Original Article

Success Rate Compared between Sevoflurane Insufflation via Simple Oxygen Mask and Propofol Intravenous Infusion in Small Children Undergoing MRI: A Randomized Controlled Trial

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Objective: To compare the success rate between sevoflurane insufflation via simple oxygen mask and propofol intravenous infusion in children aged 1 to 6 years undergoing magnetic resonance imaging [MRI].

Materials and Methods: This randomized controlled trial was conducted in pediatric patients aged 1 to 6 years who were scheduled to undergo MRI scan at the Faculty of Medicine Siriraj Hospital during the October 1, 2015 to October 31, 2016 study period. Patients were randomized into the sevoflurane insufflation (2% sevoflurane) via simple oxygen mask group or the propofol intravenous infusion (propofol 100 mcg/kg/min) group. The primary outcome was success rate of MRI scan, defined as scan completed without any pause. Causes of interruption during MRI, including hypotension, bradycardia, hypoventilation, desaturation, and movement, were recorded and analyzed. Secondary outcomes were Pediatric Anesthesia Emergence Delirium [PAED] scale, postoperative nausea and vomiting [PONV], and MRI quality.

Results: One hundred and forty-four pediatric patients were included. Sevoflurane insufflation yielded a significantly higher MRI success rate than propofol infusion (69.4% vs. 48.6% respectively; $p = 0.011$). No significant differences were observed between groups for hypotension, movement, or hypertension. Bradycardia occurred significantly more often in the propofol group than in the sevoflurane group ($p = 0.043$). Emergence time was significantly shorter in the sevoflurane group than in the propofol group (26.1$\pm$16.7 vs. 32.2$\pm$17.4 minutes, respectively; $p = 0.040$). There was no significant difference between groups for PAED scale, PONV, or MRI quality.

Conclusion: The present study found a significantly higher MRI success rate in the sevoflurane insufflation group than in the propofol infusion group. Sevoflurane insufflation technique should be considered a safe and effective method of anesthesia for small children undergoing painless imaging procedures.

Keywords: Insufflation, MRI, Children, Sevoflurane, Propofol

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The number of pediatric patients undergoing magnetic resonance imaging [MRI] for medical diagnosis increases annually. Pediatric patients, especially the subset aged 1 to 6 years, tend to be uncooperative in the machine's narrow, cold, dark, and noisy environment for an extended period of time. In order to obtain high-quality images in this population, proper anesthesia is required. In most cases, both deep sedation and general anesthesia are necessary[1].

Malviya et al reported a high rate of successful MRIs in pediatric patients using propofol for total intravenous anesthesia. The advantages of propofol are rapid onset and recovery. However, limitations of propofol are painful sensation during injection, and

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cardiovascular and respiratory depression[2]. Dalal et al compared propofol with chloral hydrate and pentobarbital for MRI sedation, and they reported a 13.6% rate of cardiorespiratory depression in the propofol group[3]. A drawback to the infusion technique is that it requires long extension tubes that are at risk for being kinked or disconnected.

Sevoflurane is another sedation alternative. Similar to propofol, sevoflurane has rapid onset and recovery. Bryan et al reported a higher MRI success rate in 200 patients aged 18 months to 7 years using sevoflurane (92%) than propofol infusion (80%)[4]. In that study, the airways of patients in both groups were managed by laryngeal mask airway [LMA] insertion. Sury et al reported a 92% success rate in pediatric patients undergoing MRI who weighed less than 5 kilograms and who were anesthetized using sevoflurane insufflation technique via cannula[5]. De Sanctis Briggs also reported a high level of success (98%) providing sedation for infants scheduled for MRI scan using sevoflurane, 50% oxygen, and 50% nitrous oxide via face mask[6]. Kim et al described successful sedation of children aged 3 years using sevoflurane insufflation via cannula for dental procedure and also in children aged 4 and 12 years using sevoflurane via nasal hood[7,8]. To our knowledge and based on our review of the English language literature, no previous studies have comparatively investigated success rates between sevoflurane insufflation via simple oxygen mask and other techniques in children aged 1 to 6 years scheduled to undergo MRI. Especially, there is no data which focused on causes of failure that include hypotension, bradycardia, hypoventilation, desaturation, and movement. Accordingly, the aim of this study was to compare the success rate between sevoflurane insufflation via simple oxygen mask and propofol infusion in children aged 1 to 6 years undergoing MRI.

Materials and Methods

This randomized controlled trial was conducted in pediatric patients aged 1 to 6 years who were scheduled to undergo MRI scan at the Department of Radiology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand during the October 1, 2015 to October 31, 2016 study period. Siriraj Hospital is Thailand's largest national tertiary referral center. The protocol for this study was approved by the Siriraj Institutional Review Board (Si. 456/2015) and complied with the principles set forth in the Declaration of Helsinki (1964) and all of its subsequent amendments. Written informed consent was obtained from a parent or legal guardian of all pediatric participants prior to inclusion. Patients meeting one or more of the following criteria were excluded outpatient cases (according to difference in patient intravascular volume status), having abnormal airway anatomy, family history of malignant hyperthermia, allergic to any drugs used in the study, intubated patients or patients with tracheostomy, parental denial to participate. Patients were randomly assigned to either the sevoflurane insufflation group or the propofol infusion group by block of 6 computer-generated randomization. The allocated intervention was written on a slip of paper, placed in a serially numbered opaque envelope, and sealed to prevent disclosure and potential bias. The total number of included patients was equally distributed between groups. As consecutive eligible subjects were enrolled, the envelopes were serially opened and the allocated anesthesia intervention was administered. The chief investigator who performed the intervention was the only person with knowledge of the assigned anesthetic drug, while other anesthesia providers that participated in the anesthesia procedure were blinded.

Pre-operatively, all patients were kept nil per os [NPO] as standard fasting guideline and received intravascular fluid after fasting. Patients were given intravenous midazolam (0.1 mg/kg) for premedication. Each patient received standard intraoperative monitoring, and all intra-operative and postoperative events were recorded on an anesthetic record form until the patient achieved full recovery. The time point of each drug administration, the time that patient was transferred in and out, the MRI start and finish time, the patient wake up and discharge time were recorded to facilitate calculation and evaluation of the sleep time (time since first drug injected to MRI start time), the emergence time (time since stop the drug to patient wake up time), and the post anesthetic care unit [PACU] time (time since PACU arrival to discharge time).

Sevoflurane insufflation protocol

Patients received intravenous thiopental (3 to 5 mg/kg) in the induction room before being transferred to the MRI scanning room. After transfer, 4% sevoflurane was given via simple oxygen mask for the first 5 minutes, after which sevoflurane was adjusted to 2% concentration for maintenance of anesthesia. Each movement that resulted in interruption of scanning was managed using intravenous thiopental (1 to 2 mg/kg), along with concurrent 0.5% increase in sevoflurane concentration per movement occurrence.

Propofol infusion protocol

Patients received bolus intravenous propofol (0.5 to 1 mg/kg) in the induction room and were transferred to the MRI scanning room. Sedation level was maintained by continuous intravenous propofol infusion 6 mg/kg/hr. Additional intravenous propofol bolus dose (0.5 mg/kg) was given to manage each unwanted movement, with a corresponding increase in maintenance dose of 1 mg/kg/hr for each movement occurrence.

The target depth of anesthesia in both groups was deep sedation by providing 1 minimum alveolar concentration [MAC] of sevoflurane or ~100 mcg/kg/min of propofol infusion. This is the normal dose for maintenance of anesthesia in these 2 drugs. Both groups received oxygen via simple oxygen mask with fresh gas flow 1.5 times the minute ventilation to avoid rebreathing, and patient airways were opened using the head tilt chin lift maneuver. The normal saline solution was infused as maintenance rate during the procedure to control the intravascular volume status. Patient respiratory rate was monitored by attaching the catheter of a capnogram unit at the nasal nares. Suction was a component part of the plastic shield covering the patient's head, and a scavenging system was used to prevent pollution. Complications during and immediately after the procedure were observed and recorded. If patients experienced apnea for more than 15 seconds, bag mask ventilation with 100% oxygen was employed. Hypotension was defined as a decrease in systolic blood pressure of 20% from baseline. Significant hypoventilation was defined as respiratory rate <22 and <24 times per minute in patients aged 1 to 3 years and >3 to 6 years, respectively, and oxygen saturation that decreased below 92%. Sevoflurane dial was decreased by 0.5% or propofol infusion was decreased by 1 mg/kg/hr each time hypoventilation developed. In cases where bradycardia (heart rate <90 bpm and <80 bpm in patients aged 1 to 3 years and >3 to 6 years, respectively) occurred together with hypotension, this is referred to as a significant bradycardia. In patients that developed significant bradycardia, 0.02 mg/kg of intravenous atropine was administered.

At the completion of the MRI procedure, the intervention drug was stopped. Ten liters per minute of oxygen was delivered via blow-by technique during the recovery period. MRI quality was assessed by the radiologist at the end of the procedure using a 3-point scale, with score of 1, 2 and 3 indicating an MRI quality grade of good, fair, and poor, respectively.

In the PACU, time to fully awake (crying, spontaneous eye opening, or purposeful movement), Post Anesthesia Emergence Delirium [PAED] score, postoperative nausea and vomiting [PONV], and duration of stay in the recovery room were recorded.

Measurements

Success rate in both anesthesia techniques was defined as completion of the MRI scan without any pause due to complications or movement. Failure rate in both techniques was defined as any interruption in scanning caused by hypotension, hypoventilation, bradycardia, desaturation, or movement. The primary outcome was MRI success rate between the sevoflurane insufflation and propofol infusion groups. The secondary outcomes were PAED scale, PONV, and MRI quality between groups.

Statistical analysis

Previous studies reported a success rate of 96% in average for the sevoflurane insufflation group and 80% in the propofol infusion group[4,6]. To determine the statistical significance with a type I error of 5% (2-sided) and 80% statistical power to detect the effect size between groups (type II error = 20%), 64 subjects per group was calculated. Fifteen percent was added for withdrawal. Thus, at least 72 subjects were required for each group.

Statistical data were analyzed using SPSS Statistics version 18.0 (SPSS, Inc., Chicago, IL, USA). Data are reported as number and percentage or mean $\pm$ standard deviation. Demographic data, sleep time, emergence time, and PACU time were compared using independent t-test. Categorical variables, including the primary outcome, cause of interruption (i.e., hypotension, bradycardia, movement, desaturation, and hypoventilation), PONV, PAED, and MRI quality, were compared using Chi-square test analysis. A *p*-value of less than 0.050 was regarded as being statistically significant.

Results

The Consort flow diagram is shown in Figure 1. One hundred and forty-four patients were prospectively consecutively enrolled in this study, with each of the two study groups receiving an equal allocation of patients. The mean age of patients was 45.9 months, and 54.9% (79/144) of patients were male. Patient demographic, clinical, and imaging characteristics are given in Table 1. There was no significant difference in patient age, gender, or ASA

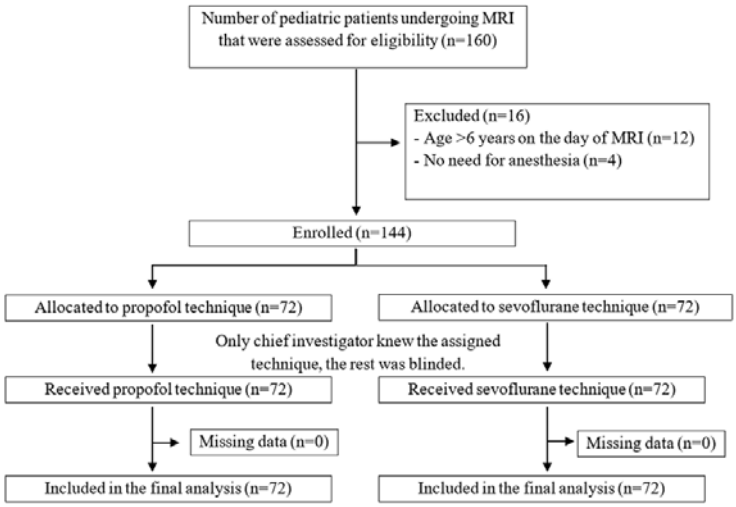

Figure 1. Consort flow diagram.

Table 1. Patient and imaging characteristics in both study groups

	Sevoflurane (n = 72)	Propofol (n = 72)	*p*-value
Age (mo)	46.4±21.1	45.4±20.2	0.790
Male	40 (55.6)	39 (54.2)	0.867
Female	32 (44.4)	33 (45.8)	
Weight (kg)	15.0±4.8	15.8±4.2	0.299
ASA classification			
I	19 (26.4)	24 (33.3)	0.731
II	52 (72.2)	47 (65.3)	
III	1 (1.4)	1 (1.4)	
MRI part			
Brain	55 (76.4)	55 (76.4)	1.000
Head and neck	1 (1.4)	1 (1.4)	
Chest	1 (1.4)	0 (0.0)	
Abdomen	2 (2.8)	2 (2.8)	
Extremities	3 (4.2)	4 (5.6)	
Spine	9 (12.5)	9 (12.5)	
Other	1 (1.4)	1 (1.4)	
MRI duration (min)	56.3±16.3	56.2±12.3	0.940

The data are presented as number (percentage) or mean ± standard deviation
* *p*-value <0.05 indicates statistical significance
ASA = American Society of Anesthesiologists; MRI = magnetic resonance imaging

classification between groups. The mean body weight of patients was 15.4 kilograms, and the mean duration of MRI was 56.25 minutes. MRI scan of the brain was the most frequently performed scan (76.4% in each of the two study groups) in the present study.

Sevoflurane insufflation yielded a significantly higher MRI success rate than propofol infusion (69.4% vs. 48.6%, respectively; $p = 0.011$) (Table 2). The causes of interrupted MRI included movement, hypotension, hypoventilation, and bradycardia (Table 3). No significant difference was observed between groups for hypotension, movement, or hypertension. However, bradycardia occurred significantly more often in the propofol group than in the sevoflurane group (*p*

Table 2. Success rate, PAED score, MRI quality, and duration of anesthesia step

	Sevoflurane (n = 72)	Propofol (n = 72)	*p*-value
Success rate (pausing = 0)	50 (69.4)	35 (48.6)	0.011*
Pausing (frequency)	22 (30.6)	37 (51.4)	
1 to 2	18 (25)	20 (27.8)1	
3 to 4	3 (4.2)	6 (22.2)	0.003*
5	1 (1.4)	1 (1.4)	
PAED score			
0 to 9	72 (100)	69 (95.8)	0.080
≥10	0 (0.0)	3 (4.2)	
MRI quality			
Good	71 (98.6)	70 (97.2)	0.560
Fair	1 (1.4)	2 (2.8)	
Sleep time (min)	10.6±3.2	11.3±2.9	0.148
Emergence time (min)	26.1±16.7	32.2±17.4	0.040*
PACU time (min)	55.0±22.0	60.1±20.0	0.152

The data are presented as number (percentage) or mean ± standard deviation
* *p*-value <0.05 indicates statistical significance
MRI = magnetic resonance imaging; PAED score = Pediatric Anesthesia Emergence Delirium score; PACU = post-anesthesia care unit

Table 3. Frequency of cause of MRI interruption

	Sevoflurane (n = 22)	Propofol (n = 37)	*p*-value
Movement (frequency)			
1 to 2	6 (27.3)	11 (29.7)	0.701
3	0 (0.0)	2 (5.4)	
Hypoventilation	3 (13.6)	1 (2.7)	0.141
Hypotension (frequency)			
1 to 2	8 (36.4)	13 (35.1)	0.474
3 to 4	3 (13.6)	11 (29.7)	
≥5	1 (4.5)	1 (2.7)	
Bradycardia	0 (0.0%)	4 (10.8)	0.043*

The data are presented as number (percentage)
* *p*-value <0.05 indicates statistical significance

= 0.043). The number of pauses or interruptions during MRI was significantly different between groups (p = 0.003) (Figure 2). The propofol group caused higher rate of more than 2 times MRI pause. Hypotension was the most common cause of interruption in both groups (67.6% in the propofol group vs. 54.5% in the sevoflurane group; p>0.05). The second most common cause of MRI interruption was movement, which was found in 35.1% of the propofol group and in 27.3% of the sevoflurane group (p = 0.701). No significant difference in MRI quality was found between groups. Neither PAED nor PONV was observed in any patient in either group.

Sleep time and PACU time were similar between groups. However, emergence time was significantly shorter in the sevoflurane group (26.1±16.7 minutes) than in the propofol group (32.2±17.4 minutes) (p = 0.040).

Discussion

The present a study to investigate the MRI success rate among children aged 1 to 6 who were anesthetized with sevoflurane insufflation versus those anesthetized with propofol intravenous infusion. Our

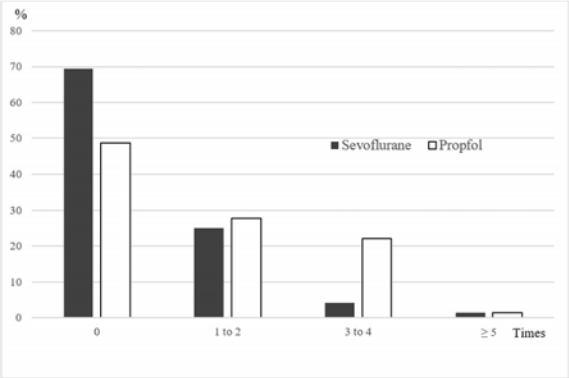

Figure 2. Number of MRI pausing.

results revealed sevoflurane insufflation to be a significantly superior anesthetic technique than propofol intravenous infusion for MRI scan in this patient population (sevoflurane group 69.4% vs. propofol group 48.6%; $p = 0.011$). There are some explanations for this difference in success rate between groups. First, despite the fact that sevoflurane concentration in patients treated with the insufflation technique is lower and less accurate than the concentration delivered by laryngeal mask airway [LMA] or tracheal tube, it produces a sufficient depth of anesthesia for this kind of painless procedure. Ogurlo et al reported that sevoflurane 1.5%, 1.25%, or 1% via face mask could be successfully used for MRI in children[9]. Second, during sevoflurane insufflation with spontaneous breathing, patients can adjust their breaths according to stimuli created by the MRI procedure. In contrast, the propofol infusion technique uses a fixed rate of infusion to ensure the inducement of deep anesthesia; however, the depth of sedation produced may be deeper than the level of sedation that is needed for this painless procedure. In addition, propofol infusion may cause more cardiorespiratory depression due to the deeper plane of anesthesia. In future study, we will compare two techniques at the same depth of anesthesia using bispectral index [BIS] monitoring.

The findings from a previous RCT study by Bryan et al support the findings of our study that anesthesia with sevoflurane (via laryngeal mask airway) produced a higher MRI success rate than that caused by propofol infusion in young children (92% vs. 80%, respectively)[4]. In the Bryan et al study, only movement and monitoring errors were evaluated as causes of MRI scan interruption. In present study, hypotension, movement, bradycardia, desaturation, and hypoventilation were all evaluated for their role in causing interruption during the MRI scan. Accordingly, MRI success rates were lower in our study in both groups. The number of MRI interruption was also our secondary outcome. In the present study, we found that MRI interruption could occur in both study groups, but that the sevoflurane insufflation technique caused significantly less procedural interruption than the propofol infusion technique.

Our results revealed a higher incidence of bradycardia in the propofol group than in the sevoflurane group. Tramer et al reported an incidence of bradycardia when using propofol of 23.3% in 19 control trials and 4.8% in case series[10]. In contrast, Kanaya et al reported that the sevoflurane group did not show any significant change in heart rate variability throughout the study period when compared to the propofol group[11]. Sevoflurane's minimal or absent effect on heart rate variability may be due to its only mild effect on cardiovascular depression. This emphasizes the superiority of sevoflurane insufflation over propofol infusion in this population and clinical setting.

The quality of emergence from anesthesia in children is routinely measured by PAED score. Cravero et al reported an incidence of emergence agitation as high as 60% in non-premedicated children undergoing MRI scans that received sevoflurane anesthesia[12]. Accordingly, we expected that children in the sevoflurane group in our study might have a higher incidence of emergence agitation. Surprisingly, the PAED score was slightly lower in the sevoflurane group than in the propofol group, with no significant difference between groups. We postulate that this difference between studies may be due to the administration of midazolam before the procedure.

Propofol is a rapid acting sedative-hypnotic with a short functional half-life and a rapid recovery phase. Hassan et al reported equal recovery time between continuous drip and intermittent bolus propofol (10±11 minutes vs. 10±12 minutes, respectively) for anesthesia during MRI[13]. Bharti et al compared recovery time between propofol-based and sevoflurane-based anesthesia in microlaryngoscopic surgery, and they found a relatively similar Aldrete score between groups (9.4±5.6 in propofol group vs. 11.2±4.9 in sevoflurane group)[14]. In contrast, we found the emergence time to be significantly shorter in the sevoflurane group than in the propofol group (26.1±16.7 minutes vs. 32.2±17.4 minutes, respectively). It should be noted, however, that sevoflurane insufflation via

oxygen face mask may not achieve a 1 MAC liked definite airway. Moreover, the concentration of sevoflurane using a mask delivers a concentration lower than the setting on the vaporizer dial. That acknowledged, this procedure at this level of drug concentration still produced an adequate depth of anesthesia for this pain-free procedure. However, use of propofol infusion 100 mcg/kg/min may induce deeper sedation than is needed for this painless procedure. In the further study, the depth of anesthesia may be adjusted more accurately by using BIS or some other type of monitoring system.

Although, a high MRI success rate using sevoflurane insufflation via simple oxygen mask was observed in this study, we remain concerned about pollution from sevoflurane insufflation. In the present study, the receiver coil covered the patient's head with a plastic dome that was connected to a scavenging system, but we could not assess residual inhalation in the MRI theatre due to a lack of the MRI compatible equipment. Further study into the effects of pollution in this setting is warranted.

Limitations

The present study has some mentionable limitations. First, all patients in our study were induced to a deep level of sedation; however, the actual depth of sedation could have varied due to variations in drug concentration between the mask and infusion delivery methods. Second, the radiologist who evaluated the quality of MRIs was not the same person in every case. As such, there may have been variation in the subjective interpretation of MRI quality. And last, the pollution was not completely eliminated in this study.

Conclusion

The present study found a significantly higher MRI success rate in the sevoflurane insufflation group than in the propofol infusion group. Sevoflurane insufflation technique should be considered a safe and effective method of general anesthesia for small children undergoing painless imaging procedures.

What is already known on this topic?

In small children undergoing MRI, the normal anesthesia protocol is either general anesthesia (with laryngeal mask airway or endotracheal tube) or total intravenous anesthesia.

What this study adds?

This randomized controlled trial found sevoflurane insufflation via simple oxygen mask to be a safer, more effective, and more time efficient anesthesia technique compared to propofol infusion in young children undergoing MRI.

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Trial registration

Thai Clinical Trials Registry as TCTR 20140828001.

Potential conflicts of interest

The authors declare no conflict of interest.

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