

2014 TCTAP

Wrap-Up Interview

Renal Artery Stenting Controversy

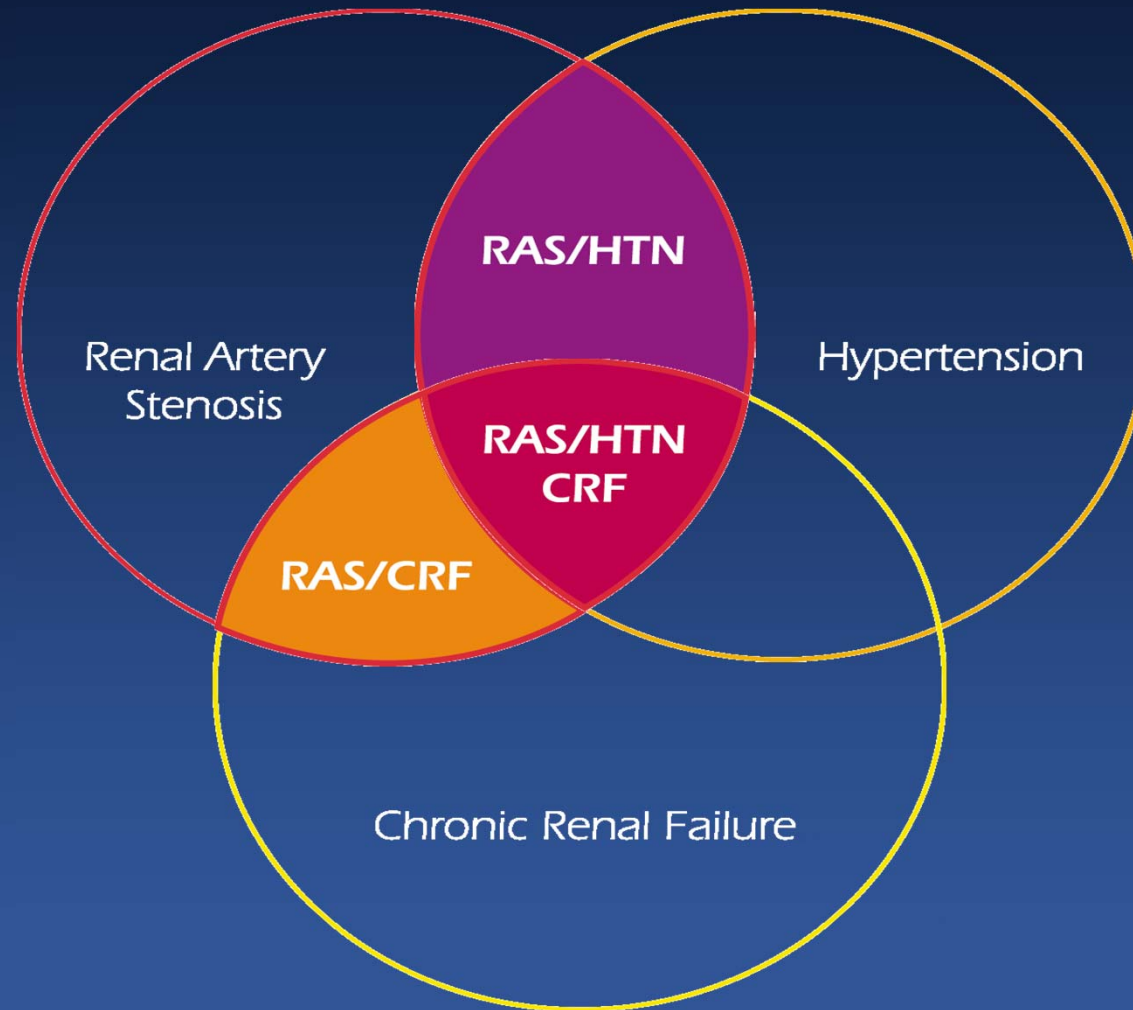
Moderator

Krishna J. Rocha-Singh

Interviewees

**Richard R. Heuser, Michael R. Jaff,
John Robert Laird, Jr.**

The Complex Dilemma of RAS



Interrelation among Renal Artery Stenosis, Hypertension and Chronic Renal Failure and “Hard” CV Events

Specific Issues in Brief

Renal Artery Stenting:

- Major recent RCTs: CORAL & ASTRAL
 - What do they tell us?
- What is the optimal strategy for the selection of the optimal stent candidate?
- How do recent Symplicity HTN-3 Trial design issues influence your interpretation of the CORAL results?

Renal Artery Stenting Criteria

Clinical Criteria:

- Resistant or Uncontrolled HTN and the failure of ≥ 3 medication one of which was a diuretic or intolerance to drugs

Anatomic Criteria:

- $\geq 70\%$ diameter stenosis or 50-70% with hemodynamic confirmation of lesion severity:
 - [-- ≥ 20 mmHg Dopamine-Induced mean pressure gradient]
 - [-- >0.9 Aortic to Distal lesion pressure gradient]

Renal Artery Revascularization: Societal Guidelines

- **Hypertension**
 - Accelerated, Resistant, or Malignant (IIaB)
 - Unilateral Small Kidney or Medication Intolerance (IIaB)
- **Atherosclerotic Nephropathy (Ischemic Nephropathy)**
 - Bilateral or Solitary (IIaB) or Unilateral (IIbC)
- **Cardiac Destabilization**
 - Recurrent, Unexplained Pulmonary Edema/CHF (IB)
 - Unstable Angina (IIaB)

CORAL Inclusion Criteria

Clinical Syndrome:

- Hypertension \geq 2 anti-hypertensive medications, OR
- Renal dysfunction defined as Stage 3 or greater CKD

AND

Atherosclerotic Renal Artery Stenosis:

- Angiographic: \geq 60% and $<$ 100%, OR
- Duplex: systolic velocity of $>$ 300 cm/sec, OR
- Core lab approved MRA, OR
- Core lab approved CTA

CORAL Primary Endpoints

Composite of major cardiovascular or renal events:

- Cardiovascular or Renal Death
- Stroke
- Myocardial Infarction
- Heart Failure Hospitalization
- Progressive Renal Insufficiency
- Permanent Renal Replacement Therapy

Screening and (Difficult) Enrollment

Screened Patients
(N=5322)

Patient Refusal (N=801)

Was there a lack of equipoise?

Randomized
(N=947)

Stent Plus Medical Therapy (N=467)
Received Stent (N=434, 94.6%)
Not Attempted (N=9, 1.9%)
False + Non-Invasive Study (N=13, 2.8%)
Failed Stent (N=3, 0.9%)

Medical Therapy Only (N=480)
Cross Over to Stent before Endpoint (N=12, 2.5%)

Excluded for Scientific Integrity (N=8)

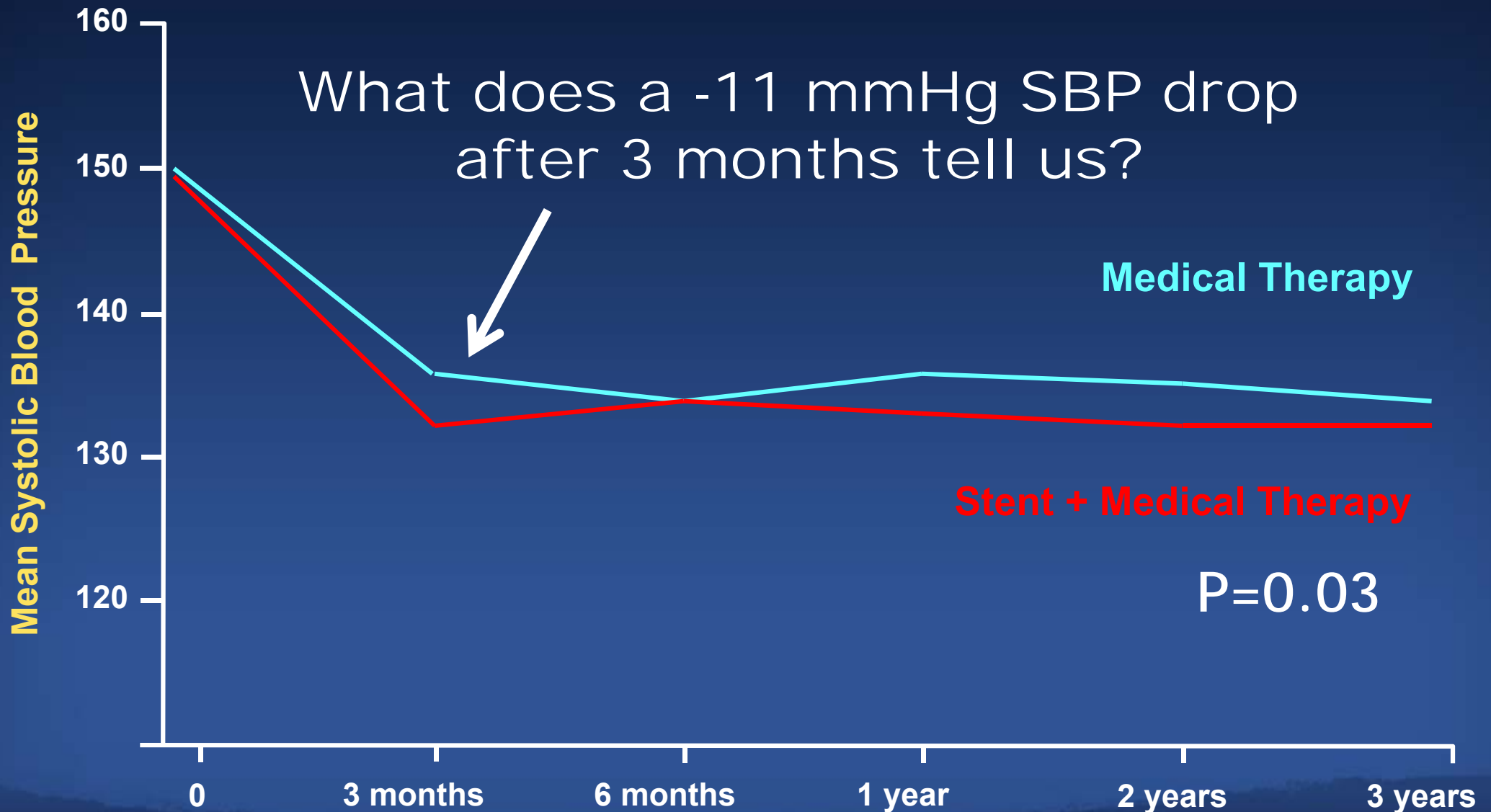
Excluded for Scientific Integrity (N=8)

Included in Primary Analysis (N=459)

Included in Primary Analysis (N=472)

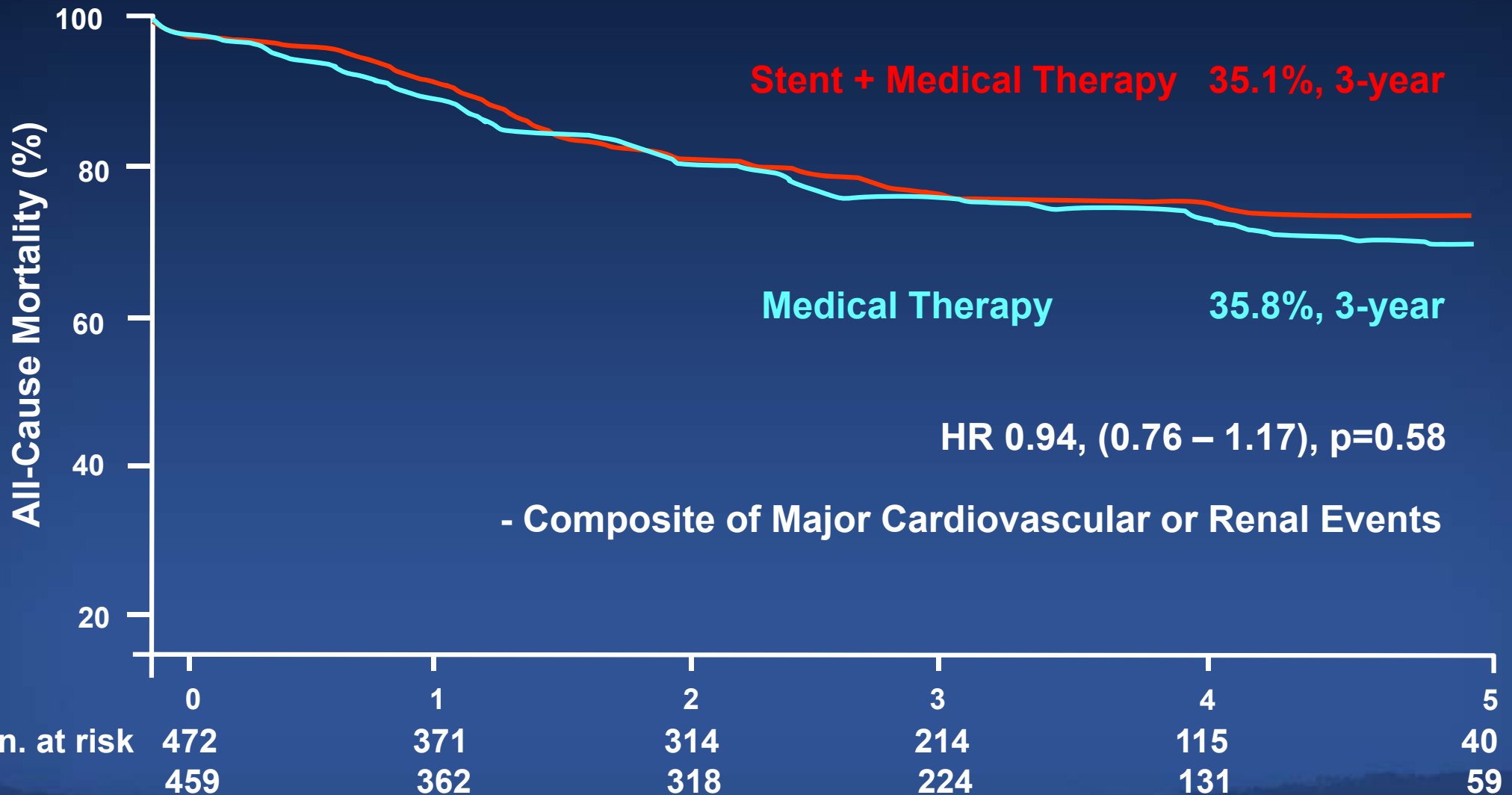
CORAL Trial (n = 947)

Renal Artery Stenting in Preventing Cardiovascular and Renal Events



CORAL Trial (n = 947)

Renal Artery Stenting in Preventing Cardiovascular and Renal Events



CORAL CRITIQUE:

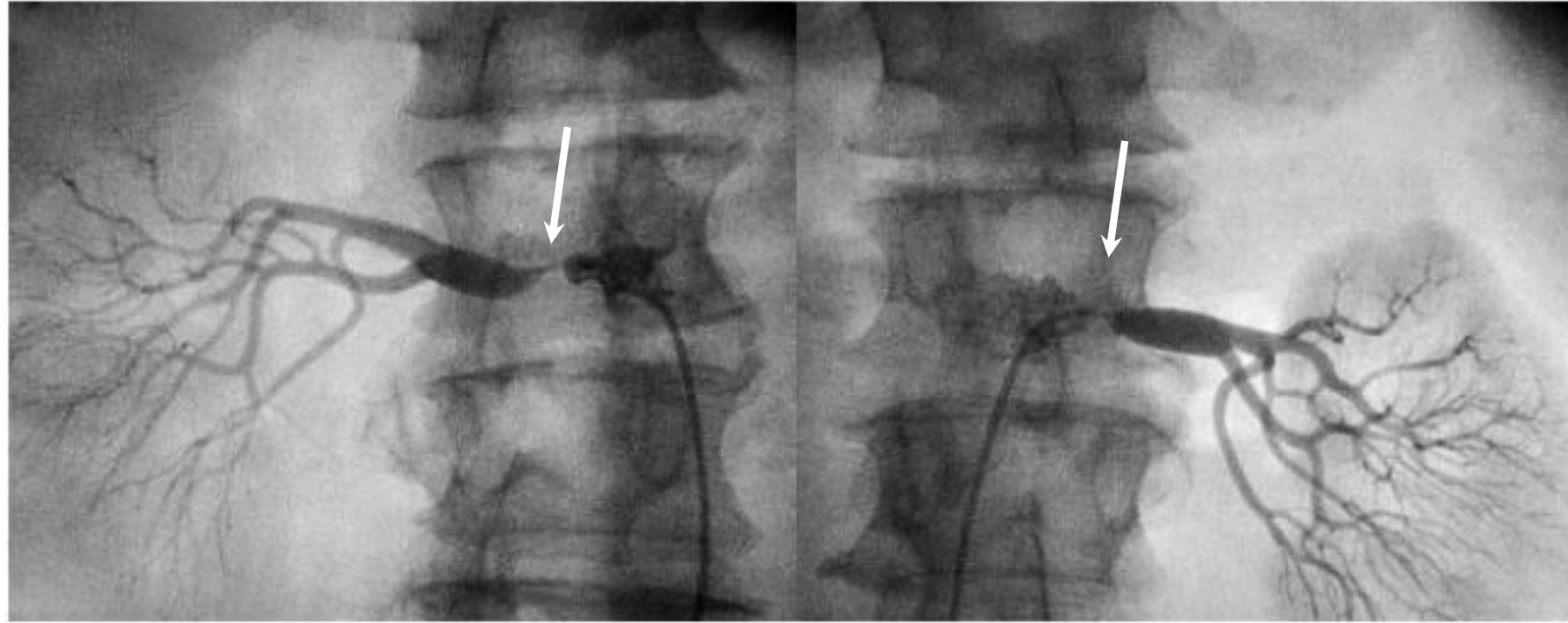
- Was there a patient selection bias introduced in the trial due to physician's "knowing" who to treat, not treat, and randomize?
- Were these patients on MAXIMAL tolerable antihypertensive therapy?
 - How do you explain the -11 mmHg decline in the non-sham control arm
- Were the renal artery lesions "critical"?

Discussion

Renal Artery Stenting

- CORAL: A challenging trial design; what did we learn for our money?
- So, how have the results of the trial changed your practice?
- OK...what would you do with this patient?

Stent or No Stent?



62 year old FM, +NIDDM, +CAD, +HTN (2 meds max. doses + HCTZ) Scr 1.5 & SBP 155/85 mmHg