Cover page

Official Title:

Incidence of Postoperative Cognitive Decline in Surgical Patients With Preexisting Cognitive Impairment: A Prospective Cohort Study

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1. Background

Cognitive impairment is prevalent among the elderly population, with increasing rates as global aging accelerates. Preexisting cognitive impairment (PreCI) in surgical patients is associated with a higher incidence of postoperative cognitive decline (POCD), delirium, hospital readmission, and mortality. However, data regarding the incidence of POCD in Chinese patients with PreCI undergoing elective non-cardiac surgery under general anesthesia is currently lacking. This study aims to fill this evidence gap by prospectively investigating the incidence of POCD in this patient population.

2. Objectives

Primary Objective:

To determine the incidence of postoperative cognitive decline (POCD) at 3 months after surgery in elderly patients (≥60 years) with preexisting cognitive impairment undergoing elective non-cardiac surgery under general anesthesia.

Secondary Objectives:

To evaluate the incidence of POCD at 12 months postoperatively.

To assess neuropsychiatric symptoms (NPI-Q), functional abilities (BADL, IADL), and dementia severity (CDR) at 3 and 12 months postoperatively.

3. Study Design

A single-center, prospective, single-arm cohort study with a normative comparison group for RCI-based incidence calculation.PreCI Surgical Group: Elderly patients with cognitive impairment undergoing elective general anesthesia non-cardiac surgery. Normative Comparison Group: Cognitively normal elderly subjects for reference data of natural cognitive change over time.

4. Study Population

Inclusion Criteria (PreCI Group):

-Age ⩾ 60 years

-Diagnosed as having mild cognitive impairment or mild dementia by MMSE and MoCA-B screening

-Scheduled for elective non-cardiac surgery under general anesthesia

Exclusion Criteria:

-Expected difficulty in neuropsychological assessment (e.g., severe hearing/visual impairments, language barrier)

-Residence outside Shenzhen

Normative Comparison Group:

-Age ⩾ 60 years

-No history of general anesthesia surgery within the past 12 months

-Mini-Cog score > 1

Exclusion Criteria:

-Planned elective surgery under general anesthesia within the next 12 months

-History of suspected or diagnosed cognitive impairment, or screening indicating cognitive impairment using MMSE and MoCA-B

-Expected difficulty in completing neuropsychological assessments (e.g., inability to communicate in Mandarin, blindness, or deafness)

-Usual residence outside Shenzhen

5. Outcome Measures

Primary Outcome:

Incidence of POCD at 3 months postoperatively, defined using the Reliable Change Index (RCI) methodology.

Secondary Outcomes:

Incidence of POCD at 12 months

NPI-Q, BADL, IADL, and CDR scores at 3 and 12 months

6. Assessment Tools

Mini-Cog

MMSE

MoCA-B

NPI-Q

CDR

BADL, IADL

7. Sample Size Estimation

PreCI group: 252 patients (accounting for 15% attrition, based on estimated 14.9% POCD incidence at 3 months)

Normative group: 88 participants (allowing for 15% attrition)

8. Statistical Analysis Plan (SAP)

8.1 Descriptive Analysis:

Continuous variables will be expressed as mean ± SD or median (IQR) as appropriate. Categorical variables will be presented as frequencies and percentages.

8.2 Incidence of POCD:

POCD defined by RCI $\leqslant$ -1.96 in at least two cognitive domains or composite Z-score $\leqslant$ -1.96.

Frequencies and percentages reported at each follow-up time point.

Subgroup analysis based on surgery type, anesthesia type, baseline cognitive scores.

Intention-to-treat (ITT) analysis applied.

8.3 Handling of Missing Data:

Missing data imputed using multiple imputation techniques.

Sensitivity analyses conducted to evaluate robustness of results.

8.4 Adjustment for Confounding:

Multivariable logistic regression used to adjust for potential confounders: age, sex, education, comorbidities, surgery type.

8.5 Statistical Software:

All analyses performed using R software

9. Data Management

Data recorded via electronic and paper CRFs. Regular data monitoring, double data entry, and periodic audits to ensure data quality.

10. Ethics and Informed Consent

Study approved by the Ethics Committee of Peking University Shenzhen Hospital. Written informed consent obtained from all participants or their legal representatives before enrollment.

11. Publication Plan

Results will be published in peer-reviewed journals and presented at relevant academic conferences.