



BIOTECH, DEVICES, STARTUPS

## Ardian Corrals Out-of-Control High Blood Pressure With First-of-its-Kind Device

Luke Timmerman 11/17/10

There are plenty of cheap and effective drugs out there for lowering high blood pressure. But [Ardian](#), a small device company in Mountain View, CA, is presenting some intriguing clinical trial results today that suggest it might have developed something that works when all else fails.

Ardian's treatment was tested in a study of 106 patients who had been taking an average of five different medications per day, and still had dangerously high blood pressure. The study showed the new treatment, in combination with standard drugs, was able to bring average blood pressure scores down from 178 over 97 to 146 over 85 after six months of follow-up, while those who just got standard treatments were essentially unchanged. The findings are being presented today at the American Heart Association's Scientific Sessions in Chicago, while being published simultaneously in a peer-reviewed medical journal, *The Lancet*.

These findings are a big step ahead for [Ardian](#), a private company founded in 2003 to pursue a novel catheter-based approach against high blood pressure that works a bit like angioplasty. The company has shown some signs that its approach has promise in small studies, but this is the first time it has shown such a big benefit in a placebo-controlled trial. High blood pressure is thought to affect more than [74 million](#) adults in the U.S., according to the American Heart Association, and an estimated one-fifth of them have what's called "[resistant hypertension](#)," which means either that the existing drugs don't work well enough, or they can't stick with the treatment schedule. So if the Ardian treatment can confirm this finding in one more larger trial, it could tap into a big potential market. The worldwide market for high blood pressure drugs is worth about \$30 billion, Ardian says.

"This is a big achievement," says [Murray Esler](#), the principal investigator of the trial and associate director of the Baker IDI Heart and Diabetes Institute of Melbourne, Australia. "This is a totally revolutionary mechanism for treating hypertension."

The Ardian treatment strategy is unlike usual pills like beta-blockers or ACE inhibitors that work to relax blood vessels. The Ardian treatment, which it calls the Symplicity Catheter System, is designed so that a physician can thread a catheter through the femoral artery in the thigh into the renal artery that feeds the kidney with blood. Once there, a tiny device emits radio-frequency waves to shut down overactive nerves surrounding the kidneys; these nerves have been implicated as culprits in patients with resistant hypertension. It's a one-time procedure that takes about 40 minutes, and is supposed to permanently reduce blood pressure, Elser says.

Some context is necessary to interpret the results properly. About 85 percent of patients experienced at least a 10 point drop in the systolic blood pressure score (the top number), which is a benchmark for success with blood pressure medicines, Esler says. About 39 percent of the patients on the Ardian treatment had their systolic scores drop to 140 or below—which is considered the goal, while 10 percent of patients didn't experience any drop. So the experience on the treatment varies among individuals. "There's no explanation for it," Esler says.

Researchers found no serious adverse events like cardiovascular complications or kidney damage, Esler says. Heading into the study, doctors were curious to see whether doing such a procedure might damage the kidney artery, cause a blood clot, he says. But the study is designed to follow patients for three years, so doctors will want to see how the effectiveness holds up over time, and see whether any complications emerge later on.

Still, the data being announced today is clearly important for Ardian's future as a business. The device is already cleared for sale in the European Union, and this latest batch of clinical results has encouraged the company to push ahead with a pivotal clinical trial that will be designed to help the company win FDA approval to start selling it in the U.S., CEO Andrew Cleeland says.

"This is a very important clinical event," Cleeland says.

Ardian now has data from 150 patients, some of whom have seen their blood pressure declines sustained for as long as two years, Cleeland says. Armed with that database, the company plans to consult with FDA about the next step, a 300-patient, placebo-controlled study that the company hopes to get underway before the end of March, he says.

The company, backed by medical device giant Medtronic, Morgenthaler Ventures, Advanced Technology Ventures, Split Rock Partners, and Emergent Medical Partners, is "well funded," Cleeland says.

Over time, Ardian hopes to test its treatment in high blood pressure patients who haven't failed all prior medications, which could open up a much broader market opportunity. Trials will have to be run that cost money and take time to prove that. But it's clearly part of the long-term vision. And Ardian is also hoping to extend its treatment to patients with heart failure, and chronic kidney disease, in which overactive nerves are thought to play a role as well.

"That's our dream," Cleeland says. "We want to help a lot of people."

*Luke Timmerman is the National Biotech Editor of Xconomy, and the Editor of Xconomy Seattle. You can e-mail him at [ltimmerman@xconomy.com](mailto:ltimmerman@xconomy.com), or follow him at [twitter.com/ldtimmerman](https://twitter.com/ldtimmerman)*