IMPORTANT ISSUES TO CONSIDER WHEN CONDUCTING RESEARCH IN LABORATORY DIAGNOSTICS

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Abstract. This article provides information and conclusions about laboratory-related diagnostic tests and important issues to consider when conducting research in laboratory diagnostics.

Key words: Laboratory, clinical, test, diagnosis, marker, diagnosis, standard, symptom, gold standard.

ВАЖНЫЕ ВОПРОСЫ ПРИ ПРОВЕДЕНИИ ИССЛЕДОВАНИЙ В ЛАБОРАТОРНОЙ ДИАГНОСТИКЕ

Аннотация. В этой статье представлены информация и выводы о лабораторных диагностических тестах, важных вопросах, которые следует учитывать при проведении исследований в области лабораторной диагностики.

Ключевые слова: Лаборатория, клиника, тест, диагностика, маркер, диагностика, стандарт, симптом, золотой стандарт.

Relevance of the problem: Compared with the diagnostic test reports published in the main foreign academic journals of laboratory medicine, the articles published in domestic journals have more or less flaws, mainly due to experimental design flaws, non-standardized writing of articles.

Purpose of studies: In our purpose of studies, we integrate reporting standards for diagnostic accuracy (STARD) and quality assessment of diagnostic accuracy studies (QUADAS) instruments. Today, studying the importance of laboratory diagnostics, as well as turning the scientific research results into clinical practice.

Test methods and materials.

Overview of QUADAS standards and STARD reporting specifications

In the era of evidence-based medicine, clinicians place great emphasis on using the best available "evidence" as a basis for clinical decision-making. The so-called "evidence" mainly comes from the conclusions of existing clinical studies. In clinical research practice, many different clinical trials are often conducted on the same clinical problem, and the conclusions drawn are also different. One of the tasks of evidence-based medicine is to conduct systematic reviews (SR), combine the results of many clinical studies with scientific statistical methods, and

provide the best evidence for clinical decision-making. At the same time, SR can identify the reasons for the differences between the results of different clinical studies and provide a reference for further similar studies. Assessing the quality of existing clinical studies is essential in the SR process. The conclusions of high-quality clinical studies are more reliable, so they have a higher weight in SR. In this context, the QUADAS standard was born. The QUADAS standard includes a total of 14 items for system reviewers to assess the research quality of diagnostic trials from 14 trial design details. For each item in the QUADAS standard, the experts gave detailed evaluation principles in the explanation: if the study meets the design points specified in the standard, you can get 1 point; otherwise you get -1 point; If the content cannot be evaluated, it is recorded as 0 points. The higher the sum of the QUADAS scores, the higher the research quality of the diagnostic test and the stronger the reliable conclusion.

The START Reporting Protocol is a checklist developed by the STARD Group (a research group consisting primarily of statisticians and laboratory medicine scientists) to standardize the writing of diagnostic test research reports. This checklist contains a total of 25 entries, detailing what to describe in each section of the diagnostic test paper, and its purpose is to alert readers to potential research bias (internal validity) and to help analyze the applicability (external validity) of the findings). Since the development of the STARD reporting specification in 2003, it has been rapidly recognized by academic journal editors and clinical research scientists.

2. Discussion of several issues worthy of attention when conducting diagnostic studies in light of QUADAS standards and STARD reporting specifications

Time of data collection

Based on the time of data collection, diagnostic tests can be divided into prospective studies and retrospective studies. The difference between them is that a prospective study first has a test plan, and then conducts a diagnostic test according to the test plan (while examining the "gold standard" and "evaluable test" for patients); and retrospective. no pre-designed study design A good trial design is a retrospective collection of studies by researchers. Prospective studies can control for case recruitment during implementation and potential confounding factors during the interpretation of results, so they usually have a high argument; retrospective studies cannot control for various confounding factors, so the strength of the argument is weak. Currently, almost all high-quality diagnostic tests in the world are prospective studies.

Article 6 of the STARD reporting specification clearly states that when writing diagnostic test studies, researchers must indicate in the Materials and Methods section whether the study is prospective or retrospective. But, unfortunately, some local scientific articles on diagnostic tests do not explain the nature of the research in the "Materials and Methods" column, but explain the sample size of the research subjects, the status of the diagnosis of the disease, and some basic clinical studies. Characteristics. This non-standard reporting method often leaves readers unable to judge the quality of the research and the strength of the argument, and also weakens the penetrating power of research findings in the field. In addition, an important task of conducting SR is to analyze whether the differences between the conclusions of different studies are due to the characteristics of the experimental design, thus providing a reference for peers to continue research in this area. If the timing of the study is not explained in the research paper, it often makes it difficult for systematic reviewers to analyze the sources of heterogeneity between different studies, and this weakens the impact of research in the field.

Selection of research subjects

Disease diagnosis is primarily based on simple and readily available clinical data (eg, medical history, symptoms, and demographic characteristics). But some diseases are very similar in terms of symptoms and signs, and it is often impossible to determine the presence of the disease. Based on the above information, the patient has a target disease, make a clear conclusion. For example, in patients with dyspnea as the chief complaint, it is not possible to determine that the cause of the dyspnea is heart failure based on symptoms and signs alone, because some patients with asthma, pneumonia, aortic dissection, and myocardial infarction may also have symptoms. possible from shortness of breath. Currently, clinicians must use available physical examination, visual examination, or laboratory testing methods (such as BNP determination) to make a definitive diagnosis of whether a patient is suffering from heart failure. It is clear that the research objects of diagnostic tests should be a group of people with similar symptoms and signs, and laboratory examination methods, imaging methods, etc. should be used to confirm the diagnosis. In some local diagnostic tests, healthy people were designated as a control group. Such a design is insufficient to reflect the ability of laboratory indicators in the differential diagnosis of diseases, and the inclusion of diagnostic tests often leads to erroneous conclusions. The first article of the QUADAS standard makes a clear statement about the disease spectrum of the research object of the diagnostic test, if the diagnostic test uses healthy individuals as controls, it is considered unqualified and the QUADAS score of this standard. - 1 point.

In addition, it should be noted that, unlike interventional studies, the test group (disease group) and control group (non-disease group) of the diagnostic test are formed naturally, so the proportionality (i.e., there) is There is no requirement for . there is no need to follow the rules of case-control and intervention studies).In sexual research, the "Principle of Balance"), the main thing is that the research object should be clinically representative and complete and can reflect the characteristics of the population. should be evaluated in a clinical workup to make a diagnosis. For example, the BE FAST study published in 2012 was a study to evaluate the diagnostic value of serum glial fibrillary acidic protein (GFAP) in hemorrhagic cerebrovascular disease and ischemic cerebrovascular disease. The subjects were 205 patients with symptoms of cerebrovascular disease and symptoms appeared. in 4.5 hours. Among them, only 39 patients with hemorrhagic cerebrovascular diseases and 166 patients with non-hemorrhagic cerebrovascular diseases were involved.

Inclusion, exclusion and recruitment of subjects

Determining the inclusion and exclusion criteria of research subjects is an important part of diagnostic test research, as it determines to a certain extent the scope of application of research findings. Inclusion criteria should generally include chief complaints, medical history, and symptoms of research subjects; exclusion criteria should usually be diseases that can be diagnosed without new diagnostic methods or excluded for special reasons. For example, Potocki evaluated the diagnostic value of MR-proANP and NT-proBNP for heart failure in patients with dyspnea. Inclusion criteria for the study were: patients presenting to the emergency department with a chief complaint of shortness of breath; exclusion criteria: age <18 years; dialysis patients and trauma patients. Inclusion and exclusion criteria better reflect the characteristics and clinical presentation of patients with clinically suspected heart failure. Article 2 of the QUADAS standard requires that researchers have clear case selection criteria when conducting a diagnostic test study; otherwise, the research score for that record is 0 or -1, resulting in skewed total QUADAS scores. overall quality of learning. In addition, when writing a research paper, you should follow the STARD

reporting specification rules 15 and 18 and detail the clinical characteristics of the subjects who finally entered the study so that readers can analyze the scope of application. research findings.

The method of recruitment of research subjects is an aspect that should be fully considered in the design of a diagnostic test study. Improper recruitment methods result in a lack of clinical representativeness of the ultimately recruited study subjects and affect the reliability of study conclusions. Using random recruitment and continuous recruitment to recruit people who come to the hospital for a certain period of time, meet the inclusion criteria, and do not meet the exclusion criteria without violating medical ethics should be the proper way of doing things. Only in this way can the integrity of the clinical representativeness of the research subjects be ensured, so "diagnostic research does not need to follow the principle of balance". Articles 4 and 5 of the STARD reporting specification require researchers to indicate in their research papers how they were involved in the work.

Determination of the gold standard

When evaluating clinical diagnostic tests, the first step is to establish a "gold standard," that is, a standard that can ultimately diagnose a disease. For example, the gold standard for the diagnosis of tumors is pathological examination, the gold standard for the diagnosis of sepsis is blood culture, and the gold standard for the diagnosis of ischemic heart disease is coronary angiography. It should be noted that although the gold standard is the final tool for disease diagnosis, this does not exclude the role and status of new tools in disease diagnosis. Although the gold standard is the final standard for disease diagnosis, it also has insurmountable disadvantages, such as: pathological examination is an invasive examination, and the test results depend on the experience of the pathologist; blood cultures are time-consuming and laborious, and may delay the diagnosis of patients. Coronary angiography requires advanced medical equipment and has certain side effects (contrast medium can cause acute kidney injury). Therefore, we need to study new diagnostic methods to overcome the shortcomings of the gold standard and enrich the diagnostic methods of diseases. The gold standard established during diagnostic studies should be a recognized diagnostic standard of disease and should be detailed in the reporting document. This is clearly defined in Article 7 of the STARD reporting specification and Articles 3 and 9 of the QUADAS standard. In addition, the role of the gold standard in the process of conducting diagnostic tests should not be limited to the diagnosis of diseases, but should also include the exclusion of diseases. That is, whether or not a final diagnosis of the target disease is established, all subjects should receive the gold standard examination. In articles 5 and 6 of the QUADAS standard, researchers are required to undergo the gold standard examination of all subjects during diagnostic studies.

It is important to note that when conducting a diagnostic study, the gold standard and the evaluated test should be independent of each other, that is, the diagnosis of the disease and the implementation of the evaluated test should be blinded to each other. : clinicians do not know the specificity of the test to be evaluated in making the diagnosis of the disease. As a result, to avoid potential diagnostic errors, the tests to be evaluated should be performed without knowing the final diagnosis of the patients. This is clearly defined in Articles 7, 10 and 11 of the QUADAS standard. Article 11 of the STARD reporting specification also requires the author to state whether blinding was used in the research process when writing the report paper. However, we can also see that the research quality of prospective studies is higher compared to retrospective studies, because in prospective studies, researchers can use blinded methods and avoid waiting for evaluation when setting gold standards.

Summary. Today, the idea of evidence-based medicine has permeated every corner of clinical medicine, and it has become the consensus of most clinicians to focus on the quality of "evidence" and the strength of arguments. Conducting high-quality diagnostic test studies and writing standardized diagnostic research papers will undoubtedly play a positive role in the development of evidence-based medicine. By following the principles of scientific design in conducting diagnostic tests and following standardized reporting methods in writing reports, research results can gain peer attention and have a place in shaping or updating future disease diagnostic guidelines. possible translation of scientific research results into clinical practice.

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