

# Stents don't benefit renal artery stenosis patients

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Dr. Lance Dworkin, professor of medicine at the Warren Alpert Medical School of Brown University and a physician at Lifespan and University Medicine, and Dr. Tim Murphy, professor of diagnostic imaging at the Alpert Medical School, and a physician at Lifespan and Rhode Island Medical Imaging, each played leading roles in the design, conduct, and data analysis of a major study of stents in treating renal artery stenosis. Dworkin, the study chair, and Murphy are senior and second authors of the paper in the *New England Journal of Medicine*.

Dworkin spoke with David Orenstein, Brown's science news officer, about the trial's results and what they mean for the future of [renal artery stenosis](#) treatment.

## What were you looking to find out?

The purpose of the study was to try to evaluate the utility of [renal artery](#) stenting in the treatment of [patients](#) with adverse sclerotic renal artery stenosis. This debate has been going on for a couple of decades. Starting in the 1980s there were reports of patients who, when they had the renal arteries opened, had dramatic improvements, sometimes improvements in kidney function, sometimes marked improvements in [blood pressure](#). Over the ensuing 20 years this became a very, very common procedure with tens of thousands of them being done in the United States. But there never was a clinical trial that showed this was beneficial. There were a few randomized clinical trials that were done up until about 2002,

and they were all basically negative. But the technology at the time was fairly primitive and people didn't accept the results.

It was in that context that we started planning this study in 1999. It was funded in 2004. One of the important things of the trial was that rather than look at surrogate end points like blood pressure or kidney function we wanted to look at hard clinical events: mortality, stroke, heart attacks, and progressive kidney disease.

Around 2010 there were two other negative studies but both of them looked at surrogate endpoints. Neither of them was powered to look at real patient outcomes. There were problems in the design of both of those trials, so a lot of people who were doing these procedures just rejected the results.

## **What did you find?**

Our study really provides a much more definitive answer to the question. It was a very rigorous trial in terms of the study design. There was absolutely no difference in outcome between patients who were stented vs. those who were treated medically alone. They are exactly the same, and the study was powered to detect a 25-percent difference. It's definitively negative because not only are the average event rates the same but the confidence intervals (ranges of possible values) are so narrow it really excludes the possibility of even a 25-percent difference. It's really pretty unequivocal that there is clearly no benefit in terms of these events.

## **How do you think these results will be received?**

I think it's going to dramatically reduce the number of these procedures that are done in the United States. We enrolled a population that is very

similar to patients who are commonly treated with this procedure. For patients that are otherwise stable, the medical intervention that we used is something that is readily translatable to clinical practice. To treat the blood pressure we used common drugs that are available as generics now. The patients were given vouchers so that they went to the pharmacy to get their medications. Using a regimen like that was equally effective in terms of preventing adverse events. It seems to me, that should be the standard of care for the majority of these patients. There may be occasional patients who fail medical therapy either because their blood pressure really can't be controlled or they have really rapidly progressive kidney failure, where you might still try to do something like this, but it really shouldn't be the tens of thousands of stable patients who are currently treated this way.

It's interesting to me what the Centers for Medicare and Medicaid Services will do. They currently cover this procedure, and a lot of the procedures are funded through Medicare. We'll have to wait and see what they do based on this new evidence but it's possible that they might limit coverage for this at least to certain clinical situations, if not eliminate it all together.

## **You found that stents successfully opened the arteries. Why didn't that help patients?**

Technically it is possible to do this procedure safely. You can open up the renal arteries most of the time. We used experienced operators who went through a brief training period before we allowed them to participate in the randomized trial. The complication rate from the procedure is very low. Despite that, there wasn't a benefit. I think one of the reasons is that the medical therapy has just gotten better. We now have drugs that can block the systems that are responsible for hypertension and adverse outcomes in these patients to the degree that

opening the renal artery just doesn't add very much.

## **So what is the prognosis today for people with renal artery stenosis?**

If you look at the outcomes in both groups or even just in the medical therapy alone group, they are pretty good. There were relatively few deaths. There were relatively few strokes and heart attacks. There were relatively few people who went on to end-stage renal failure. A majority of patients did well on the medical therapy despite the fact that these are elderly people often times with hypertension and chronic kidney disease. A high percentage of patients had diabetes. But despite that, they did relatively well with the [medical therapy](#).

We've come up with a medical regimen that's practical and very effective in these patients. That may be one of the most important outcomes from the trial. Besides just answering this question about whether the stenting is useful, we've sort of established what could become the standard medical approach to treating these patients. I'm very interested in that because that's something that's hardly been written about at all.

## **Tell us about the study team and the role of Brown, Lifespan, and your practice groups.**

We had a research team that came from multiple disciplines. We had nephrologists and hypertension specialists who take care of a lot of patients with hypertension but don't do procedures. We had interventional cardiologists and interventional radiologists who do the procedures, and some vascular surgeons. This was done at over 100 centers around the world. The majority of them were in the United States and Canada, but we also had sites in South America and Europe

and in Australia and New Zealand. So it was an effort of a lot of people from different backgrounds, all of whom whether they did these procedures or not, were really hoping to get a definitive answer about whether this is a useful process.

In terms of Brown's involvement, we were part of the administrative leadership of the study overall. I was the senior leader and study chair and chaired the steering committee and the operations committee which basically made all the decisions of the design and conduct of the trial. Dr. Tim Murphy was the co-PI for the study and a member of the operations group. He chaired the publications committee and also played a central role in both the design and implementation of the trial.

We were also one of the top enrolling centers in terms of entering patients into the trial. We also were one of the sites that enrolled the greatest percentage of minority patients. One of the goals of the study was to make sure that we had minorities sufficiently represented so the results would apply to them also.

We played a critical role in this study. It would never have been done without our participation. We were involved right from the beginning in the design of the trial and then all the way through its completion.

It was very carefully and well constructed study, about as good as you can do in this disease. Putting it together with all the previous trials that are also negative, I just don't think there is any question of whether there is any benefit to this procedure. It's relatively minor or close to nothing for the majority of patients with this disease.

Provided by Brown University

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