INPLASY PROTOCOL

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Support: **None**

Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest:
None.

Head-to-head comparison of the efficacy of Xpert MTB/RIF Ultra and Xpert MTB/RIF for the diagnosis of tuberculous pleurisy: 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 Ultra and Xpert MTB/RIF for the diagnosis of tuberculous pleurisy (TBP) head-to-head using meta-analysis method.**
Condition being studied: **Tuberculous pleurisy (TBP) is the most common extrapulmonary tuberculosis, but its early diagnosis is still very challenging. Xpert MTB/RIF Ultra is used in the diagnosis of extrapulmonary tuberculosis, and has achieved good diagnostic efficacy. However, head to head comparison of the diagnostic efficacy of Xpert Ultra and Xpert for TBP is still uncertain.**
Information sources: **We will search Embase, PubMed, the Cochrane Library, China National Knowledge Infrastructure (CNKI), and the Wanfang database for researches.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 August 2020 and was last updated on 26 July 2021 (registration number INPLASY202080047).

INTRODUCTION

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

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

Condition being studied: **Tuberculous pleurisy (TBP) is the most common**

extrapulmonary tuberculosis, but its early diagnosis is still very challenging. Xpert MTB/RIF Ultra is used in the diagnosis of extrapulmonary tuberculosis, and has achieved good diagnostic efficacy. However, head to head comparison of the diagnostic efficacy of Xpert Ultra and Xpert for TBP is still uncertain.

METHODS

Search strategy: Wenfeng Yu and Yanqin Shen will conduct the search strategies. No language restrictions in our search process. Search strategy of PubMed will be listed as follows: #1 "Tuberculosis, Pleural"[Mesh] OR "Pleural Tuberculoses" OR "Pleural Tuberculosis" OR "Pleural TB" OR "Tuberculoses, Pleural" OR "Pleurisy, Tuberculous" OR "Pleurisies, Tuberculous" OR "Tuberculous Pleurisies" OR "Tuberculous Pleurisy" OR "Pleural Effusion"[Mesh] OR "Effusion, Pleural" OR "Effusions, Pleural" OR "Pleural Effusions" OR "Extrapulmonary tuberculosis" OR "Extra pulmonary tuberculosis" #2 "Xpert Ultra" OR "GeneXpert Ultra" #3 Xpert OR GeneXpert #4 #1 AND #2 AND #3.

Participant or population: Patients with TBP.

Intervention: Xpert MTB/RIF Ultra.

Comparator: Xpert MTB/RIF.

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

Eligibility criteria: Full-text original researches that head to head comparison of the diagnostic efficacy of Xpert Ultra and Xpert for TBP will be included. Clear and appropriate reference standards are defined in researches. True positive (TP), false positive (FP), false negative (FN), and true negative (TN) values for the assay can be extracted or calculated directly from the studies. We will exclude case reports, articles written in languages other than Chinese and English, researches with < 10 specimens, conference reports, and abstracts without full articles.

Information sources: We will search Embase, PubMed, the Cochrane Library, China National Knowledge Infrastructure (CNKI), and the Wanfang database for researches.

Main outcome(s): The main outcome will be measured in terms of sensitivity and the specificity of the diagnostic test of interest. Sensitivity refers to the probability that the index test result will be positive in an infected case. Specificity refers to the probability that the index test result will be negative in a non-infected case.

Data management: Wenfeng Yu and Yanqin Shen will conduct the search strategies. Strategy of data synthesis: We will first obtain the values corresponding to TP, FP, FN, and TN in each included study, and calculated the estimated pooled sensitivity and specificity of Xpert MTB/RIF Ultra and Xpert MTB/RIF associated with the 95% confidence interval (CI), against CRS or culture. 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. I2 statistics will be used to assess heterogeneity between the studies and a reference standard. While 0% will indicate no observed heterogeneity, values greater than 50% will be considered to imply substantial heterogeneity. We will explore different types of samples, different patient selection method, decontamination methods, sample conditions, and homogenization as potential sources of heterogeneity, using subgroup and meta-regression analyses. At least four published studies will be required to perform the meta-analysis for predefined variable types. STATA (version 15.0; Stata Corp., College Station, TX, USA) with the midas command package or Meta-DiSc software version 1.4 (XI Cochrane Colloquium, Barcelona, Spain) were used to carry out meta analyses and meta-regression analyses.

Quality assessment / Risk of bias analysis: The two investigators will independently use a revised tool for Quality Assessment

of Diagnostic Accuracy Studies (QUADAS-2) to assess study quality separately and the discrepancy between reviewers will be solved by discussion with a third investigator (Da Chen). According to the PRISMA-DTA statement, systematic review and meta-analysis of diagnostic test accuracy studies was not required to assess publication bias.

Strategy of data synthesis: We will first obtain the values corresponding to TP, FP, FN, and TN in each included study, and calculated the estimated pooled sensitivity and specificity of Xpert TB/RIF Ultra associated with the 95% confidence interval (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. I2 statistics will be used to assess heterogeneity between the studies and a reference standard. While 0% will indicate no observed heterogeneity, values greater than 50% will be considered to imply substantial heterogeneity. We will explore different types of samples, different patient selection method, decontamination methods, sample conditions, and homogenization as potential sources of heterogeneity, using subgroup and meta-regression analyses. At least four published studies will be required to perform the meta-analysis for predefined variable types. 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 Ultra for TBP. Such as different specimen type, patient selection method, decontamination method, sample condition, method of homogenization.

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

Language: No restriction.

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 Ultra, tuberculous pleurisy, meta-analysis.

Contributions of each author:
Author 1 - Wenfeng Yu - The author drafted the manuscript, searched databases, selected literatures, managed data and assessed quality.
Author 2 - Yanqin Shen - The author searched databases, selected literatures, managed data and evaluated quality.
Author 3 - Pengfei Zhu - The author drafted and revised the manuscript.
Author 4 - Da Chen - The author provided statistical expertise, read, feedback and approved the final manuscript.