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Renal Artery Duplex Ultrasound Criteria for the Detection of Significant In-Stent Restenosis

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Objectives: To define velocity criteria by ultrasonography for the detection of hemodynamically significant (>60%) renal artery in-stent restenosis (ISR). Background: The restenosis rate after renal artery stenting ranges between 10% and 20%. While duplex ultrasound criteria have been validated for native renal artery stenosis, there are no uniformly accepted validated criteria for stented renal arteries. Methods: Vascular laboratory databases from two academic medical centers were retrospectively reviewed for patients who underwent renal artery stenting followed by duplex ultrasound evaluation and angiography (CT angiography or catheter angiography) as the gold standard. Results: A cohort of 132 stented renal arteries that had angiographic comparisons was analyzed. Eighty-eight renal arteries demonstrated 0–59% stenosis while 44 renal arteries revealed 60–99% stenosis by angiography. Both the mean peak systolic velocity (PSV) and the renal artery-to-aortic ratio (RAR) were significantly higher in renal arteries with 60–99% restenosis compared with those with 0–59% restenosis (PSV: 382 cm/sec ± 128 vs. 129 cm/sec ± 62, $P<0.001$; RAR: 5.3 ± 2.4 vs. 2.1 ± 1.0, $P<0.001$). The optimal PSV and RAR cutoffs for detecting 60–99% ISR were calculated by receiver operator characteristics curve analysis. The velocity criteria that are associated with these results will be discussed. Conclusion: Duplex ultrasonography is an accurate technique to identify significant restenosis in stented renal arteries. The PSV and RAR cutoffs for detecting renal artery ISR are higher than those in native, unstented renal arteries. A normal duplex ultrasound after renal artery stenting virtually excludes significant restenosis.

Key words: restenosis; ultrasound; stent; renal arteries

INTRODUCTION

Atherosclerotic renal artery stenosis is a common, often overlooked disorder that is associated with significant morbidity and mortality. It is estimated that approximately 7% of individuals 65 years or older have renal artery stenosis [1], and its prevalence may be as high as 40% in subsets of high-risk patients [2,3].

Although the indications for the treatment of renal artery stenosis remain controversial, over the past decade the use of endovascular therapy for the treatment of renal artery stenosis has increased dramatically [4,5]. While angioplasty and stent deployment is technically successful in 99% of cases, the rate of restenosis after renal artery stenting ranges between 10% and 20% in most contemporary series [6,7]. To identify restenosis, it is recommended that patients be followed with renal artery duplex ultrasonography every 6 months following renal artery stent implantation [8–12].

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Additional Supporting Information may be found in the online version of this article.

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Duplex ultrasound of the renal arteries is an accurate method of detecting native renal artery stenosis and correlates well with renal arteriography as the gold standard [8–10]. Current ultrasound protocols for the diagnosis of renal artery stenosis rely primarily on the detection of increased flow velocities within the renal artery [8–10]. Whereas specific velocity criteria have been validated for the diagnosis of native renal artery stenosis [10], the same criteria may not apply to stented renal arteries. After stent placement, the artery is less compliant resulting in increased flow velocities, even in the absence of restenosis [13]. This concept has been tested and confirmed in stented internal carotid arteries [13]. The aim of this study was to define optimal velocity criteria for the detection of hemodynamically significant (>60%) renal artery in-stent restenosis (ISR).

METHODS

Vascular laboratory databases from two academic medical centers (Mount Sinai Medical Center, New York, NY, and the Massachusetts General Hospital, Boston, MA) were retrospectively reviewed for patients who had undergone renal artery stenting, followed by both renal artery duplex ultrasound and imaging with either computed tomographic angiography (CTA) or catheter-based renal angiography within 6 months of the renal artery duplex ultrasound. Patients underwent renal artery stenting between 2002 and 2007. The vast majority of stents used were Genesis™ (Cordis, Bridgewater, NJ), Express™ (Boston Scientific, Natick, MA), Herculink™ (Abbott Vascular, Abbott Park, IL), and Racer™ (Medtronic, Minneapolis, MN). Angiography by CTA has been shown to be comparable with catheter-based angiography to evaluate renal stent patency [14–18]. All patients referred for angiography had a clinical reason to investigate restenosis, such as resistant hypertension, worsening renal function, or recurrent episodes of pulmonary edema [9]. The study was approved by the Institutional Review Boards of the two participating medical centers.

Duplex Ultrasound

All ultrasound examinations were performed in an IAC accredited vascular laboratory (www.intersocietal.org/vascular) according to previously published protocols. [10] All exams were performed using a Philips iU 22 (Bothell, Washington) or a GE LOGIQ E9 (Milwaukee, WI). The entire abdominal aorta was imaged in the sagittal and transverse planes to evaluate for plaques and aneurysm. Spectral analysis of the aorta and renal arteries was performed with appropriate beam-to-vessel alignment and an angle-correction technique of < 60 degrees for absolute velocity measurements. A peak systolic velocity (PSV) value was obtained in the aorta at the level of the superior mesenteric artery. Peak systolic and end-diastolic velocities within the renal arteries were obtained at the ostium, proximal, mid and distal vessel bilaterally from both the anterior and the flank approaches. A careful search for accessory renal arteries was performed using the same Doppler interrogation technique. The renal-to-aortic ratio (RAR) was calculated using the PSV from within the aorta near the superior mesenteric artery origin divided by the maximum PSV within the proximal renal artery. The RAR values was not used in the presence of an abdominal aortic aneurysm or when peak systolic velocities within the aorta were >100 cm/sec or <40 cm/sec. The degree of turbulence was noted within and immediately distal to the stent.

Angiography

Renal artery angiography was performed by either CT or catheter-based angiography. Renal artery stenosis by angiography was divided into two categories: 0–59% stenosis (no significant restenosis) and 60–99% stenosis (significant restenosis). Studies were interpreted by an attending vascular interventionalist who was blinded to the interpretation of the duplex ultrasound. CTAs were performed according to established protocols on a 64-slice Volume CT General Electric scanner using standard acquisition parameters. Cross-referenced axial, coronal, and sagittal projections were used to select the renal arteries from a volumetric data set. The center-line tool from a 3D workstation was used to reconstruct renal artery data sets into curved multiplanar images. The degree of stenosis by CTA was determined by a commercially available quantitative vessel analysis package (Vitrea 2, Vital Images, Minnetonka, Minnesota). Catheter-based renal angiography was performed using digital subtraction angiography using a 5 Fr pigtail catheter, with the catheter tip positioned next to the renal artery ostium. Angiography was able to visualize in-stent stenosis in cases with mid-distal stent stenosis by performing the angiograms in an oblique view to optimize visualization of the entire course of the stent. When this imaging was not optimal or when a proximal in-stent stenosis was suspected, a selective angiogram was obtained which typically involved engaging the stent with a .014″ guidewire and performing a subtraction angiogram through a 6 Fr guidecath positioned in the aorta outside the stent.

Statistics

Data analysis was performed using the SAS 9.2 software (SAS Institute, Cary, NC). Velocity data were

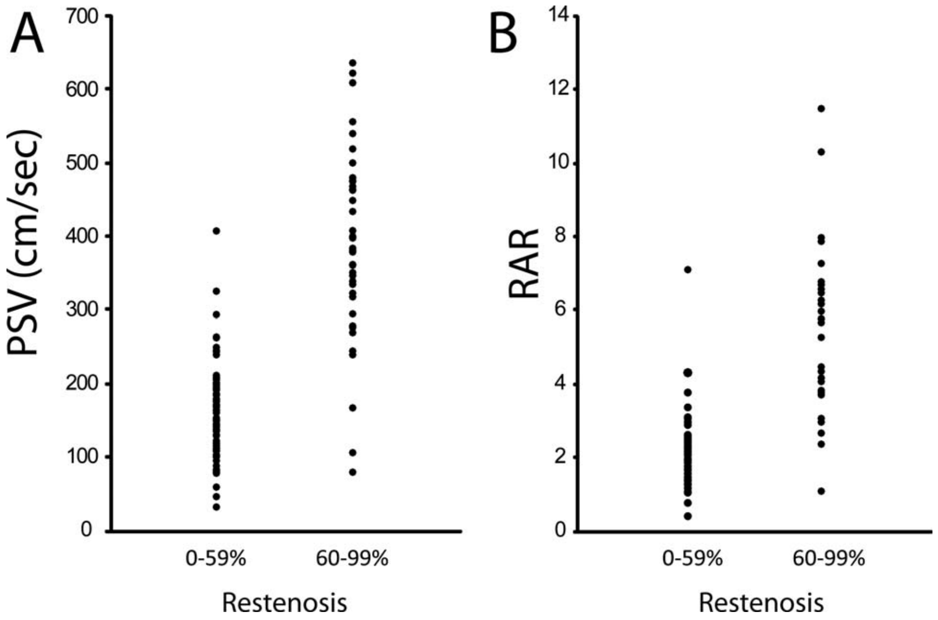

Fig. 1. Scatter plots showing PSV (left) and RAR (right) determinations for each renal artery evaluated in the cohort, according to the absence (0–59%) or presence (60–99%) of restenosis by angiography.

TABLE I. PSV and RAR Values According to the Presence (60–99%) or Absence (0–59%) of Renal Artery In-Stent Restenosis by Angiography

Variable	*n*	Mean	Standard deviation	Minimum	Maximum
PSV (cm/s)					
0–59%	88	158	62	34	409
60–99%	44	382	129	84	637
RAR					
0–59%	64	2.0	0.98	0.44	7.3
60–99%	36	5.4	2.3	0.8	11.5

expressed as mean with standard deviation. An analysis of variance was used to compare the mean values of PSV, RAR, to the presence or absence of significant renal artery ISR. Significant renal artery ISR was considered to be ≥60% stenosis by angiography. Receiver operating characteristic (ROC) curves were used to assess the discrimination of both PSV and RAR for the detection of restenosis [19]. The optimum threshold for each of these variables, as predictors of stenosis, was determined by calculating the sum of the sensitivity and specificity for each possible cutoff and taking the cutoff which gave the maximum [19]. A $P < 0.05$ was considered statistically significant.

RESULTS

There were a total of 139 renal arteries from 106 patients that had angiographic comparisons within 6 months. Approximately 70% of all studies were done within 3 months. There were six ultrasound studies that were excluded from this study because they were technically inadequate for interpretation (the feasibility of obtaining adequate images was 96%). One artery was occluded and was excluded from the analysis since detection by ultrasound is not based on detection of increased flow velocities. Of the remaining 132 arteries, 88 had 0–59% and 44 had 60–99% ISR by angiography. Figure 1 demonstrates scatter plots of PSV and RAR determinations according to the absence (0–59%) or presence (60–99%) of significant ISR. Table I summarizes the distribution of PSV and RAR measurements according to the presence of restenosis. The mean PSV in renal arteries with 60–99% restenosis was 3-fold higher than in those with 0–59% restenosis (382 cm/sec ±128 vs. 129 cm/sec ±62, $P < 0.001$). The mean RAR was also significantly higher in renal arteries with 60–99% restenosis compared to those with 0–59% restenosis (5.3 ± 2.4 vs. 2.1 ± 1.0, $P < 0.001$). Of note, RAR was only calculated in 100 of the 132 renal arteries because of the presence of an abdominal aortic aneurysm, or a peak systolic aortic velocity < 40 cm/sec, or >100 cm/sec, resulting in a feasibility of 76%. Once an association between PSV and RAR with the presence of significant restenosis was demonstrated, we sought the optimal cutoff value of both of these Doppler parameters that would allow the most accurate detection of ISR.

Defining Ultrasound Criteria for Renal Artery ISR

The sensitivity, specificity, positive predictive value, and negative predictive value for various PSVs and

RARs for the detection of 60–99% renal artery restenosis are shown in Table II. There was no single PSV cutoff that would accurately discriminate 60–99% from 0 to 59% restenosis in all patients. A PSV < 241 cm/sec was useful in excluding ISR (negative predictive value 96%): 78 of 81 renal arteries with PSV < 241 cm/sec had 0–59% restenosis. A PSV ≥ 296 cm/sec was accurate in predicting ISR (positive predictive value 94%): 33 of 35 renal arteries with a PSV ≥ 296 cm/sec had ISR by angiography. A PSV between 241 and 295 cm/sec represented an indeterminate zone in which renal artery restenosis could not be diagnosed or excluded on the basis of PSV alone. Of 16 renal arteries with PSV in this range, eight had 0–59% restenosis, and eight had 60–99% restenosis. Among renal arteries with PSV 241–295 cm/sec, RAR was comparable in renal arteries with and without significant restenosis (4.3 ±1.2 vs. 3.49 ± 0.7; $P = 0.2$). The optimum threshold for RAR for predicting 60–99% restenosis was ≥ 4.4, with a positive predictive value of 96%; the sensitivity, however, was relatively low at 64%. A RAR less than 2.6 accurately excluded ISR (negative predictive value of 95%).

Figure 2 receiver operator characteristics (ROC) curves for both PSV and RAR, comparing them to the gold standard of either CT or catheter angiography. Both PSV and RAR were very good discriminators, approximating the ideal ROC curve which would connect the extreme bottom left, top left and top right points of the graph. PSV, however, was a single better predictor of restenosis. The area under the curve was 0.95 and 0.92 for PSV and RAR, respectively. These areas emphasize the diagnostic accuracy of duplex ultrasonography for the detection of significant renal artery ISR.

TABLE II. Performance Parameters (%) for Various PSV and RAR Measurements for the Detection of 60–99% Renal Artery In-Stent Restenosis

Variable	Sensitivity	Specificity	PPV	NPV
PSV (cm/s)				
≥200	93	81	71	96
≥202	93	82	72	96
≥203	93	83	73	96
≥207	93	84	74	96
≥209	93	85	76	96
≥210	93	86	77	96
≥213	93	88	79	96
≥241	**93**	**89**	**80**	**96**
≥245	86	89	79	93
≥246	86	90	81	93
≥247	80	90	80	90
≥251	80	91	81	90
≥264	80	93	85	90
≥265	80	94	87	90
≥271	80	95	90	90
≥278	80	97	92	90
≥280	77	97	92	89
≥295	75	97	92	89
≥296	**75**	**98**	**94**	**89**
≥319	73	98	94	88
≥324	68	98	94	86
≥336	66	98	94	85
≥340	66	99	96	85
≥348	64	99	96	84
≥352	61	99	96	84
≥362	59	99	96	83
≥363	57	99	96	82
RAR				
≥2.6	**91**	**83**	**75**	**95**
≥2.6	89	83	74	93
≥2.7	89	84	76	93
≥2.9	86	84	76	91
≥3	86	86	77	92
≥3.1	83	89	81	90
≥3.1	80	91	83	89
≥3.4	80	92	85	89
≥3.7	80	94	88	89
≥3.8	78	94	87	88
≥3.9	75	97	93	87
≥4.1	72	97	93	86
≥4.2	67	97	92	84
≥4.3	64	97	92	82
≥4.4	**64**	**98**	**96**	**83**
≥4.5	58	98	95	80
≥5.3	55	98	95	79
≥5.7	47	98	94	77

NPV = negative predictive value; PPV = positive predictive value.
Bold indicates that the numbers with the best sens/spec/PPV/NPV for detecting instent restenosis.

DISCUSSION

Duplex ultrasonography of the renal arteries combines direct visualization of the renal arteries (B-mode imaging) with color Doppler measurements of various hemodynamic parameters in the renal artery and within the kidney [20,21]. Prior studies have compared duplex ultrasound to angiography for the diagnosis of renal artery ISR [22–28] and with the exception of one report [25], these studies demonstrated that the PSV is higher in stented renal arteries as compared with unstented renal arteries. In their study involving 33 stented renal arteries, Bakker et al. showed that increasing the PSV cutoff from 180 cm/sec to 226 cm/sec yielded a sensitivity of 100% and a specificity of 90% for the diagnosis of >50% ISR [22]. In the Renal Artery Stenting with Noninvasive Duplex Ultrasound Follow-up (RENAISSANCE) trial, the ultrasound criteria used by an independent vascular ultrasound core laboratory to diagnose >50% renal artery ISR (PSV ≥ 225 cm/sec with post-stenotic turbulence or a RAR of ≥ 3.5) in 98 stented renal arteries yielded a sensitivity of 83%, a specificity of 92%, and a positive predictive value of 94% [26]. More recently, Chi and associates reported that in 31 stented

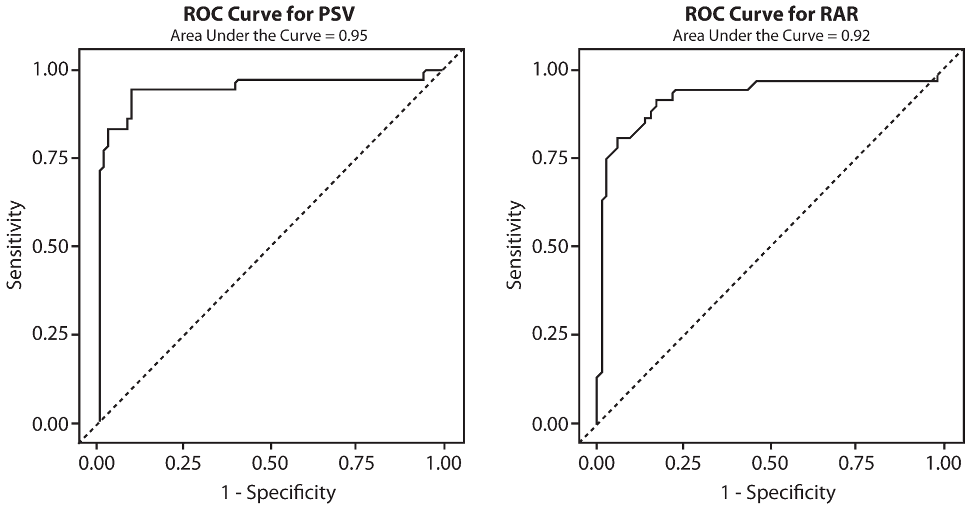

Fig. 2. Receiver operator characteristics (ROC) curves for PSV (left) and RAR (right).

renal arteries with angiographic evidence of ISR, a PSV of 395 cm/sec diagnosed >70% restenosis with a sensitivity of 83%, specificity of 88%, and a positive predictive value of 71% [23]. Increased flow velocities were also demonstrated in renal arteries that were stented for renal flow preservation during endovascular repair of aortic aneurysms, rather than for the treatment of stenosis [29].

Consistent with these observations, we found that peak systolic velocities in stented renal arteries were significantly higher compared to known normal velocities of native renal arteries [10]. Although the precise mechanism explaining the increased velocities is not fully understood, it is likely that deployment of a metallic stent transforms the normally expansile and compliant artery into a more rigid, non-compliant conduit. In such a vessel, the energy that is normally expended in arterial wall dilation during arterial pulsation is dissipated in the form of increased flow velocities [30–34]. In light of these findings, it is necessary to redefine the abnormal flow velocities in stented renal arteries.

To our knowledge, the present study is the largest to-date to examine the duplex ultrasound criteria for the diagnosis of renal artery ISR. Previous studies from our laboratories have demonstrated that a PSV of ≥200 cm/sec with post-stenotic turbulence on color Doppler imaging with a RAR of ≥3.5 was consistent with 60–99% stenosis [10]. These criteria detect this degree of native renal artery stenosis with a sensitivity of 98%, specificity of 98%, positive predictive value of 97% and negative predictive value of 99%. Application of these same criteria in our cohort of stented renal arteries, however, would have resulted in a decrease in specificity from 98% to 81% (potentially leading to unnecessary subsequent examinations due to false-positive Doppler ultrasound results) as well as in a significant decrease in the positive predictive value, from 97% to 71%. The criteria for diagnosing stenosis in native renal arteries therefore cannot be reliably used to detect renal artery ISR.

In the current study, the PSV threshold to diagnose renal artery ISR was redefined (Table III). Through receiver operator characteristics analysis, we demonstrated that a PSV < 241 cm/sec was accurate in excluding significant renal artery restenosis (negative predictive value of 96%). A PSV ≥296 cm/sec was very accurate in identifying 60–99% restenosis, with a positive predictive value of 94%. Using the RAR (as a single parameter) of ≥ 4.4 was also accurate in identifying patients with 60–99% renal artery ISR (positive predictive value of 96%). However, PSV was a better predictor of renal artery ISR than RAR, as reflected by a larger area under the curve in the ROC analysis (0.95 vs. 0.92, Figure 2).

A PSV between 241 cm/sec and 295 cm/sec represented an indeterminate zone in which renal artery ISR could not be reliably confirmed or excluded on the basis of the PSV alone. When the PSV is between 241 cm/sec and 295 cm/sec, one must carefully examine the turbulence present within and immediately distal to the stent, the appearance of the stent on B-mode and color Doppler imaging, and then make a judgment as to the severity of the stenosis. By examining the ultrasound appearance of stented renal arteries that are normal and comparing them to arteries with ISR, the physician interpreting the ultrasound should be able to accurately differentiate between the two scenarios where the velocity of blood flow is between 241 and 295 cm/sec (Supporting Information Videos).

TABLE III. PSV Criteria for the Detection of 60–99% Renal Artery In-stent Restenosis

Variable	Interpretation	Performance parameters
PSV (cm/s)		
<241	Accurate in excluding significant (≥60%) restenosis.	NPV = 96%
241–295	Indeterminate zone. Cannot rule-out or rule-in significant (>60%) restenosis.	–
≥296	Accurate in predicting 60–99% restenosis.	PPV = 94%
RAR		
<2.6	Accurate in excluding significant (≥60%) restenosis.	NPV = 95%
2.6–4.3	Indeterminate zone. Cannot rule-out or rule-in significant (>60%) restenosis.	–
≥4.4	Accurate in predicting 60–99% restenosis.	PPV = 96%

NPV = negative predictive value; PPV = positive predictive value.

Limitations

Despite being the largest series to evaluate duplex ultrasound parameters in stented renal arteries, this study has several important limitations. First, this was a retrospective cohort study, and as such there is potential for sampling bias. All patients in this cohort underwent angiography, which is usually reserved for patients in whom there is concern for ISR. Therefore, the pre-test probability of ISR was higher in the cohort we analyzed compared to unselected patients who have undergone renal artery stenting. Consistent with this, the rate of ISR in our cohort was 33% (44 of 132 arteries), which is higher than the expected 10–20%. Second, the time from when the duplex ultrasound and angiography were performed could be up to 6 months, a timescale in which restenosis may progress. The lesion and findings in the study done first (usually ultrasound) may therefore not have matched those in the second study (usually angiography). Third, there is lack of agreement regarding which test is the gold standard in assessing renal artery ISR. It has been shown that the degree of stenosis is often overestimated by visual inspection during angiography [11]. At present, the best way to accurately determine the degree of ISR is by intravascular ultrasound (IVUS) with translesional pressure gradients [9,11].

In conclusion, patients should undergo surveillance duplex ultrasound as recommended by current guidelines [8,12]. The velocity criteria for hemodynamically significant ISR are not the same as for native renal artery stenosis. In the current series, a PSV less than 241 cm/sec excluded ISR with a negative predictive value of 96%, and a PSV of >296 cm/sec identifies ISR with a positive predictive value of 94%. If the PSV is between 241 cm/sec and 295 cm/sec, other parameters (B-mode appearance, turbulence on color Doppler) are used to make the correct diagnosis. As with most duplex ultrasound criteria for stenosis/restenosis, significant variability may exist in different vascular laboratories [35]. Therefore, the criteria we propose for diagnosing renal artery ISR should be validated in individual laboratories.

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