INPLASY PROTOCOL

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Review Stage at time of this submission: **Preliminary searches.**

Conflicts of interest:
None.

Diagnostic accuracy of the Xpert MTB/RIF assay for tuberculous pericarditis: A protocol of systematic review and meta-analysis

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Review question / Objective: **This study aims to evaluate the diagnostic accuracy of Xpert MTB/RIF for tuberculous pericarditis (TBP) using meta analysis method.**
Condition being studied: **TBP is the most common reason for pericarditis in areas with high TB burden. TBP leads to an increased risk of constrictive pericarditis, cardiac tamponade, and mortality. Early diagnosis and treatment can reduce the mortality of TBP. The diagnosis of TBP is still challenging due to the low amount of bacteria in pericardial effusion. Xpert MTB/RIF is widely used in the diagnosis of extrapulmonary tuberculosis, and has achieved good diagnostic efficacy. However, the diagnostic accuracy of Xpert MTB/RIF on TBP has not been studied well.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 June 2020 and was last updated on 13 June 2020 (registration number INPLASY202060045).

INTRODUCTION

Review question / Objective: **This study aims to evaluate the diagnostic accuracy of Xpert MTB/RIF for tuberculous pericarditis (TBP) using meta analysis method.**

Rationale: **The application of Xpert MTB/RIF in the diagnosis of TBP has its unique advantages.**

Condition being studied: **TBP is the most common reason for pericarditis in areas with high TB burden. TBP leads to an**

increased risk of constrictive pericarditis, cardiac tamponade, and mortality. Early diagnosis and treatment can reduce the mortality of TBP. The diagnosis of TBP is still challenging due to the low amount of bacteria in pericardial effusion. Xpert MTB/RIF is widely used in the diagnosis of extrapulmonary tuberculosis, and has achieved good diagnostic efficacy. However, the diagnostic accuracy of Xpert MTB/RIF on TBP has not been studied well.

METHODS

Search strategy: The search strategies will be conducted by Guoacn Yu and Fangming Zhong. There will be no language restrictions on our search. Search strategy of PubMed will be as follows:
#1 "Pericarditis, Tuberculous"[Mesh] OR "Pericarditides, Tuberculous" OR "Tuberculous Pericarditides" OR "Tuberculous Pericarditis"
#2 "Tuberculosis"[Mesh] OR tuberculosis OR Tuberculoses OR "Kochs Disease" OR "Koch's Disease" OR "Koch Disease" OR "Mycobacterium tuberculosis Infection" OR "Infection, Mycobacterium tuberculosis" OR "Infections, Mycobacterium tuberculosis" OR "Mycobacterium tuberculosis Infections"
#3 "Pericardial Effusion"[Mesh] OR "Effusion, Pericardial" OR "Effusions, Pericardial" OR "Pericardial Effusions" OR Hemopericardium OR Chylopericardium OR Chylopericardiums
#4 #2 AND #3
#5 "Extra pulmonary tuberculosis" OR " Extrapulmonary tuberculosis"
#6 #1 OR #4 OR #5
#7 Xpert OR geneXpert
#8 #6 AND #7 Similar search formulae will be used for Embase, the Cochrane Library, CNKI, and Wanfang databases.

Participant or population: Patients with TBP.

Intervention: Xpert MTB/RIF.

Comparator: Comparator is not an obligatory criteria (single arm study can be enrolled if P, I ,O is satisfied because this study will measure the diagnostic accuracy of Xpert MTB/RIF for TBP).

Study designs to be included: Any types of studies can be enrolled.

Eligibility criteria: Inclusion criteria: full-text original studies, reference standards were well-defined and appropriate to the studies, the articles directly provided true positive (TP), false positive (FP), false negative (FN), and true negative (TN) values for the assay or included the data necessary to calculate these measures. Exclusion criteria: case reports, articles written in languages other than Chinese and English, studies with < 10 samples, conference reports, and abstracts without full articles.

Information sources: We will search PubMed, Embase, the Cochrane Library, the Wanfang database, and China National Knowledge Infrastructure (CNKI) for studies evaluating the diagnostic accuracy of Xpert MTB/RIF for TBP until June 2020. References cited in the included articles and reviews will be further explored for possible candidate studies.

Main outcome(s): Sensitivity, specificity, the area under summary receiver operating characteristic (SROC) curve (AUC) and their respective 95% confidence intervals (CIs).

Data management: Guocan Yu and Fangming Zhong will search databases based on the searching strategy (using Mesh keywords, Emtree keywords relevant to Xpert MTB/RIF and TBP). Literature search records will be imported into ENDNOTE X9.2 literature management software. The two investigators independently will assess the candidate articles by reviewing their titles and abstracts, followed by the full text, for inclusion. Discrepancies between the two investigators will be resolved by discussion with a third investigator (Hong Zheng). We will extract data including author name; year; country; TP, FP, FN, and TN values for the assay; reference standard; patient selection method; some steps (e.g., homogenization); specimen type; and

condition along with other parameters. The same two investigators independently extract the necessary information from each of the included articles; we cross checked the information they obtained. Discrepancies in the two data sets will be settled by a discussion with a third investigator, similar to that used during the literature selection phase. Data from studies against two different reference standards will be treated separately.

Quality assessment / Risk of bias analysis: Quality assessment of diagnostic accuracy studies-2 (QUADAS-2) will be used by 2 independent reviewers (Guocan Yu and Fangming Zhong) and the discrepancy between reviewers will be solved by discussion with a third investigator (Hong Zheng). Funnel chart was used to evaluate whether publication bias exists in the included studies.

Strategy of data synthesis: We will obtain the values corresponding to TP, FP, FN, and TN in each included study, and calculate the estimated pooled sensitivity and specificity of Xpert MTB/RIF associated with the 95% CI, against CRS or culture, using bivariate random-effects models. Forest plots for sensitivity and specificity will be generated for each study. The areas under summary receiver operating characteristic (SROC) curves (AUC) will be subsequently calculated. At least four published studies are required to perform the meta-analysis for predefined variable types. Data from studies against CRS and culture will be analyzed separately. Stata version 15.0 (Stata Corp., College Station, TX, USA) with the midas command packages will be used to generate forest plots of sensitivity and specificity with 95% CI for each study and carry out meta-analyses and meta regression analyses.

Subgroup analysis: If the necessary data are available, subgroup analyses will be done to evaluate the diagnostic accuracy of Xpert MTB/RIF for TBP. Such as different specimen type, patient selection method (convenience or consecutive), decontamination method (with or without N-acetyl-L-cysteine/sodium hydroxide), sample condition (fresh or frozen), method of homogenization (mechanical or otherwise).

Sensibility analysis: Sensitivity analysis is used to explore the source of heterogeneity when the heterogeneity is obvious.

Language: No.

Country(ies) involved: China.

Other relevant information: The strength of the body of evidence will be assessed using The Grading of Recommendations Assessment, Development and Evaluation (GRADE) guideline.

Keywords: Diagnostic accuracy, Xpert MTB/RIF, tuberculous pericarditis, meta-analysis.

Contributions of each author:

Author 1 - Guocan Yu - The author drafted the manuscript, searched databases, selected literatures, managed data and assessed quality.

Author 2 - Fangming Zhong - The author searched databases, selected literatures, managed data and evaluated quality.

Author 3 - Yanqin Shen - The author drafted and revised the manuscript.

Author 4 - Hong Zheng - The author provided statistical expertise, read, feedback and approved the final manuscript.