Vol 5 | Issue 2 | 2015 | 86-93.

e-ISSN 2248 – 9142
print-ISSN 2248 – 9134

International Journal of
Current Pharmaceutical & Clinical Research
www.ijcpcr.com

COMPARATIVE STUDY OF IV PROPOFOL WITH IV MIDAZOLAM AS AN EFFECTIVE PROCEDURAL SEDATION IN CHILDREN UNDERGOING CT SCAN

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ABSTRACT

A comparative prospective, randomized clinical trial of procedural sedation using IV propofol and IV midazolam in children posted for elective CT scan was conducted at VIMS combined hospitals, Bellary, during the period June 2010 to May 2011. The study subjects consisted of randomly selected 50 children belonging to ASA grade 1 and ASA grade 2 physical status who were divided into two groups-A and B. Patients in group A received 0.1mg/kg of IV midazolam and patients in group B received 0.5 mg/kg of 1% lignocaine (preservative free) and then IV propofol at the dose of 1mg/kg. Time to sedation onset, sedation scores at different intervals, recovery time, total sedation time, intra procedural hemodynamic changes, complications and side effects were noted and compared in both the groups. The two groups were comparable with respect to age, sex, weight and ASA grade. Sedation efficacy was similar in two groups without any statistical significance. Time to sedation onset, recovery time and total sedation time were comparatively less in propofol group compared to that in midazolam group. The incidence of hypotension and desaturation was comparable in two groups. Apnoea was noted in 1 patient in propofol group. Keeping all the above considerations in mind, Propofol can be an appropriate agent for procedural sedation especially in the setting of busy sedation services.

Key words: Propofol, Midazolam, procedural sedation, Recovery time, Total sedation time.

INTRODUCTION

"A crying child is safer than a sedated child!"[1] was a long held, erroneous belief. Pain in children historically has been underreported, under treated and misunderstood. Until recently, children too young to verbalize were believed too young to experience pain or fear, and they often received NO Analgesia or Sedation during the diagnostic or therapeutic procedures and also in major surgery. The indications for sedation of children are different from that of adults. Sedation in children is often administered to control behavior or allay anxiety to allow the safe completion of the procedure. A child's ability to control his/her owns behavior to cooperate for a procedure depends both on his/her chronologic and developmental age. Often, children younger than 6 years and those with developmental delay require sedation and/or analgesia for the better outcome of the procedure [2,3]. As a result, Procedural Sedation & Analgesia has become the standard practice to help facilitate care of such group. The availability of short acting analgesics, sedatives & hypnotics, specific drug antagonists, new non invasive monitoring devices & implementation of safe Procedural sedation & Analgesia protocols enable the effective and better procedural outcome in medical practice today. [4] There are essentially two categories of medications used during procedural sedation; those used to sedate the patient & those used to relieve pain.

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In case of children for CT scan, sedation is sufficient in the absence of painful conditions. The best approach to any sedative medication administration is to use small doses and titrate drug dosing to achieve the desired patient response while reducing the risks of over medication [4].

The present study compares Midazolam and Propofol given intravenously for sedation during CT scanning in children.

Objectives

1. To compare the effectiveness, recovery time from sedation and complications of IV propofol with those of IV Midazolam for procedural sedation in children aged between 1-6 years scheduled to undergo CT scan.
2. To study the overall outcome of use of IV Midazolam and IV Propofol for sedation in children.

MATERIALS AND METHODOLOGY

Study setting and design

A prospective randomized trial of procedural sedation was conducted in children of 1-6 yrs old of either sex scheduled to undergo elective CT scan under the setting of VIMS (Vijayanagara Institute of Medical Sciences) Hospital Bellary, induced with either IV Propofol or IV Midazolam between June 2010 to May 2011.

The present study was conducted to compare conditions of sedation for CT scan in 50 children, randomly divided and allocated to two groups of 25 each, to receive either 0.1 mg/kg of IV Midazolam (GroupA) or 1mg/kg of IV Propofol (Group B) (after 0.5 mg/kg of 1% preservative free lignocaine to reduce Propofol injection pain).

Inclusion and exclusion criteria

Children in the age group of 1-6 yrs of either sex, belonging to ASA 1&2 class scheduled to undergo elective CT scan of brain were included in the study. However children with acute URTI, LRTI or reactive airway disease, those requiring diagnostic imaging for head injury or patients with other painful conditions, children who were sedated due to the effect of other medications prescribed for their illness and allergy to test drug / egg / soyabean were excluded from the study.

Ethical considerations

The study was given ethical approval by Ethical Review Committee of Vijayanagara Institute of Medical Sciences. All ethical requirements including confidentiality of responses and informed consent were stringently ensured throughout the project.

Protocol of the study

Pre-anaesthetic evaluation

The children undergoing elective CT scan brain were evaluated day before by thorough history regarding name, age, sex, address, current illness, seizure control or not, medications in use, past medical history, especially prior sedation/anesthesia history and its outcome, pertinent family history etc. They were also subjected to the thorough physical examination where in weight of the child, vital signs, airway examination especially for anatomical variations, cardio respiratory system and neurological/mental status was evaluated. Routine blood investigations like Hb%, RBS, Blood urea, Serum creatinine and other investigations advised as necessary.
The patient is fasted as per the ASA preprocedure fasting guidelines (Table no. 01) for procedural sedation. [5]

After thorough preanaesthestic evaluation, Patients with the exclusion criteria already discussed were excluded from the study. After explanation of the procedure to parents/guardians consent was obtained. The eligible 50 children of 1-6 years old scheduled for CT scan were randomly allocated into 2 different groups (Group A and Group B) of 25 each. No.22 IV cannula was requested to be placed by the pediatrics resident on the forearm large veins before shifting child for intended CT scan brain, with maintenance fluid (Ringer Lactate) online.

Anaesthetic Setup in CT room [3]

The basic anaesthesia machine with Jackson Ree's Modification of Ayre's T Piece is used in all the cases. Before the procedure, a routine checklist is performed. Size-appropriate suction catheters and a functioning suction apparatus, Oxygen supply including backup, size-appropriate airways (nasopharyngeal and oropharyngeal), laryngoscope with Miller blades [checked and functioning], endotracheal tubes, LMA, nasal cannula, stylets, face mask, back up bag-valve-mask, the test drugs along with basic anaesthetic agents, relaxants (including Suxamethonium, vecuronium, atracurium),

'Emergency' drugs (Adrenaline, Atropine, Calcium), Benzodiazepine antagonist (Flumazenil), monitors including pulse oximeter and noninvasive blood pressure, ECG) along with stethoscope, and a defibrillator.

During this study radiology department nurse is present who administers the drugs as per sedation protocol. The pediatric resident trained in BLS was also present as supporting personnel to assist the study investigator to manage any adverse events. The patient is monitored by the study investigator.

On arrival of patient in the CT scan room, a presedation evaluation was also performed or reconfirmed just before the sedation procedure. Vital signs i.e. blood pressure, pulse rate, respiratory rate and O2 saturation are recorded with NIBP monitor and pulse oximeter.
Sedative medications are administered as follows:

Group A: Patients to receive midazolam at the dose of 0.1mg/kg body weight IV, over 1min.
Group B: Patients to receive (preservative free) 1% lignocaine at the dose of 0.5mg/kg IV and then propofol at 1mg/kg I V (administered till the loss of eyelid reflex).

Once the patient attains Ramsey score of four or five, the radiology attender is asked to position the child with immobilizing board at the head level and then the CT technician is allowed to proceed with the scanning. At the end of scan, patient is shifted from the CT table to recovery room nearer to radiology suite. Parents/Guardian was allowed to present in the CT scan room throughout the procedure.

Parameters studied

Onset and achievement of adequate sedation is monitored based on the Ramsey sedation scale (Table no. 02) [4]. Sedation scores are recorded before the sedative agent administration, after the drug administration, CT scan start, CT scan end and every 5 minutes in the recovery room till the patient meets the discharge criteria, based on the Aldrete Recovery score (Table no. 03). [6]. Continuous heart rate, blood pressure, respiratory rate and oxygen saturation monitoring is done prior to sedative drug administration, after the drug given, start of CT scan, end of CT scan and every 5 minutes till the patient is discharged to pediatric unit for continued monitoring of all parameters for about 30 minutes.

Ramsey sedation Scale [4]

Efficacy Parameters of the Study [7]

Sedation was considered efficacious if the patient loses consciousness, undergoes the procedure without movement and no significant complications. A Ramsey scale sedation score of 4 or 5 indicates effective sedation for the CT scan.

Sedation induction time (IT): It was defined as the interval from time of administration of the test drug to the time of achievement of sedation adequate to perform the CT scan.

Scan time: It was defined as the length of time between the start of CT scan to the completion of the imaging sequences.

Recovery time (RT): It was defined as the time that elapsed between scan completion and meeting of discharge criteria.

Total sedation time (TST): It was defined as the time interval between administration of the study drug and patient readiness for discharge.

a. Children with RSS of 6 for two or more consecutive (5 min) scoring intervals are considered to have oversedation and excluded from the study. Such patients are observed carefully during and after the procedure till they reach the base line functional status.

b. Failure to achieve adequate sedation is indicated by patient being awake / moving interfering with CT scan. This is considered as failure of the sedation regimen and excluded from the study. Such patients are given additional bolus of IV propofol 1 mg/kg or top up of 0.5 mg/kg in incremental doses and complete the scan.

Adverse events

Any adverse events during and after the procedure such as hypotension, hypoxemia, emesis, agitation, apnoea, respiratory depression, laryngospasm, bradycardia were noted.

Hypotension: It was defined as fall of systolic blood pressure >15% from the basal value associated with altered peripheral perfusion (delayed capillary refill time). It is treated with a 20 ml/kg intravenous bolus of Ringer Lactate, and increments of Inj. Mephentermine 3mg, as necessary.

Bradycardia: It was defined as a heart rate below 60 beats per minute and if persistent, treated with inj. Atropine 0. 3mg IV.

Hypoxemia : It was defined as pulse oximetric oxygen saturation of less than 92%; then, interventions like repositioning of oximeter probe, repositioning of the airway are carried out, and if there is no improvement, oxygen is administered via nasal cannula at the rate of 4 l/min.

Emesis occurring any time after administration of the sedation drugs was noted.

Agitation, defined as uncontrollable distress or inconsolability despite parental presence was also noted.

Apnoea (cessation of respiration for >20 seconds) if seen is noted and treated by airway positioning and mask ventilation with 100% oxygen.

Laryngospasm was identified by the occurrence of airway obstruction or stridor with a decline in pulse oximetry readings that is not relieved by airway manipulation, suction and insertion of oral or nasal airway, and required assisted ventilation or neuromuscular blockade to achieve adequate ventilation.

Other adverse events such as pain or discomfort during injection and transient myoclonus were noted.

RESULTS

The present study was conducted to compare conditions of sedation for CT scan in 50 children, randomly divided and allocated to two groups of 25 each, to receive either 0.1 mg/kg of IV Midazolam (GroupA) or 1mg/kg of IV Propofol (Group B) (after 0.5 mg/kg of 1% preservative free lignocaine to reduce Propofol injection pain).There was no significant difference in the distribution of the patients with respect of age and gender and similarly both groups were comparable with respect to body weight and ASA class.

Time to achieving necessary sedation for the CT scan (Sedation induction time) was slower in Group A with 2.40min (± 0.50) compared to Group B with 0.62min (± 0.10) which is strongly significant with p<0.001. (Table no. 05)

Recovery from the test drug induced sedation was earlier in Group B: The mean recovery time in group A was 28.04 min (SD 5.57) and in group B only 12.28 min (SD 1.51), the difference being strongly significant with p<0.001.

Mean Total sedation time in group A was 34.96 min (±5.26) and in group B 16.56 min (±1.64) (strongly significant with p<0.001), indicating a longer duration of sedation in group A. (Table no. 05)

The mean sedation score at start of CT in group A was 4.00 (±SD 0.00) which was significantly low (p<0.001) compared to group B which was 4.52 (±0.51). (Table 3 & graph 6) where as the mean sedation score at the end of CT scan in group A was 4.68 (± 0.47) and in group B 4.04 (± 0.20), indicating significantly higher and persistent sedation in group A (p<0.001). (Table no. 06)

The mean sedation score after 5min of end of CT scan in group A was 4.32 (±0.48) and in group B 2.40 (±0.76), indicating early recovery from sedation in group B (with p<0.001). (Table no. 06)

The overall incidence of complications are statistically similar in both the groups (p=0.747). 13/50 patients developed minor, and reversible complications. In group A, 6 patients and in group B, 7 patients showed complications. 3 (12%) patients in both the groups developed hypotension and 3 (12%) patients in each developed pulse oximetric desaturation. 1 (4%) patient developed apnea in group A which was spontaneously corrected with airway repositioning. (Table no. 07)

Table 1. ASA preprocedure fasting guidelines

Type of food	Fasting period
Clear liquids	2 hours
Breast milk	4 hours
Light solids	6 hours

Table 2. Ramsey sedation Scale

Sedation score	Clinical response
1	Fully awake
2	Drowsy but awakens spontaneously
3	Asleep but arouses and responds appropriately to simple verbal commands
4	Asleep, unresponsive to commands, but arouses to shoulder tap or loud verbal stimulus
5	Asleep and only responds to firm facial tap and loud verbal stimulus
6	Asleep and unresponsive to both firm facial tap and loud verbal stimulus

Table 3. Aldrete recovery score [6]

Activity		Points
	Voluntary movement of all limbs to command	2
	Voluntary movement of 2 extremities to command	1
	Unable to move	0
Respiration		
	Breathe deeply and cough	2
	Dyspnea, hypoventilation	1
	Apnoea	0
Circulation		
	BP ± 20 mm Hg of preanesthesia level	2
	BP > 20-50 mm Hg of preanesthesia level	1
	BP > 50 mm Hg of preanesthesia level	0
Consciousness		
	Fully awake	2
	Arousable	1
	Unresponsive	0
Color		
	Pink	2
	Pale, blotchy	1
	Cyanotic	0
Total score must be > 8 at conclusion of monitoring.		

Table 4. Comparision of the Patients between the two groups

Comparision of the Patients between the two groups				
Variable		**Group A (N=25)**	**Group B (N=25)**	**P value**
		n (%)	n (%)	
Age in years				
	1 to 2 yrs	7 (28%)	4 (16%)	0.568*
	2 to 4 yrs	5 (20%)	5 (20%)	
	4 to 6 yrs	13 (52%)	16 (64%)	
	Mean ± SD	3.64 ± 1.51	4.10 ± 1.53	0.290
Sex				
	Male	12 (48%)	17 (68%)	
	Female	13 (52%)	8 (32%)	0.168
Weight in Kgs				
	5 - 10 kgs	8 (32%)	4 (16%)	0.329*
	11 - 15 kgs	10 (40%)	10 (40%)	
	16 - 20 kgs	7 (28%)	11 (44%)	
	Mean ± SD	13.68 ± 4.09	15.24 ± 3.59	0.158
ASA class				
	I	17 (68%)	17 (68%)	
	II	8 (32%)	8 (32%)	>0.999

*Chi-square trend analysis.

Table 5. Comparision of Efficacy Parameters among the two groups

Comparison of Efficacy Parameters among the two groups			
Parameter	**Group A**	**Group B**	**P value**
	Mean ± SD	Mean ± SD	
Sedation Induction time (min)			
	2.40 ± 0.50	0.62 ± 0.10	p<0.001
Recovery time			
	28.04 ± 5.57	12.28 ± 1.51	p<0.001
Total sedation time			
	34.96 ± 5.26	16.56 ± 1.64	P<0.001

Table 6. Comparision of Sedation Scores

Comparison of Sedation Scores				
Intervals		Group A	Group B	P value
Sedation score at Start of CT				
	4	25(100%)	12(48%)	<0.001
	5	0 (0%)	13(52%)	
	Mean ± SD	4.0±0.0	4.52±0.51	<0.001
Sedation score at CT scan end				
	4	8(32%)	24(95%)	<0.001
	5	17(68%)	1(5%)	
	Mean ± SD	4.68±0.47	4.04±0.20	<0.001
Sedation score after 5 min CT end				
	1	0 (0%)	4(16%)	
	2	0 (0%)	7(28%)	
	3	0 (0%)	14(56%)	
	4	17(68%)	0 (0%)	
	5	8(32%)	0 (0%)	
	Mean ± SD	4.32±0.48	2.40±0.76	<0.001

Table 7. Comparison of Intra-procedural complication between the groups

Comparison of Intra-procedural complication between the groups		
Complications	**Group A (N=25)**	**Group B (N=25)**
	n (%)	**n (%)**
Absent	19(76%)	18(72%)
Present	6(24%)	7(28%)
Apnoea	0 (0%)	1(4%)
Hypotension	3(12%)	3(12%)
Desaturation	3(12%)	3(12%)
Bradycardia	0 (0%)	0 (0%)
Dysarrhythmias	0 (0%)	0 (0%)
Laryngospasm	0 (0%)	0 (0%)

DISCUSSION

This prospective randomized comparative study is undertaken in children posted for elective CT (plane/contrast) because they represent a relatively homogenous population in whom moderate sedation may be indicated during CT scanning.

The eligible 50 children of 1-6years of age were allocated into group A (midazolam) and group B (propofol) of 25 each and received IV midazolam at the dose of 0.1mg/kg and IV propofol at the dose of 1mg/kg respectively. Time to sedation induction, sedation scores at various intervals {prior drug administration, after the drug administration, at start of CT scan, at the end of CT scan and every 5min after the CT scanning till the child attained the discharge criteria (Aldrete score >8)}, recovery time, total sedation time, hemodynamic changes and the likely complications were compared in both the groups.

Patient characteristics

In the present study both groups were comparable with respect to age, gender, weight and ASA class. These similarities permitted comparison between propofol and midazolam with respect to effectiveness, recovery time and complication rate.

Table 8. Sedation induction time

Study group	Gupta et al [8]	Present study
Midazolam group	2.5 ± 0.9min	2.40 ± 0.50min
Propofol group	0.5 ± 0.22min	0.62 ± 0.10min

In a randomized prospective controlled trial by Gupta and colleagues [6] showed the shorter time to sedation in propofol group compared to that of midazolam ($p<0.05$). All these observations show rapid onset of action of propofol compared to that of midazolam and our results concur with the above study. [8]

Table 9. Sedation scores during the procedure:

Study group	**Charles J Havel et al's study** [7]	**Arya and Damle's study** [9]	**Tamsin Dunn et al's study** [10]	Present study
Midazolam group	4	4	5	4
Propofol group	4	4	4	4.52

In our study, the mean sedation score at CT start in group A (Midazolam) was 4.00 (SD 0.00) and in group B (Propofol) 4.52 (SD 0.51). The mean sedation score at CT end in group A was 4.68 (SD 0.47) and in group B 4.04 (SD 0.20. The mean sedation score after 5min of CT end in group A was 4.32 (SD 0.48) and in group B 2.40 (SD 0.76) which is significantly high in group A with $p<0.001$. All patients in both the groups met Ramsey sedation score of 4 during the CT scanning which was our study goal and there were no sedation failures (sedation score <4) or over sedation (sedation score 6). The declining sedation score in group B compared to group A in 3 different intervals show the short sedation time with Propofol, based on its pharmacokinetics. Our study's goal of sedation score of 4 or 5 as per Ramsey sedation scale was comparable with the above studies.[7][9][10] Over sedation was observed in 4 patients who were reversed with Flumazenil in a study by Tamsin Dunn et al,[10] whereas we did not find any such cases.

Table 10. Recovery time

Study group	**Charle's J Havel et al** [7]	**Pratila MG et al** [11]	Present study
Midazolam group	76 ± 47.5min	25min	28.04 ± 5.57min
Propofol group	14.9 ± 11.1min	8min(PI) 14 min(PB)	12.28 ± 1.51min

Our observation with respect to shorter mean recovery time in Propofol group compared to that of Midazolam group concur with those of the above studies [7,11].

Table 11. Total Sedation time

Study Group	Tamsin Dunn et al [10]	Present study
Midazolam group	45min	34.96 ± 5.26min
Propofol group	3min	16.56 ± 1.64

In our study, the mean total sedation time in group A (midazolam) was 34.96min (SD 5.26) and in group B (propofol) 16.56min (SD 1.64) this highlights the positive role of propofol with short duration of action needed for the short stay in the procedure room. In a study by Tamsin Dunn et al,[10] total sedation time in propofol group was shorter compared to that of our study.

Intraprocedural complications

In our study the main complications noted were hypotension and desaturation in both the groups. Hypotension without peripheral perfusion compromise was noticed in 3/25 (12%) patients in Midazolam group which was similar in Propofol group i.e. 3/12 (12%). Desaturation was noticed in 3/25(12%) patients in Midazolam group and the same in Propofol group i.e. 3/25 (12%) which was transient and corrected by airway repositioning and oxygen administration through nasal cannula within 30sec. 1 patient developed apnoea in Propofol group which was intervened by airway repositioning and mask ventilation. None of the patients had laryngospasm, dysarrythmias and bradycardia. Hence the complication rate was similar in both the groups and statistically not significant.

In a similar study by Charles J Havel et al [7] hypotension was seen in 18/42 (42.9%) patients in Propofol group and 19/23 (45.2%) patients in Midazolam group without perfusion compromise. The incidence of desaturation was noticed in 5/43 (11.6%) patients in Propofol group and 5/46 (10.9%) in Midazolam group. No apnoea was noted in any of the patients. This study showed comparable complication rate and no statistical significance. In a study by Pratila, MG et al,[11] desaturation was observed in 0.3% of patients in midazolam group and 2.2% in propofol group ($p<0.004$). Apnoea was seen in 3 patients with propofol and none in midazolam. No significant cardiovascular complications were noted. In another study by Gupta et al,[8] equal incidence of hypotension and desaturation was observed in midazolam and propofol groups which was comparable. Apnoea was noticed in 3 patients of propofol group and none in midazolam group. The results of our study concur with these studies.

CONCLUSION

In the present study, Propofol was found to induce sedation that was effective and comparable to that of Midazolam in children posted for CT scanning. The time to sedation onset, recovery from sedation and hence total sedation time was considerably less than that for Midazolam. No significant difference was detected between Propofol and Midazolam with respect to the incidence and severity of side effects and complications. But since the incidence of apnoea (transient) is more likely with Propofol compared to Midazolam, it is imperative that personnel well trained in advanced airway management skills be present during the procedure. Keeping all the above considerations in mind, Propofol can be an appropriate agent for procedural sedation especially in the setting of busy sedation services.

ACKNOWLEDGEMENT

We thank all the pediatric patients who participated in the study and their parents who supported the study, without whom this study would not have been possible. The authors thank all the staff members of Radiology department of VIMS Bellary for their guidance and support. The authors are also grateful to authors/editors/ publishers of all those articles, journals and books from where the literature for this article has been reviewed and discussed.

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