Original Research Paper

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" A PROSPECTIVE RANDOMIZED COMPARATIVE STUDY EVALUATING THE SEDATION WITH IV DEXMEDETOMIDINE VERSUS IV KETAMINE IN PEDIATRIC PATIENTS UNDERGOING DIAGNOSTIC RADIOLOGICAL PROCEDURES CT, MRI "

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ABSTRACT Monitored anaesthesia care involves administering a combination of drugs for anxiolytic, hypnotic, amnestic and analgesic effect. The study was undertaken for evaluation of ketamine and dexmedetomidine for diagnostic procedures in children for assessing the haemodynamic control,sedation and recovery under Monitored Anaesthesia Care. Fifty (50) patients were divided into 2 groups. 25 in ketamine group (Group K) and 25 in dexmedetomidine group (Group M). Scores for Sedation, Heart rate , Mean arterial Blood Pressure(MAP), and Peripheral oxygen saturation were recorded preoperatively (baseline), intra operatively (at 5,10,15,20,30,min), until the completion of imaging & Post-imaging monitoring of SBP, DBP, MAP, Heart Rate, SPO2 ,sedation and recovery(at 5, 10, 15, 30, 60, min)

CONCLUSION: The study showed iv Dexmedetomidine to be a better agent for monitored anaesthesia care compared to iv ketamine for diagnostic procedures like CT, MRI.

KEYWORDS : Ketamine, Dexmedetomidine, CT MRI

INTRODUCTION:

Monitored anaesthesia care involves administering a combination of drugs for anxiolytic, hypnotic, amnestic and analgesic effect. Diagnostic procedures in children like MRI, CT are done with sedation under monitored anaesthesia care (MAC) or general anaesthesia. Several drugs such as ketamine, Dexmedetomidine, propofol, benzodiazepines and opioids have been used for MAC either alone or in combination. Dexmedetomidine can be safely and effectively used for procedural sedation, surgeries, sedation in ICU, awake intubation, shockwave lithotripsy, endoscopic examination and as an adjuvant to anaesthetics. The present study is undertaken at Kurnool medical college, for evaluation of ketamine and dexmedetomidine for diagnostic procedures in children for assessing the haemodynamic control, sedation and recovery under Monitored Anaesthesia Care.

MATERIALS AND METHODS:

After obtaining approval from the Hospital Ethics Committee, patients of either sex undergoing Diagnostic procedures such as MRI,CT under sedation were enrolled in this study to evaluate ketamine and Dexmedetomidine at Kurnool government hospital from march 2017 to march 2018. Fifty (50) patients were divided into 2 groups. 25 in ketamine group (Group K) and 25 in dexmedetomidine group (Group M). Prospective randomized study of 50 patients who underwent diagnostic procedures such as MRI,CT with the average duration of 30 mins were taken under study. All the cases were maintained by spontaneous mask ventilation . The study cases had fasting period of 6 hrs for solid food and 4 hrs for clear fluids.

On arrival in the scaning room, after confirming adequate NBM status, vitals were monitored. **Group K** ($n = 25$) Ketamine 1mg/kg I.V was given during procedure followed by 0.2mg/kg every 15 minutes until completion of procedure. **Group D** ($n = 25$) dexmedetomidine 1 µg/kg over 10 min I.V and 1 µg/kg/hr infusion was given during procedure .During this period the patients were assessed by Scores for Sedation, Heart rate ,Systolic Blood Pressure(SBP), Diastolic Blood pressure(DBP), Mean arterial Blood Pressure(MAP), and Peripheral oxygen saturation were recorded preoperatively (baseline), intra operatively (at 5,10,15,20,30,min), until the completion of imaging & Post-imaging monitoring of SBP, DBP, MAP, Heart Rate, SPO2 ,sedation and recovery(at 5, 10, 15, 30, 60, min).

Sedation was measured by **Ramsay Sedation Score**

1- Patient anxious and agitated or restless
2- Patient co-operative, oriented, and tranquil
3- Patient responds to verbal commands while sleeping
4- Patient exhibits brisk response to light glabellar tap or loud voice while sleeping. 5- Patient exhibits a sluggish response to light glabellar tap or loud voice
6- Patient exhibits no response

ALDRETE SCORE

Activity: Able to move voluntarily or on command	
Four extremities	2
Two extremities	1
No extremities	0
Respiration:	
Able to breathe deeply and cough freely	2
Dyspnea,shallow and limited breathing	1
Apnoea	0
Circulation	
Systolic BP <20 mmHg of preoperative	2
Systolic BP 20-50 mmHg of preoperative	1
Systolic BP $\pm$ 20 mmHg of preoperative	0
Consciousness	
Fully awake	2
Arousable on calling	1
Deeply sedated	0
Oxygen saturation	
Saturation >92%	2
Needs O_2 for maintaining >90&	1
O_2 saturation <90 % with O_2 supplementation	0

After administering the drugs and when RSS of 5 was achieved, procedure commenced . During imaging, heart rate (HR), Non Invasive blood pressures , SPO2, , and sedation were recorded at 5,10,15,20,30 mins interval intra operatively and at 5,10,15,30,60mins interval post procedure.

The procedure lasted for less than 60 minutes in almost all the patients. After the completion of procedure, patients were shifted to the PACU and were monitored for hemodynamic parameters, and adverse events, post operatively.

STATISTICAL ANALYSIS:

Chi square test and Fisher's exact tests were applied for qualitative data. Unpaired Student T test was used for comparing the trends for all parameters in the two groups. A P value of <0.05 was considered significant.

RESULTS:

Table – 1 Baseline vitals of the groups

At baseline before the imaging, the mean values of variable in the two groups were in this fashion-

S. NO	VARIABLE	K Group		D Group		T TEST	P VALUE
		MEAN	SD	MEAN	SD		
1	AGE (Yrs)	5.72	2.03	5.24	1.87	0.87	0.38
2	WEIGHT(kgs)	15.52	3.33	14.52	2.74	1.18	0.25
3	PULSE RATE(BPM)	110.44	10.96	116	13.76	1.58	0.12

4	SBP(mm HG)	87.36	7.13	85.28	5.71	1.14	0.26
5	DBP(mm HG)	55.92	5.61	54.24	4.33	1.18	0.24
6	MAP(MM HG)	66.4	4.97	64.59	4.05	1.41	0.16
7	SP02 (%)	99.52	0.50	99.72	0.54	1.36	0.18
8	SEDATION SCORE	1.72	0.46	1.64	0.48	0.60	0.55

The baseline characteristics pre imaging were almost similar in both the groups, with whatever differences observed were statistically insignificant,
p values > 0.05.

Chart.1

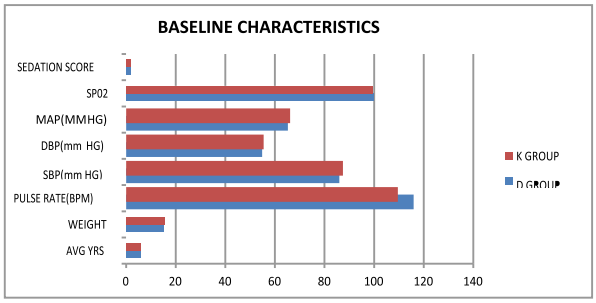
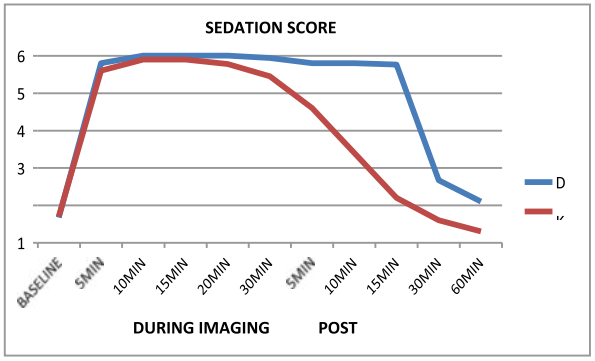


Table –2 Sedation score trend in the groups

It was observed that the sedation scores were statistically insignificant during imaging except at 30 minutes, and were statistically significant post imaging at all times noted. (P value < 0.05)

Chart-2



DISCUSSION:

In recent years, there has been an increased amount of imaging procedures under sedation in paediatric group. Children make excellent candidates for sedation during imaging procedures as they are usually healthy, free from systemic diseases.

The reason for choosing the study is to compare ketamine, the most commonly used sedative with novel drug Dexmedetomidine, which has additional anxiolytic property with very low respiratory depression for periprocedural haemodynamic stabilization, sedation for imaging procedures like CT,MRI in children.

Preoperatively Heart rate, Mean arterial pressure and Spo2 were statistically insignificant (P>0.05).

MAP levels throughout imaging and post imaging were higher at all times noted among K group than D group and difference was statistically significant.

Heart rates in both groups were relatively lower in D group than K group through out imaging and Post imaging and were statistically significant.

Spo2 levels in both groups were similar and statistically insignificant. Sedation scores were similar in both groups during imaging and were more in D group than K group post imaging and were statistically significant.(p < 0.05).

Arian and colleagues reported a sedation induction time of 25 min and recovery time of 34 min with dexmedetomidine in adults. The onset of sedation time and recovery time was shorter in our study. This could be explained by the fact that the subjects in our study were children and that the duration of infusion was shorter Bradycardia was not observed in any child similar results was shown by **Abeer M et al**. In **AbeerM et al** study, loading dose of 1 mg/kg ketamine intravenously followed by an infusion of 50–75 µg/kg/min for the duration of the procedure. Children in their study were discharged at a mean time of almost 60 min. Similar discharge time was seen in our study also. A recent report has suggested that the incidence of moderate to severe emergence phenomena associated with ketamine use is only 1.6%, considerably less , which is going with our study. The mechanism of action of dexmedetomidine is due its ability to block sympathetic stress response, decrease analgesic and anesthetic requirements, decrease respiratory depression and bradycardia, and decrease the incidence of arrhythmias.

Dexmedetomidine induced sedation qualitatively resembles normal sleep.Stimulation of α-2A receptors in the nucleus ceruleus inhibits noradrenergic neurons which produces sedation branded as "arousable sedation which is distinguished from sedation induced from drugs acting on GABA system which produce a clouding of consciousness. Our study showed significant high mean sedation scores (2.1±0.3) for 60 minutes post imaging period in D group as compared to K group (1.32±0.48) . This was also reflected in the study of **Abeer M Eldeek et al**. The sedation score in our study was more due to the use of ketamine 1mg/kg bolus dose followed by infusion of 0.2 mg/kg/hr. Dexmedetomidine induced sedation qualitatively resembles normal sleep.

Stimulation of α-2A receptors in the nucleus ceruleus inhibits noradrenergic neurons which produces sedation branded as "arousable sedation which is distinguished from sedation induced from drugs acting on GABA system which produce a clouding of consciousness. Our study showed significant high mean sedation scores (2.1±0.3) for 60 minutes post imaging period in D group as compared to K group (1.32±0.48) .This was also reflected in the study of **Abeer M Eldeek et al**.

Hence dexmedetomidine provides dose dependent increase in anxiolysis and sedation and can be used as direct infusion of bolus dose of 1µg/kg followed by infusion of 1µg/kg per hour for profound sedation. There was no significant difference between both groups in mean values of SpO2 at all points of time showed no significant difference statistically (p>0.05). This prospective observational study reveals that anaesthesia with dexmedetomidine produces stable haemodynamic parameters throughout imaging period.. A smooth postoperative recovery without respiratory depression, nausea, vomiting is an added advantage.

CONCLUSION:

In this study evaluation of efficacy of sedation in pediatric age group was the prime goal by comparing iv ketamine and iv dexmedetomidine .As these procedures are done in non-operating setups (scanning room),there are high chances of adverse cardio respiratory events.This study reveals that there is increase in hemodynamics with ketamine and emergence was also not smooth.

However, with Dexmedetomidine, hemodynamics are stable with smooth emergence. The study showed iv Dexmedetomidine to be a better agent for monitored anaesthesia care compared to iv ketamine for diagnostic procedures like CT, MRI.

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