

A Data-Driven Look At Interventions For Carotid Disease:

Do They Represent Exuberant Enthusiasm, Financial Opportunity For Industry, Doctors And Institutions, Or A Path To Excessive Risk?

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Disclosures

- National Institutes of Health: Executive investigator/PI: COSS; SAMMPRIS, MOST, and STEP trials
- Collaborator: CASSISS and CMOSS trials
- DSMBs: Silk Road (ROADSTER and NITE trials); Penumbra (MIND and THUNDER trials); NoNO (ESCAPE NEXT and FRONTIER trials)
- Microvention: LVIS Trial core lab
- Euphrates Vascular: Stock Options

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Asymptomatic Carotid Intervention

- ACAS (JAMA 1995) and ACST (Lancet 2005) trials showed a benefit of CEA over medical therapy
- However –
 - Reduction of risk on medical therapy over time [Naylor 2009]
 - Subgroup analysis shows less benefit for women (Stroke 2004)
 - Less benefit with older patients (Lancet 2010)

Subgroup	Surgical	Medical	OR	95% CI
Males				
ACAS	51,102	97,102	0.50	0.35-0.72
ACAS	18,044	38,047	0.45	0.25-0.81
TOTAL	69,146	135,149	0.49	0.36-0.66
Females				
ACAS	31,634	34,037	0.90	0.65-1.48
ACAS	16,091	14,097	1.10	0.62-1.92
TOTAL	47,725	48,134	0.96	0.63-1.45

Goldstein and Rothwell 2004

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Asx Carotid Intervention Data

No new RCT data of intervention against medical therapy to support efficacy of intervention

- CREST – Similar outcomes between CEA and CAS (NEJM 2010)
- TCAR – Case series and non-randomized registry data for outcomes
- Meta-analysis– 7 studies, 24k patients - similar outcomes for CEA/CAS/TCAR (Ghannam Stroke 2024)
- USPSTF 2014 and 2022 – harms of screening outweigh any benefit – moderate certainty [JAMA 2024].
- Conclusion - current benefit of intervention is marginal at best and may not extend to broad population with Asx stenosis

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Why are we treating so many patients that probably don't need it?

Kahneman and Tversky – "Thinking Fast and Slow" 2011; Thaler "Nudge" 2008
We are hard wired to make decisions quickly (thinking fast), and unfortunately, many of the factors that come into that decision are unconscious and not factual. Many are emotional.

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Factors Favoring Treatment


- Objective facts make good story
 - Many strokes are caused by carotid stenosis
 - ACAS and ACST found a benefit with CEA
 - Carotid stenosis is easily treated by CEA/CAS/TCAR with low risk
- Unconscious drivers
 - It takes longer to explain why not to fix the stenosis – inconvenient and harder
 - Patients want their problems fixed - emotional
 - Referring physicians want problems fixed - may send elsewhere
 - If they have a stroke on medical care I'll feel responsible (and so will the plaintiff's attorney)
 - I'll get paid more with CEA/CAS/TCAR
 - The hospital makes more with CEA/CAS/TCAR - this supports my clinic, OR time, team
 - If I'm the first to use 100 new devices I'll be on the podium



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Eagerly awaiting the real answers

- Awaiting CREST 2 and ECST 2 read outs soon
 - ECST 2 interim data (Munich 2023) – no benefit
- Need to be focusing on high-risk subgroups
 - plaque biology, ulceration, intraplaque hemorrhage
 - hemodynamic impairment (Silvestrini Stroke 1999)
 - microemboli (Madani Neurology 2011)
- Tailored interventions - Future RCTs to prove relative benefits for different techniques (e.g. TCAR vs CAS/CEA for older age (Dakour-Arudi JVS 2020))
- Better devices – BGC, covered stents



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