BMJ Open

Study protocol for a randomised controlled clinical trial comparing desflurane-based versus propofol-based anaesthesia on postanaesthesia respiratory depression in patients with obstructive sleep apnoea after major abdominal surgery

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ABSTRACT

Introduction Patients with obstructive sleep apnoea (OSA) are more sensitive to postanaesthesia respiratory depression. Whether different anaesthetic regimens (intravenous-based or inhalational-based general anaesthesia) affect the postanaesthesia respiratory depression is controversial. Although desflurane has been reported that presents favourable rapid recovery profile in special patients including whom with OSA, the strong clinical evidence of the benefit on postanaesthesia respiratory depression is far from being revealed. This study aims to fill this knowledge gap by investigating the postanaesthesia respiratory depression in postanaesthesia care unit (PACU) in patients with OSA after major abdominal surgery, followed by desflurane-based anaesthesia compared with propofol-based anaesthesia.

Methods and analysis Eight hundred and fifty-four patients with OSA scheduled for elective major abdominal surgery will be randomly 1:1 assigned to desflurane-based (n=427) or propofol-based anaesthesia (n=427) using a computer-generated randomisation scheme with permuted block size maintained by a centralised randomisation centre. Patients will be assessed before and a consecutive 3 days after their surgery according to the standardised tasks. Demographic data as well as surgical and anaesthesia information will be collected for the duration of the procedure. Incidence of postanaesthesia respiratory depression in PACU as well as anaesthesia recovery, emergence delirium, postoperative nausea and vomiting, rescue analgesia, duration of PACU and hospital stay, and any other adverse events will be assessed at the given study time point. Investigators performing postoperative follow-up are not involved in both anaesthesia implementation and postoperative care.

Ethics and dissemination This study protocol has been approved by the ethics board at Xiang'an Hospital of Xiamen University (XAHLL2019003). The results of this study will be published in a peer-review journal and presented at national conferences as poster or oral presentations. Participants wishing to know the results of this study will be contacted directly on data publication.
Trial registration number ChiCTR2000031087.

Strengths and limitations of this study

► This is a properly powered multicentre clinical trial with good internal validity due to randomisation and allocation to groups as well as high external validity due to a representative sample size.

► The study will investigate desflurane-based inhalational anaesthesia versus propofol-based intravenous anaesthesia on postanaesthesia respiratory depression in patients with obstructive sleep apnoea after major abdominal surgery.

► Since the differences of anaesthesia management cannot be masked, anaesthesiologists cannot be blinded to receiving the anaesthesia.

► Only the early postanaesthesia respiratory depression (30 min as primary endpoint) will be explored, the longer-term effects of later respiratory depression (24 hours or longer as primary endpoint) are encouraged in the future.

► Study findings might not apply to patients except for whom without obstructive sleep apnoea receiving non-abdominal surgical procedure.

INTRODUCTION

Obstructive sleep apnoea (OSA), which is the most common serious manifestation of sleep-disordered breathing, is caused by recurrent episodes of upper airway obstruction occurring during sleep. Its prevalence has increased worldwide because of obesity and

the increasing age of the general population. Current estimates suggest that moderately severe OSA is present in approximately 11.4% of men and 4.7% of women.[1 2] In surgical patients, its prevalence is even greater with up to 22%.[3]

Obesity is the greatest risk factor for OSA and approximately 70% of patients with OSA are obese.[4 5] Anatomical configuration and adipose tissue redistribution in obese patients with OSA contribute to airway obstruction and worsened oxygenation during mask ventilation and endotracheal intubation.[6 7] Besides, clinical evidence has demonstrated that hypoventilation caused by upper airway collapse in perioperative settings is an important component of the mechanism of postoperative respiratory complications.[8–10] Patients with OSA are more sensitive to the respiratory depressant effects of sedative drugs and opioids because these drugs tend to decrease pharyngeal dilator tone and increase the likelihood of upper airway collapse.[11] Consequently, such patients undergoing surgery have a higher incidence of postoperative respiratory complications, including airway obstruction, hypoxaemia, pneumonia, respiratory failure, reintubation and requirement of non-invasive ventilation, as well as prolonged hospitalisations than those without OSA.[8 9]

Anaesthetic factors bring a major contribution to the development of postoperative complications in patients with OSA. Anaesthesiologists are interested in the perioperative respiratory depression with different anaesthetic regimens in patients with OSA considering the controversial evidence at present. Previous small sample studies showed the similar change in Apnoea-Hypopnoea Index (AHI) and minimum percutaneous oxygen saturation (SpO_2) during the first postoperative night in patients undergoing either regional or general anaesthesia with various agents including inhalational agents and opioids.[10 12] However, others showed a significant difference in respiratory and cardiovascular complications in patients followed general anaesthesia compared with neuraxial anaesthesia and peripheral nerve blocks.[13] Besides, previous study showed that neither anaesthetic regimen (propofol/remifentanil vs sevoflurane/remifentanil anaesthesia) increased postoperative nocturnal obstructive and hypoxaemic episodes in patients with OSA following general anaesthesia.[11] In contrast, some studies suggested that propofol used alone or in combination with sevoflurane appears to be associated with more oxygen desaturations in children.[14] Compared with inhaled anaesthetic sevoflurane and intravenous agent propofol, desflurane, have lowest blood/gas and fat/blood partition coefficients, and therefore, shares the advantage of faster onset and offset of anaesthesia, yielding to a more rapid recovery especially in obese patients undergoing ambulatory or long-lasting major surgery.[15–18]

Since the strong clinical evidence of the benefit on postanaesthesia respiratory depression in patients with OSA followed desflurane-based anaesthesia is far from being revealed, therefore, we designed the current

prospective, randomised, controlled trial to investigate the postanaesthesia respiratory depression in postanaesthesia care unit (PACU) in patients with OSA after major open or laparoscopic abdominal surgery followed desflurane-based anaesthesia compared with propofol-based anaesthesia.

METHODS AND ANALYSIS
Patient and public involvement
The patients or the public are not involved in the design, conduct, reporting or dissemination of the research, and no attempt will be made to assess the burden of the intervention on the patients themselves. No healthy volunteers will be recruited.

Study locations
This prospective multicentre randomised controlled clinical trial study will conduct at three sites within Fujian, China, between January 2022 and December 2023. Xiang'an Hospital of Xiamen University (Xiamen, Fujian, China with principal investigator (PI) Dr. Lichao Hou) will serve as the coordinating centre, as the hospital is the head of medical centre of Xiamen University. Additional study sites will include the following: Dongfang Hospital of Xiamen University (Fuzhou, Fujian, China with co-PI Dr. Guozhong Chen) and the First Affiliated Hospital of Xiamen University (Xiamen, Fujian, China with site PI Dr. Ruizhe Liao). Xiang'an Hospital of Xiamen University is responsible for developing and maintaining the case report forms (CRFs, online supplemental material), data management and analysis.

Confidentiality
The participant master list including the participant name and linked study identity document (ID) will be kept by the study (co-) PI and site coordinator. All of identifying information except the unique study identification number will be concealed on the CRFs to ensure participants' confidentiality. At the end of the study, the CRF documents and electronic study data will be stored for a minimum of 5 years.

Randomisation
After informed consent is obtained, patients will be randomly 1:1 assigned to desflurane-based or propofol-based anaesthesia using a computer-generated randomisation scheme with permuted block size maintained by a centralised randomisation centre. Randomisation will be conducted 1 day prior to the surgery.

Allocation concealment
Randomisation procedure in which group assignments will be performed and concealed by using central randomisation. The list of randomisation is available only to those independent site study team members, who will not participate in other activities involving study patients.
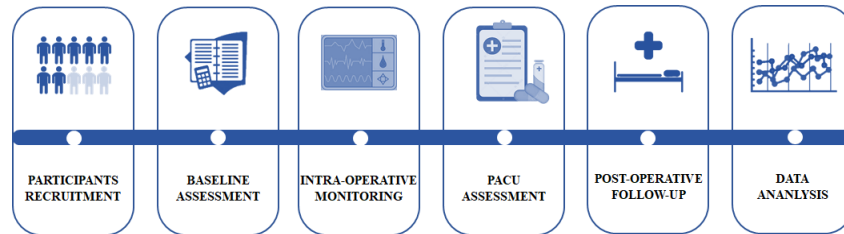
Figure 1 The overall visual schematic of the study design. PACU, postanaesthesia care unit.

Blind method

Study will be performed single-blinded in terms of the differences of anaesthesia management cannot be masked. In order to decrease the potential information bias, investigators performing postoperative follow-up are not involved in both anaesthesia implementation and postoperative care. The respiratory depression assessment in PACU will be conducted by two investigator types: one anaesthesiologist will only perform the general anaesthesia, and the anther will perform the postanaesthesia follow-up in PACU who is blinded to the randomisation and will be, therefore, necessarily unblinded to the treatment conditions. However, even though the postoperative data collector is not aware about the anaesthesia conducted inside the operation theatre, the anaesthesia note will be available in the patient file.

Recruitment and consent

All patients undergoing selective open or laparoscopic major abdominal surgery will be screened 1 day before the operation for eligibility. An overall visual schematic of the study design is illustrated in figure 1. Adult patients (aged 18 years or older) known for non-treated OSA or suspected of having a high risk of OSA, both gender, ASA I–III, undergo selective open or laparoscopic urological and digestive surgery with an anticipated operation time 2 hours or more under general anaesthesia will be recruited for the study. Before screening, a comprehensive airway evaluation would be performed according to ASA practice guidelines that including medical history, physical examination (eg, length of upper incisors, relationship of maxillary and mandibular incisors during normal jaw closure, relationship of maxillary and mandibular incisors during voluntary protrusion of mandible, inter-incisor distance, visible of uvula, shape of palate, compliance of mandibular space, thyromental distance, length of neck, thickness of neck, range of motion of head and neck), as well as radiology.[19] OSA or high risk of OSA will be screened with a STOP-BANG score >3 points before surgery.[20]

The STOP questionnaire contains the following four questions[21 22]:
1. Do you Snore loudly?
2. Do you often feel Tired, fatigued, or sleepy during daytime?
3. Has anyone Observed you stop breathing during your sleep?

4. Do you have or are you being treated for high blood Pressure?

BANG information contains the following four demographic questions[21 22]:
1. Body mass index (BMI) >35 kg/m^2.
2. Age 50 years or older.
3. Neck circumference (>41 cm in females or >43 cm in males).
4. Male Gender.

For each question, answering 'yes' scores 1 and 'no' scores 0, for a total score that ranges from 0 to 8.

Patients will be excluded when they meet any criteria mentioned in the followings:
1. History of difficult airway or any findings during airway evaluation predicting high risk of difficult airway that would preclude standard induction of anaesthesia.
2. Patients known for treated OSA.
3. Any contraindication to epidural analgesia.
4. Emergency surgery.
5. Severe respiratory disease (ie, chronic obstructive pulmonary disease, asthma, pulmonary fibrosis).
6. Severe cardiovascular disease.
7. Severe psychiatric or neurological disease.
8. Severe hepatic or renal disease (baseline alanine transaminase (ALT), aspartate transaminase (AST), blood urea nitrogen (BUN) and/or creatinine >1.5).
9. History of allergy or contraindication to anaesthetic agents.
10. History of delirium.
11. History of hallucinations.
12. Potential risk for malignant hyperthermia (family history).
13. History of chronic opiates or benzodiazepine abuse in last 90 days.
14. History of chronic alcohol abuse in last 90 days.
15. Pregnancy and breastfeeding women.
16. Inability to consent.
17. Refusal.

Patients will be withdrawn when they meet any criteria mentioned in the followings:
1. Life-threatening adverse events.
2. Participant retracts the informed consent.
3. Withdrawn by investigators considering safety.
4. Lost to follow-up.

Detailed information about the study background and the protocol will be given to the patients and their direct

Table 1 The potential adverse events and medicine rescue

Adverse events	Intensity	Assessment	Treatment
Hypotension (SBP <90 mm Hg)	Mild	SBP 80–89 mm Hg >3 min	Close monitoring with or without fluid therapy
	Moderate	SBP 70–79 mm Hg >2 min	Ephedrine 6 mg×2
	Severe	SBP 70–79 mm Hg >2 min and unresponsive to ephedrine or SBP 60–69 mm Hg	Norepinephrine 4 µg×2
	Life-threatening	SBP 60–69 mm Hg and unresponsive to norepinephrine or SBP <60 mm Hg	Intensive intervention and terminate the trial
Hypertension (SBP >140 mm Hg or DBP >90 mm Hg)	Mild	SBP 141–160 mm Hg or DBP 91–100 mm Hg >3 min	Close monitoring
	Moderate	SBP 161–170 mm Hg or DBP 101–105 mm Hg >2 min	Urapidil 12.5 mg×2
	Severe	SBP 161–170 mm Hg or DBP 101–105 mm Hg >2 min and unresponsive to urapidil	Nitroglycerin 0.1–1.0 µg/kg/min
	Life-threatening	SBP 171–180 mm Hg or DBP 106–110 mm Hg and unresponsive to nitroglycerin	Intensive intervention and terminate the trial
Bradycardia (HR <56 bpm)	Mild	HR 51–55 bpm	Close monitoring
	Moderate	HR 46–50 bpm>5 min	Atropine 0.5 mg×2
	Severe	HR 46–50 bpm >5 min and unresponsive to atropine or HR 41–45 bpm >3 min	Isoproterenol 0.05–0.1 µg/kg/min
	Life-threatening	HR 41–45 bpm >3 min and unresponsive to atropine or HR <41 bpm	Intensive intervention and terminate the trial
Tachycardia (HR >100 bpm)	Mild	HR 101–119 bpm	Close monitoring
	Moderate	HR 120–139 bpm >5 min	Esmolol 25 mg×2
	Severe	HR 120–139 bpm >5 min and unresponsive to esmolol 25 mg or HR 140–159 bpm >3 min	Esmolol 50 mg×2
	Life-threatening	HR 140–159 bpm >3 min and unresponsive to esmolol 50 mg or HR >159 bpm	Intensive intervention and terminate the trial
Hypoxaemia (SpO_2 <95%)	Mild	SpO_2 92%–95%	Close monitoring with or without nasal cannula, nasopharyngeal or oropharyngeal airway
	Moderate	SpO_2 90%–91%	Mask ventilation
	Severe	SpO_2 92%–95% and unresponsive to mask ventilation or SpO_2 85%–89%	Eliminating possible causes with or without CPAP
	Life-threatening	SpO_2 85%–89% and unresponsive to treatment or SpO_2 <85%	Intensive intervention and terminate the trial
Pain (NRS >5)	Mild	NRS 1–3	Close monitoring
	Moderate	NRS 5–6	PCEA with or without oxycodone 0.1 mg/kg
	Severe	NRS 7–10 and unresponsive to PCEA	PCEA with oxycodone 0.1 mg/kg
PONV (VAS >20)	Mild	VAS 10–30	Close monitoring with or without additional ondansetron 0.1 mg/kg
	Moderate	VAS 50–60	Eliminating possible causes with additional ondansetron 0.1 mg/kg
	Severe	VAS 70–100 and unresponsive to ondansetron	Eliminating possible causes with chlorpromazine 5–10 mg
Emergence delirium	NA	CAM-ICU	Eliminating possible causes of delirium with or without dexmedetomidine 0.2–0.4 µg/kg/hour

CAM, Confusion Assessment Method; CPAP, Constant Positive Airway Pressure; DBP, Diastolic Blood Pressure; HR, Heart Rate; ICU, Intentive Care Unit; NA, Not Applicable; NRS, Numerical Rating Scale; PCEA, Patient-Controlled Epidural Analgesia; PONV, Postoperative Nausea and Vomiting; SBP, Systolic Blood Pressure; VAS, Visual Analogue Scale.

relatives after the recruitment, and any possible questions brought forward will be answered. As patients meeting eligibility criteria and agreeing to participate in the study, a written informed consent will be obtained before any specific study procedure initiated. The baseline data (demographic data, medical and surgical history, routine clinical examination and airway evaluation) will be collected. A STOP-BANG score will be evaluated

according to the STOP questionnaires and BANG demographic questions, thereafter.

Anaesthesia protocol

After A-line and V-line prepared, patients will encouraged to experience a 5 min preoxygenation period (fractional inspired oxygen=1.0) in a 25° head-up position, meanwhile, sulfentanyl 0.3 μg/kg intravenous as a bolus will be given. Thereafter, general anaesthesia induction will be performed by sequence bolus of propofol 2–3 mg/kg intravenous and rocuronium 0.8~1.0 mg/kg intravenous. Then, tracheal intubation will be performed with Airtra. Dexamethasone 8 mg as an intravenous bolus will be given as a part of opioid-sparing multimodel analgesic strategy and postoperative nausea and vomiting (PONV)-prophylaxis. Patients in desflurane group will be receive a 4~8 v/v% desflurane inhalation using similar fresh gas flow (1 L/min) and carrier gas, while patients in propofol group will be receive an intravenous target-controlled infusion (TCI) of propofol with the target blood concentration 3–6 μg/mL once the patient has been intubated. In both groups, remifentanil 0.1–0.2 μg/kg/min will be intravenously infusion and the depth of anaesthesia will be titrated according to the instantaneously registered narcotrend monitoring in order to achieve a Narcotrend Index between 46 and 20 (D2 –E1). Moreover, age-adjusted minimum alveolar concentration (MAC) will be monitored in desflurane-based anaesthesia group, considering that 1 MAC is equivalent to end-tidal concentrations of desflurane 6.0 v/v% for subjects approximately age 40 years and that decreases approximately 6.7% per decade for subjects age 20–40 years and 5.5% per decade for 40–60 years according to the updated data from pharmacodynamics.[23] Bolus of rocuronium will be given during the surgical procedure to maintain TOF ≤1 until 30 min before the end of operation. During the operation, apart from the routine monitoring recommend by ASA, dynamic arterial blood pressure, cardiac output, and stroke volume variation (SVV) are monitored. Intraoperative lung protective ventilation strategy would be performed. Respiratory rate will be adjusted to maintain end-tidal CO_2 levels at 35–40 mm Hg with an 8 mL/kg ideal body weight tidal volume with positive end expiratory pressure 5 cm H_2O. Lung manoeuvres are performed after intubation and before extubtion. Goal-direct fluid therapy guided by SVV is performed. Briefly, a total of 250 mL of colloid (succinylated gelatin) is delivered as bolus when SVV is 12 or more. Cardiotonic therapy is considered when patients experience low cardiac output. Vasoconstrictor drugs are considered to hypotension period. A volume of 1–3 mL/kg/hour crystalloid is delivered as background infusion intraoperatively. About 30 min before the end of operation, ondansetron 0.1 mg/kg will be given as a standard for PONV-prophylaxis. All anaesthetic agents will be administered until the end of the surgical procedure. Patients of both groups will be extubated when awake and then transferred to PACU. All patients are to receive sugammadex 2 mg/kg to reverse residual neuromuscular blockade in PACU.

Analgesia protocol

All patients will receive perioperative opioid-sparing multimodel analgesic strategy as the followings:
1. Patient education will be performed by a well-trained study staff at admission and anaesthesiologist 1 day before surgery.
2. First dose of non-steroidal anti-inflammatory drugs (NSAIDs) will be given without contraindications and epidural catheter will be placed before induction of anaesthesia.
3. Dexamethasone 10 mg as a bolus intravenous will be given after induction of anaesthesia.
4. Intravenous lidocaine 2 mg/kg over 15 min followed by 2 mg/kg/hour infusion will be given without contraindications intraoperatively.
5. Intraoperative intravenous sulfenfentanyl and remifentanil were described in the anaesthesia protocol. Intraoperative epidural analgesia would be started with 5–8 mL of 0.2% ropivacaine 5 min after 3 mL test dose of 2% lidocaine.
6. Patient controlled epidural analgesia (0.2% ropivacaine +0.08 mg/mL morphine at 2 mL/hour; bolus: 2 mL; lockout time: 15 min) is performed for up to 3 days postoperatively.
7. Oral NSAIDs (celecoxib 100 mg, orally, two times per day, for up to 7 days postoperatively) will be started postoperatively as early as possible without contraindication.
8. Intravenous oxycodone 0.1 mg/kg as rescue when a Numerical Rating Scale (NRS) score more than four points.

Postanaesthesia rescue in PACU

A 30 min standard monitoring in PACU is required. The following parameters will be assessed: routine clinical examination including the respiratory and cardiovascular function, ECG, PONV, Aldrete score and emergence delirium. Risk factors will be figured out and causes will be eliminated when patients experience any adverse event. The potential adverse events including their assessment criteria and intensity, as well as medicine rescue according to previous study are listed in table 1.[24] All patients would receive a low concentration of oxygen therapy in PACU, however, it is not necessary for all of them received routine oxygen therapy when leaving PACU. Moreover, blood gas analyses would be performed before participants leave PACU.

Postoperative respiratory function monitoring in the ward

Since the longer-term effects of later respiratory depression are of greater interest and clinical importance, we would focus on a longer respiratory depression by using oximetry monitoring during postoperative 24 hours period and overnight polysomnography. A comprehensive and standard criteria including oxygen saturation

levels, carbon dioxide levels and sedation levels were applied to diagnose the respiratory depression in the revised protocol according to the American Society of Anesthesiologists (ASA) recommendation.[25] Moreover, routine postoperative examination including physical, lab and imaging examination would be performed according to the clinical pathway.

Data collection
Demographic data
Age, gender, ASA classification, height, weight, BMI, STOP-BANG score, AHI and Mallampati airway score.

Surgical and anaesthesia information
Surgery duration, anaesthesia duration, intraoperative haemodynamic data, intraoperative remifentanil consumption, intraoperative fluid consumption and urine output.

Primary endpoint
Incidence of postanaesthesia respiratory depression in PACU. A combination endpoints of respiratory depression are defined as the following four respiratory-specific events:

1. Hypoventilation (three episodes of <8 respirations/min).
2. Apnoea (episode lasting more than 10 s).
3. Hypoxaemia (three episodes of oxyhaemoglobin desaturations (<90%, with or without nasal cannula), as measured by pulse oximetry).
4. Painsedation mismatch (defined as a Richmond Agitation Sedation Score of −3 to −5 and a pain NRS of >5).

Secondary endpoints
1. The incidence of longer-term effects of later respiratory depression during postoperative 24 hours period.
2. Recovery times (measured from the stop of study treatment inhalation or infusion): time to open eyes, time to follow commands, time to extubation, time to modified Aldrete score more than 9.
3. Incidence of emergence delirium in the PACU as assessed with the 'Four-point Agitation Scale'.
4. Incidence and degree of PONV as assessed by a VAS in the PACU and 12–24 hour postoperatively. The VAS PONV ranges from no PONV (score of 0) to extreme PONV (score of 100).
5. Rescue analgesia in PACU.
6. The duration of PACU and hospital stay.
7. Incidence of (serious) adverse events at any study time point.

Statistical analysis
Sample size calculation
Sample size calculation was performed with G*Power V.3.1.9.2 for Windows (http://www.gpower.hhu.de/). The incidence of postanaesthesia respiratory depression was 46%–54% in patients with OSA according to previous and our pilot study. Based on these data, we estimated that a sample size of 388 patients in each group would allow showing an 20% relative increase incidence of postanaesthesia respiratory depression indicated by the combination endpoints (primary outcome) with a power of 80% at a significance level of 5% (two sided) (minimal sample size of 776) using a z test. Assuming a drop-out rate of 10%, the sample size increased to 854.

Statistical methods
Data are presented as mean (SD) or median (IQR for continuous variables and number (percentage) for categorical variables. The primary end point was a binary variable indicating the occurrence of respiratory-specific events. We decided the priori to perform subgroup analyses of factors associated with respiratory depression by age, gender, BMI, smoking history, severity of OSA and surgical procedure (<50 years vs 50–70 years vs >70 years, male vs female, obese vs non-obese, smoker vs non-smoker and AHI 5–15 events/hour vs 15–30 events/hour vs >30 events/hour, STOP-BANG score 3–5 points vs more than 5 points, open vs laparoscopic procedure), which allowed adjustment for factors that differed by age, gender, BMI, cut-off of STOP-BANG score and surgical procedure, and that may be associated with the risk of respiratory depression. Besides, considering all the anaesthetics including propofol, desflurane, and remifentanyl used intraoperatively were fast-acting, a subgroup analysis was planned to identify the possible difference between early and late postoperative period (1 hour vs 1–6 housr vs 6–12 hours vs 12–24 hours). We compared patients in desflurane-based and propofol-based anaesthesia group using the Student's t-test or rank sum test for continuous variables and the χ^2 test for categorical variables. The results of the subgroup analyses are summarised using the OR and 95% CI. Two-tailed values of p<0.05 were considered statistically significant. Statistical analyses were performed with GraphPad Prism V.8.0 for Windows (Graph Pad Software, San Diego California USA).

DISCUSSION
The present multicentre prospective randomised controlled clinical trial may provide clinical evidence of the benefit on postanaesthesia respiratory depression in patients with OSA followed desflurane-based anaesthesia. This clinical evidence may clarify whether theoretical concerns regarding the risk of different anaesthetic regimens (intravenous-based vs inhalational-based anaesthesia) increase postanaesthesia respiratory depression in special patients including whom with OSA are justified or not. With the proposed larger sample size, we will not only be able to replicate and validate this completely novel finding, but we will also be able to identify more specified respiratory depressive effect associated with intravenous and inhalational analgesic, as sugammadex and opioid-sparing multimodel analgesic strategy are applied to minimise the potential influence derived from residual rocuronium and opioid. Besides, further characterisation of the possible risk factors will be found out according to the subgroup analysis. These findings will lay the foundation

for making the anaesthesia plan in medical practice for the patients with OSA.

ETHICS AND DISSEMINATION
Risks and ethical considerations
Ethics approval will be obtained prior to the commencement of screening and enrolment at each site. As this study involves none of blood work, there are no assumed risks associated with the proposed assessment procedures. Participants will be carefully monitored during surgery and the following assessment times for any signs of discomfort, and assessment can be stopped at any time by the trained study stuff. Confidential information will be safely stored during and after the study. Research participants and their relatives will be informed that enrolment in this study will not affect their medical care in any way, and that they have the right to refuse participation or withdraw at any time.

Dissemination of results
The results of this study will be published in a peer-review journal and presented at national conferences including Chinese Society of Anesthesiology and Chinese Association of Anesthesiologists as poster or oral presentations. Participants wishing to know the results of this study will be contacted directly on data publication.

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