BMC Anesthesiology

STUDY PROTOCOL

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Effect of intraoperative noise isolation on postoperative nausea and vomiting in patients undergoing gynecological laparoscopic surgery: protocol for a randomized controlled trial

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Abstract

Background Postoperative nausea and vomiting (PONV) are common complications following general anesthesia, particularly in gynecological laparoscopic surgeries. This study aims to evaluate the effect of intraoperative noise isolation on PONV incidence.

Method This single-center, prospective, randomized controlled trial will enroll 192 adult patients undergoing laparoscopic gynecological surgery. Patients will be randomly assigned in a 1:1 ratio and stratified by age into either the control group (Group C), without noise-cancelling headphones, or a noise reduction group (Group NR), using noise-cancelling headphones from anesthesia induction until the end of surgery. All patients will receive intraoperative dexamethasone and ondansetron prophylaxis. The primary outcome is the incidence of PONV within 48 h post-surgery. Secondary outcomes include PONV severity at 24 and 48 h, antiemetic use, pain scores, need for rescue analgesia, Quality of Recovery-15 (QoR-15) scores, Richards-Campbell Sleep Questionnaire (RCSQ) scores, hemodynamic interventions, extubation time, length of stay in PACU and hospital, adverse events (hypertension, hypotension, bradycardia, tachycardia, desaturation after extubation, postoperative shivering, emergence agitation, allergic reactions, severe arrhythmias arrhythmia, cardiac arrest, hypothermia), patient satisfaction, and postoperative complications based on the Postoperative Morbidity Survey (POMS). Analyses will be conducted using modified intention-to-treat (mITT) and per-protocol (PP) populations.

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Discussion We hypothesize that intraoperative use of noise-cancelling headphones will reduce PONV incidence in patients undergoing gynecological laparoscopic surgery. The findings could enhance postoperative care protocols for thoracoscopic gynecological procedures.

Trial registration Chinese Clinical Trial Registry (ChiCTR2400087460).

Keywords Postoperative nausea and vomiting, Postoperative outcomes, Gynecological laparoscopic surgery, Noise isolation

Introduction

Postoperative nausea and vomiting (PONV) are common complications following anesthesia and surgery [1, 2], with prevalence rates ranging from 20 to 80% in patients undergoing gynecological laparoscopic surgery [3]. PONV significantly affects the perioperative period, potentially impairing the quality of patient recovery. It not only diminishes patient comfort and satisfaction but also disrupts essential functions such as oral intake. In severe cases, PONV can lead to serious complications, including wound dehiscence, prolonged hospital stays, and increased healthcare costs [4–7]. The mechanisms underlying PONV are complex and multifactorial, involving the use of anesthetic drugs, patient-specific factors, and the type of surgery performed [8].

The application of noise-cancelling headphones to reduce noise exposure during laparoscopic surgery under general anesthesia has been shown to significantly alleviate postoperative motion-induced pain and reduce the overall use of opioid analgesics [9]. However, the effect of this intervention on the incidence of PONV remains unexplored. Previous studies have indicated that auditory evoked potentials (AEPs) reflect the brain's electrophysiological responses to auditory stimuli, which can provide insights into the state of consciousness during anesthesia [10]. Mid-latency AEPs, in particular, are associated with 40 Hz activity, which is closely linked to levels of consciousness under anesthesia [11]. Notably, hearing is the only sense that remains active during general anesthesia, and environmental noise may exacerbate patient anxiety, a recognized risk factor for PONV [12–14].

In this context, it is hypothesized that using noise-cancelling headphones to reduce noise disturbances in the operating room could decrease the incidence of PONV. Although direct evidence supporting the effectiveness of noise-canceling headphones in reducing PONV is currently lacking, exploring this intervention is warranted given the potential psychological and physiological effects of noise on patients.

To address this, we have designed a single-center randomized controlled trial to evaluate the effectiveness of noise reduction in mitigating PONV and to assess its overall impact on the recovery process in patients undergoing gynecological laparoscopic surgery.

Methods

Study Design

This study is an investigator-initiated, single-center, prospective, randomized controlled clinical trial. A total of 192 patients will be enrolled at the First Affiliated Hospital of Soochow University in Suzhou, China. As a tertiary teaching hospital, this institution performs approximately 5,000 gynecological surgeries annually. After the induction of anesthesia, participants will be randomly assigned to undergo laparoscopic gynecological surgery either with or without the use of noise-cancelling headphones. A stratified block randomization design will be used to ensure balanced allocation across groups. The study flow diagram is depicted in Fig. 1, and Table 1 outlines the schedule of patient enrollment, study interventions, and outcome measurements, in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement (Supplemental S1) [15]. This trial will be conducted in compliance with the Declaration of Helsinki, and informed consent will be obtained from all participates.

Inclusion criteria

Patients eligible for inclusion in the study must meet the following criteria:

(1) Female patients aged between 18 and 65 years;
(2) Classified as American Society of Anesthesiologists (ASA) physical status I-II;
(3) Scheduled to undergo laparoscopic gynecological surgery under general anesthesia with an estimated operative time of more than 30 min.

Exclusion criteria

The exclusion criteria are as follows:

(1) Patients who are pregnant or breastfeeding;
(2) Patients with a history of tumor chemotherapy;
(3) Patients with a mean hearing threshold of > 40 dB at six frequency points (500, 1000, 2000, 4000, 6000 and 8000 Hz), as determined by pure tone audiometry (PTA);
(4) Patients with comorbidities that increase the risk of PONV, such as impaired gastric motility or vestibular disease;

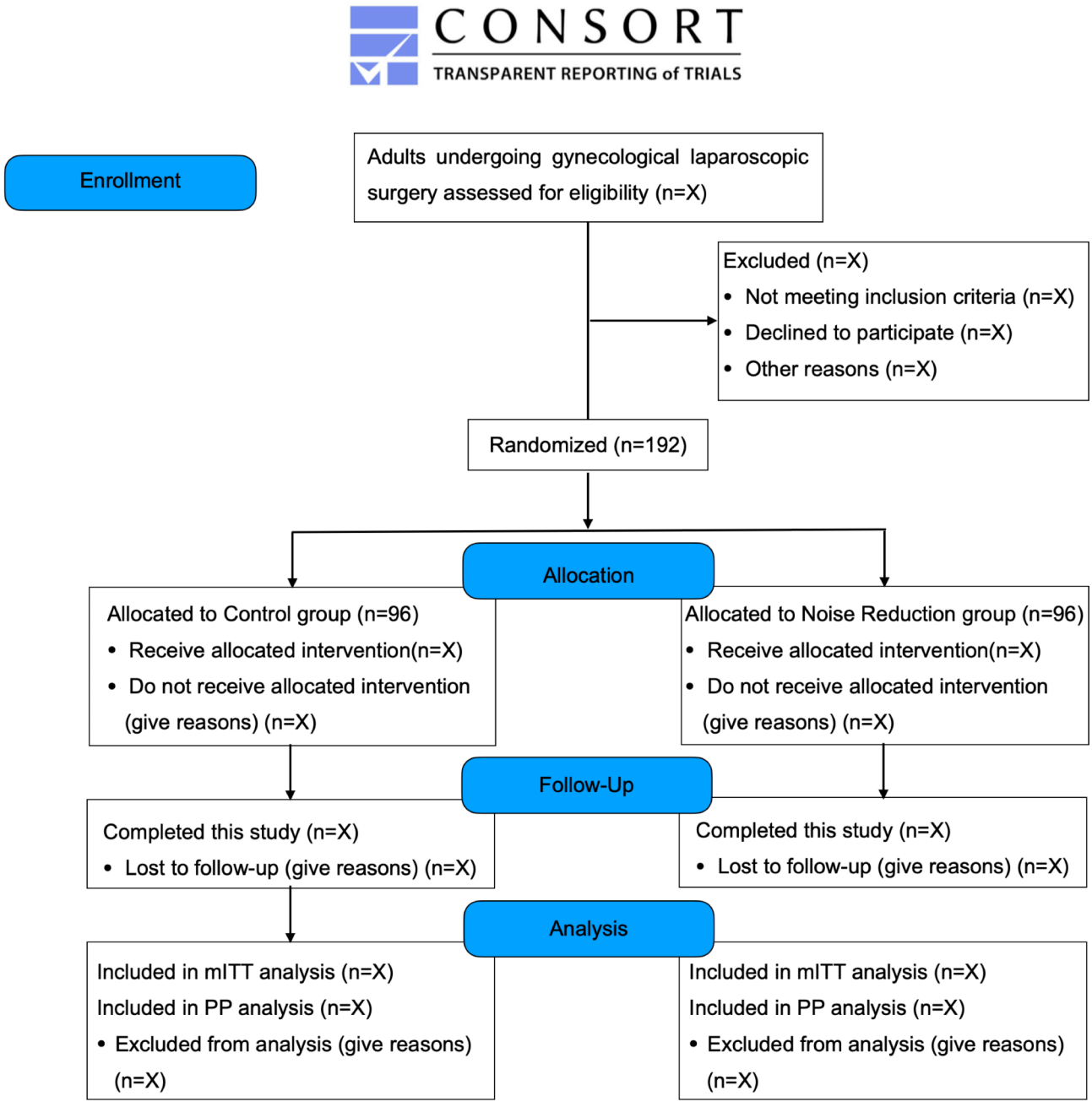

Fig. 1 Flow chart of this trial

(5) Patients with abnormal liver or renal function (Child-Pugh class C or those undergoing renal replacement therapy);
(6) Patients with a history of long-term abuse of sedative, antidepressant, psychoactive drugs, or alcohol;
(7) Patients with central nervous system disease, psychiatric disease, or communication disorders;
(8) Patients taking antiemetic, psychotropic drugs, or glucocorticoids within 24 h before surgery;
(9) Patients unable to wear headphones due to auricular deformity or other reasons;
(10) Patients who have demonstrated allergic reactions to the pharmaceutical agents used in the study protocol.

Withdrawal criteria

Patients may be withdrawn from the study under the following circumstances:

Table 1 Schedule of patient enrollment, study interventions, and measurements complying with the SPIRIT statement

	Study Period							
Timepoint	**Enrollment**	**Allocation**	**Post-allocation**					**Close-out**
	Preoperative visit	***Before surgery***	***During surgery***	***PACU***	***24 h postoperatively***	***48 h postoperatively***	***Hospital discharge***	***Day 30***
Enrollment								
Inclusion criteria	×							
Exclusion criteria	×							
Written informed consent	×							
Baseline characteristics	×							
Apfel rating[a]	×							
APAIS rating[b]	×							
PTA testing[c]	×							
SORT rating[d]	×							
Preoperative comorbidities	×							
Randomization		×						
Allocation		×						
Interventions								
Control subjects			×					
Wearing headphone sets			×					
Endpoints measures								
Incidence of PONV				×	×	×		
Severity of PONV				×	×	×		
Antiemetic rescue therapy				×	×	×		
Time to extubation				×				
Length of PACU stay				×				
NRSscoring at rest[e]				×	×	×		
NRS score for cough[e]				×	×	×		
Perioperative anaesthesia-related adverse events[f]			×	×	×	×		
Medication use for adverse event management			×	×	×	×		
QoR-15 rating[g]					×	×		×
RCSQ Sleep scale[h]					×	×		
Patient satisfaction						×		
Length of hospital stays							×	
Major complications 1,2 and 30 days (POMS) [I]					×	×		×

According to SPIRIT statement of defining standard protocol items for clinical trials

[a] Apfel: PONV risk scoring system, the risk factors include female sex, non-smoking status, history of motion sickness or PONV, and postoperative opioid use

[b] APAIS: Amsterdam Preoperative Anxiety and Information Scale。

[c] PTA: Pure Tone Audiometry rating

[d] SORT rating: the Surgical Outcome Risk Tool

[e] NRS: numeric rating scale

[f] including: hypertension, hypotension, bradycardia, tachycardia, desaturation, postoperative shivering, emergence agitation, allergic reactions, severe arrhythmias arrhythmia, cardiac arrest, hypothermia

[g] QoR-15 scores: Quality of Recovery 15 scores

[h] RCSQ Sleep scale: Richards-Campbell Sleep Scale

[I] POMS: Postoperative Morbidity Survey.

(1) The occurrence of serious adverse events necessitating withdrawal for patient safety;
(2) Withdrawal requested by the patients or their family at any point during the study;
(3) Investigator's decision to withdraw a patient due to circumstances that preclude continuation in the trial.

Termination criteria

The trial may be terminated under the following circumstances:

(1) Identification of early leakage of the blinding protocol;

(2) Detection of significant protocol violations during trial execution;
(3) Unfeasibility of the trial due to severe delays in patient recruitment or a high frequency of protocol deviations.

Randomization and blinding

A stratified block randomization design will be employed. An independent researcher, not involved in data collection, data management, or statistical analysis, will use an online randomization tool (https://www.sealedenvelope.com/simple-randomiser/v1/lists) to generate a randomized list in a 1:1 ratio. Randomization will be conducted using blocks of 2 and 4, stratified by age (18–35 years, 36–50 years, and 51–65 years). The randomization sequence will be securely preserved and concealed in opaque sealed envelopes. Upon the patient's entry into the operating theatre, a nurse anesthetist who is not involved in patients recruitment or follow-up assessment will open the envelope and assign the patient to either the noise-cancelling headphone group or the non-noise-cancelling group. To maintain blinding, a therapeutic towel will cover the head and ears of all patients after anesthesia induction, ensuring that patients, surgeons, nurses, follow-up assessors, and statisticians remain blinded to the group assignment until the final analysis.

Anesthesia

All patients will fast for 6–8 h prior to surgery, with no premedication administered. Baseline blood pressure will be recorded in the preoperative waiting area. Following admission to the operating theatre, patients will undergo continuous monitoring of vital signs, including heart rate, peripheral oxygen saturation (SpO_2) and non-invasive blood pressure. Anesthesia depth will be monitored using the Bispectral Index (BIS, Aspect Medical Systems in Newton, Massachusetts), while intraoperative analgesia will be assessed using the Surgical Pleth Index (SPI, GE Healthcare, Helsinki, Finland) [16].

General anesthesia will be induced sequentially with sufentanil 0.2–0.4 μg/kg and propofol 1.5-2.5 mg/kg. After induction, when the Modified Observer's Alertness/Sedation Scale (MOAA/S) score reaches 0, intravenous rocuronium 0.6 mg/kg will be administered to facilitate endotracheal intubation. Patients will be ventilated with a tidal volume of 6-8 ml/kg and a respiratory rate of 12–16 breaths/min, maintaining end-tidal carbon dioxide levels between 35-45mmHg. Positive end-expiratory pressure (PEEP) will be set at 5–10 cmH_2O, and the inspired oxygen fraction will be adjusted to 50–80% to ensure $SpO_2 \geq 95\%$. Anesthesia depth will be titrated to maintain a BIS value of 40–60 using 0.7–1.2 minimal alveolar concentration (MAC) sevoflurane. Patients will be covered with a warm blanket to maintain a nasopharyngeal temperature of 36–37 °C. Intravenous rehydration will be provided with Ringer's lactate solution, with hydroxyethyl starch administered as needed based on intraoperative circulating volume. Intraoperative analgesia will be maintained with sufentanil and remifentanil, with 0.1–0.2 μg/kg of sufentanil administered prior to incision and a continuous infusion of remifentanil at 0.1–0.2 μg/kg/min. Additional doses of sufentanil (0.1–0.2 μg/kg) may be given based on SPI readings when remifentanil is discontinued at the end of surgery, and rocuronium may be supplemented as needed.

For analgesia, 50 mg of flurbiprofen and 0.2 mg/kg of oxycodone, a potent μ- and κ-opioid receptor agonist, will be administered intravenously before the end of surgery. Additionally, 200 mg of sugammadex will be used to reverse neuromuscular blockade following the completion of skin suturing. Patients will be extubated either in the operating room or in the PACU, with supplemental oxygen delivered at 3 L/min via nasal cannula post-extubation. A modified Aldrete score of ≥ 9 will indicate readiness for discharge from the PACU to the surgical ward [17].

To prevent PONV, all patients will receive intravenous dexamethasone 5 mg during anesthesia and palonosetron 0.25 mg, a selective 5-hydroxytryptamine 3 (5-HT3) receptor antagonist, at the end of the procedure. If severe PONV occurs, an additional dose of palosetron 0.25 mg will be administered as rescue antiemetic therapy. For postoperative pain management, patients will receive intravenous flurbiprofen 50 mg every 12 h or tramadol 1 mg as needed. Perioperative care will remain consistent across both study cohorts, except for the specific study interventions.

During surgery and in the PACU, hypotension (mean blood pressure < 65 mmHg or a > 30% decrease from baseline) will be treated with intravenous ephedrine 6–10 mg or phenylephrine 50–100 μg. Bradycardia (heart rate < 50 beats/minute) will be managed with intravenous atropine 0.3–0.5 mg. Hypertension (mean blood pressure > 20% above baseline) will be treated with intravenous nicardipine 0.5 mg, and tachycardia (heart rate > 100 beats/minute) will be treated with esmolol 20 mg. Desaturation ($SpO_2 < 90\%$ on room air) after extubation, either in the operating room or in the PACU, will be managed with oxygen supplementation at 5–10 L/min via nasal cannula or mask ventilation, if necessary.

Study interventions

Patients in the control group (Group C) will not wear noise-cancelling headphones during anesthesia, whereas patients in the noise reduction group (Group NR) will wear noise-cancelling headphones (Peltor™ X5A, 3 M™, Poland; signal noise reduction of 37 dB) from the induction of anesthesia until the end of surgery. After surgery,

all patients will be transferred to the PACU for postoperative monitoring and care.

Primary outcome

The primary outcome of this study is the incidence of PONV, defined as the occurrence of any nausea, retching, or vomiting event in the PACU and at 24 and 48 h after surgery.

Secondary outcomes

The secondary outcomes include the following:

(1) Severity of PONV in the PACU and at 24 and 48 h after surgery. Severity of PONV will be assessed as follows: none, mild (does not interfere with activities of daily living), moderate (sometimes interferes with activities of daily living), and severe (inability to perform activities of daily living or ≥ 3 vomiting episodes) [18, 19];
(2) Use of antiemetic medication in the PACU and at 24 and 48 h postoperatively;
(3) Pain scores in the PACU and at 24 and 48 h postoperatively, assessed using a numerical rating scale (NRS, 0–10; 0 = no pain, 10 = worst pain), as well as the patient's perception of the worst pain experienced [20, 21];
(4) Need for rescue analgesia in the PACU and at 24 and 48 h postoperatively;
(5) Quality of Recovery-15 (QoR-15) scale scores at 24, 48 h, and 30 days postoperatively; the QoR-15 scale consists of 15 items, each scored up to 10 points, with a maximum total score of 150 [22];
(6) Richards-Campbell Sleep Questionnaire (RCSQ) scores at 24 and 48 h postoperatively [23];
(7) Interventions for perioperative hemodynamic events;
(8) Time of extubation;
(9) Length of stay in the PACU and the hospital;
(10) Incidence of adverse events;
(11) Patient satisfaction at 48 h postoperatively, assessed using a 5-point Likert scale (5 = highly satisfied, 4 = satisfied, 3 = neutral, 2 = dissatisfied, and 1 = very dissatisfied) [24];
(12) Postoperative complications assessed based on the Postoperative Morbidity Survey (POMS) at 24, 48 h, and 30 days postoperatively [25–27].

Safety outcomes

Safety outcomes will be assessed separately for all subjects and then combined, encompassing both intraoperative and postoperative adverse events. The incidence of postoperative adverse events will be tracked up to postoperative day 2 (study day 3). Monitored adverse events include hypertension, hypotension, bradycardia, allergic reactions, severe arrhythmias, cardiac arrest, hypothermia, desaturation, postoperative shivering, and emergence agitation. Definitions of adverse events are provided in Supplementary S2. These events will be assessed during anesthesia, in the PACU, and postoperatively. Any adverse events related to the study intervention must be reported to the Data Monitoring Committee (DMC) using an "Adverse Event Form" within 24 h. In the case of a serious adverse event, such as an unexpected deterioration in the patient's clinical condition during the perioperative period, the attending anesthetist may need to unblind, adjust treatment, or discontinue the trial.

Data collection and registration

An independent researcher will collect relevant demographic data, including age, year of birth, height, weight, smoking status, history of motion sickness, and other pertinent information. Established risk factors for PONV, such as female gender, non-smoking status, history of motion sickness or PONV, and postoperative opioid use, will be documented [28]. Apfel's PONV risk score, which ranges from 0 to 4 and indicates a 20% increased risk of developing PONV for each point, will be calculated based on the number of identified risk factors [28]. Additionally, a pure tone audiometry (PTA) test will be conducted to assess hearing, and scores from the Amsterdam Preoperative Anxiety and Information Scale (APAIS) [29] and the Surgical Outcome Risk Tool (SORT) [30] will be recorded. Information on comorbidities, such as diabetes mellitus and hypertension, history of oral medications, and the patient's preoperative vital signs and laboratory test results, will also be documented. Furthermore, patients will be assessed for the risk of major postoperative adverse events using POMS (Supplementary S3).

Perioperative data, including details on anesthesia induction, maintenance medications, type of surgery, duration of surgery and anesthesia, pathological findings, and total fluid balance, will be recorded. At the conclusion of the surgical procedure, primary and secondary outcome indicators will be compiled. All data will be documented on the case report form and entered into an electronic database. Once data registration is complete, the electronic database will be locked. An independent Data Monitoring Committee (DMC) will oversee the trial process and data management. Any ambiguities related to data collection or adherence to the medication protocol will be addressed by the DMC to reach a final decision.

Sample size

A preliminary trial conducted between March 2024 and May 2024 involved the random assignment of 23 patients to each group. All patients underwent laparoscopic gynecological surgery, with the test group provided noise-cancelling headphones, while the control group did not.

The pre-test results demonstrated that the incidence of PONV at 48 h after surgery was 21.74% in the test group and 47.83% in the control group. These findings are consistent with previous studies, which report a PONV incidence ranging from 42 to 60% in patients undergoing laparotomy gynecological surgeries [21, 31, 32]. Based on these findings, we hypothesized that the incidence of PONV in laparoscopic gynecological surgery under general anesthesia would be approximately 45% at 48 h post-surgery. The utilization of intraoperative noise isolation with noise-cancelling headphones is expected to reduce the incidence of PONV to 25% at 48 h postoperatively, representing an absolute reduction of 20% compared to the control group. The required sample size was calculated using PASS (version 21.0.3, NCSS, LCC, Kaysville, UT, USA) with a significance level (α) of 0.05 and a power (β) of 0.2, resulting in 86 patients per group. To account for a potential 10% dropout rate, the sample size was increased to 96 patients per group, totaling 192 patients.

Statistical analysis

Descriptive statistics will be used to summarize demographic data and baseline characteristics. Continuous variables will be presented as means with standard deviations (SD) for normally distributed data, or as medians with interquartile ranges (IQR) for non-normally distributed data. Categorical variables will be reported as counts and percentages. Outcome data will primarily be analyzed using the modified intention-to-treat (mITT) approach, with supplementary analyses conducted using a per-protocol (PP) analysis.

The mITT population will include all randomized patients who undergo gynecological laparoscopic surgery and receive the assigned intervention, provided that the primary outcome measurement is available. Patients will be analyzed according to their randomized groups, regardless of additional surgical procedures performed within 30 days postoperatively. Patients who receive non-protocol antiemetic therapy will also be included in the mITT analysis. The results of the mITT analysis will be the primary basis for drawing study conclusions. A sensitivity analysis will be performed using the PP population, which will include patients adhering strictly to the study protocol. Exclusion criteria for the PP analysis include: receive chemotherapy within 48 h of surgery, failure to receive palonosetron or dexamethasone intraoperatively, use of non-prescribed antiemetic drugs postoperatively, use of patient-controlled intravenous analgesia (PCIA) with opioids, conversion from laparoscopic to open surgery during the operation, or use of intravenous maintenance without sevoflurane. These exclusions are necessary as these factors could confound the incidence of PONV.

Baseline characteristics between groups will be evaluated using standardized mean differences (SMD), with an SMD greater than 0.1 considered indicative of imbalance. The normality of continuous variables will be evaluated using the Shapiro-Wilk test. Normally distributed continuous variables will be analyzed using independent samples t-tests, whereas non-normally distributed variables will be analyzed using the Mann-Whitney U test. Categorical variables will be compared using the Chi-squared test or Fisher's exact test, depending on the distribution of the data.

Mixed-effects linear regression models for continuous outcomes, and mixed-effects logistic regression models will be used for categorical outcomes. The fixed effects in our mixed-effects models will include group assignment, stratification factors, smoking status, history of motion sickness or PONV, duration of surgery, and covariates with SMD > 0.1. These variables have been identified in prior studies as significant predictors of PONV [28].

The effect of the intervention (noise reduction group vs. control group) will be quantified using mean difference (MD) with 95% confidence intervals (CI) for continuous outcomes, and relative risks (RR) with 95% CIs for categorical outcomes using a log-binomial model. Ordinal logistic regression models will be employed to assess outcomes with discrete but ordered categories. Absolute risk differences (RD) will also be reported with 95% CIs.

Subgroup analyses will explore PONV incidence based on factors such as the Amsterdam Preoperative Anxiety and Information Scale (APAIS) score (≤ 12 vs. >12), smoking status, history of motion sickness or PONV, Apfel PONV risk score (1–2 vs. 3–4), pure tone audiometry (PTA) test results (0-25dB vs. 26-40dB), and age groups (18–35 years, 36–50 years, 51–65 years). Multiple testing adjustments will be applied for secondary outcomes using the Benjamin-Hochberg procedure, with a significance level set at a q-value of less than 0.05. Given the risk for type I error from multiple comparisons, secondary outcomes will be considered exploratory.

All statistical tests will be two-sided, with a P value less than 0.05 considered statistically significant. No interim analyses will be conducted, and missing data will not be imputed. Analyses will be conducted using R software version 4.4.1 (http://www.R-project.org).

Discussion

This single-center, prospective, double-blind, randomized controlled study includes 192 adults undergoing gynecologic laparoscopic surgery. The primary objective is to evaluate whether intraoperative noise isolation can reduce the incidence of PONV within the first 48 h postoperatively. Additional outcomes to be assessed include the severity of PONV, use of antiemetic medications, time to extubation, length of stay in the PACU,

resting and coughing NRS pain scores, administration of medications for anesthesia-related adverse events, and the QoR-15 score. Further evaluations will include the RCSQ sleep scale, patient satisfaction, length of hospital stay, and major postoperative complications according to Postoperative Morbidity Survey (POMS) at 1, 2, and 30 days postoperatively. The trial's implementation and reporting will adhere to the Consolidated Standards of Reporting Trials (CONSORT) guidelines [19].

Research indicates that the mean noise level during abdominal surgeries often exceeds 55 dB [33], which is significantly higher than the level recommended by World Health Organization (WHO) [34]. Studies have shown that all patients are exposed to high noise levels during abdominal surgery. Noise as an environmental stimulus can increase patient anxiety, a known risk factor for PONV [35]. Consequently, elevated intraoperative noise exposure has been linked to a higher incidence of PONV. The use of noise-cancelling headphones in the operating room may reduce noise disturbance and subsequently lower the incidence of PONV. Previous research has also demonstrated that noise-cancelling headphones can reduce postoperative pain and opioid consumption [34]. Since opioid-containing anesthesia is associated with higher rates of PONV compared to opioid-free anesthesia [36], noise-cancelling headphones may positively impact PONV outcomes.

Previous studies have primarily examined the effect of intraoperative noise isolation on postoperative pain, consistently demonstrating that noise isolation using noise-canceling headphones significantly reduces postoperative pain and hypersensitivity due to surgical trauma [34]. This study specifically investigates the potential for reducing the incidence of PONV through intraoperative noise isolation. Notably, high-intensity noise in the operating room can interfere with communication among medical staff [37–39], reduce the attention of the surgeons and anesthesiologists, and negatively affect the surgical process [40]. The impact of these factors on PONV and overall surgical performance remains unclear and warrants objective evaluation. Therefore, this study includes regression analyses, adjusting the primary outcome of PONV incidence using multifactorial logistic modeling or linear regression. Although exploratory, further investigation is needed to establish a clear correlation between intraoperative noise and PONV.

Our study has several limitations. First, all patients underwent gynecologic laparoscopic surgery, which may limit the generalizability of the results to other types of surgeries. Further research should explore the effect of noise isolation on different surgical procedures. Second, follow-up after patient discharge could introduce bias into the results. Third, this trial employed combined intravenous and inhalation anesthesia, which differs from total intravenous or inhalation anesthesia alone. Future studies should assess whether noise isolation mitigates PONV under different anesthetic techniques. Finally, as a single-center trial, these findings require validation in multicenter studies.

In conclusion, this randomized clinical trial aims to evaluate the impact of using noise-cancelling headphones during laparoscopic gynecological surgery under general anesthesia on PONV incidence. The intraoperative use of noise-cancelling headphones as a noise isolation strategy is a cost-effective, safe, and practical intervention. Implementing this approach is expected to reduce the incidence and severity of PONV, improve patient outcomes, and enhance the quality of anesthesia care through a simple and feasible method.

Abbreviations

PONV	Postoperative nausea and vomiting
PACU	Postanesthesia care unit
QoR-15	Quality of recovery-15
RCSQ	Richards-campbell sleep questionnaire
POMS	Postoperative morbidity survey
mITT	Modified intention-to-treat
PP	Per-protocol
AEPs	Auditory evoked potentials
ASA	American society of anesthesiologists
PTA	Pure tone audiometry
SpO_2	Peripheral oxygen saturation
BIS	Bispectral index
SPI	Surgical pleth index
MOAA/S	Modified observer's alertness/sedation scale
PEEP	Positive end-expiratory pressure
5-HT3	5-hydroxytryptamine 3
DMC	Data monitoring committee
APAIS	Amsterdam preoperative anxiety and information scale
SORT	Surgical outcome risk tool
SD	Standard deviations
IQR	Interquartile ranges
PCIA	Patient-controlled intravenous analgesia
SMD	Standardized mean differences
MD	Mean difference
CI	Confidence intervals
RR	Relative risks
RD	Risk differences
CONSORT	Consolidated standards of reporting trials
SPIRIT	Standard protocol items: recommendations for interventional trials
I POMS	Postoperative morbidity survey

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12871-025-02924-3.

Supplementary Material 1

Supplementary Material 2

Supplementary Material 3

Acknowledgements

The authors would like to extend their gratitude to the patients participating in this trial, as well as to the medical, nursing, and research teams for their invaluable assistance in conducting this study.

Author contributions
C F and F X drafted the manuscript. HY L and FH J have made substantial contributions to the conception. All authors participated in revising the manuscript substantially. ZH Y, YS L, WW H and FH J provided administrative support. All authors reviewed and approved the final manuscript.

Funding
This work will be supported by National Natural Science Foundation of China (82072130, 82302456, 82301387), Key Medical Research Projects in Jiangsu Province (ZD2022021), Suzhou Clinical Medical Center for Anesthesiology (Szlcyxzxj202102), Undergraduate Training Program for Innovation and Entrepreneurship, Soochow University (2024C033), and Extracurricular Academic Research Fund for Undergraduates, Soochow University (KY2024257B).

Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
This study protocol was approved by the Ethics Committee of the First Affiliated Hospital of Soochow University (Approval No.2024 – 259) on July 9, 2024. The trial has been registered at the Chinese Clinical Trial Registry (http://www.chictr.org.cn, identifier: ChiCTR2400087460) on July 29, 2024, prior to the enrollment of the first participant. This trial will adhere to the principles outlined in the Declaration of Helsinki, and informed written consent will be obtained from all patients.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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Received: 2 October 2024 / Accepted: 22 January 2025
Published online: 30 January 2025

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