Clinical guidelines for H. pylori screening and post-treatment testing endorse the use of urea breath test (UBT), H. pylori stool antigen test (HpSAT), and biopsy-related tests. Due to protracted wait times at our patient service centers and non-compliance in children and elderly with complications for the UBT, we sought to compare UBT and HpSAT in the city of Calgary, Canada with a population close to 1.4 million people.

Methods: To achieve this, a prospective diagnostic trial was performed comparing UBT to HpSAT in patients presenting with dyspepsia. A total of 150 patients agreed to undergo UBT (150-CUBT kit, Heliko, Isodiagnostika Inc.) and consented to provide a stool specimen for simultaneous HpSAT testing (DiaSource LIASON® XL, Heliko SA Monoclonal chemiluminescent immunoassay) in our central laboratory.

Results: Our data showed that concordant results were obtained in 148/150 (98.7%) patients with a positivity rate of 18%. One of two discrepant UBT (positive HpSAT/negative UBT) resulted after repeat testing. Using UBT as the gold standard, HpSAT had a sensitivity of 96.30% (95% CI: 91.05 to 99.11) and specificity of 100% (95% CI: 97.05 to 100.00). A positive predictive value of 100% and negative predictive value of 99.2% (95% CI: 98.73 to 99.88) was obtained. For patients where drug information was available, 38/120 (31.7%) had received an antibiotic associated with H. pylori in the preceding 12 months, with UBT and HpSAT providing concordant results in 37/38 (97.4%) of these individuals. Of note, 6/130 (4.6%) patients had received a specific combination anti-H. pylori treatment, and all 6/6 (100%) had concordant negative results suggesting successful eradication. A post-implementation economic evaluation of labor and materials associated with testing demonstrated a cost savings of approximately USD 5.47 per specimen in this locale.

Conclusions: Our study confirms that HpSAT is a viable alternative to UBT for H. pylori screening in our jurisdiction with equivalent test performance and cost savings. Pre-and post-test performance analysis of test result rates, wait times, and test turn around times will also be presented.

The prevalence of H. pylori infection affects nearly half of the world’s population. In developed countries, the prevalence is below 40%, whereas, in developing countries, the prevalence varies from about 20% to 40% in some adult populations. In First Nations populations living in northern Canada, the prevalence is high, often greater than 50%. According to the Maastricht IV/Florence Consensus Report regarding the Management of Helicobacter pylori infection, the main non-invasive tests that can be used for the test-and-treat strategy are the UBT and monoclonal HpSAT. According to 2018 Houston Consensus Conference guidelines, all patients receiving treatment for H. pylori receive post-treatment confirmation, such as UBT, HpSAT, or histology. According to the 2015 Canadian Agency for Drugs and Technologies in Health “Clinical and Cost-effectiveness guidelines”, the EIa-based and ICA-based tests using monoclonal antibody were comparable with endoscopy and/or urea breath test to determine the H. pylori eradication therapy.

A prospective diagnostic trial was performed comparing UBT to HpSAT in patients presenting with dyspepsia. A total of 150 patients agreed to undergo UBT (150-CUBT kit, Heliko, Isodiagnostika Inc.) and consented to provide a stool specimen for simultaneous HpSAT testing (DiaSource LIASON® XL, Heliko SA Monoclonal chemiluminescent immunoassay) in our central laboratory. UBT

- HpSAT is performed as an immunoperoxidase-based test using a high-throughput enzyme immunoassay system.
- DiaSource LIASON® XL Heliko SA Monoclonal chemiluminescent immunoassay
- Patients who had previously been treated
- Results are available in approx. 24 hours.

H. pylori Stool Antigen Test (HpSAT)

- HpSAT is performed as an immunoperoxidase-based test using a high-throughput enzyme immunoassay system.
- DiaSource LIASON® XL Heliko SA Monoclonal chemiluminescent immunoassay
- Results are available in approx. 24 hours.

H. pylori stool antigen test

- UBT
- HpSAT
- Varies by region and ethnic subgroups ranging from about 20% to 40% in some adult populations. In First Nations populations living in northern Canada, the prevalence is high, often greater than 50%.

For patients where drug information was available, 38/120 (31.7%) had received an antibiotic associated with H. pylori in the preceding 12 months, with UBT and HpSAT providing concordant results in 37/38 (97.4%) of these individuals. Of note, 6/130 (4.6%) patients had received a specific combination anti-H. pylori treatment, and all 6/6 (100%) had concordant negative results suggesting successful eradication.

Conclusion

- H. pylori stool antigen testing (HpSAT) provides equivalent results to Urea Breath Test (UBT) in this population.
- Replacement of UBT by HpSAT was driven by a dyspepsia screening algorithm change resulting in improved waiting times and reduced costs in this jurisdiction.
- HpSAT is not contra-indicated in the young and elderly with UBT compliance issues.
- A small proportion of patients (6/150) had received prior H. pylori treatment and the HpSAT demonstrated cure in line with the UBT result.

Further evaluation of HpSAT in post-treatment situations may be warranted.

References


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