The Ruesch Report

The Ruesch Center
for the Cure of Gastrointestinal Cancers
AT GEORGETOWN LOMBARDI
COMPREHENSIVE CANCER CENTER

CLINICAL TRIALS

Does the tumor microbiome play a role in early-onset colorectal cancer?

BY BENJAMIN WEINBERG, MD

The human body is composed of around a trillion cells, and there are a trillion to a trillion-and-a-half bacterial cells composing our gut microbiome. Of these bacteria, some are good and help us digest foods. Others can behave badly and are associated with diseases such as autoimmunity and cancer. Bizarrely, the presence or absence of certain gut bacteria can lead patients to respond differently to certain medications.

This finding has been demonstrated in patients with melanoma skin cancer undergoing immunotherapy: those patients with "good" gut bacteria had more tumor shrinkage compared to patients with "bad" gut bacteria, even though they were given the same drug! The specific bacteria may not matter as much as long as there is diversity within the microbiome – the more types of bacteria present, the better.

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2019 ASCO Annual Meeting Update

BY BHAVANA SINGH, MD, MSC

The 2019 ASCO Annual Meeting took place between May 31 and June 4 at the McCormick Center in Chicago, Illinois. In contrast to prior ASCO Annual Meeting themes, this year's conference focused on "Caring for Every Patient, Learning from Every Patient," which led to a great deal of discussion regarding endpoints that truly matter to patients. This patient-oriented theme was highlighted by the guest speaker at the opening ceremony, Atul Gawande, MD, a surgeon at Boston's Brigham and Women's Hospital and a best-selling author whose books include "Being Mortal." Gawande emphasized the importance of palliative care in the practice of oncology, stressing that palliative care often means different things for different patients. He emphasized that by asking the patient what is important to them and what their priorities are, and using medicine to help them achieve those goals, it may be possible to restore "a life worth living," if only for a little while longer.

In addition, thousands of submitted abstracts allowed researchers to present

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Highlights of the 10th Annual Symposium

My One-Year Sabbatical — A Time to Regain Perspective

BY JOHN L. MARSHALL, MD

Honestly, I had no idea what to expect. With the decision to take a sabbatical for one year, I would have to stop seeing patients. I love my patients. I have a calling to see patients, specifically cancer patients. How would I feel not doing the thing I love most? I needed the break from my routine for many reasons, and this included a break from patient care. I wondered if this would be the promised rest and fresh perspective that I needed or simply a source of guilt for the year ahead?

I spent the first half of 2019 preparing for the sabbatical transition to begin in July. I informed the staff. We worked very hard to recruit the best new physicians we could find. Success! We expanded our fellowship role so that our most experienced fellows could now take on more responsibility in patient care. Success! We expanded our nurse practitioner staff, again adding the best and the brightest. Success! We informed our patients of the changes ahead. Success? I don't think so. This was by far the most challenging aspect of my transition. On the one hand, my patients were happy for me, pleased and supportive. But on the other hand, many patients could not help but express their feelings of abandonment. Doctors and patients—especially cancer doctors and cancer patients—have a truly special bond, and I was breaking it. All my patients can find me by email, phone, or Starbucks. I vowed to be available and respond to their needs over the year ahead. Many were about to go through the roughest patch of their cancer journey. I would be there.

July came; no clinic for me. My colleagues covering for me were all working very, very hard. Added clinics, more phone calls, more emails, more orders to sign. My email was pretty quiet; I was occasionally copied on a patient issue, I occasionally received an email wishing me well. Certainly not the flood of questions I was expecting, maybe even needing. Didn't they need me? Was I in fact replaceable? After the initial feelings of dispensability, I smiled. I am blessed with the best colleagues anywhere. Not only are they incredible people, they are the best doctors and nurse and administrators on the planet. My patients quickly learned that. They do not need me, they need us.

With that, I exhaled, actually relaxed for maybe the first time in a decade or two, and started to refocus on our mission: curing all patients with GI cancers. Thanks to all for the opportunity. I will do my best to come back not only refreshed, but newly inspired. And maybe some of my patients will want me back?

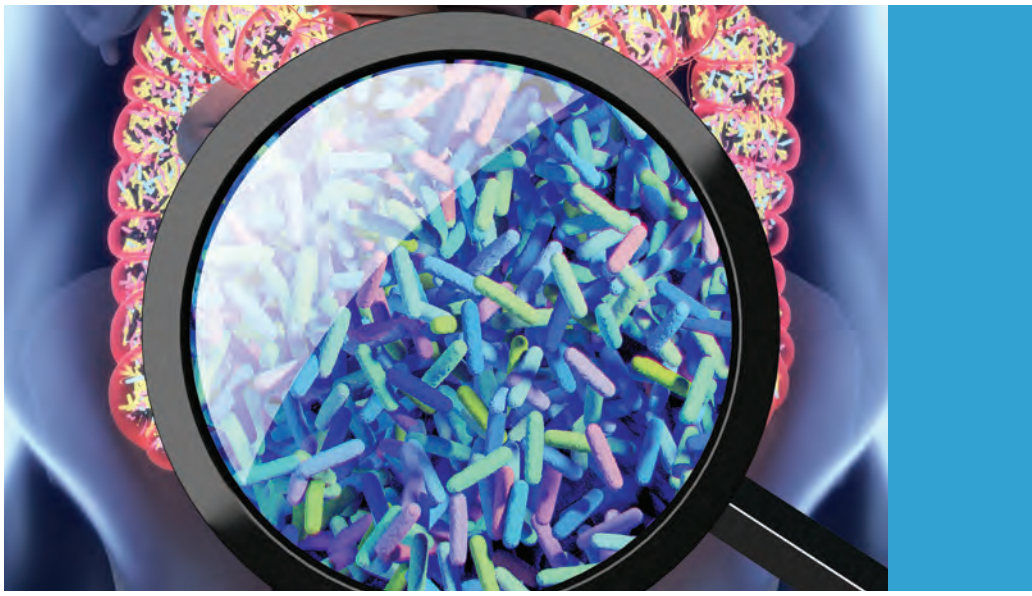
"...I exhaled, actually relaxed for maybe the first time in a decade or two, and started to refocus on our mission: curing all patients with GI cancers.

Does the tumor microbiome play a role in early-onset colorectal cancer? *(continued from page 1)*

The field of microbiome research has exploded exponentially in recent years. The gut microbiome exists as an interplay between the environment (what we eat), our immune system, and our inherited susceptibility to disease (genetics). All of these factors are independently associated with development of cancer; therefore, the microbiome is a potential target both to prevent cancers and to treat them once they occur.

In this vein, the findings by Riquelme and colleagues[1] are especially eye-opening. The **investigators looked at the bacteria that reside within pancreatic tumors** and compared bacterial and immune profiles from patients who lived more than 5 years following surgery to those who lived less than 5 years. **The long-term survivors had a higher diversity of bacteria, a specific bacterial profile, and higher levels of immune cells within the tumor.** Moreover, when they transplanted stool from long- vs. short-term pancreatic cancer survivors into mice with pancreatic tumors, the investigators could induce similar changes in the bacteria and the level of immune cells of mouse pancreatic tumors. This proof-of-principle could serve as the basis for future therapies designed to retrain the body's immune system to fight pancreatic cancer.

Our own research[2] explores the differences in tumor microbiome in young- versus older-onset colorectal cancer. **There has been a dramatic rise in individuals under the age of 50 developing colorectal cancer in the last 20 years, and no one has demonstrated a clear cause for this trend.** Hypotheses include processed foods and the coincident epidemics of diabetes and obesity, but these alone are not enough to account for the increase in young-onset colorectal cancer. Thus, we are collecting tumor samples from patients with colorectal cancer diagnosed before age 45 and after age 65 and comparing their bacterial DNA. **Our hope is that this research will find specific bacteria that play a causative role in young-onset colorectal cancer.** Some bacteria that coexist with tumors may be passengers, just along for the ride, while others may be vital drivers promoting cancer growth. We need to figure out who is who, unlocking new doors to prevent and treat gastrointestinal cancers. These findings could alter how we screen for colorectal cancer in younger individuals by establishing a high-risk microbiome. They could also offer novel therapeutic options including antibiotics, probiotics, and vaccines to target the bacterial chaperones and slow down cancer growth.



[1] Riquelme E, Zhang Y, Zhang L, et al. Tumor microbiome diversity and composition influence pancreatic cancer outcomes. Cell 178(4):795-806, 2019. https://www.pancan.org/news/bacteria-may-impact-pancreatic-cancer-survival/

[2] Research is funded by the Colorectal Cancer Alliance's Chris4Life Research Grant in Young Onset Colorectal Cancer and the Victoria Casey and Peter Teeley Foundation.

CLINICAL TRIALS

The Success of the Ruesch Pilot Grant

A Phase 1 study to test safety and dose of proglumide as an anti-fibrotic agent, Dr. Jill Smith.

BY MARION L HARTLEY AND THE RUESCH TEAM

The Ruesch Center continues its mission to fund promising cancer research projects based on its own peer-review process. In 2018, we reached a milestone of more than $1,000,000 in cumulative grant awards to members of MedStar Georgetown University Hospital and the MedStar Network.

Our philosophy is to provide seed money for early-stage research that has the best chance of leading to cures for various GI cancers. We aim to provide researchers with initial funding for their scientific inquiries that is often so hard to find. With this seed funding, they are able to collect the vital preliminary data that they need to pursue larger funding sources and awards. This is evidently paying off because Jill P Smith, MD of the Division of Gastroenterology at Georgetown University was recently awarded a large National Cancer Institute Division of Cancer Prevention (NCI DCP) grant based on data generated from research carried out using seed money from one of these Ruesch pilot grants.

Our philosophy is to provide seed money for early-stage research that has the best chance of leading to cures for various GI cancers.

Her NCI DCP-funded "Phase 1 study to test safety and dose of proglumide as an anti-fibrotic agent" is enabling Dr. Smith and her team to carry out a true translational bench to bedside trial: the "bench" work was carried out using Ruesch Center seed money, and the "bedside" work is being funded by the DCP as a Phase I trial. Dr. Smith's NCI DCP funding started this month and she has IRB approval for her trial, which will be initiated soon.

To explain a little about her study, nonalcoholic fatty liver disease and nonalcoholic steatohepatitis (NASH) are highly prevalent in the United States. These conditions are an increasing cause of cirrhosis and hepatocellular carcinoma (HCC), and often necessitate liver transplantation. Dr. Smith's project will repurpose an old drug, proglumide, for conditions of chronic inflammation and fibrosis (i.e., NASH).

In her Phase I clinical study, she and her team will determine safety and tolerability, and the recommended oral dose of proglumide to be administered to subjects with NASH moving forward. After completion of this Phase I trial, Dr. Smith plans to conduct a Phase 2 trial to prove that proglumide reverses fibrosis (scarring) in the liver of subjects with NASH. If effective, then she and her team will extend their studies to other conditions that cause fibrosis or cirrhosis in the liver.

The Ruesch Center is proud to have provided Dr. Smith with the resources needed to get this concept off the ground. We congratulate Dr. Smith and her team on their recently won government grant and wish them well in their pursuit of effective treatments for individuals at risk for fibrosis or cirrhosis, and ultimately HCC.

CLINICAL TRIALS

Clinical Trial Highlights

BY MARION L. HARTLEY, PHD

Phase I Study of Proton Therapy in Adjuvant Pancreatic Cancer (PROTON - PANC). Study # 2018-1021

This study is a Ruesch Center initiative, headed by Dr Benjamin Weinberg. The investigators hypothesize that patients who have had the bulk of their primary pancreatic tumor removed will benefit from enhanced local control with the addition of radiation therapy to systemic, adjuvant mFOLFIRINOX (FFX: Leucovorin, 5-FU, irinotecan, and oxaliplatin chemotherapy). The term adjuvant refers to chemo- and/or radiotherapy used just after cancer surgery to help decrease the risk of the disease remaining or coming back. Proton Therapy (PRT) is an exciting novel radiation therapy option for pancreatic ductal adenocarcinoma (PDAC), and in this study, the investigators utilize 5 fraction PRT, delivered over 1 week, during adjuvant FFX to minimize interruptions in chemotherapy as well as to reduce the length of time from surgical resection to initiating adjuvant radiation therapy. Conventional radiation therapy is typically delivered over 5 weeks and is commonly given after the completion of adjuvant chemotherapy. Conventional radiation therapy cannot be given concurrently with FFX due to combined toxicities. In contrast, PRT significantly reduces the exposure of normal tissues to the effects of radiation therapy and has already been safely delivered using a 5 fraction schedule with chemotherapy in other scenarios.

To be eligible for this study, patients must have pathologically-confirmed pancreatic adenocarcinoma of the pancreatic head and undergone pancreaticoduodenectomy with curative intent. For other inclusion criteria, please contact our study team.

→ https://clinicaltrials.gov/ct2/show/NCT03885284

continued ▶

Study Treatment Descriptions

Proton-based radiotherapy (PRT). A proton is a positively charged particle, and a machine called a synchrotron or cyclotron speeds up these particles, creating high energy protons that are set to travel to the desired area and depth in the body. Therefore, these protons give a highly targeted radiation dose to the tumor cells, which destroys them, while delivering a minimal radiation dose outside of the tumor. This should effectively fight cancer (especially in combination with chemotherapy), while causing fewer acute and long-term toxicities compared to conventional radiation therapy.

Ad-CEA vaccine
CEA is a type of protein that is overproduced in various tumor cell types. Upon administration, the **Ad-CEA vaccine** may raise a patient's immune response against tumor cells expressing the CEA antigen, resulting in immune-mediated tumor cell death.

Avelumab and Durvalumab
Background: A protein called PD-1 is present on the surface of certain T cells (a type of immune cell) when they are activated against tumor cells. However, many tumor cells (annoyingly for us) protect themselves against T cell attack by producing the protein PD-L1 on their surface, which binds with PD-1 on the T cells and inactivates them along with any immune response against the tumor.

Mode of activity: **Avelumab and Durvalumab** inhibit PD-L1 and its binding with PD-1, promoting a strong anti-tumor immune response.

These "checkpoint inhibitors" have been approved by the FDA for the treatment of certain solid tumors, but are still under investigation for the treatment of gastrointestinal (GI) cancers.

CV301 is an immunotherapy treatment vaccine that targets two tumor-associated antigens (proteins), CEA and MUC-1, which are overproduced in the majority of solid tumors. CV301 is still under study and has not yet been FDA approved. Pre-clinical data show that this agent can upregulate PD-L1 on antigen expressing tumor cells, indicating that the tumor is under attack from T cells. This presents an opportunity for a greater response in patients who might otherwise not benefit from durvalumab or any other checkpoint inhibitor alone.

CLINICAL TRIALS

Clinical Trial Highlights *(continued)*

A Randomized Phase II trial of Standard of Care Alone or in Combination with Ad-CEA vaccine and Avelumab in Patients with Previously Untreated Metastatic or Unresectable Colorectal Cancer

Study # 2017-1543

This is an NCI-initiated trial, headed at the Ruesch Center by Dr Benjamin Weinberg, which is designed to evaluate the potential improvement in progression free survival (PFS) of patients with metastatic or unresectable colorectal cancer treated with standard of care plus avelumab and Ad-CEA vaccine compared to standard of care alone. It is hoped that the addition of immune therapies to standard of care will provide extra benefit to patients.

Standard of care will consist of 6 –12 two week cycles of bevacizumab + FOLFOX (5-FU, leucovorin, oxaliplatin) followed by two week cycles of bevacizumab + capecitabine/5-FU until disease progression.

If disease progression occurs in patients who are assigned to receive standard of care alone, they will then be offered avelumab + Ad-CEA vaccine in combination with a standard chemotherapy regimen.

To be eligible for this study, patients must have previously untreated pathologically confirmed metastatic or unresectable colorectal cancer. Prior adjuvant therapy is acceptable

→ https://clinicaltrials.gov/ct2/show/NCT03050814

A Phase I/II Trial of the PD-L1 Inhibitor Durvalumab plus CV301 in Combination with Maintenance Chemotherapy for Patients with Metastatic Colorectal or Pancreatic Adenocarcinomas.

Study # 2017-1189

This study is a Ruesch Center initiative, again headed by Dr Benjamin Weinberg, which is being carried out in 2 phases. The first phase will establish a safe but effective dose of durvalumab to administer with CV301 and maintenance chemotherapy. The second phase will establish the efficacy of the durvalumab plus CV301 plus chemotherapy combination, administered at the doses chosen in phase 1 of the study, to patients whose colorectal or pancreatic cancer is stable on or responding to first-line therapy for metastatic disease.

It is hoped that we will see a greater anti-tumor activity with the combination of CV301 and durvalumab than we would see if each agent was administered alone.

Enrolled patients will have their tumor biopsied (sampled)—once before study initiation (unless suitable tissue has already been collected) and again during the study, while receiving treatment. Participants will be routinely tested for disease response to treatment (CT or MRI scans) and undergo safety tests (blood and urine sampling).

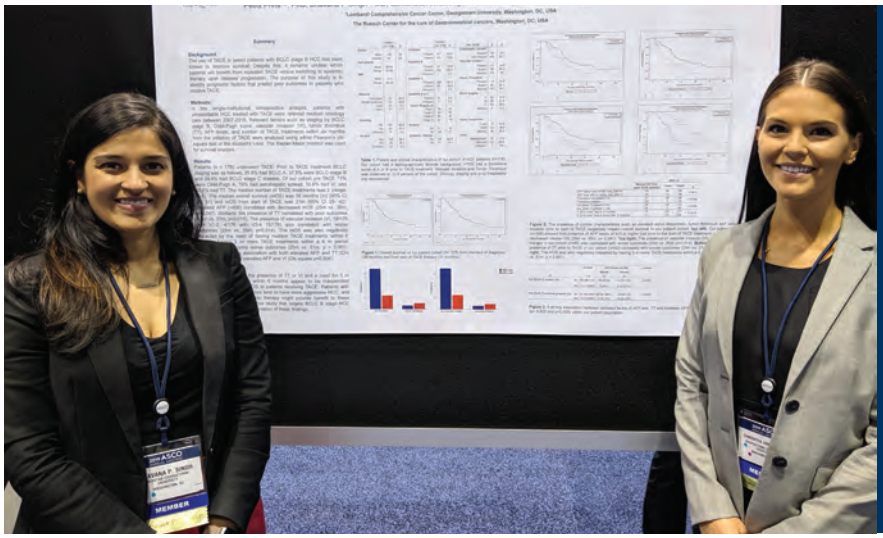
To be eligible for this study, patients must have histologically confirmed metastatic colorectal or pancreatic adenocarcinomas and be stable on, or responding to first-line therapy for metastatic disease. Patients must be willing and able to provide a tissue biopsy of their tumor.

→ https://clinicaltrials.gov/ct2/show/NCT03376659

Catch up on our investigator-initiated clinical trials The Ruesch Center faculty and their NIH collaborators are really making an effort to change the standard of care.

2019 ASCO Annual Meeting Update *(continued from page 1)*

practice-changing data across various fields. Data yielded from targeted therapy and immunotherapy studies were particularly encouraging, and one of the plenary sessions on PARP inhibitors in pancreatic cancer stood out to those in attendance.



The plenary session for the phase III POLO trial in pancreatic adenocarcinoma marked major advances for a patient population that has represented a clinically unmet need for some time. In this randomized, controlled trial, researchers compared maintenance olaparib (Lynparza) versus placebo in patients with a germline *BRCA1* or *BRCA2* mutation and metastatic pancreatic cancer who initially received first-line, platinum-based chemotherapy. The POLO trial demonstrated that the **PARP inhibitor olaparib led to significantly improved Progression-Free Survival in patients with germline BRCA-mutated metastatic pancreatic cancer versus placebo** (7.4 months vs. 3.8 months). This study is important for several reasons and is the first biomarker-driven trial in pancreatic cancer.

Another notable finding was that the **median duration of response for those patients who received olaparib was about 24 months vs. about 4 months for placebo**; overall survival results are still pending at this time. Although these results are only applicable in a small proportion of pancreatic cancer patients (only 4-7% of this population harbor a germline *BRCA* mutation), they represent a major finding in the world of gastrointestinal cancer research.

There were several other notable gastrointestinal cancer trials that were presented throughout the conference. A major one of these aimed to determine the ideal duration of adjuvant oxaliplatin-based therapy (3 vs. 6 months) for patients with high-risk stage II colorectal cancer. These results were presented by the IDEA trial researchers, Ivenson et al. The group took data from several past trials, in which patients received the investigator's choice of FOLFOX or CAPOX adjuvant therapy, and retrospectively randomized these patients to duration of therapy. This study suggested non-inferiority for 3 months versus 6 months of CAPOX, but inferiority of 3 months versus 6 months of FOLFOX — meaning that an extra 3 months of CAPOX does not yield any extra benefit for patients, whereas the opposite is true for FOLFOX.

Finally, in advanced gastric or gastroesophageal junction cancer, the randomized, phase III KEYNOTE-062 trial achieved its primary endpoint. This abstract, presented by Tabernero et al., showed that for patients with programmed cell death ligand 1 (PD-L1)-positive, HER2-negative, advanced gastric or gastroesophageal junction cancer, **initial therapy with pembrolizumab resulted in noninferior overall survival compared to standard chemotherapy**. Additionally, pembrolizumab monotherapy showed **clinically meaningful improvement in overall survival among patients with tumors that had high levels of PD-L1 expression**. At 2 years' follow-up, 39% of patients who received pembrolizumab alone were alive, compared to 22% of people who received standard chemotherapy. The trial also evaluated combined pembrolizumab and standard chemotherapy treatment and found that this regimen did not improve survival relative to chemotherapy alone.

The abstracts discussed here are a select snapshot of the thousands of abstracts presented at ASCO this year and represent continuing ground-breaking work in the pursuit of a cure for all patients with cancer. However, throughout the meeting, physicians kept coming back to the theme, "Caring for Every Patient, Learning from Every Patient," imploring the next generation of cancer researchers and physicians to focus not only on destroying tumors but also on the impact of their therapies on the patients they care for.

The Ruesch Center's Presence at ASCO International Meetings

BY MARION HARTLEY, PHD AND CRAIG LUSTIG, MPA

The American Society of Clinical Oncology (ASCO) Annual Meeting is one of the largest annual oncology meetings in the world, attracting 42,500 attendees from all over the globe this year (May 31st-June 4th, 2019). Around 20% of the attendees who submitted information regarding their area of expertise claimed to have a specific interest in GI cancer research. The ASCO Gastrointestinal Cancers (ASCO GI) Symposium is a smaller, more specialized meeting focused solely on GI cancers, which occurs in January each year and attracts over 3500 attendees.

The Ruesch Center for the Cure of GI Cancers has had a presence at the last four ASCO Annual Meetings (in Chicago) and ASCO GI Symposia (in San Francisco). Our team manages an exhibit at both meetings, which raises awareness of our efforts and the beneficial services we provide to patients, clinicians, and researchers, including symposia, patient advocacy efforts, cutting edge research studies, and clinical trials.

At this year's ASCO Annual Meeting, the round table within our exhibit booth provided a central point for all Ruesch and Georgetown team members (past, present, and future) to keep in contact and meet up socially and scientifically with friends and associates, as well as hold meetings with collaborators to discuss current and future research projects and future funding. This year, many of us got to meet for the first time our most recently recruited medical oncologist and faculty member, Dr. Marcus Noel. Welcome, Dr. Noel and family! We look forward to having you fully on board in November!

ASCO meetings also provide important opportunities to convene our research and advocacy partners. The Ruesch Center regularly hosts research working group meetings, bringing together Ruesch Center researchers with collaborators from other institutions for in-person updates on the development and progress of shared research projects.

Last but certainly not least, the ASCO Annual and ASCO GI meetings serve

as the biannual meeting venue for the GI Cancers Alliance (GICA). Initially formed by the Ruesch Center in 2015, the GICA meetings bring together more than 40 GI advocacy organizations, academic medical centers, and industry partners to develop a shared agenda for collaboration to elevate the voice of the GI cancer community.

In summary, The Ruesch Center's presence as an exhibitor at the ASCO Annual Meeting and the smaller ASCO GI Symposium promotes communication and gives us a fresh perspective on our work and our goals. ASCO meetings are the perfect way to stay up-to-date with the latest research in the GI cancer field and to feel part of a much larger community.

// PATIENT CARE

New Members of the GI Team

Candace Mainor, MD

Assistant Professor of Medicine, Division of Hematology and Oncology, Department of Medicine

Dr. Mainor is a medical oncologist who treats patients with solid tumor malignancies. Her specific clinical research interest includes cancer prevention, therapy-related toxicity management, and health care disparities. She earned her medical degree at the University of Maryland School of Medicine and completed her internal medicine residency at the University of Maryland Medical Center. Dr. Mainor then completed her fellowship training in Hematology and Oncology at the University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center. Dr. Mainor is board-certified in Internal Medicine and Medical Oncology, and board eligible in Hematology. Dr. Mainor was a medical oncologist at the United States Food and Drug Administration (FDA) Division of Oncology Products, Office of Hematology and Oncology Products, and Center for Drug Evaluation and Research. While at the FDA, Dr. Mainor reviewed clinical trials and clinical development programs for the safety and efficacy of study design.

Marcus S. Noel, MD

Associate Professor of Medicine, Division of Hematology and Oncology, Department of Medicine
Co-Director, Clinical Research Management Office

Marcus S. Noel, MD joined the Georgetown Lombardi Comprehensive Cancer Center as an Associate Professor of Medicine, Division of Hematology and Oncology, Department of MedicineCo-Director, Clinical Research Management Officer. Dr. Noel is a medical oncologist who specializes in the treatment of gastrointestinal cancers.His research efforts focus on novel drug developments for pancreatic cancer. He received his bachelor of arts in biology from Case Western Reserve University and his medical degree from Rutgers Medical School formerly Robert Wood Johnson Medical School. Dr. Noel completed his internal medicine residency and medical oncology fellowship at the University of Rochester Medical Center in 2013. He was recently an assistant professor of medicine at the Wilmot Cancer Institute in Rochester NY.

Neel Trivedi, MD

Senior Fellow, Division of Hematology and Oncology, Department of Medicine

Dr. Trivedi is a medical oncologist specializing in gastrointestinal malignancies. Dr. Trivedi understands that each patient is an individual with unique needs and strives to provide personalized care to everyone. He obtained both his undergraduate degree in psychology and his medical degree at the University of Virginia. He completed his post-graduate medical training at MedStar Georgetown with a residency in internal medicine.

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New Members of the GI Team *(continued)*

Bhavana Singh, MD

Senior Fellow, Division of Hematology and Oncology, Department of Medicine

Dr. Singh is a medical oncologist who specializes in gastrointestinal malignancies, including the treatment of colorectal cancers. Her research interests include molecular profiling in solid tumors, targeted drug therapy use, and global oncology. She obtained her undergraduate degree from Duke University and her medical degree from the University of Miami Miller School of Medicine. She completed her internal medicine residency training at Duke University Hospital.

Sara Swenson, NP

Nurse Practitioner

Prior to joining MedStar Georgetown, Sarah spent 8 years at the University of Texas MD Anderson Cancer Center as a nurse with the surgical oncology unit and treated a variety of patients with gastrointestinal cancers. She recently graduated from Texas Woman's University with her master's degree.

Amy M. Hillsman, NP

Nurse Practitioner

Amy started her oncology career in 2003 and is a board-certified adult nurse practitioner. She received a bachelor of science in nursing (BSN) at the University of Alabama in Huntsville and a master of science in nursing (MSN) at the University of Maryland.

Kristin Sneegas, MSM

Strategic Communications Manager

Kristin focuses on program development, communications, marketing, stakeholder engagement, community and brand building initiatives and events. She received her Masters of Science in Marketing from Johns Hopkins, where she worked in marketing and communications for 11 years.

LIVING WITH CANCER

The Importance of Keeping a Positive Outlook

BY RICHARD SHIN
(FORMER RUESCH INTERN)

Rony Reyes hails from Annapolis, Maryland, and is 57 years of age. He is currently on a Ruesch Center clinical study testing the efficacy of Opdivo (nivolumab)—a cancer medicine that works with a patient's immune system to inhibit the growth and spread of cancer cells in their body (also called immunotherapy).

Reyes was diagnosed with gastric cancer in 2017, and after radiation therapy and 18 months of treatment with Keytruda (pembrolizumab), which is another immunotherapy, Reyes' endoscopies came up clean. Then in 2019, a series of clinic visits revealed that his gastric cancer had returned and spread to a lymph node in his shoulder. This was when he was referred to Dr. Ruth He, an experienced oncologist at the Ruesch Center, Georgetown Lombardi.

"She showed me a few options [for treatment], but she chose one that she thought was the best for me," said Reyes, vigorously nodding. From his medical history and actions, it was clear that Reyes followed the choices of his doctors with much enthusiasm.

Now, having been on Opdivo for the past 6 months, Reyes was excited to talk about his routine and progress. "I take one [pill] every day after breakfast...a good 95% of my daily activities I still do," he said with satisfaction, going on to reveal that at his last scan his tumor had stopped progressing.

When asked how he felt about the clinical study's prospects, he responded, "Well...attitude is everything. If my attitude is very positive, then I transmit that to my family and therefore my family will be just as happy...I really hope that it works as intended."

Because Reyes had not shown any significant side effects while on the study, he will continue to take Opdivo for as long as necessary, a regimen that could continue for several more months yet. In the meantime, Reyes notes that his family has been nothing but positive about the clinical study and his treatment — an attitude perhaps bolstered by his own enthusiasm.

LIVING WITH CANCER

What to Know About Nutrition Therapy During Cancer Treatment

BY KRISTIE L. KAHL, M.S.

An oncology dietitian offered advice on how to improve appetite and eat healthy before, during and after treatment for gastrointestinal cancers.

An individual's focus on nutrition therapy during treatment for gastrointestinal cancers can aid outcomes and improve quality of life, according to Rachel Wong, an oncology dietitian at the Georgetown University Hospital, Lombardi Comprehensive Cancer Center.

"With (gastrointestinal) cancers there are a lot of potential side effects that can occur from the cancer itself or from the treatment," she explained at the Fourth Annual GI Cancer Patient Summit. "So, the most important thing I talk to my patients about is weight maintenance and maintaining muscle mass...we really want to try to do as much as we can to make sure you don't lose any more weight and gain some weight back."

During and after cancer treatment, Wong added, the goals of nutrition are to proactively manage treatment-related side effects; to preserve nutrition that the body stores and prevent weight loss; to consume adequate macro- and micronutrients that are needed to optimize nutritional status; to reduce the risk for cancer recurrence, secondary cancers or chronic disease; and to maximize quality of life.

To start, a healthy eating plate consists of the following:

- Healthy oils, such as olive and canola oil
- Limited butter and avoiding trans fat
- More vegetables – the greater the variety the better
- Plenty of fruits of all colors
- Water, tea or coffee (with little or no sugar)
- Limited milk/dairy (one to two servings per day) and juice (one small glass per day), avoiding sugary drinks
- A variety of whole grains, such as whole-wheat bread, whole-grain pasta and brown rice
- Limited refined grains, such as white rice and white bread
- Fish, poultry, beans and nuts
- Limited red meat and cheese, avoiding bacon, cold cuts and other processed meats

During treatment, Wong recommends for patients to plan and prepare meals in advance. "This is something you can do for yourself," she added. "Medication and things like that have to be managed by the doctor, but you have a hand in eating and preparing your food and planning your day out. That is something that can help you significantly."

In addition, Wong recommends for patients to choose high protein and calorie foods; drink at least 64 oz. of water daily; add snacks between meals, especially if one is feeling full quickly;

try different sauces for more variety in foods; set goals; and keep a food log.

Beside maintaining a healthy diet, Wong added that combatting symptoms like depression could also assist with nutrition issues.

"Oftentimes, (depression) causes you to stay at home and not want to go out and do things. So, I spend a lot of time telling patients to do things to improve their mood like going for a walk and getting some sunlight instead of staying in bed all day," she said. "These aren't direct nutrition-related suggestions, but they in turn affect how you eat. You feel better, you feel stronger, you eat better."

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LIVING WITH CANCER

Cancer Survivorship

BY APRIL STAFFORD, BSN, RN, MSHS

If you or anyone you know has been treated for cancer lately, you may have heard of something called Cancer Survivorship. The purpose of survivorship is to answer the "Now what?" questions after treatment is completed, and to make sure patients have the tools they need to monitor their progress well and maximize wellness moving forward.

At MedStar Georgetown, Cancer Survivorship consultations are available for patients who have been diagnosed with stage I, II or III cancers, completed treatment with chemotherapy, radiation, immunotherapy and/or hormone therapy, and are now cancer-free. Patients are eligible for a consultation visit for one year after diagnosis or until treatment is completed, whichever is later.

Patients referred to the Lombardi Cancer Survivorship Clinic receive an hour-long consultation with Dr. Bhumika Gandhi, an internal medicine physician with survivorship expertise who has also worked with our pediatric cancer survivorship patients. The consultation includes an exam, a comprehensive treatment review to anticipate any long-term treatment side effect management, and when to schedule any follow up procedures, scans and visits. A pre-visit questionnaire is completed by the patient before the visit and additional educational resources are given to the patient in response to their specific answers. Two mobility assessments are administered during the visit and referrals are made based on the results. Patients are given the contact information for the Clinical

Nurse Coordinator, who serves as an ongoing point of contact at any time after the consultation should any additional needs or concerns arise. At the conclusion of their visit, they are given a printout of their Survivorship Care Plan and treatment summary that is individually customized to their own situation, along with a copy to give to their PCP at their next visit.

Survivorship consultations are not intended to take the place of regular visits with their PCP or oncologist. Instead they provide cancer survivors with a comprehensive monitoring plan that can be shared with other providers and an additional resource for moving past treatment.

Free Yoga in the Hospital Hallway

BY MORGAN E. KULESZA

The Georgetown Lombardi Arts and Humanities Program provides weekly yoga classes to MedStar Georgetown University Hospital patients, caregivers, and staff members. Classes are free, mats are provided, and all levels are welcome! It's a great way to release tension and build energy in the middle of the day.

Classes take place on Mondays from 12-12:30pm with instructor Deborah Riley, on Wednesdays from 12-12:30pm with instructor Alison Waldman, and on Thursdays from 12:30-1pm with instructor Katie Harris Banks. Classes are held on the 7th floor hallway between the Main and Bles buildings.

A thirty-minute yoga classes can make a positive impact on your day. One attendee, the mother of a patient who attended a Thursday class told Katie Harris Banks how much it helped:

"I've been sleeping in a chair for four months with my son and everything was hurting. After this yoga class all the pain just vanished. It's so important to take the time, it doesn't have to be much, but it helps."

If you'd like to sign up for weekly yoga class reminders and schedule updates, contact morgan.kulesza@georgetown.edu

Patients Were the Teachers in our Fifth Annual Ruesch Summer Internship Program

BY PETRA PRINS, MSC, PHD

This year we celebrated our fifth Ruesch summer internship program, which continues to attract students from across the US and abroad, including India. This year, as in previous years, we invited 12 undergraduate/ graduate students to participate in our program during the months of June and July.

We continually strive to bring novel learning experiences to the program each year, and this year we piloted a new patient-teacher project; in addition to the traditional program of shadowing physicians in different clinical settings and doing clinical research, we matched 12 marvelous patients to each of the 12 students with the aim of providing the physicians of our future with the most personal of cancer care experiences—the patient experience. Students were asked to interact on a personal level with their patient-teacher. They sat at the other side of the oncologists desk with their patient-teacher, heard their diagnosis, felt the elation or fear of a good or bad prognosis, saw what matters to them during their hospital experience, and saw how patients and their families deal with a cancer diagnosis, their treatment, and everything else that goes with it.

The new addition to our program proved to be a great success and allowed students to experience more of the human side of patient care, in addition to the clinical and research side. One of the students, Antara Sarkar, said the following about the program: "It's been a really incredible experience to get to see cancer care from so many different angles... it's just so incredible to get the full-picture experience of cancer. Hopefully that will contribute to us becoming knowledgeable, as well as compassionate and empathetic, healthcare providers."

As part of their patient-teacher learning experience, we asked each student to write a personal thank you letter to their patient. One student wrote: "What touched me the most these past few months was your humility. When you revealed your troubles to me or offered to let me observe your procedures, I was awed by how open you were with subjects that many would be afraid to share. This openness was both assuring and inspiring — assuring in the sense that I was comfortable learning these things about you, and inspiring because I knew that one day, I wanted to be someone who could help you out. Accompanying you and, for a short time, being part of your journey I have learned a couple things that I will think about and work on for the future, and I'm grateful that you opened my eyes to these issues."

Another student, Rhea Verma had the following to say: "When I first heard about the student-patient match that the Ruesch Summer Program was creating, I didn't know what to expect. I knew nothing about ports, the infusion center process, the unexpected hospital trips, and how to take an insurance company to trial. I knew little of the resilience and strength of late stage cancer patients, both of these traits which I saw in Laura. I could never have expected to look forward to our meetings in the clinic every week, and to finish this summer considering her a friend. Talking with Laura was such an enriching and enjoyable experience; it was the most valuable part of my summer at Georgetown." In response, her patient-teacher, Laura Stuart, was equally pleased with the opportunity to teach by sharing her experience: "Having Rhea Verma as my shadow during my many visits to MedStar Georgetown hospital this summer was a very positive experience. She was extremely supportive, making hours of treatment much more tolerable. She was smart, interesting, fun to converse with, and had such an easy manner about her. Best of all she supplied me with wonderful meals of Indian cuisine on my infusion days. Can't get any better than that."

Association of Physical Activity With Survival and Progression in Patients with Metastatic Colorectal Cancer

MARION L HARTLEY, PHD

Everyone knows that a sedentary lifestyle is not good for our health. However, it gets more specific than that: inactivity is a risk factor for colorectal cancer (CRC) and, in those who have CRC without distant metastases, lack of physical exercise can actually increase recurrence and mortality.

It was not apparent if this effect translated to patients with metastatic disease, so researchers in a large cooperative group study decided to prospectively investigate the effect of physical activity on 1,218 patients undergoing chemotherapy for metastatic CRC (mCRC). Using a questionnaire, which was given to patients within 1 month after initiation of their therapy, they asked subjects to report the average length of time spent being physically active each week over the previous 2 months, and whether this activity was generally vigorous (e.g. running, bicycling, tennis, and lap-swimming) or non-vigorous (e.g., walking and yoga). They then translated this data into "metabolic equivalent task (MET) hours" per week. The MET hours were then correlated with overall survival (OS), progression-free survival (PFS), and new grade 3 or greater treatment-related adverse events.

"Inactivity is a risk factor for colorectal cancer (CRC) and, in those who have CRC without distant metastases, lack of physical exercise can actually increase recurrence and mortality."

It was found that patients who were more physically active in general had a longer progression-free survival and experienced less treatment-related toxicity than those who were sedentary. Greater non-vigorous activity alone, particularly walking, was associated with longer progression-free survival, as well as an increase in overall survival, which was not statistically significant but highly compelling nonetheless.

This study underlines the relationship between physical exercise and improved CRC outcomes, extending the benefit to patients with metastatic disease.

So, patients with CRC at any stage will benefit from stepping out, even for a short leisurely walk, daily. The fresh air and the daylight helps to keep spirits high, and who doesn't want some extra time without disease progression? Dr. Marshall, Director of the Ruesch Center, prescribes a dog for his patients, but if they don't have one of those, a smartphone exercise tracker can still be highly motivating.

For more details, please see the study published in the Journal of Clinical Oncology by Guercio et al, titled "Physical Activity With Survival and Progression in Metastatic Colorectal Cancer/ Results From Cancer and Leukemia Group B (Alliance):SWOG 80405" and the interpretative article in the ASCO Post, titled "Does Exercise Improve Outcomes in Patients With Metastatic Colorectal Cancer?"

// ADVOCACY

New Board Member — Lee Jones

The Ruesch Center is pleased to announce the appointment of Lee Jones to our advisory board. Mr. Jones is a colon cancer survivor who was treated at Georgetown Lombardi Cancer Center and Surgical Oncology, MedStar Georgetown University Hospital. He has since become a patient and research advocate working with Fight Colorectal Cancer's Research Advocate Training and Support (RATS) program. He is also a member of the Georgetown Oncology Institutional Review Board; a reviewer of research proposals for the Patient-Centered Outcomes Research Institute (PCORI), US Department of Defense, and American Society of Clinical Oncology (ASCO); a board member of the Cancer Action Coalition of Virginia; a member of PCORI's Clinical Trials Advisory Panel; a member of the Patient Engagement Committee of the Alliance of Regenerative Medicine; and an advocate member of the SWOG Cancer Research Network's survivorship committee. We are excited for the perspective he brings to the board and look forward to his advice on modeling active advocate inclusion and aligning trials/research with patient needs.

ADVOCACY GROUP SPOTLIGHT

Global Liver Institute as part of October Liver Cancer Awareness Month

Liver cancer is the most rapidly increasing cancer in both men and women. More people are developing liver cancer, and more people are dying from it. Now more than ever, we must come together to fight liver cancer and save lives. That is why we have set the ambitious — but reachable — goal of **doubling the five-year survival rate of liver cancer by 2030**. Together with our partners, including the Ruesch Center for the Cure of GI Cancers, the Global Liver Institute is elevating the interests and issues of liver cancer patients and care partners.

Katie Couric is the Inaugural Speaker at Georgetown's Edward M. Kovach Cura Personalis Endowed Lecture

BY SARAH SURGENOR, MA

On Wednesday, August 7, 2019, Georgetown Lombardi Comprehensive Cancer Center welcomed Katie Couric, an award-winning journalist and the co-founder of cancer advocacy nonprofit Stand Up To Cancer, for the inaugural Edward M. Kovach *Cura Personalis* Endowed Lecture.

Couric's lecture, **"The Healing Power of Communication,"** was moderated by Georgetown Lombardi medical oncologist John Marshall, MD, and took the form of a conversation. The lecture focused on **holistic caregiving that celebrates the principle of cura personalis**, or "care for the whole person," personified by the outstanding medical professionals who made Edward Kovach's experience as a patient such a positive one.

Edward Kovach attended Georgetown for both his undergraduate and law degrees.

In 2014, Kovach was diagnosed with pancreatic cancer and placed his trust and confidence in Georgetown, under the medical care of Marshall, a specialist in gastrointestinal cancers who directs the Ruesch Center for the Cure of GI Cancers at Georgetown Lombardi.

Kovach lived with this illness for another 3 1/2 years, a remarkable feat for patients with stage IV pancreatic cancer. Kovach's wife, Kathleen, their five children and their families have decided to show Kovach's gratitude and love for Georgetown by memorializing him with an endowed lecture, an effort led by his daughter Alexandra.

Reprinted from Lombardi Communications (August 10, 2019).

13k people viewed the lecture on Facebook. If you missed it, you can still stream the lecture on the Ruesch YouTube Channel using bit.ly/KovachLecture

Join our Team: Purple Stride, Washington DC

On June 13, 2020, the Ruesch Center will partner with Pancreatic Cancer Action Network at the DC Purple Stride Event.

This year we'll be joining forces with Kristin Ferguson, an Oncology Nurse at the Georgetown Lombardi Comprehensive Cancer Center, who has created a team in memory of her Mother. **If you'd like to join the team or donate, please select "Kristin Ferguson"**. You can also reach her page via **bit.ly/PanCANFerguson**

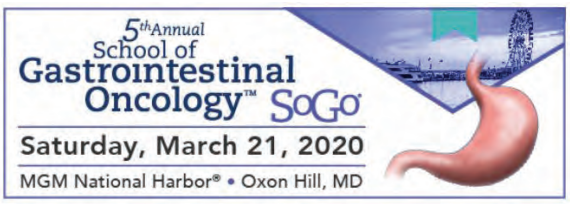
Whether you're running or walking, meet us at the finish line to end this disease.

Save the Date: Ruesch Center Golf Tournament April 27, 2020

Last year's Golf Tournament was a resounding success with 27 teams participating, we increased funding for the center. The 4thAnnual Ruesch Center Golf Tournament is scheduled for **April 27**, 2020. **For more information about participation or sponsorship, email rueschcenter@georgetown.edu**

Highlights of the 10th Annual Symposium

- The Emerging Role of the Microbiome
- The Expanding Role of Immune Therapy in GI Cancer
- Special sessions in GI oncology nursing and neuroendocrine cancer
- The patient symposium, featuring disease-specific sessions, topical breakouts and sessions focusing on patient-centered care and how patients can become research advocates.



MAKE A GIFT

Your contribution to The Ruesch Center enables critical GI cancer research and educational programs for patients and clinicians.

Your support helps to advance crucial clinical research, and allows us to convene patient advocacy organizations to present a stronger and more unified voice for GI cancer research.

With your continued support we can move closer to a cure for GI cancer.

→ Visit Ruesch.Georgetown.edu/Gift to make a gift today.

UPCOMING EVENTS

November 23, 2019
Lomardi Gala
LEARN MORE →

December 6-7, 2019
Ruesch Center Symposium

March 21, 2020
School of Gastrointestinal Oncology® (SOGO™®)
REGISTER NOW →

April 27, 2020
Ruesch Center Golf Tournament

June 13, 2020
Purple Stride
JOIN THE TEAM OR DONATE →

WHO WE ARE

The Otto J. Ruesch Center for the Cure of Gastrointestinal Cancers seeks to focus national efforts on curing all cancers that affect the digestive tract, including mouth, esophageal, stomach, pancreatic, liver, bile duct, colorectal, and anal cancers. Combining expertise in molecular medicine, translational research and a patient-centered philosophy, the Ruesch Center will realize the dream of individualized curative therapies through research, care and advocacy. The Ruesch Center is part of Georgetown Lombardi Comprehensive Cancer Center and MedStar Georgetown University Hospital.

OUR MISSION

To integrate scientific discoveries with a patient-centered philosophy to transform the standard of care for GI cancer patients.

Ruesch.Georgetown.edu/Newsletter

The Ruesch Center
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