A Proposed Method for Using a Reimbursement Moratorium to Encourage Recruitment for a Randomized Study of Carotid Endarterectomy

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HEREIN I REVIEW EVIDENCE showing that carotid endarterectomy has not been proved effective in stroke prevention, propose a means for setting up an extensive randomized trial which could rapidly accrue numbers of patients sufficient to definitively resolve the issue, and discuss the implications of such an approach.

Background

Barnett, Plum, and Walton1 have expressed their uncertainty as to whether carotid endarterectomy is an appropriate maneuver for the prevention of stroke. My own review2 of the results of carotid endarterectomy on the vessel relevant to a prior ischemic episode gives ample justification for their uncertainty. In the very large surgical literature, I found only one randomized study3 and only six4-9 uncontrolled reports of patients who had had relevant carotid endarterectomy for transient ischemic attack, reversible ischemic neurologic deficit, or minor stroke. By the criterion of duration of stroke-free survival, the surgical patients in the randomized study did not do better than the control patients. By the weak "historical control" method, the sole way of analyzing non-controlled data, only one-sixth of the small pool of non-controlled studies can be considered to have shown results favoring surgery.

Barnett, Plum and Walton have expressed the hope that a large multicenter study will eventually firmly demonstrate whether or not carotid endarterectomy has value for stroke prevention. That large trials can be definitive has recently been shown dramatically: the international trial of extracranial-intracranial by-pass10 randomized 1377 patients; 55.8 months of followup decisively proved that surgery was not beneficial.

Favoring a trial such as Barnett, Plum and Walton desire, and in the hope of facilitating its organization and operation, I herein propose a method for easing the problem of patient recruitment.

Proposal

A moratorium should be established on third-party reimbursement for surgical fees and for hospital costs for endarterectomy except for patients who have first been submitted to a suitable randomization procedure. Surgeons employing supervised random allocation should be paid 100% of the customary surgical fee for each patient randomized and then managed (surgically or non-surgically) according to the protocol; the hospital should be reimbursed fully for all appropriate care provided to randomized patients.

This program should continue until trend-line monitoring suggests an interim revision (i.e.: discontinuation of surgery even under protocol; or conversely: ad libitum surgery in certain or in all circumstances). The interim state should continue until follow-up of the initial randomized cohort has produced definite answers.

Discussion

The following comments are relevant.

(1) The proposal would not forbid endarterectomy outside of the protocol, but would require that the patient personally pay for the costs of surgery. Is this unreasonable? Quite to the contrary: it is unreasonable for a patient to expect to be reimbursed when he chooses a costly treatment for which there is no scientific justification.

(2) Would surgeons who have been receiving substantial income from the performance of endarterectomies suffer sudden major financial loss because of this study? Not if they are assiduous in promoting the protocol among suitable candidates. A surgeon randomizing as many patients in a year as he had previously treated surgically in a year would suffer no sudden loss of income.

(3) Might such a study not lead to long-term income loss for surgeons? Yes, if endarterectomy is proven not to be valuable. On the other hand, demonstration of effectiveness could be expected to lead to an increase in the demand for such surgery.

(4) Might surgeons be expected to oppose the proposal because of fear of financial loss should endarterectomy be proven ineffectual in the long run? One would think not: Dyken and Pokras11 estimate that 85,000 endarterectomies were done in the United States in 1982, which would suggest strong confidence in the procedure among large numbers of surgeons.

(5) Who will pay for the study? The costs should be borne by the third-party carriers of health care costs. As indicated above, payments to surgeons should not
change substantially. Initially there should be great savings in hospital costs attendant upon a drop of at least 50% in the number of endarterectomies performed. These savings should easily cover the costs of the study.

(6) What are the long-term financial implications for the third-party carriers? That depends on the outcome of the study: decreased costs if the results lead to the abandonment of endarterectomy; unchanged or possibly increased surgical costs if the procedure is proven useful. It is, of course, conceivable that increased surgical costs for a procedure proven useful could be offset by a reduction in stroke-care costs: if the procedure does indeed prevent strokes, then there will be fewer patients requiring treatment and expensive long-term care for the consequences of stroke.

(7) The thrust of the protocol would be to face essentially every endarterectomy candidate (for the duration of the study) with a decision concerning participation in a research endeavor. Is there precedent for such an idea? Apparently so: Kolata, in reviewing recent recommendations concerning the management of carcinoma of the breast, notes: "The consensus panel urges that every woman with breast cancer participate in a clinical trial."

To make analogy to the breast carcinoma situation is, incidentally, particularly relevant: from 1900 to 1980 radical mastectomy was widely accepted — without basis in randomized trial — as the standard treatment for breast carcinoma. The situation was dramatically changed by the large randomized 1970–1979 study of radical versus non-radical surgery for stage I and stage II disease, which showed no advantage from the radical approach.

(8) Why could not a voluntary protocol be used, as was the case with the extracranial-intracranial by-pass study? The problem here is the perception of endarterectomy as valuable (witness 85,000 procedures per year in the United States). If endarterectomy is easily available, it is possible that recruitment for a randomized study would be crippling slow (See Taylor et al for a discussion of the value of rapid early patient accrual). Also, there might subsequently be criticism of the results in the grounds that patients accepting the protocol differ substantially from those refusing to be recruited. Uniform nation-wide recruitment efforts under the described protocol could minimize this possibility: if the annual number of patients randomized is close to the 85,000 recently operated per year, the issue of biased selection will be mooted.

Summary
As indicated by Barnett, Plum and Walton, a definitive clinical trial to resolve the issue of the effectiveness of carotid endarterectomy is clearly needed. A proposal to foster such a trial, through a moratorium on third-party reimbursement other than for randomized patients, has herein been presented.

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References
A proposed method for using a reimbursement moratorium to encourage recruitment for a randomized study of carotid endarterectomy.

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