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Heart | TRANSPLANT UPDATE

INSIDE:

Could—or Should—Amyloidosis Patients Get a Heart Transplant?

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Baylor University Medical Center at Dallas
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HEART

Could—or Should—Amyloidosis Patients Get a Heart Transplant?

For many patients diagnosed with cardiac amyloidosis (or protein buildup in the heart), treatment options can be limited. But in the past decade, advancements in transplant cardiology have bridged that gap—giving select patients a new beating heart, and with it, a fighting chance for survival.

Those advancements are thanks in large part to the cardiologists on the medical staff of Baylor University Medical Center, part of Baylor Scott & White Health. As part of the institute's amyloidosis capabilities, cardiologists have helped increase awareness about the approaches to the disease and the different therapeutic options that exist for this population of patients who for years had little choice beyond palliative care.

Now, as clinical research in transplant cardiology grows, physicians have access to compelling data and outcomes showing its potential for cardiac amyloidosis.

Making the Case for Transplantation

One such study, coauthored by Parag Kale, MD, medical director of the Amyloidosis Program and cardiologist on the medical staff at Baylor Dallas, in the *American Journal of Transplantation*, found that nearly 90 percent of select amyloidosis patients survived more than a year after receiving a transplanted heart. After three years post-transplant, Dr. Kale posits, the rate could be more than 80 percent. When compared to the average survival for amyloidosis patients without a heart transplant—anywhere from six months to four years—the data makes a good case for transplantation, but only for a very select group of patients.

"There has always been a case-by-case approach for transplantation in patients with cardiac amyloidosis who have symptoms of heart failure," Dr. Kale said. "Ideally, a transplant candidate would have no other organs affected by protein deposits beyond the heart, and they'd also have stable renal and gastrointestinal functions, among many other factors."

Of those other factors, age plays a large role.

"We typically don't consider transplant for patients over 70 to 72, unless they're physically robust and able to withstand major surgery," he said.

"But what matters most is the disease state," Dr. Kale added. "Unfortunately, amyloidosis is usually diagnosed at more advanced stages, when the patients have become too sick for transplant. For them, transplantation is too great a risk."

Early Detection for Broader Treatment Options

Luckily, imaging technology has evolved over the past decade, helping diagnose cases in earlier—and more

Ruling Out Amyloidosis

Typically male patients, age 50 or older, persistently experiencing any of the below signs and symptoms:

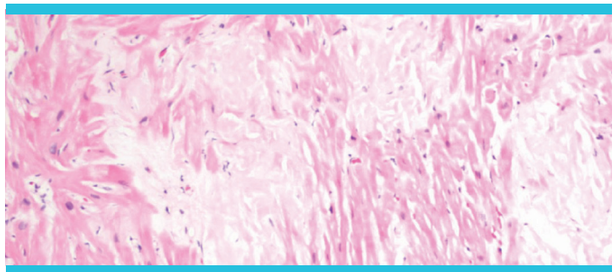
- High levels of urine protein
- Discoloration of the skin
- Tingling and numbness in legs and feet
- Loss of balance
- Experiencing chronic inflammatory disease such as lupus, rheumatoid arthritis and inflammatory bowel disease
- Signs of heart failure, including swelling of the feet and ankles, weakness, fatigue and nausea

NEWS

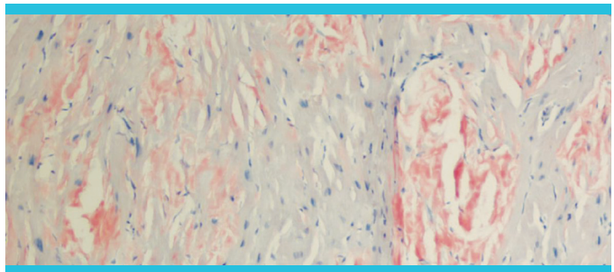
New Study to Expand Access Protocol of Patisiran for Patients With Hereditary ATTR Amyloidosis

The purpose of this study is to provide expanded access to patisiran, an investigational medicine not yet approved by the Food and Drug Administration (FDA), for use outside of a clinical trial to treat patients with a serious disease who have no comparable or satisfactory alternative treatment options. Patients who qualify and are interested may have access to treatment with patisiran through this program for a potential duration of up to four years, or until it becomes commercially available in the U.S.

For inclusion and exclusion criteria or more information, visit BSWHealth.com/Amyloidosis.



Cardiac muscle at 200x magnification. Amyloid is the pink hyaline material infiltrating muscle, separating muscle bundles.



Congo Red special stain at 200x magnification. Amyloid is demonstrated by the salmon pink material infiltrating muscle, separating the pale blue muscle bundles.

manageable—stages when transplantation offers the biggest benefit. But even with transplant's rising involvement in amyloidosis, the surgery is rarely a first choice.

Rather, specialists consider the procedure only after other efforts—namely medication adjustments for pain, fluid retention and heart rate—show little progress.

Multispecialty Collaboration

All of that considered, if a patient passes those initial filters, they might be a transplant candidate. At that point, a multispecialty collaboration takes place to further assess their eligibility for surgery.

"It's truly a partnership between several disciplines here at the Baylor Annette C. and Harold C. Simmons Transplant Institute," Dr. Kale said. "We work closely with our onsite teams in hepatology, oncology, pathology, nephrology and gastroenterology for testing, including biopsies and analyses. Basically, we want to ensure that the patient's underlying disease can be controlled after transplant, and that they'll have a better chance for survival."

Some amyloid cases call for a multi-organ transplantation plan, such as when patients need a combination of heart and liver transplants, or a heart and bone marrow transplant.

An Industry Uptick

Transplantation's rising involvement in amyloidosis is thanks to increased industry attention to the diagnosis, and extreme vetting of transplantation (and other treatments) as a therapeutic option.

"We've seen amyloidosis go from being an obscurity to something that's increasingly recognized by the heart failure community—and cardiologists in general," Dr. Kale said. "I'm encouraged by the clinical interest in this disease, and by the opportunity to draw attention to the fact that simple changes in medications—as well as early consideration for transplant—could improve outcomes greatly."

PARAG KALE, MD

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There is ongoing research in developing molecules for the treatment of ATTR type amyloidosis. In addition, the chemotherapy has evolved for the treatment of AL amyloidosis with more effective regimens and improved outcomes.

An Exciting Era of Transplantation

Especially, he added, when you consider the promising long-term outcomes of heart transplant in general: Between 50 and 60 percent of recipients survive the 10-year mark.

"We're in an exciting era of transplantation, one where we can offer heart transplant to patients who only recently (over the past 10 years or so) haven't had access to it, amyloidosis included," Dr. Kale said.

Throughout his tenure at Baylor Annette C. and Harold C. Simmons Transplant Institute, he's seen the benefits first-hand. Amyloidosis survivors, now with new hearts, meet regularly at the Institute's patient-run amyloidosis support group.

"They invite speakers, get together and share a common bond with each other," Dr. Kale said. "That kind of rapport—that kind of community—just wouldn't exist without the kind of advancements now available to them. It makes every day worth it." ■

CONTACT

For information regarding treatment options for amyloidosis, or for a specialist referral for amyloidosis management, please call 214.820.6856.

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