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How to conduct a high-quality systematic review on diagnostic research topics

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ABSTRACT

The methodological rigour of original studies on a diagnostic or prognostic research topic, and systematic reviews of these primary studies, varies; improving overall quality is warranted. This paper, the second of the series, outlines key concepts and essential steps required to conduct a high-quality systematic review on diagnostic topics. It is comprised of six aspects: clarifying the project objectives; generating an appropriate research question; searching the literature and selecting study criteria; assessing risk of bias of eligible studies, reporting and analyzing data, and interpreting data and making conclusions. This review emphasizes clarifying the role of the index test(s), including the "PIRO" components in a diagnostic research question, setting a hypothesis and threshold for an accurate test if needed, searching for existing systematic reviews, assessing the risk of bias for individual studies using the Quality Assessment of Diagnostic Accuracy Studies (QUADAS)-2 tool, considering methodological heterogeneity before performing a meta-analysis, managing uninterpretable or inconclusive data, and assessing the overall quality of the aggregate evidence using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach. We believe clinicians and health researchers would benefit from this methodological training.

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1. Background

During our work to screen medical literature, we noticed that the methodological rigour of many publications on diagnostic or prognostic topics can be improved. We present a concise and clear series of reviews to help clinicians and health researchers to grasp the basic critical contents on how to conduct a high-quality original study or systematic review for diagnostic or prognostic research topics from a methodological perspective. This is the second paper in this series focusing on how to conduct a high-quality systematic review on diagnostic topics. The first article focused on how to conduct a high-quality original study on diagnostic research topics [1].

The key goal to conduct a systematic review on diagnostic topics is to provide the newest and most accurate information on a particular test or examination to assist clinicians, patients, and stakeholders, etc. to facilitate healthcare decision-making. While several existing methodological papers on the execution of diagnostic test systematic reviews were published over 10 years [2,3]; new techniques and tools have been developed since then. For example, ROBIS [4], an assessment tool for systematic reviews on treatment, diagnostic, or prognostic topics, has recently been published. The main objective of this tool was to present how to assess systematic reviews rather than how to conduct them. Another reporting checklist for diagnostic systematic reviews is currently under development – PRISMA-DTA [5]. The Cochrane handbook for systematic reviews of diagnostic test accuracy is a comprehensive guideline [6], but this handbook has 11 chapters and is in various stages of completion. Thus, there is a gap in the development and reporting advice available. Based on existing methodological norms, international quality standards associated with diagnostic tests, and our experience, we propose six strategies for clinicians and health researchers to produce a high-quality systematic review on diagnostic topics:

- Clarifying the project objectives
- Generating an appropriate research question
- Searching the literature and selecting study criteria
- Assessing the risk of bias of eligible studies
- Reporting and analyzing data
- Interpreting data and making conclusions

We will mainly use one of our previously published diagnostic systematic reviews as an example - multiparametric magnetic resonance imaging (MPMRI) in the diagnosis of prostate cancer [7].

2. Clarifying the project objectives

Diagnostic tests can be used to classify patients that can lead to appropriate treatment and outcome improvement. Ideally, studies that measure the effects of the test results on patient outcomes can directly assess the clinical utility of the diagnostic tests. However, in many cases, we only have studies with test accuracy outcomes; also in certain situations, treatment trials may not be required to assess the clinical value of the tests. For example, if a new index test has similar sensitivity to an old index test but also has other positive characteristics (e.g., the new index test is safer, more specific or less costly), we may conclude the new test is a good alternative to the old test without conducting a separate systematic review linking its performance to the specific treatment because the link was already established [8]. Lord and colleagues listed several circumstances where studies with test accuracy outcomes were sufficient to assess its clinical utility and contrasted circumstances where the data were incomplete [8].

It is also important to define the role of a new test when determining its clinical value. In general, there are three roles for a new test: replacement, triage, and add-on [9]. We have explained the three roles clearly in our first paper of this series [1]. Clarifying the role of the new test can help clinicians and health researchers to understand why this diagnostic question is important and how this new test may potentially change patient management and improve patient outcomes.

Additionally, a hypothesis is an option to be established regarding an acceptable minimum level of a new test's diagnostic accuracy (such as a sensitivity and specificity of $\geq$90%) or the non-inferiority of two or more new tests [10]. According to the hypothesis, the investigators of the systematic review can easily make conclusions based on whether the results of the tests reach the pre-planned clinical threshold or not. This clinical threshold is different from the test threshold for positivity, which is the cut-off point used for a positive test result.

3. Generating an appropriate research question

As recommended in our first paper, “PIRO” should be reflected in a diagnostic research question: “P” represents patients, “I” represents index test, “R” represents reference standard, and “O” represents outcomes. Diagnostic studies should include diagnostic accuracy outcomes (e.g., sensitivity and specificity) and can also include the direct benefits (convenience of a test performed at home), adverse effects, (e.g., complications for MPMRI) or burdens of a test (e.g., fewer biopsy cores needed from MPMRI). Studies that include outcomes based on the management from the test results can be regarded as intervention studies (e.g., mortality in patients with MPMRI followed by targeted versus that in patients with transrectal ultrasound-guided systematic biopsy). Here is an example of a diagnostic research question: For biopsy-naïve patients with an elevated risk of clinically significant prostate cancer (according to prostate-specific antigen [PSA] levels and/or nomograms), is MPMRI followed by targeted biopsy better than TRUS-guided systematic biopsy in detecting clinically significant prostate cancer and positively changing patient management, when

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