

Editorial

The Place of Angioplasty and Stenting in the Treatment of Carotid Artery Stenosis

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Kuwait Medical Journal 2007, 39 (2): 95-97

Varying degrees of stenosis of the internal carotid artery is a common problem in patients who have peripheral vascular disease. The correct treatment of this condition has been a matter of some debate for years and surgical endarterectomy or grafting, popularized in the 1950s by DeBakey and Eastcott, remained a controversial operation until two large randomized trials proved in patients who had severe (>70%) symptomatic carotid stenosis that surgery was very beneficial^[1,2]. The results of these large randomized trials were taken as a signal to do many more carotid endarterectomies, both in patients who were symptomatic and asymptomatic, even though the trials related to symptomatic and not asymptomatic patients.

With this increase in activity it was perhaps inevitable that someone would have the idea that if the artery was narrowed then it should be treated by angioplasty and stenting as were many other arteries in other parts of the body. Since Dotter^[3] first described arterial dilatation as a possible way of treating such lesions interventional radiologists and more recently cardiologists have consistently tried to expand the areas in which dilatation can be applied. The invention of stents took this process even further because a tool is now available which will keep the artery open and prevent collapse to its previous state.

In the early days of angioplasty the effect of dilatation and stenting in terms of release of emboli were not fully appreciated and therefore a number of interventional radiologists started to insert stents into the carotid arteries and published what appeared to be excellent results^[4]. At the outset one of them realised that emboli may go into the brain and tried to construct a primitive protection device which would avoid this happening, again publishing excellent results^[5]. Because of the novelty and potential profit from inserting stents

companies became involved in pushing the process forward and a variety of stents and protection devices were invented. A large number of papers emerged from many centres claiming that stenting was as good as or better than endarterectomy and avoided the serious side effects of a scar and temporary cranial nerve palsy. None of these publications were level 1 evidence, usually they were single center experiences and as such of little scientific value. Comparing endarterectomy and stenting was always going to be difficult and remained so, mainly because authors who favoured stenting wished if possible to avoid dealing with those cases which may cause complications and entering exactly the same patients into the two arms of such trials is always difficult.

The first randomized trial to address this problem was done in Leicester. This trial was stopped by the monitoring committee because of the excessive complications of angioplasty. This trial was done on the basis of intention to treat without exclusions and remains the only trial of that nature where the cases compared were identical^[6]. Because this trial contained such small numbers it was not sufficient to influence patterns of treatment. Other randomized trials then came along comparing the two treatments, the first being the CAVATAS trial^[7]. This trial was flawed because the protocol changed half way through and the level of complications at 10% for endarterectomy and stenting was clearly unacceptable. The next trial, the SAPPHERE trial^[8], was another randomized trial which suggested that endarterectomy and stenting had similar results but stenting had less complications of a myocardial nature. This trial is deeply flawed and has now largely been discounted. It was however the trial used by the FDA in America to allow stenting to be carried out in high risk patients. Because of the involvement of industry and many other problems

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with this trial the results are now largely ignored^[9]. Both the CAVATAS and SAPHIRE trials suffered from the disadvantages that many of the patients were asymptomatic. More recently two further trials have been performed in symptomatic patients, the French EVS3A trial and the German Space trial. The French trial showed a significant advantage for endarterectomy in these patients and the German trial showed that endarterectomy was better but not significantly so than angioplasty^[10,11]. Meta-analysis has now confirmed that carotid endarterectomy is 40% better than angioplasty and stenting for patients with symptomatic disease. The situation has now been reached where meaningful guidance can be given to those doctors who are treating such patients and also patients can be given evidence to allow them to make an informed decision about which treatment to undertake. It goes without saying that such patients, whether they be symptomatic or asymptomatic, should be on appropriate medical treatment with antiplatelet agents and statins which have now been shown to reduce the incidence of stroke by 30%^[12,13].

The main problem now remaining is what to do with asymptomatic patients. In many countries more than two-thirds of the cases dealt with by invasive techniques are asymptomatic and the evidence that they should be treated at all is poor. The recent ACAS trial^[14] has shown that surgery prevents ipsilateral stroke provided the complication rate is < 3%. This trial did not clearly take into account the benefits of statin treatment and it remains the case that very few patients with asymptomatic severe stenosis will benefit from any invasive treatment. The risk of stroke and death at 30 days in a patient without any symptoms is around 1.5%. In the SAPHIRE trial for example where 70% of the patients were asymptomatic, 5.8% had a stroke which means that the treatment was causing more strokes than would have occurred if nothing had been done. There is no question that some patients do develop a stroke with asymptomatic carotid stenosis. The problem is we do not know who they are and too many patients have unnecessary procedures at a high complication rate to prevent a small number of strokes. At present our efforts should be directed towards finding out which plaques are dangerous and some authors have been trying to do this by plaque analysis which may in the long term allow us to pick out those patients who are at risk^[15]. Certainly in patients who are asymptomatic, females have little if any advantage from invasive treatment. Further trials in future may give us a better idea of what we should be doing for such patients.

The correct treatment for patients with carotid stenosis has been confused for many years but randomized trials are now pointing the way to the correct approach. In patients who are symptomatic with severe, >70% stenosis, carotid endarterectomy is undoubtedly the best and safest treatment for these patients provided the operation is done by surgeons who are properly trained with an acceptable complication rate of < 5%. In patients who are unfit for surgery or who have a hostile neck then angioplasty and stenting would be a reasonable alternative but the patients need to be told in the consenting process about the risks involved. For asymptomatic patients with severe stenosis the majority should not have any form of invasive treatment at present unless those with dangerous plaques are selected by some technique such as plaque analysis. Patients with a unilateral occlusion and a 70% or more stenosis of the opposite side should probably have treatment although again the evidence for this remains poor. It is vital that the complication rate in those who have treatment should be low and certainly less than 3%. It should be remembered that even in patients who do not have overt strokes, new ischemic lesions can be seen on brain scanning and these can be associated with dementia in the long term^[16]. It goes without saying that all patients should be on proper medical treatment with antiplatelet agents and statins which reduces the stroke by over 30%.

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