# INPLASY PROTOCOL

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## Corresponding author: Min Wang

happywmin@126.com

### **Author Affiliation:**

PLA Strategic Support Force Medical Center.

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# Diagnosis using artificial intelligence based on the endocytoscopic observation of the gastrointestinal tumours: a systematic review and meta-analysis

Wang, M<sup>1</sup>; Chen, S<sup>2</sup>; Zhong, CQ<sup>3</sup>; Zhang, T<sup>4</sup>; Xu, YX<sup>5</sup>; Guo, HY<sup>6</sup>; Wang, XY<sup>7</sup>; Huang, X<sup>8</sup>; Zhang, SA<sup>9</sup>; Chen, Y<sup>10</sup>; Li, LY<sup>11</sup>.

Review question / Objective: With the development of endoscopic techniques, several diagnostic endoscopy methods are available for the diagnosis of malignant lesions, including magnified pigmented endoscopy and narrow band imaging (NBI). The main goal of endoscopy is to achieve the real-time diagnostic evaluation of the tissue, allowing an accurate assessment comparable to histopathological diagnosis based on structural and cellular heterogeneity to significantly improve the diagnostic rate for cancerous tissues. Endocytoscopy (ECS) is based on ultrahigh magnification endoscopy and has been applied to endoscopy to achieve microscopic observation of gastrointestinal (GI) cells through tissue staining, thus allowing the differentiation of cancerous and noncancerous tissues in real time. To date, ECS observation has been applied to the diagnosis of oesophageal, gastric and colorectal tumours and has shown high sensitivity and specificity.Despite the highly accurate diagnostic capability of this method, the interpretation of the results is highly dependent on the operator's skill level, and it is difficult to train all endoscopists to master all methods guickly. Artificial intelligence (AI)-assisted diagnostic systems have been widely recognized for their high sensitivity and specificity in the diagnosis of GI tumours under general endoscopy. Few studies have explored on ECS for endoscopic tumour identification, and even fewer have explored ECS-based AI in the endoscopic identification of GI tumours, all of which have reached different conclusions. Therefore, we aimed to investigate the value of ECS-based AI in detecting GI tumour to provide evidence for its clinical application.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 February 2023 and was last updated on 22 February 2023 (registration number INPLASY202320096).

### INTRODUCTION

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Condition being studied: Endocytoscopy (ECS) performs real-time cellular imaging using ultrahigh magnification to distinguish malignant from benign lesions.Artificial intelligence (AI)-assisted diagnostic systems have been widely accepted in diagnosing gastrointestinal (GI) tumours under general endoscopy. This paper aimed to investigate the diagnostic value of ECS-based AI in detecting GI tract tumours.

## **METHODS**

Participant or population: The inclusion criteria were as follows:(1) Study type: Diagnostic trials on ECS-based AI-assisted diagnostic systems for the diagnosis of gastric, oesophageal, and colorectal cancers published in English or completed clinical trials that have not yet been published.(2) Subjects: Patients who received ECS tests by an AI-assisted diagnostic system and yielded clear diagnostic results.(3) Diagnostic method: An AI-assisted diagnostic system based on any AI algorithm using the surgical pathological examination results as the gold standard.

Intervention: ECS-based diagnostic trials that rely on AI-assisted diagnostic systems for the diagnosis of gastric, oesophageal, and colorectal cancers.

**Comparator:** ECS-based diagnostic tests that do not rely on AI-assisted diagnostic systems for the diagnosis of gastric, esophageal and colorectal cancers.

Study designs to be included: Retrospective study.

**Eligibility criteria:** The gold standards for the tests were the pathological results.

Information sources: PubMed, Embase, Web of Web of Science,Cochrane Library, and on http://www.ClinicalTrials.gov

Main outcome(s): The Sen combined, Spe combined, +LR combined, -LR combined and their 95% confidence intervals (95% Cls), as well as the DOR were calculated. SROC curve analysis, including calculation of the AUC.

Quality assessment / Risk of bias analysis: Two researchers separately and simultaneously used the QUADAS-2, a risk of bias assessment tool, to assess the risk of bias for all target literature. After the assessment was completed, a test check was performed to improve the accuracy of the evaluation. Cochrane.

Strategy of data synthesis: Statistical analysis was performed using RevMan 5.4 and Stata 15.0. The 2×2 contingency table for the diagnosis of GI tract tumours by the **ECS-based AI-assisted diagnostic systems** was listed separately according to the gold standard. The Sen combined, Spe combined, +LR combined, -LR combined and their 95% confidence intervals (95% CIs), as well as the DOR were calculated. SROC curve analysis, including calculation of the AUC, was performed to evaluate the diagnostic value of the Al-assisted diagnostic systems.AUC values below 0.5, 0.5 to <0.7, 0.7 to 0.9 and above 0.9 indicate that the system had no, low, high and very high diagnostic value, respectively.

Subgroup analysis: None.

Sensitivity analysis: Combination sensitivity.

Language restriction: English.

Country(ies) involved: China.

**Keywords:** endocytoscopy; artificial intelligence; gastrointestinal tract tumours; systematic review and meta-analysis.

#### **Contributions of each author:**

Author 1 - Min Wang - WM performed the literature search and conducted the data analysis and drafted the manuscript. Email: happywmin@126.com Author 2 - Sheng Chen - performed the literature search and conducted the data analysis and drafted the manuscript. Email: chenshengemc@163.com Author 3 - Changqing Zhong - performed the literature search and conducted the data analysis and drafted the manuscript. Email: zcq123456789@126.com Author 4 - Tao Zhang - performed the literature search. Email: zt 102@163.com Author 5 - Yongxing Xu - performed the literature search. Email: xuyongxingstar@163.com Author 6 - Hongyuan Guo - conducted the data analysis and drafted the manuscript. Email: ghy1566@163.com

Author 7 - Xiaoying Wang - conducted the data analysis and drafted the manuscript. Email: yy\_xxww@163.com Author 8 - Xin Huang - conducted the data analysis and drafted the manuscript. Email: huangxinlvxudan@163.com Author 9 - Shuai Zhang - conducted the data analysis and drafted the manuscript. Email: edwardeffi@163.com Author 10 - Yan Chen - provided the idea for the review and revised the manuscript. Email: wjwcy@sohu.com Author 11 - Lianyong Li - provided the idea for the review and revised the manuscript. Email: lilianyong001@163.com