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STUDY PROTOCOL

# Patient Refusal of Patient-Controlled Analgesia: Incidence, Associated Factors, and Reasons—A Prospective Mixed-Methods Cohort Study Protocol in a Chinese Tertiary Hospital

Yue Shen[1,*], Guanyu Yang[1,*], Jing Sang[1], Liumei Li[1], Jiayao Tian[2], Zhentao Sun[3], Qinjun Chu[1]

[1]Department of Anesthesiology and Perioperative Medicine, Zhengzhou Central Hospital Affiliated to Zhengzhou University, Zhengzhou, Henan, People's Republic of China; [2]The First Clinical Medical College, Lanzhou University, Lanzhou, Gansu, People's Republic of China; [3]Department of Anesthesiology, Pain and Perioperative Medicine, the First Affiliated Hospital of Zhengzhou University, Zhengzhou, Henan, People's Republic of China

*These authors contributed equally to this work

Correspondence: Zhentao Sun, Department of Anesthesiology, Pain and Perioperative Medicine, the First Affiliated Hospital of Zhengzhou University, Jianshe East Road 1, Zhengzhou, Henan, 450052, People's Republic of China, Tel +8613603455483, Email fccsunzt@zzu.edu.cn; Qinjun Chu, Department of Anesthesiology and Perioperative Medicine, Zhengzhou Central Hospital Affiliated to Zhengzhou University, Tongbai North Road 16, Zhengzhou, Henan, 450007, People's Republic of China, 450007, Email jimmynetchu@163.com



**Background:** Patient-controlled analgesia (PCA) is an effective method for managing postoperative pain, yet a significant number of eligible patients in China decline its use. The reasons for this refusal are not fully understood, limiting the development of patient-centered pain management strategies. This study aims to investigate the incidence, influencing factors, and underlying reasons for PCA refusal among surgical patients.

**Methods:** A prospective, mixed-methods cohort study will be conducted at a tertiary hospital in China. A total of 4,000 adult patients scheduled for surgery and eligible for PCA will be enrolled. Before the standard preoperative anesthesiology consultation, participants will complete a baseline assessment of sociodemographic, clinical, and cognitive factors related to PCA. After a standardized PCA recommendation, patients' acceptance or refusal will be recorded. Quantitative data will first be analyzed using least absolute shrinkage and selection operator (LASSO) regression to select predictors; subsequently, multivariable logistic regression will be used to identify factors associated with refusal. Patients who refuse PCA will be invited to participate in semi-structured interviews to explore their decision-making motivations. Interviews will be documented through detailed written notes and analyzed using qualitative content analysis to identify the primary reasons for refusal; data collection will continue until saturation is reached. Postoperative pain scores and decision regret among refusers will also be assessed.

**Discussion:** This study will provide insights into PCA refusal from both quantitative and qualitative perspectives. The findings are expected to inform the development of targeted patient education programs and improve shared decision-making processes, ultimately enhancing postoperative pain management and recovery outcomes.

**Trial Registration:** Chinese Clinical Trial Registry (ChiCTR2600116056). Registered on January 5, 2026.

**Keywords:** patient-controlled analgesia, postoperative pain, decision-making, mixed-methods, cohort study, factors

## Introduction

Postoperative acute pain is a common clinical issue that affects patient recovery and well-being.[1] A large-scale, population-based study in China revealed that 48.7% of surgical patients endure moderate to severe pain in the postoperative period.[1] Inadequately managed pain is not merely a source of suffering; it is associated with a higher incidence of complications, including cardiovascular events, pulmonary infections, and delayed mobilization, which can

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prolong hospital stays.[2,3] Furthermore, severe acute pain is a recognized risk factor for the development of persistent chronic pain syndromes.[2,3]

Patient-controlled analgesia (PCA) is widely regarded as a gold standard for postoperative pain control, forming an integral part of enhanced recovery after surgery (ERAS) protocols,[4] and is routinely indicated for major surgeries that produce high acute pain, including complex orthopedic, open abdominal, non-ambulatory laparoscopic surgery, thoracic, and major reconstructive procedures.[5] By permitting patients to self-administer predetermined doses of analgesic medication, PCA effectively achieves individualized analgesia, and its analgesic efficacy has been confirmed by multiple clinical trials.[6–8]

Despite its established efficacy and recommendation in clinical guidelines, the utilization of PCA in China remains suboptimal; a previous investigation reported that only 47.05% of patients for whom PCA was indicated actually received it.[9] Low utilization is likely multifactorial, influenced by clinician prescribing patterns, institutional protocols, insurance coverage, and patient refusal, among other factors.[9] This gap between evidence-based recommendation and clinical practice is therefore not attributable to any single cause, but patient acceptance remains one of the least understood contributors.

When PCA is uniformly offered, the extent of refusal and the reasons behind it are poorly defined, yet they represent a potentially modifiable barrier to optimal analgesia. Accordingly, this study focuses specifically on the incidence and determinants of patient refusal in a setting where the decision to offer PCA has been standardized. Existing research has predominantly focused on the pharmacological and technical optimization of PCA, with scant attention paid to the psychosocial, cognitive, and economic factors that influence patient decision-making.[5,10] Preliminary qualitative insights and clinical observations suggest that deeply held misconceptions—such as the erroneous equation of PCA with drug addiction, exaggerated fears of side effects, and concerns about financial cost—may be powerful deterrents.[9] However, a systematic, large-scale investigation into the prevalence and relative importance of these factors is lacking. Emerging evidence further indicates that misconceptions about opioid-based analgesia and fear of addiction are more prevalent among older adults and those living in rural areas,[11,12] where health literacy regarding analgesics is often lower. This underscores the need to explore how these and other sociodemographic variables influence PCA refusal.

This knowledge deficit limits the development of patient-centered communication strategies. Current preoperative consultations often fail to adequately address these underlying patient concerns, potentially resulting in refusal and subsequent undertreatment of pain. Therefore, this study proposes a mixed-methods approach to thoroughly investigate the phenomenon of PCA refusal. The objectives are threefold: to quantify the incidence of refusal, to identify key predictive factors through quantitative methods, and to explore the underlying reasons and decision-making processes through qualitative interviews. The goal is to generate an evidence base that can inform the creation of targeted interventions to improve patient education, shared decision-making, and overall postoperative pain management outcomes.

# Methods

## Study Objectives

1. To determine the incidence of patient refusal of PCA after a standardized preoperative anesthesiology consultation.
2. To identify the sociodemographic, clinical, and cognitive factors associated with PCA refusal.
3. To explore, through qualitative interviews, the reasons, perceptions, and decision-making processes of patients who refuse PCA.

## Study Design

This is a prospective, single-center, mixed-methods cohort study. The study will adhere to the STROBE guidelines.

## Ethical Considerations

The study protocol has been approved by the Institutional Review Board of Zhengzhou Central Hospital Affiliated to Zhengzhou University (Approval number: ZXYY2025169) and registered on the Chinese Clinical Trial Registry

(ChiCTR2600116056). The study will be conducted in accordance with the principles of the Declaration of Helsinki. Written informed consent will be obtained from all participants. All data will be de-identified to ensure confidentiality. Participants are informed that their decision regarding study participation will not affect their clinical care.

## Study Setting and Participant Recruitment

The study will be conducted at the Zhengzhou Central Hospital Affiliated to Zhengzhou University. Participant recruitment commenced in February 2026 and is ongoing, with anticipated completion in October 2026. On the day before scheduled surgery, a trained research nurse will screen all adult patients scheduled for procedures typically requiring postoperative PCA for eligibility based on the inclusion and exclusion criteria.

Inclusion Criteria: Patients will be eligible if they are (1) aged 18 years or older; (2) classified as American Society of Anesthesiologists (ASA) physical status I to III; and (3) scheduled for surgery under general anesthesia that is listed in the institutional PCA recommendation catalogue (see Supplementary File 1). This catalogue encompasses surgical procedures that are expected to produce moderate-to-severe postoperative pain (NRS $\geq$ 4) based on national and international expert consensus and historical pain outcomes.[13,14] Determination of eligibility will be performed by cross-referencing the patient's scheduled procedure with the catalogue, carried out by the trained research nurse during screening.

Exclusion Criteria: Patients will be excluded if they have (1) a known contraindication or allergy to any medication used in PCA (eg., opioids, NSAIDs); (2) severe cognitive impairment or communication barriers that preclude completing the assessment; (3) a current pregnancy or are lactating; or (4) declined to participate in the study.

## Study Procedures

A schematic overview of the study design and participant flow is provided in Figure 1.

1. Baseline Assessment and Informed Consent: Eligible patients will be approached by a research nurse on the day before surgery. After providing written informed consent, participants will complete a structured baseline questionnaire prior to their standard anesthesiology preoperative visit. This questionnaire will collect data on sociodemographics, clinical characteristics, and PCA-related knowledge and attitudes, as detailed in the "Measures" section. Before giving consent, patients will be explicitly informed that declining to participate in the study will not influence their subsequent clinical care or the PCA recommendation they receive from the anesthesiologist.
2. Standardized Anesthesiology Consultation: Following the baseline assessment, all patients will undergo a routine preoperative evaluation conducted by an anesthesiologist. This consultation will include a standardized segment for PCA recommendation, during which the anesthesiologist will: inform the patient of the likelihood of significant postoperative pain (NRS $\geq$ 4) and the medical recommendation for PCA; explain the principle, benefits, and safety features of PCA; disclose associated costs and insurance coverage details; and allow time for patient questions.
3. Decision Recording and Group Allocation: The patient's final decision regarding PCA use (acceptance or refusal) will be documented immediately after this consultation by the research nurse. Patients will subsequently be categorized into the "PCA Acceptance Group" or the "PCA Refusal Group" for analysis.
4. Qualitative Data Collection: All patients in the PCA Refusal Group will be invited to participate in a semi-structured interview conducted by a trained qualitative researcher. Using a flexible topic guide (see Supplementary File 2), these 5–10 minute interviews will explore decision-making motivations through open-ended questions (eg., "Could you please walk me through the main reasons behind your decision not to use PCA?"). With participant permission, interviews will be documented through detailed written notes by the researcher. Audio recording will not be used for two main reasons: first, patients in this clinical setting may be more willing to disclose sensitive information (eg., concerns about addiction or financial burden) when they are not being recorded, thus enhancing the candor of responses; second, written note-taking is more practical in a busy preoperative environment and minimizes workflow disruption. To minimize recall bias, researchers will expand the notes immediately after each interview session. To reduce filter bias, the interviewer will use a structured note-taking template aligned with the topic guide to ensure systematic capture across all domains, and will record participants' expressions in their own words as far as possible

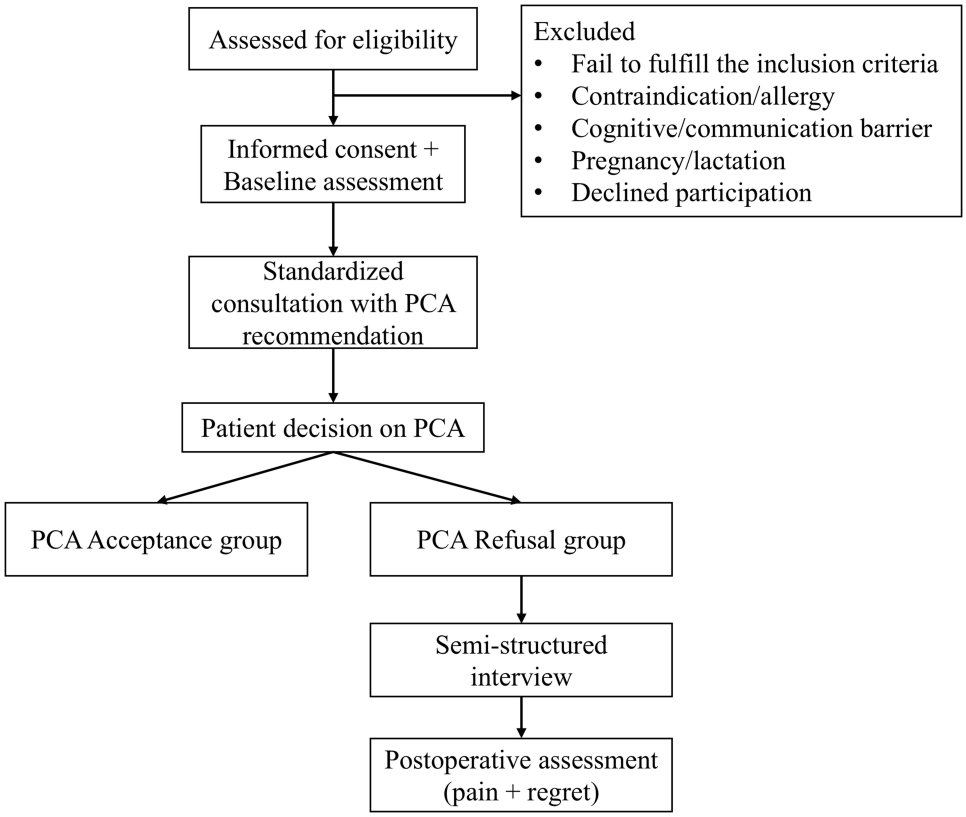


**Figure 1** Study flow diagram.
**Abbreviation**: PCA, patient-controlled analgesia.

rather than paraphrasing. In addition, the researcher conducting the interview and expanding the notes will not be the same person who performs the primary coding of that interview, ensuring that the analyst approaches the data without prior exposure to the live interaction. Interviews will continue until data saturation is reached, defined as the point at which subsequent interviews no longer yield new codes or themes relevant to the research question.[15] Saturation will be assessed iteratively through ongoing analysis by two researchers independently, and data collection will cease once consensus is reached that no new themes are emerging. Based on methodological literature on qualitative sample sizes, saturation is anticipated within 30–50 interviews;[15] however, recruitment will continue beyond this range if new themes continue to emerge. If the number of patients in the refusal group is insufficient to reach saturation (eg., due to a lower-than-expected refusal rate), the interview phase will be extended to include all eligible refusers.

5. Postoperative Assessment: At 24 hours after surgery, patients who refused PCA will be asked to rate the worst pain intensity experienced during the first 24 postoperative hours, both at rest and during activity, using the NRS pain score. Decision regret will be assessed through a structured, three-part inquiry: (1) Behavioral intention: "Knowing what you know now, if you could decide again, would you choose to accept PCA?" (Yes/No); (2) Subjective regret: "Do you regret your original decision to refuse PCA?" (Yes/No); (3) Attribution: "Could you briefly tell me why you feel that way?" With participant permission, the researcher will record this open-ended explanation in detailed written notes during the interview, which will then be categorized using content analysis to identify primary reasons for regret or non-regret.

## Data Collection

All data will be initially documented on paper-based Case Report Forms (CRFs). To ensure accuracy, data will be entered electronically and undergo a double-entry verification process. All collected data, both quantitative and qualitative, will be de-identified at the point of entry into the research database using unique study codes to ensure confidentiality.

Qualitative data will consist of the researchers' detailed written notes taken during the interviews, which will be reviewed and expanded immediately after each session to ensure completeness. These expanded notes will serve as the data for content analysis.

# Measures

## Independent Variables

The study will examine a comprehensive set of independent variables, which are categorized as follows:

Sociodemographic Factors: Sex, age, Body Mass Index (BMI), occupation type (manual labor/mental labor/unemployed), place of residence (urban/rural), education level (primary school and below/middle school to high school/college and above), and type of health insurance (Urban Employee Basic Medical Insurance/Urban and Rural Resident Basic Medical Insurance/commercial insurance/no insurance).

Clinical Characteristics: ASA physical status classification (I/II/III), history of chronic pain (yes/no), history of long-term analgesic use (yes/no), and documented diagnosis of anxiety or depression in the medical record prior to the current admission (yes/no).

PCA-Related Cognitions and Attitudes: Previous PCA use (yes/no), knowledge of PCA's purpose (yes/no), understanding of PCA operation (yes/no), concerns about cost (yes/no), consideration of drug side effects (eg., nausea, vomiting, respiratory depression; yes/no), belief that PCA impacts postoperative recovery (eg., wound healing, mobilization; yes/no), fear of addiction (yes/no), advice from relatives or friends received prior to the current decision regarding PCA use (recommend use/recommend against use/no advice), perceived tolerance of postoperative pain (yes/no), and preference for ward-based postoperative analgesia (yes/no).

## Dependent Variable

The primary dependent variable is patients' decision regarding PCA use, operationalized as a binary outcome (acceptance vs. refusal). "Refusal" indicates that the patient declined the use of PCA after the standardized preoperative recommendation.

## Primary Outcome

The incidence of PCA refusal among eligible patients.

## Secondary Outcomes

1. The factors associated with PCA refusal;
2. The qualitative reasons underlying the decision to refuse PCA;
3. Postoperative pain intensity among patients who refused PCA, measured as the worst NRS score at rest and during activity during the first 24 hours after surgery;
4. The proportion of patients who regret their decision to refuse PCA, and the reasons for regret or non-regret.

## Data Analysis

Statistical analyses will be performed using R software (version 4.4.3). Normality of continuous variables will be assessed using the Kolmogorov–Smirnov test. Normally distributed continuous variables will be presented as mean ± standard deviation, and non-normally distributed variables as median (interquartile range). Categorical variables will be presented as counts (percentages).

Primary quantitative analysis: To identify factors associated with PCA refusal, a two-step modeling approach will be employed. First, least absolute shrinkage and selection operator (LASSO) regression will be performed to select factors associated with PCA refusal from the full set of independent variables. The optimal penalty parameter ($\lambda$) will be determined through 10-fold cross-validation, based on the minimum mean squared error criterion. Variables with non-zero coefficients in the LASSO model will then be entered into a multivariable binary logistic regression model to identify factors associated with PCA refusal. A $p$-value of less than 0.05 will be considered statistically significant.

Qualitative analysis: All expanded written interview notes from patients who refused PCA will be combined into a single dataset for analysis. The expanded written interview notes will be analyzed using qualitative content analysis. This process will involve repeated reading of the notes to achieve immersion in the data, followed by the identification and extraction of all meaning units related to the reasons for PCA refusal. These meaning units will then be condensed, coded, and grouped into categories based on their shared content, forming the primary themes that explain patients' decision-making. Coding and initial category development will be performed independently by two researchers (Y.S. and G.Y.). They will then meet to compare their codes and resolve any discrepancies through discussion until consensus is achieved; if needed, a third author (Q.C.) will be consulted. The final thematic stratification is thus decided jointly by the two primary coders. Saturation will be assessed iteratively during data collection as described in the study procedures, ensuring that recruitment ceases once no new themes emerge. In addition, the free-text descriptions of reasons for regret or non-regret among patients who refused PCA will be analyzed using the same qualitative content analysis approach, with frequencies of each resulting category reported.

Secondary quantitative outcomes: Postoperative pain intensity among patients who refused PCA will be summarized using mean ± standard deviation or median (interquartile range) as appropriate for data distribution, separately for worst NRS scores at rest and during activity. The proportion of patients expressing decision regret (those answering "Yes" to the subjective regret question) will be reported as a percentage with an exact 95% confidence interval.

## Sample Size

The sample size was calculated for the primary quantitative objective of identifying factors associated with PCA refusal using multivariable logistic regression. Based on historical data (a 6-month audit) from our institution, the estimated refusal rate is 2.5%. The sample size was determined based on the events-per-variable (EPV) criterion. To accommodate the number of predictors likely to be retained by the LASSO selection (estimated up to 10) with an EPV of 10, a minimum of 100 refusal events is required. Therefore, to capture 100 events given a 2.5% refusal rate, a total sample size of 4,000 participants is needed (100/0.025 = 4,000). Enrollment will continue until 100 patients who refuse PCA have been accrued, ensuring that the required number of events is obtained even if the true refusal rate deviates from the estimate.

# Discussion

This protocol outlines a mixed-methods investigation into an important aspect of postoperative care: patient refusal of recommended analgesia. The combination of a large prospective cohort design with in-depth qualitative inquiry is a strength, allowing for both the quantification of the problem and an understanding of the patient experiences and beliefs that underlie it.

This mixed-methods design is anticipated to generate a multi-layered understanding of PCA refusal. The quantitative component will establish a statistical profile of patients who decline PCA and quantify the strength of association between various factors and the refusal outcome. The subsequent qualitative inquiry will then provide context and depth to these statistical associations, uncovering the lived experiences, reasoning processes, and nuanced perceptions that purely quantitative data cannot capture.

An explanatory sequential approach will be used to integrate the two components of the study. Specifically, the quantitative findings will first identify predictors associated with PCA refusal, and the qualitative findings will then be used to explain and contextualize these results. At the interpretation stage, the two sets of findings will be compared for convergence and complementarity to develop a more comprehensive understanding of patients' decision-making.

The integration of these findings is expected to yield a conceptual framework that maps the interplay between measurable patient characteristics and their subjective decision-making drivers. This evidence base is a prerequisite for moving beyond speculative explanations and towards the development of empirically grounded, patient-centered interventions aimed at addressing the underlying reasons for PCA refusal.

The findings of this research may inform clinical practice. By identifying the primary drivers of refusal, this study will provide the evidence base needed to redesign preoperative patient education. This could include the development of targeted informational leaflets, visual aids, or video materials that directly address common misconceptions and concerns.

Furthermore, the results can be used to train anesthesiologists in more effective, patient-centered communication techniques that proactively engage with these barriers during the preoperative consultation.

## Limitations

This study has several limitations inherent to its design that warrant careful consideration. First, the single-center design may limit geographic generalizability; however, the large sample and mixed-methods approach provide insights that are likely transferable to other tertiary-care settings with similar PCA practices. Second, because the cohort includes a broad spectrum of surgical procedures, clinical heterogeneity is introduced. Procedure-related pain trajectories vary substantially, and while we will adjust for relevant covariates (eg., type of surgery, anticipated pain level), residual confounding by surgical complexity cannot be fully excluded. Third, postoperative pain intensity was pragmatically recorded only in the refusal group because of the personnel resources required for a study of this size. This precludes direct analgesic-effectiveness comparisons between acceptors and refusers and limits the interpretation of pain-related secondary outcomes. Fourth, the qualitative arm carries risks of social desirability bias and recall bias (pain ratings at 24 hours), although trained interviewers and a neutral setting were employed to mitigate these. Fifth, as an observational study, no causal conclusions can be drawn; associations between cognitive factors and PCA refusal may still be influenced by unmeasured confounding or reverse causation. Finally, patients who consented to the semi-structured interview may differ systematically from those who declined, introducing potential selection bias into the qualitative findings. These limitations should be weighed alongside the study's pragmatic strengths when interpreting the results.

## Conclusion

In conclusion, this prospective mixed-methods study protocol aims to investigate an important area in postoperative care—patient decision-making regarding analgesia. By systematically exploring the incidence, associated factors, and reasons underlying PCA refusal, it is expected to generate evidence that may inform interventions designed to align clinical practice more closely with patient values and perceptions, ultimately striving to improve postoperative outcomes and the quality of surgical care.

## Trial Status

The protocol was finalized prior to recruitment launch. Patient recruitment commenced in February 2026 and is expected to be completed by October 2026.

## Data Sharing Statement

After the completion of the study, the datasets generated and analyzed during the study will be available from the corresponding author (Qinjun Chu) upon reasonable request. The data will be made available in accordance with the principles of data sharing and open access, while ensuring participant confidentiality.

## Ethics Approval and Consent to Participate

The study protocol has been approved by the Institutional Review Board of Zhengzhou Central Hospital Affiliated to Zhengzhou University (Approval number: ZXYY2025169) and registered on the Chinese Clinical Trial Registry (ChiCTR2600116056). The study will be conducted in accordance with the principles of the Declaration of Helsinki. Written informed consent will be obtained from all participants.

## Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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## Disclosure

The authors report no conflicts of interest in this work.

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