

## References

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## Carotid Endarterectomy

Sir,

We read with great interest the article by Peiper *et al.*<sup>1</sup> concerning the early and late outcomes of carotid eversion endarterectomy (CEE) compared with traditional carotid endarterectomy with patch closure (CEAP). In this retrospective study the authors concluded that the safety and durability of the two surgical techniques were comparable. We have recently published three papers<sup>2–4</sup> on the same subject, so we would like to offer some comments on the issues raised by Peiper *et al.*<sup>1</sup> In the first prospective study regarding 336 primary carotid endarterectomies (CEAs) performed in 310 patients, randomly attributed to two groups (169 CEEs and 167 CEAPs),<sup>3</sup> we found that CEE is generally superior to the gold standard CEAP in reducing perioperative stroke risk rate (0% vs. 2.9%;  $p=0.03$ ) as well as late occlusive events (0% vs. 3.7%;  $p=0.01$ ), though the outcome of the CEAP technique in our hands correlated well with the results of the principal multicentre trials. Our second prospective study<sup>4</sup> confirmed our findings regarding clinical outcome and the incidence of restenosis in 86 patients undergoing bilateral CEA, in whom CEAP was performed on one side and CEE on the other. Patients were randomly selected for sequential surgical treatment involving either patching/eversion or eversion/patching. The overall perioperative mortality was 0%, and, though the difference in the incidence of perioperative ipsilateral ischaemic stroke was not significant (3.5% vs. 0%), the greater rate of combined transient ischaemic events and strokes with CEAP approached significance (7% vs. 1.2%;  $p=0.06$ ). In addition, CEAP had a significantly higher incidence of restenoses (4.7% vs. 0%;  $p=0.02$ ) and of combined late occlusive events and restenoses (13% vs. 1.2%;  $p=0.004$ ). The better results appear to be related: (1) to the significantly lower carotid cross-clamping time required for CEE, which avoids the need to selectively use an intraluminal shunt; and (2) to the improvement in several technical details, i.e. the routine correction of the residual distal internal carotid artery elongation and preservation of the original carotid configuration, especially with regard to the inclination and amplitude of the ostium of the internal carotid artery.

On the basis of these findings, we are enthusiastic about the CEE – hence our interest in obtaining more information concerning the results reported with CEE

## Author's Reply

We thank Messrs Morgan, Fraser and Bradbury for their interesting comments in response to the editorial on “Patient-assessed health outcomes in peripheral arterial disease”.<sup>1</sup>

We agree that the assessment of quality of life should be integral in the design of future trials to determine the optimal therapy for intermittent claudication. Until recently, most studies for lower limb peripheral vascular disease have focussed on measures of patency as outcome measures. We are aware that the “Vasculol”<sup>2</sup> has been developed for the assessment of quality of life in peripheral vascular disease, but we feel that its use in patients with intermittent claudication is limited by a fundamental methodology flaw in its development. Patients with intermittent claudication do not experience the problems of rest pain or tissue loss, as evident in patients with critical limb ischaemia. Unfortunately, four out of 21 items in the “Vasculol” relate to problems that are more relevant to patients with critical limb ischaemia. Item 7 “Pain in the foot (or leg) after going to bed at night”, item 8 “pins and needles and numbness”, item 13 “pain in the foot (or leg) when at rest” and item 17 “ulcers in the leg (or foot)” are simply not applicable for the claudicant and therefore invalidate the “Vasculol” when scored for patients with intermittent claudication. Therefore we believe that the “Vasculol” is not a true condition-specific quality of life measure for intermittent claudication, which is still required and we therefore cannot recommend it as a valid outcome measure in studies for intermittent claudication.

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by Peiper *et al.*<sup>1</sup> to clarify certain doubts that have arisen on reading the article. From the analysis of the data, although the difference was not significant, the local (carotid occlusion) and neurological complication (stroke) rates were higher in the CEE group (1% vs. 0.8%, and 1.5% and 1.1%, respectively). We are not told when carotid occlusion and stroke occurred in the CEE group, if they were intraoperative (embolism? embolism from shunting? haemodynamic factors?) or postoperative (delayed thrombosis due to residual intimal flaps or residual distal vessel redundancy?), how they were investigated, or if all early occlusive events led to stroke. Nor is any information provided on how many patients with a perioperative occluded carotid artery or a perioperative/postoperative non-haemorrhagic stroke were re-explored. Finally, since the authors used cw Doppler ultrasound and colour-coded duplex ultrasound as a quality control, we do not know why any technical defects responsible for the early failures were not seen and corrected at the time of the operation. Since most major early local and neurological complications are related to surgical errors, and are therefore avoidable, it would have been very useful to know where the eversion technique failed.

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### Author's Reply

We would like to congratulate Dr. Ballotta and his co-workers on their superior results after eversion endarterectomy of the internal carotid artery (ICA). These results were not reached in our study. In 475 consecutive cases we observed seven cases of permanent ipsilateral stroke events. This rate of 1.5%

corresponds well with literature.<sup>1–3</sup> All these events were detected in the early postoperative course. Two patients underwent re-operation for early thrombosis of their ICA, but did not recover completely. The other five patients suffered from intraoperative embolism. Two of them had been operated upon under implantation of an intraluminal shunt. Embolism in the last three patients probably occurred during preparation.

One explanation for these events may be the learning curve during the first procedures after inauguration of the new technique in our clinic. Cw-Doppler-ultrasound and colour-coded duplex ultrasound examinations carried out postoperatively as a quality control led to education of the surgeons and to better results in the meantime. Even during our study period, no ischaemic stroke event occurred during the last 100 procedures.

Another explanation might be that in our department carotid surgery was carried out by seven surgeons, some of them residents in training. A final aspect might be the selection of patients. Pre-selection on the basis of morphological changes has a great influence on postoperative neurological complication rates. Using the eversion technique only in cases of bifurcation stenosis or changes at the origin of the internal carotid artery, very low complication rates may be achieved. During our study period we avoided any pre-selection of patients. Even patients presenting with unfavourable morphology (especially high extension of the plaque) underwent eversion thromboendarterectomy. This might also explain higher postoperative morbidity. Meanwhile, patients are classified as feasible for eversion (90–95%) and difficult for eversion (5–10%) at our institution.

In summary, we also regard the eversion technique in carotid surgery as superior to the thromboendarterectomy and patch plasty closure concerning rate of restenosis, duration of clamping and operation, and neurological outcome, but failed to prove the latter in our study.

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