Journal of the American College of Cardiology
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Published by Elsevier Science Inc.

Vol. 38, No. 6, 2001
ISSN 0735-1097/01/$20.00
PII S0735-1097(01)01590-X

EDITORIAL COMMENT

Another Nail in the Coffin of Carotid Endarterectomy*

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The randomized carotid stent versus carotid surgery trial reported by Brooks et al. (1) in this issue of the *Journal* is a notable accomplishment in several respects. By reporting results in 104 patients, it becomes the largest randomized carotid artery stent versus carotid endarterectomy trial published to date (to my knowledge). It is also an excellent example of team building with a surgeon, a cardiologist and a neurologist working together to optimize patient care. The authors are to be congratulated on conducting a randomized trial with prospective independent neurology oversight.

The trial, as do all clinical trials, has strengths and weaknesses. The strengths include reasonably good methodology with routine preprocedural and postprocedural objective patient assessment by a neurologist and carotid duplex ultrasound scans within 24 h of the procedure and serially thereafter. Magnetic resonance imaging was performed at 6 and 12 months after the procedure to detect asymptomatic cerebrovascular ischemic events.

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The major weakness of this trial is the relatively small number of patients in each group which makes the extraordinary low adverse event rates difficult to put in perspective. The likelihood that a true difference between the two treatments exists, and was not detected due to the small sample size (beta error), is more likely than the authors appear willing to admit. The low adverse event rates in both surgery and stent groups may have been due to chance, excellent operator skills or more likely a combination of both.

The authors make an unconvincing attempt to quantify hospital costs, length of stay and patient discomfort, which do not appear to have been prespecified end points. We are told there was little periprocedural discomfort in both groups, which is not surprising. In the uncomplicated stent patients, hospital stay was shorter compared to surgery, but this was not true for patients who experienced complications. Specifically, excessive anticoagulation in each of the three carotid stent patients receiving platelet glycoprotein 2b3a inhibitors resulted in retroperitoneal bleeding, prolonging their hospital stay. One carotid stent patient suffered a lower extremity complication that required amputation and a prolonged (68 days) hospital stay. Five patients underwent coronary artery surgery following carotid treatment, but we are not told the distribution of these patients between stent or surgery groups in order to appreciate their impact on hospital stay. Clearly, if hospital stay were to be a prespecified end point, then confounding variables, such as a planned second procedure, would be distributed evenly among the groups.

It is not clear from the article (1) how the cost and charge data were applied to the procedures and the "variable costs" were not specifically defined. In Table 5, for example, I cannot tell where the cost of the predischarge carotid duplex scan is allocated, or what algorithm was used to apportion the nursing costs. When comparing stenting to surgery, the increased cost of the disposable equipment (i.e., balloons and stents) will need to be balanced against the shorter hospital stay to determine the net cost reduction or increase. Regardless, an early-phase randomized trial is not the best way to assess treatment costs given that some procedures are mandated by the protocol, and not necessarily by clinical need.

Support for the parity in outcomes achieved in this study comes from the recently published Carotid And Vertebral Artery Transluminal Angioplasty Study (CAVATAS) multicenter trial, which randomized more than 500 patients with symptomatic (96%) carotid artery stenoses to either balloon angioplasty (bail-out stenting was allowed in 26%) or surgery (2). The authors of CAVATAS acknowledged that the results of balloon angioplasty would be out of date when their study was published, as carotid stent placement has emerged in the past few years as the preferred method.

CAVATAS demonstrated equal benefit for prevention of stroke and death in both the surgery and angioplasty groups at 30 days, which was sustained for 3 years, albeit at a higher rate than previously reported. The 30-day incidence of any stroke lasting more than 7 days or death was 10% in both groups in the CAVATAS trial, substantially higher than in the current report. The CAVATAS authors noted that the 95% confidence intervals (CIs) were quite wide (surgery group, 9.9%; 95% CI, 6.2% to 13.6%) and overlapped with the surgical results of both the European Carotid Surgery Trial (7.0%; 95% CI, 5.8% to 8.1%) and the North American Symptomatic Carotid Endarterectomy Trial (6.5%; 95% CI, 5.2% to 7.8%). The authors concluded that endovascular techniques were superior to surgery because angioplasty provided equal protection against stroke and death and avoided risks related to the neck incision and the administration of general anesthesia.

Detractors and skeptics of carotid stent placement are quick to point out the now infamous "stopped trial" by Naylor et al. (3) in which five of seven carotid stent patients suffered a stroke. These patients were treated by an inter-

*Editorials published in the *Journal of the American College of Cardiology* reflect the views of the authors and do not necessarily represent the views of *JACC* or the American College of Cardiology.

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ventional radiologist with very limited carotid stent experience and were treated with inadequate antiplatelet therapy by today's standards.

Another trial that was stopped early by the sponsor, but has not yet been published, is the Wallstent trial which randomized 219 symptomatic patients and reported a 30-day end point of any stroke or death in 12.1% of the stent group and 4.5% in the surgery group ($p = 0.049$) and a 1-year ipsilateral stroke rate of 3.6% in the surgery group compared to 12.2% in the stent group ($p = 0.022$) (4). Once again, the stent-related complications clustered around the inexperienced operators, while experienced operators experienced very few complications. There is a learning curve for optimal carotid stent deployment as demonstrated by Roubin et al. (5) who have the largest (to my knowledge) published series of carotid stent placement. Clearly, poor preparation and lack of experience regarding carotid stent operators are linked with poor outcomes.

Carotid stenting is by far the most contentious area of medicine today. This percutaneous alternative to carotid surgery, predominantly performed by cardiologists, has already become established in experienced centers as the standard of care for patients at increased risk for surgery or those with anatomically unfavorable lesions for carotid endarterectomy (6). When large randomized trials in low risk carotid endarterectomy candidates demonstrate equal or better outcomes for stenting compared to surgery, then this commonly performed vascular operation will become a rarity. The impact of this potential change in clinical practice has not been lost on our surgical colleagues who will be forced to navigate between the Scylla of giving up this patient volume to interventionalists and the Charybdis of retraining in the field of endovascular intervention.

What does Brooks et al. (1) teach us? First, it shows that in a relatively small sample of carefully selected, symptomatic patients with extracranial stenotic disease, and treated at a single hospital, both surgery and stenting can be performed safely and effectively with excellent results. Care must be taken in translating these excellent results to everyday practice as the risks and complications of both carotid surgery and endovascular intervention are governed by variable anatomic and clinical parameters (7). Comparing outcomes between nonrandomized or unmatched groups will lead to incorrect conclusions.

Brooks et al. (1) have positively demonstrated the up side of carotid stenting, with very low procedural adverse events, excellent patient acceptance and excellent late patency. However, the authors' claim "that CAS (carotid artery stenting) has reached clinical equipoise with CEA (carotid endarterectomy)" is not justified considering the limitations of their study. However, with these promising data in hand, balanced against the sobering knowledge that not every trial of carotid stent placement has been able to achieve these excellent results, the large multicenter randomized CREST trial has begun, which will attempt to answer these pressing clinical questions more definitively.

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