INPLASY PROTOCOL

To cite: Shen et al. Diagnostic accuracy of nucleic acid amplification tests for abdominal tuberculosis: a protocol of systematic review and meta-analysis. Inplasy protocol 202060030. doi: 10.37766/inplasy2020.6.0030

Received: 09 June 2020

Published: 09 June 2020

Corresponding author:
Guocan Yu

dabaitwo@163.com

Author Affiliation:
Hangzhou Red Cross Hospital

Support: **None.**

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

Conflicts of interest:
None.

Diagnostic accuracy of nucleic acid amplification tests for abdominal tuberculosis: a protocol of systematic review and meta-analysis

Shen, Y[1]; Fang, L[2]; Ye, B[3]; Yu, G[4].

Review question / Objective: **This study aims to evaluate the diagnostic accuracy of nucleic acid amplification tests for abdominal tuberculosis using meta-analysis method.**
Condition being studied: **Abdominal tuberculosis is a severe extrapulmonary tuberculosis, which can lead to serious complications. Early diagnosis and treatment are very important for prognosis and the diagnosis of abdominal tuberculosis is still difficult.**
Information sources: **PubMed, Embase, the Cochrane Library, the Wanfang database, and China National Knowledge Infrastructure**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 June 2020 and was last updated on 09 June 2020 (registration number INPLASY202060030).

INTRODUCTION

Review question / Objective: **This study aims to evaluate the diagnostic accuracy of nucleic acid amplification tests for abdominal tuberculosis using meta-analysis method.**

Rationale: **Nucleic acid amplification tests have their own unique advantages in the application of abdominal tuberculosis.**

Condition being studied: **Abdominal tuberculosis is a severe extrapulmonary tuberculosis, which can lead to serious complications. Early diagnosis and**

treatment are very important for prognosis and the diagnosis of abdominal tuberculosis is still difficult.

METHODS

Search strategy: #1 "Tuberculosis, Gastrointestinal"[Mesh] OR "Gastrointestinal Tuberculosis" OR "Intestinal tuberculosis" OR "Peritonitis, Tuberculous"[Mesh] OR "Tuberculosis, Peritoneal" OR "peritoneal tuberculosis" OR "Tuberculous ascites" OR "Tuberculous Peritonitis" OR "abdominal tuberculosis" OR "intra-abdominal tuberculosis" #2 ("Nucleic Acid Amplification Techniques"[Mesh] OR "Polymerase Chain Reaction"[Mesh] OR "Real-Time Polymerase Chain Reaction"[Mesh] OR "Reverse Transcriptase Polymerase Chain Reaction"[Mesh] OR "Multiplex Polymerase Chain Reaction"[Mesh] OR "genexpert"[tw] OR Xpert OR "genotype"[tw]) #3 #1 AND #2.

Participant or population: Patients with abdominal tuberculosis.

Intervention: Nucleic acid amplification tests.

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 nucleic acid amplification tests for abdominal tuberculosis).

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 English and Chinese, studies with < 10 samples, conference reports, and abstracts without full articles.

Information sources: PubMed, Embase, the Cochrane Library, the Wanfang database, and China National Knowledge Infrastructure.

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

Data management: Yanqin Shen and Likui Fang will search databases based on the searching strategy (using Mesh keywords, Emtree keywords relevant to nucleic acid amplification tests and abdominal tuberculosis). 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 (Guocan Yu). 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); test method; 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 (Yanqin Shen and Likui Fang) and the discrepancy between reviewers will be solved by discussion with a third investigator (Guocan Yu). 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 nucleic acid amplification tests 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. 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 nucleic acid amplification tests for abdominal tuberculosis. Such as different test method, 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: If the heterogeneity is obvious, sensitivity analysis is used to explore the source of heterogeneity.

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

Language: No.

Country(ies) involved: China.

Keywords: Diagnostic accuracy, nucleic acid amplification tests, abdominal tuberculosis, meta-analysis.

Contributions of each author:
Author 1 - Yanqin Shen - The author drafted the manuscript, searched databases, selected literatures, managed data and assessed quality.
Author 2 - Likui Fang - The author searched databases, selected literatures, managed data and evaluated quality.
Author 3 - Bo Ye - The author drafted and revised the manuscript.
Author 4 - Guocan Yu - The author provided statistical expertise, read, feedback and approved the final manuscript.