Direct Duplex Scanning Parameters in the Diagnosis of Renal Artery Stenosis: A Study to Validate and Optimize Cut-off Points

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Objective

To test the efficiency of the direct duplex scanning parameters in the diagnosis of renal artery stenosis (RAS), and verify whether or not the cut-off points recommended by medical literature are the most appropriate means to distinguish lesion severity.

Methods

Prospective study, including 62 patients with RAS, submitted to a duplex ultrasound scan and selective arteriography. The peak systolic velocity (PSV) and the renal-aortic ratio (RAR) were measured. Statistical analysis included the ROC (receiver operating characteristic curve), unpaired student's t-test, sensitivity, specificity, positive and negative predictive values and accuracy.

Results

The arteriography revealed RAS 0-59% in 31 arteries (24%); RAS 60-99% in 91 arteries (72%) and 5 occlusions (4%). ROC analysis demonstrated that the lesion detection efficiency of PSV and RAR were similar with areas below the curves of 0.96 and 0.95, respectively. Considering the cut-off points recommended by medical literature, PSV of 180 cm/sec presented a sensitivity of 100% and specificity of 81%, while the RAR of 3.5 presented a sensitivity of only 79%, with a specificity of 93%. These parameters were analyzed in conjunction (direct criteria) revealing a sensitivity of 79% and specificity of 97%. The optimized cut-off points were: PSV of 189 cm/sec and RAR of 2.6, demonstrating sensitivity and specificity rates of 100%, 87%, 96% and 87% respectively.

Conclusion

The individual use of optimized peak systolic velocity (PSV) was the most efficient parameter in the detection and grading of RAS.

Key words

Renal artery stenosis, duplex scanning, systolic peak velocity.

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Hypertension is considered the most prevalent disease in the world affecting roughly 10-20% of the adult population[1] and approximately 50% of the population over age 70[2]. On average 5-10% have secondary hypertension[3], which can be as high as 50% in a hypertensive population with a well defined clinical picture[4]. Renal artery stenosis is the most common cause of secondary hypertension and the easiest to identify[5]. With the exception of hypertension caused by oral contraceptives, secondary hypertension caused by renal artery stenosis responds to treatment better than any other type of high blood pressure, it is easy to control and can even be cured with surgical intervention[6]. Obliterating atherosclerosis is responsible for more than 90% of the cases of renal artery stenosis and to a lesser degree fibromuscular dysplasia (FMD)[7].

Approximately one quarter of the patients with RAS could develop ischemic nephropathy[8]. It is estimated that renovascular hypertension (RVHT) is responsible for 20% of the patients with end stage kidney failure who require permanent dialysis support[9]. Therefore, patients with hypertension and progressive chronic renal insufficiency should be investigated to exclude the hypothesis of renovascular hypertension (RVHT) in order to prevent the kidney damage from developing into irreversible atrophy[10].

Currently, a variety of diagnostic tests for RVHT detection is widely available. A triage examination should be innocuous, economical, dispense the use of nephrotoxic contrast agents or ionizing radiation and most importantly present high sensitivity with an elevated negative predictive value[11].

Based on the success obtained in carotid artery studies and postoperative evaluations of kidney transplants, duplex scanning was implemented to investigate RAS a little more than twenty years ago[12,13,14,15]. The use of this method was made possible by the development of low frequency transducers and modern image processing techniques that enabled detection of deep abdominal vessels [16].

Initially some of the criteria for RAS detection were based on the parameters used for carotid assessment such as: PSV higher than 100 cm/sec, no flow during the diastole and blurring of the Doppler spectrum during the systole (equivalent to turbulence in color mode)[12], among others. Later, researchers from the Washington University proposed new RAS evaluation criteria using the renal-aortic ratio (RAR) of 3.5 [6,15,16,17], and the peak systolic velocity (PSV) of 180 cm/sec[15,18]. These criteria were accepted and have been widely used for publications purposes up to present times discarding all other criteria.

Currently, the ROC curve is being used in radiology and new studies are being published to test the cut-off points established by medical literature, generating controversy regarding its validity. Similarly, this study proposes to test the efficiency of the direct duplex scanning parameters for diagnosing RAS using the ROC curve and verify if the cut-off points recommended by medical literature are the most appropriate means to distinguish lesion severity.

Methods

This is a prospective study, conducted through an inter-institutional study between the Radiology Department of the Medical School of the Federal University of Rio de Janeiro, and its Total Care Image Diagnosis department. The study was approved by the Research Ethics Committee of the Medical School of the Federal University of Rio de Janeiro.

The study was conducted between August 2002 and August 2004. Seventy-eight patients and 159 renal arteries were investigated. The patients were from two different backgrounds. The majority consisted of patients referred by vascular surgery after the detection of RAS 60-99%, diagnosed by conventional arteriography. The clinical history of these patients was either for intermittent claudication and multiple risk factors for atherosclerosis or for the investigation of RVHT. The minority consisted of patients referred by the cardiology department with a history of refractory hypertension, using three or more anti-hypertensive medications with or without risk factors for cardiovascular disease and therefore with a high probability that they had RVHT.

Duplex scanning was performed on all patients. For the group of patients that had previously undergone a conventional arteriography, the sonographer was not informed of the renal artery affected or the severity of the lesion. For the second group that had not previously undergone a conventional arteriography, only those who presented a positive duplex scan (RAS 60-99%) were referred for diagnostic confirmation by selective arteriography. Therefore, 62 patients (127 renal arteries) with significant stenosis (RAS 60-99%) in at least one renal artery were included in the study.

Exclusion criterion was based on the absence of RAS 60-99% in at least one of the renal arteries (since these patients were not indicated for a selective arteriography). Other exclusion factors included: patients whose duplex scan was not in accordance with the proposed study protocol, as well as patients with a history of previous angioplasty and stent implant surgery or renal artery revascularization surgery.

The duplex scans were performed by the same sonographer physician, one of the authors of this study (CMC), using a Hewlett Packard, sonos model 4500 equipment and a 1.8 – 4.0 MHz sector transducer and a 3.0 – 3.5 MHz convex transducer. Patient preparation consisted of absolute fasting for 12 hours. All patients were submitted to a selective arteriography (standard test) within three months of the duplex scan due to the therapeutic indication of percutaneous angioplasty. Each arteriography was evaluated independently by two observers (one a co-author of this study). Lesion grading was performed by means of visual observation and quantitative measurement (by the tracings made by the computer program) was only conducted in the case of borderline stenosis or disagreement. The findings of the arteriography were classified in three groups: normal artery or with a slight to moderate lesion (RAS 0-59%); significant stenosis (RAS 60-99%) and occlusion.

Parameters analyzed: PSV and RAR – The first step of the examination protocol was to visualize the aorta and the ostial renal arteries using a transabdominal approach with the patient in a supine position. Next, the flank approach was used with the patients placed on their left and right sides to trace the renal artery path to the hilum of the kidney.

The evaluation included detecting the highest PSV along the entire length of the renal artery, using a Doppler incidence angle of 60°. The cut-off point recommended by medical literature of 180 cm/sec[15,18,19,] was considered to distinguish lesion severity (RAS 60-99%).

RAR is the ratio between the PSV detected in the renal artery and the PSV in the aorta. The cut-off point recommended by medical literature for RAR of 3.5 [6,15-19] was considered for lesion grading of 60-99%. The aorta PSV (with a fixed incidence angle of 60°) was obtained between the level of the origins of the superior mesenteric arteries and renal arteries, keeping as distal as possible from the presence of dilations or local aorta stenosis.

PSV and RAR were analyzed in conjunction for the so called direct criteria and later, the results for each variable were calculated individually. Stenosis severity was classified according to the criteria of Strandness DE Jr and associates as shown in sidebar I[18,19].

Occlusion of the renal artery was considered when there was no flow detected along its length and the longitudinal measurement of the kidney was less than 9.0 cm[18,19].

Analysis of accessory renal arteries was not included in the scope of this study except in the case of a main artery occlusion which diverted the flow to a pervious accessory artery.

Chart 1 – Classification criteria proposed by Strandness et al[18,19] for renal artery stenosis severity and occlusion

PVS < 180 cm/sec	normal test
PVS < 180 cm/sec	non-graduated stenosis
PSV > 180 cm/sec & RAR < 3.5	stenosis < 60%
PSV > 180 cm/sec & RAR > 3.5	stenosis > 60%
No renal artery flow & kidney < 9.0 cm	occlusion

PSV- peak systolic velocity; RAR renal-aortic ratio.

Statistical analysis was performed using the computer program Statistical Package for the Social Sciences (SPSS). The unpaired Student's t-test was used to compare the averages and standard deviations (SD) of each duplex scan parameter to assess renal artery stenosis, enabling the analysis of the efficiency of each one to detect and grade the lesions. All differences were considered statistically significant when $p < 0.005$. The Receiver Operating Characteristic (ROC) curve was used to analyze each parameter tested, enabling evaluation of the areas below the curves and optimization of the respective cut-off points. Combined and individual calculations for sensitivity, specificity, positive predictive value, negative predictive value and accuracy were performed for each parameter.

Results

In this study, 127 renal arteries from 62 patients were evaluated using duplex scanning and a selective arteriography. The sample consisted of 37 women (60%) and 25 men (40%). Ages varied between 22 and 86 years (mean 66.9 years ± 10.9). The technical success rate obtained for renal artery detection by duplex scanning was 100%. The arteriography results are shown in table 1

Table 1 – Selective arteriography results for the diagnosis of renal artery stenosis

Degree of Stenosis	No of Arteries (n)	(%)
0-59%	31	24%
60-99%	91	72%
Occlusion	05	4%
Total	127	100%

Bilateral damage of 60-99% was found in 28 patients (45%). There was one case (1.6%) of RAS 60-99%, in a patient with just one kidney (with a previous history of nephrectomy due to renal atrophy). From the 5 patients that presented renal artery occlusions, two kidneys were fed by an accessory renal artery. In two other patients, the accessory renal artery was located in the kidney, contralateral to the occlusion for a total of 4 cases with accessory renal arteries. The remaining accessory renal arteries were not accounted for and therefore were not included in the numerical variable calculations. As such, the calculation spreadsheet included the 118 main renal arteries and the 4 accessory renal arteries, excluding the 5 occlusions, for a total of 122 arteries.

In reference to lesion etiology, 55 patients (89%) had obliterating atherosclerosis and 7 (11%) had fibromuscular dysplasia (FMD). Table II shows the occurrence of stenosis in accordance with age, gender, risk factors and serum levels of urea and creatinine according to lesion etiology: Parameters analyzed: PSV and RAR – Significant statistical differences were found for the PSV and RAR values between the groups of patients with RAS 0-59% and RAS 60-99% ($p < 0.005$), as shown in table 3.

The ROC analysis revealed similar PSV and RAR areas below the curve, that is, 0.96 and 0.95, respectively (when the largest possible area was defined as 1.0). The ROC analysis established the optimal cut-off points of PSV as 189 cm/sec and RAR as 2.6, as shown in figure 1 and table 4.

The results were analyzed individually using the different cut-off points. The best parameter for lesion diagnosis was PSV with 100% sensitivity for both cut-off points of 180 and 189 cm/sec, and specificity of 81% and 87%, respectively. The RAR cut-off point of 3.5 had low sensitivity (79%) and high specificity (93%) but improved drastically with cut-off point optimization. These results are shown in table 5.

The ROC analysis showed that the combined analysis of the direct criterium was improved after optimization of the cut-off points, as shown in table 6.

Figure 2 shows an example of a 78 year old female patient with a history of diabetes, dyslipidemia and sudden aggravation of hypertension, who became refractory to the three anti-hypertensive medications in use. The colored duplex scan detected ostial stenosis of the right renal artery with PSV = 392 cm/sec and RAR = 2.7. Considering the cut-off points recommended by medical literature the classification for this stenosis would be RAS 0-59%. However, the selective arteriography revealed RAS of 60-99%. This false-negative result of the duplex scan using the cut-off points recommended by medical literature demonstrates the elevated limit of the 3.5 RAR.

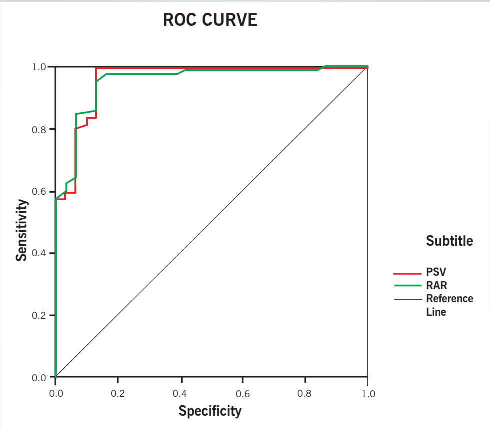

Fig. 1 – Areas below the peak systolic velocity (PSV) and the renal-aortic ratio (RAR) demonstrated by the ROC (receiver operating characteristic curve) analysis.

Table 2 – General characteristics of the population according to the renal artery stenosis etiology

	A	FMD	p
Age *	69.3 ± 7.8 years	48.1 ± 14.3 years	0.001
Gender ♀	100 %	85.7 %	0.225
Secondary Hypertension	100 %	100 %	1
Smoking **	52.7 %	28.6 %	0.440
Associated Vasculopathy	89 %	14.3 %	0.001
Diabetes Mellitus	40 %	0 %	0.037
Dyslipidemia	89 %	57 %	0.024
Serum urea*	56.7 ± 26.3 mg/ dl	51.8 ± 39.6 mg/ dl	0.668
Serum Creatinine*	1.5 ± 1.01 mg/ dl	1.6 ± 1.9 mg/ dl	0.903

*OA – obliterating atherosclerosis; FMD- fibromuscular dysplasia. * Mean and SD values. **Smoking: smokers + ex-smokers; significance level p < 0.005; 95% confidence interval.*

Table 3 – Comparison of mean and standard deviation values for the direct duplex scan parameters in accordance with the grade of renal artery stenosis (RAS) of 0-59% and 60-99%

Parameter	*RAS 0-59%	**RAS 60-99%	p
PSV	155.4 ± 72.9	431.5 ± 172.1	< 0.005
RAR	1.86 ± 0.89	5.46 ± 2.67	< 0.005

PSV- peak systolic velocity (cm/sec); RAR- renal-aortic ratio. Level of significance p < 0.005; 95% confidence interval.

Table 4 – Verification of the efficiency and optimization of the cut-off points of the direct duplex scan parameters using the ROC curve analysis

ROC	Area	Standard Error	p	Lower Limit*	Upper Limit*	Cut-off Point
PSV	0.962	0.020	0.001	0.922	1.002	189
RAR	0.954	0.021	0.001	0.914	0.995	2.6

*PSV - peak systolic velocity (cm/sec); RAR - renal-aortic ratio; significance level p < 0.005; ROC - receiver operating characteristic curve; *95% confidence interval.*

Table 5 – Results obtained from individual testing of each parameter in relation to the cut-off points recommended in medical literature and those determined by the ROC curve

	Cut-off Point	S	Sp	PPV	NPV	A
PSV	180	100%	81%	94%	100%	95%
PSV	189	100%	87%	96%	100%	97%
RAR	3.5	79%	93%	97%	60%	83%
RAR	2.6	96%	87%	96%	87%	93%

PSV - peak systolic velocity 180 cm/sec and 189 cm/sec; RAR – renal-aortic ratio of 3.5 and 2.6; S - sensitivity; Sp - specificity; PPV – positive predictive value; NPV – negative predictive value; A- accuracy

Table 6 – Results obtained from the direct criterium (combined) using the cut-off points recommended by medical literature and those determined by the ROC curve

	S	Sp	PPV	NPV	A
PSV 180 cm/sec & RAR 3.5	79%	97%	99%	61%	84%
PSV 189 cm/sec & RAR 2.6	96%	94%	98%	89%	95%

Direct criterium: PSV- peak systolic velocity; RAR- renal-aortic ratio; S- sensitivity; Sp- specificity; PPV- positive predictive value; NPV- negative predictive value; A- accuracy.

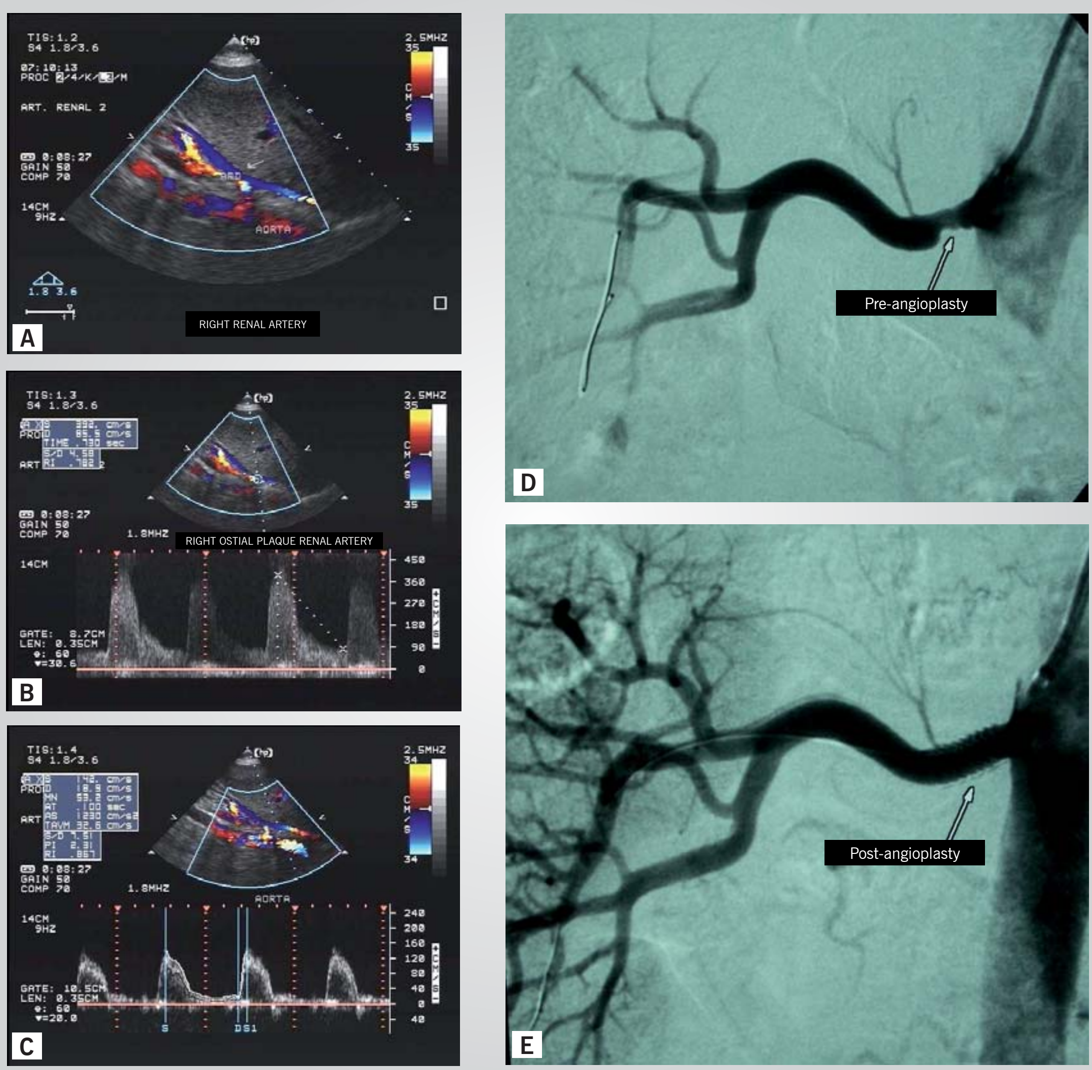

Fig. 2 - A 78 year old female patient with a history of diabetes and dyslipidemia, with a sudden aggravation of hypertension that had previously been controlled. A) The colored duplex scan *detected flow turbulence at the origin of the right renal artery. B) Peak systolic velocity in the renal artery = 392 cm/sec (60° angle). C) Peak systolic velocity in the aorta = 142 cm/sec (60° angle) and renal-aortic ratio = 2.7. D) The selective arteriography revealed right ostial renal artery stenosis of 60-99%. E) Percutaneous angioplasty and stent implant were performed.*

Discussion

This study revealed three findings of special interest. 1) The cut-off points determined by the ROC curve had a significantly higher diagnostic efficiency than those recommended by medical literature, particularly in reference to RAR. 2) The most efficient individual parameter to diagnose and grade renal artery stenosis was PSV. 3) The adoption of a combined direct criteriumimproved specificity with a slight drop in sensitivity.

Although the prevalence of RVHT is low, the selection of patients with RAS 60-99% on at least one side elevated the prevalence (75%) in our case study. As it is known there is a direct relationship between low prevalence of this disease and a low positive predictive value that could not guarantee good results regardless of the test series used on a random population[11]. This explains the elevated positive predictive value (PPV) and the reduced negative predictive value (NPV) in this study, obtained from the direct criterium for both the cut-off points recommended in medical literature and those determined by the ROC curve.

For the first time in the 1980's, researchers from Washington University established evaluation parameters for the duplex scan to study renal arteries that have been used up to the present date. Initially, they confirmed that differences in the individual velocity measurements in the aorta were directly related to velocity variations in the renal arteries and therefore a relation should be made between the renal artery and aorta flow velocities. These authors found a RAR limit of 3.5 to diagnose significant stenosis[16], that was later accepted by other researchers [6,15].

This same group from the Washington University performed duplex scans on the renal arteries of healthy individuals in order to confirm variations in normal artery velocities and obtained an average PSV of 100 cm/sec ± 20 cm/sec. These authors emphasized that due to the exit angle of the renal artery angle from the aorta, combined with its depth and sinuous curve, that the exact Doppler insonation angle over the origin is difficult to obtain which explains the great variation in these velocities. Therefore, to avoid false-positive results, the PSV value was extrapolated to the limit of 180 cm/sec which is more than two times higher than the normal standard deviation values obtained in healthy individuals[18].

Based on these studies, various authors have tested the accuracy of the duplex scan to diagnosis RAS using the parameters and cut-off points that they recommend. Unfortunately, at that time, analysis using the ROC curve was extremely limited in the radiology field and therefore it was not used to determine the cut-off points. Even today, these cut-off points are widely accepted and there are very few studies on the validation and optimization of these parameters.

Parameters analyzed: PSV and RAR – The technical success rate for detecting the renal arteries was 100%, concurrent with the success rates of recent studies (95-100%) [20,21]. The mean values ± SD of renal artery PSV presented a significant statistical difference ($p < 0.005$) between the groups with RAS 0-59% and RAS 60-99% (see table 3) in agreement with the results obtained in various publications [22,23,24].

In the present study, the ROC curve demonstrated that the efficiency of PSV and RAR are similar, as shown by the areas below the curves of 0.96 and 0.95, respectively (fig. 1). Although the areas under the curves did not present a significant statistical difference, PSV was the parameter that most accurately distinguished stenosis of 0-59% from stenosis of 60-99%, due to its excellent sensitivity (100%). The optimal cut-off point of 189 cm/sec as determined by the ROC curve proved to be more appropriate than the cut-off recommended by medical literature since it maintained a sensitivity of 100% and elevated the specificity and accuracy of this parameter (table 4).

RAR in the evaluation of RAS 60-99% presented mean values of 5.46 ± 2.67 ($p < 0.005$) revealing however, a considerable overlap in the values between the groups with RAS 0-59% and 60-99% (table 3). These results agree with the findings of Baumgartner and associates, that while examining the reproducibility of this method in healthy individuals, demonstrated that the RAR presented an average of 0.85 ± 0.41, suggesting that values lower than 3.5 could be associated with significant renal artery stenosis, without losing the specificity of the method[20].

Although a RAR of 3.5 had produced an elevated specificity (93%) it provoked considerable loss in sensitivity (79%). The optimal cut-off point of 2.6 as defined by the ROC curve (table 4) increased the sensitivity (96%) and accuracy (93%) of this parameter in relation to the cut-off point recommended by medical literature (79% and 83% respectively). In addition, it also improved the NPV of this parameter without interfering in the PPV (table 5).

A detailed analysis of the data revealed that the limited efficiency of RAR corresponded to the accentuated variability of the denominator used for its calculation. Patients with heart failure and abdominal aorta aneurisms presented lower PSV in the aorta and therefore elevated indexes of RAR. On the other hand, patients with aortoiliac occlusive disease presented higher PSV in the aorta and consequently lower indexes of RAR. Based on this, these results suggest that there are no advantages for using RAR as an individual parameter to diagnose RAS of 60-99% when compared to the individual use of PSV in the renal artery.

The reduced sensitivity (79%) and elevated specificity (97%) demonstrated by the direct criterium (PSV and RAR in conjunction) with the cut-off points recommended by medical literature, were also explained by the specific behavior of RAR. However, the cut-off points determined by the ROC curve proved to be superior, for they increased sensitivity without causing a drastic deficit in the criterium specificity. They also improved the NPV, which lowered the number of false-negatives (table 6).

It is well known that the most important issue for a doctor is a positive result from a sensitive test[25], since a sequential test should have, par excellence, the highest sensitivity and the highest NPV. As such, PSV was the most efficient parameter to evaluate RAS in this case study, due to its 100% sensitivity, 100% NPV and 97% accuracy.

The PSV cut-off point determined by the ROC curve in the present study (189 cm/sec) which is higher that the value recommended by medical literature (180 cm/sec), is concurrent with the values obtained in other studies that have been published more recently which reveal better results when the PSV cut-off point is increased to values between 198 - 220 cm/sec [22,26,27,28]. In contrast to these findings, Motew and associates obtained better results with a cut-off point of 180cm/sec than with the value of 200 cm/sec [23] and Napoli and associates preferred the cut-off point of 159 cm/sec rather than 180 cm/sec [24], due to the higher sensitivity rates obtained with these limits.

Our results demonstrated that the optimal cut-off point for the RAR, as determined by the ROC curve, was lower than that recommended by medical literature. This result agrees with the findings of other authors who also demonstrated that by reducing the RAR cut-off point to values between 2.5 and 3.2, the sensitivity was increased which lowered the occurrence of false negatives [24,26,27,28]. On the other hand, Miralles and associates demonstrated that the RAR with a cut-off point of 3.3 presented low sensitivity and that this parameter did not contribute to lesion diagnosis when compared to the individual use of PSV [22].

In the present study, the cut-off points determined by the ROC curve favor the increased sensitivity of the direct criterium in comparison to the low sensitivity obtained when using the cut-off points recommended by medical literature (table 6). These findings are in accordance with those of Conkbayir and associates, who obtained higher sensitivity with a combination of PSV of either 180 cm/sec or 200 cm/sec and RAR of 3.0 (when compared to the sensitivity obtained with the cut-off points recommended by medical literature), stressing that the determining factor for the improved results was the lower RAR cut-off point[28]. These findings also concur with the study conducted by House and associates, who obtained better results using a combination of PSV of 180 cm/sec and RAR of 3.0[27]. Although Engelhorn and associates had obtained high sensitivity rates using the cut-off points recommended by medical literature, they emphasized that in the cases of false-negatives results, the PSV was approximately 200 cm/sec and the RAR was lower than 3.5 [29].

In our study, a comparative analysis between the efficiency of the optimized direct criterium and the individual efficiency of the optimized PSV enabled us to observe that the optimized PSV presented superior sensitivity and accuracy and demonstrated that the role of RAR in this case study was less important.

In the case of occlusion diagnosis, our study agreed with the arteriography in 3 of the 5 occlusion cases (60%). Of these, 4 occlusions presented proximal flow to the renal artery path as a result of collateral vessel development. This finding concurs with those of other researchers that also related the same limitation of the duplex scan in occlusion diagnosis due to the detection of collateral flow patterns close to the path of the blocked renal artery [16, 30, 31].

In conclusion, the optimized PSV was the most efficient parameter in the diagnosis and grading of RAS in this case study. The RAR cut-off point recommended by medical literature proved to be very high for distinguishing lesion severity. Even after optimizing the RAR cut-off point, individual use of RAR presented an inferior value when compared to the individual use of PSV and the optimized direct criterium.

The elevated disease prevalence in this case study was the main limiting factor since it is well known that this elevates sensitivity which in turn can elevate the number of false-positive results. Based on this, the results cannot be extrapolated for the population in general which presents a low prevalence of this disease. We believe that further research is required in order to verify whether or not these findings can be reproduced in a population with a lower prevalence of the disease and if the optimization of the cut-off points could reduce the unacceptable number of false-negative results of the duplex scan in the diagnosis of RAS.

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Potential Conflict of Interest

No potential conflict of interesrt relevant to this article was reported.

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