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Original Article

Efficacy and Safety of Propofol Drip versus Thiopental with Midazolam in Children Undergoing Magnetic Resonance Imaging Studies

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ABSTRACT

Introduction: Pediatrics often require sedatives during Magnetic Resonance Imaging (MRI) due to its lengthy, loud, and restricted space. This study aims to compare efficacy and safety of propofol drip and thiopental with midazolam for children undergoing MRI. **Methods:** This randomised double-blinded cohort study was conducted in patients aged 3-10 years old with ASA status I-II scheduled for outpatient MRI. Exclusion criteria include airway abnormalities, allergic reactions to anesthetic agents, renal, hepatic, and seizure history, or was pre-medicated. Patients were administered propofol (group PF) or midazolam with thiopental (group TH). Data including patient history, physiologic parameters, duration, recovery, discharge time, and adverse events were recorded. Data was statistically analysed using Chi Square and Student T-test. **Results:** A total of 34 patients were included in this study, 18 in PF and 16 TH. Sedation onset, recovery time, and mean discharge was significantly shorter in PF versus TH (6 vs 10 mins ($p < 0.0001$); 8 vs 13 mins ($p < 0.0001$), and 69 vs 89 mins ($p < 0.0001$)). No significant differences in duration and physiologic parameters between both groups were found. No adverse events occurred in both groups. 6.25% of patients in group PF and 33.33% in group TH had inadequate sedation. **Conclusion:** This study found PF has faster sedation onset and recovery time in comparison to TH for children undergoing MRI with no significant differences in physiologic parameters and adverse events. Further studies conducted on a larger population investigating efficacy and adverse events of alternative sedatives is recommended.
Keywords: Propofol, Thiopental, MRI, Children.

INTRODUCTION

Magnetic Resonance Imaging (MRI) is a radiodiagnostic procedure which often causes anxiety in patients due to its lengthy, loud, and restricted space. Completion of an MRI sequence requires patient cooperation by remaining immobile.

If this is not achieved, the entire sequence must be repeated.[1] However, the aforementioned MRI environment, may reduce patient cooperation to obtain high quality image, especially in the pediatric population.[2-3] Sedatives are often administered in pediatrics undergoing MRI in comparison to other imaging modalities such as CT scans and radiography.[4]

According to the American Academy of Pediatrics, aims of sedation in diagnostic or therapeutic procedures undergone by pediatrics are: (1) to ensure patients' safety and welfare, (2) to reduce discomfort or pain, (3) to control anxiety, (4) to minimize psychological trauma, (5) to assist in controlling behavior or movement for safe completion of the procedure, and (6) for safe discharge of patients.[5]

Determining the appropriate sedative dose to be administered is complex. If the dosage is insufficient, this may lead to procedure failure, incorrect findings, and trauma due to unexpected movements. If an excessive dose is administered, complications including apnea, airway difficulties, hypotension, and cardiac arrest may occur.[6-7] Hemodynamic and respiratory stability monitoring whilst ensuring sedation in patients undergoing MRI also remains a challenge due to special monitoring and equipments required which do not interfere with the MRI. This adds 21% risk to an otherwise safe MRI procedure, causing complications including respiratory depression and hypoxemia.[8-9]

Popular sedatives used for the pediatric population include thiopental sodium, midazolam, and propofol. Existing literatures have shown contrasting results in regards to their effectiveness and adverse effects.[7,810-12] This study aims to compare efficacy and safety of propofol drip and thiopental in combination with midazolam for children undergoing MRI.

MATERIALS AND METHODS

This randomised double-blinded cohort study has been reviewed and approved by Institutional Research Ethics (approval number: 212/K-LKJ/ETIK/III/2023) and is in accordance with the Declaration of Helsinki. This study was conducted from January 2020 to October 2023 where pediatrics who underwent MRI studies with use of sedatives were examined. Informed consent was obtained by parents or legal guardians of children undergoing MRI studies following thorough explanation of the procedure. Children aged 3-10 years old with ASA status I-II scheduled for outpatient MRI was included in this study. Patients with ASA status III-IV, airway abnormalities, had history of allergic reactions to anesthetic agents (midazolam, propofol, or thiopental), experienced illness prior to the procedure (nausea and vomiting, fever, diarrhea, cough), bradycardic, hypoxic, had renal or hepatic

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abnormalities, experienced convulsion or myoclonia perioperatively, or was given pre-medications were excluded from the study.

Prior to scheduled MRI, past medical history, surgical history, sedation history, current medications, allergies, physical examination and laboratory results was recorded. Data regarding patient re-evaluation on the day of the procedure was also measured including baseline vital signs. Patients were then placed IV cannulation and given D50.3 NaCL 500 mL which was titrated according to patient's weight.

Patients were then randomised into group PF (receiving propofol) or group TH (receiving midazolam with thiopental) using a computerised random number generation.. Propofol was given with loading dose of 1-2 mg/kg, followed by propofol drip 75-100 mcg/kg/min intravenously and titrated based on patient's heart rate (group PF). Midazolam with a dosage of 0.05-0.1 mg/kg intravenously. Thiopental was given with a dosage of 3-5 mg/kg bollus with supplemental boluses of 1-2 mg/kg (group TH).

When a Ramsay score of 5 was achieved and hemodynamic was stable, patients were transferred on the scanning table. Onset of sedation was recorded. Patients were then positioned to have their neck extended by having a shoulder roll placed under the neck. If Ramsay score of 5 was not achieved, propofol infusion rate was increased to 100 to 150 mcg/kg/min (group PF) or was given additional thiopental bollus 1-2 mg/kg (group TH). Patients who move during the procedure (inadequate sedation) was given additional midazolam 0.05 mg/kg for patients who were given TH or 1 mg/kg of PF. Four to five liters of supplemental oxygen was provided via face mask for all patients. Parameters including heart rate, oxygen saturation, and respiratory rate were measured and recorded in five minute intervals.

Propofol drip was stopped as soon as the scan was finished. All patients were transferred to recovery room after the scan. Children were discharged when they have awakened to their baseline mental and ambulatory status, and able to maintain a patent airway. Recovery and discharge time was measured.

All data collected were analyzed by using Statistical Package for the Social Sciences 25.0 (SPSS). Chi square to assess significance of relationship and Student T test to compare physiologic parameters, sedation onset, recovery time, and discharge time between patients who were administered PF and TH were conducted. Mean percentage of rise and drop from baseline of physiologic parameters were computed as follows: Σ [(Xt-Xo/xo)]/tn x 100 where Xt is the physiologic parameter at time interval t, Xo is the baseline physiologic parameter (t= 0) and tn is the number of time intervals.

RESULTS

A total of 34 patients were included in this study. Eighteen patients were administered TH with midazolam and 16 were given PF. Table 1 shows the demographic data for patients in the two groups. No significant differences in demographics were found between the two groups.

Table 2 shows the reason for conducting MRI. 73.5% patients underwent MRI procedure for cranial imaging. Other purposes for undergoing MRI include pituitary, cervicothoracic, thoracolumbar, lumbosacral, abdominal, and lower leg examinations.

Table 3 shows duration of procedure, sedation duration, recovery and discharge time between the two groups. Duration of the MRI procedure in group PF undergoing cranial MRI was significantly faster than group TH (p< 0.0052). However, an overall duration between the two groups were not statistically significant (p= 0.0816). Sedation onset, recovery time, and shorter mean discharge was significantly shorter in group PF in comparison to TH, which was 6 vs 10 minutes (p <0.0001); 8 vs 13 minutes (p <0.0001), and 69 vs 89 minutes (p <0.0001) respectively. This is also shown in Figure 1.

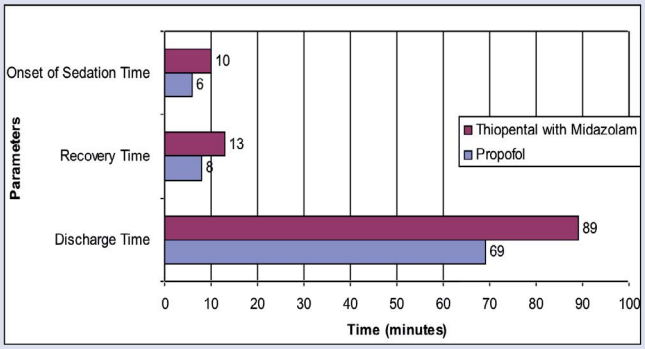

Figure 1: Sedation Onset, Recovery Time, and Discharge Time.

Table 1: Demographic Data.

		Group PF (n = 16)	Group TH (n = 18)	p-value
Weight (kg)		15.3 ± 3.8	14.5 ± 3.1	0.48
Age (years)		4.7 ± 2.1	4.3 ± 1.5	0.57
Gender				0.61
	Male	8 (44.4%)		
	Female	10 (55.5%)		
ASA				0.94
	ASA I	2 (12.5%)		
	ASA II	14 (87.5%)		

Table 2: Types of MRI Procedure.

	Group PF (n = 16)	Group TH (n = 18)	Total (n = 34)	p-value
Cranial	**11 (68.8%)**	**14 (77.8%)**	**25 (73.5%)**	**0.48**
Others	5	4	9	0.57
Pituitary	1	1	2	0.61
Cervicothoracic	2	0	2	
Thoracolumbar	0	1	1	
Lumbosacral	1	1	2	
Abdominal	1	0	1	
Lower leg	0	1	1	

Table 3: Types of MRI Procedure.

	Group PF (n = 16)	Group TH (n = 18)	p-value
Duration	11 (68.8%)	14 (77.8%)	0.48
All Procedures	41.9 ± 11.3	49.9 ± 9.7	0.08
Cranial	38.3 ± 6.3	47.3 ± 7.9	< 0.01
Sedation Onset (mins)	5.8 ± 1.7	11.2 ± 4.7	< 0.0001
Recovery Time (mins)	7.9 ± 1.7	13.4 ± 2.8	< 0.0001
Discharge Time (mins)	68.7 ± 11.4	88.5 ± 10.9	< 0.0001

Table 4 shows the physiologic parameters of group PF and TH including heart rate, oxygen saturation, and respiration rate. Variability of the parameters were calculated by the mean percentage rise and drop from the recorded baseline. No significant differences in mean percentage rise and drop of parameters between the two groups were found.

Table 5 shows adverse events during MRI procedure including prolonged sedation, nausea and vomiting, bradycardia, desaturation, apnea, convulsions, and unplanned admission. No adverse events occurred in both groups. However, 6.25% of patients in group PF and 33.33% in group TH had inadequate sedation.

Table 4: Physiologic Parameters Group PF and TH.

	Group PF (n = 16)	Group TH (n = 18)	p-value
Mean Heart Rate (beats per minute) ± SD			
t = 0	88.2 ± 8.6	90.9 ± 8.31	0.35
Percentage of rise	2.5% ± 0.5	2.4 % ± 0.8	0.89
Percentage of drop	7.9% ± 2.9	5.8% ± 2.4	0.04
Mean Oxygen Saturation (%) ± SD			
t = 0	99.5 ± 0.5	99.4 ± 0.6	0.80
Percentage of rise	1.0% ± 0.0	1.2% ± 0.5	0.35
Percentage of drop	1.1% ± 0.01	1.0% ± 0.00	N/A
Mean Respiration Rate (breaths per minute) ± SD			
t = 0	21.9 ± 2.2	22.1 ± 1.6	0.86
Percentage of rise	11.1% ± 0	4.7% ± 0.5	0.06
Percentage of drop	11.4% ± 3.8	10.2% ± 2.5	0.29

Table 5: Adverse Events and Inadequate Sedation.

	Group PF (n = 16)	Group TH (n = 18)
Adverse Events (%)	0	0
Sedation Success (%)		
Inadequate Sedation (%)	6.25	33.33
Adequate Sedation (%)	93.75	66.67

DISCUSSION

Pediatrics often require sedation when undergoing MRI due to its noisy and restricted environment and lengthy procedure. Using sedation may increase the probability of an adverse event to occur in an otherwise low risk procedure, including apnea, airway difficulties, hypotension, and cardiac arrest.[6-7] This is due to the MRI environment which limits access and equipments that may be used for monitoring purposes.[8-9]

Dosage and type of sedative used should be meticulously considered to maintain sedation for completion of the procedure and prevention of complications. Various sedatives are used today for sedation in pediatrics undergoing MRI including inhalational and intravenous agents. An ideal sedative agent is one that maintains a patient's ventilation, provides hemodynamic stability, maintains immobility, and allows easy titration which allows faster sedation onset and recovery with minimal adverse effects.[10]

The faster duration, sedation onset, recovery time, and discharge time as well as no adverse events occurring in group PF, favors use of propofol in comparison to thiopental with midazolam. However, there remains contrasting evidences in existing literatures comparing the two sedatives.[7,810-12]

This study found duration of the MRI procedure in group PF undergoing cranial MRI was significantly faster than group TH ($p< 0.0052$). Sedation onset, recovery time, and shorter mean discharge was also significantly shorter when using propofol in comparison to thiopental with midazolam, which was 6 vs 10 minutes ($p <0.0001$); 8 vs 13 minutes ($p <0.0001$), and 69 vs 89 minutes ($p <0.0001$) respectively. Variability of physiological parameters including heart rate, oxygen saturation, and respiratory rate were calculated by the mean percentage rise and drop from the recorded baseline. No significant differences in mean percentage rise and drop of parameters between groups PF and TH were found. This study also found that no adverse events occurred in both groups. However, 6.25% of patients in group PF and 33.33% in group TH had inadequate sedation.

This is consistent with results obtained from a prospective trial conducted on 160 patients by Geyik et al. Patients were given either propofol 2 mg/kg with an additional propofol of 1 mg/kg if needed or thiopental 2 mg/kg with an additional dose of 1 mg/kg intravenously if required. This study found that use of propofol may be used effectively for sedation in pediatrics due to minimal adverse effects and its rapid induction. Propofol was also able to be titrated and controlled by the anesthesiologist. [8]

These findings differ from a clinical trial of 80 patients conducted by Hasani et al comparing propofol and thiopental. Propofol was administered using a dosage of 0.5 mg/kg and thiopental 2.0/kg. Patients were then evaluated using the University of Michigan Sedation Scale to determine depth of sedation. This study found a significantly longer recovery time in PF group (55 minutes vs 26.9 minutes) and more common complications including desaturation (1.6%), bradycardia (11%), apnea (0.8%), and airway obstruction (1.1%).[7] This varying results may be affected by dosage and method of administrating the sedatives.

One advantage of continuous propofol sedation is the ability to titrate the drug to effect, even for prolonged imaging procedures.[13] Therefore, no or minimal additional agents would be required to supplement propofol sedation. The rapid recovery after propofol is discontinued at the doses recommended in this study suggests that complication of oversedation can be quickly minimized by stopping the drip and providing hemodynamic and/or respiratory stability. This may contribute to absence of cardiovascular and respiratory complications such as bradycardia, hypotension and apnea.[6]

Other drugs are commonly used as sedatives including chloral hydrate, pentobarbital, ketamine, and dexmetomidine. Prior studies have demonstrated that dexmedetomidine allows preservation of respiratory drive with less adverse effects in comparison to traditional sedatives such as chloral hydrate and pentobarbital.[14-16] A study conducted by Kang et al reported that administration of midazolam with propofol may also reduce risk of airway complications in comparison to use of propofol alone with similar recovery time.[17] Alternative methods of sedation include use of inhalation agents such as sevoflurane or nitrous oxide delivered using a laryngeal mask airway (LMA).[18-20]

This study is limited by the data and resources available to conduct research on a larger population. Furthermore, limited sedative agents are available, thus limiting the ability for comparison with other sedatives. Further trials comparing efficacy and safety profiles with a larger study population should be conducted to identify the optimal sedative to be used in pediatric patients undergoing MRI.

CONCLUSION

This study found that propofol has a faster sedative onset, recovery, and discharge time in comparison to thiopental with midazolam in pediatric patients undergoing MRI. No significant differences were found in the measured physiologic parameters and adverse events between the two groups. Further studies conducted on larger population with larger age gaps are required. Comparison of efficacy and adverse events with other sedative alternative available is also recommended to investigate the optimal sedative which may assist in pediatric MRI studies.

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Nil.

DECLARATION OF INTEREST STATEMENT

Authors declare no conflict of interest.

ETHICAL APPROVAL AND CONSENT TO PARTICIPATE

This study has been approved by Institutional Ethical Committee with registration number 212/K-LKJ/ETIK/III/2023 on March 2023.

Written and verbal consent have been obtained from participants in this study.

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