INPLASY PROTOCOL

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Corresponding author: Haowen Pang

2916551464@qq.com

Author Affiliation:

Department of Oncology, The Affiliated Hospital of Southwest Medical University Southwest Medical University.

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A systematic review and metaanalysis of 68Ga-FAPI PET for the evaluation in Digestive system tumors

Huang, DL¹; Wu, JH²; Zhong, HS³; Li, YF⁴; Han, YH⁵; He, YH⁶; Chen, Y⁷; Lin, S⁸; Pang, HW⁹.

Review question / Objective: We aimed to summarize the current evidence of 68Ga-FAPI PET/CT or PET/MR for the assessment of primary tumors, lymph node metastases, and distant metastases in digestive system tumors. Besides, we also aimed to perform a meta-analysis of the sensitivity of 68Ga-FAPI PET diagnosis to discriminate between digestive system tumors, primary lesions, and non-primary lesions (lymph node metastases and distant metastases)

Condition being studied: Digestive system tumors are one of the well-prevalent tumors in the world nowadays. The assessment of digestive system tumor metastasis by conventional imaging seems to be unsatisfactory. 68Ga-FAPI, which has emerged in recent years, seems to be able to evaluate digestive system tumor metastasis. We aimed to summarize the current evidence of 68Ga-FAPI PET/CT or PET/ MR for the assessment of primary tumors, lymph node metastases, and distant metastases in digestive system tumors. Besides, we also aimed to perform a meta-analysis of the sensitivity of 68Ga-FAPI PET diagnosis to discriminate between digestive system tumors, primary lesions, and nonprimary lesions (lymph node metastases and distant metastases).

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 September 2022 and was last updated on 12 September 2022 (registration number INPLASY202290051).

INTRODUCTION

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METHODS

Search strategy: We will search, with no time restrictions, the following databases for relevant English language literature: PubMed (MEDLINE), the Cochrane Central **Register of Controlled Trials (CENTRAL)** and Web of Science. The search string will be built as follows: (A) "Digestive" OR "Gastric" OR "Gastrointestinal" OR "Pancreatic" OR "Pancreas" OR "Pancreatic" OR " Colorectal" OR "Hepatic" OR "Hepatocellular" OR "Liver " AND (B) "Cancer" OR "Neoplasm" OR "Tumor" OR "Tumour" AND (C) "FAPI" OR "FAP" OR "fibroblast activation protein" AND (D) "PET" OR "PET/CT" OR "PET/MRI " OR "Imaging" .The electronic database search will be supplemented by a manual search of the reference lists of included articles.

Participant or population: (a) reviews, editorials, letters, overviews, guidelines; (b) case reports or small case series studies (studies with less than 10 patients with relevant data); and (c) articles not included in this review (e.g., studies reporting 68Ga-FAPI rather than digestive system tumors, studies applying imaging agents other than 68Ga-FAPI).

Intervention: Imaging results of 68Ga-FAPI PET/CT or PET/MR scans of patients with tumors and their lesions and metastases.

Comparator: Imaging results of 68Ga-FAPI PET/CT or PET/MR scans of non-tumor patients and their lesions and metastases.

Study designs to be included: Prospective Research and Retrospective study.

Eligibility criteria: (A). Number of cases less than 10 (B). Studies with unclear designations, such as studies with an expanded scope like abdominal tumors, which included both tumors of the digestive system and tumors of other parts of the body, were not fully described in the study. Therefore, this study was excluded.

Information sources: Search strategy - A comprehensive search was performed through PubMed/MEDLINE and Cochrane Library databases (search from build to July 12, 2022). The search strategy was (A) "Digestive" OR "Gastric" OR "Gastrointestinal" OR "Pancreatic" OR "Pancreas" OR "Pancreatic" OR " Colorectal" OR "Hepatic" OR "Hepatocellular" OR "Liver " AND (B) "Cancer" OR "Neoplasm" OR "Tumor" OR "Tumour" AND (C) "FAPI" OR "FAP" OR "fibroblast activation protein" AND (D) "PET" OR "PET/CT" OR "PET/MRI " OR "Imaging". No time limit was set for the database search, but a language limit was set, limited to English articles. There was no continued manual collection or contacting of authors for articles not published online. To achieve more rigorous selection criteria, two investigators (Li, Wu) manually screened the selected references.

Main outcome(s): Sensitivity of 68Ga-FAPI PET diagnosis to discriminate between digestive system tumors, primary lesions, and non-primary lesions (lymph node metastases and distant metastases).

Quality assessment / Risk of bias analysis:

The quality of studies included in the metaanalysis was assessed according to the revised Quality Assessment of Diagnostic Accuracy Studies tool (QUADAS-2). The latter was used to assess the risk of bias for the following criteria: patient selection, index test, reference test, and process/ time, while the applicability of patient selection, index test, and reference test was assessed.

Strategy of data synthesis: Random-effects model analysis was performed to assess sensitivity. Pooled data were given 95% confidence intervals (95% CI) and displayed using forest plots. Likelihood ratios greater than 2.00 or less than 0.50 and 95% CIs excluding 1.0 were considered statistically significant. Random-effects model analysis and forest plots were constructed using STATA version 15.1.

Subgroup analysis: We analyzed the patient sensitivity of 68Ga-FAPI PET/CT or PET/MR for tumors of the digestive system. Subgroup analysis was then performed, including primary and metastatic lesions. In addition, we performed subgroup analysis for each organ of the digestive system, such as gastric cancer and pancreatic cancer.

Sensitivity analysis: We determined the sensitivity of 68Ga-FAPI PET/CT or PET/MR by comparing the positive cases of 68Ga-FAPI PET/CT or PET/MR scans of gastrointestinal tumors with the pathological results.

Country(ies) involved: China.

Keywords: Digestive system tumors 68Ga-FAPI PET Gastric cancer68Ga-FAPI.

Contributions of each author:

Author 1 - Delong Huang. Email: 2916551464@qq.com Author 2 - Junhao Wu. Author 3 - Haoshu Zhong. Author 4 - Yunfei Li. Author 5 - Yuanhang Han. Author 6 - Yuhang He. Author 7 - Yue Chen. Author 8 - Sheng Lin. Author 9 - Haowen Pang.

Other relevant information: Delong Huang, Junhao Wu and Haoshu Zhong contributed equally to this work. Sheng Lin and Haowen Pang are co-corresponding authors, they contributed equally to this work.