Trial Protocol and Statistical Analysis Plan

（Version of protocol: V 1.0　　Date of last revision: 2026.6.10）

Risk Factors for Postoperative Nausea and Vomiting in Patients Undergoing Nasal Surgery Under General Anesthesia: A Multicenter Prospective Observational Cohort Study

Study Acronym:	**N-PONV Study**
Name of institute:	Department of Anesthesiology, Eye & ENT Hospital of Fudan University, China
Principal investigator:	Wenxian Li
Participating Center:	Jiangsu Province Hospital
	Huzhou Central Hospital

Study Governance Structure

Committee	Responsibilities	Members
Steering Committee，SC	Provides overall academic leadership and oversees the scientific design of the study.	● Wenxian Li, Eye & ENT Hospital of Fudan University ● Yuan Han, Eye & ENT Hospital of Fudan University ● Wei Zhang, Fudan University
Executive Committee，EC	Oversees the day-to-day conduct of the study, coordinates study implementation, and makes operational decisions.	● Hongjun Liu, Eye & ENT Hospital of Fudan University ● Xingyu Geng, Eye & ENT Hospital of Fudan University ● Zijian Zhao, Jiangsu Province Hospital• Lili Feng, Eye & ENT Hospital of Fudan University ● Xinyi Zhou, Eye & ENT Hospital of Fudan University
Data and Safety Monitoring Board，DSMB	Monitors data integrity and participant safety and conducts interim analyses.	● Ji’e Jia, Eye & ENT Hospital of Fudan University ● Jiali Jiao, Shanghai Jiao Tong University
Clinical Events Committee ，CEC	Reviews disputed clinical events and independently adjudicates study outcomes.	● • Wenxian Li, Eye & ENT Hospital of Fudan University• Yuan Han, Eye & ENT Hospital of Fudan University• Ji’e Jia, Eye & ENT Hospital of Fudan University

Protocol Amendment History

Version	Version Date
1.0	June 10, 2026

Protocol Synopsis

Protocol Title	Risk Factors for Postoperative Nausea and Vomiting in Patients Undergoing Sinonasal Surgery under General Anesthesia
Study Design	Multicenter, prospective, observational cohort study
Protocol Version and Date	Version: v1.0; Date: June 10, 2026
Principal Investigator	Wenxian Li
Participating Centers	**Coordinating Center:** Eye & ENT Hospital of Fudan University **Participating Center 1:** Jiangsu Province Hospital **Participating Center 2:** Huzhou Central Hospital
Ethics Approval	To be obtained

1. Background

1.1 Postoperative nausea and vomiting is a common adverse event that substantially affects the perioperative patient experience

Postoperative nausea and vomiting (PONV) is one of the most common adverse events following general anesthesia and one of the complications with the greatest impact on patients' perioperative experience. Previous studies and international consensus guidelines have shown that the overall incidence of PONV is approximately 20%–30% among general surgical patients undergoing general anesthesia and may reach 70%–80% in high-risk patients [1–3]. Although PONV does not usually directly increase mortality, it can substantially reduce patient comfort and satisfaction, delay discharge from the post-anesthesia care unit (PACU) and discharge after ambulatory surgery, and increase nursing workload and healthcare costs. In severe cases, PONV may lead to complications such as dehydration, electrolyte disturbances, pulmonary aspiration, wound dehiscence, bleeding, and esophageal injury [1]. Therefore, PONV is not only an important component of anesthesia quality management and patient-reported outcomes but also a key concern in enhanced recovery after surgery and ambulatory surgical care.

1.2 Existing PONV risk-assessment tools do not adequately reflect the characteristics of patients undergoing specialty-specific procedures

The development of PONV is multifactorial, occurs across multiple perioperative phases, and demonstrates substantial interindividual variability. Established risk factors for PONV in adults include patient-related factors, such as female sex, nonsmoking status, a history of PONV or motion sickness, and younger age, as well as anesthesia- and surgery-related factors, including general anesthesia, volatile anesthetics, nitrous oxide, postoperative opioid use, duration of anesthesia, and type of surgery [1]. The simplified Apfel score is currently the most widely used tool for PONV risk stratification in adults; however, it incorporates only four factors: female sex, nonsmoking status, a history of PONV or motion sickness, and postoperative opioid use [1,4]. Moreover, existing risk scores were primarily developed in general surgical populations and do not adequately account for specialty-specific exposures. Consequently, they may not fully

explain the heterogeneity in PONV risk associated with differences in surgical technique, blood loss, packing, irrigation fluids, airway management, and perioperative antiemetic strategies across surgical specialties.

1.3 Patients undergoing sinonasal surgery have a high incidence of PONV and exhibit distinct specialty-specific characteristics

Sinonasal surgery—including endoscopic nasal surgery, sinus surgery, septal surgery, turbinate surgery, nasal polyp surgery, and rhinoplasty-related procedures—is commonly performed under general anesthesia and involves several specialty-specific characteristics that may increase the risk of PONV.

First, the nasal cavity and nasopharyngeal surgical fields are highly vascular. Intraoperative bleeding, postoperative oozing, and the swallowing of blood or secretions may stimulate the gastrointestinal tract and precipitate nausea and vomiting. Second, sinonasal procedures frequently involve nasal, nasopharyngeal, or oropharyngeal packing. Packing materials and pharyngeal irritation may increase postoperative throat discomfort, stimulate the swallowing reflex, and contribute to nausea. Third, endoscopic sinus surgery often requires controlled hypotension and the continuous administration of opioids or short-acting opioids to optimize the surgical field. Meanwhile, the method of anesthetic maintenance, opioid dose, fluid administration, choice of airway device, and extubation strategy may all influence early postoperative nausea and vomiting. Fourth, patients undergoing sinonasal surgery frequently experience postoperative nasal obstruction, headache, dizziness, aural fullness, facial pressure or pain, and sleep disturbance. These symptoms may interact with nausea and vomiting and affect patients' perceptions of the quality of postoperative recovery.

Existing studies of PONV following sinonasal surgery have reported considerable variability in incidence. In a prospective randomized controlled trial conducted by Korkut et al. among patients undergoing sinonasal procedures, the incidence of PONV at 2 hours after surgery was 71%, 68%, and 50% following rhinoplasty, functional endoscopic sinus surgery, and septal surgery, respectively. The corresponding rates at 4 hours were 59%, 53%, and 37%, and those at 8 hours were 35%, 39%, and 21%, respectively [5]. Another study of functional endoscopic sinus surgery reported an

overall postoperative PONV incidence of 36% [6]. More recently, in the setting of total intravenous anesthesia and relatively standardized antiemetic prophylaxis, the incidence of PONV after endoscopic sinus surgery has been reported to be as low as 7.9%, suggesting that anesthetic technique, opioid exposure, analgesic strategies, and prophylactic antiemetic regimens may substantially modify PONV risk in this population [7].

However, most previous studies have focused on a single procedure, a single center, or the evaluation of a specific intervention. These studies generally had limited sample sizes and did not systematically assess sinonasal surgery-specific factors, distinct postoperative time windows, PONV severity, rescue antiemetic use, or longer-term follow-up outcomes.

1.4 Post-discharge nausea and vomiting remains insufficiently studied in patients undergoing sinonasal surgery

In addition to PONV occurring within the first 24 hours after surgery, post-discharge nausea and vomiting (PDNV) and delayed nausea and vomiting are also clinically relevant. An international consensus guideline cited a United States study of 2,170 ambulatory surgical patients in which the incidence of PDNV within 48 hours after discharge was 37%. Independent predictors included female sex, age younger than 50 years, a history of PONV, opioid administration in the PACU, and nausea in the PACU [1].

With the increasing adoption of ambulatory surgery, short-stay hospitalization, and enhanced recovery pathways in sinonasal surgery, assessment limited to the PACU or the early postoperative period may underestimate the true burden of nausea and vomiting experienced by patients. Therefore, evaluating the primary outcome during the first 0–24 hours after surgery, together with extended assessments of relevant complications on postoperative day 3 and postoperative day 30, may provide a more comprehensive characterization of the recovery trajectory of patients undergoing sinonasal surgery under general anesthesia.

1.5 A large, multicenter, prospective cohort study of patients undergoing sinonasal surgery under general anesthesia is warranted

Current PONV prevention and management guidelines emphasize risk-stratified care and recommend strategies to reduce baseline risk, including minimizing perioperative opioid exposure, preferentially using propofol-based total intravenous anesthesia, avoiding volatile anesthetics and nitrous oxide, providing appropriate fluid therapy, and implementing multimodal antiemetic prophylaxis [1]. However, in real-world sinonasal surgical practice, substantial interinstitutional variation exists in anesthetic maintenance techniques, airway management, analgesic and antiemetic regimens, intraoperative bleeding-control strategies, packing practices, and postoperative follow-up procedures.

Existing evidence remains insufficient to establish the real-world incidence of postoperative PONV and its independent associated factors among Chinese adults undergoing sinonasal surgery under general anesthesia. In addition, standardized, multicenter perioperative clinical databases based on prospective data collection using uniform case report forms (CRFs) are lacking.

Against this background, the present study is designed as a multicenter, prospective, observational cohort study enrolling adult patients scheduled to undergo sinonasal surgery under general anesthesia. The study will systematically collect data on baseline patient characteristics, previous PONV-related history, preoperative anxiety and sleep status, anesthetic management, opioid and antiemetic use, type of surgery, blood loss, packing, and other sinonasal surgery-specific factors. Postoperative assessments will include the incidence and severity of PONV, pain, sinonasal surgery-related discomfort, and postoperative complications.

This study is expected to characterize the occurrence of PONV and other postoperative complications and identify associated risk factors in adults undergoing sinonasal surgery under general anesthesia. The findings may provide a foundation for future risk-stratification models, individualized antiemetic strategies, optimization of perioperative management, and multicenter clinical research.

2. Study Objectives and Hypotheses

2.1 Study Objectives

1) Primary Objective

To determine the incidence of postoperative nausea and vomiting (PONV) within 24 hours after surgery among adult patients undergoing sinonasal surgery under general anesthesia and to explore the associated risk factors.

2) Secondary Objectives

- To characterize the types, distribution, and incidence of postoperative complications in this population;
- To explore factors associated with the occurrence of postoperative complications in this population; and
- To establish a perioperative clinical database of patients undergoing sinonasal surgery under general anesthesia, thereby providing a data foundation and feasibility framework for the subsequent development of risk-prediction models, optimization of perioperative management strategies, and conduct of multicenter clinical studies.

2.2 Study Hypotheses

1) Primary Hypothesis

The incidence of PONV is relatively high among adult patients undergoing sinonasal surgery under general anesthesia, and its occurrence is independently associated with patient baseline characteristics, anesthetic management, type of surgery, perioperative medication use, and other relevant factors.

2) Secondary Hypotheses

- Postoperative complications among adult patients undergoing sinonasal surgery under general anesthesia exhibit identifiable patterns in terms of type, distribution, and incidence;
- The occurrence of postoperative complications in this population is associated with patients' baseline clinical status, anesthetic exposures, surgical complexity, and perioperative management factors; and

- Prospectively collected multicenter perioperative clinical data can be used to establish a clinically valuable database for patients undergoing sinonasal surgery under general anesthesia, thereby providing a data foundation for risk stratification, predictive model development, and perioperative quality improvement.

3. Study Design

3.1 Study Design

This is a multicenter, prospective, observational cohort study. The study aims to determine the incidence of postoperative nausea and vomiting (PONV) among adult patients undergoing sinonasal surgery under general anesthesia and to identify factors associated with its occurrence. It will also characterize the types, distribution, and incidence of other postoperative complications in this population and explore their associated factors.

The study comprises three phases: the screening period, the perioperative period, and the follow-up period.

1) Screening Period

The screening period extends from the signing of the informed consent form to the start of surgery and shall not exceed 7 days. Informed consent may be obtained on the inpatient ward or at the preoperative anesthesia clinic. Following provision of written informed consent, screening procedures will be completed within 7 days before surgery. Only participants who meet all inclusion criteria and none of the exclusion criteria will be eligible for enrollment.

Laboratory test results obtained within 7 days before surgery, including complete blood count, urinalysis, serum biochemistry, and coagulation tests, may be used for screening. Electrocardiographic findings obtained within 7 days before surgery may also be accepted. Results of infectious disease screening obtained within 30 days before surgery may be used. Any test result outside the normal reference range shall be assessed by an investigator to determine its clinical significance.

2) Perioperative Period

The perioperative period extends from the participant’s entry into the operating room until discharge from the post-anesthesia care unit or recovery area. Discharge from the recovery area is defined as the point at which the participant has recovered sufficiently in the PACU, recovery area, or operating room to be transferred to a postoperative care unit, such as a general ward or intensive care unit.

The day of surgery is designated as Day 0 (D0), and the initiation of anesthetic induction is defined as Hour 0.

3) Follow-up Period

The follow-up period extends from discharge from the PACU or recovery area to 6 months after surgery, calculated according to calendar days. Participants will complete the study after all assessments specified in the schedule of study procedures have been completed and all complications have been adequately controlled.

3.2 Sample Size Calculation

For observational studies of risk factors, the sample size should be sufficient to ensure stable estimation in multivariable regression models and to minimize the risk of overfitting. Accordingly, the sample size for this study was primarily determined on the basis of the ratio between the number of primary outcome events and the number of model degrees of freedom.

The primary analysis model will include a prespecified set of core candidate risk factors selected on the basis of clinical relevance and prior evidence. The number of model degrees of freedom will be restricted to no more than approximately 13–15. Assuming approximately 18–20 primary outcome events per degree of freedom, approximately 270 PONV events would be required to support a multivariable model containing 13–15 degrees of freedom.

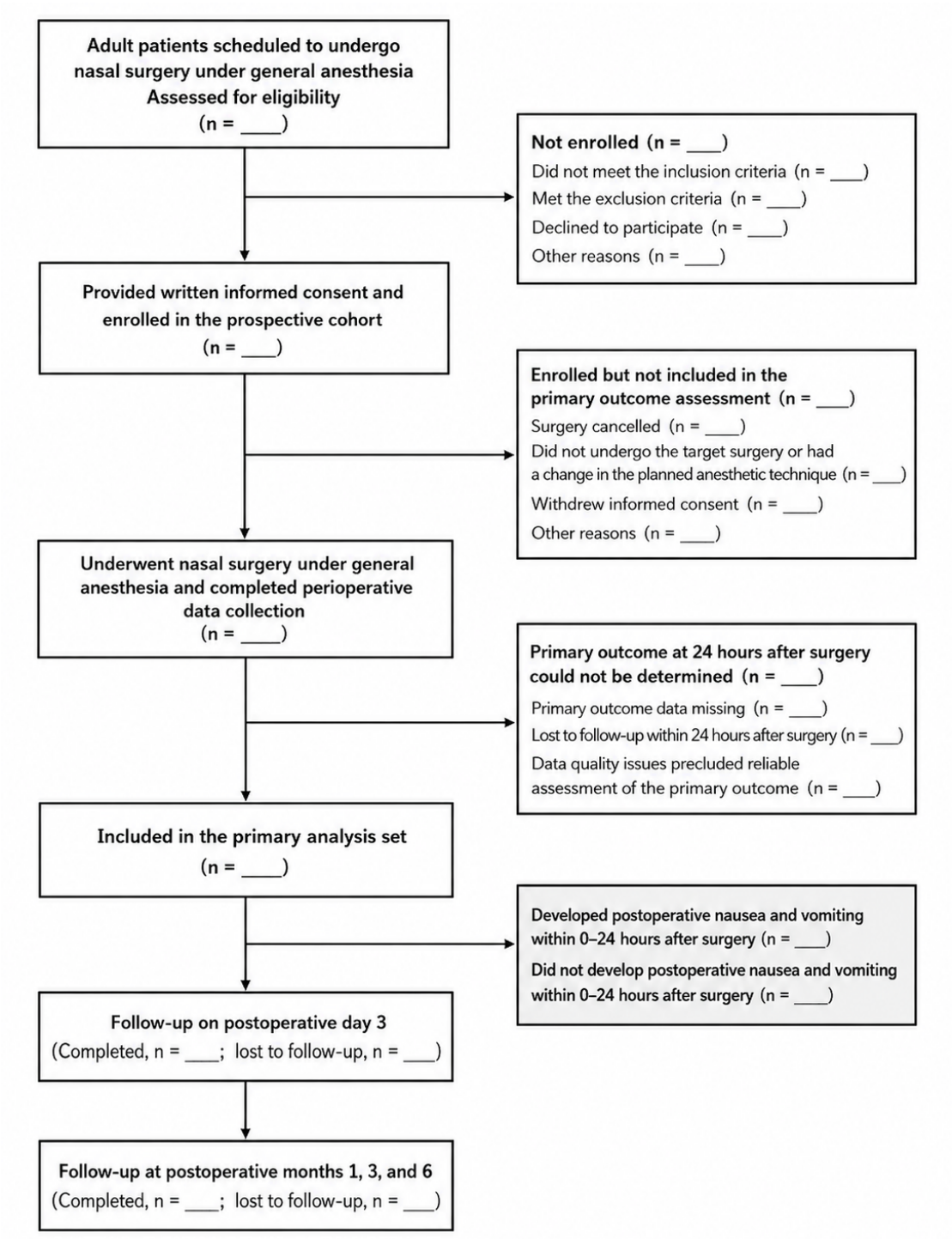
Previous studies and clinical experience at the participating centers suggest that the incidence of PONV within 24 hours after sinonasal surgery under general anesthesia is approximately 25%–35%. Assuming an incidence of 30%, at least 900 analyzable participants would be required to obtain approximately 270 PONV events.

Because this is an inpatient perioperative study with short-term follow-up and the primary outcome occurs within 24 hours after surgery, the risk of loss to follow-up is expected to be relatively low. In addition, the primary outcome and core covariates will be collected through electronic medical records, anesthesia information systems, and standardized case report forms to minimize missing data for the primary outcome and key covariates.

Allowing for an estimated non-analyzable rate of approximately 10%, the study plans to enroll approximately 1,000 participants to ensure an adequate number of cases in the primary analysis set.

Should the observed incidence of PONV be lower than anticipated, or should the proportion of missing data for the primary outcome or key covariates exceed expectations, the number of degrees of freedom in the primary analysis model will be further restricted according to the actual number of observed primary outcome events. Priority will be given to prespecified core risk factors with clear clinical relevance, whereas additional variables will be reported only in exploratory analyses.

3.3 Study Flowchart


Adult patients scheduled to undergo nasal surgery under general anesthesia Assessed for eligibility (n = ____)
Not enrolled (n = ____)
Did not meet the inclusion criteria (n = ____)
Met the exclusion criteria (n = ____)
Declined to participate (n = ____)
Other reasons (n = ____)
Provided written informed consent and enrolled in the prospective cohort (n = ____)
Enrolled but not included in the primary outcome assessment (n = ____)
Surgery cancelled (n = ____)
Did not undergo the target surgery or had a change in the planned anesthetic technique (n = ____)
Withdrew informed consent (n = ____)
Other reasons (n = ____)
Underwent nasal surgery under general anesthesia and completed perioperative data collection (n = ____)
Primary outcome at 24 hours after surgery could not be determined (n = ____)
Primary outcome data missing (n = ____)
Lost to follow-up within 24 hours after surgery (n = ____)
Data quality issues precluded reliable assessment of the primary outcome (n = ____)
Included in the primary analysis set (n = ____)
Developed postoperative nausea and vomiting within 0–24 hours after surgery (n = ____)
Did not develop postoperative nausea and vomiting within 0–24 hours after surgery (n = ____)
Follow-up on postoperative day 3 (Completed, n = ____; lost to follow-up, n = ____)
Follow-up at postoperative months 1, 3, and 6 (Completed, n = ____; lost to follow-up, n = ____)

4. Study Conduct

4.1 Study Sites

This multicenter study will be conducted in the operating rooms and rhinology wards of the following three centers in China:

Coordinating Center: Eye & ENT Hospital of Fudan University

Participating Center 1: Jiangsu Province Hospital

Participating Center 2: Huzhou Central Hospital

4.2 Study Timeline

June 2026 to July 2026: Development of the case report forms (CRFs), completion of ethics review, and registration with the clinical research center.

July 2026 to December 2026: Participant enrollment and data collection.

January 2027 to March 2027: Data consolidation, statistical analysis, preparation of the final study report, and study close-out.

5. Study Population

5.1 Inclusion Criteria

Participants must meet all of the following criteria:

1) Scheduled to undergo sinonasal surgery under general anesthesia;

2) Aged 18 years or older; and

3) Willing to participate in the study and able to provide written informed consent.

5.2 Exclusion Criteria

Participants meeting any of the following criteria will be excluded:

1) Inability to comply with study procedures for any reason, including language barriers, cognitive impairment, or inability to complete questionnaire-based assessments; or

2) Considered unsuitable for participation in the study at the investigator's discretion.

5.3 Withdrawal Criteria

Participants who voluntarily withdraw informed consent or request withdrawal from the study during the study period will be excluded from the primary effectiveness analysis in accordance with the prespecified statistical analysis plan. Their case report forms (CRFs) will nevertheless be retained for audit and review purposes. The reasons for and numbers of such withdrawals will be documented individually in the study flow diagram.

5.4 Discontinuation and Loss-to-Follow-up Criteria

1) Cancellation of surgery after written informed consent has been obtained;

2) Loss to follow-up. All instances of loss to follow-up shall be documented in detail, and reasonable efforts shall be made to re-establish contact whenever feasible. Such participants will continue to be followed in accordance with the protocol where possible and will be included in the full analysis set and safety analysis set. The reasons for and numbers of such cases will be reported individually in the study flow diagram; and

3) Incomplete data or data-quality issues that preclude reliable assessment of the primary outcome. All missing or unusable data shall be documented. Such participants will be included in the safety analysis set and sensitivity analyses, and the reasons for and numbers of such cases will be reported individually in the study flow diagram.

6. Perioperative Management

6.1 Preoperative Assessment

The timing and location of the preoperative assessment will be determined in accordance with the requirements of each participating center. Written informed consent may be obtained in the inpatient ward, preoperative anesthesia clinic, or another appropriate clinical setting. The interval between signing the informed consent form and the start of surgery shall not exceed 7 days.

Designated study personnel will be responsible for collecting preoperative baseline characteristics and other relevant covariates.

6.2 Anesthetic Management

1) All participants will undergo preanesthetic assessment, anesthetic induction, and anesthetic maintenance in accordance with the routine clinical anesthesia practices of the respective participating center. All anesthetic medications will be administered according to standard clinical practice and will not be influenced by participation in this study.

2) All participants will receive routine preoperative preparation and intraoperative monitoring in accordance with local practice. Standard monitoring will include peripheral intravenous access, noninvasive blood pressure, electrocardiography (ECG), peripheral oxygen saturation (SpO_2), and body temperature. Invasive procedures, such as radial arterial catheterization or central venous catheterization, may be performed when clinically indicated by the nature of the surgery or the patient's condition.

3) Preoperative medication: The choice of preoperative medication will not be standardized and will be determined by the attending anesthesiologist in accordance with the routine practice of the respective center.

4) Anesthetic induction: The choice of induction agents will not be standardized and will be determined by the attending anesthesiologist according to local practice. Drug doses will be individualized on the basis of patient characteristics and the type of surgery.

5) Airway management: The attending anesthesiologist will select a laryngeal mask airway or endotracheal tube in accordance with local practice. The manufacturer, type, and size of

the airway device, as well as the airway-management strategy and any instruments used for airway placement, will not be standardized.

6) Anesthetic maintenance: The choice of maintenance agents will not be standardized and will be determined by the attending anesthesiologist according to local practice. Drug doses will be individualized on the basis of patient characteristics and the type of surgery.

7) Prophylactic analgesia and antiemetic therapy: The choice of prophylactic analgesic and antiemetic medications will be determined by the attending anesthesiologist in accordance with the routine practice of the respective center.

6.3 Emergence and Recovery Management

1) Reversal of neuromuscular blockade: No standardized protocol will be mandated. The attending anesthesiologist will determine whether reversal is required and will select the reversal agent, dose, and timing of administration in accordance with local practice.

2) Location of airway-device removal: The location of removal will not be standardized. The attending anesthesiologist will determine whether the artificial airway is removed in the operating room or in the post-anesthesia care unit.

3) Airway-device removal strategy: No standardized removal strategy will be mandated. The attending anesthesiologist will determine the timing and approach to airway-device removal according to local practice.

6.4 Postoperative Follow-up

Participants will be followed for 6 months after surgery. Follow-up assessments after hospital discharge will be conducted by telephone.

This is an observational study and involves no additional study-specific intervention. All medical care received by participants will consist of routinely used clinical management strategies at the participating centers. Each center will provide standard clinical care in accordance with its usual procedures.

Should any adverse event related to study participation occur, the investigators will make every reasonable effort to ensure that the participant receives the necessary medical care. In

the event of postoperative injury or death attributable to participation in the study, the investigators will arrange prompt treatment, cover the costs of appropriate medical care, and provide relevant financial compensation in accordance with applicable requirements.

7. Study Variables and Data Sources

This section is intended to provide explicit definitions of all exposures, predictors, potential confounders, and effect modifiers evaluated in the study. Diagnostic criteria will be specified where applicable. For each variable of interest, detailed information regarding the data source and the method of assessment or measurement will be provided.

Time Point	Study Variables	Definitions/Diagnostic Criteria and Assessment Methods	Data Sources
< D0: Screening Period			
Preoperative Assessment	**Demographic characteristics:** Ethnicity, age, sex, American Society of Anesthesiologists (ASA) physical status classification, height, weight, body mass index (BMI), smoking history, alcohol consumption history, menstrual status, history of present illness, past medical history, surgical history, and history of specific exposures	Specific exposures include occupational exposure to organic substances, such as cotton dust, fuel gas, and wood dust, as well as exposure to inorganic dusts or substances, such as bleach, metals, and cement.	Electronic medical records and preoperative assessment
	Individual susceptibility factors: Previous history of postoperative nausea and vomiting (PONV) and post-discharge nausea and vomiting (PDNV)	**1. PONV:** nausea and/or vomiting occurring within 24 hours after surgery. **2. PDNV:** nausea and/or vomiting occurring after hospital discharge.	Electronic medical records and preoperative assessment
	Preoperative physiological and behavioral factors: Preoperative laboratory test results, baseline vital signs, baseline postoperative recovery status, preoperative anxiety and depression scores, duration of preoperative fasting from solids and fluids, and baseline preoperative sleep status	1. Baseline vital signs: blood pressure, heart rate, respiratory rate, and peripheral oxygen saturation measured at rest within 24 hours before surgery. 2. Baseline recovery status: assessed preoperatively using the 15-item Quality of Recovery questionnaire (QoR-15). 3. Preoperative anxiety and depression: assessed using the Hospital Anxiety and Depression Scale (HADS). 4. Long-term preoperative sleep status: assessed using the Pittsburgh Sleep Quality Index (PSQI). 5. Short-term preoperative sleep quality: assessed using the Richards–	Electronic medical records, preoperative assessment, and consultation with the attending anesthesiologist

		Campbell Sleep Questionnaire (RCSQ).	
D0: Perioperative Period			
Preoperative preparation	Types and doses of preoperative medications; types and volumes/doses of prophylactic fluid administration; and name of the surgical procedure	The surgical procedure shall be documented using the standardized procedure name specified in the **2022 National Clinical Version 3.0 Classification and Coding of Surgical Procedures**, based on the procedure actually performed. For all medications and fluids, the complete proprietary name and manufacturer shall be recorded; this requirement also applies to all subsequent medication and fluid records.	Recorded by the study investigator with reference to ward records and the anesthesia record
Anesthesia induction	Types and doses of medications; types and volumes/doses of infused fluids; and adverse events occurring during induction, including severe hypoxemia, cardiac arrest, laryngospasm, bronchospasm, regurgitation and pulmonary aspiration, severe arrhythmia, and severe anaphylactic reactions	1. **Severe hypoxemia:** a decrease in peripheral oxygen saturation (SpO_2) to a nadir of ≤90%. 2. **Cardiac arrest:** an extreme event occurring during induction that requires chest compressions or defibrillation. 3. **Laryngospasm:** partial or complete airway obstruction caused by reflex closure of the glottis. 4. **Bronchospasm:** airway narrowing and airflow limitation caused by sudden contraction of bronchial smooth muscle. 5. **Regurgitation and pulmonary aspiration:** entry of oropharyngeal or gastric contents into the respiratory tract. 6. **Severe arrhythmia:** an arrhythmia requiring emergency treatment or resulting in hemodynamic instability, organ hypoperfusion, cardiac arrest, or the need for advanced life-support interventions. Examples include ventricular tachycardia (VT), ventricular fibrillation (VF), high-grade atrioventricular block, severe bradyarrhythmia, and tachyarrhythmia causing hypotension or circulatory collapse. 7. **Severe anaphylactic reaction:** a severe hypersensitivity reaction	Recorded by the attending anesthesiologist or an anesthesia assistant, with reference to the anesthesia record

		accompanied by persistent hypotension or circulatory failure.	
Airway establishment	Manufacturer, category, and model of the airway device; airway management strategy, including post-induction airway establishment, awake airway establishment, or airway establishment under unconsciousness with spontaneous ventilation preserved; adjunctive devices used during airway establishment; number of airway-establishment attempts; changes in devices; cuff pressure when an effective laryngeal mask airway seal is achieved; and laryngeal mask airway sealing pressure. Adverse events occurring during airway establishment shall also be recorded, using the adverse-event definitions specified for the induction phase.	1. **Post-induction airway establishment:** establishment of a definitive airway after induction of general anesthesia. 2. **Awake airway establishment:** performance of airway procedures while the patient remains conscious and maintains spontaneous ventilation. 3. **Airway establishment under unconsciousness with spontaneous ventilation preserved:** airway management performed under anesthesia or deep sedation while spontaneous ventilation is maintained. 4. **Number of airway-establishment attempts:** for tracheal intubation, one complete attempt is counted from the time the laryngoscope blade or other intubation device passes the patient's incisors or gingival margin and enters the oral cavity until the device is completely withdrawn from the mouth. For placement of a laryngeal mask airway, one attempt is counted from the time the body of the device passes the lips and enters the oral cavity until successful ventilation is confirmed or the device is completely removed from the patient. 5. **Successful airway establishment:** regular chest movement without audible air leakage during mechanical ventilation and the presence of six consecutive end-tidal carbon dioxide waveforms. 6. **Cuff pressure:** pressure within the inflatable cuff of the airway device. 7. **Laryngeal mask airway sealing pressure:** the airway pressure at which gas leakage around the laryngeal mask airway first occurs. To measure sealing pressure,	Recorded by the attending anesthesiologist or an anesthesia assistant

		the anesthesia machine shall be switched to manual ventilation mode, the fresh gas flow set at 3 L/min, and the adjustable pressure-limiting valve set at 35 cmH_2O. The sealing pressure shall be recorded once the airway pressure reaches a plateau.	
Anesthesia maintenance	Types and doses of medications; types and volumes/doses of infused fluids; respiratory and hemodynamic parameters at key time points; intraoperative adverse events; and surgical field visibility score	1. Respiratory and hemodynamic parameters extracted from the anesthesia record shall include ventilation mode (volume-controlled or pressure-controlled ventilation), tidal volume, airway pressure, respiratory rate, inspiratory-to-expiratory ratio, positive end-expiratory pressure, blood pressure, heart rate, peripheral oxygen saturation, and end-tidal carbon dioxide. 2. **Surgical field visibility:** assessed using the Fromme–Boezaart scale, with a score of ≥3 defined as poor surgical field visibility.	Recorded by the attending anesthesiologist or an anesthesia assistant and extracted from the anesthesia information system
Emergence and recovery	Types, doses, and timing of medications administered during emergence; timing, location, and strategy for removal of the artificial airway, including awake versus sedated removal and planned versus unplanned removal; respiratory and hemodynamic parameters at key time points, including initiation of recovery, administration of reversal agents, removal of the artificial airway, and completion of recovery; and complications occurring during emergence, including agitation, respiratory adverse events, airway rescue interventions, regurgitation and pulmonary aspiration, pain, nausea and vomiting, sore throat, and hoarseness. All adverse events shall be followed until symptom	1. **Awake extubation or removal:** the patient has regained consciousness by the time tracheal extubation or removal of the laryngeal mask airway is completed. 2. **Removal under sedation:** the patient has not regained consciousness by the time tracheal extubation or removal of the laryngeal mask airway is completed. 3. **Planned airway removal:** the intentional and controlled removal of a tracheal tube or laryngeal mask airway by an anesthesiologist after the patient's spontaneous ventilation, airway-protective reflexes, hemodynamic status, level of consciousness, and other physiological parameters have met predefined safety criteria and after appropriate assessment and preparation. 4. **Unplanned airway removal:** removal occurring outside	Recorded by the anesthesiologist or nurse responsible for post-anesthesia recovery

	resolution, and the treatment course shall be documented.	the intended diagnostic or therapeutic plan. This includes accidental displacement of a tracheal tube or laryngeal mask airway before extubation criteria have been met or before airway removal has been planned, as well as urgent removal necessitated by unexpected awakening or intolerance of the airway device. 5. **Agitation and sedation assessment:** the Richmond Agitation–Sedation Scale (RASS) shall be recorded at the time of airway removal in the post-anesthesia care unit and before transfer back to the ward. 6. **PONV assessment:** the number and severity of vomiting episodes, characteristics of vomitus, and overall severity of PONV shall be recorded. PONV severity shall be assessed using the PONV Intensity Scale. Multiple episodes of vomiting or retching occurring within a short period, such as within 5 minutes, shall be counted as one event. Separate events must be distinguished by a clearly defined interval without vomiting or retching. 7. **Respiratory adverse events during emergence:** laryngospasm, bronchospasm, hypoxemia, coughing or choking, airway obstruction, and related events. Hypoxemia is defined as peripheral oxygen saturation <90%. 8. **Airway rescue interventions:** repositioning, supplemental oxygen administration, controlled mask ventilation, and reinsertion of a tracheal tube or laryngeal mask airway. 9. Postoperative sore throat and hoarseness shall be assessed and documented. 10. Postoperative pain shall be assessed using the Numerical	

		Rating Scale (NRS).	
D0–D180: Follow-up Period			
Postoperative follow-up on D0	Pain, postoperative nausea and vomiting (PONV) and its severity, and rhinologic symptoms occurring within 24 hours after surgery shall be recorded. All adverse events shall be followed until symptom resolution, and the corresponding treatment course shall be documented.	1. **PONV:** the number of vomiting and/or retching episodes and the characteristics of vomitus shall be recorded during the following postoperative intervals: 0–2 h, 2–6 h, 6–12 h, and 12–24 h. 2. **Postoperative pain:** Numerical Rating Scale (NRS) scores at rest and during movement shall be recorded at 0–2 h, 2–6 h, 6–12 h, and 12–24 h after surgery, together with the use of rescue analgesics. 3. **Rhinologic symptoms:** rhinologic symptoms shall be assessed at 0–2 h, 2–6 h, 6–12 h, and 12–24 h after surgery. Symptoms include nasal obstruction; excessive nasal discharge or blood-stained nasal discharge; difficulty breathing through the nose; nasal pain; nasal swelling or tenderness; dizziness; headache; periorbital swelling, distension, or pain; epiphora; aural fullness or pressure; ear pain; toothache; dry throat; sore throat; facial pain or pressure; difficulty falling asleep because of nasal symptoms; reduced or absent sense of smell; and reduced or absent sense of taste. Preoperative status and postoperative severity shall be documented for each item using a 0–5 scale: 0 = no problem; 1 = very mild; 2 = mild; 3 = moderate; 4 = fairly severe; and 5 = very severe. 4. **PONV severity:** assessed at 6 and 24 hours after surgery.	In-ward follow-up conducted by an anesthesia nurse; telephone follow-up for patients who have already been discharged
Postoperative follow-up on D3	Complications and adverse events related to the index surgery occurring within the first 3 postoperative days shall be recorded. All adverse events shall be followed until symptom	1. **Postoperative pain:** NRS pain scores on postoperative day 3, use of rescue analgesics, patient-reported analgesic effectiveness, and pain intensity at rest and during movement. 2. **Post-discharge**	Telephone follow-up for patients who have been discharged

	resolution, and the corresponding treatment course shall be documented.	**nausea and vomiting (PDNV):** severity grading of nausea and vomiting occurring after discharge. 3. **Pulmonary complications:** occurrence and severity of pulmonary complications within 3 days after surgery. 4. **Rhinologic symptoms:** postoperative rhinologic symptoms shall be assessed and documented.	
Postoperative follow-up on D30	Complications and adverse events related to the index surgery occurring within 1 month after surgery shall be recorded. All adverse events shall be followed until symptom resolution, and the corresponding treatment course shall be documented.	1. **Postoperative pain:** NRS pain scores at rest and during movement within 30 days after surgery, together with the use of rescue analgesics. 2. **Rhinologic symptoms:** postoperative rhinologic symptoms shall be assessed and documented. 3. **Pulmonary complications:** occurrence and severity of pulmonary complications within 30 days after surgery. 4. **Anxiety and depression at 1 month after surgery:** assessed using the Hospital Anxiety and Depression Scale (HADS). 5. **Sleep status at 1 month after surgery:** assessed using the Pittsburgh Sleep Quality Index (PSQI).	Telephone follow-up for patients who have been discharged
Postoperative follow-up on D180	Complications and adverse events related to the index surgery occurring within 6 months after surgery shall be recorded. All adverse events shall be followed until symptom resolution, and the corresponding treatment course shall be documented.	1. **Postoperative pain:** NRS pain scores at rest and during movement within 30 days after surgery, together with the use of rescue analgesics. 2. **Rhinologic symptoms:** postoperative rhinologic symptoms shall be assessed and documented. 3. **Pulmonary complications:** occurrence and severity of pulmonary complications within 30 days after surgery. 4. **Anxiety and depression at 1 month after surgery:** assessed using the Hospital Anxiety and Depression Scale (HADS). 5. **Sleep status at 1 month after surgery:** assessed using the Pittsburgh Sleep Quality Index (PSQI).	Telephone follow-up for patients who have been discharged

Quality Control and Bias Mitigation: Self-administered questionnaires should preferably be completed independently by the patients, without leading or suggestive questioning by the research staff. For patients whose first language is not Mandarin Chinese or who have difficulty understanding spoken Mandarin, interpreter assistance shall be provided as needed to overcome language barriers. Because the collected information forms part of the routine preoperative assessment and is appended to the anesthesia record, the anesthesiologists completing the records are not blinded to patient information. However, participating anesthesiologists shall remain unaware of the specific study hypotheses until data collection has been completed.

8. Outcome Measures and Definitions

8.1 Primary Outcome

The primary outcome is the incidence of postoperative nausea and vomiting (PONV) within 24 hours after surgery. PONV is defined as the occurrence of nausea, retching, or vomiting at any time during the first 24 postoperative hours. A patient shall be classified as having experienced PONV if at least one episode of nausea, vomiting, or retching occurs within 24 hours after surgery, irrespective of severity or frequency. Events shall be recorded during the following postoperative time windows: 0–2 h, including the period in the post-anesthesia care unit (PACU); 2–6 h; 6–12 h; and 12–24 h.

8.2 Secondary Outcomes

1) Incidence of clinically significant PONV.

PONV severity shall be assessed using the PONV Intensity Scale at 6 hours after surgery, at discharge for patients undergoing same-day surgery who are discharged on the day of surgery, at 24 hours after surgery, and on postoperative day 3 if post-discharge nausea and vomiting (PDNV) occurs. Clinically significant PONV is defined as a total score of ≥50 at any assessment time point.

2) Incidence of vomiting and retching within 24 hours after surgery.

To ensure that all vomiting and retching events are included in the analysis, any episode reported either by the patient or by healthcare personnel shall be considered an event.

3) Number of vomiting or retching events within 24 hours after surgery.

Multiple episodes of vomiting or retching occurring within a short period, defined as within 5 minutes, shall be counted as a single event. Separate events must be distinguished by a clearly defined interval without vomiting or retching.

4) Characteristics of vomitus.

- Vomitus shall be classified as follows:
- Clear fluid: transparent or nearly transparent fluid, potentially consisting of water, gastric secretions, or saliva;
- Food residue: undigested or partially digested food particles;

- Bilious fluid: yellow-green or green fluid;
- Bloody fluid: bright red or pink fluid, or fluid containing macroscopically visible blood;
- Coffee-ground material: dark brown or black-brown granular material, suggestive of blood altered by exposure to gastric acid;
- Mucoid or frothy material: material consisting predominantly of mucus, saliva, or foam.

5) Use of postoperative antiemetic medications.

The medication administered, dose, timing of administration, and treatment response shall be recorded. Treatment response shall be categorized as complete resolution, improvement, or no response.

6) Fatigue at hospital discharge.

Fatigue severity at discharge shall be assessed using the Functional Assessment of Chronic Illness Therapy–Fatigue questionnaire (FACIT-F).

7) Postoperative sleep quality.

Postoperative sleep quality shall be assessed at 24 hours, postoperative day 3, and postoperative day 30.

8) Postoperative complications.

Postoperative complications shall be assessed at 24 hours, postoperative day 3, and postoperative day 30. These shall include respiratory adverse events; postoperative pain and its severity; the incidence and severity of PDNV; and the incidence and severity of postoperative pulmonary complications.

9) Rhinologic symptoms.

Rhinologic symptoms shall include nasal obstruction, rhinorrhea, nasal fullness or swelling, nasal pain, olfactory dysfunction, dizziness, headache, ocular discomfort, aural fullness, ear pain, facial pain or pressure, and nocturnal awakening caused by a sensation of breathlessness. Preoperative status and postoperative symptom severity shall be documented for each item using a 0–5 scale: 0 = no problem; 1 = very mild; 2 = mild; 3 = moderate; 4 = fairly severe; and 5 = very severe.

9. Data Collection and Assessment

Perioperative data shall be manually recorded on paper case report forms by data recorders who are independent of the study. The collected data shall then be entered daily by designated personnel into the electronic data capture (EDC) system of the Eye & ENT Hospital of Fudan University.

9.1 Preoperative Data

1) Patient demographic characteristics: initials, ethnicity, sex, age, height, weight, occupation, menstrual status and, if applicable, the day of the menstrual cycle; smoking history, including pack-years and years since smoking cessation; alcohol consumption history, including duration of alcohol use and whether alcohol consumption has ceased; and American Society of Anesthesiologists (ASA) physical status classification.

2) Medical history and comorbidities, including:

- Previous anesthesia exposure, surgical history, history of PONV or PDNV, chronic diseases, and medication history, including the disease, medication, dose, and duration of treatment;
- Other relevant medical conditions, including gastrointestinal disorders, such as esophageal disease, achalasia, obstruction, dilatation, gastroparesis, exposure to gastrointestinal irritants, and inflammatory disorders including gastritis, hepatitis, pancreatitis, enteritis, and cholecystitis; intracranial disorders, such as malignant hypertension and elevated intracranial pressure caused by brain cancer, other intracranial tumors, or intracranial hemorrhage; migraine; hypotension caused by vascular factors or physiological changes secondary to spinal or epidural blockade; motion sickness; vestibular and labyrinthine disorders, such as labyrinthitis, vestibular neuritis, and inner-ear tumors; pregnancy-related conditions, including morning sickness and hyperemesis gravidarum; metabolic disorders, such as diabetic ketoacidosis, adrenal disorders, thyroid disorders, parathyroid disorders, and uremia; anxiety disorders; and a history of chemotherapy.

3) Major laboratory and ancillary examination results.

4) Preoperative assessments, including:

- Preoperative baseline recovery status, assessed using the 15-item Quality of Recovery questionnaire (QoR-15; Appendix 1);
- The time points at which preoperative fasting from solids and fluids commenced;
- Preoperative anxiety, assessed using the Hospital Anxiety and Depression Scale (HADS; Appendix 2);
- Sleep during the night immediately preceding surgery, assessed using the Richards–Campbell Sleep Questionnaire (RCSQ; Appendix 3);
- Long-term preoperative sleep quality, assessed using the Pittsburgh Sleep Quality Index (PSQI; Appendix 4).

9.2 Data Collected During Anesthesia Induction and Maintenance

1) Types and doses of medications administered during induction;

2) Data related to airway establishment, including the devices used for tracheal intubation, such as a laryngoscope, stylet, flexible bronchoscope, or bougie, and the number of airway-establishment attempts;

3) Types and doses of medications administered for anesthesia maintenance;

4) Types and doses of antiemetic medications;

5) Intraoperative respiratory parameters, including ventilation mode, categorized as volume-controlled or pressure-controlled ventilation, tidal volume, airway pressure, respiratory rate, inspiratory-to-expiratory ratio, and positive end-expiratory pressure;

6) Intraoperative blood pressure, heart rate, peripheral oxygen saturation, and end-tidal carbon dioxide;

7) Intravenous fluid administration and transfusion of blood products, including the type and amount administered;

8) Respiratory adverse events occurring during induction or maintenance, including laryngospasm, bronchospasm, hypoxemia, coughing or choking, and airway obstruction. Hypoxemia is defined as peripheral oxygen saturation <90%;

9) Other adverse events occurring during induction or maintenance, including allergic reactions, severe arrhythmias, and cardiac arrest;

10) Key time points, including the initiation of anesthesia induction, start of surgery, and completion of surgery;

11) Surgical field visibility score, assessed using the Fromme–Boezaart scale (Appendix 5), with a score of ≥3 defined as poor surgical field visibility.

9.3 Data Collected During Emergence and Recovery

1) Location of emergence and recovery, categorized as the operating room, post-anesthesia care unit (PACU), or postoperative monitoring unit;

2) Blood pressure, heart rate, peripheral oxygen saturation, end-tidal carbon dioxide, ventilation mode, tidal volume, and airway pressure during emergence and recovery;

3) Types and doses of reversal agents;

4) Types and doses of other medications administered during recovery;

5) Strategy for removal of the artificial airway, including the patient's level of consciousness at removal, categorized as awake or sedated, and whether the removal was planned or unplanned;

6) Number of vomiting or retching events during emergence and recovery, using a 5-minute interval to distinguish separate events; characteristics of vomitus; and occurrence of PONV during emergence and recovery;

7) Types and doses of antiemetic medications administered during emergence and recovery;

8) Richmond Agitation–Sedation Scale (RASS) scores recorded at the time of artificial airway removal in the recovery unit and before transfer to the ward (Appendix 6);

9) Respiratory adverse events during emergence and recovery, including laryngospasm, bronchospasm, hypoxemia, severe coughing or choking, and airway obstruction. Hypoxemia is defined as peripheral oxygen saturation <90%, and severe coughing is defined as coughing lasting for >10 seconds. Airway rescue interventions shall also be recorded, including supplemental oxygen administration, repositioning, jaw-thrust maneuver, mechanical ventilation via face mask, reinsertion of an artificial airway, cricothyrotomy, and tracheostomy;

10) Highest pain score during emergence and recovery, assessed using the Numerical Rating Scale (NRS). The NRS is a unidimensional pain assessment instrument comprising 11 integers ranging from 0 to 10, with progressively higher scores indicating greater pain intensity. Pain shall be categorized as mild for scores of 1–3, moderate for scores of 4–6, and severe for scores of 7–10;

11) Other adverse events during emergence and recovery, including allergic reactions, arrhythmias, administration of rescue analgesics, sore-throat grade, and hoarseness grade, as specified in Appendix 7;

12) Key time points, including the initiation of recovery, administration of reversal agents, removal of the artificial airway, and completion of recovery.

9.4 Postoperative Data

1) The following data shall be recorded during the postoperative intervals of 0–2 h, 2–6 h, 6–12 h, and 12–24 h:

- Number of vomiting or retching events;
- Characteristics of vomitus;
- Postoperative NRS pain scores at rest and during movement;
- Rhinologic symptoms, including nasal obstruction; excessive nasal discharge or blood-stained nasal discharge; difficulty breathing through the nose; nasal pain; nasal swelling or tenderness; dizziness; headache; periorbital swelling, fullness, or pain; epiphora; aural fullness or pressure; ear pain; toothache; dry throat; sore throat; facial pain or pressure; difficulty falling asleep because of nasal symptoms; reduced or absent sense of smell; and reduced or absent sense of taste.For each rhinologic symptom, the preoperative status and postoperative severity shall be documented using a 0–5 scale: 0 = no problem; 1 = very mild; 2 = mild; 3 = moderate; 4 = fairly severe; and 5 = very severe.

2) PONV severity shall be assessed at 6 hours, 24 hours or at hospital discharge, and on postoperative day 3 using the PONV Intensity Scale (Appendix 8);

3) Types and doses of postoperative rescue analgesics and antiemetic medications;

4) Time to resumption of physical activity and oral intake;

5) Fatigue at hospital discharge, assessed using the Functional Assessment of Chronic Illness Therapy–Fatigue questionnaire (FACIT-F; Appendix 9);

6) At 1, 3, and 6 months after surgery, the following shall be recorded:

- For patients with persistent postoperative pain, NRS pain scores at rest and during movement, pain location, and use of rescue analgesics;
- Occurrence and severity of postoperative pulmonary complications. Postoperative pulmonary complications shall be defined according to the European Perioperative Clinical Outcome definitions specified in the EPCO consensus statement (Appendix 10);
- Rhinologic symptoms;
- Anxiety and depression scores assessed using the HADS (Appendix 2);
- Sleep quality assessed using the PSQI (Appendix 4).

10. Adverse Events (AEs)

10.1 Definition

An adverse event (AE) is defined as any unforeseeable and unfavorable medical occurrence associated with any medical intervention during the study period. The event may or may not be causally related to the study intervention. An AE may present as any undesirable symptom, including an abnormal laboratory finding, clinical sign, or transient illness.

10.2 Monitoring and General Management

1) Adverse events shall be continuously monitored during anesthesia, surgery, and recovery, as well as at 6, 12, and 24 hours after surgery. Once an AE occurs, it shall be followed until complete resolution or discontinuation of treatment.

2) Treatment shall be provided in accordance with routine clinical practice. The investigational intervention device may be temporarily or permanently discontinued when clinically indicated. The timing and reason for interruption or discontinuation shall be documented in the case report form (CRF).

10.3 Expected Perioperative Adverse Events and Management Measures

1) Tachycardia: heart rate >100 beats/min. Management may include intravenous fluid administration for patients with hypovolemia, adjustment of anesthetic dosage, and/or administration of medications such as esmolol.

2) Hypertension: systolic blood pressure >160 mmHg or an increase of >30% from baseline. Management may include adjustment of anesthetic dosage and/or administration of antihypertensive agents, such as intravenous bolus or continuous infusion of urapidil or nicardipine.

3) Bradycardia: heart rate <50 beats/min. Management may include adjustment of anesthetic dosage and/or intravenous bolus administration of atropine.

4) Hypotension: systolic blood pressure <90 mmHg or a decrease of >30% from baseline. Management may include intravenous fluid administration for patients with hypovolemia,

adjustment of anesthetic dosage, and/or administration of vasoactive agents, such as intravenous bolus administration of ephedrine or phenylephrine, or continuous intravenous infusion of norepinephrine.

5) Respiratory depression: respiratory rate <10 breaths/min. Supplemental oxygen shall be administered, and the underlying cause shall be identified and treated.

6) Hypoxemia: peripheral oxygen saturation <95% for more than 10 seconds, or <90% at any time. If hypoxemia occurs during mechanical ventilation, the underlying cause shall be identified and treated. If it occurs during spontaneous breathing after removal of the artificial airway, supplemental oxygen shall be administered first, followed by treatment directed at the underlying cause.

7) Nausea and/or vomiting: after hypotension or hypertension has been excluded or treated and hypoxemia has been corrected, an antiemetic not previously administered intraoperatively, such as metoclopramide, shall be given.

8) Sedation: defined as a Richmond Agitation–Sedation Scale (RASS) score of ≤−2. The patient shall be closely monitored, with pharmacological reversal and/or respiratory support provided when necessary.

9) Agitation: defined as a RASS score of ≥+2. The patient shall be closely monitored, and sedative treatment shall be provided when necessary.

10.4 Documentation

1) All adverse events shall be documented in detail, including the circumstances of occurrence, event type, time of diagnosis, management measures, duration, and patient outcome.

2) All adverse events shall be followed until complete recovery or discontinuation of treatment.

11. Serious Adverse Events (SAEs)

11.1 Definition

A serious adverse event (SAE) is defined as any unexpected medical occurrence that results in death, is life-threatening, causes persistent or significant disability or loss of function, or results in any other serious medical consequence.

11.2 SAE Documentation

All SAEs shall be documented in detail, including the circumstances of occurrence, event type, time of diagnosis, management measures, duration, and any resulting sequelae.

11.3 SAE Reporting

All SAEs shall be reported in writing to the principal investigator and the ethics committee within 24 hours of their occurrence or identification.

11.4 Urgent Safety Measures

The principal investigator may implement immediate urgent measures when necessary to protect the safety of study participants. The ethics committee shall be notified of such measures within 3 days.

12. Participant Timeline

12.1 Recruitment

This study will recruit adult patients scheduled to undergo rhinologic surgery under general anesthesia. At each participating center, investigators will conduct preliminary screening based on the planned surgical procedure and anesthetic management plan. Recruitment materials will be provided to patients and their family members to explain the study objectives, procedures, and potential benefits.

Participation in the study may provide potential clinical benefits to participants. The entire recruitment process shall be conducted in strict accordance with Good Clinical Practice (GCP) requirements.

12.2 Informed Consent

Trained anesthesiologists will provide potential participants with a detailed explanation of the study procedures, interventions, and potential risks and benefits and will provide a written informed consent form. After adequate time for consideration, patients may independently decide whether to participate. Participants may withdraw from the study at any time without prejudice.
Baseline data will be collected after written informed consent has been obtained. During the study, participants may contact the research team at any time regarding health-related concerns. Any adverse event (AE), whether related or unrelated to the study, shall be reported promptly by the investigator to the person responsible for the clinical study.

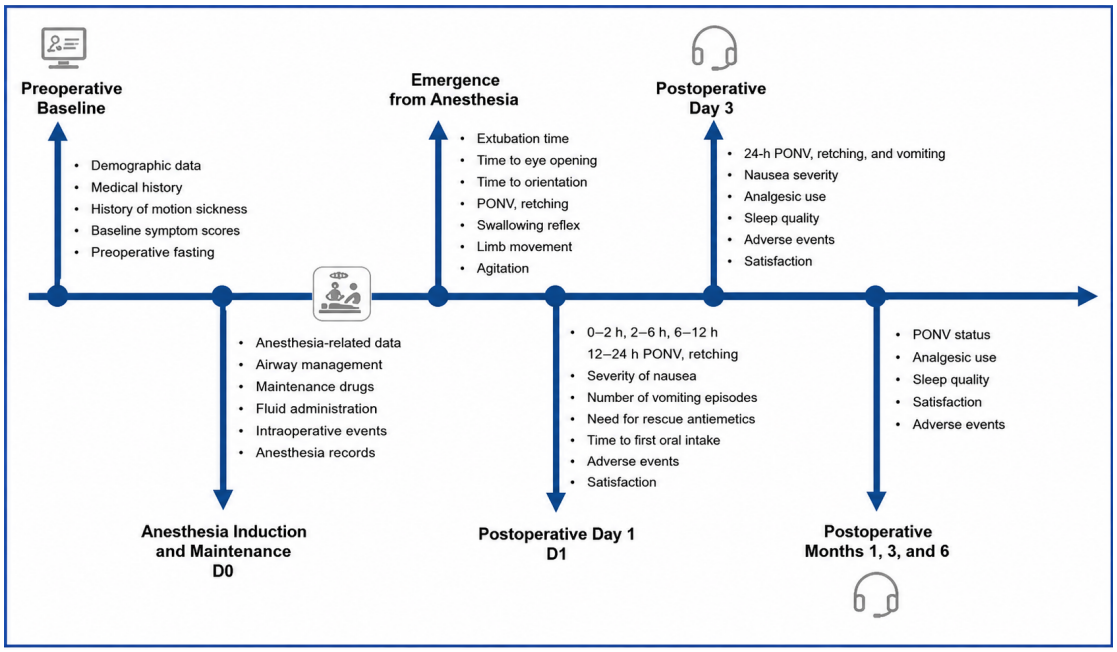
12.3 Verification of Eligibility Criteria

All potential participants will be screened strictly in accordance with the predefined inclusion and exclusion criteria. Eligibility shall be reconfirmed before the participant enters the operating room to ensure continued compliance with the study requirements.

12.4 Screening

All patients scheduled for surgery will be screened. The following information shall be recorded: participant name, unique identification number (screening number), eligibility status, and enrollment status.

12.5 Participant Timeline



Schedule of Enrollment, Interventions, and Assessments

13. Site Recruitment and Personnel Training

13.1 Study Sites

1) Inclusion Criteria for Study Sites

A participating study site must meet all of the following criteria:

- Be a medical institution that routinely performs airway management for rhinologic surgery;
- Have adequately qualified personnel available to conduct the study-related procedures;
- Have obtained approval from its local ethics committee.

2) Exclusion Criteria for Study Sites

A site shall not be included if any of the following conditions applies:

- The site is unable to complete the planned participant enrollment within the specified study period;
- The study team is unstable, has a high staff turnover rate, or lacks adequate capacity to implement the study;
- The site is unable to comply with the study protocol, data quality-control requirements, or Good Clinical Practice (GCP) requirements;
- The site has a recent record of major research misconduct or ethical noncompliance.

13.2 Training and Qualification Requirements for Study Personnel

1) Organization of Training and Assignment of Responsibilities

The principal investigator shall develop the training plan and appoint a project coordinator to organize and deliver the training. The purpose of the training is to ensure that all participating personnel understand the study protocol, standard operating procedures, and data documentation requirements.

All training activities shall be documented and archived. Training shall be completed within the month preceding study initiation.

2) Training Content

Training on study implementation shall cover participant recruitment, screening using the online Excel screening log and case report form (CRF), the informed consent process, study documentation, and procedures for the identification and reporting of adverse events.

Training on study data documentation and management shall include the structure of the paper CRF, the meaning of each variable, standardized completion procedures, data-entry requirements for the electronic CRF, data-upload pathways, file-naming conventions, and data quality-control requirements.

Training on ethics submissions shall include preparation of ethics application materials, such as the study protocol and informed consent form, submission procedures through the ethics review system, and document version control.

Personnel responsible for data entry and quality control shall also receive training on the use of the electronic data capture (EDC) system, consistency and accuracy between paper CRFs and electronic records, and the principles of data protection and confidentiality.

14. Data Management and Record Retention

14.1 Confidentiality

All participant-related information shall be treated as confidential. Only the participant's name, date of birth, and medical record number shall be collected for tracking and identification purposes. All study materials shall be stored securely and shall not be disclosed to unauthorized individuals.

14.2 Data Storage

Study data shall first be recorded on paper case report forms (CRFs) and subsequently entered into the electronic data capture (EDC) system of the Eye & ENT Hospital of Fudan University. Access to the data shall be restricted to authorized users and protected by individual usernames and passwords.

One member of the research team shall be responsible for data entry, and a second researcher shall independently verify the entered data. All paper CRFs shall be securely stored in sequential order.

14.3 Archiving

All study documents and data shall be centrally archived by the study sponsor for at least 5 years. Electronic data shall be retained on a long-term basis.

14.4 Participant-Identifiable Data

Each participant shall be assigned a unique study identification number and identified by initials.

15. Study Termination

The study shall be terminated under any of the following circumstances:

1) A serious safety concern arises during the study;

2) A major error or deficiency is identified in the study protocol;

3) Problems arise in relation to study funding, personnel, or management that prevent the study from being conducted appropriately;

4). The relevant administrative authority decides to terminate the study.

Study suspension or termination may be temporary or permanent. All case report forms (CRFs) completed before suspension or termination shall be retained for reference and record-keeping purposes.

16. Statistical Analysis Plan (Version 1.0)

This statistical analysis plan (SAP) will be finalized before database lock and the initiation of formal statistical analyses. Any analyses that deviate from this SAP will be identified in the final study report or manuscript, together with the reasons for such deviations.

16.1 General Principles

This is a multicenter, prospective, observational cohort study. The primary objectives of the statistical analyses are to describe the occurrence of postoperative nausea and vomiting (PONV) among adult patients undergoing rhinologic surgery under general anesthesia and to evaluate the independent associations of prespecified patient-related, anesthesia-related, surgery-related, and rhinologic surgery-specific factors with the occurrence of PONV within 24 hours after surgery.

The primary objective of this study is not to develop a clinical prediction model. The results of all multivariable models will be used for risk-factor association analyses, and adjusted effect estimates and their corresponding measures of uncertainty will be reported. Because this is an observational study, odds ratios (ORs) will be interpreted as measures of statistical association and not directly as causal effects.

This SAP will be finalized before database lock and the initiation of formal statistical analyses. Any analyses that deviate from this SAP will be described in the final study report or manuscript, together with the reasons for such deviations.

16.2 Analysis Populations

The full analysis set will include all enrolled patients who complete rhinologic surgery under general anesthesia and have available data for the primary outcome of PONV within 24 hours after surgery. The primary analysis will be conducted in the full analysis set.

The complete-case set will include patients with complete data for the primary outcome and all covariates included in the primary analysis model. Complete-case analysis will be conducted as a sensitivity analysis.

If the proportion of missing covariate data is considered non-negligible, a multiple-imputation analysis set will be established under the assumption that data are missing at random. This analysis set will include patients with available primary-outcome data whose missing covariate values have been handled using the prespecified multiple-imputation procedure.

Patients with missing primary-outcome data will not be included in the primary analysis. The number, proportion, and reasons for missing primary-outcome data will be described, and their potential influence on the study conclusions will be evaluated in sensitivity analyses.

16.3 Outcome Variables

1. Primary Outcome

The primary outcome is the occurrence of PONV within 24 hours after surgery. PONV is defined as the occurrence of nausea, retching, or vomiting at any time during the first 24 postoperative hours. A patient will be classified as having a positive primary outcome if at least one episode of nausea, retching, or vomiting occurs within 24 hours after surgery.

The primary outcome will be recorded during the following postoperative time windows:

1. 0–2 hours after surgery;
2. 2–6 hours after surgery;
3. 6–12 hours after surgery;
4. 12–24 hours after surgery.

2. Secondary Outcomes

Secondary outcomes include:

1. Incidence of clinically significant PONV;
2. Incidence of vomiting or retching within 24 hours after surgery;
3. Number of vomiting events within 24 hours after surgery;
4. Characteristics of vomitus;
5. Use of postoperative antiemetic medications;
6. Fatigue at hospital discharge;
7. Postoperative sleep quality;
8. Postoperative complications;
9. Rhinologic symptoms.

16.4 Candidate Risk Factors

Candidate risk factors will be prespecified on the basis of previous literature, clinical plausibility, and the study hypotheses. These factors will include patient-related, anesthesia-related, surgery-related, and rhinologic surgery-specific factors.

Patient-related factors will include, but will not be limited to, age, sex, body mass index, smoking status, previous history of PONV, history of motion sickness, American Society of Anesthesiologists (ASA) physical status classification, relevant comorbidities, and, when available, preoperative nausea or anxiety status.

Anesthesia-related factors will include, but will not be limited to, anesthetic technique, airway device, intraoperative opioid dose, postoperative opioid use, method of neuromuscular blockade reversal, prophylactic antiemetic regimen, intraoperative fluid volume, and duration of anesthesia.

Surgery-related factors will include, but will not be limited to, type of rhinologic surgery, whether a combined surgical procedure was performed, duration of surgery, estimated blood loss, volume of irrigation fluid, nasal packing, nasopharyngeal packing, pharyngeal packing, and postoperative bleeding requiring repeat packing.

Rhinologic surgery-specific factors will include, but will not be limited to, postoperative swallowing of blood, the presence of blood in vomitus or gastric contents, nasopharyngeal blood accumulation, postoperative epistaxis, postoperative suctioning, management of packing materials, and the timing of resumption of oral fluid and food intake.

16.5 Primary Analysis Model

The primary analysis will use a multivariable logistic regression model to evaluate the associations between prespecified candidate risk factors and the occurrence of PONV within 24 hours after surgery. The dependent variable will be whether PONV occurs within 24 hours after surgery.

Given the multicenter study design, study center will be accounted for in the primary model. If the number of study centers and the number of events within each center are sufficient to support a mixed-effects model, the primary model will be a mixed-effects logistic regression model with study center included as a random intercept.

If the random-effects model is unstable because of a small number of centers, insufficient numbers of events within centers, or model nonconvergence, a logistic regression model incorporating study center as a fixed effect will be used as the primary or alternative analysis.

Model results will be reported as adjusted ORs, 95% confidence intervals, and P values. For the principal risk factors, the number of PONV events, total number of patients, and PONV incidence in each exposure group will also be reported.

16.6 Strategy for Variable Inclusion in the Primary Model

Variables will be included in the primary model according to the following principles:

1. Variable inclusion will be prespecified on the basis of previous evidence, clinical importance, and the study hypotheses;
2. Variables will not be selected on the basis of P values from univariable analyses;
3. Established PONV risk factors and rhinologic surgery-specific risk factors will be prioritized;
4. The number of model parameters will be restricted according to the number of observed PONV events to reduce the risk of overfitting;
5. Variables that are highly correlated or demonstrate substantial collinearity will not be included simultaneously in the primary model;
6. Variables that may lie downstream on the causal pathway will be included cautiously and, when appropriate, evaluated only in exploratory analyses.

16.7 Handling of Continuous Variables

Continuous variables will generally be analyzed in their continuous form and will not be arbitrarily dichotomized. The distributions of variables such as age, body mass index, duration of surgery, duration of anesthesia, intraoperative opioid dose, and intraoperative fluid volume, as well as their relationships with the outcome, will first be examined.

If a potentially nonlinear relationship is observed between a continuous variable and PONV, restricted cubic splines may be used for exploratory modeling. If the sample size or number of events is insufficient to support complex modeling, a linear term or prespecified clinically meaningful categories may be used.

When categorization of a continuous variable is required, the categories will be based on clinically accepted thresholds, previous literature, or prespecified quantiles. The categorization rules will be finalized before statistical analysis.

16.8 Collinearity Assessment and Model Diagnostics

Before construction of the multivariable model, correlations and collinearity among candidate variables will be assessed. Collinearity will be evaluated using a combination of correlation matrices, variance inflation factors, and clinical judgment.

Highly correlated variables, such as duration of surgery and duration of anesthesia, anesthetic technique and anesthetic drug dose, or nasal packing and type of surgery, will generally not be included simultaneously in the primary model unless there is a clear clinical rationale for doing so.

Model convergence, outliers, influential observations, and model stability will be examined. If the model is unstable, the number of parameters may be reduced, sparse categories may be combined, variable coding may be revised, or an alternative model may be used. Any such modifications will be described in the study report.

Because the primary objective of this study is risk-factor association analysis, model discrimination, calibration, and clinical predictive performance will not be considered primary results. Predictive performance measures, such as the area under the receiver operating characteristic curve and calibration plots, may be reported only as exploratory descriptions and will not be used to support conclusions regarding a clinical prediction model.

16.9 Handling of Missing Data

The proportion and pattern of missing data will be described for all study variables. Missing primary-outcome data will not be imputed for the primary analysis.

If the proportion of missing covariate data is low, complete-case analysis may be used. If the proportion of missing covariate data is considered non-negligible, missing covariates will be handled using multiple imputation by chained equations under the assumption that data are missing at random.

The imputation model will include the primary outcome, all variables included in the primary analysis model, study center, and available auxiliary variables associated with the missing-data mechanism.

The consistency of results between the multiple-imputation analysis and complete-case analysis will be evaluated as part of the sensitivity analyses. Variables with excessive missingness, limited clinical interpretability, or substantially inconsistent recording standards across centers will not be included in the primary model but may be reported separately in exploratory analyses.

16.10 Secondary Analyses

Secondary analyses will evaluate the associations between prespecified candidate risk factors and secondary outcomes.

Binary secondary outcomes, such as vomiting or retching within 24 hours after surgery, use of rescue antiemetic medication, and clinically significant PONV, will be analyzed using logistic regression or mixed-effects logistic regression.

Count outcomes, such as the number of vomiting or retching events, will be analyzed using Poisson regression or negative binomial regression, depending on the observed data distribution and the presence of overdispersion.

PONV severity scores will initially be summarized descriptively, and an appropriate regression method will be selected according to their distribution. If the score distribution is markedly skewed, nonparametric summaries, quantile regression, or conversion to the binary outcome of clinically significant PONV may be considered.

Analyses of complications occurring on postoperative day 3 and postoperative day 30 will primarily be descriptive and exploratory.

16.11 Subgroup and Exploratory Analyses

Exploratory subgroup analyses may be conducted according to prespecified clinical factors, including sex, anesthetic technique, presence or absence of nasal or nasopharyngeal packing, type of rhinologic surgery, and study center.

Where appropriate, interaction terms may be included to explore whether the association between a candidate factor and the outcome differs across subgroups. All subgroup analyses will be considered exploratory and will not form the basis of the primary conclusions. Their results will therefore be interpreted cautiously.

16.12 Sensitivity Analyses

Sensitivity analyses will include, but will not be limited to, the following:

1. Repeating the primary analysis in the complete-case set;
2. Including study center as a fixed effect rather than a random effect;
3. Applying an alternative definition of PONV, such as excluding isolated mild nausea;
4. Using clinically significant PONV as an alternative primary outcome;
5. Excluding patients with major protocol deviations or incomplete follow-up;
6. Reconstructing the model after excluding variables with a high proportion of missing data;

7. Conducting exploratory analyses of patients with missing primary-outcome data under different assumptions regarding the missing-data mechanism;
8. Performing additional adjustment or stratified analyses according to prophylactic antiemetic use;
9. Repeating the analysis after excluding patients who received early postoperative rescue antiemetic medication but had incomplete outcome documentation;
10. Repeating the analysis using alternative coding schemes for rhinologic surgery-specific factors.

16.13 Multiplicity

The primary analysis will focus on the prespecified primary outcome and candidate risk factors. No formal adjustment for multiple comparisons will be applied to secondary outcomes, subgroup analyses, or exploratory analyses.

The corresponding findings will be interpreted as exploratory evidence, and overinterpretation will be avoided. Conclusions will not be based solely on P values. Interpretation will emphasize the magnitude of effect estimates, 95% confidence intervals, clinical plausibility, and consistency across analyses.

16.14 Statistical Software

All statistical analyses will be performed using R or other validated statistical software. The final manuscript will report the name and version of the software used, together with the principal statistical packages employed.

16.15 Reporting of Results

Study results will be reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for cohort studies.

The report will include the participant screening and enrollment process, baseline and perioperative characteristics, the extent and pattern of missing data, the incidence of PONV, results of the primary multivariable model, and results of the sensitivity analyses.

17. Trial Oversight and Quality Control

17.1 Executive Committee (EC)

The Executive Committee will comprise the principal investigator and the principal investigator's research team and will be responsible for the day-to-day coordination of the study.

17.2 Steering Committee (SC)

The Steering Committee will comprise independent experts, co-investigators, and public representatives. It will be responsible for reviewing protocol amendments, overseeing study progress, and considering and implementing recommendations made by the Data and Safety Monitoring Board.

17.3 Data and Safety Monitoring Board (DSMB)

The Data and Safety Monitoring Board will operate independently of the study team and will comprise two clinical experts and two statisticians. Its principal responsibilities will be safety monitoring and making recommendations regarding early study termination.

All serious adverse event reports will be submitted to the DSMB immediately upon receipt. The DSMB will review all SAE reports submitted to it and, when necessary, advise the principal investigator as to whether further action is required.

17.4 Monitoring of Study Conduct

1. Designation of a Site Sub-investigator

At each participating center, the principal investigator will designate a sub-investigator who will be responsible for the day-to-day oversight of study implementation at that site.

2. Scope of Ongoing Monitoring

The site sub-investigator will oversee the following:

1. Compliance of study implementation with standardized procedures;

2. Accuracy of data documentation;

3. Identification, timely management, and complete documentation of all adverse events;

4. Completeness and consistency of recorded data;

5. Adherence to the inclusion and exclusion criteria and compliance of enrolled participants with the study requirements.

3. Data Queries and Verification

For cases involving missing data, logical inconsistencies, or incomplete follow-up data, a data query form (DQF) will be issued to the investigator. The investigator will be required to respond, correct, or supplement the relevant information within the specified timeframe until all queries have been satisfactorily resolved.

4. Data Quality Control

After data entry has been completed, all case report forms will be independently checked and cross-verified by a second researcher. All quality-control procedures must be completed before database lock and before the data may proceed to formal statistical analysis.

5. Periodic Review and Feedback

Cross-site comparisons and discussions of data quality will be conducted quarterly. Centralized or online retraining will be organized when necessary. All major sources of bias or departures from standardized procedures will be documented and discussed at meetings of the principal investigators.

17.5 Training of Investigators and Clinical Staff

1. The investigator training program will be developed by the principal investigator. A research coordinator will be appointed to organize and implement the training program and to document and retain all related training records. Investigator training will be completed within the month preceding study initiation.

2. General training that must be completed before study initiation will include Good Clinical Practice principles, the study protocol, study-specific standard operating procedures and work plans, instructions for completion of the case report form, and other relevant requirements for study conduct.

3. Investigators responsible for perioperative assessments and data collection will receive task-specific training, including the skills required to complete participant follow-up.

4. During the study, monitoring will be conducted for the first two participants enrolled at each study site and subsequently for one of every 10 participants. Monitoring will be based on video and/or audio recordings of the study procedures.

5. Additional investigator training will be provided throughout the study whenever necessary.

18. Ethical Considerations

18.1 Trial Management and Ethical Approval

The study protocol must be reviewed and approved by the local clinical research ethics committee before study initiation. Investigators shall conduct the study in strict accordance with the Declaration of Helsinki and applicable Chinese regulations governing clinical research.

The principal investigator shall be responsible for reporting the progress and current status of the study to the ethics committee in accordance with applicable requirements.

18.2 Written Informed Consent

For each potential participant, the investigator shall provide a comprehensive written explanation of the study objectives, procedures, and potential benefits and risks. Each potential participant shall be informed of the right to withdraw consent at any time without prejudice.

A written informed consent form shall be provided to every potential participant. A participant may be enrolled only after the informed consent form has been signed by the participant or the participant's legally authorized representative. The signed informed consent form shall be retained as part of the essential clinical study documentation.

18.3 Privacy and Confidentiality

During the study, participant data shall be identified using a unique study identification number and the participant's initials. All personal information relating to study participants shall be kept strictly confidential.

Storage cabinets containing study documents shall remain locked. Access to identifiable study information shall be restricted to authorized study personnel, inspectors authorized by

the institutional scientific research administration department, and members of the ethics committee.

Study findings may be published in scientific journals; however, no information that could directly identify individual participants shall be disclosed.

19. Funding

This study is supported by departmental and institutional funding.

20. Declaration of Interests

The investigators declare that they have no conflicts of interest.

21. Dissemination of Study Findings

Data generated from this study will be disseminated to the scientific community in a timely and responsible manner. Upon completion of the study, a detailed scientific report will be prepared and submitted for publication in a reputable peer-reviewed, open-access scientific journal.

The Steering Committee (SC) will determine the membership of the writing committee, which will be primarily responsible for the final data analysis and preparation of the scientific report. All members of the writing committee must comply with internationally recognized authorship criteria and shall jointly review and approve the final manuscript before submission.

The study findings will also be presented at international scientific conferences.

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APPENDICES

Appendix 1. Quality of Recovery-15 Questionnaire (QoR-15)

Part A

How have you been feeling during the past 24 hours?

Please select a score from 0 to 10, where 0 means “none of the time” [very poor] and 10 means “all of the time” [excellent].

No.	Item	None of the time	Score	All of the time
1	Able to breathe easily	None of the time	0 1 2 3 4 5 6 7 8 9 10	All of the time
2	Able to enjoy food	None of the time	0 1 2 3 4 5 6 7 8 9 10	All of the time
3	Feeling rested	None of the time	0 1 2 3 4 5 6 7 8 9 10	All of the time
4	Had a good sleep	None of the time	0 1 2 3 4 5 6 7 8 9 10	All of the time
5	Able to look after personal hygiene and use the toilet independently	None of the time	0 1 2 3 4 5 6 7 8 9 10	All of the time
6	Able to communicate with family or friends	None of the time	0 1 2 3 4 5 6 7 8 9 10	All of the time
7	Receiving support from hospital doctors and nurses	None of the time	0 1 2 3 4 5 6 7 8 9 10	All of the time
8	Able to return to work or usual household activities	None of the time	0 1 2 3 4 5 6 7 8 9 10	All of the time

9	Feeling comfortable and in control	None of the time	0 1 2 3 4 5 6 7 8 9 10	All of the time
10	Having a feeling of general well-being	None of the time	0 1 2 3 4 5 6 7 8 9 10	All of the time

Part B

During the past 24 hours, have you experienced any of the following?

Please select a score from 0 to 10, where 0 means “all of the time” [very poor] and 10 means “none of the time” [excellent].

No.	Item	All of the time	Score	None of the time
11	Moderate pain	All of the time	0 1 2 3 4 5 6 7 8 9 10	None of the time
12	Severe pain	All of the time	0 1 2 3 4 5 6 7 8 9 10	None of the time
13	Nausea or vomiting	All of the time	0 1 2 3 4 5 6 7 8 9 10	None of the time
14	Feeling worried or anxious	All of the time	0 1 2 3 4 5 6 7 8 9 10	None of the time
15	Feeling sad or depressed	All of the time	0 1 2 3 4 5 6 7 8 9 10	None of the time

Scoring: The total score ranges from 0 to 150, with higher scores indicating better postoperative recovery.

Appendix 2. Hospital Anxiety and Depression Scale (HADS)

No.	Item	0 points	1 point	2 points	3 points
1	I feel tense or “wound up.” (A)	Not at all	From time to time,	A lot of the time	Most of the time

			occasionally		
2	I still enjoy the things I used to enjoy. (D)	Definitely as much	Not quite so much	Only a little	Hardly at all
3	I get a sort of frightened feeling as if something awful is about to happen. (A)	Not at all	A little, but it does not worry me	Yes, but not too badly	Very definitely and quite badly
4	I can laugh and see the funny side of things. (D)	As much as I always could	Not quite so much now	Definitely not so much now	Not at all
5	Worrying thoughts go through my mind. (A)	Only occasionally	From time to time, but not too often	A lot of the time	A great deal of the time
6	I feel cheerful. (D)	Most of the time	Sometimes	Not often	Not at all
7	I can sit at ease and feel relaxed. (A)	Definitely	Usually	Not often	Not at all
8	I have lost interest in my appearance. (D)	I take just as much care as ever	I may not take quite as much care	I do not take as much care as I should	Definitely
9	I feel restless, as if I have to be on the move. (A)	Not at all	Not very much	Quite a lot	Very much indeed
10	I look forward with enjoyment to things. (D)	As much as I ever did	Rather less than I used to	Definitely less than I used to	Hardly at all
1	I get sudden feelings of panic. (A)	Not at all	Not very often	Quite often	Very often

1					indeed
12	I feel as if I am slowing down. (D)	Not at all	Sometimes	Very often	Nearly all the time
13	I get a sort of frightened feeling, like “butterflies” in the stomach. (A)	Not at all	Occasionally	Quite often	Very often
14	I can enjoy a good book, radio program, or television program. (D)	Often	Sometimes	Not often	Very seldom

Scoring

- **Anxiety subscale (HADS-A): Items 1, 3, 5, 7, 9, 11, and 13; total score range: 0–21.**
- **Depression subscale (HADS-D): Items 2, 4, 6, 8, 10, 12, and 14; total score range: 0–21.**
- **Higher scores indicate more severe symptoms of anxiety or depression.**

Appendix 3. Richards-Campbell Sleep Questionnaire (RCSQ)

Please recall your sleep during the previous night and mark your response on a 100-mm visual analog scale (VAS). The left endpoint represents 0 = worst, and the right endpoint represents 100 = best.

No.	Question	Anchor Words: Left Endpoint → Right Endpoint	Score (0–100)
1	My sleep last night was:	Very light → Very deep	_____
2	When I tried to fall asleep last night, I:	Could not fall asleep at all → Fell asleep almost immediately	_____

3	During the night, I was:	Awake almost the entire night → Awake very little	_____
4	When I woke up during the night, I:	Could not fall back asleep → Fell back asleep almost immediately	_____
5	Overall, I would describe my sleep last night as:	Very poor → Very good	_____

Scoring

Each item is scored from 0 to 100 using a 100-mm visual analog scale. Higher scores indicate better perceived sleep quality.

The overall RCSQ score is calculated as the mean of the five item scores and ranges from 0 to 100.

- **RCSQ score < 50: indicates poor sleep quality**
- **RCSQ score ≥ 50: indicates acceptable sleep quality**

Appendix 4. Pittsburgh Sleep Quality Index (PSQI)

Self-Rated Items 1–9

Item 1. During the past month, what time have you usually gone to bed at night?

Usual bedtime: _____

Please enter the exact time, for example, 23:00.

Item 2. During the past month, how long has it usually taken you to fall asleep each night?

Sleep latency: _____ minutes

Item 3. During the past month, what time have you usually gotten up in the morning?

Usual wake-up time: _____

Please enter the exact time, for example, 07:00.

Item 4. During the past month, how many hours of actual sleep have you usually obtained each night?

This may be different from the number of hours spent in bed.

Actual sleep duration: _____ hours

Item 5. Sleep Disturbances

During the past month, how often have you had trouble sleeping because of the following reasons?

Response options for each subitem:

- 0 = Not during the past month
- 1 = Less than once a week
- 2 = Once or twice a week
- 3 = Three or more times a week

Subitem	Reason for Sleep Disturbance	0	1	2	3
a	Could not fall asleep within 30 minutes	□	□	□	□
b	Woke up during the night or early morning	□	□	□	□
c	Had to get up to use the bathroom	□	□	□	□
d	Could not breathe comfortably	□	□	□	□
e	Coughed or snored loudly	□	□	□	□
f	Felt too cold	□	□	□	□
g	Felt too hot	□	□	□	□
h	Had bad dreams	□	□	□	□
i	Experienced pain	□	□	□	□
j	Other reason; please describe: _____	□	□	□	□

Item 6. Use of Sleep Medication

During the past month, how often have you taken medication to help you sleep, whether prescribed or obtained without a prescription?

- 0 = Not during the past month
- 1 = Less than once a week
- 2 = Once or twice a week
- 3 = Three or more times a week

Score: □ 0 □ 1 □ 2 □ 3

Item 7. Difficulty Staying Awake

During the past month, how often have you had difficulty staying awake while driving, eating meals, or engaging in social activities?

- 0 = Not during the past month
- 1 = Less than once a week
- 2 = Once or twice a week
- 3 = Three or more times a week

Score: □ 0 □ 1 □ 2 □ 3

Item 8. Difficulty Maintaining Enthusiasm
During the past month, how much difficulty have you had maintaining enough enthusiasm to get things done?

- 0 = No difficulty
- 1 = Only a slight difficulty
- 2 = Somewhat of a difficulty
- 3 = A very considerable difficulty

Score: □ 0 □ 1 □ 2 □ 3

Item 9. Overall Sleep Quality
During the past month, how would you rate your overall sleep quality?

- 0 = Very good
- 1 = Fairly good
- 2 = Fairly bad
- 3 = Very bad

Score: □ 0 □ 1 □ 2 □ 3

Appendix 5. Fromme–Boezaart Surgical Field Scale

Grade	Assessment Criteria
0	No bleeding.
1	Slight bleeding; no suctioning required.
2	Slight bleeding; occasional suctioning required. The surgical field is not threatened.
3	Slight bleeding; frequent suctioning required. Bleeding threatens the surgical field a few seconds after suction is removed.
4	Moderate bleeding; frequent suctioning required. Bleeding threatens the surgical field immediately after suction is removed.
5	Severe bleeding; constant suctioning required. Bleeding appears faster than it can be removed by suction, and the surgical field is severely compromised.

Scoring

The Fromme–Boezaart Surgical Field Scale ranges from 0 to 5, with higher scores indicating more severe bleeding and poorer surgical field visibility.

Appendix 6. Richmond Agitation–Sedation Scale (RASS)

Score Clinical State Description

+4 Combative Overtly combative or violent; poses an immediate danger to staff.

+3 Very agitated Pulls at or attempts to remove the endotracheal tube, gastric tube, intravenous catheters, or other devices; may behave aggressively toward staff.

+2 AgitatedFrequent non-purposeful movement; fights the ventilator.

+1 Restless Anxious or apprehensive, but movements are not aggressive or vigorous.

0 Alert and calm Spontaneously alert and calm.

−1 Drowsy Not fully alert, but has sustained awakening to voice, with eye contact for more than 10 seconds.

−2 Light sedation Briefly awakens to voice, with eye contact for less than 10 seconds.

−3 Moderate sedation Movement or eye opening in response to voice, but no eye contact.

−4 Deep sedation No response to voice, but movement or eye opening in response to physical stimulation.

−5 Unarousable No response to voice or physical stimulation.

Appendix 7. Grading of Postoperative Sore Throat and Hoarseness

Postoperative Sore Throat

Grade	Assessment Criteria
0	No sore throat.
1	Mild sore throat.
2	Sore throat similar in severity to that experienced with a common cold.

3	Sore throat more severe than that experienced with a common cold.

Postoperative Hoarseness

Grade	Assessment Criteria
0	No hoarseness.
1	Mild hoarseness noticed only by the patient.
2	Hoarseness noticeable to other people.
3	Severe hoarseness; unable to speak.

Appendix 8. Postoperative Nausea and Vomiting Intensity Scale

Part A. Assessment at 6 Hours After Surgery

For day-case surgery, if the patient has already been discharged, the assessment should be performed at the time of discharge.

Q1. Have you experienced any vomiting or retching?*

Response	**Score**
a) No	0
b) Once or twice	2
c) Three or more times	50

Q2. Have you experienced nausea?

Nausea is defined as an unpleasant sensation in the stomach accompanied by a slight urge to vomit.

If nausea occurred, did it interfere with your daily activities, such as getting out of bed, moving freely in bed, walking normally, or eating and drinking?

Response	**Score**
a) No nausea	0
b) Interfered occasionally	1
c) Interfered frequently or most of the time	2
d) Interfered all of the time	25

Q3. Was your nausea mainly:

Response	**Score**
a) Intermittent—"it came and went"	1
b) Constant—"it was present almost or nearly all of the time"	2

Q4. How long did the nausea last?

Duration of nausea: _____ hours

The duration may be recorded as a whole number or a decimal.

Calculation of the Part A Score

If the response to **Q1 is c)**, then:

Part A score = 50

Otherwise:

Part A score = the higher score from Q1 or Q2 × Q3 score × duration reported in Q4

Postoperative nausea and vomiting intensity score from 0 to 6 hours:

A = _____

Definition of a Separate Vomiting or Retching Episode

Multiple vomiting or retching events occurring within a short period, such as within **5 minutes**, should be counted as **one episode**.

To count events as separate episodes, there should be a clearly identifiable interval without vomiting or retching between the events.

Overall Scoring

Clinically important postoperative nausea and vomiting is defined as:

A total postoperative nausea and vomiting intensity score of 50 or higher at any assessment time during the study period.

Scores obtained at **6 hours, 24 hours, and, when clinically relevant, 72 hours after surgery** may be added to quantify the overall intensity of postoperative nausea and vomiting during the entire study period. Scores for each assessment interval may also be analyzed separately.

Final postoperative nausea and vomiting intensity score from 0 to 72 hours:

A + B + C = _____

Appendix 9. Functional Assessment of Chronic Illness Therapy–Fatigue Questionnaire (FACIT-Fatigue)

Please indicate how true each statement has been for you during the past 7 days.

No.	Item	Not at all	A little bit	Somewhat	Quite a bit	Very much
1	I feel fatigued.	0	1	2	3	4
2	I feel weak all over.	0	1	2	3	4
3	I feel listless (“washed out”).	0	1	2	3	4
4	I feel tired.	0	1	2	3	4
5	I have trouble starting things because I am tired.	0	1	2	3	4

6	I have trouble finishing things because I am tired.	0	1	2	3	4
7	I have energy.	0	1	2	3	4
8	I am able to do my usual activities.	0	1	2	3	4
9	I need to sleep during the day.	0	1	2	3	4
10	I am too tired to eat.	0	1	2	3	4
11	I need help doing my usual activities.	0	1	2	3	4
12	I am frustrated by being too tired to do the things I want to do.	0	1	2	3	4
13	I have to limit my social activity because I am tired.	0	1	2	3	4

Scoring

The FACIT-Fatigue questionnaire contains 13 items. Each item is rated from 0 to 4.

For calculation of the standard FACIT-Fatigue total score:

- **Items 7 and 8 are scored directly.**
- **The remaining items are reverse-scored.**
- **The item scores are summed to produce a total score ranging from 0 to 52.**

Higher scores indicate less fatigue and better functioning; lower scores indicate more severe fatigue.

Appendix 10. Definitions of Postoperative Pulmonary Complications According to the European Perioperative Clinical Outcome Consensus

Postoperative pulmonary complication	Definition
Respiratory infection	The patient has received antibiotics for a suspected respiratory infection and meets at least one of the following criteria: new or changed sputum, new or changed lung opacities on chest imaging, fever, or a white blood cell count greater than 12×10^9/L.
Postoperative respiratory failure	A postoperative arterial oxygen partial pressure (PaO_2) below 8 kPa (60 mmHg) while breathing room air, a ratio of arterial oxygen partial pressure to inspired oxygen fraction (PaO_2/FiO_2) below 40 kPa (300 mmHg), or an arterial oxygen saturation measured by pulse oximetry (SpO_2) below 90% requiring supplemental oxygen therapy.
Pleural effusion	Chest radiography demonstrating blunting of the costophrenic angle, loss of the sharp silhouette of the ipsilateral hemidiaphragm in the upright position, evidence of displacement of adjacent anatomical structures, or, in the supine position, a hazy opacity in one hemithorax with preserved vascular shadows.
Atelectasis	Lung opacity associated with displacement of the mediastinum, hilum, or hemidiaphragm toward the affected area, together with compensatory hyperinflation of the adjacent non-atelectatic lung.
Pneumothorax	Air within the pleural space, with no vascular bed surrounding the visceral pleura.

Abbreviations

- **FiO_2: fraction of inspired oxygen**
- **PaO_2: arterial partial pressure of oxygen**
- **SpO_2: peripheral oxygen saturation measured by pulse oximetry**
- **PPCs: postoperative pulmonary complications**