

Transplant Update

A Report from Baylor Annette C. and Harold C. Simmons Transplant Institute Volume 7 • Number 1



Uniquely Designed Clinical Trial Will Evaluate New HeartMate 3™

2

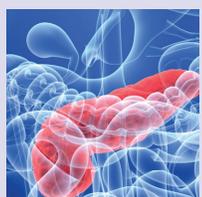
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Lung Transplant Maintains Quality Despite Increasing Patient Complexity

3

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Baylor Dallas Recognized for Pancreatitis Treatment and Care

4

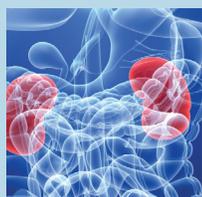
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5

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Desensitization Program Allows More Patients to Receive Kidney Transplants

6

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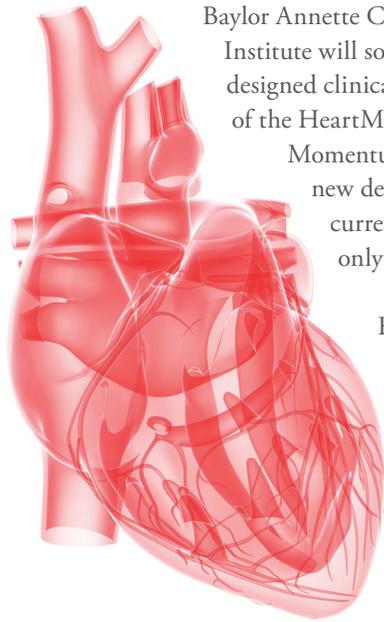


Online Continuing Medical Education – Complex Care: Treatment Trends and Improved Outcomes

7

An online continuing medical education activity designed to provide physicians with practice strategies for complex care and treatment of chronic liver disease and heart failure.

Uniquely Designed Clinical Trial Will Evaluate New HeartMate 3™



Baylor Annette C. and Harold C. Simmons Transplant Institute will soon begin enrolling patients in a uniquely designed clinical trial to evaluate the safety and effectiveness of the HeartMate 3™ Left Ventricular Assist System. The Momentum 3 U.S. IDE clinical trial will compare the new device to the HeartMate II®, one of two devices currently approved for bridge-to-transplant and the only device approved for destination therapy.

For the first time ever, the trial of a left ventricular assist device (LVAD) is designed with both a short-term and long-term endpoint. Researchers at up to 60 centers are enrolling more than 1,000 patients to simultaneously evaluate the device as a bridge-to-transplant and a destination therapy.

“In previous LVAD trials, the device was initially evaluated as a bridge to transplant. And then another trial had to be conducted for destination therapy. If the results of this trial are positive, it will speed up the process of approval by literally years, making this LVAD available to patients that much sooner,” said Shelley A. Hall, MD, FACC, chief of transplant cardiology and mechanical circulatory support/heart failure at Baylor University Medical Center at Dallas.

Candidates for the trial include any patient who has an indication for an LVAD, which includes those with stage D congestive heart disease secondary to a weakened heart, usually caused by coronary artery disease, prior heart attack or viral cardiomyopathy. Up to 50 patients at each research center will be randomized to either HeartMate II or HeartMate 3™.

As LVAD technology has improved, the challenge has been how to reduce complications, which include infection, bleeding and thromboembolic events. The HeartMate 3™ incorporates a smaller pump and does not require an abdominal implant pocket. The device is implanted directly above the diaphragm next to the native heart and is attached to the aorta, leaving natural circulation in place while providing all of the energy necessary to propel blood throughout the body.

“The science behind the new design is sound, so we hope this will decrease the risk of complications,” Dr. Hall said. “Technology is continuing to move forward at a much faster rate than our ability to treat heart failure with pills or by modifying the immune system after transplant. This may be a very promising therapy for our patients with advanced heart failure.” ■



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Shelley A. Hall, MD, FACC

Chief of transplant cardiology and mechanical circulatory support/heart failure at Baylor University Medical Center at Dallas



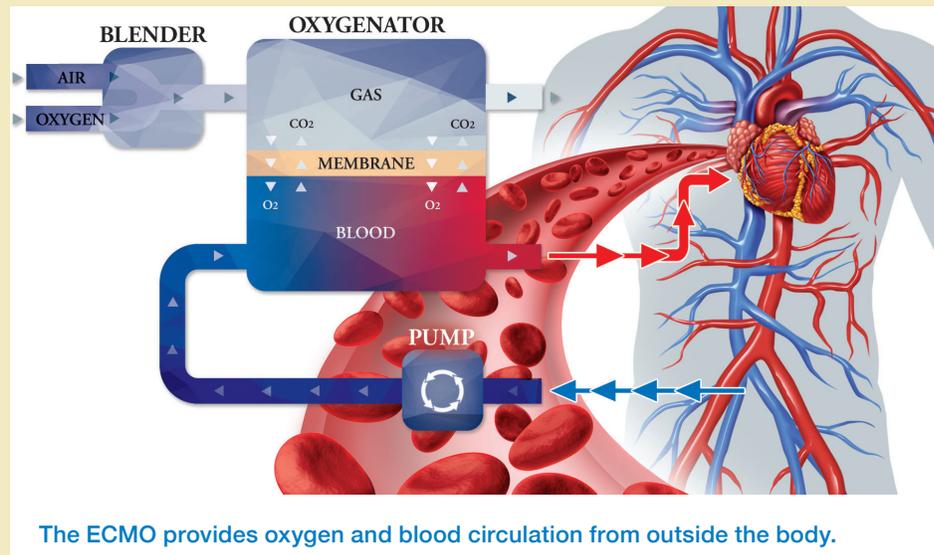


Lung Transplant Maintains Quality Despite Increasing Patient Complexity

As the lung allocation score reflects, lung transplant recipients at Baylor University Medical Center at Dallas have become much sicker at the time of transplant. However, Baylor Dallas has maintained excellent one-year survival rates (90.17 percent) compared to the national average (87.47 percent). In addition, the mortality rate for patients on the waiting list remains low.

“We know that if we were just accepting lower-risk patients, their lung allocation scores would not be high enough for them to be transplanted,” said Randall L. Rosenblatt, MD, MACP, FACC, chief of pulmonary services and medical director of lung transplantation at Baylor Dallas. “Many of the patients we see now are older, which puts them at higher risk, and have more advanced disease. They also may have more associated complications such as pulmonary hypertension, mild renal involvement and diabetes. Our quality data reinforces the value and impact of having an experienced, multidisciplinary team as part of the advanced lung disease program.”

As the lung transplant program has developed and matured, Dr. Rosenblatt said the team has gained much more knowledge about both pre-operative and perioperative care. Quality outcomes have been achieved through utilization of transplant pulmonologists, thoracic surgeons and intensivists, as well as nephrologists and infectious disease specialists who have significant skill and knowledge in the care of transplant patients.



Patients with advanced lung diseases also have benefited from Baylor Dallas’ extracorporeal membrane oxygenation (ECMO) program. ECMO therapy can provide temporary support for heart or lung failure while organ recovery occurs or alternatively as a life-support bridge to heart or lung transplantation. The program is one of the busiest adult ECMO programs in the region and supports multiple facilities in North Texas, Oklahoma, Arkansas and Louisiana.

“Establishment of the ECMO program has allowed us to salvage patients who, heretofore, would not even have been considered for transplant,” Dr. Rosenblatt said. “The depth of resources that we have at Baylor in terms of both people and technology is remarkable.”

In 2014, the lung transplant team at Baylor Dallas performed 37 lung transplants, making it the 19th busiest program in the United States according to the United Network for Organ Sharing. ■

One-year Survival Rates

90.1%	87.4%
Baylor Dallas	National Average

Baylor Dallas Recognized for Pancreatitis Treatment and Care



Baylor University Medical Center at Dallas has been named a **National Pancreas Foundation Center** by The National Pancreas Foundation (NPF). Baylor Dallas is currently the only center in Texas and surrounding states of Arkansas, Louisiana, New Mexico and Oklahoma to receive this designation.

NPF Centers focus on multidisciplinary treatment of pancreatitis by treating the “whole patient.” These centers focus on the best possible outcomes and an improved quality of life.

To be labeled an NPF Center, a medical center must have gastroenterologists experienced in therapeutic endoscopy, including EUS and ERCP, pathologists with expertise in gastrointestinal disease, interventional radiologists with gastroenterology expertise, pancreatobiliary surgeons with experience and expertise in distal pancreatectomy, Whipple’s resection, total pancreatectomy, drainage procedures for pseudocysts and pancreatitis - Puestow and cyst-enterostomies, and an islet auto-transplantation program for patients with chronic, debilitating pancreatitis. Special services required include advanced endocrinology, dietitian/nutrition support, pain control/management, pancreatic function testing and clinical trials.

Pancreas Care at Baylor Encompasses Experts in Gastroenterology, Imaging, Transplantation and Oncology

The clinical team at the Baylor Pancreatic Cancer Research and Treatment Center includes physicians from a variety of specialties, including gastroenterology, interventional endoscopy, surgery, oncology, radiology, pathology, pain management and genetics. Highly trained nurses, genetic counselors and nutritionists also serve as team members. These specialists are recognized leaders in pancreatic disease care, and can offer diagnostic and treatment options that are not available at most hospitals.

Baylor Dallas offers in-depth expertise for many pancreatic diseases including treatment for chronic pancreatitis through auto- islet cell transplants, performed by medical teams within Baylor Annette C. and Harold C. Simmons Transplant Institute. In the procedure, the pancreas and spleen are removed and the patient’s own islet cells are extracted. They are then infused into the patient’s liver, where they take hold and produce insulin to blunt

diabetes which would otherwise occur. The Liver and Pancreas Disease Center, another unique facility at Baylor Dallas, is dedicated to treatment patients with liver and pancreas cancer. This center’s team coordinates each patient’s tumor management and plan of care among the specialist on the Baylor medical staff. Since the program’s inception in 1998, more than 5,000 patients have received treatment.

In July 2015, The *U.S. News Best Hospitals* rankings ranked Baylor University Medical Center at Dallas No. 1 in the Dallas-Fort Worth area and No. 3 in Texas. Baylor Dallas was also ranked among the best gastrointestinal disorders (#25) and cancer (#34) programs in the country by *U.S. News Best Hospitals*.

Other NPF Centers include Johns Hopkins Medicine, the Mayo Clinic, New York Presbyterian Hospital/Columbia University Medical Center, and Brigham and Women’s Hospital, among others. ■

“ We are gratified to be recognized for our expertise and the comprehensive nature of our care.

– **Scott Celinski, MD**

Co-medical director of the Pancreatic Cancer Research and Treatment Center and a surgeon on the medical staff at Baylor Dallas

“ It’s humbling to be recognized as one of a few centers in the country to provide comprehensive care in treating complex diseases of the pancreas.

– **Lawrence Schiller, MD**

Acting chief of gastroenterology, Baylor Dallas



Living Donor Transplantation, Move To Regional Allocation Increases Access to Liver Transplant

The number of deceased donor livers in the United States has remained relatively stable over the past 10 years. However, the average wait for patients on the waiting list is two years. Furthermore, significant geographic differences exist in access to liver transplantation across the United States. Candidates in parts of the country with high donation rates may receive transplants when they are much less ill, while candidates who live in areas with low donation rates often wait until they are very sick before they receive a liver transplant.

There are now nationwide discussions to change the geographic area of the various organ distribution regions to normalize waiting times based on the severity of disease. The goal is to eliminate local variations and differences in MELD score at time of transplant by widening the allocation areas. For instance, in one proposal, Texas would be in an organ distribution region that extends all the way to Florida. These discussions are ongoing and are expected to come to a conclusion sometime this year.

“The government mandate that geography should not be a factor in whether a patient receives a liver transplant is noble. But there are numerous logistical issues that must be taken into consideration,” said James Trotter, MD, program director for general and transplant hepatology for Baylor Scott & White Health. “There will be increased costs. Organs will have to be preserved for a longer time, which can affect the quality of the organ at time of transplant, especially less than perfect donor livers. There are significantly more potential weather and travel problems bringing an organ from Miami to Dallas than from Fort Worth to Dallas.”

At Baylor University Medical Center at Dallas, some patients are able to receive a liver transplant sooner rather than later through the growing living donor liver transplantation program. In 2014, a total of a dozen living donor liver transplants were performed at Baylor Dallas, and in 2015 surgeons on the medical staff preformed 17 living donor transplants.

Benefits of living donor liver transplantation include:

- A living donor liver is the best quality liver for transplantation.
- Prompt use of a living donor liver maximizes the chance that the recipient will receive a transplant before the condition worsens.
- The surgery can be scheduled at the convenience of the donor and recipient.

Baylor Dallas is only one of two Texas medical facilities that perform the operation, and one of the top five in the United States in the number of living donor liver transplants performed annually.

In addition to transplant services, Baylor Scott & White Health has significantly expanded its general hepatology services to help manage the growing number of patients with liver disease, which, in many cases, is tied directly to the obesity epidemic in the nation. Twelve hepatologists are currently on the medical staff at Baylor Dallas and Baylor Scott & White All Saints Medical Center - Fort Worth.

“It is important for physicians to diagnose liver disease and refer them to Baylor as appropriate,” Dr. Trotter said. “There are new treatments available that are highly effective such as the new drugs for hepatitis C. Our goal is to help patients avoid a liver transplant whenever possible.” ■

“

Living donor liver transplantation is a very complex surgery that requires a great deal of experience and expertise. As more patients and donors explore this possibility, they are learning we have been able to achieve safe, quality outcomes for both donor and recipient.

Giuliano Testa, MD

Surgical director of living donor liver transplantation at Baylor Dallas

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Desensitization Program Allows More Patients to Receive Kidney Transplants



Baylor Scott & White All Saints Medical Center - Fort Worth and Baylor University Medical Center at Dallas have begun a desensitization protocol, which is available at very few medical centers in the nation.

Approximately 25 to 30 percent of patients who are on the waiting list for a kidney transplant are considered “sensitized.” Highly sensitized patients exhibit high levels of antibodies against the HLA antigens of some of the potential donor population, leaving them with long wait times for receiving a donated organ. And once transplanted, they have a greater risk of graft loss from rejection.

A patient is considered sensitized if the results of a panel reactive antibody test (PRA) are greater than 20. The PRA provides an estimate of the amount of antibody against foreign tissue that a patient has and predicts the likelihood of having an antibody against a particular donor. Sensitized patients may wait twice as long for a compatible deceased donor kidney compared to a non-sensitized patient.

“Patients become sensitized primarily as a result of exposure to blood products, a failed kidney transplant or pregnancy,” said Angelito F. Yango, Jr., MD, a nephrologist on the medical staff at Baylor Scott & White All Saints Medical Center - Fort Worth. “Because their bodies will react to foreign tissue, such as a potential kidney allograft, their chances of getting a transplant are much lower. Some patients wait five to 10 years without an offer.”

Because the numbers of highly sensitized patients are increasing, Baylor Scott & White All Saints Medical Center - Fort Worth and Baylor University Medical Center at Dallas have begun a desensitization protocol, which is available at very few medical centers in the nation.

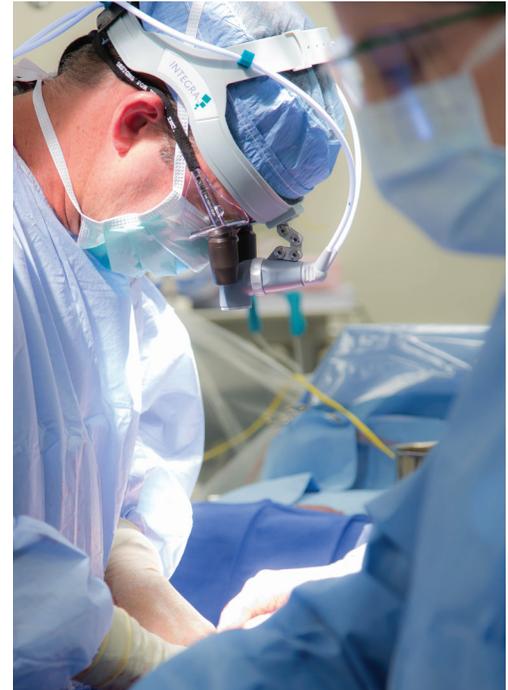
The protocol consists of the administration of intravenous immunoglobulin (IVIG) at monthly intervals. IVIG contains the pooled antibodies from 5,000 to 10,000 different blood donors and can potentially decrease the antibody level in a sensitized patient. The treatment continues until physicians begin to see a decline in antibody levels. Some patients respond in six to eight months; others have received the treatment up to 18 months. Desensitization can be used for patients who are on the waiting list for a deceased donor, as well as those who have a potential living donor.

“Without desensitization, the rate of transplantation for these patients is less than 10 percent,” Dr. Yango said. “We started our program with 20 patients, and, to date, we have successfully transplanted 10 of them.” ■

ONLINE CONTINUING MEDICAL EDUCATION

Complex Care: *Treatment Trends and Improved Outcomes*

The 2016 Complex Care: Treatment Trends and Improved Outcomes online continuing medical education activity is designed to provide physicians with practice strategies for complex care and treatment of chronic liver disease and heart failure.



Presented by Baylor Annette C. and Harold C. Simmons Transplant Institute at Baylor University Medical Center at Dallas and Baylor Scott & White All Saints Medical Center - Fort Worth

For Primary Care and Specialty Care Physicians

This activity has been approved for
AMA PRA Category 1 Credit™

TOPIC:

SPEAKER:

Updates in Management of Chronic Liver Disease

Sumeet K. Asrani, MD

Surgical Alternatives for Heart Failure Patients in 21st Century

Gonzalo Gonzalez-Stawinski, MD

Application of Transplantation Techniques in Complex Hepatopancreatobiliary Surgery

Peter Kim, MD, MSc, FACS, FRCS(C)

Liver Transplantation

Göran Klintmalm, MD, PhD, FACS

Heart Failure Treatment for the 21st Century

Johannes Kuiper, MD

Surgical Treatment of Diseases of the Chest

David Mason, MD

Ethics of Living Donor Transplantation

Giuliano Testa, MD

Update in Hepatitis C

James Trotter, MD

REGISTRATION

The 2016 Complex Care: Treatment Trends and Improved Outcomes CME online continuing medical education course is available to physicians until February 15, 2017.

The course and program materials will be provided for \$50. The cost will be applied to each physician's annual nonmonetary compensation amount if available.

*Because G9MD.net requires manual approval of each account, registrations submitted after business hours may not be activated until the next business day.

- Register for an account at <http://g9md.net> (Note: Registrants are required to upload a profile image { .jpg, .png, or .gif } to complete registration.)
- After registration has been approved within minutes*, log in and click “CME” in the main menu bar.
- Click on “Complex Care: Treatment Trends and Improved Outcomes CME” to begin the course.
- For technical help with g9md.net, please contact Ashley Perry at aperry@g9md.net or 214.865.1071.

CME CREDIT

The A. Webb Roberts Center for Continuing Medical Education of Baylor Health Care System, Dallas designates this enduring material for a maximum of 3.75 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

The A. Webb Roberts Center for Continuing Medical Education of Baylor Health Care System, Dallas is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.



**Annette C. and Harold C. Simmons
Transplant Institute**

Baylor University Medical Center at Dallas
Baylor Scott & White All Saints Medical Center – Fort Worth

Part of **BaylorScott&White HEALTH**

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Transfer Information

Baylor Annette C. and Harold C. Simmons Transplant Institute is the integration of transplant services at Baylor University Medical Center at Dallas and Baylor Scott & White All Saints Medical Center - Fort Worth. Together, Baylor Dallas and Baylor Scott & White - Fort Worth are one of the largest multispecialty transplant centers in the country.

For more information, please call 1.800.774.2487.

With one phone call, a physician can request additional information, an appointment for a patient, or a consult. Call 1.800.774.2487 and a Baylor Annette C. and Harold C. Simmons Transplant Institute representative will assist you.

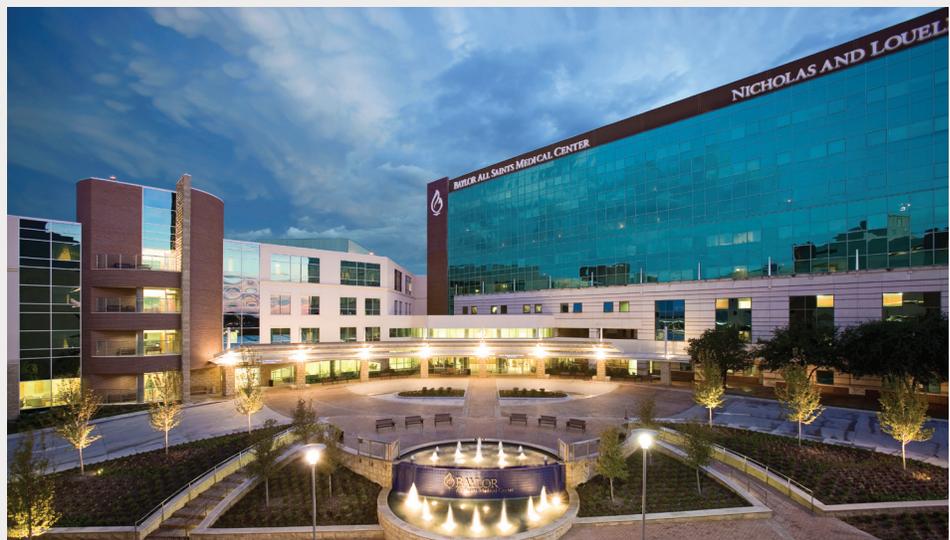
To learn more about the transplant programs and criteria, visit BaylorHealth.edu/Transplant.

If you wish to be taken off this mailing list, please call 1.800.9BAYLOR.

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