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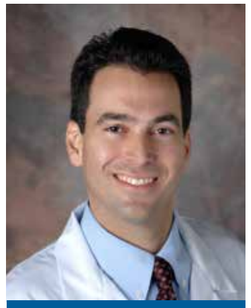

Carlos Alemañy, MD
Medical Director
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AHCI Offers New Phase III Clinical Trial for Women with Platinum-Resistant/Refractory Ovarian Cancer

Olvi-Vec-022 GOG-3076: A Randomized Phase III Study Assessing the Efficacy and Safety of Olvi-Vec followed by Platinum-doublet Chemotherapy and Bevacizumab Compared with Platinum-doublet Chemotherapy and Bevacizumab in Women with Platinum-Resistant/ Refractory Ovarian Cancer (OnPrime Study)

National PI: Robert Holloway, MD

The OnPrime study is a multi-center, randomized, open-label, Phase III study evaluating the safety and efficacy of Olvi-Vec (olvimulogene nanivacirepvec), an oncolytic vaccinia virus, followed by platinum-doublet chemotherapy and bevacizumab compared to the active comparator arm with platinum-doublet chemotherapy and bevacizumab. The study population includes women diagnosed with platinum-resistant/refractory ovarian cancer (includes fallopian tube cancer and primary peritoneal cancer). The study agent, Olvi-Vec, will be administered via intraperitoneal (IP) catheter. In both arms, patients will receive a systemically delivered platinum-doublet plus bevacizumab (or biosimilar).

In the OnPrime Phase III protocol, patients will receive a single cycle of Olvi-Vec (i.e., 2 consecutive doses) via surface placement of an IP catheter which will be removed 2-7 days after the last dose of virus, lessening issues commonly associated with prolonged IP catheter placement for chemotherapy treatment.

The **national principal investigator (PI) of the OnPrime study, AHCI's Robert Holloway, MD**, who was PI of the VIRO-15 study, noted that Olvi-Vec was shown to be well tolerated, and most adverse reactions resolved with additional hydration. No additional unexpected toxicities were noted from the subsequent platinum-doublet chemotherapy +/- bevacizumab after virotherapy.

In Genelux' VIRO-15 Phase Ib/II study in women with platinum resistant/refractory ovarian cancer (PRROC), IP delivered Olvi-Vec was clinically demonstrated to infect tumor tissue and kill tumor cells through oncolysis and shown to re-sensitize patients to subsequent platinum-based therapy.

Please contact the Oncology Research Office via Alejandra Ricaurte, RN, at Alejandra.Ricaurte@AdventHealth.com for information about this new clinical research study.

The following physicians at AdventHealth Cancer Institute serve as clinical trial investigators:

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Hepatic Arterial Infusion Pump Offers New Hope to Patients with Liver Metastases from Colorectal and Bile Duct Cancers

In June, AdventHealth Cancer Institute (AHCI) became the second center in Florida to offer hepatic artery infusion (HAI) as a treatment option for patients with colorectal liver metastases or cholangiocarcinoma (bile duct cancer). Used in combination with systemic chemotherapy, HAI increases response rates, shrinking the liver tumors and resulting in conversion to resection for about 50% of patients.

During this procedure, an HAI pump is surgically placed just below the skin in the lower abdomen and connected by a small catheter into the gastroduodenal artery. This pump slowly delivers a high concentration of floxuridine, about 400 times the amount that can be delivered through a vein, directly to the liver. The liver metabolizes the floxuridine without systemic absorption, reducing toxicity and minimizing side effects.

Colorectal cancer is the fourth most common cancer in the U.S. with an estimated 151,030 new cases and 52,580 deaths projected for 2022. Unfortunately, more than half of colorectal cancer patients develop liver metastases, the leading cause of death for these patients. While resection of the liver metastases is the strongest contributor to long-term survival, only about 15 to 20% of cases are resectable.

Median survival for patients with unresectable colorectal liver metastases who receive systemic chemotherapy is only about 32 to 36 months. The three-year survival rate for patients who are able to undergo resection is around 80% so being able to convert more patients to resection is a significant improvement. With the HAI pump, we can achieve the same long-term outcomes as if the patient presented initially with resectable disease, providing new hope to patients who are otherwise running out of therapeutic options."

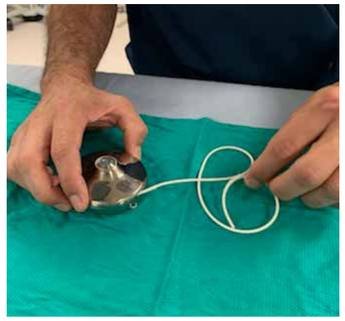
Improving Chemotherapy Response Rates

Overall response rates for treatment of colorectal liver metastases with systemic chemotherapy alone are only about 10 to 30%. Adding the HAI pump as an adjuvant increases these rates to around 80%. It also provides a new possible treatment for patients with cholangiocarcinomas, which have historically lacked effective systemic chemotherapy options.

While the HAI pump has been around for nearly 30 years, we now have better systemic chemotherapies. By taking a multi-modality approach and adding the pump to these newer regimens, we can achieve a remarkably better response for patients. Using the HAI pump, we can deliver a stronger chemotherapy agent directly to the liver tumors while sparing the surrounding healthy tissue. And because of the limited systemic toxic side effects, we can concurrently treat the patients with full doses of systemic chemotherapies.

A Multidisciplinary Approach to Achieve the Best Possible Outcomes

Successful implementation of this new treatment option at AHCI requires a multidisciplinary approach and coordination across multiple teams, including medical oncology, surgical oncology, nuclear medicine, infusion unit nurses, operating room nurses and pharmacists, to achieve the best possible patient outcomes. All have completed specialized training. Our planning started nearly a year ago with guidance from colleagues at Duke University. We wanted to offer our patients access to the same level of care without having to travel so far from home.



In June, under the leadership of Sebastian de la Fuente, MD, an AHCI surgical team implanted an HAI pump in a young patient with metastatic colon cancer, becoming the second center in Florida to offer this technology.

The surgery to place the HAI pump is performed under general anesthesia, similar to placement of a traditional chemotherapy port. Most patients then receive a new infusion through their pump every two weeks at the AHCI Infusion Center in Orlando for the duration of their prescribed treatment regimen. Periodic imaging allows the treating oncologists to monitor progress and determine if and when surgical resection is possible. Early intervention tends to yield better outcomes.

AHCI hopes to increase patient access to this new treatment approach and remains committed to bringing the latest advances in colorectal cancer care to the Central Florida community.

For more information or to refer a patient, call one of our Gastrointestinal Oncology Nurse Navigators: Erica Corcoran, MSN, RN, OCN, AOCNS, ONN-CG, at 407-303-5981 or Wyntir Purtha, BSN, RN, OCN, at 407-303-5959.

John R. T. Monson, MD
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Post-Operative Functional Outcomes in Early Age Onset Rectal Cancer

REACCT Collaborative Study Published in *Frontiers in Oncology*

Background: Impairment of bowel, urogenital and fertility-related function in patients treated for rectal cancer is common. While the rate of rectal cancer in the young (<50 years) is rising, there is little data on functional outcomes in this group.

Methods: The REACCT international collaborative database was reviewed, and data on eligible patients analyzed. Inclusion criteria comprised patients with a histologically confirmed rectal cancer, <50 years of age at time of diagnosis and with documented follow-up, including functional outcomes.

Results: A total of 1,428 (n=1,428) patients met the eligibility criteria and were included in the final analysis. Metastatic disease was present at diagnosis in 13%. Of these, 40% received neoadjuvant therapy and 50% adjuvant chemotherapy. The incidence of post-operative major morbidity was 10%. A defunctioning stoma was placed for 621 patients (43%); 534 of these proceeded to elective restoration of bowel continuity. The median follow-up time was 42 months. Of this cohort, a total of 415 (29%) reported persistent impairment of functional outcomes, the most frequent of which was bowel dysfunction (16%), followed by bladder dysfunction (7%), sexual dysfunction (4.5%) and infertility (1%).

Conclusion: A substantial proportion of patients with early-onset rectal cancer who undergo surgery report persistent impairment of functional status. Patients should be involved in the discussion regarding their treatment options and potential impact on quality of life. Functional outcomes should be routinely recorded as part of follow up alongside oncological parameters.

For more information or to refer a patient, call one of our Gastrointestinal Oncology Nurse Navigators: Erica Corcoran, MSN, RN, OCN, AOCNS, ONN-CG, at 407-303-5981 or Wyntir Purtha, BSN, RN, OCN, at 407-303-5959.

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Outcomes for Endoscopic Submucosal Dissection of Pathologically Staged T1b Esophageal Cancer: A Multicenter Study

Study Published in *Gastrointestinal Endoscopy*

*Abel Joseph [1], Peter V Draganov [2], Fauze Maluf-Filho [3], Hiroyuki Aihara [4], Norio Fukami [5], Neil R Sharma [6], Amitabh Chak [7], **Dennis Yang** [2], Salmaan Jawaid [8], John Dumot [7], Omar Alaber [7], Tiffany Chua [5], Rituraj Singh [6], Lady Katherine Mejia-Perez [9], Ruishen Lyu [9], Xuefeng Zhang [10], Suneel Kamath [11], Sunguk Jang [9], Sudish Murthy [12], John Vargo [9], Amit Bhatt [9]*

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Background and Aims: The outcomes of endoscopic submucosal dissection (ESD) for T1b esophageal cancer (EC) and its recurrence rates remain unclear in the West. Using a multicenter cohort, we evaluated technical outcomes and recurrence rates of ESD in the treatment of pathologically staged T1b EC.

Methods: We included patients who underwent ESD of T1b EC at 7 academic tertiary referral centers in the United States (n = 6) and Brazil (n = 1). We analyzed demographic, procedural and histopathologic characteristics, and follow-up data. Time-to-event analysis was performed to evaluate recurrence rates.

Results: Sixty-six patients with pathologically staged T1b EC after ESD were included in the study. A pre-procedure staging EUS was available in 54 patients and was Tis/T1a in 27 patients (50%) and T1b in 27 patients (50%). En-bloc resection rate was 92.4% (61/66), and R0 resection rate was 54.5% (36/66). Forty-nine of 66 patients (74.2%) did not undergo surgery immediately after resection and went on to surveillance. Ten patients had ESD resection within the curative criteria, and no recurrences were seen in a 13-month (range, 3-18.5) follow-up period in these patients. Ten of 39 patients (25.6%) with noncurative resections had residual/recurrent disease. Of the 10 patients with noncurative resection, local recurrence alone was seen in 5 patients (12.8%) and metastatic recurrence in 5 patients (12.8%). On univariate analysis, R1 resection had a higher risk of recurrent disease (hazard ratio, 6.25; 95% confidence interval, 1.29-30.36; P = .023).

Conclusions: EUS staging of T1b EC has poor accuracy, and a staging ESD should be considered in these patients. ESD R0 resection rates were low in T1b EC, and R1 resection was associated with recurrent disease. Patients with noncurative ESD resection of T1b EC who cannot undergo surgery should be surveyed closely, because recurrent disease was seen in 25% of these patients.

For more information or to refer a patient, call one of our Gastrointestinal Oncology Nurse Navigators: Erica Corcoran, MSN, RN, OCN, AOCNS, ONN-CG, at 407-303-5981 or Wyntir Purtha, BSN, RN, OCN, at 407-303-5959.

Mohamedtaki Tejani, MD
Medical Director
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A Phase II, Randomized Study of Magrolimab with Bevacizumab and FOLFIRI in Previously Treated Patients with Advanced Inoperable Metastatic Colorectal Cancer

Poster Presented at European Society for Medical Oncology (ESMO)

*Marwan G. Fakih[1], **Mohamedtaki Tejani[2]**, Xuehan Ren[3], David Landes[3], Scott Werneke[3], Kelly K. Curtis[3], J. Randolph Hecht[4]*

*[1]City of Hope Comprehensive Cancer Center, Duarte, CA; [2]**AdventHealth Cancer Institute, Orlando, FL**; [3]Gilead Sciences, Inc, Foster City, CA; [4]David Geffen School of Medicine at UCLA, Santa Monica, CA*

Background: For patients with metastatic colorectal cancer (mCRC) who are ineligible/unable to derive benefit from novel targeted therapies or immunotherapies, standard of care (SOC) doublet or triplet chemotherapy-based regimens associated with toxicity and limited responses are the only available treatment options. Magrolimab is an antibody blocking CD47, a "don't eat me" signal on cancer cells, resulting in tumor phagocytosis by macrophages and nonclinical activity in hematologic and solid tumor malignancies. Chemotherapeutic agents can enhance prophagocytic signals on tumor cells, leading to the potential for synergistic antitumor activity with magrolimab. This study is evaluating the safety, tolerability and efficacy of magrolimab with bevacizumab + FOLFIRI in advanced inoperable mCRC.

Trial Design: This Phase II, (ph2) randomized, open-label study consists of safety run-in and ph2 cohorts. Eligible pts (≥18 y) progressed on or after 1 prior systemic therapy with chemotherapy based on 5-FU with oxaliplatin and bevacizumab. Magrolimab is administered intravenously with an initial 1-mg/kg priming dose to mitigate on-target anemia, followed by a 30-mg/kg dose during cycle 1 (28-day cycles) in the safety run-in to determine a recommended ph2 dose (RP2D) and evaluate pharmacokinetics and immunogenicity. In ph2, patients will be randomized 2:1 to magrolimab in combination with bevacizumab + FOLFIRI vs bevacizumab + FOLFIRI. After the magrolimab priming dose on day (D)1, the RP2D will be administered weekly starting on D8 for the next 6 doses, followed by every other week. Bevacizumab is administered at 5 mg/kg on D1 and D15 each cycle. FOLFIRI is administered per SOC on D1, D2, D15, and D16 of each cycle. Patients may continue treatment until unacceptable toxicity, progressive disease by RECIST 1.1 or patient/investigator choice. Primary endpoints include incidence of dose-limiting toxicities and adverse events (safety run-in) and progression-free survivial (PFS) by investigator (ph2). Secondary endpoints include magrolimab concentration vs. time, antidrug antibodies (safety run-in), objective response rate, PFS by independent central review, duration of response and overall survival (ph2). NCT05330429.

For more information or to refer a patient, call one of our Gastrointestinal Oncology Nurse Navigators: Erica Corcoran, MSN, RN, OCN, AOCNS, ONN-CG, at 407-303-5981 or Wyntir Purtha, BSN, RN, OCN, at 407-303-5959.

Sarfraz Ahmad, PhD
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Updates on Clinical Trials in Diagnosis and Therapy of Colorectal Cancer

International Collaborative Research Chapter Published in a Book "Colon Cancer Diagnosis and Therapy" by Springer Nature

*Farhan Ullah[1], Hariharasudan Mani[2], Maha Wazir1, Sana Hussain[1], Saeed Ali[2], **Sarfraz Ahmad[3]***

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Colorectal cancer (CRC) is the third most common cancer overall. It could be sporadic, which is most common at 70% of CRC cases, inherited (5%), or familial (25%). The most common genes that are affected in CRC are oncogenes, tumor suppressor genes and genes related to the DNA repair mechanisms. Structural screening tests (such as colonoscopy, sigmoidoscopy) are superior to stool tests. Studies have shown that colonoscopy has reduced incidence of CRC by 67% and case fatality rate by 65%.

Microsatellite instability (MSI), chromosomal instability (CIN) and CpG island methylator phenotype (CIMP) are the major mutations that occur in CRC. These can also act as a biomarker, which could be detected in stool, blood or tumor biopsy. Based on patient characteristics and tumor features, CRC patients could be divided into four groups (from Group 0 to Group 3).

First-line chemotherapeutic agents for adjuvant chemotherapy are FOLFOX (5-FU/LV/oxaliplatin) or cepecitabine/LV/oxaliplatin. Palliative chemotherapy options involve 5-FU with leucovorin, cepacitabine alone, FOLFOX or FOLFIRI regiments (5-FU/LV/irinotecan). Efficacy of combination regimens are enhanced by the use of monoclonal antibodies such as anti-VEGF (bevacizumab) and anti-EGFR (cetuximab, panitumumab).

Some of the alternative treatments currently ongoing are discussed in this chapter. These include agarose tumor microbeads where tumor growth inhibitory factor causing a negative inhibitory signal is found to slow the tumor growth. Chronic inflammatory products such as cytokines, chemokines, reactive oxygen species (ROS), reactive nitrogen species and arachidonic acid derivatives are risk factor(s) for CRC, and COX inhibitors such as NSAIDs could have some effect prophylactically and for treatment against CRC. Probiotics could act on CRC possibly by apoptosis of diseased cells and also possibly by antioxidant effect. Functional foods containing polyphenols could reduce ROS, thereby reducing CRC by maintaining a balance between ROS and antioxidants. Metal-based drugs such as platinum-based agents (like carboplatin, oxaliplatin) and gold-based drugs (such as auranofin) also exert anti-tumor effect, possibly through platinum-DNA adducts and ROS, respectively.\

For more information or to refer a patient, call one of our Gastrointestinal Oncology Nurse Navigators: Erica Corcoran, MSN, RN, OCN, AOCNS, ONN-CG, at 407-303-5981 or Wyntir Purtha, BSN, RN, OCN, at 407-303-5959.

Rushang Patel, MD, PhD
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AHCI's Bone Marrow Transplant Program Achieves FACT Reaccreditation

AHCI's Bone Marrow Transplant Program has once again achieved accreditation from the Foundation for the Accreditation of Cellular Therapy (FACT), recognizing its high quality medical and laboratory practice in cellular therapies. FACT is a non-profit corporation co-founded by the International Society for Cell and Gene Therapy (ISCT) and the American Society for Transplantation and Cellular Therapy (ASTCT) for the purposes of voluntary inspection and accreditation in the field of cellular therapy.

FACT standards are evidence-based requirements set by world-renowned experts vested in the improvement and progress of cellular therapy. Standards for hematopoietic progenitor cells (HPC) and other nucleated cells obtained from bone marrow, peripheral blood, and umbilical and placental cord blood are developed by consensus within committees consisting of knowledgeable clinicians, scientists, technologists and quality experts who represent the entire continuum of cell manufacturing and administration.

Organizations that achieve FACT accreditation have developed and implemented a foundation of high-quality practices that result in cell products and patient care that are sought after by physicians and patients.

For more information or to refer a patient, call one of our Bone Marrow Transplant Nurse Navigators: Austin Carroll, BSN, RN; Anna Cullivan, BSN, RN; or Vielka Hernandez, RN, at 407-303-2825.

Ahmad Awada, MD
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Immunotherapy in the Treatment of Platinum-Resistant Ovarian Cancer: Current Perspectives

Clinical Research Review Article Published in *OncoTargets and Therapeutics*

Ahmad Awada MD; Sarfraz Ahmad, PhD; Nathalie D. McKenzie,MD; Robert W. Holloway, MD

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Summary

Epithelial ovarian cancer (EOC) is the most lethal gynecologic cancer. The gold standard therapeutic approach is a combination of surgery plus chemotherapy. Unfortunately, 80% of patients with EOC suffer recurrence within 2 years, and the overall response rate for platinum-resistant EOC to cytotoxic chemotherapy or poly-(adenosine diphosphate)-ribose polymerase (PARP) inhibitor is modest. New therapies are needed to improve overall survival.

The role of immunotherapy has been established in endometrial and cervical cancers; however, its effective use in EOC has been limited due to the intrinsic genomics and micro-immune environment associated with EOC. Studies evaluating immunotherapy, largely immune checkpoint inhibitors (ICI), have shown limited activity, yet some patients benefit greatly. Thus, significant efforts must be devoted to finding new strategies for the use of immunotherapy/immunomodulatory drugs (IMiDs). Immunotherapy has a well-tolerated safety profile; however, cost-effectiveness can be an obstacle. The aim of this article is to review the most recent research into the use of IMiDs in patients with platinum-resistant epithelial ovarian cancer.

For more information or to refer a patient, call GYN Oncology Nurse Navigator Althea Buckner, MSN, APRN-AOCNP, at 407-303-5909.

Sebastian de la Fuente, MD
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Advanced Upper Gastrointestinal/Hepato-Pancreato-Biliary Surgery Fellowship Program Celebrates 10th Anniversary

The Advanced Upper Gastrointestinal (GI)/Hepato-Pancreato-Biliary (HPB) Surgery Fellowship at AdventHealth Orlando started as a program to allow general surgeons further specialization in advanced GI and HPB diseases with a mission to provide the structured educational and training experience necessary to achieve expertise in these types of complex surgical procedures and patient care.

Since 2014, the one-year fellowship has been uninterruptedly accredited by the Fellowship Council, a national association of program directors and specialty societies charged with oversight of fellowship training programs to uphold uniformly high standards and produce well-trained surgeons. AdventHealth Orlando receives around 40-50 applications annually and typically fills the position with one of our top three choices.

The fellowship focuses strongly on minimally invasive techniques as well as robotic approaches for the management of complex GI and HPB disease processes within the context of advanced GI surgery training. Since 2014, all the graduating fellows have obtained jobs within these specialties and currently hold diverse positions in both academic and private settings.

This years' fellow, Andrew Guzowski, MD, came to the program after completing his general surgery residency at the Cleveland Clinic Akron General, in Ohio, and a Surgical Critical Care fellowship at the University of Michigan in Ann Arbor. The next fellow will start in August 2023 and is currently completing his residency in South Carolina.

Learn more about the Advanced Upper GI/HPB Surgery Fellowship at adventhealth.com/adventhealth-graduate-medical-education/advanced-upper-gi-hpb-fellowship.

Nathalie D. McKenzie, MD
Gynecologic Oncology Program
AdventHealth Cancer Institute

Impact of Lifestyle Interventions on Gynecologic Cancers: Beyond Diet and Exercise

Analytic Research Review Article Published in the *American Journal of Lifestyle Medicine*

Summary

A lifestyle medicine approach to compliment cancer care is less commonly researched or implemented for women with gynecologic cancers as compared to better funded malignancies such as breast, prostate and colorectal. Yet, several gynecologic malignancies are linked to obesity, estrogen/metabolic signaling pathways and an altered tumor microenvironment which could benefit greatly from a lifestyle medicine program.

Lifestyle medicine, an evidenced-based branch of science, has expanded to the prevention and treatment of disorders caused by lifestyle factors (including cancer). Modifiable lifestyle factors such as obesity, lack of physical activity/nutrient density, microbial dysbiosis, sleep disturbance and chronic stressors contribute greatly to cancer morbidity and mortality worldwide. This overarching area of research is evolving with some sub-topics in their infancy requiring further investigation.

Modern tools have allowed for better understanding of mechanisms by which adiposity and inactivity affect tumor-promoting signaling pathways as well as the local tumor environment. Through the evolving use of these sophisticated techniques, novel prognostic biomarkers have emerged to explore efficacy of pharmacologic and lifestyle interventions in cancer. This state-of-the-art analytic review article appraises recent evidence for a lifestyle medicine approach, beyond diet and exercise, to optimize survivorship and quality of life for patients with gynecologic cancers and introduces the 8-week, web-based comprehensive HEAL-GYN program.

For more information or to refer a patient, call GYN Oncology Nurse Navigator Althea Buckner, MSN, APRN-AOCNP, at 407-303-5909.

Sarfraz Ahmad, PhD
Gynecologic Oncology Program
AdventHealth Cancer Institute

Exploring Bias in Scientific Peer-Review: An ASCO Initiative

Collaborative Research Study Accepted for Publication in *JCO® Oncology Practice*

*Nathalie D. McKenzie[1], Raymond Liu[2], Alden V. Chiu[3], Mariana Chavez-MacGregor[4], Dean Frohlich[5], **Sarfraz Ahmad**[1], Carolyn B. Hendricks[6]*

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Summary

Purpose: To investigate implicit bias (IB) in the peer-review process across the American Society of Clinical Oncology (ASCO) and Conquer Cancer Foundation and propose potential mitigation strategies.

Materials and Methods: We, ASCO Working Group on Implicit Bias (WGIB), selected four data-sources: A) Literature search: i) Defining IB in peer-review, ii) Evidence of IB in peer-review, iii) Strategies to mitigate IB; B) Created and analyzed an ASCO database for gender, race and institutional affiliation regarding peer-review success; C) Constructed and conducted qualitative interviews of key-stakeholders within the ASCO board, publications and grants committee on experience with IB within ASCO, and; D) Constructed, delivered and analyzed results of a member survey on perception of IB within ASCO.

Results: Historically uncommon, PubMed articles on IB in peer-review subsequently increased exponentially in the past two decades. Qualitative interviews of ASCO key stakeholders reveal that system changes and IB training were priorities. Committee members surveyed reported their peer-review decisions could be affected by IB and that mitigating IB should be a priority. Most reported having never been trained on IB. Available data from the ASCO database support stakeholder findings, suggesting there exists a disproportionate representation of males and better-known institutions among both reviewer positions and awardees. Ethnicity/race data was insufficiently reported. Limited data on interventions/strategies to mitigate IB in the peer-reviewed literature suggest there are feasible processes for grants, program committees and journals.

Conclusion: Limited data reveals the peer-review process at ASCO is not exempt from IB and suggest association to gender and institutional affiliation. WGIB recommends three actions to mitigate IB within peer-review: i) Create awareness and a culture of inclusivity, ii) Create systems to reduce IB, and iii) Collect data for ongoing analysis.

For more information or to refer a patient, call GYN Oncology Nurse Navigator Althea Buckner, MSN, APRN-AOCNP, at 407-303-5909.

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Gynecologic Oncology Department
AdventHealth Cancer Institute

The Added Value of SLN Mapping with Indocyanine Green in Low- and Intermediate-risk Endometrial Cancer Management: A Systematic Review and Meta-analysis

International Collaborative Research Study Published in the *Journal of Gynecologic Oncology*

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Summary

Objective: The aim of this study was to assess the sentinel lymph node (SLN) detection rate in presumed early-stage, low- and intermediate-risk endometrial cancers, the incidence of SLN metastases, and the negative predictive value of SLN mapping performed with indocyanine green (ICG).

Methods: A systematic review with meta-analyses was conducted. Study inclusion criteria were A) low- and intermediate-risk endometrial cancer; B) the use of ICG per cervical injection; C) a minimum of 20 included patients per study to assess the negative predictive value of SLN mapping; and D) a subsequent lymphadenectomy was an additional inclusion criterion.

Results: Fourteen studies were selected, involving 2,117 patients. The overall and bilateral SLN detection rates were 95.6% (95% confidence interval [CI] = 92.4% - 97.9%) and 76.5% (95% CI = 68.1% - 84.0%), respectively. The incidence of SLN metastases was 9.6% (95% CI = 5.1% - 15.2%) in patients with grade 1-2 endometrial cancer and 11.8% (95% CI = 8.1% - 16.1%) in patients with grade 1-3 endometrial cancer. The negative predictive value of SLN mapping was 100% (95% CI = 98.8% - 100%) in studies that included grade 1-2 endometrial cancer and 99.2% (95% CI = 97.9% - 99.9%) in studies that also included grade 3.

Conclusion: SLN mapping with ICG is feasible with a high detection rate and negative predictive value in low- and intermediate-risk endometrial cancers. Given the incidence of SLN metastases is approximately 10% in those patients, SLN mapping may lead to stage shifting with potential therapeutic consequences. Given the high negative predictive value with SLN mapping, routine lymphadenectomy should be omitted in low- and intermediate-risk endometrial cancer.

For more information or to refer a patient, call GYN Oncology Nurse Navigator Althea Buckner, MSN, APRN-AOCNP, at 407-303-5909.

Collaborative Clinical Research Presentations at the International Gynecological Cancer Society (IGCS) Annual Global Meeting

Study Title	Authors	Abstract No.
Malignant Peritoneal Cytologic Contamination with Robotic Hysterectomy for Endometrial Cancer	**Gwacham NI, Kilowski KA, Recio FO, Awada A,** Zhu J, Patel A, Holloway J, **McKenzie ND, Ahmad S, Kendrick JE, Holloway RW**	78 e-Poster
Phase III Study of Efficacy & Safety of OLVI-VEC and Platinum-doublet + Bevacizumab Compared to Platinum-doublet + Bevacizumab in Platinum-resistant/refractory Ovarian Cancer (OnPrime; GOG-3076) [NCT05281471]	**Holloway RW,** Thaker PH, Mendivil AA, **Ahmad S,** Bell MC, Chambers SK, Chan JK, Coleman RL, Crafton SM, Crane E, Eskander R, Finkelstein K, Graybill1 W, Herzog TJ, John VS, Landrum L, Leiser A, McHale MT, Miller RW, Monk BJ, Moore KN, O'Malley DM, Reid T, Richardson DL, Silasi D-A, Sunde JS, Tewari K	1435 e-Poster TiP (Trial in Progress)

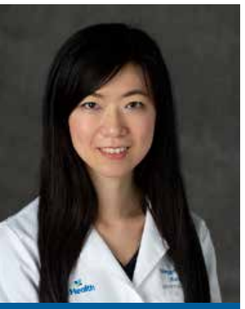
AHCI Welcomes New Gynecologic Oncology Fellow-in-Training

Theresa M. Kuhn, MD

Theresa M. Kuhn, MD's first year of fellowship in gynecologic oncology at AdventHealth Cancer Institute (AHCI) will focus on clinical care and research. Throughout her previous training, Dr. Kuhn has co-authored multiple peer-reviewed scholarly publications and presentations, focusing on HPV and cervical cancer as well as surgical outcomes in gynecologic oncology. She plans to continue pursuing these clinical research interests during her AHCI fellowship.

Dr. Kuhn is board certified by the American Board of Obstetrics and Gynecology and the National Board of Medical Examiners. In addition, she recently sat for her surgical critical care boards from the American College of Surgeons (ACS). She is a member of the American Medical Association (AMA), The American College of Obstetricians and Gynecologists (ACOG), the Society of Gynecologic Oncology (SGO), and the American Society of Colposcopy and Cervical Pathology, where she served as a member of the Assessment Committee from 2020-2022.

Prior to beginning her AHCI fellowship, Dr. Kuhn completed a one-year fellowship in trauma and surgical critical care at the University of Connecticut, Hartford, where she was their first OB-GYN Fellow. Before that, she completed fellowships in advanced pelvic surgery and lower anogenital screening and treatment at Emory University in Atlanta, Georgia. Dr. Kuhn completed her residency in obstetrics and gynecology at Rutgers New Jersey Medical School in Newark, New Jersey, where she developed her interest in gynecologic oncology and research. She served as one of the chief residents for her program and received recognition as "The Best Teaching Resident" and for the "Best Resident Research Project" for her prospective analysis of the effect of forced cough at the time of colposcopic-directed biopsy. In addition, she received the SGO award for "Outstanding Resident in Gynecologic Oncology" and the Society of Laparoscopic Surgeons' (SLS) award for "Outstanding Minimally Invasive Surgery (MIS) Resident." Dr. Kuhn earned her medical degree from American University of the Caribbean School of Medicine in St. Martin.



Mengni Guo, MD
Internal Medicine Residency Program
AdventHealth

A Single Center Retrospective Study of the Impact of COVID-19 Infection on Immune-related Adverse Events in Cancer Patients Receiving Immune Checkpoint Inhibitors

Collaborative Research Study Published in the *Journal of Immunotherapy*

Mengni Guo[1], *Jieying Liu1, Ruoyu Miao*[2], *Zohaib Ahmed*[1], *James Yu1, Jian Guan*[3], ***Sarfraz Ahmad***[4], *Shuntai Zhou*[5], *Angela Grove*[6], *Manoucher Manoucheri*[1], ***Mark A. Socinski***[6], ***Tarek Mekhail***[6]

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Summary

Immune checkpoint inhibitors (ICIs) can cause a variety of immune-related adverse events (irAEs). The coronavirus disease 2019 (COVID-19) is associated with increased amounts of pro-inflammatory cytokines, which may affect the outcome of irAEs. Data are limited regarding the impact of COVID-19 on irAEs in ICI-treated cancer patients. Hence, in this study, we retrospectively analyzed ICI-treated adult patients with malignant solid tumors at a single institution between August 2020 and August 2021.

Patients who had the most recent ICI treatment over 1 month before or after the positive COVID-19 test were excluded from the study. For the COVID-19 positive group, only the irAEs that developed after COVID-19 infection were considered as events. A total of 579 patients were included in our study, with 46 (7.9%) in the COVID-19 positive group and 533 (92.1%) in the COVID-19 negative group. The baseline characteristics of patients in the two groups were similar.

With a median follow-up of 331 days (range: 21-2,226), we noticed a non-significant higher incidence of all-grade irAEs in the COVID-19 positive group (30.4% vs. 19.9%, p=0.18). The incidence of grade 3 and 4 irAEs was significantly higher in the COVID-19 positive group (10.9% vs. 3.2%, p=0.02). Multivariate analysis confirmed the association between COVID-19 infection and increased risk of severe irAE development (odds ratio: 1.08, 95% confidence interval: 1.02-1.14, p=0.01). Our study suggested that COVID-19 may pose a risk of severe irAEs in cancer patients receiving ICIs. Close monitoring and possibly delaying ICI administration could be considered when cancer patients are infected with COVID-19.

Terek Mekhail, MD
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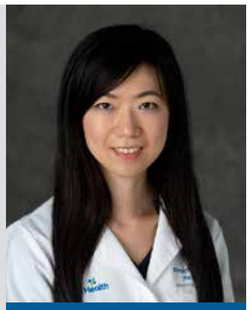
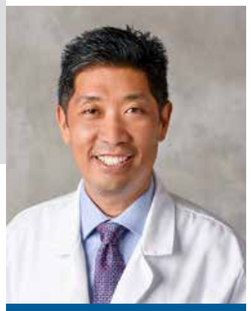
AdventHealth Cancer Institute



Mengni Guo, MD
Internal Medicine Residency Program
AdventHealth



Vincent Hsu, MD
Medical Director, Continuing Medical Education
Assistant Director, Internal Medicine Residency Program
AdventHealth

COVID-19 Outcomes in Stage IV Cancer Patients Receiving Immune Checkpoint Inhibitors

Collaborative Research Study Published in the *SN Comprehensive Clinical Medicine*

Mengni Guo[1], ***Jieying Liu***[1], *Shuntai Zhou*[2], ***James Yu***[1], ***Zohaib Ahmed***[1], ***Sarfraz Ahmad***[3], ***Manoucher Manoucheri***[1], ***Mark A. Socinski***[4], ***Tarek Mekhail***[4], ***Vincent Hsu***[5]

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Summary

Cancer patients are a vulnerable population in the current coronavirus disease 2019 (COVID-19) outbreak. The impact of immune checkpoint inhibitors (ICIs) on the outcomes of COVID-19 infection in cancer patients remains largely unclear. We retrospectively investigated all solid cancer patients who received at least one cycle of ICIs at a single institution between August 2020 and August 2021.

All stage IV solid cancer patients who were on or ceased ICI treatment when diagnosed with COVID-19 were eligible. All COVID-19 infections were confirmed by RT-PCR. Risk factors for hospitalization, severe symptoms and death were analyzed. A total of 56 patients were included in our study. Twenty (35.7%) patients require hospitalization, 12 (21.4%) developed severe symptoms, and 10 (17.9%) died from COVID-19 infection. ICI treatment was interrupted in 37 patients (66.1%), 24 of whom (64.9%) had treatment resumed. Eight (80%) COVID-19-related death occurred in unvaccinated individuals. Re-infection occurred in seven patients (12.5%), and three of them died from their second COVID-19 infection.

Factors associated with hospitalization were high Charlson comorbidity score (OR 1.56, 95% CI 1.10-2.23, p=0.01) and lymphocyte ≤ 1,500 mm3 (OR 10.05, 95% CI 2.03-49.85, p=0.005). Age, chemoimmunotherapy and ICI treatment duration were not associated with increased risk of hospitalization, severe symptoms or COVID-19-related mortality. ICI therapy does not impose an increased risk for severe COVID-19 infection in stage IV cancer patients. Vaccination should be encouraged among this population. Clinicians should be cognizant of a potential worse outcome in COVID-19-reinfected patients.

Sarfraz Ahmad, PhD
AdventHealth Cancer Institute

The Role of Lipids and Fatty Acid Metabolism in the Development of Prostate Cancer

International Collaborative Research Study Published in the *Indian Journal of Biochemistry & Biophysics*

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Summary

The re-programming of lipid metabolism and signaling pathways is the central aspect of cancer biology. It is hypothesized that tumor cells can alter the lipid spectrum in order to fulfill their metabolic requirements. Furthermore, they can alter potential tumors and suppressive mechanisms in which lipids' involvement is essential. Recently, more attention has been given on the alteration of lipid metabolism during prostate cancer development, and investigations have shown unique regulation of "de novo" lipid synthesis in cancer cells. Cancer cells often use newer pathways and enzymes to simplify the synthesis of fatty acids, and the newly synthesized lipids affect cellular processes, which impacts cancer cell proliferation and survival outcomes. Herein, we aimed to study the influence of lipid profile alterations on the development of prostate cancer.

We found that the total amounts of lipids and phospholipids were increased within tissues from men with the malignant prostate tumor as compared with the benign prostate tissue. Significant changes were also observed in the composition of saturated and unsaturated fatty acids within the malignant tumor tissues. Intensification of lipid peroxidation has also been observed in malignant prostate tumors compared to benign prostate tumors. Collectively, these findings further highlight the fact that lipid and fatty acids play unique regulatory roles in the cellular development of prostate malignant transformation.

New Clinical Trials Available at AdventHealth Cancer Institute

ADULT

BREAST

BR007: A Phase III clinical trial evaluating de-escalation of breast radiation for conservative treatment of stage I, hormone sensitive, HER2-negative, oncotype recurrence score

OP-1250-003: A Phase Ib, open-label, multicenter study of OP-1250 in combination with the CDK4/6 inhibitor ribociclib or with the PI3K inhibitor alpelisib in adult subjects with advanced and/or metastatic HR positive, HER2 negative breast cancer

GS-US-592-6238: A randomized, open-label, Phase III study of sacituzumab govitecan versus treatment of physician's choice in patients with previously untreated, locally advanced, inoperable or metastatic triple-negative breast cancer whose tumors do not express PD-L1 or in patients previously treated with anti-PD(L)1 agents in the early setting whose tumors do express PD-L1 (ASCENT-03)

GS-US-592-6173: A randomized, open-label, Phase III study of sacituzumab govitecan and pembrolizumab versus treatment of physician's choice and pembrolizumab in patients with previously untreated, locally advanced, inoperable, or metastatic triple-negative breast cancer, whose tumors express PD-L1

GASTROINTESTINAL

GS-US-587-6156: A Phase II study to evaluate the efficacy and safety of magrolimab in combination with bevacizumab and FOLFIRI in previously treated, advanced inoperable metastatic colorectal cancer (CRC) patients

20210098: A Phase Ib/III study of bemarituzumab plus chemotherapy and nivolumab versus chemotherapy and nivolumab alone in subjects with previously untreated advanced gastric and gastroesophageal cancer with FGFR2b overexpression

GENITOURINARY

VT# IST-21-11721: A Phase II trial of lurbinectedin combined with avelumab as switch maintenance first-line therapy for metastatic urothelial carcinoma with stable or responding disease following platinum-based chemotherapy (VT# IST-21-11721)

SWOG S1931: A Phase III trial of immunotherapy-based combination therapy with or without cytoreductive nephrectomy for metastatic renal cell carcinoma (Probe Trial)

GYNECOLOGIC

Olvi-Vec-022: A randomized Phase III study assessing the efficacy and safety of Olvi-Vec followed by platinum-doublet chemotherapy and bevacizumab compared with platinum-doublet chemotherapy and bevacizumab in women with platinum-resistant/refractory ovarian cancer (OnPrime Study) GOG 3076

HEMATOLOGY/LYMPHOMA (Non-Transplant)

ACE-LY-312: A combination of acalabrutinib with R-CHOP in subjects with previously untreated non-GCB DLBCL (ACE-LY-312) (ESCALADE)

GS-US-546-5857: A Phase III, randomized, open-label study evaluating the safety and efficacy of magrolimab in combination with azacitidine versus physician's choice of venetoclax in combination with azacitidine or intensive chemotherapy in previously untreated patients with TP53 mutant acute myeloid leukemia

HEMATOLOGY/LYMPHOMA (Transplant)

68284528MMY3004: A Phase III randomized study comparing bortezomib, lenalidomide and dexamethasone (VRd) followed by ciltacabtagene autoleucel, a chimeric antigen receptor T cell (CAR-T) therapy directed against BCMA versus bortezomib, lenalidomide and dexamethasone (VRd) followed by lenalidomide and dexamethasone (Rd) therapy in participants with newly diagnosed multiple myeloma for whom hematopoietic stem cell transplant is not planned as initial therapy

EQ-100-02: A study of itolizumab in combination with corticosteroids for the first-line treatment of acute graft versus host disease (EQUATOR)

THORACIC

D5087C00001: A Phase III, randomized, open-label study of savolitinib in combination with osimertinib versus platinum-based doublet chemotherapy in participants with EGFR mutated MET-overexpressed and/or amplified, locally advanced or metastatic non-small cell lung cancer who have progressed on treatment with osimertinib (SAFFRON)

D9705C00001: A Phase III, randomized, double-blind, placebo-controlled, multicenter, international study of durvalumab and domvanalimab (AB154) as sequential therapy in participants with locally advanced (stage III), unresectable non-small cell lung cancer whose disease has not progressed following definitive, platinum-based concurrent chemoradiation therapy (PACIFIC 8)

BASKET/MULTI-SITE/SOLID TUMOR

SGNB7H4V-001: A Phase I study of SGN-B7H4V in advanced solid tumors

PRT2527-01: A Phase I, open-label, multicenter, dose escalation study of PRT2527 in patients with advanced solid tumors

TTX-080-001: A Phase I dose escalation and dose expansion study of TTX-080, an HLA-G antagonist, as monotherapy and in combination with pembrolizumab or cetuximab in patients with advanced solid malignancies

ONC-392-001: Safety, pharmacokinetics (PK), and efficacy of ONC-392 as a single agent and in combination with pembrolizumab in advanced solid tumors and NSCLC: an open label Phase IA/IB study (PRESERVE-001)

For more information or to refer a patient, call the Clinical Research Office at 407-303-7302. Eligibility criteria may also be viewed at www.adventhealthcancerinstitute.com.

PEDIATRIC

BRAIN

ACNS1422: A Phase II study of reduced therapy for newly diagnosed average-risk WNT-driven medulloblastoma patients

ACNS1723: A Phase II study of dabrafenib with trametinib after local irradiation in newly diagnosed BRAFV600-mutant high-grade glioma (HGG) (IND# 145355)

ACNS1831: A Phase III randomized study of selumetinib versus carboplatin/vincristine in newly diagnosed or previously untreated neurofibromatosis Type 1 (NF1) associated low-grade glioma (LGG)

ACNS1833: A Phase III randomized non-inferiority study of carboplatin and vincristine versus selumetinib in newly diagnosed or previously untreated low-grade glioma (LGG) not associated with BRAFV600E mutations or systemic neurofibromatosis Type 1 (NF1)

NEUROBLASTOMA AND EMBRYONAL TUMORS

AGCT1532: A randomized Phase III trial of accelerated versus standard BEP chemotherapy for patients with intermediate and poor-risk metastatic germ cell tumors

ANBL00B1: Biology: neuroblastoma biology studies

ANBL1232: A Phase III study utilizing response and biology-based risk factors to guide therapy in patients with non-high-risk neuroblastoma

AGCT1531: A Phase III study of active surveillance for low-risk and a randomized trial of carboplatin vs. cisplatin for standard-risk pediatric and adult patients with germ cell tumors

ANBL1531: A Phase III study of 131I-metaiodobenzylguanidine (131I-MIBG) or crizotinib added to intensive therapy for children with newly diagnosed high-risk neuroblastoma (NBL) (IND# 134379)

BONE AND SOFT TISSUE SARCOMAS

ARST1921: A safety, pharmacokinetic and efficacy study of a gamma-secretase inhibitor, nirogacestat (PF-03084014; IND# 146375), in children and adolescents with progressive, surgically unresectable desmoid tumors

ALTE16C1: Effects of modern chemotherapy regimens on spermatogenesis and steroidogenesis in adolescent and young adult (AYA) survivors of osteosarcoma

ARST1431: A randomized Phase III study of vincristine, dactinomycin, cyclophosphamide (VAC) alternating with vincristine and irinotecan (VI) versus VAC/VI plus temsirolimus (TORI, Torisel, NSC# 683864) in patients with intermediate risk (IR) rhabdomyosarcoma (RMS)

COMPANION STUDIES

ALTE05N1: Umbrella long-term follow-up protocol

HEPATIC MALIGNANCY

AHEP1531: Pediatric Hepatic Malignancy International Therapeutic Trial (PHITT)

RENAL TUMORS

AREN03B2: Renal tumors classification, biology and banking study

LEUKEMIA (ALL/AML)

AALL1821: A Phase II study of blinatumomab (NSC# 765986, IND# 125462) in combination with nivolumab (NSC# 748726, IND# 125462), a checkpoint inhibitor of PD-1, in B-ALL patients aged >/=1 to <31 years old with first relapse

AAML1831: A Phase III randomized trial for patients with de novo AML comparing standard therapy, including gemtuzumab ozogamicin (GO), to CPX-351 with GO, and the addition of the FLT3 inhibitor gilteritinib for patients with FLT3 mutations

AALL1631: International Phase III trial in Philadelphia chromosome-positive acute lymphoblastic leukemia Ph+ ALL testing imatinib in combination with two different cytotoxic chemotherapy backbones

AALL1621: A Phase II study of inotuzumab ozogamicin in children and young adults with relapsed or refractory CD22+ B-acute lymphoblastic leukemia (B-ALL)

AALL1731: A Phase III trial investigating blinatumomab in combination with chemotherapy in patients with newly diagnosed standard risk or down syndrome B-lymphoblastic leukemia (B-ALL) and the treatment of patients with localized B-lymphoblastic lymphoma (B-LLy)

AALL1732: A Phase III randomized trial of inotuzumab ozogamicin for newly diagnosed high-risk B-ALL; risk-adapted post-induction therapy for high-risk B-ALL, mixed phenotype acute leukemia, and disseminated B-LLy

CELLULAR THERAPY

EXCEL: A Phase II pilot study of donor-derived ex-vivo expanded natural killer cell infusions in children and young adults with high-risk acute myeloid leukemia receiving myeloablative HLA-haploidentical hematopoietic cell transplant, a multicenter Pediatric Transplantation and Cellular Therapy Consortium (PTCTC) study (EXCEL Trial) PTCTC CT200

NK Cell Biospecimen: Edited natural killer cells as an immunotherapeutic approach for the treatment of pediatric cancers

MULTI-DISEASE SITES

ALTE2031: StepByStep - A randomized trial of a mobile health and social media physical activity intervention among adolescent and young adult childhood cancer survivors

APEC14B1: The Project: Every Child Protocol: A registry, eligibility screening, biology and outcome study

APEC1621SC: NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) screening protocol

APEC1621 (A-N): NCI-COG Pediatric MATCH (Molecular Analysis for Therapy Choice) master version control protocol

For more information or to refer a patient, contact one of our Pediatric Research Coordinators Bridgette Valley, RN, or Salisha Geetooah, RN, at 407-303-2090.