

Efficacy of intranasal dexmedetomidine for removal of inhaled foreign bodies in children by flexible fiberoptic bronchoscopy: a randomized, double-blind, placebo-controlled clinical trial

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Abstract

Background: The traditional technique for foreign body removal is rigid bronchoscopy. However, fiberoptic bronchoscopy is becoming more popular for foreign body removal. Compared with rigid bronchoscopy, fiberoptic bronchoscopy is better suited for removing foreign bodies from the distal airways and upper lobe bronchi because of the smaller diameter and greater flexibility of the bronchoscope.

Dexmedetomidine, a highly selective α_2 adrenergic agonist, reduces preoperative anxiety, reduces the requirement for general anesthetics, and does not induce respiratory depression. The safety and efficacy of intravenous dexmedetomidine have been confirmed in patients undergoing fiberoptic bronchoscopy. Intranasal dexmedetomidine reportedly produce satisfactory sedation in children. We hypothesized that intranasal dexmedetomidine at $1 \mu\text{g}\cdot\text{kg}^{-1}$ administered 25 minutes before anesthetic induction can reduce the incidence of adverse events during fiberoptic bronchoscopy under sevoflurane inhalation general anesthesia. Methods: Forty preschool-aged children (6–48 months) with an American Society of Anesthesiologists physical status of I or II were randomly allocated to receive either intranasal dexmedetomidine at $1 \mu\text{g}\cdot\text{kg}^{-1}$ or normal saline at $0.01 \text{ ml}\cdot\text{kg}^{-1}$ 25 minutes before anesthetic induction. The primary outcome was the incidence of perioperative adverse events. The heart rate, respiratory rate, separation score, tolerance of the anesthetic mask, agitation score, anesthetic induction time, consumption of sevoflurane, and recovery time were also recorded. Results: The incidence of laryngospasm, breath-holding, and coughing were significantly lower in patients who received intranasal dexmedetomidine than saline (15% vs. 50%, $P=0.018$; 10% vs. 40%, $P=0.028$; and 5% vs. 30%, $P=0.037$, respectively). Patients who received intranasal dexmedetomidine had a lower separation score ($P=0.017$), more satisfactory tolerance of the anesthetic mask ($P=0.027$), a significantly shorter anesthetic induction time (5.75 ± 1.4 vs. 7.75 ± 2.5 min, $P=0.004$), and less consumption of sevoflurane (38.18 ± 14.95 vs. 48.03 ± 14.45 ml, $P=0.041$). The recovery time was similar in both groups, and the frequency of postoperative agitation was significantly lower in patients who received intranasal dexmedetomidine ($P=0.004$). Conclusions: Intranasal dexmedetomidine at $1 \mu\text{g}\cdot\text{kg}^{-1}$ can reduce the incidence of laryngospasm, breath-holding, and coughing during fiberoptic bronchoscopy for foreign body removal via its sedative and analgesic effects. Moreover, intranasal dexmedetomidine can reduce postoperative agitation without a prolonged recovery time.

Background

Tracheobronchial foreign body (FB) aspiration is a life-threatening emergency situation in children [1]. Undiagnosed or delayed treatment of a tracheobronchial FB may result in pneumonia, atelectasis, lung abscess formation, or fetal airway obstruction [4,6,7]. Prompt and early successful removal of a FB is associated with reductions in complications and mortality [2,3]. The traditional main technique for FB removal is rigid bronchoscopy; however, the limitation of rigid bronchoscopy is that the FB must be located in the left or right main bronchus or the main bronchus [26]. Fiberoptic bronchoscopy is becoming more popular for the removal of FBs [18,27,28]. Compared with rigid bronchoscopy, fiberoptic bronchoscopy is better suited for removing FBs from the distal airways and upper lobe bronchi because

of the smaller diameter and greater flexibility of the bronchoscope [18]. The procedure is performed through a laryngeal mask airway (LMA) under general anesthesia. Oxygen desaturation, body movement, laryngospasm, bronchospasm, and breath-holding are common adverse events during FB removal [4,5].

Dexmedetomidine, a highly selective α_2 adrenergic agonist, provides sedation without respiratory depression [22,23]. Dexmedetomidine as a premedication reduces preoperative anxiety [15,16], reduces the anesthetic requirement, and deepens the level of anesthesia [20,21]. The sedative effect of dexmedetomidine during fiberoptic bronchoscopy has been evaluated in a few studies, which confirmed that dexmedetomidine is useful in reducing intratracheal stimuli (reducing the incidence of coughing, breath-holding, and laryngospasm) and enhancing patients' degree of comfort without the risk of respiratory depression [8,9,19]. Intranasal dexmedetomidine at a dose of $1 \mu\text{g}\cdot\text{kg}^{-1}$ produces satisfactory sedation in children before anesthetic induction [10]. However, the effect of premedication with intranasal dexmedetomidine on reducing the incidence of adverse events during flexible bronchoscopy remains undetermined in children.

This prospective, randomized, double-blind, placebo-controlled study was performed to evaluate whether intranasal dexmedetomidine at a dose of $1 \mu\text{g}\cdot\text{kg}^{-1}$ administered 25 minutes before anesthetic induction can reduce the incidence of adverse events during fiberoptic bronchoscopy under sevoflurane inhalation general anesthesia.

Methods

This prospective, randomized, double-blind, placebo-controlled study was registered with the China Clinical Research Information Service (Registration number: ChiCTR1800017273). After approval by the China Registered Clinical Trial Ethics Committee (ChiECRCT-20180113) and provision of informed consent by the children's parents or legal guardians, we enrolled 40 children with an American Society of Anesthesiologists physical status of I or II and age of 6 to 48 months who were undergoing FB removal under fiberoptic bronchoscopy from 10 August 2018 to 25 December 2018. Patients with congenital disease, a family history of malignant hyperthermia, coagulation disorders, asthma, severe preoperative respiratory impairment (i.e., single-lung emphysema or other type of severe atelectasis), and allergy to anesthetics were excluded from the study.

All patients fasted for 6 hours for solids, 4 hours for breast milk, and 2 hours for clear fluids and were premedicated with atropine at $10 \mu\text{g}\cdot\text{kg}^{-1}$ intravenously 30 minutes before the induction of anesthesia. The patients were randomly assigned to one of two groups ($n = 20$ patients each) by a simple computerized concealed-envelope method: Group D (dexmedetomidine) or Group C (saline). At 25 minutes before anesthetic induction, the patients were administered either intranasal dexmedetomidine (20171202; Nhwa Pharmaceutical Co., Ltd., Jiangsu, China) at $1 \mu\text{g}\cdot\text{kg}^{-1}$ ($100 \mu\text{g}$ in 1 ml) or intranasal normal saline at $0.01 \text{ ml}\cdot\text{kg}^{-1}$ (Figure 1). At the time of separation from their parents and entrance into the operation room, each patient's separation score [11] was recorded.

Routine patient monitoring included measurement of the oxygen saturation (SpO_2), respiratory rate (RR), heart rate (HR), end-tidal carbon dioxide (EtCO_2), and end-tidal sevoflurane (EtSevo). Additionally, a bispectral index (BIS) monitor (A-2000; Aspect Medical Systems, Norwood, MA, USA) was used in each patient. The EtCO_2 and EtSevo levels were measured by a capnography sensor placed between the L-piece and Bain circuit.

Anesthesia was induced via mask using 5% to 8% sevoflurane in 100% oxygen at $6 \text{ L}\cdot\text{min}^{-1}$ until the BIS decreased to 40, and the LMA was then inserted. Tolerance of the anesthetic mask [11] during induction was graded on a 4-point scale and recorded. Anesthesia was maintained using 3% to 6% sevoflurane in fresh gas at $4 \text{ L}\cdot\text{min}^{-1}$ to maintain the BIS at 40 to 60. Sevoflurane was discontinued after completion of the procedure, and the children were allowed to breathe 100% oxygen at $6 \text{ L}\cdot\text{min}^{-1}$ spontaneously. The LMA was removed when the patient moved spontaneously or exhibited a jaw thrust. After removal of the LMA, the patient was transferred to the post-anesthesia care unit (PACU) for recovery, given oxygen at 4 to $6 \text{ L}\cdot\text{min}^{-1}$ via mask, and monitored for the HR and SpO_2 . Each patient's agitation score [11] in the PACU was recorded, and the patients were discharged from the PACU when the SpO_2 remained at $>92\%$ for 10 min on room air.

Before induction, the HR, RR, and SpO_2 were recorded at baseline (T_0). The HR, RR, SpO_2 , and BIS were then recorded at the following time points: LMA insertion (T_{LMAI}), insertion of the fiberoptic bronchoscope (T_{bron}), 5 min after beginning the procedure ($T_{5\text{min}}$), the end of the procedure (T_{end}), at LMA removal (T_{LMAR}), 5 min after LMA removal (T_{LMAR5}), and at discharge from the PACU (T_{dis}). The following adverse events were recorded: oxygen desaturation, carbon dioxide retention, coughing, body movement, bronchospasm, laryngospasm, breath-holding during the procedure, and coughing in the PACU. Oxygen desaturation was defined as an SpO_2 of $<90\%$ for 10 s. Carbon dioxide retention was defined as an EtCO_2 of $\geq 45 \text{ mmHg}$ at the end of the procedure. The anesthesia time, procedure time (time from bronchoscope insertion to removal), extubation time (time from discontinuation of sevoflurane to LMA removal), and recovery time (time from discontinuation of sevoflurane to opening of eyes either spontaneously or by vocal command) were recorded. The Gas Man anesthesia simulator (Med Man Simulations, Boston, MA, USA) was used to calculate the consumption of sevoflurane.

If laryngospasm or bronchospasm occurred during the procedure, the fiberoptic bronchoscope was immediately removed and continuous positive airway pressure was applied at $10 \text{ cmH}_2\text{O}$. If this measure did not relieve the laryngospasm and the saturation dropped to $\leq 90\%$ according to the oximeter, $2 \text{ mg}\cdot\text{kg}^{-1}$ of propofol was administered intravenously. If these measures still failed to relieve the laryngospasm or bronchospasm and the SpO_2 decreased to $<85\%$, intravenous suxamethonium was administered at $1 \text{ mg}\cdot\text{kg}^{-1}$. In the case of body movement and coughing, $2 \text{ mg}\cdot\text{kg}^{-1}$ of propofol and $1 \mu\text{g}\cdot\text{kg}^{-1}$ of remifentanyl were administered intravenously. In the case of breath-holding, manual positive-pressure ventilation was applied.

Statistical analysis

The t-test was performed for continuous variables, and the chi-square test was performed for categorical variables. The statistical analysis was performed with SPSS software, version 20.0 (IBM Corp., Armonk, NY, USA), and a *P*-value of <0.05 was considered statistically significant.

Results

Forty patients were screened, underwent randomization, and completed the study protocol (Figure 2). There were no differences in the patients' characteristics between the two groups except that the HR was significantly lower in patients who received intranasal dexmedetomidine than saline (136 ± 21 vs. 151 ± 14 beats·min⁻¹, respectively; *P*=0.015) (Table 1). All of the FBs were organic (walnuts, peanuts, sunflower seeds, melon seeds, raisins, and pears).

The incidence of laryngospasm was significantly lower in Group D than C (Table 2) [15% vs. 50%, respectively; odds ratio (OR), 0.176; 95% confidence interval (CI), 0.039–0.797; *P*=0.018]. There was a significantly lower incidence of breath-holding and coughing during the procedure in Group D than C (10% vs. 40%, respectively; OR, 0.176; 95% CI, 0.030–0.924; *P*=0.028 and 5% vs. 30%, respectively; OR, 0.123; 95% CI, 0.013–1.138; *P*=0.037). The incidence of oxygen desaturation and coughing in the PACU was similar between the two groups.

The RR remained more stable in Group D than C (*P*<0.001) (Fig.3). In contrast, the RR was lower in Group C during the procedure and recovered postoperatively. The incidence of carbon dioxide retention was significantly lower in Group D than C (25% vs. 60%, respectively; OR, 0.222; 95% CI, 0.058–0.858; *P*=0.025). The mean HR was lower in Group D (*P*<0.001).

The preoperative separation scores were significantly lower in Group D than C (*P*=0.017) (Table 3). Patients in Group D had more satisfactory tolerance of the anesthetic mask (*P*=0.027) and required less time for anesthetic induction (5.75 vs. 7.75 min, *P*=0.004). The mean, maximum, and minimum BIS values of the patients during procedure were similar in Groups D and C (42 ± 9 vs. 47 ± 8 , *P*=0.087; 50 ± 10 vs. 55 ± 7 , *P*=0.107; and 31 ± 13 vs. 34 ± 12 , *P*=0.484, respectively) (Table 4). EtSevo was significantly lower in Group D than C (*P*<0.001) (Fig. 4). Consumption of sevoflurane, the agent for maintenance of anesthesia, was significantly lower in Group D than C (38.18 ± 14.95 vs. 48.03 ± 14.45 ml, respectively; *P*=0.041).

The extubation time was similar in Groups D and C (6.8 ± 4.0 vs. 6.3 ± 2.8 min, respectively; *P*=0.617) (Table 5). The recovery time was longer in Group D, but there was no significant difference between the two groups (21.2 ± 16.6 vs. 14.8 ± 8.0 min, *P*=0.130). The frequency of agitation during recovery was 25% (n=5) in Group D and 70% (n=14) in Group C (*P*=0.004). The agitation scores were significantly lower in Group D than C (*P*=0.017).

Discussion

Our principle finding is that intranasal dexmedetomidine at a dose of $1 \mu\text{g}\cdot\text{kg}^{-1}$ 25 min before anesthetic induction can reduce the incidence of laryngospasm, breath-holding, and coughing during fiberoptic bronchoscopy for FB removal in children. Furthermore, intranasal dexmedetomidine was associated with lower separation scores, frequency of agitation, and agitation scores and did not prolong the recovery time.

Dexmedetomidine provides uniquely sedative and analgesic effects without respiratory depression [8,12,29], even when administered at doses higher than recommended for sedation [24]. These properties render dexmedetomidine a potentially useful drug for airway surgery. Dexmedetomidine infusion for airway FB removal attenuates the airway response to fiberoptic bronchoscopy similar to remifentanyl [9]. We also observed a lower incidence of laryngospasm, breath-holding, and coughing during the procedure in Group D, suggesting that intranasal dexmedetomidine relieves intratracheal and laryngeal stimuli during fiberoptic bronchoscopy; this effect is possibly mediated via its sedative and analgesic properties. Dexmedetomidine also attenuates the airway response to endotracheal extubation [13,25]. In addition, as shown in previous studies [15,16], we found that premedication with intranasal dexmedetomidine reduced patients' separation anxiety and resulted in more satisfactory tolerance of the facial mask during anesthetic induction. Decreased secretion from crying during patients' separation from their parents and anesthetic induction can reduce the incidence of laryngospasm and coughing.

In contrast to previous report [9,13,25], we observed a similar incidence of coughing in the PACU between the two groups. We hypothesized that the similar incidences in postoperative coughing may have been associated with the intratracheal use of acetylcysteine during the procedure. The duration of FB aspiration was similar between the two groups. Most of our patients had pneumonia and symptoms of coughing and phlegm production before fiberoptic bronchoscopy. This may have also contributed to the similar incidence of coughing in the PACU.

Similar to a previous study [9], the RR was more stable in Group D and the lower incidence of carbon dioxide retention indicated that dexmedetomidine did not impair the respiratory drive. We observed a lower RR in Group C during the procedure, which must have been associated with inhalation of a higher concentration of sevoflurane because the RR decreased as the concentration of sevoflurane increased [14]. The significantly reduced consumption of sevoflurane can reduce the environmental pollution caused by sevoflurane.

In the present study, intranasal dexmedetomidine did not significantly prolong the patients' recovery time, but it did significantly reduce the incidence of postoperative agitation. Emergence agitation occurs frequently in children during recovery from sevoflurane anesthesia. Postoperative restlessness is associated with a risk of self-injury and is a source of stress for both caregivers and family members. Dexmedetomidine has been used for the management of postoperative agitation because of its sedative and analgesic effects [17].

The main limitation of this study is that we only used a single dose of dexmedetomidine; we did not compare the effect of different doses. However, in a study of <4-year-old patients by Yuen et al., intranasal dexmedetomidine at 1 $\mu\text{g}\cdot\text{kg}^{-1}$ had sedative effects similar to that at 2 $\mu\text{g}\cdot\text{kg}^{-1}$. All patients in the present study were 6 to 48 months of age; therefore, we believe that intranasal dexmedetomidine at 1 $\mu\text{g}\cdot\text{kg}^{-1}$ can provide sufficient sedation.

Conclusions

Intranasal dexmedetomidine at 1 $\mu\text{g}\cdot\text{kg}^{-1}$ can reduce the incidence of laryngospasm, breath-holding, and coughing during fiberoptic bronchoscopy for FB removal via its sedative and analgesic effects. Moreover, intranasal dexmedetomidine can reduce postoperative agitation without a prolonged recovery time.

Abbreviations

FB: Foreign body; PACU: Post-anesthesia care unit; LMA: Laryngeal mask airway; HR: Heart rate; RR: Respiratory rate; SpO₂: Oxygen saturation; EtCO₂: end-tidal carbon dioxide; EtSevo: End-tidal sevoflurane; BIS: Bispectral index. T, tracheal; RB, right bronchus; LB, left bronchus; BB, bilateral bronchus.

Declarations

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

YMB: Contributed to performing all statistical analysis, drafting the manuscript. YSM: Performing all statistical analysis, obtaining study participants. JN: Acquisition of data. LW: Contributed to design of the work, writing the manuscript.

Ethics approval and consent to participate

After approved by China Registered Clinical Trial Ethics Committee (ChiECRCT-20180113), the trial was performed at West China Second University Hospital, Sichuan University. The written informed consent

was obtained from parents or legal guardians of all participants in the trial.

Consent for publication

The written consents of publication were obtained from parents or legal guardians of all participants.

Competing interests

The authors have no conflict of interest.

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Tables

Table 1. Demographic characteristics

| Variables | D Group | C Group | <i>P</i> value |
|---|----------|-----------|----------------|
| Age (months) | 17.2±6.3 | 18.0±6.6 | 0.737 |
| Sex (male/female) | 15/5 | 14/6 | 0.723 |
| Weight(Kg) | 10.9±2.2 | 10.8±1.2 | 0.965 |
| Site of foreign body (T/RB/LB/BB) | 1/11/6/2 | 0/10/9/1 | 0.576 |
| Duration of foreign body aspiration (days) | 8.3±8.9 | 11.3±14.2 | 0.430 |
| Complications | | | |
| Obstructive emphysema | 11 (55) | 16(80) | 0.091 |
| Pneumonia | 18 (90) | 20 (100) | 0.147 |
| Atelectasis | 4 (20) | 1 (5) | 0.151 |
| Baseline value | | | |
| Heart rate (times min ⁻¹) | 136±21 | 151±14 | 0.015 |
| Respiratory rate (times min ⁻¹) | 37±9 | 37±5 | 0.911 |
| Oxygen saturation (%) | 99±1 | 99±1 | 0.334 |

Data are expressed as mean \pm standard deviation, number of patient, and percent of groups. T, tracheal; RB, right bronchus; LB, left bronchus; BB, bilateral bronchus.

Table 2. Adverse events.

| Adverse events | Group D | Group C | <i>P</i> value | OR[95%CI] |
|--------------------------|---------|---------|----------------|---------------------|
| Desaturation (<90%) | 6 (30) | 10 (50) | 0.197 | 0.429 (0.117-1.568) |
| Laryngospasm | 3 (15) | 10 (50) | 0.018 | 0.176 (0.039-0.797) |
| Bronchospasm | 0 | 1 (5) | 0.311 | 1.053 (0.952-1.164) |
| Breath-holding | 2 (10) | 8 (40) | 0.028 | 0.176 (0.030-0.924) |
| coughing | 1(5) | 6(30) | 0.037 | 0.123(0.013-1.138) |
| Body movement | 3 (15) | 8 (25) | 0.077 | 0.265 (0.058-1.209) |
| Carbon dioxide retention | 5(25) | 12(60) | 0.025 | 0.222(0.058-0.858) |
| Coughing in PACU | 15 (75) | 14 (70) | 0.723 | 1.286 (0.013-1.138) |

Data are expressed as number of patient, and percent of groups.

Table 3. Separation score, tolerance of anesthetic mask, and agitation score.

| Variables | Group D | Group C | <i>P</i> value |
|------------------------------------|---------|----------|----------------|
| Separation score 2/3/4 | 9/9/2 | 2/10/8 | 0.017 |
| Tolerance of anesthetic mask 2/3/4 | 2/9/9 | 1/2/17 | 0.027 |
| Agitation score 2/3/4/5 | 8/7/4/1 | 1/5/10/4 | 0.017 |

Data are expressed as number of patients.

Table 4. BIS value.

| Variables | Group D | Group C | <i>P</i> value |
|-------------------|---------|---------|----------------|
| Mean BIS value | 42±9 | 47±8 | 0.087 |
| Maximum BIS value | 50±10 | 55±7 | 0.107 |
| Minimum BIS value | 31±13 | 34±12 | 0.484 |

Data are expressed as mean ± standard deviation. BIS: bispectral index.

Table 5. Time quantum.

| Variables | Group D | Group C | <i>P</i> value |
|--|------------|----------|----------------|
| Duration of anesthetic induction (min) | 5.75±1.4 | 7.75±2.5 | 0.004 |
| Duration of procedure (min) | 19.2±14.1 | 18.1±8.8 | 0.789 |
| Extubation time (min) | 6.8±4.0 | 6.3±2.8 | 0.617 |
| Recovery time (min) | 21.2±16.64 | 14.8±8.0 | 0.130 |

Data are expressed as mean ± standard deviation.

Figures



Fig.1. 100ug/ml dexmedetomidine or 1ml normal saline in 1ml syringe for intranasal.

Figure 1

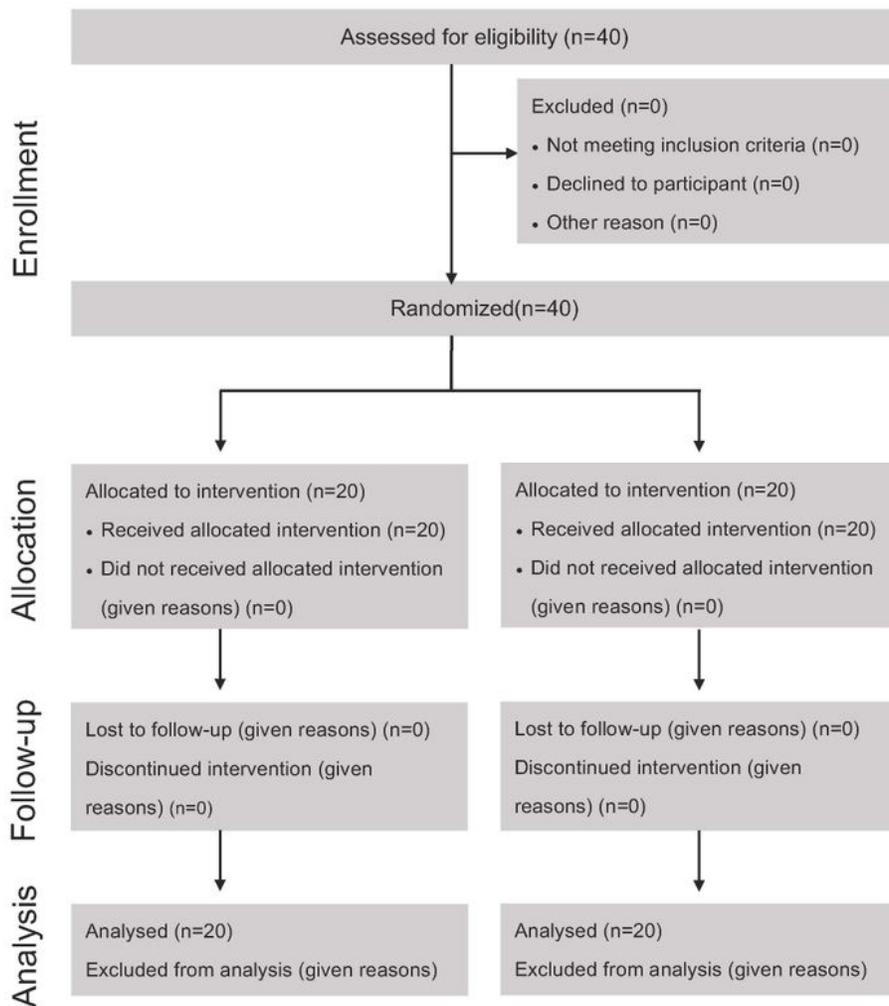


Fig.2. CONSORT flow diagram

Figure 2

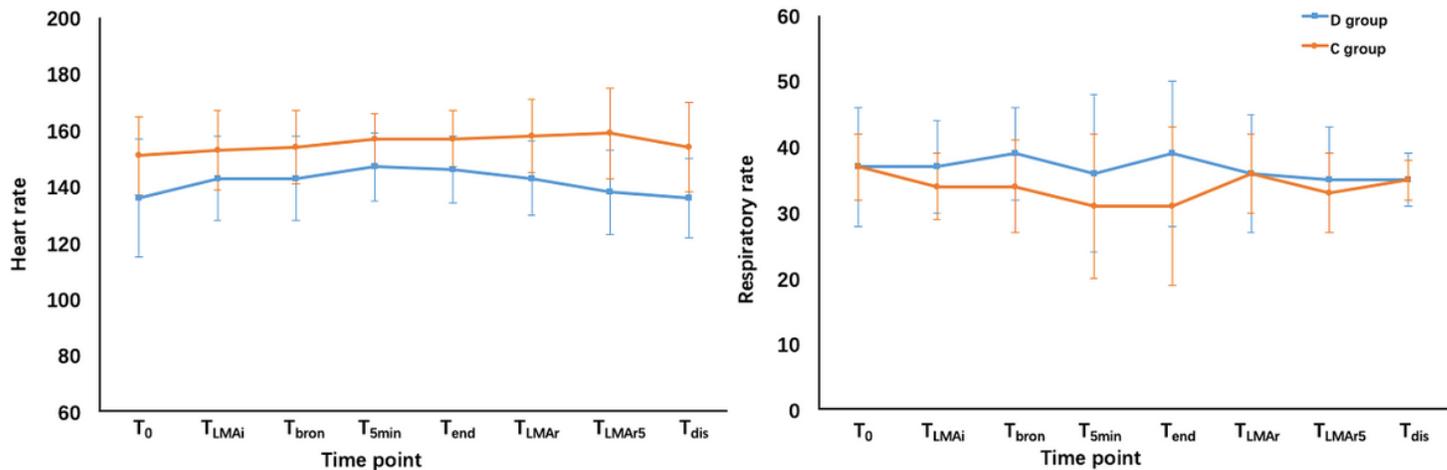


Fig.3. Heart rate and respiratory rate at different time points during the study period. T₀, baseline level before anesthesia; T_{LMAi}, LMA insertion; T_{bron}, begin of fiberoptic bronchoscopy; T_{5min}, 5mins during the procedure; T_{end}, the end of the procedure; T_{LMAr}, LMA removal; T_{LMAr5}, 5mins after LMA removal; T_{dis}, discharge from PACU.

Figure 3

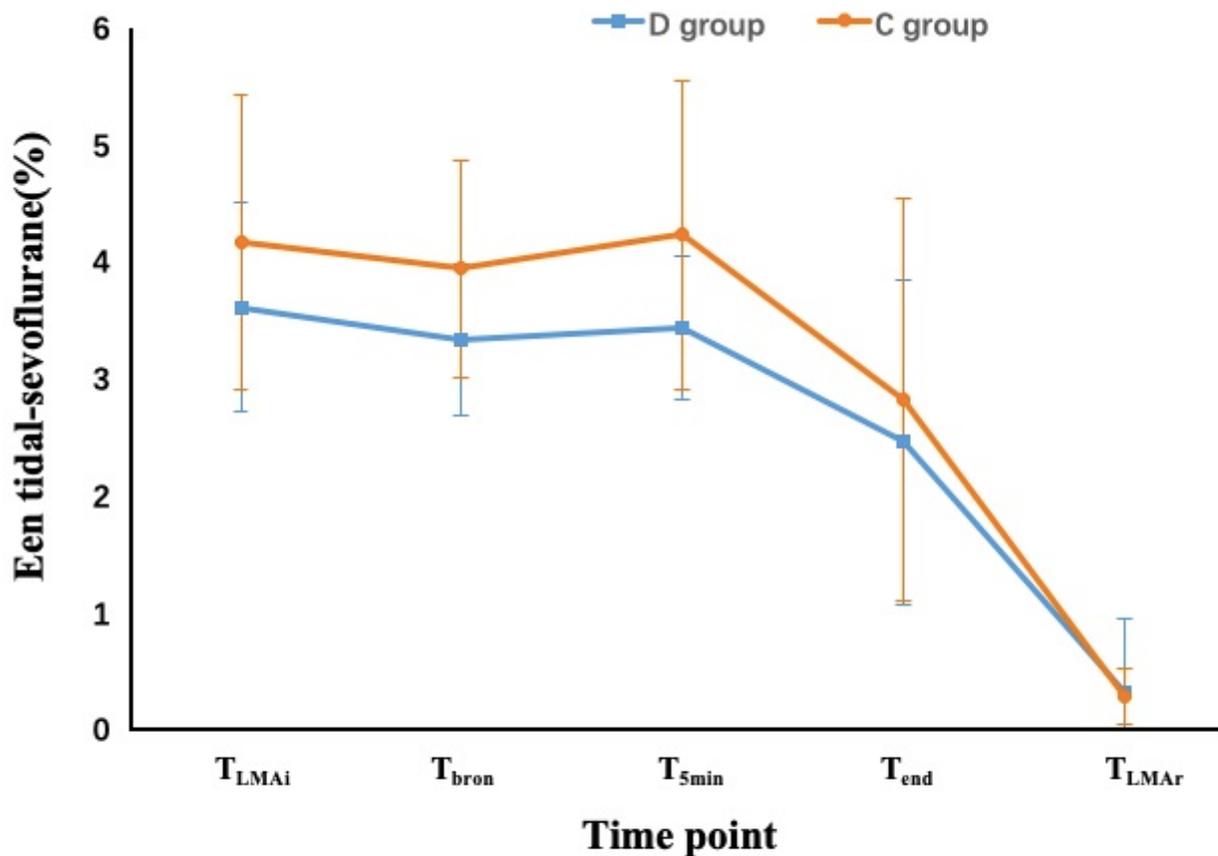


Fig.4. End tidal sevoflurane at different time points during the study period. T_{LMAi}, LMA insertion; T_{bron}, begin of fiberoptic bronchoscopy; T_{5min}, 5mins during the procedure; T_{end}, the end of the procedure; T_{LMAr}, LMA removal. .

Figure 4