PATIENT PROFILE

James Willingham

Vascular Access—A Major Component To Treating Kidney Failure with Hemodialysis

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To listen to the lilt and laughter in James Willingham's voice one would be hard-pressed to believe that this 66-year-old was diagnosed with kidney failure, referred to as end-stage renal disease (ESRD), 5 years ago while in the hospital for congestive heart failure and cardiac asthma, and that he has been undergoing hemodialysis treatments three times a week ever since.

"I was in the hospital being treated for my heart and asthma conditions when they checked my kidneys and found that they were functioning at only 10 to 15 percent of normal. They immediately put me on dialysis," says James. Dialysis is a treatment for kidney failure; the dialysis machine cleanses the blood—a vital process that would normally be done by working kidneys. Patients with ESRD need either dialysis or a kidney transplant to live.

A couple of months after his ESRD diagnosis, James was asked if he would like to take part in one of the clinical studies being conducted by the Dialysis Access Consortium, or DAC, sponsored by the NIDDK. The DAC Study was testing the impact of anti-clotting reagents in preventing early failure in "vascular access," which is required for dialysis. A vascular access is the site on the body where blood is removed and returned during dialysis treatments.

James responded in the affirmative. "I figured that even if I couldn't help myself, maybe I could help someone else" as a result of participating in the study.

"I have my good days and bad," says James, "but if I exercise a bit, and don't go overboard with what I eat and drink, I can live a pretty good life on dialysis."

Family History

According to James, there's been a long history of high blood pressure and type 2 diabetes in his family. Yet, none of his four siblings has ESRD. However, three of his first cousins, the children of his mother's sister, are on dialysis as well.

James has known that he's had high blood pressure since his high school days. He's not sure exactly when, but later in life he was also diagnosed with type 2 diabetes. "When I was young I never took it seriously, never treated it," he says. But by around age 50, it caught up with him, eventually resulting in his kidney failure. He began taking steps to improve his health.

He no longer needs to take insulin for his diabetes. "I control it mostly by diet," he says. He also walks 2 to 3 miles a week.

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Dialysis and the Importance of Good Vascular Access

When renal failure occurs, the kidneys lose their capacity to remove bodily waste from the blood. Hemodialysis is a method for removing waste products such as urea and creatinine, as well as extra water from the blood when the kidneys are no longer functioning properly.

An important first step before starting regular hemodialysis sessions is preparing a vascular access on the body that will be used at each dialysis session for inserting a needle and tubing, through which blood is circulated out of the body, to the dialysis machine for cleansing, and then back into the body. The vascular access site is usually placed in the forearm or the upper arm. To maximize the amount of blood cleansed during hemodialysis treatments, the vascular access should allow continuous high volumes of blood flow. For easier and more efficient removal and replacement of blood with fewer complications, the access should be prepared weeks or months before dialysis is required.

Because James' kidney disease was diagnosed at such a late stage, he needed dialysis immediately. Consequently, physicians temporarily outfitted him with a traditional catheter in his chest. Catheters are not ideal for permanent vascular access because they can clog, become infected, and cause narrowing of the veins in which they are placed. But if hemodialysis needs to start quickly, as it did in James' case, a catheter will work for several weeks or even months while a more permanent, surgically created access has time to develop. In this situation the catheter was left in James' chest for an entire year, as no infections or any other complications developed.

Types of Vascular Access

In addition to traditional catheters, which are recommended only for temporary use, the two other types of vascular access are arteriovenous fistulas (AV fistulas) and arteriovenous grafts (AV grafts).

A properly functioning AV fistula is considered the best long-term vascular access for hemodialysis because it provides adequate blood flow, lasts a long time, and has a lower complication rate than other types of access. A fistula is an opening or connection between any two parts of the body that are usually separate—for example, a hole in the tissue that normally separates the bladder from the bowel. While most kinds of fistulas are a problem, an AV fistula is useful for hemodialysis patients because it causes the vein to grow larger and stronger for easy access to the blood system.

A surgeon creates an AV fistula by connecting an artery directly to a vein. Usually placed in the forearm, the vein of a new AV fistula will grow thicker after 3-6 months so that it can take repeated needle insertions and allow blood to flow quickly to the dialyzer. Once AV fistulas are working well for dialysis treatments, they tend to last longer than other types of dialysis access like catheters and AV grafts. A good fistula can function up to 10 years or longer.

Because James has smaller, weaker veins that wouldn't develop properly into a fistula, he was given an AV graft, a vascular access that connects an artery to a vein using a synthetic tube, or graft, implanted under the skin in his arm. The graft becomes an artificial vein that can be used repeatedly for needle placement and blood access during hemodialysis. A graft doesn't need to develop as a fistula does, so it can be used sooner after placement, often within 2 to 3 weeks.

Compared with properly formed fistulas, however, grafts tend to have more problems with clotting and infection and need replacement sooner. However, a well-cared-for graft can function for several years. Fortunately, that was James' case.

The Dialysis Access Consortium (DAC) Study

The NIDDK established the Dialysis Access Consortium, which consists of seven primary clinical centers and a data coordinating center, to undertake interventional clinical trials to improve outcomes in dialysis patients who received either a fistula or a graft.

Two randomized placebo-controlled clinical trials were designed. The first trial evaluated the effects of the antiplatelet agent clopidogrel (Plavix®) on prevention of early AV fistula failure. The AV fistula trial ended in 2007 and revealed that clopidogrel did not improve the likelihood that an AV fistula would develop into a useable fistula for dialysis. The second clinical trial, which James participated in, focused on AV grafts for dialysis access. The AV graft trial studied a drug that combines dipyridamole with aspirin, and had the goal of preventing the narrowing of the vascular access in hemodialysis patients with grafts.

James, who says he is grateful for having been able to take part in the study, took his medication every day, twice a day; once in the morning and once in the evening, and reports having had no complications with his graft.

"The study was a very good experience for me," James says. "I had help monitoring the graft to make sure it was open and that my blood pressure was good. And my outpatient dialysis nurse was terrific. She took very good care of me, talked with me and told me how I was doing every step of the way." He says he did his part by keeping the graft clean and not picking up heavy objects with the grafted arm.

Dialysis is not the most pleasant of processes. "I've been on dialysis every Monday, Wednesday, and Friday morning for 5 years now, and each session lasts about 4 hours. That's a long time to sit in that chair. And it's very painful. It's a 16-gauge needle, about the size of a plastic coffee stirrer that they stick in you. And you don't want the needle to come out or you have a problem." So to be able to maintain a free-flowing, uninfected vascular access without complications is a real plus for patients like James.

The AV graft trial that James was in ended early in 2008, and the results will soon be made public. From James' perspective, he believes in the process. "It is studies like these that help people like me," he says, with that lively, friendly tone in his voice that he employs so well.

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Hope through Further Research

To improve the quality of life of patients with end-stage renal disease, the NIDDK currently supports additional clinical and basic science research efforts. For example, the Frequent Hemodialysis Network is conducting two clinical trials: the Daily Trial is comparing conventional hemodialysis (2.5 hours, 3 days per week) to more frequent hemodialysis (1.5 - 2.75 hours, 6 days a week) and the Nocturnal Trial is comparing home conventional hemodialysis delivered 3 days per week to nocturnal home hemodialysis given 6 times per week. Another example of NIDDK-supported efforts for patients with ESRD is a new consortium that will pursue studies to understand the high rate of AV fistula failure seen in many patients that have an AV fistula placed for dialysis access.

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The NIDDK is also supporting the Chronic Renal Insufficiency Cohort (CRIC) to better understand how chronic kidney disease progresses to ESRD. Another effort supported by NIDDK is the Animal Models of Diabetic Complications Consortium, which has the goal of improving or creating animal models of human diabetes complications, including diabetic kidney disease. Diabetic kidney disease is currently the leading cause of ESRD in the U.S. The animal models will help scientists to elucidate the causes of kidney disease and develop prevention and treatment approaches. Finally, the NIDDK distributes science-based information on dialysis and other aspects of kidney disease to patients, health care providers, and the general public through its National Kidney and Urologic Diseases Information Clearinghouse (*http://kidney.niddk.nih.gov/*) and its National Kidney Disease Education Program (*http://nkdep.nih.gov*).

The Dialysis Access Consortium Arteriovenous Graft study was carried out at seven NIDDK-funded research sites: Boston University (Dr. Laura Dember); Duke University (Dr. Arthur Greenberg); the University of Iowa (Dr. Bradley Dixon); the University of Maine (Dr. Jonathan Himmelfarb); the University of Texas, Southwestern (Dr. Miguel Vazquez); the University of Alabama (Dr. Michael Allon); and Washington University in St. Louis (Dr. James Delmez). The Data Coordinating Center was located at the Cleveland Clinic (Dr. Gerald Beck). Three satellite sites were supported by NIDDK and five satellite sites were supported by industry.