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ORIGINAL ARTICLE

Lower incidence of emergence agitation in children after propofol anesthesia compared with sevoflurane: a meta-analysis of randomized controlled trials

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Abstract
Background Emergence agitation (EA) from general anesthesia has been reported as an adverse effect of sevoflurane in children. We describe a meta-analysis of randomized controlled trials that compared the incidence of EA between children who underwent sevoflurane anesthesia and those who underwent propofol anesthesia.
Methods A literature search was conducted to identify clinical trials that met our inclusion criteria. Prospective randomized trials comparing sevoflurane and propofol anesthesia in children less than 15 years of age were included in the meta-analysis. Data from each trial were combined using the random effects model to calculate pooled odds ratios (ORs) and their corresponding 95 % confidence intervals (CIs). The heterogeneity of data was assessed by Cochran's Q and I^2 tests. Sensitivity analysis was conducted for study quality, patient age, and type of surgical procedure.
Results The meta-analysis included 14 studies, in which 560 patients received sevoflurane and 548 received propofol. The pooled OR for EA was 0.25 with a 95 % CI of 0.16–0.39 ($P = 0.000$), which indicates that propofol anesthesia resulted in a lower incidence of EA. The heterogeneity of data was not statistically supported ($P = 0.191$). All sensitivity analyses strengthened the evidence for the lower incidence of EA with propofol.
Conclusions Our meta-analysis demonstrated that EA in children is less likely to occur after propofol anesthesia compared with sevoflurane anesthesia.

Keywords Emergence agitation · Sevoflurane · Propofol

Introduction

Emergence agitation (EA) from general anesthesia is often seen at the end of anesthesia in children. EA is a problem defined as "a disturbance in a child's awareness of and attention to his or her environment, with disorientation and perceptual alterations including hypersensitivity to stimuli and hyperactive motor behavior in the immediate postanesthesia period" [1]. The incidence of EA is influenced by a variety of factors and can be as high as 80 % [2]. Much effort has been applied to try to reduce the incidence and severity of EA, with varying degrees of success. Sevoflurane remains the most commonly used inhalational anesthetic for children, but we have shown that maintenance of anesthesia with sevoflurane is a major risk factor for EA [3].

Propofol is a widely used intravenous anesthetic with desirable characteristics of a smooth and rapid recovery profile and few postoperative side effects. In adult

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populations, propofol maintenance has been associated with improved recovery profiles in terms of cognitive function, compared with sevoflurane maintenance [4]. Speculation that propofol maintenance might also allow for calm wake-up in pediatric populations has spurred the conduct of randomized controlled comparative studies of propofol and sevoflurane anesthesia. However, these studies have not always shown consistent results for EA, with some strongly favoring propofol anesthesia and others indicating essentially no difference in the incidence of EA between the two anesthetics.

The inconsistent results among studies may have arisen from differences in study design, backgrounds of patients, and other confounding factors. Thus, it remains unclear whether propofol anesthesia consistently results in a lower incidence of EA in children. Furthermore, even if this is correct, it is difficult to evaluate the impact on treatment based on a conventional narrative review of the available evidence. In contrast, a systematic review and meta-analysis are required to determine the consistency of treatment and to calculate the effect size. In this study, we took this approach to compare the incidences of EA in propofol and sevoflurane anesthesia in children.

Methods

We conducted a systematic review, following the recommendations in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement for improving the quality of meta-analyses [5]. A literature search was performed using MEDLINE, EMBASE, the Database of the American College of Physicians Journal Club, the Cochrane Database of Systematic Reviews, the Cochrane Central Register of Controlled Trials, and the Database of Abstracts of Reviews of Effects. Every effort was made to find studies reporting on EA or an equivalent state after sevoflurane or propofol anesthesia in children. The following text searches, search headings, and combinations thereof were used: sevoflurane, propofol, child, agitation, and delirium. A manual search of references listed in reports and reviews was also performed. The most recent search was conducted on February 7, 2012. No language limitation was imposed.

Two authors (A.K. and N.K.) independently assessed each article to determine whether it met the following inclusion criteria. Disagreements were resolved by consensus through discussion among authors and the final decision was made by the senior author (S.K.). To be included in the analysis, a study had to be a prospective randomized trial, compare the use of sevoflurane and propofol, report the results of ambulatory procedures on children aged 15 or less, and report the incidence of EA or an equivalent state after general anesthesia. We rejected articles with insufficient data, but attempted to contact the corresponding author by e-mail in these cases to collect unpublished data, if available.

Unmasked quality assessment of the selected published studies was performed by two investigators (A.K. and N.K.) on composite aspects of study quality (six in total, with scores of 0 or 1: randomization, standardized anesthesia protocol, blindness of outcome measurement, comparability, withdrawals, and definition of EA). Differences in opinion were again settled by consensus, and the final decision was made by the senior author (S.K.). Data abstraction was also performed independently by A.K. and N.K. using standardized data collection forms. Data extracted from eligible studies included patient age, type of surgical procedure, premedication, and supplement to general anesthesia. Dichotomous data on the incidence of EA after sevoflurane or propofol anesthesia were also extracted from eligible studies. Because it has been postulated that rapid awakening per se may be a risk factor for EA, we also extracted extubation time if this was reported in the article.

Statistical analysis

All statistical analyses were performed using Comprehensive Meta-analysis Version 2 (Biostat, Englewood, NJ, USA). Analyses of EA were performed using the odds ratio (OR), which represents the odds of EA occurring in the sevoflurane group compared with that in the propofol group. An $OR < 1$ indicates that propofol is expected to cause less frequent EA compared to sevoflurane. $P < 0.05$ was considered statistically significant. The random effects model was used to determine the pooled effect estimates on the incidence of EA.

Because eligible studies had clinical and methodological diversity, the heterogeneity of collected data was assessed by Cochran's Q and I^2 tests. The I^2 statistic was used to assess the impact of heterogeneity on the results. This statistic indicates the percentage of the variability in effect estimates that is the result of heterogeneity, rather than sampling error [6]. Given the low statistical power of this test, especially when trials have small sample sizes or are few in number, we set a cutoff P value of 0.10 and an I^2 value of 50 % as a homogeneity threshold to avoid false-negative results. That is, $P < 0.10$ and $I^2 > 50$ % indicated heterogeneity and prevented reliance on a combination of the study results.

Sensitivity analysis was performed by recalculating the pooled OR using data with a study quality rating >4. Age, pain, and surgical procedures are potential confounding factors affecting the incidence of EA, and therefore the data were classified using the following subgroups, which

were separately analyzed: patients aged ≤7 years old, patients anesthetized for non-painful diagnostic procedures, and patients anesthetized for adenotonsillectomy.

Extubation times, expressed as mean ± standard deviation (SD), were extracted from the articles. When the standard error was reported, we determined the SD as the standard error multiplied by the square root of the number of subjects. Variables that were not reported numerically were estimated by extrapolating data from published figures. When median data were reported, the mean and SD were estimated by assuming that the mean was equivalent to the median and that the SD was equal to half the median value. The combined effect sizes were calculated using the random effects model and expressed as a weighted mean difference (WMD) with a 95 % confidence interval (CI). $P < 0.05$ was considered statistically significant.

Publication bias can limit the validity of meta-analyses because of the relative paucity of published studies with high statistical power. The potential for publication bias was investigated by constructing funnel plots of log OR against the size of the study [7]. Asymmetrical funnel plots can indicate the presence of publication bias because OR estimates suggesting strong associations in an expected direction may be preferentially published. When publication bias was suspected based on visual inspection, Duval and Tweedie's Trim and Fill method was applied to estimate the impact of publication bias on the observed summary effect size [8].

Results

Based on our search of electronic databases, we initially identified 55 articles for review. Of these studies, 38 were excluded because they were not pertinent, or were review articles or letters. The remaining 17 articles were thoroughly checked to verify that they met our inclusion criteria. From this group of 17, 3 were excluded because of a focus on adult patients for research [9], EA incidence data were not reported and were not available from the authors [10], and the full text was not available and data could not be obtained from the corresponding author [11], respectively. Therefore, 14 studies [12–25] were ultimately identified by the defined search strategy, fulfilled the inclusion criteria, and contained the required data for the planned comparison. The process used to identify eligible studies is illustrated in Fig. 1, and the details of the 14 selected trials are summarized in Table 1. As shown in Table 1, these trials compared sevoflurane and propofol anesthesia in minor surgical or diagnostic procedures in children. Therefore, we considered it appropriate to combine the results of these studies for analysis.

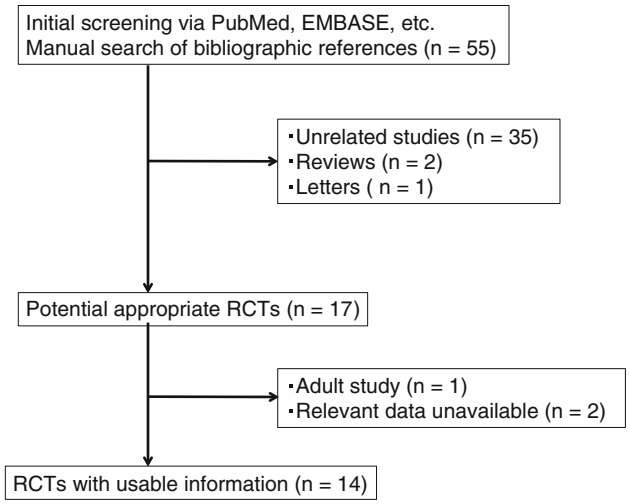

Fig. 1 Flow chart of the meta-analysis. *RCT* randomized controlled trial

The 14 trials included a total of 560 patients anesthetized with sevoflurane and 548 patients anesthetized with propofol in whom the incidence of EA was evaluated. The pooled OR for all studies was 0.25 with a 95 % CI of 0.16–0.39 ($P = 0.000$), which indicates that propofol anesthesia resulted in a lower incidence of EA (Fig. 2). Heterogeneity of data for EA was statistically refuted [$Q = 17.189$, $df(Q) = 13$, $P = 0.191$, $I^2 = 24.372$].

Sensitivity analysis was employed by recalculating the pooled OR, using high-quality studies. A pooled OR of 0.22 (95 % CI 0.12–0.39, $P = 0.000$) was obtained when subgroup analysis was performed for the nine studies [15–19, 21–23, 25] that had a study quality rating >4. Subgroup analyses were also performed to explore the effects of known confounding factors on the incidence of EA (Table 2). When the pooled analysis was restricted to studies of patients aged ≤7 years old [16, 18–20, 22, 25], the pooled OR was 0.22 (95 % CI 0.12–0.42, P = 0.000). A pooled OR of 0.32 (95 % CI 0.10–0.97, $P = 0.044$) was obtained in subgroups formed from subjects in the two studies focused on non-painful diagnostic procedures [16, 22]. In five studies of adenotonsillectomy procedures [15, 17, 20, 21, 25], the pooled OR was 0.13 (95 % CI 0.060–0.27, $P = 0.000$). In all subgroup analyses, the EA incidence with propofol anesthesia was lower than that with sevoflurane anesthesia.

Of the 14 trials, 9 articles [12, 15–19, 21, 24, 25] included extubation times for a total of 247 patients anesthetized with sevoflurane and 235 patients anesthetized with propofol. Pooled analysis of extubation time demonstrated significantly earlier times for extubation in patients anesthetized with sevoflurane (WMD_{min}, 1.09; 95 % CI 0.096–2.09, $P = 0.032$) (Fig. 3). Heterogeneity of data on

Table 1 Characteristics of included studies

Study (reference number)	Year	Patient age	Type of surgery	Premedication (route)	Supplemental analgesia	N_2O	Study quality	Remarks
Guard et al. [12]	1998	2–8 years	Urological surgery	None	Lumbar or caudal epidural block	Both groups	4	"Excitation" was considered as EA
Lopéz Gil et al. [13]	1999	6–144 months	Minor surgery below the umbilicus	Midazolam 0.5 mg/kg (oral)	Fentanyl 3 μg/kg followed by 1 μg/kg/h	Both groups	3	LMA was used. "agitated" and "crying" were considered as EA
Gürkan et al. [14]	1999	3–15 years	Strabismus surgery	None	None	Both groups	3	
Picard et al. [15]	2000	3–10 years	Tonsillectomy	None	Acetaminophen 20 mg/kg and ibuprofen 10 mg/kg (rectal) local infiltration of bupivacaine	Both groups	6	
Uezono et al. [16]	2000	1–5 years	Eye examination	Midazolam 0.5 mg/kg (oral)	Acetaminophen 30 mg/kg (rectal)	None	5	Crossover study
Koçak et al. [17]	2001	6.3 ± 1.6 years[a]	ENT surgery[b]	Midazolam 0.03–0.05 mg/kg	Paracetamol suppositories	Sevo group only	5	Recovery score of ≧2 was considered as EA
Kubo et al. [18]	2001	months–6 year	Inguinal hernia surgery	None	Ilioinguinal nerve block	Both groups	5	Japanese literature. No-premedication groups were adopted for data analysis
Cohen et al. [19]	2003	2–36 months	Ambulatory surgery	None	Fentanyl 2 μg/kg or caudal block	Both groups	5	
Auerswald et al. [20]	2006	1–5 years	Adenotonsillectomy	Midazolam 0.35 mg/kg (oral)	Alfentanil 20 μg/kg	None	4	German literature. Agitation score "range 0" was considered as EA. "Sevoflurane—alfentanil" and "propofol—alfentanil" were adopted for analysis
Nakayama et al. [21]	2007	2–11 year	Otorhinolaryngological surgery	None	Fentanyl 2 μg/kg, flurbiprofen 1 mg/kg	Both groups	6	Both preschool- and school-age groups were included. EA data after eye opening were adopted
Bryan et al. [22]	2009	3 months–7 years	MRI scans	None	None	None	5	PAED score >10 was considered as EA. LMA was used. Study patients included those with neurodevelopmental diagnoses treated with an anticonvulsant and/or psychotropic medications
König et al. [23]	2009	2–12 years	Ambulatory dental surgery	Midazolam 0.5 mg/kg	Acetaminophen 20 mg/kg (oral), fentanyl ≧2 μg/kg	Both groups	6	PAED score >10 was considered as agitation. Patients with developmental delay were included
Deng et al. [24]	2009	3–12 years	Cleft lip and palate repair surgery	Phenobarbital 3–5 mg/kg (im.)	Fentanyl 3 μg/kg	None	4	Chinese literature

Table 1 continued

Study (reference number)	Year	Patient age	Type of surgery	Premedication (route)	Supplemental analgesia	N_2O	Study quality	Remarks
Pieters et al. [25]	2010	3–7 years	Adenotonsillectomy	None	Fentanyl 2 μg/kg	None	6	Data from 1 min after extubation were used. PAED score ≧16 was considered as agitation

Medications were administered intravenously unless otherwise indicated

N_2O nitrous oxide, *EA* emergence agitation, *PAED* pediatric anesthesia emergence delirium

[a] Mean ± standard deviation

[b] ENT surgery, ear–nose–throat surgery, including adenoidectomy with bilateral myringotomy, insertion of tubes, and/or tonsillectomy

extubation time was statistically significant [$Q = 26.863$, $df(Q) = 8$, $P = 0.001$, $I^2 = 70.220$].

A funnel plot that explores possible publication bias in the meta-analysis is shown in Fig. 4. Some asymmetry on the right-hand side is apparent, indicating that some studies with favorable conclusions for sevoflurane may be missing. Duval and Tweedie's Trim and Fill method was used to compensate for the effect of possible missing studies. As shown in Fig. 4, the adjusted OR was 0.36 (95 % CI 0.22–0.59, $P = 0.000$).

Discussion

Our meta-analysis confirmed that EA occurred less frequently with propofol anesthesia than with sevoflurane in children. The results of this analysis are consistent with the findings in adult populations regarding the higher quality of emergence from propofol anesthesia [26]. In the pediatric population, a consensus among anesthesiologists has yet to be established, but multiple controlled trials comparing propofol and sevoflurane have been conducted to answer the question of whether propofol anesthesia consistently results in a lower incidence of EA in children. All trials that met our inclusion criteria yielded an OR of <1 for EA after propofol administration, whereas only seven studies showed a statistically significant difference (Fig. 2). This inconsistency among trials could result from a number of reasons. Certain trials may have insufficient power to detect differences between the two anesthetics. Because many trials used an ad hoc scale to evaluate EA, the validity of diagnoses across the trials may be suspect. The strength of meta-analysis depends on suitable calculations of effect sizes and their combination in a single statistical analysis. This process allows a determination of whether the effects are consistent across studies and minimizes the potential impact of confounding factors.

The results of our sensitivity analyses strengthened the evidence for a lower incidence of EA after propofol anesthesia in children (Table 2). The recalculation of data derived only from high-quality studies also revealed a significant difference between propofol and sevoflurane. With the recognition that different types of surgical procedure could be a significant confounding factor affecting the incidence of EA, adenotonsillectomy procedures were analyzed separately as a subgroup. An adenotonsillectomy is typically thought of as a procedure that includes a high risk of EA. As shown in Table 2, the pooled results of five tonsillectomy studies also demonstrated a significantly lower incidence of EA following propofol anesthesia. The pooled OR also indicated that propofol anesthesia results in a lower incidence of EA than sevoflurane in the

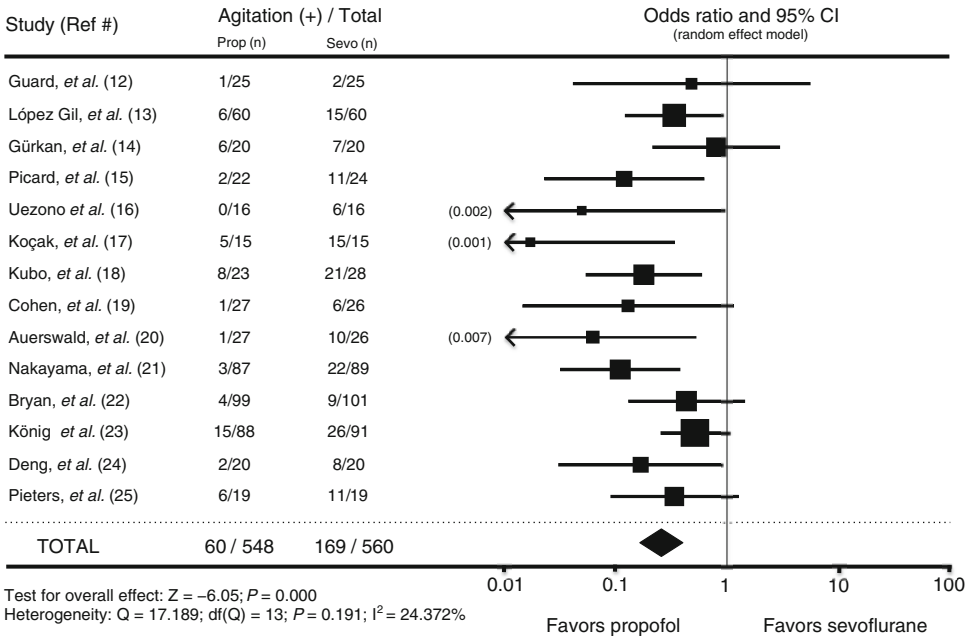

Fig. 2 Meta-analysis of emergence agitation resulting from sevoflurane (Sevo) versus propofol (Prop). The center of each *black square* represents the odds ratio for individual trials; the corresponding *horizontal line* represents the 95 % confidence interval (CI). The area of each *square* is proportional to its contribution to the weighted summary estimate. *Arrowheads* indicate that the study data are scaled out. The *black diamond* represents the pooled result (OR 0.25, 95 % CI 0.16–0.39, $P = 0.000$). *Ref #* reference number, *n* number of patients

Table 2 Effects of subgroup analysis on meta-analysis comparing sevoflurane and propofol

Subgroup	References	Pooled OR (95 % CI)	*P* value	Heterogeneity *P* value
High-quality studies (score >4)	[15–19, 21–23, 25]	0.217 (0.120–0.391)	0.000	0.144
Preschool children (aged ≤7 years)	[16, 18–20, 22, 25]	0.219 (0.116–0.415)	0.000	0.515
Nonpainful procedures	[16, 22]	0.316 (0.103–0.971)	0.044	0.185
Adenotonsillectomy	[15, 17, 20, 21, 25]	0.128 (0.060–0.274)	0.000	0.368

OR odds ratio, *CI* confidence interval

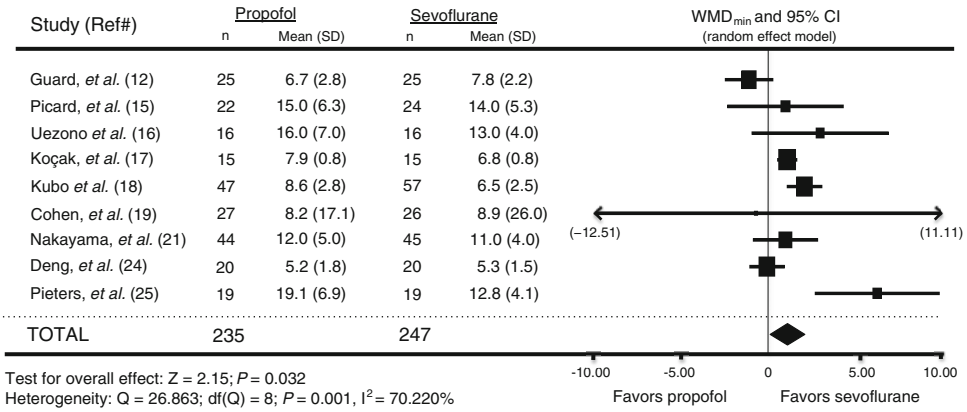

Fig. 3 Meta-analysis of extubation time between propofol and sevoflurane anesthesia. Effect sizes are represented by the weighted mean differences (WMD), shown as *black squares*. The area of each square is proportional to its contribution to the weighted summary estimate. *Horizontal lines* represent the lower and upper limits of the 95 % confidence intervals. *Arrowheads* indicate that the study data are scaled out. The *black diamond* represents the pooled result (WMD_{min} 1.09, 95 % CI 0.096–2.09, $P = 0.032$). *Ref #* reference number, *n* number of patients, WMD_{min}, weighted mean difference (minutes)

preschool age group. Because pain is a well-known major factor that can cause EA, subgroup analysis using data from non-painful diagnostic procedures may eliminate the possible confounding effects of pain on the incidence of EA. As shown in Table 2, propofol still resulted in a lower incidence of EA in children in the absence of pain.

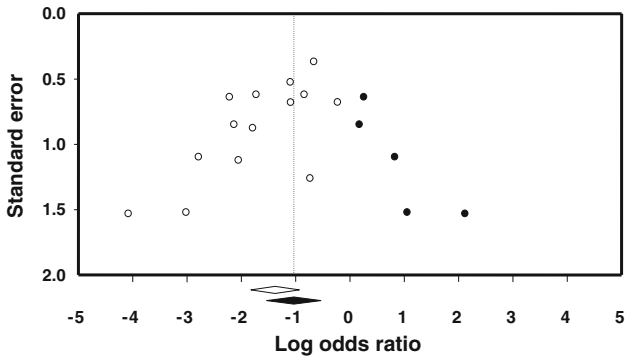

Fig. 4 Funnel plot exploring possible publication bias. The *x*-axis is the log odds ratio; the *y*-axis indicates the log standard error of the study. The observed studies are shown as *open circles* and the observed point estimate in log units is shown as an *open diamond*. The *filled circles* indicate imputed studies that adjust the bias because of possibly missing studies, using Duval and Tweedie's Trim and Fill method. The *black diamond* indicates the adjusted point estimate ($OR_{adjusted}$ 0.36, 95 % CI 0.22–0.59, $P = 0.000$). The *vertical dotted line* indicates the overall adjusted odds ratio

The reasons for the higher incidence of EA after sevoflurane remain largely unknown. Under certain circumstances, sevoflurane may have a side effect on the central nervous system, based on reports of epileptiform seizure activity on electroencephalography in nonepileptic patients [27, 28]. However, desflurane, which also has a high incidence of EA [29], has not been shown to be epileptogenic in humans. Thus, the epileptogenicity of sevoflurane is unlikely to be a major reason for the higher incidence of EA in children. Another hypothesis is that rapid emergence may be associated with the higher incidence of EA of sevoflurane, because use of newer insoluble inhalational anesthetic agents appears to result in a high incidence of EA [30]. Our pooled analysis revealed that sevoflurane anesthesia resulted in slightly quicker extubation compared with propofol anesthesia. However, these results should be interpreted with caution because the heterogeneity of the data was high, and higher heterogeneity implies greater variation in true effect sizes as a consequence of various confounding factors. Because extubation time was not a primary endpoint of most studies included in the meta-analysis, and extubation criteria were not clearly defined in most of the studies, the data for extubation time should not be considered reliable. The reported differences in extubation time between propofol and sevoflurane were small and can be considered clinically insignificant. In addition, it has been shown that delayed stepwise decreases in sevoflurane concentration do not prevent EA [31], and thus the causative role of abrupt emergence from anesthesia on EA is questionable.

Our meta-analysis has a number of limitations. First, each study was based on a different study protocol, which can cause significant data heterogeneity, and although our statistical analyses did not reveal this, there may be arguments against combining results based on different protocols in the calculation of pooled ORs and for drawing conclusions using this approach. Second, because a meta-analysis is based on published articles, there is a possibility of publication bias, whereby studies that report significant findings are more likely to be published in indexed journals. In this study, because we found significant asymmetry in a funnel plot, Duval and Tweedie's Trim and Fill method was used to eliminate the effect of possible publication bias. The adjusted summary effect was still observed to be in favor of propofol, in terms of reduced EA risk. Last, in this analysis, we did not aim to clarify the safety of propofol infusion for pediatric use. Although no adverse reactions related to propofol administration were reported in the articles we selected, cases of propofol infusion syndrome characterized by lactic acidosis, rhabdomyolysis, and bradyarrhythmic cardiac failure have been described after even relatively short-term infusion of propofol for general anesthesia [32, 33].

In conclusion, the present meta-analysis of currently available randomized controlled trials (RCTs) that compared the incidence of EA in children after sevoflurane and propofol anesthesia indicates that propofol has a lower probability of EA compared to sevoflurane, with a pooled OR of 0.25 (95 % CI 0.16–0.39, $P = 0.000$). Various sensitivity analyses further strengthened these findings. Our analyses also indicated that extubation is slightly quicker with sevoflurane anesthesia than with propofol, but significant data heterogeneity makes it difficult to conclude that excessively rapid emergence plays a role in the higher incidence of EA after sevoflurane anesthesia.

Conflict of interest Akihiro Kanaya, Norifumi Kuratani, Daizoh Satoh, and Shin Kurosawa reported no conflicts of interest.

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