Comparison of the Sensitivity of Probe-Based Confocal Laser Endomicroscopy and Pathological Biopsy for Gastric mucosal lesions

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1. Study Title

Comparison of the Sensitivity of Probe-Based Confocal Laser Endomicroscopy and Pathological Biopsy for Gastric mucosal lesions before Endoscopic Submucosal Dissection

2. Study Design

This is a single-center, retrospective observational study designed to compare the diagnostic performance of Probe-Based confocal laser endomicroscopy (pCLE) and pre-endoscopic submucosal dissection (ESD) pathological biopsy for gastric mucosal lesions, with the pathological results of ESD specimens as the gold standard.

3. Study Objectives

3.1 Primary Objective

To compare the sensitivity of pCLE and pre-ESD pathological biopsy in diagnosing positive gastric mucosal lesions (high-grade intraepithelial neoplasia and early gastric cancer) before ESD.

3.2 Secondary Objectives

To compare the secondary diagnostic indicators of pCLE and pre-ESD pathological biopsy, including **specificity**, **accuracy**, **positive predictive value (PPV)**, and **negative predictive value (NPV)** for positive gastric mucosal lesions.

4. Study Population

4.1 Source of Study Population

Patients who were admitted to our hospital and underwent both pCLE examination and ESD treatment during the study period will be enrolled retrospectively by reviewing electronic medical records, endoscopy databases, and pathological archives.

4.2 Sample Size Calculation

The sample size was calculated using PASS software (version 15.0). Based on preliminary data and clinical experience regarding the diagnostic sensitivity of pCLE and pathological biopsy for gastric mucosal lesions, a total sample size of 169 leisongs was determined to ensure the study has sufficient statistical power (α=0.05, β=0.20).

4.3 Inclusion Criteria

Patients aged between 18 and 75 years (inclusive) at the time of pCLE examination;

Patients who underwent pCLE examination before ESD and subsequently received ESD treatment.

4.4 Exclusion Criteria

Lack of pre-ESD pathological biopsy results;

ESD pathological results indicate advanced gastric cancer;

Incomplete clinical, endoscopic, or pathological data that affect result analysis.

5. Definitions of Diagnostic Outcomes

5.1 Gold Standard

The pathological results of ESD specimens, which are considered the gold standard for diagnosing gastric mucosal lesions due to their ability to provide comprehensive tissue assessment of the entire lesion.

5.2 Positive and Negative Results Definition

Positive results: High-grade intraepithelial neoplasia (HGIN) and early gastric cancer (EGC) confirmed by pathological results of ESD specimens.

Negative results: Low-grade intraepithelial neoplasia (LGIN), atrophic gastritis, and erosive gastritis confirmed by results of ESD specimens.

6. Study Procedures

6.1 Data Collection

A dedicated research team will retrospectively collect data from electronic medical records and relevant databases, including:

Demographic data: Age, gender, medical history, smoking/alcohol history, etc.;

Endoscopic data: Time of pCLE examination and ESD, location and size of gastric lesions, pCLE imaging findings;

Pathological data: Pre-ESD biopsy pathological results, ESD specimen pathological results (including lesion type, differentiation degree, invasion depth, etc.);

Treatment-related data: Intraoperative and postoperative complications.

6.2 Diagnostic Assessment

Two independent experienced endoscopists (blinded to ESD pathological results) will review and interpret pCLE images to determine whether the lesion is positive or negative according to the established diagnostic criteria for gastric mucosal lesions by pCLE. In case of disagreement, a third senior endoscopist will make a final judgment through consultation.

Pre-ESD pathological biopsy results will be directly extracted from the pathological reports issued by the hospital's pathology department, and classified as positive or negative based on the above definitions.

ESD pathological results will be used as the gold standard to classify each patient's lesion as positive or negative, and then compare the diagnostic performance of pCLE and pre-ESD biopsy.

7. Statistical Analysis

Statistical analysis will be performed using SPSS 26.0 software. Measurement data will be expressed as mean ± standard deviation (SD) or median (interquartile range) based on normality test results. Categorical data will be expressed as counts (percentages).

Diagnostic indicators (sensitivity, specificity, accuracy, PPV, NPV) of pCLE and pre-ESD biopsy will be calculated with ESD pathology as the gold standard. The 95% confidence intervals (95% CI) of these indicators will be computed.

The difference in diagnostic performance between the two methods will be compared using the McNemar test. A two-tailed P-value < 0.05 will be considered statistically significant.

8. Quality Control

Data collection: A standardized data collection form will be used, and two researchers will independently extract data. Discrepancies will be resolved by consulting the original medical records and consensus with a third researcher.

pCLE interpretation: Only endoscopists with more than 3 years of experience in pCLE diagnosis will participate in image interpretation, and blinding to ESD results will be strictly implemented to avoid bias.

Pathological confirmation: ESD and pre-ESD biopsy specimens will be diagnosed by senior pathologists in the department of pathology, ensuring the accuracy of the gold

standard.