



Effective Health Care

Comparative Effectiveness of Management Strategies for Renal Artery Stenosis: 2007 Update

Executive Summary

This report is an update to a Comparative Effectiveness Review on management strategies for renal artery stenosis (RAS) from October 2006. The systematic review included all studies of patients with atherosclerotic RAS (ARAS) that compared two or more interventions. It also reviewed recent prospective cohort (single arm) studies of angioplasty with stent placement, prospective cohort studies of medical interventions, cohort studies of RAS natural history, and prospective or large retrospective studies of surgical bypass. This update evaluated the same questions and used the same eligibility criteria, updating the literature search through April 23, 2007. This report does not address the management of fibromuscular dysplasia, renal transplant recipients, or patients who have a previous failed revascularization.

The Key Questions addressed by the original report and this update are:

1. For patients with atherosclerotic renal artery stenosis in the modern management era (i.e., since JNC-5 in 1993¹), what is the evidence on the effects of aggressive medical therapy

¹ Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure (1993). These guidelines marked a substantial change from previous guidelines in treatment recommendations for hypertension, including more aggressive blood pressure targets. This timepoint also marks when ACE inhibitors began to be used more routinely for patients with severe hypertension.

Effective Health Care Program

The Effective Health Care Program was initiated in 2005 to provide valid evidence about the comparative effectiveness of different medical interventions. The object is to help consumers, health care providers, and others in making informed choices among treatment alternatives. Through its Comparative Effectiveness Reviews, the program supports systematic appraisals of existing scientific evidence regarding treatments for high-priority health conditions. It also promotes and generates new scientific evidence by identifying gaps in existing scientific evidence and supporting new research. The program puts special emphasis on translating findings into a variety of useful formats for different stakeholders, including consumers.

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(i.e., antihypertensive, antiplatelet, and antilipid treatment) compared to renal artery angioplasty with stent placement on long-term clinical outcomes (at least 6 months), including blood pressure control, preservation of kidney function, flash pulmonary edema, other cardiovascular events, and survival?

- 1a. What are the patient characteristics, including etiology, predominant clinical presentation, and severity of stenosis, in the studies?
- 1b. What adverse events and complications have been associated with aggressive medical therapy or renal artery angioplasty with stent placement?
2. What clinical, imaging, laboratory, and anatomic characteristics are associated with improved or worse outcomes when treating with either aggressive medical therapy alone or renal artery angioplasty with stent placement?
3. What treatment variables are associated with improved or worse outcomes of renal artery angioplasty with stent placement, including periprocedural medications, type of stent, use of distal protection devices, or other adjunct techniques?

The original report evaluated 60 unique studies. The updated search found an additional nine articles, representing eight new studies. One article provided new data on quality of life (QoL) from a previously published trial; a second article reported on a nonrandomized comparative study; and the remaining articles were on cohort studies of angioplasty with stent. Notably, only two trials have compared angioplasty (without stent placement) with medical therapy and followed patients for at least 6 months. The other comparative studies were of shorter duration, were nonrandomized, or had other limitations. The remaining studies were cohort studies of different interventions.

An analysis of a previously reported randomized trial that compared immediate angioplasty and either medical therapy alone or medical therapy followed by angioplasty at 3 months found either no significant differences or inconsistent differences in QoL at 3 and 12 months. The other recently published studies had results generally similar to those from the previously published articles included in the original report.

None of the studies evaluated the principal question of interest—namely, the relative effects of intensive medical therapy and angioplasty with stent for patients with ARAS. The quality of the evaluated studies was limited because of inadequate reporting and/or collection of data, incomplete analyses, and often inconsistent use of interventions (e.g., combining angioplasty with and without stent); limited applicability due to restrictive patient eligibility or inadequate reporting; and limited power of studies due to small sample size.

The evidence does not support one treatment approach over the other for the general population of people with ARAS.

- Weak evidence suggests no difference in mortality rates.
- There is acceptable evidence that, overall, there is no difference in kidney outcomes between patients treated medically only and those receiving angioplasty without stent, although the relevance of this finding to current practice is questionable due to changes in treatment options. However, improvements in kidney function were reported only among patients receiving angioplasty.
- There is acceptable evidence that combination antihypertensive treatment results in large decreases in blood pressure, but there is inconsistent evidence regarding the relative effect of angioplasty and medication on blood pressure control.
- There is weak evidence suggesting similar rates of cardiovascular events between interventions; however, it is likely that the studies were too small to detect different rates of cardiovascular events.
- Weak evidence suggests no difference in QoL with medical treatment alone or with angioplasty.
- The evidence does not adequately assess comparisons of adverse events between medical treatment alone and angioplasty.
- There is weak evidence that patients with bilateral RAS may have more favorable outcomes with angioplasty than medical therapy.
- Weak or inconsistent evidence does not support statements on whether other clinical features (such as demographics or indicators of RAS severity) or diagnostic tests predict whether patients would

have better clinical outcomes with angioplasty or with medical therapy alone.

- There is no evidence regarding the value of periprocedural interventions with angioplasty.

Full Report

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