

INPLASY

Diagnostic accuracy of T2Candida for invasive candidiasis: a Bayesian systematic review and meta-analysis

INPLASY202380045

doi: 10.37766/inplasy2023.8.0045

Received: 10 August 2023

Published: 10 August 2023

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ADMINISTRATIVE INFORMATION

Support - None.

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

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202380045

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 August 2023 and was last updated on 10 August 2023.

INTRODUCTION

Review question / Objective What is the benefit in terms of diagnostic accuracy linked with the use of T2Candida for the diagnosis of invasive candidiasis, compared with standard methods, namely blood cultures?

Condition being studied T2Candida, based on T2 magnetic resonance technology, is a Food and Drug Administration (FDA) tool approved for the diagnosis of candidemia and invasive candidiasis, potentially rapidly detecting the five most commonly isolated *Candida* sp. in approximately 5 h directly from the whole blood. Invasive candidiasis (IC) has relevant attributable mortality and early appropriate antifungal treatment is associated with improved outcomes. Unfortunately, treatment of invasive candidiasis is frequently delayed, mainly since cultures of blood and specimens from deep-seated sites of infection present sensitivity of approximately 50% and slow turnaround times. T2Candida is a promising tool, a non-culture based diagnostic platform, that can

increase sensitivity and improve turnaround times when it comes to candidemia and IC.

METHODS

Search strategy An appropriate selection of keywords will consent to retrieve useful records from three medical databases.

Participant or population Patients affected by candidemia or IC.

Intervention T2Candida (index text).

Comparator Traditional diagnostic methods for IC, e.g. blood cultures (reference standard).

Study designs to be included Test accuracy studies having a cross-sectional design in which the index test result of each study participant is compared with the corresponding result, for the same participant, obtained with the reference standard (the two tests need to be performed at the same time).

Eligibility criteria To be included, the diagnostic accuracy studies will have to report sufficient detail to extract or calculate the number of true positives, false positives, false negatives, true negatives; namely, sufficient data to create a 2 x 2 table.

Information sources MEDLINE, EMBASE, SCOPUS.

Main outcome(s) Outcomes evaluated for the clinical utility of T2Candida for diagnosis candidiasis will include the performance characteristics of sensitivity, specificity, diagnostic odds ratios, likelihood ratios, positive predictive values (PPVs), and negative predictive values (NPVs). Factors influencing test performance and heterogeneity among studies will also be assessed.

Quality assessment / Risk of bias analysis The QUADAS-2 will be used for the assessment of risk of bias and applicability of primary studies included.

Strategy of data synthesis In the primary meta-analysis, we will pool assay sensitivities and specificities from the studies selected. Since blood cultures for *Candida* represent an imperfect reference standard, we will use latent class Bayesian bivariate random-effects model. This model accounts for the imperfect reference test estimating the true disease status of each participant by exploiting results from both the index and the reference test. Hence, as opposed to traditional bivariate models, this model does not imply that the reference test has a perfect (or near perfect) accuracy. For each analysis, we will present sensitivity and specificity estimates using the latent true disease status as the criterion standard, as well as pooled sensitivity and specificity. We will also compute 95% credible intervals (CrIs) for each result. Briefly, in a Bayesian framework, the 95%CrI for a parameter is the interval within which it is estimated to fall, with a probability of 95%.

All analyses will be performed by using the MetaBayes and MetaDTAr packages in the R environment.

Subgroup analysis If feasible, analyses will be conducted according to type of infections (candidemia vs IC) and other variables (e.g., adult vs pediatric patients).

Sensitivity analysis As a sensitivity analysis, we will also run a Bayesian meta-analysis considering blood cultures as perfect gold standard as well as frequentist random effects meta-analysis.

Language restriction English.

Country(ies) involved Italy.

Keywords *Candida*; T2Candida; diagnostic accuracy; Bayesian; meta-analysis; latent-class analysis; imperfect goldstandard.

Contributions of each author

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