Continuing uncertainty about the value of percutaneous revascularization in atherosclerotic renovascular disease: a meta-analysis of randomized trials


CRD summary
This review examined the effect of revascularisation on blood pressure and serum creatinine levels in patients with atherosclerotic renovascular disease. The authors concluded that the results of the meta-analysis exclude the possibility of a large improvement after angioplasty, but a moderate clinical benefit cannot be ruled out. The authors' conclusions are based on a small number of participants, and the methods used in the review may be biased.

Authors' objectives
To assess the effect of revascularisation on blood-pressure (BP) and serum creatinine (SCr) levels in patients with atherosclerotic renovascular disease (ARVD).

Searching
A number of databases were searched to identify both primary studies and systematic reviews. The databases searched were listed in the paper, along with the search terms; however, no search dates were provided. In addition, the authors handsearched major journals in the field, contacted experts and checked the reference lists of retrieved papers. The authors also searched grey literature for unpublished and ongoing trials.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) were eligible for inclusion.

Specific interventions included in the review
Studies that assessed revascularisation with percutaneous balloon angioplasty and/or endovascular stenting (with usual medication as required), compared with medical therapy alone, were eligible for inclusion.

Participants included in the review
Participants with unilateral or bilateral ARVD were included in the review.

Outcomes assessed in the review
The primary outcome measures assessed were BP and SCr levels at 6 months, and changes in these measures from baseline.

How were decisions on the relevance of primary studies made?
The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
The authors did not state that they assessed validity.

Data extraction
The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction.

Data on the type of participants, interventions, duration of follow-up and the main end points were extracted and tabulated. The mean and standard deviation (SD) for each outcome measure were extracted and, for each trial, the difference and its variance between the outcome measure means for each group were calculated. Where data were
missing for a certain follow-up time, the data were imputed and sensitivity analyses were undertaken to test the robustness of the assumption. The results presented assumed the average SD for the missing data.

**Methods of synthesis**

*How were the studies combined?*

The studies were combined in a meta-analysis. The authors did not report whether a random-effects or fixed-effect model was used to combine the outcome means. Publication bias was not assessed.

*How were differences between studies investigated?*

Differences between the studies were assessed using the chi-squared test.

**Results of the review**

Three RCTs (total n=210: angioplasty group n=104, medical therapy alone group n=106) were included.

**BP.**

There were no statistically significant differences between the groups for systolic and diastolic BP at the 6-month follow-up. Compared with the medical therapy group, the mean systolic and diastolic BP were, respectively, 2.9 mmHg (95% confidence interval, CI: -9.1, 3.4) and 0.35 mmHg (95% CI: -3.6, 2.9) lower in the angioplasty group. When the mean change in BP between baseline and the 6-month follow-up was compared between the groups, there was a greater reduction in systolic BP in the angioplasty group, with a difference of 6.3 mmHg (95% CI: -11.7, -0.8) in the mean change between the two groups. Similarly, for diastolic BP there was a greater reduction in the angioplasty group, with a difference of 3.3 mmHg (95% CI: -6.2, -0.4) in the mean change. No statistical heterogeneity was observed between the trials for any of these outcomes.

**SCr levels.**

The SCr level at the 6-month follow-up was 9.7 mmol/L (95% CI: -18.7, -0.73) lower in the angioplasty group, while SCr clearance (reported in 2 studies) was 0.14 mL/s (95% CI: 0.02, 0.3) greater. When the change in SCr from baseline to the 6-month follow-up was analysed, there were no statistically significant differences between the groups, with a difference of 6.2 mmol/L in the mean change (95% CI: -12.5, 0.15). Likewise, when the changes over time in SCr clearance were investigated, there were no statistically significant difference between the groups. There was no evidence of statistical heterogeneity between the trials for any of these outcomes.

**Authors’ conclusions**

The authors concluded that, although the combined results of the meta-analysis excluded the possibility of a large improvement in renal function or hypertension after angioplasty, a moderate but clinically worthwhile benefit cannot be ruled out.

**CRD commentary**

The review question was clearly defined in terms of the intervention, participants, outcome measures and study design. A number of relevant sources were searched to identify both published and unpublished studies. However, it was unclear whether any language restrictions were imposed on the publications. The review methods were poorly reported in terms of the inclusion of studies, data extraction and whether a validity assessment was undertaken. It is therefore unclear whether any efforts were made to reduce bias and errors in the review process, or whether the quality of the studies was taken into account when interpreting the results.

The use of meta-analyses to combine the studies appears to have been appropriate, and differences between the studies were adequately explored. However, the authors' conclusions were based on a small number of participants, for which approximately one quarter of the results reported at 6 months' follow-up were imputed. Given this factor, and the uncertainty of the review methods used, the authors' conclusions should be treated as preliminary until further research is undertaken.
Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors stated that the three reported trials were too small to determine reliably the role of angioplasty in ARVD. Further large scale RCTs comparing revascularisation (using balloon angioplasty with or without stent insertion) and medical management are needed.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.