Preliminary Study of the Use of Drug-eluting Stents in Atherosclerotic Renal Artery Stenoses 4 mm in Diameter or Smaller

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PURPOSE: To describe restenosis and clinical outcomes with drug-eluting stents (DESs) and compare them to those of bare metal stents (BMSs) in the treatment of symptomatic atherosclerotic renal artery stenosis (RAS) in the same patients.

METHODS AND MATERIALS: A retrospective study was performed of all patients with RAS treated with a DES (Taxus Express 2 or Cypher). DESs were used for RASs with luminal vessel diameters of 4 mm or smaller and BMSs were used for those larger than 4 mm.

RESULTS: Sixteen patients (eight women; mean age, 72 years ± 8) underwent treatment of 27 RASs for worsening renal function ($n = 10$) and uncontrolled hypertension ($n = 6$). Eighteen RASs were treated with 23 DESs (Cypher, $n = 12$; Taxus, $n = 11$) and nine were treated with BMSs. The average follow-up was 22 months ± 10. After the procedure, the mean systolic blood pressure decreased significantly ($P < .05$), with no change in the mean diastolic pressure, serum creatinine, or number of antihypertensive medications. By Kaplan-Meier estimates, the 1- and 2-year patency rates for DESs were 78% and 68%, respectively; and for BMSs, the respective rates were 58% and 47% (P = NS). The average diameters of RASs were 3.4 mm ± 0.6 in the DES group and 5.3 mm ± 0.6 in the BMS group ($P < .05$). There were two technical failures (7.7%) in the DES group. There was one minor complication and a non–flow-limiting dissection.

CONCLUSIONS: DESs were used to treat RASs with good technical results and low restenosis rates compared with BMSs despite the smaller artery diameters in the DES group.

J Vasc Interv Radiol 2008; 19:833–839

Abbreviations: BMS = bare metal stent, RAS = renal artery stenosis, RI = resistive index

RENAL artery stenosis (RAS) may present with hypertension and/or chronic renal insufficiency. In elderly subjects, atherosclerosis is the major cause of RAS, and in 90% of patients it involves the ostium and/or the proximal third of the main renal artery (1). Percutaneous renal artery angioplasty with stent placement is a well recognized treatment for atherosclerotic RAS (2,3). Reported technical success rates of this procedure are 98%–100% (4). However, restenosis rates of bare metal stents (BMSs) used for treating RAS are reported to be 15%–20% at 6 months by duplex ultrasound (US) surveillance for renal arteries with diameters larger than 5 mm (4). Moreover, renal arteries with diameters smaller than 4 mm are associated with a lower patency rate because of the higher incidence of in-stent restenosis caused by the smaller initial renal artery diameter (4).

Drug-eluting stents (DESs) have been used for the treatment of stenosis involving the coronary arteries and are associated with lower restenosis rates. Their use may offer a potential alternative to BMSs in renal arteries with diameters smaller than 4 mm (4). There have been several case reports of the use of DESs for the treatment of de novo RASs involving the bifurcation of the renal artery or in-stent restenosis (5–7). The present article present a single-institution experience in patients with RAS treated with DES placement for uncontrolled hypertension and/or worsening renal function.

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From the SIR 2008 Annual Meeting.

None of the authors have identified a conflict of interest.

DOI: 10.1016/j.jvir.2008.03.017

Table 1
Study Group Demographics

Variable	Study Group ($N = 16$)
Male sex (%)	8 (50)
Age (y)	
Mean ± SD	71 ± 7
Median	70
Range	56–86
White race	16 (100)
Risk factors (%)	
Hypertension	16 (100)
Diabetes	6 (37.5)
Dyslipidemia	14 (88)
Coronary artery disease	9 (53)
Peripheral atherosclerosis disease	3 (19)
Stroke	4 (25)
Carotid disease	3 (19)
Statin usage	14 (88)
Smoking (current or past)	13 (81)
Family history of CAD	12 (75)
Indication	
Chronic renal insufficiency	10 (62.5)
Hypertension	6 (37.5)

Note.—Values in parentheses are percentages. CAD = coronary artery disease.

MATERIALS AND METHODS

Institutional review board approval was obtained before the present study was performed. A retrospective review was performed of all patients who underwent DES placement for RAS. Patients who had bifurcation lesions involving the main renal artery or were undergoing hemodialysis were excluded. DESs were used for RASs in vessels with reference luminal vessel diameters no greater than 4 mm and balloon-expandable BMSs were used in vessels with diameters larger than 4 mm. The demographics and comorbidities of patients are included in **Table 1**. Baseline and follow-up data were obtained retrospectively, with prospective follow-up data obtained regarding outcomes of death, renal transplantation, and hemodialysis. The primary endpoints included death, need for revascularization because of in-stent restenosis, dialysis, or renal transplantation at the time of follow-up. This information was obtained through our medical records ending in December 2007.

Definitions and Endpoints

RAS was defined as a diameter reduction of greater than 50% by visual estimate compared with its immediate distal nondilated main renal arterial segment (8). An RAS was defined as ostial if it was located within a 5-mm distance from the renal artery origin from the aorta and defined as nonostial if it was located more than 5 mm away from the renal artery origin (21). Technical success was defined by less than 30% residual stenosis by visual estimate after deployment of the stent on completion angiography. In-stent restenosis was defined as more than 50% stenosis by visual estimate on follow-up angiography. All complications were recorded according to the guidelines published by the Society of Interventional Radiology (8). Contrast agent–induced nephropathy was defined by a 20% increase in serum creatinine level 48 hours after the procedure.

Renal Duplex US

Renal duplex US was used for screening and quantification of the severity of RAS (8). Baseline and follow-up duplex US studies were performed with a 2.5–4.5-MHz phased-array transducer (128/XP; Acuson, Mountain View, California or Sequoia 512; Siemens Medical Systems, Erlangen, Germany). RAS or restenosis was defined on renal duplex US as at least 60% stenosis if the angle-corrected peak systolic velocity was at least 180 cm/sec or the peak systolic velocity and/or ratio of the renal artery peak systolic velocity to the aortic peak systolic velocity was at least 3.5 (aortic valve measured near the renal artery origin from the aorta) at a Doppler insinuation angle no greater than 60°. Resistive indexes (RIs) were obtained by interrogation of the upper and lower intrarenal segmental arteries. RIs from the middle segmental arteries were used whenever available. An average of the two of three intrarenal segmental artery RIs was used to calculate the mean RI.

RAS Placement

All procedures were performed according to the same technique. Before renal angiography, informed consent was obtained from the patient for potential renal angioplasty and stent placement. In all patients, the right common femoral artery was accessed with an 18-gauge, 7-cm angiographic needle (Cook, Bloomington, Indiana). A 6-F vascular sheath (Terumo, Somerset, New Jersey) was placed in the artery over a 0.035-inch Bentsen guide wire (Cook). A 6-F internal mammary guide catheter (Boston Scientific, Natick, Massachusetts) was used to engage the origin of the renal artery. Angiography was performed with 4–8 mL of Visipaque 320 (GE Healthcare, Princeton, New Jersey) or 4–8 mL of gadopentetate dimeglumine (Magnevist; Berlex, Wayne, New Jersey) in patients with severe chronic renal insufficiency to determine the extent of stenosis. For RAS, a 0.014-inch Reflex wire (Cordis, Warren, New Jersey) was typically placed into the renal artery. During the procedure, all patients were given a bolus of heparin intravenously (50 U/kg body weight). A Cypher or Taxus stent was deployed based on the operator's preference. The length and diameter of the stent used was based on the length of the stenosis and the diameter of the nondiseased artery distal to the stenosis. Pressure gradients were obtained only if there was a question of lesion severity. A mean gradient measured simultaneously between the aorta to the distal renal artery of 5 mm Hg or a systolic gradient of more than 10 mm Hg was considered hemodynamically significant. This measurement was performed if there was a question of RAS.

One patient had uncontrolled hypertension and was taking four antihypertensive medications. A magnetic resonance (MR) imaging study with MR angiography (**Fig 1**) showed that there was a chronic total occlusion of the inferior renal artery and a contralateral high-grade RAS (**Figs 1a,b**). Despite vascular occlusion, cortical thickness and perfusion appeared to be preserved in the left kidney (**Fig 1c**). Angiography of the superior pole artery with gadolinium demonstrated perfusion of the lower part of the kidney through capsular collateral vessels. With a Gold Glide 70° 0.018-inch hy-