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Revascularization *versus* medical therapy for renal-artery stenosis

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Atherosclerotic renovascular disease is a common condition with a rate of death of about 16% per year, largely from associated cardiovascular disease. Stenosis of the renal artery is associated with both hypertension and chronic kidney disease. Treatment has traditionally focused on correcting renal-artery stenosis, with endovascular revascularization having gradually replaced open surgical techniques. Three small, randomized, controlled trials showed no significant benefits of angioplasty over medical therapy. The Angioplasty and Stenting for Renal Artery Lesions (ASTRAL) trial was designed to determine reliably whether revascularization together with medical therapy improves renal function and other outcomes, as compared with medical therapy alone, in patients with atherosclerotic renal-artery stenosis.

Methods: Patients were eligible to participate if they had atherosclerotic stenosis in at least one renal artery that was considered potentially suitable for endovascular revascularization. Patients were not eligible if they required surgical revascularization or were considered to have a high likelihood of requiring revascularization within 6 months, if they had nonatheromatous cardiovascular disease, or if they had undergone previous revascularization for renal-artery stenosis. Patients were randomly assigned either to undergo revascularization in addition to receiving medical therapy or to receive medical therapy alone, in a 1:1 ratio. Randomization was stratified according to the serum creatinine level, estimated glomerular filtration rate (as calculated by the Cockcroft-Gault method), severity of renal-artery stenosis, kidney length on renal ultrasonography, and rate of progression of renal impairment in the previous year (with rapid progression defined as an increase in the serum creatinine level of more than 20% or of more than 1.13 mg/dl. For patients who were assigned to undergo revascularization, the procedure was performed as soon as possible after randomization (ideally, within 4 weeks).

Results: From September 2000 through October 2007, a total of 806 patients were enrolled (403 in each study group) at 57 hospitals (53 in the United Kingdom, 3 in Australia, and 1 in New Zealand). The proportions of patients with different degrees of improvement or deterioration of renal function at 12 months were similar in the two groups . In a per-protocol analysis, there was no significant difference in the primary outcome between the 317 patients who underwent successful revascularization and the 379 patients who received medical therapy only. There were no significant

differences in the primary outcome in any of the protocol-specified subgroups, which were defined according to the serum creatinine level, estimated glomerular filtration rate, severity of renal-artery stenosis, kidney length, and previous rate of progression of renal impairment. In a post hoc subgroup analysis, we also found no significant difference in the primary outcome between the 163 patients with severe anatomical disease (103 patients with bilateral renal-artery stenosis of more than 70% and 60 patients with renal-artery stenosis of more than 70% in a single functioning kidney) and patients without such severe anatomical disease (P=0.23) During the 5-year study period, systolic blood pressure decreased in the two study groups, with no significant difference between the groups.

Conclusion: The investigators found no evidence of a worthwhile clinical benefit in the initial years after revascularization in patients with atherosclerotic renal-artery stenosis. The overall results of a large trial may disguise a worthwhile clinical benefit in smaller subpopulations of patients. However, they found no evidence that the effect of revascularization differed among patients with varying degrees of renal disease, with the serum creatinine level, estimated glomerular filtration rate, severity of stenosis, and renal length used as variables. An important post hoc subgroup analysis of patients for whom many clinicians currently advocate revascularization (those with either bilateral renal-artery stenosis of more than 70% or renal-artery stenosis of more than 70% in a single functioning kidney) also showed no significant difference in outcome between patients with severe renal-artery stenosis and those without such severe disease.

Comment on a paper:
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