

SPRING 2015

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## The Cost and Clinical Benefits of Early Referral for Esophageal pH Monitoring

Gastroesophageal reflux disease (GERD) affects some 25 percent of adults in America and is the most common gastrointestinal indication for seeking medical attention in the world today. The economic impact of GERD on the country's healthcare system is immense, accounting for billions of dollars spent each year for prescription and over-the-counter medications to control reflux symptoms. Proton pump inhibitors (PPIs) account for the majority of GERD-related spending, and an estimated \$9.4 billion per year is spent on PPIs in the U.S. alone.

### The Cost Analysis

Gastroenterologists at NewYork-Presbyterian/Weill Cornell Medical Center, led by gastrointestinal surgeon **Rasa Zarnegar, MD**, hypothesized that prompt referral for esophageal pH monitoring

would be more cost effective than prolonged empiric courses of PPIs. "Nowadays the moment a person steps into a physician's office and says they have heartburn or any symptoms of reflux, very often the first trigger is to put them on medication. Unfortunately, that medication can be administered for some patients for decades," says Dr. Zarnegar, who specializes in endocrinology and minimally invasive approaches to the management of esophageal disease and GERD. "The concept of our paper, which was published in the *Journal of Gastrointestinal Surgery*, was to show not only that a lot of people who are on medications are usually misdiagnosed, but also that they don't have reflux. Therefore, it is very important to get the correct testing done to ensure that a patient has reflux before going on medications long-term."

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## Meeting the Need for Comprehensive Care of Motility and Acid Related Disorders

While motility disorders affect a significant portion of the population, specialized care in this area has been notably limited. With the appointment of **Bani Chander Roland, MD**, as the Director of the Center for New York Motility, Neurogastroenterology and Acid Related (GERD) Disorders, NewYork-Presbyterian/Columbia University Medical Center seeks to address this need.

"The absence of an established, comprehensive GI motility and reflux center in the New York City region has resulted in a large volume of patients who have unmet needs for care," says Dr. Roland. Under Dr. Roland's direction, the new Center is committed to improving the health of these patients by



*Dr. Bani Chander Roland*

providing access to cutting-edge diagnostic techniques, novel therapeutic medicines and devices, and through management decisions that are based on the latest research.

"Motility disorders are very common in patients with irritable bowel syndrome and chronic, multi-systemic illnesses," says Dr. Roland. "In the past, many patients with chronic unexplained gastrointestinal symptoms or so-called 'functional' bowel disorders were told that their symptoms

were psychosomatic. However, we are now realizing the contribution of gastrointestinal dysmotility, alterations in the microbiome, and local immune activation or inflammation in these patients."

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## The Cost and Clinical Benefits of Early Referral for Esophageal pH Monitoring *(continued from page 1)*

Dr. Zarnegar, in collaboration with Thomas J. Fahey III, MD, Chief of Endocrinology Surgery at NewYork-Presbyterian/Weill Cornell Medical Center, who advised on the study design and reviewed the data, and Weill Cornell gastroenterologists, who included Brian P. Bosworth, MD, and Carl V. Crawford, MD, created a cost model on a cohort of 100 patients with possible GERD who underwent pH monitoring. The gold standard for objectively diagnosing GERD is the documentation of prolonged, frequent acid reflux events using reflux monitoring, which most commonly involves a 24-hour continuous ambulatory esophageal pH monitoring system.

The additional costs incurred from pH monitoring were compared to the potential savings from avoiding unnecessary PPI usage in patients with a negative pH study. The costs of PPI therapy reach equivalence with pH monitoring after 6.4 to 23.7 weeks, depending on the PPI regimen. A total of 21,411 weeks of PPIs were prescribed beyond the recommended eight-week trial, of which 32 percent were for patients who had a negative 24-hour pH monitoring study. If the sensitivity of pH monitoring was 96 percent, early referral for pH monitoring would have saved between \$1,197 and \$6,303 per patient over 10 years.

**“We’re striving, especially with reflux, to make it a more objective disease and have real data to prove the diagnosis prior to putting people on long-term medications for this very common disease.”**

— Dr. Rasa Zarnegar

“We believe this strategy remains cost-effective as long as the sensitivity of pH monitoring is above 35 percent,” notes Dr. Zarnegar. The researchers concluded that prompt referral for pH monitoring after a brief empiric PPI trial is a more cost-effective strategy than prolonged empiric PPI trials for patients with both esophageal and extraesophageal GERD symptoms.

### The Clinical Advantage

The researchers also point out that there are other important benefits to accurate diagnosis of GERD and the avoidance of unnecessary consumption of PPIs, which as with many medications, carry risks with long-term use.

“Many people deal with reflux, sometimes on a daily basis,” says Dr. Crawford. “When we look at how we treat things in society, we have different options. We can change our lifestyles or we can take medications, and sometimes for some individuals, changing a lifestyle is very difficult. If a person can’t change their lifestyle and deal with these particular symptoms, then they may adopt medications. And really nothing that we do in medicine is without some sort of drawback.

“If people who may have a long history and probably a long future of reflux adopt an acid suppressant medication, it changes the body’s physiology,” continues Dr. Crawford. “By reducing the amount of gastric acid inside of the stomach and reducing symptoms of reflux, you’re actually going against what the human



*(Seated) Dr. Thomas J. Fahey III and Dr. Carl V. Crawford; (standing) Dr. Brian P. Bosworth and Dr. Rasa Zarnegar*

body typically would do in order to help it digest food. It becomes a balancing act. If you’re not processing food the right way, you’re not going to be able to extract all the nutrients from foods. The medications may also work on other cell types in addition to the cells that live in the stomach that produce the acid.”

If medications are effective, says Dr. Bosworth, patients end up staying on them indefinitely; however, when they are not effective, they still wind up staying on them indefinitely and sometimes this results in long-term, continued ineffective use of medication.

The Weill Cornell physicians also point out that multiple endoscopies are often ordered to determine if something else is going on, also adding to the burden of cost. “Sometimes there won’t be any actual definitive evidence so that the patient can continue or stop therapy or change the whole therapeutic structure to try to maximize the control of symptoms with what is going on pathophysiologically,” says Dr. Bosworth. “The goal of our study was to see if an intervention, such as implementing pH monitoring to objectively determine if there was reflux, would be able with a high degree of certainty tell patients that their acid reflux was or was not acid-based.”

If not acid-based, says Dr. Bosworth, a proton pump inhibitor would not be an effective medication to continue, thereby, minimizing the long-term complications from the drug and shifting them to more effective therapeutic strategies.

The researchers concur that in an era of trying to deliver high value care where patients, providers, and insurance companies are cost-conscious, being able to implement a therapeutic change based on rational decision-making capabilities, such as wearing a pH esophageal monitor, would seem to be a rational choice. “However, there are barriers to that decision in terms of the patient’s discomfort,” says Dr. Bosworth. “This is just another procedure that they have to undergo yet again. But this is one that can actually change the care that they’re being offered and that, hopefully, is something that actually benefits them.”

According to Dr. Crawford, physicians who prescribe PPIs do so to help a patient’s symptoms, but may also tend to leave a patient on these medications for too long. “There are certain patient

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## Meeting the Need for Comprehensive Care of Motility and Acid Related Disorders *(continued from page 1)*

The Center currently offers a comprehensive range of motility testing for esophageal, gastric, small bowel, and colonic motility disorders, including high resolution esophageal manometry, Bravo wireless pH testing, 24 hr pH/Impedance, wireless motility capsule testing, and high resolution anorectal manometry.

Dr. Roland notes that the complex multisystem diseases of many patients suffering from underlying motility disorders creates a need for cross-specialty collaboration. “Effective care really requires input not only from a GI motility perspective, but often a collaboration with a variety of medical and surgical subspecialties,” explains Dr. Roland. “In coming to Columbia, I knew that I would be surrounding myself with faculty who are leaders not only within the field of gastroenterology, but also in other divisions, creating an opportunity for really exciting collaborative clinical care and research. These collaborations will enhance delivery of clinical care for our patients and research productivity.”

Dr. Roland joined the Division of Digestive and Liver Diseases at NewYork-Presbyterian/Columbia in November 2014 from Johns Hopkins Medicine, where she specialized in motility and neurogastroenterology, with a subspecialty interest in small intestinal bacterial overgrowth and small bowel dysmotility. After receiving her BA from the Johns Hopkins University, she went on to receive her MD from New York University School of Medicine, and then completed a clinical research focused fellowship in digestive and liver diseases at Yale University School of Medicine. She also received additional subspecialty training in neurogastroenterology and motility at Temple University School of Medicine. Dr. Roland also spent time learning antroduodenal manometry, a method to evaluate small bowel motility, at the Motility Center of The Mayo Clinic.

### Research into Emerging Therapies

Within the field of neurogastroenterology, there has been a notable emergence of novel endoscopic and pharmacological therapies, in part due to significant discoveries in the underlying pathophysiological mechanisms of motility disorders. “There has been a range of innovative therapeutic technologies introduced recently, including the gastric electrical stimulation implants for patients with gastroparesis, endoscopic submucosal myotomy in patients with achalasia, and we will very likely see the emergence of other innovation therapies, potentially even nerve transplantation for treatment of motility disorders in the near future,” says Dr. Roland.

Dr. Roland’s own research has focused on the use of innovative techniques to advance the field, with a specific drive toward the creation of diagnostic and therapeutic methods that will positively impact patient care. With an approach balancing clinical and translational research, Dr. Roland has made significant contributions in the investigation of the role of small intestinal dysmotility and the microbiome in small intestinal bacterial overgrowth (SIBO). She hopes to translate fundamental and multifaceted information about SIBO and the microbiome into practical applications that ultimately alleviate the suffering of those with conditions such as irritable bowel syndrome and other gastrointestinal disorders.

“While we have started to make progress in research into motility disorders that affect the esophagus, the stomach, and colon, there is still very little known about motility disorders that affect the small bowel and how to go about treating dysmotility in this portion of the gut,” says Dr. Roland. “The relationship between gastrointestinal

motility and the microbiome has also yet to be clarified.”

Recent research, including that of Dr. Roland, has incorporated novel deep sequencing methods to help to better understand the relationship not only between the gut microbiome and human health, but also more recently the relationship between the microbiome and GI disorders and systemic illness. Deep sequencing of the intestinal microbiome has been transformative in advancing the understanding of diseases such as obesity and type 2 diabetes by facilitating the identification of novel candidate bacterial species and the metabolic functions that are associated with these diseases.

“Deep sequencing techniques of the microbiome have the potential to progress our understanding of GI motility disorders, complex syndromes such as SIBO, and a range of systemic illnesses,” says Dr. Roland. “There is significant hope that better understanding of the components and function of the gut microbiome developed through research utilizing these methods will lead to a rationale for targeted manipulation and therapeutic treatment strategies. My current research is based on studying and establishing a potential link between alterations in GI motility sphincteric function in the gut, as well as intestinal microbiology.” She notes that we are just beginning to understand mechanisms contributing to SIBO and the microbial profile in many of these disorders.

Through the use of novel diagnostic techniques such as the wireless motility capsule (WMC, *SmartPill*), Dr. Roland is engaging in cutting-edge research with very near and positive effects on patient care. In particular, her research has revealed new knowledge about the effects of ileocecal valve dysfunction, prolonged bowel transit time, intestinal pH, and a host of other motility parameters in contribution to the evolution of SIBO in patients.

Explaining the wider implications of this novel use of the WMC, Dr. Roland notes, “Data that can be obtained easily from the wireless motility capsule can be used to help uncover pathophysiological mechanisms to facilitate phenotyping of these patients based on distinct etiopathogenesis. This research may provide a basis for rational and targeted therapeutic strategies in SIBO, functional bowel disease, and a variety of other gastrointestinal disorders.”

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### The Cost and Clinical Benefits of Early Referral for Esophageal pH Monitoring *(continued from page 3)*

populations that may actually benefit from surgeries to help fix the problem of reflux. And a lot of patients may be denied some of these surgeries, which would free them from medications and give them better control of their symptoms,” he says. “Our study looked at the monetary cost to drive the point that there is also a health cost or a health risk associated with not treating GERD in the right way. And we were really trying to determine if there is a level at which there is a cost in health intersection where we can say that these patients have been treated with these medications for too long and that they need to be treated another way or evaluated in a different light.”

“I think the importance of these studies is to shed light on better ways of managing people with reflux,” says Dr. Zarnegar. “Clinicians should be mindful of the cost implications of prolonged

empiric trials of PPIs, and they should consider referring patients for pH monitoring earlier in the course of their treatment.”

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