COMPARATIVE STUDY OF EFFICACY OF DEXMEDETOMIDINE VERSUS PROPOFOL FOR SEDATION IN PEDIATRIC PATIENTS UNDERGOING MAGNETIC RESONANCE IMAGING: A PROSPECTIVE STUDY.

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Abstract

Background & aim: There is closed noisy environment and the patient needs to be immobile for a substantial time for successful conduction of magnetic resonance imaging (MRI). We can use propofol, but it can cause hypotension, respiratory depression and loss of airway reflexes. Dexmedetomidine causes conscious sedation without respiratory depression. The aim of our study was to compare the efficacy of dexmedetomidine versus propofol, in conducting MRI in children.

Methods: This prospective, randomized, comparative study was conducted after getting approvals and written and informed assent. Total 60 children of 2-10 years age, ASA grade I and II, undergoing MRI were randomized into: group D: received injection dexmedetomidine i.v. infusion @0.8- 1.0 ug.kg^{-1} over 10 min, followed by continuous infusion @0.4-0.6 ug.kg^{-1}.h^{-1} or group P: received injection propofol @1 mg.kg-^{1} bolus i.v., followed by continuous infusion @100 ug.kg^{-1}.min^{-1}.The sedation level was measured using the Ramsay Sedation Score (RSS) every 1 minute until the score of 5 was achieved. The rescue sedation was administered as injection ketamine 1-2 mg.kg-^{1} i.v. Patients were allowed to breathe spontaneously. Quality of MRI was evaluated using 3-point scale. Any episode of adverse event was noted. Quantitative data was analyzed using student t test and qualitative, using chi square test.

Results & conclusion: The mean time for onset and the duration of sedation was longer in group D than group P, (P=0.004 and 0.030 respectively). Total 40% patients requiring rescue sedation in group D and 10% in group P. Hence propofol is better than dexmedetomidine for sedation in children undergoing MRI.

Key words: Dexmedetomidine, magnetic resonance imaging, propofol

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DOI: - 10.48047/ecb/2023.12.si10.00415

Introduction:

With the advancement in the field of radio-diagnostic procedures, frequency of magnetic resonance imaging (MRI) has increased in adult as well as pediatric population. There is closed and noisy environment which is very disturbing and uncomfortable to the patient. Moreover, it is very sensitive to motion artifacts.[1] Hence, the patient needs to be adequately calm and immobile for a varying length of time. In children we require to sedate them for successfully conducting MRI.[2] For the purpose of successfully conducting MRI, we can use propofol since it has shorter emergence, faster induction and recovery. However, it can cause hypotension, respiratory depression, bradycardia and loss of protective airway reflexes.[3,4] Dexmedetomidine, a potent and highly selective α2- receptor agonist, has novel property of providing conscious sedation without respiratory depression. However, it causes dose dependent decrease in heart rate and mean arterial blood pressure.[5] Hence, we designed this study so as to compare the effectiveness and safety of propofol versus dexmedetomidine for providing desirable sedation in children undergoing MRI.

Material & methods:

This prospective, randomized, comparative study was conducted in the Department of Anesthesiology and Critical Care at a tertiary care hospital. The approval was obtained from the institutional Ethical committee. The study was prospectively registered with clinical trials registry of India: (CTRI/2022/07/044434).

A total of 60 children of age group 2-10 years, having physical status of 1 and 2 according to American society of Anesthesiologists (ASA I/II), undergoing MRI were included in the study after obtaining written informed consent from the parent. The procedure followed the guidelines laid down under Helsinki declaration. Children were allocated random number using computer generated randomization tables, into either of the study groups. The parents of children as well as the person noting observations were unaware of the study drugs. The study drugs were supplied in sealed envelopes as pre filled syringes by the pharmacy. Children with known drug allergy, anticipated difficult airway, active respiratory infection or cardiac illness were not included in the study.

All MRI compatible anaesthetic equipment were checked, and base line heart rate, blood pressure, oxygen saturation (SpO_2) and respiratory rate were recorded.

Group D: received injection dexmedetomidine i.v. infusion @ 0.8- 1.0 $ug.kg^{-1}$ over 10 min, followed by continuous infusion @ 0.4-0.6 $ug.kg^{-1}.h^{-1}$. [12]

Group P: received injection propofol @ 1 $mg.kg^{-1}$ bolus i.v., followed by continuous infusion @ 100 $ug.kg^{-1}.min^{-1}$. [12] The recordings were done in a prescribed proforma, similar for all patients.

The sedation level of the children was measured using the Ramsay Sedation Score (RSS) for every 1 minute until the score of 5 was achieved.[6] Thereafter, the children were positioned on scanning table after ensuring that respiratory and hemodynamic parameters are within physiological limits. The aim was to achieve RSS of 5 or more. If RSS of 5 was not achieved until 25 minutes [12] after commencing infusion of the study drug, the rescue sedation was administered as injection ketamine in the dose of @1-2 $mg.kg^{-1}$, slowly i.v. Children were allowed to breathe spontaneously. O_2 was administered @ 4-5 litre/min, via paediatric Hudson mask. Respiratory functions were assessed throughout the procedure, if fall in Spo2 was noted below 93% for 30 seconds, the scan procedure was interrupted and oxygen was administered with anatomical face mask and respiration assisted using Bain circuit. The study drug was discontinued temporarily. Once the Spo2 was achieved to 98-100%, the imaging process was started again. The RSS was assessed every 5 minutes until the imaging was over and thereafter till the score of 3 or less was achieved. At the end of the scan, drug infusion was stopped and the patient was shifted to recovery area. The quality of MRI was evaluated using 3point scale (1= no motion, 2= minor movement, 3= major movement necessitating another scan); score 1 and 2 were considered satisfactory for imaging.[12]

Site and duration of MRI, onset of sedation, duration of sedation, increment of infusion required, rescue sedation required and recovery time were noted. Any episode of hypotension, bradycardia, nausea, vomiting, respiratory discomfort and desaturation were noted. Criteria for hypotension and bradycardia were taken as >20% decrease in heart rate and blood pressure from base line values. Respiratory depression was taken as RR<10/min.

At the end of the study data was collected and analyzed using SPSS (Statistical Package of Social Sciences) software, version 23. Continuous data were recorded as numbers, represented as Mean ± SD and analyzed applying student t test. Categorical data were represented as numbers and analyzed using chi square test. Intergroup statistical analysis was performed by applying

student t test. A P value of less than 0.05 was considered as statistically significant.

Sample size calculation:

Comparison of two mean formula:

N=size per group;

σ= Standard Deviation= σ1 and σ2

M = mean difference (M1-M2) = 30.2-28.6=1.6 [Duration of sedation (min)]

$Z_{1-\alpha/2} = Z_{0.05/2} = Z_{0.025} = 1.96$ — From Z table at type I error of 5

$Z_{1-\beta} = Z_{0.20} = 0.842$ — at 80% power = 0.84

The formula for calculated sample size is given below

$$n = \frac{(\sigma 1^2 + \sigma 2^2) x [Z\ 1-\alpha/2 + Z\ 1-\beta]^2}{(M1 - M2)^2}$$

$$= (1.74 + 1.34)^2 (1.96 + 0.84)^2 / (50-31)^2$$
$$= (3.08)^2 * 7.84 / (1.6)^2$$

$$= 9.48 * 7.84 / 2.56$$
$$= 74.37 / 2.56$$
$$= 29.05$$
$$= 30$$

Reference article: Kamal K, Asthana U, Bansal T, Dureja J, Ahlawat G, Kapoor S. Evaluation of efficacy of dexmedetomidine versus propofol for sedation in children undergoing magnetic resonance imaging. Saudi J Anaesth 2017;11:163-8

Result: The mean age, sex ratio, the distribution of patients according to site, duration and quality of MRI were comparable in both the groups. (Table 1)

Table 1: Demographic Characteristics

Variables	**Mean ± SD**		**P value**	**test used**
	Group lD (Dexmedetomidine) (n=30)	**Group P (Propofol) (n=30)**		
Age (yrs) (Mean±SD)	6.80±3.044	6.23±3.319	0.493*	t-test
Sex				
Male	19	17	0.598*	Chi-square test
Female	11	13		
Site of MRI (%)				
Head	16 (53.33)	24 (80)	0.215*	Chi-square test
Limb	1 (3.33)	0 (0)		
Pelvis	3 (10)	1 (3.33)		
Spine	6 (20)	4 (13.33)		
Others	4 (13.33)	1 (3.33)		
Duration of MRI (min) (Mean±SD)	37.00±8.196	37.60±6.117	0.749*	t-test
Quantity of MRI (%)				
1	18 (42.9)	24 (57.1)	0.091*	Chi-square test
2	12 (66.7)	6 (33.3)		

* Not significant

The mean time for onset of sedation in group D was much longer than group P, the difference being highly significant (P=0.004). Likewise, the mean duration of sedation was also greater in group D than group P (P=0.03). The number of patients requiring rescue sedation as injection ketamine @1-2 $mg.kg^{-1}$was also significantly higher in group D (40%) than group P (10%) (P=0.030). (Table 2)

Table 2: Sedation characteristics

Variables	**Group D (Dexmedetomidine) (n=30)**	**Group P (Propofol) (n=30)**	**P value**	**Test**
Onset of Sedation (min) (Mean±SD)	5.29±0.532	4.94±0.691	**0.004***	t-test
Duration of Sedation (min) (Mean±SD)	12.33±3.315	10.13±2.360	**0.030***	t-test
Number of patients requiring rescue sedation (%)	12 (40%)	3 (10%)	**0.007***	Chi-square test

* Significant at 5% interval level

The sedation score (RSS) was comparable at 5, 10 and 20, 30 and 40 minutes in both the groups. (Table 3)

Table 3: Ramsay Sedation Score

Point of time		**Dexmedetomidine**				**Propofol**				
		1-3	3-6	6-9	9-12	1-3	3-6	6-9	9-12	**P value**
5 min	N	1	9	12	8	5	14	7	4	0.09
	%	3.3%	30.0%	40.0%	26.7%	16.7%	46.7%	23.3%	13.3%	
10 min	N	1	29	0	0	0	30	0	0	0.31
	%	3.3%	96.7%	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%	
20 min	N	0	30	0	0	0	30	0	0	--
	%	0.0%	100.0%	0.0%	0.0%	0.0%	100.0%	0.0%	0.0%	
30 min	N	0	30	0	0	1	29	0	0	0.31
	%	0.0%	100.0%	0.0%	0.0%	3.3%	96.7%	0.0%	0.0%	
40 min	N	1	29	0	0	1	29	0	0	--
	%	3.3%	96.7%	0.0%	0.0%	3.3%	96.7%	0.0%	0.0%	

Bradycardia was seen in 1 patient in group D while there was no episode of bradycardia seen in group P. Hypotension was seen in 2 patients in group D and no episode of hypotension was seen in group P. Respiratory depression was seen in 2 patients in group P while there was no similar episode seen in group D. Episode of nausea and vomiting was seen in 1 patient in group D while there was no such episode seen in group P. There was no allergic reaction noted in both the groups. (Table 4)

Table 4: Adverse events

Variables	**Group D (Dexmedetomidine) (n=30)**	**Group P (Propofol) (n=30)**
Bradycardia	1	0
Hypotension	2	0
Respiratory Depression	0	2
Nausea / Vomiting	1	0
Allergic Reaction	0	0

Discussion:

MRI scanning is a useful diagnostic imaging tool with its high accuracy and no risk of radiation. Hence, its use has increased in recent years in pediatric as well as in adult patients. But it requires examinee's full cooperation and to remain motion less for a substantial period of time, which is difficult in pediatric patients. A co- operative adult patient can rest in stable position but children require adequate level of sedation for successful conduction of MRI. Moreover, it is usually conducted as out-patient procedure hence preferred to be conducted under drug which is having minimal residual action and minimal respiratory depression. Thus, we compared dexmedetomidine since it has short half- life and causes no respiratory depression along with preservation of airway reflexes.

In present study, interpretable MRI scans were obtained for all subjects, whether they were sedated with dexmedetomidine or propofol. This was possible because there was no or very minimal movement of the children undergoing MRI, rated on 3 point scale and majority of patients in both the study groups achieved score of 1point. The results of our study were in consensus with a study where successful MRI sleep studies were recorded in 98% of children in dexmedetomidine group and 100% in propofol group.[7] However, another group of researchers had different opinion. They observed that adequate sedation was obtained in 83% of the children who received injection

dexmedetomidine 1.0 ug.kg^{-1} initial dose followed by continuous infusion of 0.5 μg· kg^{-1}· h^{-1}and 90% of the children who received injection propofol 3 mg.kg-^{1} initial dose followed by a continuous infusion of 100 μg·kg^{-1}·min^{-1}.[12] High failure rates in their study may be because they did not use ketamine as rescue sedation. We have used rescue sedation as inj. ketamine in the dose of 1-2 mg.kg^{-1} as and when required during the procedure.

The mean onset of sedation in present study was 5.29±0.53 minutes in group D and 4.94±0.691 minutes in group P, the difference being highly significant statistically (P=0.004). This was found to be in contrast with the study conducted by Koroglu et al., where the average onset of sedation was found to be 19 min in patients who received dexmedetomidine. The longer onset of sedation could be attributable to the difference in end point of accepted level of adequate sedation taken as RSS score of 6 in their study as contrast to an RSS of 5 in present study.[8]

On comparing both the groups, 1 episode of bradycardia and 2 episodes of hypotension were recorded in group D, as Dexmedetomidine exerts its effects by binding to alpha 2 receptor, which decreases nor epinephrine release and inhibition of its sympathetic activity, which may lower heart rate and blood pressure.[9]

No patient in propofol group experienced nausea and vomiting, this may be due to antiemetic effect of propofol.[10] Only 1 patient experienced episode of nausea and vomiting in group dexmed etomidine, the episode may be attributable to disease involving CTZ pathway.[11] These findings were found to be consistent with those of Koroglu et al., who did not report any similar episode of nausea and vomiting in their study. Allergic reaction was not observed in both the groups.

Limitations of study: bi spectral index monitoring was not done.

Future scope: More studies can be conducted with greater sample sizes and comparing different doses of propofol and dexmedetomidine.

Conflict of interest: None

Source of support: NIL

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