

Transplant Update

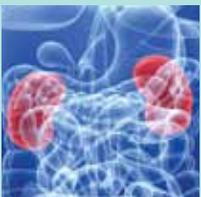
A Report from Baylor Annette C. and Harold C. Simmons Transplant Institute Volume 6 • Number 1



Newly Approved Drugs Show High Cure Rates for Hepatitis C

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Two new drugs are providing hope to the approximately 3.2 million people in the United States who are infected with the hepatitis C virus. Unlike the previous therapy, the new drugs have minimal side effects and offer most patients an almost 90 percent chance at cure in just 12 weeks.



Living Donation Decreases Wait for Kidney Transplant

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Baylor Awarded Patent for Major Advance in Islet Cell Transplant

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Baylor Research Institute has been awarded a patent from the U.S. Patent Office for a potential strategy to improve the outcomes of islet cell transplantation for patients with type 1 diabetes and chronic pancreatitis.



Baylor Dallas Offers Comprehensive Care for Advanced Lung Disease

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Baylor Dallas Offers Life-Saving Mechanical Circulatory Support

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Newly Approved Drugs Show High Cure Rates for Hepatitis C

There are approximately 3.2 million people in the United States who are infected with the hepatitis C virus. Unlike the previous therapy, the new drugs have minimal side effects and offer most patients an almost 90 percent chance at cure in just 12 weeks.

Sofosbuvir, a polymerase inhibitor, is approved for use in combination with ribavirin for patients with genotypes 2 and 3. Twelve weeks of therapy for naïve genotype 2 and 24 weeks of therapy for naïve genotype 3 patients result in sustained virologic response (SVR) in more than 90 percent of patients.

“The new drug has essentially no side effects and when combined with ribavirin is extremely well tolerated,” said Jacqueline G. O’Leary, MD, MPH, medical director of hepatology research at Baylor University Medical Center at Dallas. “Patients who have had interferon in the past are amazed. Interferon makes you feel like you have the flu the whole time.”

Treatment-naïve patients with genotype 1 have a 12-week option of triple therapy with sofosbuvir, ribavirin and interferon. This regimen showed an SVR of 89 percent. Sofosbuvir also is approved for re-treatment

patients although cure rates are not yet available.

“Patients with genotype 1 who can’t tolerate interferon may be treated with 24 weeks of sofosbuvir and ribavirin,” Dr. O’Leary said. “It’s good to have that as an option for interferon ineligible or intolerant patients.”

Simeprevir, a protease inhibitor, has also been approved for use in combination with interferon and ribavirin for patients with genotype 1. However, when simeprevir was combined with sofosbuvir for just 12 weeks in a small phase II study, more than 90 percent of patients with advanced fibrosis who were prior null responders to pegylated interferon and ribavirin achieved SVR.

“We literally had no new drugs for a decade,” Dr. O’Leary said. “Then in 2011, there was the first release of direct-acting anti-viral agents. Although this was a major advance,

Quick Facts

- Over 29 years ago, Baylor pioneered the first liver transplant program in the Southwest.
- One of three programs in the nation to perform 3,752 liver transplants.*
- Baylor’s expertise in the areas of hepatitis B and C is internationally renowned.

* Volumes are based on liver transplants at Baylor University Medical Center and Baylor All Saints Medical Center.

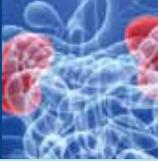
tolerability remained an issue that limited who could be treated and cured. Now just two years later, we have curative therapies for the vast majority of patients. There has been a complete revolution in how we care for patients with hepatitis C.” ■

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Jacqueline G. O’Leary, MD, MPH



Hepatitis C



Living Donation Decreases Wait for Kidney Transplant

Over the last several years, the demand for kidney transplantation has continued to increase. Unfortunately, organ donation from deceased donors has not increased to meet this need. At Baylor University Medical Center at Dallas and Baylor All Saints Medical Center at Fort Worth, patients with advanced kidney disease increasingly are encouraged to consider living donor kidney transplant.

Living kidney donation offers many advantages. The five-year graft survival for a kidney from a living donor is 85 percent. Patient survival rates are even better. In contrast, patients on dialysis, both young and old, face a one- and five-year mortality of 20 percent and 50 percent, respectively.

“Living donor kidney transplant may make it possible for a patient to stop dialysis sooner or even avoid starting dialysis,” said Steven Hays, MD, director of hemodialysis and renal replacement therapy, and medical director of living donor kidney program at Baylor Dallas. “In addition, a kidney from a living donor is the best quality kidney. It begins to function more quickly after transplant and can last almost twice as long as kidneys from deceased donors.”

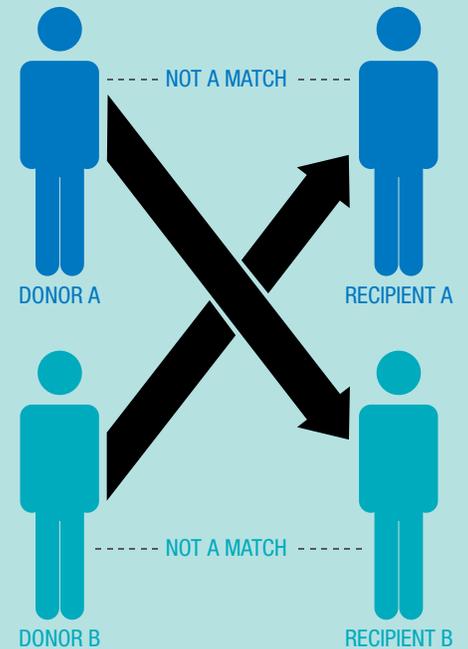
Once patients’ kidney function drops to one third of normal, they are prepped for dialysis.

When kidney function goes below 20 percent of normal, they can be worked up for transplant. Some patients may be on the waiting list for a transplant from a deceased donor before going on dialysis.

“Initially, a patient may have a number of willing living donors,” Dr. Hays said. “But once the patient goes on dialysis, these potential donors sometimes change their minds because they see the patient surviving on dialysis. At Baylor, our goal is to screen any potential living donors very early in the process. This may allow the patient to undergo a kidney transplant before the need to start dialysis.”

If a patient has a willing donor who is not a match as a result of blood type or other factors, paired donor kidney transplant is an option. In paired donor transplantation, two patient-and-donor pairs (A and B) that do not match are identified. The donor of pair “A” must be identified to be compatible with the recipient of pair “B.” Additionally, the donor of pair “B” must be identified to be compatible with the recipient of pair “A.” This allows each paired recipient to receive a kidney transplant. In addition to the national registries Baylor currently accesses, the transplant team is looking at additional ways to expand the paired donation program. ■

PAIRED DONOR PROGRAM



Program Highlight

To better serve patients in West Texas and the Panhandle, a weekly Kidney Transplant Outreach Clinic was established in Lubbock to offer both pre-transplant evaluations and post-transplant care.

When a patient receives a kidney transplant at either Baylor Dallas or Baylor Fort Worth, the goal is to get the patient home within a two- to three-week timeframe.

Quick Facts

- With 3,740 kidney transplants performed, our kidney and kidney/pancreas program is one of the largest in Texas.*
- According to the Scientific Registry of Transplant Recipients (SRTR) one-year survival rates, survival rates for Baylor kidney recipients exceed the national average.

*Volumes are based on kidney transplants at Baylor University Medical Center and Baylor All Saints Medical Center.

Baylor Awarded Patent for Major Advance in Islet Cell Transplant

Baylor Research Institute has been awarded a patent from the U.S. Patent Office for a potential strategy to improve the outcomes of islet cell transplantation for patients with type 1 diabetes and chronic pancreatitis.

The Baylor research team determined that withaferin A (WA), a plant-derived compound with strong anti-inflammatory and anti-oxidant properties, is a strong inhibitor of the inflammatory response in islets, protecting them against cytokine-induced cell damage while improving the survival of transplanted islets. The results suggest that WA could be incorporated as an adjunctive treatment to current immunosuppressive therapies to improve islet transplant outcome.

“Currently, no anti-inflammatory compound with broad benefits such as withaferin A is used in the islet transplant field. The experimental research performed at Baylor on

this compound has improved the basic understanding of the molecular mechanism involved in islet damage during the peritransplant period,” said Bashoo Naziruddin, PhD, director of the Islet Cell Laboratory at Baylor University Medical Center at Dallas.

The Baylor research team was the first to report that when islet cells are injected back into the patient they are subject to a severe inflammatory reaction, which can damage the islet cells. Using molecular analysis, they obtained evidence that the inflammatory reaction occurs within hours of the transplant.

“Islet cell transplant continues to show promise for treating patients with type 1 diabetes. Auto islet cell transplant already is used successfully to treat patients with chronic pancreatitis,” Dr. Naziruddin said. “We hope the use of WA will strengthen existing immunosuppressive strategies to improve current islet

Quick Facts

- North Texas’ first islet cell transplant.
- Baylor’s islet cell laboratory is one of only a few in the country to process cells for transplantation.
- Baylor achieves 100 islet cell isolations.

transplant outcomes by preserving the mass and function of engrafted islets.”

In addition to Dr. Naziruddin, inventors of the patented procedure include Marlon Levy, MD, FACS, medical director, Islet Cell Transplant Program, Baylor Health Care System, Shinichi Matsumoto, MD, PhD, former director of the Islet Cell Laboratory at Baylor All Saints Medical Center at Fort Worth, and Han Peng, graduate student. ■





Baylor Dallas Offers Comprehensive Care for Advanced Lung Disease

The Advanced Lung Disease Program at Baylor University Medical Center at Dallas offers a full range of advanced therapies for patients with complex, chronic and rare lung diseases. Among the diseases treated are suppurative lung diseases, such as cystic fibrosis and bronchiectasis, interstitial lung diseases, pulmonary hypertension, and obstructive lung diseases such as asthma, chronic bronchitis, and emphysema.

Patients are cared for by a multidisciplinary team of physicians on the medical staff who have expertise in specific areas of pulmonary medicine, nurse practitioners, nurse coordinators, respiratory therapists, dietitians, and social workers. Genetic counselors are available as needed.

Baylor Dallas recently began to offer bronchial thermoplasty for patients with asthma. Recently approved by the Food and Drug Administration, this innovative device applies mild heat inside the airways to reduce excessive smooth muscle. The reduction in muscle tissue helps to minimize airway constriction during an asthma attack and may reduce the incidence of such attacks.

In the last year, Baylor Dallas has introduced the use of extracorporeal membrane oxygenation (ECMO) for respiratory failure. Because

it oxygenates the blood, ECMO can temporarily support patients with acute respiratory failure from such causes as the H1N1 flu virus, other types of pneumonia and trauma, allowing the patient's own lungs to recover. ECMO also may be used as a bridge to lung transplant for patients on the waiting list whose condition begins to deteriorate.

"We are committed to providing our patients with advanced therapies that can reduce symptoms, improve their quality of life and, in many cases, save their lives," said Charlene Cink, director of the heart and lung transplant program and mechanical circulatory support at Baylor Dallas.

In addition to a full range of radiology testing, Baylor Dallas' sophisticated tools for diagnosing lung disease include inhalation

challenges for airway diseases, exercise testing to determine the etiology of dyspnea, standard body plethysmography, diffusion testing and nasolaryngoscopy.

Because the complexity of care for advanced lung disease patients can be time consuming, the Advanced Lung Disease Program provides all diagnostic and therapeutic options under one umbrella, making the process more efficient for both patients and referring physicians. The program also offers patients access to clinical trials to evaluate potential therapeutic agents.

"Baylor offers patients with advanced lung disease a comprehensive slate of both standard and experimental therapies," Cink said. "And if those treatments fail, patients can be rapidly evaluated for a lung transplant." ■



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Charlene Cink



Quick Facts

- In June 2013, Baylor Dallas formed a new lung transplant surgical team.
- Baylor Dallas performed 29 lung transplants in 2013, compared with 16 lung transplants in 2012.
- Dedicated nurses are on call 24/7 for the management of advanced lung disease patients.

Baylor Dallas Offers Life-Saving Mechanical Circulatory Support

For patients with acute heart or lung failure, Baylor University Medical Center at Dallas offers life-saving treatment through its comprehensive mechanical circulatory support program. The tertiary care center manages a high volume of cases, with referrals coming from throughout the North Texas region.

“Baylor offers advanced therapies that are most successful in centers with a great deal of experience,” said Themistokles Chamo-georgakis, MD, associate director of heart transplantation and mechanical circulatory support at Baylor Dallas. “Our goal for this program is to serve as a hub and facilitate the transfer of critically ill patients, as needed, so they have the best chance for recovery.”

Extracorporeal membrane oxygenation (ECMO) is available for patients with acute cardiovascular or respiratory failure.

Implanted percutaneously, ECMO can provide biventricular circulatory support, as well as respiratory support. For patients who are too unstable for a major intervention, ECMO may be used to temporarily support their circulation to determine if they are a candidate for a longer-term option, such as an implantable ventricular assist device, heart or lung transplant, or conventional open-heart surgery.

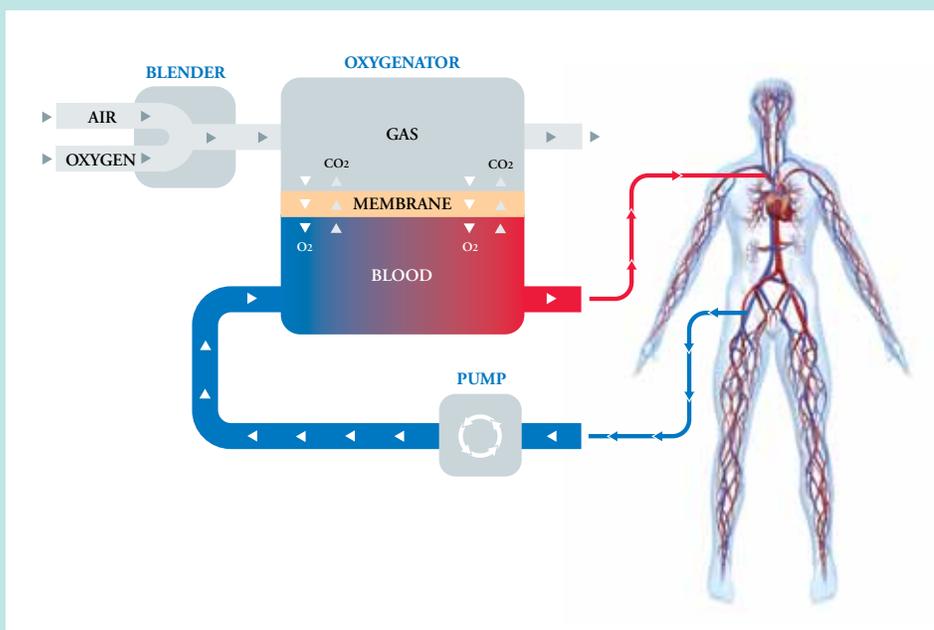
“ECMO is indicated when patients in severe respiratory failure are refractory to maximal mechanical ventilation,” said Alexis Shafii, MD, FACS, medical director of extracorporeal membrane oxygenation at Baylor Dallas. “Management of these patients can be quite complex, but this advanced therapy gives them the best chance of survival.”

Dr. Shafii said historically the survival rate has been approximately 25 percent for adult cardiac indications and about 50 percent for respiratory indications. With the improvements in ECMO technology and patient selection, results are improving. At Baylor Dallas, survival results with ECMO for cardiac and respiratory failure are approximately 50 and 60 percent, respectively.

“In general, patients with respiratory failure do significantly better with ECMO,” he said. “The indications for lung support are primarily reversible conditions of the lungs, such as severe pneumonia. In cardiac diseases, it is more difficult for the heart to recover. However, the option for bridging to a long-term mechanical support device (i.e., LVAD), has contributed to the improving survival rate of cardiac patients on ECMO.”

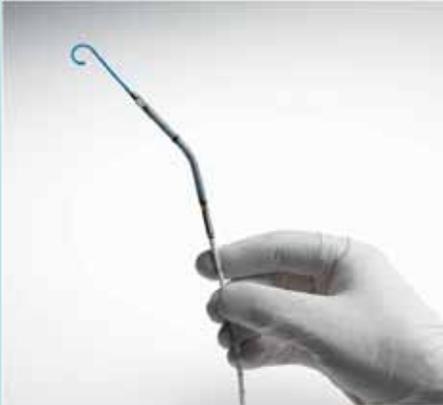
Baylor Dallas also employs the Impella®, a temporary left ventricular assist device, for short-term support of patients with severe heart failure or cardiogenic shock. In some cases, this device supplements treatment with veno-arterial ECMO by providing better decompression of the left ventricle and left atrium. The Impella also may be used in a diagnostic capacity to assess renal function or potential right ventricular dysfunction, both of which can impact a patient’s candidacy for an LVAD or transplant.

For longer-term support as a bridge to transplant, Baylor Dallas has two device options: the HeartMate II® and the HeartWare® Ventricular Assist System. HeartWare features the HVAD® pump, a small full-output circulatory support device designed to be implanted next to the heart in the pericardial space. This lower profile device may be implanted through less-invasive procedures, leading to potentially shorter surgery times and quicker recoveries.



Extracorporeal Membrane Oxygenation (ECMO)

Image courtesy Abiomed, Inc.



Impella® Temporary Left Ventricular Device Detail of Pump (left) and System

Image courtesy HeartWare, Inc.

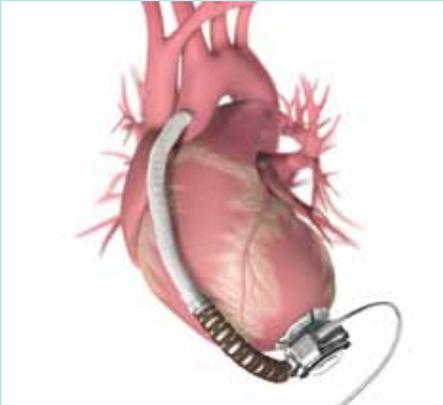


Illustration of Implanted HeartWare® Ventricular Assist System

For patients who are not able to receive a heart transplant, Baylor Dallas can offer improved quality of life through implantation of a left ventricular assist device (LVAD). The HeartMate II offers increased longevity and durability, and has been designed to decrease the risk of infection and other complications.

Image courtesy Thoratec Corporation

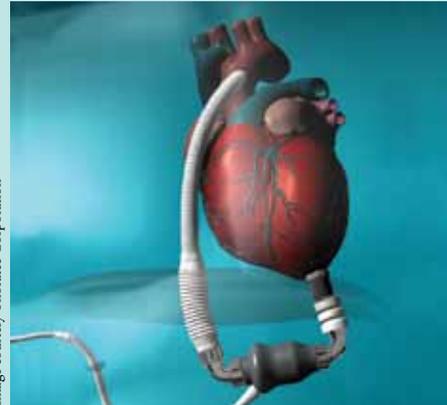


Illustration of Implanted HeartMate II® Left Ventricular Assist Device

In some advanced heart failure patients, the right ventricle is very weak, and an LVAD alone may not provide adequate support. For these patients, Baylor Dallas offers three options:

1. pulsatile ventricular assist device left and right,
2. continuous flow left side and pulsatile right side, and
3. total artificial heart.

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The ultimate biventricular support is heart transplantation. But if a donor heart is not available, all of these options are critical to keeping patients alive. Our one-year survival rate for heart transplant patients is close to 90 percent, and our circulatory support outcomes are comparable.

Themistokles Chamogeorgakis, MD

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Heart Transplant Program Highlights

- Number one program in Texas in terms of volumes
- Second largest heart transplant program in the nation
- Median wait time for heart transplant for status 1A patients is less than 10 days
- Surgical expertise and medical management before and after transplant result in survival statistics that exceed the national average
- Patients are provided with transplant care throughout their lifetime
- Dual Listing Program

Patients must meet certain anatomic criteria to be suitable candidates for the total artificial heart. Each of these options may be used as a bridge to transplantation.

Baylor Dallas—the largest heart transplant program in Texas in 2013 and one of the largest in the United States—recently performed 100 heart transplants in a 14-month period.

“The ultimate biventricular support is heart transplantation,” Dr. Chamogeorgakis said. “But if a donor heart is not available, all of these options are critical to keeping patients alive. Our one-year survival rate for heart transplant patients is close to 90 percent, and our circulatory support outcomes are comparable.” ■

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 All Saints Medical Center at Fort Worth. Together, Baylor Dallas and Baylor 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.



Baylor University Medical Center at Dallas • 3410 Worth St., 9th Floor, Dallas, TX 75246



Baylor All Saints Medical Center at Fort Worth • 1400 Eighth Ave., Fort Worth, TX 76104

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