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Enhancing Colon Cancer Screening through Polyp Detection

Noninvasive Diagnostic Analyzes Metabolites to Determine if Patients have Precancerous Polyps
Gail Dutton

Metabolomic Technologies (MTI) has developed a technology that detects colonic polyps, the precursor to colorectal cancer (CRC), using a noninvasive urine test. Unlike fecal-based tests, PolypDx™ detects polyps before they become cancerous, according to the company. The assay, now in beta testing, has the potential to improve patient compliance. By enabling early intervention, it also may reduce the high healthcare costs associated with treating CRC, by reducing the numbers of surgeries and hospitalizations.

“In Canada, colonoscopies are not the first line of defense. Instead, our healthcare system uses fecal-based tests,” Reg Joseph, CEO, explains. For those tests, patients collect their samples at home and send them to a lab. With that approach, compliance rates across Canada are as low as 14%. “Because the fecal tests detect CRC only 50% of the time, often people without polyps and cancer undergo colonoscopies. Eighty percent of patients referred for colonoscopies that are based upon fecal tests do not have CRC. Because of the invasive nature of this procedure and lack of patient compliance, many are not screened in time.”

PolypDx addresses those issues, MTI reports. It is a single spot test that analyzes metabolites in the urine to determine whether patients have CRC and, more importantly, whether they have colonic polyps. The test has a sensitivity of 71% and a specificity of 61% in terms of polyp detection. In contrast, standard-of-care fecal-based tests are designed to detect CRC—not colonic polyps. When used to detect polyps, fecal-based tests have sensitivities of 1–15%. Therefore, PolypDx represents a significant advance in polyp detection.

“We’re continuing to improve sensitivity and specificity for PolypDx by screening against a larger metabolomic library,” Joseph says. The current version is based on an NMR platform. An improved version offering higher throughput and enhanced ease of use is being developed on a mass spectroscopy platform. It is expected to become available in 2015. Mass spec instruments are used routinely in large diagnostics labs, so this new test kit can be integrated easily into current workflows.

“We’re working with Alberta Health Services and DynaLIFEDx to look at scaling up this test for large population screening,” Joseph says. Alberta Health Services is collaborating with MTI to release the assay kit as early as

possible. MTI plans to commercialize the first version of the test in late 2014.

Ultimately, MTI envisions PolypDx as a routine screening tool that will be used before patients undergo a colonoscopy. “We’d like to be able to screen thousands of patients per day using one instrument,” Joseph says.

“More than 95% of colon cancer patients develop cancer through adenomatous colonic polyps. If we can identify these patients before the onset of cancer, the chance of survival is more than 90%.” The PolypDx assay kit is expected to be priced at about \$50. The annual U.S. burden for CRC treatment is \$14 billion.

MTI’s platform also may be harnessed for other diseases. MTI is developing ColoDx™ for CRC. Additionally, “We can see the preliminary signatures for prostate and breast cancers.” Urine-based assays for those diseases are in the early development phase.

Collaboration

The technology spun out of the University of Alberta in Canada, which is known globally for metabolomics research. Company founders, gastroenterologist Richard Fedorak, M.D., and colorectal surgeon Haili Wang, M.D., collaborated with the university’s metabolomics group, which was collecting bio-samples to identify potential diagnostics for a variety of diseases. A retrospective study led to a prospective study and, eventually, PolypDx.

“MTI is actively seeking partnerships and strategic commercial partners,” Joseph says.

MTI is collaborating with BGI-Shenzhen to develop the assays for the Chinese market. The assay is undergoing validation and clinical trials in China. According to Yong Zhang, Ph.D., head, proteomic division, BGI-Shenzhen, “Our company is the best positioned to co-develop MTI’s diagnostic tests for the Chinese market, assist with the regulatory process, and market the technology.”

“In the West, the regulatory landscape for multivariate tests like metabolomics is a bit gray. China, however, has a progressive regulatory framework that is focused around driving down the costs of disease for a large, new middle class that is demanding high-quality healthcare.” Therefore, “Preventive strategies—including diagnostics—are on the fast track.” Additionally, the University of Alberta has had research collaboration with BGI-Shenzhen for the past five years. Leveraging that relationship enables MTI to showcase a translational project and make a real difference, quickly, in individuals’ health.

Joseph says MTI’s finances are sound. MTI is funded by angel and super angel investors and by grants from Alberta Innovates—Health Solutions, the National Research Council of Canada’s Industrial Research Assistance Program, and Alberta Enterprise and Advanced Education. “Our burn rate isn’t excessively high, so regional financing will take us through the next few years.”

Metabolomic Technologies

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Focus: MTI, a spin-off company from the University of Alberta, develops metabolomic-based diagnostic tests for the management of chronic diseases.

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