"TCAR, like TFCAS, Has Durable Effectiveness Without Increased Mortality At 2-Years & Beyond"

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What Is The Aim Of Carotid Revascularization?

SUSTAINED Survival Free of Ipsilateral Stroke, Stent Durability & Low Restenosis Rates

The ICA Represents an *UNIQUE* Hemodynamic Environment: ***HIGH FLOW, LOW RESISTANCE***

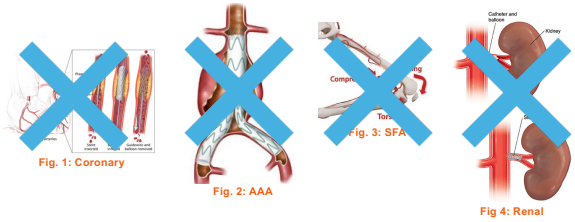


Fig. 1: Coronary

Fig. 2: AAA

Fig. 3: SFA

Fig 4: Renal

Patient-Level Data Acquired from RCTs:

EVA3S, SPACE, ICSS, and CREST to Assess Long-term Outcomes of CAS & CEA for Symptomatic Carotid Stenosis

> Lancet Neurol. 2019 Apr;18(4):348-356. doi: 10.1016/S1474-4422(19)30028-6. Epub 2019 Feb 6.

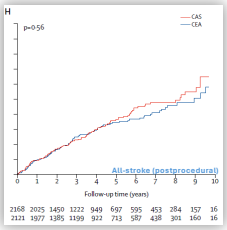
Long-term outcomes of stenting and endarterectomy for symptomatic carotid stenosis: a preplanned pooled analysis of individual patient data

Thomas G Brott [1], David Calvet [2], George Howard [3], John Gregson [4], Ale Algra [5], Jean-Pierre Becquemin [6], Gert J de Borst [7], Richard Bulbulia [8], Hans-Henning Eckstein [9], Gustav Fraedrich [10], Jacoba P Greving [11], Alison Halliday [8], Jeroen Hendrikse [12], Olav Jansen [13], Jenifer H Voeks [14], Peter A Ringleb [15], Jean-Louis Mas [2], Martin M Brown [16], Leo H Bonati [17], Carotid Stenosis Trialists' Collaboration

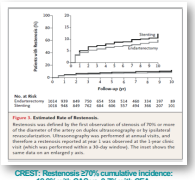
N = 4,754 Patients Followed to a maximum of 12.4 years

Patient-Level Data Acquired from RCTs: EVA3S, SPACE, ICSS, and CREST

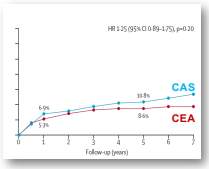
(G,H) All stroke. The risk of events estimates are provided for all outcomes, including both periprocedural and postprocedural events on the left of the figure (G) and for postprocedural events only (ie, >120 days; H) on the right of the figure. p values are for treatment differences using the log-rank test. CAS=carotid artery stenting; CEA=carotid endarterectomy.



No Difference in Rate of Significant Restenosis (≥70%) From The CREST or ICSS Randomized Controlled Trials of TFCAS vs. CEA



CREST: Restenosis ≥70% cumulative incidence: 12.2% with CAS vs. 9.7% with CEA, Hazard Ratio (HR) 1.24



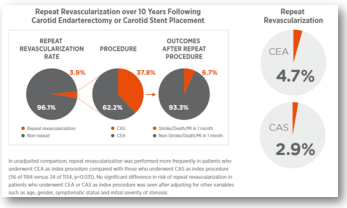
ICSS: Restenosis ≥70% out to 7 years demonstrated no difference between CAS and CEA

Brott TG, Howard G, Roubin GS, et al. Long-Term Results of Stenting versus Endarterectomy for Carotid-Artery Stenosis. *N Engl J Med.* 2016;374(11):1021-1031. doi:10.1056/NEJMoa1505215

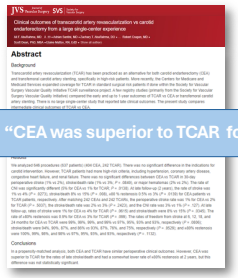
Bonati LH, Dobson J, Featherstone RL, et al. Long-term outcomes after stenting versus endarterectomy for treatment of symptomatic carotid stenosis: the International Carotid Stenting Study (ICSS) randomised trial. Lancet. 2015;385(9967):529-538. doi:10.1016/S0140-6736(14)61184-3

10-year CREST Data Demonstrate that patients randomized to CAS demonstrated lower rates of revascularization vs. patients randomized to CEA

Conclusions: A low rate of repeat revascularization was seen without any significant difference among patients who underwent CEA or CAS over 10 years.



Qureshi QI, et al. Repeat Revascularization over 10 Years Following Carotid Endarterectomy or Carotid Stent Placement: An Analysis of Carotid Revascularization Endarterectomy Versus Stent Trial. World Neurosurg. 2021 Oct;153:e871-e876. doi: 10.1016/j.wneu.2021.07.116. Epub 2021 Aug 2



VQI-derived single-center PSM analysis
TCAR vs. CEA in HSR pts with 2-year endpoint[1]

"CEA was superior to TCAR for the rates of stroke/death" at 2 years

Key Takeaways:

- **Sample size:** 242 TCARs, substantially underpowered for intermediate term follow-up.
  - ***29 TCAR patients*** and 55 CEA patients at 2 years in the Propensity Score Matched (PSM) freedom from stroke analysis
  - ***30 TCAR patients*** and 58 CEA patients at 2 years in the PSM freedom from stroke/death analysis
- **Differing Conclusions:** From larger ***NATIONAL LEVEL*** analyses reporting data from the same source (VQI) during the same time-frame:

95% CI, 0.95-1.37; P = .157).

- **Single Center (Bias):** Selection bias has notable impact in a single center analysis where there are specific attitudes to decision-making for carotid revascularization strategies within a small group of physicians (dependent on patient factors and legacy practice)
- **SSR Not Applicable:** The authors state "these data do raise concern for the performance of a carotid stent in standard risk patients with life expectancy greater than 2 years"
  - CANNOT EXTRAPOLATE: Standard risk patients do not have the co-morbidity profile that would impact on late stroke and mortality

1. AbuRahma AF, Santini A, AbuRahma ZT, Lee A, Veith C, Clegg N, Cregan R, Dean S, Mattox E. Journal Pre-proof Clinical Outcomes of Trans Carotid Artery Revascularization vs. Carotid Endarterectomy from a Large Single Center Experience. Ann Surg. 2022 Oct 1;276(4):599-567. doi: 10.1097/SLA.0000000000005609. Epub 2022 Jul 13. PMID: 37438667
2. Malas MB, Elsayed N, Nassim I, Dakour-Aridi H, Veith FJ, Scheinerman MS. Propensity-score-matched analysis of 1-year outcomes of transcarotid revascularization with dynamic flow reversal, carotid endarterectomy, and transfemoral carotid artery stenting. J Vasc Surg. 2022 Jan;75(1):213-221.e1. doi: 10.1016/j.jvs.2021.07.242. Epub 2021 Sep 6. PMID: 34500827
3. Malas MB, Dakour-Aridi H, Kashyap VS, Eldrup-Jorgensen J, Wang SL, Hotaganahalli RL, Cronenwett JL, Scheinerman MS. Trans Carotid Revascularization With Dynamic Flow Reversal Versus Carotid Endarterectomy in the Vascular Quality Initiative Surveillance Project. Ann Surg. 2022 Aug 1;276(2):398-405. doi: 10.1097/SLA.0000000000004496. Epub 2020 Sep 15.

Critical Appraisal:

All-cause mortality rather than neurologic or stroke-related mortality was captured, which is not the crucial endpoint.

A - Periprocedural (30-day) stroke/death outcomes were **equivalent**, therefore the 2yr stroke differences **are not** due to inherent safety differences of the procedures.

B - Rate of The rate of restenosis ≥80% was not statistically significant (p=0.099).

C - Most restenoses were asymptomatic & the rates of freedom from reintervention at two years were similar (99%).

- DUS "restenosis" of the stented carotid artery is therefore not a clinically meaningful endpoint.

Rate of late (non-periprocedural) stroke at 2 years **was not statistically higher for TCAR**, but trends up (p=0.08), reflecting the co-morbidity differences in favor of CEA:

2-year rates of stroke/death statistically higher for TCAR (p=0.05)

- This is largely driven by the mortality endpoint difference (given the lack of statistical significance in the stroke endpoint) in patients with substantial co-morbidities undergoing TCAR. This confounding exists despite PSM.[2]

1. AbuRahma AF, Santini A, AbuRahma ZT, Lee A, Veith C, Clegg N, Cregan R, Dean S, Mattox E. Journal Pre-proof Clinical Outcomes of Trans Carotid Artery Revascularization vs. Carotid Endarterectomy from a Large Single Center Experience. Ann Surg. 2022 Oct 1;276(4):599-567. doi: 10.1097/SLA.0000000000005609. Epub 2022 Jul 13. PMID: 37438667
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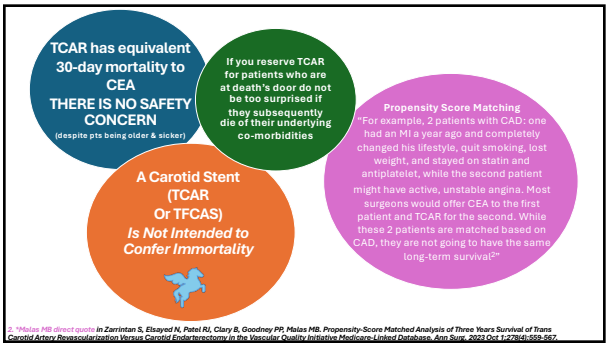

2. *Malas MB direct quote *In* Zarrintan S, Elsayed N, Patel RJ, Clary B, Goodney PP, Malas MB. Propensity-Score Matched Analysis of Three Years Survival of Trans Carotid Artery Revascularization Versus Carotid Endarterectomy in the Vascular Quality Initiative Medicare-Linked Database. Ann Surg. 2023 Oct 1;278(4):599-567.