Original Article

A non-randomized controlled study of total intravenous anesthesia regimens for magnetic resonance imaging studies in children

Bhuvaneswari Balasubramanian, Anila D. Malde, Shantanu B. Kulkarni

Department of Anaesthesiology, Lokmanya Tilak Municipal Medical College and Lokmanya Tilak Municipal General Hospital, Mumbai, Maharashtra, India

Abstract

Background and Aims: We studied the efficacy and safety of different total intravenous anesthesia used for pediatric magnetic resonance imaging (MRI).

Material and Methods: Children of 1–7 years age (n = 88), undergoing MRI received a loading dose of dexmedetomidine 1 μg/kg over 10 min, ketamine 1 mg/kg, and propofol 1 mg/kg in sequence. University of Michigan Sedation Scale (UMSS) of 3 was considered an acceptable level for starting the scan. Rescue ketamine 0.25–0.5 mg/kg was given if UMSS remained <3. After the loading dose of drugs, some children attained UMSS = 4 or progressive decline in heart rate, therefore, did not receive any infusion. The rest received either dexmedetomidine (0.7 μg/kg/h) (n = 35) or propofol (3 mg/kg/h) (n = 38) infusion for maintenance. Ketamine 0.25 mg/kg was used as rescue. Sedation failure was considered if either there was inability to complete the scan at the pre-set infusion rate, or there was need for >3 ketamine boluses or serious adverse events occurred. Statistical Package for Social Sciences 20 was used for analysis.

Results: Initiation of scan was 100% successful with median induction time of 10 min. Maintenance of sedation was successful in 100% with dexmedetomidine and 97.4% with propofol infusion. Recovery time (25 min v/s 30 min), discharge time (35 min v/s 60 min), and total care duration (80 min v/s 105 min) were significantly less with propofol as compared to dexmedetomidine (P = 0.002, 0.000, and 0.000, respectively). There were no significant adverse events observed.

Conclusion: Dexmedetomidine 1μg/kg, ketamine 1 mg/kg, and propofol 1 mg/kg provide good conditions for initiation of MRI. Although dexmedetomidine at 0.7μg/kg/h and propofol at 3 mg/kg/h are safe and effective for maintenance, propofol provides faster recovery.

Keywords: Ambulatory, dexmedetomidine, ketamine, magnetic resonance imaging, pediatric, propofol, sedation

Introduction

Magnetic resonance imaging (MRI) in children is a lengthy procedure and requires immobility to avoid motion artifacts in a noisy and claustrophobic environment. Maintenance of hemodynamic stability and normal spontaneous respiration is very important. The access to the patient is limited; hence, intravenous anesthesia regimens are preferred. Propofol induced upper airway obstruction, ketamine induced hypertension, and hypertonicity, and dexmedetomidine induced bradycardia were some of the adverse effects found when they were used in isolation.[1-6] When two drug combinations were used, the initiation and recovery were found to be faster than the single drug regimens, but propofol infusion rates required for maintenance remain high (4.5–10 mg/kg/h) causing airway complications. This raised the possibility of combining all the three drugs, namely

Address for correspondence: Dr. Anila D. Malde, Block No. 3, Nagjibhai Mansion, Manubhai P. Vaidya Marg, Ghatkopar (East), Mumbai - 400 077, Maharashtra, India
E-mail: dradmalde@yahoo.com

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dexmedetomidine, propofol, and ketamine in lower doses to achieve the balance of stable hemodynamics, spontaneous respiration, and immobility while reducing adverse events. Our aim was to check the following hypotheses: (1) a regimen consisting of dexmedetomidine 1μg/kg, ketamine 1mg/kg, and propofol 1mg/kg produces effective and safe initiation of scan. (2) For longer studies, dexmedetomidine (0.7 μg/kg/h) or propofol (3 mg/kg/h) infusions are safe and effective for maintenance of sedation, following initiation with above regimen.

Material and Methods

This prospective non-randomized controlled study was conducted in the MRI suite of a tertiary care teaching institution. The study was approved by institutional ethics committee, and registered with Clinical Trial Registry of India (www.ctri.nic.in) (CTRI/2017/03/008008). Thorough history was obtained. The children of 1–7 years of age, American Society of Anesthesiologists (ASA) physical status I or II undergoing MRI from December 2016 to May 2017 were included in the study. Patients with severe cardiovascular or pulmonary pathology, raised intracranial pressure, active seizure, craniofacial anomaly, suspected difficult airway, or contraindication to any of the anesthetic agents being used were excluded from the study. The parents of the children included in the study were briefed about the study and assured confidentiality. A written informed consent was obtained from the parent of each patient before starting the procedure.

ASA fasting guidelines were followed. Baseline values of heart rate, blood pressure, respiratory rate, and oxygen saturation were recorded upon arrival in the preparation room. We assessed and noted pre-sedation behavior on a 4-point scale: 1 = calm, cooperative, 2 = anxious but reassurable, 3 = anxious and not reassurable, and 4 = crying or resisting. A 22G or 24G venous cannula was inserted in the dorsum of the hand or leg in the holding area. Sedation was initiated with a loading dose of intravenous dexmedetomidine at 1 μg/kg over 10 min followed by intravenous ketamine at a dose of 1 mg/kg and intravenous propofol 1mg/kg. The level of sedation achieved was assessed by the University of Michigan Sedation Scale (UMSS)[7] as follows: 0 = awake and alert, 1 = minimally sedated i.e., responds to verbal conversation or sound; 2 = moderately sedated i.e., arouses to light tactile stimuli, 3 = deeply sedated i.e., arouses to deeper physical stimuli, and 4 = unarousable to stimuli. UMSS of 3 was considered an acceptable level of sedation for starting the scan. All the three drugs were given one after the other. At any point of induction, if UMSS 3 was achieved after either one or two drugs out of three, then further drug was not given. If required, the infusion was started as per the discretion of the attending anesthesiologist. If this level was not achieved, the child received additional ketamine boluses of 0.25–0.5 mg/kg. The induction time was noted. This was defined as the time from the end of the loading dose of dexmedetomidine to the attainment of the UMSS of 3. The child was appropriately positioned on the scan table using a soft neck roll; supplemental oxygen at 4–6 L/min was given using a face mask; and the pulse oximetry, and respiratory monitors were attached. Time to start the scan was defined as the time from the end of the loading dose of dexmedetomidine to the start of the scan.

Children who achieved a UMSS of 4 after the initial loading doses of drugs or showed a progressive decline in the heart rate did not receive any infusion for maintenance at the discretion of the attending anesthesiologist (n = 15). If needed, they would have received ketamine boluses of 0.25 mg/kg. The rest of the children received either dexmedetomidine infusion (n = 35) at 0.7 μg/kg/h or propofol (n = 38) infusion at 3 mg/kg/h for maintenance of anesthesia during the MRI study as per the concerned anesthesiologist. Maintenance infusion was given from beginning of scan to completion of scan, and the infusion time was noted. Scan time was the time from start of scan to its completion. Heart rate, respiratory rate, and oxygen saturation were monitored using MRI compatible monitors. Rescue sedation in the form of ketamine 0.25 mg/kg i.v. was given if there were excessive movements or hyperventilation affecting the scan quality. The number of bolus doses required was noted. The requirement of repeat scan sequence or discontinuation of scan owing to excessive movements or hyperventilation was noted. At any point of the procedure, if the child developed any of the adverse reactions, the infusion rate was reduced or stopped at the concerned anesthesiologist's discretion.

We noted the success of the regimen at the end of the scan. Sedation failure occurred if there was inability to complete the scan (scan interruption and need for the new scan) at the pre-set infusion rate owing to gross patient movement, need for repeated ketamine boluses (>3 times), or the presence of significant serious adverse events.[8] The radiologist was also asked to rate the quality of scan that was defined on a 3-point 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. The child was then shifted to the recovery area and was monitored till awakening. The recovery time was noted as the time from the end of sedation to awakening defined by a UMSS of 1. The anesthesiologist monitored the heart rate, blood pressure, respiration (rate and

quality), and oxygen saturation in the recovery room. We noted any emergence delirium on the Watcha scale – 0 = Asleep, 1 = Calm, 2 = Crying but consolable, 3 = Crying but cannot be consoled, 4 = Agitated, and thrashing around.[9]A score of 3 or more on the Watcha scale was considered as emergence agitation. Need for treatment with intravenous midazolam was noted for the agitation.

Periprocedural adverse events were recorded: (1) Bradycardia was defined as a decline in HR as defined in pediatric advanced life support (PALS) guidelines;[10] whether it needed treatment with intravenous atropine; (2) hypotension as decline in systolic blood pressure as defined in PALS guidelines; whether it needed treatment with fluid bolus 10 mL/kg; (3) bradypnea as defined in PALS guidelines; (4) desaturation as SpO_2 <95%; (5) laryngospasm; (6) apnea as cessation of respiration for 20 s; (7) any need for airway intervention measures (jaw thrust, Guedel's or laryngeal mask airway, endotracheal tube, and positive pressure ventilation); (8) nausea or vomiting needing treatment with intravenous ondansetron; (9) paradoxical reaction as irritability at the time of induction of sleep; whether it needed treatment with additional propofol bolus, and (10) shivering that needed treatment.

The child was discharged or shifted to the ward after the following discharge criteria were met: stable vital signs, return to baseline consciousness, absence of any side effects, and ability to ambulate.[8] The discharge time was the time from the end of sedation infusion till discharge. The whole care duration was the time from the start of the venous access till discharge.

One of the main aims was to compare propofol and dexmedetomedine infusions for long MRI studies. The sample size of 32 per group was calculated by power and sample size calculator software version 3.1.2, 2014 from the following: (1) Wu *et al.* noted a sedation success rate of 90% in propofol group versus 60% in dexmedetomidine group.[11] (2) Alpha error of 0.05, and (3) Beta error of 0.2 (80% power).

The collected data were analyzed using Statistical Package for Social Sciences (SPSS) version 20. (IBM Corp., IBM SPSS statistics for Windows, Armonk, NY.). Qualitative variables were compared using the Chi-square test. Normally distributed quantitative variables (age, weight) were compared by ANOVA followed by unpaired *t* test. Quantitative variables not normally distributed (induction time, time to start scan, scan time, infusion time, recovery time, discharge time, and total care duration) were compared using Kruskal-Wallis test followed by Mann-Whitney U test. A *P* value less than 0.05 was considered statistically significant.

Results

A flow diagram is depicted in Figure 1. In all, 88 patients received initiation of sedation with dexmedetomidine, ketamine, and propofol. The initiation was successful in all patients. For maintenance, 35 patients received dexmedetomidine, 38 patients received propofol, and 15 did not receive any infusion. The groups were comparable in demographic criteria and pre-sedation behavior [Tables 1 and 2]. Maintenance sedation failure occurred in one patient in the propofol group [Table 3]. The failure occurred as the child had a higher anxiety level (Pre-sedation score-3), required 2 additional doses of ketamine 0.5 mg/kg to achieve a UMSS of 3 at induction, moved during the scan at the pre-set infusion rate, and required more than 3 rescue ketamine doses during the procedure. None of the patients developed hypotension, hypertension, or tachycardia. There were no peri-procedural incidents of laryngospasm, apnea, or desaturation. Although patients developed bradycardia, it did not require any treatment. Only two patients developed bradypnea for a short duration that did not need any treatment [Table 4]. None of the patients required insertion of an airway device for airway obstruction. Recovery time, discharge time, and total duration were significantly longer for dexmedetomidine group followed by propofol group and no infusion group [Table 5].

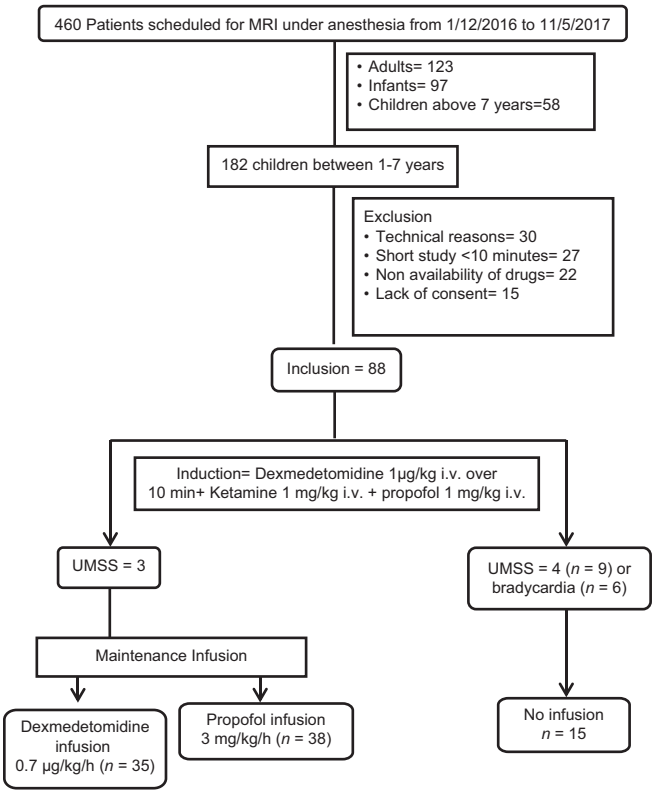

Figure 1: Flow diagram explaining the patient recruitment and study protocol

Table 1: Demographic variables

Parameters	Dex (*n*=35)	Propofol (*n*=38)	No infusion (*n*=15)	*P*
Age[†]	4.53 (1.5)	3.81 (1.7)	4.24 (1.7)	0.165
Weight[†]	13.94 (3.5)	12.89 (4.1)	12.67 (3.7)	0.405
Gender[#]				
Male	19 (54.3%)	22 (57.9%)	08 (53.3%)	0.934
Female	16 (45.7%)	16 (42.1%)	07 (47.7%)	
ASA[#]				
ASA 1	09 (25.7%)	10 (26.3%)	04 (26.7%)	0.997
ASA 2	26 (74.3%)	28 (73.7%)	11 (73.3%)	
Scan[#]				
Brain	25 (71.4%)	27 (71.1%)	14 (93.3%)	0.684
Spine	02 (5.7%)	04 (10.5%)	01 (6.7%)	
Urography	02 (5.7%)	01 (2.6%)	00 (0%)	
Cochleography	03 (8.6%)	01 (2.6%)	00 (0%)	
Face	01 (2.9%)	00 (0%)	00 (0%)	
Inguinal	00 (0%)	01 (2.6%)	00 (0%)	
Upper limb	02 (5.7%)	02 (5.3%)	00 (0%)	
Lower limb	00 (0%)	02 (5.3%)	00 (0%)	
Pre-sedation behavior[#]				
1	20 (57.1%)	22 (57.9%)	08 (53.3%)	0.272
2	14 (40%)	12 (31.6%)	07 (46.7%)	
3	00 (0%)	04 (10.5%)	00 (0%)	
4	01 (2.9%)	00 (0%)	00 (0%)	

Dex=Dexmedetomidine. [†]Data presented as mean and standard deviation and compared using ANOVA; [#]Data presented as number (%) and compared using Chi-square/Fischer's exact test

Table 2: Inferential statistics

Parameters	Dex (*n*=35)	Propofol (*n*=38)	No infusion (*n*=15)	Comparison among 3 groups	Dex vs. Propofol
Induction time	10 (3) [5-13]	9.5 (2) [3-15]	10 (3) [5-11]	*P*=0.384	*P*=0.221
Time to start scan	11 (2) [5-40]	11 (2) [5-25]	10 (2) [8-15]	*P*=0.742	*P*=0.661
Scan time	30 (20) [15-100]	35 (27) [20-120]	30 (10) [20-60]	*P*=0.111	*P*=0.521
Infusion time	30 (20) [15-100]	35 (25) [20-105]		Not applicable	*P*=0.501

Dex=Dexmedetomidine. Data presented as median (interquartile range) [minimum-maximum] and analyzed using Kruskal-Wallis test followed by Mann-Whitney U test

Table 3: Scan success rate, Quality of scan, Repeat scan, and Discontinuation of scan

Parameters	Dex (*n*=35)	Pro (*n*=38)	No infusion (*n*=15)	*P*
Scan success rate	35 (100%)	37 (97.4%)	15 (100%)	0.514
Scan quality				
Excellent	27 (77.1%)	32 (84.2%)	12 (80%)	0.662
Good	08 (22.9%)	05 (13.2%)	03 (20%)	
Poor	00 (0%)	01 (2.6%)	00 (0%)	
Repeat scan requirement	01 (2.9%)	01 (2.6%)	00 (0%)	0.809
Discontinuation of scan	01 (2.9%)	02 (5.3%)	00 (0%)	0.619

Dex=Dexmedetomidine, Data presented as number (percentage) and compared using Chi-square test/Fischer's exact test

Discussion

The goals of sedation in the pediatric patient for radiological procedures are (1) To provide immobility and thereby good quality uninterrupted scans; (2) to minimize physical discomfort and pain; (3) To control anxiety, minimize psychological trauma, and provide amnesia; (4) To provide early, safe discharge. MRI is a non-invasive and painless procedure. Therefore, adults usually do not require anesthesia or sedation. However, a child may not remain motion-free in a cold, claustrophobic, and unknown environment, especially if there is a pre-existing painful condition. General anesthesia with tracheal intubation or supraglottic airway devices and mechanical ventilation is too invasive, time, and resource consuming. Although sedation is less invasive, cost, and time saving, the protocols need to be standardized to get maximum efficiency and safety.

Single drugs have been tried for sedation in MRI. Chloral hydrate and pentobarbital had a higher incidence of sedation failures and complications warranting the search for better agents.[12] Midazolam used alone has been associated with an unpredictable and prolonged level of sedation.[13] Ketamine used alone is associated with emergence reactions, dysphoria, hypertonicity, and hypertension demanding the need of anticholinergics and midazolam.[5,14] Dexmedetomidine as a sole agent has been associated with a slower onset of sedation, delayed recovery, and a 16–20% incidence of bradycardia.[6,15-18] Propofol used alone required doses of 2.5–3 mg/kg for initiation of scan and was associated with upper airway obstruction and hypotension.[3,18-20]

Two drug combinations have been tried to reduce the dose and thus side effect of individual drug. Bernal *et al.* demonstrated sedation failure rates of 38% in propofol group, 46% in dexmedetomidine group versus 11% in combination group for functional MRI.[21] Boriosi *et al.* noted that the combination of dexmedetomidine and propofol caused lesser respiratory adverse events (5.9% v/s 26.7%) but prolonged recovery and discharge time when compared to propofol alone.[1] Although the combination of ketamine and dexmedetomidine has been extensively used for procedural sedation, the literature for its use in MRI is limited. Tammam noted a faster onset, shorter recovery time, and fewer adverse events using dexmedetomidine and ketamine combination compared to either drug alone.[22] However, the drugs were given intramuscularly that is rarely used nowadays. The second drawback is that midazolam which is known to prolong sedation, was used as rescue. There were no significant respiratory and hemodynamic effects noted using intravenous ketamine 1 mg/kg and dexmedetomidine 1 μg/kg in a series of three children with trisomy 21 and obstructive sleep apnea for MRI. However, there are no prospective studies with this combination.[23]

Most extensively studied combination as a sedative for MRI are ketamine and propofol.[2,3,8,24] Addition of ketamine 0.5 mg/kg to propofol improved the sedation success rate, reduced the propofol requirement for induction and maintenance, provided better hemodynamic stability, faster recovery, and decreased incidence of propofol injection pain.[2,3] When two drug combinations involved propofol with ketamine/dexmedetomidine, the propofol infusion requirements have been 4.5–10 mg/kg/h, thus, leading to a higher incidence of airway complications. This raised the possibility of combining all the three drugs namely dexmedetomidine, propofol, and ketamine in lower doses improving efficacy and thereby, reducing adverse events.

Ülgey *et al.* used a combination of dexmedetomidine 1 μg/kg over 10 min, ketamine 1mg/kg, and propofol 1 mg/kg for cardiac catheterization studies in children.[25] They noticed a reduced need for airway intervention, decreased movement during local anesthetic infiltration, and throughout the procedure, shorter recovery, and good hemodynamic stability. No nausea, vomiting, convulsions, coughing, hiccups, or excessive oral secretions were noted. They noted that the average amount of propofol delivered (2.5 ± 1.7 mg/kg) was significantly lesser than that delivered to the ketamine and propofol group (9.9 ± 3.1 mg/kg) ($P < 0.001$) for maintenance of sedation. After extensive search on PubMed from 2005 onwards, we could not find any published data on the use of this combination in MRI; therefore, we used this regimen. The induction time and scan initiation time using this combination were 10 and 11 min in our study. For 17% of the patients, this combination was sufficient for the full procedure.

The maintenance infusions of dexmedetomidine at 0.7 μg/kg/h ($n = 35$) were used in our study. Koroglu *et al.* noted a success rate of 83% using dexmedetomidine at 0.5 μg/kg/h.[26] Using dexmedetomidine at 0.7 μg/kg/h, we noted a success rate of 100%. Sethi *et al.* compared three doses of propofol infusion for maintenance of anesthesia in MRI after ketamine, propofol, and midazolam induction and found that the infusion rate of 50 μg/kg/min was associated with the shortest recovery time and stable hemodynamics.[8] From Ülgey's and Sethi's studies, we used propofol infusion at 3 mg/kg/h, and our

Table 4: Adverse events

Parameters	Dex (*n*=35)	Propofol (*n*=38)	No infusion (*n*=15)	*P*
During the procedure	03 (8.6%)	04 (10.5%)	03 (20%)	0.495
Bradycardia	03 (8.6%)	03 (7.9%)	03 (20%)	0.389
Bradypnoea	01 (2.9%)	00 (0%)	01 (6.7%)	0.326
Coughing	00 (0%)	01 (2.6%)	00 (0%)	0.514
Post procedure	01 (2.9%)	00 (0%)	01 (6.7%)	0.326
Bradycardia	01 (2.9%)	00 (0%)	01 (6.7%)	0.326
Watcha score ≥3	00 (0%)	00 (0%)	00 (0%)	

Dex=Dexmedetomidine. Data presented as number (percentage) and compared using Chi-square test/Fischer's exact test

Table 5: Recovery, Discharge, Total care duration

Parameters	Dex (*n*=35)	Propofol (*n*=38)	No infusion (*n*=15)	Comparison among 3 groups	Dex v/s Pro
Recovery time	30 (30) [10-75]	25 (10) [10-40]	20 (15) [15-40]	*P*=0.007*	*P*=0.002*
Discharge time	60 (40) [20-110]	35 (11) [20-55]	30 (15) [20-50]	*P*<0.001*	*P*<0.001*
Total duration	105 (60) [40-187]	80 (16) [15-161]	70 (25) [33-120]	*P*<0.001*	*P*<0.001*

*Dex=Dexmedetomidine. Data presented as median (IQR) [minimum-maximum] and compared using Kruskal-Wallis test followed by Mann-Whitney U test. *P<0.05*

success rate was 97.4%. Most of the studies have not defined sedation success criteria, and they have been retrospective studies.[1,2,14,16,18,27] We defined our sedation success criteria. We selected ketamine 0.25 mg/kg i.v. bolus as rescue for maintenance of sedation as it can remain common to both the groups, has a faster onset and does not compromise airway or hemodynamics. We found excellent to good quality scans that are comparable to previous studies.[8,27] The need for discontinuation or repeat scans were less than those in previous studies.[26,28]

To facilitate ambulatory radiological procedures in children, the anesthetic combination should facilitate rapid recovery. We noted faster recovery and hence, overall care time with propofol as compared to dexmedetomidine. This corroborates with recent pharmacokinetic data that demonstrate elimination half-life of 2 h with dexmedetomidine versus 25 min with propofol. This is of significance in increasing the daily turnover and thus, cost efficiency in a busy setup.

Bradycardia was the most common adverse event albeit occurring in very few cases and requiring no intervention. Bradycardia with dexmedetomidine infusion in our study was 8.7% that was similar to 3% in the meta-analyses involving 21 studies.[29] We noted minimum respiratory adverse events compared to other studies using higher doses. Ketamine, dexmedetomidine, and propofol have been implicated in reducing emergence delirium post sedation or general anesthesia in various studies.[5,6,30] We also did not find emergence reaction in our study. The omission of benzodiazepine and anticholinergics was helpful in avoiding excessive sedation and dryness of mouth.

Limitations of our study: It was a non-randomized study. Hence, chances of bias are high. Although we did not take any special efforts in blinding, the radiologists were unaware of drugs used. Recovery room anesthetist noting down recovery, discharge time, etc. were most of the time unaware of the drugs administered because of busy schedule.

Conclusion

A multidrug intravenous regimen consisting of dexmedetomidine 1 μg/kg, ketamine 1 mg/kg, and propofol 1 mg/kg is effective and safe for initiation of scan. For longer studies, infusions of dexmedetomidine at 0.7 μg/kg/h or propofol at 3 mg/kg/h provide good quality maintenance of sedation. Among the two, propofol offers a faster recovery and an earlier discharge as compared to dexmedetomidine.

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Conflicts of interest
There are no conflicts of interest.

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