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COMMENTARIES

CMS considers expanding reimbursement for carotid stenting

Frank J Veith
Editor-in-Chief, Vascular

On January 25, 2012, Medicare (CMS) held a meeting to consider issues related to the current management of carotid arterial disease. One of the most important of these issues is whether or not Medicare should expand reimbursement for carotid artery stenting (CAS) to include patients with asymptomatic and low or standard surgical risk symptomatic carotid stenosis. Opinions vary widely regarding the justification for such expanded reimbursement. Since this is such an important issue for both patients and physicians, and since the economic consequences of expanded reimbursement are substantial, the editors of VASCULAR deemed it worthwhile to present opposing views on whether or not the existing data justify expansion of the criteria for reimbursement for CAS. The following two articles present these opposing views.

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Why the United States Center for Medicare and Medicaid Services should not extend reimbursement indications for carotid artery angioplasty/stenting

A potential crisis looms in the United States of America – 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 under-signed, 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 of America 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):

(i) Concurrent with carotid stent placement when furnished in accordance with the FDA-approved protocols governing Category B Investigational Device Exemption (IDE) clinical trials;

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(ii) 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 post-approval studies;
(iii) 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 for carotid endarterectomy (CEA) and who also have symptomatic carotid artery stenosis >70%;
(iv) Patients who are at high risk for CEA and have symptomatic carotid artery stenosis of 50%–70%, in accordance with the Category B IDE clinical trials or in accordance with the NCD on carotid artery stenting post-approval studies;
(v) Patients who are at high risk for 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 post-approval studies.

According to the same NCD, patients at high risk for CEA are defined as having significant co-morbidities and/or anatomic risk factors (i.e. recurrent stenosis and/or previous radical neck dissection), so that they would be considered poor candidates for CEA. Significant co-morbid 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 for CEA in the prior carotid artery stenting trials and studies, such as ARCHeR, CABERNET, SAPPHIRE, BEACH and MAVERIC II.

Over the last 2–3 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 results of randomized trials of medical (non-invasive) 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 for operated patients with moderate or severe (70–99% NASCET equivalent) symptomatic[8] carotid stenosis and about 0.5–1% 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 three times lower than for randomized surgical trial CEA patients,[5] about five times lower than randomized surgical trial non-operated patients,[5] three 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. CAS in CREST,[24] large registries and population-based studies[28–30] has been associated with about double the peri-procedural rate of stroke or death

compared to CEA. Further, in CREST, among asymptomatic patients, the rate of peri-procedural stroke/death or later ipsilateral stroke projected to four years was 4.5% for 594 patients who had CAS and 2.7% for the 587 who had CEA (67% higher, $P = 0.07$). This outcome measure reached statistical significance when symptomatic patients were added (6.4% vs 4.7%, 36% higher, $P = 0.03$). 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 peri-procedural 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 peri-procedural 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 90–95% of these procedures are being performed for asymptomatic carotid stenosis,[29,34] exposing patients to unnecessary risk and causing unjustified expenditure of at least 1–2 billion US health-care dollars each year[10,12,35–38] at a time when 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 increasing 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-care 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] CAS is also associated with a much higher peri-procedural 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 for '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.

Author disclosures

Dr Anne Abbott's salary is sourced from a National Health and Medical Research Council Fellowship (ID 472700).

Professor Henry Barnett was PI of the North American Symptomatic Carotid Endarterectomy Trial (NASCET).

Professor Jonathon Beard is on the Steering Committee of the International Carotid Stenting Study (ICSS).

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Professor Gustav Fraedrich is a member of the steering committee of the 'Carotid Stenting Trialists Collaboration' (CSTC) and a member of the steering committee of the

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Professor Dimitris Mikhailidis has given talks and attended conferences sponsored by Merck, Sharp and Dohme.

Professor Wesley Moore is a co-PI for the CREST and member of the CREST Executive Committee.

Professor 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.

Professor Sandercock is the independent chair of the MRC/NIHR ACST-2 Trial.

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Conflicts of interest

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The co-signatories:

Corresponding author: Anne L Abbott
Baker IDI Heart & Diabetes Institute; Florey Neuroscience Institutes, Melbourne, Australia
Corresponding address: Baker IDI Heart & Diabetes Institute, 75 Commercial Road, Melbourne, 3004, Australia; e-mail: Anne.L.Abbott@gmail.com

Mark A Adelman
New York University Langone Medical Center, New York, NY 10016, USA; e-mail: Mark.Adelman@nyumc.org

Andrei V Alexandrov
Comprehensive Stroke Center, University of Alabama Hospital, South Birmingham, AL 35249, USA; e-mail: avalexandrov@att.net

Henry JM Barnett
Robarts Research Institute, University of Western Ontario, Toronto, ON N6A 5K8, Canada; e-mail: hjmb@bell.net

Jonathan Beard
Sheffield Vascular Institute, Northern General Hospital, Sheffield S5 7AU, UK; e-mail: j.d.beard@btinternet.com

Peter Bell
University of Leicester and University of Leicester Hospitals, Leicester, UK; e-mail: peterrfbell@googlemail.com

Martin Björck
Department of Surgical Sciences, Section of Vascular Surgery, Uppsala University, SE-751 86 Uppsala, Sweden; e-mail: martin@bjorck.pp.se

David Blacker
Department of Neurology, Sir Charles Gairdner Hospital, Nedlands, Western Australia 6009, Australia; e-mail: David.Blacker@health.wa.gov.au

Clifford J Buckley
Texas A&M Health Sciences Center College of Medicine; Department of Surgery, Division of Vascular Surgery, Scott and White Health Care Systems; Central Texas Veterans Health Care System, TX, USA; e-mails: Clifford.Buckley@VA.GOV or cbuckley@swmail.sw.org

Richard P Cambria
Division of Vascular and Endovascular Surgery, Massachusetts General Hospital; Harvard Medical School, Boston, MA 02114, USA; e-mail: RCAMBRIA@PARTNERS.ORG

Anthony J Comerota
Jobst Vascular Institute, The Toledo Hospital, Toledo, OH 43606, USA; e-mail: anthony.comerotamd@promedica.org

E Sander Connolly
Department of Neurological Surgery, Columbia University, New York, NY 10032, USA; e-mail: esc5@columbia.edu

Alun H Davies
Faculty of Medicine, Imperial College School of Medicine, Level 4, Charing Cross Hospital, London W6 8RF, UK; e-mail: a.h.davies@imperial.ac.uk

Hans-Henning Eckstein
Technische Universität München; Department of Vascular and Endovascular Surgery, Klinikum rechts der Isar der Technischen Universität München, München, Germany; e-mail: HHEckstein@web.de

Rishad Faruqi
Department of Surgery, Stanford University, Stanford; Department of Surgery, University of California; Department of Vascular and Endovascular Surgery, Kaiser Permanente Medical Center, Santa Clara, CA, USA; e-mail: Rishad.Faruqi@kp.org

Gustav Fraedrich
Department of Vascular Surgery, Medical University, Anichstrasse 35, A-6020 Innsbruck, Austria; e-mail: gustav.fraedrich@i-med.ac.at

Peter Gloviczki
Division of Vascular and Endovascular Surgery, Mayo Clinic, Rochester, MN 55905, USA; e-mail: gloviczki.peter@mayo.edu

Graeme J Hankey
Royal Perth Hospital; School of Medicine and Pharmacology, University of Western Australia, Perth, Western Australia 6000, USA; e-mail: gjhankey@cyllene.uwa.edu.au

Robert E Harbaugh
Penn State Institute of the Neurosciences; Department of Neurosurgery; Department of Engineering Science and Mechanics; Department of Neurosurgery, Penn State University, M.S. Hershey Medical Center, Hershey, PA 17033-0850, USA; e-mail: rharbaugh@psu.edu

Eitan Heldenberg
Vascular Laboratory and Outpatient Clinic, Assaf Harofeh Medical Center, Zerifin, 70300; Sackler faculty of Medicine, Tel Aviv University, Israel; e-mail: eitanh@asaf.health.gov.il

Steven J Kittner
University of Maryland School of Medicine, Baltimore, MD 21201, USA; e-mail: skittner@umaryland.edu

Timothy J Kleinig
Royal Adelaide and Lyell McEwin Hospitals; University of Adelaide, Adelaide, Australia; e-mail: tkleinig@hotmail.com

Dimitri P Mikhailidis
Department of Clinical Biochemistry (Vascular Disease Prevention Clinics), Royal Free Hospital Campus, University College London Medical School, University College London (UCL), London NW3 2QG, UK; e-mails: MIKHAILIDIS@aol.com; mikhailidis@hotmail.com

Wesley S Moore
Division of Vascular Surgery, The David Geffen School of Medicine at UCLA, Los Angeles, CA 90095-6908, USA; e-mail: WMoore@mednet.ucla.edu

Ross Naylor
Clinical Sciences Building, Leicester Royal Infirmary, Leicester, LE2 7LX, UK; e-mail: ross.naylor@uhl-tr.nhs.uk

Andrew Nicolaides
Imperial College; Vascular Diagnostic Centre, London, UK; e-mail: anicolaides1@gmail.com

Kosmas I Paraskevas
Department of Vascular and Endovascular Surgery, Klinikum Nürnberg Süd, Nürnberg 90471 Germany; e-mail: paraskevask@hotmail.com

David M Pelz
Departments of Medical Imaging and Clinical Neurological Sciences, University of Western Ontario; Department of Diagnostic Radiology, Neuroradiology Section, University Hospital, London Health Sciences Centre, London, Ontario, Canada; e-mail: Pelz@uwo.ca. or David.Pelz@lhsc.on.ca

James W Prichard
Yale Medical School, New Haven, CT, USA; e-mail: james.prichard@yale.edu

Grant Purdie
SMVS Neurology at the Queen Elizabeth Hospital; QEH Specialist Centre, Woodville, South Australia 5011, Australia; e-mail: Grant.Purdie@health.sa.gov.au

Jean-Baptiste Ricco
Vascular Surgery Service, University of Poitiers, Poitiers, France; e-mail: jeanbaptistericco@gmail.com

Thomas Riles
Department of Surgery, New York University School of Medicine, New York, NY 10016, USA; e-mail: Thomas.Riles@nyumc.org

Peter Rothwell
Nuffield Department of Clinical Neurosciences (Clinical Neurology), University of Oxford, John Radcliffe Hospital, Oxford, OX3 9DU, UK; e-mail: peter.rothwell@clneuro.ox.ac.uk

Peter Sandercock
Department of Clinical Neurosciences, Western General Hospital, Edinburgh EH4 2XU, UK; e-mail: Peter.sandercock@ed.ac.uk

Henrik Sillesen
Department of Vascular Surgery, Rigshospitalet, University of Copenhagen, Copenhagen, Denmark; e-mail: sillesen@mac.com

J David Spence
University of Western Ontario; Stroke Prevention & Atherosclerosis Research Centre, Robarts Research Institute, London, ON N6G 2V2, Canada; e-mail: dspence@robarts.ca

Francesco Spinelli
Department of Cardiovascular and Thoracic Sciences, University of Messina, 98121 Messina, Italy; e-mail: f.spinelli@mac.com

Aaron Tan
The Queen Elizabeth and Lyell McEwin Hospitals, Adelaide, South Australia, Australia; e-mail: Aaron.Tan@health.sa.gov.au

Ankur Thapar
Charing Cross Hospital, London W6 8RF, UK; e-mail: a.thapar09@imperial.ac.uk

Frank J Veith
New York University School of Medicine; Cleveland Clinic and Lerner School of Medicine of Case Western Reserve University; Department of Surgery, F. Edward Hebert School of Medicine, Uniformed Services, University of the Health Sciences, NY, USA; e-mail: fjvmd@msn.com

Wei Zhou
Vascular and Endovascular Surgery, Stanford University; Vascular Section, Palo Alto VA Health Care System, Division of Vascular and Endovascular Surgery, Stanford, CA, USA; e-mail: weizhou@stanford.edu

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Should Medicare reimbursement for carotid artery stenting be extended to standard and low risk symptomatic and asymptomatic patients with carotid stenosis?

This article is being written at the kind invitation from the editor-in-chief of *Vascular* to respond to one submitted earlier by Dr Anne Abbott and colleagues, which we have not seen. We appreciate this opportunity to add to the dialogue.

The question being posed actually requires addressing several relevant issues in the management of carotid disease before it can be fully answered with an appropriate understanding of all the facts. These will include the status of carotid angioplasty/stenting (CAS) and carotid endarterectomy