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A Comparison of Intranasal Dexmedetomidine and Intranasal Midazolam for Sedation in Pediatric Diagnostic MRI

Dr.Yogesh Chauhan (Assistant Professor)
Dr.Ankita Patel (Assistant Professor)
Dr. Heena Chhanwal (Professor and Head)
Dr. Meshwa Desai (Senior Resident)
GCS Medical College, Hospital and research centre,Ahmedabad-380025, Gujarat,India.

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I. Introduction

With advent of telemedicine use of diagnostic imaging modalities like CT Scan, MRI have been ubiquitously used in patients of all age groups. Children undergoing MRI radiological imaging studies often require sedation to avoid anxiety, motion artifacts. In pediatric patients there is also increased difficulty in gaining intravenous access, parental separation, and induction of anesthesia. [1]

Sedation facilitates overcoming these difficulties, with midazolam being the most commonly used agent. There is a risk of respiratory depression with midazolam. Additional midazolam also has no analgesic action.

Alternatively, dexmedetomidine, a selective α_2 agonist, can be used. It has both analgesic and sedative action and no risk of respiratory depression.

In our prospective, randomized, double-blind study, we compared intranasal midazolam (0.2 mg/kg) and intranasal dexmedetomidine (1 μg/kg) in terms of hemodynamics; parental separation anxiety scale; and onset, level, and sedation quality at the time of patient induction.

II. Materials And Methods

This study included 50 patients ASA-I and II aged 1-10yrs undergoing diagnostic MRI.Ethical committee approval and written informed consent was obtained.

Refusal from parents, ASA grade III and IV , age <1 yr or > 10 years, congenital heart disease, upper respiratory infection, emergency MRI were excluded from the study.

Preanaesthetic assessment included: medical and surgical history ; general, airway and systemic examination with Complete Blood Count and Renal Function tests. On day of procedure nil by mouth status ensured and consent was taken.

Patients were randomly allocated into two groups , 25 patients each:

Group M :0.2mg/kg intranasal midazolam ;

Group D: 1μg/kg intranasal dexmedetomidine.

The drugs were instilled using 1ml tuberculin syringe. To avoid bias observer anesthesiologist was blinded to the drug.

During MRI the saturation, heart rate, blood pressure were monitored and noted at 5 minutes interval for 30 minutes. The sedation level of the patient was assessed by the Modified Observer's assessement of alertness/sedation scale (MOAA/S) , a 6 point scale. Parental separation anxiety scale(PSAS) a 4 point scale was also noted for comparison between both groups.

Modified Observer's assessement of alertness/sedation scale (MOAA/S):

Score	Responsiveness
6	Agitated
5	Responds readily to name spoken in normal tone
4	Lethargic response to name spoken in normal tone
3	Responds only after name is called loudly and/or repeatedly
2	Responds only after mild prodding or shaking
1	Does not respond to mild prodding or shaking
0	Does not respond to deep stimulus

Parental separation anxiety scale(PSAS)

Behaviour of the child during separation from parents	Criteria	Score
Excellent	Patient unafraid, cooperative, or asleep	1
Good	Slightly afraid/crying, quiet with reassurance	2
Fair	Moderately afraid and crying, not quiet with reassurance	3
Poor	Crying, need for restraint	4

Adequate sedation was defined as a MOAA/S score 4 or less and when patient allowed intravenous cannulation without crying. If satisfactory sedation was not achieved, inj intravenous propofol 0.5 mg/kg administered.

STATISTICAL ANALYSIS

The parametric data were analysed using the unpaired t test at a confidence interval of 95 % , with an allowable error of 5%. The binary data was analysed using the chi square test. All results where $p< 0.05$ were considered as statistically significant.

III. Results

The demographic profile (age, sex, weight) and the duration of scan was comparable between the two groups(Table 1). The data were analysed using unpaired t -test. The difference was statistically not significant at $p =0.05$, hence the demographic profile was comparable.

Table 1: Comparison of demographic data between both the groups

PARAMETERS	GROUP M (n= 25)	GROUP D (n= 25)	P
Age (years)	4.16	4.04	0.28
Sex (Male/Female)	16/9	10/15	
Weight (Kg)	10.77	10.88	0.4
Mean duration of scan (mins)	35.12	35.6	0.09

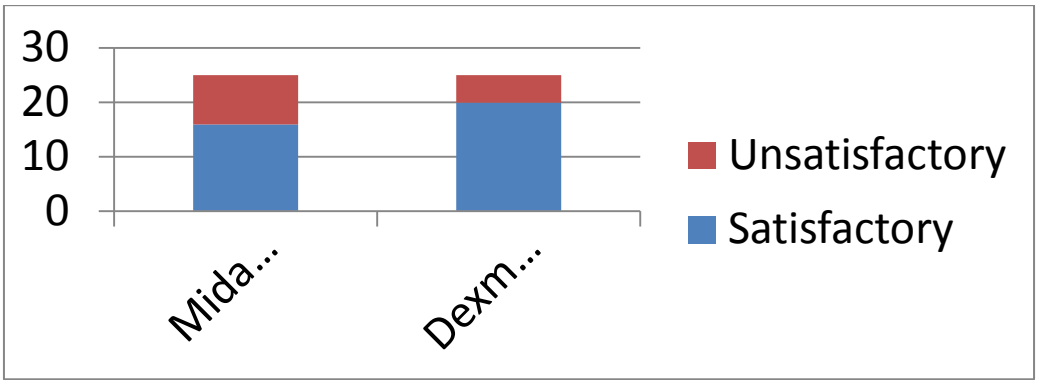

Figure 1: Sixteen out of 25 (64%)patients achieved satisfactory sedation(MOASS ≥ 4) in group M, while 20 out of 25 (80 %) patients of Group D achieved satifactory sedation.

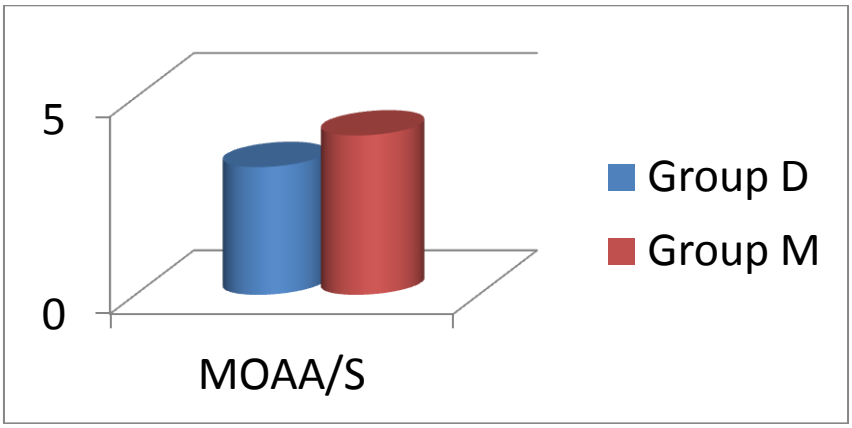

Figure 2: Group M has a mean MOAA/S score of 4.04 ± 2SD while Group D has a mean MOAA/S score of 3.24 ± 2SD at 95% Confidence interval (P≤0.0068) the difference is statiscally significant.

Additionally in Group M twelve out of 25 (48%)patients showed successful parental separation. While in Group D 19 out of 25 (76%) showed successful separation, with a satistically significant difference (Table 2).The chi square value of this test is greater than the chi square value at p = 0.05, hence the difference is statistically significant.

Table 2: Comparison of successful parental separation between both the groups:

SUCCESSFUL PARENTAL SEPARATION	MIDAZOLAM	DEXMEDETOMIDINE
YES	12 (48%)	19 (76%)
NO	13 (52%)	6(24%)

The vital parameters for both the groups were comparable: HR(Figure 3), Spo2 (Figure 4), BP (Figure 5).

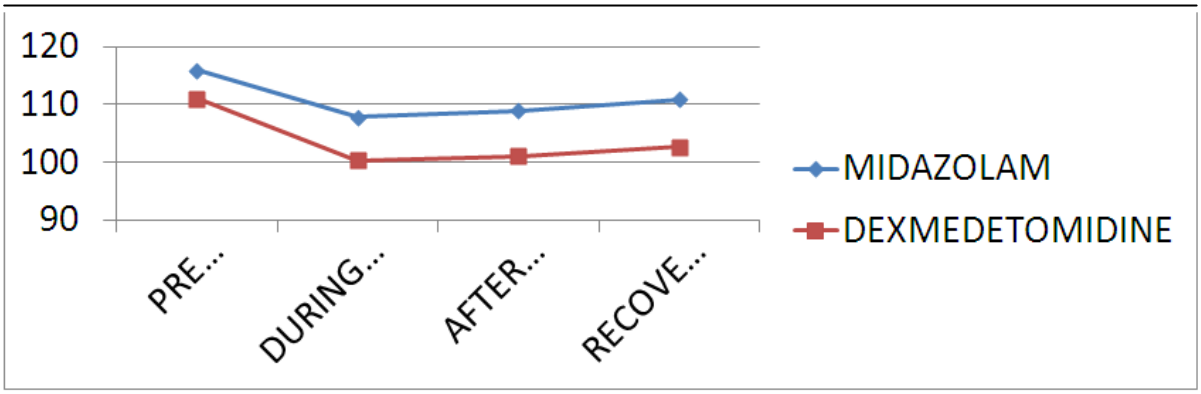

Figure 3: Comparison of mean Heart Rate of two groups.

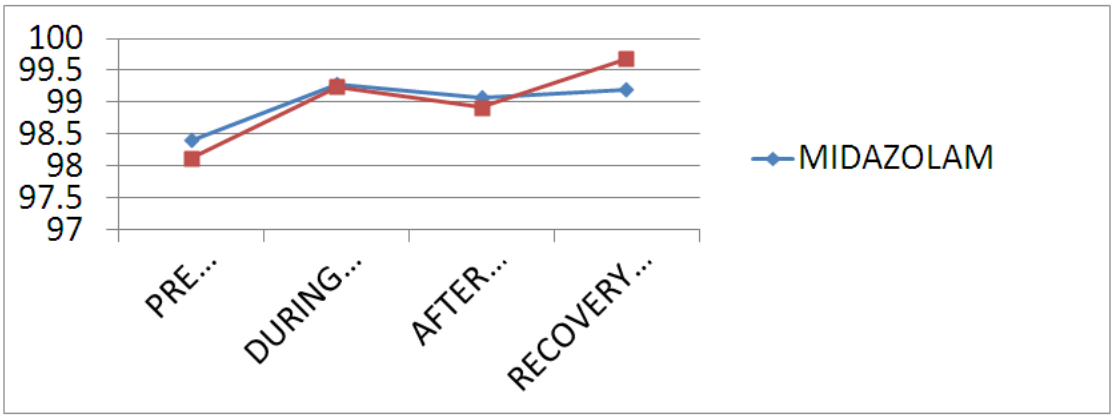

Figure 4: Comparison of mean SpO_2 of two groups.

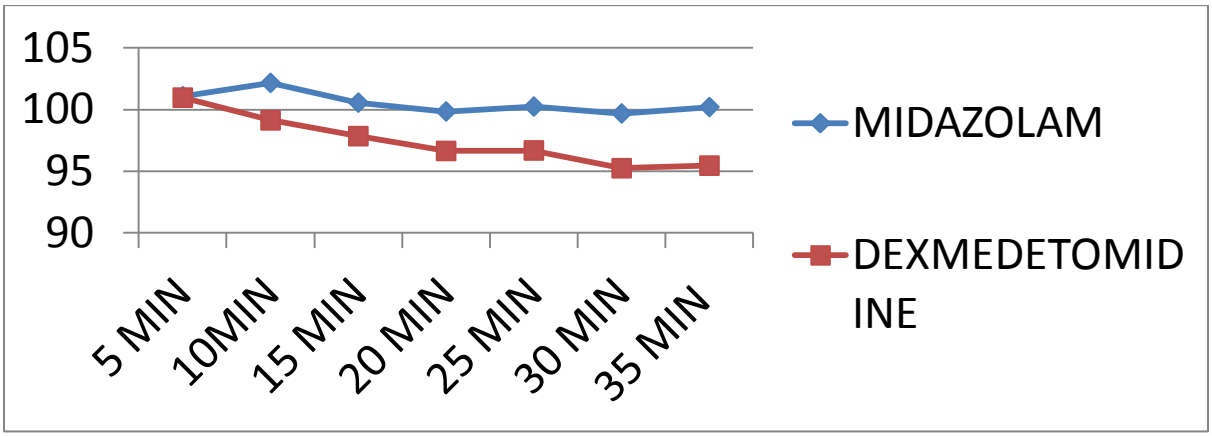

Figure 5: Comparison of mean Blood pressures of two groups.

IV. Discussion :

For pediatric MRI sedation is required for allaying fear, anxiety and smooth parental separation. It also provides vagolytic,analgesic, antiemetic, antisecretory, amnesic effect. Midazolam, most commonly used premedication is associated with respiratory depression along with hiccups, post operative behavioral changes. [2]

Dexmedetomidine is newer more selective centrally acting alpha 2 agonist. It has a shorter half life. Previous evidences have shown that it is a safer drug for pediatric sedation. [3,4]

Intranasal route is non invasive, convenient, eliminates first pass metabolism and results in faster onset of action.[5,6]Hence in our study we used intranasal midazolam. Dexmedetomidine is an intravenous formulation exclusively. It is widely used via intranasal route in adults and pediatric patients. Yuen *et. al* showed children had significant sedation using intranasal dexmedetomidine.[7-9]

In the study 80% patients of group D achieved satisfactory sedation, while only 64% of group M achieved satisfactory sedation(Figure 1); statistically significant. Mean sedation score of Group D is 3.24 while

that of Group M was 4.04 (Figure 2). Hence a better sedation achieved via Group D. Gupta *et. al* and Sheta *et. al* have reported similar findings.[11,14]

Successful parental separation achieved in 76% of Group D while only 48% in Group M. (Table 2) at p = 0.05, hence the difference is statistically significant. Mostafa and Morsy compared intranasal dexmedetomidine, ketamine and midazolam as premedication had a parental separation score Grade 1 as 93.8 %, 68% and 87.5% respectively. [12] Sundaram and Mathian also had similar results.[13]

No significant change observed in saturation of both groups, with none of them had Spo2< 95% at any time. Baseline heart ratesof both the groups were comparable. Dexmedetomidine , sympatholytic in nature and decresed circulatory cathecolamines. Hence the mean SBP is lower for group D Sundaram and Mathian also had similar results.[13]

None of the patients in any group had any complications : bradycardia, hypotension, respiratory depression after administering the drug. Similar findings are noted in previous studies. [8,11,12] Many studies have shown that intranasal midazolam causes restlessness, euphoria,paradoxical reactions. [15,16]However our study did not report any such adverse effects. Dexmedetomidine also did not cause any nasal burning, irritatation, hiccups or respiratory depression. Its action on locus coeruleus produces unusual calm easily arousalable sedation and subsequently quickly falls back to sleep when not stimulated; similar to natural sleep. [14]

V. Conclusion :

Intranasal dexmedetomidine 1µg/kg is effective for sedation in children undergoing MRI and it resulted in better sedation score and parental separation as compared to intranasal midazolam 0.2mg/kg without much side effects or complications.

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Nil.

CONFLICT OF INTEREST:
There is no conflict o interest.

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