

## Blood test enables heart-transplant recipients to undergo fewer biopsies, study shows

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After his heart transplant in 2005, Ramon Llenado underwent a biopsy every week, then every month, then every three months. Most heart transplant patients face a lifetime of these invasive tests, which involve snipping out tiny pieces of heart to check for possible organ rejection.

"Doctors thread this little wire through your neck all the way to your heart," said Llenado, of Walnut Creek, Calif. "It's not so much painful as it is nerve-wracking."

But for the past two years, Llenado, 63, hasn't had any biopsies at all. As a participant in a randomized clinical trial at the Stanford University School of Medicine, his doctors have been using a relatively new blood test to determine his risk for rejection. As long as Llenado passes the blood test, he skips the routine biopsy.

In what could represent a major shift in the management of heart transplant patients, a multicenter Stanford-led study to be published online April 22 in the [New England Journal of Medicine](#) shows that doctors can safely decrease the number of biopsies performed on heart transplant patients by using a commercially available blood test along with an echocardiogram to identify patients at low risk for rejecting their transplanted hearts.

"This study demonstrates that, instead of a shotgun approach in which we biopsy all patients at arbitrary intervals, we can now limit use of the heart biopsy to patients who are at highest risk for rejection," said

Michael Pham, MD, MPH, clinical assistant professor of cardiovascular medicine at Stanford and the study's first author. "This practice is in line with what our colleagues in kidney and [liver transplantation](#) already do, but cardiologists have not had a reliable blood test until now to categorize the risk for our heart transplant recipients."

The study, which was conducted at 13 U.S. heart transplant centers, including Stanford University Medical Center and the Palo Alto Veterans Affairs Health Care System, followed 602 patients for a period of two years. All participants included in the study were in stable health and had received their transplanted hearts in the previous six months to five years. Researchers randomly assigned each patient to either the routine biopsy treatment plan, a method that has been the standard of care for heart transplant patients, or to the blood test in addition to clinical and echocardiogram assessment.

The concept for the trial began with senior author Hannah Valentine, MD, professor of cardiovascular medicine, who designed the study to determine whether it was safe to reduce the number of necessary biopsies by using the blood test.

"I've been really passionate over the last 25 years of my career in coming up with non-invasive markers for acute rejection," said Valentine. "I did a quality-of-life survey that showed patients are terrified of having heart biopsies. They're anxious for weeks before. They hate it."

The blood test, which uses genomics technology to present a snapshot of the immune status of the transplanted heart patient, is currently offered at 65 transplant centers in the United States. The U.S. Food and Drug Administration cleared the use of the test in heart transplant recipients in August 2008.

The study was funded by XDx Inc., a molecular diagnostics company in

Brisbane, Calif., that makes the AlloMap blood test used in the study. Stanford University owns equity in XDx. Both Pham and Valentine reported receiving grant support from the company. Valentine also reported serving on one of the company's advisory board meetings.

Routine biopsies to screen for rejection episodes have been part of the post-surgical treatment plan for heart transplant patients since 1973. In the early days of heart transplants, surgeons struggled with a high rate of post-surgical deaths due to rejection.

"When the biopsy was first introduced, it allowed transplant physicians to detect rejection and intervene before the heart's function was compromised," said Pham. Successful detection and treatment of early stage rejection, in turn, significantly improved survival rates.

About 30 percent of all heart transplant patients experience a rejection episode at least once in the first year following transplantation. When the biopsies reveal the onset of organ rejection, doctors then know to adjust the patient's immunosuppressive drug regimen, often saving their lives.

A heart biopsy involves inserting a catheter through a vein in the neck, then carefully threading it into the heart. Tiny pieces of tissue are clipped from the heart, then examined under a microscope for signs that the immune system is rejecting the new heart.

The risk of complications from heart biopsies is slight, less than 1 percent. But those complications are potentially life-threatening and can cause irreversible heart-valve damage.

This is one of the few "comparative-effectiveness" studies, in which two or more treatment methods are assessed head-to-head, involving heart transplant patients, said Valentine. These types of studies are difficult to conduct among [heart transplant](#) recipients because of the limited

numbers of patients available for clinical trials. "Comparative-effectiveness studies of this kind have become a national priority, because they are essential for determining whether clinical treatments or diagnostics really work and provide patients with the best care possible," she said.

According to the study's results, patients monitored with the non-invasive blood tests, as compared with those who underwent routine biopsies, had similar two-year rates of rejection, graft dysfunction, death or re-transplantation (14.5 percent vs. 15.3 percent). The number of biopsies needed in the blood test group was reduced by 73 percent, and a patient satisfaction survey showed that patients preferred the blood test approach to the biopsy.

Researchers are also conducting a cost analysis comparing the two procedures, Pham said, but the results are not yet available. The [blood test](#) costs \$3,000, while costs for a heart biopsy average around \$4,000.

Provided by Stanford University Medical Center

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