Diagnostic performance of ^{18}F-FDG PET or PET/CT for detection of myocarditis

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Abstract

Objective: The purpose of the current study was to evaluate the diagnostic accuracies of fluorine-18-fluorodeoxyglucose (^{18}F-FDG) positron emission tomography (PET) or PET/computed tomography (CT) for diagnosis of myocarditis through and a meta-analysis. **Materials and Methods:** The PubMed, Cochrane database, and Embase database were searched from inception through November 30, 2022 for studies evaluating diagnostic performance of ^{18}F-FDG PET or PET/CT for diagnosis of acute myocarditis. Based on data extracted from patient-based analysis, we calculated the pooled sensitivity and specificity with the 95% confidence intervals (CI). Also, we calculated positive and negative likelihood ratios (LR+ and LR-), and constructed summary receiver operating characteristic curves. **Results:** Across 5 studies (6 results, 264 patients), the pooled sensitivity of ^{18}F-FDG PET or PET/CT was 0.57 (95% CI; 0.26-0.84) and a pooled specificity of 0.89 (95% CI; 0.74-0.96). Likelihood ratio (LR) syntheses gave an overall positive likelihood ratio (LR+) of 5.1 and negative likelihood ratio (LR-) of 0.48. The pooled DOR was 11 (95% CI; 2-47). In meta-regression analysis, no variable was the source of the study heterogeneity. **Conclusions:** Fluorine-18-FDG PET or PET/CT showed insufficient sensitivity and moderate specificity for diagnosis of myocarditis. These results indicated that cautious application of ^{18}F-FDG PET or PET/CT should be paid for detection of myocarditis.

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Introduction

Myocarditis is an inflammatory disease of the myocardium caused by various conditions including viral infection, autoimmune reaction, toxin exposure and drugs, or idiopathic causes [1]. The disease occurs more commonly in young adults, particularly in young men and is the major cause of death in young adults [2, 3]. Also, the disease is expected to account for significant cases of dilated cardiomyopathy [4].

Acute myocarditis can be either infectious or non-infectious in etiology. Infectious causes include viruses, bacteria, fungi, and protozoa, with viruses being the leading cause of infectious myocarditis [5]. The clinical presentations of myocarditis are very variable and non-specific, being from asymptomatic, to severe complicated myocarditis [6, 7].

The early and accurate detection of myocarditis still remains challenging as clinical symptoms are variable and no single test could confirm the diagnosis. The endomyocardial biopsy (EMB) is the gold standard method for the diagnosis of myocarditis with some limitations [8, 9]. The sensitivity of EMB for detecting active inflammatory myocardium is limited as a result of a high false-negative rate due to sampling error related to the patchy distribution nature of the disease, and severe complications occur in 0.1% to 0.5% of procedures [10].

Thus, accurate and non-invasion imaging techniques are clinically required for diagnosis of myocarditis. The traditional non-invasive anatomical imaging technique, cardiac magnetic resonance imaging (CMR) has become an essential tool in the diagnosis process of patients with myocarditis [1]. The degree of cellular uptake of fluorine-18-fluorodeoxyglucose (^{18}F-FDG) is influenced by the expression of glucose transporter proteins, which is enhanced in activated inflammatory cells as well as tumor cells. Thus, ^{18}F-FDG positron emission tomography (PET) or PET/computed tomography (CT) have been proposed to be useful imaging modalities in the diagnosis and management of patients with suspected infectious diseases [11-13]. However, the role of ^{18}F-FDG PET or PET/CT in myocarditis is still challenging and not fully established.

The purpose of the current study is to meta-analyze the published data on the diagnostic accuracies of ^{18}F-FDGPET or PET/CT for diagnosis of myocarditis, in order to provide more evidence-based data and to address further studies in the evaluation of diagnostic value of ^{18}F-FDG PET or PET/CT for detection of myocarditis.

Materials and Methods

We used the Preferred Reporting of Systematic Reviews and Meta-Analyses of Diagnostic Test Accuracy Studies (PRISMA-DTA) statement to improve the reporting of our research [14].

Data sources and search strategy

A structured approach was followed to identify the patient population, interventions, comparators, outcomes, and study design (PICOS criteria) [14]. We conducted electronic English-language literature searches of PubMed, Cochrane database, and Embase from the earliest available date of indexing through 30 November 2022. We also hand-searched the reference lists of identified publications for additional studies. The search strategy included both subject headings (MeSH terms) and keywords for the target condition (Acute myocarditis), the imaging techniques under investigation (^{18}F-FDG PET or PET/CT), and the interventions (Diagnosis). We used a search algorithm based on a combination of terms: (1) "PET" OR "positron emission tomography" OR "positron emission tomography/computed tomography" OR "PET/CT" OR "positron emission tomography-computed tomography" OR "PET-CT" AND (3) "Myocarditis".

Criteria for inclusion in the current study

Studies were eligible if the following PICOS criteria were met: a) Patient population consisted of acute myocarditis confirmed histologically; b) The imaging techniques with ^{18}F-FDG PET or PET/CT; c) Histopathologic analysis was available as a reference standard; d) The study outcome described acute myocarditis.

We excluded studies if a 2×2 table could not be extracted from the data, if there were fewer than 5 patients, and if multiple reports were published for the same study population. In the latter case, the most detailed or recent publication was extracted. Duplicate publications were excluded, as were publications such as review articles, case reports, conference papers, and letters, which do not contain the original data. Two researchers independently reviewed titles and abstracts of the retrieved articles, applying the above-mentioned selection criteria. Articles were rejected if clearly ineligible. The same two researchers then independently evaluated the full-text version of the included articles to determine their eligibility for inclusion.

Data extraction and quality assessment

Information about basic study (authors, year of publication, and country of origin), study design (prospective or retrospective), patients' characteristics and technical aspects were collected. Each study was analyzed to retrieve the number of true positive (TP), true negative (TN), false positive (FP), and false negative (FN) findings of ^{18}F-FDG PET or PET/CT and MRI for diagnosis of acute myocarditis according to the reference standard. Only studies providing such complete information were finally included in the meta-analysis. Quality of the included studies was assessed based on 15-item modified Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2) [15]. Two reviewers independently assessed each potentially eligible study and assigned them as a quality rating of "good," "fair," or "poor". Quality assessment was conducted based on following criteria: study design and presence of bias including selection, performance, recording, and reporting bias. Studies with high risk of bias were defined as poor quality, presence of moderate risk (did not affect the results) as fair quality, and those with minimal risk as good quality. Disagreements were settled with consensus decision. Disagreement between the 2 authors was resolved by discussion.

Data synthesis and analysis

All data from each eligible study were extracted. Categorical variables are presented as frequencies or percentages, and continuous variables are presented as mean values unless stated otherwise. Measures of the diagnostic performance, including sensitivity, specificity, and diagnostic odds ratios (DOR), are reported as point estimates with 95% confidence intervals (CI). A DOR can be calculated as the ratio of the odds of positivity in a disease state relative to the odds of positivity in the non-disease state, with higher values indicating better discriminatory test performance [16]. Between-study statistical heterogeneity was assessed using I2 and the Cochrane Q test on the basis of the random-effects analysis [17]. Publication bias was examined using the effective sample size funnel plot and associated regression test of asymmetry described by Deeks and colleagues [18]. We used the bivariate random-effects model for analysis and pooling of the diagnostic performance measures across studies, as well as comparisons between different index tests [19, 20]. The bivariate model estimates pairs of logit transformed sensitivity and specificity from studies, incorporating the correlation that might exist between sensitivity and specificity. We also used the model to create hierarchical summary receiver operating characteristic curves and to estimate the area under the curve [21]. When statistical heterogeneity was substantial, we performed meta-regression to identify potential sources of bias [22]. Two-sided $P \leq 0.05$ was considered statistically significant. Statistical analyses were performed with commercial software programs (STATA, version 13.1; Stata Corp LP, 4905 Lakeway Drive, College Station, TX, 77845, USA)and Meta-disc (version 1.4) downloadable freely from URL: http://www.hrc.es/investigacion/metadisc_en.htm.

Results

Literature search and selection of studies

After the comprehensive computerized search was perfomed

and references lists were extensively cross-checked, our research yielded 719 records, of which 103 records of duplicated abstracts were excluded after reviewing the title and abstract. Also, 247 non-relevant studies, 222 conference abstracts, 12 case reports, 12 letters, 20 editorial, 11 notes, and 79 review articles were excluded. Remaining 13 full text articles were assessed for eligibility and 8 articles were excluded due to insufficient data for the calculation of sensitivity and specificity of ^{18}F-FDG PET or PET/CT. Finally, 5 studies (6 results) were selected and were eligible for meta-analysisand no additional studies were found screening the references of these articles [23-27]. The characteristics of the included studies are presented in Table 1. The detailed procedure of study selection in the current meta-analysis is shown in Figure 1.

Table 1. *Characteristics of the included studies.*

Authors	Year	Country	Study design	Analysis	Patient number	M/F	Age (Range)	^{18}F-FDG dose (MBq)	Interpretation of PET	Gold-standard	Cause of myocarditis
Ederhy S	2022	France	R	PB	60	NA	66	NR	VA	EMB	ICI
Nagesh CM	2015	India	R	PB	36	17/19	9.8 (6-17)	5.2 MBq/kg	VA	Modified Jones criteria	RHD
Nensa F	2018	Germany	P	PB	55	31/24	NA	132±63	VA	EMB	NR
Ozawa K	2013	Japan	R	PB	29	18/11	48	5.8±1.8 MBq/kg	VA	EMB	NR
Peretto G	2022	Italy	P	PB	75	49/26	47	3.5-4.5 MBq/kg	VA	EMB	Arrhythmic

Analysis; PB, Patient-based, EMB; Endomyocardial biopsy, NA; Not available, NR; Not reported, Study design; R, Retrospective: P, Prospective

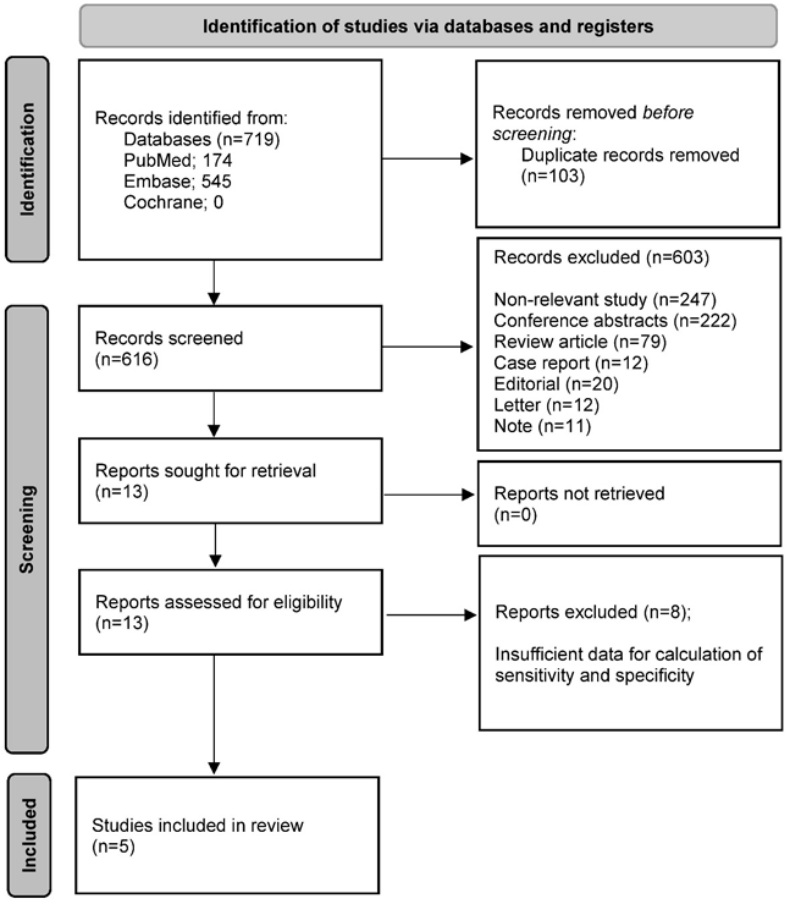

Figure 1. Flow diagram of the search for eligible studies on the diagnostic performances of ^{18}F-FDG PET or PET/CT for diagnosis of myocarditis.

Study description, quality, and publication bias

We conducted all analyses based on per-patient data analysis. There were a total of 255 patients in the included studies, and the age ranged from 6 to 66 years. One study did not report the sex distribution of their study cohort [23]. Three studies [23, 24, 26] enrolled patients retrospectively, and 2 studies [25, 27] collected the data prospectively. All studies used visual analysis for interpretation of ^{18}F-FDG PET or PET/CT images for detection of myocarditis. Three studies [23, 24, 27] described the cause of myocarditis and 2 studies 25, 26 did not reported the cause of the disease. The principal characteristics of 5 studies included in the meta-analysis are included in Table 1. To assess a possible publication bias, Deeks's funnel plot asymmetry tests were designed. The non-significant slope indicates that no significant bias was found. The P value was 0.43 (Figure 2).

Methodological quality assessment

According to the QUADAS-2 tool, overall risk of bias in patient selection was high in one study (20%), unclear in four (80%) studies. Risk of bias in the index test was high in one study (20%), unclear in two studies (40%), and low in two (40%). Risk of bias in the reference standard test was unclear in four (80%) studies, low in one study (200%). Flow and timing had high in one study (20%), unclear in two studies (40%), and low in two (40%). Applicability concerns in patient selection were unclear in two (40%) studies, and low in three (60%) studies. Applicability concerns in the index test were low in one (20%) study and unclear in three studies (60%). Applicability concerns in reference standard were low in all (100%) studies. Figure 3 shows methodological quality summary of included studies.

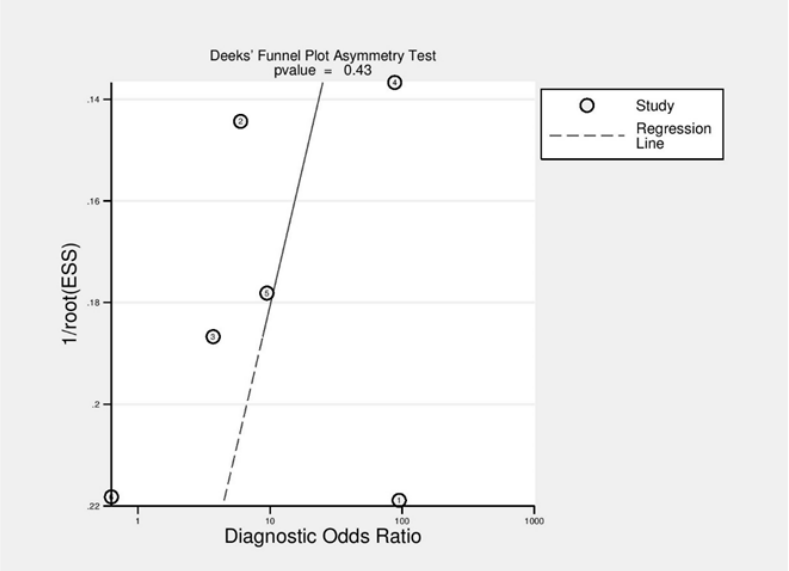

Figure 2. Results of Deeks`s funnel plot of asymmetry test for publication bias. Non-significant slope indicates that no significant bias was found. (ESS; Effective sample size).

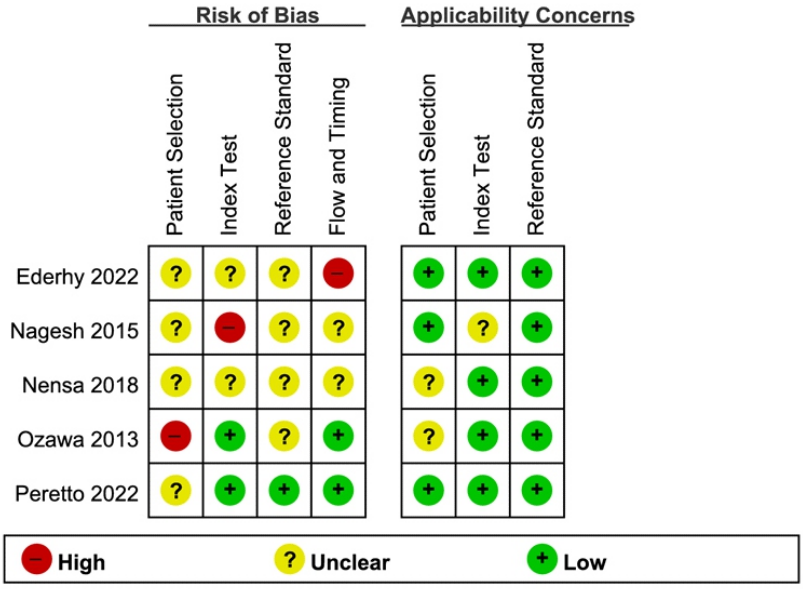

Figure 3. Risk of bias and applicability concerns summary.

Diagnostic performances of ^{18}F-FDG PET or PET/CT

The results of ^{18}F-FDG PET or PET/CT for diagnosis of acute myocarditis from 5 included studies (6 results) in the current meta-analysis are presented in Figure 4. The pooled sensitivity was 0.57 (95% CI; 0.26-0.84) with heterogeneity (I^2= 91.6, 95% CI; 86.6-96.7, P<0.001) and a pooled specificity of 0.89 (95% CI; 0.74-0.96) with heterogeneity (I2=61.9, 95% CI; 27.9-95.8, P=0.02). Likelihood ratio (LR) syntheses gave an overall positive likelihood ratio (LR+) of 5.1 (95% CI; 2.0-13.4) and negative likelihood ratio (LR-) of 0.48 (95% CI; 0.43-1.02). The pooled DOR was 11 (95% CI; 2-47). Figure 5 shows hierarchical summary receiver operating characteristic (ROC) curve and indicates that the areas under the curve (AUC) was 0.87(95% CI; 0.84-0.90) of ^{18}F-FDG PET or PET/CT.

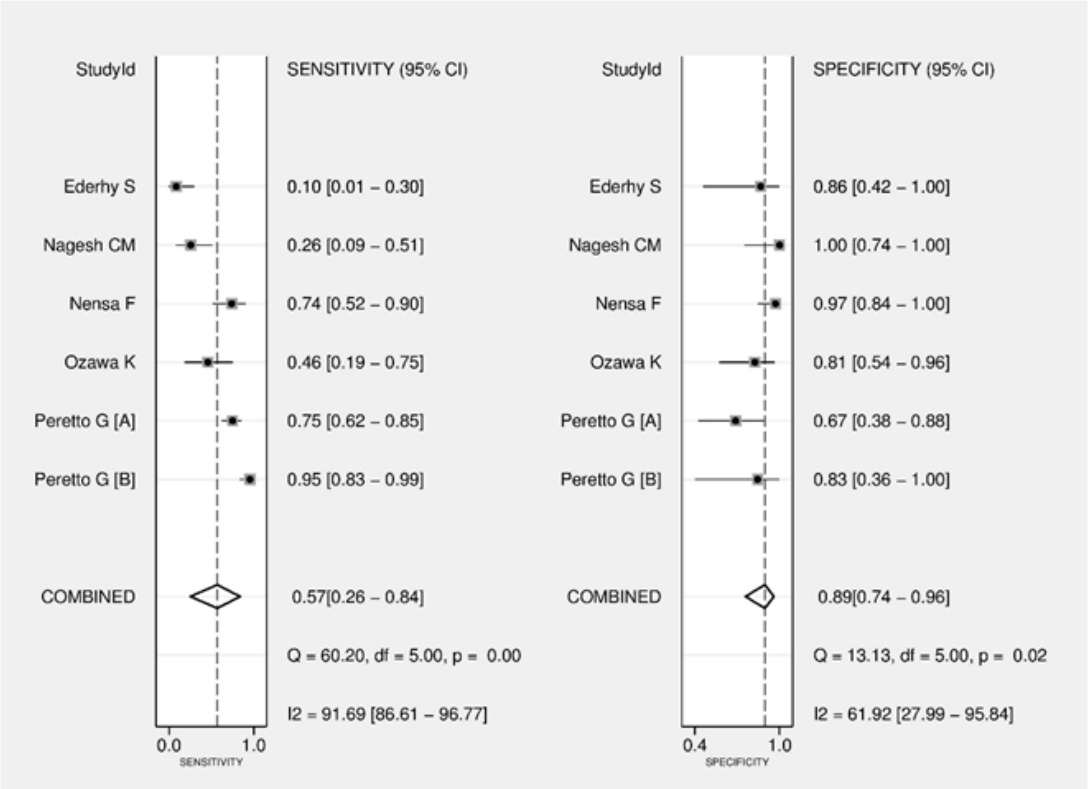

Figure 4. Forest plot of pooled sensitivity and specificity of ^{18}F-FDG PET or PET/CT for diagnosis of myocarditis.

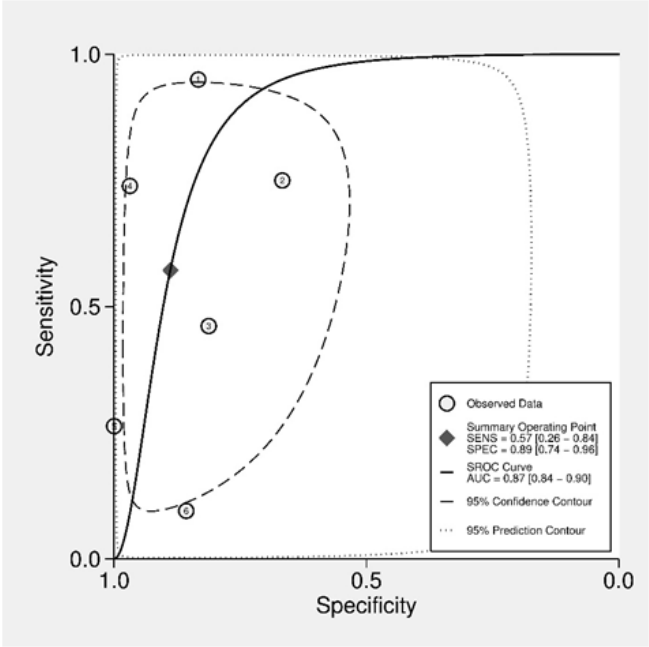

Figure 5. Summary receiver operating characteristic (SROC) curves for diagnosis of myocarditis using ^{18}F-FDG PET or PET/CT.

Heterogeneity evaluation and meta-regression analysis

Between-study heterogeneity was present among studies. A meta-regression analysis was performed to explore the potential sources of heterogeneity in the current studies (Table 2).Meta-regression analysis showed that no variable was the potent source of heterogeneity.

Likelihood ratio scatter-gram

Figure 6 shows the likelihood ratio scatter-gram which displays the summary point of likelihood ratios obtained as functions of mean sensitivity and specificity in the right lower quadrant suggesting that ^{18}F-FDG PET or PET/CT might not be useful for exclusion and confirmation of myocarditis.

Discussion

The current meta-analysis showed a low sensitivity and a moderate specificity of ^{18}F-FDG PET or PET/CT for diagnosis of myocarditis. Furthermore, the DOR was low and the likelihood ratio scatter-gram indicated that ^{18}F-FDG PET or PET/CT for diagnosis of myocarditis might not be useful for confirmation of presence of myocarditis and not for its exclusion.

The degree of cellular uptake of ^{18}F-FDG is influenced by the expression of glucose transporter proteins, which is enhanced in activated inflammatory cells as well as tumor cells. Thus, ^{18}F-FDG PET or PET/CT have been proposed to be useful imaging modalities in the diagnosis and management of patients with suspected infectious diseases [11-13]. Fluorine-18 FDG PET or PET/CT have been reported to as a useful diagnostic modality in identifying cardiac involvement of sarcoidosis [28, 29]. However, little is known, regarding the clinical usefulness of ^{18}F-FDG PET or PET/CT for diagnosis of

Table 2. *Effects of moderators.*

Variables	Coefficient*	SE	DOR	95% CI of DOR		P**
Population (Adult vs Pediatrics)	-2.988	3.1173	0.05	0	8026.2	0.5135
Study design (Prospective vs Retrospective)	2.879	2.3615	17.8	0	191.3	0.4373
Cause of myocarditis (Reported vs Not reported)	-1.785	1.9084	0.17	0	569.7	0.5212

** Regression coefficient. ** P-value of random effect meta-regression using maximum likelihood estimation (ML) between study variances and the weighted least squares of study size for regression model estimation.*
Population (1, Adult vs 0, Pediatrics); Study design (1, Prospective vs 0, Retrospective); Cause of myocarditis (1, Reported vs 0, Not reported).DOR; Diagnostic odds ratio, SE; Standard error, CI; Confidence interval

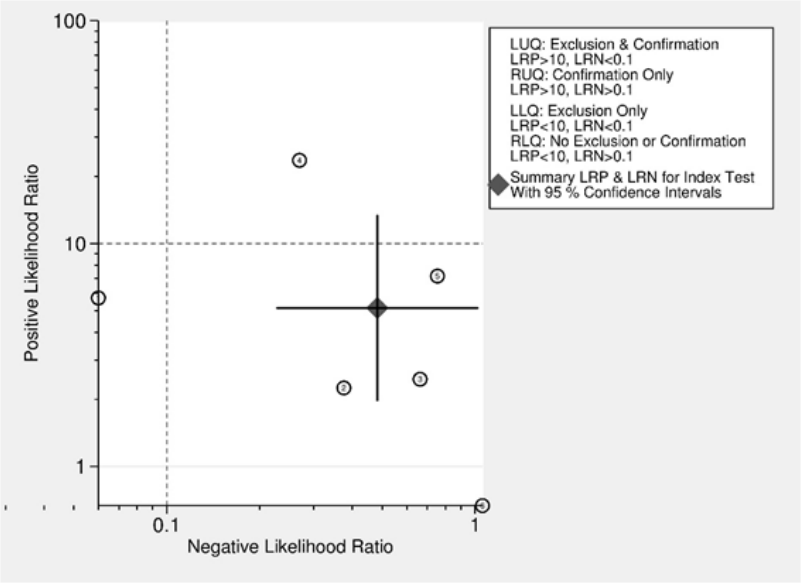

Figure 6. Likelihood ratio scatter-gram of ^{18}F-FDG PET or PET/CT for diagnosis of myocarditis.

myocarditis. Currently, the clinical evidence is limited to observational studies of ^{18}F-FDG PET or PET/CT for localization of infected sites of active inflammation in suspected acute myocarditis patients [26, 30].

In a study conducted in rheumatic carditis patients, ^{18}F-FDG PET or PET/CT showed low sensitivity for diagnosis and is not recommended as a routine imaging modality for the diagnosis of rheumatic carditis [24]. A recent study suggested that ^{18}F-FDG PET has a limited diagnostic value for the diagnosis of immune check point inhibitor (ICI) associated myocarditis with ^{18}F-FDG PET sensitivity for ICI-myocarditis is below 30% [23]. However, other recent study investigated the value of ^{18}F-FDG PET scan in arrhythmic myocarditis [27]. In their study, the sensitivity was 75% referring to EMB, and 73% to CMR and the specificity was 67% referring to EMB, and 59% to CMR [27]. They concluded that ^{18}F-FDG PET scan may be a clinically useful diagnostic technique in arrhythmic myocarditis, in particular when CMR is unsuitable because of irregular heartbeat or implantable cardioverter-defibrillator-related artifacts. In comparison with CMR (LGE and/or T2), Nensa et al. (2018) reported that sensitivity and specificity of ^{18}F-FDG PET was 74% and 97% with good agreement between CMR and PET [25].

The current meta-analysis showed a considerable heterogeneity of sensitivity and specificity between studies. The included studies were statistically heterogeneous in their estimates of sensitivity and specificity. This heterogeneity is likely to arise through diversity in methodological aspects between different studies and the basic differences among the patients in the included studies may have contributed to the observed heterogeneity of the results too. Also, major limitation was the time interval between beginning of myocarditis symptoms and ^{18}F-FDG PET or PET/CT imaging. Ozawa et al. (2013) tried to determine optimum periods for ^{18}F-FDG PET examination in subjects with suspected acute myocarditis, and compared ^{18}F-FDG PET with EMB using the latest definition of ^{18}F-FDG PET for inflammatory left ventricular myocardium [26]. They suggested that if possible, ^{18}F-FDG PET should be performed within 14 days after the onset to maintain high diagnostic accuracy compared with EMB [26]. The studies included in the current meta-analysis, the time interval of ^{18}F-FDG PET or PET/CT in suspected myocarditis patients showed wide range of periods and/or unknown time intervals. Also, one important factor should be considered for the source of inter-study heterogeneity of the current meta-analysis. One of the most critical areas for the detection of myocarditis is the optimal preparation of patients for a fasting ^{18}F-FDG PET/CT scans and diet preparations. The prolonged, greater than 12 hour fasting is supported to effectively achieve reduced serum insulin and glucose levels, and thereby suppress physiologic myocardial glucose influx in the myocardium [31]. The differences between the preparation protocols of the studies included in the meta-analysis might affect the diagnostic accuracy of ^{18}F-FDG PET/CT for detection of myocarditis and cause the heterogeneity of this meta-analysis. To minimize bias in the selection of studies and in the data extraction, reviewers who were blinded to the journal, author, institution, and date of publication independently selected articles based on the inclusion criteria, and scores were assigned to study design characteristics and examination results by using a standardized form that was based on the QUADAS-2 tool. Also, publication bias is a major concern in all meta-analyses as studies reporting significant findings are more likely to be published than those reporting non-significant results. We assessed the publication bias in our analysis by using funnel plots which showed no definite asymmetry.

In conclusion, in terms of diagnostic accuracies, ^{18}F-FDG PET or PET/CT should not be used for a routine diagnostic imaging modality in suspected myocarditis patients. Furthermore, cautious application of ^{18}F-FDG PET or PET/CT should be paid for detection of myocarditis.

The authors declare that they have no conflicts of interest.

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