Ostial Renal Artery Stent Placement in Patients 75 Years of Age or Older

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Renal artery stent placement has been shown to improve blood pressure (BP) and stabilize renal function in patients with atherosclerotic renovascular disease. However, limited data are available in patients ≥75 years of age.

We analyzed the presten characteristics and clinical outcomes of patients aged ≥75 years who underwent renal artery stenting at our institution. We compared these data with those from the remainder of our stent cohort.

Nineteen of 89 (21.3%) stent patients were ≥75 years old. Before intervention, those ≥75 years were significantly more likely to be women (84.2% v 55%; P = .02), current or former smokers (78.6% v 36.8%; P = .002), and on a greater number of antihypertensive medications (3.68 v 2.80; P = .048). Average clinical follow-up was similar in both groups (23.9 v 23.2 months; P > .05). At last available follow-up, there were more deaths in those ≥75 years (7/19 v 5/70; P = .038). No significant difference was found in the incidence of dialysis after intervention (3/19 v 7/70). Seventy-four percent of those ≥75 years had improved BP, 21% were stable, and 5% were worse. Renal function was improved in 26%, stable in 53%, and worse in 21%. Among those ≥75 years, there was a significant decrease in systolic BP (186.9 to 144.4; P < .01). There was a trend toward decreased diastolic BP and medications. These clinical results did not differ significantly from patients <75 years.

Patients ≥75 years of age with atherosclerotic renovascular disease have a higher incidence of mortality 2 years after renal artery stent placement, but they seem to derive clinical benefit comparable to younger patients. Am J Hypertens 2001;14:983–988 © 2001 American Journal of Hypertension, Ltd.

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Although there have been relatively few published studies, the limited data available suggest that elderly patients with ARVD have higher complication rates and lower rates of response to percutaneous renal artery angioplasty (PTRA) than to surgical revascularization.1 However, surgical revascularization is associated with significant morbidity and mortality, especially in elderly patients. One study that examined the morbidity of surgical revascularization in the elderly found that the quality of life in elderly patients 1 year after renal artery bypass was comparable to patients with amyotrophic lateral sclerosis or home oxygen-dependent chronic obstructive lung disease.2

Recently, there has been increased enthusiasm for renal artery stent placement in patients with ARVD.3 In numerous observational studies, renal artery stent placement has been shown to improve blood pressure (BP) control and...
Table 1. Prestent clinical characteristics of patients <75 years and ≥75 years old who underwent ostial renal artery stent placement

<table>
<thead>
<tr>
<th></th>
<th>&lt;75 years</th>
<th>≥75 years</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>70</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td>Age (y)</td>
<td>63.1 ± 8.0</td>
<td>79.8 ± 4.3</td>
<td></td>
</tr>
<tr>
<td>Men/women</td>
<td>32/38</td>
<td>3/16</td>
<td>.018</td>
</tr>
<tr>
<td>Bilateral RAS</td>
<td>39 (55.7%)</td>
<td>16 (84.2%)</td>
<td>NS</td>
</tr>
<tr>
<td>Current or former smokers</td>
<td>55 (78.6%)</td>
<td>7 (36.8%)</td>
<td>.002</td>
</tr>
<tr>
<td>Atherosclerotic heart disease</td>
<td>36 (51.4%)</td>
<td>11 (57.9%)</td>
<td>NS</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>26 (37.1%)</td>
<td>7 (36.8%)</td>
<td>NS</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>16 (22.9%)</td>
<td>3 (15.8%)</td>
<td>NS</td>
</tr>
<tr>
<td>Chronic renal insufficiency</td>
<td>46 (65.7%)</td>
<td>17 (89.5%)</td>
<td>NS</td>
</tr>
<tr>
<td>Systolic BP (mm Hg)</td>
<td>179.8 ± 23.6</td>
<td>186.9 ± 33.5</td>
<td>NS</td>
</tr>
<tr>
<td>Diastolic BP (mm Hg)</td>
<td>87.5 ± 14.5</td>
<td>86.4 ± 13.8</td>
<td>NS</td>
</tr>
<tr>
<td>Serum creatinine (mg/dL)</td>
<td>2.09 ± 1.44</td>
<td>2.47 ± 1.30</td>
<td>NS</td>
</tr>
<tr>
<td>BP medications (#)</td>
<td>2.80 ± 1.43</td>
<td>3.68 ± 1.57</td>
<td>.048</td>
</tr>
</tbody>
</table>

RAS = renal artery stenosis; NS = not significant; BP = blood pressure.
Data shown are actual numbers or means ± SD except where stated. Numbers in parentheses indicate percentage of respective group.
NS = P ≥ .05.

stabilize renal function in diverse patients with ARVD.4–14 At least for ostial lesions, renal artery stent placement is usually considered to yield superior results to routine PTRA.15 However, there has been little data published looking specifically at the results of renal artery stenting in patients ≥75 years of age.

We undertook this observational cohort study to determine the present clinical characteristics and clinical results of stenting in patients ≥75 years of age who underwent renal artery stent placement at our institution for ostial ARVD. We compared these results to the remainder of our ARVD ostial stent cohort (those <75 years of age) to determine differences in present clinical characteristics and whether the results were similar.

Methods

Between April 1992 and July 1997, 100 renal artery stents were placed in 90 patients with atheromatous (nontransplant) renal artery disease at our institution. Demographics of the study population are shown in Table 1. Patients underwent baseline arteriography followed by placement of a stainless steel articulated (the first 12 patients) or nonarticulated (the remaining 78 patients) Palmaz stent (Johnson & Johnson Interventional Systems Co., Warren, NJ) at the site of the stenosis. Selective angiography was performed after stent implantation to insure proper deployment.

The clinical indications for this procedure were renovascular hypertension with or without suspected ischemic nephropathy. Any renal artery lesion with a more than 60% diameter stenosis as measured by angiography or a systolic pressure gradient of >10 mm Hg (or a mean gradient >5 mm Hg) was considered hemodynamically significant. Only lesions that fulfilled this criteria were selected for intervention. In keeping with our usual protocol, all hemodynamically significant ostial lesions were routinely stented after angioplasty. In patients with bilateral ostial atherosclerotic disease, the decision to intervene on one or both renal arteries was at the discretion of the attending interventional radiologist and the referring physician. Only patients who underwent actual deployment of a stent were included in this analysis. All patients who had stent deployment and at least 1 month of clinical follow-up were included in accordance with intention to treat analysis. The appropriate institutional review committee approved experimental protocols and the process for obtaining informed consent.

The medical records of all 90 patients were reviewed. Before stent placement, the following information was obtained through patient interview and review of the chart: age, gender, approximate duration of hypertension, most recent BP, most recent serum creatinine (SCr), number of antihypertensive medications, smoking history, and the presence or absence of peripheral artery disease (PVD), chronic renal insufficiency (CRI), known atherosclerotic heart disease (ASHD), and diabetes (DM). Chronic renal insufficiency was defined as a preprocedure SCr ≥1.5 mg/dL.

The renovascular anatomy was determined at the time of angiography by the attending radiologist. The presence of unilateral (URAS) or bilateral (BRAS) disease was determined using the previous definition for hemodynamic significance.

Patients were then divided into two groups based on age at the time of procedure: 1) <75 years old, and 2) ≥75 years old.

After stent placement, clinical follow-up information was obtained by review of clinic and hospital charts and phone contact with the patients and their referring physicians. The following follow-up data was obtained whenever possible at each follow-up contact: most recent BP, most recent SCr, number of prescribed antihypertensive
medications, incidence of further renal artery interventions, death, initiation of dialysis, and major complications of stent placement.

Blood pressure was considered improved if at the last available follow-up there was: 1) a decrease in diastolic BP (DBP) of ≥15 mm Hg on a similar medical regimen; 2) a decrease in systolic BP (SBP) of ≥20 mm Hg on a similar medical regimen; or 3) a decrease in the number of drugs by ≥2 with no significant increase in SBP or DBP. Blood pressure was considered worse if there was an increase in DBP of ≥15 mm Hg, an increase in SBP of ≥20 mm Hg, or an increase in the number of medications by ≥2 without significant decreases in BP. Blood pressure was considered stable if neither of the above criteria were met. Renal function was considered improved if there was a decrease in SCR of >20%, worse if there was an increase in SCR of >20%, and stable if there was a ≤20% change. By definition, if preprocedure SCR was <1.5, renal function could not be considered improved, only stable or worse.

Only patients with at least 1 month of available clinical follow-up were included in the following analysis. The prevalence of the aforementioned present clinical characteristics of those patients ≥75 years of age were compared to those <75 years of age using an unpaired t test; when either the normality test or the test of equal variance failed a Mann-Whitney rank sum test was performed. Incidence of death, initiation of dialysis, SCR, BP, and average number of medications were also compared between the two groups using a paired t test or the test of equal variance. When either the normality test or the test of equal variance failed, a Mann-Whitney rank sum test was performed. Incidence of further renal artery interventions, death, initiation of dialysis, SCr, BP, and average number of antihypertensive medications were also compared between the two groups using a paired t test or rank some test as appropriate. Sigma Stat-2 (SPSS Inc., Chicago, IL) was the statistical program used. Rates of blood pressure and SCR improvement, stabilization, and worsening were calculated separately for those patients <75 years of age and those ≥75 years of age.

Results

Clinical follow-up was available for 89 of the 90 patients who underwent ostial renal artery stent placement in a total of 99 renal arteries (ie, one patient had no available clinical follow-up data). The mean age of this cohort was 66.7 years. All patients (100%) had a known history of hypertension and were taking antihypertensive medications. Sixty-two of 89 (69.7%) had evidence of chronic renal insufficiency. Bilateral renal artery lesions were present in 54 of 89 patients (60.7%). Initial technical success (defined as reasonable appearing angiographic result or a diminution of the preprocedure pressure gradient) was achieved in 96 of 99 arteries (97.0%).

Of these 89 patients, 70 (78.7%) were <75 years of age and 19 (21.3%) were ≥75 years of age. The present clinical characteristics of each group are given in Table 1. There were statistically significant differences in the prevalence of female sex, current or former smoking, and number of BP medications prescribed.

Complications included: puncture site pseudoaneu-

rysms (one requiring surgical repair), renal artery dissection (either at time of PTRA or stenting), in situ stent thrombosis (all resolved at least partially with urokinase), displacement of the stent into the aorta (easily recovered), retroperitoneal bleed, suspected cholesterol embolization, and death within 30 days of the procedure. There was no statistically significant difference in the incidence of complications between groups; 21.1% in those ≥75 years and 14.3% in those <75 years. There was one death within 30 days of stenting; this case was an 86-year-old woman with intractable pulmonary edema and who had experienced two cardiac arrests within 1 week before stent placement. At arteriography, this patient was found to have bilateral severe stenosis >95% in diameter, one of which was stented. After the procedure she had an initial brisk diuresis followed by acute deterioration in renal function and recurrent pulmonary edema. Urgent follow-up angiography revealed a thrombus within the stent, which did not respond well to intraarterial thrombolysis.

Average follow-up in these 89 patients was similar in both groups: 23.2 (range, 1 to 68 months) vs 23.9 (range, 1 to 60) months (P > .05). At the last available clinical follow-up, there were seven deaths (36.8%) in those ≥75 years old and six deaths (7.1%) in those <75 years. The difference in rate of death was statistically significant (P = .02).

Before renal artery stent placement, 1 patient ≥75 years and 1 patient <75 years were on chronic dialysis; these patients are not included in the following analysis. In those ≥75 years, there were three cases (15.8%) of dialysis initiation (at an average of 2.7 months postprocedure; range, 1 to 6 months), and in those <75 years, there were seven cases (10.0%) of dialysis initiation (at an average of 15.9 months postprocedure; range, 1 to 47 months) (P > .05).

Preprocedure and last available follow-up average BP, SCr, and number of antihypertensive medications are shown in Fig. 1. Among those ≥75 years, there was a significant decrease in mean SBP (186.9 to 144.0 mm Hg; P < .001). Mean DBP (86.0 to 80.5 mm Hg) and drugs (3.68 to 2.78) decreased but did not reach statistical significance. Mean SCr increased slightly but did not reach statistical significance (2.47 to 2.62 mg/dL).

In patients <75 years of age, there was a significant decrease in mean SBP (179.8 to 149.7 mm Hg; P < .001) and DBP (87.5 to 79.6 mm Hg, P < .001) Drugs administered decreased but did not reach statistical significance (2.80 to 2.67). Mean SCr increased but did not reach statistical significance (2.09 to 2.35 mg/dL).

As shown in Fig. 2, 74% of those ≥75 years had improved BP, 21% were stable, and 5% were worse. Renal function was improved in 26%, stable in 53%, and worse in 21% of patients. These numbers are similar to those seen in the segment of the cohort who were <75 years old.
Discussion

There is increased recognition that ARVD is a potentially reversible cause of hypertension and renal insufficiency. Simultaneously, there have been numerous observational studies that have shown that renal artery stent placement improves BP control and stabilizes renal function in patients with ARVD. Subsequently, the popularity of this procedure appears to be increasing among interventional radiologists, vascular surgeons, and cardiologists.

In the cohort of patients who underwent renal artery stenting at our institution, 21% were 75 years of age or older. Many of the earlier published studies of stent placement did not include a single patient over the age of 75 years. In the largest contemporary observational studies, the mean age of patients undergoing renal artery stenting is usually 66 to 71 years, with a wide range of 44 to 90 years. Yet, to our knowledge there has been no previous attempt either to relate the clinical outcome of this intervention to age or to determine the risks and benefits of renal artery stenting in older patients relative to the younger population undergoing these procedures.

As with other disease processes, older patients with ARVD present unique challenges, and the results observed in younger patients may not be applicable to the older population. For example, when compared to younger patients, surgical mortality rates for repair of intact abdominal aortic aneurysms (AAA) have been shown to be twice as high in patients ≥70 years of age. Just as in the setting of AAA, elderly patients undergoing invasive procedures like renal artery stenting may be at increased risk for complications owing to a heavier and more diffuse atherosclerotic burden and the presence of significant comorbid conditions. However, unlike AAA, ARVD is not usually a life-threatening condition, and the response to intervention is varied. As such, we may be exposing elderly patients to increased risk without added benefit,
especially as it appears that many patients with ARVD can be managed medically.\textsuperscript{15}

The data from this retrospective observational study indicate that although they differed in the prevalence of female sex, history of smoking, and number of BP medications, the two groups (\(\geq 75\) or \(< 75\) years of age) were quite similar before intervention. Specifically, there was no significant difference in SBP, DBP, SCr, and history of diabetes, PVD, or atherosclerotic heart disease. Of course, selection bias may have played a role in this similarity as will be discussed below.

Examining the risks of the procedure, the incidence of significant complications were no greater in older versus younger patients. Selection bias may have also played an important role in this result. The only death within 30 days of the procedure did occur in a patient \(\geq 75\) years old. However, this was an extremely ill woman with significant cardiovascular comorbidities as evidenced by her two cardiac arrests in the few days before stent placement.

Examining benefits of the procedure, after a mean follow-up of approximately 2 years, the clinical results in both groups were impressive and comparable to those found in similar observational studies of renal artery stenting. In both age groups, BP was considered improved, although the total medication requirements did not change. Kidney function was unchanged overall. Some changes might have been more evident with larger sample sizes. Patients \(\geq 75\) years of age had a decrease of 42.6/5.8 mm Hg, and 74\% had evidence of BP improvement. The decrease in SBP was statistically significant.

With the advent of new antihypertensive agents, it is now possible to control BP in a substantial number of patients with renovascular hypertension.\textsuperscript{3,15,18–20} As such, for many investigators the emphasis on intervention has shifted to preservation of renal function as opposed to BP control.\textsuperscript{20–23} In terms of renal function response to stenting, in patients \(\geq 75\) years old there was a mild, nonsignificant increase in SCr, but renal function was either improved or stable in 79\%. As shown in Fig. 1 and 2, the BP and renal function results are quite similar to that obtained in the younger cohort.

The incidence of hemodialysis initiation was low and similar in both groups. The incidence of end-stage renal disease (ESRD) is increasing most strikingly in the elderly population. Between 1987 and 1992, the incidence rate of ESRD increased by 12.4\% to 17.1\% per year in the US population \(\geq 75\) years of age.\textsuperscript{24} The elderly now make up 44.5\% of the ESRD population in this country, and there is ample evidence that hemodialysis leads to significant decreases in both the quality and quantity of life in elderly patients.\textsuperscript{25} Multiple studies have shown that ARVD is a substantial contributor in the progression of ESRD; 10 to 15\% of new hemodialysis patients have angiographic evidence of ARVD.\textsuperscript{26,27} Other studies have suggested that renal artery stenting can preserve renal function and lead to the discontinuation of dialysis.\textsuperscript{5} Although our data do not quantify the usefulness of using renal artery stenting for renal preservation, they do suggest that there is no significant difference in benefit between younger and selected older patients.

The incidence of death within 2 years of stent placement was significantly higher in the older patient population. Although this result may not be surprising, it does have important clinical ramifications as a number of elderly patients may not survive to reap the benefits of this intervention.

Like all available research pertaining to the results of renal artery stenting, the most important weakness of this current study is its retrospective observational design. It is certainly conceivable that there is a significant selection bias such that only the healthiest and most robust patients \(\geq 75\) years of age were referred for intervention. The presence of a selection bias is supported by the fact that the preprocedure clinical characteristics of the older patients were extremely similar to those of the younger group. However, the inclusion of a critically ill patient who had suffered two cardiac arrests in the week before intervention suggests that perhaps the selection bias is not as strong as one might expect. We also did not directly assess changes in quality of life after the stent placement, and it is important to recall that quality of life is extremely important when considering the appropriateness of interventions in our older citizens.

The most important conclusion that can be drawn from these data is that compared to younger patients, renal artery stenting is equally efficacious and no more risky in patients \(\geq 75\) years old as long as they are carefully selected. This study was not designed to determine the best treatment modality for older patients with ARVD. Future studies should directly compare PTRA, renal vascular stenting, surgical bypass, and medical management in a randomized fashion stratified by age. On the basis of results of this current data, it would be ethical and important to include patients \(\geq 75\) years of age.

References


