Surgical Oncology: Providing Structure to Support Clinical Research

Surgical oncology is a discipline within the field of general surgery that specializes in the surgical treatment of patients with cancer. Besides having training and experience in cancer surgery, the surgical oncologist must also have a working knowledge of other treatment modalities, including chemotherapy and radiotherapy, to understand how surgery plays a part in the multidisciplinary management of cancer.

Creating a Division of Surgical Oncology at Baylor University Medical Center at Dallas

Beginning a year ago, the Division of Surgical Oncology was created as an academic subunit of the medical staff at Baylor Dallas. Although some have always informally identified themselves as surgical oncologists, the reason for the formal creation of this new division was to increase the academic activities of clinical surgeons and to provide infrastructure for the support of clinical research.

According to John Preskitt, MD, Division of Surgical Oncology, surgeons on the medical staff at Baylor Dallas who have appointments in the Department of Surgery may apply through medical staff services to become members of the division, provided they fulfill certain requirements, which are reviewed every 2 years:

• An active appointment at Baylor Charles A. Sammons Cancer Center at Dallas and active participation in the site-specific tumor conferences, where cases are discussed and treatment recommendations are made.

(Continued on page 3)
From the Director

“The disease of cancer will be banished from life by calm, unhurrying, persistent men and women, working with every shiver of feeling controlled and supressed, in hospitals and laboratories, and the motive that will conquer cancer will not be pity nor horror; it will be curiosity to know how and why.”

H. G. Wells, 1927

The great writer of science fiction captured the truth of the long uphill battle against the multiple diseases that comprise what we refer to as cancer. Surgical removal of tumors was the first known modality to treat cancer, with recorded descriptions dating from 1600 bc in Egypt. In 1809, Ephraim McDowell removed a 22-pound ovarian tumor, heralding the modern era of surgical oncology.¹ The advent of anesthesia and antisepsis in the latter half of the 19th century accelerated the use of surgical intervention, and in the 20th century, radiation and chemotherapy joined surgery in the triad of cancer treatment.

In this issue of CancerUpdate, we share advances in surgical oncology at Baylor University Medical Center at Dallas. The establishment of the division of Surgical Oncology, under the leadership of Dr. John Preskitt, will focus our efforts on continuing improvement in patient care, education, and research. Breast surgical oncology provides an illustration of how the collaborative efforts of well-trained, focused surgeons along with colleagues in radiation and medical oncology have contributed to advances that have moved us forward from the radical mastectomies of Halsted to the conservative multimodality approaches of today. Our patient navigators help bring it all together, focused on the patient.

The old adage, “to cut is to cure,” usually is not accurate standing alone; perhaps a more appropriate phrase in the modern era is “to cut is to care”—and that caring includes prevention, diagnosis, sometimes cure with and without other modalities, and sometimes palliation.

Surgeons with appointments in the Department of Surgery are encouraged to become members of the division. There are advantages to being a member, especially if they are interested in pursuing research. Quarterly meetings of the faculty provide a fertile environment for the exchange of ideas and establishment of useful networks. Division personnel, including Angelia Drake, RN, BSN, program manager of the Division of Surgical Oncology, Suzanna Newall, MS, CCRP, research analyst I, Ansar Sheikh, CCRP, research analyst II, and LaDonna Brown, executive assistant to Dr. Preskitt, assist clinicians with their research, providing resources and information on how to access them. PRN nurses (Susanna Frackiewicz, RN, and Jo Nease, RN) abstract charts for the division’s studies. Innovative new resources to support research are being developed. Funding from several sources is available through the division to support research activities.

Dr. Preskitt commented: “The creation and enhancement of this new division and the considerable resources that Baylor Dallas and Baylor Sammons Cancer Center are providing show the commitment to making Baylor a destination cancer program. There are not a lot of places that have the ability or desire to dig deep and put these resources in place.”

The Surgical Oncology Clinical Research Database: Meta-Registry for Quality Clinical Patient Data
A major asset of Baylor University Medical Center at Dallas that contributes to the research enterprise is its large patient base and ongoing excellence in patient care. Until now, however, it has been difficult for a researcher to collect patient data for a study because those data are housed in various locations:

- We maintain a tumor registry on cancer patients, including information on cancer type, site, disease stage at diagnosis, type of treatment, and treatment outcomes.
- The Enterprise Data Warehouse (EDW) is a central repository of Baylor information used to support enterprise analytics, reporting, and research. According to Nancy Hall, ITIL, CDMP, director of EDW, the database contains information from data sources across the enterprise, including patient demographics, ADT (Admit, Discharge, Transfer), financial, clinical, and operational systems. Data are extracted from multiple systems and then structured and organized in a manner that allows the various types of information to be analyzed at various levels of detail. Information in the EDW is presented through a variety of methods, including executive dashboards, operational scorecards, and scheduled and ad hoc reports.
- The Department of Pathology works closely with surgical oncologists to provide diagnosis, assessment of adequacy of surgical resection, and additional information about prognosis that may influence treatment decisions. George Snipes, MD, PhD, medical director of Molecular Pathology at Baylor Dallas, reports that the department is currently capable of running antibody tests for 200 different proteins, approximately 1% of the protein complement of the human genome. They can isolate DNA and RNA from surgical specimens to look for mutations in oncogenes and tumor suppressors. As more biomarkers of specific targeted pathways are identified, more information will be collected.

To facilitate the research process, the Division of Surgical Oncology is establishing the Surgical Oncology Clinical Research Database, or SOCRD, which will serve as a meta-registry where multiple databases can be connected in a useful way. It will provide a central location where information from all these sources can be stored, validated, and accessed.

Clinicians and information technology experts from Baylor University Medical Center at Dallas have completed a “proof of concept” beta test of the meta-registry, drawing initially on data from the EDW, tumor registry, and pathology systems and focusing on one tumor site (thyroid carcinoma/head and neck). With the successful completion of that test, phase II of the development was launched on December 1, 2011; it will incorporate information about additional tumor sites (breast, hepatocellular carcinoma) and is scheduled for completion in early 2012.
The working group from Baylor Dallas includes Drs. Preskitt and Snipes, Nancy Hall, Angelia Drake, and Jennifer Peattie, clinical applications manager with the Baylor Annette C. and Harold C. Simmons Transplant Institute, as well as a team of division members and experts, including surgeons John C. O’Brien, MD, Michael Grant, MD, and Robert Goldstein, MD, Edward de Vol, PhD, from Quantitative Sciences, and pathologist Michelle Shiller, DO, MSPT. They are building the infrastructure to be comprehensive, robust, and dynamic, while maintaining the confidentiality required by the Health Insurance Portability and Accountability Act. “The protection of confidential information is critical, and that protection is ensured through a disciplined and scientific methodology in how we put things into and pull them out of this meta-registry,” said Dr. Preskitt.

One of the tools to protect confidentiality will be the use of de-identified data. According to Angelia Drake, a long-term goal for SOCRD will be to include a de-identifying tool that will allow the physician-investigators to query de-identified subjects/data to determine counts or confirm a hypothesis before obtaining institutional review board (IRB) approval. For example, a physician interested in a clinical question about a specific patient group (e.g., women over 50 with advanced breast cancer who smoke) could query the system to determine the number of patients meeting these criteria. If the de-identified data supported pursuing a clinical study, these results would be brought to the division’s research committee for review/approval to move forward with study development and the IRB process.

While SOCRD is initially being populated with a core set of data, the database will include a registry builder module, giving us the ability to build our own registries. Additional sources of data will come into the database, including data from clinical trials, follow-up data on patients, quality-of-life surveys, etc. “This will be a dynamic database,” said Dr. Snipes. “We need to follow patients as long as we can. We won’t be closing too many files.” He qualified this, however, to take account of studies that require that data not be changed: “In some cases, such as drug trials, we need to lock down the data. To achieve this, we will take ‘snapshots’ at various times, while still maintaining the fluid quality of the database.”

Everyone involved with SOCRD is excited about the potential of this new tool to facilitate research at Baylor Dallas. Dr. Snipes commented: “SOCRD will provide a rich source of clinical information. In this era of precision medicine, if we can connect our pathologic data with outcome data, we can do a better job of identifying and validating new molecular markers.” Dr. Preskitt believes that SOCRD will be an important tool in recruiting young, well-trained surgical oncologists to Baylor Dallas: “Baylor is attractive to them because of our large and diverse patient population. Many of these young surgeons are looking for a more academic environment, and SOCRD is going to be a major step in that direction.”
### March 2012

1. **American College of Radiology 5th Annual PET/CT Symposium**  
   March 1–4, 2012  
   Stowe, Vermont  
   [http://www.acr.org/petctsymposium](http://www.acr.org/petctsymposium)

9. **28th Annual Miami Breast Conference**  
   March 9–12, 2012  
   Miami, Florida  
   [www.cancerlearning.com](http://www.cancerlearning.com)

21. **Society of Surgical Oncology Annual Cancer Symposium**  
   March 21–24, 2012  
   Orlando, Florida  
   [www.surgonc.org](http://www.surgonc.org)

24. **Society of Gynecologic Oncologists Annual Meeting on Women’s Cancer**  
   March 24–27, 2012  
   Austin, Texas  
   [www.sgo.org/content.aspx?id=3866](http://www.sgo.org/content.aspx?id=3866)

31. **American Association for Cancer Research Annual Meeting 2012**  
   March 31–April 4, 2012  
   Chicago, Illinois  
   [www.aacr.org/home/scientists/meetings--workshops/aacr-annual-meeting-2012.aspx](http://www.aacr.org/home/scientists/meetings--workshops/aacr-annual-meeting-2012.aspx)

### April 2012

13. **35th National Conference on Breast Cancer**  
   April 13–15, 2012  
   Hollywood, Florida  
   [www.acr.org/Secondary MainMenu Categories/MeetingsandEvents/acr_meetings/nCBC2012.aspx](http://www.acr.org/Secondary MainMenu Categories/MeetingsandEvents/acr_meetings/nCBC2012.aspx)

### May 2012

9. **Molecularly Targeted Therapies: Mechanisms of Resistance**  
   May 9–12, 2012  
   San Diego, California  
   [www.aacr.org/home/scientists/meetings--workshops/special-conferences/mechanisms-of-resistance.aspx](http://www.aacr.org/home/scientists/meetings--workshops/special-conferences/mechanisms-of-resistance.aspx)

### June 2012

1. **American Society of Clinical Oncology**  
   June 1–5, 2012  
   Chicago, Illinois  

14. **World Conference on Interventional Oncology**  
   June 14–17, 2012  
   Chicago, Illinois  
   [www.wcio2012.org/p/cm/l/dfid=1](http://www.wcio2012.org/p/cm/l/dfid=1)

15. **17th World Congress for BronchoLOGY and Interventional Pulmonology**  
   June 15–19, 2012  
   Cleveland, Ohio  

18. **Pancreatic Cancer: Progress and Challenges**  
   June 18–21, 2012  
   Lake Tahoe, Nevada  

### May 2012

28. **Multinational Association of Supportive Care in Cancer/International Society of Oral Oncology 2012 International Symposium on Supportive Care in Cancer**  
   June 28–30, 2012  
   New York, New York  
   [www.kenes.com/mascc](http://www.kenes.com/mascc)

### April 2012

   See details on page 14
Breast Surgical Oncology

Breast cancer is by far the most common cancer treated at Baylor University Medical Center at Dallas, comprising more than 20% of the total caseload. With over 700 patients with breast cancer treated each year, Baylor University Medical Center at Dallas is the largest breast cancer treatment center in North Texas.

One of the reasons patients choose to come here for treatment is the availability of experienced surgeons using the most up-to-date surgical approaches. In addition to surgical oncologists and general surgeons who routinely perform breast cancer surgery as part of their practices, there are four full-time, fellowship-trained breast surgeons—Michael Grant, MD, Sally Knox, MD, Tuoc Dao, MD, and Rachael Zent, MD—all of whom received their fellowship training in breast surgical oncology at Baylor Dallas. (See sidebar.) This surgical excellence is part of a multidisciplinary team approach that provides the patient with a seamless transition into different stages of care.

The Role of Surgery in Breast Cancer Management

Breast cancer management was largely driven by radical surgery until the last half of the 20th century. The radical mastectomy developed by William Halsted in the late 19th century, which removed the affected breast, axillary lymph nodes, and pectoralis muscles on the affected side, was in wide use until the late 1970s. By then, surgeons increasingly used a modified radical mastectomy, in which the pectoralis muscles were left in place.

By the 1980s, a move towards even less invasive surgery was gaining traction, driven by the increasing use of screening mammography, which reduced the average size of tumors at initial presentation. The results of numerous large-scale clinical trials indicated that for many women with small tumors, breast-conserving therapy (BCT), consisting of lumpectomy and radiation therapy, yielded survival rates that were equivalent to those seen in women who received more extensive surgery. Excisional biopsies to diagnose and stage cancers were largely replaced with fine-needle aspiration, core needle, and stereotactic biopsies. By the 1990s, the necessity of complete axillary lymph node dissection was also being questioned. The development of sentinel lymph node (SLN) biopsy meant that this additional procedure, with potentially serious effects on long-term quality of life, could be avoided in many patients.

Today, surgery remains the initial local treatment for most women with breast cancer, and nearly 75% of women with newly diagnosed breast cancer are candidates for BCT. However, almost half of these women ultimately choose to have a mastectomy, usually followed by reconstruction, and this trend has grown over the past 10 years, especially among younger women. It is a trend that surgeons on the medical staff at Baylor Dallas have observed among their patients, and treatment options have been adapted because of it.

Changing Approaches to Breast Cancer Surgery

Michael Grant, MD, FACS, a breast surgical oncologist on the medical staff at Baylor Dallas, has been observing the changing treatment preferences among women with breast cancer over the past decade. There are a variety of reasons why women might choose mastectomy over BCT: lack of education about treatment outcomes, logistic difficulties in accessing extended radiation therapy, cultural biases of the patients, or physician preferences. However, Dr. Grant believes that a major driver of the trend is younger women. Breast tumors that occur in this patient group tend to be more aggressive. They may also be more difficult to detect, because breast tissue is often denser in younger patients, so that the possibility of a false-negative mammogram is increased. Dr. Grant commented: “Younger women don’t trust mammograms, and they just don’t want to worry about it anymore. In fact, 40% of our younger patients who undergo a mastectomy are also choosing to have a prophylactic mastectomy of the other breast.”

A factor that encourages women to choose mastectomy is the availability of excellent breast reconstruction, frequently
coupled with a skin-sparing mastectomy that preserves the natural look of the patient’s breast. Insurance companies are now required by law to pay for reconstructive surgery as well as for surgery to restore symmetry between the two breasts.

At Baylor Dallas, surgeons are experienced in all types of reconstructive surgeries—DIEP (deep inferior epigastric perforator) flap, TRAM (transverse rectus abdominis myocutaneous flap), and perforator flap—but prefer to use implant reconstruction. According to Dr. Grant, the surgery for the autologous tissue flap reconstructions is complex and recovery is longer. In addition, many patients, especially those who are significantly over- or underweight, may not be good candidates for this surgery.

Implant reconstruction has seen major technological advancements over the last 10 years. One major advance involves the use of AlloDerm® (Lifecell Corp., Branchburg, NJ), a patented tissue matrix that was originally developed as a graft for burn patients. It is created from donated human skin by removing the cells (and thus the possibility of tissue rejection), while retaining all of the important biochemical and structural components. During reconstructive surgery, the implant is placed under the pectoralis muscle. However, the muscle typically doesn’t cover the entire implant, so part of it is exposed. Historically, the surgeon would lift up portions of other muscles, like the serratus anterior muscle along the outer aspect of the lower breast, to help provide complete muscle coverage over the implant. Instead, surgeons on the medical staff at Baylor Dallas use AlloDerm® to create a crescent shaped “sling” at the bottom to hold the implant in and cover it. This can provide for a more predictable placement of the implant and allows the surgeon to control the shape of the lower half of the breast.

A second technological advance in implant reconstruction is the use of cohesive gel implants instead of silicone liquid gel. These implants have been nicknamed “gummy bear implants” because of their denser texture. While still considered investigational in the United States, cohesive gel implants have been used with great success at various institutions around the country, including Baylor Dallas, as a part of ongoing clinical trials. They tend to maintain their shape and are not susceptible to leakage. “The use of the AlloDerm® sling in conjunction with cohesive gel implants is giving our patients excellent cosmetic results from their postmastectomy reconstructive surgeries,” said Dr. Grant.

The Seeger Surgical Breast Oncology Fellowship

The Seeger Surgical Breast Oncology Fellowship is in its 30th year at Baylor University Medical Center at Dallas. The fellowship was established with an endowment from Mr. and Mrs. Wirt Davis in honor of her parents, Helen Buchanan and Stanley Joseph Seeger. The program was originally headed by Harold Cheek, MD, the first surgeon in North Texas to limit his practice to diseases of the breast. At that time, it was the only surgical breast oncology fellowship in the country; now, there are 32 Society of Surgical Oncology-approved fellowship programs available nationwide.

The Seeger Surgical Breast Oncology Fellowship is currently headed by Ronald C. Jones, MD, chief of surgery at Baylor Dallas. He remarked on the significance of the fellowship: “We are training surgeons dedicated to surgical breast oncology. In addition, some fellows from the Baylor program finish and then go on to complete a residency in plastic surgery in order to perform breast reconstructive surgery. They thereby become the ‘total package’ for tumor removal and reconstruction.”

The educational goals of the 1-year fellowship include breast surgery, community service and outreach, genetics, medical oncology, surgical pathology, plastic and reconstructive surgery, psycho-oncology, radiation oncology, clinical research, and mammography. During the mammography rotation, fellows gain experience in ultrasound-guided breast biopsies as well as stereotactic breast biopsies. More than 600 new patients with breast cancer are seen at Baylor Dallas each year, giving the breast fellows significant experience in operative and nonoperative management of diseases of the breast.

Since the program’s inception, 25 surgeons have completed the fellowship, including the four surgical breast oncologists currently on the medical staff at Baylor Dallas. Dr. Jones commented: “These former fellows are not only an integral part of our current program, but they also support breast oncology in the Dallas-Fort Worth area as well as the rest of the country. With the development of more breast cancer programs in the United States, we routinely get at least one inquiry a month from programs wanting to add a qualified surgical breast oncologist to their staff.”
Research in Breast Surgical Oncology: On the Lookout for Practice-Changing Results

A key component in maintaining the quality of breast surgical oncology is the incorporation of the latest research findings into day-to-day practice. This may involve a clinician’s active participation in clinical research studies, but it equally involves awareness of potentially practice-changing research being conducted around the country and around the world.

SLN biopsy has become the standard of care for breast cancer management, but many questions remain as to best practices for this technology. Intraoperative assessment of the SLN typically involves touch imprint cytology or frozen section stained with hematoxylin and eosin (H&E). Permanent section may use immunohistochemical staining in addition to H&E, allowing the identification of extremely small lesions (isolated tumor cells, defined as lesions not larger than 0.2 mm in diameter) that may not be visible with H&E. How frequently would the treatment recommendation made on the basis of intraoperative pathology change after analysis of permanent sections? Are the types of lesions identified clinically important?

Michelle Shiller, DO, MSPT, a pathologist on the medical staff at Baylor Dallas, has worked with surgeons to collect data for two studies. In the first study, 488 consecutive SLN biopsies were retrospectively reviewed to determine the accuracy of intraoperative pathology compared with permanent section in identifying lesions in the SLN. The findings from this study, which were published in the April 2011 Baylor University Medical Center Proceedings, indicated that the sensitivity and specificity of SLN biopsy at Baylor Dallas compares favorably with percentages reported in the literature. For macrometastases (lesions >2.0 mm), the sensitivity was 88%, for micrometastases (lesions >0.2 mm and no larger than 2.0 mm), the sensitivity was 72%, and for isolated tumor cells, the sensitivity was 60%. Specificity was 100% in all cases.

Dr. Shiller is now involved with a follow-up study entitled “A retrospective evaluation of the sensitivity and specificity of diagnosing axillary lymph node status: bridging pathologic diagnosis with clinical outcomes over 5 years” (BRI IRB #011-175). This study is reassessing the original patient group to determine how pathology results influenced the clinical management of the patients. The study will determine if patients with a finding of micrometastases or isolated tumor cells underwent an axillary lymph node dissection, and if not, why not. It will also reassess the status of the SLN as a prognostic indicator by examining disease-free survival, recurrence, and occurrence of ipsilateral or contralateral second primary tumors. The data from this study are being acquired now and will contribute to a breast cancer registry that will ultimately be incorporated into the new Surgical Oncology Clinical Research Database.

In assessing the latest research findings presented at national meetings, clinicians must judge carefully whether a study is potentially practice-changing. Barry Wilcox, MD, a radiation oncologist on the medical staff and medical director of radiation oncology at Baylor Dallas, commented on a recent clinical trial that attracted attention at the 2010 meeting of the American Society of Clinical Oncology (K.S. Hughes, abstract 507). In this study, 636 patients with early stage, estrogen receptor-positive breast cancer who were 70 years of age or older were randomized to receive either tamoxifen alone or tamoxifen plus radiation after lumpectomy. At 10.5 years follow up, the addition of radiation resulted in a 6% reduction in recurrence rate, but no difference in survival. These results were much anticipated, but they are not necessarily practice-changing, according to Dr. Wilcox. “These results present an additional treatment option for older women. Radiation therapy is typically offered to patients over 70, but discussion with the patient has to be individualized as to the risks and benefits that apply for that specific patient. Many women are just not keen on taking radiation therapy. They may have significant comorbidities or have difficulty in getting to and from the cancer center for daily treatments over a 5- to 6-week period. Whatever the reason, they would like to know if they are putting themselves at serious risk by saying ‘no.’ We now have data to give them some solid information.”
Patient Navigation: Helping the Patient with the Next Step

For many types of cancer, surgery will be part of the recommended treatment plan, used to confirm a diagnosis or to provide initial local treatment of the disease. To proceed with treatment, the patient will need to link up with a surgical oncologist. At Baylor Charles A. Sammons Cancer Center at Dallas, the patient navigation program assists with this step in the journey.

When the patient navigation program learns that a patient has been diagnosed with cancer, their first step is to forward the patient’s records to John Preskitt, MD, director of the Division of Surgical Oncology. Dr. Preskitt determines what type of physician the patient needs to see. If a surgical oncology referral is needed, then referral is made to a surgeon specializing in the appropriate type of procedure.

The patient navigator then facilitates the visit to the surgeon: collecting the records, making the appointment, calling the patient, and making sure the patient shows up for the appointment. The navigator counsels the patient about the upcoming visit, with advice to bring a friend or family member to the appointment to assist in asking the appropriate questions and taking note of what the physician says. If requested, the patient navigator will even attend the appointment with the patient.

The day after the appointment, the navigator follows up with the patient for input on the visit and to review treatment information.

The ability of the patient navigation program to deliver this level of service has been helped by the recent hiring of three new nurse navigators. Min Patel, RN, has been at Baylor Dallas for more than 20 years and specializes in patients with gastrointestinal, renal, and prostate cancers. Mary Stonebridge, RN, comes to the program with 40 years of experience; her focus areas are hematological diseases and skin cancers. Karen Hieston, RN, with more than 35 years of experience, specializes in patients with breast cancer.

Cynthia Robinson-Hawkins, MBA, RN, manager of Baylor Dallas’ patient navigation program, is delighted to have the three new patient navigators on board: “With more staff and specialization, our navigators can spend more time with specific patients. If a patient needs them for 2 hours, they can spend 2 hours. We are moving toward our ultimate goal: that every patient diagnosed with cancer at this institution will have access to a patient navigator.”

For more information, call the Baylor Sammons Cancer Center patient navigation program at 214.820.3535.
Hepatocellular Carcinoma: A Success Story in Cancer Treatment

Hepatocellular carcinoma (HCC) was diagnosed in an estimated 24,120 people in the United States during 2010, with 18,910 dying from the disease that year. The incidence of HCC in this country has been rising because of the increased incidence of hepatitis C, a known risk factor. Overall, the prognosis is poor; across all stages, the 5-year survival rate is only 12%. Even for patients with early stage disease at diagnosis, 5-year survival is only 24%.

However, new treatment options over the last 10 years have resulted in significant responses in selected patients, making HCC treatment one of the big success stories in the field of oncology. Surgical resection of the tumor remains the gold standard, but very few patients are good candidates for surgery, especially those with underlying liver disease. Because liver cancers do not tend to spread to other sites, it is possible to treat them locally with modalities that are designed to be intense at the tumor site with minimal exposure to the rest of the body. These local treatments can provide symptomatic relief and, for patients who go on to have a liver transplant, significantly improve outcomes after transplant. With various combinations of these treatments tailored to the individual, some patients are cured; others may have quality of life improved dramatically.

Baylor Liver and Pancreas Disease Center at Baylor University Medical Center at Dallas is one of the few places that offers all of these treatment options in one program—from surgical resection to chemotherapy, radiosurgery, and transplantation. According to Robert Goldstein, MD, director of Baylor Liver and Pancreas Disease Center and assistant director of Baylor Annette C. and Harold C. Simmons Transplant Institute, “Very few institutions are as dedicated as Baylor in treating these very complex patients and staying at the forefront of treatment options.”

Treating HCC at Baylor

Baylor Liver and Pancreas Disease Center, which started in 1998 as a center without walls, now exists as a single functional entity located in the new Baylor Charles A. Sammons Cancer Center at Dallas. The center is designed to focus on the convenience and comfort of the patient. For incoming patients, there is a single phone number to call, managed by a nurse who gathers all of the relevant information. The information is evaluated, consults are scheduled, and imaging and laboratory data is collected so that when the patient comes to the center, a treatment plan can be presented on the same day.

Baylor Liver and Pancreas Disease Center is part of Baylor Annette C. and Harold C. Simmons Transplant Institute, one of the largest liver transplant programs in the world, with 600 new referrals last year. Of these, 150 patients present with HCC. Most (>90%) have underlying liver disease from hepatitis B or C, alcoholic cirrhosis, or other causes and are not good candidates for surgical resection. These patients are recommended for secondary and tertiary local treatments. Depending on the characteristics of the primary tumor and the response to the local treatments, patients may become candidates for liver transplant.

Interventional Radiology and Its Role in the Treatment of HCC

Interventional radiology uses imaging to advance a catheter or probe into the body to provide nonsurgical local treatment (chemotherapy or radiation) directly at the site of the disease. For HCC, the success of interventional radiology depends upon the liver having two blood supplies: the portal vein and the hepatic artery. The portal vein, which drains blood from the intestines to the liver, provides the main blood supply for a normal liver. HCC develops its blood supply through angiogenesis fed by the hepatic artery system. If the arterial system is blocked, blood supply to the tumor—but not to the normal liver—will be blocked.

Radiologists on the medical staff at Baylor University Medical Center at Dallas are using a process called chemoembolization to simultaneously deliver high-dose chemotherapy to the tumor and embolize the artery providing blood to the tumor. They do this using microscopic beads about one-third the width of a human hair. Chemotherapy drugs (typically doxorubicin, carboplatin, and 5-fluorouracil), which bind tightly but not irreversibly to the beads, are directed into a small branch of the arterial system, where they get stuck, forming a blockade. Over the course of several weeks, the chemotherapy
drugs soak off, delivering a high concentration to the tumor with minimal exposure to the rest of the body.

In intrahepatic artery infusional chemotherapy, used in patients with numerous hepatic tumors, the catheter is directed to the main hepatic artery, and chemotherapy is dripped in so that the entire liver is treated at once. Normal liver tissue does not appear to be damaged by this treatment. There is a slightly higher risk of chemotherapy-related adverse events, but the drug therapies are designed to take advantage of the direct delivery into the liver. For example, more than 60% of 5-fluorouracil is extracted on the first pass through the liver. For the remaining drug, the half life in the blood is very short, about 10 minutes.

Another interventional radiology treatment uses yttrium-90-labeled microspheres (TheraSpheres®) that are injected into the arteries that supply the tumor. The microspheres are highly radioactive, but the radioactivity has a short path length, traveling only a few millimeters from the tumor. This minimizes damage to adjacent normal tissue.

Because of the large volume of patients from around the world who come to Baylor Liver and Pancreas Disease Center, our radiologists are involved in a sizable number of cases requiring interventional radiology. Mark Walberg, MD, a medical oncologist on the medical staff at Baylor Dallas, commented, “To do it right, you need a good interventional radiologist who does it all the time. Not many places perform these procedures very often.”

### Other Treatment Options

Depending on tumor characteristics and location, as well as patient characteristics and preference, other treatment options offered for HCC include:

- **Radiofrequency ablation (RFA)** uses frictional heating produced when ions in the tissue attempt to follow the changing directions of a high-frequency alternating current. RFA is performed percutaneously under imaging or laparoscopic guidance and has shown great success in the treatment of nonresectable HCC.
- **The Cyberknife® Robotic Radiosurgery System** delivers beams of high-dose radiation to tumors with pinpoint accuracy. This method identifies the target through real-time imaging to better control for patient movement or breathing. While delivery of 50 to 75 Gy of radiation can be made to the tumor, only about 16 Gy is delivered to the surrounding tissues. Because damage to normal tissue is minimized, the equivalent of 8 weeks of radiation can be delivered in only 3 to 5 days.
- **Proton beam radiotherapy** utilizes highly charged subatomic particles that can be focused and repeatedly administered over a series of days.

- Baylor Liver and Pancreas Disease Center is one of the few programs in the country to offer irreversible electroporation for the treatment of HCC. In this therapy, a series of microsecond electrical pulses permanently opens the pores in cell membranes of cancerous tumors, inducing cell death.

(Continued on back cover)
Skull Base Tumors: Minimally Invasive Surgery to Reduce Trauma to the Brain

The Skull Base Center at Baylor University Medical Center at Dallas is one of the few places in Texas that offers comprehensive treatment for complex tumors in and around the skull base. The skull base platform—made up of the ethmoid, sphenoid, occipital, paired frontal, and paired parietal bones—forms the floor of the brain, separating it from other facial structures. The anatomy of this area is complex, with the spinal cord and multiple nerves, as well as the major blood vessels of the brain, head, and neck, passing through openings in the skull base.

Skull base tumors can originate in the paranasal sinuses and extend into the skull base. They may also originate from tissues around the brain (e.g., meningiomas, sarcomas) or represent metastatic foci of disease. Benign tumors, including pituitary tumors and neuromas, often involve the skull base.

Surgical approaches for the removal of skull base tumors are challenging because of the area’s intricate anatomy, the deep location of the tumors, and their proximity to critical structures. Traditionally, craniotomy was preferred, involving a scalp incision, removal of bone, and approach to the tumor from above or from the side. Alternatively, an incision might be made in the face, with dismantling of the facial bones. For a lesion in the middle of the head, these approaches would involve pushing normal brain tissue out of the way in order to access the tumor, a procedure that could have adverse consequences.

Innovative Surgical Approaches for Skull Base Tumors

The Skull Base Center brings together a multidisciplinary, sub-specialized team of experts to provide comprehensive and individualized care to patients with skull base lesions. A commitment to minimally invasive surgery has facilitated the creation of surgical techniques that enhance safety and efficacy while reducing morbidity, length of hospital stay, and the likelihood of complications.

Amol Bhatki, MD, a surgeon, otolaryngologist, and co-director of Baylor University Medical Center at Dallas’ Skull Base Center, reports that many tumors can now be safely removed with endoscopic transnasal techniques. “We evaluate the tumors for location, size, vascularity, and whether they are benign or malignant,” he said. “Overall, we are now able to remove more than 50% of them using the transnasal approach. This decreases the chance of pain or complications; you don’t have to manipulate the brain, so morbidity is decreased and recovery is faster.”

For those patients who are not good candidates for the transnasal approach, some tumors may be removed using the focused orbito-zygomatic keyhole craniotomy with extradural dissection, a technique developed at the Skull Base Center. These surgeries involve a small access hole directly over the corridor that leads to the tumor. While a classical craniotomy would involve traversing the dura and using landmarks in the brain to move to the tumor site, the keyhole craniotomy moves inside the braincase but outside of the dura to the point of closest access to the tumor. This minimizes brain and nerve manipulation. “You have to be very familiar with the anatomy and structures that are there,” said Dr. Bhatki. “These techniques are in the repertoire of only a few neurosurgeons.”

The Role of Interventional Neuroradiology in the Management of Skull Base Tumors

Surgery can be especially risky for tumors that are highly vascular, including meningiomas and some metastases. Interventional neuroradiologists perform detailed cerebral angiography to precisely delineate the blood supply to the tumor, then use catheters and microcatheter techniques for preoperative embolization to reduce or eliminate blood flow to the tumor. Embolic agents may include polyvinyl alcohol, microspheres, liquid embolic agents, or gelatin sponge. These techniques are ideally performed 24 to 72 hours before surgery. By reducing blood loss, preoperative embolization reduces operative time and the period of recovery.
In selected cases where the blood supply to the tumor cannot be obliterated using interventional neuroradiology, antiangiogenic medications can be given. These agents are able to traverse the blood-brain barrier and tend to aggregate at the tumor site.

Case Studies from the Skull Base Center
Following are selected case studies of patients treated at the Skull Base Center using minimally invasive surgical techniques:

Patient 1 is a 25-year-old lawyer who had symptoms of right nasal congestion for 6 months. She did not improve with allergy treatment or antibiotics. A mass was discovered inside her nostril, and a biopsy confirmed esthesioneuroblastoma. She underwent endoscopic endonasal skull base surgery, and the entire tumor was completely removed from around the right eye and from the dura mater. The patient did not require facial incisions or craniotomy. She recovered quickly and was discharged in 3 days. She has been cancer free for over 20 months and currently lives a productive and energetic life.

Patient 2 is a 54-year-old man with a 9-year history of renal cell carcinoma who reported the rapid deterioration of vision in his right eye. MRI revealed a skull base tumor that was displacing his optic nerve, causing his visual loss. He underwent endoscopic endonasal resection and during surgery was found to have 2 simultaneous lesions: a pituitary tumor below and a metastatic renal cell carcinoma above. Both tumors were removed, and the optic nerve was decompressed. The patient’s vision returned to normal after surgery. Since finishing a course of postoperative radiation, he has had no evidence of recurrence for 6 months.

Patient 3 is a 70-year-old college professor who reported right nasal congestion and pressure for several months. Routine medications did not improve his symptoms. Scans revealed a large sinus tumor with extension into the right eye socket and brain. Biopsy confirmed esthesioneuroblastoma. The tumor was initially embolized by interventional neuroradiologists, then the entire tumor was removed endoscopically including the component invading the orbit and brain. After receiving adjuvant radiation therapy, the patient has been cancer free for 1 year and has resumed his professorial duties.
Working Within a Paradigm Shift

A paradigm shift is in progress, moving the field of skull base surgery from invasive open-skull techniques to minimally invasive endoscopic techniques with the promise of efficacy and reduced morbidity. Patients and physicians alike are seeing the benefit of these new approaches and realizing the importance of receiving care at a high-volume center with experienced clinicians. However, Dr. Bhatki cautioned against a philosophy of trying to fit all patients into this new paradigm, “If you have a hammer, the whole world shouldn’t become a nail. We need to carefully evaluate each patient, then reach into our tool box and pick the best tool.”

Patient 3

Before: MRI shows a large, vascular tumor (T) involving the right sinuses and extending into the right eye socket and invading the tissues of the brain (white arrow).

After: One year after treatment, there is no evidence of tumor recurrence. His eyes function normally. The brain lining reconstruction is healthy and intact (white arrowhead).

Coming in April 2012: 4th Annual Marvin J. Stone Lectureship

Baylor University Medical Center and Baylor Charles A. Sammons Cancer Center at Dallas will host the 4th Annual Marvin J. Stone Lectureship on April 10, 2012, in the Beasley Auditorium, located in Truett Hospital at Baylor Dallas. This year’s recipient of the Marvin J. Stone Lectureship is Fred Appelbaum, MD, the director of the Clinical Research Division at the Fred Hutchinson Cancer Research Center as well as the head of the Division of Medical Oncology at the University of Washington in Seattle. In addition to his other duties, Dr. Appelbaum is the head of the program in clinical transplant research at the Fred Hutchinson Cancer Research Center. Dr. Appelbaum’s presentation is entitled “The Challenges of Hematopoietic Cell Transplantation.”

The Marvin J. Stone Lectureship was instituted in 2009 in honor of Marvin J. Stone, MD, MACP. Dr. Stone served as chief of oncology at Baylor Dallas and director of Baylor Sammons Cancer Center from 1976 to 2008. He currently heads the internal medicine clerkship for the third-year medical student hematology/oncology rotation and the medical oncology fellowship program at Baylor Dallas.

SangKon Oh Receives 4-year Grant for Prostate Cancer Study

SangKon Oh, PhD, an associate investigator at Baylor Research Institute, has been awarded a 4-year grant from the American Cancer Society for his study entitled, “Antibody-based Combination Immunotherapy against Prostate Cancer.” Dr. Oh started at Baylor in 2005 as an assistant investigator after completing his postdoctoral and fellowship training in cancer and viral immunology at the National Cancer Institute. Dr. Oh’s goal is to develop novel immunogenic vaccines and antibodies that more effectively target prostate cancer cells and cause tumor regression.
New Dedicated Cancer Hospital Begins Service: Phase I

Baylor Cancer Hospital, the first dedicated cancer hospital in North Texas and only the second in the state, has begun its staged opening as part of the expansion of oncology services at Baylor University Medical Center at Dallas.

The following units and services opened in January as part of phase I:
- Blood and Marrow Transplant (BMT) Unit, occupying a 24-bed induction unit on the 7th floor. This is a replacement for the unit that was temporarily located in Roberts Hospital.
- A 24-bed nursing unit on the 6th floor that handles overflow from the BMT Unit, as well as serving hematologic oncology patients.
- Satellite oncology pharmacy on the 3rd floor.
- BMT processing lab on the 2nd floor, which handles processing of stem cells and bone marrow products.
- Lobby on the 1st floor with patient support and registration services.
- Apheresis Center on the 1st floor containing 8 bays with beds.
- Washer/dryer and shower facilities for families and caregivers.

As the last part of phase I, an infusion center with 12 infusion chairs and 4 infusion beds will open in March 2012.

The Evaluation and Treatment Center is an exciting new service that will be available 24 hours a day, 7 days a week for established oncology patients at Baylor University Medical Center at Dallas who are sick or otherwise in need of assistance. Most cancer patients who experience an unexpected health crisis may end up in a hospital emergency room, where appropriate treatment may be delayed and the risk of pathogen exposure can be significant. By coming directly to the Evaluation and Treatment Center, our cancer patients will be able to avoid the inconvenience and risks of the emergency room setting, saving time and possibly removing the need for a hospital admission if problems can be taken care of in this ambulatory setting.

Phase II of the opening of Baylor Cancer Hospital is scheduled for completion by the end of 2012 and will include two general oncology nursing units (48 beds total), a new palliative care unit, an imaging center, and a patient food services unit that will provide concierge-style dining for patients.

Baylor Cancer Hospital has been designed to provide a place of healing, calming, and spirituality for everyone involved in the cancer journey. The surroundings are attractive, and well designed, rooms are larger to accommodate family members. Additional amenities have been introduced to ensure that the environment is attractive and convenient. Alan M. Miller, MD, PhD, chief of oncology, Baylor Health Care System, and medical director, Baylor Sammons Cancer Center, commented about the stress undergone by patients who are thrust into unfamiliar surroundings: “The more that can be done to ease the strangeness and discomfort of the surroundings, the easier it is for patients to concentrate on what they need to do to get well.”
# New Clinical Trials at Baylor Charles A. Sammons Cancer Center at Dallas

<table>
<thead>
<tr>
<th>Site</th>
<th>Location</th>
<th>Number</th>
<th>Principal investigator</th>
<th>Title</th>
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<tbody>
<tr>
<td>Hematologic Malignancies</td>
<td>Baylor Research Institute</td>
<td>011-168</td>
<td>Edward D. Agura, MD</td>
<td>KIR genotyping for unrelated donor selection prior to hematopoietic cell transplantation for AML: selecting a favorable KIR donor</td>
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<tr>
<td></td>
<td>Baylor Research Institute</td>
<td>011-058</td>
<td>Edward D. Agura, MD</td>
<td>A randomized, multicenter, phase III study of allogeneic stem cell transplantation comparing regimen intensity in patients with myelodysplastic syndrome or acute myeloid leukemia</td>
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<td></td>
<td>Baylor Research Institute</td>
<td>010-295</td>
<td>Joseph W. Fay, MD</td>
<td>Studies of the immune system following influenza vaccination in patients with multiple myeloma after hematopoietic stem cell transplantation</td>
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<td></td>
<td>Baylor Research Institute</td>
<td>011-190</td>
<td>Alan Miller, MD, PhD</td>
<td>Studies of the blood of patients with allogeneic hematopoietic stem cell transplantation using molecular techniques</td>
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<tr>
<td>Breast</td>
<td>Baylor Research Institute</td>
<td>011-117</td>
<td>Joyce O’Shaughnessy, MD</td>
<td>Follow up study of breast health outcomes and selected biomarkers in women at high risk for breast cancer: the Serial Evaluation of Ductal Epithelium (SEDE) clinical trial</td>
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<td></td>
<td>Texas Oncology</td>
<td>10302</td>
<td>Joyce O’Shaughnessy, MD</td>
<td>Randomized, open-label study of abiraterone acetate (JNJ-212082) plus prednisone with or without exemestane in postmenopausal women with ER+ metastatic breast cancer progressing after letrozole or anastrozole therapy</td>
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<td></td>
<td>Texas Oncology</td>
<td>10065</td>
<td>John Pippen, MD</td>
<td>A phase Ib/II multicenter, randomized, open-label, dose-escalation and confirmation study of eribulin in combination with capecitabine</td>
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<td></td>
<td>Texas Oncology</td>
<td>10167</td>
<td>Cynthia Osborne, MD</td>
<td>A randomized phase II trial of preoperative MM-121 with paclitaxel in HER2-negative breast cancer</td>
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<tr>
<td>Head and Neck</td>
<td>Texas Oncology</td>
<td>11072</td>
<td>Eric Nadler, MD</td>
<td>Phase I/II study of PX-866 and cetuximab</td>
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<td>Lung</td>
<td>Texas Oncology</td>
<td>10315</td>
<td>Kartik Konduri, MD</td>
<td>A phase II double-blind, placebo-controlled study of IPI-504 and docetaxel in previously treated patients with stage IIIIB or IV non-small cell lung cancer</td>
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<td></td>
<td>Texas Oncology</td>
<td>1104</td>
<td>Roy Paulson, MD</td>
<td>Iressa clinical access</td>
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</table>
Patients and their physicians can now access information about open clinical trials in oncology at Baylor Sammons Cancer Center by following these steps:

- Go to BaylorHealth.edu/Sammons.
- Click on “Cancer Clinical Trials” on the right-hand menu.
- From the list of studies that appears, click on the study that is of interest to you to view details such as the inclusion/exclusion criteria.

For additional details or questions about the studies, please contact the Office of Clinical Oncology Research Coordination at 214.818.8472 or via e-mail at Cancer.Trials@BaylorHealth.edu.

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<tr>
<td>Prostate</td>
<td>Texas Oncology</td>
<td>10278</td>
<td>Thomas Hutson, DO</td>
<td>A phase III randomized, double-blind, placebo-controlled study of tasquinimod in men with metastatic castrate-resistant prostate cancer</td>
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<td></td>
<td>Texas Oncology</td>
<td>11167</td>
<td>Charles Cowey, MD</td>
<td>A registry of sipuleucel-T therapy in men with advanced prostate cancer</td>
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<td>Renal</td>
<td>Texas Oncology</td>
<td>10157</td>
<td>Thomas Hutson, DO</td>
<td>An open-label, randomized, multicenter, phase III study to compare the safety and efficacy of TKI258 versus sorafenib in patients with metastatic renal cell carcinoma after failure of antiangiogenic (VEGF-targeted and mTOR inhibitor) therapies</td>
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<td></td>
<td>Texas Oncology</td>
<td>11055</td>
<td>Thomas Hutson, DO</td>
<td>A rollover protocol to allow continued access to tivozanib (AV 951) for subjects enrolled in other tivozanib protocols</td>
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<td></td>
<td>Texas Oncology</td>
<td>09217</td>
<td>Thomas Hutson, DO</td>
<td>An open-label, multicenter, randomized phase II study evaluating the safety and efficacy of docetaxel in combination with ramucirumab (IMC-1121B) drug product or IMC-18F1 or without investigational therapy as second-line therapy in patients with locally advanced or metastatic transitional cell carcinoma of the bladder, urethra, ureter, or renal pelvis following disease progression on first-line platinum-based therapy</td>
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<td>Skin</td>
<td>Baylor Research Institute</td>
<td>011-150</td>
<td>Thomas Hutson, DO</td>
<td>The high-dose aldesleukin (IL-2) “SELECT” trial: a prospective tissue collection protocol to investigate predictive models of response to high-dose IL-2 treatment in patients with advanced melanoma</td>
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Site-Specific Tumor Conferences at Baylor Charles A. Sammons Cancer Center at Dallas

At Baylor Sammons Cancer Center, a key element at the heart of our approach to patient care and education is the site-specific tumor conference program. Rather than focusing solely on recommendations for patient care, the site-specific conferences also aim to educate participants. Unlike tumor boards, the conferences offer continuing medical education credit for physicians who attend. Because several patients with the same diagnosis are presented at each conference, attendees are provided with an in-depth review from specialists, accompanied by lively discussion.

Most of the site-specific tumor conferences are held on the 10th floor conference center in the new Baylor Sammons Cancer Center. The gynecology and skull base conferences currently remain in the Truett Hospital conference rooms.

For information about site-specific tumor conferences at Baylor Sammons Cancer Center, please call 214.820.4073.

<table>
<thead>
<tr>
<th>Conference schedule:</th>
<th>1st Tuesday</th>
<th>2nd and 4th Tuesday</th>
<th>3rd Tuesday</th>
<th>4th Tuesday</th>
<th>5th Tuesdays</th>
<th>1st and 3rd Wednesday</th>
<th>2nd and 4th Wednesday</th>
<th>5th Tuesday</th>
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<tr>
<td>Bone and Soft Tissue</td>
<td>Breast</td>
<td>Chest</td>
<td>Endocrine</td>
<td>Gastrointestinal</td>
<td>Gynecology</td>
<td>Head and Neck</td>
<td>Head and Neck Journal Club</td>
<td>Head and Neck Journal Club*</td>
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<td>1st Tuesday</td>
<td>Thursdays</td>
<td>1st, 2nd and 4th Wednesday</td>
<td>3rd Tuesday</td>
<td>Alternating Thursdays</td>
<td>Wednesdays</td>
<td>2nd and 4th Tuesday</td>
<td>5th Tuesdays</td>
<td>Rotating Wednesdays</td>
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<tr>
<td>Hematology*</td>
<td>Liver</td>
<td>Lymphoma*</td>
<td>Neuro-oncology</td>
<td>Skin</td>
<td>Stem Cell Transplant*</td>
<td>Urology</td>
<td>Rotating Wednesdays</td>
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<tr>
<td>Rotating Wednesdays</td>
<td>2nd Tuesday</td>
<td>Rotating Wednesdays</td>
<td>2nd and 4th Wednesday</td>
<td>1st and 3rd Wednesday</td>
<td>Rotating Wednesdays</td>
<td>3rd Wednesday</td>
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*Rotate during the month
Recent Publications from Baylor Sammons Cancer Center

July 18, 2011, to November 8, 2011


Liver Transplant
Liver transplant offers the best opportunity for long-term remission or cure in patients who are not candidates for tumor resection. Historically, people who received transplants tended to have recurrences after the transplant, indicating that tumor cells were shedding into the blood. Currently, with the availability of effective local treatments to destroy or significantly downsize the primary tumor, fewer than 5% of patients with HCC who receive a transplant have a recurrence. According to Dr. Walberg, “This significant cure rate is one of the big success stories in cancer treatment.”

Determining the Best Treatment Option: A Look Back Over the Last Decade
Although a variety of treatment options are available for the local treatment of liver tumors in preparation for liver transplant, only limited data are available about long-term outcomes associated with these options.

To gain more information in this critical area, researchers at Baylor Liver and Pancreas Disease Center are participating in a study that is collecting data from over 350 patients with primary HCC who received liver transplants at the center from 2002 to 2010 (BRI IRB # 009-261). These patients received local treatment for their tumors as a bridge to transplant. According to Jane Dempster, BSN, RN, MBA, coordinator for Baylor Liver and Pancreas Disease Center, “This will be a single-center study, capitalizing on our large patient population. Because all of the individuals in the study were subsequently transplanted, we have the native liver available to analyze and see how effective the local treatments were.”

Data are now being abstracted about pretreatment tumor size and location, type of treatment, imaging results just prior to transplant, and pathology. As the study progresses, researchers will also be looking at patient survival, to determine any correlations between outcome and local treatment response.

Data gathered from this study will contribute to a hepatobiliary registry as part of the new Surgical Oncology Clinical Research Database.