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PCR technology *is the Gold Standard* in identifying organisms. TZAM Diagnostics has commercially available a Multiplex PCR test for *H. pylori* that provides a superior result to all other options available. It finds what the other methodologies miss to help you correctly diagnose your patients. **Dr. Tat-Kin Tsang**, founder of TZAM Diagnostics, will be presenting at the upcoming DDW convention in San Diego the weekend of the 19th -21st of May, 2012.

The date, time and subjects are listed below. If you are planning on going, please take the time to attend the session(s) and ask questions. If you are unable to attend and would like an abstract; please contact your Field Consultant. If you would like more information on **TZAM's Multiplex PCR testing for *H. pylori*, please e-mail Customer Service.** If you would like to start utilizing the testing for your patients, contact the Field Consultant below or our firm directly at 610-833-8156. We are available 6 am - 9 pm Eastern, Monday-Friday.

Charles W. Stout I.I.I. JD

President/CEO
MRG LLC for TZAM Diagnostics
E-Mail: CustomerService@MRG-LLC.com

Scheduled Presentations by Dr. Tat-Kin Tsang, founder and President of TZAM Diagnostics

ID	Presenter	Title	Session	Session Title	Date/Time	Location
1300517	Tat-Kin Tsang	**DETECTION OF HELICOBACTER PYLORI IN ASIAN PATIENTS WITH GASTRITIS/INTESTINAL METAPLASIA**	Poster Session	IMPROVEMENT IN GI AND ENDOSCOPY	May 19 9:31 AM	Halls C-G
1288175	Tat-Kin Tsang	**Development of Novel Optical Technologies For Early Colon Carcinogenesis Detection Via Nanoscale Mass Density Fluctuations: Potential Implications for Endoscopic Diagnostics**	Topic Forum	New Technology: Colon Imaging	May 21 4:00 PM	3

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Gastroenterology & Endoscopy News

In the News ISSUE: JANUARY 2012 | VOLUME: 63:1

PCR More Sensitive than IHC Staining for Identifying *H. pylori* Infection PCR May Allow More Patients with *H. pylori* To Undergo Treatment

by Monica J. Smith

National Harbor, Md.—Immunohistochemistry (IHC) staining may fail to identify *Helicobacter pylori* in a significant number of patients, who then may be misdiagnosed with functional dyspepsia, according to research presented at the 2011 American College of Gastroenterology annual meeting. Advanced polymerase chain reaction (PCR) testing may be the answer for proper diagnosis and treatment in these cases.

Abdominal pain, stomach upset, gas and bloating are common complaints among patients who visit a gastroenterologist. "But a lot of gastroenterologist colleagues tell me that although they find inflammation, irritation and gastritis on endoscopy, the biopsies do not show *H. pylori*," said Rudra Rai, MD, assistant professor of medicine at Johns Hopkins University School of Medicine, Baltimore. "It was our gut feeling, no pun intended, that we may not be identifying *H. pylori* bacteria as well as possible."

There are a couple of reasons why this may be. For example, the use of proton pump inhibitors has become increasingly common over the past two decades, which can reduce the number of bacteria or their appearance, and more people take antibiotics, which can change the size and shape of *H. pylori*.

"This has made the bacteria less easy to identify; *H. pylori* appears to have changed a bit since first described 20 years ago," Dr. Rai said. "I think the biopsies that were adequate in the past are probably no longer the best tool. We need a tool to look for *H. pylori* without any kind of intraobserver bias, which can identify small amounts of bacteria or morphologically different-looking bacteria."

PCR the More Sensitive Test

Dr. Rai and Metul Shah, MD, of the Gastro Center of Maryland, Columbia, performed a prospective study of 325 adults with chronic gastroduodenal symptoms undergoing upper endoscopic examination to compare IHC with a commercially available multiplex PCR test (from TZAM Diagnostics) for detecting *H. pylori* infection. The new PCR test has been on the market for about three years.

With the ability to examine very small strands of DNA, PCR has been the gold standard for molecular examination for at least the past 20 years, but it also has been plagued by high rates of false-positives.

"[PCR] can amplify DNA dramatically, but when you amplify anything, you'll notice a ton of surrounding 'noise,' " Dr. Rai explained. "That has always been the issue with PCR—how do you remove the background noise and the false-positives?"

The multiplex PCR used in this study, Dr. Rai said, can look for 10 segments of bacteria simultaneously, without the noise. "You can put a lot of confidence in a positive result being a true-positive; I think this test can be entirely accurate, and I think it beats out the current standard of care," he said.

In the study, a single experienced pathologist identified *H. pylori* in 26 of the 325 patients (8%) by IHC. The positive diagnosis in those patients was corroborated by PCR, which identified the bacteria in 38 additional patients, for a total of 64 (19.7%). Based on these findings, the IHC test was 100% specific but only 40.63% sensitive, when compared with PCR. In contrast, PCR testing was 100% sensitive when compared with IHC, and identified many additional patients.

Subpopulation analyses revealed further differences in sensitivity between the two tests. In men, the detection rate of *H. pylori* was 27% by PCR and 12% by IHC; in women, PCR detected *H. pylori* 16% of the time compared with only 5% by IHC. "That gives you a sensitivity of 35%," Dr. Rai said. By race, the gaps in sensitivity were even more striking. "In Caucasian patients," of which there were 139, "the PCR detection rate was 16%, whereas the IHC detection rate was only 2.1%, giving it a sensitivity of only 15%," Dr. Rai said.

The authors concluded that advanced PCR diagnostics identified *H. pylori* in far more patients, and that IHC would have missed the infection in the majority of those who have it, and they would likely be misdiagnosed. "If we believe these results, 59% of these patients would have been missed on IHC and likely diagnosed with functional dyspepsia, where the treatment strategies are very different," Dr. Rai said. "Most of these patients experienced significant improvement after treatment."

In practice, when *H. pylori* is suspected, Dr. Rai takes one biopsy for IHC and one for PCR. Insurance companies will not pay for PCR if the IHC results are positive, but if the IHC results are negative, PCR will be covered. Both tests cost about the same. Interpreting PCR is a breeze, Dr. Rai said. "We get the results back within two or three days, and it's a simple yes or no answer, although if you want to know how many loci were positive, that information is available."

If the test is positive, a 10- to 14-day course of treatment "changes the landscape for that patient," Dr. Rai said.

Caveat

Jonathan Leighton, MD, professor of medicine, Mayo Clinic, Scottsdale, Ariz., found the study intriguing.

"There is a subgroup of patients with dyspeptic symptoms for whom we don't have a good diagnosis. If some of these patients were found to have *H. pylori* that we are not detecting, that would be significant," he said. But this would require further studies to corroborate Dr. Rai's findings, along with a better understanding of exactly what the PCR is identifying.

"Are they detecting active *H. pylori* infection, or proteins or products of *H. pylori* that are in the tissue but not necessarily a sign of active disease?" he asked. Also, although patients who were treated for *H. pylori* experienced relief of symptoms, it is not clear what it means that they got better. "There's always the placebo effect in uncontrolled trials that needs to be considered," Dr. Leighton said. "Ultimately, anything we do in medicine should be reflected in improved clinical outcomes for our patients. Larger, controlled trials will be needed to confirm the findings. Otherwise, it is an intriguing study that warrants further investigation."

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