TEXAS IMMUNO-ONCOLOGY BIOREPOSITORY

UNDERSTANDING THE TOXICITIES OF IMMUNO-ONCOLOGY THERAPIES

PRACTICE-CHANGING ADJUVANT IMMUNOTHERAPY ESOPHAGEAL/GASTROESOPHAGEAL CANCER TRIAL RESULTS EMERGING FROM OUR PROGRAM
CANCER HATES PIONEERS

BAYLOR SCOTT & WHITE ONCOLOGY
Cancer hates pioneers. Because we’re focused on one thing: Destroying it. Cancer research studies at Baylor Scott & White Charles A. Sammons Cancer Center – Dallas, located on the campus of Baylor University Medical Center, part of Baylor Scott & White Health, are conducted through Baylor Scott & White Research Institute, Texas Oncology and The US Oncology Network. Each reviews, approves and conducts clinical trials independently.

HOSPITAL-BASED CANCER PROGRAMS
Baylor Scott & White has the largest network of hospital-based cancer programs in Texas with 15 cancer centers. Baylor Scott & White is the third largest network of cancer centers accredited by the Commission on Cancer in the nation.

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Our COVID-19 Safe Care measures are in place across our hospitals, surgery centers and clinics, in accordance with CDC guidance and recommendations by our clinical experts. Learn more at BSWHealth.com/SafeCare.

For more information, call 214.820.3535 or visit us at BSWH.md/Oncology.
It is my great pleasure to introduce the Autumn 2020 issue of the Baylor Scott & White Cancer Update. These newsletters will keep you up to date with the latest from Baylor Scott & White Charles A. Sammons Cancer Center – Dallas, a destination cancer research and treatment center located on the campus of Baylor University Medical Center (Baylor Dallas), part of Baylor Scott & White Health.

In this issue, we announce the opening of the Texas Immuno-Oncology Biorepository (TIOB) in September 2020. This ambitious project will collect longitudinal biological samples (blood, urine, stool, tissue and others) from a diverse population of TExans from early-stage to late-stage cancers in an attempt to study the evolving immunological changes that occur during a patient’s entire duration with cancer. In addition, we will be studying samples from patients already being treated with a wide variety of immunotherapeutics from checkpoint inhibitors and cellular therapeutics (CAR-T, NK cells, T cell receptor) to oncolytic viruses and tumor-infiltrating lymphocyte therapy.

As the largest not-for-profit health system in Texas, Baylor Scott & White intends to leverage its existing research infrastructure to build a research biospecimen resource at an unprecedented scale. The feature article describes how we will open the door to a new era of collaborative immuno-oncology research by realizing our goal of treating every patient and learning from every patient.

This issue will also tackle the concept of how we can utilize the TIOB to gain a more comprehensive understanding of which patients are more likely to have grade 3 – 5 immunological side effects from cellular immunotherapies and how we can develop strategies to mitigate adverse events.

We also describe exciting new results emerging from our cancer program with the phase III global CheckMate577 esophageal/gastroesophageal junction cancer trial that utilized adjuvant nivolumab demonstrating a doubling in the primary end point of disease-free survival in patients with operable stage II/III disease. I had the pleasure of presenting the first results of this potentially practice-changing study during the Presidential/Plenary Symposium of the 2020 European Society for Medical Oncology (ESMO) conference. This study in esophagogastric cancers is the first trial after melanoma to demonstrate a benefit for the use of a PD-1 inhibitor in the adjuvant setting and signals the start of a whole new era in cancer care whereby we will be using checkpoint inhibitors in early-stage resectable disease for a wide range of tumor types both in the adjuvant and the neoadjuvant setting.

Finally, we introduce a highly novel and innovative program that we have launched for the early identification and treatment of breast cancer. Our High-Risk Breast Screening Program, which recently opened in North Texas, is realizing its mission of identifying women at increased risk of breast cancer and offering them enhanced counseling and screening options. The Breast Cancer Research and Treatment Center at Baylor Dallas has also expanded to offer new ways to promote efficiency and enhanced patient care for breast cancer surgery. The programs are both integrated with the TIOB, allowing patients the option to contribute to research during their cancer care journey.

We invite you to learn about these innovative programs here at Baylor Dallas.

Ronan Kelly, MD, MBA
Chief of Oncology, Baylor Scott & White Health - North Texas
Director, Baylor Scott & White Charles A. Sammons Cancer Center
Ronan Kelly, MD, MBA

A new era for oncology research

Recent immuno-oncology clinical trials have been incredibly successful at generating durable clinical responses across a range of cancers. However, less than 5% of people with cancer participate in clinical trials. Most of the participants are Caucasian, and many are younger with good performance status and minimal comorbidities. This means that the cancer experiences of most Americans remain understudied, leaving physicians with insufficient knowledge about how their patients will respond to immuno-oncology treatment and if mechanisms of resistance are the same across populations of patients that may have different immune microenvironments. Clinical trial deserts throughout Texas exist, and we have very limited data on minority groups or how different genomic or microbiome signatures may influence response and/or toxicity.

Baylor University Medical Center, in collaboration with Baylor Scott & White Research Institute (BSWRI), has responded to this gap in knowledge by creating the Texas Immuno-Oncology Biorepository (TIOB). The TIOB, which opened in September 2020, will prospectively collect clinical data and biospecimens on an unprecedented scale across Baylor Scott & White’s network, providing a unique opportunity to better understand how cancer treatment affects the health of everyone with cancer.

The goal of the TIOB is something entirely new: to both care for every patient and learn from every patient in a real-world environment throughout academic and community settings alike. This places the patients as partners in the larger journey toward understanding how cancer evolves and how the immune system can fight it. Over time, the TIOB will enroll patients across all cancer types to develop a more complete understanding of human cancer experiences.

According to Ronan Kelly, MD, MBA, director of oncology at Baylor Dallas and chief of oncology for Baylor Scott & White Health in North Texas, “As the largest network of hospital-based cancer programs in Texas and the third largest Commission on Cancer-accredited network of cancer hospitals in the US, we have access to an amazingly diverse population of people undergoing cancer treatment. These are people with a broad range of different ethnicities, different diets and different life experiences. It presents an excellent opportunity for us to usher in a new era of cancer research.”

The TIOB will collect samples from patients undergoing treatment from stage 1 to stage IV disease in a longitudinal manner for a patient’s entire journey with cancer. There also will be a particular emphasis on patients receiving immuno-oncology therapies, including checkpoint inhibitors and cellular therapies, in an attempt to understand mechanisms of resistance at a population level. Dr. Kelly explains why the TIOB will focus on therapies that boost the patient’s own immune system. “Immuno-oncology is revolutionizing the way we treat cancer. We have come a long way in the last 10 years, but we really only have a surface-level understanding of the complexities of the tumor-adjacent immune microenvironment, which could reveal why some patients respond to therapy and some do not. It is time to dig deeper so we can realize the dream of long-term cancer control for everyone.”
Developing the TIOB has required a strong commitment to coordination and quality assurance. Built on the networked clinical research infrastructure provided by BSWRI, the TIOB takes traditional tissue biorepositories to a new level. Sheila Dobin, PhD, clinical cytogeneticist, medical geneticist and co-principal investigator for the TIOB in Central Texas, describes how the TIOB differs from a traditional biorepository, which typically only stores archival tissue. “The TIOB will collect samples prospectively on a regular schedule that coincides with the patient’s clinic visits. One of our big questions is why some people develop resistance to immuno-oncology therapies over time. By taking longitudinal samples, we can find that answer.” Participants will be asked to provide samples every three to 12 months, depending on their treatment schedule.

The TIOB will also collect more samples than a traditional biorepository, including blood, urine and stool, as well as any tumor tissue beyond what is needed for clinical care. By including these minimally invasive samples, researchers can investigate markers of cancer status that might reduce the need for biopsies and other invasive diagnostic approaches.

Lucas Wong, MD, a physician-researcher at Baylor Scott & White Medical Center – Temple, describes how the TIOB fits in with the existing clinical trial infrastructure at BSWRI. “We will also offer TIOB participation to people with early-stage disease and to those who are participating in our immuno-oncology clinical trials, including people who are no longer on active treatment. Although current clinical trials collect some research data, the focus is on the treatment and the trials end with limited follow-up asking ‘why?’ If the clinical response does not meet expectations. There are many missed opportunities for understanding how an individual’s response to treatment might be improved. Because this project is led in part by a network of academic medical centers, we now have the opportunity to look deeper and find new insights that could produce big results.”

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Sheila Dobin, PhD
Clinical Cytogeneticist, Medical Geneticist, Co-Principal Investigator for the TIOB in Central Texas

As the director of the Cytogenetics laboratory at Baylor Scott & White Medical Center – Temple for over 35 years, Dr. Dobin developed a local biorepository that would serve as the precursor to the TIOB. According to Dr. Dobin, “We were lucky to have that experience with a tissue biorepository to get this project up and running more quickly. Small-scale testing of our processes is essential before integrating them into our system, and we already have a team in place that is dedicated to quality. This strong foundation has enabled us to succeed in managing the logistical complexities of the TIOB.”

The potential of the unprecedented scale of the TIOB requires a commitment to the highest levels of quality in sample collection, processing and storage. All samples are immediately de-identified with a unique identification number, so the participant’s protected health information is kept secure. All patient data, including clinical data, is stored in a centralized database. In addition, a trained BSWRI tissue coordinator is available to guide the patient through informed consent, collect specimens, and transport them to a secure, centralized facility for quality assessment and storage. The storage facilities are located both in Dallas and Temple, TX.

Dr. Wong describes how the centralized design of the TIOB can support collaboration. “A researcher might identify a great hypothesis and wonder how to test it. Because all our information is stored centrally, the data management team can quickly determine how the TIOB can accelerate that research. This gives us the opportunity to support many projects, each of which will enhance our understanding of how the immune system can be used to stop cancer.”

The TIOB pathway

START

The patient gives written consent.

FIRST

Baseline samples, including urine, blood and stool, are collected and possibly tissue biopsy (if indicated).

NEXT

After 3 months, more samples are collected.

3 months

After 6 months, more samples are collected.

6 months

Sample collection continues every 3 months. (Unless consent is withdrawn.)

THEN:

If disease progresses, sample collection will continue with treatment as directed.
Enabling a new type of research

The large-scale data collection planned for the TIOB has opened the door to novel research endeavors that were previously not possible. To stimulate this research, Baylor Dallas has established a collaborative relationship with the Translational Genomics Research Institute (TGen) to apply TGen’s expertise in large-scale genomics and next-generation analytical capabilities to the TIOB resources with the goal of rapidly improving immuno-oncology cancer care.

Daniel Von Hoff, MD, an internationally recognized leader in oncology therapeutic development, describes some of the research that is made possible by the TIOB, “One area of great interest is the microbiome. As we learn more about the colonies of microbes that inhabit the human body, we have come to realize what an incredible impact they can have on health. We know the microbiome is extremely diverse among people and is affected in a complex way by cancer and its treatment. With the TIOB and advances in technology, such as next-generation sequencing, we can now start to ask how these interactions work on a large scale.”

With the knowledge gained from the TIOB, the researchers envision the potential impact on cancer care, including using microbiome status as a prognostic indicator of treatment success and potentially modifying the microbiome for maximal therapeutic efficacy.

As part of the TIOB collaboration, BSRWI and TGen hope to also test the prognostic potential of cell-free nucleic acids (DNA and RNA) found in the blood. These circulating cell-free DNA and RNA fragments can serve as markers of cancer status. Another source of insight comes from extracellular vesicles (EVs), which are lipid bilayer-enclosed particles that are roughly 1,000 times smaller than the average human cell and are packed with nucleic acids, proteins and other cellular contents. Research on EVs dates to the 1940s, but they were only recently recognized as critical components of cell-cell communication in cancer metastasis and immune response. According to Dr. Von Hoff, “EVs act like an intranet for the body.”

Michael Berens, PhD, an expert in translational therapeutics for cancer, describes the excitement around cell-free DNA and RNA, “Now that we have much more sensitivity to detect rare genetic markers in the blood, there is great potential to use this information. It is going to be transformative to medical care to use a blood or urine sample and start to learn from the circulating DNA and RNA about the cancer status of the patient. Is the tumor responding? Is the immune system benefiting from treatment? How is the tumor adapting to therapy? These are powerful opportunities to understand the disease state in real time without waiting for imaging or biopsy results.”

Dr. Berens also describes how advances in computing power and bioinformatics can be leveraged to understand the massive amount of data generated by genomic analysis. “There are over 24,000 genes in the human genome and hundreds of thousands of DNA regions that are used to modify how those genes behave. This means we need to sort through hundreds of thousands of measurements to find the handful of DNA regions that are most instructive for an individual’s health status. Genomics analysis methods are constantly improving and, when combined with the latest advances in artificial intelligence and machine learning, provide a new opportunity to tame this vast quantity of information.”

The TIOB relationship represents a new chapter in the six-year-long collaborative relationship between TGen and Baylor Scott & White Research Institute.
“We have come a long way with managing toxicities over the last few years. In the early studies, physicians were hesitant to give any kind of medicine that would suppress the immune system for fear that it would prevent the benefits of CAR-T cells. We now know that once the T cells have expanded, they don’t lose their effectiveness. This means we can go ahead and treat side effects early in their course. It has made a big difference.”

He describes two characteristic toxicities of CAR-T cells: cytokine release syndrome (known as CRS) and immune cell-associated neurologic syndrome (known as ICANS). Cytokine release syndrome is caused by the expansion of the CAR-T cells, leading to a systemwide immune reaction that can manifest with symptoms such as fever, low blood pressure, fast heart rate, low oxygen levels and pulmonary infiltrates. Symptoms tend to begin two to three days after infusion. According to Dr. Holmes, “For most patients, CRS is mild and manageable. However, for some, it is serious and requires supportive care. We keep patients in the hospital for a week after the infusion to monitor and treat side effects as necessary.”

ICANS, unlike CRS, manifests with cognitive impairment around four to six days after infusion. Dr. Holmes describes the proposed mechanism of ICANS. “We think ICANS is caused via a mechanism similar to CRS, but cytokines enter the central nervous system and cause the symptoms. However, these symptoms do not always appear together.”

Dr. Holmes says that physicians often want to know if patients who are not candidates for autologous stem cell transplants can receive CAR-T cells. “The answer is often yes. There are many people who can tolerate CAR-T therapies but not autologous stem cell transplants. In fact, we have been pleased to note that in real-world treatment, many people can tolerate CAR-T therapies who were not considered candidates for the original clinical trials. We have learned so much.”

Baylor Dallas is an authorized treatment center for all three FDA-approved CAR-T cell therapies and maintains an active portfolio of CAR-T cell clinical trials to drive the next generation of cellular therapeutics.

Houston Holmes, MD

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JUNCTION CANCER TRIAL

GASTROESOPHAGEAL IMMUNOTHERAPY ESOPHAGEAL/GROUNDBREAKING ADJUVANT JUNCTION CANCER TRIAL

Practice changing results emerging from our program with the potential to change the standard of care for operable disease

The phase 3 randomized, multi-center CheckMate577 trial (NCT02743494) has announced that it met the primary endpoint of disease-free survival in patients with esophageal or gastroesophageal junction cancer at interim analysis, with a manageable safety profile. The trial compared adjuvant treatment with the anti-PD-1 immune checkpoint inhibitor nivolumab to placebo (current standard of care is close observation) in patients who had received neoadjuvant chemoradiation and surgical resection for stage I/II disease.

Esophageal cancer has a 20% five-year survival rate and is the 7th leading cause of cancer death.

According to Ronan Kelly, MD, director of Baylor Scott & White Charles A. Sammons Cancer Center - Dallas and international principal investigator on the CheckMate577 trial, “Only about 30% of patients will have a pathological complete response after standard of care neoadjuvant chemoradiation and surgery. Prior to this study, we had no data showing that additional chemotherapy might help the remaining 70% of people.”

CheckMate577 enrolled 794 patients across 27 countries, making it the largest adjuvant IO study to date for patients with operable esophageal or gastroesophageal junction cancer. It is the first and only therapy to show improved disease-free survival for an adjuvant therapy in this patient population.

Nivolumab doubled the disease-free survival (22.4 months for nivolumab and 11.0 months for placebo, p<0.0003). The median treatment duration was 10 months for nivolumab compared to nine months for placebo. The safety profile was consistent with prior studies of nivolumab monotherapy. The rate of serious treatment-related adverse events of grade three and higher was 5% for nivolumab compared to 1% for placebo. Treatment-related discontinuation occurred in 9% of those taking nivolumab and 3% of those taking placebo.

Dr. Kelly described the potential for this therapeutic option to be rapidly incorporated into clinical practice. “These results give hope to a population of patients who had few to no treatment options available. The efficacy and safety observed in this trial is great news for these patients.”

Nivolumab is also approved for adjuvant treatment of advanced, resected melanoma. The results of the CheckMate 577 study place esophageal/gastroesophageal junction cancer as one of the second tumor type to show a benefit in the adjuvant setting for a PD1 inhibitor, likely heralding the start of a new era of IO in early-stage disease.

These results were presented by Dr. Kelly in the Presidential/Plenary Symposium at the European Society for Medical Oncology 2020 virtual meeting in September.

CheckMate 577 is a global, phase 3, randomized, double-blind, placebo-controlled trial.

**Key eligibility criteria**
- Stage I/II EC/GEJC
- Adenocarcinoma or squamous cell carcinoma
- Neoadjuvant CRT + surgical resection (R0* performed within 4 - 16 weeks prior to randomization)
- Residual pathologic disease -
  - ypT1N or ypN0
  - ECOG PS 0 - 1

**Stratification factors**
- Histology (squamous vs. adenocarcinoma)
- Pathologic lymph node status
  - (≥ ypN1 vs. ypN0)
- Tumor cell PD-L1 expression
  - (≥ 1% vs. < 1%)

**Primary endpoint:**
- DFS*

**Secondary endpoints:**
- OS
- OS rate at 1, 2, and 3 years
- Total treatment duration of up to 1 year*
- Median follow-up of 24.4 months (range, 6.2 - 44.9)∗
- Geographical regions: Europe (38%), US and Canada (32%), Asia (13%), rest of the world (16%)

*Nivolimumab provided superior DFS with a 31% reduction in the risk of recurrence or death and a doubling in median DFS versus placebo

Nivolumab 240 mg Q2W + 16 weeks then 480 mg Q4W

Placebo G2W + 16 weeks then Q4W

**Summary**
- Nivolumab is the first adjuvant therapy to provide a statistically significant and clinically meaningful improvement in DFS versus placebo in resected EC/GEJC following neoadjuvant CRT.
- 31% reduction in the risk of recurrence or death and a doubling in median DFS
- DFS benefit across multiple pre-specified subgroups
- Nivolumab was well tolerated with an acceptable safety profile.
- Incidence of serious TRAEs and TRAEs leading to discontinuation were ≈ 9% with nivolumab and 3% with placebo
- These results represent the first advance in years for this group of patients, potentially establishing adjuvant nivolumab as a new standard of care.
HIGH-RISK BREAST SCREENING PROGRAM

Yearly mammograms are the standard of care for women at average risk of developing breast cancer. However, for women at higher risk of breast cancer, this screening method may not be enough to catch these cancers early. To improve early breast cancer detection, the Darlene G. Cass Women’s Imaging Center at Baylor Dallas has launched the High-Risk Breast Screening Program. Its goal is to identify women at an increased risk for breast cancer and offer them personalized counseling and screening services.

Sean Raj, MD, breast radiologist on the medical staff at Baylor Dallas, is the medical director of the High-Risk Breast Screening Program. He describes his journey toward founding this program: “Breast cancer has always stood out to me as one of the most profound medical problems. One in eight women—an incomprehensibly massive number of women—will be affected by this disease. It really led me to wonder how we could diagnose breast cancer smarter and earlier.”

Dr. Raj began to think about typical screening programs and how the one-size-fits-all model provides inadequate care to those at highest risk. The threshold for high-risk status is a 20% lifetime breast cancer risk. Approximately 15% of women fall into this category, and most don’t even know it. Risk factors can be hereditary, such as mutations in the BRCA1 or BRCA2 breast cancer susceptibility genes. Personal factors, such as cancer history, obstetric history, lifestyle choices and age, also contribute to risk.

According to Dr. Raj, “We were fortunate to have the crucial support of the Baylor Scott & White Health Foundation - Dallas and the annual Celebrating Women funding campaign to develop this innovative program. Because women at high risk often have more aggressive cancer, it is essential that we identify these cancers as soon as possible.”

The High-Risk Breast Screening Program opened in March 2020 and offers personalized and patient-centered risk assessment and initial counseling services at no cost.

Patients are first identified as potentially at high risk based on their screening mammogram. The program’s dedicated nurse navigator then personally engages the patient, and a Cancer Risk Assessment survey is completed together, which provides a risk classification score using models of lifetime risk. Dr. Raj says that the initial enthusiasm for the project has been amazing. “Over 40% of these patients classified as high risk based on the preliminary screening mammogram have engaged in our program, learned about their risk and have created a plan that will lead to a healthier future. This level of interest has exceeded all expectations, and we are thrilled to be impacting the lives of women in North Texas.”

The team takes an individualized and comprehensive approach to every woman confirmed as high risk, including discussing strategies for risk-reduction, proposing adjunctive screening for potentially aggressive breast cancers, and recommending follow-up care with geneticists and other specialists (breast surgery and oncology), as needed. For many women, this means considering supplementary screening with automated breast ultrasound, contrast-enhanced mammography or abbreviated MRI.

Dr. Raj says, “Many studies in the last decade have shown a dramatic benefit of adjunctive screening for high-risk women in addition to screening mammography. By shortening the interval between screenings, it is possible to detect these aggressive cancers early. This means smaller surgeries with less scarring, potentially less toxic chemotherapy and less morbidity, as well as fewer breast cancer related deaths.”

The program is intended to supplement the relationship with the patient’s referring physician, and all communications with the patient are documented for the referring physician, including the patient’s calculated risk score, strategies and suggestions.

The High-Risk Breast Screening Program is also integrated with the TIOB (see page 6). According to Dr. Raj, “We now have an opportunity to learn from women predisposed to developing aggressive cancers and can harness this information to create smarter, more effective therapeutics through partnerships with the TIOB and the pharmaceutical industry.”

As early recognition of the program’s success, the High-Risk Breast Screening Program was named as a finalist for the 2020 D CEO’s Excellence in Healthcare awards. Looking toward the future, Dr. Raj says the goal is to expand the High-Risk Breast Screening Program throughout Baylor Scott & White and beyond. “We truly believe that if we can identify breast cancer earlier through smarter personalized screening, we can change the way breast cancer is diagnosed and defeated.”

To improve early breast cancer detection, the Darlene G. Cass Women’s Imaging Center at Baylor Dallas has launched the High-Risk Breast Screening Program. Its goal is to identify women at increased risk for breast cancer and offer them personalized counseling and screening services.
Another improvement is the addition of a lighted retractor system to the operating room to enhance visibility in the surgical cavity. This process improvement has increased the ease of performing nipple-sparing mastectomies and other procedures that are performed through small surgical incisions. Dr. Wallace says, “The addition of more specialized lighted equipment facilitates a more cosmetic approach to surgery, and that is something I am very passionate about.”

In addition to these innovations in perioperative care, the Breast Cancer Research and Treatment Center is closely aligned with new initiatives including the High-Risk Breast Screening Program (see page 16) and the TIOB (see page 6). Dr. Wallace describes the collaborative relationship. “Baylor Dallas is committed to improving services for people at high risk for developing breast cancer. For every patient who comes into Baylor Dallas, we calculate his or her lifetime risk for developing breast cancer using the Tyrer-Cuzick model and refer them to the High-Risk Breast Screening Program if they meet the threshold. We also discuss the TIOB with each new breast cancer patient and refer them to the research coordinator for participation.”

Looking toward the future, the Breast Cancer Research and Treatment Center will apply for 2022 accreditation with the National Accreditation Program for Breast Centers (NAPBC), a quality program of the American College of Surgeons. This process will increase multidisciplinary communication, guide quality initiatives on campus and strengthen community outreach. According to Dr. Wallace, “We look forward to the opportunity to formalize our commitment to excellence through NAPBC accreditation, which will benefit our program, our patients and the community.”
June 1, 2020, through September 30, 2020
RECENT PUBLICATIONS
FROM BAYLOR SCOTT & WHITE SAMMONS CANCER CENTER


### CURRENT CLINICAL TRIALS

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