Embolic Protection Devices in Patients with Renal Artery Stenosis with Chronic Renal Insufficiency: A Clinical Study

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PURPOSE: To present clinical outcomes with the use of embolic protection devices (EPDs) and renal artery stents in patients with chronic renal insufficiency (CRI) and renal artery stenosis (RAS).

MATERIALS AND METHODS: A retrospective study was conducted in 23 patients with RAS and CRI who were treated with renal artery stent placement with an EPD. Follow-up data were obtained through medical records.

RESULTS: In 23 patients (18 men; 78%) with an average age of 69.4 years ± 11 (range, 46–86 y), 32 renal arteries were treated for worsening renal function (n = 17; 74%) or uncontrolled hypertension and worsening renal function (n = 6; 26%). Nine FilterWire EZ devices were used in eight patients (35%) and 17 SpideRX devices were used in 15 patients (65%). The average follow-up was 8 months ± 5. After the stent procedure, the mean systolic blood pressure decreased significantly (P < .05) whereas the diastolic pressure remained unchanged. There was a significant increase in the mean estimated glomerular filtration rate from 32.9 mL/min ± 12.9 at baseline to 41.3 mL/min ± 13.7 at last follow-up (P < .05). In 96% of patients, there was improvement or stabilization of kidney function. In six of the 17 SpideRX devices (35%), macroscopically evident embolic material was observed in the device after stent placement. There were two minor and two major complications.

CONCLUSIONS: Renal artery stent placement combined with the use of a SpideRX or FilterWire EZ device is associated with an good clinical outcome with a reasonable safety profile.

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Abbreviations: CRI = chronic renal insufficiency, eGFR = estimated glomerular filtration rate, EPD = embolic protection device, K-DOQI = Kidney Disease Outcome and Quality Initiative, RAS = renal artery stenosis

PERCUTANEOUS renal artery angioplasty with stent placement has become the cornerstone therapy for the treatment of atherosclerotic renal artery stenosis (RAS). The reported technical results are excellent, with a 98%–100% procedural success rate (1). However, improvement in renal function is difficult to predict. Improvement in kidney function is reported to occur in only 30%–40% of patients, stabilize in another 30%–40%, and deteriorate in 20%–30% (2,3). Many factors have been hypothesized as the cause for the deterioration in kidney function, including contrast medium–induced nephrotoxicity, progressive concomitant nephrosclerosis from multiple cardiovascular risk factors, diffuse distal atherosclerosis involving nontreated vessels, and atheroembolism (4).

Atheroembolism is believed to be caused by the release of microscopic plaque fragments and cholesterol crystals from the RAS or atherosclerotic aorta. This can occur during catheter manipulation in the suprarenal aorta or while crossing the RAS, which results in subsequent embolization into the renal parenchyma (4). A few studies have reported that postprocedural renal function deterioration is caused by atheroembolic complications (4). The majority of these studies were performed with the use of balloons and stents on a 0.035-inch platform, which may have contributed to the atheroembolism. Currently, it is hypothesized that the newer low-profile balloons and stents on a 0.014-inch platform may reduce the risk of atheroembolism.

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Embolic protection devices (EPDs) have been used to prevent atheroembolism during treatment of stenosis involving saphenous vein bypass grafts used as arterial conduits for coronary artery disease and in conjunction with the placement of a carotid artery stent (5). Recently, several reports (6–11) have described the use of these devices to prevent atheroembolism during renal artery stent placement. It has been hypothesized that these devices may help prevent atheroembolism during renal artery stent procedures. The purpose of the present article is to present our initial experience with two EPDs, the FilterWire EZ (Boston Scientific, Natick, Massachusetts) and SpideRX (ev3, Plymouth, Minnesota), for the treatment of RAS in patients with chronic renal insufficiency (CRI).

MATERIALS AND METHODS

Approval was obtained from the institutional review board to review medical records before this study was conducted. A retrospective review of all patients who had CRI and RAS and underwent renal artery angioplasty with stent placement with the use of an EPD from June 2005 to October 2006 was performed. Baseline and follow-up data were obtained retrospectively, with prospective follow-up data obtained on outcomes of death, renal transplantation, and hemodialysis. All patients had worsening renal function (ie, baseline estimated glomerular filtration rate [eGFR] ≤60 mL/min) with or without hypertension. Endpoints included death, revascularization, dialysis, or renal transplantation at time of follow-up obtained through our medical records ending in June 2007.

The severity of CRI before intervention was classified according to the Kidney Disease Outcome and Quality Initiative (K-DOQI) by obtaining an eGFR with the Modification of Diet in Renal disease equation (12):

$$\text{eGFR} = 186 \times \text{serum creatinine} - 1.154 \times \text{age} - 0.203 \times 0.742\ (\text{female sex}) \times 1.210\ (\text{black race})$$

For the purposes of a more detailed analysis, we divided stage 3 into 3A (eGFR of 45–59 mL/min) and 3B (eGFR of 31–44 mL/min).

Definitions and Endpoints

RAS was defined by a diameter reduction of greater than 50% by visual estimate compared with the immediately distal nondilated main renal arterial segment (13). An RAS was defined as ostial if it was located within 5 mm of the renal artery origin from the aorta and nonostial if it was located more than 5 mm away from the renal artery origin. Technical success of the stent procedure was defined by less than 30% residual stenosis by visual estimation after deployment. Technical success of the EPD procedure was defined by successful deployment of the device, retrieval of the device, and adequate filtration. This was reported as the number of successful EPD deployments per number of total attempted EPD deployments. Partial protection of the kidney was usually noted when the device was deployed in the primary branch of the renal artery. Complete protection of the kidney was defined as complete protection of the renal artery with the device being deployed in the main renal artery. 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 (13). Improvement in kidney function was defined as an increase in kidney function by one stage at last follow-up compared with the baseline measurement immediately before stent placement. Stabilization in kidney function was defined as no change in K-DOQI stage at last follow-up compared with the baseline measurement immediately before stent placement. Decrease in kidney function was defined as a change in K-DOQI stage by at least one stage at last follow-up compared with the baseline measurement immediately before stent placement. Contrast medium–induced nephropathy was defined as a 20% increase in serum creatinine level at 48 hours after the procedure.

Renal Duplex Ultrasound

We used renal duplex ultrasound (US) for screening and quantification of severity of RAS (13). 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, 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 aortic velocity ratio was at least 3.5 (with aortic velocity measured near the renal artery origin from the aorta) at a Doppler insinuation angle no greater than 60°. Resistive indexes were obtained by interrogation of the upper and lower intrarenal segmental arteries. Indexes from the middle segmental arteries were used whenever available. The average of the two or three intrarenal segmental artery resistive indexes was used to calculate the mean index.

Renal Artery Stent Placement

All patients were admitted to the hospital the day before the procedure for overnight hydration with bicarbonate and or oral N-acetylcysteine (600 mg twice daily). Other than those with contraindications such as fluid overload and asthma, patients were prehydrated with oral fluids and or intravenous crystalloids with or without N-acetylcysteine (Mucomyst; Bristol-Myers Squibb, Princeton, New Jersey) to prevent the potential nephrotoxic effects of contrast medium. Before renal angiography, informed consent was obtained from the patient for potential renal angioplasty and stent implantation. All procedures were performed with use of the same technique, and the right common femoral artery was accessed with an 18-gauge, 7-cm angiographic needle (Cook, Bloomington, Indiana). A 6-F or 7-F vascular sheath (Terumo, Somerset, New Jersey) was placed in the artery over a Bentson guide wire (Cook). A 6-F or 7-F internal mammary guide catheter (Boston Scientific) 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; Bayer, Wayne, New Jersey) to