

Surgical Treatment of Carotid Disease

The Old, the New, and the Future

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Disclosures

- None

Epidemiology

- Stroke is the 4th most common cause of death in the US in 2010
- Approximately 800,000 strokes occur every year
- 35% of which resulted in death and severe disability
- Extracranial carotid disease represents the most preventable cause of ischemic stroke

Risk Factors

- HTN
- Smoking
- Hyperlipidemia
- Diabetes
- Age
- Males
- Family History

Pathophysiology of a Stroke

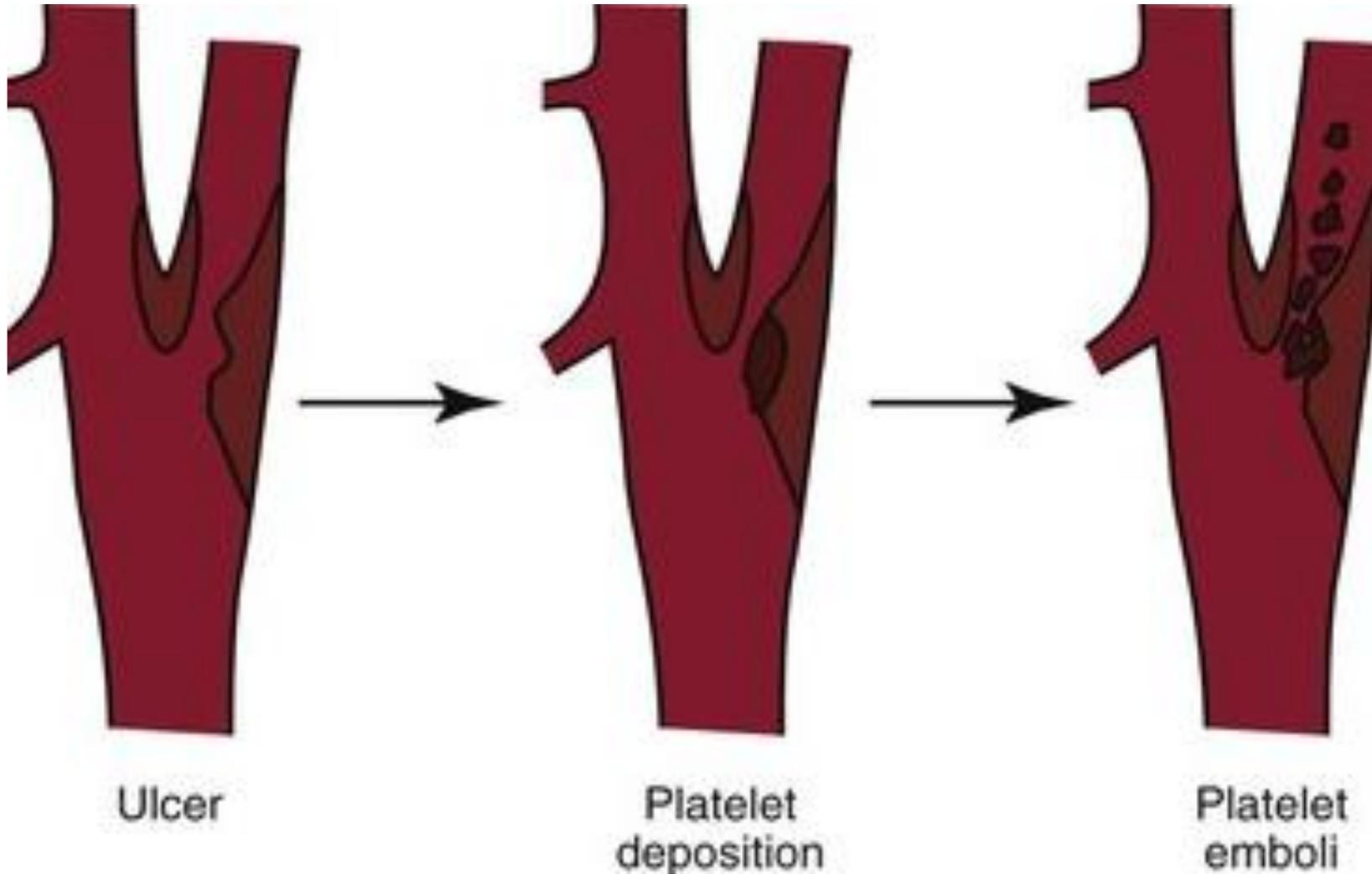


Image credit: Rutherford's Vascular Surgery

Treatment Options

- Medical Management
 - Aspirin, Plavix, Statin
 - Optimal blood pressure control
- Surgical Intervention
 - Carotid Endarterectomy (CEA)
 - Carotid Artery Stenting (CAS)
 - Transcarotid Revascularization (TCAR)

When to Operate?

ACAS

- 39 Medical Centers
- 1,662 Patients
- Risk of ipsilateral stroke over 5 years
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 - Surgical: 5.1%

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**Surgery for Asymptomatic
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NASCET

- 50 Medical Centers
- 659 Patients
- Risk of ipsilateral stroke at 2 years
 - Medical: 26%
 - Surgical: 9%

Surgery for Asymptomatic Patients >60% stenosis

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Surgery for Asymptomatic Patients >60% stenosis

NASCET

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Surgery for Symptomatic Patients >50% Stenosis

Carotid Endarterectomy



Image credit: Northern Sydney Vascular Website

Post-Operative Management

- Most patients go to a monitored bed postoperatively
- Neuro exams every few hours in the immediate post-operative period
 - Should include motor strength in bilateral extremities, smile, and sticking out their tongue

Complications

- Stroke
 - 1-2%
- Nerve Injury
 - Most common complication
 - 5-20% in most retrospective studies
- Myocardial infarction
 - 25-50% of all perioperative deaths
- Hyperperfusion syndrome
 - Infrequent but carries 75-100% mortality

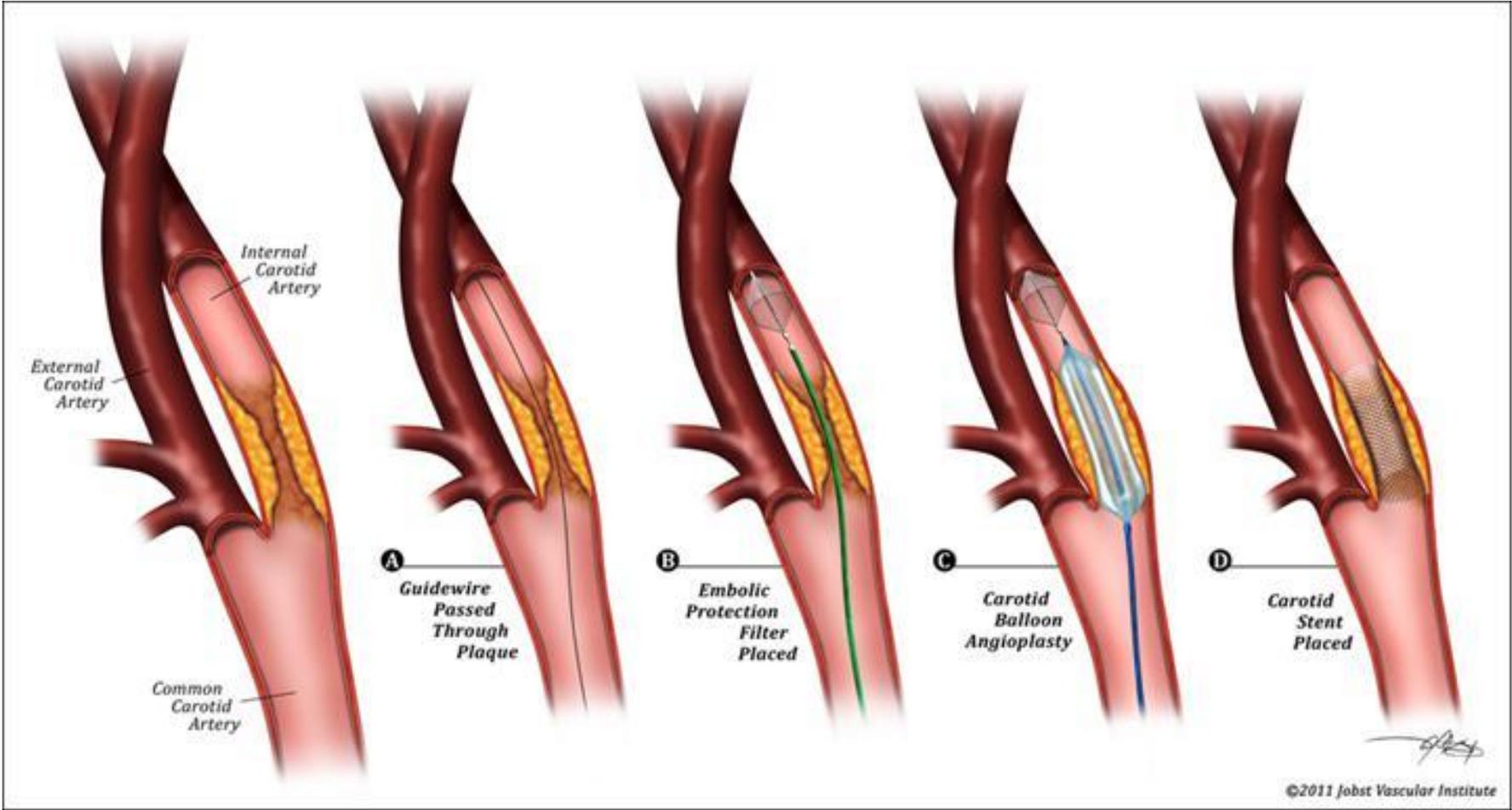
Long-Term Results

- CEA has been proven to provide excellent long-term clinical and anatomic results
- 5-year stroke free survival reported to be 92-96%
- Durable intervention

Carotid Artery Stenting

- 1989 first balloon-expandable stent was deployed in the carotid artery
- Development of cerebral protection devices
- Carotid Artery Stenting deemed a feasible alternative to CEA
- Proponents: simple, quick, minimally invasive

CAS Technique



Pitfalls of Carotid Artery Stenting



- Embolization during unprotected catheterization of the aortic arch and supra-aortic vessels
- Suboptimal embolic protection during CAS

So what are people doing?

- The 2013 National Inpatient Sample suggests that 85% of carotid patients undergo CEA and 15% of patients undergo carotid stenting
- No consensus regarding widespread adoption of CAS
- CAS has consistently demonstrated higher overall peri-procedural stroke rates

CREST Trial

- Largest randomized trial comparing outcomes of CEA vs. CAS
- No significant difference in the 4-year rates of primary end point
- Stroke is more common after CAS
- MI is more common after CEA
- Long lesion length, sequential lesions, severe distal tortuosity, narrow mouth ulcers confer high procedural stroke risk of CAS

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Putting it all together...

- 1. High risk patient population that would not tolerate a CEA
- 2. Minimally invasive approach that may have a higher stroke rate
- 3. CEA remains the primary procedure even for patients with increased surgical risk

What it all means...

- High-risk patients requiring carotid revascularization constitute an unmet clinical need

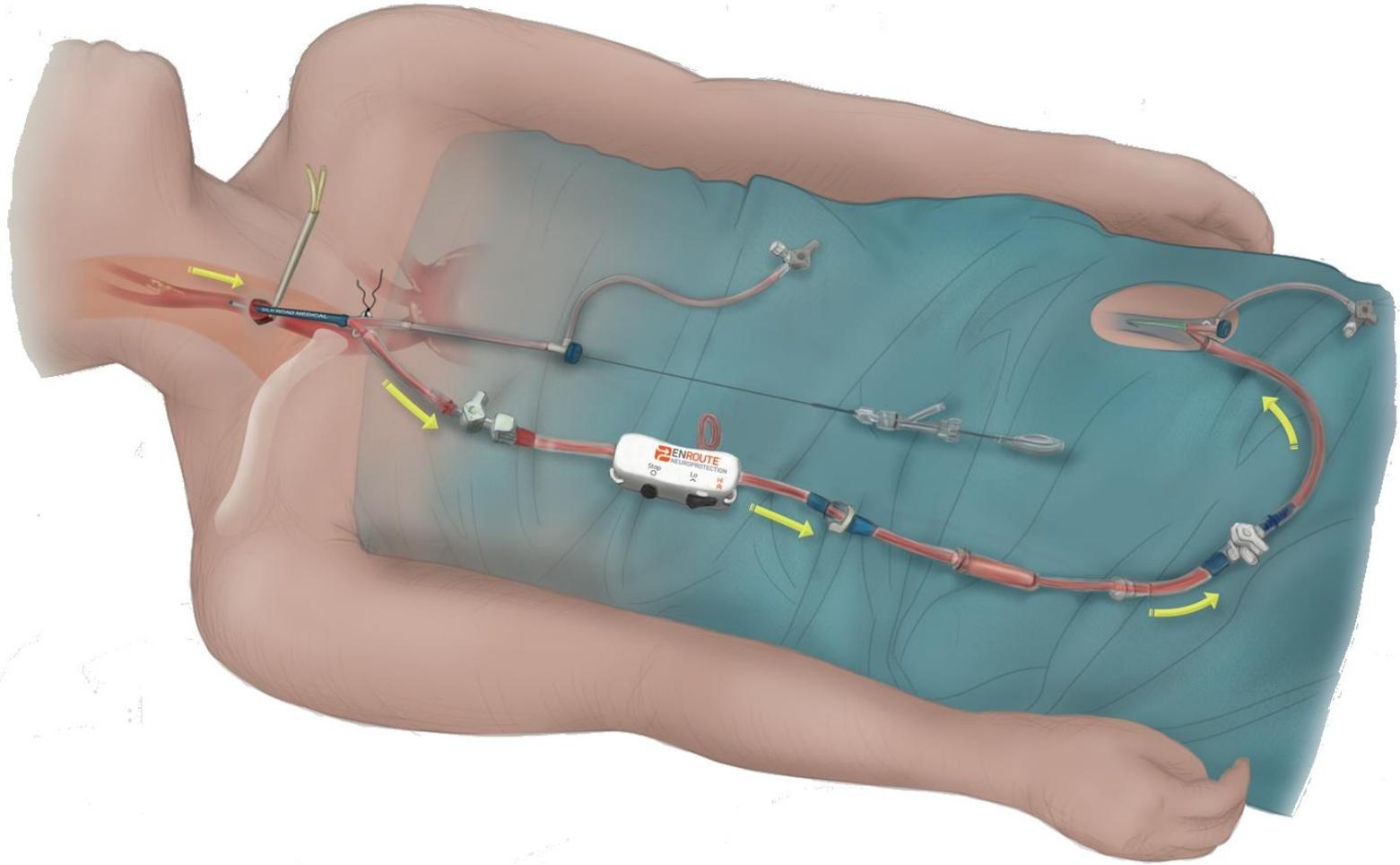
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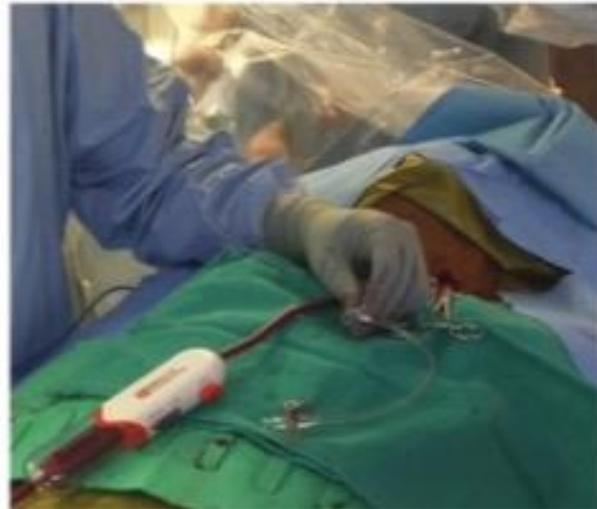
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 - This is where transcarotid revascularization comes into play.

TCAR



Houston Firsts



ROADSTER Study Design

- A prospective, single arm, multicenter clinical trial of the ENROUTE Transcarotid Neuroprotection System
- Primary endpoint : Composite of all stroke, death, and myocardial infarction at 30 days

Results

- 208 patients enrolled at 18 sites
 - 67 lead in cases
 - 141 pivotal cases
 - 105 asymptomatic
 - 36 symptomatic

Major Adverse Events

Table VIII. Hierarchical presentation of the major adverse event (*MAE*) rate for the intention to treat (*ITT*) population

<i>Parameters and statistics</i>	<i>ITT population (N = 141)</i>
Patients who experienced an MAE, ^a No. (%)	5 (3.5)
Exact binomial, 95% CI	1.16-8.08
<i>P</i> value	.0047
Events \leq 30 days of the index procedure	
Patients who died, No. (%)	2 (1.4)
Patients who had a stroke, No (%)	2 (1.4)
Patients who had an MI, No. (%)	1 (0.7)

CI, Confidence interval; *MI*, myocardial infarction.

^aDefined as stroke, death, myocardial infarction.

Major Adverse Events

- All stroke rate in the pivotal group was 1.4% (2 of 141)
- Stroke and death rate was 2.8% (4 of 141)
- Stroke, death and MI was 3.5% (5 of 141)

Discussion

- CREST : CEA had an MI rate of 2.3% and CAS of 1.1%
 - TCAR : 0.7% MI rate
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TCAR matches MI rate of CAS and stroke/death rate of CEA

The Future

- Can minimally invasive be even more minimally invasive?
- Newer stents and devices
- Completely percutaneous procedures