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11:25 a.m.

PTRA and Stenting for Renal Insufficiency: What Do We Know about Outcomes?

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Introduction

Renal insufficiency, or ischemic nephropathy is becoming, or should be, the most frequent indication for intervention in renal artery occlusive disease. The clinical, anatomic and physiologic status of the patient must all be integrated and considered in the selection of patients for intervention to yield the best possible risk-benefit for the procedure.

The Indications for Renal Artery Intervention

Clinical

1. Recent onset or progressive moderate to severe renal dysfunction
2. Severe or difficult to control hypertension
3. Recurrent pulmonary edema
4. Jeopardized kidney

Anatomic

1. Stenosis > 60% diameter
2. Post stenotic dilatation
3. Collateral circulation
4. Diminished renal size (jeopardized kidney)

Physiologic

1. Radionuclide scan
2. Renal vein renin assay
3. Duplex ultrasound
4. Trans-stenotic pressure gradient > 10% peak systolic arterial pressure, or > 5% mean arterial pressure

When to Intervene and When Not!

The potential benefits of intervention must be measured against the potential risks and the natural history of the disease. The natural history studies exaggerate the progression of atheromatous renal artery disease. The potential risks of renal artery interventions, especially cholesterol embolization, are under recognized and under reported. Unfortunately only few physicians performing renal artery interventions are sufficiently familiar with and understand the implications of the GFR/Serum Cr curve (**Figure 1**).

Severe iatrogenic renal parenchymal damage due to diagnostic and therapeutic intravascular procedures in patients with normal preintervention GLOBAL Serum Cr values can be masked. Thus, 50% of total renal mass, or one of the kidneys can be "destroyed" without any change in global renal function measured by Serum Cr values, although the creatinine clearance and individual ipsilateral renal function will be reduced. There is much greater risk when treating patients with elevated Serum Cr, whose renal function is at the "knee" of the curve, where there is very diminished renal reserve. In such patients, even an additional 10% loss of renal parenchyma can put the patient on dialysis. For this reason, we believe that it is imperative to confirm the physiological significance of a stenosis by demonstrating a hemodynamically significant trans-stenotic pressure gra-

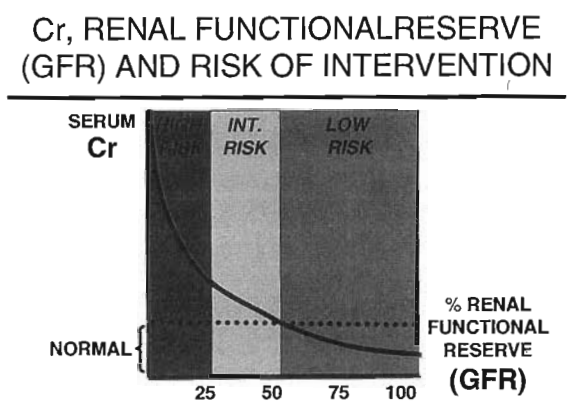

Figure 1.

dient prior to renal artery interventions, in addition to adequate clinical and anatomic indications.

The initial arteriographic evaluation must begin with an aortogram; NEVER with selective catheterization in a potentially very diseased aorta (**Figures 2a** and **2b**). If a proximal/ostial renal artery stenosis is found, *selective* catheterization is contraindicated, unless an intervention is planned, in which case pressure measurements, as indicated above must be obtained prior to intervention.

The minimum pressure gradient that justifies intervention (using a 4 F catheter) is > 10% peak systolic arterial pressure, or > 5% mean arterial pressure.

The Techniques of Renal Arteriography, Angioplasty and Stenting

The techniques described below were developed and evolved over an almost 25-year experience. They concentrate on two major goals, which are particularly relevant in the patient with compromised renal function:

- Limiting the amount of nephrotoxic iodinated contrast medium.
- Limiting and simplifying the manipulations in the diseased abdominal aorta and renal arteries.

Aortography

Prior to selective renal artery catheterization an aortogram must be performed. This allows evaluation of the presence, location and extent of atheromatous disease in the aorta and in the renal artery, and the planning of the interventional procedure. We use the OmniFlush (AngioDynamics, Queensbury, NY) catheter for aortography, because its design prevents cephalad reflux into the celiac and superior mesenteric arteries which can overlap the renal arteries and also "steal" contrast from the desired areas of interest. Since the renal arteries originate at the L 1 vertebral body, the sideholes of the catheter are positioned at the T 12 L 1 interspace. Aortography and right renal artery stent deployment is generally performed in the 20–30° LAO projection because the right renal artery usually arises 30° ventrally to the "equator" (13) of the aorta, whereas the left renal artery usually originates directly laterally at the "equator". Axial MRA or CTA images at the level of the renal artery are very helpful in determining the optimal obliquity for aortography.

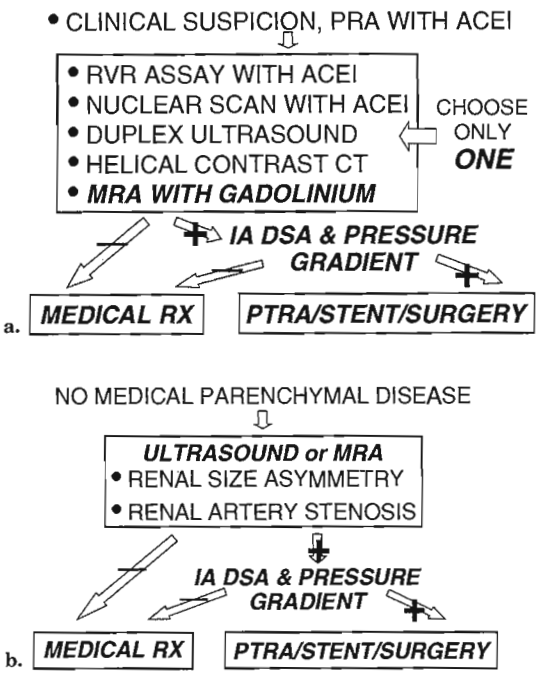

Figure 2. Algorithms for diagnosis and treatment of **(a)** ischemic nephropathy and **(b)** renovascular hypertension.

Since many of these patients have marginal or poor renal function, we try to limit the total amount of iodinated contrast medium. Nephrotoxicity is primarily due to the iodinated part of the contrast molecule, therefore we use "half strength" 30% concentration (150 mg I/ml) contrast medium, and perform aortography using only 15 ml total volume injected at 15 ml/sec. If the renal artery origin(s) are not satisfactorily demonstrated with the "half strength" contrast, a "targeted" repeat aortogram can be performed at the now precisely known level of the renal arteries using only 5–10 ml of "full strength" contrast.

Selective Renal Artery Catheterization

We identify the location of the renal artery and the stenosis in relation to the bony landmarks (spine and ribs) and calcifications in the aorta and the renal artery using a non-subtracted aortogram image displayed on a television monitor or as hard copy on a view box. We use a SoftVue (soft tipped) Sos Omni Selective (AngioDynamics, Queensbury, NY) catheter for selective catheterization of the renal artery and for crossing stenoses. This "recurve" design is similar to the Simmons type configuration, but has a shorter side arm and is significantly easier and less dangerous to reconstitute its shape. We do not perform contrast test injections during catheterization of the renal artery. Selective catheterization of the stenotic renal artery is performed with the image intensifier in the oblique projection where the origin ("nubbin") of the renal artery is en face. The SoftVue (soft tipped) Sos Omni Selective catheter with a very soft floppy "Bentson" type guidewire extending approxi-

mately one cm from the catheter tip is slowly advanced cephalad with the catheter tip pointed laterally toward the origin of the renal artery. This maneuver deflects the tip of the wire parallel to the aortic wall, and even slightly pointing toward the lumen. The wire will readily enter the funnel shaped origin or "nubbin" of the stenotic (or even an occluded) renal artery with a characteristic lateral flick and then it can be gently advanced across the lesion. This maneuver diminishes the volume of contrast used for the diagnostic and therapeutic interventions.

Most occluded renal arteries have a few millimeter long funnel shaped origin ("nubbin") proximal to the occlusion, which can be identified and entered as described above; if no "nubbin" is identified, percutaneous recanalization cannot/should not be attempted. For crossing occlusions we initially use a straight hydrophyllic guidewire which is forced (pulled) against the funnel shaped nubbin of the origin of the occluded renal artery by the stiffer AngiOptic version of the Sos Omni Selective (AngioDynamics, Queensbury, NY) catheter. The hydrophyllic wire should be exchanged out for a non-hydrophyllic wire as soon as possible, since hydrophyllic wires are more likely to produce iatrogenic vessel perforation, or be withdrawn from the vessel inadvertently. Following successfully crossing the lesion, the trans-stenotic pressure gradient must be documented. In the presence of a significant gradient, the soft guidewire is exchanged for a stiffer wire such as the TAD II (Mallinckrodt, St Louis, MO) over which the diagnostic catheter is exchanged for an appropriately sized (usually 6-8 mm diameter) balloon catheter for angioplasty. Prior to stenting, the vessel can be pre-dilated with a relatively small 5 mm diameter balloon catheter, and exchanged for a 65 cm long 6 F sheath with a long tapered introducer, such as the Daig (St Jude Medical), Bright Tip (Cordis, Miami, FL), or the Balkin (Cook, Bloomington, IN). Alternatively predilation can be more simply accomplished by advancing the sheath and introducer through the stenosis primarily; this is our currently favored technique. For renal artery stenting only balloon expandable stents should be used. In the past we used the Palmaz (Cordis, Miami, FL) stent but currently prefer the OmniFlex (AngioDynamics, Glenns Falls, NY) because of its MR transparency. For approximate balloon/stent sizing we use the length of the curved tip of the OmniFlush (AngioDynamics, Queensbury, NY) catheter; the distance from the top of the curve to the bottom of the tip is always 15 mm. The premounted stent is delivered on a balloon catheter through the 6- or 7-F guiding catheter (for 0.035-inch wire based systems) into the stenotic area. Operators should also be familiar with 0.018 inch wire based systems for renal artery stenting. The guiding sheath is then withdrawn into the aorta, leaving the balloon/stent combination and the guidewire in place and an angiogram is performed through the sheath to aid in the accurate placement of the stent in the renal artery. Contrast injections for stent positioning are performed using only 5 ml of 30% contrast injected at 10ml per second. Minor adjustments in the position of the stent can generally be easily performed by advancing or withdrawing the balloon catheter with the mounted stent prior to deployment. The guiding catheter itself can be used if necessary to help in stabilizing the position of the stent during these maneuvers but this should be only used as a last resort since the stent could be damaged by the more rigid guiding catheter. Once the stent is in satisfactory position as evaluated by an angiogram in the appropriate oblique view (the x-ray beam should be perpendicular to the long axis of the origin of the renal artery from the aorta), the balloon is inflated and the stent deployed.

We prefer to deploy the stent with a couple of millimeters extending into the aorta and a few millimeters extending past the stenotic lesion. Palmaz and OmniFlex stents shorten slightly when expanded. The pulsation of the aorta and the renal artery during the cardiac cycle produces a moderate amount of unpredictable movement of the balloon catheter stent combination. There may also be some unpredictable and difficult to control movement of the balloon catheter stent combination during balloon inflation. For these reasons, we prefer to deploy 15-mm long stents for most ostial stenoses. If too short a stent is used or if it is inaccurately placed then a second stent partially overlapping the first one must be deployed to cover the entire lesion. This may decrease long-term patency due to extra foreign material and increases the risk of complications. For removing the balloon from the stent after deployment, the sheath should first be gently advanced into the stent as far as it will easily go over the trailing end of the deflated, but open to air balloon. This maneuver wraps the balloon to minimize the risk of the balloon "wings" catching in, and inadvertently dislodging the deployed stent.

Risks of Renal Angioplasty and Stent Placement

During passage of catheters and guidewires through the atheromatous aorta and renal arteries for dilation and stent deployment, the artery can go into spasm, be occluded, perforated, dissected, ruptured or cholesterol crystals may be embolized either into the renal circulation or elsewhere. In-situ thrombosis or thromboembolism from areas of manipulation can also occur. These complications are all very rare; each occurs in fewer than one percent of cases. Many complications are pharmacologically reversible or can be treated by redilatation or stent deployment.

Results

At New York Presbyterian Hospital Weill Cornell Center, from May 1989 through January 1997, we attempted to place Palmaz stents in 94 renal arteries in 84 patients. Eighty-seven stents were placed for ostial stenoses. Seventy-seven percent of stents were placed primarily in ostial lesions or total occlusions and 28% after previous failed angioplasties. Indications for intervention were:

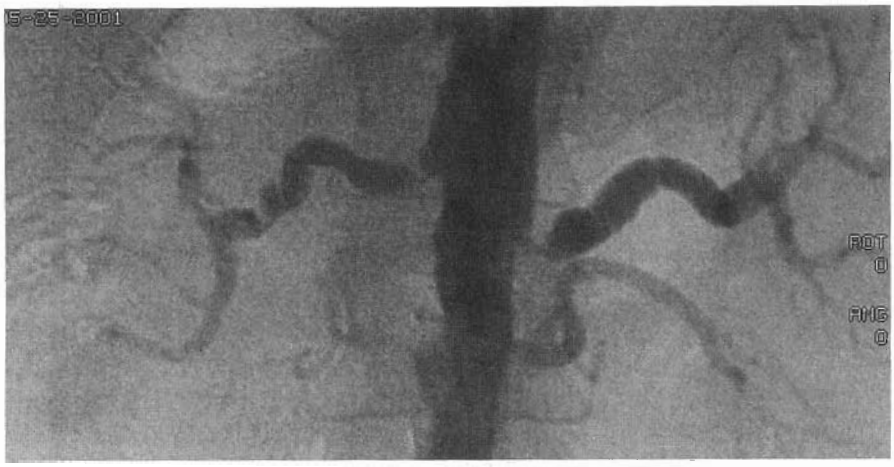

Figure 3. Sixty-five-year-old female with severe and difficult to control hypertension and severe bilateral renal artery stenosis: DSA before stents.

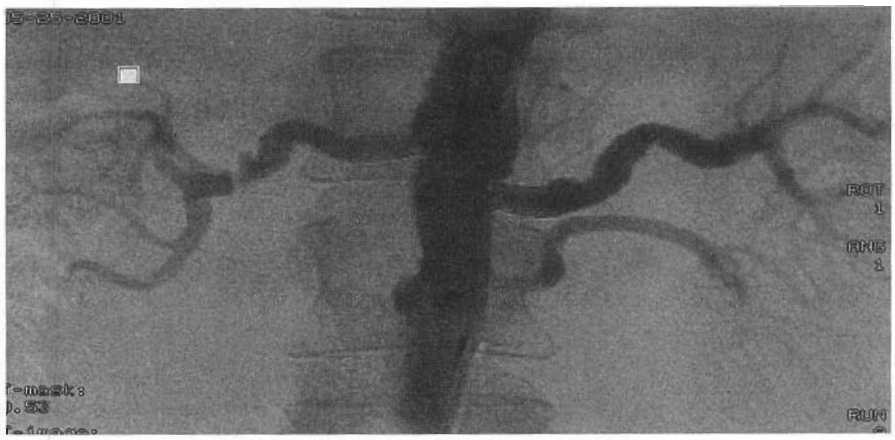

Figure 4. DSA after bilateral OmniFlex Stent.

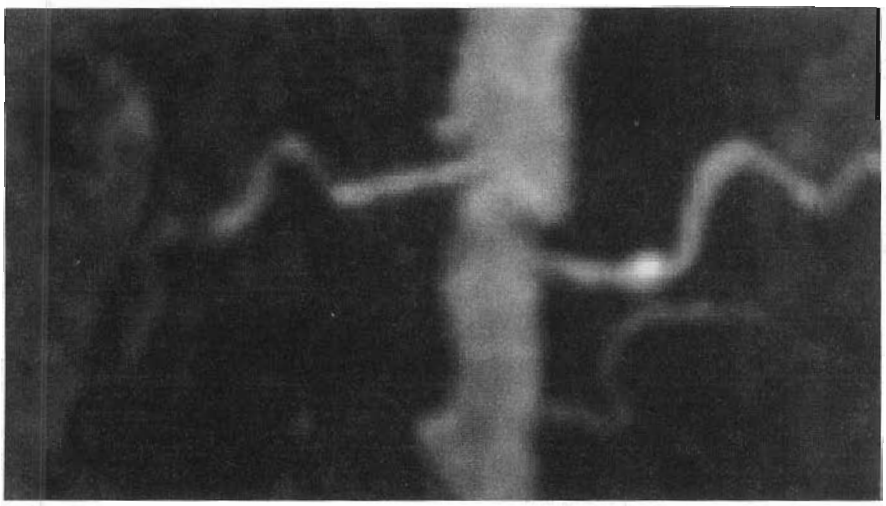

Figure 5. MRA after bilateral OmniFlex Stent.

hypertension in 96%; renal failure in 60%; (Cr > 1.5 mg/dl in 60%. and > 2.0 mg/dl in 45%); and recurrent flash pulmonary edema in 30% of patients. Some patients had multiple indications.

Ninety-eight percent of procedures were technically successful. There were seven procedural complications: two thrombosed branch renal arteries partially lysed with urokinase, two puncture site pseudoaneurysms, one puncture site hematoma requiring a transfusion, and three cases of cholesterol embolization (CCE) one with permanent and two with transient renal failure. Angiographic follow-up has been performed in 36% of implanted stents. Seventy-eight percent of stents were widely patent, 22% of stents showed >60% restenosis. One patient died prior to follow-up from an unrelated cause. Clinical follow-up was available in 100% of patients at a mean of 18 months (0–46); in 22 patients follow-up was at more than 15 months.

The mean blood pressure prior to stenting was 183/91 mm Hg and at the latest clinical follow-up 149/78

mm Hg ($P < .001$). The number of antihypertensive medications was reduced from a mean of 2.93 + 1.4 to 2.08 + 0.9. Seventy-six percent of patients with Cr > 2.0 mg/dl benefited; 50% had > 20% decrease in Cr, and 25% had stabilized their serum Cr. Eleven of 13 patients with recurrent pulmonary edema and bilateral renal artery stenosis were cured following stenting of one or both renal arteries.

Imaging Follow-up

MRA is not possible in ferrous stainless steel stents. The OmniFlex stent is constructed from platinum, a non ferromagnetic metal, which produces little artifact and is MR TRANSPARENT. The OmniFlex is the only balloon expandable stent which is MR transparent. This is clearly very important, when restenosis is suspected. CTA is limited by the need for iodinated contrast and stent artefacts in evaluating restenosis, DSA is invasive and also requires iodinated contrast and ultrasound gives only indirect measures of patency.

Conclusion

In patients with physiologically significant renal artery stenosis, renal artery stenting is a useful alternative to open surgical repair, with similar intermediate term results, for the treatment of renal dysfunction, poorly controlled hypertension or recurrent pulmonary edema.

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11:40 a.m.

An Update on Current Devices for PTRA and Stenting and Is There a Role for Protection?

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