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ORIGINAL ARTICLE

Effect of single-dose dexmedetomidine on emergence agitation and recovery profiles after sevoflurane anesthesia in pediatric ambulatory surgery

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Abstract
Purpose To study the effects of dexmedetomidine (DEX), a selective α_2-adrenoreceptor agonist, on emergence agitation (EA), recovery profiles, and parents' satisfaction after sevoflurane anesthesia in pediatric ambulatory surgery.
Methods In a double-blind trial, 81 children (ASA PS 1 or 2, 1–9 years) undergoing same-day or overnight-stay surgery were randomly assigned to receive intravenous DEX 0.3 μg kg^{-1} ($n = 39$) or saline ($n = 42$) over 10 min after induction of anesthesia. Anesthesia was induced and maintained with sevoflurane using a facemask or laryngeal mask airway with spontaneous respiration. Agitation was assessed with a 1–4 point scale and pain with a 0–10 point scale. The patients' parents were interviewed 24 h after surgery, and adverse events and the parents' level of satisfaction with perioperative care were recorded.
Results The incidence of EA (agitation scale score 3 or 4) was significantly lower in the DEX group (28%) than in the saline group (64%) ($P = 0.0011$). The mean pain scales in the DEX group were significantly lower than in the saline group during the stay in the post-anesthesia care unit (PACU) ($P < 0.01$). The incidence of adverse events, times to the first drinking and voiding in the PACU, time spent in the PACU, and parents' satisfaction level were not different between the two groups.
Conclusion Intravenous DEX at a dose of 0.3 μg kg^{-1} after induction of anesthesia reduced sevoflurane-associated EA and postoperative pain in pediatric ambulatory surgery, with no increase in the incidence of adverse events and with no change in parents' satisfaction level.

Keywords Dexmedetomidine · Emergence agitation · Sevoflurane · Children · Ambulatory surgery

Introduction

Sevoflurane is a popular anesthetic for children used worldwide because of its low pungency, rapid onset, and fast recovery properties. However, it is associated with higher incidence of emergence agitation (EA) (up to 80% [1–3]) than halothane. EA in children is generally short-lived with no after-effect. However, it is a troublesome phenomenon, because it can result in injury to the patient or damage to the surgical site, leads to dissatisfaction and anxiety for the parents, and requires extra nursing care with associated costs. In pediatric ambulatory surgery, EA is a particularly difficult problem, because EA itself and its treatment using sedatives or analgesics may delay discharge and the patient's return home. Extended hospital stays discourage both patients and their caregivers from undergoing ambulatory surgery [4]. Therefore, ambulatory pediatric anesthesiologists should try to prevent EA in order to provide efficient and high-quality care that is a positive experience for patients and their parents.

To reduce the incidence of EA, prophylactic use of benzodiazepines, opioid analgesics, and α_2-adrenoreceptor

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agonists have been tried, but the results have been variable [1, 5–14]. Dexmedetomidine (DEX), a highly specific α_2-adrenoreceptor agonist (receptor selectivity, $\alpha_2/\alpha_1 = 1620/1$), has sedative and analgesic properties without significant respiratory depression at clinical dosages [15, 16]. DEX is reported to significantly reduce EA frequency after sevoflurane anesthesia in pediatric surgery and non-surgical procedures in inpatient [5, 6] and outpatient [7, 8] settings. However, these reports did not include follow-up data and measures of parents' satisfaction levels. Follow-up is an important part of perioperative management of ambulatory surgery in order to find adverse events, give advice to patients and caregivers, increase their satisfaction, and improve practice. In this study, in addition to corroborating the effects of DEX on post-sevoflurane EA in children undergoing same-day or overnight stay surgery, we investigated the recovery profiles during the stay in the post-anesthesia care unit (PACU) and 24 h after PACU discharge, and also recorded parents' satisfaction levels.

Materials and methods

We investigated 81 pediatric patients (ASA physical status 1 or 2, 1–9 years old, body weight >10 kg) who were scheduled to receive same-day surgery ($n = 50$) or overnight stay surgery ($n = 31$) under general anesthesia between October 2004 and April 2007 in the Day Surgery Unit (DSU), Kyoto University Hospital. The study was approved by the institutional ethics committee and informed consent was obtained from the parents. Patients who did not consent, or with mental retardation, neurological or heart disease, uncontrollable asthma, or any type of acute illness were excluded from this study.

All patients and their parents were admitted to the DSU in the morning on the day of surgery. They waited in the pediatric pre-anesthesia holding area in the DSU. The children received no premedication and moved to an operating room in the DSU accompanied by their mother or father. The parent was permitted to be present during induction of anesthesia. Children were randomly assigned to receive either saline (group S, $n = 42$) or DEX (group D, $n = 39$) using a randomization list. General anesthesia was induced with 8% sevoflurane in 6 l min^{-1} oxygen using a facemask, and they breathed spontaneously. An intravenous (i.v.) catheter was inserted after induction of anesthesia and the airway was secured with facemask or laryngeal mask airway (LMA). Patients in group D received DEX 0.3 μg kg^{-1} diluted in 5 ml saline over 10 min via the i.v. catheter whereas patients in group S received 5 ml saline. The attending anesthesiologists, surgeons, and nurses were blinded to the treatment assignment of a patient. Anesthesia was maintained and adjusted by an attending anesthesiologist with 2–5% sevoflurane in 2 l min^{-1} oxygen and 4 l min^{-1} air to provide a stable heart rate (HR), blood pressure (BP), and pulse oximetric arterial oxygen saturation (SpO_2) with spontaneous respiration. All patients received an acetaminophen (total 40 mg kg^{-1}) or diclofenac (total 1 mg kg^{-1}) suppository after induction of anesthesia and at the end of surgery. Ropivacaine infiltration into the surgical field was done except for laser irradiation or myringotomy with tube insertion. No urinary catheters were inserted. The HR, BP, SpO_2, endtidal concentrations of carbon dioxide and sevoflurane (ET_{CO_2} and ET_{sev}), and respiratory rate (RR) were monitored throughout the procedure. At the end of surgery, sevoflurane was discontinued, and LMA was removed before the patients fully woke up in the operating room. The children were transferred to the PACU in the DSU after their eyes opened spontaneously.

In the PACU, parents were allowed to stay beside their child and SpO_2 and HR were monitored. A PACU nurse blinded to the patient assignment recorded adverse events, for example postoperative vomiting (POV) and urinary retention, and the drugs administered. In addition, they recorded a modified Aldrete score for children (0–10 point scale) [17], the times when they drank fluids and voided, and the time of discharge from the PACU. Postoperative nausea (PON) was not assessed because it is difficult to evaluate in children. Pain was treated with fentanyl 0.5 μg kg^{-1} intravenously or an acetaminophen suppository 20 mg kg^{-1}, and POV was medicated with a domperidone suppository 1 mg kg^{-1}. If SpO_2 fell to <92%, oxygen was given by use of a facemask.

Behavior during both the pre and post-operative periods was rated on a four-point agitation scale (1, calm; 2, not calm but could be easily calmed; 3, not easily calmed, moderately agitated, or restless; and 4, combative, excited, or disoriented) [2] by an observer blinded to the patient assignment. Agitation scores of 3 or 4 were defined as an agitation episode. Patients' pain while in the PACU was assessed with the children and infants postoperative pain scale (CHIPPS, 0–10 point scale) [18] by the same observer. Children were discharged from the PACU when they were calm with minimum pain, no vomiting, stable vital signs, and could drink fluids and void. Patients who were scheduled for same-day discharge returned home directly. If the discharge criteria were not satisfied, they were transferred to the ward (unplanned hospital admission). Patients who were scheduled for an overnight-stay were transferred to the ward. If a problem prevented discharge and return home, the patient's hospital stay was extended (unplanned extended hospital stay).

In the morning on the day after surgery, a PACU nurse or anesthesiologist blinded to the patient assignment followed up each child with a telephone call or by direct

Table 1 Patients' characteristics and surgical and anesthetic data

	Group S ($n = 42$), saline controls	Group D ($n = 39$), DEX-treated
Age (years)	2.9 ± 2.5	3.6 ± 2.2
Weight (kg)	14.7 ± 6.3	16.1 ± 4.6
Gender (male/female)	21 (50%)/21 (50%)	21 (54%)/18 (46%)
ASA PS (1/2)	40 (95%)/2 (5%)	35 (90%)/4 (10%)
Planned hospital stay (same-day discharge/overnight stay)	24 (57%)/18 (43%)	26 (67%)/13 (33%)
Airway		
Face mask	8 (19%)	2 (5%)
LMA	34 (81%)	37 (95%)
Type of surgery		
Plastic surgery		
Laser irradiation	21 (50%)	14 (36%)
Excision of nevus or skin tumor	10 (24%)	10 (26%)
General surgery		
Inguinal hernia repair	4 (10%)	7 (18%)
Urology		
Orchidopexy	4 (10%)	1 (3%)
Orthopedic surgery		
Removal of nails	1 (2%)	3 (8%)
Otolaryngology		
Myringotomy with tube insertion	1 (2%)	3 (8%)
Orodental surgery		
Tooth extraction	1 (2%)	1 (3%)
Duration of surgery (min)	41 ± 32	49 ± 38
Duration of anesthesia (min)	72 ± 37	81 ± 36
Intraoperative fluid volume (ml)	301 ± 137	378 ± 105

Values are mean ± SD or number (%)

LMA, laryngeal mask airway

meeting with his/her parent; using a standardized questionnaire with some modifications as previously described [4]. Parents were asked about post-discharge symptoms including pain and POV, using a verbal rating score (0–10; 0, no symptom; 10, the severest symptom imaginable). Scores were also obtained for resumption of normal activity (RNA) (0–10; 0, no activity; 10, back to normal activity) and satisfaction with the global surgical and anesthesia care (0–10; 0, very dissatisfied; 10, very satisfied). The preference for an outpatient-based procedure was also evaluated (Question: If your child should undergo the same operation in the future, would you choose the outpatient setting again? Answer: Yes or no).

Statistical analysis was performed using SAS software (SAS Institute, Cary, NC, USA). Demographic data, for example age, body weight, duration of anesthesia and surgery, and the fluid volume infused, were compared using unpaired Student's *t* tests. Categorical data expressed as a number or percentage were compared by chi-squared analysis and Fisher's exact test. The Mann–Whitney *U* test was used to compare recovery times and modified Aldrete, agitation, pain, and post-operative interview scores. Intra and post-operative hemodynamic and respiratory variables in the same subjects were compared by use of the Bonferroni test after repeated-measures analysis of variance. Trends over time in the two groups were compared using repeated-measures analysis of variance and time-matched data were compared by use of the Bonferroni test. Differences at $P < 0.05$ were considered to be statistically significant.

Results

The two patient groups did not differ significantly with regard to preoperative characteristics, types of surgery, duration of surgery and anesthesia, and intraoperative i.v. fluid volume (Table 1). Agitation scale scores in group D were lower than in group S on discharge from the operating room (2(1–3), median (25th–75th percentile) vs. 3(2–3); $P = 0.0049$) and on PACU admission (2(1–3) vs. 3(2–3); $P = 0.012$). The incidence of EA (agitation score 3 or 4) was significantly lower in group D than in group S at discharge from the operating room (28 vs. 64%;

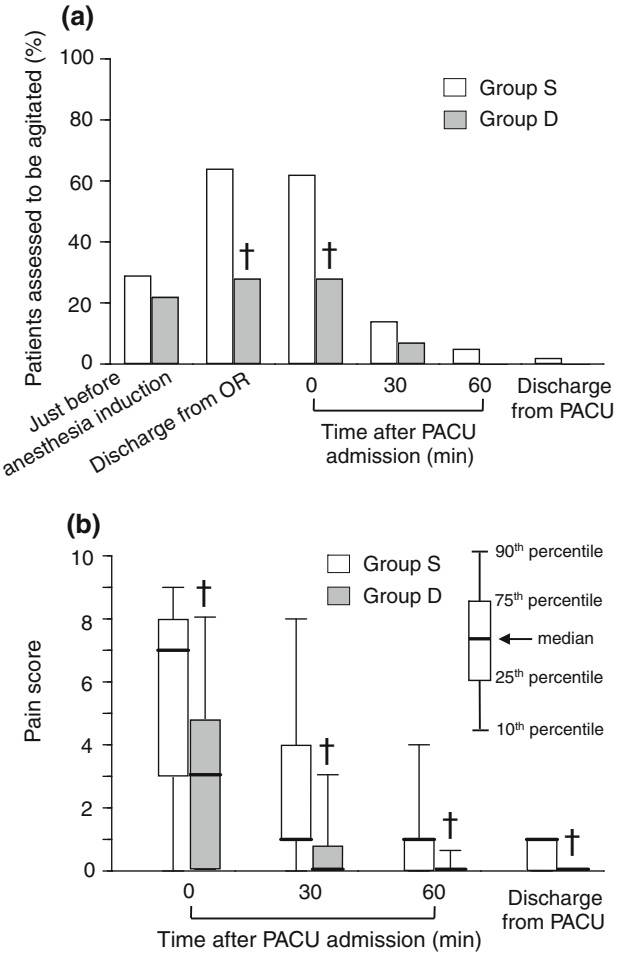

Fig. 1 Changes in percentage of agitated children (**a**) and pain score (**b**). Children who scored of 3 or 4 on the agitation scale were assessed as agitated. *PACU* post-anesthesia care unit, *group S* saline control group, *group D* DEX-treated group, *OR* operating room. $^{\dagger}P < 0.05$ versus group S (chi-squared analysis and Fisher's exact test **a**, Mann–Whitney *U* test **b**)

$P = 0.0011$) and on PACU admission (28 vs. 62%; $P = 0.0023$) (Fig. 1a). The pain scores in group D were significantly lower than in group S on PACU admission ($P = 0.0006$), at 30 min ($P < 0.0001$) and 60 min ($P = 0.0016$) after PACU admission, and on PACU discharge ($P = 0.0012$) (Fig. 1b). HR was lower in group D than in group S from just after the end of DEX injection until 30 min after PACU admission (Fig. 2a). In group D, systolic BP from just after the end of DEX injection till the end of surgery was lower than the pre-anesthesia level (Fig. 2b). Systolic BP, RR, and ET_{CO_2} did not differ between the two groups during anesthesia (Fig. 2b; Table 2). ET_{sev} in group D was lower than in group S just after the end of DEX/saline infusion and at the beginning of surgery (Table 2). SpO_2 did not differ between the two groups during anesthesia and during the stay in the PACU. The time from PACU admission until the modified Aldrete score was ≥9, and until taking a drink, voiding, and discharge from the PACU were no different between the two groups (Table 3). Incidences of POV, anti-emetic and analgesic medications, and oxygen supplementation were very low in both groups (Table 3). No patients required unplanned hospital admission/extended hospital stays. No parent whose child underwent same-day surgery made an emergency telephone call to the hospital, or returned to the hospital with his/her child after discharge and return home. Parents' responses to the 24-h postoperative interview were no different between the two groups with regard to postoperative symptoms, RNA scores, preference for outpatient-based procedures, and global satisfaction scores (Table 4).

Discussion

This study indicates that DEX administration reduces the incidence of EA after sevoflurane anesthesia in children, confirming previous results [5–8]. Furthermore, this study demonstrates that DEX at a dose of 0.3 μg kg^{-1} after induction of anesthesia does not affect recovery profiles and parents' satisfaction levels.

The etiology of EA in children is not fully understood but possible risk factors are rapid emergence from anesthesia, intrinsic characteristics of an anesthetic, postoperative pain, preschool age, otolaryngologic surgical procedures, preoperative anxiety, and child temperament [1]. Meta-analysis of 23 randomized controlled trials revealed that EA occurred more frequently with sevoflurane than halothane [3]. Rapid awakening after sevoflurane anesthesia has been assumed to be a cause for the phenomenon. However, it is currently thought that rapid emergence is not the only cause of EA, because recovery from propofol anesthesia, which also has rapid emergence properties, is associated with low incidence of EA [19]. The genesis of EA after sevoflurane anesthesia has been uncertain up to now.

The presence of pain is thought to be one of the major causes of EA, but painless treatment does not guarantee calm emergence from sevoflurane anesthesia [1]. Isik et al. [7] reported that EA was seen in 48% of pediatric patients after sevoflurane anesthesia while undergoing magnetic resonance imaging. Since it is often difficult to distinguish EA in children from screaming because of pain, adequate postoperative pain treatment should be administered. The use of fentanyl as a preemptive analgesic reduces the incidence of EA [11, 12]. However, potent opioid analgesics are associated with various adverse postoperative symptoms, especially PON/POV, which delay post-anesthesia recovery and cause unplanned hospital admissions; thus, non-opioid analgesic techniques and minimization of opioid use are

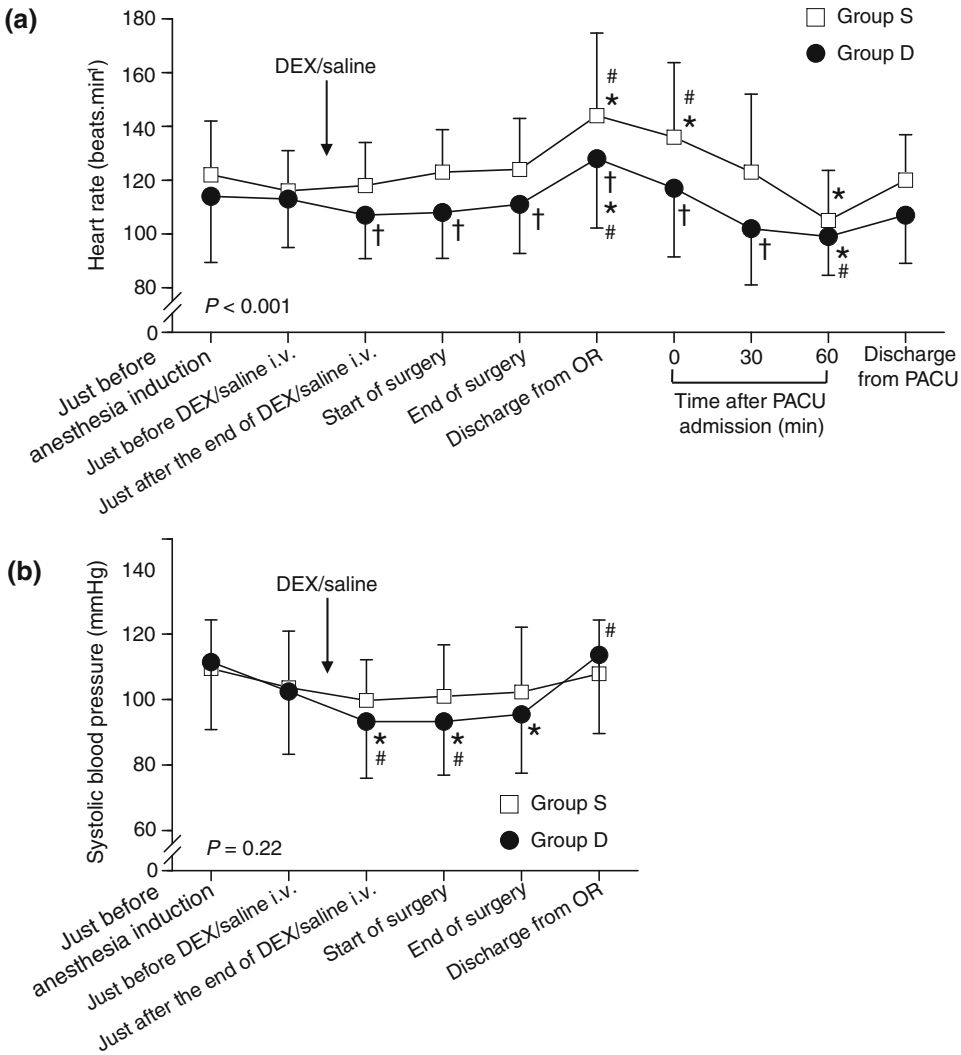

Fig. 2 Time courses of heart rate (**a**) and systolic blood pressure (**b**). Values are mean ± SD. *PACU* post-anesthesia care unit, *OR* operating room, *group S* saline control group, *group D* DEX-treated group. *P* value compares trends over time with treatments (repeated-measures analysis of variance). $^{\dagger}P < 0.05$ versus group S, $^{*}P < 0.05$ versus just before anesthesia induction, $^{\#}P < 0.05$ versus just before DEX/saline i.v. (Bonferroni test after repeated-measures analysis of variance)

Table 2 Changes in respiratory variables during anesthesia

	SpO_2 (%)		RR (min^{-1})		ET_{CO_2} (mmHg)		ET_{sev} (%)	
Group	S	D	S	D	S	D	S	D
Just before anesthesia induction	99 ± 1.0	99 ± 1.3						
Just before DEX/saline i.v.	99 ± 1.3	99 ± 0.7	31 ± 6.7	32 ± 6.1	41 ± 8.6	41 ± 8.7	3.6 ± 1.0	3.4 ± 1.0
Just after the end of DEX/saline i.v.	99 ± 1.2	99 ± 0.9	32 ± 4.7	34 ± 6.7	41 ± 7.3	44 ± 6.7	3.2 ± 0.8	2.8 ± 0.5*,†
Operation start	99 ± 1.0	99 ± 1.0	34 ± 6.2	34 ± 7.0	43 ± 7.7	45 ± 8.9	3.3 ± 0.7	2.8 ± 0.5*,†
Operation end	99 ± 1.1	99 ± 1.7	32 ± 7.3	30 ± 7.0	43 ± 9.3	44 ± 7.0	2.0 ± 0.9*	1.9 ± 0.7*
Emergence	99 ± 1.9	99 ± 1.7						
P value	0.46		0.83		0.52		0.0024	

Values are mean ± SD

P value compares trends over time with treatments (repeated-measures analysis of variance). $^{*}P < 0.05$ versus Just before DEX/saline i.v., $^{\dagger}P < 0.05$ versus group S (Bonferroni test after repeated-measures analysis of variance)

S saline control group, *D* DEX-treated group, SpO_2 pulse oximetric arterial oxygen saturation, *RR* respiratory rate, ET_{CO_2} endtidal concentration of carbon dioxide, ET_{sev} endtidal concentration of sevoflurane

Table 3 Recovery profiles in the PACU

	Group S ($n = 42$), saline controls	Group D ($n = 39$), DEX-treated
Modified Aldrete score on PACU admission	10 (10–10)	10 (9–10)
Use of analgesic drug	1 (2%)	1 (3%)
Use of antiemetic drug	1 (2%)	0 (0%)
Use of oxygen	1 (2%)	0 (0%)
Vomiting	3 (8%)	3 (7%)
Urinary retention	0 (0%)	0 (0%)
Time from PACU admission		
To modified Aldrete score ≥9 (min)	0 (0–1.5)	0 (0–5)
To drink fluids (min)	65 (50–108)	90 (63–131)
To void (min)	115 (90–130)	124 (76–160)
To actual discharge from PACU (min)	133 (104–165)	160 (128–205)
Unplanned admission/extended hospital stay	0 (0%)/0 (0%)	0 (0%)/0 (0%)

Values are expressed as median (25th–75th percentile) or number (%)

PACU post-anesthesia care unit

Table 4 Data from interviews 24 h after operation

	Group S ($n = 42$), saline controls	Group D ($n = 39$), DEX-treated
Symptoms after discharge[a]		
Sleepiness	0 (0–0)	0 (0–1.5)
Dizziness	0 (0–0)	0 (0–0)
General malaise	0 (0–0)	0 (0–2)
Fever	0 (0–0)	0 (0–0)
Sleeplessness	0 (0–0)	0 (0–0)
Bleeding	0 (0–0)	0 (0–0)
Pain	0 (0–0)	0 (0–1.5)
Hoarseness	0 (0–0)	0 (0–0)
Vomiting	0 (0–0)	0 (0–0)
Appetite loss	0 (0–0)	0 (0–0)
Thirst	0 (0–0)	0 (0–0)
Urinary disturbance	0 (0–0)	0 (0–0)
RNA[b] score	10 (9.25–10)	10 (9–10)
Preference[c]	42 (100%)	38 (97%)
Satisfaction score[d]	10 (10–10)	10 (10–10)

Values are expressed as median (25th–75th percentile) or number (%)

[a] Verbal rating score; 0, no symptom; 10, the severest symptom imaginable

[b] RNA, resumption of normal activity; score 0, no activity; score 10, back to normal activity

[c] Preference for outpatient-based procedure; the ratio of positive answers to all answers

[d] Global satisfaction with the surgical procedure and anesthesia care; score 0, very dissatisfied; score 10, very satisfied

preferable in ambulatory surgery [20]. In our study, acetaminophen/diclofenac and ropivacaine infiltration were used for analgesia and the POV ratio was low (7%).

The effects of midazolam premedication on the incidence of EA remain controversial [9, 10] and midazolam has been reported to increase the incidence of prolonged recovery [10]. α_2-Adrenoreceptor agonists, for example clonidine and DEX, have also been used for management of EA, because of their sedative and analgesic effects [1, 5–8, 14]. DEX is a more highly specific α_2-adrenoreceptor agonist (α_2/α_1, 1620/1) than clonidine (α_2/α_1, 220/1). In our study, DEX at a dose of 0.3 μg kg^{-1} reduced the incidence of post-sevoflurane EA (from 64 to 28%), which is similar to previously reported reductions [5–8], and also reduced postoperative pain intensity. The previous reports on the beneficial effect of DEX on EA did not describe the postoperative recovery profiles up to 24 h after surgery or parents' satisfaction. We studied children undergoing same-day or overnight stay surgery and followed up the recovery profiles not only in the PACU but also on the day after surgery. Our study suggests that DEX reduces EA and also reduces pain, without increasing the frequency of POV and other adverse symptoms up to 24 h after surgery with no change in parents' satisfaction level.

In our study, DEX administration reduced the dose of sevoflurane required during surgery, confirming the anesthesia-sparing effect of DEX [15, 16]. It is possible that the reduced incidence of EA was because of the reduced sevoflurane dose. However, there is evidence that suggests the incidence of sevoflurane-associated EA

is not dose-dependent or exposure time-dependent [1]. In previous studies, DEX decreased EA frequency when the sevoflurane concentration was fixed [5, 7] and when ET_{sev} was similar in both DEX and placebo-treated groups [8].

DEX has possible hemodynamic side effects [15, 16]. Rapid bolus i.v. administration of DEX causes an immediate increase in BP and decrease in HR, and subsequent decreases in BP and HR [21]. Because rapid injection may result in excessive hemodynamic alterations, it is recommended that DEX be administered slowly. Administration of 0.5 μg kg^{-1} DEX intravenously over 5 min caused approximately 10 and 25% reductions in BP and HR, respectively, within 15 min after infusion in children anesthetized with 1 MAC of sevoflurane [22]. In our study, i.v. administration of 0.3 μg kg^{-1} DEX over 10 min decreased systolic BP by about 10%, and HR in group D was also approximately 10% lower than in group S from the end of DEX infusion until 30 min after PACU admission. No treatments for these reductions in BP and HR were required. The more stable HR and BP in our study compared with the previous report [22] are probably because of the lower dose and slower administration of DEX, and adjustment of the sevoflurane dose by the attending anesthesiologists. DEX has minor effects on the respiratory system [15, 16, 22]. In our study, RR, ET_{CO_2}, and SpO_2 were similar in the two groups and no clinically meaningful respiratory adverse effects, for example laryngospasm, bronchospasm, or ventilatory depression, were noted during the perioperative period. Our method of DEX administration is safe in children with regard to hemodynamic and respiratory effects. Continuous administration of 0.2 μg kg^{-1} h^{-1} DEX did not change BP and HR significantly [8], and thus continuous infusion may be preferable from the perspective of hemodynamic stability; although it is somewhat inconvenient and there is a possibility that an effective dose may not be attained in a short-duration surgery/procedure.

A higher dose of DEX would further reduce the incidence of EA. However, this might cause excessive hemodynamic changes and sedation, thereby delaying post-anesthesia recovery and precipitating parents' dissatisfaction. DEX at a dose of 0.5 or 1.0 μg kg^{-1} reduces post-sevoflurane EA significantly, but also prolongs the early phase of post-anesthesia recovery [6, 7]. In our study, 0.3 μg kg^{-1} DEX tended to slow post-anesthesia recovery, probably because of the residual sedative effect of DEX, but not to a statistically significant extent. In a study of patients undergoing inpatient surgery, caudally administered DEX (1.0 μg kg^{-1}) reduced the incidence of post-sevoflurane EA (from 27 to 7%), reduced the analgesic requirement, and improved the quality of sleep without hemodynamic instability; but also prolonged the duration of sedation [23]. The optimum dose and technique for administering DEX to reduce EA without adverse events in ambulatory pediatric surgery are not yet known. Further studies are needed to assess the effects of different doses and administration techniques of DEX.

In conclusion, this study demonstrates that a 0.3 μg kg^{-1} dose of i.v. DEX administered over 10 min after induction of anesthesia reduces post-sevoflurane EA and postoperative pain in pediatric ambulatory surgery. This method of DEX administration was safe and did not affect recovery profiles or parents' satisfaction.

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