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[Intervention Review]

Balloon angioplasty, with and without stenting, versus medical therapy for hypertensive patients with renal artery stenosis

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ABSTRACT

Background

Atherosclerotic renal artery stenosis is the most common cause of secondary hypertension. Balloon angioplasty with stenting is widely used for the treatment of hypertensive patients with renal artery stenosis but the effectiveness of this procedure in treating hypertension, improving renal function and preventing adverse cardiovascular and renal events remains uncertain. This is an update, to include the results of recent, important large trials, of a review first published in 2003.

Objectives

To compare the effectiveness of balloon angioplasty (with and without stenting) with medical therapy for the treatment of atherosclerotic renal artery stenosis in patients with hypertension. The following outcomes were compared: blood pressure control, renal function, frequency of cardiovascular and renal adverse events, presence or absence of restenosis of the renal artery, side effects of medical therapy, numbers and defined daily doses of antihypertensive drugs.

Search methods

For this update the Cochrane Peripheral Vascular Diseases Group Trials Search Co-ordinator searched the Specialised Register (last searched May 2014) and CENTRAL (2014, Issue 4). Bibliographies were also reviewed and trial authors were contacted for more information.

Selection criteria

Randomised controlled trials (RCTs) comparing balloon angioplasty with medical therapy in hypertensive patients with haemodynamically significant renal artery stenosis (greater than 50% reduction in luminal diameter) and with a minimum follow-up of six months.

Data collection and analysis

Data were extracted independently on trial design, participants, interventions and outcome measures. A formal meta-analysis was completed to assess the effect on blood pressure, renal function and cardiovascular and renal adverse events. Peto's odds ratios (ORs) and corresponding 95% confidence intervals (CI) for dichotomous outcomes and mean differences (MD) and corresponding 95% CIs for continuous variables were calculated.



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Main results

Eight RCTs involving 2222 participants with renal artery stenosis were included in the review. The overall quality of evidence included in this review was moderate. Limited pooling of results was possible due to the variable presentation of some of the trial outcomes. Meta-analysis of the four studies reporting change in diastolic blood pressure (BP) found a small improvement in diastolic BP in the angioplasty group (MD -2.00 mmHg; 95% CI -3.72 to -0.27) whilst the meta-analysis of the five studies reporting change in systolic BP did not find any evidence of significant improvement (MD -1.07 mmHg; 95% CI -3.45 to 1.30). There was no significant effect on renal function as measured by serum creatinine (MD -7.99 µmol/L; 95% CI -22.6 to 6.62). Meta-analysis of the three studies that reported the mean number of antihypertensive drug requirements for the angioplasty group (MD -0.18; 95% CI -0.34 to -0.03). Repeat angiography was only performed on a small number of participants in a single trial and it was therefore not possible to comment on restenosis of the renal artery following balloon angioplasty. Based on the results of the seven studies that reported cardiovascular and renal clinical outcomes there were no differences in cardiovascular (OR 0.91; 95% CI 0.75 to 1.11) or renal adverse events (OR 1.02; 95% CI 0.75 to 1.38) between the angioplasty and medical treatment groups. A small number of procedural complications of balloon angioplasty were reported (haematoma at the site of catheter insertion (6.5%), femoral artery pseudoaneurysm (0.7%), renal artery or kidney perforation or dissection (2.5%) as well as peri-procedural deaths (0.4%)). No side effects of medical therapy were reported.

Authors' conclusions

The available data are insufficient to conclude that revascularisation in the form of balloon angioplasty, with or without stenting, is superior to medical therapy for the treatment of atherosclerotic renal artery stenosis in patients with hypertension. However, balloon angioplasty results in a small improvement in diastolic blood pressure and a small reduction in antihypertensive drug requirements. Balloon angioplasty appears safe and results in similar numbers of cardiovascular and renal adverse events to medical therapy.

PLAIN LANGUAGE SUMMARY

Balloon angioplasty versus medical therapy for patients with renal artery obstruction and high blood pressure

Atherosclerosis can cause narrowing and hardening of the main blood vessel supplying the kidneys (renal artery stenosis) resulting in high blood pressure. Even using drugs that lower blood pressure (antihypertensives) atherosclerotic renal artery narrowing tends to progress. Poor blood flow results in a lack of oxygen (renal ischaemia) and loss of kidney function, causing kidney failure. Currently, possible treatments are medical treatment with blood pressure lowering drugs, balloon angioplasty with stent insertion (insertion of a balloon-like tube which is inflated to open up the artery followed by insertion of a metal tube which remains in place to try and keep the artery open), and surgery to reconstruct the artery. The review authors identified eight controlled trials in which a total of 2222 adults were randomised to have balloon angioplasty or drug treatment only. The overall quality of the evidence was considered to be moderate because the methodological quality of the studies varied substantially and two of the studies had not provided sufficient data to be able to assess their risk of bias. Overall, the data were insufficient to show that one treatment was better than the other for preventing loss of kidney function or restenosis of the renal artery. Those treated with balloon angioplasty may require fewer antihypertensive drugs or lower doses and experience a slight improvement in diastolic but not systolic blood pressure. Balloon angioplasty appears to be safe and there were similar numbers of renal and cardiovascular adverse events in participants treated with either approach. A small number of procedural complications of balloon angioplasty were reported (collection of blood outside the blood vessel at the site of catheter insertion (6.5%), dilated groin artery (0.7%), renal artery or kidney perforation or tear (2.5%) as well as deaths shortly before, during or after the procedure (0.4%)). No side effects of medical therapy were reported.