude that, premedication in paediatric patients using intranasal dexmedetomidine is more effective than intra nasal midazolam in providing sedation and satisfactory conditions during parental separation. In terms of providing ambient conditions during preoxygenation and IV cannulation, both the drugs midazolam and dexmedetomidine are effective with dexmedetomidine slightly better than midazolam. Therefore, intranasal dexmedetomidine is more efficacious than intranasal midazolam as premedication in children undergoing tonsillectomy.

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