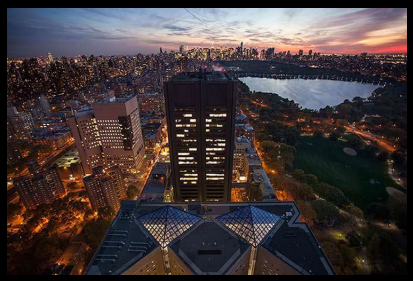
RENAL ARTERY STENOSIS IN 2025:
WHERE ARE WE AND WHERE ARE WE GOING?



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Professor of Radiology and Surgery
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Disclosure of Relevant Financial Relationships

Within the prior 24 months, I have had a financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

Nature of Financial Relationship	Ineligible Company
Grant/Research Support	Boston Scientific, INARI, Penumbra, Ethicon, Black Swan, Instylla, Gore, Reva Medical, Imperative Vascular, Inquis Medical, Becton Dickinson
Consultant Fees/Honoraria	Boston Scientfic, Penumbra, Medtronic, Imperative Vascular, Abbott Vascular, AIDOC, Siemens Healthineers
Individual Stock(s)/Stock Options	Imperative Vascular, Innova Vascular, Thrombolex, Summa Vascular, AIDOC, Votis
Royalties/Patent Beneficiary	N/A
Executive Role/Ownership Interest	N/A
Other Financial Benefit	N/A

All relevant financial relationships have been mitigated. Faculty disclosure information can be found on the app

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Why is there all this controversy surrounding renal artery stenting?

- No good data
- No clear indications
- No clear techniques
- No clear predictors of outcomes

Increase in Utilization of Percutaneous Renal Artery Interventions by Medicare Beneficiaries, 1996–2000

The Renal Stenting Downturn

IN JUST 6 YEARS

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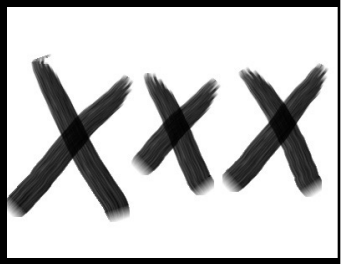
Three modern randomized trials for Renal Artery Revascularization

1. STAR
2. ASTRAL
3. CORAL



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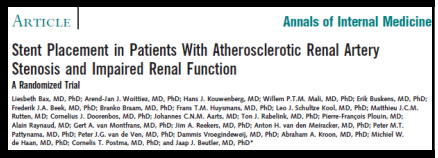
STAR


ARTICLE | Annals of Internal Medicine

Stent Placement in Patients With Atherosclerotic Renal Artery Stenosis and Impaired Renal Function
A Randomized Trial

- Randomized
- 10 centers
- 140 patients, CrCl < 80, ARAS 50% or greater
- Stent vs. Medical Rx
- Medical Rx: HTN meds, Statin, ASA
- Primary endpoint: 20% or more decrease in CrCl
- Secondary endpoints: safety, CV morbidity and mortality

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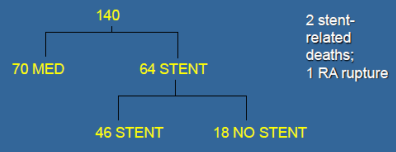
Randomized Trials of Stent vs. Meds

STAR

- n=140 Patients, Cr_{Cl} <80; RAS > 50%
- Primary endpoint: ≥ 20 % ↓ in Cr_{Cl}



2 stent-related deaths;
1 RA rupture

Bax L, et al. Ann Intern Med 2009;150:840-8.

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STAR

- Primary endpoint in 22% medical, 16% stent
- p=.06, 27% treatment effect
- "A considerable number of stent-related complications occurred, including 2 procedure-related deaths…suggesting that renal stenting for ARAS may cause more harm than benefit in a community setting."

Bax L, et al. Ann Intern Med 2009;150:840-8.

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The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Revascularization versus Medical Therapy for Renal-Artery Stenosis

The ASTRAL Investigators*

ABSTRACT

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ASTRAL Trial Schema

Diagnosis of significant ARVD
(Unilateral or Bilateral)
Revascularization not contraindicated

Uncertain whether to revascularize
Randomisation

Revascularization
with angioplasty and/or stent
(and medical treatment)

No revascularization
Medical Treatment only

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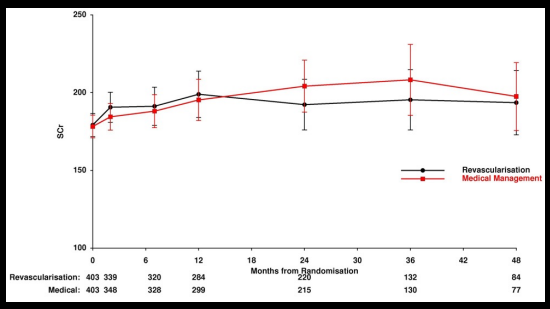
PLOT OF SCr OVER TIME



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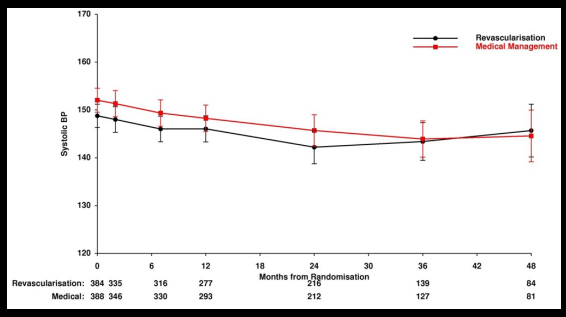
PLOT OF SYSTOLIC BP OVER TIME



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ORIGINAL ARTICLE

Stenting and Medical Therapy for Atherosclerotic Renal-Artery Stenosis

Christopher J. Cooper, M.D., Timothy P. Murphy, M.D., Donald E. Cutlip, M.D., Kenneth Jamerson, M.D., William Henrich, M.D., Diane M. Reid, M.D., David J. Cohen, M.D., Alan H. Matsumoto, M.D., Michael Steffes, M.D., Michael R. Jaff, D.O., Martin R. Prince, M.D., Ph.D., Eldrin F. Lewis, M.D., Katherine R. Tuttle, M.D., Joseph I. Shapiro, M.D., M.P.H., John H. Rundback, M.D., Joseph M. Massaro, Ph.D., Ralph B. D'Agostino, Sr., Ph.D., and Lance D. Dworkin, M.D., for the CORAL Investigators*

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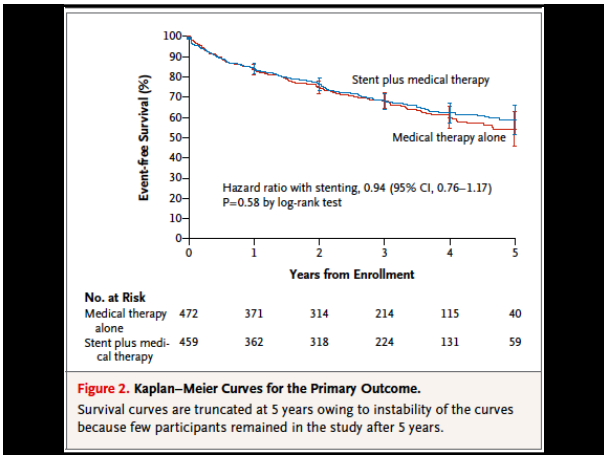

Figure 2. Kaplan–Meier Curves for the Primary Outcome.
Survival curves are truncated at 5 years owing to instability of the curves because few participants remained in the study after 5 years.

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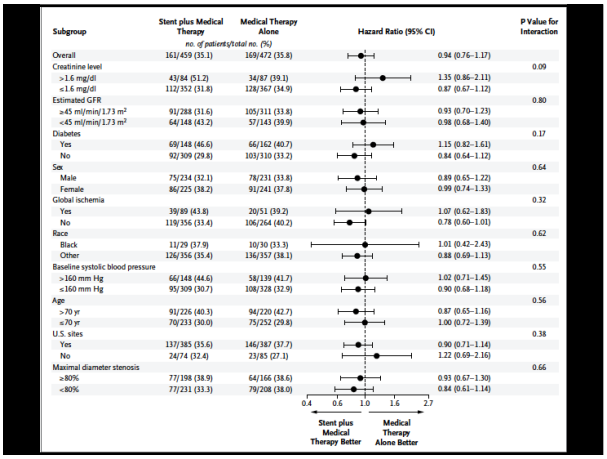

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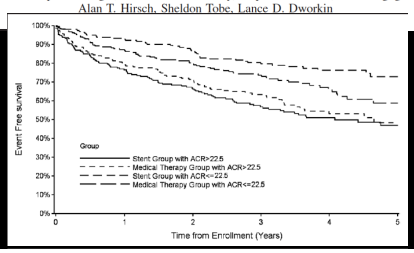
Clinical Trial: CORAL

Relationship of Albuminuria and Renal Artery Stent Outcomes

Results From the CORAL Randomized Clinical Trial (Cardiovascular Outcomes With Renal Artery Lesions)

Timothy P. Murphy, Christopher J. Cooper, Karol M. Pencina, Ralph D'Agostino, Joseph Massaro, Donald E. Cutlip, Kenneth Jamerson, Alan H. Matsumoto, William Henrich, Joseph I. Shapiro, Katherine R. Tuttle, David J. Cohen, Michael Steffes, Qi Gao, D. Christopher Metzger, William B. Abernethy, Stephen C. Textor, John Briguglio, Alan T. Hirsch, Sheldon Tobe, Lance D. Dworkin



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Hypertension

AHA SCIENTIFIC STATEMENT

Revascularization for Renovascular Disease: A Scientific Statement From the American Heart Association

Vivek Bhalla, MD, Vice Chair; Stephen C. Textor, MD, Chair; Joshua A. Beckman, MD; Ana I. Casanegra, MD, MS; Christopher J. Cooper, MD; Esther S.H. Kim, MD, MPH; James M. Luther, MD, MSCI; Sanjay Misra, MD, FAHA; Gustavo S. Oderich, MD; on behalf of the American Heart Association Council on the Kidney in Cardiovascular Disease; Council on Hypertension; Council on Peripheral Vascular Disease; and Council on Cardiovascular Radiology and Intervention

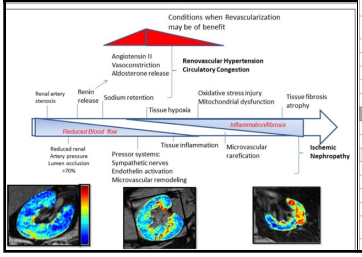

Table 2. Populations and Characteristics Considered for Renal Revascularization

Clinical populations
Unilateral renal artery stenosis with characteristic syndromes (see below)
Fibromuscular dysplasia with hypertension*
High-risk clinical syndromes*
Rapidly progressive hypertension*
Rapidly declining estimated glomerular filtration rate*
Flash pulmonary edema*
Bilateral renal artery stenosis with progressive loss of renal functional mass
Single native kidney renal artery stenosis
Special populations:
Renal allograft: transplant renal artery stenosis with or without calcineurin inhibitors
Episodic, circulatory congestion with bilateral atherosclerotic renovascular disease
Progressive loss of glomerular filtration rate with occlusive atherosclerotic renovascular disease and no other kidney disease (ischemic nephropathy)
Aortic disease with renovascular protection as part of endovascular repair
Left-ventricular assist device
Radiation-induced renovascular disease with clinical syndromes
Other diseases: eg, Takayasu arteritis, extrinsic vascular compression
Pediatric patients with mid aortic syndrome or fibromuscular variants
Characteristics suggestive of clinical benefit from revascularization
Recent onset or exacerbation (<1 y) of hypertension*
Absence of proteinuria*
Identifiable activation of renin-angiotensin system*
Hyperreninemia*
With unilateral renal artery stenosis, lateralization of renal vein renin*
Younger age
Radiographic evidence of progressive renal artery occlusion
Treatment-resistant hypertension (documentation of hypertension by ambulatory blood pressure and medication adherence)
Angiotensin-dependent glomerular filtration rate

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Populations and Characteristics Considered for Renal Revascularization

- **Clinical populations**
- **Unilateral renal artery stenosis with characteristic syndromes (see below)**
- **Fibromuscular dysplasia with hypertension***
- **High-risk clinical syndromes***
- **Rapidly progressive hypertension***
- **Rapidly declining estimated glomerular filtration rate***
- **Flash pulmonary edema***
- **Bilateral renal artery stenosis with progressive loss of renal functional mass**
- **Single native kidney renal artery stenosis**
- **Special populations:**
- **Renal allograft: transplant renal artery stenosis with or without calcineurin**
- **inhibitors**
- **Episodic, circulatory congestion with bilateral atherosclerotic renovascu-**
- **lar disease**
- **Progressive loss of glomerular filtration rate with occlusive atherosclerotic**
- **renovascular disease and no other kidney disease (ischemic nephropathy)**
- **Aortic disease with renovascular protection as part of endovascular repair**
- **Left-ventricular assist device**
- **Radiation-induced renovascular disease with clinical syndromes**
- **Other diseases: eg, Takayasu arteritis, extrinsic vascular compression**
- **Pediatric patients with mid aortic syndrome or fibromuscular variants**

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Characteristics suggestive of clinical benefit from revascularization

- Recent onset or exacerbation (<1 y) of hypertension*
- Absence of proteinuria*
- Identifiable activation of renin-angiotensin system*
- Hyperreninemia*
- With unilateral renal artery stenosis, lateralization of renal vein renin*
- Younger age
- Radiographic evidence of progressive renal artery occlusion
- Treatment-resistant hypertension (documentation of hypertension by ambu-
- latory blood pressure and medication adherence)
- Angiotensin-dependent glomerular filtration rate

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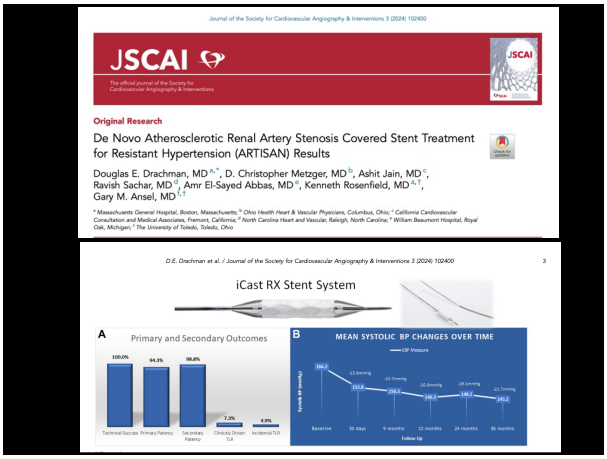

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Indications for RAS in 2025?

- Bilateral high grade disease with a significant translesional gradient/FFR:
  - Refractory hypertension (medical failure)
  - Renal insufficiency with acute deterioration
  - Flash pulmonary edema with cardiac disturbance syndrome
  - NO/LOW Albuminuria
- Unilateral disease with a significant translesional gradient/FFR:
  - Solitary kidney
  - Renal Transplant
  - Refractory hypertension

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