Study finds lasting, reliable performance for wireless pacemaker

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A dual-chamber wireless pacemaker provides reliable performance over three months, bolstering evidence for this new pacemaker option, according to results from a multi-center, international clinical trial co-led

by a Weill Cornell Medicine and NewYork-Presbyterian investigator.

The results, published July 8 in *Circulation*, showed that the two tiny pieces of this wireless pacemaker system reliably communicate, achieving the goal of synchronizing contraction of the upper and lower heart chambers 98% of the time. The research team, including Dr. James Ip, professor of clinical medicine at Weill Cornell Medicine and a cardiac electrophysiologist at NewYork-Presbyterian/Weill Cornell Medical Center, also found that the device continued to work well when patients engaged in various activities or when their heart rates were elevated.

"We've entered a new era of pacing," Dr. Ip said. "We are not limited to the wired devices we've been using for more than 60 years. We now have new technology and methods to help patients and reduce complications."

Pacemakers deliver an electrical signal to regulate the heartbeat in people with slow heart rhythms. A traditional pacemaker is implanted under the skin in the chest and has wires (leads) threaded through veins to the heart. However, the devices can lead to potential complications.

"The wire is the Achilles heel of the pacemaker," Dr. Ip said. "If you bend it enough times, it can break. While wired pacemakers have been the standard-of-care for reliable pacing for years, the technology can be improved."

If the wire breaks, physicians must remove it, which can be difficult if significant scar tissue has formed around it over time. Additionally, bacteria may attach to the wire, leading to potentially severe bloodstream infections. People who frequently engage in activities that involve a lot of arm movement may be particularly at risk of wires breaking.

Individuals who are thinner or have thinner skin may be at risk of having the device itself erode through the skin. Patients with blocked vessels, compromised immune systems, or who are on dialysis or are at elevated risk for infection may also not be good candidates for wired pacemakers.

About ten years ago, new wireless pacemakers became available that can stimulate the heart's lower chamber, called the ventricle, providing an alternative to wired pacemakers for patients with some types of heart rhythm problems. The tiny devices are threaded through a blood vessel in the groin to the heart and screwed in place, a procedure that is less invasive than the implantation of wired devices.

In May 2023, a clinical trial published in the *New England Journal of Medicine*, co-authored by Dr. Ip, demonstrated the safety and effectiveness of a wireless pacemaker implanted in the heart's upper chamber, the atrium, that can stimulate both the upper and lower chambers.

The study took place at 55 sites across the United States, Canada, and Europe, including NewYork-Presbyterian/Weill Cornell Medical Center and NewYork-Presbyterian/Columbia University Irving Medical Center. In July 2023, the U.S. Food and Drug Administration (FDA) approved the device based on the study's results, making the option of a wireless pacemaker available to patients with a broader range of heart rhythm problems.

The new study builds on those results by providing longer-term data on how reliably the dual chamber stimulating device performs in various circumstances, such as when patients are engaged in activity that raises their heart rate or when they change positions like standing up or lying down. During a follow-up visit 3 months post-implantation, study investigators asked 384 patients who participated in the initial clinical trial to wear an external heart monitor to assess the device's performance

while they completed various activities.

"We have proven that the two separate pieces of the new pacemaker system communicate with each other very well even when people change positions, engage in activities, or when their heart rates rise," Dr. Ip said. "Also, the device actually performs better than how it tells you it is functioning."

As a result, Dr. Ip said clinicians should be able to rely on the devices' recordings rather than ask patients to wear a cumbersome heart monitor to assess the devices' performance. He cautioned that the devices are still first-generation and have a few disadvantages.

For example, their small batteries may not last as long as the larger ones in traditional wired pacemakers. But he expects leadless pacemakers will continue to get better as the technology improves. In the meantime, he and his colleagues will continue to evaluate the devices' performance and said they offer patients a valuable option.

"I've been involved in researching and implanting wireless pacemakers for over a decade, starting with animal studies, then clinical trials in humans, and now after FDA approval," Dr. Ip said. "It is very gratifying to see how the technology has evolved over time and how these devices genuinely help people."

More information: James E. Ip et al, Atrioventricular Synchrony Delivered by a Dual-Chamber Leadless Pacemaker System, *Circulation* (2024). DOI: 10.1161/CIRCULATIONAHA.124.069006

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