VEITH 2018
Tuesday, November 13
SESSION 15:
PROGRESS IN THE TREATMENT OF RENAL AND VISCERAL ARTERY DISEASE

When Is Renal Artery Stenting a Worthwhile Procedure – Despite The RCTs Showing It Has No Value

THOMAS SOS, MD
NYPH CORNELL
New York, NY

Potential conflicts of interest

- Royalties
  - AngioDynamics, Inc.
  - Cook, Inc.
- Ownership
  - Confluent Medical, Inc. (NDC, Inc.)
  - Venity, Inc.

THOMAS SOS, MD
NYPH CORNELL
New York, NY

ASTRAL and STAR
WHAT HAVE WE LEARNED/BEEN TOLD?

BEST MEDICAL THERAPY IS EQUIVALENT TO RENAL ARTERY STENTING FOR TREATMENT OF RENAL VASCULAR HYPERTENSION and ISCHEMIC NEPHROPATHY!

THOMAS SOS, MD
NYPH CORNELL
New York, NY

ASTRAL and STAR
WHY STENTING “FAILED” vs MEDICAL RX STUDY DESIGN

IT'S THE GRADIENT, STUPID!!!

THOMAS SOS, MD
NYPH CORNELL
New York, NY

ASTRAL and STAR

STUDY DESIGN

- STATISTICAL
  - BOTH UNDERPOWERED
- CLINICAL
  - ASTRAL
    - PATIENTS MOST LIKELY TO BENEFIT WERE EXCLUDED BY DESIGN (“NEED SURGERY or LIKELY TO NEED REVASCULARIZATION IN 6 MONTHS, VERY SEVERE STENOSES”)
  - STAR
    - NO PRESSURE GRADIENT MEASURED
- TECHNICAL/OPERATOR INEXPERIENCE?
  - BOTH
    - VERY FEW CASES DONE BY MOST CENTERS
    - HIGH COMPLICATION RATE
    - MEDICAL THERAPY EASIER TO STANDARDIZE and ADMINISTER

THOMAS SOS, MD
NYPH CORNELL
New York, NY

CORAL
CENTRAL STUDY DESIGN

INCLUSION CRITERIA

- HYPERTENSION ≥ 155 mmHg ON 2 OR MORE ANTIHYPTERTENSIVE MEDICATIONS
- STENOSIS OF ONE OR MORE RENAL ARTERY
  - ≥ 80% - <100%
  - ≥ 60% - < 80% BY ANGIOGRAPHY
- ≥ 20 mmHg SYSTOLIC PRESSURE GRADIENT

PROTOCOL

- ONLY US SITES
- ENROLLMENT TO BE COMPLETED IN 2007-2010
- MANDATORY ANGIOGRAPHY

THOMAS SOS, MD
NYPH CORNELL
New York, NY

The Cardiovascular Outcomes with Renal Atherosclerotic Lesions (CORAL) Study

Rationale and Methods

The CORAL Study was designed to determine whether renal artery stenting modifies the natural history for patients with atherosclerotic renal-artery stenosis and hypertension or chronic kidney disease.
**Coral Conclusions**

- **Coral:** "Renal artery stenting did not confer a significant benefit in people with atherosclerotic renal artery stenosis and hypertension or chronic kidney disease."
- **SOS:** The Coral results apply only to the population studied: Most with hemodynamically insignificant or uncertain stenosis and without confirmatory pressure gradients.
- **Coral, Astral and Star Prove that stenting hemodynamically non-significant renal artery stenosis which is not and cannot be the cause of the disease does not and cannot cure it!

**NEWSFLASH**

**84F CHF, CKD (SCr 2.9), HTN, COPD**

- Admitted to CCU
  - Oliguria → Anuria, SCr 2.9 > 4.6
  - Sonography R kidney 9.8 cm, B/L mild RI
  - BP 180/80
  - BNP (B Natriuretic Peptide): 2000 pg/mL
  - Severe decompensated CHF
  - Failing diuretics
  - Pulmonary edema
  - Respiratory failure > intubated
- Dx’s: AKI, CKD, 2°CARD DYSFXN

**Clinical Course**

84F CHF, CKD (SCr 2.9), HTN, COPD

**84F CHF, CKD (SCr 2.9), HTN, COPD**

**Clinical Course**

84F CHF, CKD (SCr 2.9), HTN, COPD

**Clinical Course**

84F CHF, CKD (SCr 2.9), HTN, COPD
FORGET THE HYPE and HEADLINES

WHEN NOT TO INTERVENE:
ATHEROMATOUS RENAL ARTERY STENOSIS

- NO SIGNIFICANT PRESSURE GRADIENT
- EASILY CONTROLLED HYPERTENSION
- MILD STABLE RENAL DYSFUNCTION
- INCIDENTALLY DISCOVERED STENOSIS

WITHOUT PRIOR CLINICAL EVALUATION

→ NO INTERVENTION

FORGET THE HYPE and HEADLINES

WHEN TO INTERVENE:
ATHEROMATOUS RENAL ARTERY STENOSIS
CLINICAL CRITERIA

- RENAL DYSFUNCTION
  - RECENT ONSET OR PROGRESSIVE
  - MODERATE TO SEVERE
- HYPERTENSION
  - SEVERE OR DIFFICULT TO CONTROL
- PULMONARY EDEMA
  - RECURRENT FLASH
- ?JEOPARDIZED RENAL PARENCHYMA?

FORGET THE HYPE and HEADLINES

WHEN TO INTERVENE:
ATHEROMATOUS RENAL ARTERY STENOSIS
ANATOMIC CRITERIA

- ≥ 70% D STENOSIS (~85% XS AREA)
- POST STENOTIC DILATATION
- COLLATERAL CIRCULATION
- ?REDUCTION OF RENAL SIZE?
  - LENGTH DISCREPANCY ≥ 1.5 cm
  - DOCUMENTED LENGTH ≥ 1 cm
- ?RENAL LENGTH > 7-8 cm
The Renal Stenting Debate

**CONCLUSION:**

...ONE SIDE WOULD INTERVENE IN ANY PATIENT WHO HAS AT LEAST A 50% STENOSIS, WHETHER OR NOT THE PATIENT HAS CLINICAL SYMPTOMS. THE OTHER SIDE WOULD NOT INTERVENE IN ANY RENAL ARTERY STENOSIS, REGARDLESS OF THE PRESENCE AND SEVERITY OF THE SYMPTOMS. ...HYPERTENSION TO SEVERE RENAL DYSFUNCTION...PHYSICIANS WHO WOULD TAKE THE MIDDLE GROUND WOULD TRY TO FIND SOME REASONABLE CRITERIA FOR Intervention...THE APPROPRIATENESS OF RENAL ARTERY STENTING HAS YET TO BE SUFFICIENTLY RESOLVED. THE BEST HOPE SO FAR IS CORAL, BUT I FEAR...ITS RESULTS MAY NOT YIELD THE CLARITY WE ALL SEEK.

**BY THOMAS A. SOS, MD**
STUDIES MUST COMPARE OUTCOMES AT INDIVIDUAL SITES ACCORDING TO THE NUMBER OF CASES AND THE EXPERIENCE OF THE OPERATORS TO BETTER UNDERSTAND THE OVERALL RESULTS (MULTIVARIATE ANALYSIS).

PATIENTS MAY BE BETTER SERVED, IF RENAL ARTERY STENTING IS PERFORMED ONLY IN CENTERS WITH HIGH VOLUME, VERY EXPERIENCED OPERATORS AND DOCUMENTED EXCELLENT RESULTS.

WHAT HAVE WE LEARNED?

BEST MEDICAL THERAPY IS EQUIVALENT TO RENAL ARTERY STENTING FOR TREATMENT OF RENAL VASCULAR HYPERTENSION AND ISCHEMIC NEPHROPATHY!

RENAL ARTERY STENOSIS, HYPERTENSION AND RENAL INSUFFICIENCY

THE PROBLEM?

IT IS THE SOLUTION!

ISCHEMIC NEPHROPATHY

DIAGNOSIS AND TREATMENT

CLINICAL SUSPICION, NO HX MED. NEPHROPATHY

ULTRASOUND OR MRA WITH GAD

* RENAL SIZE ASYMMETRY
* RENAL ARTERY STENOSIS
* ?INCREASED RESISTIVE INDEX?

MEDICAL RX
PTRA/STENT/SURGERY

RENAL VASCULAR HYPERTENSION

DIAGNOSIS AND TREATMENT

CLINICAL SUSPICION, PRA WITH ACEI

RVR ASSAY WITH ACEI
NUCLEAR SCAN WITH ACEI
DUPLEX ULTRASOUND
HELICAL CONTRAST CT
MRA WITH GADOLINIUM

IA DSA & PRESSURE GRADIENT

MEDICAL RX
PTRA/STENT/SURGERY

CORAL TRIAL
(CARDIOVASCULAR OUTCOMES in RENAL ATHEROSCLEROTIC LESIONS)

CONCLUSIONS

"RENAL ARTERY STENTING DID NOT CONFER A SIGNIFICANT BENEFIT...WHEN ADDED TO COMPREHENSIVE, MULTIFACTORIAL MEDICAL THERAPY IN PEOPLE WITH ATHEROSCLEROTIC RENAL-ARTERY STENOSIS AND HYPERTENSION OR CHRONIC KIDNEY DISEASE."
11/13/2018

SLOW SITE and PATIENT RECRUITMENT

NEEDED CHANGE!

OR

STOP

RELAX INCLUSION CRITERIA

OR

STOP STUDY

# 5b: CROSSING STENOSES

SOFTVU SOS Omni Selective™ and BENTSON™

THE SOS FLICK

84F CHF, CKD (CR 2.8), HTN, COPD.

2mm BALLOON

5mm x 2cm STENT

5mm x 2cm STENT

INTER-OBSERVER VARIABILITY IN THE ANGIOGRAPHIC ASSESSMENT OF RENAL ARTERY STENOSIS.

Brigit C. van Jaarsveld, Herman Pieterman, Lucas C. van Dijk, Andries J. van Seijen, Pieta Krijnen, Frans H.M. Derkx, Arie J. Man in't Veld, Maarten A.D.H. Schalekamp, on behalf of the DRASTIC study group
ASSESSMENT OF RENAL ARTERY STENOSIS SEVERITY BY PRESSURE GRADIENT (Pd/Pa)
and RENIN PRODUCTION

\[ \frac{P_d}{P_a} = \text{RENAL ARTERY PRESSURE DISTAL TO STENOSIS} \]

\[ \frac{P_a}{P_a} = \text{AORTIC PRESSURE} \]

DE BRUYNE B, et al, Journal of the American College of Cardiology
Volume 48, Issue 9 , 7 November 2006, Pages 1851-1855

CONCLUSIONS

"RENAL ARTERY STENTING DID NOT CONFER A SIGNIFICANT BENEFIT...WHEN ADDED TO COMPREHENSIVE, MULTIFACTORIAL MEDICAL THERAPY IN PEOPLE WITH ATHEROSCLEROTIC RENAL-ARTERY STENOSIS AND HYPERTENSION OR CHRONIC KIDNEY DISEASE."

CORAL TRIAL
(CARDIOVASCULAR OUTCOMES in RENAL ATHEROSCLEROTIC LESIONS)

SLOW SITE and PATIENT RECRUITMENT

NEEDED CHANGE!

RELAX INCLUSION CRITERIA
STOP STUDY

STOP

# 2: LIMIT CONTRAST

FLUSH CATHETERS

4 F PIGTAIL
4 F (SOS) OMNIFLUSH™

1:75 sec
30% Iodine 10cc @ 10cc/sec

# 5b: CROSSING STENOSES

SOFTVU SOS OMNI SELECTIVE™ and BENTSON™

THE SOS FLICK

84F CHF, CKD (CR 2.8), HTN, COPD

2mm BALLOON
5mm x 2cm STENT
5mm x 2cm STENT