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An expert on renal artery therapy discusses when intervention is appropriate, the best methods for diagnosis, and some of the shortcomings of prospective, randomized studies of renal therapies.

What is the current state of reimbursement for renal artery stenting?

The Centers for Medicare & Medicaid Services (CMS) held a hearing in 2006 and are about to rule on how renal artery stenting procedures will be reimbursed. I wrote an article for *Endovascular Today* about a year ago,[1] which prompted CMS to ask me to testify. CMS has proposed to make no change to the National Coverage Decision addressing angioplasty in the renal arteries. The final ruling should be made soon; it is possible that they will restrict reimbursement for cases performed under a formal investigative protocol.

When is renal artery intervention appropriate? For which patients would you not consider intervention?

Patients with recent onset, increasing azotemia, and/or hypertension that is difficult to control with aggressive medical therapy should be considered for intervention if they have physiologically significant renal artery stenosis (RAS) (a mean translesional gradient of at least 10 mm Hg). Asymptomatic and even symptomatic patients whose symptoms are probably not due to the RAS, but rather to other causes, with a moderately severe atheromatous RAS (approximately 50%–70% diameter) without a gradient as previously mentioned, should not undergo prophylactic intervention. There is now good evidence that medical therapy, including statins, can prevent or slow progression of atheroma more safely and as successfully as the more risky intervention.

Is angiography still the standard test for diagnosing atheromatous renal artery stenosis? What about the risks, such as worsening renal function?

Properly performed magnetic resonance angiography is still the best noninvasive test for detecting RAS; the risks of gadolinium-induced nephrogenic systemic fibrosis are probably significantly less than the risks associated with computed tomographic angiography with iodinated contrast producing transient or permanent renal failure. In experienced hands, duplex renal ultrasound is probably a very good and reasonable alternative.

However, if a physician wants to avoid the risks of gadolinium magnetic resonance angiography and computed tomographic angiography and does not trust renal duplex, in patients with a high clinical suspicion for RAS, it is very reasonable to perform a diagnostic arteriogram. If positive, it can be immediately followed by intervention. The arteriography should be performed by an experienced operator using a 4-F or smaller diameter catheter and no more than a total of 10 to 15 mL of 50% dilution of low-osmolar iodinated contrast.

What is your opinion on using embolic protection filters off-label in renal indications?

There is continued controversy about many of the already existing renal technologies, such as protection devices. Many of these are too long and rigid, and by anchoring in the renal artery at a right angle from the aorta, they can be inadvertently pulled on during a difficult case, resulting in renal artery trauma trauma.

Furthermore, the evidence for the effectiveness of embolic protection devices is almost anecdotal. There is good evidence that much of cholesterol emboli are produced during manipulations in the aorta before and during the initial crossing of the stenosis. Even the best filters cannot protect against this.

There may eventually be an effective renal artery filter, and although I do not think that the majority of emboli occur after the filter is placed, any additional measure of safety can be helpful in a patient with severely compromised renal function.

What improvements would you like to see in endovascular renal therapy?

We are still looking to decrease the 15% to 20% recurrence rate because there is no evidence-based effective treatment for restenosis.

The CORAL, STAR, and ASTRAL trials evaluated clinical outcomes of patients treated with medical therapy compared to patients treated with both medical therapy and renal artery stenting. What are your thoughts on these trials?

There are no results yet available for CORAL. They have enrolled approximately 430 of the projected 1,080 patients. The trial is somewhat handicapped by methodological changes: the prerandomization imaging was changed.

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Noninvasive imaging was added to catheter arteriography, and the mandatory protection device became optional. Patient enrollment was also slower than expected, and some new sites were added. This may dilute the quality of operators, although CORAL does require a pre-enrollment roll-in of one case submitted for core lab evaluation. Obviously, the medical arm benefits from the relative ease of following the protocol and more uniformity of the quality of treatment.

ASTRAL only included and randomized patients for whom the treating physicians could not decide whether to treat using medical therapy or stenting. ASTRAL showed no superiority of stenting over medical therapy for renal function at up to 2-year follow-up. Most patients with classic indications for stenting, as I described, were excluded, and there was a relatively high crossover from the medical to the surgical arm. The technical success rate for stenting was only 88%, which is less than what we have seen in the best hands. Another part of the problem is that in all of these studies, each operator will contribute relatively few patients.

The ASTRAL results may indicate that the results "are what they are" in the "real world" of operators. STAR preliminary data also show—and CORAL will most likely show—similar results. The data may accurately reflect the facts that the kidney and the usually very diseased aorta surrounding the renal arteries are the worst substrate for risks of stenting in any organ. Therefore, most operators, even those who think they are good, are not really good enough and should not perform renal artery stenting. Simply because an operator can ultimately get a stent in the renal artery (after causing a lot of cholesterol embolization trying to enter the artery, prior to the deployment of the protection device) does not mean that he has done so safely. These are the weaknesses of large prospective, randomized trials compared to large single-center studies.

What are your recommendations based on the results of the studies that have been released, partially released, or are still in progress?

I believe that the renal arteries are the most difficult arteries within the body to treat with stenting because of the major problems with cholesterol embolization. The more experienced the operator is and the fewer passes he makes for entering the renal artery, the less likely it is for complications to occur.

In my opinion, the results of these studies show that some operators do not have enough experience, and I would therefore recommend that renal artery stenting be restricted to relatively few major centers in the US where interventionists have the most experience and can perform the procedure with relatively low complication rates. Better results can be achieved with greater experience. These newer studies reflect the fact that renal artery stenting, even in appropriately selected patients, may not achieve optimal results. The average operator does not achieve those results because if cholesterol embolization is caused in the process of placing the stent, there will be no benefit to the procedure, and renal function will diminish. ■

1. Sos TA. The renal stenting debate: is this procedure underused or overused? Yes. Endovasc Today. 2006;1:64-68.