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PRACTICE GUIDELINE FOR THE PERFORMANCE OF ANGIOGRAPHY, ANGIOPLASTY, AND STENTING FOR THE DIAGNOSIS AND TREATMENT OF RENAL ARTERY STENOSIS IN ADULTS

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

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 these guidelines 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 these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

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

Hypertension is a common problem, estimated to affect approximately 25% to 30% of the adult U.S. population. It causes significant morbidity and mortality, with end-organ damage frequently affecting the kidneys and cardiovascular system. Although hypertension is most often “essential” or idiopathic in origin, renovascular disease is an important and potentially remediable cause of both hypertension and progressive renal insufficiency.

Approximately 3% to 5% of the hypertensive population has a renovascular etiology for their hypertension. Increasing age and coexisting atherosclerosis have significant effects on the prevalence of renovascular hypertension. The incidence of renovascular hypertension varied from 0% to 29% (with a weighted mean of 4%) among 8,899 patients in 12 studies (including their own) reviewed by Anderson et al [1].

Certain clinical scenarios may significantly increase the likelihood that renovascular disease is present (e.g.,

abrupt onset of hypertension before the age of 30), but increasingly this is a disorder that is seen in older patients with complicating illnesses such as diabetes and systemic atherosclerosis that may render the diagnosis (and treatment) more difficult. This document reviews those circumstances that should prompt further evaluation for a possible renovascular cause of hypertension or chronic renal insufficiency. It also discusses both the noninvasive imaging and the angiographic evaluation of such patients. Practice guidelines for the performance of renal artery angioplasty and stenting are reviewed, as well as considerations of what constitutes a successful intervention. Guidelines for the training and ongoing credentialing of practitioners performing these interventions are also presented.

II. DEFINITIONS

For the purpose of this guideline, the following definitions apply:

Cardiac disturbance syndrome – recurrent “flash” pulmonary edema, not felt to be secondary to impaired cardiac function, as sometimes seen in the setting of bilateral renal artery stenosis or unilateral stenosis of the renal artery to a solitary kidney [2-4].

Hypertension - Hypertension 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” [5]. The sixth report of The Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure defined hypertension as “systolic blood pressure 140 mm Hg or greater, diastolic blood pressure 90 mm Hg or greater, or taking antihypertensive medication” [2].

Accelerated hypertension – sudden worsening of previously controlled hypertension.

Malignant hypertension – sudden onset of severe hypertension with the coexistence of end-organ damage, which may include left ventricular hypertrophy, congestive heart failure, visual or neurological disturbance, and/or grade III-IV retinopathy.

Renovascular hypertension (also known as renal vascular hypertension) – hypertension secondary to renal artery stenosis.

Renovascular hypertension (cure of) – restoration of blood pressure to below 140/90 mm Hg while taking no antihypertensive medications.

Resistant hypertension – hypertension 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 hypertension, resistance is defined as failure of an adequate triple-drug regimen to reduce the SBP to below 160 mm Hg [2].

Renal Artery Stenosis – narrowing of the renal artery lumen by 50% or greater, expressed in this guideline as a percentage of the diameter of a normal renal vessel, i.e., % renal artery stenosis = 100 x (1 – [the narrowed lumen diameter / the normal vessel diameter]).

Ostial renal artery stenosis – narrowing of the renal artery at its origin from the aorta, generally considered to be within its proximal 5 mm but may be extended to within 10 mm if confirmed by cross-sectional imaging [6].

Truncal renal artery stenosis – nonostial renal artery stenosis occurring proximal to renal artery branching.

Renal Revascularization – any procedure that restores unobstructed arterial blood flow to the kidney.

Technically successful renal revascularization – less than 30% residual stenosis measured at the narrowest point of the vascular lumen and restoration of the pressure gradient to 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 [7].

Unstable angina – new-onset angina, angina at rest, or crescendo angina [4].

III. INDICATIONS/CONTRAINDICATIONS

A. Diagnosis of Renovascular Hypertension

Clinical features suggestive of renovascular hypertension were enumerated by the Cooperative Study of Renovascular Hypertension in 1972 and have been expanded upon since that time [8-11]. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC7) states that “testing for identifiable causes (for hypertension) is not indicated generally unless BP control is not achieved.” JNC7 further states that “reversible causes of renal failure always should be sought and treated” [2].

1. Given this background, current JNC7 indications for screening for renal artery stenosis (RAS) include:
 - a. Onset of hypertension before the age of 30, especially without a family history, or recent onset of significant hypertension after the age of 55.
 - b. An abdominal bruit, particularly if it continues into diastole and is lateralized.
 - c. Accelerated or resistant hypertension.
 - d. Recurrent (flash) pulmonary edema.
 - e. Renal failure of uncertain cause, especially with a normal urinary sediment and less than 1 gram of protein per daily urinary output.
 - f. Coexisting, diffuse atherosclerotic vascular disease, especially in heavy smokers.
 - g. Acute renal failure precipitated by antihypertensive therapy, particularly angiotensin-converting enzyme (ACE) inhibitors or angiotensin II receptor blockers [2].

2. American Heart Association guidelines additionally suggest that screening is appropriate for:
 - a. Malignant hypertension, defined as hypertension with end organ damage including left ventricular hypertrophy (LVH), congestive heart failure (CHF), visual or neurologic disturbance, or advanced retinopathy.
 - b. Hypertension with a unilateral small kidney.
 - c. Hypertension associated with medication intolerance.
 - d. Unstable angina in the setting of suspected RAS [12].

In the proper clinical setting these signs may prompt evaluation for arterial stenosis as the cause of hypertension or reduced renal function. Additional evaluations to determine anatomic and functional parameters predictive of success following renal revascularization include: the status of the arterioles distal to the renal artery stenosis, bilaterality of reconstructable disease, the amount of renal mass available for revascularization, function of the involved kidney as demonstrated by nuclear scintigraphy or other means, plasma renin levels (which have low sensitivity and high specificity for response to renal revascularization), the severity of the RAS, the presence of intrinsic renal disease on the affected side (measured by duplex determinations of resistive index or more rarely direct renal biopsy) [13-16], and possibly the measurement of pathophysiologically linked serum biomarkers, including brain natriuretic peptide (BNP) [17].

Any antihypertensive treatment regimen that effectively lowers blood pressure is associated with slowed progression of renal failure and improved cardiovascular survival [18]. In addition to its role as a potent vasoconstrictor, angiotensin II stimulates cellular hypertrophy and proliferation. Recent investigations indicate that high levels of angiotensin II are likely to contribute to vascular and ventricular hypertrophy, accelerate atherosclerosis, and cause progressive glomerular sclerosis independent of their hemodynamic effect [19]. Whenever possible, an ACE inhibitor should be part of the treatment of hypertension, since these drugs have been shown to be organ-protective beyond their antihypertensive effect in certain renal disease categories. Their use should not be limited by a correctable renal artery stenosis [20-22]. Renal artery imaging should be performed to exclude stenosis as the etiology of unexplained renal failure. Renal revascularization to permit the use of an ACE inhibitor in the treatment of hypertension is justified.

B. Treatment of Renal Artery Stenosis

Although a stenosis is the result of an abnormal process in the arterial wall, it is not usually of hemodynamic significance until the luminal cross-sectional area is reduced by 75% or the vessel diameter is narrowed by over 50%. These numbers 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 [23]. Although mild stenoses are of no hemodynamic significance, most angiographers would agree that a stenosis that narrows the luminal diameter by 75% almost certainly is significant [24,25]. The physiologic significance of lesser degrees of stenosis may depend on the resistance of the peripheral renal vasculature or the condition of the renal auto-regulatory system [26-28].

Another method of determining the physiologic significance of a stenosis is to measure a pressure gradient across the lesion. There is no consensus, however, 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. While some authors have defined a significant pressure gradient as 10% of the systolic pressure, others have used a 10, 15, or 20 mm Hg systolic pressure gradient. Difficulty in measuring the pressure without affecting it, and the physiologic variations that occur during its measurement, make pressure gradient thresholds questionable.

There is emerging science regarding the best method for determining the hemodynamic relevance of RAS, including the routine use of low profile pressure sensing

wires instead of catheters positioned across the stenosis and determination of renal fractional flow reserve following the intra-arterial administration of vasodilator medications [29]. The accuracy of hemodynamic measurements can be increased by simultaneously measuring the aortic pressure via a guiding catheter in the aorta and the pressure distal to the renal artery stenosis by a pressure wire [29-31]. These techniques and devices are not available in every vascular laboratory and are not universally accepted. Therefore, it is the responsibility of each interventionalist to establish an objective test for hemodynamic significance for use in his or her laboratory to evaluate stenoses that appear to be of borderline significance by criteria presently applied to linear measurement. Other tests that can lend support to the clinical significance of a renal artery stenosis of borderline hemodynamic significance include selective renal vein renin analysis, transcutaneous Doppler ultrasonography, and nuclear renography [25,32-35].

A hemodynamically significant renal artery stenosis may stimulate the renin-angiotensin system, resulting in systemic hypertension; however, other factors determine its clinical significance. These 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, impairment in renal function, evidence of progressive nephron loss, comorbid medical conditions, and quality-of-life factors. Therefore in most cases, the clinical significance of a renal artery stenosis and the likelihood that the clinical syndrome can be improved should guide the decision to revascularize a kidney rather than its morphologic or hemodynamic characteristics.

The majority of patients with hemodynamically significant RAS associated with hypertension and reduced renal function can be managed medically without a risk of increased mortality or progression to end-stage renal disease. Renal mass and function must be followed very closely if medical treatment is the chosen option. This is especially true for those patients with bilateral renal artery stenosis or stenosis of a solitary kidney who have twice the risk of mortality and 1.5 times the risk of significant deterioration of renal function than patients with unilateral RAS and 2 kidneys [20]. Patients should also be followed for changing or emerging clinical indicators that may prompt a re-evaluation of the need for renal revascularization (e.g., precipitant heart failure or loss of renal function).

In summary, the benefit of prophylactic treatment of very-high-grade stenoses to preserve renal mass is unproven. The decision to treat must be based on consideration of the patient's age, anticipated longevity, renal function, ability to withstand a procedural complication, the condition of the contralateral kidney, and the ease of performance of the procedure. Revascularization should

be based on clinical symptoms and limited to hemodynamically significant stenoses.

IV. SUCCESS RATES

A. Benefits of Renal Revascularization

RAS may be asymptomatic or may produce renovascular hypertension (RVH), ischemic nephropathy (IN), and cardiac disturbance syndromes (i.e., recurrent "flash" pulmonary edema not felt to be secondary to impaired left ventricular systolic function or unstable angina in the setting of significant RAS). In addition, RAS produces pathophysiologic alterations that may be associated with a concordant increased risk of cardiovascular events, including myocardial infarction and stroke. Thus the benefits of revascularization need to be individually determined based on the underlying clinical condition prompting intervention.

B. Clinical Success Following Renal Revascularization

1. Renovascular hypertension

- a. Cure of hypertension in the patient with atherosclerotic renal artery stenosis

Although a distinguishing advantage for revascularization compared with medical therapy alone is the potential for a hypertension cure, only a small percentage of patients with atherosclerotic RAS are reported as cured following revascularization [36]. The clinical profile of the patient most likely to be cured has not been defined; an effort should be made to define this clinical profile during future investigations [37-46].

- b. Cure of hypertension in the patient with fibromuscular renal artery stenosis

The mean cure rate for renal revascularization for stenoses secondary to fibromuscular dysplasia (FMD) was 44% in a meta-analysis by Martin et al. No attempt was made to separate the results of treatment of the various types of FMD in this document [47]. It seems reasonable to assume that the majority of those treated had the "medial fibroplastic" type of FMD, which is the most common variety. This type affects 60% to 70% of patients with FMD, and most likely a higher percentage of the adult population [48].

Contrary to what one might predict, the technical and clinical results of angioplasty

in those patients with FMD involving the renal artery branches were as good as those involving only the main renal artery [49,50]. Using logistic regression, Davidson et al found that younger age, milder hypertension, and shorter duration of hypertension were statistically significant independent variables predicting successful results from percutaneous transluminal renal angioplasty (PTRA) in FMD [51]. Schreiber et al found progression of medial fibroplasia in 33% of 66 patients with FMD who were observed without intervention; however, none progressed to occlusion or developed renal failure [52].

Therefore cure of hypertension is a reasonable goal in a patient with the medial fibroplastic form of renal artery fibromuscular dysplasia. It is logical to assume that the cure rate will be higher in patients with unilateral involvement (62% in the University Hospital Zurich Cooperative Study on Fibromuscular Hyperplasia) [53]. Branch stenoses are not a contraindication to angioplasty. There are not enough data on endovascular revascularization of other forms of FMD to substantiate a recommendation. The rate of cure of renovascular hypertension due to the medial fibroplastic type of FMD is sufficiently high to recommend PTRA as a first line of treatment. Medical therapy should be reserved for older patients with FMD who have a prolonged history of hypertension. The success of treatment of other types of FMD is inconclusive, and treatment must be chosen based on personal clinical experience.

c. Benefits of renal revascularization other than “cure” of hypertension

Three recent prospectively randomized controlled trials [54-56] and all of the studies included in 3 meta-analyses [40,42,47] have reported that renal revascularization results in a decrease of blood pressure on lower doses of medication. Blood pressure and antihypertensive dose reduction have been shown to be preserved at 24 month follow-up after intervention [57]. Whether controlling blood pressure on less medication outweighs the risks of the revascularization procedure must be considered on an individual case basis [58-

60]. Whenever possible, an ACE inhibitor or angiotensin blocker should be part of the antihypertensive treatment, since this drug has been shown to have renoprotective properties that are as important as or more important than its antihypertensive effect and is the preferred medication in many cases of nonrenovascular hypertension [22]. Therefore, although normotensive blood pressure levels can be maintained medically in cases of renovascular hypertension, it is not attained without some risk to the kidney with the stenotic renal artery, and if the clinician chooses to treat hypertension without knowing the status of renal artery patency he or she must be alert to signs of decreased renal function and loss of renal mass.

2. Ischemic nephropathy

The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure recommends investigation of renal failure that occurs in patients being treated for hypertension. It suggests that surgical or endovascular revascularization may be necessary to preserve renal function, even though many patients with high-grade RAS remain stable for prolonged periods if blood pressure is well controlled [61].

a. Criteria for benefit from revascularization

There is a great deal of controversy concerning the degree of benefit that can be expected from revascularization of the patient with ischemic nephropathy. The main issue concerns measurement of the effect of the intervention. It is well recognized that there is progressive nephron loss with aging. This loss is manifest by a progressive decline in the glomerular filtration rate (GFR) and the size of the kidneys. 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 renal artery stenosis. The benefit of revascularization depends on recovering the functional loss, eliminating that portion of the accelerated cell death due to ischemia, and returning the rate of decline of the glomerular filtration rate to that attributable to age and other coexisting disease processes

other than ischemia. Delay in revascularization has been associated with a reduction in clinical benefit [44].

The slope of the linear relation between the reciprocal of creatinine concentration and time can be used to delineate the rate of change in renal function [62]. Failure of progression along the slope of decline in renal function may indicate a benefit from intervention even though there has been no improvement in baseline serum creatinine. This method cannot compensate for the limitations in the use of creatinine values for assessing renal function, and users must be aware of the potential pitfalls in its use when there has been a change in muscle mass or diet [63]. Measurements of GFR remain the recommended determinant of functional outcomes [64].

b. Results of treatment in patients with ischemic nephropathy

No improvement in mean renal function was reported in 3 prospectively randomized studies of renal revascularization [11,54,56]. These trials were criticized in a review by Sacks et al who found fault with the analysis and interpretation of the data by the authors [59]. The investigators in these trials found no statistical difference between continuous measures of the mean serum creatinine value at baseline and following treatment.

The problem with using the change in the mean creatinine level can be illustrated by the following example. Suppose an intervention was performed on 10 patients, each with a serum creatinine level of 3.0 mg/dl, and that at the time of final follow-up 8 had a serum creatinine of 2 mg/dl and the serum creatinine level had risen to 7.0 mg/dl in 2 patients. Using a 20% reduction of serum creatinine as a binary criterion for benefit, 80% would have benefited from the procedure and 20% would have failed to benefit. Using the mean change in serum creatinine of the treated cohort measured as a continuous variable as the criterion for success, there would have been no benefit in this patient cohort. This oversimplification illustrates the problem with using a mean or average of a test that has a greater mathematical limit on the potential to improve than it does on the potential to fail. It also ignores benefit that can be derived by

stabilizing the rate of nephron loss as discussed previously.

Studies of renal revascularization that have analyzed the reciprocal slope of glomerular function have found statistically significant improvement in renal function in the population treated [65-67]. Studies reporting binary results, using a less than 20% deterioration and/or a 20% lowering of the serum creatinine as a measure of functional stabilization or benefit, find a mean of 54% improved and 26% stabilized by surgical revascularization [13,14,68,69]. Using binary criteria, 2 meta-analyses determined that renal artery stenting resulted in 30% improved and 38% stabilized [42] and 26% improved and 48% stabilized [40], although neither meta-analyses showed a significant decrease in overall serum creatinine values. A meta-analysis by the Agency for Healthcare Research and Quality (AHRQ) notes that improvements in kidney function were reported only among the angioplasty cohort studies and not in studies evaluating medical therapy alone” [36].

Endovascular revascularization can result in improvement of the GFR in selected patients with ischemic nephropathy. Signs that a patient with ischemic nephropathy is likely to benefit from revascularization include: 1) normal appearance of the arterioles distal to the renal artery stenosis; 2) bilaterality of reconstructable disease; 3) a near normal volume of renal mass available for revascularization; 4) a test demonstrating function of the involved kidney; 5) renal biopsy demonstrating well preserved glomeruli and tubules with minimal arteriolar sclerosis; 6) severe, difficult to control hypertension; and 7) abrupt onset of renal insufficiency [15,16,70].

3. Cardiac disturbance syndromes and prevention of cardiovascular events

Renal artery stenosis may worsen angina or congestive heart failure in patients with coronary artery disease, left ventricular dysfunction, or cardiomyopathy due to complex pathophysiologic alterations, including changes in the renin-angiotensin-aldosterone axis, resulting in a state of volume overload and peripheral vascular constriction [3,71-73]. Renal revascularization may result in relief of these cardiac syndromes [4,72], particularly for patients with bilateral RAS.

Over 70% of patients may remain free of congestive heart failure and unstable angina at 12-month mean follow-up [3,4]. Restoring unobstructed renal blood flow has the additional potential benefit of allowing safe usage of ACE inhibitors without the risk of worsening renal failure and reducing coronary perfusion. The prevention of cardiovascular events and associated mortality is a possible salutary effect of renal revascularization that is currently undergoing investigation in large-scale trials [74,75].

C. Technical Success Following Renal Revascularization

Although stents were initially used only to treat hemodynamically significant residual stenosis or a flow limiting dissection following balloon angioplasty, they have become the standard of care for ostial RAS. A meta-analysis by Rees reports 99% technical success following stent placement in 1,128 arteries compared with 55% for ostial and 70% for nonostial stenoses treated by balloon angioplasty in 1,417 arteries. There was 77% patency at a mean 7.9 months angiographic follow-up in 563 arteries that were stented [76]. Leertouwer et al, reported 26% restenosis in 236 arteries examined angiographically at a mean follow-up of 19 months [42]. This is not significantly better than 30% restenosis following balloon angioplasty in 515 patients reported by Rees, who points out that “the benefits of stents for long-term patency relative to PTA are mostly related to the markedly superior initial success rates rather than reduction of restenosis” [76].

Stents dilated to less than 6 mm, female sex, age greater than 65 years and smoking are statistically significant risk factors for restenosis. In the U.S. Multicenter Renal Artery Stent Trial [76] the lowest risk group was men with renal arteries 6 mm or greater who had a restenosis rate of 10.5%. There are very little data regarding stent use in nonostial renal artery stenosis; however, there are studies suggesting that these lesions may respond favorably to balloon angioplasty alone [77]. Increased technical success and patency would be expected if the reference vessel diameter is 6 mm or greater.

The use of stents in ostial and nonostial locations is relatively contraindicated if they traverse renal artery branches or if restenosis would be likely to make surgical revascularization difficult or impossible. Renal artery stents have no established role in the primary treatment of fibromuscular dysplasia. They are the preferred treatment for ostial stenosis in arteries whose reference diameter is 6 mm or greater. Their use in vessels below 5 mm should be limited to technically failed balloon angioplasty. Their

primary use is in lesions where the normal diameter is 5 mm or greater and is left to the discretion of the interventionalist.

V. COMPLICATIONS – RISKS OF ENDOVASCULAR REvascularIZATION

The rates of complications and technical success of endovascular revascularization have shown some variability over time. Studies have shown improved success rates with diminished complications as experience with the procedure increases, and as new technologies are introduced. Overall complication rates reported in the literature have ranged from 12% to 36%, with an estimated mean of approximately 14%.

Groin hematoma and puncture site trauma are 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%).

Two large series [78,79] and 2 meta-analyses [42,50] were reviewed for this guideline. There was no overlap of data among these studies, which include 2,994 revascularizations (980 vessels stented) in 2,474 patients. The total complication rate ranged from 12% [42] to 36% [79] with a mean complication rate of 14% excluding radiological-technical complications (“events that occur during catheterization or stent deployment that have no clinical consequences but lead to an increase in procedural time and/or cost”) [79]. Groin hematoma and puncture site trauma were the most common complications reported. 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% [42,50]. Symptomatic embolization occurred in 1% to 8% of the patients [42,79]. 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% [42,50].

Cholesterol embolization resulting in decreased renal function or visceral or peripheral symptoms is expected in less than 3% of cases [42,50,78,79]. 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 [80].

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 [81].

VI. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

The physician performing renal angioplasty/stenting must fully appreciate the benefits, alternatives, and risks of the procedure. He or she must have a thorough understanding of vascular anatomy (including congenital and developmental variants and common collateral pathways), angiographic equipment, radiation safety considerations, and physiologic monitoring equipment and must have access to an adequate supply of catheters, guidewires, and 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, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or Le College des Medecins du Quebec and has performed the following procedures:
 - a. Meets the requirements of the [Practice Guideline for the Performance of Diagnostic Arteriography in Adults](#). At least 10 of the cases should be renal arteriograms.
and
 - b. Performance of at least 30 successful systemic (e.g., 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). In addition, at least 5 of these 30 cases must have been arterial lysis procedures.
or
2. Successful completion of an Accreditation Council for Graduate Medical Education (ACGME) approved radiology residency training program or an American Osteopathic Association (AOA) approved residency program and/or interventional/vascular radiology fellowship, and must have a minimum of 6 months training on a service that is primarily responsible for performing percutaneous peripheral, visceral, and neurodiagnostic arteriography and vascular/interventional

radiology. Documented formal training in the performance of invasive catheter angiographic procedures must be included. During this training, the physician should have performed the following procedures:

- a. Meets the requirements of the [Practice Guideline for the Performance of Diagnostic Arteriography in Adults](#). At least 10 of the cases should be renal arteriograms.
and
 - b. Performance of at least 30 successful systemic (e.g., 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). In addition, at least 5 of these 30 cases must have been arterial lysis procedures.
or
3. Successful completion of an ACGME approved nonradiology residency or fellowship training and must have a minimum of 6 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 [Practice Guideline for the Performance of Diagnostic Arteriography in Adults](#). At least 10 of the cases should be renal arteriograms.
and
 - b. Performance of at least 30 successful systemic (e.g., 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). In addition, at least 5 of these 30 cases must have been arterial lysis procedures.
or
 4. Training by experience. Physicians qualifying in this manner must meet the same training requirements as in 1, 2, and 3 above by having performed the requisite number of procedures under the supervision of a physician who has previously met the training outlined above.

Note: These cases must be documented so that the director of the training program can certify that the physician is proficient in the performance of the

procedures with acceptable success and complication rates as defined in section X of this document.

5. 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 exposure to both patients and radiologic personnel, and monitoring requirements.
 - 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 guide-wire 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 (e.g., 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 renal stenting procedures to maintain their skills, with acceptable success and complication rates as laid out in this guideline. 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 Guideline for Continuing Medical Education \(CME\)](#).

B. Qualified Medical Physicist

A Qualified Medical Physicist is an individual who is competent to practice independently one or more of the subfields in medical physics. The American College of Radiology (ACR) considers certification and continuing education and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice one or more of the subfields in medical physics and to be a Qualified Medical Physicist. The ACR recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physics in Medicine, or for MRI, by the American Board of Medical Physics (ABMP) in magnetic resonance imaging physics.

The appropriate subfields of medical physics for this guideline are Diagnostic Radiological Physics and Radiological Physics.

A Qualified Medical Physicist should meet the [ACR Practice Guideline for Continuing Medical Education \(CME\)](#). (ACR Resolution 17, 1996 – revised in 2008, Resolution 7)

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 position¹ 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 policy² 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, when deemed appropriate by the performing physician, are an integral part of the team for preprocedure and postprocedure patient management and education and are recommended in monitoring the patient during the procedure.

F. Other Licensed Independent Practitioner

Licensed independent practitioners may be involved in renal artery angioplasty and stenting procedures in

¹The 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 guideline, “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)

² See the [ACR Practice Guideline for the Use of Intravascular Contrast Media](#). (2007 - ACR Resolution 38)

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.

VII. SPECIFICATIONS OF THE EXAMINATION

Several technical requirements are necessary 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 [82] and the Intersociety paper on optimum resources for endovascular treatment in [83].

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 to produce higher quality studies with reduced risk and time of study, the facility should include at a minimum:

1. A high-resolution image receptor (preferably with a 28 to 40 cm field of view) and imaging chain with standard angiographic filming capabilities. Digital subtraction angiographic systems with high spatial resolution are recommended, as they allow for reduced volumes of contrast material and reduced examination times. The use of cineradiography or small field mobile image intensifiers is inappropriate for the routine recording of noncoronary angiography, because they have an unacceptably high patient and operator radiation dose. In accordance with the as low as reasonably achievable (ALARA) principle, a radiation dose measurement package including pulsed fluoroscopy and last image hold capabilities is recommended.
2. Adequate angiographic supplies such as catheters, guidewires, stents, balloons, needles, and introducer sheaths. In particular, small caliber guidewires capable of pressure measurements 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 overinjection.
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 Practice Guideline for Adult Sedation/Analgesia](#).)
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 Practice Guideline for Adult Sedation/Analgesia](#).)
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 Practice Guideline on Informed Consent for Image Guided Procedures](#).

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 non-operating room settings including bedside procedures. “Time out” must be conducted in the location where the procedure will be done, just before starting the procedure and must:
- Involve the entire operative team.
 - Use active communication.
 - Be briefly documented, such as in a checklist, and include at least:
 - Correct patient identity.
 - Correct side and site.
 - Agreement on the procedure to be done.
 - Correct patient position.
 - Availability of correct implants and any special equipment or special requirements.

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:
- 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 written 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 typed report is not likely to be on the chart the same day, a more detailed summary of the study should be written 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.
- 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.

VIII. DOCUMENTATION

Documentation should be in accordance with the [Practice Guideline for Reporting and Archiving of Interventional Radiology Procedures](#).

IX. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, radiologic technologists, and all supervising physicians have a responsibility to minimize radiation dose to individual patients, to staff, and to society as a whole, while maintaining the necessary diagnostic image quality. This concept is known as “as low as reasonably achievable (ALARA).”

Facilities, in consultation with the medical physicist, should have in place and should adhere to policies and procedures, in accordance with ALARA, to vary

examination protocols to take into account patient body habitus, such as height and/or weight, body mass index or lateral width. The dose reduction devices that are available on imaging equipment should be active; if not, manual techniques should be used to moderate the exposure while maintaining the necessary diagnostic image quality. Periodically, radiation exposures should be measured and patient radiation doses estimated by a medical physicist in accordance with the appropriate ACR Technical Standard. (ACR Resolution 17, adopted in 2006 – revised in 2009, Resolution 11)

X. 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 elsewhere in the ACR Practice Guidelines and Technical Standards book.

These guidelines are to be used in quality improvement (QI) programs to assess the diagnosis and treatment of renal artery stenosis. 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 renal artery stenosis and will increase the success rate of the procedure.

While practicing physicians should strive to achieve perfect outcomes (e.g., 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 guidelines, 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, e.g., 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 renal artery stenosis, 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 may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Thus, setting universal thresholds is very difficult and each department is urged to alter the thresholds as needed to higher or lower values to meet its own QI program needs.

A. Indications for Catheter-Directed Diagnostic Angiography (Threshold – 95%)

Appropriate indications for screening (see section IIIa), and at least one of the following:

1. Noninvasive vascular imaging suggests that a significant renal artery stenosis is present (greater than 50%).
2. Noninvasive vascular imaging is technically inadequate, equivocal, or cannot be obtained.
3. Noninvasive imaging is not likely to have adequate sensitivity and specificity.
 - a. Onset of hypertension occurs in a patient under the age of 30.
 - b. Over the age of 30, but fibromuscular dysplasia is suspected as the etiology of renal artery stenosis.
4. There are appropriate indications for screening and a very high clinical suspicion of RAS in which case noninvasive screening can be bypassed.

B. Indications for Angioplasty or Stenting (Threshold – 95%)

1. A hemodynamically significant renal artery stenosis.
2. Greater than 50% diameter stenosis or greater than 75% reduction in cross sectional area.
3. A systolic pressure gradient greater than:
 - 10% of the systolic pressure, or
 - 10, 15 or 20 mm Hg.

C. Relative Contraindications for Renal Artery Stent Deployment (Threshold – 5%)

1. A renal bifurcation lesion where more than 50% of a kidney will be excluded 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 [84].

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

1. Defined by minimal thresholds of <30% residual stenosis or <10 mm Hg 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

	Reported Rate	Threshold
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 prolonging 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 (e.g., 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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**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.

*Guidelines and 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 guidelines and standards published before 1999, the effective date was January 1 following the year in which the guideline or standard was amended, revised, or approved by the ACR Council.

Development Chronology for this Guideline

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