Angiology
63(8) 639-644

DOI: 10.1177/0003319711436076
http://ang.sagepub.com
SAGE

Why the US Center for Medicare and Medicaid Services Should Not Extend Reimbursement Indications for Carotid Artery Angioplasty/Stenting

Anne L. Abbott, MD, PhD, FRACP[1], Mark A. Adelman, MD[2], Andrei V. Alexandrov, MD[3], Henry J. M. Barnett C. C., MD[4], Jonathan Beard, FRCS, ChM, MEd[5], Peter Bell, MD, FRCS[6,7], Martin Björck, MD, PhD[8], David Blacker, MD, FRACP[9], Clifford J. Buckley, MD, FACS[10,11,12], Richard P. Cambria, MD[13,14], Anthony J. Comerota, MD, FACS, FACC, RVT[15], E. Sander Connolly Jr, MD[16], Alun H. Davies, MA, DM, FRCS, FHEA, FEBVS, FACPh[17], Hans-Henning Eckstein, MD, PhD[18,19], Rishad Faruqi, MD, FACS[20,21,22], Gustav Fraedrich, MD[23], Peter Gloviczki, MD[24], Graeme J. Hankey, MD, FRACP[25], Robert E. Harbaugh, MD, FAANS, FACS, FAHA[26,27,28], Eitan Heldenberg, MD[29], Steven J. Kittner, MD, MPH[30], Timothy J. Kleinig, PhD, FRACP, MBBS[31,32], Dimitri P. Mikhailidis, MSc, MD, FRSPH, FCP, FFPM, FRCP, FRCPath[33], Wesley S. Moore, MD[34], Ross Naylor, MD, FRCS[35], Andrew Nicolaides, MS, FRCS, PhD[36], Kosmas I. Paraskevas, MD[37], David M. Pelz, MD, FRCPC[38], James W. Prichard, MD[39], Grant Purdie, MD, FRACP[40], Jean-Baptiste Ricco, MD, PhD[41], Thomas Riles, MD[42], Peter Rothwell, MD, PhD, FRCP, FMedSci[43], Peter Sandercock, MA, DM, FRCPE, FMedSci[44], Henrik Sillesen, MD, DMSc[45], J. David Spence, MBA, MD, FRCPC, FAHA, FCAHS[46,47], Francesco Spinelli, MD[48], Aaron Tan, FRACP[31], Ankur Thapar, MBBS, MRCS[49], Frank J. Veith, MD[42,50,51], and Wei Zhou, MD[52,53]

[1] Baker IDI Heart & Diabetes Institute and Florey Neuroscience Institutes, Melbourne, Australia
[2] Vascular and Endovascular Surgery, New York University Langone Medical Center, New York, NY, USA
[3] Comprehensive Stroke Center, University of Alabama Hospital, South Birmingham, AL, USA
[4] University of Western Ontario, Toronto, Ontario, Canada
[5] Sheffield Vascular Institute, Northern General Hospital, Sheffield, United Kingdom
[6] University of Leicester, Leicester, UK
[7] University of Leicester Hospitals, Oadby, Leicester, United Kingdom
[8] Department of Surgical Sciences, Section of Vascular Surgery, Uppsala University, Uppsala, Sweden
[9] Department of Neurology, Sir Charles Gairdner Hospital, Nedlands WA, Australia
[10] Texas A&M Health Sciences Center College of Medicine, TX, USA
[11] Department of Surgery; Director Division of Vascular Surgery, Scott and White Health Care Systems, TX, USA
[12] Central Texas Veterans Health Care System, TX, USA
[13] Division of Vascular and Endovascular Surgery, Massachusetts General Hospital, Boston, MA, USA
[14] Harvard Medical School, Boston, MA, USA
[15] Jobst Vascular Institute, The Toledo Hospital, Toledo, OH, USA
[16] Department of Neurological Surgery, Columbia University, New York, NY, USA
[17] Imperial College School of Medicine, Level 4, Charing Cross Hospital, London, UK
[18] Technische Universität München, Germany
[19] Department of Vascular and Endovascular Surgery, "Klinikum rechts der Isar der Technischen Universität München"München, Germany
[20] Department of Surgery, Stanford University, Stanford, CA, USA
[21] Department of Surgery, University of California, San Francisco, CA, USA
[22] Department of Vascular and Endovascular Surgery, Kaiser Permanente Medical Center, Santa Clara, CA, USA
[23] Department of Vascular Surgery, Medical University, Innsbruck, Austria
[24] Division of Vascular and Endovascular Surgery, Mayo Clinic, Rochester, MN, USA
[25] Royal Perth Hospital and University of WA, Australia
[26] Penn State Institute of the Neurosciences, PA, USA
[27] Department of Neurosurgery, Penn State University, MS Hershey Medical Center, Hershey, PA, USA
[28] Department of Engineering Science and Mechanics, Penn State University, MS Hershey Medical Center, Hershey, PA, USA
[29] Assaf Harofeh Medical Center, Zerifin, Tel Aviv University, Israel
[30] University of Maryland School of Medicine, Baltimore, MD, USA
[31] Neurology Department, Royal Adelaide and Lyell McEwin Hospitals, Adelaide, SA, Australia
[32] University of Adelaide, SA, Australia
[33] Department of Clinical Biochemistry (Vascular Disease Prevention Clinics), Royal Free Hospital Campus, University College London Medical School, University College London (UCL), Pond Street, London, UK

A potential crisis looms in the United States—related to the proposal for the US Center for Medicare and Medicaid Services (CMS) to allow wider indications for government reimbursement for carotid angioplasty/stenting (CAS). We, the undersigned, are writing to advise CMS to reject this proposal based on overwhelming evidence that it would have serious negative health and economic repercussions for the United States and any other country that may follow such inappropriate action. The purpose of this message is not to advise on existing CMS policy. Instead, we wish to advise that current Medicare coverage for CAS should not be extended to routine practice management of asymptomatic carotid stenosis or symptomatic carotid stenosis where the patient is considered at "low/average risk" of complications from carotid endarterectomy (CEA). We understand that, currently, CMS covers the cost of CAS for the indications listed below (the National Coverage Determination [NCD] for Percutaneous Transluminal Angioplasty [PTA] March 5, 2010):

1. Concurrent with carotid stent placement when furnished in accordance with the Food and Drug Administration (FDA)-approved protocols governing Category B Investigational Device Exemption (IDE) clinical trials.
2. Concurrent with the placement of an FDA-approved carotid stent and an FDA-approved or -cleared embolic protection device for an FDA-approved indication when furnished in accordance with FDA-approved protocols governing postapproval studies.
3. Concurrent with the placement of an FDA-approved carotid stent with an FDA-approved or -cleared embolic protection device for the patients who are at high risk of CEA and who also have symptomatic carotid artery stenosis >70%.
4. Patients who are at high risk of CEA and have symptomatic carotid artery stenosis of 50% to 70%, in accordance with the Category B IDE clinical trials or in accordance with the NCD on carotid artery stenting postapproval studies.
5. Patients who are at high risk of CEA and have asymptomatic carotid artery stenosis >80%, in accordance with the Category B IDE clinical trials regulation or in accordance with the NCD on CAS postapproval studies.

According to the same NCD, patients at high risk of CEA are defined as having significant comorbidities and/or anatomic risk factors (ie, recurrent stenosis and/or previous radical neck dissection), so that they would be considered poor candidates for CEA. Significant comorbid conditions include but are not limited to:

- congestive heart failure (CHF) class III/IV;
- left ventricular ejection fraction (LVEF) <30%;
- unstable angina;
- contralateral carotid occlusion;
- recent myocardial infarction (MI);
- previous CEA with recurrent stenosis;
- prior radiation treatment to the neck; and
- Other conditions that were used to determine patients at high risk of CEA in the prior carotid artery stenting trials and studies, such as ARCHER, CABERNET, SAPPHIRE, BEACH, and MAVERIC II.

Over the last 2 to 3 years, the available evidence to direct current best stroke-prevention management of carotid stenosis has been reviewed by a number of leading academic clinicians. Current routine practice management of carotid stenosis is based on the results of randomized trials of medical (noninvasive) intervention alone versus additional CEA for patients with symptomatic[1-3] or asymptomatic[4-7] carotid stenosis. In these trials, patients were randomized up to 30 years ago (1981-1994 and 1983-2003, respectively). Overall, an average annual stroke prevention benefit of about 3.0% was measured

[34] Division of Vascular Surgery, The David Geffen School of Medicine at UCLA, Los Angeles, CA, USA
[35] Clinical Sciences Building, Leicester Royal Infirmary, Leicester, UK
[36] Vascular Diagnostic Centre, Imperial College, London, UK
[37] Department of Vascular and Endovascular Surgery, Klinikum Nürnberg Süd, Germany
[38] Departments of Medical Imaging and Clinical Neurological Sciences, University of Western Ontario, London, Ontario, Canada
[39] Yale Medical School, New Haven, CT, USA
[40] The Queen Elizabeth Hospital, Adelaide, SA, Australia
[41] Vascular Surgery Service, University of Poitiers, France
[42] Department of Surgery at New York University School of Medicine, New York, NY, USA
[43] Nuffield Department of Clinical Neurosciences (Clinical Neurology), University of Oxford, John Radcliffe Hospital, Oxford, UK
[44] Department of Clinical Neurosciences, Western General Hospital, Edinburgh, UK
[45] Department of Vascular Surgery, Rigshospitalet, University of Copenhagen, Denmark
[46] Neurology and Clinical Pharmacology, University of Western Ontario, Ontario, Canada
[47] Stroke Prevention & Atherosclerosis Research Centre, Robarts Research Institute, London, Ontario, Canada
[48] Department of Cardiovascular and Thoracic Sciences, University of Messina, Messina, Italy
[49] Royal College of Surgeons, Charing Cross Hospital, London, UK
[50] Vascular Surgery, Cleveland Clinic and Lerner School of Medicine of Case Western Reserve University, Cleveland, OH, USA
[51] Department of Surgery, F. Edward Hebert School of Medicine, Uniformed Services, University of the Health Sciences, Riverdale, NY, USA
[52] Vascular and Endovascular Surgery, Stanford University, CA, USA
[53] Vascular Section, Division of Vascular and Endovascular Surgery, Palo Alto VA Health Care System, Stanford, CA, USA

Corresponding Author:
Anne L.Abbott, Baker IDI Heart & Diabetes Institute 75 Commercial Road, Melbourne, 3004. Australia
Email: anne.l.abbott@gmail.com

for operated patients with moderate or severe [70%-99% North American Symptomatic Carotid Endarterectomy Trial (NASCET) equivalent] symptomatic[8] carotid stenosis and about 0.5% to 1% for operated patients with moderate or severe (50%-99% NASCET equivalent) asymptomatic[7,9] carotid stenosis compared to patients who received medical intervention alone. More recently, trials of CAS versus CEA (without a medical intervention-only arm) were performed, demonstrating that the perioperative stroke risk is about twice as high with stenting when compared with CEA (see below). These trials were most likely designed assuming medical intervention has not changed since the randomized surgical trials, aiming to find at least an equivalent CEA stroke prevention benefit. However, it is now clear that the stroke prevention efficacy of medical intervention has steadily and significantly improved over the last 30 years and continues to improve,[10-14] consistent with other observed falls in risk of stroke,[15-17] heart attack, and sudden death.[18] Currently used benchmarks for a stroke prevention benefit from CEA over medical intervention (a 30-day procedural risk of stroke/death of 3% for asymptomatic carotid stenosis[19] or 6% for symptomatic carotid stenosis)[20] are outdated. Therefore, the demonstration of stroke prevention equivalence between CAS and CEA using these benchmarks (even if this had been achieved) would be insufficient to justify a current, routine practice indication for CAS.

The inappropriateness of the recent push for widening CMS coverage for carotid stenting is particularly evident with respect to ASYMPTOMATIC carotid stenosis because the randomized surgical trial stroke prevention benefit from CEA was so small and conditional. However, the most recent standardized measurements of the average annual rate of ipsilateral stroke among patients receiving medical intervention alone approximate only 0.5%.[11,21-23] This is about 3 times lower than for randomized surgical trial CEA patients,[5] about 5 times lower than randomized surgical trial nonoperated patients,[5] 3 times lower than CREST stented patients,[24] and about half the rate of CREST CEA patients.[10,11,24] The push for routine practice stenting for asymptomatic carotid stenosis is based largely on the recently published CREST results,[24] and perhaps other clearly flawed randomized data,[25,26] comparing CEA with CAS (without a medical intervention-only arm) and implications of "equivalence" with CEA.[27] As mentioned, such equivalence, even if supported by the data, would not be sufficient to justify a current, routine practice indication for CAS for asymptomatic carotid stenosis.

However, to add insult to injury, an equivalent stroke prevention benefit between CAS and CEA has not been demonstrated. Carotid angioplasty/stenting in CREST,[24] large registries, and population-based studies[28-30] has been associated with about double the periprocedural rate of stroke or death compared to CEA. Further, in CREST, among asymptomatic patients, the rate of periprocedural stroke/death or later ipsilateral stroke projected for 4 years was 4.5% for 594 patients who had CAS and 2.7% for the 587 who had CEA (67% higher, $P = .07$). This outcome measure reached statistical significance when symptomatic patients were added (6.4% vs 4.7%, 36% higher, $P = .03$). The inclusion of higher risk symptomatic patients, and larger sample sizes, allows easier detection of statistically significant differences. Supporters of routine CAS for asymptomatic carotid stenosis have tried to use a higher incidence of periprocedural myocardial infarction (including minor infarction) associated with CEA to justify a higher stroke/death risk with CAS.[31] However, this is invalid and distracting because the aim of invasive carotid intervention is to prevent stroke. Further, in CREST, at least, a larger proportion of patients who suffered periprocedural myocardial infarction associated with CAS (compared to CEA) died during follow-up.[32] More importantly, procedure-associated myocardial damage would be prevented entirely if unnecessary CEA and CAS interventions were not performed in the first place. In addition, it should also be noted that CAS has higher procedural costs compared to CEA.[33]

The current situation regarding CEA and CAS for patients with asymptomatic stenosis in the United States is unjustified and outdated. Up to about 90% to 95% of these procedures are being performed for asymptomatic carotid stenosis,[29,34] exposing patients to unnecessary risk and causing unjustified expenditure of at least 1 to 2 billion US health care dollars each year[10,12,35-38] at a time when the health care costs need to be justified.[39] Despite no previous CMS coverage for routine practice CAS for asymptomatic carotid stenosis, rates of CAS procedures are increasingly dramatically, especially among cardiologists.[40,41] Extending the approved indications for CAS will open the floodgates for widespread CAS and expose patients to unnecessary risk and greatly increase unjustified health expenditure.[33]

Broadening the indications for CAS reimbursement for SYMPTOMATIC carotid stenosis is also inappropriate. The request for such broadening of reimbursement will, once again, be based on the CREST trial conclusions[24] and the recently published American Heart Association (AHA) Guideline (approved by 13 other organizations),[27] which states that "CAS is an *alternative* to CEA for the treatment of symptomatic carotid stenosis ...." Equivalence of the two procedures is implied.[42,43] Unfortunately, the actual CREST data,[44] most other randomized trial data,[45-47] meta-analyses,[48,49] and registry data[28-30] do not justify this presumed equivalence of CAS and CEA for symptomatic carotid stenosis.[50,51] In symptomatic patients, CAS, overall, is associated with about double the 30-day, 120-day, 6-month, and/or 4-year risk of stroke or death compared to CEA. The excessive CAS procedural risk of stroke or death is particularly notable in patients over 70 years of age,[52] yet not confined to the oldest age groups.[44] Carotid angioplasty/stenting is also associated with a much higher periprocedural risk of brain-imaging-detected ischemic lesions than CEA[53] and a higher incidence of carotid restenosis.[54-56] No studies have shown CAS is better than CEA in preventing stroke in patients with symptomatic carotid stenosis and procedural costs are significantly higher with CAS.[33] Thus, the extension of Medicare reimbursement to routine treatment of "low" and "standard" CEA risk patients with symptomatic carotid stenosis is not currently justified.

Thus, in summary, at this time, the evidence does not support broadening reimbursement for CAS to routine management of patients with asymptomatic carotid stenosis or patients

with symptomatic carotid stenosis considered at "low or standard" risk from CEA. It is acknowledged that this situation may change in the future.

Authors' Note

This special communication was first published in *European Journal of Vascular and Endovascular Surgery*, Vol 43, Abbott A. et al., Why the United States Center for Medicare and Medicaid Services should not extend reimbursement indications for carotid artery angioplasty/stenting, Copyright 2012 European Society for Vascular Surgery. Published by Elsevier Limited. All rights reserved (doi: 10.1016/j.ejvs.2011.12.006). Corrected proof available online 6th January 2012: http://www.sciencedirect.com/science/article/pii/S1078588411007866. Permission to re-publish has been obtained.

Authors' Disclosures

Henry Barnett was PI of the North American Symptomatic Carotid Endarterectomy Trial (NASCET). Jonathon Beard is on the Steering Committee of the International Carotid Stenting Study (ICSS).David Blacker has received sponsorship to scientific meetings from Boehringer Ingelheim. He has previously been a member of the advisory board for NovoNorsdisk (regarding Factor VII) and receives funding for involvement in the Prevention of cerebrovascular and cardiovascular Events of ischaemic origin with teRutroban in patients with a history oF ischaemic strOke or tRansient ischaeMic attack (PERFORM) Study. Richard Cambria is co-PI for a future transcervical carotid stenting/flow reversal trial (ROADSTER). Anthony Comerota received research funding for the Jobst Vascular Institute to participate in the Carotid Revascularization Endarterectomy vs. Stenting Trial (CREST). Alun Davies receives funding from the Stroke Association on the evaluation of carotid plaque. Hans-Henning Eckstein is Co-PI of the Stent-Supported Percutaneous Angioplasty of the Carotid Artery versus Endarterectomy (SPACE-2) Study. He was a member of the Steering Committee of the SPACE-1 Study. Gustav Fraedrich is a member of the steering committee of the "Carotid Stenting Trialists Collaboration" (CSTC) and member of the steering committee of the SPACE-2-Study. He was a member of the Writing Committee of the SPACE-1 Study. Graeme J. Hankey was a member of the European Carotid Surgery Trialists' (ECST) Collaborative Group and the North America Symptomatic Carotid Endarterectomy Trial (NASCET) Collaborators. Steven Kittner receives research funding from the National Institute of Neurological Disorders and Stroke (NINDS) and from the Medical Research Service of the Department of Veterans Affairs. Dimitri P Mikhailidis has given talks and attended conferences sponsored by Merck, Sharp and Dohme. Wesley Moore is a CO-PI for the CREST and member of the CREST Executive Committee. Peter Rothwell is on the Data Monitoring Committee of the SPACE-2 trial. He is Chair of the Endpoint Adjudication Committee of the Asymptomatic Carotid Artery Surgery Trial-2(ACST-2). He is on the Steering Committee of the European Carotid Surgery Trial-2 (ECST-2) and the General Anaesthetic versus Local Anaesthetic for Carotid Surgery (GALA) Trial. Peter Sandercock is the independent chair of the MRC/NIHR ACST-2 Trial. J. David Spence has received lecture fees or consulting fees from Merck, Novartis and Boehringer-Ingelheim and sponsorship to scientific meetings from Boehringer-Ingelheim. He obtains research funding from the Canadian Institutes of Health Research, the Heart & Stroke Foundation of Canada (Ontario) and the National Institutes of Health. Ankur Thapar receives research funding from the Stroke Association, the Royal College of Surgeons of England and the Circulation Foundation. Wei Zhou receives National Institute of Health, NINDS and AHA research funding for evaluating outcomes of carotid interventions.

Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The authors disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: Anne L. Abbott's salary is sourced from a National Health and Medical Research Council Fellowship (ID 472700).

References

1. Mayberg MR, Wilson SE, Yarsu F, et al. Carotid endarterectomy and prevention of cerebral ischemia in symptomatic carotid stenosis. Veterans Affairs Cooperative Studies Program 309 Trialist Group. *JAMA*. 1991;266(23):3289-3294.
2. The European Carotid Surgery Trialists' Collaborative Group. Randomised trial of endarterectomy for recently symptomatic carotid stenosis: final results of the MRC European Carotid Surgery Trial (ECST). *Lancet*. 1998;351(9113):1379-1387.
3. North American Symptomatic Carotid Endarterectomy Trial Collaborators. Beneficial effect of carotid endarterectomy in symptomatic patients with high-grade carotid stenosis. North American Symptomatic Carotid Endarterectomy Trial Collaborators. *N Engl J Med*. 1991;325(7):445-453.
4. Hobson RW 2nd, Weiss DG, Fields WS, et al. Efficacy of carotid endarterectomy for asymptomatic carotid stenosis. The Veterans Affairs Cooperative Study Group. *N Engl J Med*. 1993;328(4):221-227.
5. Executive Committee for the Asymptomatic Carotid Atherosclerosis Study. Endarterectomy for asymptomatic carotid artery stenosis. *JAMA*. 1995;273(118):1421-1428.
6. Halliday A, Mansfield A, Marro J, et al. Prevention of disabling and fatal strokes by successful carotid endarterectomy in patients without recent neurological symptoms: randomised controlled trial. *Lancet*. 2004;363(9420):1491-1502.
7. Halliday A, Harrison M, Hayter E, et al. 10-year stroke prevention after successful carotid endarterectomy for asymptomatic stenosis (ACST-1): A multicentre randomised trial. *Lancet*. 2010;376(9746):1074-1084.
8. Rerkasem K, Rothwell PM. Carotid endarterectomy for symptomatic carotid stenosis. *Cochrane Database Syst Rev*. 2011;(4):CD001081.
9. Chambers BR, Donnan GA. Carotid endarterectomy for asymptomatic carotid stenosis. *Cochrane Database Syst Rev*. 2005;(4):CD001923.
10. Abbott AL. Medical (nonsurgical) intervention alone is now best for prevention of stroke associated with asymptomatic severe carotid stenosis: Results of a systematic review and analysis. *Stroke*. 2009;40(10): e573-e583.
11. Abbott AL. Why all the landmark trials supporting surgery to prevent strokes from carotid stenosis are now obsolete: when is carotid intervention now indicated? Presented at the 37th Annual Vascular and Endovascular Issues, Techniques and Horizons

(VEITHsymposium)2010: New York Hilton, New York City. http://www.veithsymposium.org/pdf/vei/3766.pdf. Accessed January 18, 2012.
12. Naylor AR, Gaines P, Rothwell P. Who benefits most from interventions for asymptomatic carotid stenosis: Patients or professionals? *Eur J Vasc Endovasc Surg*. 2009;37(3): 625-632.
13. Naylor AR. What is the current status of invasive treatment of extracranial carotid artery disease? *Stroke*. 2011;42(7): 2080-2085.
14. Spence JD, Coates V, Li H, et al. Effects of intensive medical therapy on microemboli and cardiovascular risk in asymptomatic carotid stenosis. *Arch Neurol*. 2010;67(2):180-186.
15. Rothwell PM, Coull AJ, Giles MF, et al. Change in stroke incidence, mortality, case-fatality, severity, and risk factors in Oxfordshire, UK from 1981 to 2004 (Oxford Vascular Study). *Lancet*. 2004;363(9425):1925-1933.
16. Broderick JP. The challenges of intracranial revascularization for stroke prevention. *N Engl J Med*. 2011;365(11): 1054-1055.
17. Chimowitz MI, Lynn MJ, Derdeyn CP, et al. Stenting versus aggressive medical therapy for intracranial arterial stenosis. *N Engl J Med*. 2011;365(11):993-1003.
18. Unal B, Critchley JA, Fidan D, Capewell S. Life-years gained from modern cardiological treatments and population risk factor changes in England and Wales, 1981-2000. *Am J Public Health*. 2005;95(1):103-108.
19. Goldstein LB, Bushnell CD, Adams RJ, et al. Guidelines for the primary prevention of stroke. A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. *Stroke*. 2011;42(2):517-584.
20. Furie KL, Kasner SE, Admas RJ, et al. Guidelines for the prevention of stroke in patients with stroke or transient ischemic attack: A guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2011;42(1): 227-276.
21. Goessens BM, Visseren FL, Kapelle LJ, Algra A, van der Graaf Y. Asymptomatic carotid artery stenosis and the risk of new vascular events in patients with manifest arterial disease: The SMART study. *Stroke*. 2007;38(5):1470-1475.
22. Markus HS, King A, Shipley M, et al. Asymptomatic embolisation for prediction of stroke in the Asymptomatic Carotid Emboli Study (ACES): a prospective observational study. *Lancet Neurol*. 2010;9(7):663-671.
23. Marquardt L, Geraghty OC, Mehta Z, Rothwell PM. Low risk of ipsilateral stroke in patients with asymptomatic carotid stenosis on best medical treatment: a prospective, population-based study. *Stroke*. 2010;41(1): e11-e17.
24. Brott TG, Hobson RW 2nd, Howard G, et al. Stenting versus endarterectomy for treatment of carotid-artery stenosis. *N Engl J Med*. 2010;363(1):11-23.
25. Brooks WH, McClure RR, Jones MR, Coleman TL, Breathitt L. Carotid angioplasty and stenting versus carotid endarterectomy for treatment of asymptomatic carotid stenosis: a randomized trial in a community hospital. *Neurosurgery*. 2004;54(2):318-324; discussion 324-325.
26. Yadav JS, Wholey MH, Kuntz RE, et al. Protected carotid-artery stenting versus endarterectomy in high-risk patients. *N Engl J Med*. 2004;351(15):1493-1501.
27. Brott TG, Halperin JL, Abbara S, et al. 2011 ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS Guideline on the Management of Patients With Extracranial Carotid and Vertebral Artery Disease: Executive Summary: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American Stroke Association, American Association of Neuroscience Nurses, American Association of Neurological Surgeons, American College of Radiology, American Society of Neuroradiology, Congress of Neurological Surgeons, Society of Atherosclerosis Imaging and Prevention, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society of NeuroInterventional Surgery, Society for Vascular Medicine, and Society for Vascular Surgery. *Stroke*. 2011;42(8): e420-63.
28. Sidawy AN, Zwolak RM, White RA, Siami FS, Schermerhorn ML, Sicard GA; Outcomes Committee for the Society for Vascular Surgery. Risk-adjusted 30-day outcomes of carotid stenting and endarterectomy: results from the SVS vascular registry. *J Vasc Surg*. 2009;49(1):71-79.
29. Rockman CB, Garg K, Jacobowitz GR, et al. Outcome of carotid artery interventions among female patients, 2004 to 2005. *J Vasc Surg*. 2011;53(6):1457-1464.
30. Giles KA, Hamdan AD, Pomposelli FB, Wyers MC, Schermerhorn ML. Stroke and death after carotid endarterectomy and carotid artery stenting with and without high risk criteria. *J Vasc Surg*. 2010;52(6):1497-1504.
31. Blackshear JL, Roubin GS, Hill MD, Leimgruber PP. Myocardial infarction after carotid stenting and endarterectomy: results from the carotid revascularization endarterectomy versus stenting trial. *Circulation*. 2011;123(22):2571-2578.
32. Naylor AR. Hearts and Minds. *Eur J Vasc Endovasc Surg*. 2012; 43:1–3.
33. Paraskevas KI, Moore WS, Veith FJ. Cost implications of more widespread carotid artery stenting consistent witht the American College of Cardiology/American Heart Association Guideline. *J Vasc Surg*. 2012;55:585–587.
34. Hertzer NR. The nationwide inpatient sample may contain inaccurate data for carotid endarterectomy and carotid stenting. *J Vasc Surg*. 2012;55:263–266.
35. Hankey GJ. Ischaemic stroke–prevention is better than cure. *J R Coll Physicians Edinb*. 2010;40(1):56-63.
36. Spence JD, Pelz D, Veith FJ. Asymptomatic Carotid Stenosis: identifying patients at high enough risk to warrant endarterectomy or stenting. *Stroke*. 2011;42. Published online July 28, 2011.
37. Naylor AR. Time to rethink management strategies in asymptomatic carotid artery disease. *Nat Rev Cardiol.* 2012;9:116-24.
38. Bell P. *Best medical treatment is best for most asymptomatic cases*. Presented at the 38th Annual Vascular and Endovascular Issues, Techniques and Horizons (VEITHsymposium) 2011: New York Hilton, New York City. http://www.veithsymposium.org/pdf/vei/4583.pdf. Accessed January 18, 2012.
39. Redberg RF. *Squandering Medicare's money*. *New York Times*, 25th May 2011. *New York Times.* 26th May 2011 PA35.

http://www.nytimes.com/2011/05/26/opinion/26redberg.html. Accessed January 18, 2012.
40. Nallamothu BK, Lu M, Rogers MA, Gurm HS, Birkmeyer JD. Physician specialty and carotid stenting among elderly medicare beneficiaries in the United States. *Arch Intern Med*. 2011; 171(20):1804-1810.
41. Berkowitz SA, Redberg RF. Dramatic increases in carotid stenting despite nonconclusive data. *Arch Intern Med*. 2011;171(20): 1794-1795.
42. Paraskevas KI, Veith FJ, Riles TS, Moore WS. Is carotid artery stenting a fair alternative to carotid endarterectomy for symptomatic carotid artery stenosis? *Eur J Vasc Endovasc Surg*. 2011; 41(6):717-719.
43. Paraskevas KI, Veith FJ, Riles TS, Moore WS. Is carotid artery stenting a fair alternative to carotid endarterectomy for symptomatic carotid artery stenosis? A commentary on the AHA/ASA guidelines. *J Vasc Surg*. 2011;54(2):541-543; discussion 543.
44. Silver FL, Mackey A, Clark WM, et al. Safety of Stenting and Endarterectomy by Symptomatic Status in the Carotid Revascularization Endarterectomy Versus Stenting Trial (CREST). *Stroke*. 2011;42(3):675-680.
45. Mas JL, Chatellier G, Beyssen B, et al. Endarterectomy versus stenting in patients with symptomatic severe carotid stenosis. *N Engl J Med*. 2006;355(16):1660-1671.
46. Ederle J, Dobson J, Featherstone RL, et al. Carotid artery stenting compared with endarterectomy in patients with symptomatic carotid stenosis (International Carotid Stenting Study): an interim analysis of a randomised controlled trial. *Lancet*. 2010;375(9719):985-997.
47. Mas JL, Trinquart L, Leys D, et al. Endarterectomy versus angioplasty in patients with symptomatic severe carotid stenosis (EVA-3S) trial: results up to 4 years from a randomised, multicentre trial. *Lancet Neurol*. 2008;7(10):885-892.
48. Bonati LH, Dobson J, Algra A, et al. Short-term outcome after stenting versus endarterectomy for symptomatic carotid stenosis: a preplanned meta-analysis of individual patient data. *Lancet*. 2010;376(9746):1062-1073.
49. Economopoulos KP, Sergentanis TN, Tsivgoulis G, Mariolis AD, Stefanadis C. Carotid artery stenting versus carotid endarterectomy: A comprehensive meta-analysis of short-term and long-term outcomes. *Stroke*. 2011;42(3):687-692.
50. Paraskevas KI, Mikhailidis DP, Moore WS, Veith FJ. Optimal contemporary management of symptomatic and asymptomatic carotid artery stenosis. *Vascular*. 2011;19(3):117-120.
51. Carotid Stenting Guidelines Committee: an Inter-collegiate Committee of the RACP (ANZAN, CSANZ), RACS (ANZSVS) and RANZCR. Guidelines for patient selection and performance of CAS. *Intern Med J*. 2011;41(4):344-347.
52. Bonati LH, Fraedrich G. Age modifies the relative risk of stenting versus endarterectomy for symptomatic carotid stenosis—a pooled analysis of EVA-3 S, SPACE and ICSS. *Eur J Vasc Endovasc Surg*. 2011;41(2):153-158.
53. Bonati LH, Jongen LM, Haller S, et al. New ischaemic brain lesions on MRI after stenting or endarterectomy for symptomatic carotid stenosis: a substudy of the International Carotid Stenting Study (ICSS). *Lancet Neurol*. 2010;9(4):353-362.
54. Eckstein HH, Ringleb P, Allenberg JR, et al. Results of the Stent-Protected Angioplasty versus Carotid Endarterectomy (SPACE) study to treat symptomatic stenoses at 2 years: a multinational, prospective, randomised trial. *Lancet Neurol*. 2008;7(10): 893-902.
55. Bonati LH, Ederle J, McCabe DJ, et al. Long-term risk of carotid restenosis in patients randomly assigned to endovascular treatment or endarterectomy in the Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS): long-term follow-up of a randomised trial. *Lancet Neurol*. 2009;8(10):908-917.
56. Arquizan C, Trinquart L, Touboul PJ, et al. Restenosis is more frequent after carotid stenting than after endarterectomy: The EVA-3S study. *Stroke*. 2011;42(4):1015-1020.