ORIGINAL ARTICLE

A randomized trial evaluating low doses of propofol infusion after intravenous ketamine for ambulatory pediatric magnetic resonance imaging

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ABSTRACT

Objective: Our study compared the discharge time after pediatric magnetic resonance imaging (MRI) following sedation with propofol infusion dose of 100, 75 and 50 mcg/kg/min given after a bolus dose of ketamine and propofol. **Materials and Methods:** One hundred children of American Society of Anesthesiologists status 1/2, aged 6 months to 8 years, scheduled for elective MRI were enrolled and randomized to three groups to receive propofol infusion of 100, 75 or 50 mcg/kg/min (Groups A, B, and C, respectively). After premedicating children with midazolam 0.05 mg/kg intravenous (i.v.), sedation was induced with bolus dose of ketamine and propofol (1 mg/kg each) and the propofol infusion was connected. During the scan, heart rate, noninvasive blood pressure, respiratory rate, and oxygen saturation were monitored. **Results:** The primary outcome that is, discharge time was shortest for Group C (44.06 ± 18.64 min) and longest for Group A (60.00 ± 18.66 min), the difference being statistically and clinically significant. The secondary outcomes that is, additional propofol boluses, scan quality and awakening time were comparable for the three groups. The systolic blood pressure at 20, 25 and 30 min was significantly lower in Groups A and B compared with Group C. The incidence of sedation related adverse events was highest in Group A and least in Group C. **Conclusion:** After a bolus dose of ketamine and propofol (1 mg/kg each), propofol infusion of 50 mcg/kg/min provided sedation with shortest discharge time for MRI in children premedicated with midazolam 0.05 mg/kg i.v. It also enabled stable hemodynamics with less adverse events.

Key words: *Ambulatory, ketamine, magnetic resonance imaging, pediatric, propofol, sedation*

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INTRODUCTION

There is a growing need for magnetic resonance imaging (MRI) in children for accurate diagnosis and appropriate medical treatment. Children have to lie down motionless inside a noisy claustrophobic environment for duration often longer than 30 min. Therefore, the children need deep sedation for MRI to be completed successfully and without undesired patient movement, discomfort, pain and anxiety.[1,2] Simultaneously, the sedation protocol should ensure rapid recovery with minimum incidence of adverse events.

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Several anesthetic drugs such as intravenous (i.v.) pentobarbiturate, dexmedetomidine, midazolam, fentanyl, propofol and oral chloral hydrate have been used for sedation for pediatric MRI.[3,4] Of these, propofol is the most favorable and widely used. The conventional doses of propofol when used alone for induction and maintenance of sedation for pediatric MRI are 2-6 mg/kg and 100-250 mcg/kg/min, respectively.[5-7] Deep sedation with high doses of propofol can predispose children to airway obstruction, respiratory depression, hypotension and bradycardia; low doses may cause patient movement necessitating the scan to be repeated.[8]

Recent studies have shown that the use of propofol in combination with ketamine for sedation in ambulatory surgery and emergency procedures provided better sedation

with lesser side-effects than using propofol alone.[9-13] In recent times, small doses of ketamine have been used along with propofol for pediatric MRI sedation.[14,15] At our institute, we have been using small bolus dose of ketamine with propofol for inducing sedation for pediatric MRI. With this regimen, subsequent propofol infusion doses needed are found to be lower than the conventional propofol infusion dose (100-250 mcg/kg/min).

The hypothesis of this double-blind study was that use of low dose of propofol infusion following bolus dose of ketamine and propofol would allow MRI scan completion with faster recovery and lower adverse events. Therefore, we compared sedation characteristics including discharge time, scan quality, need for additional propofol boluses, hemodynamic parameters and adverse events of three doses of propofol infusion: 100, 75 and 50 mcg/kg/min, after the bolus dose of ketamine and propofol (1 mg/kg each). We chose discharge time (time to achieve modified Aldrete score of >9) as the primary outcome of the study because quick recovery and safe discharge from medical supervision are an important goal of pediatric sedation.[16] Furthermore, discharge time can be a surrogate measure of the possible time-saving and efficiency accruing to the MRI facility with different sedation regimens. A shorter discharge time means a reduced need for intensive monitoring after scan completion, less burden on the MRI facility, and greater parental and patient satisfaction.

MATERIALS AND METHODS

After approval by Institutional Ethics Committee, 100 children of American Society of Anesthesiologists (ASA) status 1/2, aged 6 months to 8 years, scheduled for elective MRI at Employees' State Insurance Postgraduate Institute of Medical Sciences and Research, New Delhi were recruited for this double-blind randomized prospective study (October 2012-April 2013). Informed consent of the parents was obtained. Children of ASA status 3 or above, severe cardiovascular or pulmonary pathology, history of propofol allergy, anatomical anomaly or suspected difficulty of airway were excluded. Before enrolment, a thorough preanesthetic check of the children was conducted and relevant data collected included body imaging site and any special concerns such as seizure disorder, developmental delay, treatment with antiepileptic medications, or recent upper respiratory infection (URI). The children were enrolled by the principal investigator and randomized to Groups A, B, or C using a computer generated list, the group allotment was concealed in sealed envelopes. The propofol infusion doses for sedation for Groups A, B, and C were 100, 75 and 50 mcg/kg/min, respectively.

A preprocedural fasting of 6 h for solids and 2 h for clear fluids was ensured for the MRI. Before the start of scan (1.5 Tesla, Philips Achieva, USA) the anesthesia assistant at the MRI center was given the sealed envelope, he calculated the propofol infusion rate (mL/h) according to the child's body weight and allotted group. The resident anesthesiologist, children's parents, radiologist and staff nurse were all blinded to the randomization.

In the preinduction room, the anesthesiologist secured a 22 or 24 gauge cannula and gave midazolam 0.05 mg/kg i.v. to the child 30 min before the scan. The child was escorted by his parent into the scan room, and monitors (Invivo Precess, Philips, USA) including electrocardiograph noninvasive blood pressure (NIBP) and pulse oximeter were attached. After recording baseline heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), respiratory rate (RR) and SpO_2 (oxygen saturation), sleep was induced with bolus of ketamine (1 mg/kg) and propofol (1 mg/kg); the parent was then asked to leave the scan room. Level of sedation was assessed using University of Michigan Sedation Scale ((UMSS, 0 = awake and alert; 1 = minimally sedated: Responds to verbal conversation or sound; 2 = moderately sedated: Arouses to light tactile stimuli; 3 = deeply sedated: Arouses to deeper physical stimuli; 4 = unarousable to stimuli).[17] UMSS = 3 was considered an acceptable level of sedation for starting the scan; if this level was not achieved, propofol boluses of 0.5 mg/kg were given. After the child was deeply sedated (UMSS = 3), the anesthesia assistant connected, and started propofol infusion at the precalculated rate, he was thereafter not involved in the study. The resident anesthesiologist noted the induction time that is, time to achieve UMSS 3 after the bolus of ketamine and propofol. The child was appropriately positioned on the scan table using a soft neck roll, supplemental oxygen at 3-4 L/min was given, and nasal capnography was attached. After ensuring the patency of the airway and adequacy of respiration, the scan was started.

The resident anesthesiologist remained inside the MRI room during the scan. In case of any patient movement, additional propofol bolus (0.5 mg/kg) was given, and the total number of boluses needed was recorded as the need for additional sedation. On scan completion, propofol infusion was stopped, and awakening time that is, time to attain UMSS <1 after stopping propofol infusion was recorded. HR, SBP, DBP, RR and SpO_2 were recorded at 5 min from inducing sedation until the child's awakening. The scan time that is, time from start of scan to its completion was also noted. The radiologist in the MRI console was asked to grade the scan quality on the following scale: Excellent = no movement or scan artifacts; good = minor movement or scan artifacts; and poor = major movement

causing scan pausing or repeat of one or more scan sequences but not necessitating a new scan. Inability to complete the scan (scan interruption and need for the new scan) at the preset propofol infusion rate due to gross patient movement, or need for repeated propofol boluses (>3 times), or significant serious adverse events was recorded as sedation failure. In these patients, the group concealment was broken, and sedation was continued at the discretion of the supervising consultant anesthesiologist. These children were excluded from statistical analysis.

After awakening, the child was transported to the adjacent recovery room where HR, NIBP, RR and SpO_2 (Intellivue MV40, Philips, USA) were monitored by the staff nurse. The resident anesthesiologist assessed the child at 30 min interval until he/she was ready for discharge from medical supervision. The discharge time that is, time to attain modified Aldrete score of >9 was recorded after transfer to recovery.[18] The need to monitor the child for >2 h in recovery was recorded as delayed discharge. On discharge, the child was allowed to go home with their parents. All children were followed-up telephonically the next day and the parents asked about any complications such as behavior changes, motor imbalance, respiratory problems, nausea or vomiting.

The occurrence of any of following adverse events in the scan or recovery room was recorded:

- Cardiovascular: Bradycardia (20% decline in HR from baseline, treated with i.v. atropine), hypotension (20% decline in SBP or DBP from baseline, treated with fluid bolus 10 mL/kg).
- Respiratory: Bradypnea (RR <12/min), desaturation (SpO_2 <95%) or apnea (cessation of respiration for 20 s), treated with appropriate airway intervention measures (jaw thrust, guedels or laryngeal mask airway, endotracheal tube, and positive pressure ventilation).
- Gastrointestinal: Nausea or vomiting (treated with i.v. ondensetron).
- Paradoxical reaction: Irritability at the time of induction of sleep (treated with additional propofol bolus 1 mg/kg).
- Emergence reaction: Bad dreams or agitation on awakening (treated with i.v. midazolam 0.05 mg/kg).

Statistical analysis

With the effect size of 0.50 at two tailed alpha value (0.05) and a beta value (0.2), it was determined that 90 patients (30/group) were sufficient to detect a significant difference in discharge time between any of Groups A, B, and C, respectively. To make up for any data loss due to drop outs we enrolled 100 patients in total. Statistical analysis was performed by the SPSS software 17.0 for Windows(SPSS Institute, Inc., Chicago, IL, USA). Continuous variables are presented as mean ± standard deviation, and categorical variables are presented as absolute numbers and percentages. Data were checked for normality using Shaipro–Wilk test before statistical analysis. Normally distributed continuous variables including age, weight, hemodynamic variables and times (induction, scan, awakening, and discharge) were compared using one-way analysis of variance (ANOVA). Hemodynamic variables over time within the groups were analyzed using repeated measures ANOVA. If the *F* value was significant and variance was homogeneous, Tukey multiple comparison test was used to assess the differences between the individual groups. Categorical variables (sex, ASA status, sedation failure, propofol boluses, scan quality, and adverse events) were analyzed using the Pearson's Chi-square test. For all statistical tests, a $P < 0.05$ was taken to indicate a significant difference.

RESULTS

Of 100 children enrolled for this study, 5 were excluded from analysis due to failure of sedation. A total of 84 children underwent MRI of brain, 4 of spine, 3 of pelvis, 2 of abdomen, 1 of shoulder, and 1 of the lower limb. Special concerns noted during preanesthetic check were seizure disorder in 42, treatment with antiepileptic medications in 18, developmental delay in 18 and recent URI in 10.

Table 1 shows demographic data and sedation characteristics of the three groups. The three groups were statistically comparable with respect to age, weight, sex and ASA status. In addition to the initial bolus dose of ketamine and propofol (1 mg/kg each), 28 patients needed additional propofol boluses of 0.5 mg for inducing sleep (UMSS score >3). The induction time, scan time and awakening times as well as the need additional sedation during the scan were statistically comparable. Statistically significant difference was seen in the discharge times of the three groups ($P = 0.007$); intergroup comparisons showed statistically significant difference between Groups A and C ($P = 0.01$), but no difference between Groups A and B or Groups B and C. None of the children had delayed discharge.

Figure 1 shows the scan quality which was statistically comparable for the three groups. On analysis of hemodynamic variables, SBP at baseline, 5, 10 and 15 min was statistically comparable for the groups, while statistically significant difference was found in SBP at 20, 25, 30 min between the groups [$P = 0.01$, $P = 0.02$, $P = 0.01$, respectively, Figure 2]. On comparing SBP at various points of time within each group, though a decline was observed in all three groups, this was not statistically significant. The DBP, HR and RR were comparable at various points

of time between the groups with no significant variation seen within each group [Figures 3-5]. The mean SpO_2 was 99% and above at all points of time for the three groups.

Adverse cardiovascular events were seen in 9 patients (28%) in Group A (hypotension in 5, bradycardia in 3, hypotension with bradycardia in 1), 5 (16%) in Group B (hypotension in 4, bradycardia in 1) and 1 (3%) in Group C (hypotension). Statistically significant difference was seen in the comparison of cardiovascular events between the

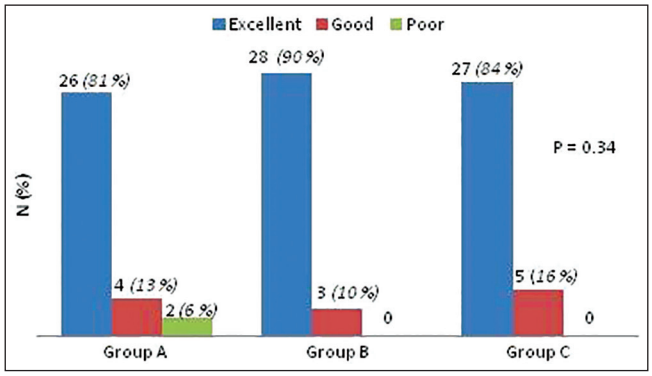

Figure 1: Comparison of scan quality. The scan quality was statistically comparable for the groups

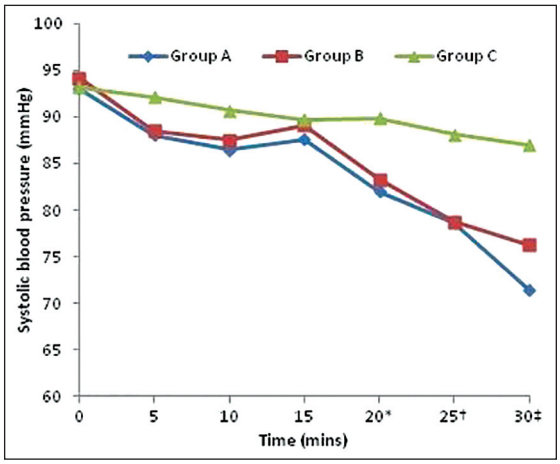

Figure 2: Comparison of systolic blood pressure (SBP). Statistically significant difference was seen in SBP at 20, 25, 30 min (*P = 0.01, †P =0.02, ‡P = 0.01). *Post-hoc* analysis showed statistically significant difference between Groups A and C (*P = 0.01, †P = 0.02, ‡P = 0.01), Groups B and C (*P = 0.03, †P = 0.04, ‡P = 0.04) with no statistical difference between Groups B and C (*P = 0.87, †P = 1.00, ‡P = 0.43)

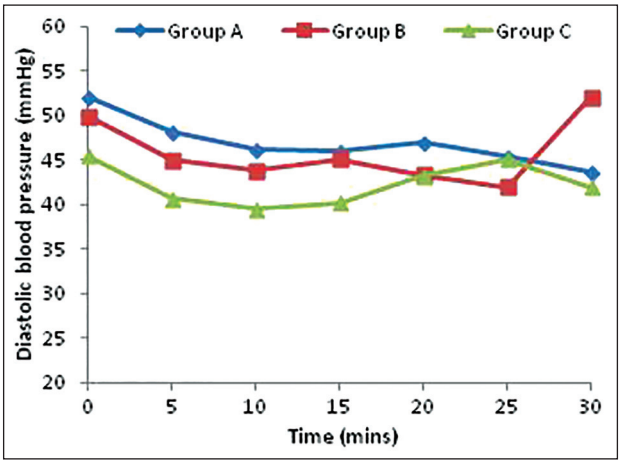

Figure 3: Comparison of diastolic blood pressure. No statistically significant difference seen between or within the groups

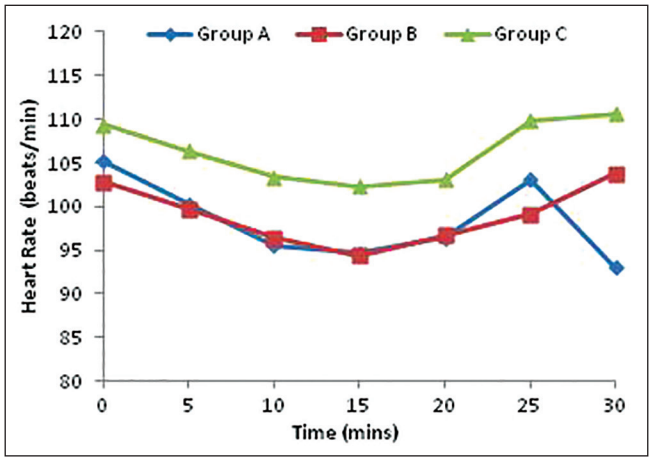

Figure 4: Comparison of heart rate. No statistically significant difference seen between or within the groups

Table 1: Demographic data and sedation characteristics of children

Variables	Group A (n = 32)	Group B (n = 31)	Group C (n = 32)	P value
Age (years)	3.50±2.12	3.90±1.79	3.27±1.70	0.40
Male/female	14/18	17/14	16/16	0.68
Weight (kg)	11.25±3.33	12.56±2.99	11.19±2.21	0.11
ASA status (I/II)	6/26	4/27	7/25	0.64
Additional sedation propofol boluses: 0/1/2/3	23/7/2/0	27/4/0/0	25/6/0/1	0.31
Induction time (min)	1.16±0.37	1.00±0.26	1.09±0.30	0.14
Scan time (min)	23.19±8.59	19.52±6.25	22.59±6.50	0.10
Awakening time (min)	3.44±2.35	2.84±2.25	2.34±1.81	0.13
Discharge time (min)*	60.00±18.66	49.35±22.65	44.06±18.64	0.007
Sedation failure (%)	2/34 (6)	2/33 (6)	1/33 (3)	0.82

**Post-hoc* analysis showed statistically significant difference in discharge times between Groups A and C (P = 0.01). No statistical difference was seen in discharge times between Groups A and B (P = 0.13) and Groups B and C (P = 0.68), ASA: American Society of Anesthesiologists

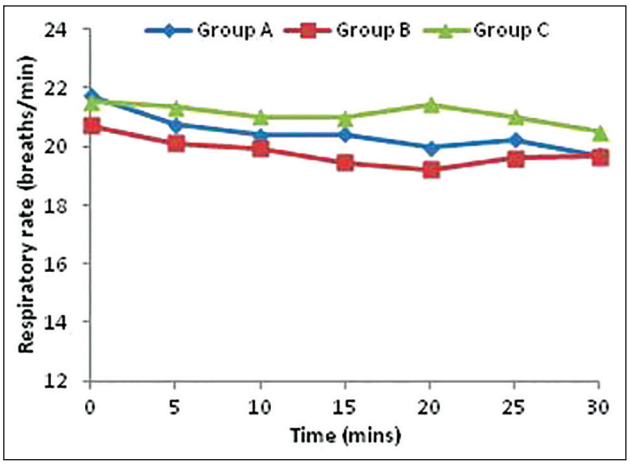

Figure 5: Comparison of respiratory rate. No statistically significant difference seen between or within the groups

three groups ($P = 0.02$). *Post-hoc* analysis showed this difference to be statistically significant between groups A and C ($P = 0.01$) with no statistical difference between Groups A and B ($P = 0.25$) or Groups B and C ($P = 0.10$). Respiratory events (bradypnea without desaturation, not needing airway manipulation) was seen only in 4 patients (13%) in Group A, with no statistical difference between the three groups ($P = 0.08$). All adverse events occurred during the scan except for one child in Group A who had bradycardia in the recovery room. No other adverse were seen in any children nor any complications reported in the telephonic follow-up.

As regards, the 5 cases of failure of sedation, their scans were completed without rescheduling or using general anesthesia. In 3 cases (1 each in Groups A, B, and C), there was repeated patient movement during the scan, necessitating increase in the propofol infusion dose by 50 mcg/kg/min. In the fourth case (Group B), patient had apnea immediately after induction of sedation. Requiring jaw trust and assisted ventilation with 100% oxygen for 2 min. The scan was subsequently carried out using reduced infusion dose (i.e., 50 instead of 75 mcg/kg/min). In the fifth case (Group A), the cannula got displaced while positioning the child for scan causing interruption of propofol infusion; a new cannula was secured and the scan restarted after reconnecting the infusion.

DISCUSSION

Our study compared three infusion doses of propofol that is, 100, 75, and 50 mcg/kg/min (Groups A, B, and C, respectively) for elective ambulatory pediatric MRI after inducing sleep with ketamine and propofol boluses (1 mg/kg each). The primary outcome that is, discharge time was shortest for Group C (44.06 ± 18.64 min) and longest for Group A (60.00 ± 8.66 min), the difference being statistically and clinically significant. The secondary outcomes that is, additional propofol boluses, scan quality and awakening time were comparable for the three groups. The results show that administration of small dose of ketamine prior to propofol induction reduced the propofol infusion dose needed for sedation for pediatric MRI in children premedicated with midazolam. Furthermore, use of propofol infusion in low dose of 50 mcg/kg/min for pediatric MRI provided shortest discharge time, hemodynamic stability, and least incidence of adverse events.

The conventional doses of propofol used for induction and maintenance of sedation for pediatric MRI are 2-6 mg/kg and 100-250 mcg/kg/min, respectively.[5-7] However, these doses sometimes cause adverse events such as apnea, involuntary movements, injection site pain and hypotension.[8] A recent study found that propofol in induction dose of 2.69 mg/kg (95% confidence interval 2.35-5.95) was adequate for MRI scan in children with cerebral palsy; however 5 out of 20 patients suffered desaturation with partial airway obstruction immediately following the bolus dose.[19] In an observational study, Usher *et al.* found mean induction and maintenance dose of propofol used for pediatric MRI were 3.9 mg/kg and 193 mcg/kg/min, respectively, and that at these doses, airway patency was maintained but with a significant decline in RR.[20]

Recently, ketamine and propofol have been used in combination for sedation in pediatric MRI. In the study by Tomatir *et al.*, use of small dose ketamine (0.5 mg/kg) in pediatric MRI allowed successful scan completion with lower induction and maintenance doses of propofol (1.5 mg/kg, 75 mcg/kg/min), besides maintaining hemodynamic stability.[14] In our study, induction with ketamine and propofol boluses (1 mg/kg each) allowed maintenance of sedation with even lesser propofol infusion dose that is, 50 mcg/kg/min (Group C). Also, Eich *et al.*, in their observational study showed that use of single dose of ketamine (0.5 mg/kg) reduced the propofol requirement for pediatric MRI (11.9 ± 3.4 mg/kg/h in propofol group to 8.0 ± 2.6 mg/kg/h in propofol plus ketamine group), besides resulting in faster recovery after scan completion.[15]

Some studies suggest that combination of propofol and ketamine can provide better sedation with lesser side-effects than using either drug alone.[9-13] Mortero *et al.* showed that small dose ketamine co-administered with propofol for sedation for ambulatory surgery attenuated the propofol induced hypoventilation with positive effect on mood and recovery of cognitive functions.[21] Another advantage of a small dose ketamine is that it mitigates the injection pain

and reduces unintentional movement seen with propofol bolus.[22] Also, the analgesic effects of ketamine is helpful in positioning children with underlying painful conditions (e.g., osteomyelitis, arthritis or trauma) for the scan.[23,24] The demerits of use of ketamine include hypersalivation, emesis or emergence reaction. None of our patients developed these side-effects, which could be due to premedication with midazolam, restricting the dose of ketamine to 1 mg/kg and it being used in combination with propofol.

Studies evaluating propofol sedation for pediatric MRI have reported advantages including short induction time, uniform depth of sedation, infrequent need for additional sedation and rapid recovery.[3,19,25,26] We also observed similar benefits despite using a small dose of ketamine at induction. The induction and awakening times observed were short and mean discharge times in all groups were ≤60 min, contributing to time-saving at MRI center.

In our study, additional sedation was required in 21% patients, the additional propofol boluses needed in the three groups being statistically comparable [Table 1]. This could have been due to our using low propofol infusion doses. In their study Usher *et al.* found movement to be common with propofol infusion doses under 175 mcg/kg/min; however, the use of high doses of propofol infusion doses (150-250 mcg/kg/min) in order to suppress involuntary movements has been shown to be associated with a significant incidence of sedation related adverse event.[3,5,20] In a previous paper, Cortellazzi *et al.* have remarked that 'designing a sedation protocol implies a tradeoff between maximizing the effectiveness of sedation and minimizing the incidence of adverse events, while meeting a number of organizational needs'.[27] Our sedation regimen using low doses of propofol infusion doses after ketamine and propofol bolus was designed keeping in mind these goals for pediatric MRI sedation. The use of low doses of propofol infusion did not adversely affect the overall scan quality in our study, which was excellent in 85%, good in 13% and poor in only 2%.

Dalal *et al.* have reported a 13.6% incidence of respiratory events with propofol sedation for MRI in infants.[3] Pershad *et al.* also found a 26.6% incidence of adverse events including respiratory depression and hypotension with use of propofol infusion for pediatric MRI.[5] In our study, while the incidence of respiratory and cardiovascular events in Group A was akin to these studies using conventional propofol infusion dose (100-250 mcg/kg/min), we observed a much lower incidence in Groups B and C. Except for one child who had apnea at induction and needed assisted bag mask ventilation for 2 min, none of the children in our study required airway manipulation.

The results of our study are applicable to healthy children undergoing outpatient MRI. The suitability of the regime used in the study for sick children (ASA 3, 4 or E) needs further evaluation. In our study, we used midazolam as premedication to calm the children and allay any anxiety while waiting for their scan. However, it is possible that midazolam premedication could also have enhanced the success of the sedation regimen. Another limitation of our study is that we did not restrict the study population to children undergoing any specific type of MRI in terms of body imaging site or use of i.v. contrast. Though the mean scan times were comparable for the three groups, a considerable difference in the scan times of different types of scans was seen.

CONCLUSION

Our study shows that in children premedicated with midazolam, safe sedation for pediatric MRI can be provided with propofol infusion dose of 50 μg/kg/min following induction with bolus of ketamine and propofol (1 mg/kg each). Short discharge times, stable hemodynamics and low adverse events are significant advantages of this regimen. However, 21% of the patients needed additional propofol boluses to complete the scan.

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