Original Article

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Comparative Evaluation of Effect, Onset & Duration of Intranasal Dexmedetomidine Vs Midazolam for Paediatric Sedation During Diagnostic CT Scan

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Abstract

Background: Separation anxiety among children is common and normal.Children undergoing radiological imaging studies often require sedation to avoid panic episodes & severe anxiety for induction of Anaesthesia. It is important for the child to lie still during the scanning procedure & mostly we find it difficult for the children to keep still during a CT scan, which is usually about 10–15 minutes.

This study aimed at comparing and evaluating the efficacy of use of intranasally administered Dexmedetomidine Vs intranasal midazolam for paediatric sedation undergoing diagnostic CT scan studies.

Methods: 100 paediatric patients within age group 1-10 years were divided into 2 groups of 50 patients each, Group I & II respectively, were given either intranasal Dexmedetomidine or Intranasal Midazolam. The depth of sedation was assessed by using University of Michigan sedation scale.

Results: This study concluded that Intranasal Dexmedetomidine is superior & more effective than Midazolam for pediatric sedation.

Keywords: Intranasal; Dexmedetomidine; Midazolam; Pediatrics; Children; Sedation; CT Scan.

Introduction

Mostly we find it difficult for the children to keep still during a CT scan study, which is usually about 10–15 minutes duration. Children undergoing radiological imaging studies often require sedation to avoid panic episodes & anxiety from parental separation. Therefore, it is important for the child to lie still during the scanning procedure for proper diagnostic studies for early definitive management.

To avoid spontaneous movements that can interfere during diagnostic studies, intranasal sedative medications can be useful in paediatric patients undergoing diagnostic CT Scan.

There are a number of methods which can be employed to limit the movement of the child during a scan.[1] Non-pharmacological[2] Sedation

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and[3] General anaesthesia (GA).

Non-pharmacological interventions include behavioural and cognitive approaches such as desensitization, distraction and relaxation.

A pharmacological agent should have rapid onset and offset, predictable duration, minimal side effects and rapid recovery, easy availability and ability to decrease anaesthetic drug requirement.[11] In young children, particularly in those with behavioural difficulties, it can be difficult for them to keep still for the length of the time required. In these children, sedation and GA need to be considered.

Historically, chloral hydrate and pentobarbital have been the drug of choice for paediatric sedation in radiology departments. Because of their extended half-life, they have been associated with prolonged recovery times and sedation-related morbidity. In an effort to decrease our rate of failed sedations, reduce our recovery room time and improve our adverse event rate, other pharmacological agents had been introduced.[1]

There are many i.v. sedative agents available for pediatric imaging including Dexmedetomidine, Midazolam, Etomidate and Propofol. Amongst these, Midazolam and Dexmedetomidine are commonly used due to minimal side effects.

Therefore, the purpose of this study was to evaluate the preprocedural sedative effects, anxiety level changes and the ease of child-parent separation, and the recovery profile of preprocedure intranasal Dexmedetomidine sedation compared with that of intranasal Midazolam in children scheduled for diagnostic CT Scan.

Materials & Methods

After Institutional Ethics Committee (IEC) approval, a prospective, observational study was done in randomly 100 paediatric patients aged between 1 and 10 years of age, which were under American Society of Anesthesiologists (ASA) grade I and II undergoing diagnostic CT scan study. An informed written consent was taken from parents/ guardians of children prior to this study.

Children aged between 1-10 years, with ASA grade I & II undergoing elective minor procedures or radiological scans were included in this study. Children aged>10 years, with otorhinological diseases or respiratory or cardiac diseases, contraindicated for CT scan, known case of allergy to Dexmedetomidine or Midazolam, patients previously on any other sedatives, were excluded in this study.

All patients underwent pre-anaesthetic check-up (PAC) for detail history, examination and appropriate investigations including serum creatinine levels. All patients were kept Nil by Mouth (NBM) for 4-6 hours. On the day of procedure, NBM status and written consent was confirmed.

In both groups, intravenous (IV) line was secured using 22 or 24G cannula in either of the limbs.

Monitors viz, Electrocardiogram (ECG), Pulse-Oximeter were attached and the baseline values of heart rate (HR), oxygen saturation (Spo2), ECG & the state of alertness were observed before administering the drug followed by the time of administration, onset of action & duration of drug on the children were noted.

Group I received Intranasal Dexmedetomidine 2mcg/kg & Group II received Intranasal Midazolam 0.2mg/kg, then Oxygen was applied through the face mask at the flows of 4-5 L/min.

The vitals including HR, SP02, ECG & sedation score were recorded at the baseline, then after 5mins interval, then 10, 15 & 30 mins interval. Onset and degree of sedation in both groups was assessed at 0, 5, 10, 15 and 30 minutes.

The accurate monitoring for depth of sedation is very important. In our study, we have used University of Michigan Sedation Scale (UMSS) for sedation score.

University of Michigan Sedation Scale (UMSS)[12]
Score 0: *Awake and Alert*

Score 1: Minimally sedated Tired/sleepy, appropriate response to verbal conversation and/ or sound.

Score 2: Moderately sedated- Somnolent/sleeping, easily aroused with light tactile stimulation or a simple verbal command.

Score 3: Deeply sedated Deep sleep, arousable only with significant physical stimulation.

Score 4: Unarousable.

Afterwards, the paediatric patients were monitored for 30 mins postprocedural in post-anaesthesia recovery unit with oxygen administration via facemask.

Results

A total of 100 pediatric patients were included in our study. Both the groups were comparable with respect to baseline demographic variables like age, gender, height and weight.

Table 1: Comparison of Onset.

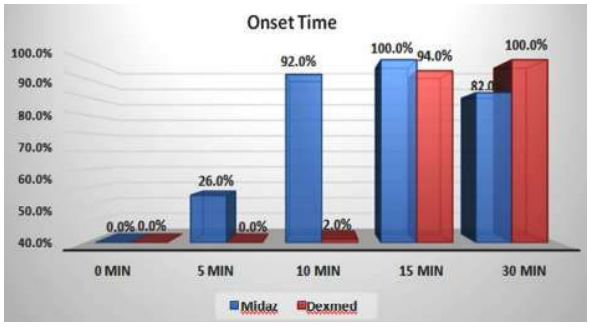
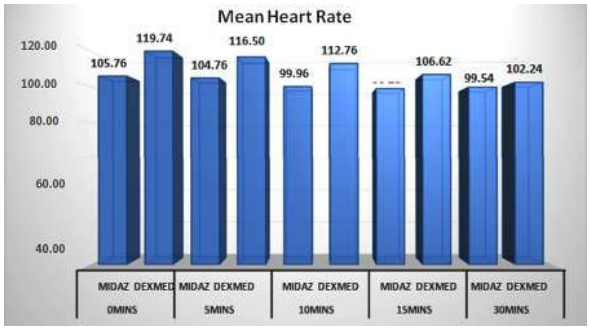
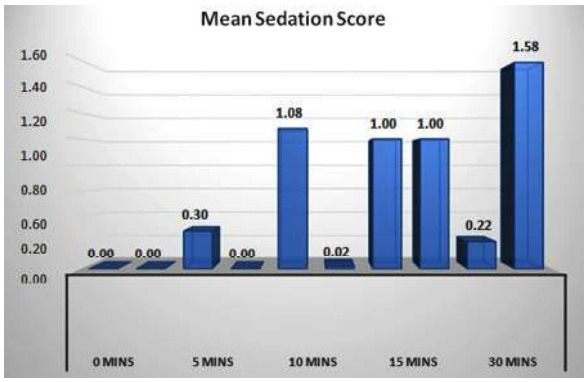


Table 2: Comparison of Heart Rate.



There was no significant difference between the groups.

Table 3: Comparison of Sedation Score.



Result: Overall, in the Dexmedetomidine group there was a higher incidence of satisfactory sedation at separation from parents than in the midazolam group, a reduced incidence of postprocedure agitation, and a significant reduction in the rescue doses of analgesic drugs in the Dexmedetomidine group.

Discussion

Children undergoing radiological imaging studies often require sedation to avoid panic episodes & severe anxiety. The risk factors which seem to be associated with high incidence of perioperative anxiety in children include: age 1 to 10 years, previous poor quality medical encounters, poor social adaptability and increased parental anxiety.[11] Maladaptive behavioural response such as general anxiety, night-time crying, enuresis, separation anxiety occur in up to 44% of children two weeks after procedure.[5]

Fear of physicians, injections, procedure and CT room in children is much more than in adults. Separation from the parents to a totally unknown world with unknown faces makes the procedural experience more traumatic for young children. Despite the many advances in non-pharmacologic interventions, practitioners still rely on sedative premedicants.[6] Therefore, sedation by pharmacological means is required. The ideal pharmacological agent should have rapid onset, predictable duration & rapid recovery.[5]

Dexmedetomidine provides conscious sedation, anxiolysis and analgesic effects without causing respiratory depression.[6] Midazolam, has become the most frequently used pre-anaesthesia medication given to children, by multiple routes of administration. It has a faster onset and limited duration of action when administered intranasally.[6,9]

Intranasal route is noninvasive, convenient, and easy, not requiring much of patient co-operation and fast onset of action.[9,5]

Compared with midazolam premedication, Dexmedetomidine premedication reduced the HR during the preprocedural sedation period after induction. Dexmedetomidine is known to decrease sympathetic outflow and circulating catecholamine levels and therefore would cause a decrease in HR.[9] There was no evidence of oxygen desaturation, respiratory depression, or apnea in our study, which was similar to the study done by Davis et al, on 88 children, which indicates that the doses used for both intranasal administered Midazolam and Dexmedetomidine are safe and comparable to the findings of other studies.[10]

Even, the use of Dexmedetomidine can provide additional analgesic benefits for pediatric patients following premedication and therefore, the patients treated with Dexmedetomidine required less postprocedural rescue analgesia as observed in one of the study.[6]

The Study included a total of 100 paediatric patients who were randomly divided into one of the following two groups (50 each) using random numbers: Group A–receiving intranasal

Dexmedetomidine 2ug/kg and; Group B–receiving intranasal Midazolam 0.2mg/kg. Onset and degree of sedation in both group was assessed at 0, 5, 10, 15 and 30 minutes. Whether parental separation at the time of induction was successful was recorded. Both the groups were comparable with respect to baseline demographic variables like age, gender and BMI. By the end of 5 and 10 minutes, sedation was achieved in 26% and 92% of the cases of Midazolam group as compared to 0% and 2% of the cases in Dexmedetomidine group. By the end of 15 minutes, the difference was non-significant 83 (100% vs 94%; p-0.24). At the end of 15 minutes, sedation was achieved in 100% and 94% of the cases in Midazolam & Dexmedetomidine group respectively.

In the present study, successful parental separation was seen in 80% cases of Dexmedetomidine group as compared to 48% cases in Midazolam group respectively. Therefore, Dexmedetomidine premedication of paediatric patients resulted in more satisfactory separation from parents compared with midazolam.

Limitations & Drawbacks

We accept the fact that there are some major drawbacks in our study. First of all the sample size is very small to have a significant power of analysis. Secondarily, we have studied only the patients in 1-10 years of age group scheduled for diagnostic CT Scan study. The differences in age may have influenced some of the results because the pharmacokinetics and pharmacodynamics between younger and older children vary. Third, significant heterogeneity was observed in some of the analyses (separation from parents, HR and sedation score preprocedural); therefore, the results should be assessed with caution. Finally, although considerable clinical data have been reported, Dexmedetomidine is not approved for use in children in many country. Thus, its use in children is considered cautious in its administration to at-risk patients is warranted.

Conclusion

This study compares two intranasal drugs i.e, Dexmedetomidine and Midazolam in achieving adequate sedation in paediatric population undergoing diagnostic CT Scan and concluded that the Dexmedetomidine is superior to Midazolam premedication because it resulted in excellent separation from parents and reduced post-procedure agitation & pain. Midazolam though has early onset but shorter duration of action and may require post-procedural rescue analgesia, while Dexmedetomidine has relatively late onset but longer duration of action & post-procedural analgesia & is more effective compared to Midazolam.

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