INPLASY PROTOCOL

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Conflicts of interest:
None.

Efficacy of Raman Spectroscopy in Discrimination of Gastric Cancer: Protocol for A Systematic Review and Meta-Analysis

Jin, H[1]; Zhang, M[2].

Review question / Objective: **What is the pooled sensitivity, specificity and diagnostic accuracy of Raman spectroscopy on the diagnosis of gastric cancer?**
Condition being studied: **In the era of minimally destructive treatment, the early diagnosis is more important than anything. Diagnosis and treatment for gastric cancer is also following this innovation. Gastric cancer is one of the most common cancer in the world and second most common cause of cancer-related deaths. When gastric cancer is detected in an advanced stage, the 5-year survival rate is low: 10%–20%. Fortunately, the 5-year survival rates of patients with early gastric cancer, limited to the mucosa or the submucosa, were 99% and 96%, respectively. Currently, gastroscopy is still the major method for clinical detection of gastric cancer; however, those flat lesions or microlesions are easily overlooked and more difficult to biopsy. On the other hand, biopsy examination remains the gold standard for cancer diagnosis, but it is defective in its invasiveness, long waits, and complicated procedures. Therefore, it is really necessary to develop non-invasive, objective, and sensitive optical diagnostic technologies for detecting premalignant lesions and early cancers during endoscopy.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 December 2020 and was last updated on 21 December 2020 (registration number INPLASY2020120102).

INTRODUCTION

Review question / Objective: **What is the pooled sensitivity, specificity and diagnostic accuracy of Raman spectroscopy on the diagnosis of gastric cancer?**

Rationale: **The pooled sensitivity, specificity and accuracy of Raman spectroscopy will be calculated based on the extracted**

values of true positive, true negative, false positive and false negative values in the clinical trials. The aforementioned data can be extracted based on the charts that contain the primary data in the clinical trials.

Condition being studied: In the era of minimally destructive treatment, the early diagnosis is more important than anything. Diagnosis and treatment for gastric cancer is also following this innovation. Gastric cancer is one of the most common cancer in the world and second most common cause of cancer-related deaths. When gastric cancer is detected in an advanced stage, the 5-year survival rate is low: 10%–20%. Fortunately, the 5-year survival rates of patients with early gastric cancer, limited to the mucosa or the submucosa, were 99% and 96%, respectively. Currently, gastroscopy is still the major method for clinical detection of gastric cancer; however, those flat lesions or microlesions are easily overlooked and more difficult to biopsy. On the other hand, biopsy examination remains the gold standard for cancer diagnosis, but it is defective in its invasiveness, long waits, and complicated procedures. Therefore, it is really necessary to develop non-invasive, objective, and sensitive optical diagnostic technologies for detecting premalignant lesions and early cancers during endoscopy.

METHODS

Search strategy: Published literatures will be searched comprehensively and extensively from acknowledged authenticated databases including PubMed/Medline, Embase, OVID, Web of Science, Cochrane Library, ClinicalTirals.gov (http://www.ClinicalTrials.gov) and China National Knowledge Infrastructure (CNKI) for related articles published from January 2008 to November 2020. The guidelines of meta-analysis performance will be austerely followed certainly. Afterwards, according to the quality, relevancy and availability, we intend to filtrate the articles that we searched and identified before. No regional and language restriction are intended to be applied for the duration of the entire searching and filtration process. The keywords (query) of our primary search will be as follows: (((((((gastric carcinogenesis) OR (gastric carcinoma)) OR (gastric cancer)) OR (stomach cancer)) OR (gastric neoplasm)) AND (Raman spectroscopy)) OR (Raman)) OR (RS).

Participant or population: We include patients pathologically diagnosed with gastric cancer who simultaneously went through both the golden comparator and Raman spectroscopy.

Intervention: As far as we are concerned, our research is a diagnostic test. Therefore, the only intervention will be that the patients should undergo at least once Raman spectroscopy examination.

Comparator: The control will be those people who are disease-free or patients with other kinds of diseases other than gastric cancer.

Study designs to be included: Randomized controlled trial or applying any kind of observational designs, including cross-sectional, case-control and cohort designs.

Eligibility criteria: Inclusion criteria: 1) reporting the use of RS in gastric cancer; 2) being a randomized controlled trial and/or using any observational designs, including cross-sectional, case-control and cohort designs; 3) reporting the sensitivity, specificity values or true positive (TP), false positive (FP), true negative (TN) and false negative (FN) values, based on which sensitivity and specificity values can be calculated.

Information sources: Published literatures will be searched comprehensively and extensively from acknowledged authenticated databases including PubMed/Medline, Embase, OVID, Web of Science, Cochrane Library, ClinicalTirals.gov (http://www.ClinicalTrials.gov) and China National Knowledge Infrastructure (CNKI) for related articles published from January 2008 to

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Main outcome(s): The diagnostic sensitivity, specificity and accuracy.

Additional outcome(s): The positive likelihood ratio, negative likelihood ratio, diagnostic odds ratio.

Data management: Original parameters, indicating the diagnostic efficiency as well as basic information concerning this article itself, from those included studies will be analyzed by two proficient investigators independently. In the process, unexpected discrepancies will be cautiously discussed and resolved. Generally, 9 diagnostic efficiency related parameters will be extracted and further analyzed, including sensitivity, specificity, corresponding TP, TN, FP, FN values, accuracy and spectra data. What`s more, the title, first author, nationality, department, ethnicity, study design, sex and median age of the patients and enrollment year will also be extracted.

Quality assessment / Risk of bias analysis: The quality of each study will be evaluated based on the Quality Assessment of Diagnositc Accuracy Studies-2 tool. Moreover, the risk of bias will be acquired by RevMan 5.3 (The Cochrane Collaboration). We intend to assess the articles in the following processes: sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias) and others.

Strategy of data synthesis: In order to evaluate the diagnostic accuracy of Raman spectroscopy for gastric cancer, we are going to calculated the pooled sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), odds ratios (ORs) and diagnostic likelihood ratios (DLRs) with their 95% confidence intervals (CIs). The forest plots will be generated to display sensitivity and specificity estimates using Meta-Disc version 1.4 (Clinical Biostatistics Unit, UK). The bivariate model and the hierarchical summary receiver operating characteristic (HSROC) model will be used so as to summarize test performance [18]. We intend to use these methods to respect the binomial structure of diagnostic accuracy data, thus jointly summarizing paired measures simultaneously, e.g. sensitivity and specificity or, positive and negative likelihood ratios (LRs). Meanwhile, as a random effects approach, given the prevalence of heterogeneity among included studies due to different or implied thresholds, bivariate /HSROC meta-analyses allow for pooled results. The above methods will be conducted by metandi (Meta-analysis of diagnostic accuracy using hierarchical logistic regression) command of STATA 14.2 (StataCorp, USA). Furthermore, we will generate summary receiver operator characteristics (SROC) curves to estimate the relationship between sensitivity and specificity. The area under curve (AUC) will be calculated to evaluate the overall performance of RS simultaneously. The SROC curved is made through Meta-Disc version 1.4 (Clinical Biostatistics Unit, UK).

Subgroup analysis: None.

Sensibility analysis: Not intend to do the sensitivity analysis.

Language: English.

Country(ies) involved: China.

Other relevant information: None.

Keywords: Gastric cancer.

Dissemination plans: We intend to publish the protocol, which will be the main dissemination plan.

Contributions of each author:

Author 1 - Hongyu Jin - The author came up with the plans of the research and did preliminary research. In the meantime, Hongyu Jin took charge of writing the original draft. Additionally, Hongyu Jin assisted Man Zhang in data processing and cross check the data extracted.
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Author 2 - Man Zhang - The author is responsible to research relevant clinical trials published so far and extract the original data.
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