Clinical trial of world’s smallest pacemaker among many recent ‘firsts’ for Providence

By John Rumler
For The Scribe

Bill Pike knew that Providence St. Vincent Medical Center’s Heart and Vascular Institute was the Northwest’s only medical center investigating the world’s smallest pacemaker, and he wasn’t the least bit nervous about becoming the first patient participating in its clinical trials.

The institute is gaining a national reputation for excellence in cardiac care research and is the regional leader in heart-related clinical trials. In August 2014 David Underriner, chief executive for Providence in Oregon, announced that the institute received a $25 million donation from Nike Inc. founder Phil Knight and his wife, Penny.

Atrial Fibrillation

Pike, 76, was due to get a cardiac pacemaker, and after finding out about the unique opportunity from his heart specialist, Randy Jones, MD, he eagerly signed on.

The Medtronic Micra Transcatheter Pacing System, also known as “the Micra,” is one-tenth the size of traditional pacemakers. It is shaped like, and about the same size as, a large vitamin. It takes just 20 to 25 minutes to implant the device.

“Because of its small size, this pacemaker can be implanted into the patient without any surgical incisions in the chest,” said Jones, an electrophysiologist with Providence Heart and Vascular Institute. “This less invasive process may lead to faster recovery times, and the fact that this technology is totally wireless reduces the chances of device-related complications.”

The device is inserted via catheter into a vein in the patient’s leg, as a point of entry, and then is advanced to the heart. Once the Micra is in place, small tines are used to attach it to the heart wall. The Micra then delivers electrical impulses through a tiny electrode, which stimulates the heart to beat at a normal rhythm.

Although pacemakers were introduced in the mid-1960s and quickly became widely used, they have remained basically unchanged for decades, Jones said, and the Micra device is considered to be the biggest innovation in 50 years.

The pacemaker’s only contraindication is with people who are morbidly obese, and the cost is just $1,000 more than standard pacemakers. The lone problem so far is that the Micra pacemaker and implanting procedure is so new, there aren’t any insurance billing codes for it.

Pike, a retired mechanical engineer, said the procedure was pain free. “I felt wonderful. I could have probably gone home afterward, but I stayed overnight because it was a clinical trial.” Pike said he was amazed the tiny battery can last so long (up to 10 years) and he is enjoying sending his cell-phone pictures of the tiny Micra to friends and relatives.

Providence Heart and Vascular Institute, which has a team of 80 physicians, is one of 35 centers across the U.S. participating in the Micra clinical trial.

“The trial of the Micra is the latest in an exciting year of technological advances that are helping change the way we treat patients,” said Dan Oseran, MD, medical director, Providence Heart and Vascular Institute.

In addition to introducing the Micra to the region, Providence Heart and Vascular Institute has several other “firsts” in 2014. In November, Providence St. Vincent interventional cardiologists became the first in the Northwest to use the Lutonix drug-coated balloon catheter as minimally invasive therapy for peripheral artery disease, which affects about 8 million people in the nation.

The angioplasty balloon, which is coated with a therapeutic dose of the drug paclitaxel, is the first and so far only FDA-approved drug-coated balloon (DCB) in the nation, and has been used successfully since 2012 in Europe.

The procedure, an alternative to traditional bypass surgery, is expected to become the standard in a few years, said Ethan Korngold, MD, medical director of research at Providence Heart and Vascular Institute.

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