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Ultrasound Renal Denervation: Interdisciplinary Approach to Better Patient Outcomes

Announcer:
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Chapter 1

Dr. Fisher:
We are standing at an inflection point. This is a very exciting moment. I'm looking forward to exploring new therapies for our patients with hypertension, while we focus on the importance of an interdisciplinary approach to manage high blood pressure, and improving care for all our patients who have hypertension.

This is CME on ReachMD, and I am Dr. Naomi Fisher.

Dr. Rader:
And I'm Dr. Florian Rader. I direct the Hypertension Center at Cedar-Sinai, Los Angeles.

Dr. Fisher:
We have a lot to discuss today, so let's begin. Florian can you open by telling us about the burden of hypertension?

Dr. Rader:
Yeah, thanks, Naomi. So, the global burden of hypertension is really immense. Nearly half of adults meet criteria for hypertension and although elevated blood pressure is the number one modifiable risk factor for cardiovascular mortality, less than 30% achieve optimal blood pressure with antihypertensive treatment. These statistics only apply to developed countries and in some countries if we're looking towards Africa or Asia, control rates might be in the single digits. So, I think it's really important to find new ways to lower blood pressure. The importance of lowering blood pressure comes from the notion that decreasing blood pressure, even by relatively small amounts, like 5 to 10 mm of mercury, substantially lowers the risk of cardiovascular complications of hypertension, such as stroke, heart failure, myocardial infarction.

The first step to improve blood pressure is always to adjust your lifestyle, optimizing your diet, finding a regular exercise program, keeping a healthy weight, and avoiding some habits that can increase blood pressure. However, all too often these lifestyle modifications are just too difficult to maintain over time and antihypertensive medicines, unfortunately, become necessary to lower blood pressure, always having that goal in mind of bringing blood pressure below 130/80 mm mercury. Now, as we know, there is a ton of medication options out there. And just recently this year at scientific meetings, heard about some very exciting new developments of new pharmacologic therapies.

But yet, although they are very effective hypertension control seems still to be so dismal. So, on that point, Naomi, maybe you can tell us about the limitations of current available antihypertensive treatment options and how their shortcomings effect patients.

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Dr. Fisher:
Yeah, I agree with you. And even some of the exact same words that you used; I often use to explain the global burden for disease for high blood pressure is enormous. And despite dozens of effective medications, which are generally affordable, control rates are dismal, and in the US at least, they are falling. So, there are plenty of reasons. The first is that hypertension is complex. We're not talking about a single disease with one cure, but rather a syndrome. There are genetic contributions, but without doubt, environmental risk factors play an enormous role getting us where we are today with the prevalence rates rising and control rates falling. And you talked about unhealthy diet and lifestyle changes. We're facing an obesity epidemic, which contributes directly, and overweight and obesity are affecting younger and younger people. Our eating habits are worse, we're eating too much salt, drinking too much alcohol, too little dietary potassium. And of course, sedentary lifestyle we put in the mix of offenders. So, these are really hard changes for people to attain, let alone to sustain and to keep up.

And for the doctors, primary care providers who manage most of high blood pressure, they have to attend to the hypertension. It's almost always asymptomatic, so I think that adds to the complication, because patients don't complain about their blood pressure, it doesn't give them any cause to complain. And at super short outpatient visit, doctors also have to manage every other complaint and disease. So, yes, there are plenty of medications. They are affordable for the most part and they are affective, but I want to add one more list to the reasons that we just talked about. Most patients are not taking their medications. And there's an astonishing statistic that I think listeners should be aware of, about 50% of patients who are prescribed medicine for blood pressure are not taking them a year later. And these reasons, which I'm sure you agree, will vary widely from cost to fear to cultural belief, sometimes just ignorance. Some patients don't have access to healthcare or medicines, and we pay careful attention, special attention, to these vulnerable populations. And of course, many patients suffer from side effects from drugs. Sometimes these side effects are predicted, like edema from a calcium channel blocker, but sometimes we can't understand their probably better classified as intolerances. I know you share a lot of patients who have these kinds of issues tolerating their medications.

Dr. Rader:
Yeah, absolutely. I think that was a great summary of all the problems that we're facing in treating hypertension and lowering blood pressure on a wide scale. So, after this first chapter, in the next chapter of our discussion, we'll delve into the role of sympathetic nervous system and how it affects blood pressure.

Then, how renal denervation, in general, works, and then also I will tell you a little bit about the clinical trial data supporting the effectiveness and the safety of ultrasound renal denervation. So, see you in a bit.

Chapter 2

Dr. Rader:
And welcome back. In the first chapter, we reviewed the burden of hypertension and why so many patients are not achieving their blood pressure goals. Now, we're moving forward, and – to discuss the mechanism of action of renal denervation.

Naomi, could you explain how the sympathetic nervous system affects blood pressure, and how it can be modulated with ultrasound renal denervation?

Dr. Fisher:
Sure. I'll be happy to. Renal denervation works by targeting the renal sympathetic nerves, both the afferent and the efferent branches. And we've learned from many animal studies and human studies that overactivity of these nerves plays a major role in many forms of high blood pressure. The early procedures targeting the sympathetic nerves, a sympathectomy, taught us that severing these nerves would drastically lower blood pressure, but of course those procedures carried a lot of morbidity. So, studies with catheter-based renal denervation followed. Let's talk about how it works.

Ultrasound renal denervation uses the Radiance catheter. This system uses ultrasound energy to treat the nerves. This endovascular catheter is threaded into the main renal arteries on each side into the right and left kidney.

Inside there's a small transducer which delivers the energy in a circumferential ring of ablation. This energy is delivered at a depth of about 1 to 6 mm from the vessel lumen, this is exactly where the renal nerves are located. And the transducer is surrounded by a water-filled cooling balloon, and that water protects the lining – protects the vessel wall.

As we'll discuss shortly, there've been three SHAM-controlled, really rigorously done trials of the Radiance program using the Paradise Renal Denervation System conducted with three different patient populations, each of them individually powered and each one met its primary endpoint, which was a greater lowering of 24-hour ambulatory systolic blood pressure at 2 months compared with SHAM.

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So, the Paradise System was approved in November of 2023 and as you know, shortly after its approval, the Spiral catheter was also approved by the FDA for the same indication. These two systems differ in terms of the energy used. The Spiral system uses a single catheter with four electrodes that are passed in a helical pattern. Energy is radiofrequency instead of ultrasound, and the technique is different. The radiofrequency energy is delivered separately to the main artery, to the accessory arteries, and branch vessels to maximize the likelihood of complete denervation. With the Paradise system, there are 2 to 3 ablations per side, 2 to 3 on the right, two to three on the left, each lasting 7 seconds. This results in an ablation time of about 40 seconds with ultrasound, and it's shorter than with radiofrequency, where there are about 15 minutes of ablation.

I think that summarizes where we stand with those two main devices. There's also a device using dehydrated alcohol, which is in earlier stages.

Now that we understand how renal denervation works, can you tell us about the clinical trial data?

Dr. Rader:
Yeah, my absolute pleasure. Really a fascinating field, and the technology of these catheters is really astounding. So, if we go back a little bit over 10 years we saw some initial uncontrolled studies of renal denervation that really led to very unrealistic expectations when it comes to the amount of blood pressure lowering with these devices. Then, they followed one sham-controlled randomized large trial that was heavily publicized, and it was pretty much a negative trail. So, the group difference between renal denervation and sham control was not statistically significant.

So, first, we had the SOLO trial in which patients were taken off their blood pressure medications and after confirmation of uncontrolled hypertension. Now the importance about this trial design is that it allowed us to see the effect of ultrasound renal denervation without confounding of background adherence, or non-adherence, to blood pressure medications. So, in SOLO, 146 randomized patients underwent either ultrasound renal denervation versus sham controlled. And those who were assigned to ultrasound renal denervation had an ambulatory daytime systolic blood pressure of 8.5 mm mercury, with a group difference compared to sham control group of 6.3 mm mercury at 2 months. So, this was really to see what the pure effect of renal denervation is.

Then TRIO followed. So, in TRIO, we tested ultrasound renal denervation in patients who were truly resistant to blood pressure medications with uncontrolled hypertension despite 3 or more blood pressure medications. So, they followed the usual definitions of resistant hypertension. The problem with studying such a group of patients is that as soon as patients have to take more than 1 blood pressure medication consistently, adherence or nonadherence can dramatically change the outcome of a trial. Oftentimes we see really exaggerated placebo effects in these studies. So, to overcome this limitation every participant was started on a fixed dose triple-combination pill that included an angiotensin receptor blocker, a calcium channel blocker, and a thiazide-type diuretic. These fixed-dose triple-combination pills increase adherence and sort of homogenize the background therapy of all participating patients. So, in this trial we randomized 136 patients and those who were assigned to ultrasound renal denervation had an ambulatory daytime systolic blood pressure reduction, again, of 8 mm mercury with a 5 mm mercury group difference compared to sham control at 2 months.

And now, lastly, we performed a pooled analysis of patients who were enrolled in SOLO, and then an even larger extension study of SOLO, the RADIANCE-2 trial, which included patients who were uncontrolled on 1 to 2 medications and TRIO that we just discussed. So, truly resistant hypertensive patients. This study was aimed to show the effect of ultrasound renal denervation in a variety of hypertensive patients. So, this pooled analysis included 293 patients who underwent ultrasound renal denervation, and 213 patients who underwent sham control.

Again, we saw statistically significant and clinically meaningful reductions in ambulatory systolic blood pressure of minus 8.5 mm mercury in the ultrasound renal denervation group, with a group difference compared to control of 5.9 mm mercury. This pooled analysis really showed us, too, what to expect from this procedure in terms of blood pressure reduction in a variety of hypertensive patients, but importantly, it also showed us that the safety of this procedure is really very solid.

I think if there's one thing that we cannot argue about here, is that the safety of ultrasound renal denervation is really excellent. Initial worries about damage to the renal arteries or possibly a negative effect on renal function over time has really not panned out. And we've looked now at longer interim follow-up data, at least in the SOLO cohort, for up to 36 months, and the safety as well as the durability of this procedure is really outstanding.

Dr. Fisher:
I think you gave a terrific summary. We have data from three separate randomized clinical trials, we have pooled data that really indicate the efficacy – efficacy of renal denervation across different types of patients, right? Patients who have mild to moderate to severe, and even resistant, hypertension with an efficacy that's in the range that can really reduce cardiovascular risk.

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In chapter 3, let's discuss how to identify patients who may be candidates for ultrasound renal denervation, what providers need to know about treating these patients, and the role of the Hypertension Center.

For those just tuning in, you're listening to CME on ReachMD. I'm Dr. Naomi Fisher, and here with me today is Dr. Florian Rader. We're discussing how ultrasound renal denervation affects hypertension and the role of the hypertension center.

Chapter 3

Dr. Rader:
Okay. Welcome back to part 3 of our session on ultrasound renal denervation. Naomi, I think a crucial part of making this new procedure successful and really maximizing its benefit, is how to select the right patient. So, let's talk about that a little bit. How do you decide who might be the patient – or the right patient for ultrasound renal denervation.

Dr. Fisher:
I think this is a question that a lot of providers are really tackling and struggling with right now. You've explained already that renal denervation has been proven effective across a spectrum of patients with hypertension, including those who have true resistant hypertension, as well as those with mild and moderate hypertension, and this is why the indication is so broad. I think it's helpful to review the indication from the FDA. Renal denervation has been approved indicated as adjunctive therapy when lifestyle modification and medications fail to control a patient's blood pressure.

So, that said, let's talk about how we decide which patient this is most appropriate for. First, as in the indication, we always start with lifestyle – weight loss, dietary sodium restriction. That goes without saying for every patient that you and I, and all providers take care of. And of course, patients should have uncontrolled hypertension, but let's remind listeners that means confirming that blood pressures that are high in the office are matched by high blood pressures at home, either using a 24-hour ambulatory blood pressure monitor or home blood pressure monitoring. This way we won't be treating patients who have white coat hypertension. We really want to focus on patients who have sustained high blood pressure.

Once that's confirmed, there're some patients whose blood pressure is really easily controlled with one or two medications and they're tolerating those pills well. For these patients, I think medical therapy should be continued. So, let's examine the other patients who might be candidates for renal denervation, and the most obvious group are patients who have resistant hypertension. And that means, as you know, their blood pressure is uncontrolled despite taking three drugs, typically from an ace inhibitor or angiotensin receptor blocker class, a calcium channel blocker, and a diuretic at maximal doses, or maximally tolerated doses. Or patients who require four blood pressure medications to control their hypertension. This category of patients, those with true resistant hypertension, is the most obvious place to start and in fact, all of the studies with renal denervation focuses on these patients first. What we've come to realize, they represent a small fraction of patients with high blood pressure because there are so many patients who have been prescribed medications but do not actually take them, as we discussed. So, the next step means we help our patients, we optimize adherence. But many of these patients could benefit from blood pressure reduction with device-based therapy with renal denervation and they may actually prefer it.

I'd like to add one more consideration. There are patients with certain treatable secondary causes of hypertension, and I think they should not be directed to renal denervation. Most commonly, primary aldosteronism, which is highly prevalent and usually undiagnosed. Screening should be performed in eligible patients, because targeted effective treatment is available for them. And there are other rare causes of hypertension like Cushing's disease and pheochromocytoma, that should be excluded if they're suspected clinically. But I don't think that common contributing factors like sleep apnea and obesity should be exclusionary.

Florian, I'd like to hear your thoughts. What are your thoughts about choosing the right patient? And maybe you can also focus on any requirements prior to the procedure and in follow-up afterward.

Dr. Rader:
Yeah, Naomi, I couldn't agree more with you. So, I think it comes down to the patients who had several unsuccessful attempts of lowering and controlling blood pressure, and then, in a shared decision-making conversation, we would decide whether we should try another medication or go to ultrasound renal denervation.

So, I do believe that evaluation of potential candidates for ultrasound renal denervation by an experienced hypertension program will probably maximize its benefit.

So, regarding pre–renal denervation requirements, there's not a whole lot. I think you've mentioned all the necessary workups. First of all, confirming uncontrolled hypertension outside of the doctor's office., Second of all, ruling out secondary causes that require a specialized work-up or treatment primary aldosteronism is one that you just mentioned that is really important, I think, to identify. And

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then finally, and that might be a little bit debatable, is I would prefer getting pre–renal denervation imaging with a CT angiogram of the renal arteries just to make sure we're not sending patients to the Cath lab who are not eligible for this procedure in the first place.

Talking about the after renal denervation follow-up. So there's a few points I want to make. First of all, it will be fairly easy. So, assessment of vascular access is really something that a nurse or nurse practitioner can do. I think vascular complications with modern vascular closure devices is quite – is quite rare. Um, then overall, follow-up of the renal anatomy or imaging of the renal artery is just simply not necessary because the damage to the vascular system from renal denervation is just such a rare occurrence.

I think what's really important to after-renal denervation is educating the patient to make sure they're not stopping their medication, because, as our studies have showed us, most patients will require ongoing medical treatment despite blood pressure lowering with this procedure. So, getting on board with the fact that, yes, medical treatment will be necessary, and having the patient follow-up with somebody who continues to focus on blood pressure control, I think will be crucial.

Dr. Fisher:
Yup, I agree. We're going to continue to gather more data about efficacy and safety as we move into this post-marketing phase now.

We talked already a bit, or at least you mentioned, the positive impact of incorporating a hypertension center into patient care, and I know you have a terrific hypertension center at Cedar-Sinai. I'd like to hear from you, how should a hypertension center be developed? Can you share your experience?

Dr. Rader:
Yeah, sure. So, there's definitely no one-size-fits-all approach, I think. The most important initial step is to find a healthcare provider, and that could be one of several specialties who's interested in hypertension and really wants to make this a focus of their practice. And then, there's guidelines of course, that help us create clinical protocols. Most importantly, I think on how to assess blood pressure both in the office, and out of the office. Incorporating an ambulatory blood pressure monitoring, I believe, is quite important for the assessment of hypertensive patients. Then having the ability of screening for these secondary causes of hypertension that we just mentioned before and having the ability of refer patients with a suspicion for secondary causes to refer them to specialties that can adequately treat those. Finally, creating treatment protocols using preferred medications is also fairly simple, and should be able to be done by most centers, really.

Now, I am a cardiologist. You, Naomi, are an endocrinologist, and also know many, many hypertension experts who are nephrologists or even primary or family doctors. So, I think there really many options to start a program. There are some helpful tools out there. Specifically the American Heart Association has really a big effort right now going on in encouraging and supporting centers to develop hypertension centers of excellence. And they also certify these centers once they achieve certain standards of hypertension management. If you want to incorporate ultrasound renal denervation into your hypertension center, of course, you will need to find an interventionalist who becomes not only proficient in this procedure, but also shows a high level of enthusiasm for renal denervation, so you can make this program, really, a successful one.

Now, Naomi, I have one more important question for you. I predict that there will be a significant interest of getting ultrasound renal denervation from the patient side. So, how much input do you think should the patient have when it comes to deciding whether ultrasound renal denervation is a feasible treatment option, and how much of a shared decision will there really be?

Dr. Fisher:
You're absolutely right, Florian. We have now multiple patient preference studies that have been published conducted in populations in different countries around the world, and all of them have found that a significant percentage of patients would prefer a device-based treatment to taking additional medications if they need blood pressure control. So, it's clear, I think, to all of us that shared decision-making has to guide every plan to proceed to renal denervation. And that means we have to discuss patient preferences, thoughtful risk/benefit discussions with our patients. It'll take time, but it's really critical.

We've learned from these studies that doctors and patients don't always want the same thing, or not always motivated by the same factors. When asked which patients' doctors would refer for renal denervation, and which patient they thought were the best candidates, doctors said, I will refer patients who have the worst hypertension, the most severe hypertension and those who are taking the most medications.

But patients' surveys found something very different, right? Preference for renal denervation, first of all, didn't depend on blood pressure. So, regardless of blood pressure starting at 140 or 180, there was a very standardized – there was a universal preference for blood pressure – there was a universal preference for renal denervation across the board. And second, the preference wasn't greater in those who were taking more medications. In fact, if you wanted to look at which population of patients most wanted renal denervation, it

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was those patients who were not taking any medications at all. So, another suggestion is that we really have to talk to our patients, because we can't possibly imagine what it is that's driving them without speaking to them.

I'd like to mention that renal denervation has now entered two important guidelines, both published in 2023, because on this topic, both of them emphasize shared decision-making.

So, we have the European Society of Hypertension 2023. Renal denervation now appears with a level 2B recommendation and the guidelines state that renal denervation be considered as an additional treatment for patients who have resistant hypertension, or as an option for patients with uncontrolled hypertension despite using drug combination therapy or if drug treatment elicits side effects that impacts quality of life. They emphasize shared decision-making, and they emphasize the importance of having specialized centers that you talked about to care for these patients.

And we also have the SCAI Guidelines. The Society for Cardiovascular Angiography and Intervention, together with the NKF, National Kidney Foundation. And they recommend renal denervation for patients with resistant hypertension, and also patients with uncontrolled hypertension attempting lifestyle changes and medications, but who are either intolerant of more medication or don't wish to take more medication. I think it's interesting that we're hearing the same kind of words, the same patterns, because we're reaching an agreement across societies, across countries, across specialties, about the role that this procedure may play. And again, the SCAI Guidelines emphasized shared decision-making. Also talked about patients with higher cardiovascular risk may be the ones with the greatest benefits, so we should make sure that we talk about it with these patients especially.

Dr. Rader:
Yeah, I could not agree more. I think the guidelines obviously will evolve, I think, over time as we gain more experience with renal denervation in clinical practice. But I also do think that many patients will take stewardship of the treatment options, and doctors will have to be effective in communicating the right choices for the patient's hypertension management.

Dr. Fisher:
Terrific. This has been a fascinating conversation. I've really enjoyed speaking with you. And before we wrap up, let's each provide a final take-home message for our audience. Florian, what do you hope our listeners will leave with today?

Dr. Rader:
Yeah, so, of course, I always want listeners to be more excited about hypertension management and find the focus on really optimal hypertension care. But importantly, I think, it is important to realize that renal denervation has become now a clinical reality, and that now it is a treatment option for those patients in whom treatment with lifestyle modifications and pills alone just hasn't worked out.

Dr. Fisher:
Terrific. I agree. It's time to bring hypertension to center-stage.

I am grateful for every single opportunity to put hypertension in the spotlight and for programs like this that can help educate all of us. We have an entirely new pillar of management for our patients if lifestyle modifications and medications are not tolerated, or not effective enough.

That's all the time we have for today. I want to thank our audience for listening in, and thank you, Dr. Florian Rader, for joining me and for sharing all of your valuable insights and expertise. It was a great pleasure speaking with you today.

Dr. Rader:
I also want to thank Dr. Fisher for her insights. It was a real and absolute pleasure to be here.

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