Public title

English: Prospective study of high-penetration super-resolution transcranial ultrasound for early identification of postoperative intracranial metallic targets after aneurysm clipping

Scientific title

English: Clinical Model-Based Evaluation of High-Penetration Super-Resolution Transcranial Ultrasound for Early Diagnosis of Intracranial Metallic Foreign Bodies in Patients After Intracranial Aneurysm Clipping

Scientific title acronym： HPSR-TCUS ClipDx

Study subject ID

2026-078

Approved by ethic committee

Yes

Approved No. of ethic committee

S2026-078-01

Name of the ethic committee

Medical Ethics Committee of Chinese PLA General Hospital

Date of approved by ethic committee

2026-02-05

Contact Name of the ethic committee

Jiang Cao

Contact phone of the ethic committee

+86010-66937166

Target disease

Postoperative status after intracranial aneurysm clipping (clinical model with implanted metallic clips)

Study type

Observational study

Study design

Prospective, single-center, blinded, controlled diagnostic accuracy study

Study phase

N/A (not a drug or therapeutic interventional phase study)

Objectives of Study

To evaluate the patient-level early diagnostic performance of high-penetration super-resolution transcranial ultrasound for identifying intracranial metallic targets, and to further assess clip-level detection, localization, agreement, and its complementary value to routine postoperative imaging.

Description for medicine or protocol of treatment in detail

This study does not alter routine clinical treatment. All participants will undergo standardized high-penetration super-resolution transcranial ultrasound within 3 hours after surgery. Postoperative CT is mandatory for all participants; CTA or other routine postoperative imaging will be obtained only when clinically indicated.

Inclusion criteria

1. Age 18–85 years;
2. Positive group: patients undergoing intracranial aneurysm clipping with implanted metallic clips; negative control group: postoperative craniotomy patients without implanted clips;
3. Ability to complete transcranial ultrasound within 3 hours after surgery;
4. Availability of postoperative CT;
5. Written informed consent from the participant or legally authorized representative.

Exclusion criteria

1. Inability to complete standardized transcranial ultrasound;
2. Missing postoperative CT;
3. Inability to establish the composite reference standard;
4. Presence of non-study-related metallic materials that may substantially interfere with target identification;
5. Withdrawal of consent;
6. Investigator judgment that continued participation is inappropriate.

Interventions

Positive group: standardized high-penetration super-resolution transcranial ultrasound within 3 hours after surgery, plus routine postoperative CT and CTA/other routine imaging when clinically indicated.

Negative control group: standardized high-penetration super-resolution transcranial ultrasound within 3 hours after surgery, plus routine postoperative CT.

Group

- Metallic-clip model group
- Negative postoperative control group

Sample size

- Positive group:39
- Negative control group: 39

Total sample size

78

Countries of recruitment and research settings

China

Beijing

Haidian District

The First Medical Center, Chinese PLA General Hospital

Tertiary A

Primary indicator

1.Outcome Name： Patient-level sensitivity for identifying the presence or absence of intracranial metallic targets

Measure time point of outcome： Within 24 hours after surgery upon completion of composite reference standard adjudication

Measure method： Index test compared against a blinded composite reference standard

2.Outcome Name： Patient-level specificity for identifying the presence or absence of intracranial metallic targets

Measure time point of outcome： Within 24 hours after surgery upon completion of composite reference standard adjudication

Measure method： Index test compared against a blinded composite reference standard

---

Participant age

18–85 years

Gender

Both

Randomization Procedure

None

Process of allocation concealment

None

Blinding

Image readers will be blinded to the composite reference standard; adjudicators of the composite reference standard will be blinded to ultrasound results; a second independent reader will perform blinded re-reading of the raw images. Full blinding is not claimed for image acquisition.

Rules of uncover or ceasing blinding

Not applicable

Length of follow-up

Primary endpoint adjudication within 24 hours after surgery; procedure-related discomfort recorded until completion of study-related in-hospital observation.

Statistical method

At the patient level, 2×2 contingency tables will be used to estimate sensitivity, specificity, PPV, NPV, and 95% confidence intervals (Wilson or exact method). At the clip level, generalized estimating equations or mixed-effects models will account for within-patient clustering. Categorical agreement: Cohen's kappa; continuous agreement: ICC and Bland–Altman. Prespecified sensitivity and subgroup analyses will be performed.

IPD sharing

Yes

The way of sharing IPD

After publication of the primary results, de-identified individual participant data, the data dictionary, and essential protocol information may be made available through controlled access upon reasonable request and subject to ethics approval, rather than through unrestricted public release.

Data collection and Management

Data will be collected and managed using standardized case report forms (CRFs) and the hospital electronic data capture (EDC) system [to be specified]. Raw imaging data will be archived in de-identified form. Double checking, logic checks, and blinded data review will be implemented.

Data and Safety Monitoring Committee

No independent DSMC will be established for this minimal-risk diagnostic accuracy study; oversight will be provided by the study team, the institutional ethics committee, and routine clinical safety systems.