Urea and Antibody Testing for the Detection of *H. pylori*

H. pylori infection is extremely common in the United States, affecting about 20% of people under 40 years old and 50% of those over 60 years old[1]. Deciding which test to use in a particular situation depends upon whether a patient requires evaluation with upper endoscopy. This decision is mainly based on the patient's age and the existence of alarm features such as bleeding, anemia, early satiety, and family history of GI cancer. If the clinical decision is to opt for a non-endoscopic- testing evaluation, there are two leading non-endoscopic testing methods for *H. pylori* infection: Antibody Tests (ABT) and Urea Breath Tests (UBT). The ABT is more commonly used than the UBT due to its long-term use in clinical practice and its lower cost. Despite this fact, the clinical outcomes of the UBT greatly outperform the ABT.

Nonendoscopic Diagnostic Tests (from the ACG Guidelines)

- Antibody testing is inexpensive and widely available but poor PPV in populations with a low prevalence of H. pylori infection limits its usefulness in clinical practice.
- The UBTs and fecal antigen tests provide reliable means of identifying active H. pylori infection before antibiotic therapy.
- The UBT is the most reliable nonendoscopic test to document eradication of H. pylori infection.

UBT is more specific and sensitive than ABT

In its 2007 *Guidelines on the Management of H. pylori Infection*, the American College of Gastroenterology (ACG) cited a study that performed a meta-analysis on a few commercially available ABT kits. The results showed their overall sensitivity to be 85% and their specificity to be 79%. Three of the qualitative whole blood antibody kits were compared in another study cited in the guidelines, with results indicating sensitivities ranging from 76% to 84% and specificities of 79–90%. Most studies suggest that the UBT has a sensitivity and specificity that typically exceeds 95%, showing excellent test reproducibility[2]. This implies that the UBT is more accurate than the ABT for the initial diagnosis of *H. pylori* infection[3,4].

The clinical usefulness of the ABT is dependent on H. pylori prevalence; this is not the case with UBT.

Positive Predictive Values (PPV) of ABT are greatly influenced by the prevalence of *H. pylori* infection[2] and the test's performance characteristics are poor in a low-prevalence population[4]. Moreover, *"… in a community with an H. pylori prevalence of less than ~ 20%, as is the case in much of the United States, though a negative antibody test suggests the absence of infection, a positive test is no better than a coin toss in predicting the presence of active infection …"* [2].

In comparison, the UBT is considered the test of choice when there is a low or intermediate prevalence of the infection, which offsets the UBT's higher cost [4]. In summary, the UBT provides excellent Positive as well as Negative Predicative Values by identifying active *H. pylori* infection regardless of *H. pylori* prevalence, which, as explained above, is an important consideration in developed countries, such as in the U.S. and in Europe[5].

UBT is the most reliable non-endoscopic post treatment test

ABT is of little benefit in documenting *H. pylori* eradication, as IgG antibodies can remain present for years following the successful treatment of the infection. In contrast to ABT, UBT provides an accurate means of post treatment testing, which makes it useful before and after *H. pylori* therapy. *"…When endoscopic follow-up is unnecessary, testing to prove eradication of H. pylori infection is best accomplished with the UBT…"* [2]. Systematic reviews of the studies performed in this context indicate that UBT is the best option, with a sensitivity of 94% and a specificity of 95%[5].

In Summary

Based on current guidelines and abundant literature, ABT is not considered an adequate clinical choice for *H. pylori* infection evaluation in low to medium prevalence populations such as that found in the United States.

The best test for the detection of an active infection is the Urea Breath Test, which has been found to be highly sensitive and specific regardless of *H. pylori* infection prevalence. In addition, UBT has been shown as a preferred non-invasive testing method for post-treatment follow-up, as it indicates an active infection. While the ABT is more commonly used in non-endoscopic testing for *H. pylori* infection, the UBT clearly provides superior performance.

Recommendations (Form the Maastricht III Consensus Report)

- Serology based office tests have no current role in the management of H pylori infection.
- H pylori eradication should be confirmed at least four weeks after treatment. A UBT is recommended if available.

References:

1 *National Institutes of Health of the U.S. Department of Health and Human Services, NIDDK, NIH Publication No. 07–4225; October 2004*

2 *American College of Gastroenterology Guideline on the Management of Helicobacter pylori Infection, Chey W, Wong B, Am J Gastroenterol 2007; 102:1808–1825*

3 *Update on Helicobacter pylori Treatment, ABLES AZ, SIMON PDI, MELTON ER, Am Fam Physician 2007; 75:351-8.*

4 *American Gastroenterological Association Technical Review on the Evaluation of Dyspepsia, Talley N J, Vakil NB, Moayyedi P; Gastroenterological 2006 Vol. 129, No. 5*

5 *Current concepts in the management of Helicobacter pylori infection: the Maastricht III Consensus Report, Gut 2007;56;772-781*

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