Clinical research protocol

The application of extracellular vesicle detection in gastric juice based on metamaterial sensing in the diagnosis of gastric cancer and related diseases

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1. Research background

Gastric cancer is an important type of cancer worldwide, ranking fifth in terms of global cancer incidence and fourth in terms of mortality.[1] In fact, the majority of gastric cancer cases are diagnosed at an advanced stage, with a poor prognosis and limited treatment options.[2] The 5-year survival rate for early-stage gastric cancer is over 90%, while that for advanced gastric cancer is only about 10%.[3]

Therefore, early and precise endoscopic examination is of great significance in reducing the mortality rate of gastric cancer and improving the prognosis of patients. Gastric juice is a digestive fluid that directly contacts the gastric tissue and bypasses the metabolic function of the liver. It contains a large number of shed malignant cells and tumor products, which makes it possible to be an ideal biomarker with satisfactory sensitivity and specificity.[4]

At present, many researchers have begun to focus on gastric juice as a research subject, mainly concentrating on the study of nucleic acid molecules such as miRNA, cirRNA, lncRNA, and microRNA in gastric juice. These molecules are believed to be related to the development and progression of gastric cancer and thus can be used for the diagnosis and prognosis analysis of gastric cancer.[5, 6, 7]

In the existing research, studies on extracellular vesicles in gastric juice are scarce. As an important component of functional molecules in the body, extracellular vesicles play a key role in the development and progression of diseases. By deeply exploring the composition of extracellular vesicles in gastric juice, we can investigate their potential role in the development of gastric cancer, search for possible biomarkers, and thereby provide new clues and basis for the early diagnosis, prognosis assessment, and treatment strategy formulation of gastric cancer.

References

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2. Purpose of research

This project aims to study extracellular vesicles in gastric juice under different disease conditions, screen out liquid biopsy markers for the early diagnosis of gastric cancer, and identify biomarkers for disease progression or high-risk populations to achieve early disease prediction, guide endoscopic detailed examination, and reduce missed diagnoses. The research will be conducted at Beijing Friendship Hospital, Capital Medical University. By analyzing the diagnosis and treatment process and gastric juice samples of patients undergoing gastroscopy, the characteristics of extracellular vesicles in gastric cancer patients will be determined, and further guidance for endoscopic detailed examination will be provided. We will conduct the research in accordance with the "Measures for the Ethical Review of Biomedical Research Involving Human Subjects" and the principles of the "Declaration of Helsinki".

3. Research contents

After obtaining informed consent from the patients, all the medical history and treatment records of the patients who underwent gastroscopy since the onset of the disease, as well as gastric fluid samples, including laboratory and imaging data, were collected and recorded. The medical history and treatment records and gastric fluid samples were analyzed and an article was written.

4. Study protocol

4.1. Study design

Observational study (retrospective)

4.2. Subjects

4.2.1 Study population: patients who underwent gastroscopy and treatment in Beijing Friendship Hospital, Capital Medical University from Dec. 2025 to Dec. 2026.

4.2.2 Research Center: Beijing Friendship Hospital Affiliated to Capital Medical University.

4.2.3 Planned enrollment: 100 patients, in which the ratio of gastric cancer and non-cancer patients was 1:1.

4.2.4 Inclusion and exclusion criteria

Inclusion criteria: 1. Patients underwent gastroscopy and treatment at the Endoscopy Center of Beijing Friendship Hospital, Capital Medical University, and received pathological biopsy. 2. Previous gastroscopy suggested the possibility of lesions. 3. No previous history of gastrointestinal cancer.

Exclusion criteria: 1. Patients could not cooperate with the examination or had contraindications to endoscopy. 2. Previous history of gastrointestinal tumors, gastrointestinal surgery, physical and chemical injuries of the gastrointestinal tract. 3. Severe bile reflux. 4. Take simethicone and other defoaming agents before examination. 5. Patients with serious diseases of heart, lung, kidney, brain, blood and other important organs.

4.3 Research process

1. Patients who met the inclusion criteria were enrolled, and the demographic and medical information of the subjects were collected, including name, gender, age, primary disease, past history, gastroscopic biopsy pathological report, etc.

2. the use of previous studies in gastroscopy drain to collect the clinical routine during the rest of the specimens of gastric juice, extracellular vesicle separation and metabonomics analysis, about 10 to 20 ml/time, according to the result of pathology for specimens of patients with gastric cancer patients and patients with gastric cancer group, the identification of potential biomarkers, diagnosis model is established.

4.4 Observation target

(1) Demographic data and clinical information: name, age, gender;

(2) Pathological results of endoscopic tissue biopsy;

(3) Physical and chemical properties of gastric juice (pH value, absorbance, etc.);

(4) Diagnostic analysis of extracellular vesicles in gastric juice.

4.5 Determination of Sample Size

This study is an observational and descriptive one, with no specific sample size requirement. However, based on current domestic and international literature reports, approximately 100 cases are expected to be needed. Meanwhile, adjustments will be made as appropriate considering the situation of patient loss to follow-up and incomplete sample information in our center that cannot be used.

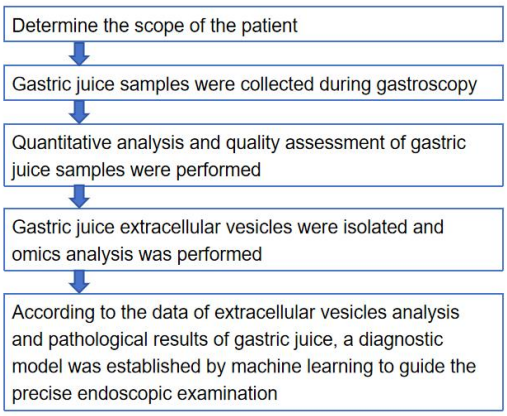
4.6 Informed consent situation

After confirming that the patients meet the inclusion and exclusion criteria, the principal investigator informs all the subjects of the experimental protocol. With the patients' consent, they sign the informed consent form.

4.7 Confidentiality of research information

The personal information of the subjects will be processed, stored and used in an anonymous manner. The information and data generated during the research process will be properly kept in accordance with the regulations. After the research is completed, the publication of the research results will not disclose the personal information of the subjects.

5. Technical route



6. Statistical method

Statistical software SPSS19.0 was used to analyze the data of this cohort study, and P value < 0.05 was considered statistically significant. For quantitative data, if the data were in accordance with the normal distribution, the mean ± standard deviation was used to describe the data. The t test was used for comparison between two groups, and the one-way analysis of variance was used for comparison between multiple groups. If the data did not meet the normal distribution, "median" was used to describe the data, and the differences were compared using the Mann-Whitney rank sum test. For qualitative data, "rate (95%CI)" was used to describe, chi-square test was used to compare the differences between groups, and Logistic regression was used for cross-sectional multivariate analysis of risk factors.

7. Quality Control

Formulate research plans to ensure the accuracy, completeness and comprehensiveness of data; record and preserve relevant documents for the purpose of retracing the quality control process; strictly keep patients' information confidential.

8. Description of Team Members' Qualifications and Division of Labor

Li Min (digestive internal medicine): project director, signed the participants informed consent.

Hao-Su Zhan (digestive internal medicine): responsible for screening/participants into groups, data collection, etc