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Critical Appraisal of a Diagnostic Test Study

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Introduction

Be able to evaluate a diagnostic test is not an easy task. Diagnostic tests are invaluable tools used to distinguish between patients having a disease and those who have not. It is essential to be able to critically appraise published articles on a diagnostic test. The list of questions below can help you better appreciate and understand the diagnostic studies better. The Table 1 shows the checklists needed to make a critical analysis of a diagnostic test study [1-12].

Appraisal questions
Was there a clear question for the study to address? A question should include information about: population, test, setting and outcomes. A consecutive sequence or random selection of patients is enrolled. Inappropriate exclusions are avoided. This includes patients and settings match the key question.
Was the diagnostic test evaluated in a representative spectrum of patients (like those in whom it would be used in practice)? Was the reference standard applied regardless of the diagnostic test result?
Was the test (or cluster of tests) validated in a second, independent group of patients?
Was there a comparison with an appropriate reference standard? Is this reference test(s) the best available indicator in the circumstances?
Are the valid results of this diagnostic study important?

Sample Calculations		Target disorder		Totals
		Present	Absent	
Diagnostic test result	Positive	A (TP)	B (FP)	a+b
	Negative	C (FN)	D (TN)	c+d
Totals		a+c	b+d	a+b+c+d

Sensitivity=a/ (a+c) Specificity=d/ (b+d)
Likelihood ratio for a positive test result=LR+ =sens/(1-spec)
Likelihood ratio for a negative test result=LR- = (1-sens)/spec
Positive Predictive Value=a/ (a+b) Negative Predictive Value=d/ (c+d)
Pre-test probability (prevalence)= (a+c) / (a+b+c+d)
Pre-test odds=prevalence/ (1-prevalence)
Post-test odds=pre-test odds ´ LR
Post-test probability=post-test odds/ (post-test odds+1)
Accuracy (TP+TN) / (TP+FP+TN+FN)

Diagnostic Odds Ratio: LR+/LR– = (TP/FN) / (FP/TN)
Did all patients get the diagnostic test and reference standard?
Were both received regardless of the results of the test of interest? Check the 2 × 2 table (verification bias).
Was the reference standard applied regardless of the index test result? Is the diagnostic test available, affordable, accurate, and precise in your setting?
The index test results interpreted without knowledge of the results of the reference standard. If a threshold is used, it is pre-specified. The index test, its conduct, and its interpretation are similar to that used in practice with the target population of the guideline.
There is an appropriate interval between the index test and reference standard. All patients receive the same reference standard. All patients recruited into the study are included in the analysis.
Are test characteristics presented? What is the measure? What does it mean? Can you generate a clinically sensible estimate of your patient's pre-test probability (from personal experience, prevalence statistics, practice databases, or primary studies)?
Are the study patients similar to your own? Is it unlikely that the disease possibilities or probabilities have changed since the evidence was gathered?
Was there an independent, blind comparison between the index test and an appropriate reference ('gold') standard of diagnosis?
The reference standard is likely to correctly identify the target condition. Reference standard results are interpreted without knowledge of the results of the index test. The target condition as defined by the reference standard matches that found in the target population of the guideline
Could the results of the test have been influenced by the results of the reference standard?
Was there blinding? Were the tests performed independently (review bias).
Were the methods for performing the test described in sufficient detail to permit replication?
Is the disease status of the tested population clearly described?
Presenting symptoms
Disease stage or severity
Co-morbidity
Differential diagnoses (Spectrum Bias)
Were the methods for performing the test Described in sufficient detail Was a protocol followed?
What are the results? Are the sensitivity and specificity and/or likelihood ratios presented? Are the results presented in such a way that We can work them out?

How sure are we about the results? Consequences and cost of alternatives performed? Could they have occurred by chance? Are there confidence limits? What are they?
Can the results be applied to your patients/the population of interest? Do you think your patients/population is so different from those in the study that the results cannot be applied? Such as age, sex, ethnicity and spectrum bias.
Can the test be applied to your patient or population of interest? Resources and opportunity costs Level and availability of expertise required to Interpret the tests Current practice and availability of services
Will the resulting post-test probabilities affect your management and help your patient?
Could it move you across a test-treatment threshold? Would your patient be a willing partner in carrying it out?
Were all outcomes important to the individual or population considered? Will the knowledge of the test result improve patient wellbeing? Will the knowledge of the test result lead to a change in patient management?
What would be the impact of using this test on your patients/population? How well was the study done to minimise bias? What is your assessment of the applicability of this study to our target population? Would the consequences of the test help your patient?

Table 1: Critical appraisal of a diagnostic test study.

Use this checklist can improve the evaluation of diagnostics testing studies.

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