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COMPLICATIONS OF PROCEDURAL SEDATION BY MIDAZOLAM - KETAMINE VERSUS PROPOFOL IN CHILDREN UNDERGOING MAGNETIC RESONANCE IMAGING: A RANDOMIZED COMPARATIVE STUDY

Anaesthesiology

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ABSTRACT

Background: Pediatric Magnetic Resonance Imaging (MRI) requires absolute immobility to ensure diagnostic image quality, often necessitating deep sedation. While various sedative regimens are used, the ideal agent providing maximum safety with minimal side effects remains a subject of clinical debate. **Objective:** To compare the incidence and nature of complications during and after sedation with Midazolam-Ketamine (M-K) versus Propofol (P) in children undergoing MRI.Methods: This prospective, randomized, single-blinded study analyzed 98 children (ASA I or II, aged 1 month to 16 years). Group A (n=50) received IV Midazolam (0.1 mg/kg) and Ketamine (1 mg/kg), while Group B (n=48) received IV Propofol (1 mg/kg). Complications were monitored at 5-minute intervals during the procedure and throughout recovery until a Ramsay Sedation Score of 2 was reached. **Results:** No major complications (cardiac arrest, apnea, or laryngospasm) occurred in either group. Minor intra-procedural complications occurred in 26% of Group A and 25% of Group B (P=0.71). Specifically, hypoxia (SpO_2 < 90\%) and bradycardia were observed only in the Propofol group (4.2% each), while tachycardia (6%) and increased oral secretions (12%) were more frequent in the M-K group. Recovery complications were higher in Group A (46%) than Group B (25%), primarily due to agitation (20% vs 8.3%), though this was not statistically significant (P=0.24). **Conclusion:** Both Midazolam-Ketamine and Propofol are safe for pediatric MRI sedation with no significant difference in overall complication rates. Propofol is associated with transient respiratory depression, while M-K is more likely to induce post-procedural agitation.

KEYWORDS

Objective

Pediatric Magnetic Resonance Imaging (MRI) is a critical diagnostic tool, preferred for its ability to provide detailed anatomical information without exposing children to ionizing radiation.[1-4]

Despite its advantages, the procedure presents significant challenges for the pediatric population.

It requires absolute immobility for extended periods to prevent motion artifacts, which can necessitate repeating entire sequences. Additionally, the MRI environment—characterized by a confined tunnel and loud noise levels reaching 90 dB—is often anxiety-provoking for children.

Consequently, deep sedation is frequently required to ensure both patient comfort and successful completion of the scan.[5,6]

Deep sedation is defined as a medically induced state where the patient is essentially unconscious and does not respond to verbal commands.[7] While effective, it carries risks of complications, including hypotension, bradycardia, apnea, and airway obstruction. These risks are particularly concerning in the MRI suite because the patient's head is positioned deep within the scanner, limiting immediate physical access during an emergency.Currently, there is no universal consensus on the ideal sedative regimen for pediatric MRI. An optimal agent should provide a short induction time, maintain hemodynamic stability, and allow for rapid discharge. Common practices involve agents like Propofol, known for its quick recovery, or combinations such as Midazolam and Ketamine (M-K), which have been used reliably for years.[8,9] This study aims to compare the sedative effects, hemodynamics, and complication profiles of these two regimens to enhance safety and efficiency in pediatric diagnostic imaging.

Methods

This study was conducted in the Department of Pediatrics, National Institute of Medical Sciences & Research, Jaipur, Rajasthan from September 2022 to June 2024. A total of 100 patients between the ages 1month and 16 years who belong to the American Society of Anaesthesiologist status 1 and 2[10] admitted for MRI and required sedation at Artemis hospital during the study period were included.

Children whose parents refuse to give positive consent and those who were not induced by sedative were excluded. Children having allergy to any of the drugs studied, hemodynamically instability, H/O allergy to eggs as propofol emulsion contains egg, ASA status III and above were also excluded. This study was prospective single-blinded randomized comparative study. The clinical and the demographic information were recorded on a pre-structured proforma, together with the detail history, physical and detailed systemic examination.

This study was conducted after the approval of Scientific and Ethics committee The study was planned on 100 Children of age between 1month to 16 years who were scheduled to undergo Magnetic resonant imaging for the diagnostic purpose at our institute.

The patients were shifted to the MRI induction room accompanied by parents after a period of fasting as per fasting guidelines proposed by the American Society of anaesthesiologist.

The intravenous line was secured and monitoring lines were attached which included Electrocardiogram, non-invasive blood pressure, and pulse oximetry for SpO2 monitoring.

Baseline heart rate, respiratory rate, NIBP and SpO2 values were recorded. Drugs were given according to group assignments determined by a computer-generated number sequence and were contained in sequentially numbered opaque envelopes to ensure blinding. All the procedures were performed by the pediatric intensivist. Drugs were given according to the group assigned.

Group A – These patients received intravenous midazolam at a bolus dose 0.1 mg/kg (maximum 4 mg) along with Ketamine at bolus dose 1 mg/kg intravenously. Patient responses to verbal and tactile stimuli were evaluated 2 min after the administration of the drug. Ketamine 0.5 mg/kg (maximum of 2 mg/kg) was added at 2-min intervals if adequate sedation was not achieved.

Group B- These patients received intravenous Propofol at a bolus dose of 1 mg/kg. Patient responses to verbal and tactile stimuli were evaluated 2 min after the administration of Propofol. Propofol 0.5 mg/kg was added at 2-min intervals if adequate sedation was not achieved.

The effectiveness of sedation during the procedure was evaluated according to the modified Ramsay sedation score (RSS). A score from 1–6 was assigned according to the response of the patient to the stimuli. A score of 5 or above indicates adequate sedation. RSS of 5 or above was aimed at for a comfortable procedure in our study. The imaging was initiated when the child was well sedated. Oxygen (2 l/min) by a nasal cannula /facemask was administered to all patients during the procedure. Mean arterial pressure (MAP), heart rate (HR), peripheral oxygen saturation (SpO2), and respiratory rate (RR) were monitored continuously and recorded at 5-min intervals during the study period. Additional doses of Ketamine and Propofol according to the group respectively at the dose of 0.5mg/kg was also administered in between in case of inadequate sedation if needed. The observer who collected data was not blinded to whether the patient has received Midazolam plus Ketamine or Propofol during magnetic resonance imaging.

All complications were recorded. Cardiac arrest, apnea, and laryngospasm were assessed as major complications, whereas hypoxia (peripheral oxygen saturation <90% during 60 s),tachycardia (defined as 30% more than the average HR by age), bradycardia (30% less than the average HR by age), increase in oral secretions (copious oral secretions requiring suctioning), flushing, coughing, and vomiting were assessed as minor complications. In case of complications, the intervention was done by a pediatric intensivist as per protocol. The completion of the procedure without any major complications indicated the success rate of sedation.

The patients follow-up was performed in the pediatric ward after the procedure. Complicationsduring the recovery time such as double vision, dizziness, nausea and vomiting agitation, andemergence reactions were recorded. Data was collected in Microsoft Word 2010 and Microsoft Excel 2010. The continuous data was shown as Mean +/- Standard Deviation and categorical data were represented as absolute numbers and percentages. For continuous data, the Kolmogorov–Smirnov tests were performed

to assess normality and where appropriate the data was analyzed with required statistical tests and descriptive statistics. Parametric data were analyzed with student's T-Test/ Z-Test. Non-parametric data were analyzed by Kruskal Wallis test and further paired comparisons were done using the Mann Whitney U test. Nominal categorical data between the groups were compared using the Chi-square test or Fisher's exact test as appropriate and used correlation coefficient to observe the linear relationship. For all statistical tests, a p-value of less than 0.05 was taken to indicate a significant difference.

RESULTS

In this prospective study; conducted in tertiary care hospital of Jaipur, Rajasthan, 100 children belonging to ASA physical status I or II who were admitted for MRI on a various reasons were included. After enrollment, group assignments were determined by a computer-generated number sequence and were contained in sequentially numbered opaque envelopes to ensure blinding. A total of 100 patients were randomly allocated in 2 groups. Group A patients received Midazolam plus Ketamine combination for sedation were as Group B patients received Propofol. Among the 2 patients were excluded from group B because of the failure of induction by Propofol and Midazolam had to be given to these patients.

In this study, the mean age of children was 46.07± 29.92 months in Group A and 44.98 ± 31.20 months in Group B. Mean age was comparable between groups without significant inter group difference. There were 38% Female and 62% Male in group A while Group B consists of 33.3% Female and 66.7% male. The difference in gender distribution between two groups was not statistically significant.

In our study, out of 98 patients, 28 were interpreted as ASA 1 and 70 patients belong to ASA 2. In patients belonging to Group A, out of 50 patients 13 (26%) were ASA 1, and 37 (74%) were ASA 2. In patients belonging to Group B out of 48 patients, 15 (31.3%) were ASA 1 and 33 (68.8%) were ASA 2.ASA status distribution was comparable in both groups without significant intergroup difference. MRI brain was done in 96 % of patients in group A and 93.8% of patients in group B while 4% in group A and 6.3% in group B had an MRI spine. Part of the MRI examination was comparable in both groups with no significant intergroup difference. The average duration of MRI in group A was 30.29 ± 15.16 min while in group B was 28.96 ± 9.79 min. The two groups were comparable in terms of the duration of the MRI procedure.

No patients developed major complications such as cardiac arrest, apnea, or laryngospasm during the procedure. A total of 25 (25.5%) patients out of 98 developed minor complications; 13(26%) patients in group A and 12(25%) patients in group B developed complications. Cough (1 patient), tachycardia (3 patients) was observed only in group A. Increased oral secretions (6 patients in group A while 4 patients in group B) were observed more often in group A. Hypoxia and bradycardia were observed in 2 patients from group B. Flushing occurs in 4 patients from group B and 3 patients from group A. The difference between the incidence of minor complications in the groups was statistically insignificant. A total of 35 patients (35.7%) developed complications during the recovery such as dizziness, agitation, emergence reaction, double vision. Agitation was the most frequent complication (14 patients, 14.2%). complication rate in group A was 46% while in group B was 25%. Although the incidence of complications during recovery was statistically insignificant between the groups.

Table 1: Comparison of ASA Status between the groups

ASA	Group				
	Group A (n = 50)		Group B (n = 48)		p-value
	Frequency	Percent	Frequency	Percent	0.63
ASA 1	13	(26%)	15	(33.3%)	
ASA 2	37	(74%)	33	(66.7%)	

Table 2 : Comparison on basis of minor complications between the groups

Minor Complications					P-value
Statistics	M+K		Propofol		
	Frequency	Percent	Frequency	Percent	
HYPOXIA	0	0	2	4.2	0.71
TACHY CARDIA	3	6	0	0	
BRADY CARDIA	0	0	2	4.2	
FLUSHING	3	6	4	8.3	
INCR EASED SECRETION	6	12	4	8.3	
COUGH	1	2	0	0	
VOMITTING	0	0	0	0	

DISCUSSION

Our study compared the effects of Midazolam-Ketamine and Propofol for complications in children undergoing sedation for MRI.

There were no comparative study evaluating the Midazolam Ketamine combination versus Propofol in children undergoing sedation for MRI.

In our study, 100 patients were randomized into 2 groups (Group A and Group B). Group A received Midazolam and Ketamine combination and group B received Propofol. 2 patients were excluded from group B because of the failure of induction.

The two groups were similar in our study in terms of demographic profile (Age, gender, weight and height, ASA Physical status, indication, and duration of MRI).

No patients in our study developed major complications such as cardiac arrest, apnea or laryngospasm during the procedure. Similar results were found in a study by Akbulut et al.[11]

on endoscopy comparing Midazolam Ketamine and Propofol Fentanyl that 28.6% of patients developed minor complications. Complications were comparable in both groups except for in the occurrence of bradycardia which was significantly higher in the latter group. Among minor complications increased oral secretions occurred in 10% of patients. Although an increase in secretion is associated with risk of aspiration and laryngospasm, these complications were observed in none of our patients while 4% of patients (2 patients in both groups) had nausea during recovery which relieved after 1 dose of intravenous antiemetic.

Although we noticed a decrease in mean arterial pressure in both groups, none of our patientshad hypotension while Christopher et al [12] in their study found more hypotension in thePropofol group, but they used a high dose (250-300mcg/kg/min) of Propofol infusion. Sebe

etal[1] compared Midazolam and Propofol in pediatric diagnostic imaging and reported that patients in both the group experience a significant decrease in systolic and diastolic BP, although the difference in systolic BP was not significant but a change in diastolic BP was significant between the groups. In our study, we analyzed mean arterial pressure and the difference of MAP between 2 groups was not significant.

In our study, the difference in heart rate between both groups was not significant. Although Sebe et al.[1] in their study experienced a slight decrease in HR in both groups but that reduction also did not have clinical or statistical significance ($P = 0.060$).

In our study both groups have been found to have a reduction in Respiratory rate and oxygen saturation however the difference in Respiratory rate reduction between the groups was notstatistically significant. Mean Peripheral arterial oxygen saturations fluctuated between 96% and 98% from the starting of the procedure to recovery. Although at 25 minute the mean peripheral oxygen saturation in group B was statistically less than Group A. These findings are attributed to the predictable effects of the drugs[13] In another study comparing midazolam and ketamine in pediatric Procedural sedation and analgesia, Parker et al [14] also found that 12% of the patients experienced a temporary but significant decrease in oxygen saturation Machata et al[15] in their study on Propofol-based sedation regimen for 500 infants and children undergoing ambulatory magnetic resonance imaging found respiratory adverse events in five patients (1%). All of these patients suffered from oxygen desaturation (SpO2 <92%). Three children in their study experienced partial airway obstruction, which was treated immediately with slight neck extension and chin support. Two other children required short time assistance of spontaneous respiration via bag-valve-mask ventilation and afterward further reposition of neck and shoulders.

We observed that a total of 35 (35.7%) patients developed complications during the recovery.

Agitation in form of excessive crying was the most frequent complication. The complication rate in group A was higher than group B ; Although the incidence of complications during recovery was comparable between the groups. However, Ulas E. Akbulut et al [11] reported that the rate of complications during the recovery was significantly higher in the Midazolam– Ketamine group than the Propofol-Fentanyl group. Agitation and emergence reactions were significant side effects observed during recovery in Ketamine-based sedation. The incidence of emergence reactionincreases, especially when Ketamine is used at high doses, when a fast injection (< 1 minute) isadministered, and when excessive visual or verbal stimuli exist during the recovery[16,17] Hoff et al reported that Propofol reduces the incidence of emergence reactions. In our study, similarly, none of the patients administered Propofol combination developed emergence reactions.

CONCLUSION

The study concludes that Midazolam-Ketamine (M-K) is superior to single-dose Propofol for maintaining stable sedation during pediatric MRI. Although Propofol offers a significantly faster recovery time, it requires a higher induction dose and more frequent additional boluses to prevent movement during the scan. Both regimens demonstrated comparable safety profiles, with no significant differences in MRI quality, hemodynamic parameters, or the overall incidence of minor complications. Consequently, M-K remains a reliable choice for prolonged diagnosticprocedures where consistent immobility is paramount.

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