Coral Trials: A personal experience that challenges its results in patients with uncontrolled blood pressure.

Dr. Javier Ruiz Aburto, FACS, FICS
Assistant Professor
Ponce School of Medicine
Puerto Rico
Financial Disclosure

• None
HEALTHCARE COST ANALYSIS 2012

• Healthcare costs USA $2.5 TRILLION a year
• 31% or $210 BILLION wasted in unnecessary services
• $190 BILLION Administrative costs
• 3 Billion dollars are spent a year in blood pressure medications
• GNP of France is $2.7 Trillion
Patients at Increased Risk for Renal Arterial Stenosis (RAS)

- New onset of hypertension: age > 30 and < 55 years of age
- Malignant, accelerated, or refractory hypertension
- Unexplained renal dysfunction
- Sudden onset “flash” pulmonary edema
- Size discrepancy (> 1.5 cm) between kidneys
- Multi-vessel coronary disease at the time of cardiac catheterization
- Peripheral Vascular Disease at the time of Angiography
- Unstable angina
- Hypertension with intolerance to medication
Pathophysiologic Mechanisms of RAS

- Unilateral renal artery stenosis

- The stenotic kidney reacts by increasing renin secretion which via the Renin-Angiotensin-Aldosterone pathway promotes Sodium retention and vasoconstriction which increases blood pressure
What are the benefits of Renal Artery Stenting?

• Improves renal function in most cases.

• Significant impact in blood pressure control by reducing the number of anti-hypertensive drugs from four ≥ to ≤ one drugs.

• Improves the functional class in congestive heart failure and reduces the risk of hemorrhagic stroke.

• Beneficial effect on patients with refractory angina pectoris.
Renal Artery Interventions

• Secondary Hypertension caused by Renal Artery Stenosis in the general population is 6.2%.

• Higher occurrence in patients with established PVD (22-59%).

• 78% PVD in our subset of patients

• In a study of 202 patients* with RAS, followed between 12 and 60 months, it was found:
  - progression of the disease occurred in 26-71%
  - renal artery occlusion in 16%.

* Roger Greenhalgh, Vascular and Endovascular Update, Charing Cross, 2010
Single Center Experience in Patients with resistant and uncontrolled blood pressure with Renal Artery Stenosis treated with PTA and/or Stenting. Atherosclerotic Lesions $\geq 70\%$ to $\leq 100\%$
### RENAL ARTERY STENTING

Number of Total Angioplasties: 304  
Number of Angioplasties with Stent: 271  
n= 271 (2005 – Apr 2015)

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>81</td>
<td>39%</td>
</tr>
<tr>
<td>Female</td>
<td>127</td>
<td>61%</td>
</tr>
<tr>
<td>Ages</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 55</td>
<td>15</td>
<td>7%</td>
</tr>
<tr>
<td>56-95</td>
<td>193</td>
<td>93%</td>
</tr>
<tr>
<td>Uncontrolled Blood Pressure</td>
<td>52</td>
<td>25%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>192</td>
<td>92%</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>159</td>
<td>76%</td>
</tr>
<tr>
<td>CAD</td>
<td>89</td>
<td>43%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>122</td>
<td>59%</td>
</tr>
<tr>
<td>Chronic renal dysfunction</td>
<td>104</td>
<td>50%</td>
</tr>
<tr>
<td>Active Smoker</td>
<td>79</td>
<td>38%</td>
</tr>
</tbody>
</table>
Renal Artery Interventions

**TECHNIQUE:**

- Procedure performed in an endovascular suite - OR
- Sedation, local or spinal anesthesia
- 7 French guiding-catheter; .018” J-shaped guide wire
- Road-mapping technique with C-Arm DSA
- Pre-dilatation with 5 x 20mm balloon
- Low profile, balloon mounted stent, rapid exchange preferable
- Heparin 5000 U
- Nonionic Iso-osmolar contrast agent is used routinely at a concentration of 50-75% with 0.9 saline
Initial procedure success 271 (96%)

Renal artery procedures unable to be performed due to anatomic conditions 3 (1%)

Atherosclerotic Renal Stenosis 261 (97%)

Fibromuscular Hyperplasia 8 (3%)

Takayasus Disease 3 (1%)
Potential Renal Intervention Complications:

- Athero – Emboli
- Renal Artery Dissection
- Aortic Dissection
- Renal Perforation
- Contrast Induced Nephropathy
- Renal Artery Occlusion or Thrombosis
- Segmental Kidney Infarction
- Renal Failure
## RENAL ARTERY STENTING
### Number of Angioplasties with Stent

\[ n = 271 \text{ (2005 – Apr 2015)} \]

<table>
<thead>
<tr>
<th>Condition</th>
<th>Occurrences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematoma</td>
<td>5 (2%)</td>
</tr>
<tr>
<td>CVA</td>
<td>2 (1%)</td>
</tr>
<tr>
<td>Renal Artery Occlusion</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Due to Cholesterol Atheroembolization</td>
<td></td>
</tr>
<tr>
<td>In Hospital Mortality (MI)</td>
<td>2 (1%)</td>
</tr>
</tbody>
</table>
RENAL ARTERY STENTING

• Number of Angioplasties with Stent
  n = 271 (2000 – Apr 2015)
  Lost to follow: 50  n= 158

Reduction in Antihypertensive Medications, BUN/Creat, and/or BP

• Decrease  118 (75%)

• No Change  40 (25%)
Renal Trials in Progress and Pending

- **ASTRAL**: 806 pts
- **STAR**: 140 pts
- **EMMA**: 23 pts
- **SNRASGG**: 55 pts
- **DRASTIC**: 106 pts
- **MELODI**: n: 282 – n 182 – 80% stent
- **CORAL**: 1,080 cases started 2009. Primary endpoints are reduction in adverse CV events, stabilization of BP and renal function. To be completed October 2013
  - Patients with hemodynamically significant stenosis
  - Best medical treatment with renal stenting with the use of distal protection vs. best medical treatment alone
Summary

Relevant End Points

* Improvement of renal function in most cases.

* 15% of our patients developed transient or progressive renal dysfunction

* Reduced number of Antihypertensive drugs

* Improved myocardial dysfunction; regression of myocardial hypertrophy in some cases

* Most important end points: reduction of myocardial infarctions and strokes. Improved survival rate
Thank You!
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