EDITORIAL

Carotid Artery Stenting for Patients with Asymptomatic Carotid Disease (and News on TACIT)

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With the publication of five randomised trials comparing the safety and efficacy of carotid artery stenting versus endarterectomy in symptomatic patients, the quality of data continues to improve. A recent Cochrane collaboration review concluded that ‘data from randomised trials comparing endovascular treatment for carotid artery stenosis with carotid endarterectomy suggest that the two treatments have similar early risks of death or stroke and similar long-term benefits’. The review commented that because of the heterogeneity of data, wide confidence intervals and also presumably because of a lack of long-term follow up, recruitment to on-going trials for symptomatic patients should be encouraged.

However, a simple review of the published literature on the subject of carotid artery stenting shows that nearly half the patients treated with this new technology are asymptomatic. In the global carotid registry asymptomatic patients accounted for 47% of those reported, but in some centres patients with asymptomatic carotid disease accounted for 74% of treatments. Similarly in the SAPPHIRE Trial, 70.1% of patients in the randomised group were asymptomatic. What then is the quality of the data to support this treatment, how does it compare against carotid endarterectomy and best medical therapy, and is it cost efficient?

There is only one randomised trial comparing carotid stents versus carotid endarterectomy in asymptomatic carotid disease that has been published. The quality of the data that appeared on the web-based journal should be critically reviewed—after 85 patients were randomised, the authors concluded that the treatments were equally efficacious and of similar costs. Away from this trial the quality of data is also poor. Often results of using carotid artery stents in asymptomatic patients are not separated from symptomatic patients and the numbers are mainly small. The global registry is self-reported and details a 30-day complication rate of 2.5% in patients were cerebral protection was used and 4.78% in patients where there is no cerebral protection. The 30-day complication rate in the published literature where the results are separated out, details a peri-procedural adverse event rate of between 0 and 11.1%. Within the SAPPHIRE Trial, the 30-day risk of stroke and death was 5.4% and at 1 year the risks were 9.9%. These patients were considered to be surgically high risk and it is, therefore, not surprising to find that the comparative surgical figures for these two periods in this study are 10.2 and 21.5%. Apart from the short follow-up in the SAPPHIRE Trial, there are no long-term data to indicate that carotid artery stenting provides any improved prophylaxis against stroke over and above either best medical therapy or carotid endarterectomy.

How cost efficient is carotid artery stenting? Without any good published literature on the subject with long-term outcomes this is an impossible question to answer. The available literature on the comparative costs of stenting and surgery are contradictory and necessarily reflect the health system within which they were compared. However, if it is assumed that the outcome results are as good as carotid endarterectomy in a group of patients who do not receive what is currently considered to be best medical therapy, then it can be questioned if it is in the best interests of any health system to offer a form of therapy that will...
preclude 53 strokes after 1000 carotid stents at 5 years.33 The implication of course is that 947 patients will have had a procedure that conferred no benefit and presumes a peri-procedural event rate of 3%. If the event rate is higher than this then the conferred benefit upon the population is of even less benefit. The published literature would indicate that some units do run a 30-day complication rate higher than 3% and within the SAPPHIRE study a procedural risk of 5.4% means that only 32 strokes will have been prevented after 1000 treatments at 5 years (always assuming the high-risk patients live that long), with 968 patients undergoing treatment that will have conferred no benefit.

It is generally considered, particularly by stroke physicians, that best medical therapy has progressed considerably since, the major carotid endarterectomy trials. Whether this renders carotid endarterectomy obsolete cannot currently be answered since, in both the ACST and ACAS Trials that best medical therapy was not mandated or prescribed. The role of best medical therapies compared to surgery recently received an editorial in this journal.33 It was recognised that the introduction of current concepts in anti-platelet therapy, statins, ACE inhibitors and appropriate blood pressure control may confer some advantages over the historical understanding of the natural history of asymptomatic disease. However, to suggest that surgical intervention remains of value simply because clinicians and surgeons are poor at prescribing modern concepts of best medical therapy33 is a poor argument. Perhaps more time and effort should be dedicated to the introduction and maintenance of optimal therapy rather than pursuing an asymptomatic stenosis on which to operate. In addition, the concept that, because there is a lag phase in the benefit conferred by best medical therapy in patients with carotid disease, then carotid endarterectomy is advantageous,33 surely does not stand up to close scrutiny. There is also a lag phase in the benefit of carotid endarterectomy since, any long-term benefit from active intervention is delayed because the initial peri-surgical complication rate. The simple answer, therefore, is that we have no data at present to suggest carotid artery stenting is of benefit over and above best medical therapy in patients with asymptomatic carotid disease. Perhaps, since, surgical trials did not deliver what is now considered to be best medical therapy, the same can also be said of carotid endarterectomy in asymptomatic disease.

How then should we proceed? Surely this discussion opens the way for a trial of both carotid artery stenting and carotid endarterectomy versus best medical therapy. The transatlantic carotid intervention trial (TACIT) is a multinational multidisciplinary collaboration involving surgeons, radiologists, cardiologists and stroke physicians across Europe and the USA. It aims to have secured funding and begin the randomisation of 2400 patients between prescribed best medical therapy and endarterectomy or stenting by 2006. The trials are looking for 100 centres across the Atlantic and it is hoped that units will see fit to participate in what is considered to be an important study. For further details please feel free to contact me at p.a.gaines@sheffield.ac.uk and I will pass your details on to the appropriate country co-ordinator.

References

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