The Extracranial/Intracranial Bypass Study

PHYSICIANS IN their eagerness to help patients often become enthusiastic or supportive of a particular therapy based on their own limited experience or on the anecdotal experiences of others before there is clear evidence that a particular treatment is useful or effective. Many treatments are proposed and carried out often at great expense and sometimes with considerable risk long before there is any sound evidence that they improve on the natural history of a particular condition. This problem has received much public attention and as a result has strengthened the requirements by the Food and Drug Administration to prove the efficacy of new drug therapies before they are sold to the public.

Similar requirements have not as yet been imposed on surgical therapies. Too often surgical treatment for a particular condition gains enthusiasm and wide use before any clear evidence of effectiveness. This problem has been particularly evident in the field of atherosclerotic vascular disease involving the treatment of its cardiac and cerebral complications.

The recent suggestions for extracranial/intracranial arterial anastomosis in the prevention and treatment of stroke have without question a logical basis. This is especially true when atherosclerosis in cerebral vessels lies distal to the surgically accessible portion of the internal carotid artery. Anastomosis of the superficial temporal artery to the middle cerebral artery or one of its branches to improve cerebral circulation in such situations is beginning to be carried out frequently in a number of centers across the United States. In an effort to determine the effectiveness of this therapy 20 major medical centers in the United States and 3 centers outside the United States have joined together in a collaborative study of this therapy. The objective is to determine whether extracranial/intracranial bypass grafting will reduce by 50% or more the incidence of first or recurrent completed stroke in patients with certain forms of cerebrovascular disease. The study will be directed at individuals with transient ischemic attacks, reversible ischemic neurological disability and also at patients with partial nonprogressing stroke and at completed but noncalamitous strokes. The study will be a randomized one with a strict protocol and an obligatory follow-up for five years after surgery. Only those patients with radiologic evidence of middle cerebral artery stenosis or occlusions, inaccessible internal carotid artery stenosis of more than 50%, internal carotid artery occlusion or with combinations of these radiological criteria will be considered for treatment. The diagnostic evaluation for all patients will include a complete physical and neurological examination, angiographic studies of both carotid circulations intracranially and extracranially and, when available, computerized tomography and cerebral blood flow measurements. The operative procedure will be standardized. Using either the superficial temporal artery or the occipital artery, the anastomosis usually will be made with the cerebral artery nearest to the presumed area of cerebral ischemia. All patients will be studied postoperatively with appropriate cerebral angiograms to determine patency of the anastomosis and when possible with flow studies to determine the capacity of the bypass.

To adequately determine the effectiveness of extracranial/intracranial anastomosis in the prevention of stroke, upwards of 600 patients will be needed for the study. For such studies, it is extremely desirable that they do not drag on and that the patient material is added as rapidly as possible. It is hoped that more participants will be found who will be able to accept the protocol and to add patients to the study in a systematic way. The larger the number of centers cooperating, and the more patients entered, the sooner the evidence of effectiveness or ineffectiveness of this particular surgical treatment will be available to the public. The study is being conducted under the leadership of Dr. Henry J. Barnett, professor and chairman of the Department of Clinical Neurological Sciences at the University of Western Ontario in London, Ontario and is being supported by the U.S. National Institute of Neurological and Communicative Disorders and Stroke. The group of centers and Dr. Barnett are to be commended for their foresight and willingness to cooperate in providing a rapid and careful analysis of a potentially very valuable treatment for the prevention of stroke.

The planning and conduct of studies similar to this will be certainly the future way of assessing the value of any new surgical treatments designed to prevent stroke or any other complications of atherosclerotic vascular disease. Hopefully, it will be impossible for a surgical procedure designed to prevent or alleviate cerebral ischemia or stroke to gain widespread use before careful study of its ability to alter the natural course of the condition has been made. It is hoped that the neurological and the neurosurgical community of the United States and Canada will do everything to aid this study and when possible to contribute patients and expertise towards its success.

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