Expert Review of Cardiovascular Therapy

ISSN: 1477-9072 (Print) 1744-8344 (Online) Journal homepage: informahealthcare.com/journals/ierk20

Carotid artery stenting: it's all about appropriate patient selection and keeping to the indications

Kosmas I Paraskevas, Jonathan D Beard & Frank J Veith

To cite this article: Kosmas I Paraskevas, Jonathan D Beard & Frank J Veith (2014) Carotid artery stenting: it's all about appropriate patient selection and keeping to the indications, Expert Review of Cardiovascular Therapy, 12:7, 783-786, DOI: 10.1586/14779072.2014.921118

To link to this article: https://doi.org/10.1586/14779072.2014.921118

Carotid artery stenting: it's all about appropriate patient selection and keeping to the indications

Expert Rev. Cardiovasc. Ther. 12(7), 783–786 (2014)

Kosmas I Paraskevas

Author for correspondence: Sheffield Vascular Institute, Northern General Hospital, Sheffield S5 7AU, UK
Tel.: +44 77 6122 6403
paraskevask@hotmail.com

Jonathan D Beard

Sheffield Vascular Institute, Northern General Hospital, Sheffield S5 7AU, UK

Frank J Veith

Divisions of Vascular Surgery, The Cleveland Clinic and New York University Langone Medical Center, New York, NY, USA

With increasing carotid artery stenting (CAS) expertise and improved CAS equipment, recent trials have demonstrated better results for CAS compared with earlier studies. As a result, it may be argued that CAS is currently non-inferior to carotid endarterectomy (CEA), at least in some patient subgroups. Consequently, there have been recent calls for extending CAS indications to include average surgical risk patients with symptomatic or asymptomatic carotid stenosis. However, CAS remains a less cost-effective option than CEA. Opening the floodgates to unrestricted CAS for both symptomatic and asymptomatic carotid patients would have considerable cost implications for any health system. Appropriate patient selection and keeping to the indications are crucial to optimize CAS outcomes.

The optimal management of patients with carotid stenosis is a highly controversial issue and subject to extensive debate [1,2]. In the last few years, carotid artery stenting (CAS) has repeatedly challenged and attempted to replace the 'gold standard' of carotid endarterectomy (CEA) as the treatment of choice for symptomatic carotid artery stenosis. In a previous issue of *Expert Reviews of Cardiovascular Therapy*, Hawkins *et al.* discussed the specific characteristics that render patients with carotid artery stenosis at higher stroke risk with CAS than with CEA [3]. Increasing age and symptomatic status are the most robust predictors of clinical events after CAS, whereas certain anatomic/physiologic criteria (e.g., a type III aortic arch, the presence of aortic arch atheroma, an angulated distal internal carotid artery) increase the difficulty of performing a straightforward procedure, thereby increasing CAS risk [3].

Early randomized trials comparing CAS versus CEA in symptomatic patients reported inferior results for CAS [4–7]. Differences in carotid plaque morphology and a higher incidence of microemboli during CAS compared with CEA in symptomatic patients may account for these inferior results. However, it was recognized that improvements in CAS technology (mesh covered stents, reversal of flow embolic protection and transcervical approaches), better patient selection, centralization of CAS procedures and improvements in CAS expertise could enhance CAS outcomes in the future [4–8].

According to some recent guidelines, CAS rather than CEA is recommended in certain symptomatic patients with >50% stenosis who are considered at high surgical risk for anatomical reasons, for example, those with tracheal stoma and scarred necks from radiotherapy or surgery [9–11]. In addition, CAS is recommended in symptomatic patients with severe comorbidities (such as severe uncorrectable coronary heart disease, congestive heart failure or chronic obstructive pulmonary disease) [9–11]. It may be argued that these recommendations are arbitrary and not supported by conclusive evidence. For example, a recent report challenged the hypothesis of 'high-risk candidate for CEA' and demonstrated excellent results with CEA in such 'high-risk' patients [12]. Another

Keywords: carotid artery stenting • carotid endarterectomy • stroke • symptomatic

EXPERT REVIEWS

 10.1586/14779072.2014.921118 ISSN 1477-9072

report supported that the current criteria for CAS overestimate its efficacy in symptomatic patients and in individuals at high surgical risk [13]. This single-center, non-randomized, retrospective cohort study compared the outcomes of patients undergoing CAS (n = 271) versus CEA (n = 830) during a 6-year period. Among symptomatic patients, physiologic high-risk status (age >80 years, congestive heart failure, left ventricular ejection fraction <30%, unstable angina, a history of myocardial infarction ≤30 days before, hemodialysis, severe lung disease, contralateral carotid occlusion and before or after coronary artery bypass graft/valve repair) was associated with increased stroke/death rates in patients undergoing CAS compared with CEA (14.3 vs 2.7%, respectively; $p < 0.01$). Furthermore, anatomic high-risk status (contralateral laryngeal nerve palsy, carotid restenosis, history of neck irradiation, high or lesion and prior neck surgery) was associated with a trend toward increased stroke/death rates in CAS versus CEA patients (16.1 vs 0.0%, respectively; $p = 0.14$). Finally, among symptomatic patients undergoing CAS, patients with physiologic and anatomic high-risk factors had higher stroke/death rates compared with non-high-risk CAS patients (14.3 vs 0.0% and 16.1 vs 0.0%, respectively; for both $p \leq 0.05$) [13]. These results demonstrate that CAS may not be a preferable option over CEA in patients considered as 'high risk', and at least some of these extremely high-risk patients are probably best treated by intensive medical therapy without any intervention.

Another area where CAS has received intense criticism is the applicability of the results of clinical trials in the 'real-world' setting; in other words, the ability to replicate the results of CAS clinical trials outside these trials. A well-conducted study used the Nationwide Inpatient Survey data files from 2005 to 2009 (n = 81,638 CAS patients) [14]. Of these, 16,078 (19.6%) patients underwent the procedure as part of a clinical trial. The mean age of the patients, the proportion of women and non-whites treated with CAS as part of a clinical trial were all lower compared with those treated outside clinical trials. Furthermore, the in-hospital mortality was >twofold higher among patients treated with CAS outside compared with inside clinical trials (1.12 vs 0.53%, respectively; $p = 0.0005$). Finally, the composite end-point of stroke, cardiac events and death was significantly ($p = 0.02$) higher among patients treated with CAS outside versus inside clinical trials [14]. Based on these and other results, a group of stroke-prevention clinicians from the USA and other countries advised the Centers for Medicare and Medicaid Services not to extend the current reimbursement indications for CAS, as this would have negative health and economic consequences for the countries that would follow such an inappropriate action [15–19].

Some authors have supported extending the indications of CAS to include patients with asymptomatic carotid artery stenosis [20–22]. The arguments supporting this recommendation are that CAS is associated with low stroke/death rates and also improves the neurocognitive performance of asymptomatic carotid patients [20–22]. However, it has been argued that most asymptomatic patients should be managed by best medical therapy alone and that neither CAS nor CEA should be routinely offered to these patients because of the large number of patients that require treatment to prevent one stroke [23,24]. Until the optimal management of asymptomatic carotid patients is resolved, the use of CAS for most asymptomatic patients should be considered questionable, and certainly not one that should be funded by healthcare organizations. On the other hand, it is clear that recent CAS registries have demonstrated better outcomes compared with earlier ones. Improvement in clinical outcomes with CAS has been associated with the development of embolic protection devices, namely proximal flow reversal (e.g., the Mo.Ma® Ultra flow interruption device, Medtronic, Invatec S.p.a., Roncadelle, Italy [25] or the Gore® Parodi Anti-Embolic System, W.L. Gore, Flagstaff, AZ, USA) [26,27] and distal filter protection devices (e.g., the FiberNet distal filter system) [28]. Proximal embolic protection devices achieve external and common carotid artery endovascular occlusion, thus resulting in cessation or reversal of blood flow. This technique is associated with a very low stroke incidence and thus improved CAS results. Some studies have reported better results with flow reversal devices than with filters [29,30]. However, the benefits of flow reversal have not been observed universally [31–33].

Another way to achieve better outcomes with CAS is by using an approach other than the classic one via the femoral artery. The performance of CAS via the femoral approach may be difficult or even impossible due to the presence of extensive aortoiliac occlusive disease or anatomic variations of the aortic arch (e.g., bovine aortic arch). In such patients, a different approach might offer advantages and better outcomes. For example, in patients with a bovine aortic arch and left internal carotid artery stenosis, a right radial or brachial approach may be associated with better outcomes [34]. Another approach which has gained favor in the last few years is the transcervical route. A recent systematic review showed that CAS via the transcervical approach is a safe procedure that is associated with a low incidence of stroke and complications [35].

In conclusion, recent advances in CAS (e.g., flow reversal, transcervical approach, better stents, etc.) may improve CAS results and render CAS an appropriate '*alternative*' to CEA at least in specific patient subgroup. Implementation of best medical therapy [1,36–38], appropriate patient selection and keeping to the right indications are crucial to optimize CAS outcomes. All physicians performing CAS or CEA should keep an independently audited record of their outcomes because patient benefit depends upon low complication rates.

Financial & competing interests disclosure

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

No writing assistance was utilized in the production of this manuscript.

References

1. Paraskevas KI, Mikhailidis DP, Moore WS, Veith FJ. Optimal contemporary management of symptomatic and asymptomatic carotid artery stenosis. Vascular 2011;19(3):117-20
2. Paraskevas KI, Abbott AL, Veith FJ. Optimal management of patients with symptomatic and asymptomatic carotid artery stenosis: work in progress. Expert Rev Cardiovasc Ther 2014;12(4):437-41
3. Hawkins BM, Abu-Fadel MS, Rosenfield K. Risk assessment for carotid artery stenting. Expert Rev Cardiovasc Ther 2014;12(5): 565-72
4. Paraskevas KI, Mikhailidis DP, Veith FJ. Carotid artery stenting may be losing the battle against carotid endarterectomy for the management of symptomatic carotid artery stenosis but the jury is still out. Vascular 2009;17(4):183-9
5. Paraskevas KI, Mikhailidis DP, Veith FJ. Mechanisms to explain the poor results of carotid artery stenting (CAS) in symptomatic patients to date and options to improve CAS outcomes. J Vasc Surg 2010; 52(5):1367-75
6. Paraskevas KI, Mikhailidis DP, Veith FJ. Are symptomatic patients appropriate candidates for carotid artery stenting? No (at least not at present). Vascular 2010; 18(4):185-8
7. 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):541-3
8. 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):717-19
9. Brott TG, Halperin JL, Abbara S, et al. American College of Cardiology; American Stroke Association; American Association of Neurological Surgeons; American College of Radiology; American College of Radiology; Society of NeuroInterventional Surgery; Society for Vascular Medicine; Society for Vascular Surgery. 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. 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. Circulation 2011;124(4):e54-130
10. Ricotta JJ, Aburahma A, Ascher E, et al. Society for Vascular Surgery. Updated Society for Vascular Surgery guidelines for management of extracranial carotid disease. J Vasc Surg 2011;54(3):e1-31
11. Furie KL, Kasner SE, Adams RJ, et al. on behalf of the American Heart Association Stroke Council, Council on Cardiovascular Nursing, Council of Clinical Cardiology, and Interdisciplinary Council on Quality of Care and Outcomes Research. 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):227-76
12. Marcucci G, Accrocca F, Antonelli R, et al. High-risk patients for carotid endarterectomy: turned down cases are rare. J Cardiovasc Surg (Torino) 2012;53(3): 333-43
13. Yoshida S, Bensley RP, Glaser JD, et al. The current national criteria for carotid artery stenting overestimate its efficacy in patients who are symptomatic and at high risk. J Vasc Surg 2013;58(1):120-7
14. Qureshi AI, Chaudhury SA, Hussein HM, et al. A comparison of outcomes associated with carotid artery stent placement performed within and outside clinical trials in the United States. J Vasc Surg 2012; 56(2):317-23
15. Abbott AL, Adelman MA, Alexandrov AV, et al. Why the United States Center for Medicare and Medicaid Services (CMS) should not extend reimbursement indications for carotid artery angioplasty/ stenting. Eur J Vasc Endovasc Surg 2012; 43(3):247-51
16. Abbott AL, Adelman MA, Alexandrov AV, et al. Why the United States Center for Medicare and Medicaid Services (CMS) should not extend reimbursement indications for carotid artery angioplasty/ stenting. Vascular 2012;20(1):1-7
17. Abbott AL, Adelman MA, Alexandrov AV, et al. Why the United States Center for Medicare and Medicaid Services (CMS) should not extend reimbursement indications for carotid artery angioplasty/ stenting. Int Angiol 2012;31(1):85-9
18. Abbott AL, Adelman MA, Alexandrov AV, et al. Why the United States Center for Medicare and Medicaid Services (CMS) should not extend reimbursement indications for carotid artery angioplasty/ stenting. Angiology 2012;63(8):639-44
19. Abbott AL, Adelman MA, Alexandrov AV, et al. Why calls for more routine carotid stenting are currently inappropriate: an international, multispecialty, expert review and position statement. Stroke 2013; 44(4):1186-90
20. Gray WA, Macdonald S, Schneider PA. Should Medicare reimbursement for carotid artery stenting be extended to standard and low risk symptomatic and asymptomatic patients with carotid stenosis? Vascular 2012;20(1):7-11
21. Gray WA. Carotid stenting or carotid surgery in average surgical-risk patients: interpreting the conflicting clinical trial data. Prog Cardiovasc Dis 2011;54(1):14-21
22. Ortega G, Alvarez B, Quintana M, et al. Asymptomatic Carotid Stenosis and Cognitive Improvement using Transcervical Stenting with Protective Flow Reversal Technique. Eur J Vasc Endovasc Surg 2014. [Epub ahead of print]
23. 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):e573-83
24. Naylor AR, Gaines PA, Rothwell PM. Who benefits most from intervention for asymptomatic carotid stenosis: patients or professionals? Eur J Vasc Endovasc Surg 2009;37(6):625-32
25. Coppi G, Moratto R, Silingardi R, et al. Advancements in the Mo.Ma system procedure during carotid artery stenting. J Cardiovasc Surg (Torino) 2009;50(6): 789-93
26. Nikas D, Reith W, Schmidt A, et al. Prospective, multicenter European study of the GORE flow reversal system for providing neuroprotection during carotid artery stenting. Catheter Cardiovasc Interv 2012;80(7):1060-8
27. Grunwald IQ, Reith W, Kuhn AL, et al. Proximal protection with the Gore PAES can reduce DWI lesion size in high-grade stenosis during carotid stenting. EuroIntervention 2014. [Epub ahead of print]

28. Bauer C, Franke J, Bertog SC, et al. FiberNet - a new embolic protection device for carotid artery stenting. Catheter Cardiovasc Interv 2014;83(6):1014-20
29. Goode SD, Hoggard N, Macdonald S, et al. Assessment of reverse flow as a means of cerebral protection during carotid artery stent placement with diffusion-weighted and transcranial Doppler imaging. J Vasc Interv Radiol 2013;24(4):528-33
30. Schonholz C. Flow reversal protects the brain from macro- and microembolization better than filters do. J Vasc Interv Radiol 2013;24(4):533-4
31. Mokin M, Dumont TM, Chi JM, et al. Proximal versus distal protection during carotid artery stenting: analysis of the two treatment approaches and associated clinical outcomes. World Neurosurg 2014;81(3-4): 543-8
32. Castro-Alfonso LH, Abud LG, Rolo JG, et al. Flow reversal versus filter protection: a pilot carotid artery stenting randomized trial. Circ Cardiovasc Interv 2013;6(5):552-9
33. Harada K, Kakumoto K, Morioka J, et al. Combination of flow reversal and distal filter for cerebral protection during carotid artery stenting. Ann Vasc Surg 2014;28(3): 651-8
34. Montorsi P, Galli S, Ravagnani PM, et al. Carotid artery stenting in patients with left ICA stenosis and bovine aortic arch: a single-center experience in 60 consecutive patients treated via the right radial or brachial approach. J Endovasc Ther 2014; 21(1):127-36
35. Sfyroeras GS, Moulakakis KG, Markatis F, et al. Results of carotid artery stenting with transcervical access. J Vasc Surg 2013;58(5): 1402-7
36. Liapis CD, Bell PR, Mikhailidis D, et al. ESVS Guidelines Collaborators. ESVS guidelines. Invasive treatment for carotid stenosis: indications, techniques. Eur J Vasc Endovasc Surg 2009;37(Suppl 4):1-19
37. Liapis CD, Bell PF, Mikhailidis DP, et al. ESVS Guidelines Collaborators; European Society for Vascular Surgery. ESVS Guidelines: section A – prevention in patients with carotid stenosis. Curr Vasc Pharmacol 2010;8(5):673-81
38. Liapis CD, Bell PF, Mikhailidis DP, et al. ESVS Guidlines Collaborators; European Society for Vascular Surgery. ESVS Guidelines: section B - diagnosis and investigation of patients with carotid stenosis. Curr Vasc Pharmacol 2010;8(5): 682-91