Asymptomatic Patients with Carotid Stenosis Should be Treated with Best Medical Therapy Given Improvements in Outcomes!

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I <u>will</u> be discussing products that are investigational





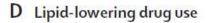


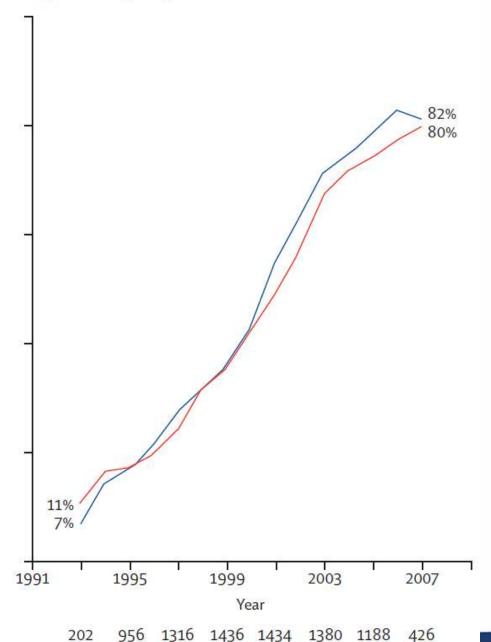
 The improvement in medical management has changed the playing field











1448 1456

1390

1198

412

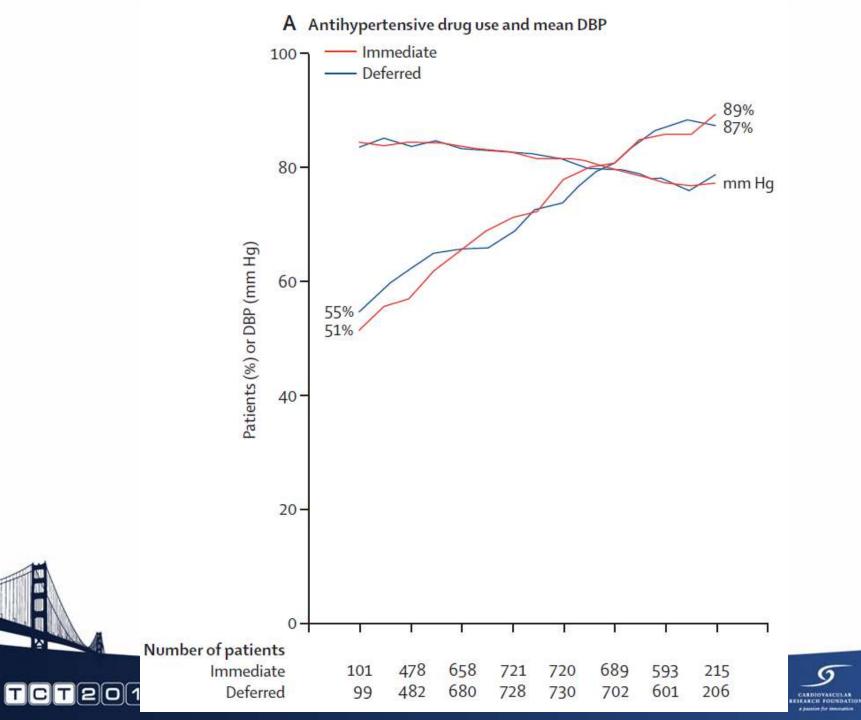
Figure 4: Current use (at or after randomisation) of various medical treatments by year of follow-up and by original treatment allocation (to immediate or deferred CEA) CEA=carotid endarterectomy.

DBP=diastolic blood pressure.



198

1356



Topical Reviews

Section Editors: Guiseppe Lanzino, MD, and Michael Tymianski, MD, PhD

What Is the Current Status of Invasive Treatment of Extracranial Carotid Artery Disease?

A. Ross Naylor, MD, FRCS

Abstract—Year 2011 sees the publication of US guidelines that recommend expanding indications for carotid artery stenting into "average-risk" patients, whereas guidelines from Australia/New Zealand largely do not. This article reviews the status of invasive treatment of carotid disease and highlights 2 controversial issues that were not really addressed in these guidelines: (1) a lack of emphasis on the importance of intervening rapidly after transient ischemic attack/minor stroke; and (2) why continue to recommend that only "highly selected" asymptomatic patients should undergo intervention when virtually no-one pays any attention? (Stroke. 2011;42:2080-2085.)





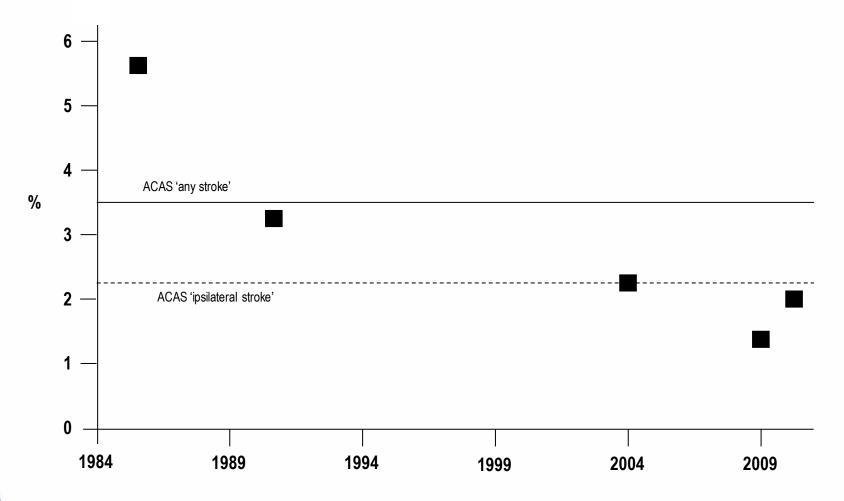




Figure. Average annual stroke rates in medically treated patients with asymptomatic carotid stenosis. indicates any stroke 70% to 99% stenosis.





 And what about intensive medical management?







ORIGINAL ARTICLE

Stenting versus Aggressive Medical Therapy for Intracranial Arterial Stenosis

Marc I. Chimowitz, M.B., Ch.B., Michael J. Lynn, M.S., Colin P. Derdeyn, M.D., Tanya N. Turan, M.D., David Fiorella, M.D., Ph.D., Bethany F. Lane, R.N., L. Scott Janis, Ph.D., Helmi L. Lutsep, M.D., Stanley L. Barnwell, M.D., Ph.D., Michael F. Waters, M.D., Ph.D., Brian L. Hoh, M.D., J. Maurice Hourihane, M.D., Elad I. Levy, M.D., Andrei V. Alexandrov, M.D., Mark R. Harrigan, M.D., David Chiu, M.D., Richard P. Klucznik, M.D., Joni M. Clark, M.D., Cameron G. McDougall, M.D., Mark D. Johnson, M.D., G. Lee Pride, Jr., M.D., Michel T. Torbey, M.D., M.P.H., Osama O. Zaidat, M.D., Zoran Rumboldt, M.D., and Harry J. Cloft, M.D., Ph.D., for the SAMMPRIS Trial Investigators*

Measures of Risk Factors at Baseline and 4 Months

Clinical Factor		Baseline	4 Months
Blood pressure	Systolic blood pressure– mm Hg	147±22	135±17
Lipids	LDL cholesterol – mg/dl	98±37	73±26
Glycated hemoglobin in patients with diabetes	Level of glycated hemoglobin - %	8.3±2.3	7.5±2.0





ORIGINAL ARTICLE

Stenting versus Endarterectomy for Treatment of Carotid-Artery Stenosis

Thomas G. Brott, M.D., Robert W. Hobson, II, M.D., George Howard, Dr.P.H., Gary S. Roubin, M.D., Ph.D., Wayne M. Clark, M.D., William Brooks, M.D., Ariane Mackey, M.D., Michael D. Hill, M.D., Pierre P. Leimgruber, M.D., Alice J. Sheffet, Ph.D., Virginia J. Howard, Ph.D., Wesley S. Moore, M.D., Jenifer H. Voeks, Ph.D., L. Nelson Hopkins, M.D., Donald E. Cutlip, M.D., David J. Cohen, M.D., Jeffrey J. Popma, M.D., Robert D. Ferguson, M.D., Stanley N. Cohen, M.D., Joseph L. Blackshear, M.D., Frank L. Silver, M.D., J.P. Mohr, M.D., Brajesh K. Lal, M.D., and James F. Meschia, M.D., for the CREST Investigators†







- 1,181 asymptomatics
- 30-day stroke and death rates low,
 2.5% for CAS and 1.4% for CEA







- CREST 5 year rates, 5.4% and 3.4%
- ACAS 5 year rate for Medical 11%
- If Medical 30% better today, at 7.7%, absolute difference would be ~ 3.3% or 5 year NNT of ~ 30 (ACAS ~18)





Recommendations: CREST-2









_______CN/S/ Centers for Medicare & Medicaid Services

- "The body of randomized trials and post approval studies does not demonstrate that CAS can be performed at that level." [<3%]
- "Concerning for asymptomatic patients since these patients do not have symptoms by definition and may be exposed to risks from the procedure."
- "Continues to highlight the need for a randomized trial comparing CAS with optimal medical therapy."



- Test whether Carotid Revascularization is superior to Medical Management
- >= 70% stenosis by angio or ultrasound
- Interventional Arm: CEA or CAS by CREST and TACIT Teams
- Medical Arm: SAMMPRIS team & protocol
- Effect size: 1.2% (changed medical practice)
- 950 patients at 70 centers





Thanks
for your
Attention







_______CN/S/ Centers for Medicare & Medicaid Services

 "for CAS to be considered an alternative to CEA and improve health outcomes for asymptomatic patients with asymptomatic stenosis > 80%, the perioperative morbidity and mortality rates should be less than 3%."



