Clinical observation and risk factor analysis of the incidence of postoperative PTSD in children

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1. Research Background

Child mental health has become a key concern for society. According to data from UNICEF and the World Health Organization, about 20% of the 1.2 billion adolescents aged 10 to 19 worldwide experience mental health problems. In China, approximately 17.6% of children and adolescents suffer from various levels of psychological issues. Adverse psychological experiences during childhood often continue to affect their emotions, behaviors, and social adaptability as they grow older.

Preoperative anxiety, pain, unfamiliar hospital environments, and uncertainty about surgery may lead to the development of Post-Traumatic Stress Disorder (PTSD) in children undergoing general anesthesia. Severe anxiety not only increases the risk of PTSD but also raises the likelihood of postoperative bleeding and hematoma. Repeated exposure to general anesthesia may further negatively impact a child's mental health.

Studies have shown that 10.2% of children aged 6 to 13 who undergo surgery under general anesthesia develop PTSD postoperatively, and 26.4% exhibit at least one PTSD-related symptom. These children often present with behavioral withdrawal, separation anxiety, and sleep disturbances. Half of them may experience additional issues such as substance abuse, anxiety, depression, or even suicidal ideation.

Although perioperative psychological health in children is receiving increased attention, there is still a lack of data on the incidence of PTSD after general anesthesia in children and a systematic analysis of the associated risk factors.

References:

1. Potemra HMK, Lin J, Bertrand AA, et al. Long-Term Effect of Multiple Operations on Psychosocial Function in Teenage Cleft Lip and Palate Patients. *Plast Reconstr Surg.* 2020;146(1):61e–68e.
2. Ben Ari A, Margalit D, Udassin R, Benarroch F. Traumatic Stress among School-Aged Pediatric Surgery Patients and Their Parents. *Eur J Pediatr Surg.* 2019;29(5):437–442. doi:10.1055/s-0038-1660449

2. Research Objective

This study aims to investigate the incidence and associated risk factors of postoperative PTSD in children undergoing general anesthesia through a prospective, multicenter cohort design.

3. Study Design

3.1 Study Sites and Population

From August 10, 2025, to November 20, 2025, this study will recruit participants from three centers: Plastic Surgery Hospital, Chinese Academy of Medical Sciences (hereinafter referred to as “Plastic Surgery Hospital”), Beijing Children’s Hospital affiliated with Capital Medical University (hereinafter “Children’s Hospital”), and Capital Institute of Pediatrics affiliated with Capital Medical University (hereinafter “Pediatrics Center”).

The study will enroll children aged 6 to 12 years scheduled for elective surgery under general anesthesia. Exclusion criteria include: a history of psychiatric disorders or significant cognitive impairment, recent upper respiratory tract infection or severe pulmonary disease (within the past two weeks), undergoing emergency surgery or trauma-related surgery under general anesthesia, or preoperative chronic pain.

All perioperative data potentially related to the development of PTSD will be collected. Each patient will be followed up by email at one month and six months after surgery.

3.2 Inclusion and Exclusion Criteria

Inclusion Criteria:

- Children aged 6–12 years scheduled for elective surgery under general anesthesia.
- Parent or legal guardian provides informed consent and agrees to complete a 1-year follow-up.

Exclusion Criteria:

- History of psychiatric disorders (e.g., PTSD, anxiety disorders), substance abuse, long-term use of steroids or hormonal medications.
- Significant cognitive impairment that hinders understanding of study procedures.
- Emergency surgery or trauma-related procedures requiring urgent general anesthesia.
- Recent (within two weeks) upper respiratory tract infection or severe pulmonary disease.

Withdrawal Criteria:

- Serious adverse events: including but not limited to intraoperative anaphylactic shock, severe respiratory depression, cardiac arrest, etc.
- Voluntary withdrawal: participants can withdraw from the study at any time

without providing a reason.

- Non-compliance: inability or unwillingness to adhere to the study protocol and procedures.
- Investigator judgment: based on clinical assessment, the investigator may determine that continued participation poses a risk or is not appropriate.

3.3 Assessment Schedule

Step	Screening	Surgery Day (Day 0)	Postoperative Days	Day 30	Day 180
Informed Consent	✓				
Basic Clinical Information	✓				
Clinical Diagnosis		✓			
Medical History	✓				
Laboratory Tests	✓				
Child Trait Anxiety (STAI)	✓				
Child Anxiety Level (VAS)			✓ (Day 1–3)		
Child Depression (CDI, pre-op)	✓				
Child Depression (SMFQ)				✓	
Child PTSD Symptoms (CPSS)	✓			✓	✓
Parent State Anxiety (STAI)	✓	✓	✓		
Parent Trait Anxiety (STAI)	✓				
Social Support (SSRS)	✓				
Inclusion/Exclusion Criteria	✓				

Step	Screening	Surgery Day (Day 0)	Postoperative Days	Day 30	Day 180
Surgery and Anesthesia Data		✓			
Preoperative Anxiolytics		✓			
Parental Satisfaction (Likert)				✓	
Post-op Pain (FPS-R)			✓ (Day 1–3)		
Anesthesia Complications		✓	✓		
Surgical Complications			✓	✓	
Safety Assessment	✓				
Adverse Event Monitoring			✓		
CRF Completion		✓			

3.4 Observational Indicators

1) Surgery and Anesthesia-related Factors:

- **Surgical type:** The specific name of the surgery will be recorded in detail and classified into four levels (I–IV) based on complexity, technical difficulty, and risk level.
- **Duration of anesthesia:** Measured in minutes.
- **Recovery time (PACU/ICU):** Time from entering PACU/ICU postoperatively to full recovery, measured in minutes.
- **Length of hospital stay:** Number of hospitalization days.
- **Preoperative anxiolytic medication/intervention:** Whether anxiolytic medication or psychological measures were used before surgery, and the type used.
- **Overall surgical satisfaction:** Measured using the Likert scale. Scores ⩾4 are

considered satisfactory, <4 are unsatisfactory.

- **Postoperative pain:** Evaluated using the Faces Pain Scale-Revised (FPS-R). Score 4 indicates mild pain, 6 moderate, 8 severe, 10 extreme. Pain scores on postoperative days 1, 2, and 3, as well as frequency, will be recorded. Pain is defined as clinically significant if the score is ⩾6 and lasts ⩾2 hours.
- **Anesthesia-related complications:** Evaluated using Clavien-Dindo classification. Grade ⩾II is considered moderate or higher.
- **Surgery-related complications:** Evaluated using Clavien-Dindo classification. Grade ⩾II is considered moderate or higher.

2) Child-related Factors:

- **Age and Gender:** Recorded in years and categorized as male/female.
- **Height and Weight:** Measured using standard protocol (cm and kg).
- **Anxiety level:** Preoperatively assessed by State-Trait Anxiety Inventory (STAI); postoperatively by Visual Analogue Scale (VAS).
- **Depression level:** Preoperatively measured with Children's Depression Inventory (CDI); postoperatively with Short Mood and Feelings Questionnaire (SMFQ).
- **Baseline PTSD screening score:** Assessed using the Child PTSD Symptom Scale (CPSS).
- **Number of previous surgeries under general anesthesia:** As reported by parents.
- **History of psychological trauma:** Based on parent or child report (e.g., history of abuse, accidents).
- **Preoperative psychological preparation:** Whether psychological counseling or education was provided before surgery.

3) Family-related Factors:

- **Parental anxiety levels:** Measured with STAI at preoperative, intraoperative, and postoperative stages.
- **Single-parent status:** Recorded as 0 = non-single-parent, 1 = single-parent.
- **Only child status:** 0 = has siblings, 1 = only child.
- **Parental educational level:** Assessed via questionnaire (junior high, vocational

school, high school, college, bachelor's, graduate).

- **Household income:** Recorded in 10,000 yuan increments annually.
- **Social support level:** Measured with the Social Support Rating Scale (SSRS).
- **Parent–child relationship type:** Categorized as 1. Democratic; 2. Indulgent; 3. Authoritarian; 4. Neglectful.

4. Data Management and Statistical Analysis Plan

Data Management:

All data will be managed via an electronic data capture (EDC) system operated by a third-party provider. This system is a standard tool in modern clinical research, ensuring data security, integrity, and traceability through role-based access control and audit trails.

Personally identifiable information such as name, ID number, or address will not be collected. All data will be de-identified (e.g., "Subject 001, a child from region X, age Y"), ensuring participant confidentiality even in the event of a data breach.

In case of a data breach:

- **Timely reporting** to data governance bodies and the ethics committee.
- **Investigation** into the cause, scope, and participant impact.
- **Corrective actions** such as system upgrades or enhanced encryption.
- **Policy revision** for better future protection.
- **Legal compliance** and assumption of any resulting responsibilities by the research institution.

Statistical Analysis:

- **Descriptive statistics:** Mean ± SD for normally distributed continuous variables; median (IQR) for skewed data; frequency (%) for categorical data.
- **Primary outcome:** Overall incidence of PTSD and 95% confidence interval (CI).
- **Secondary outcomes:** PTSD incidence at 1 month and 6 months post-op and 95% CI. Compare time-point differences using Chi-square or Fisher's exact test.
- **Risk factor analysis:**

    - **Univariate analysis:** t-tests for normal continuous variables, Mann-Whitney U test for skewed data, and Chi-square/Fisher's exact test for categorical variables.
    - **Multivariate analysis:** Variables with $P<0.1$ from univariate analysis will enter binary logistic regression to identify independent risk factors.
- **Subgroup analysis:** Based on clinical or demographic characteristics (e.g., age, sex, surgery type) to evaluate effect modifications.

5. Bias Control

- **Selection bias:** Minimized through clearly defined inclusion and exclusion criteria and data collection from multiple centers to enhance external validity.
- **Information bias:** Standardized data collection procedures, use of validated scales, and repeated assessments at multiple time points to minimize measurement errors.
- **Measurement bias:** Multiple instruments are used to assess not only children's psychological health but also environmental and family factors. All evaluators, particularly those assessing psychological outcomes, will be professionally trained and subject to regular quality control.
- **Confounding bias:** Multivariable regression models will adjust for potential confounders. At the design stage, confounders such as age and gender can be balanced using matching methods like Propensity Score Matching (PSM).
- **Attrition bias:** Strategies will include long-term follow-up and maintaining contact with participants. Appropriate methods for handling missing data will be applied to reduce bias.
- **Time bias:** Standardized follow-up time points are set to ensure data comparability.

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6. Quality Control

- All research staff will strictly follow SOPs and the approved study protocol.
- Data must be recorded promptly, directly, accurately, and clearly, with signatures and dates.
- Regular internal audits will be conducted to ensure data accuracy and completeness. Corrections must follow standardized procedures.

- Validated statistical software will be used for data analysis, and double data entry will be adopted for input accuracy.

7. Safety Assessment

- The study protocol adheres to clinical practice standards and is not expected to pose any serious risk to participant life or safety.

8. Adverse Event Reporting

- Definition of Adverse Events (AEs):
  AEs refer to negative outcomes during diagnosis or treatment caused by factors other than the natural course of the disease. In this study, common AEs may include emotional distress during follow-up (e.g., emotional fluctuations caused by recalling traumatic events, or repeated psychological assessments increasing psychological burden) and inconvenience from remote interviews affecting the accuracy or effectiveness of assessments.
- Documentation and Reporting of AEs:
  If an AE occurs during the study, the time of occurrence and handling details must be recorded in the original medical record. A serious AE form must be completed and submitted to the clinical research center within 24 hours for events that pose a significant threat to participant health or safety.
- Prevention and Handling of AEs:
  Before participation, children and their guardians will receive a detailed explanation of the study's purpose, procedures, potential risks, and benefits to ensure informed consent. Evaluations will be conducted by trained personnel using appropriate interview techniques to minimize psychological burden. A stable and reliable telemedicine platform with technical support will be used to ensure smooth remote assessments. Participants will be compensated for travel or time lost. A detailed AE reporting and handling protocol will be implemented for timely and appropriate responses.

9. Ethical Review and Informed Consent

- 9.1 Ethical Approval:
  The study protocol, informed consent forms, and participant-related materials were submitted to the Ethics Committee of the Plastic Surgery Hospital, Chinese Academy of Medical Sciences, and received approval on June 3, 2025 (Approval No. [2025] Registration No. 178). Researchers are required to submit an annual report to the ethics committee (if applicable). In case of study termination or completion, a written notification must be submitted. Any changes to the protocol or informed consent documents must be approved by the ethics committee prior to implementation, unless immediate changes are needed to

protect participants from direct risk, in which case the ethics committee will be informed afterward.

- 9.2 Informed Consent:
  Investigators must provide participants or their guardians with an easy-to-understand and ethics-approved informed consent form, allowing sufficient time for consideration. Written informed consent must be obtained before enrollment. Updated versions of consent forms and related information will be shared with participants during the study. All signed consent forms will be retained as essential clinical trial documents.

10. Publication Plan

- The results of this study may be published in medical journals. However, in accordance with legal requirements, all patient information will remain confidential. Personal data will not be disclosed unless required by law. If necessary, government regulatory authorities, the hospital ethics committee, and relevant personnel may access patient records as per regulations.