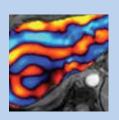
# TransplantUpdate

A Report from Baylor Annette C. and Harold C. Simmons Transplant Institute Volume 6 • Number 2



### **Elastography May Predict Decompensation in Patients with Liver Disease**

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## **Dual Listing for Heart Transplant Shaves Wait to Seven Days**

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## **Baylor Achieves Excellent Results with Total Pancreatectomy/Auto Islet Transplants**

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## **Baylor Dallas Studies New Drugs for Interstitial Lung Disease**

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### Kidney/Pancreas Transplant Patients Face Short Wait Times with Positive Outcomes

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## **Elastography May Predict Decompensation** in Patients with Liver Disease

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A recent study at the Mayo Clinic, coauthored by Sumeet Asrani, MD, now a hepatologist on the medical staff at Baylor Dallas, examined the role of magnetic resonance elastography in compensated and decompensated liver disease. Researchers hypothesized that liver shear stiffness could be an important non-invasive predictor of hepatic decompensation.

"Elastography is very helpful in determining if a patient has cirrhosis, but we wanted to see if it would predict how a patient with compensated cirrhosis would fare long term," Dr. Asrani said. "Previously, we've had no good non-invasive tools to predict decompensation."

In the study, which was published in the May 2014 issue of *Journal of Hepatology*, 167 patients with compensated disease had baseline elastography. At 27-month follow-up, 7 percent had decompensation. Dr. Asrani and colleagues determined that a patient with compensated cirrhosis and liver stiffness above 5.8 kilopascals was five times more likely to develop decompensation within the next two years.

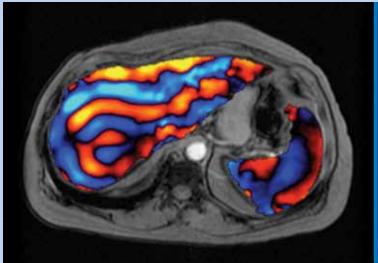
"Cirrhotics who had higher liver stiffness were more likely to have decompensation," Dr. Asrani said. "This gives us additional information on how to care for patients. If a patient has low stiffness, maybe we don't need to follow him or her every six months. Alternatively, patients with higher stiffness may benefit from early interventions, such as prophylactic antibiotics, or if they have hepatitis C, receive antiviral therapy sooner rather than later."

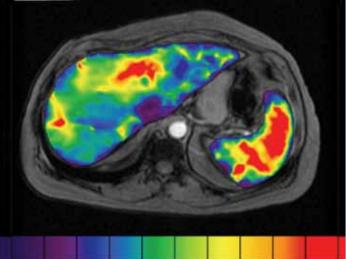
#### **Quick Facts**

- Over 29 years ago, Baylor pioneered the first liver transplant program in the Southwest.
- One of three programs in the nation to perform 3,828 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.

Researchers at Baylor Dallas are also looking into the role of ultrasound-based elastography in predicting decompensation after liver transplant.





Left: Wave elastogram image graphically showing raw data used to create elastography. Right: Post processed elastogram image designating areas of variable stiffness with color. (Areas in red have greatly reduced elasticity.)



While the United Network for Organ Sharing allows patients to register at two or more transplant centers, this opportunity is not very well known, even among physicians. The tremendous growth of the Cardiac Transplant Program at Baylor University Medical Center at Dallas, currently the number-one program in North Texas in terms of volume, has led to the creation of a dual listing program for heart transplant patients. Now the median time on the waiting list for Status 1A patients is a remarkable seven days.

"Numerous patients and physicians have asked us for dual listing when they see the growth of our program," said Gonzo Gonzalez-Stawinski, MD, chief of heart transplantation and mechanical circulatory support at Baylor Dallas. "We are getting calls from patients locally and from patients who are listed at transplant centers in other states." Baylor Dallas has collaborated with two companies that facilitate transportation on private jets so that patients can arrive in the appropriate timeframe for their transplant. Alternatively, some patients choose to move to the Dallas/Fort Worth area to wait for transplant. Because of the brief time to transplant, patients do not incur a large financial burden. In addition, Twice Blessed Houses on the campuses of Baylor Dallas and Baylor All Saints Medical Center at Fort Worth offer affordable housing for transplant patients and their caregivers. Financial specialists are available to help patients be dual listed if there are any insurance issues.

Baylor will accept the evaluation and test results from patients who are listed with reputable transplant centers. "Depending on the amount of time between listing and our reevaluation, we may or may not repeat testing," Dr. Gonzalez said. "In most cases, this does away with the added expense of retesting. We try to guarantee a patient will

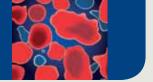


- Number one program in Texas in terms of volumes
- Second largest heart transplant program in the nation
- Median wait time for heart transplant for status 1A patients is seven days
- Surgical expertise and medical management before and after transplant result in survival statistics that exceed the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

be listed within seven days of consult. This is a very quick turnaround for listing, especially for patients who are dual listed, but part of the evaluation process is already done."

At a certain point after transplant, Dr. Gonzalez said, they are open to lateralizing care to the patient's original transplant center if that center is recognized for its quality of care. "We'll collaborate with the referring center so they can continue post-operative care close to home if we deem that center has a quality of performance," he said.





## **Baylor Achieves Excellent Results with Total Pancreatectomy/Auto Islet Transplants**

Baylor University Medical Center at Dallas has achieved excellent results for patients undergoing total pancreatectomy followed by autologous islet cell transplant (TP/AIT) as an innovative treatment for chronic pancreatitis. The program is approaching its 100th case of TP/AIT.

In the TP/AIT procedure, the pancreas is surgically removed and taken to the lab, where the patient's own islet cells are extracted. These cells are then infused into the patient's liver through the portal vein, where they take hold and ideally begin to produce insulin again on their own.

"Our primary goals for these patients with chronic pancreatitis are to achieve freedom from pain and good glycemic control," said Marlon F. Levy, MD, FACS, surgical director of transplantation at Baylor Fort Worth.

Before surgery, 93 percent of patients are dependent on narcotics. Seventy percent are narcotic-free one year after surgery. Those who remain on narcotics are often being treated for unrelated pain (such as joint or back pain), are on much lower doses, and have a much lower pain score.

Good results have also been achieved with glycemic control. Forty percent of patients are free of exogenous insulin, and a large majority of the patients have favorable HgA1C profiles, despite removal of their pancreas.

"While some patients do have a lengthy recovery, overall our experience tracks very well with the benchmarks outlined by the University of Minnesota's program, which leads the nation in TP/AIT cases," Dr. Levy said.

#### **Quick Facts**

- First facility in the Southwest to be approved by the American Society of Transplant Surgeons as a surgical training program in pancreas transplantation.
- Pancreas patient survival rates at Baylor University Medical Center and Baylor All Saints Medical Center exceeded the national average for one-year survival.
- The program\* has performed 254 pancreas transplants.

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

At Baylor, TP/AIT is sometimes performed on patients who are already diagnosed diabetics. The approach to all TP/AIT candidates is to assess basal and stimulated c-peptide production, regardless of insulin or oral hypoglycemic requirements. If endogenous insulin production is present, physicians favor preserving the islets with auto-transplantation.

"Our clinical activity allows us to field a strong research team," Dr. Levy said. "We have three scientists who are contributing significantly to the advancement of islet transplant and regularly present results in basic science, as well as clinical, research projects. Currently, our main focus is on reducing inflammatory events that accompany islet engraftment in the liver."



A Baylor scientist at work in the islet cell lab.

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## **Baylor Dallas Studies New Drugs for Interstitial Lung Disease**

The Center for Advanced Heart and Lung Disease at Baylor University Medical Center at Dallas is participating in clinical trials to evaluate new drug therapies for interstitial lung disease.

Nintedanib is a small molecule inhibitor of PDGFR—platelet derived growth factor/receptor, FGFR—fibroblast growth factor/receptor, and VEGFR—vascular endothelial growth factor/receptor, which is being developed for the treatment of interstitial pulmonary fibrosis, also known as usual interstitial pneumonia (UIP).

As published in the *New England Journal of Medicine* in May, nintedanib demonstrated a positive effect on the forced vital capacity (FVC) decline, which was the primary endpoint of the study. A decline in FVC over time is a reliable predictor of mortality in patients with interstitial pulmonary fibrosis.

Among the group of patients who took nintedanib, the annual decline in forced expiratory volume (FEV1) was 0.06 liters, in contrast to the placebo group's decline of 0.19 liters. Improvements were also seen in secondary outcomes such as the number of exacerbations and overall quality of life.

The Advanced Lung Disease program participated in another phase III study that is evaluating the effect of nintedanib after 12 months of therapy through high-resolution computerized tomography, quantitative lung fibrosis score, lung function, six-minute walk test and the St. George respiratory questionnaire. Patients with UIP will continue to be evaluated over a period of up to 18 months.

Because of the positive impact seen in the preliminary studies, the FDA has issued Breakthrough Therapy Designation for nintedanib. With the present study having

completed full enrollment, the Baylor Dallas program is expecting participation in the extension trial.

Baylor Dallas also will participate in the extension studies on pirenidone, an oral antifibrotic therapy, which also showed some benefit in slowing the decline of lung function in this disease. This data was also published in the *New England Journal of Medicine* in May.

"The data that was presented at the American Thoracic Society international conference in May and recently published in the *New England Journal* showed a positive benefit on the primary outcomes with both drugs," said Randall L. Rosenblatt, MD, MACP, FACCP, medical director of lung transplantation and chief of pulmonary and critical care at Baylor Dallas. "This is exciting because for the first time we have drugs that may have an impact on the disease. While not curative, they do seem to slow the deterioration."

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. 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.

#### **Quick Facts**

- In June 2013, Baylor Dallas formed a new lung transplant surgical team.
- Baylor Dallas performed 29 lung transplants in 2013 and 31 year to date in 2014, compared with 16 lung transplants in 2012.
- Dedicated nurses are on call 24/7 for the management of advanced lung disease patients.



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Randall L. Rosenblatt, MD, MACP, FACCP

## **Kidney/Pancreas Transplant Patients Face Short Wait Times with Positive Outcomes**

At Baylor University Medical Center at Dallas and Baylor All Saints Medical Center at Fort Worth, patients on the list for a simultaneous kidney/pancreas transplant wait on average no longer than three months. This data, which was analyzed over a five-year period, contrasts sharply with the wait times at other centers in Dallas/Fort Worth and Texas, which range from 7.1 months to 62 months.

In addition, recently released data from the Scientific Registry of Transplant Recipients showed Baylor had 100 percent patient, kidney and pancreas graft survival over the past two and half years.

"For patients with a PRA of 0, the median wait time from listing to transplant was 81 days. For patients with a PRA greater than 0, the wait was 104 days," said Richard Ruiz, MD, surgical director of pancreas transplantation and a transplant surgeon on the medical staff at Baylor Dallas. "We can offer a definite advantage for patients seeking a kidney/pancreas transplant."

PRA, or panel reactive antibodies, is a measure of how sensitized a patient is, which affects the possibility of matching with a donor organ. A higher PRA increases the likelihood that a patient may not match. A patient may become sensitized as a result of a previous transplant, blood transfusion or pregnancy.

Simultaneous kidney-pancreas transplants are performed for patients with either Type 1 or Type 2 diabetes who qualify. The dual transplant functions better than a kidney alone, because the new pancreas protects the transplanted kidney from the harmful effects of diabetes. As a result, the new kidney performs better and longer in the kidney/pancreas transplant recipient. Many kidney/pancreas transplant recipients are free of diabetes years after their transplant. Combined kidney/pancreas recipients also report a higher quality of life than kidney-alone patients.

"Because our wait list is short, we can get a patient transplanted as quickly as possible," Dr. Ruiz said. "On a few occasions, a patient was listed for less than a week when he or she was called in for transplant."



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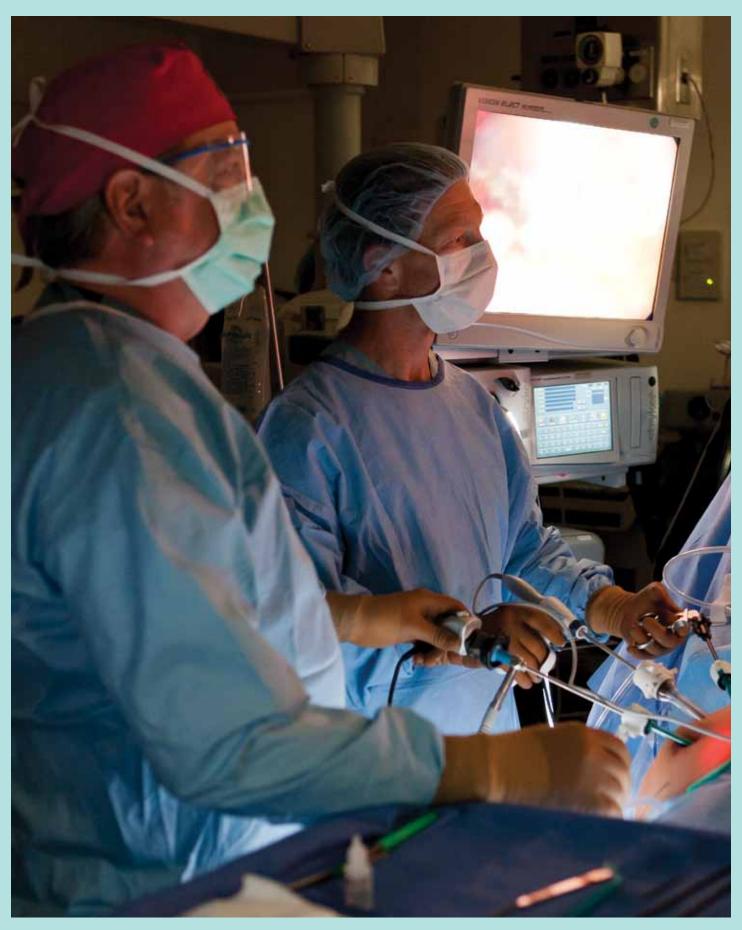
- With 3,909 kidney transplants performed, our kidney and kidney/ pancreas program is one of the largest in Texas.\*
- According to the Scientific Registry of Transplant Recipients (SRTR) one-year survival rates, survival rates for Baylor kidney recipients exceed the national average.

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

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Richard Ruiz, MD



Baylor All Saints Medical Center at Fort Worth recently completed its 1,000th kidney transplant, one of only 10 transplant centers to reach this milestone. When combined with Baylor University Medical Center at Dallas, more than 3,909 transplants have been performed.



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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 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.



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