What’s the Best Treatment for Arterial Blockages?

One of the greatest advances in modern medicine was the realization that doctors’ personal experience is not sufficient evidence for the preference of one treatment to another. The double-blind trial was developed to overcome various kinds of bias and prejudice in both patient and doctor, and on the whole has been a great methodological success. It is not perfect, however.

A trial recently published in the *New England Journal of Medicine* illustrates this. It was designed to establish whether endarterectomy (the surgical removal of arterial blockage) or stenting (the insertion of a tube and filter) is a better treatment for narrowing of the carotid artery, a condition that leads to strokes.

The trial was carried out in 117 centers in the United States and Canada, by surgeons and interventionists who were certified as having good results beforehand. Eligible patients, of whom there were originally 2502, were divided randomly into those who received endarterectomy and those who were stented. The end points of the trial were stroke, heart attack and death.

There was no difference between the two treatments at four years, but the researchers then extended the follow-up period to ten years. By then, the number of patients who were followed up had dwindled to 1607. 895 of the original patients were not included for various reasons, among them that they had died (186).

The results showed that there was no statistically significant difference in the outcomes. 11.8 per cent of the stented group had any one (or more) of the end points against 9.9 per cent

of those who had had endarterectomy. 6.9 per cent of the stented group had had strokes while 5.6 per cent of the endarterectomy had had strokes. Although none of the differences among various sub-groups was statistically significant, they were all slightly in favor of endarterectomy and one has to remember that statistically significant difference is not a measure or real or actual difference; and the authors seemed believe that there *was* a difference between the two modes of treatment because they attribute the difference to the fact that the patients assigned to stenting were slightly more at risk in the first place.

The authors conclude that there is nothing to choose between the two types of treatment. I found their statistical presentation very difficult to understand, and checked it with an eminent colleague who specializes in comparative trials, who likewise found it muddled and difficult to understand; but it is likely that most surgeons and interventionists will just accept the conclusion without testing it further.

An accompanying editorial raises further difficulties. How far is a trial which selects for the best practitioners in the field applicable to the general population of practitioners? It might not be at all applicable. Furthermore, the trial has no control group for the medical treatment of carotid stenosis, which has improved greatly since it was first shown years ago that endarterectomy is beneficial in severe carotid stenosis without symptoms.

In other words, the two treatments here compared might not be necessary at all in a large number of cases. Certainly the quantity of such procedures performed in various advanced countries varies greatly. The editorial's authors say that with modern medical treatment, neither endarterectomy nor stenting are necessary except in the most severe asymptomatic stenosis, and that this means that approximately 80 per cent of the procedures carried out in the United States for carotid stenosis are unnecessary – not a trivial matter, given the

rate of complication.

Even if this trial established more unequivocally than it does that stenting is as good as endarterectomy, it does not establish in what cases either is necessary. Is your journey really necessary, asked the poster in England during the war? Is your procedure really necessary might be a good poster to put up in hospitals.

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