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Defeating diabetes: Islet cell transplants are proving to be a 'functional cure' for some

Tuesday, October 25, 2005 *By Vickie Snow, Staff writer*

Kim Menard once fainted at O'Hare International Airport and regained consciousness in an ambulance.

It happened at home, too.

"My husband saved me many times, because I wouldn't wake up in the night," she said.

The episodes stemmed from out-of-whack blood sugar levels that fluctuate without warning or symptoms, a condition called hypoglycemic unawareness that's caused by diabetes.

For Menard, who was diagnosed with type 1 diabetes at age 13, it was yet another issue to deal with in addition to having to prick her finger a dozen times a day and avoiding too much physical activity.

That is, until September. Menard, 46, had an experimental transplant in Chicago that, just eight days later, eliminated the need for insulin injections. Now, she's embracing life without needles and unconsciousness.

"I have never felt better in my life," she said. "And I don't need a baby sitter anymore."

Since January, Menard and seven others have undergone transplants at the University of Illinois Medical Center at Chicago. The minimally invasive procedure replaces defective cells with insulin-producing cells, called islet cells, from donor pancreases.

Worldwide, some 500 transplants have been performed.

Menard and the other patients will be scrutinized for several years to study long-term insulin production and detrimental side effects, but early results are promising.

"I would call it a functional cure," said Dr. Jose Oberholzer, a pioneer in islet cell transplants and the hospital's director of cell and pancreas transplants. "We haven't cured the cause, why the body destroys the cells. But, for the patient who had diabetes and doesn't anymore, it's a cure."

As expected, each patient responded differently. Some still need insulin, but others, such as Menard, do not.

"It has cured me," said Menard, who plans to celebrate with a vacation to Aruba. "Now, I can travel alone, which I never could do before because of low blood sugar. I'll be able to do more physical activity without having to stop to test my blood sugar."

She's hoping the study — and others like it around the world — will help the 3 million Americans with type 1, or juvenile onset, diabetes. It's an autoimmune disease in which cells in the pancreas that produce insulin are destroyed. Insulin is a hormone that helps the body use blood sugar or glucose for energy.

Islet cell transplants have been the focus of research for decades, with major breakthroughs over the past five years.

"Progress up to 2000 was slow and painful," said Brian Flanagan, acting program director of islet biology and transplantation at the Juvenile Diabetes Research Foundation. The New York-based group monitors international research and funds much of it.

Oberholzer is one of the experts who developed the islet cell transplant, called the Edmonton Protocol. He leads a consortium that includes the University of Chicago Hospitals and Northwestern University School of Medicine.

A transplant begins with the patient awake but numb from local anesthesia. A small incision is made in the abdomen. A radiologist uses ultrasound to guide placement of a catheter into the main blood vessel in the liver. Islet cells are then injected through the catheter.

The procedure takes an hour or two. The patient stays in the hospital for 12 hours.

Usually, two or three additional transplants are needed before a patient can stop injecting insulin, Flanagan said.

Following the procedure, immunosuppressant drugs are prescribed to prevent the immune system from attacking the islets.

Each patient's recovery is different. Menard said she didn't need insulin just eight days after the procedure.

"It's amazing to me the change it's made in my life in just a few days," she said.

Not every diabetic is a candidate for islet cell transplant, and there are risks involved.

"We don't sell this like a piece of cake," Oberholzer said. "Ethically, we must choose patients who suffer the worst. If we didn't have limitations, everyone with diabetes would be a candidate."

Candidates for a transplant are patients such as Menard, who can't feel when blood sugar levels are dangerously low.

"Normally, a person feels that" and can eat something to make them feel better, Oberholzer said. "But these people wake up and don't remember how they got there."

Uncontrolled levels can lead to a shutdown of brain activity, a coma-like state or death.

For some, an insulin pump will alleviate only part of the problem and not make a big difference in quality of life.

Desperate cases can require a pancreas transplant, which has risks.

People with chronic pancreatitis, not diabetes, often need to have their pancreas removed. The subsequent lack of insulin leads to surgical diabetes. Before that occurs, however, the islet cells from the pancreas can be injected into a patient's liver to prevent diabetes.

When it comes to an islet cell transplant, the benefits must be weighed against the risk of side effects from the anti-rejection drugs, including a slight risk of infection and cancer.

One of three Americans will have cancer in their lifetime, Oberholzer said, and the risk with transplant is only 1 percent to 2 percent more.

Another risk is blood clots, which can occur in the portal vein but can be prevented with medication.

Complications usually do not arise for two to three years after transplant, Flanagan said.

"There are quite a number of complications and adverse events," which may include slight bleeding or the flu, he said. A partial clinical registry reports such events at 18 of 19 transplant facilities around the world.

Sometimes, a patient's health is so poor that a transplant and side effects would be an improvement worth the risk.

"It's a difference between fainting at the wheel or getting into the car and knowing you'll be OK," Flanagan said.

More patients will need to be studied for several years to see a long-term impact on quality of life.

"It's too early to tell," Flanagan said, "but I can envision that it will have."

In addition to keeping tabs on Menard and seven other patients, Oberholzer and his team at the University of Illinois Medical Center at Chicago are looking for people to participate in phase two of the trial. The two-year study involves 50 patients and will begin early next year.

"Hopefully, we'll have sufficient proof to make the transition from experimental study to standard medical care," Oberholzer said.

The biggest obstacle in islet cell transplants is the lack of organ donors. There are only about 6,000 donors; about 18 million people have diabetes.

Because islet cells make up only 1 percent of pancreatic tissue, each transplant uses two or three pancreases. Furthermore, not every organ is in condition suitable for use.

The heavier the patient, the more islet cells necessary.

If more donor organs were available, people with type 2, or adult onset, diabetes could have transplants, too.

To combat the shortage, researchers have used insulin from pigs, but human tissue can reject it. Someday, stem cell research may contribute to islet cell availability.

Menard knows she's part of a long-term study. She knows that someday she may have to inject insulin again. And that's just fine with her.

"It gives me hope," she said. "I don't know if it'll last, but I want people to know about it."

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