

INPLASY PROTOCOL

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Corresponding author:
Qingwei Ren

suprenqingwei@163.com

Author Affiliation:
Department of
Gastroenterology, Dongyang
Hospital of traditional Chinese
medicine, Dongyang, China.

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None declared.

Lymph nodes primary staging of colorectal cancer in 18F-FDG PET/MRI: A systemic review and meta-analysis

Ren, QW¹; Chen, YY²; Shao, XJ³; Guo, LZ⁴; Xu, XX⁵.

Review question / Objective: To assess the diagnostic efficacy of 18F-FDG PET/MRI for lymph node metastasis primary staging in patients with colorectal cancer (CRC).

Condition being studied: Recent studies found that 18F-FDG PET/MRI also grants CT extra effect in the identification of metastases and discrimination of ambiguous lesions, which improves diagnostic accuracy and efficiency. To date, there is no systematic review conducted to further validate the diagnostic performance of 18F-FDG PET/MRI for lymph node metastatic primary staging in CRC patients. We present this systematic review and meta-analysis expecting to provide evidence-based reference 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 26 November 2022 and was last updated on 26 November 2022 (registration number INPLASY2022110141).

INTRODUCTION

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METHODS

Participant or population: Lymph node metastasis in patients with colorectal cancer.

Intervention: 18F-FDG PET/MRI.

Comparator: No.

Study designs to be included: Retrospective or prospective.

Eligibility criteria: Studies that met the following criteria would be included: (i) Assessing the efficacy of 18F-FDG PET/MRI for LN metastasis identification; (ii) Histopathological results or image follow-up used as the golden standard for LN metastasis and TNM staging; (iii) Complete data available; retrospective or prospective. Studies reported and published in non-English, literature reviews, letters to the author, comments, case reports or case series, and studies with patients having recognized risk factors will be excluded.

Information sources: PubMed, Cochrane Library, and Embase.

Main outcome(s): The main outcomes include the sensitivity (SEN), and specificity (SPE) based on the data extracted, and calculate the 95% confidence interval (95%CI) of each variable and receiver operating characteristic (ROC) curve.

Quality assessment / Risk of bias analysis: Two reviewers independently proceed with the quality assessment of included studies via the Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2), which refers to 4 domains including patient selection, index test, reference standard, and flow and timing. Each domain will be graded as "high", "low", or "unclear". Disagreements will settle via discussion.

Strategy of data synthesis: A heterogeneity test will be conducted using I^2 statistic. An I^2 less than 50% with the p value greater than 0.1 indicate no significant heterogeneity considered among the included studies, then fixed-effect model

will be adopted, otherwise (I^2 greater than 50% with the p value less than 0.1), there will be significant heterogeneity and random-effect model will be used for meta-analysis. Spearman correlation coefficient is adopted for assessment of threshold-effect via Meta-Disc (version 1.4). Meta-regression and sensitivity analysis is performed for identifying and processing the heterogeneity. A p value less than 0.05 will be considered statistically significant. Deeks' funnel plot is used for publication bias assessment. An asymmetrical will indicate significant publication bias. The degree of asymmetry is determined using DOR logarithm regression against half of the proper sample size. When looking at the slope coefficient, a p value less than 0.05 indicated a significantly asymmetric funnel plot.

Subgroup analysis: We will conduct subgroup analyses according to the study characteristics, including sample size, race, and study-design, if the presence of heterogeneity is demonstrated.

Sensitivity analysis: Sensitivity analysis: The sensibility analysis will be conducted using Stata 15.

Language restriction: English.

Country(ies) involved: China.

Keywords: PET/MRI, Colorectal, Lymph node metastasis, FDG, Diagnosis, Meta-analysis.

Contributions of each author:

Author 1 - Qingwei Ren - Author 1 drafted the conceptualization, methodology, software, writing- original draft, data curation, and visualization.

Author 2 - Yanyan Chen - Author 2 drafted: the conceptualization, supervision, project administration, and funding acquisition.

Author 3 - Xuejun Shao - Author 3 drafted the investigation, writing - original draft, writing - reviewing and Editing.

Author 4 - Lanzhong Guo - Author 4 drafted the investigation, writing - original draft, writing - reviewing and Editing.

Author 5 - Xinxin Xu - Author 5 drafted the methodology, software, writing- original draft.

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