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ACR–SIR PRACTICE PARAMETER FOR THE PERFORMANCE OF ANGIOGRAPHY, ANGIOPLASTY, AND STENTING FOR THE DIAGNOSIS AND TREATMENT OF RENAL ARTERY STENOSIS IN ADULTS

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care¹. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

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The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of this document is to assist practitioners in achieving this objective.

¹ *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing*, ___ N.W.2d ___ (Iowa 2013) Iowa Supreme Court refuses to find that the *ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures* (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, *Stanley v. McCarver*, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

This practice parameter was revised collaboratively by the American College of Radiology (ACR) and the Society of Interventional Radiology (SIR).

Hypertension (HTN) is a common problem, affecting 29.1% of the adult United States population [1]. If poorly controlled, HTN causes significant morbidity and mortality, with end-organ damage frequently affecting the kidneys, as well as the cerebrovascular and cardiovascular systems. Although HTN is most often essential, or idiopathic in origin, renovascular disease is an important and potentially remediable secondary cause of HTN and progressive renal insufficiency. The definition of renovascular hypertension (RVH) is still being elucidated, so the incidence of RVH varies in the literature from 0% to 29% with a weighted mean of 4% in an analysis of 8,899 patients in 12 studies [2]. The prevalence of RVH increases with age and coexisting atherosclerosis in other vascular beds.

Not all renal artery stenosis (RAS) is symptomatic, and the incidence of incidental renal artery atherosclerotic disease increases with age [3]. In an asymptomatic 65-year-old, the incidence of RAS is 2%, but in an elderly patient with cardiovascular disease, the prevalence may be as high as 40% [4,5]. Few patients with RAS, even many with severe HTN or chronic renal failure, will have RVH. Certain clinical scenarios may significantly increase the likelihood that HTN is truly RVH (eg, abrupt onset of HTN before the age of 30), but identifying RVH in an older population with a high prevalence of RAS is challenging [6]. Performing an effective vascular consultation for HTN, renal insufficiency, or incidental RAS requires an understanding of the physiology of renal vascular disease, the most appropriate screening examinations, and the indications for renal angiography. Renal vascular consultation also requires mastery of the indications, contraindications, outcomes, risks, and alternatives to endovascular renal vascular intervention.

This document reviews those circumstances that should prompt evaluation for RVH or renal ischemia. It also discusses both the noninvasive imaging and the angiographic evaluation of such patients. Practice parameters for the performance of renal artery angiography and percutaneous renal artery angioplasty and stenting (PTRAS) are reviewed, as well as considerations of what constitutes a successful intervention. Practice parameters for the training and ongoing credentialing of practitioners performing these interventions are also presented.

II. DEFINITIONS

For the purpose of this practice parameter, the following definitions apply:

Hypertension: HTN is defined by the 1999 World Health Organization's International Society of Hypertension Guidelines for the Management of Hypertension as "systolic blood pressure of 140 mm Hg or greater and/or a diastolic blood pressure of 90 mm Hg or greater in subjects who are not taking antihypertensive medication" [7]. The sixth report of The Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure defined HTN as "systolic blood pressure 140 mm Hg or greater, diastolic blood pressure 90 mm Hg or greater, or taking antihypertensive medication" [8].

Accelerated hypertension: Sudden worsening of previously controlled HTN, which may indicate the development of a secondary cause of HTN.

Resistant hypertension: HTN should be considered resistant if the systolic blood pressure (SBP) cannot be reduced to below 140/90 mm Hg in patients who are adhering to an adequate and appropriate triple-drug regimen that includes a diuretic, with all 3 drugs prescribed in near maximal doses. For patients older than age 60 with isolated systolic HTN, resistance is defined as failure of an adequate triple-drug regimen to reduce the SBP to below 160 mm Hg.

Cardiac disturbance syndrome: Recurrent “flash” pulmonary edema, not felt to be secondary to impaired cardiac function. This can be seen in the setting of bilateral RAS or unilateral stenosis of the renal artery to a solitary kidney [8-10].

Hypertensive crisis: According to AHA guidelines, “Hypertensive crises can present as hypertensive urgency or as a hypertensive emergency.”

Hypertensive urgency: SBP of 180 mm Hg or greater, or diastolic blood pressure of 100 mm Hg or greater. There may be associated headache, shortness of breath, nosebleeds, or anxiety.

Hypertensive emergency: Hypertensive urgency plus the coexistence of end-organ damage, which may include retinal hemorrhage, stroke, angina, myocardial infarction, aortic dissection, or pulmonary edema.

Malignant hypertension: HTN with end-organ damage including left ventricular hypertrophy (LVH), congestive heart failure (CHF), visual or neurologic disturbance, or advanced retinopathy.

Renal artery stenosis (RAS): Anatomic narrowing of the renal artery lumen diameter by 50% or greater, expressed in this practice parameter as a percentage of the diameter of a normal renal vessel, ie, % RAS = 100 x (1 – [the narrowed lumen diameter / the normal vessel diameter]).

Ostial renal artery stenosis: Anatomic narrowing within the proximal 5 mm of the artery. Lesions within 10 mm of the aorta may also be considered ostial, when atheromatous plaque increases the distance between the extra-aortic renal artery and the aortic lumen on cross-sectional imaging [11].

Truncal renal artery stenosis: Nonostial RAS occurring proximal to renal artery branching.

Renovascular hypertension: RVH is a secondary HTN due to activation of the renin-angiotensin system by a hemodynamically significant RAS [12].

Ischemic nephropathy (IN) –: Renal vascular compromise leading to decreased estimated glomerular filtration rate (eGFR) without evidence of a medical cause. There may or may not be evidence of decreasing renal mass.

Renal revascularization: Any procedure that restores unobstructed arterial blood flow to the kidney.

Technically successful endovascular renal revascularization: Less than 30% residual stenosis measured at the narrowest point of the vascular lumen and pressure gradient less than the selected threshold for intervention. In the presence of an angiographically visible dissection at the treatment site, the residual lumen is measured from the widest opacified lumen regardless of luminal dissections, knowing that the true lumen is difficult to measure accurately in this situation [13].

Clinical Success in the Endovascular Treatment of Renal Vascular Hypertension or Ischemia:

Cure: Restoration of blood pressure below 140/90 mm Hg and no longer taking antihypertensive medications. For renal insufficiency, a cure would be return of eGFR to normal baseline levels.

Partial response: Reduced blood pressure by 10 mm Hg systolic or diastolic on the same medications, or a comparable blood pressure on a reduced number or dose of medications after renal intervention. For renal insufficiency, improvement, or stabilization of eGFR is a partial response [14].

III. METHODS

The goal of the authors for this review was to produce a practice parameter for the indications, methods, and quality improvement measures for diagnostic angiography and arterial interventions in renal artery occlusive disease. A process for developing a systematic approach to guideline development was published by the Institute of Medicine in 2011 [15].

A Medline search was performed for English language articles published through February 2014 with the following keywords: renovascular hypertension, renal artery stent, renal artery stenosis, or renal artery angioplasty complications. Randomized trials in adult populations, except those relating to congenital or inherited disorders, were selected for review. In developing a consensus document, the authors also reviewed case series, case reports, and expert opinion titles for relevance in answering the following questions: indications for renal artery imaging and renal angiography, indications for percutaneous renal artery intervention, procedure techniques, patient management, outcomes of renal artery angioplasty and stenting, quality thresholds, qualifications for operators, and facilities required to safely perform these procedures. The quality of evidence and the strength of recommendation was assessed according to the GRADE system [16]. Those standards form the basis for the process used in creating this practice parameter. The level of evidence is defined as strong, moderate, weak, or very weak. The strength of the recommendation is categorized as strong or weak.

IV. INDICATIONS/CONTRAINDICATIONS FOR RENAL VASCULAR IMAGING OR ANGIOGRAPHY

Although recent randomized trials have raised doubts about the clinical efficacy of renal angioplasty and stenting for RAS, noninvasive imaging still has an important role in clinical diagnosis and management. Clinical features suggestive of RVH were first enumerated by the Cooperative Study of Renovascular Hypertension in 1972 [17] and have been regularly updated through the time of the American College of Cardiology guidelines in 2005 [18-22]. The indications for screening for RAS historically include the following:

- Onset of HTN before the age of 30, especially without a family history, or recent onset of significant HTN after the age of 55
- An abdominal bruit, particularly if it continues into diastole and is lateralized
- Accelerated or resistant HTN (RHTN)
- Recurrent (flash) pulmonary edema
- Renal failure of uncertain cause, especially with a normal urinary sediment and less than 1 gram of protein per daily urinary output
- Coexisting, diffuse atherosclerotic vascular disease, especially in heavy smokers
- Acute renal failure precipitated by antihypertensive therapy, particularly angiotensin-converting enzyme (ACE) inhibitors or angiotensin II receptor blockers
- Malignant HTN with a unilateral small kidney
- HTN associated with medication intolerance

As doubts about the clinical efficacy of renal artery intervention have evolved, the seventh report of the Joint National Committee (JNC 7) on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure published in 2004 more generally listed clinical signs of secondary HTN that may require further testing: young age, physical examination findings, RHTN, abnormal laboratory values, sudden onset of HTN, or worsening of previously well-controlled HTN [23]. The JNC 7 report recommends duplex ultrasound or MRA for evaluation of the renal arteries. Indications for renal vascular imaging have not been updated by the ACC or JNC since that time [24].

The ideal timing for imaging evaluation is not well defined. Any antihypertensive treatment regimen that effectively lowers blood pressure is associated with slowed progression of renal failure and improved cardiovascular survival [25]. Prior to referral for RAS imaging, appropriate diligence is needed in reviewing the blood pressure history and what medication combinations have been tried to control HTN [24]. In particular, the history of ACE inhibitor usage and clinical response to ACE inhibitors is used in determining if renal artery

imaging is needed. The use of ACE inhibitors or angiotensin receptor blockers (ARB) in the setting of a significant RAS may cause a decrease in renal function [26,27]. Renal artery imaging should be performed to exclude stenosis as the etiology of unexplained new renal failure associated with initiating ACE inhibitors or ARBs.

Diagnostic angiography remains the gold standard for identifying a RAS [28]. Angiography may be indicated, in the appropriate clinical setting, following the discovery of a RAS by noninvasive imaging, or in settings where RVH or ischemic nephropathy (IN) is suspected clinically but noninvasive imaging is equivocal. Renal angiography not only provides better quantification of the degree of stenosis, it provides an opportunity to determine the physiologic significance of a stenosis.

Although a stenosis results from pathology of the arterial wall, it is clinically important only when that process reduces the vessel lumen to the point of hemodynamic significance. Although a 50% diameter reduction is associated with hemodynamic significance, rising renin excretion is clinically the marker that suggests a RAS is potentially causing RVH [29]. Excess renin excretion probably only reliably occurs when the luminal diameter is reduced by 80% or more [30]. This number will vary depending on characteristics of the stenosis such as its length, irregularity, and multiplicity, the resistance of the distal vascular bed, and the available collateral blood supply [31,32].

The physiologic significance of a stenosis depends on the resistance of the peripheral renal vasculature or the condition of the renal autoregulatory system [33-35]. Doppler ultrasonography and nuclear renography may be useful in assessing the significance of a RAS, but the gold standard for measuring the physiologic significance of a stenosis is simultaneously measuring the gradient between the aortic pressure via a guiding catheter near the ostium and a pressure wire distal to the RAS [29,36,37]. The use of a low-profile pressure-sensing wire or microcatheter to obtain the measurement distal to the stenosis prevents false elevation of the gradient that could occur if a larger catheter were used, as this might obturate the stenosis.

Several standards have been proposed for determining hemodynamic significance, and there is no consensus as to whether an absolute systolic, peak systolic, or mean pressure should be used, whether the pressure should be measured during a resting or hyperemic state, or at what level the criterion for hemodynamic significance should be set. Different investigators have variously defined a significant pressure gradient as 10% of the systolic pressure, a 10, 15, or 20 mm Hg systolic pressure gradient, or a 10 mm mean gradient. Given the variable clinical response to renal angioplasty a more conservative approach to systolic gradients probably requires a systolic gradient of 20 mm Hg to be considered clinically significant (that which activates the renin-angiotensin system) [38]. Measurement of renin levels in humans with balloon inflation used to create variable stenoses revealed that a 10% mean-pressure gradient raises renin levels. The use of mean pressure is now a widely accepted measure of clinical significance [39]. Other authors have found that a dopamine-stimulated mean pressure compared to an unstimulated mean pressure gradient of 20 mm Hg indicates a significant gradient [40]. Extrapolating from the coronary literature, the determination of renal fractional flow reserve (FFR), following the intra-arterial administration of 30 mg papaverine, has also been shown to predict physiologic significance through measurements of renal vein renin levels better than systolic pressure gradients [29,41]. A FFR of 0.9 or less, which corresponds to a stimulated (hyperemic) systolic gradient of 21 mm Hg, is physiologically significant. Other tests that can lend support to the clinical significance of a RAS of borderline hemodynamic significance include intravascular ultrasound or selective renal vein renin sampling [32,42-45].

Prior to leaving the topic of the indications for renal angiography, it is worth discussing potential prerequisites for performing angiography. Additional laboratory testing that may be useful in determining whether or not to proceed to angiography include low urine protein levels, high plasma renin levels (which have low sensitivity and high specificity for response to renal revascularization), and elevated brain natriuretic peptide (BNP) [46]. Angiotensin II, a potent vasoconstrictor that stimulates cellular hypertrophy and proliferation, likely contributes to vascular and ventricular hypertrophy, accelerates atherosclerosis, and causes progressive glomerular sclerosis

independent of their hemodynamic effect [47]. Whenever possible, an ACE inhibitor or angiotensin-receptor blocker (ARB) should be part of the treatment of HTN associated with chronic kidney disease, since these drugs have been shown to be organ-protective beyond their antihypertensive effect in certain renal disease categories [24].

V. SUCCESS RATES FOR RENAL ARTERY INTERVENTION

Although a hemodynamically significant RAS may stimulate the renin-angiotensin system, resulting in systemic HTN or renal ischemia, there are other factors that may influence the clinical response to treating a RAS. The etiology of the stenosis and the age of the patient are important factors in determining clinical success. Additional factors that are important in older patients include the level of blood pressure control that can be attained medically, the patient's ability to tolerate and comply with the prescribed medical regimen, any impairment in renal function or evidence of progressive nephron loss, and comorbid medical conditions. Therefore, in most cases, the clinical significance of a RAS and the likelihood that the clinical syndrome can be improved should guide the decision to revascularize a kidney rather than the morphologic or hemodynamic characteristics of the renal artery stenotic lesion. The majority of patients with hemodynamically significant RAS associated with HTN or reduced renal function can be managed medically without a risk of increased mortality or progression to end-stage renal disease [25,48-50]. However, there are patient subpopulations in whom RAS may produce RVH, ischemic nephropathy (IN), or cardiac disturbance syndromes (ie, recurrent "flash" pulmonary edema not felt to be secondary to impaired left ventricular systolic function) and in whom intervention may therefore be helpful. Thus, the benefits of revascularization need to be individually determined based on the underlying clinical condition prompting intervention.

A. Clinical Success Following Renal Revascularization

1. Atherosclerotic renovascular disease and HTN

a. HTN in the patient with atherosclerotic RAS

Although a distinguishing advantage for revascularization compared with medical therapy alone is the potential for a HTN cure, only a small percentage of patients with atherosclerotic renal artery stenosis (ARAS) are reported as cured following revascularization [25,48-54]. The clinical profile of the atherosclerotic patient, who is most likely to be cured, has not been defined [17,55-63]. There are findings that may help determine the outcomes of renal revascularization for atherosclerotic RAS, including the severity of the RAS, if the RAS is unilateral or bilateral, the diameter of the narrowed vessels, location of the narrowing, if there is involvement of branch points, the patency of small arteries and arterioles distal to a RAS, the renal mass available for revascularization (usually a measurement of kidney length or cortical thickness), function of the involved kidney as demonstrated by nuclear scintigraphy, and the presence of intrinsic renal disease on the affected side (measured by duplex determinations of resistive index) [64-67]. Randomized controlled trials [25,48-50,52-54,68,69] and multiple case series [14,58,60,70] report that renal revascularization results in only modest decrease in doses of medications or blood pressure. More recent studies have focused on the risk of cardiovascular events in patients with possible RVH and have failed to demonstrate an advantage to renal stent placement [25,49]. Whether controlling blood pressure on less medication or a potential reduction in blood pressure on the same medications outweighs the risks of the procedure can still be considered on an individual patient basis [71-73]. Despite the findings of these randomized controlled trials, there may be patients with high blood pressure, refractory HTN, or severe bilateral RAS who will have a positive clinical response to revascularization [14,74]. In the following sections, the clinical evidence regarding revascularization is discussed for specific indications.

b. In the patient with Resistant hypertension

Although RHTN is uncommon, the incidence of RAS, by angiography, in RHTN is high (24.1%) [6]. True RHTN (excluding noncompliant patients and white-coat syndrome) involves only a small percentage of hypertensive patients [75], and the available randomized clinical trials have often been cited for underrepresenting this population. In 2000, van Jaarsveld et al published one of the first RCT focused on atherosclerotic resistant hypertension (RHTN). The study of 106 RHTN patients with RAS found no difference between medical management and balloon angioplasty [49]. The trial has been criticized for not including renal artery stents, but a meta-analysis of all of the RCT fails to demonstrate a benefit in RHTN. There are more recent case-controlled series indicating that a carefully selected population of patients with RHTN and hemodynamically significant stenosis respond favorably to angioplasty and stenting [38,74,76,77]. Although several RCT suggest that RHTN is not an indication for PTRAS, the study populations are potentially biased, and the incongruity between these randomized trial studies and multiple case series leave questions on this indication for revascularization [78]. The clinical efficacy of treating RHTN, particularly in the setting of severe, bilateral RAS, remains potentially unproven.

c. Renal revascularization in the setting of hypertensive crisis

The literature on renal revascularization in patients with a hypertensive crisis is limited [79]. The risks of stroke and access site complications are higher if blood pressure is not well controlled. There is general agreement that blood pressure must be well controlled, with intravenous medications if necessary, prior to angiography. On the other hand, patients with severe HTN requiring hospitalization should be considered for intervention.

2. HTN in the patient with fibromuscular RAS

There is strong evidence that HTN that is associated with hemodynamically significant renal artery fibromuscular dysplasia (FMD) is an indication for angiography and percutaneous transluminal renal angioplasty (PTRAS) [80,81]. The mean cure rate in this population, following renal revascularization, is 44% to 46% in meta-analysis [70,81]. Using logistic regression, Davidson et al found that younger age, milder severity, and shorter duration of HTN were statistically significant independent variables predicting a cure following PTRAS in FMD [82]. The type of FMD may be important in predicting technical success and clinical response. Medial type affects 60% to 70% of patients with FMD [83]. Medial fibroplastic disease is similarly the most commonly reported type of FMD treated with angioplasty. The rate of cure of renovascular HTN due to the medial fibroplastic type of FMD is sufficiently high to recommend PTRAS as a first-line of treatment.

FMD most often involves the distal main and branch renal arteries. Fortunately, the technical and clinical response of FMD involving renal artery branches to angioplasty is as good as in cases in which FMD is limited to the main renal artery [84,85]. The operator must understand that treatment should not be limited to main renal artery lesions, as the best chance for a cure is achieved when all of the hemodynamically significant lesions are treated.

Renal artery FMD can be found by CT angiography (CTA) in 2.6% of potential kidney donors [86]. There is a strong association between renal FMD and carotid FMD, so a thorough screening, usually with CTA, is recommended whenever renal FMD is diagnosed. FMD can also be found in 7.3% of first-degree or second-degree relatives, so consulting with the family is an important part of the evaluation process in patients with FMD [87].

3. Renal artery dissection

Spontaneous, isolated, renal artery dissection may be detected as part of a hypertensive or renal failure evaluation. It may also be first detected due to new flank pain or hematuria. It is often idiopathic but is often associated with HTN, FMD, and connective tissue disease. Acute dissection may cause new or accelerated HTN, renal failure, or flank pain. A case series of patients with acute symptomatic idiopathic renal artery dissection (no connective tissue disorders or other associated pathology) demonstrated clinical benefit to intervention [88].

4. Atherosclerotic renal artery disease and ischemic nephropathy

There is ongoing controversy concerning the degree of benefit that can be expected from revascularization of the patient with ischemic nephropathy. It is well recognized that there is progressive nephron loss with aging. The loss is accelerated by many disease states, including ischemic nephropathy where, in addition to the loss of nephron tissue, there can be functional loss resulting from hypoperfusion and loss of renal autoregulation secondary to RAS. Measurement of eGFR remains the best measure of functional outcomes [89]. The slope of the linear relationship between the reciprocal of creatinine concentration (a surrogate for the calculation of glomerular filtration rate, eGFR) and time can be used to delineate the rate of change in renal function [90]. If the slope of this curve can be altered with PTRAS, then the consequences of CRF (chronic renal failure) and renal replacement therapy may be deferred. Altering the progression along the slope of decline in renal function may indicate a benefit from intervention despite a lack of improvement in baseline serum creatinine.

Several case series of renal revascularization for ischemic nephropathy have demonstrated statistically significant improvement in renal function at follow-up [91-93]. On the other hand, in 3 recent prospective randomized studies of renal revascularization, no improvement in renal function was reported [25,49,54]. However, other markers including baseline kidney size and resistive indices were not included in these trials [94,95]. There are 3 indications that continue to be debated regarding renal revascularization for ischemia: acute renal failure, renal failure associated with prior artery manipulations, and renal angioplasty for preservation of renal mass.

a. Acute ischemic nephropathy

Although all the RCT of ischemic nephropathy failed to demonstrate clinical benefit to revascularization, these trials enrolled patients with chronic renal insufficiency [25,48,49,54]. Renal revascularization can result in improvement of GFR in selected patients with acute ischemic nephropathy [74,96]. Signs that a patient with acute ischemic nephropathy is likely to benefit from revascularization include 1) normal appearance of the arterioles distal to the RAS; 2) bilateral severe RAS; 3) a near-normal volume of renal mass available for revascularization; 4) renogram demonstrating adequate function of the involved kidney; 5) renal biopsy demonstrating well-preserved glomeruli and tubules with minimal arteriolar sclerosis; 6) severe, difficult to control HTN; 7) abrupt onset of renal insufficiency [48,50,66,67,74,97,98]; and 8) renal artery fractional flow reserve over 0.80 [99]. Delay in revascularization has been associated with a reduction in clinical benefit [17].

b. Renal failure associated with prior arterial interventions

None of the randomized trials of renal artery interventions for chronic renal failure address the management of patients with prior renal artery interventions. Acute renal failure in the setting of RAS related to prior renal artery bypass, aortic endograft encroachment, or prior renal artery stent placement should be treated aggressively [100-102]. In these clinical scenarios, there is often a significant temporal relationship between serial imaging changes and deterioration in renal function that indicates a strong association between recurrent RAS and renal failure. This recommendation for

treatment is also based on the natural history of rapid progression to renal artery occlusion in previously treated renal arteries [103-105].

c. Prophylactic treatment for renal mass preservation

There is no known benefit to prophylactic treatment to preserve renal mass [106]. Nevertheless, it is recommended that renal mass and function be followed in the setting of severe RAS. This is especially true for patients with either bilateral severe RAS or a severe stenosis of the renal artery supplying a solitary kidney, as there is twice the risk of mortality and 1.5 times the risk of significant deterioration of renal function as compared with patients who have a unilateral RAS and 2 kidneys [107]. Patients should also be followed for changing or emerging clinical indicators that may prompt a re-evaluation of the need for renal revascularization (eg, precipitant heart failure or sudden loss of renal function without medical explanation).

5. Cardiac disturbance syndromes

Renal artery stenosis may worsen angina or congestive heart failure in patients with coronary artery disease, left ventricular dysfunction, or cardiomyopathy as a result of complex pathophysiologic alterations such as changes in the renin-angiotensin axis that lead to volume overload and peripheral arterial vasoconstriction [9,108-110]. Renal revascularization may relieve these cardiac syndromes, particularly in patients with bilateral RAS [10,74,109,111,112]. Over 70% of patients remain free of congestive heart failure and unstable angina at 12-month mean follow-up after PTRAS [9,10]. In particular, there are multiple case series suggesting that PTRAS in the setting of flash pulmonary edema may be beneficial [74,78,113-115]. Restoring unobstructed renal blood flow has the additional potential benefit of allowing safe usage of ACE inhibitors without the risk of worsening renal failure.

6. Prevention of cardiovascular mortality

The most recent RCTs indicate renal revascularization does not reduce the risk of cardiovascular mortality [25].

7. Summary

There is no consensus on the indications for renal intervention in the general population with atherosclerotic RAS with HTN or renal ischemia. There are several important subpopulations that will need further clinical investigation before global recommendations can be made regarding renal intervention eg, patients with hemodynamically significant atherosclerotic stenosis (as determined by a minimum 10% mean translesion pressure gradient) and poorly controlled HTN, global ischemia with renal insufficiency, and/or cardiac disturbance syndromes. The following table lists common indications for PTRAS, evidence-based management recommendations, and the level of evidence to support that recommendation.

Table 1

Indication For RAS Intervention	Renal Angioplasty Treatment	Quality of Evidence [16]	Strength of Recommendation
HTN with atherosclerotic renal artery stenosis (ARAS)	Medical therapy is equivalent to PTRAS [25,49,50,52]	High	Strong
RHTN with hemodynamically significant bilateral ARAS	PTRAS may be of benefit, particularly in young patients [74]	Low	Weak
HTN crisis with hemodynamically significant ARAS	PTRAS may be of benefit	Low	Weak
HTN with fibromuscular dysplasia	PTRA (avoid stent) is indicated	Moderate	Strong
Symptomatic renal artery dissection	PTRAS may be of benefit [88]	Moderate	Strong
Chronic renal failure with ARAS	Medical therapy is equivalent to PTRAS [25,48,54,80,81,87,116,117]	High	Strong
Acute renal failure with hemodynamically significant bilateral ARAS and low resistive index	PTRAS may be of benefit [74,96]	Low	Weak
Renal failure with prior intervention (in-stent stenosis, endograft, or open surgery)	Repeat intervention may be beneficial [102]	Very Low	Weak
Renal mass preservation with ARAS	Medical therapy preferred (PTRAS not indicated) [25,48,54]	Moderate	Strong
Cardiac disturbance syndromes with ARAS	PTRAS may be beneficial in flash pulmonary edema [74,111,113-115]	Low	Weak
Prevention of cardiovascular mortality with ARAS	Medical therapy is equivalent to PTRAS [25]	High	Strong

The technical success rates, long-term patency, and complications also must factor into the decision to proceed with revascularization.

B. Technical Success and Long-Term Patency of Renal Revascularization Procedures

Intravascular stent placement is the standard of care for revascularization of atherosclerotic ostial RAS [14,25]. Stents dilated to less than 6 mm, female sex, age greater than 65 years, and smoking are statistically significant risk factors for restenosis [118,119]. In the U.S. Multicenter Renal Artery Stent Trial, the lowest risk group was men with renal arteries 6 mm or greater, in whom there was a restenosis rate of 10.5%. There are very little data regarding stent use in nonostial RAS; however, there are studies suggesting that these lesions may respond favorably to balloon angioplasty alone [120]. Stent fracture is associated with early restenosis [104]. Increased technical success and improved long-term patency would be expected if the reference vessel diameter is 6 mm or greater. The evidence for the use of drug-eluting stents (DES) is limited, but there does appear to be enough evidence of early restenosis in accessory arteries that balloon PTA alone or DES are preferred to conventional bare-metal stents for small arteries [121-123]. There is an ongoing investigation on the use of covered stents. At present, their use as a first-line device cannot be recommended, although there is mounting evidence that they are appropriate for the management of in-stent stenosis (ISS).

Not all stent placements allow an opportunity for repeat intervention and assisted patency. The use of stents in ostial and nonostial locations is relatively contraindicated if the stent traverses renal artery branches or if restenosis would likely make surgical revascularization difficult or impossible.

Long-term stent patency and clinical outcomes in most trials include noninvasive monitoring of the stent. Follow-up of stents placed for atherosclerosis should include regular duplex ultrasound which, with appropriate baseline evaluation, provides a highly sensitive marker of ISS [124,125]. CTA has limited use in follow-up after renal artery stent placement [126,127].

Repeat intervention for ISS has twice the failure rate than primary stent placement (20% versus 11%; P=0.003) [105]. The methods for management of ISS are varied and include PTA, PTRAS, atherectomy, brachytherapy, and DES placement [128-130].

Technical success for treatment of renal FMD should be 95% or greater. There is increasing emphasis on measures of technical success other than angiographic appearance for FMD. Pressure-wire manometry and intravascular ultrasound should be available and their use considered when treating FMD. Appropriate treatment of FMD includes dilatation of the entire diseased segment, even if it involves a branch point. The operator must be comfortable with the use of dual-wire access and kissing balloons. If a satisfactory technical result is achieved, the long-term patency of the treated segment should be nearly 100%. Renal artery stents have no role in the primary treatment of fibromuscular dysplasia. Stents may be indicated in technical failures due to vessel dissection, but the remodeling capabilities of a post-PTA renal artery with mild dissection should not be underestimated by the operator.

VI. COMPLICATIONS – RISKS OF ENDOVASCULAR VASCULARIZATION

The rates of complications related to endovascular renal artery revascularization have shown improvement over time.

There are 2 large series [131,132] and 2 meta-analyses [60,85] in which there is no overlap of data among these studies, that provide complication data on 2,994 revascularizations (980 stented vessels in 2,474 patients). The total complication rate ranged from 12% [60] to 36% [132], with a mean complication rate of 14% excluding events that occur during catheterization or stent deployment that have no clinical consequences but lead to an increase in procedural time or cost [132]. Groin hematoma and puncture site trauma were the most common complications reported, with a rate of approximately 3% to 5%. Major complications (and their incidence rates) include worsening of renal function (4%), occlusion of the renal artery (2% to 3%), segmental infarction (1% to 2%), requirement for surgical intervention for either nephrectomy or salvage (2%), and death (1%). Thirty-day mortality was 1%, usually related to renal artery perforation, cholesterol embolization, acute renal failure, and arterial access puncture above the inguinal ligament. A surgical salvage operation was necessary in 1% to 2.5% [60,85]. Symptomatic embolization occurred in 1% to 8% of the patients [60,132]. Occlusion of the main renal artery was reported in 0.8% to 2.5% and occlusion of a renal artery branch causing a segmental infarction in 1.1% to 1.7% [60,85].

Operator experience is important in minimizing the complication rate. A trend toward reduced complications was demonstrated in an earlier investigation by Martin et al, which found that the total complication rate fell from 20% in the first hundred cases to 13% in the second hundred cases. The authors attributed the change to increased experience and improvement in technology and devices [133].

Cholesterol embolization resulting in decreased renal function or visceral or peripheral symptoms is expected in less than 3% of cases [60,85,131,132]. A “no-touch” technique of positioning a guide catheter in the renal ostium with a second wire extending to the suprarenal aorta may potentially reduce cholesterol embolization, but the technique is unsubstantiated [134]. The rate of cholesterol embolization may be related to the clinical outcomes of renal stent placement for renal ischemia. The postprocedural worsening of renal function that occurs in roughly one-third of renal artery stents placed for renal insufficiency may be related to distal micro-emboli. The use of a distal embolic protection device may reduce cholesterol embolization rates, and this may reduce the incidence of postprocedural worsening of renal function [135-138]. There is some evidence that antiplatelet therapy and distal embolic protection may further reduce the risk of worsening renal failure after renal artery stent placement for renal ischemia [135,139]. However, the routine use of distal protection has not been proven to be of benefit in reducing renal failure or in preserving renal mass, so is not a practice parameter recommendation.

A thorough understanding of both the appropriate medical management of RVH and the natural history of the disease without revascularization is essential in providing consultation on the risks and benefits of endovascular

therapy. The long-term effects of poorly controlled HTN or progressive renal insufficiency are the most important sequelae that should be considered if a stenotic renal artery is not revascularized in a case of apparent RVH [140]. The long-term risk of a missed opportunity to revascularize the kidney because a stenosis progressed to an occlusion appears to be small [141,142].

VII. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

The physician performing renal angioplasty/stenting must have a broad perspective on the benefits, alternatives, and risks of the procedure. He or she must have a thorough understanding of renal vascular physiology, medical management of HTN and renal ischemia, vascular anatomy (including congenital and developmental variants and common collateral pathways), angiographic equipment, radiation safety considerations, and physiologic monitoring equipment. The physician must have access to and familiarity with an adequate supply of diagnostic catheters, guiding-catheters guide sheaths and guidewires. The physician must also have awareness of the skills and numbers of ancillary personnel to perform the procedure safely.

Renal angioplasty/stenting procedures must be performed under the supervision of and interpreted by a physician who has the following qualifications pertinent to the scope of services to be provided and the specific privileges sought:

1. Certification in radiology or diagnostic radiology by the American Board of Radiology (ABR), the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or the Collège des Médecins du Québec and has performed (with supervision) a sufficient number of renal angioplasty/stenting procedures to demonstrate competency as attested by the supervising physician(s).
or
2. Completion of a radiology residency training program and/or interventional/vascular radiology fellowship approved by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada (RCPSC), the Collège des Médecins du Québec, or the American Osteopathic Association (AOA), and has performed (with supervision) a sufficient number of renal angioplasty/stenting procedures to demonstrate competency as attested by the supervising physician(s).
or
3. Completion of an ACGME-approved nonradiology residency or fellowship training and a minimum of 12 months of training on a service that is primarily responsible for performing percutaneous peripheral, visceral, or neurodiagnostic arteriography and vascular/interventional radiology. Documented formal training in the performance of invasive catheter arteriographic procedures must be included. During this training the physician should have performed the following procedures:
 - a. Meets the requirements of the [ACR–SIR–SPR Practice Parameter for the Performance of Arteriography](#) [143]. At least 10 of the cases performed should be renal arteriograms.
and
 - b. Performance of at least 30 successful systemic (eg, noncardiac and non-neurologic) arterial interventions as the primary operator, with acceptable complication rates as defined in section V of this document. At least 10 of these should be renal angioplasty or stenting (bilateral may count as 2 cases).
4. Physicians meeting any of the qualifications in 1, 2, and 3 above must also have written substantiation that they are familiar with all of the following:
 - a. Indications and contraindications for the procedure
 - b. Periprocedural and intraprocedural assessment, monitoring, and management of the patient and potential complications
 - c. Where applicable, pharmacology of moderate sedation medications and recognition and treatment of adverse reactions and complications
 - d. Fluoroscopic and radiographic equipment, mechanical injectors, digital image capture devices, digital subtraction systems, and other electronic imaging systems
 - e. Where applicable, principles of radiation protection, the hazards of radiation, and radiation monitoring requirements as they apply to both patients and personnel

- f. Where applicable, pharmacology of contrast agents and recognition and treatment of potential adverse reactions
- g. Percutaneous needle and catheter introduction techniques
- h. Technical aspects of performing the procedure, including the use of alternative catheter and guidewire systems, selective angiographic methods, appropriate injection rates and volumes of contrast media, and filming sequences
- i. Recognition of periprocedural complications and knowledge of treatment options for these complications (eg, stenting, embolization, thrombolysis, suction embolectomy, surgery)
- j. Anatomy, physiology, and pathophysiology of peripheral and visceral arterial vasculature
- k. Interpretation of peripheral and visceral arteriographic studies

The written substantiation should come from the chief of interventional radiology, director or chief of body imaging or ultrasound, or the chair of the department of the institution in which the physician will be providing these services. Substantiation could also come from a prior institution in which the physician provided the services, but only at the discretion of the current interventional director or chair who solicits the additional input.

Maintenance of Competence

Physicians must perform a sufficient number of procedures to maintain their skills, with acceptable success and complication rates as laid out in this practice parameter. Continued competence should depend on participation in a quality improvement program that monitors these rates.

Continuing Medical Education

The physician's continuing education should be in accordance with the [ACR Practice Parameter for Continuing Medical Education \(CME\)](#) [144].

B. Qualified Medical Physicist

For qualifications of the Qualified Medical Physicist, see the [ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Fluoroscopic Equipment](#) [145].

C. Registered Radiologist Assistant

A registered radiologist assistant is an advanced level radiographer who is certified and registered as a radiologist assistant by the American Registry of Radiologic Technologists (ARRT) after having successfully completed an advanced academic program encompassing an ACR/ASRT (American Society of Radiologic Technologists) radiologist assistant curriculum and a radiologist-directed clinical preceptorship. Under radiologist supervision, the radiologist assistant may perform patient assessment, patient management and selected examinations as delineated in the Joint Policy Statement of the ACR and the ASRT titled "Radiologist Assistant: Roles and Responsibilities" and as allowed by state law. The radiologist assistant transmits to the supervising radiologists those observations that have a bearing on diagnosis. Performance of diagnostic interpretations remains outside the scope of practice of the radiologist assistant. (ACR Resolution 34, adopted in 2006)

D. Radiologic Technologist

1. The technologist, together with the physician and nursing personnel, should have responsibility for patient comfort and safety. The technologist should be able to prepare and position² the patient for the procedure and, together with the nurse, monitor the patient during the procedure. The technologist should obtain the imaging data in a manner prescribed by the supervising physician. If intravenous contrast material is to be administered, qualifications for technologists performing intravenous injection should be in compliance with the current ACR policy³ and existing operating procedures or manuals at the facility. The technologist should also perform the regular quality control testing of the equipment under supervision of the physicist.
2. Technologists should be certified by the ARRT or have an unrestricted state license with documented training and experience in the imaging modality used for the imaging-guided percutaneous procedure.

E. Nursing Services

Nursing services are an integral part of the team for preprocedure and postprocedure patient management and education and are recommended in monitoring the patient during and after the procedure.

F. Other Licensed Independent Practitioner

Licensed independent practitioners may be involved in renal artery angioplasty and stenting procedures in accordance with their societal and local regulatory scope of practice under the supervision of the physician operator. Typically they will be involved with patient preparation, patient monitoring, and patient education, and in some cases they may serve as “scrub” assistants.

VIII. SPECIFICATIONS OF THE EXAMINATION

There are several technical requirements that are necessary in order to ensure safe and successful renal angiography, angioplasty, and stenting. These include adequate arteriographic equipment and institutional facilities, physiologic monitoring equipment, and support personnel. These recommendations are adapted from the CORAL trial [86] and the Intersociety paper on optimum resources for endovascular treatment [146].

A. Angiographic Equipment and Facilities

The following are considered the minimum equipment requirements for performing renal procedures. In planning facilities for these procedures, equipment and facilities more advanced than those outlined below may be desired in order to produce higher quality studies with reduced risk and examination time. The facility should include the following, at a minimum:

1. A high-resolution image receptor (preferably with a 28-cm to 40-cm field of view) and imaging chain with dose-reducing capabilities, such as pulsed fluoroscopy and last-image-hold capabilities, are recommended. Digital subtraction angiographic (DSA) systems with high spatial resolution are strongly recommended, as they allow for reduced volumes of contrast material, reduced examination times, and avoidance of complications related to the use of low radiopacity stents. In accordance with the as low as reasonably achievable (ALARA) principle, a radiation dose measurement package to provide operator and patient feedback is recommended.

²The American College of Radiology approves of the practice of certified and/or licensed radiologic technologists performing fluoroscopy in a facility or department as a positioning or localizing procedure only, and then only if monitored by a supervising physician who is personally and immediately available*. There must be a written policy or process for the positioning or localizing procedure that is approved by the medical director of the facility or department/service and that includes written authority or policies and processes for designating radiologic technologists who may perform such procedures. (1987, 1997, 2007 - ACR Resolution 12-m)

*For the purposes of this parameter, “personally and immediately available” is defined in the manner of the “personal supervision” provision of CMS—a physician must be in attendance in the room during the performance of the procedure. (Program Memorandum Carriers, DHHS, HCFA, Transmittal B-01-28, April 19, 2001)

³ See the [ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media](#).

2. Adequate angiographic supplies such as catheters, guidewires, stents, balloons, needles, and introducer sheaths. In particular, pressure wires are advisable in order to provide objective evidence of hemodynamic significance in cases of angiographically equivocal stenoses.
3. An angiographic injector capable of varying injection volumes and rates with appropriate safety mechanisms to prevent over-injection.
4. An angiography suite large enough to allow easy transfer of the patient from the bed to the table and to allow room for the procedure table, monitoring equipment, and other hardware such as intravenous pumps, respirators, anesthesia equipment, and oxygen tanks. Ideally, there should be adequate space for the operating team to work unencumbered on either side of the patient and for the circulation of other technical staff in the room without contaminating the sterile conditions.
5. An area within the institution appropriate for patient preparation prior to the procedure and for observation of patients after the procedure. At this location, there should be personnel to provide care as outlined in the Patient Care section below, and there should be immediate access to emergency resuscitation equipment.

B. Physiologic Monitoring and Resuscitation Equipment

1. Equipment should be present in the angiography suite to allow for monitoring the patient's heart rate, cardiac rhythm, and blood pressure. For facilities using moderate sedation, a pulse oximeter or an end-tidal carbon dioxide monitor should be available. (See the [ACR–SIR Practice Parameter for Sedation/Analgesia](#) [147].)
2. Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications and/or procedural complications. The equipment should be monitored and medications inventoried for drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages or sizes in the patient population.
3. Equipment for invasive pressure monitoring

C. Support Personnel

1. Radiologic technologists properly trained in the use of the diagnostic imaging equipment should assist in performing and imaging the procedure. They should demonstrate appropriate knowledge of patient positioning, arteriographic image recording, angiographic contrast injectors, adjunctive supplies, and the physiologic monitoring equipment. Certification as a vascular and interventional radiologic technologist is one measure of appropriate training. The technologists should be trained in basic cardiopulmonary resuscitation and in the function of the resuscitation equipment.
2. If the patient does not receive moderate sedation, one of the staff assisting in the procedure should be assigned to periodically assess the patient's status. In cases where moderate sedation is used or the patient is critically ill, an experienced licensed provider should be present whose sole responsibility is monitoring of the patient's vital signs, sedation state, and level of comfort/pain. This person should maintain a record of the patient's vital signs, time and dose of medications given, and other pertinent information. Nursing personnel should be qualified to administer moderate sedation. (See the [ACR–SIR Practice Parameter for Sedation/Analgesia](#) [147].)

3. For unstable patients, additional support may be necessary to ensure the safe performance of renal interventional procedures. The primary operator may be engaged in the details of the renal interventional procedures. Therefore, appropriate personnel should be available to attend to the ongoing care and resuscitation of the critically ill patients. Such personnel might include anesthesiologists; operating room, ICU, and/or ER trained nurses; or other physicians. The nurses may be radiology nurses and/or the same personnel responsible for monitoring and maintaining moderate sedation as discussed immediately above. Alternatively, the nurses may be supplied from other patient care units in the facility.

All such additional personnel should work in concert with and under the overall supervision of the primary operator performing the renal interventional procedures, but within the scopes of service as defined by their professions, state regulations, and institutional guidelines.

D. Acute Care Support

Although surgical or other emergency treatment is needed infrequently for serious complications after renal interventional procedures, there should be prompt access to surgical and interventional equipment and specialists familiar with the management of patients with complications in the unlikely event of a life-threatening complication.

E. Patient Care

1. Preprocedure care
 - a. The physician performing the procedure must have knowledge of the following:
 - i. Clinically significant history, including indications for the procedure
 - ii. Clinically significant physical or diagnostic examination, including knowledge and awareness of other clinical or medical conditions that may necessitate specific care, such as preprocedure antibiotics and other measures
 - iii. Possible alternative methods, such as surgical or medical treatments, to obtain the desired therapeutic result
 - b. Informed consent must be in compliance with all state laws and the [ACR–SIR Practice Parameter on Informed Consent for Image Guided Procedures](#) [148].
2. Procedural care
 - a. Adherence to the Joint Commission’s Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ is required for procedures in nonoperating room settings including bedside procedures. The organization should have processes and systems in place for reconciling differences in staff responses during the “time out.”
 - b. The physician performing fluoroscopy should have knowledge of exposure factors, fluoroscopic pulse rate, magnification factor, and fluoroscopic dose rate, and should consider additional parameters such as collimation, field of view, distance from the patient to the image receptor, and last image-hold.
 - c. Nursing personnel, technologists, and those directly involved in the care of patients undergoing renal interventional procedures should have protocols for use in standardizing care. These should include, but are not limited to, the following:
 - i. Equipment needed for the procedure
 - ii. Patient monitoring

Protocols should be reviewed and updated periodically.

During the use of fluoroscopy, the physician should use exposure factors consistent with the ALARA radiation safety guidelines.

3. Postprocedure care
 - a. A procedure note should be entered in the patient’s chart summarizing the major findings of the study and any immediate complications. This note may be brief if a formal report will be available within a few hours. However, if the formal report is not likely to be available on the same day, a more detailed

summary of the study should be entered in the chart at the conclusion of the procedure. In all cases, pertinent findings should be communicated to the referring physician in a timely manner.

- b. All patients should be at bed rest and observed in the initial postprocedure period. The length of this period of bed rest will depend on the patient's medical condition. Orthostasis and even hypotension can be encountered after renal artery revascularization.
- c. During the initial postprocedure period, skilled nurses or other appropriately trained personnel should periodically monitor the puncture site and the status of the patient.
- d. The patient should be monitored for urinary output, cardiac symptoms, pain, changes in blood pressure, and other indicators of systemic complications that may necessitate overnight care.
- e. The operating physician or a qualified designee should evaluate the patient after the procedure, and these findings should be summarized in a progress note. If moderate sedation was administered prior to and during the procedure, recovery from the sedation must be documented. The physician or designee should be available for continuing care during hospitalization and after discharge. The designee may be another physician or a nurse.

IX. DOCUMENTATION

Documentation should be in accordance with the [ACR–SIR Practice Parameter for Reporting and Archiving of Interventional Radiology Procedures](#) [149].

X. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, registered radiologist assistants, radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, “as low as reasonably achievable” (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel that work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection and application of dose limits) and the principles of proper management of radiation dose to patients (justification, optimization and the use of dose reference levels) http://www-pub.iaea.org/MTCDD/Publications/PDF/Pub1578_web-57265295.pdf.

Nationally developed guidelines, such as the ACR's [Appropriateness Criteria](#)[®], should be used to help choose the most appropriate imaging procedures to prevent unwarranted radiation exposure.

Facilities should have and adhere to policies and procedures that require varying ionizing radiation examination protocols (plain radiography, fluoroscopy, interventional radiology, CT) to take into account patient body habitus (such as patient dimensions, weight, or body mass index) to optimize the relationship between minimal radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used whenever appropriate. If such technology is not available, appropriate manual techniques should be used.

Additional information regarding patient radiation safety in imaging is available at the Image Gently[®] for children (www.imagegently.org) and Image Wisely[®] for adults (www.imagewisely.org) websites. These advocacy and awareness campaigns provide free educational materials for all stakeholders involved in imaging (patients, technologists, referring providers, medical physicists, and radiologists).

Radiation exposures or other dose indices should be measured and patient radiation dose estimated for representative examinations and types of patients by a Qualified Medical Physicist in accordance with the applicable ACR technical standards. Regular auditing of patient dose indices should be performed by comparing the facility's dose information with national benchmarks, such as the ACR Dose Index Registry, the NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for

the United States or the Conference of Radiation Control Program Director's National Evaluation of X-ray Trends. (ACR Resolution 17 adopted in 2006 – revised in 2009, 2013, Resolution 52).

XI. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR website (<http://www.acr.org/guidelines>).

These practice parameters are to be used in quality improvement (QI) programs to assess the diagnosis and treatment of RAS. The most important processes of care are 1) patient selection, 2) performance of the procedure, and 3) monitoring the patient. The outcome measures or indicators for these processes are indications, success rates, and complication rates. Outcome measures are assigned threshold levels.

Participation by the radiologist in patient follow-up is an integral part of the evaluation and treatment of RAS and will increase the success rate of the procedure.

Although practicing physicians should strive to achieve perfect outcomes (eg, 100% success, 0% complications), in practice all physicians will fall short of this ideal to a variable extent. Thus, indicator thresholds may be used to assess the efficacy of ongoing quality improvement programs. For the purposes of these practice parameters, a threshold is a specific level of an indicator that should prompt a review. Procedure thresholds or overall thresholds refer to a group of indicators for a procedure, eg, major complications. Individual complications may also be associated with complication-specific thresholds.

When measures such as indications or success rates fall below a minimum threshold, or when complication rates exceed a maximum threshold, a review should be performed to determine causes and to implement changes, if necessary. For example, if the incidence of symptomatic cholesterol embolization of the kidney is one measure of the quality of renal angioplasty or stenting of RAS, then values in excess of the defined threshold 6% should trigger a review of policies and procedures within the department to determine the causes and to implement changes to lower the incidence of the complication.

Thresholds for imaging and angiography have become less clear for atherosclerosis. Table 1 provides qualitative appropriateness criteria. However, technical success and complication thresholds have been well defined. In addition, the appropriate indications for performing angiography in the setting of FMD remain well defined as listed below:

- A. Indications for Angioplasty in FMD (Threshold – 95%)
 - 1. An angiographic appearance of a hemodynamically significant RAS
 - 2. A hemodynamically significant stenosis as determined by:
 - A 10% mean pressure gradient across the RAS or
 - A dopamine stimulation-induced 20 mm Hg mean pressure gradient with dopamine stimulation across the RAS
- B. Indications for Angioplasty and Stenting in ASVD (atherosclerotic vascular disease)
 - 1. Greater than 50% diameter stenosis or greater than 75% reduction in cross-sectional area
 - 2. A hemodynamically significant stenosis as determined by:
 - A 10% mean pressure gradient across the RAS or
 - A dopamine stimulation-induced 20 mm Hg mean pressure gradient across the RAS
- C. Relative Contraindications for Renal Artery Stent Deployment (Threshold – 5%)
 - 1. Angioplasty for FMD should not require the use of stents unless used to treat a flow-limiting complication of angioplasty.

2. An atherosclerotic renal bifurcation lesion where more than 50% of a kidney will be jailed by a stent
2. The presence of sepsis
3. Renal artery measuring 4 mm or less; Use of drug eluting stents in these instances may prove to be useful [123].

D. Technical Success of Percutaneous Renal Revascularization (Threshold – 90%)

1. Defined by minimal thresholds of <30% residual diameter stenosis or <10 mm Hg systolic gradient
2. Early bifurcation lesions are excluded from this analysis.

E. Complications

Complications are stratified on the basis of outcome. Major complications result in admission to a hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, prolonged hospitalization, permanent adverse sequelae, or death. Minor complications result in no sequelae; they may require nominal therapy or a short hospital stay for observation (generally overnight). See Appendix A.

The complication rates and thresholds below refer to major complications.

Specific Major Complications From Percutaneous Renal Revascularization

	<u>Reported Rate</u>	<u>Threshold</u>
30-day mortality	1%	1%
Secondary nephrectomy	<1%	1%
Surgical salvage operation	1%	2%
Symptomatic embolization	3%	3%
Main renal artery occlusion	2%	2%
Branch renal artery occlusion	2%	2%
Access site hematoma requiring surgery, transfusion, or prolonged hospital stay	5%	5%
Acute renal failure	2%	2%
Worsening of chronic renal failure requiring an increase in the level of care	2%	5%

Overall threshold for major complications from percutaneous renal revascularization – 14%

Published rates for individual types of complications are highly dependent on patient selection and are based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. Generally, the complication-specific thresholds should be set higher than the complication-specific reported rates listed above. It is also recognized that a single complication can cause a rate to cross above a complication-specific threshold when the complication occurs within a small patient volume (eg, early in a quality improvement program). In this situation, the overall procedure threshold is more appropriate for use in a quality-improvement program. In the above table, all values were supported by the weight of literature evidence and panel consensus.

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APPENDIX A

Society of Interventional Radiology Standards of Practice Committee

Classification of Complications by Outcome

Minor Complications

- A. No therapy, no consequence
- B. Nominal therapy, no consequence; includes overnight admission for observation only

Major Complications

- C. Require therapy, minor hospitalization (<48 hours)
- D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours)
- E. Permanent adverse sequelae

*Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised, or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

Development Chronology for this Practice Parameter

2004 (Resolution 26)
Amended 2006 (Resolution 16g, 17, 34, 35, 36)
Amended 2007 (Resolution 12m, 38)
Revised 2009 (Resolution 26)
Amended 2014 (Resolution 39)
Revised 2015 (Resolution 22)