POEM: Inside Out Myotomy

Multidisciplinary Approach Transforms Achalasia Care
Digestive Disease Institute at Virginia Mason

Virginia Mason’s Digestive Disease Institute optimizes patient care through innovations in research and education as well as a multidisciplinary approach to quality treatment of digestive and liver diseases.

Areas of Emphasis

Education & Training | Headed by Ian Gan, MD, the Digestive Disease Institute is launching two new research fellowships focusing on endoscopy and benign pancreatic disease.

Research | Co-directors Michael Chiorean, MD, and Flavio Rocha, MD, are expanding a diverse portfolio of clinical trials in digestive disease.

Quality Improvement | Director Otto Lin, MD, is measuring and exploring data on computer assisted propofol sedation and studying therapeutic endoscopists’ exposure to radiation.

Innovation | Lily Chang, MD, is launching a public lecture series on nutrition in the context of NAFLD, weight loss, food allergies and colorectal cancer prevention.

Centers of Excellence

The Digestive Disease Institute’s eight centers promote new knowledge and treatment through research, education, innovation and continuous quality improvement.

Bariatric Surgery Center of Excellence | Jeffrey Hunter, MD, is measuring impacts of a multidisciplinary complications conference and shared medical appointments on post-bariatric surgery patient outcomes.

Esophageal Center of Excellence | Donald Low, MD, is writing ERAS Society national guidelines and collaborating with international esophageal centers on esophageal cancer care.

Inflammatory Bowel Disease Center of Excellence | Michael Chiorean, MD, leads a multi-site IBD Journal Club and is developing a patient video on nutrition in the context of IBD, featuring dietitians with specialization in digestive disease.

Liver Center of Excellence | Director Asma Siddique, MD, is creating an evidence based pathway for care of inpatients with cirrhosis and collaborating to treat renal failure patients with hepatitis C.

Liver, Pancreas and Biliary Surgical Center of Excellence | As a National Pancreas Foundation Center of Excellence, Scott Helton, MD, and team are launching a Web-based clinician resource for pancreatitis patient care: VirginiaMason.org/pancreatitis-management.

Nutrition Center of Excellence | Director Jonathan Stoehr, MD, PhD, is working to formally report success rates with medications for weight loss and is rolling out national guideline standards for care of obese patients system-wide.

Pancreatic Center of Excellence | Co-director Vincent Picozzi, MD, is studying the impacts of dedicated pancreas cancer nutritional care while co-director Shayan Irani, MD, is building a standard approach to assessment of pancreatic cysts.

Therapeutic Endoscopy Center of Excellence | Andrew Ross, MD, is completing analysis on 1,400 ERCP cases, measuring cannulation rates and defining outcomes, and embedding peroral endoscopic myotomy (POEM) as the standard of care for achalasia.
A Conversation with
Richard A. Kozarek, MD
Executive Director, Digestive Disease Institute at Virginia Mason

Q. The need to treat obesity in the US and around the world has skyrocketed. How can GI, bariatric surgery and nutrition work together to the best effect?
A. We live in an era of indulgence. Much of our population’s health is shaped by too many calories ingested versus expended. We expand, develop central obesity, fatty liver, diabetes, metabolic syndrome, NAFLD and additional consequences of more weight than our frames are designed to support. The Digestive Disease Institute’s Nutrition, Therapeutic Endoscopy, and Bariatric Centers of Excellence offer an integrated program including nutritional and exercise counseling, endocrine support, bariatric balloons, and when all else fails, a menu of bariatric surgeries.

Q. Endoscopy has changed over the years from primarily diagnostic to therapeutic and now, to repairs and primary bariatric procedures. What do you find most exciting and promising in this work?
A. To date, the role of endoscopy has primarily been relegated to treating the complications of bariatric surgeries: repairing strictures and leaks, and narrowing large anastomotic stomas. Stay tuned. Balloons, gastroduodenal condoms, and endoscopic restrictive procedures are all coming to a theater near you. They are already at our theater.

Q. How does the Digestive Disease Institute approach motility as a multidisciplinary team?
A. How can you do an anti-reflux surgery without assuring that esophageal manometry is normal or, in select cases, that the stomach empties normally? Why does a patient need pelvic reconstruction surgery when anorectal biofeedback and pelvic physical therapy are equally effective in the majority of patients? How do we approach motility as a multidisciplinary team? Every day. Every patient. Our team’s mantra is to apply individualized therapy based on diverse clinical expertise to maximize individual outcomes in a cost-effective way.

Q. What lies in the future for digestive disease care?
A. The Digestive Disease Institute will be establishing a new Colorectal Center of Excellence under the leadership of Anjali Kumar, MD, colorectal surgeon. Complementing our existing structures will be a regularly scheduled Multidisciplinary Team Conference for IBD, research on anorectal disease, and adherence to new national standards for excellence in the treatment of rectal cancer.

Because the future rests in training and mentoring the next generation of digestive disease experts, the Digestive Disease Institute is adding two new research fellowships this year, one in endoscopy and another in benign pancreatic disorders. This initiative expands our already robust research fellowship programs in esophageal disease and pancreas cancer as well as our international visiting scholar program and clinical fellowships in HPB surgery, gastroenterology, and advanced endoscopy. Research fellowships enhance and complement our clinical training programs. Most importantly, they challenge us to continue to probe and discover new science in the endlessly fascinating world of digestive disease care.
Peroral Endoscopic Myotomy (POEM)

Advances in treatment of achalasia, including minimally invasive Peroral Endoscopic Myotomy (POEM), are a key part of the Digestive Disease Institute approach. Andrew Ross, MD, gastroenterologist and Director, Therapeutic Endoscopy Center of Excellence, and Donald Low, MD, surgeon and Director, Esophageal Center of Excellence, work together to treat achalasia using high-definition upper endoscopes, giving patients a treatment option that can result in equivalent outcomes to Heller myotomy and a much quicker recovery time. “In true multidisciplinary fashion, surgeons and gastroenterologists have combined expertise in surgical management with the expertise of interventional endoscopy. By combining our joint experience and skill, we provide the best care for the patient,” states Dr. Ross.

Multidisciplinary Care Pathways

The Digestive Disease Institute’s Barrett’s esophagus pathway, developed by a multidisciplinary team, guides treatment from endoscopic assessment to endoscopic resection, through treatment of early T1a and T1b cancers, and organizes staging, treatment and recording of more advanced stages of esophageal cancer. Patients thus consistently receive evidence-based care from all disciplines and know their multiple options for treatment.

Similarly, the esophagectomy care pathway involves surgery, anesthesia, critical care, nursing, nutrition, and physical therapy, and supports the team in improving postoperative recovery via a goal-directed approach, from work-up through treatment and recovery. “Surgeons must move their focus away from small modifications in the operation toward improving all aspects of the

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Multidisciplinary Esophageal Care

Becca Hart, RN, Andrew Ross, MD, Donald Low, MD and Jessica Koller, MD, in the OR
Multidisciplinary teamwork contributed to increased endoscopic treatment of T1a esophageal adenocarcinoma with rates of complications, morbidity and mortality similar to surgical treatment. See Schmidt, et al., Multidisciplinary treatment of T1a adenocarcinoma in Barrett’s esophagus: contemporary comparison of endoscopic and surgical treatment in physiologically fit patients, Surgical Endoscopy, 2015 Nov 5.

International Outcomes: The New Frontier

In 2009, Virginia Mason envisioned creating a web-based system to report, share and analyze internationally standardized esophagectomy outcomes. Under the management of Donald Low, MD, and Madhan Kumar Kuppusamy, MD, Ryan Hill Research Fellow, the Esophageal Complications Consensus Group (ECCG) was born. Consisting of 24 physicians from 14 countries and five continents, the ECCG defined data points critical to measuring quality outcomes after esophagectomy. Since publishing its work in Annals of Surgery in 2015 (see Publications, pg. 13), the ECCG has been beta-testing the system in 24 international high-volume centers with the first web-based dataset ever utilized to conduct surgical research. Within the first three months, over 500 esophageal resections have been entered, with data available to members for analysis.

Expansion of the system is now being explored under the auspices of the International Society for Diseases of the Esophagus (ISDE), with the aim of widening use of the tool and guiding future research. “It has been very powerful and is still evolving. Partnering with ISDE will enable objective oversight, growth in primary goals and the potential to significantly affect esophageal patient outcomes around the world,” states Dr. Low.
Motility Clinic: Making a Difference

Diagnosing motility disorders is critical to effectively diagnosing and treating common gastrointestinal diseases such as achalasia, hiatal hernia, and acid versus non-acid reflux, as well as scleroderma, anorectal disorders and pelvic floor dysfunction. Virginia Mason’s high-resolution imaging, multi-disciplinary physician expertise, dedicated nursing team, and new motility clinic are leading the way in innovative motility care delivery:

- Multidisciplinary care with cross-consultation for complex motility issues from gastroenterology, surgery, and radiology
- Same-day access and 30-minute appointments for over 1,000 patients/year
- High-resolution esophageal manometry, ambulatory esophageal pH-impedance monitoring, Bravo esophageal pH monitoring, and high-resolution anorectal manometry, timed barium swallow, scintigraphy, pelvic floor MRI
- Motility tests are interpreted within 24 hours, facilitating immediate diagnosis and treatment

- Qing Zhang, MD, brings clinical and academic motility expertise in esophageal, stomach, small bowel and rectal motility
- The physician and nursing team have personally undergone esophageal motility testing, allowing them to identify with patients, reduce anxiety and provide real-time, empathic care
- Gastric electrical stimulation for treatment of long-term gastroparesis is provided via the Enterra Therapy system, a part of one of the largest clinical trial experiences in the U.S.

“**It feels great to not make patients wait. We can now say ‘yes’ to our patients and to our physicians, assuring the most efficient and highest quality motility care.**”

— DEBORAH TOMBS, RN
DIRECTOR, GI PROCEDURES
The Digestive Disease Institute’s nationally-accredited Bariatric Surgery Center of Excellence, led by Jeffrey Hunter, MD, is setting the standard for innovation and quality, with significant impact on patient satisfaction and sustained patient outcomes.

Using a novel appointment model, the Center provides weekly, 90-minute shared medical appointments (SMA) with a surgeon and registered dietitian for up to four patients and their families at a time. In a few hours and in one stop, patients complete all preoperative visits, education and testing. For the physician and dietitian, the model maximizes practice efficiency and prevents repetition of patient visit content. The greatest response, however, has been from patients, who enjoy meeting and networking with other patients on the same journey. This innovative, interactive approach, according to Bariatric Program Manager Connie Miller, RN, “…helps alleviate their fears. They often get answers to questions they didn’t know they had.”

New Visit Model Increases Satisfaction

To achieve the highest quality outcomes, the Center has implemented a Bariatric Surgery Follow-Up Dashboard with data from 2012 to the present. Monthly, the team reviews not only reductions and follow-up in BMI, but also changes in diabetes, sleep apnea,
Jeffrey Hunter, MD, performing bariatric surgery

hypertension, hyperlipidemia and GERD. In addition, the team examines readmissions, reoperations, follow-up rates, and eight different complications. Jeffrey Hunter, MD, points out, “Patient outcomes are best when follow-up is consistent over the long term. The dashboard cues us to reach out proactively to provide care before outcomes decline.”

In addition to Weight Loss Surgery Support Groups, the Bariatric Surgery Center of Excellence launched a private Facebook group in 2015, providing a forum for patients to ask questions, acknowledge the emotional challenges of weight loss, and guide one another, all without having to leave home. “Many patients who undergo bariatric surgery have been obese for as long as they can remember and have been potentially mistreated based upon their size. When they start losing weight, comments both positive and negative can affect them socially and psychologically,” states Lily Chang, MD, Director of Innovation. Whether in person or online, these tools help patients thrive, leading to outstanding outcomes at Virginia Mason.

Comorbidities of Bariatric Patients (n=694)
MARCH 2012–OCTOBER 2015

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Jeffrey Hunter, MD, performing bariatric surgery
Quarterly, a multidisciplinary team of gastroenterologists, psychologists, surgeons, radiologists, analysts, psychiatrists and nurses meet to discuss best practices in management of bariatric surgery complications. The Center of Excellence treats an average of 90 bariatric complications cases annually, virtually all of which were referred directly from other centers and/or who had surgery long ago at another location.

“One of our biggest challenges is trying to safely revise or reverse previous procedures and find safe solutions for the problems patients are experiencing”, says Jeffrey Hunter, MD. Endocrinologist Jonathan Stoehr, MD, PhD, adds, “Another challenge is determining how to scale the services we provide to meet demand, without sacrificing quality.”

In response to these opportunities, Virginia Mason has not only improved operations to meet patient need — for example, developing a single intake assessment tool for weight loss and post-surgical complications — but most importantly, has developed and is using evidence-based, multidisciplinary care pathways for post-bariatric complications. Using these pathways allows clinicians to anticipate issues and follow best practices in caring for gastro-gastric fistula, sleeve gastrectomy leak, weight loss failure/regain, and post-bariatric hypoglycemia. “No matter who is on call, they can look to the created pathways and accurately take the correct next steps,” states gastroenterologist Michael Larsen, MD.

Bariatric Surgeon Lily Chang, MD, shares similar thoughts: “Because of our team approach and pathways on exactly how to manage specific complications, we are not reinventing the wheel each time. With best practices available and implemented in every situation, results are better for both patients and providers.”

“One of our biggest challenges is trying to safely revise or reverse previous procedures and find safe solutions for the problems patients are experiencing.”

— JEFFREY HUNTER, MD
DIRECTOR, BARIATRIC SURGERY CENTER OF EXCELLENCEx
Digestive Disease Institute research focuses on identifying promising advances in the treatment of liver, inflammatory bowel, pancreas, stomach, bile duct and esophageal disease. Our research portfolio includes translational, medical device and pharmaceutical trials as well as non-interventional research.

Selected Clinical Research Studies

To refer patients or see a complete list of currently enrolling clinical trials, call the research hotline at (206) 341-1021 or visit VirginiaMason.org/DDI-Research.

**APD334-003**: A Phase II, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multi-Center Study to Investigate the Safety and Efficacy of APD334 in Patients with Moderately to Severely Active Ulcerative Colitis

**Goal**: Determine the effect of treatment with APD334 in inducing clinical remission at 12 weeks.

**CNT01275UCO3001**: A Phase III, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multicenter Protocol to Evaluate the Safety and Efficacy of Ustekinumab Induction and Maintenance Therapy in Subjects with Moderately to Severely Active Ulcerative Colitis

**Goal**: Evaluate the efficacy and safety of IV ustekinumab in inducing clinical remission in subjects with moderately to severely active UC.

**MLN0002-3026**: A Randomized, Double-Blind, Double-Dummy, Multicenter, Active-Controlled Study to Evaluate the Efficacy and Safety of Vedolizumab IV Compared to Adalimumab SC in Subjects with Ulcerative Colitis

**Goal**: Determine the effect of vedolizumab IV compared to adalimumab SC on clinical remission at week 52.

**GS-US-326-1100**: A Phase II/III, Double-Blind, Randomized, Placebo-Controlled, Multicenter, Combined Induction and Maintenance Study Evaluating the Safety and Efficacy of GS-5745 in Subjects with Moderately to Severely Active Ulcerative Colitis

**Goal**: Evaluate the efficacy of GS-5745 to induce and maintain clinical remission at week 8 and week 52.

**GA29144**: A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Etrolizumab as an Induction and Maintenance Treatment for Patients with Moderately to Severely Active Crohn’s Disease

**Goal**: Evaluate the efficacy of etrolizumab dose regimens compared with placebo in inducing PRO2 remission at week 14 and maintaining PRO2 remission at 1 year of maintenance treatment (week 66).

**GED-0301-CD-002**: A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Investigate the Efficacy and Safety of Mongersen (GED-0301) for the Treatment of Subjects with Active Crohn’s Disease

**Goal**: Evaluate the efficacy of GED-0301 compared with placebo on clinical activity, as measured by the Crohn’s Disease Activity Index in subjects with active Crohn’s disease.

**E7034**: A Randomized Controlled Trial Comparing Covered and Uncovered Biliary Self Expanding Metal Stents (SEMS) for Pre-operative Drainage during Neoadjuvant Therapy in Patients with Pancreatic Cancer

**Goal**: Demonstrate non-inferiority of fully covered biliary SEMS to uncovered biliary SEMS in biliary drainage for the pre-operative management of biliary obstructive symptoms caused by pancreatic cancer in patients undergoing neoadjuvant therapy.

**Seattle Barrett’s Esophagus Study**

**Goal**: Identify molecular abnormalities that predispose to the development of cancer in Barrett’s esophagus and to the development of recurrence of Barrett’s esophagus after endoscopic therapy in some patients. Identify risks and protective factors that modulate progression to cancer in patients with Barrett’s esophagus.
EPISOD 4: A Registry/Observational Study of Patients Undergoing ERCP and Possible Sphincterotomy for Post-Cholecystectomy Pain

Goal: Measure the success rates for sphincterotomy in patients with post-cholecystectomy pain and some evidence for biliary obstruction (SOD type II).

PIN-PHIO1201: Clinical Study of the Efficacy and Safety of Photodynamic Therapy using Porfimer Sodium for Injection as Treatment for Unresectable Advanced Perihilar Cholangiocarcinoma

Goal: Assess the effect of adjuvant PHOPDT administered with standard medical care (SMC) compared to SMC alone on the overall survival of subjects with unresectable perihilar Bismuth type III or IV-tumor TNM stage III or IV-a cholangiocarcinoma.

HEPATITIS C

GS-US-248-0122: A Long-Term Follow-Up Registry for Subjects who Achieve a Sustained Virologic Response to Treatment in Gilead-Sponsored Trials in Subjects with Chronic Hepatitis C Infection

Goal: Assess the durability of sustained virologic response following treatment in a Gilead-sponsored hepatitis C study.

GS-US-248-0123: A Long-Term Follow-Up Registry Study of Subjects who Did Not Achieve Sustained Virologic Response in Gilead-Sponsored Trials in Subjects with Chronic Hepatitis C Infection

Goal: Characterize HCV viral sequences and the persistence or evolution of treatment emergent viral mutations in subjects who fail to achieve a sustained virologic response after treatment with a Gilead oral anti-viral containing regimen in a previous Gilead-sponsored hepatitis C study.

GS-US-337-1431: A Registry for Subjects with Cirrhosis who Achieve a Sustained Virologic Response Following Treatment with a Sofosbuvir-Based Regimen without Interferon for Chronic Hepatitis C Infection in Gilead-Sponsored Trials

Goal: Assess and measure the sustained virologic response (SVR) and clinical progression or regression of liver disease including the incidence of hepatocellular carcinoma following SVR.

GA55172: HCV US Clinical Trial Protocol: Subject Enrollment

Goal: Evaluate HCV nucleic acid in plasma (K2EDTA) and serum as aids in the management of HCV-infected individuals undergoing antiviral therapy. The assay measures HCV RNA levels at baseline and during treatment and can be used to predict sustained and non-sustained virologic response to HCV therapy.

HCV-TARGET: Hepatitis C Therapeutic Registry and Research Network-A Longitudinal, Observation Study

Goal: Monitor treatment choices in sequentially treated patients and compare baseline characteristics of each treatment group to identify possible systematic differences between treatment populations.

GS-US-337-1746: An Open-Label Study to Investigate the Efficacy and Safety of Ledipasvir/Sofosbuvir, with or without Ribavirin, in HCV Infected Subjects Who Have Failed Prior Treatment with Sofosbuvir-based Therapies

Goal: Evaluate the efficacy of treatment with Ledipasvir/Sofosbuvir (LDV/SOF) FDC for 12 weeks with or without Ribavirin (RBV) in subjects without cirrhosis, and LDV/SOF FDC for 12 weeks with RBV or LDV/SOF FDC for 24 weeks without RBV in subjects with cirrhosis, as measured by the proportion of subjects with sustained virologic response 12 weeks after discontinuation of therapy.

M14-726: Open-label Study to Evaluate the Safety and Efficiency of the Combination of Ombitasvir, Paritaprevir/r ± Dasabuvir with Ribavirin (RBV) in Adult Patients with GT or GT4 Chronic HCV Infection and Response to Prior Treatment of Early Stage Hepatocellular Carcinoma

Goal: Evaluate the safety and efficacy of ombitasvir/paritaprevir/ritonavir, with or without dasabuvir coadministered with or without ribavirin for 12 or 24 weeks in adult patients with genotype 1 or genotype 4 chronic HCV infection and treated early stage hepatocellular carcinoma with compensated cirrhosis.

M14-868: A Randomized, Open-Label, Multicenter Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of Co-Administration of ABT-493 and ABT-530 with and without RBV in Subjects with Chronic Hepatitis C Virus (HCV) Genotype 2 or Genotype 3 Infection (SURVEYOR-II)

Goal: Evaluate the safety and efficacy of ABT-493 and ABT-530 (or ABT-493/ABT-530) co-administered with and without ribavirin in adults with chronic HCV infection.

CANCER: HEPATOBILIARY

DELTIC: Drug-Eluting Bead, Irinotecan Therapy of Unresectable Intrahepatic Cholangiocarcinoma (DELTIC) with Concomitant Systemic Gemcitabine and Cisplatin

Goal: Evaluate if the combination of trans-arterial chemoembolization (LC BEAD) plus infusional chemotherapy is more effective than receiving the infusional chemotherapy alone.

A Randomized, Double-Blind, Placebo-Controlled, Multicenter Phase III Study of Regorafenib in Patients with Hepatocellular Carcinoma (HCC) after Sorafenib

Goal: Evaluate the efficacy and safety of regorafenib in patients with advanced liver cancer who have progressed on sorafenib treatment.

CANCER: PANCREAS

Pancreatic Cancer Outcomes: Biomarker Study

Goal: Develop a blood test that can accurately detect the earliest stages of pancreatic cancer and better predict a positive response to pancreatic cancer treatment.

An International, Multi-Center, Double-Blind, Randomized, Phase III Trial of 90Y-Clivatuzumab Tetraxetan plus Low-Dose Gemcitabine versus Placebo plus Low-Dose Gemcitabine in Patients with Metastatic (Stage IV) Pancreatic Adenocarcinoma who Received at Least Two Prior Treatments (PANCRT-1)

Goal: Evaluate if the combination of 90Y-clivatuzumab tetraxetan plus gemcitabine is...
safe and more effective than receiving the gemcitabine alone in treating metastatic pancreas cancer.

Evaluating Health–Related Quality of Life among Patients Treated with Abraxane and Gemcitabine for Metastatic Pancreatic Cancer: A Pilot Study

Goal: Collect and assess real-world quality-of-life data in patients with metastatic adenocarcinoma of the pancreas (mPAC) who are treated with abraxane and/or gemcitabine as first-line therapy, and patients who have failed one or more lines of chemotherapy and experienced disease progression.

A Randomized, Double-Blind, Phase III Study of the JAK 1/2 Inhibitor, Ruxolitinib or Placebo in Combination with Capecitantine in Subjects with Advanced or Metastatic Adenocarcinoma of the Pancreas who have Failed or are Intolerant to First-Line Chemotherapy (The JANUS 2 Study)

Goal: Determine the efficacy, based upon overall survival, of ruxolitinib added to capecitabine for the treatment of metastatic pancreatic cancer.

A Randomized, Open Label, Phase 2 Trial of Gemcitabine plus Nabpaclitaxel with or without FG-3019 as Neoadjuvant Chemotherapy in Locally Advanced, Unresectable Pancreatic Cancer

Goal: Evaluate the safety, tolerability and efficacy of FG-3019 administered with gemcitabine and nabpaclitaxel in the treatment of locally advanced, unresectable pancreatic cancer.

A Phase II, Single-Arm, Open-Label, Bayesian Adaptive Efficacy and Safety Study of PBI-05204 in Patients with Stage IV Metastatic Pancreatic Adenocarcinoma

Goal: Evaluate the efficacy and safety of PBI-05204, an extract of the leaves of nerium oleander, in patients with Stage IV metastatic pancreatic cancer.

Clinical Research Program Manager Lindsey Siffermann, MS, leads a research team meeting

Clinical Research Studies
(continued from previous page)

CANCER: COLORECTAL

A Double-Blind, Placebo-Controlled Trial of Efornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0–III Colon Cancer, Phase III – Preventing Adenomas of the Colon with Efornithine and Sulindac (PACES)

Goal: Evaluate whether or not the combination of efornithine and sulindac will be effective in reducing a three-year event rate of adenomas and second primary colorectal cancers in patients previously treated for Stages 0 through III colon cancer.

A Phase II/III Trial of Neoadjuvant FOLFOX with Selective Use of Combined Modality Chemoradiation versus Preoperative Combined Modality Chemoradiation for Locally Advanced Rectal Cancer Patients Undergoing Low Anterior Resection with Total Mesorectal Excision (PROSPECT)

Goal: Compare the effects, both good and bad, of the standard treatment of chemotherapy and radiation to chemotherapy using a combination regimen known as FOLFOX (the drugs 5-fluorouracil, oxaliplatin and leucovorin) and selective use of the standard treatment, depending on response to the FOLFOX.
Selected Recent Publications

Esophageal Disorders


Inflammatory Bowel Disease (IBD)


Small Bowel


Pancreato-Biliary System


Therapeutic Endoscopy


continued next page

The Digestive Disease Institute at Virginia Mason VirginiaMason.org/DDI
Selected Recent Publications
(continued from previous page)


Colon


• Lin OS, La Selva D, Cha JM, Gluck M, Ross A, Chiorean M, Kozarek RA. Validation of colonoscopic findings from a structured endoscopic documentation database against manually collected medical records data. Surg Endosc 2016; 4:107-13

Liver Disorders


SATURDAY, MAY 21

• Computer-assisted Sedation: Is it Ready for Prime Time? Otto S. Lin*

• Infections Traced to Duodenoscopes: How Common, How to Monitor, and How to Manage? With Q&A/Panel Discussion Andrew S. Ross*

• Recurrence Rates after Multi-Modality Endoscopic Eradication Therapy for Dysplastic Barrett’s Esophagus (BE) and Early Esophageal Cancer: Results from an International, Multi-Center Consortium

• Endoscopic Radiofrequency Ablation for Intraductal Extension of Ampullary Neoplasms
  Tarun Rustagi*, Shayan Irani, Nageshwar D. Reddy, Barham K. Abu Dayeh, Todd H. Baron, Christopher Gostout, Michael J. Levy, John A. Martin, Bret T. Petersen, Andrew S. Ross, Mark Topaziar

• Indications, Technical Success and Clinical Efficacy of Short-Term Plastic Pancreatic Duct Stenting: Interim Analysis of a Prospective Multi-National Registry

• The Extent of Barrett’s Esophagus Predicts Resistance to Successful Endoscopic Eradication Therapy for Barrett’s Esophagus (BE) with Dysplasia or Early Cancer (EAC): Results from an International, Multi-Center Consortium

SUNDAY, MAY 22

• Jejunostomy Feeding Tubes Placed Prior to Neoadjuvant Chemoradiotherapy Are Safe and Improve Therapeutic Efficiency During Trimodality Therapy for Esophageal Cancer Mustapha A. El Lakis*, Donald Low

• Value of EUS Risk Stratification for Pancreatic Cystic Lesions Utilizing 2012 International Consensus and Updated AGA Guidelines
  Anthony Razzak*, Shayan Irani, Michael C. Larsen, Andrew S. Ross, Seng-Ian Gan
The Digestive Disease Institute is dedicated to research for the ultimate benefit of patients. Faculty will present these findings at Digestive Disease Week 2016 in San Diego, CA.

**TUESDAY, MAY 24**

- Patient and Endoscopist Satisfaction with Computer-Assisted Propofol Sedation: A Comparative Study Against Midazolam and Fentanyl
  Otto S. Lin*, Danielle La Selva, Deborah Tombs, Richard A. Kozarek, Andrew S. Ross

- Effectiveness, Safety and Efficiency of Computer-Assisted Propofol Sedation: A Comparative Study Against Midazolam and Fentanyl
  Otto S. Lin*, Danielle La Selva, Deborah Tombs, Richard A. Kozarek, Andrew S. Ross

- One Year Experience With Computer-Assisted Propofol Sedation for Colonoscopy
  Otto S. Lin*, Danielle La Selva, Deborah Tombs, Richard A. Kozarek, Andrew S. Ross

- One Year Experience With Computer-Assisted Propofol Sedation for Esophagogastroduodenoscopy
  Otto S. Lin*, Danielle La Selva, Deborah Tombs, Richard A. Kozarek, Andrew S. Ross

- Culture and Quarantine Following High Level Disinfection of Duodenoscopes: Results of Ongoing Surveillance
  Andrew S. Ross*, Deborah Tombs, Punam Verma, Christopher Baliga, Michael Gluck

- Comparative Analysis of Techniques and Outcomes for Resection of Benign or Low-Grade Neoplasms in the Duodenum

- Digital Single-Operator Cholangioscopy (Dsoc) Improves Interobserver Agreement (IOA) and Accuracy for Evaluation of Indeterminate Biliary Strictures

- Metallic Versus Plastic Biliary Stents: Scheduled Stent Exchanges Result in Reduced Rate of Cholangitis
  Ayman A. Sakr*, Nitin Kumar, Aoife Devery, Amy Ou, Michael C. Larsen, Christopher C. Thompson

- The Buried Lumen Apposing Metal Stent (LAMS): Is this a Stent Problem, a Location Problem or Both? A Case Series
  Shayan Irani*, Richard A. Kozarek

- Presenters

**MONDAY, MAY 23**

- Utility of Emergency Department CT Scans in Patients with Ulcerative Colitis
  Dion Booras*, Michael V. Chiorean, Danielle La Selva

- A Multi-Center Evaluation of Endoscopic Submucosal Dissection in the United States: The American Experience
  Christopher G. Chapman*, Gregory B. Haber, Peter V. Draganov, Klaus Monkemuller, Andrew S. Ross, Shayan Irani, Andrew Y. Wang, Michel Kahaleh, Prashant R. Mudireddy, Poi Yu Sofia Yuen, Kristen Koller, Dennis Yang, Roxana M. Coman, Ujjwal Kumar, Anthony Razzak, Dushant S. Uppal, Vani J. Konda, Uzma D. Siddiqui, Ann Koons, Irving Waxman

- Ombitasvir/Paritaprevir/R, Dasabuvir, and Sofosbuvir Treatment of Patients With HCV Genotype 1-Infection Who Failed a Prior Course of DAA Therapy: The QUARTZ-I Study

- Percutaneous Drainage by Radiologic Approach
  Mehran Fotoohi*

- EUS-guided Gallbladder Drainage (EUS-GBD) with a Lumen-Apposing Metal Stent (LAMS) vs. Percutaneous Transhepatic Gallbladder Drainage (PT-GBD) for the Treatment of Acute Cholecystitis

- Efficacy of Sofosbuvir Including Regimens for Genotype 1 Hepatitis C Patients With or Without Liver Cirrhosis
  Hyun Phil Shin*, Asma Siddique, Blaire E. Burman

- Obscure GI Bleeding: Capsule, Balloon or Enterography? A Case-Based Approach
  Andrew S. Ross*, Laurel R. Fisher

- Economic Impact of Computer Assisted Propofol Sedation

- Culture and Quarantine Following High Level Disinfection of Duodenoscopes: Results of Ongoing Surveillance
  Andrew S. Ross*, Deborah Tombs, Punam Verma, Christopher Baliga, Michael Gluck

- Comparative Analysis of Techniques and Outcomes for Resection of Benign or Low-Grade Neoplasms in the Duodenum

- Digital Single-Operator Cholangioscopy (Dsoc) Improves Interobserver Agreement (IOA) and Accuracy for Evaluation of Indeterminate Biliary Strictures

- Metallic Versus Plastic Biliary Stents: Scheduled Stent Exchanges Result in Reduced Rate of Cholangitis
  Ayman A. Sakr*, Nitin Kumar, Aoife Devery, Amy Ou, Michael C. Larsen, Christopher C. Thompson

- The Buried Lumen Apposing Metal Stent (LAMS): Is this a Stent Problem, a Location Problem or Both? A Case Series
  Shayan Irani*, Richard A. Kozarek

- Presenters
The Digestive Disease Institute at Virginia Mason is a multidisciplinary coalition of providers from:

- Bariatric Surgery
- Endocrinology
- Gastroenterology and Hepatology
- General Thoracic Surgery
- Hematology/Oncology
- Hepatopancreatobiliary Surgery
- Interventional Radiology
- Pathology

**CONDITIONS WE TREAT**

- Achalasia
- Acute Pancreatitis
- Ascites
- Autoimmune Hepatitis
- Bariatric Complications
- Barrett’s Esophagus
- Benign Hepatic Tumors
- Bile Duct Strictures
- Bile Duct Disorders
- Biliary Duct Cancer
- Celiac Disease
- Chronic Pancreatitis
- Cirrhosis
- Colitis and Chronic Ulcerative Colitis
- Colorectal Cancer
- Colorectal Polyps
- Constipation
- Crohn’s Disease
- Cystic Fibrosis
- Esophageal and Gastric Varices
- Esophageal Cancer
- Fatty Liver Disease
- Gallstones and Bile Duct Stones
- Gastric Cancer
- Gastroesophageal Reflux Disease (GERD)
- Gastroparesis (Delayed Gastric Emptying)
- Hemochromatosis
- Hepatitis B, Hepatitis C and Chronic Hepatitis
- Hepatorenal Syndrome
- Inflammatory Bowel Disease (IBD)
- Intraductal Papillary Mucosal Neoplasm (IPMNs)
- Liver Cancer
- Neuroendocrine Tumors
- Nonalcoholic Steatohepatitis (NASH)
- Obesity
- Pancreatic Cancer
- Pancreatic Cysts
- Pancreatic Necrosis
- Primary Sclerosing Cholangitis
- Swallowing and Motility Disorders
- Ulcerative Colitis

**WHY REFER YOUR PATIENTS?**

- We treat complex patients who may be untreatable in your area
- Multidisciplinary care in GI, hepatology, surgery, oncology, endocrinology, interventional radiology and nutrition
- GI Cancer Care Coordination Team will provide your patient with personalized attention
- Clinical trials may offer new hope to patients with no other treatment options

You may refer a patient to the Digestive Disease Institute by calling (206) 223-2319, or visit VirginiaMason.org/DDI.

**Digestive Disease Institute Leadership**

- Richard A. Kozarek, MD
  Executive Director
- Lily Chang, MD
  Director, Innovation
- Michael Chiorean, MD
  Director, Inflammatory Bowel Disease Center of Excellence
- Ian Gan, MD
  Director, Training and Education
- Scott Helton, MD
  Director, Liver, Pancreatic, and Biliary Surgical Center of Excellence
- Jeffrey Hunter, MD
  Director, Bariatric Surgery Center of Excellence
- Shayan Irani, MD
  Associate Director, Pancreatic Center of Excellence
- Otto Lin, MD
  Director, Quality Improvement
- Donald E. Low, MD
  Director, Esophageal Center of Excellence
- Vincent J. Picozzi, Jr., MD
  Director, Pancreatic Center of Excellence
- Flavio Rocha, MD
  Director, Research
- Andrew Ross, MD
  Director, Therapeutic Endoscopy Center of Excellence
- Asma Siddique, MD
  Director, Liver Center of Excellence; Director, Research
- Jonathan Stoehr, MD, PhD
  Director, Nutrition Center of Excellence

Biographies of our providers are available online. Read about them at VirginiaMason.org/DDI-Team.