Renal Artery Stenting – Updated Data for Guideline and Technical Tips for Stenting

RICHARD R. HEUSER, MD, FACC, FACP, FESC, FSCAI
Chief of Cardiology, St. Luke's Medical Center,
Phoenix, Arizona
Professor of Medicine, Univ. of Arizona
College of Medicine, Phoenix, Arizona

Presenter Disclosure Information

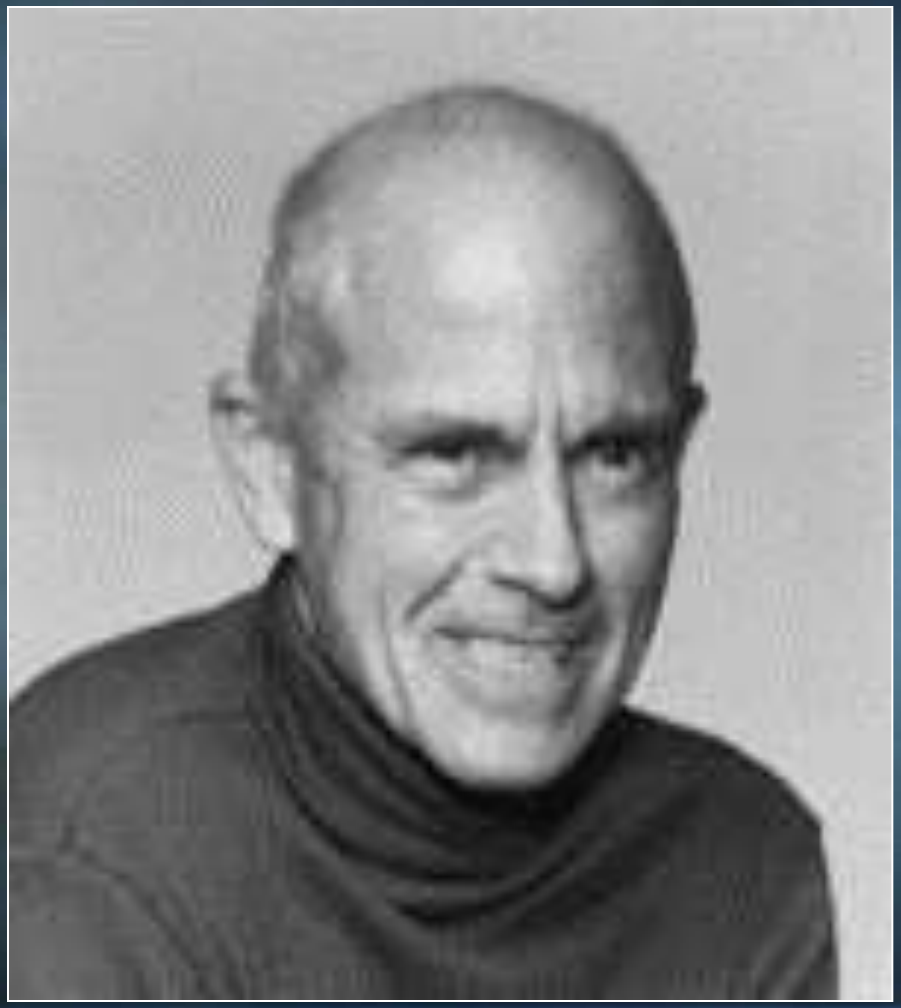
Name: ***RICHARD R. HEUSER M.D.***

Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organization listed below.

- *QuantumCor, Major Stock Holder/Medical Director;*
- *Radius Medical, Avinger and Claret Medical, Major Stock Holder;*
- *PQ ByPass, Founder and Major Stock Holder;*
- *CSI, Stockholder; and*
- *Spectranetics, Abbott, Medtronic, Bard, Abiomed, Honorarium;*
- *Medtronic, Abbott, AngioScore, Speaker; and*
- *Verve Medical, Inc., Major Stockholder*

Patents *-- RF, Snares, Wires, Balloon Catheters, Covered Stents, Devices for Arterial Venous Connection, Devices for LV and RV Closure, Sheaths*

CHARLES DOTTER
1920 - 1985



R. Heuser

Transluminal Treatment of Arteriosclerotic Obstruction

Description of a New Technic and a Preliminary Report of Its Application

By Charles T. Dotter, M.D., and Melvin P. Judkins, M.D.

Circulation, Volume XXX, November 1964

R. Heuser

In order to improve the technic, ... It consists of the development of a device suitable for percutaneous insertion, which is a functional equivalent of the present spring guide but capable of externally controlled concentric expansion over a suitable portion of its length.

Proximal stenosis of the renal, carotid, and vertebral arteries appears suitable for transvascular treatment.

Circulation, Volume XXX, November 1964

FIRST RENAL ANGIOPLASTY REPORT

THE LANCET, APRIL 15, 1978

Preliminary Communication

TREATMENT OF RENOVASCULAR HYPERTENSION WITH PERCUTANEOUS TRANSLUMINAL DILATATION OF A RENAL-ARTERY STENOSIS

ANDREAS GRÜNTZIG
WILHELM VETTER
BERNHARD MEIER
ULRICH KUHLMANN
URS LÜTOLF
WALTER SIEGENTHALER

Department of Internal Medicine, University Hospital, Zürich, Switzerland

Summary Percutaneous transluminal dilatation of a left-sided renal-artery stenosis was done in a 61-year-old patient with hypertension. Shortly after dilatation blood-pressure fell to normal and renal plasma flow increased. Dilatation might be an alternative to renal vascular surgery in severe renal hypertension.

INTRODUCTION

WE have had considerable experience of percutaneous transluminal dilatation in the treatment of peripheral arterial disease.[1] We have now used a modification of the technique[2] in a patient with hypertension caused by atherosclerotic stenosis of the left renal artery.

PATIENT AND METHODS

In a 61-year-old man with severe hypertension (systolic blood-pressure 200–230 mm Hg, diastolic 100–115 mm Hg) a left-sided subtotal atherosclerotic renal-artery stenosis was diagnosed by a selective renal arteriogram.

Percutaneous transluminal dilatation was done with a double-lumen catheter described elsewhere.[1,2] A guiding catheter was introduced through the femoral artery under local anæsthesia and advanced into the orifice of the left renal artery. Through the catheter a dilatation catheter with a tipped distensible sausage-shaped balloon segment was advanced through the renal-artery stenosis, which was dilated by inflating the balloon with a pressure pump (5–6 atm.).

Renal plasma flow was calculated from the blood-sample counts after injection of 250 μCi ^{131}I-iodohippurate.[3] ^{131}I-iodohippurate clearances of the right and left kidney were determined by a method described by May and others.[4]

RESULTS AND DISCUSSION

The figure shows subtotal stenosis of the left renal artery before dilatation (A), the position of the dilatation catheter (B), and the moderate residual stenosis after transluminal dilatation (C). Blood-pressure fell to normal three hours after dilatation and increased slightly after two weeks (160/100 mm Hg), when mild

R. Heuser

Renal Artery Stenosis

When **NOT** to Intervene

ATHEROMA

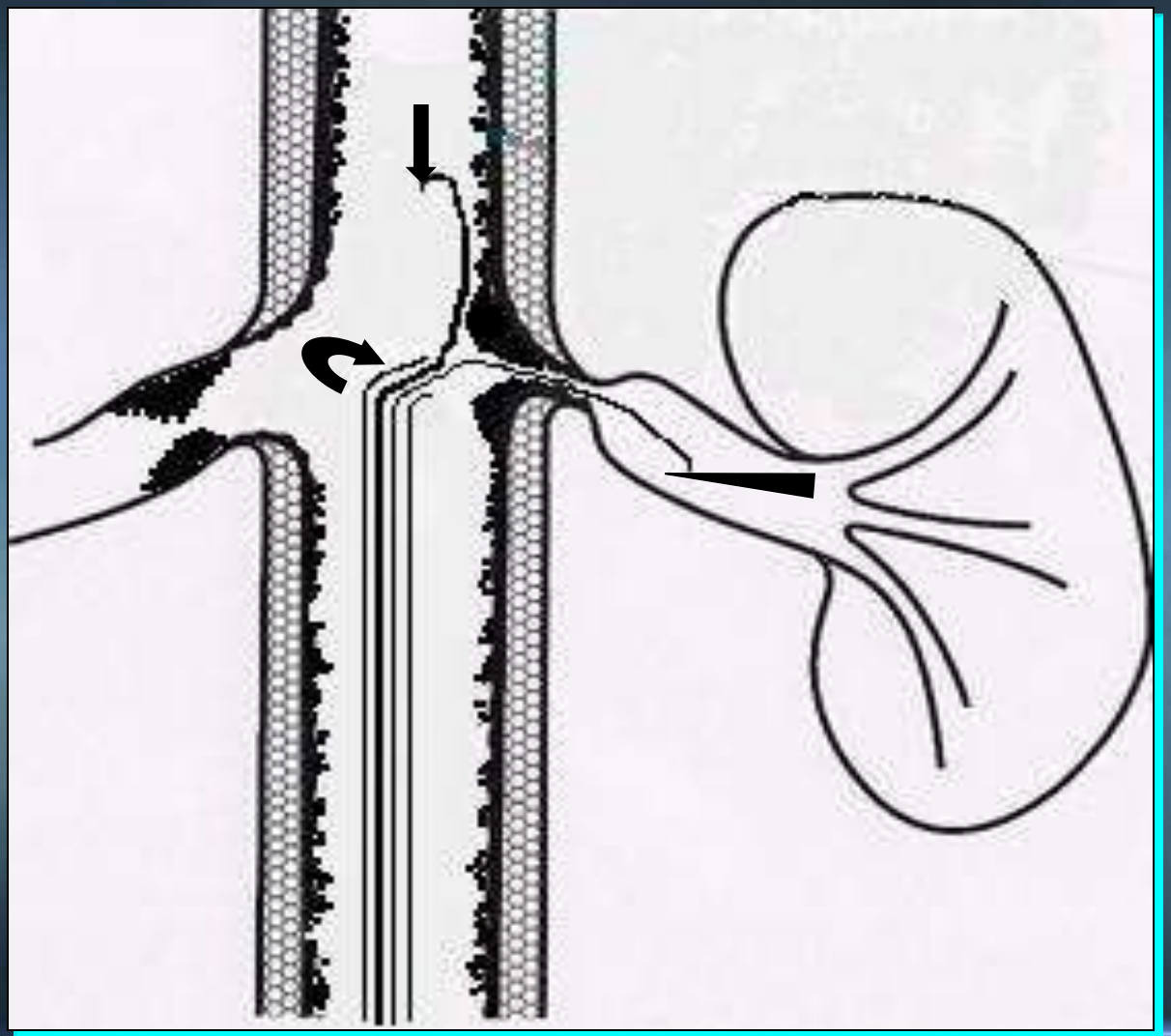
- NO SIGNIFICANT PRESSURE GRADIENT
- EASILY CONTROLLED HYPERTENSION
- MILD STABLE RENAL DYSFUNCTION ?
- INCIDENTALLY DISCOVERED STENOSIS *WITHOUT* PRIOR CLINICAL EVALUATION

NO INTERVENTION

R. Heuser

THE "NO TOUCH" TECHNIQUE

CROSSING RENAL ARTERY STENOSIS



R. Heuser

Renal Arterial Disease

Renal artery stenosis (RAS) is both a common and progressive disease in patients with atherosclerosis and a relatively uncommon cause of hypertension.

A. Clinical Indications

Current ACC/AHA Guidelines for Revascularization in RAS

Class I

- Recurrent CHF/pulmonary edema (LOE B)

Class IIa

- Unstable angina (LOE B)
- Accelerated, resistant, or malignant hypertension, or due to medication intolerance (LOE B)
- Progressive CRI in b/l RAS or solitary (LOE B)

Hirsch et al, JACC. 2006. Rooke et al, Circulation. 2011.

Current ACC/AHA Guidelines for Revascularization in RAS

Class IIb

- CRI and unilateral RAS (LOE, C)
- Asymptomatic bilateral RAS or unilateral to a solitary kidney (LOE, C)

Hirsch et al, JACC. 2006. Rooke et al, Circulation. 2011.

Aim: Meta-analysis

Significant renal artery stenosis
AND
Hypertension
AND / OR
Chronic renal insufficiency

Percutaneous revascularization + Medical therapy

Medical therapy

SURROGATE OUTCOMES: Changes in blood pressure, creatinine

CLINICAL OUTCOMES: Mortality, CHF, stroke, renal function

Inclusion/ Exclusion Criteria

Inclusion

- Randomized controlled trials in patients with RAS (≥ 50%)
  - Percutaneous revascularization vs. medical management

Exclusion

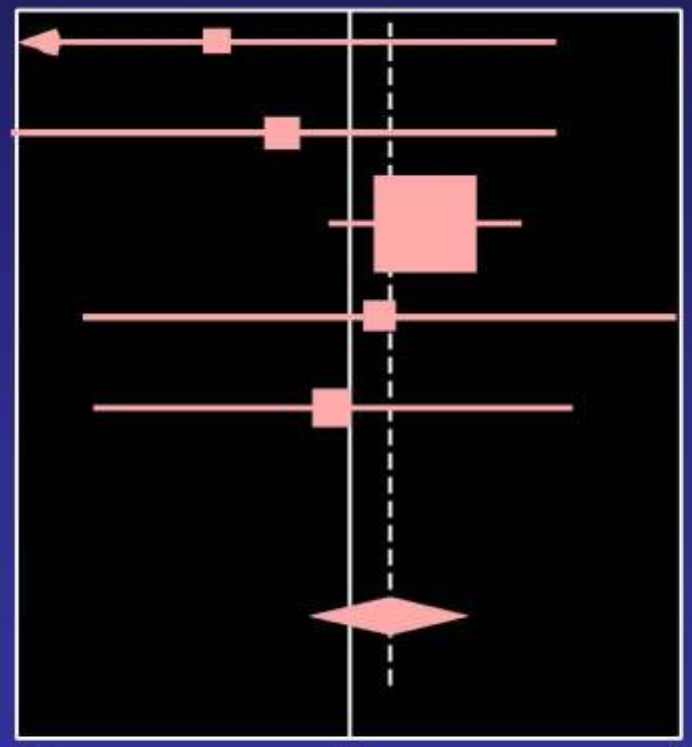
- Surgical revascularization
- Both arms revascularized

Results

Change in Systolic Blood Pressure from Baseline

Source	Weighted Mean Difference (95% CI)
EMMA	-4.00 (-14.23, 6.23)
DRASTIC	-2.00 (-10.22, 6.22)
ASTRAL	2.30 (-0.58, 5.18)
NITER	1.00 (-7.97, 9.97)
STAR	-0.50 (-7.73, 6.73)
SNRASCG (excluded)	
Overall (95% CI)	1.20 (-1.18, 3.58)

Test for heterogeneity: $I^2 = 0\%$, P = .67
Test for overall effect: P = .32



Favors Percutaneous Revascularization

Favors Medical Management

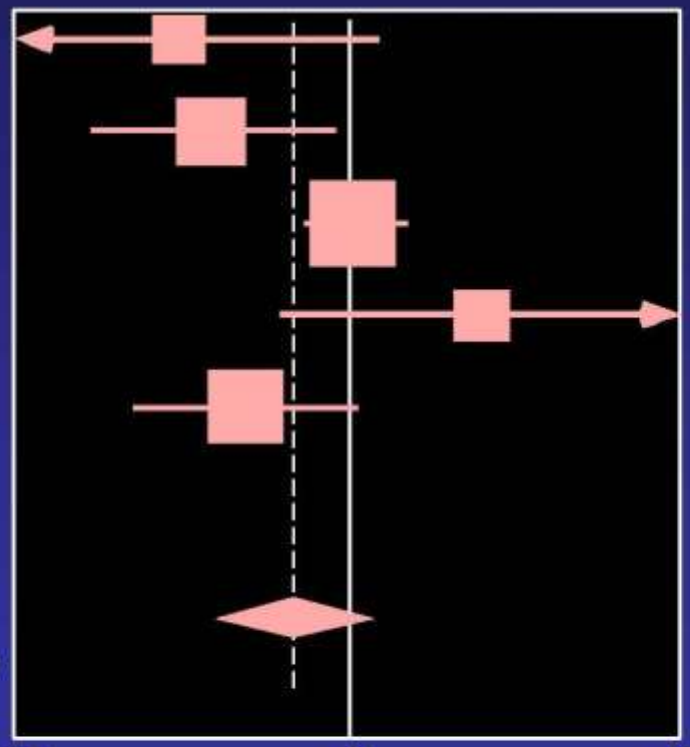
Kumbhani, Bavry, Harvey, de Souza, Scarpioni, Bhatt, Kapadia. AHJ 2011

Results

Change in Diastolic Blood Pressure from Baseline

Source	Weighted Mean Difference (95% CI)
EMMA	-5.00 (-10.91, 0.91)
DRASTIC	-4.00 (-7.62, -0.38)
ASTRAL	0.20 (-1.39, 1.79)
NITER	4.00 (-2.09, 10.09)
STAR	-3.00 (-6.40, 0.40)
SNRASCG (excluded)	
Overall (95% CI)	-1.60 (-4.22, 1.02)

Test for heterogeneity: $I^2 = 62\%$, P = .03
Test for overall effect: P = .23



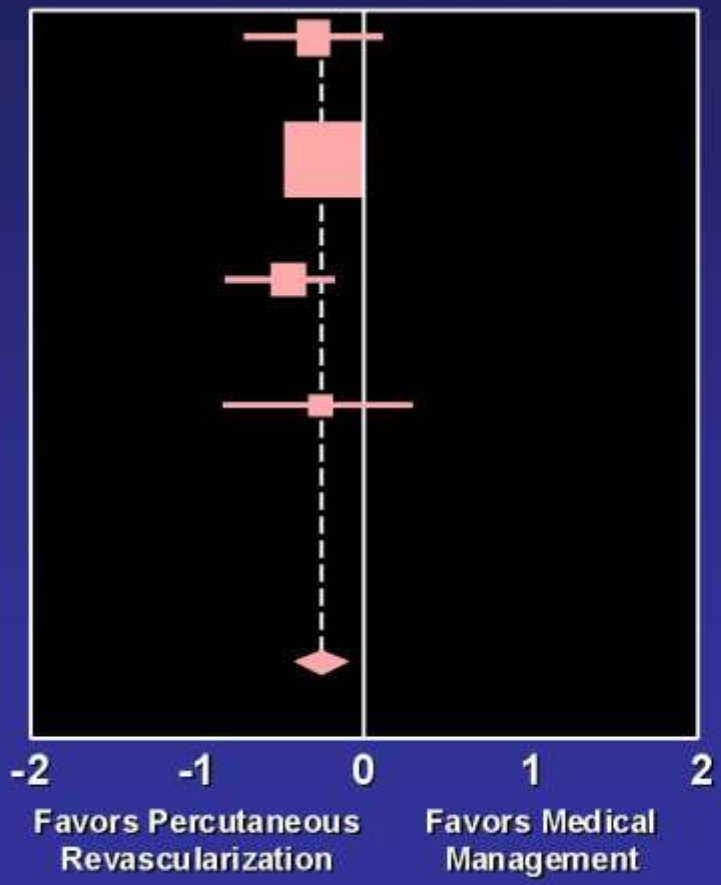
Kumbhani, Bavry, Harvey, de Souza, Scarpioni, Bhatt, Kapadia. AHJ 2011

Results

Number of Anti-hypertensive medications at end of follow-up

Source	Weighted Mean Difference (95% CI)
STAR	-0.30 (-0.72, 0.12)
ASTRAL	-0.20 (-0.36, -0.04)
DRASTIC	-0.50 (-0.84, -0.16)
NITER	-0.28 (-0.87, 0.31)
Overall (95% CI)	-0.26 (-0.39, -0.13)

Test for heterogeneity: $I^2 = 0\%$
Test for overall effect: $P < 0.001$



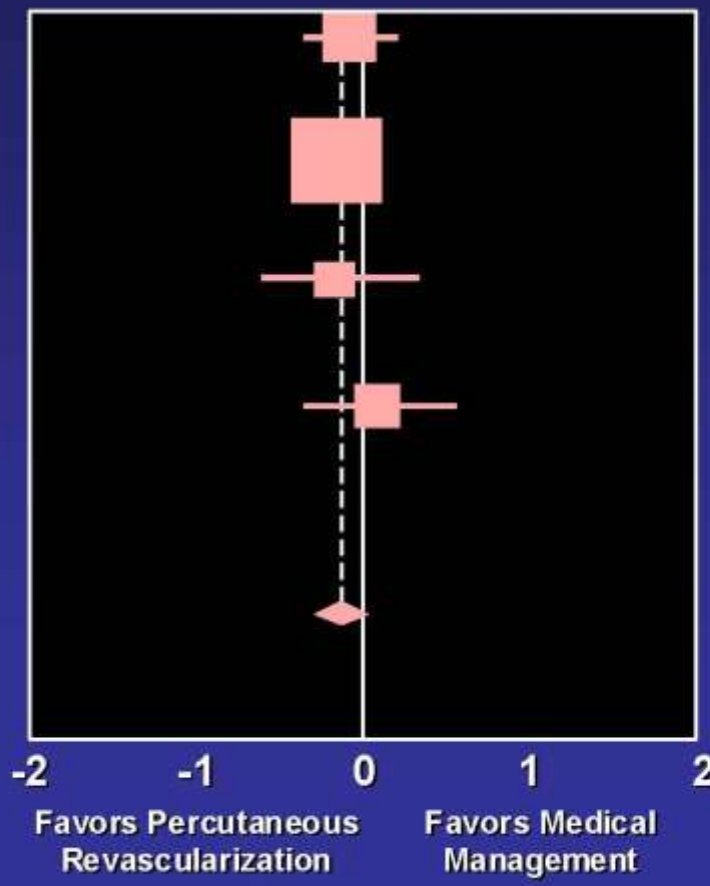
Kumbhani, Bavry, Harvey, de Souza, Scarpioni, Bhatt, Kapadia. AHJ 2011

Results

Serum creatinine at end of follow-up

Source	Weighted Mean Difference (95% CI)
STAR	-0.10 (-0.37, 0.17)
ASTRAL	-0.21 (-0.42, 0.00)
SNARSCG	-0.16 (-0.63, -0.31)
NITER	-0.08 (-0.37, 0.53)
Overall (95% CI)	-0.14 (-0.29, 0.01)

Test for heterogeneity: $I^2 = 0\%$
Test for overall effect: P = 0.06



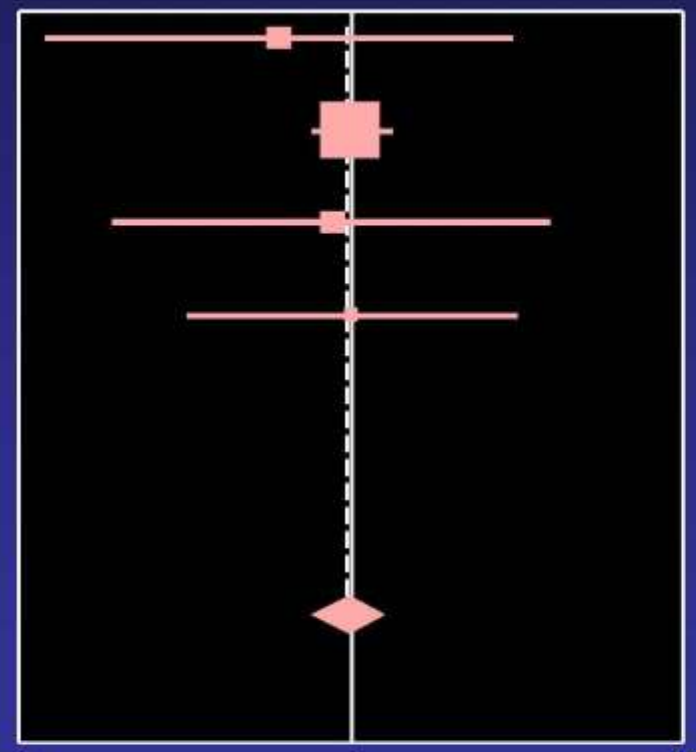
Kumbhani, Bavry, Harvey, de Souza, Scarpioni, Bhatt, Kapadia. AHJ 2011

Results

Mortality

Source	Relative Risk (95% CI)
SNRASCG	0.60 (0.12, 3.01)
ASTRAL	0.98 (0.74, 1.29)
NITER	0.86 (0.19, 3.86)
STAR	0.99 (0.32, 3.09)
EMMA (excluded)	
Overall (95% CI)	0.96 (0.74, 1.25)

Test for heterogeneity: $I^2 = 0\%$, P = .95
Test for overall effect: P = .76



Favors Percutaneous Revascularization

Favors Medical Management

14.9% vs. 15.4%

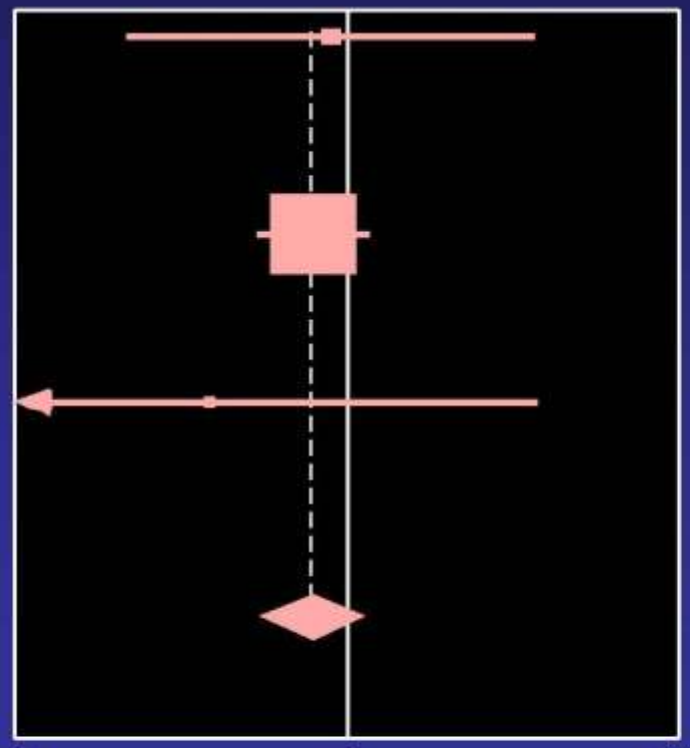
Kumbhani, Bavry, Harvey, de Souza, Scarpioni, Bhatt, Kapadia. AHJ 2011

Results

Congestive Heart Failure

Source	Relative Risk (95% CI)
SNRASCG	0.90 (0.22, 3.65)
ASTRAL	0.80 (0.55, 1.16)
STAR	0.40 (0.04, 3.71)
Overall (95% CI)	0.79 (0.56, 1.13)

Test for heterogeneity: $I^2 = 0\%$, $P = .82$
Test for overall effect: $P = .20$



Favors Percutaneous Revascularization

Favors Medical Management

9.8% vs. 12.2%

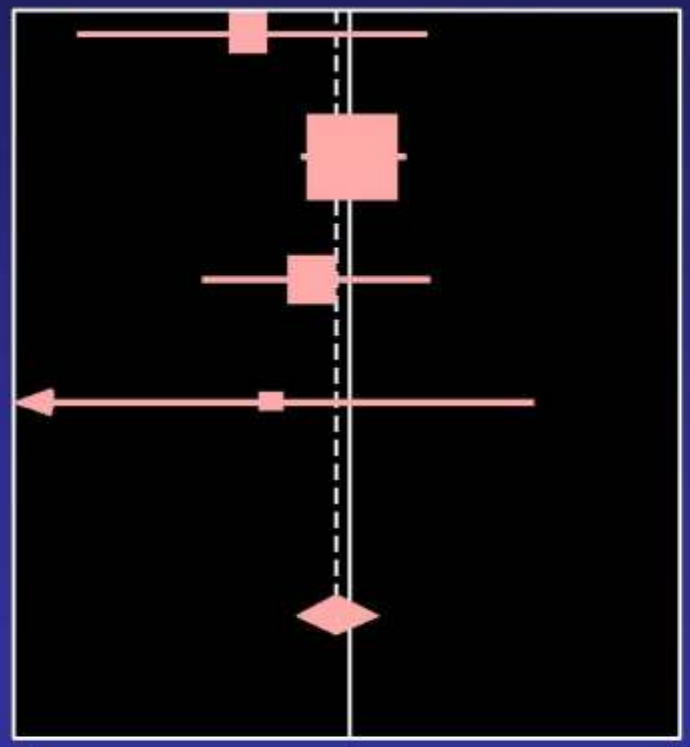
Kumbhani, Bavry, Harvey, de Souza, Scarpioni, Bhatt, Kapadia. AHJ 2011

Results

Stroke

Source	Relative Risk (95% CI)
SNRASCG	0.30 (0.04, 2.51)
ASTRAL	1.06 (0.56, 1.98)
NITER	0.64 (0.16, 2.59)
STAR	0.39 (0.02, 9.53)
Overall (95% CI)	0.86 (0.50, 1.47)

Test for heterogeneity: $I^2 = 0\%$, $P = .63$
Test for overall effect: $P = .57$



4.4% vs. 5.1%

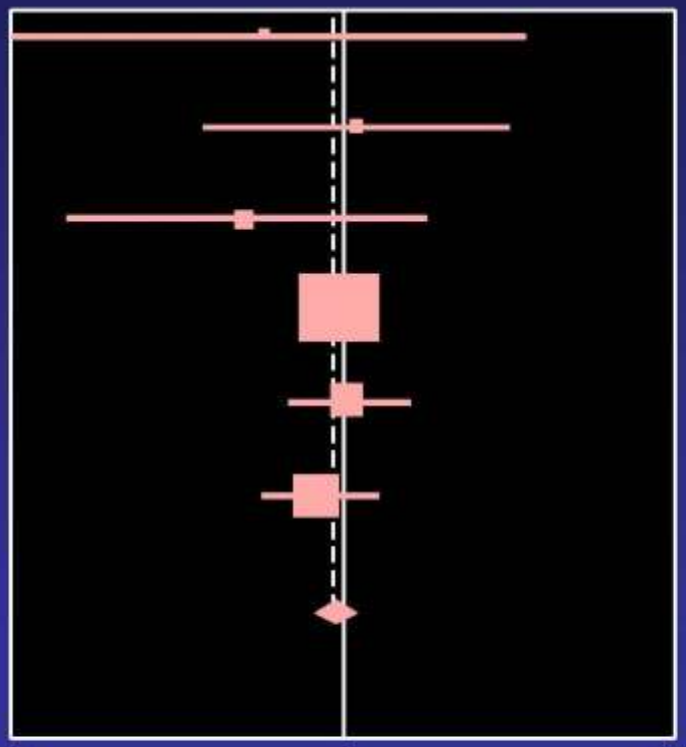
Kumbhani, Bavry, Harvey, de Souza, Scarpioni, Bhatt, Kapadia. AHJ 2011

Results

Worsening renal failure

Source	Relative Risk (95% CI)
EMMA	0.38 (0.02, 8.78)
SNRASCG	1.20 (0.18, 7.92)
DRASTIC	0.30 (0.03, 2.77)
ASTRAL	0.98 (0.67, 1.43)
NITER	1.07 (0.50, 2.28)
STAR	0.74 (0.36, 1.52)
Overall (95% CI)	0.91 (0.67, 1.23)
	11.5% vs. 12.6%

Test for heterogeneity: $I^2 = 0\%$, P = .91
Test for overall effect: P = .54



Favors Percutaneous Revascularization

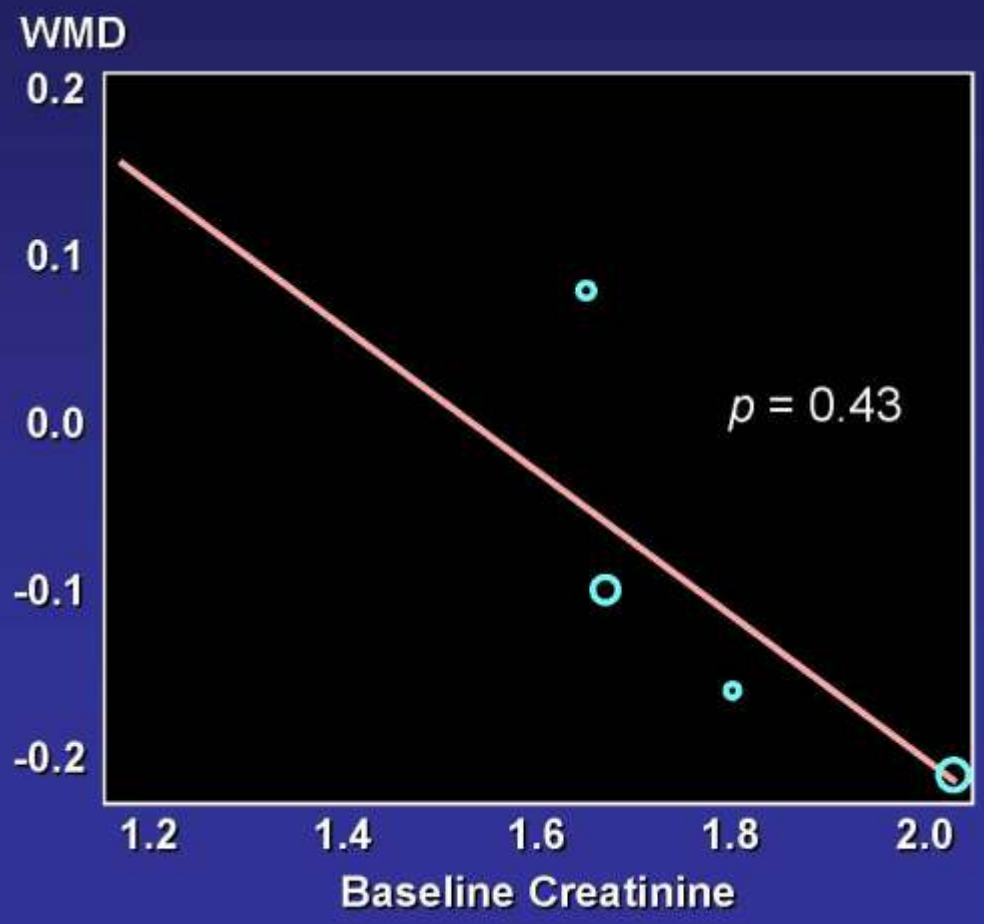
Favors Medical Management

Kumbhani, Bavry, Harvey, de Souza, Scarpioni, Bhatt, Kapadia. AHJ 2011

Meta-regression

- No difference in any of above outcomes noted
  - Baseline creatinine
  - Diabetes status
  - % bilateral stenosis
  - % cross-over
  - % angioplasty only

Sensitivity analyses showed similar results



Conclusions

Surrogate outcomes:

- Change in SBP ✗
- Change in DBP ✗
- Antihypertensive medications ↓
- Serum creatinine ✗

Clinical outcomes:

- Mortality ✗
- CHF ✗
- Stroke ✗
- Change in renal function ✗