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EDITORIAL

Assessment of a new rapid urease test (GUT test) to diagnose *Helicobacter pylori* infection

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Making a diagnosis is an important process in medicine. Performing a diagnostic test will ascertain the presence of a disease as a cause of a health problem. The value of test results depends both on the diagnostic performance and how the results will improve the outcome of illness. Diagnostic performance means that the test should evaluate what it intends to assess, and that repeated measurements give similar results. Besides performance, the diagnostic test will be chosen because of several other factors such as preferences, availability, experience, costs and so on.

Inappropriate diagnostic testing may have serious consequences for individual patients. To prevent the implementation of disappointing new diagnostic tests it is necessary to conduct appropriate assessment studies. In the current issue of the Netherlands Journal of Medicine, colleague van Keeken from Bernhoven Hospital, Oss, the Netherlands presents a study in which she and her colleagues evaluated a new rapid urease test (GUT test) to diagnose *Helicobacter pylori* infection.[1] Guidelines have been put forward for evaluating new diagnostic tests.[2] According to these guidelines three aspects are of major importance: selection of an appropriate patient population, determination of the diagnostic performance and the relation with existing diagnostic tests. Let us apply these aspects to van Keeken's study.

CLINICAL INDICATION

The initial challenge lies in the selection of an adequate patient population. The risk of not using the appropriate patient population is that the large contrast between severely ill patients and healthy individuals will overestimate the test performance. What is the appropriate patient population for a *H. pylori* test? The infection is without doubt involved in several diseases: peptic ulcer disease, gastric cancer and B cell lymphoma.[3] The impact of *H. pylori* infection and functional dyspepsia is more controversial. *H. pylori* eradication does appear to be beneficial for a small subgroup of patients with functional dyspepsia.[4] Thus, the indication to use the test is patients suspected of having peptic ulcer disease, gastric cancer, B cell lymphoma and in all probability functional dyspepsia. This, however, means that patients referred for upper gastrointestinal endoscopy are not the indicated study population. The patient population evaluated in this study consisted of 116 consecutive patients who underwent an upper gastrointestinal endoscopy. More data about the indication for *H. pylori* infection testing or upper gastrointestinal endoscopy were not given. Because of this lack of information about the reason for testing it is not possible to judge whether the test has been evaluated in an adequate patient population.

DIAGNOSTIC PERFORMANCE

There are several ways to handle the diagnostic test results from an assessment study. For qualitative tests sensitivity, specificity, and positive and negative predictive value are the most used test outcome measures. The major problem with assessment of the diagnostic performance of the *H. pylori* test is the absence of a test determining the definitive disease status (gold standard). As a result in some studies inappropriate tests are being used as a reference. In this study the authors have overcome the problem by comparing the new test directly with another rapid urease test (CLO test), and with the combination of bacterial culture and histology. Previous research has shown that using a combination of biopsy-based tests represents an appropriate reference standard to diagnose *H. pylori* infection.[5]

CONTRIBUTION OF THE NEW TEST

When it becomes clear that the diagnostic performance is adequate in the indicated patient population it is important to establish the contribution of the new test to the existing diagnostic arsenal. At the moment several methods can be used to diagnose *H. pylori* infection, both biopsy based and nonbiopsy based. The rapid urease test evaluated in this study requires an upper gastrointestinal endoscopy for retrieval of a biopsy specimen. The other biopsy-based tests are bacterial culture and histology. The results from the study showed that the overall diagnostic performances of the evaluated biopsy-based tests were not statistically different. So other aspects of the new test are of importance. The authors state that the new rapid urease test has a more rapid reaction time and is much cheaper. The outcome of the new rapid urease test (GUT test) was reliable 60 minutes after endoscopy in comparison with 24 hours for the other urease test (CLO test) and several days for culture and histology. It is, however, questionable whether this gain of time has significant clinical consequences. Another important aspect is the lower costs of the test in comparison with other rapid urease tests. *H. pylori* infection is still a major health problem worldwide.[6] A cheaper diagnostic test with equal clinical effects might lead to significantly lower overall medical costs.

CONCLUSION

The new more rapid urease test seems to be a promising new diagnostic test with equal diagnostic performance but considerably lower costs and a faster availability of the test results, in comparison with other biopsy-based *H. pylori* tests. Whether the gain in time and lower costs are sufficient to switch from the old but well-known other rapid urease tests to this new more rapid GUT test depends on the priorities and preferences of the users. However, before implementation the results from this study have to be confirmed, including the additional value of the new test to the entire diagnostic process and the cost-effectiveness.

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