

Angioplasty was no better than medication for reducing blood pressure or slowing disease progression in renal artery stenosis

van Jaarsveld BC, Krijnen P, Pieterman H, et al., for the Dutch Renal Artery Stenosis Intervention Cooperative Study Group. The effect of balloon angioplasty on hypertension in atherosclerotic renal-artery stenosis. *N Engl J Med*. 2000 Apr 6;342:1007-14.

QUESTION

In patients with atherosclerotic renal artery stenosis who have normal or mildly impaired renal function, is balloon angioplasty as effective as antihypertensive drug therapy for reducing blood pressure?

DESIGN

Randomized (allocation concealed*), blinded {outcome assessors}†,* controlled trial with 12-month follow-up.

SETTING

26 clinical centers in the Netherlands.

PATIENTS

106 patients (mean age 60 y, 62% men) with renal artery stenosis measured by renal arteriography (reduction in luminal diameter $\geq 50\%$) and normal to mildly impaired renal function (serum creatinine level ≤ 2.3 mg/dL [200 $\mu\text{mol/L}$]). Exclusion criteria were cancer, hypertension caused by a condition other than renovascular disease, unstable coronary artery disease, heart failure, or pregnancy. Follow-up was 98%.

INTERVENTION

56 patients were allocated to angioplasty and 50 patients to drug therapy. Patients in

the angioplasty group stopped taking medication before angioplasty, took aspirin starting the day before the procedure, and continued for the next 6 months. Antihypertensive drugs could be started during follow-up. At 3 months, patients in the angioplasty group could have repeated angioplasty, stent deployment, or bypass surgery if their diastolic blood pressure (BP) was ≥ 95 mm Hg or serum creatinine levels had increased by ≥ 0.2 mg/dL (20 $\mu\text{mol/L}$); also given 1 of these conditions, patients in the medication-alone group received increased doses of the drugs they had been using before randomization, and angioplasty could be done when high BP or signs of impairment of renal function were present.

MAIN OUTCOME MEASURES

The primary outcome was BP. Secondary outcomes were renal function and number and daily dose of antihypertensive drugs.

MAIN RESULTS

3 patients in the angioplasty group had revascularization; 22 patients in the medication-alone group had angioplasty. Intention-to-treat analyses showed that the

groups did not differ at 12 months for diastolic or systolic BP (160/93 mm Hg for the angioplasty group vs 163/96 mm Hg for the medication-alone group, $P = 0.5$) or for the number of drug doses (2.5 vs 3.1, $P = 0.10$). The groups also did not differ for serum creatinine levels (median 1.2 mg/dL for both groups) or creatinine clearance rates (70 vs 62 mL/min, $P = 0.1$).

CONCLUSION

For patients who have atherosclerotic renal artery stenosis with normal or mildly impaired renal function, primary angioplasty was not more effective than antihypertensive drugs alone for reducing blood pressure or limiting disease progression.

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*See Glossary.

†Information provided by author.

COMMENTARY

This useful study by van Jaarsveld and colleagues addresses a common and realistic clinical problem. It expands and complements previous small studies but will not be welcomed by those who already believe in surgical intervention for renal artery stenosis. The major weakness is that, because of the relatively high recurrence rates in stenosis caused by atheroma, many interventional radiologists and clinicians have already moved on to regular stenting after successful angioplasty.

The study clearly indicates that initial angioplasty did not improve either BP control or renal function at 12 months. The study provides no information on patients with renal artery stenosis and flash pulmonary edema nor on patients with steadily worsen-

ing renal function or BP control. Approximately 50% of patients assigned to drug therapy subsequently had "rescue" angioplasty, and the study does not permit us to determine whether they had better outcomes. An accompanying editorial points out these limitations and suggests that further study is required for patients with more severe renal impairment and tight renal artery stenosis either in a single kidney or bilaterally (1).

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Reference

1. Ritz E, Mann JF. Renal angioplasty for lowering blood pressure. *N Engl J Med*. 2000;342:1042-3.