



TITLE: Renal Artery Stents for the Treatment of Severe Hypertension

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PUBLISHER: California Technology Assessment Forum

DATE OF PUBLICATION: February 8, 2012

PLACE OF PUBLICATION: San Francisco, CA

RENAL ARTERY STENTS FOR SEVERE HYPERTENSION

A Technology Assessment

INTRODUCTION

The California Technology Assessment Forum (CTAF) is requested to review the scientific evidence for the use of renal artery stents for the treatment of severe hypertension. This is the first time that CTAF has addressed this topic.

BACKGROUND

Hypertension (HTN) is a risk factor for heart disease and stroke, and treatment of HTN can reduce mortality and cardiovascular outcomes. It is estimated that 29-31% of adults in the United States have HTN.¹ The incidence of HTN increases with age and the majority of individuals over age 65 have HTN.

A diagnosis of HTN is based on the following definitions:

Normal blood pressure systolic <120 mm Hg and diastolic <80 mm Hg

Prehypertension: Systolic 120-139 mm HG or diastolic 80-89 mm HG

Hypertension: systolic >140 mmHg or diastolic >90 mmHg.

A diagnosis of HTN is made based on the average of two or more readings at each of two or more visits after an initial screen.²

The vast majority of individuals who have HTN have primary or essential HTN. A small subset of individuals is found to have secondary HTN which is caused by an underlying condition. An

underlying cause of the HTN should be considered in individuals who have resistant or difficult to control HTN and in individuals who present with HTN at a young age.

The incidence of renal artery stenosis as a cause of HTN is low in primary HTN, but in resistant hypertension, the incidence is estimated to be as high as 10-40%.³ The two major causes of renal artery stenosis are atherosclerosis and fibromuscular dysplasia. Atherosclerosis is more common in men and the incidence increases with age. It is more often near the aortic orifice or the proximal renal artery. It is also more common in individuals with atherosclerotic disease elsewhere.⁴ Fibromuscular dysplasia is more common in women aged 50 and younger and tends to affect the distal renal artery or the intrarenal branches.

The diagnosis of renal artery stenosis is made by vascular imaging and clinically significant lesions are generally defined as those having a stenosis of >75%. The three potential treatment options for renal artery stenosis are medical therapy, percutaneous angioplasty with or without stent placement or surgery. Although medical treatment is the usual initial approach, there are some potential concerns with medical treatment. These include progression of the stenosis, impaired kidney function after angiotensin inhibition and ischemic damage to the stenotic kidney. Progression of the stenosis can lead to kidney failure and is more common in those with bilateral stenosis. Persistent severe stenosis can result in a loss of renal mass.⁵ Renal function can decline, especially with the use of angiotensin converting enzyme inhibitors.⁶

Treatment of hypertension due to renal artery stenosis: Generally the primary treatment is medical treatment of the HTN. Initial treatment includes nonpharmacologic measures and subsequent treatment involves pharmacologic measures with a variety of medications used individually and in revascularization either by angioplasty or by surgery is typically considered if medical therapy is ineffective. The goals of revascularization therapy are to improve blood pressure and to stabilize or improve renal function.

Percutaneous transluminal renal angioplasty (PTRA) with stenting is a less invasive procedure than surgery. The goal is to improve vessel patency, and improve some of the physiologic changes that result from renal artery stenosis and contribute to HTN. During angioplasty of the renal artery, a catheter is inserted and moved to the site of the stenosis. Then a balloon is inflated to improve vessel patency. With stenting, a stent (usually made of stainless steel) is then inserted into the site in hopes of keeping the vessel open. Currently the vast majority of PTRA procedures are done with stenting.

If revascularization is considered, an important question is what the relevant outcome is. Ideally, studies addressing the treatment of HTN should address whether or not treatment of the HTN reduces mortality or prevents other cardiovascular events such as myocardial infarction or stroke. However, studies addressing these outcomes need to be large with a long duration of follow-up. Particularly in the relatively small population of individuals who have renal artery stenosis as a cause for their HTN, studies of this magnitude may not be feasible.

Blood pressure reduction is often used as a surrogate outcome, since reduction in blood pressure has been associated with significant clinical outcomes. In clinical trials antihypertensive therapy has been associated with reductions in stroke of 35-40% and a reduction in myocardial infarction of 20-25%.⁷ It has been estimated that in patients with stage 1 HTN (SBP 140-159 and/or DBP 90-99 mm Hg) and additional cardiovascular risk factors, achieving a 12 mmHg reduction in BP that is sustained for 10 years could prevent one death per every 11 patients treated.⁸ Another clinically relevant outcome is progression of renal disease.

Some of the early studies of revascularization focused on angioplasty without stent placement. Currently, if angioplasty is performed, a stent is almost always placed unless the anatomy of the vessel does not allow stent placement. This assessment focuses on the use of angioplasty in conjunction with stent placement for the treatment of severe hypertension.

TA Criterion 1: The technology must have final approval from the appropriate government regulatory bodies.

Renal stents are FDA Class 3 devices with Product Code NIN. There are five renal stent systems approved by the FDA.

Product name	Manufacturer	FDA PMA approval	Material
RX Herculink Elite Renal Stent System	Abbot	2011	Cobalt chromium
Formula 414RX Balloon Expandable Renal Stent and the Formula 418 Balloon Expandable Renal Stent	Cook Medical	2011	Stainless steel
Express® SD Renal Monorail® Premounted Stent System	Boston Scientific	2008	Stainless steel
PALMAZ® Balloon-Expandable Stent for Renal Arteries	Cordis	2002	Stainless steel
Bridge™ Extra Support Over-The-Wire Renal Stent System	Medtronic	2002	Stainless steel

Abbott will be following the existing 202 patient HERCULES study cohort for a total of three years to assess the long term safety and effectiveness of the RX Herculink Elite Renal Stent System.

TA Criterion 1 is met

TA Criterion 2: The scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.

The Medline database, Cochrane clinical trials database, Cochrane reviews database and Database of Abstracts of Reviews of Effects (DARE) were searched using the search terms hypertension, renovascular, blood pressure, antihypertensive agents, renal artery, stent or endovascular. The search was performed for the period from 1966 to November, 2011. The bibliographies of systematic reviews and key articles were manually searched for additional references and references were requested from device manufacturers. The abstracts of citations were reviewed for relevance and all potentially relevant articles were reviewed in full.

Inclusion criteria for literature review consideration were:

- Study had to evaluate renal artery stenting in patients with renal artery stenosis and HTN
- Study had to be prospective
- Comparative studies had to compare renal artery stenting with another treatment
- Study had to measure clinical outcomes
- Included only humans
- Published in English as a peer reviewed article

Studies were excluded if they only focused on non-clinical outcomes. They were also excluded if they were retrospective.

A total of 235 potentially relevant articles were identified. All 235 titles were reviewed. 204 were excluded for not addressing the research question. A total of 31 abstracts were evaluated. 22 were excluded. Reasons for exclusion included not reporting clinical outcomes, not being prospective, or not comparing renal artery stenting with medical treatment. Of these, four published prospective studies and five clinical trials are included in this evaluation.

Details of the observational studies are described in Tables 1 and 2. Details of the clinical trials and the outcomes measured are described in Table 3. Clinical trials and the outcomes measured are described in Table 3 and 4. There were four prospective observational studies and five clinical trials.

Although the outcomes varied among the studies, typical outcomes included the blood pressure before and after treatment, number of anti-hypertensive medications required, and measures of renal function such as creatinine. No studies have assessed the impact of renal artery stenting on the important outcomes of mortality, cardiovascular outcomes or progression to dialysis.

Level of Evidence: 1, 3

TA Criterion 2 is met

TA Criterion 3: The technology must improve net health outcomes.

The intended outcomes of PTRA and stenting are to improve blood pressure control, reduce the need for blood pressure medications and to prevent or slow progression of renal disease, ideally with few negative effects. Although many retrospective studies have reported on the outcomes of PTRA and stent placement for renal artery stenosis, fewer prospective studies have evaluated the impact of PTRA on clinical outcomes. Study characteristics of several prospective studies that evaluated renal artery stents are described in Table 1. The results of these studies are described in Table 2.

Two early studies conducted in Greece and Austria had less than 100 patients each.^{9,10} Follow-up ranged from 28 months to 47.5 months. Both studies reported better blood pressure control with revascularization and stenting and reported that PTRA appeared safe.

In the largest observational study which was a registry study, 1,058 patients received Palmaz Stent Renal Artery Stenosis Revascularization and were followed for four years. At four year follow-up, both systolic and diastolic blood pressures had significantly decreased and the number of antihypertensive medications required had decreased from baseline (2.0 vs. 2.4: $P < 0.05$). Serum creatinine had also decreased over the four years of follow up (1.7 to 1.3: $P < 0.05$).⁹

In the ASPIRE-2 study, a U.S. multi-center study in patients in whom initial PTRA was unsuccessful, 208 patients were followed for 24 months. The primary outcome was rate of restenosis which was 17.4% at 9 months. Systolic blood pressure was decreased from 168 to 149 ($P < 0.001$). Mean serum creatinine remained unchanged from baseline, but there was a cumulative incidence of major adverse events of 19.7%. Since this study only included patients who had a failed PTRA, its generalizability is limited.

Potential Benefits

The main potential benefit would be a reduction in mortality or other cardiovascular outcomes, but to date no studies have evaluated the impact of PTRA on these clinical outcomes. Intermediate outcomes would include improvement in blood pressure control and improvement in renal function. As described above, prospective observational studies have shown improvement in blood pressure control and in renal function as measured by decline in serum creatinine with follow-up up to four years. The impact of the improved blood pressure control on clinical outcomes such as cardiovascular morbidity and mortality is not known.

Potential Risks

Potential risks associated with angioplasty and stent placement are mostly related to procedural complications. The rate of procedural complications for PTRA with or without stenting is between 5 and 15 percent.¹¹⁻¹⁶ The most common ones are puncture site hematoma and renal artery dissection. Other potential complications are artery thrombosis or perforation, acute kidney disease due to atheroemboli and radiocontrast agent reaction.

In the ASTRAL study, a RCT described below, 19 of the 38 complications that occurred within 24 hours of the procedure were serious adverse events- five renal artery embolizations, four renal arterial occlusions, four renal artery perforations, one femoral artery aneurysm, pulmonary edema, myocardial infarction (MI) and three with cholesterol emboli.

A major concern is the possibility of causing distal emboli of the atherosclerotic thrombus. Although the procedure is often performed using distal embolic protection, the impact of this practice is not currently known.

Summary

In summary, several prospective studies have evaluated PTRAs with stent for the treatment of renal artery stenosis. PTRAs with stent appear to be efficacious in reducing blood pressure and the need for blood pressure medications at two to four year follow-up. There is the potential for adverse events, especially those related to the procedure.

Although it is difficult to weigh the benefits and risks, PTRAs with stent definitely has the possibility of improving blood pressure control and improving renal function at least in the short term, and thus can improve net health outcomes.

TA Criterion 3 is met.

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Table 1: Prospective and Non-randomized Studies of percutaneous transluminal angioplasty and stent placement for renal artery stenosis

Study, Author	N	Country	Inclusion Criteria	Intervention	Intervention Outcomes
Ziakka, 2008	82	Greece	<ul style="list-style-type: none"> Atherosclerotic renal disease documented by angiogram 	Revascularization and stenting (n=36) and medical treatment (n=46)	<ul style="list-style-type: none"> Blood pressure Renal function (serum creatinine)
Ruchin, 2007	89	Austria	<ul style="list-style-type: none"> All patients referred for stenting of one or both renal arteries 	Revascularization with stent	<ul style="list-style-type: none"> Procedural morbidity and mortality Long term BP control Antihypertensive medication usage Renal function measured by serum creatinine
Dorros, 2002	1058	U.S.; multi-center	<ul style="list-style-type: none"> Stenosis of one or both renal arteries, and one or more of the following: <ul style="list-style-type: none"> accelerated, severe or malignant HTN inadequate BP control worsening renal function after control with pharmacologic agents 	All patients undergoing Palmaz or Palmaz-Schatz stent placement	<ul style="list-style-type: none"> Blood pressure control Number of blood pressure medications Renal function
Rocha-Singh, 2005	208	U.S. . multi-center (23)	<ul style="list-style-type: none"> Patients with >70% renal artery stenosis who had balloon-expandable stent after unsuccessful PTRAs 		<ul style="list-style-type: none"> Restenosis rate Renal function Blood pressure Cumulate incidence of adverse events Target lesion revascularization at 24 months

Table 2: Outcomes of Prospective and Non-randomized Studies of percutaneous transluminal renal angioplasty and stent placement for renal artery stenosis

Study, Author	N	Length of follow-up	Main outcomes	Comments
Ziakka, 2008	82	47.5 months	<ul style="list-style-type: none"> Better blood pressure control with revascularization 	Non-randomized study
Ruchio, 2007	89	28 months	<ul style="list-style-type: none"> Reduction in SBP (161.7 to 138.7 (P, 0.0001). Clinical restenosis rate 6.2% Renal function and eGFT remained stable 	Patients enrolled 1997-2003
Dorros, 2002	1058	4 years	<ul style="list-style-type: none"> Reduction in SBP and DBP at follow-up(SBP from 168 to 147 mm Hg and DPB 87 to 78 mm Hg: p<0.05 Fewer BP medications required (from 2.4 to 2.0:p,0.05) 	
Rocha-Singh, 2005	208	24 months	<ul style="list-style-type: none"> 17.4% nine month restenosis rate Systolic BP decreased from 168 to 149 (p< g0.001) Mean serum creatinine unchanged from baseline values 19.7%: cumulative incidence of major adverse events 	Included patients were only those whose balloon angioplasty was unsuccessful

SBP: Systolic blood pressure
DBP: Diastolic blood pressure

Table 3 Characteristics of Studies comparing percutaneous transluminal angioplasty and stent placement with another alternative

Study, Author	N	Country	Inclusion Criteria	Intervention	Intervention Outcomes	Follow up
Plouin, 1998 (EMMA)	49	France	<ul style="list-style-type: none"> <75 years old. Unilateral atherosclerotic RAS Diastolic BP readings >95 at least 3 times 	Antihypertensive drug treatment (n=26) vs. PTRA (N=23)	<ul style="list-style-type: none"> 24 hour ambulatory blood pressure 	6 months
Van Jaarsveld, 2000 (DRASTIC)	106	Netherlands	<ul style="list-style-type: none"> HTN and renal artery stenosis of 50% or more and creatinine of 2.3 mg/dl or less; DBP of 95 mm Hg or greater on at least two drugs or Increase in creatinine of 0.2 mg/dl with treatment with an ACE inhibitor 	PTRA (n=56) vs. drug therapy (n=50)		12 months
Van de Ven, 1999	85	Netherlands	<ul style="list-style-type: none"> Ostial atherosclerotic renal artery stenosis Hypertensive with stenosis shown to affect renal function by positive captopril venography 	PTRA (n=42) vs. PTRA with stent (n=43)	<ul style="list-style-type: none"> Primary success rate (<50% 0 residual stenosis) Cure of hypertension (DBP <90 without meds or at least a 15 mm HG reduction in BP if medications continued) 	6 months
Bax, 2009 (STAR)	140	Netherlands, France	<ul style="list-style-type: none"> Creatinine clearance <80 ml/min per 1.73m² and ARAS of 50% or greater 	Stent placement and medical treatment vs.	<ul style="list-style-type: none"> 20% or greater decrease in creatinine clearance 	2 years

Study, Author	N	Country	Inclusion Criteria	Intervention	Intervention Outcomes	Follow up
				medical treatment	<ul style="list-style-type: none"> Secondary outcomes: safety and cardiovascular morbidity and mortality 	
ASTRAL, 2009	806	United Kingdom, Australia, New Zealand	<ul style="list-style-type: none"> Atherosclerotic renal disease with “substantial stenosis” that was considered potentially suitable for revascularization” 	Randomized unblinded Revascularization with medical therapy vs. medical therapy alone	<ul style="list-style-type: none"> Primary outcome was renal function (1/ serum creatinine) Secondary outcomes: blood pressure, time to renal and major cardiovascular events 	34 months

RAS: Renal artery stenosis

PTRA: Percutaneous transluminal renal angioplasty

ACE: Angiotensin converting inhibitor

STAR: Stenting in Renal Dysfunction Caused by Atherosclerotic Renal Artery Stenosis

ARAS: Atherosclerotic renal artery stenosis

ASTRAL: Angioplasty and Stenting for Renal Artery Lesions

DRASTIC: Dutch Renal Artery Stenosis Intervention Cooperative

Table 4: Outcomes of Studies comparing percutaneous transluminal angioplasty and stent placement with another alternative

Study, Author	Mean length of Follow up	Results	Comments
Plouin, 1998 (EMMA)	6 months	<ul style="list-style-type: none"> 24 hour ambulatory blood pressure: no overall difference between groups At 6 month follow up: 1 dissection and 3 restenoses in angioplasty group 	<ul style="list-style-type: none"> Only two of the 23 PTA patients received a stent
Van Jaarsveld, 2000 (DRASTIC)	12 months	<ul style="list-style-type: none"> At three months: blood pressure similar between two groups At 12 months: no significant differences between angioplasty and drug therapy groups in systolic and diastolic blood pressures, daily drug doses or renal function 	<ul style="list-style-type: none"> Only two of those in the angioplasty group received a stent
Van de Ven, 1999	6 months	<ul style="list-style-type: none"> “Primary success rate”: 57% of those with PTA had no residual stenosis compared with 88% of those with PTRAS ; difference between groups 31% (95% C.I. 12-50) No difference in clinical results at 6 months 	<ul style="list-style-type: none"> PTRAS is better than PTA to achieve vessel patency No impact on clinical outcomes at 6 months
Bax, 2009 (STAR)	2 years	<ul style="list-style-type: none"> 16% of those in stent placement group and 22% of those in the medical group had >20% reduction in creatinine clearance (HR 0.73: 95% C.I. 0.33 to 1.61). More complications in the stenting group including two procedure related deaths 	<ul style="list-style-type: none"> Stent placement had no clear effect on progression of impaired renal function but was associated with some complications Many patients incorrectly identified as having >50% stenosis by noninvasive imaging and did not require stenting
ASTRAL, 2009	34 months	<ul style="list-style-type: none"> Rate of progression of renal impairment nonsignificantly lower in revascularization 	<ul style="list-style-type: none"> No evidence of worthwhile clinical benefit but substantial risks

Study, Author	Mean length of Follow up	Results	Comments
		<p>group</p> <ul style="list-style-type: none"> • No between group differences in systolic BP • Decrease in diastolic BP more in the medication group • Serious complications in 23 patients who underwent revascularization including two deaths and three amputations of toes or limbs 	

DRASTIC: Dutch Renal Artery Stenosis Intervention Cooperative

eGFT: Estimated glomerular filtration rate

EMMA: Essai Multicentrique Medicaments vs. Angioplastie

HTN: Hypertension

PTRA: Percutaneous transluminal renal angioplasty

PTAS: Percutaneous transluminal angioplasty and stent

STAR: Stenting in Renal Dysfunction Caused by Atherosclerotic Renal Artery Stenosis

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TA Criterion 4: The technology must be as beneficial as any established alternatives.

The primary treatment for HTN, either essential, or that caused by renal artery stenosis is medical therapy. Thus any alternative treatment must be compared with medical therapy. A total of five published trials have compared PTA and stent placement with another alternative. Two of these early trials compared PTA with or without stent placement with medical therapy in patients with renal artery stenosis.^{15,17} These two trials included a total of 156 patients, the vast majority of whom underwent angioplasty but did not have a stent placed. Neither of these studies showed any significant difference in blood pressure at 6-12 month follow-up. However because so few individuals received a stent, the potential contribution of a stent cannot be determined. A third study compared PTA alone with PTA and stent placement.¹⁸ The main outcome was the percentage that had no residual stenosis at six months. Although vessel patency at six months was better with PTAS than in PTA alone, there were no differences in clinical outcomes at 6 months.

Two more recent studies have compared PTA with stent (PTAS) to medical therapy. Both were multicenter studies and compared stent placement with medical treatment to medical treatment alone.^{13,14} In the STAR (Stent placement in patients with Atherosclerotic Renal artery stenosis) study, conducted in 10 European medical centers, 140 patients with impaired renal function (creatinine clearance less than 80 ml/minute) and renal artery stenosis of 50% or greater were randomized. The medical treatment included antihypertensives, a statin and an aspirin. Fewer patients in the PTAS group reached the primary endpoint (20% or greater decrease in creatinine clearance) but the difference was not statistically significant. There were more complications in the PTAS group including two procedure related deaths, and one patient who required dialysis due to a cholesterol embolism. There were no differences between groups in other secondary endpoints such as changes in blood pressure or cardiovascular morbidity and mortality. Although 64 patients were assigned to stent placement, only 46 of received a stent. This was in part because patients

were initially identified as having renal artery stenosis of >50% by noninvasive imaging and they did not ultimately require stenting.

The largest study to date comparing renal stent placement with medical therapy is the ASTRAL (Angioplasty and Stenting for Renal Artery Lesions) study.¹³ This was a randomized, unblinded trial and participants either underwent revascularization with medical therapy or revascularization alone. In the revascularization group, the majority (95%) received a stent. The primary outcome was renal function (measured by 1/serum creatinine) and secondary outcomes were blood pressure, and time to renal and major cardiovascular events and mortality. Median duration of follow-up was 34 months. The rate of decline of renal function was nonsignificantly lower in the revascularization group and the mean serum creatinine was also lower in the revascularization group. However, with respect to clinical outcomes, there was no difference between groups in systolic blood pressure, and diastolic blood pressure was actually a little better in the medical treatment group. There were no differences between groups in major cardiovascular events, renal events or death. Revascularization was associated with complications in 23 patients. These complications included two deaths and three amputations of toes or limbs.

There are important limitations to the available clinical trials data. Patients in the trials were not selected because they had clinical characteristics suggestive that renal artery stenosis was a significant contributor to the hypertension- thus this study could have included patients who did not have clinically significant renal artery stenosis. In addition, some of the trials included patients with stenosis from 50-70%, whereas usually only those stenosis >70% are considered significant.

In summary, a total of five RCTs have assessed the comparative efficacy of PTAS with another treatment. The first two studies only included very few individuals with stents, so conclusions cannot be drawn.^{15,17} A third study compared PTA with PTAS and showed improved vessel patency after PTAS but no effect on clinical outcomes. Two RCTs compared the clinically relevant approaches of PTAS with medical therapy with medical therapy alone. Neither of these two studies showed a benefit of PTAS in addition to medical therapy. In addition there were significant complications noted in the PTAS group. Although these trials have limitations, which may limit

their generalizability, this does not mean that we can assume that PTRAs would be effective in individuals who had clinically significant RAS. There is currently no evidence that PTAS is more effective than medical therapy.

TA Criterion 4 is not met.

TA Criterion 5: The improvement must be attainable outside of the investigational setting.

Although renal artery stenting has been used extensively outside of investigational settings, because TA criterion 4 is not met, TA criterion 5 cannot be met.

TA Criterion 5 is not met.

Conclusion

Renal artery stenting is widely used, although the evidence supporting its use is limited. Observational studies have shown that stenting can reduce blood pressure and can improve renal function. However, in randomized trials that have compared renal artery stenting with medical therapy, renal artery stenting was not associated with an improvement in clinical outcomes, and there were significant associated complications.

Recommendation

It is recommended that renal artery stenting for severe hypertension does not meet CTAF criteria 4 or 5 for safety, efficacy and improvement in health outcomes.

Recommendations of Others

Blue Cross Blue Shield Association (BCBSA)

The BCBSA Technology Evaluation Center has not conducted a review of this technology.

Canadian Agency for Drugs and Technologies in Health (CADTH)

No reports on this technology were found at the CADTH website.

National Institute for Health and Clinical Excellence (NICE)

No reports on this technology were found at the NICE website.

The National Kidney Foundation (NKF)

The NKF Kidney Disease Quality Initiative (KDOQI) provides evidence clinical practice guidelines for all stages of chronic kidney disease. The guideline “Hypertension and Antihypertensive Agents in Chronic Kidney Disease” is available at http://www.kidney.org/professionals/KDOQI/guidelines_bp/index.htm). However, the guideline does not address the use of PTRAs and/or the use of stents as an intervention for severe hypertension.

The NKF has been invited to provide an opinion on this technology and to send a representative to participate in the meeting.

Agency for Healthcare Research and Quality (AHRQ)

AHRQ published the Comparative Effectiveness of Management Strategies for Renal Artery Stenosis report in October 2006. A final update was performed on this topic in April 2007 and can be found at the AHRQ Effective Health Care Program website:

<http://www.effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?productid=51&pageaction=displayproduct>.

American College of Cardiology (ACC)

The ACC /American Heart Association (AHA) Task Force on Practice Guidelines collaborated with the Society for Vascular Surgery (SVS), Society for Cardiovascular Angiography and Interventions (SCAI), Society for Vascular Medicine and Biology (SVM) and the Society for Interventional Radiology (SIR) to develop the 2005 Guidelines for the Management of Patients with Peripheral Arterial Disease (Lower Extremity, Renal, Mesenteric, and Abdominal Aortic) which can be found at <http://content.onlinejacc.org/cgi/content/full/47/6/e1>.

The guideline recommendation states that “Percutaneous revascularization is reasonable for patients with hemodynamically significant RAS and accelerated hypertension, resistant hypertension, malignant hypertension, hypertension with an unexplained unilateral small kidney, and hypertension with intolerance to medication.” The recommendation is classified as Class IIa (Weight of evidence/opinion is in favor of usefulness/efficacy) and the level of evidence supporting the recommendation as Level B (Data derived from a single randomized trial or nonrandomized studies).

The Society of Cardiac Angiography and Interventions (SCAI)

SCAI has been invited to provide an opinion on this technology and to send a representative to participate at the meeting.

Society for Vascular Medicine & Biology (SVM)

SVM has been invited to provide an opinion on this technology and to send a representative to participate at the meeting.

Society of Interventional Radiology (SIR)

SIR has been invited to provide an opinion on this technology and to send a representative to participate at the meeting.



Society for Vascular Surgery (SVR)

SVR has been invited to provide an opinion on this technology and to send a representative to participate at the meeting

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ABBREVIATIONS USED IN THIS ASSESSMENT:

ACE: Angiotensin Converting Inhibitor

ARAS: Atherosclerotic Renal Artery Stenosis

ASTRAL: Angioplasty and Stenting for Renal Artery Lesions

DARE: Database of Abstracts of Reviews of Effects

DBP: Diastolic Blood Pressure

DRASTIC: Dutch Renal Artery Stenosis Intervention Cooperative

HTN: Hypertension

PTA: Percutaneous Transluminal Angioplasty

PTAS: Percutaneous Transluminal Angioplasty with Stenting

PTRA: Percutaneous Transluminal Renal Angioplasty

RAS: Renal artery stenosis

SBP: Systolic Blood Pressure

STAR: Stenting in Renal Dysfunction Caused by Atherosclerotic Renal Artery Stenosis

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