Long-term results of RITA-1

RITA-1 (the first Randomized Intervention Treatment of Angina trial) compared percutaneous transluminal coronary angioplasty (PTCA) and coronary artery bypass grafting (CABG) in patients with angina who required intervention. The first results, after a mean follow-up of 2.5 years, were published in 1993[1]; findings after a median of 6.5 years are now available[2].

In RITA-1, 1011 patients with chronic unstable angina were randomized to PTCA or CABG; of these, 45% had single-vessel and 55% had multi-vessel disease. The primary trial end-point was the combination of death and non-fatal myocardial infarction, and after 6.5 years there had been 87 (17%) end-points in the PTCA group and 80 (16%) in the CABG group (P=0.64). There was no significant difference in the number of deaths (39 PTCA, 45 CABG) and just under half of the deaths were due to heart disease. The risk of death or myocardial infarction was more than five times higher in the first year than in the subsequent 4 years of follow-up. Twenty-six percent of patients allocated to PTCA had a subsequent CABG during the 6.5 year follow-up period; and a further 19% had an additional non-randomized PTCA; most of these additional interventions occurred within a year of randomization, and from 3 years onwards the re-intervention rate averaged 4% per year. In the CABG group, the re-intervention rate was 2% per year. The prevalence of angina was consistently and significantly higher in the PTCA group throughout the follow-up period.

There have been nine published randomized trials comparing PTCA and CABG in patients with angina. None was very large, but BARI (the Bypass Angioplasty Revascularisation Investigation)[3] included 1829 patients and CABRI (Coronary Angioplasty vs. Bypass Revascularisation Investigation)[4] included 1054 patients. The remaining trials were smaller[5] EAST (Emory Angioplasty Bypass Surgery Trial) 396 patients, GABI (German Angioplasty Bypass Surgery Investigation) 359, the Toulouse Study 152, MASS (Medicine Angioplasty or Surgery Study) 142, the Lausanne Trial 134, and ERACI (Argentina) 127. RITA was unusual in that a significant proportion of patients with single-vessel disease were included. Results after 5 years have been published for BARI; the remainder have reported their findings after about 3 years.

Although all these trials differed slightly in design and in the sort of patients who were included, the findings are all remarkably consistent. At almost any point after initial treatment the death rate and the rate of non-fatal myocardial infarction are, by intention-to-treat, essentially the same. However, the re-intervention rate, either by CABG or PTCA, is very much higher among those initially treated by PTCA. CABG is undoubtedly the better way of relieving angina, albeit at the physical, psychological and financial cost of a major operation. The long-term follow-up of patients included in RITA-1 has shown that this pattern persists, although the relatively low rate of re-intervention from 3 years onwards in the PTCA group is reassuring.

The results of subset analyses of trials such as these must always be viewed with caution, especially when the number of patients is relatively small. Such an analysis of diabetic patients in BARI (who made up about one quarter of the total number randomized) suggested that diabetic patients fared badly if they were randomly allocated to PTCA rather than CABG, the 5 year survival in these treatment groups being, respectively, 65.5% and 80.6% (P=0.003). Subset analysis of data from CABRI seemed to support this trend. However, retrospective analysis of the outcome in diabetic patients included in EAST and RITA-1 did not confirm this, and in the long-term follow-up of RITA-1 the diabetic patients allocated to PTCA actually had a better outcome than those randomized to treatment by CABG. Another subset analysis of RITA-1 showed no difference between treatments among patients with single or multi-vessel disease.

The Health Service costs of PTCA and CABG were described after 2 years of follow-up of the RITA-1 patients[6]. Although the initial costs of treating a patient with angina by PTCA was about half that of treatment by CABG, the greater need for re-intervention in the PTCA group meant that after 2 years the total cost of initial PTCA treatment was about 80% of that of initial CABG treatment. The longer follow-up of RITA-1 has shown that this trend continues to 5 years: at that point the total average
cost of initial CABG treatment was still a little higher than that of initial treatment by PTCA, but the difference in total cost between the two treatment groups was no longer statistically significant.

Despite the consistency of the results of the various trials, there remains much that we do not know about the relative merits of PTCA and CABG in patients with angina who could be revascularized by either technique. The main problem is that both interventional techniques and medical therapy have improved since recruitment to all these trials commenced. Stents were seldom used following PTCA in any of the trials; while we know that stenting reduces stenosis and repeat PTCA we do not know how it affects the main clinical outcomes of myocardial infarction or death in the long-term. In the long-term it would seem probable that the use of stents would affect the economic balance between PTCA and CABG. Similarly, the trials were established before the use of statins became widespread, and treatment with these drugs could affect long-term outcome differently among patients initially treated by PTCA or CABG. The use of at least some glycoprotein IIb/IIIa receptor blockade certainly improves the initial outcome of high-risk patients undergoing PTCA, but the long-term effects of these drugs is not known and some of them are sufficiently expensive for them to become important in any economic analysis. Surgery has improved too, and less invasive surgical procedures may or may not have long-term advantages affecting the balance of risks and benefits of PTCA and CABG.

There is clearly a need for further trials comparing revascularization techniques using all these new management strategies, even though their results are likely to be outdated by the time the trials are published. For the moment, however, when a choice has to be made between PTCA and CABG in a patient with angina, it will have to be based on the results of RITA-1 and of the other trials published so far.

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References