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Providing Exceptional Care

In this issue of Innovations in Digestive Health, we highlight the work being carried out by multidisciplinary teams from four of the seven Centers of Excellence that compose University Hospitals Digestive Health Institute at UH Case Medical Center and UH Ahuja Medical Center. These stories showcase the patient-oriented, high-quality clinical outcomes and applied research produced by our specialists from the Gastrointestinal (GI) Cancer Center, the Inflammatory Bowel Disease Center, the Community Gastroenterology & Quality Center and the Advanced Technology & Innovation Center.

In our cover story you will read about our efforts to develop a new practical and inexpensive outcomes measurement tool that will hopefully facilitate the implementation and evaluation of surgical quality improvement initiatives across a variety of hospital settings. We have recently published in the Annals of Surgery the results of a study describing and validating this new measure in the assessment of clinical outcomes following colorectal surgery.

The first feature story in this issue focuses on how we incorporate advanced, effective techniques, such as endoscopic submucosal dissection and cryotherapy, in individualized treatment plans for patients with Barrett’s esophagus and early-stage esophageal cancers. We have the expertise to optimize care by selecting the treatment modality best suited for each patient’s unique case.

Another story explores how we have developed and implemented advanced magnetic resonance imaging protocols to achieve unequalled results in the treatment of patients with rectal cancer, pelvic floor disorders and Crohn’s disease. Other institutions around the country have adopted these protocols.

This issue also features a case study of a patient who was transferred to UH Case Medical Center because of unusual, life-threatening GI bleeding. Our finely honed multidisciplinary approach and timely use of advanced endoscopic techniques were key to the successful treatment of this patient.

Together with our colleagues, we are continually exploring new treatments and technologies that will help us improve all aspects of patient care. We encourage you to contact us to discuss how we might collaborate with you to address your patients’ needs.

Fabio Cominelli, MD, PhD
Chief, Division of Gastroenterology & Liver Disease
Director, UH Digestive Health Institute
UH Case Medical Center
Hermann Menges Jr. Chair and Professor of Medicine
Case Western Reserve University School of Medicine
Feature Story

Attacking Barrett’s Esophagus and Early-Stage Esophageal Cancers

Personalized care with a menu of advanced, effective endoscopic techniques

Specialists at University Hospitals Digestive Health Institute use the latest, most effective innovations to care for patients with Barrett’s esophagus (BE) and early-stage esophageal cancers. The goals of treatment for BE are to remove or eradicate the lesions and to promote healing by aggressive treatment of acid reflux, explains John Dumot, DO, Chief of Staff and Director, UH Digestive Health Institute at UH Ahuja Medical Center; and Professor of Medicine, Case Western Reserve University School of Medicine. Depending upon the degree of dysplasia or neoplasia, treatments include endoscopic lesion removal, cryotherapy or radiofrequency ablation.

“Recent advancements include endoscopic submucosal dissection (ESD) and cryotherapy,” says Dr. Dumot. “We tailor therapy to each patient by choosing the best suited modality based on the type of lesion, the anatomy of the surrounding esophagus and the patient’s preferences.”

Endoscopic Submucosal Dissection

“ESD, which was developed as the natural progression from esophageal mucosal resection (EMR), is more difficult to perform but is more effective in certain situations,” says Dr. Dumot. EMR allows removal of lesions that are up to 10 to 15 millimeters in diameter. In the past, larger lesions had to be removed through piecemeal mucosal resection, which made pathologic evaluation of the lateral and deep margins difficult.

“Depending upon their location, with ESD we can remove, en bloc and with intact margins, lesions as large as six centimeters,” says Dr. Dumot. “According to the published information available, primarily from Japan, the recurrence rate is lower with ESD compared with EMR.”

Barrett’s Esophagus

In individuals with Barrett’s esophagus, the normal squamous epithelium in the mucosal layer lining the lower esophagus changes to columnar epithelium in response to chronic exposure to acid and bile reflux, as seen with gastroesophageal reflux disease (GERD).

Compared with the general population, patients with BE have an 11-fold higher risk of developing adenocarcinoma of the esophagus. A recent study reported a 0.12 percent annual risk of esophageal adenocarcinoma, with incidence rates of 5.1 cases per 1,000 person-years among individuals with low-grade dysplasia, compared with 1.0 case per 1,000 person-years among those without dysplasia (Hvid-Jensen et al., N Engl J Med 2011;365:1375-1383).

Cryotherapy

“While cryotherapy is more challenging to perform than radiofrequency ablation (RFA), there are many times when RFA is not possible because the lesion is too thick or is cancerous, or the lumen wall is too irregular,” says Dr. Dumot.

As a spray application, cryotherapy is ideal for the treatment of BE or early-stage esophageal cancer lesions in patients with esophageal walls that are naturally uneven, or that have deformations caused by scarring that developed during healing after prior procedures, such as EMR or ESD.

“The ideal candidate for ESD has BE lesions or proven cancer that appears to be limited to the mucosa layer above the submucosa,” explains Dr. Dumot. Some patients with lesions that have invaded the submucosa might be candidates for endoscopic treatment if the pathologic grading is favorable, or if the individual is considered at high risk for esophagectomy. UH is one of a select group of fewer than 30 U.S. institutions that offer ESD.

Contact Our Experts

To learn more about options for your patients with Barrett’s esophagus, contact John Dumot, DO, at 216-593-1305, option #2, or Amitabh Chak, MD, at 216-844-5385.
The HARM Score: A New Tool to Promote Surgical Excellence

Leaders in the field of colorectal surgery develop a practical, inexpensive quality assurance measure.

University Hospitals Case Medical Center is one of only 18 hospitals in the U.S. to have been named to U.S. News & World Report’s 2013 – 2014 Best Hospitals Honor Roll. U.S. News & World Report ranked six UH specialties in the top 20, and the Gastroenterology and GI Surgery service provided by UH Digestive Health Institute was ranked 13th in the nation. These rankings are largely based on objective measures including patient survival, safety data and nursing staffing levels.

“In addition to excelling in patient care, we are nationally prominent in the field of outcomes research,” says Conor P. Delaney, MD, MCh, PhD, Chief, Division of Colorectal Surgery; Vice Chair, UH Department of Surgery; Director, UH Digestive Health Institute at UH Case Medical Center; Director, Case Western Reserve University School of Medicine Center for Skills and Simulation; and The Jeffrey L. Ponsky Professor of Surgical Education at Case Western Reserve University School of Medicine.

Dr. Delaney and his research group have developed and validated a new outcomes measurement tool, the HARM score, which is easily calculated from routine administrative data without the need for dedicated resources or specialized training. The research group’s goal is to devise a simple tool to facilitate surgical quality improvement initiatives that enhance patient outcomes.

Inception of a New Quality and Outcomes Tool

“Currently one of the foremost available outcomes tools, the National Surgical Quality Improvement Program (NSQIP) is very good and very well-validated, but it is expensive and complicated to maintain to the point that many hospitals in the country don’t participate in the program,” says Dr. Delaney. In his view, the ideal quality and outcomes tool would produce a score that could be applied to all hospitals using routinely available data.

“For nearly 15 years, we have been studying outcomes following colorectal surgery primarily around the context of enhanced recovery pathways – standardized care protocols that accelerate patient recovery after surgery and reduce complications rates,” explains Dr. Delaney, who has published several articles in this field. “Our research suggests that some of the most important outcome measures are hospital stay, readmissions and mortality. Coincidentally, these endpoints are among those routinely tracked by hospitals.”

To test the applicability of these three endpoints in measuring patient outcomes, Dr. Delaney’s group calculated a composite measure, which it calls the “Hospital stay, Readmission and Mortality” (HARM) score.

Validation of HARM Score

In a paper recently published in the Annals of Surgery, Dr. Delaney and his co-authors described the HARM score and how they validated its use in the assessment of clinical outcomes following colorectal surgery (Ann Surg. 2013;13:00:1-7).

The researchers analyzed a large national dataset from 650 hospitals to retrospectively test the HARM score on all colectomy discharges carried out from 2010 to 2011 at sites with a minimum of 30 cases. For each discharge, the investigators calculated a HARM score on a zero to 10 scale, based on reason for hospital admission (emergent or elective); length of hospital stay (LOS); discharge status (alive or expired); and

Minimally invasive surgical approaches help speed patient recovery and reduce complications after colorectal surgery.
30-day readmission. Their large dataset included 81,622 colectomy discharges from 324 hospitals. Most of the procedures (56 percent) were categorized as elective.

To test its validity, Dr. Delaney and his co-authors compared the HARM score against hospital-level complication rates. They evaluated complications such as postoperative infection, hemorrhage, gastrointestinal complications and blood transfusion. “We showed that for patients who had a colorectal resection, the HARM score directly correlated with complication rates,” says Dr. Delaney. “Instead of fancy tests, dedicated staff or specialized training, we used routine administrative data.”

According to Dr. Delaney, the HARM score has the potential to decrease the administrative costs associated with quality care improvement programs, while having applicability to different types of hospitals and to individual surgeons with at least 30 eligible cases.

Ongoing and Future Studies

“While the evidence so far suggests that HARM is a very robust quality and outcomes measure for major abdominal surgery, further research is needed before the HARM score will be ready for applications by governments and other agencies,” says Dr. Delaney. There are inherent limitations to the applicability of this tool (see sidebar), and prospective studies in clinical practice settings and on a national Medicare dataset are warranted, he explained.

“We are also currently studying other datasets in upper gastrointestinal surgery, liver surgery and pancreas surgery,” says Dr. Delaney. “We haven’t published these data yet but the preliminary results suggest that the HARM score is equally effective at demonstrating complication rates and outcomes for patients who have undergone different types of abdominal surgery.”

In addition, Dr. Delaney’s group has initiated collaborations with other interested researchers in the U.S. and abroad. Clinical researchers in Norway have just started testing the HARM score, and their work will help determine its applicability to populations in other countries. Dr. Delaney is also discussing the possibility of testing the HARM score as an outcomes measure for cardiac surgery with colleagues at UH Case Medical Center.

Limitations of the HARM Score

“The HARM score does not capture outcomes data on postoperative events that do not require readmission, such as the outpatient treatment of a minor wound infection with antibiotics,” says Conor P. Delaney, MD, MCh, PhD. “Also, because it would not be possible to obtain a meaningful dataset, the HARM score is not applicable for procedures that entail very short LOS and low mortality, such as gallbladder surgery.”

The HARM score does not take into account patient satisfaction, either. However, Dr. Delaney says, “patient satisfaction is something that is tracked already by HCAHPS (Hospital Care Quality Information from the Consumer Perspective) scores. There are so many potential issues with assessing and improving the quality of care that it’s most important for patients to know the safest and best hospitals for their particular needs, especially for major surgery. That’s where the HARM score has a lot of potential.”

Call Our Experts

To consult about options for your patients needing colorectal surgery or to discuss quality outcomes tools, contact Conor P. Delaney, MD, MCh, PhD, at UH Case Medical Center. Call 216-844-8087, option #2.
The past two decades have produced tremendous innovations in the medical and surgical treatment of rectal cancer, as well as in the imaging technologies used in patients with diseases of the digestive tract. **Bradley J. Champagne, MD**, Program Director, Colorectal Residency; Surgical Director, Community Gastroenterology & Quality Center, University Hospitals Digestive Health Institute, UH Case Medical Center; and Associate Professor of Surgery, Case Western Reserve University School of Medicine, and his colleagues at UH Case Medical Center and UH Seidman Cancer Center utilize an advanced magnetic resonance imaging (MRI) protocol that has been adopted by many centers around the country.

**Rectal Cancer**

"Dr. Paspulati’s protocol has contributed to the national trend to adopt MRI as the standard of care for staging and planning surgery in the treatment of patients with rectal cancer," says Dr. Champagne. "Through the combination of MRI and our surgical expertise, we have achieved local recurrence rates of approximately 3 percent, while nationally they are as high as 10 to 20 percent." Thanks to MRI and sound technique, the surgeons at UH Case Medical Center obtain great oncologic outcomes with sphincter-sparing operations in patients with low rectal cancers.

Pelvic MRI also greatly facilitates the identification of patients who would benefit from intraoperative radiation therapy (IORT), says Dr. Champagne. **Harry Reynolds, MD**, Associate Professor of Surgery, Case Western Reserve School of Medicine, helped pioneer the use of IORT for pelvic malignancies, specifically recurrent rectal cancer, and has published the group’s experience with IORT.

Other applications of MRI include the treatment of women with pelvic floor disorders. This is a group of patients for whom the indications for surgery have been nebulous. "Dynamic MRI allows us to carefully characterize the details of the pelvic floor anatomy that help determine if and when to operate," says Dr. Champagne. "At UH, colorectal surgeons and urogynecologists implement this advanced MRI technology to optimize the care of patients with rectoceles, rectal prolapse and fecal incontinence."

At a recent national forum, Dr. Champagne and his colleagues presented preliminary results from a study outlining the indications for surgery for women with pelvic floor disorders (see sidebar). Results from the study will be published in March 2014 in the American Journal of Surgery.

**Crohn’s Disease**

"The development of advanced MRI techniques has also influenced the treatment of patients with Crohn’s disease," says Dr. Champagne. Computed tomography (CT) enterography and magnetic resonance (MR) enterography have replaced small-bowel follow-through as the new standards of care for imaging of these patients. Under the leadership of **Jeffry Katz, MD**, and **Sharon Stein, MD**, physicians in the Inflammatory Bowel Disease Center have collaborated with Dr. Paspulati to develop treatment strategies using MR enterography. Dr. Katz is Medical Director, Inflammatory Bowel Disease Center, UH Digestive Health Institute; and Professor of Medicine, Case Western Reserve School of Medicine.

**Call Our Experts**

To discuss options for your patients with rectal cancers and pelvic floor disorders with some of our experts at UH Case Medical Center call Bradley J. Champagne, MD, at 216-844-8942, option #2, Jeffry Katz, MD, at 216-844-1995, option #2, Harry Reynolds, MD, at 216-844-5798, option #2, or Sharon Stein, MD, at 216-844-2873, option #2.

**UH Case Medical Center is the only center in Ohio to offer an integrated IORT suite for rectal cancer.**

**Pelvic Floor Disorders**

Another application of MRI is the treatment of women with pelvic floor disorders. This is a group of patients for whom the indications for surgery have been nebulous. "Dynamic MRI allows us to carefully characterize the details of the pelvic floor anatomy that help determine if and when to operate," says Dr. Champagne. "At UH, colorectal surgeons and urogynecologists implement this advanced MRI technology to optimize the care of patients with rectoceles, rectal prolapse and fecal incontinence."

**Research that Impacts Practice**

At the Midwest Surgical Association’s 56th annual meeting (held July 28 to 31, 2013, in Acme, Mich.), Dr. Champagne and his colleagues presented their study of a novel protocol using both clinical presentation and dynamic MRI defecography to determine which patients with constipation and symptoms of pelvic outlet obstruction met the criteria for surgical repair (Hall G, et al. Abstract 12, page 39).

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A 77-year-old man with coronary artery disease, hypertension and a pacemaker presented with shortness of breath and melena worsening over five days. Esophagogastroduodenoscopy was normal; colonoscopy revealed pan-diverticulosis without signs of active bleeding; and small bowel endoscopy indicated a small diverticulum in the distal duodenum and proximal jejunum but no signs of bleeding. Despite repeated blood infusions, the patient continued to have melena.

The patient was transferred to University Hospitals Case Medical Center and a computed tomography angiogram did not uncover the source of bleeding. Small bowel capsule endoscopy (SBCE) showed a large jejunal diverticulum surrounded by old blood. Upper balloon-assisted enteroscopy showed multiple large-sized diverticula with old blood and clots but no actively bleeding lesion or recent stigmata in the distal duodenum and throughout the jejunum. The extensive involvement of the proximal duodenum and no signs of active bleeding made surgical intervention technically difficult.

Treatment

The patient continued to require blood transfusions and began to pass maroon-colored stools. He was taken for an urgent small bowel enteroscopy with a cap-fitted pediatric colonoscope to try and isolate the specific diverticulum that was presumed to be bleeding. Fresh blood was found in the proximal jejunum, and a large diverticulum with a fresh clot and oozing blood was seen, but it was not possible to visualize a target for endoscopic therapy. Tattoo marking was applied, and the patient was sent for urgent surgery.

Surgeons performed a laparotomy and resected a 40-centimeter segment containing the tattooed area of small bowel, finding fresh blood inside. Pathologic examination confirmed the tattooed diverticulum to be the source of bleeding. No further episodes of bleeding occurred after surgery and during one year of follow-up.

Discussion

UH Case Medical Center was one of the first centers in the country to perform SBCE when it was introduced in 2001, and to perform deep small bowel enteroscopy (DSBE) with double-balloon enteroscopy in 2006, explains Gerard Isenberg, MD, MBA, Associate Chief, UH Division of Gastroenterology & Liver Disease; Director, Clinical Operations, UH Case Medical Center; and Associate Professor of Medicine, Case Western Reserve University School of Medicine.

Dr. Isenberg has extensive experience with SBCE and DSBE, and is one of the authors of the first American Society for Gastrointestinal Endoscopy guidelines for SBCE (Gastrointest Endosc. 2002;56:621-624).

“in this patient, the SBCE localized the obscure bleeding to the proximal jejunum, thus allowing continued focus from an endoscopic standpoint for possible therapy,” explains Dr. Isenberg. “Tattoo marking is another tool for assisting our surgical colleagues in the event surgery is required to allow for laparoscopic, instead of open, surgical resection.”

“This case illustrates the importance of the timing of endoscopy in reaching the appropriate diagnosis and the use of a multidisciplinary approach in successful treatment,” says Dr. Isenberg. “Evaluation of the small bowel during an episode of active bleeding proved to be the key in determining the correct diagnosis. In cases where the etiology of intestinal bleeding is unclear or other diagnostic testing is inconclusive, DSBE at the time of active bleeding may have a role to play in establishing the diagnosis and providing treatment.”

Dr. Isenberg collaborates with leading gastroenterologists, surgeons, radiologists and other specialists at the UH Digestive Health Institute to provide a comprehensive, superior team approach in the diagnosis and treatment of patients with obscure gastrointestinal bleeding.

Consult With Our Experts

To discuss state-of-the-art endoscopic and surgical management of patients with obscure gastrointestinal bleeding with Gerard Isenberg, MD, MBA, at UH Case Medical Center call 216-844-6172, option #2; with John Dumot, DO, at UH Ahuja Medical Center, call 216-593-1305, option #2; or with one of their colleagues at UH Digestive Health Institute, call 1-866-UH4-CARE (1-866-844-2273).
Dr. Stein is Surgical Director, Inflammatory Bowel Disease Center, UH Digestive Health Institute; and Associate Professor of Surgery, Case Western Reserve School of Medicine.

“Despite the vastly improved imaging obtained with MR enterography and the dramatic impact it has on patient care, very few centers offer it and have the ability to interpret the images as we do with our experts in radiology and gastroenterology,” says Dr. Champagne.

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POEM: A Novel Procedure to Restore Swallowing

University Hospitals Case Medical Center is one of approximately 10 institutions in the country offering the per-oral endoscopic myotomy (POEM) procedure for patients with dysphagia due to achalasia, and other esophageal motility disorders such as diffuse esophageal spasm and nutcracker esophagus.

Patients with achalasia lose the ability to swallow due to lack of relaxation of the lower esophageal sphincter (LES). Developed in Japan a few years ago, POEM is a new alternative to the standard surgical care called laparoscopic Heller myotomy, which involves making tiny incisions in the abdomen and dividing the muscles of the lower esophagus, LES and upper stomach.

POEM is unique in that surgeons enter the esophagus through the mouth, make a tiny incision in the inner lining of the esophagus, and cut the muscle endoscopically, without a skin incision. POEM's benefits include eliminating the need for abdominal surgery, less pain and quicker recovery. To date, UH Case Medical Center surgeons have successfully performed 47 POEM surgeries with encouraging preliminary results in resolution of swallowing difficulties in nearly all patients.

Physician News

Bradley J. Champagne, MD, FACS FASCRS, Program Director, Colorectal Residency; Surgical Director, Community Gastroenterology & Quality Center, UH Digestive Health Institute, University Hospitals Case Medical Center; and Associate Professor of Surgery, Case Western Reserve University School of Medicine, was named Program Chair for the American Society of Colon & Rectal Surgeons (ASCRS) 2014 meeting. He has also been named the Young Surgeon Representative to the Advisory Council of the American College of Surgeons.

Joseph A. Trunzo, MD, has recently joined the Division of Colorectal Surgery at University Hospitals Digestive Health Institute. Board-certified in general surgery, Dr. Trunzo is Assistant Professor of Surgery, Case Western Reserve University School of Medicine. He practices colorectal surgery as part of St. John Medical Group in Westlake and Middleburg Heights, Ohio, and has admitting privileges at St. John Medical Center and Southwest General Health Center (UH joint venture hospitals). After receiving his medical degree from Wright State University School of Medicine in Dayton, Ohio, Dr. Trunzo completed an internship and residency in general surgery at UH Case Medical Center, and was a research fellow as a Dudley P. Allen Research Scholar at UH Case Medical Center. He subsequently completed a fellowship in colorectal surgery at the Cleveland Clinic Foundation. In addition to colorectal cancer, Dr. Trunzo specializes in inflammatory bowel disease and pelvic floor disorders.

Advanced Learning Opportunity

The Gastrointestinal and GI Surgery Update Symposium held on January 18, 2014, presented the newest information on inflammatory bowel disease, advanced endoscopy and interventional endoscopy, quality standards, minimally invasive surgical outcomes, changes in the management of colorectal cancer, and hernias and reoperative surgery. Please contact Rita.Rys@UHhospitals.org to view the video of the symposium.

Speakers included:
- Fabio Cominelli, MD, PhD; Jeffry Katz, MD; and Sharon Stein, MD, on medical and surgical treatment of IBD
- John Dumot, DO; Jeffrey Marks, MD; and Jeffrey Ponsky, MD, on advanced endoscopic therapies – POEM, ESD, PEG and ERCP
- Conor P. Delaney, MD, PhD; and Harry Reynolds, MD, on minimally invasive treatment of colorectal cancer
- John Ammori, MD, on managing patients needing reoperative abdominal surgery
- Michael Koehler, MD, on integrating community gastroenterology