

## When to Treat, When to Refer, and What to Tell the Vascular Patient

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Madrid II ~ 1:25pm - 2:10pm

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### Objectives

- Know the data behind CAS, ARAS, PAD, and who to refer to a vascular specialist

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When to treat, when to refer, and what  
to tell the vascular patient

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Atherosclerotic Patients

- Cerebrovascular Disease
- Peripheral Venous Disease
- Peripheral Arterial Occlusive Disease
- Renal Artery Stenosis
- Aortic Disease
- Abdominal Atherosclerotic Disease

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Case #1  
Cerebrovascular Disease

- 72 year old gentleman with HTN, HL presents for annual examination
- Asymptomatic
- Bruit over the right neck near mandible of jaw

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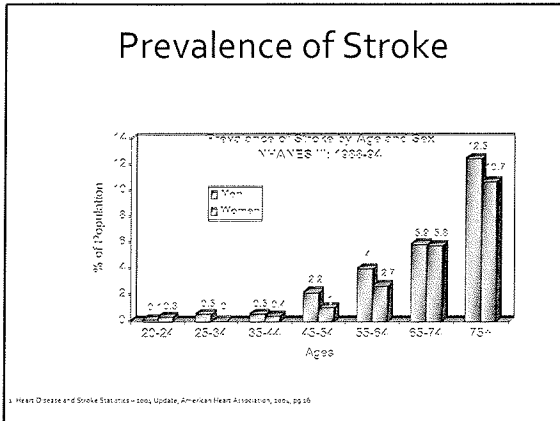
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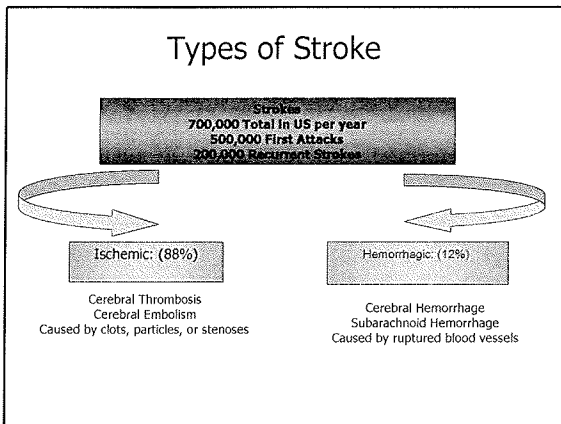
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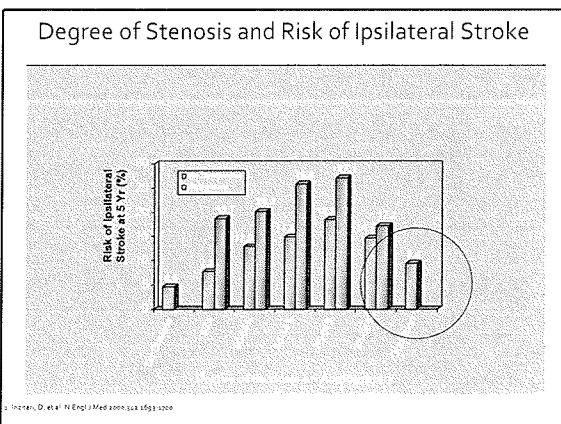
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## TIA – Transient Ischemic Attack

- TIA is a "mini stroke" that produces temporary stroke-like symptoms
- TIA symptoms are the same as those of stroke
- Usually only lasts for several minutes
- Occurs when a blood clot temporarily clogs an artery
- TIAs are extremely important predictors of stroke
- In ~ 1/3 of TIA cases a person will later have a stroke
  - 50% of cases, the stroke will occur within 1 year

1. Transient Ischemic Attack, American Stroke Association, [www.strokeassociation.org](http://www.strokeassociation.org), 2004

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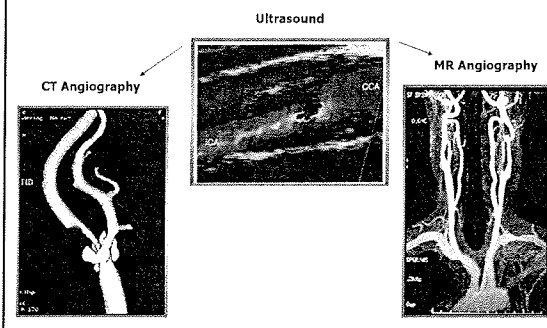
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## Diagnostic Tests



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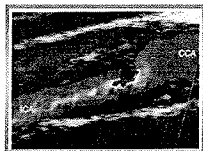
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## Ultrasound Results

- Right ICA
  - 330 cm/sec
- Left ICA
  - 89 cm/sec
- Vertebrales
  - Bilateral antegrade flow



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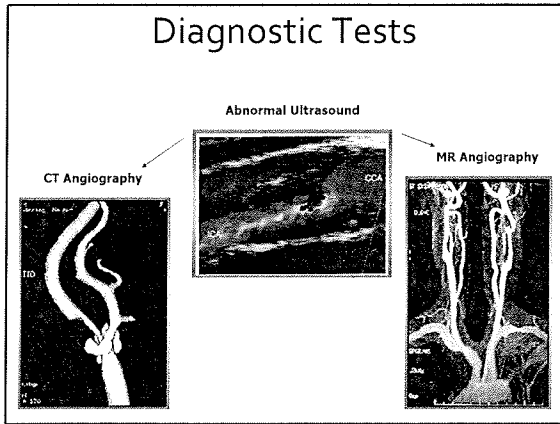
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- ### CTA Results
- Right ICA
    - 70-80% mildly calcified stenosis 1cm above the bifurcation
  - Left ICA
    - Mild plaque at the bifurcation
  - Vertebrales
    - No significant disease
  - COW not mentioned

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- ### Options
- Medical Management
  - Carotid Endarterectomy
  - Carotid Artery Stent

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### Medical Management

- Risk of CVA with this stenosis is 20% over ten years by Framingham
- Natural history of disease?
- Antiplatelet therapy
- LDL <100 mg/dL
- TG < 150 mg/dL
- BP < 130/80mm Hg
- Quit smoking
- Look for CAD

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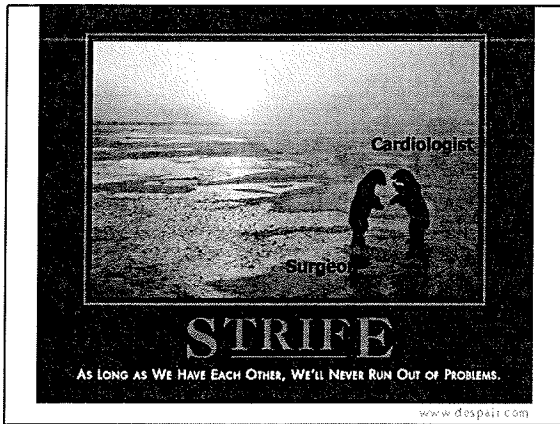
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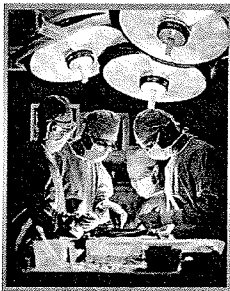
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### Carotid Endarterectomy



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## Lancet 1954

- "Reconstruction of internal carotid artery in a patient with intermittent attacks of hemiplegia."
- DeBakey and Carrera also report successful CEA procedures.

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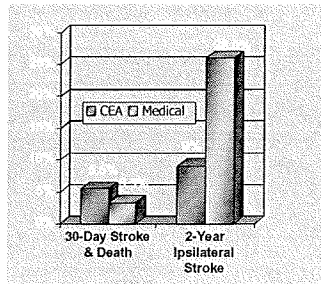
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## NASCET Results >70% Stenosis Group

- CEA had a slightly higher perioperative stroke and death rate than medical therapy.
- CEA had a significantly lower 2 year ipsilateral stroke rate. An absolute risk reduction of 17%.



1. NASCET Collaborators. Benefits of Effect of Carotid Endarterectomy in Symptomatic Patients with High-Grade Carotid Stenosis. *N Engl J Med* 1991; 325:465-53

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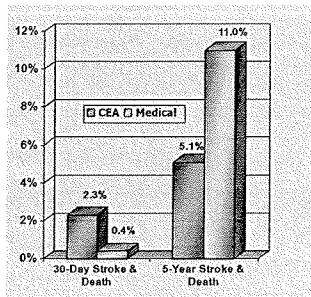
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## ACAS Results

- 30-day stroke and death slightly higher in the CEA group: 2.3% vs. 0.4%
- 1.2% stroke rate due to the pre-op angiogram
- Absolute risk reduction of 5 year ipsilateral stroke was 5.9%.



1. Executive Committee for the Asymptomatic Carotid Atherosclerosis Study. Endarterectomy for Asymptomatic Carotid Artery Stenosis. *NEJM* 1995; 333:1421-1430

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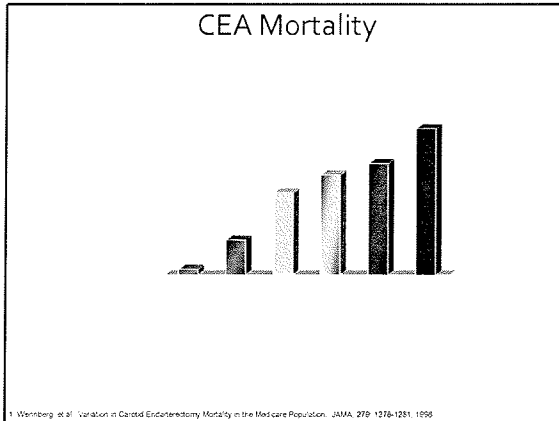
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### Carotid Endarterectomy

- **Advantages**
  - Proven history in low surgical risk patients
  - Safe and effective (if surgeon is experienced)
  - Decreases
- **Disadvantages**
  - Surgical therapy, longer recovery time
  - Risk of general anesthesia
  - Other risks
    - Potential for emboli causing stroke
    - Cranial nerve palsy
    - Infection



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### Carotid Endarterectomy

- **Anatomical Challenges**
  - High lesions (above C2)
  - Prior radical neck dissection for pharyngeal cancer with or without radiation therapy
  - CEA restenosis
  - Contralateral occlusion
  - Conditions that create spinal and neck immobility
  - Contralateral laryngeal nerve paralysis
  - History of tracheostomy tube placement
  - Patients with short obese necks



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AHA goals

- Symptomatic patients: 6% event rate
- Asymptomatic patients: 3% event rate

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What would you recommend?

- 1. Medical therapy alone
- 2. Medical therapy + CEA
- 3. Medical therapy + CAS
- 4. Need more information

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Management of Patient

- Due to lack of high risk features, referred for CEA; however, surgeon wanted a complete study including intracranial anatomy
- Very important to evaluate vessels from aorta to COW

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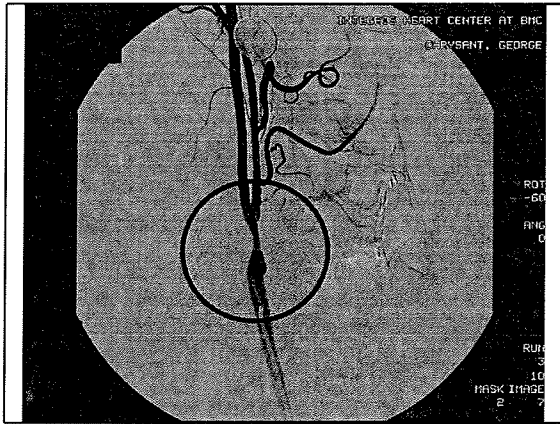
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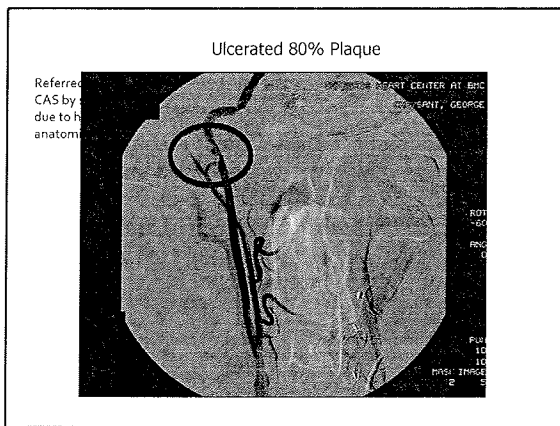
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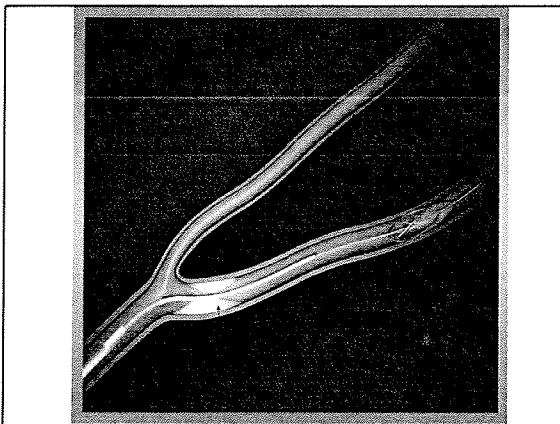
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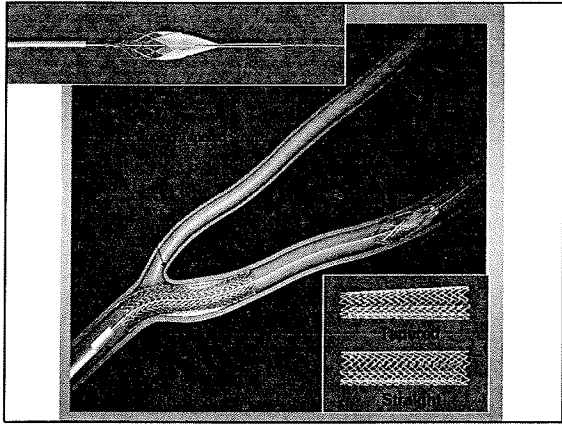
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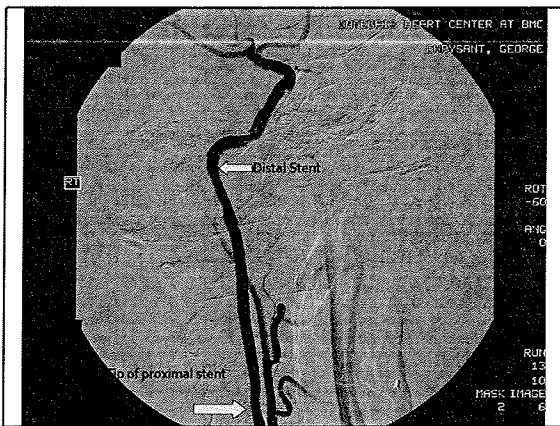
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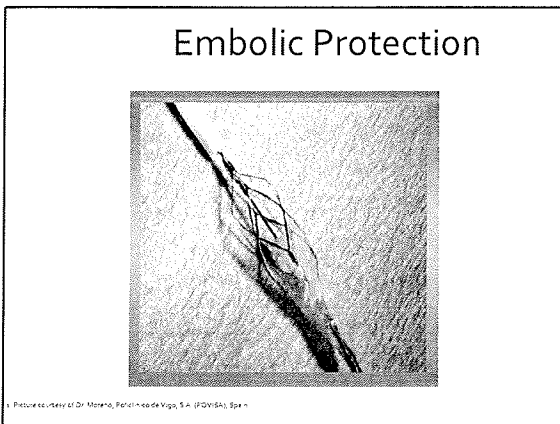
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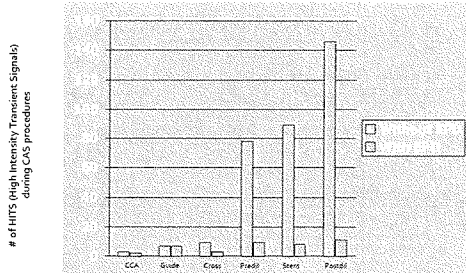
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This graph reflects how the use of an EPD may significantly reduce the incidence of embolic events during Carotid Artery Stenting (CAS).



Mathias J., Jager M. How much cerebral embolization occurs during CAS? ISCT 2008

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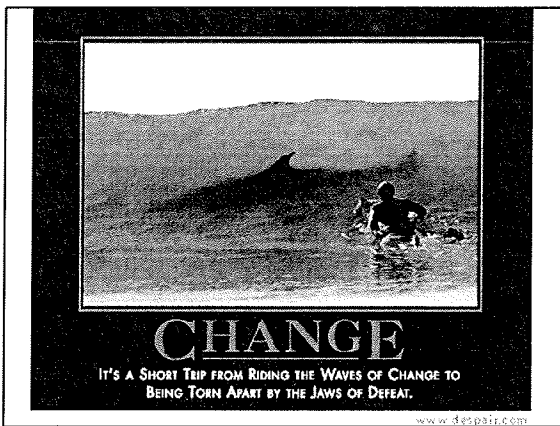
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### Conclusion of First Case

- All patients should be treated medically maximally
- CEA and CAS are equal therapies overall (there are certain situations where one is better than the other)
- Asymptomatic revascularization is still controversial
- Refer to centers with numbers consistent with the AHA goals of 3% or less for asymptomatic patients and 6% or less for symptomatic patients

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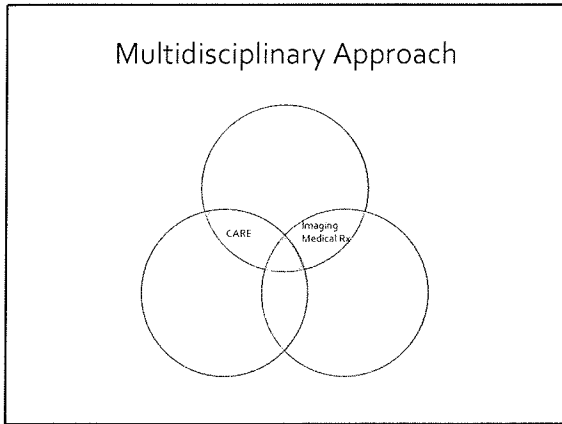
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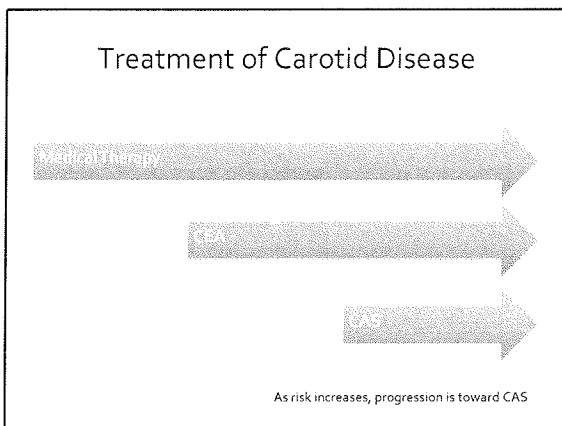
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### Case #2

#### Peripheral Artery Disease

- 55 year old car salesman with HTN, Tobacco use and HL
- Legs cramp before she "gets across the lot"
- Getting worse over the last 2 months (Rt > Lt)
- Good femoral pulses, weak popliteal pulses, palpable left DP/PT. No distal right pulses

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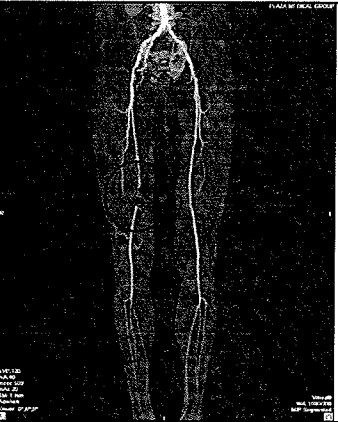
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**Abnormal ABI and CTA**



ABI:  
 Rt 0.7 -> 0.4  
 Lt 0.9 -> 0.7

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**Table 3. AHA-ACC Guidelines for Pharmacologic Management of Claudication \***

Medication and Class of Evidence	Level of Evidence	Dose	Side Effects
<b>Class I</b>			
Cilostazol	A	100 mg two times/day	Contraindicated in heart failure, headache, diarrhea, palpitations, dizziness
<b>Class IIb</b>			
Pentoxifylline	A	400 mg three times/day	Sore throat, dyspepsia, nausea, diarrhea
Arginine	B	3 g three times/day	Gastrointestinal distress, drop in hematocrit
Propionyl leucocarnitine	B	1-2 g two times/day	None or mild
Ginkgo biloba	B	120-160 mg/day	None or mild
<b>Class III</b>			
Prostaglandins	A	Beraprost 40 µg three times/day	Headache, flushing, gastrointestinal distress
Vitamin E	C	50 mg/day	None or mild
Chelation EDTA	A	1.5-3 g intravenously two times/wk	Hypocalcemia, renal failure, pruritus, gastrointestinal distress

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**TASC Recommendations**

Lesion Type	Characteristics	Recommended Treatment
A	Single stenosis ≤10 cm long Single occlusion ≤5 cm long	Percutaneous transluminal angioplasty strongly preferred
B	Multiple lesions, each ≤5 cm in length Single lesion ≤15 cm long, not involving the popliteal artery, below the knee Single or multiple lesions in the absence of contralateral tibial vessels for distal bypass Heavily calcified occlusion ≤5 cm long Single popliteal stenosis	Percutaneous transluminal angioplasty generally preferred
C	Multiple lesions >15 cm long Recurrent lesions after two endovascular interventions	Percutaneous transluminal angioplasty or surgery, depending on risk-benefit ratio
D	Occlusion >20 cm long Occlusion of the popliteal or tibial-peroneal vessels	Surgery generally preferred

TransAtlantic Inter-Society Consensus on Classification of Femoral Lesions and Recommended Approaches

From Norgren et al. *Eur J Vasc Endovasc Surg* 2007.

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What would you recommend?

- 1. Antiplatelet therapy with cilostazol and plavix alone
- 2. Cilostazol, plavix and PTA
- 3. Cilostazol, plavix and femoral to popliteal bypass surgery
- 4. Nothing until she quits smoking for 3 months

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Management of Case #2

- Plavix, cilostazol initiated
- 1 month follow-up: no improvement
- PTA and stenting of right SFA
- Smoking cessation
- Maximal medical therapy for atherosclerosis

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Case #3  
Renovascular Hypertension

- 44 yo gentleman with severe HTN, grade 1-2 retinopathy
- On Diuretic, ACE, CCB, Beta-blocker
- No bruit on exam
- BP by diary running 150-180/ 80-95 mm Hg
- Creatinine is 1.8

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### What are the options?

- 1. Renal U/S
- 2. CTA
- 3. MRA
- 4. Invasive angio.
- 1. Medical management only
- 2. Renal PTA/S
- 3. Renal denervation
- 4. Nephrectomy
- 5. Aorto-renal bypass

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### Differences in Anatomy

**Table 1. Characteristics of Atherosclerotic Renal-Artery Stenosis and Fibromuscular Dysplasia.**

Variable	Atherosclerosis	Fibromuscular Dysplasia
Age at presentation	Older (>50 yr)	Usually young (<40 yr)
Sex	Either	Usually female
Lesion location	Ostial, proximal, middle*	Middle or distal
Blood-pressure response to revascularization	Unclear	Normotension in most patients

\* Locations are listed in descending order of likelihood (i.e., ostial is more likely than proximal, which is more likely than middle).

Dworkin LD, Cooper C. *N Engl J Med* 2009.

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### Imaging Modalities and Cost

Test	Advantages	Disadvantages
Duplex ultrasonography	Non-invasive	Requires a skilled technician; limited by obesity or bowel gas
Magnetic resonance angiography	Non-invasive	Risk of nephrogenic systemic sclerosis among patients with chronic kidney disease
Computed tomographic angiography	Noninvasive	Risk of contrast nephropathy among patients with chronic kidney disease; radiation exposure
Digital-subtraction angiography	Best image quality and anatomical information	Invasive; risk of contrast nephropathy among patients with chronic kidney disease; risk of atheroembolic events; risk of vascular complications at puncture site; radiation exposure

Dworkin LD, Cooper C. *N Engl J Med* 2009.

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### Renal PTA with ARAS

- Has been controversial since the days of the DRASTIC study
- Multiple studies show everything from no benefit to patients coming off dialysis
- Questions surround what the severity of stenosis should be and how to determine if a stenosis is severe (like coronary FFR for instance)
- What is agreed upon is the indication for medical failure at 3 or more meds and presenting with acute pulmonary edema

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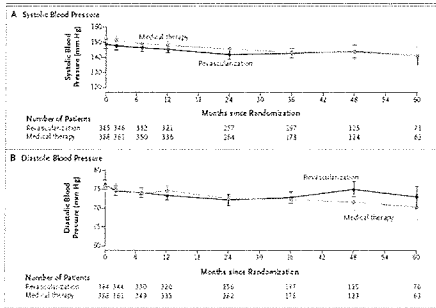
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### Blood Pressure Change in ASTRAL Trial



The ASTRAL Investigators. *N Engl J Med* 2009.

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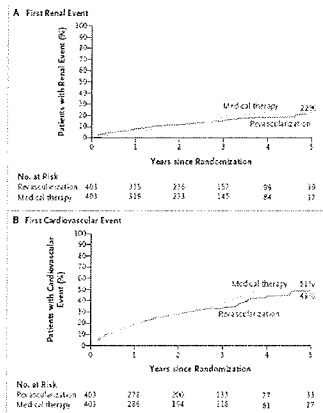
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### Primary Endpoints



The ASTRAL Investigators. *N Engl J Med* 2009.

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### Potential Flaw

Renal physiology	PTA	Meds	
Stenosis <sup>a</sup>			
Mean (range) — %	76 (40–100) <sup>b</sup>	75 (20–99)	0.29
Severity — no. (%)			
<50%	2 (2)	4 (1)	0.68
50–70%	159 (19)	164 (41)	
>70%	242 (50)	235 (58)	
Mean length of kidney (range) — cm	9.7 (6–14)	9.8 (6–20) <sup>c</sup>	0.44

Were these physiologically significant lesions?

The ASTRAL investigators. *N Engl J Med* 2009.

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### HERCULES Trial

	baseline	1 month	9 months	p-value
SBP (mmHg)	162 ± 18	145 ± 21	145 ± 21	<0.0001 <sup>a</sup>
% ACEI or ARB	76%	76%	76%	0.99 <sup>b</sup>
% Diuretics	65%	63%	60%	0.60 <sup>b</sup>
BNP (pg/mL)	181 ± 297	154 ± 235	NA	0.01

HERCULES Investigators. *Catheter and Cardiovasc Interv* 2011

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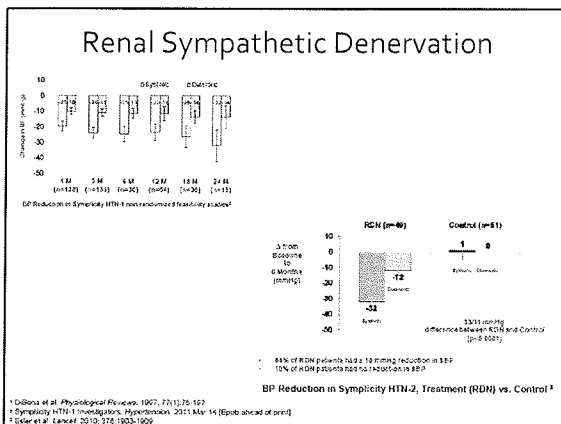
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### Management of Patient

- Screened with U/S and enrolled in HERCULES
- MRA showed bilateral severe ARAS
- Bilateral disease (90% left, 80% right)
- Bilateral renal PTA/stenting
- Criteria for trial met besides medical failure
  - >50% residual stenosis (suboptimal PTA)
  - > 30 mmHg gradient across stenosis

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### Thank You

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### Special populations: Octogenarians

- High level of CMS scrutiny in the octogenarian group
- Based on data from previous studies and registries
- Reasons for disparity in results unknown



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### CREST Event Rates

Age Group (in years)	Death & Stroke Rate
<60	1.7%
60-69	1.3%
70-79	5.3%
>= 80	12.1%*

Hobson R, et al. J Vasc Surg 2004

\*P>0.05




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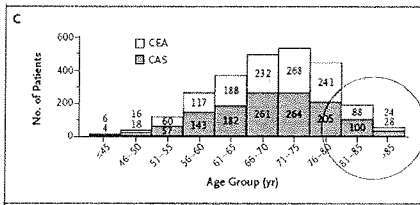
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### Distribution of patients in CREST




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### Recent registry event rates

- CAPTURE 2 (464/1987)
  - DSMI 80 and above 5.6%
  - DSMI <80 3.7%
  - Overall 30 day DSMI was 4.1%

From Gray et al. Circulation 2010




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## INTEGRIS Experience

- 42 patients, 46 lesions
- Average age 84 years
- 19 had TIA or CVA
- Average clinic follow-up 12 months
- Average ultrasound follow-up 14 months

From Chrysant GS, et al. Cardiovasc Revasc Med 2010.



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## INTEGRIS Experience

	Procedural success	U/S velocity wnl	Filter dwell time (ave)	Type III arch	Minor CVA
Symptomatic N=19 pts 20 lesions	20/20	18/20	9 min.	2	0
Asymptomatic N=23 pts 26 lesions	26/26	26/26	9 min.	4	1

From Chrysant GS, et al. Cardiovasc Revasc Med 2010.



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