

Haemodynamic Outcome And Recovery Time Using Propofol And Ketamine For Procedural Sedation In Children For Minor Cardiac Procedures – A Prospective Observational Study

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ABSTRACT

Introduction: The ideal anaesthetic technique for the management of pediatric patients scheduled to undergo cardiac catheterization should be safe, easy to administer, provide adequate sedation, amnesia, immobility, cardiovascular stability and fast recovery without residual complications. Anesthetic technique for such procedures has not been standardized. Deep sedation with pain free and spontaneously breathing patient on room air is preferred by the interventionist. There are not many studies in India about the haemodynamic outcome of single or combinations of anaesthetic agents. This study was done to note and observe the haemodynamic outcome and recovery time using propofol and ketamine for procedural sedation for pediatric cardiac catheterization laboratory procedures.

Methodology: 52 children of either sex of age 1-8 years and American Society of Anaesthesiology (ASA) physical status II undergoing cardiac catheterization were selected. Children will be premedicated with glycopyrrolate 10µg/kg, midazolam 20µg/kg, fentanyl 1µg/kg intravenously 10 minutes before taking the child inside cardiac catheterization laboratory. All children will be given propofol 2mg/kg and ketamine 1mg/kg intravenous for induction and then maintenance by intravenous infusion of 100-150µg/kg/min of propofol. Heart rate (HR), mean arterial pressure (MAP), oxygen saturation (SpO₂) and respiratory rate (RR) will be recorded every 5 minutes during the procedure. Post operatively heart rate and oxygen saturation will be recorded every 10 minutes. Recovery time was noted when the patient attains Stewards Simplified Post anaesthetic Recovery Score of 6.

Statistical Analysis: Result was expressed as mean +/- standard deviation for continuous variable and paired t test was used for statistical analysis. A p value less than 0.05 was considered statistically significant.

Results: We observed that there was significant change in heart rate compared to baseline, at 20min, 25min, 30min post induction. Changes in SpO₂ were significant from baseline at 5min, 10min, 15min, 25min, 30min post induction. Mean Arterial Pressure changes were significant from the baseline at 5min, 10min, 15min, 20min, 25min, 30min post induction. Respiratory rate changes were statistically significant from baseline at 5min, 10min, 15min, 20min, 25min, 30min post induction.

Mean recovery time was 35.98 ± 17.17 minutes

Conclusion: From the study it is concluded that using propofol and ketamine for procedural sedation in children for minor cardiac procedures is found to be safe as the haemodynamic profile was safe and recovery time was fast.

Keywords: -Cardiac catheterization; children; ketamine; propofol.

Introduction

First cardiac catheterisation on human was introduced by Werner Forssmann [1] in 1929, who inserted a catheter through his own antecubital vein to the right heart. Cardiac catheterisation laboratory procedures especially interventional procedures have increased exponentially over the last decade. Nowadays extremely complex procedures are being performed in the cath lab sometimes entailing several hours. It is very important for anaesthesiologists to become familiar [2] with the cath lab environment and communicate with cardiologist regarding patient management. Anaesthesiologist face several challenges while working in a remote location like the cath lab. These challenges include unfamiliarity [3] with the surroundings, limited help from colleagues, insufficiency of drugs, radiation exposure and limited equipment. Pediatric cathlab procedures are different from adults in several ways including different types of disease patterns in the patient, and a need for different requirements for the procedure, mandatory sedation or GA in almost all patients and a need for complete evaluation of structurally abnormal heart. Right heart catheterization is commonly done in CHD patients for

evaluation of shunting, oxygenation and pressures in different chambers and pulmonary vascular resistance. Complications which are life threatening are much higher in these patients who have supra systemic pulmonary hypertension. [4,5,6]

The ideal anaesthetic technique for management of pediatric patients scheduled to undergo cardiac catheterization should be safe, easy to administer, provide adequate sedation, amnesia, immobility, cardiovascular stability and fast recovery without residual complications. General anaesthesia with positive pressure ventilation can alter intracardiac pressures as well as shunt fraction. Therefore, GA is mainly chosen in critically ill patients, prolonged procedures, uncooperative patients and in procedures which require transesophageal echocardiography. Therefore, deep sedation with pain free and spontaneously breathing patient on room air is preferred by cardiac interventionist [6,7].

Goals of anaesthesia for catheterization are analgesia, anxiolysis, amnesia for the patient and easy separation from parents. At the same time maintenance of airway, ventilation, acid-base balance and temperature management are equally important.

Eventhough there are studies done around the world to study the haemodynamic outcome of single or combination of agents like propofol, ketamine and dexmedetomidine for sedation for pediatric cath lab procedures, there are not enough studies in India studying the same. Hence this study was undertaken in search of a stable anaesthetic Technique by which optimum conditions for cath-lab-procedures can be achieved.

Methods

This single centre, prospective observational study was done in a tertiary care centre in Kerala, India. Institutional Ethics Committee approval was secured. (Approval number GMC-KKD/RP 2018/IEC/196.)

A total of 52 children belonging to both the genders undergoing minor procedures in the cardiac catheterization laboratory in Government Medical College Kozhikode in the year period of June 2018 to December 2020 were assessed for inclusion and exclusion criteria and were included only after obtaining written informed consent from the parents. Children scheduled for elective cardiac catheterization laboratory procedure of age group 1 year to 8 years who were of ASA grade II.

Children with chromosomal anomalies or other multiple congenital anomalies, drug allergy, mechanical ventilation or inotropic support, hepatic or renal dysfunction were excluded from the study. Sample size was calculated using the formula:

$$n = (Z^2 * SD^2) / d^2$$

where the value of standard deviation and precision was taken from the study conducted by Vidyasagar Joshi et al., "Comparison of Dexmedetomidine and Ketamine versus propofol and ketamine for procedural sedation in children undergoing minor cardiac procedures in cardiac catheterization laboratory" [7], and the sample size was calculated as 52.

All patients were assessed by a detailed pre anaesthetic checkup including history, physical examination and laboratory investigation report. On the day before procedure an informed written consent was obtained from parents for the participation of their children in the study, in their native language.

All children were kept nil per oral before procedure (8 hours for solid food, 6 hours for semi solid food, 2 hours for clear fluids). Children were premedicated with glycopyrrolate 10 mcg/kg, midazolam 20 mcg/kg, fentanyl 1 mcg/kg intravenously 10 minutes before taking the child inside cardiac catheterization laboratory where anti hypothermia measures were taken under. Standard monitors including pulse oximeter, electrocardiogram, non-invasive blood pressure was attached. All children were given propofol 2 mg/kg and ketamine 1 mg/kg intravenous for induction and then maintenance by intravenous infusion of 100-150 mg/kg of propofol. Additional boluses of ketamine were given when a child showed discomfort.

Heart rate (HR), mean arterial pressure (MAP), oxygen saturation (spo2) and respiratory rate (RR) were recorded every 5 minutes during the procedure. If the heart rate falls below 20% of the baseline heart rate for that age, it was treated with atropine 0.02 mg/kg intravenous.

If mean arterial pressure falls below 20% of the baseline mean arterial pressure, were treated with fluid boluses. If there was occurrence of apnoea, hypoventilation or desaturation, it was supported with positive pressure ventilation.

Post procedure heart rate and oxygen saturation was recorded every 10 minutes. Recovery time was noted when the patient attained a score of 6 according to Stewards Simplified Post anaesthetic Recovery score. [8]

Steward Scoring System (also known as the Simplified Post-Anaesthetic Recovery Score)

Consciousness

- 2: Awake (Alert)
- 1: Responding stimuli (Arousable)
- 0: Not responding (Non-responsive)

Airway

- 2: Coughing on command or crying
- 1: Maintaining a good airway (Breathing easily)
- 0: Airway requires maintenance (Needs attention/support)

Movement

- 2: Moving limbs purposefully
- 1: Non-purposeful movements (Involuntary)
- 0: Not moving

Statistical analysis

Data was collected and analysis was done by using SPSS 18 statistical package (SPSS; inc., Chicago, IL) for windows. Result was expressed as mean +/- standard deviation for continuous variables, paired t test was used for statistical analysis.

Results

Mean age of the participants of study was 4.45 +/- 1.81 years. There were 24 males and 28 females in the study. Mean weight of the participants was 15.00 +/- 4.5 kg. Among the participants maximum weight was 27kg and minimum weight was 7kg. Around 53.8% of the procedures were ASD closure. 40.4% of the procedures were PDA closure. 3.8% of the cases were balloon dilatation. 1.9% of the procedures were cath study.

Haemodynamic parameters assessed were heart rate, oxygen saturation, mean arterial pressure and respiratory rate. Baseline values and post induction values at 5min, 10min, 15min, 20min, 25min and 30min were assessed. Comparison between baseline value and values post induction was done by paired t test. There were significant changes in heart rate compared to baseline value at 20 min, 25 min and 30 min (P < 0.05) as depicted in table 1 and figure 1.

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	baseline HR - HR (5 min)	.538	7.724	1.071	-1.612	2.689	.503	51	.617
Pair 2	baseline HR - HR(10min)	1.827	10.245	1.421	-1.025	4.679	1.286	51	.204
Pair 3	baseline HR - HR(15min)	3.096	11.556	1.603	-.121	6.313	1.932	51	.059
Pair 4	baseline HR - HR (20min)	3.962	11.802	1.637	.676	7.247	2.420	51	.019
Pair 5	baseline HR - HR (25min)	4.077	11.565	1.604	.857	7.297	2.542	51	.014
Pair 6	baseline HR - HR (30min)	4.769	10.733	1.488	1.781	7.757	3.204	51	.002

TABLE 1

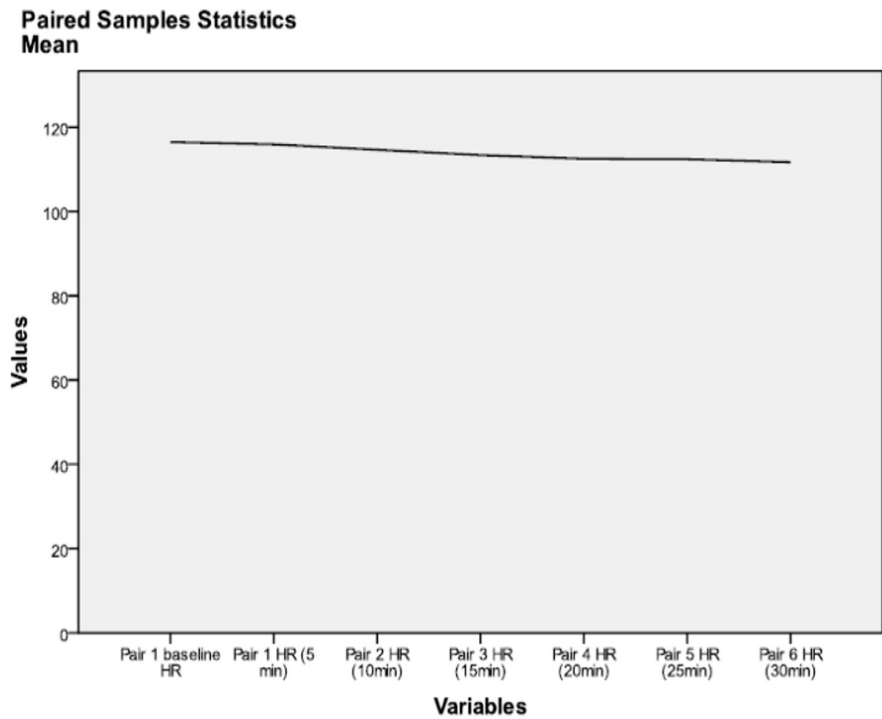


FIGURE 1

There were significant changes in SpO2 from the baseline at 5 min, 10 min, 15 min, 25 min, 30 min.

Paired Samples Test								
	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Pair 1 Baseline SpO2 - SpO2(5)	.115	.379	.052	.010	.221	2.198	51	.033
Pair 2 Baseline SpO2 - SpO2(10)	.135	.345	.048	.039	.231	2.817	51	.007
Pair 3 Baseline SpO2 - SpO2(15)	.135	.345	.048	.039	.231	2.817	51	.007
Pair 4 Baseline SpO2 - SpO2(20)	.115	.427	.059	-.004	.234	1.948	51	.057
Pair 5 Baseline SpO2 - SpO2(25)	.135	.444	.062	.011	.258	2.186	51	.033
Pair 6 Baseline SpO2 - SpO2(30)	.327	.648	.090	.146	.507	3.636	51	.001

TABLE 2

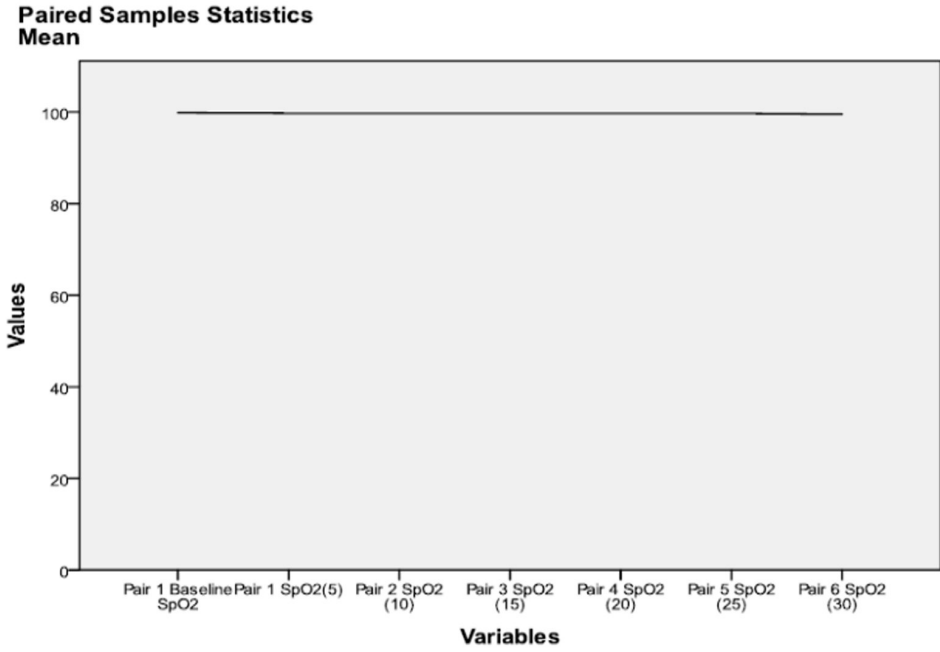


FIGURE 2

There was significant change in MAP from the baseline at 5 min, 10 min, 15 min, 20 min, 25 min and 30 min post induction.

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Pair 1 Baseline MAP - MAP(5)	4.769	5.596	.776	3.211	6.327	6.145	51	.000
Pair 2 Baseline MAP - MAP(10)	6.962	7.816	1.084	4.785	9.138	6.422	51	.000
Pair 3 Baseline MAP - MAP(15)	7.192	8.270	1.147	4.890	9.495	6.271	51	.000
Pair 4 Baseline MAP - MAP(20)	7.942	8.853	1.228	5.478	10.407	6.470	51	.000
Pair 5 Baseline MAP - MAP(25)	8.058	8.223	1.140	5.768	10.347	7.066	51	.000
Pair 6 Baseline MAP - MAP(30)	7.981	7.750	1.075	5.823	10.138	7.426	51	.000

TABLE 3

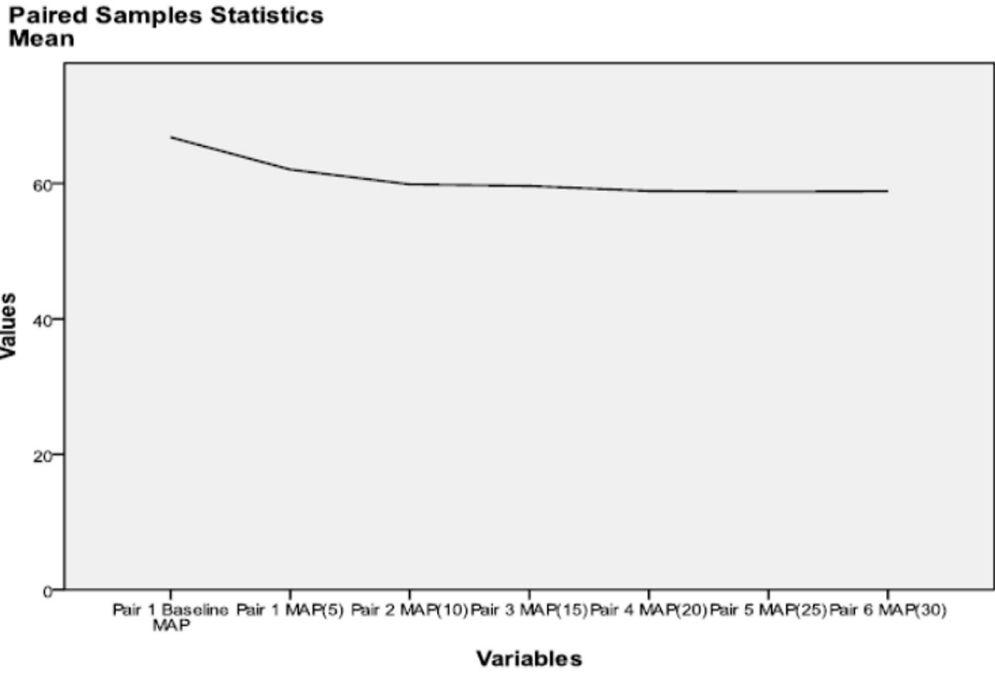


FIGURE 3

There were significant changes in respiratory rate at 5 min, 10 min, 15 min, 20 min, 25 min, 30 min.

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Pair 1 Baseline RR - RR(5)	.596	1.729	.240	.115	1.078	2.486	51	.016
Pair 2 Baseline RR - RR(10)	.481	2.128	.295	-.112	1.073	1.629	51	.109
Pair 3 Baseline RR - RR(15)	.788	2.312	.321	.145	1.432	2.459	51	.017
Pair 4 Baseline RR - RR(20)	1.308	2.165	.300	.705	1.910	4.355	51	.000
Pair 5 Baseline RR - RR(25)	1.519	2.555	.354	.808	2.231	4.287	51	.000
Pair 6 Baseline RR - RR(30)	1.615	3.088	.428	.756	2.475	3.772	51	.000

TABLE 4

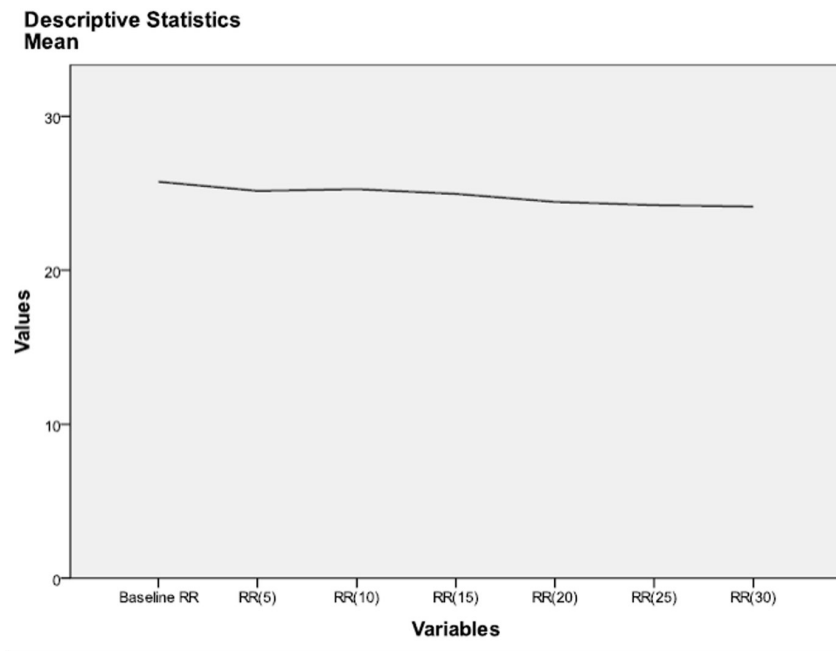


FIGURE 4

n recovery time was 35.98 +/- 17.172 minutes. Additional ketamine bolus requirement seen in 6 p

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Discussion

There is no ideal combination of drugs for providing procedural sedation in cardiac catheterization laboratory procedures. A combination of drugs that provide adequate depth of sedation, maintenance of cardiac physiology in shunt lesions and quick recovery was preferred. Commonly used drugs are ketamine, propofol and dexmedetomidine. These drugs were used in various combinations to achieve the preferred characteristics of sedation. Ketamine-propofol combination was used in this study. Ketamine has the property of increasing heart rate and systemic vascular resistance, which when used in a lower dose with propofol would reduce the occurrence of significant haemodynamic changes. Property of propofol to decrease the systemic vascular resistance and cause respiratory depression were reduced in combination with ketamine which will not cause respiratory depression. In our study there was significant change in heart rate compared to baseline at 20min, 25min, 30min post induction which could be attributed to the anxiety of

the patient or inadequate depth of anaesthesia which was treated by giving ketamine boluses.

There was no occurrence of bradycardia throughout procedure. Changes in SpO₂ were significant at 5min, 10min, 15min, 25min, 30min post induction. But clinically the patients maintained oxygen saturation with spontaneous ventilation and there was no occurrence of desaturation or apnoea. Mean arterial pressure changes were significant at 5min, 10min, 15min, 25min, 30min post induction compared to baseline which could be attributed to the effect of propofol at induction and maintenance. Respiratory rate changes were significant at 5min, 10min, 15min, 20min, 25min, 30min post induction compared to baseline. But there was no occurrence of apnoea throughout procedure. Mean recovery time was 35.98 +/- 17.17 minutes. There was no incidence of any post procedure complications like apnoea or bradycardia or excess bleeding from catheter puncture sites. Similar study was done by

Akin et al who investigated the effects of propofol and propofolketamine on haemodynamics, sedation level and recovery period in pediatric patients undergoing cardiac catheterization [7] and also recovery time using stewards recovery score and found that number of patients with more than 20% decrease in MAP was 11 in group 1 and 3 in group 2. ($P < 0.05$).

The number of patients who experienced more than 20% decrease in HR was 12 in group 1 and 5 in group 2. Ten patients in group 1 and 3 patients in group 2 required additional fentanyl doses ($p = 0.057$). Propofol combined with low dose ketamine preserves MAP better without affecting the recovery.

A study done by Kogan et al. to evaluate the safety of a propofol ketamine mixture to induce and maintain anaesthesia in spontaneously breathing pediatric patients during cardiac catheterization [10], and found that mean dose of ketamine was 26 ± 8.3 mcg/kg/min and mean dose of propofol was 68.3 ± 21.7 mcg/kg/min.

Changes in heart rate and MAP of more than 20% from baseline were observed in 4 and 5 patients respectively. A transient reduction in Oxygen saturation because of hypoventilation was observed in 3 patients and responded to oxygen administration and manual assisted ventilation. No other complications were observed.

Study by Vidya Sagar Joshi et al. compared the combination of dexmedetomidine and ketamine versus propofol and ketamine for procedural sedation in children undergoing minor cardiac procedures in cardiac catheterization laboratory [7].

With 30 children in each group, they observed that: Heart rate in the dexmedetomidine (DK) group was significantly lower during the initial 25 min after induction compared to the propofol-ketamine (PK) group. Recovery was prolonged in the DK group compared to the PK group (40.88 vs. 22.25 min).

Even ketamine boluses consumption was higher in the DK group. Similar study was done by Tosun et al [11] with the same combination in 44 children, 22 in each group and observed that the heart rate in DK group was significantly lower (average 10-20 beats/min) than PK group after induction and throughout the procedure. Ketamine consumption in DK group was significantly more than PK group (2.03 mg/kg/hr vs 1.25 mg/kg/hr) for maintenance ($p < 0.01$). The recovery time was also longer in DK group than in PK group (49.54 vs 23.16 min) respectively; $p < 0.01$).

Conclusion

From this study, it can be concluded that despite statistically significant changes in the haemodynamic parameters patients remained haemodynamically stable, hence ketofol induction followed by propofol maintenance was a good effective and safe combination for procedural sedation in pediatric cardiac catheterization laboratory procedures

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None

Disclosure of use of artificial intelligence (AI) - assistive or generative tools

The AI tools or language models (LLMs) have not been utilized in the manuscript except that software has been used for grammar corrections and references.

Declaration of use of permitted tools

All figures and tables are the author's own work. Data analysis was done using SPSS 18 statistical package (SPSS Inc. Chicago IL).

Supplementary material

None

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None

Conflicts of interest

There are no conflicts of interest

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