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## CLINICAL STUDY

# Imaging Modalities for Renal Artery Stenosis in Suspected Renovascular Hypertension: Prospective Intraindividual Comparison of Color Doppler US, CT Angiography, GD-Enhanced MR Angiography, and Digital Subtraction Angiography

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The aim of the study was to evaluate the diagnostic accuracy of Color Doppler US, CT Angiography (CTA), and GD-enhanced MR Angiography (MRA) compared with digital subtraction angiography (DSA) for the detection of renal artery stenosis in patients with clinically suspected renovascular hypertension. Fifty-eight patients with suspected renovascular hypertension were enrolled in the study. All patients underwent Color Doppler US, CTA and GD-enhanced MRA. DSA was the gold standard method for the number of renal arteries, existence and degree of stenosis, or evidence of fibromuscular dysplasia. DSA depicted 132 renal arteries, 16 stenoses, and 4 arteries with fibromuscular dysplasia. Color Doppler US failed to detect 1 main and 14 polar arteries. CTA

depicted all main renal arteries and 7/16 polar arteries, but failed to detect stenosis in two accessory vessels. Likewise, MRA did not detect stenotic accessory renal arteries, depicted 9/16 polar renal arteries, but missed two main renal arteries. All methods depicted the four main renal arteries with fibromuscular dysplasia. The overall sensitivity, specificity, and positive and negative predictive accuracy were 75%, 89.6%, 60% and 94.6%, respectively, for color Doppler US; 94%, 93%, 71%, and 99%, respectively, for CTA; and 90%, 94.1%, 75%, and 98%, respectively, for GD-enhanced MRA. CTA and GD-enhanced MRA have comparable and satisfactory results with respect to the negative predictive accuracy of the suspected renal artery stenosis. The concept of an imaging algorithm including US as screening test when appropriate and CTA or MRA as the second step-procedure is suggested. Therefore, DSA may be reserved for cases with major discrepancies or therapeutic interventions.

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## INTRODUCTION

Renovascular disease is considered the most common cause of potentially curable secondary hypertension, and is found in 1–5% of the general hypertensive population.<sup>[1]</sup> In patients with symptomatology suggestive of renovascular hypertension (e.g., poorly controlled hypertension), the prevalence of renal artery stenosis rises to 20–40%.<sup>[2]</sup> The two most common primary diseases of renal arteries are stenosis secondary to atherosclerotic renal artery disease and fibromuscular dysplasia. Atherosclerotic renal artery stenosis (renovascular disease) has become the leading cause of end stage renal disease in the elderly.<sup>[3,4]</sup> The early detection of renal artery stenosis is mandatory in order to treat it adequately and thus reduce the incidence of end stage renal disease in these patients. Therefore, the role of imaging investigation is critical to accurately determine the pathology of renal arteries and guide appropriate treatment.

The radiological imaging armamentarium related to renal arteries includes Doppler ultrasonography, conventional angiography, and CT and MR angiography.<sup>[5–8]</sup> The diagnostic role of conventional angiography continues to diminish as noninvasive CT and MR angiography develop.<sup>[4,6,8]</sup> Parameters that favor noninvasive vascular imaging include patient's comfort, duration of the examination, reduced complication rate<sup>[9,10]</sup> and diminished cost. However, conventional angiography still has superior resolution for the evaluation of small vessels and offers the option of simultaneous therapeutic interventions such as percutaneous revascularization by balloon angioplasty and/or stenting.<sup>[11]</sup> Surgical intervention is often reserved for selected cases based mainly on the mapping of findings of the renal arteries.

The accuracy of these methods is therefore essential not only to exclude a potentially treatable renovascular disorder but also to determine the appropriate therapeutic protocol.<sup>[11]</sup> The aim of the present study is to compare these four imaging methods in a patient cohort suffering from hypertension attributed to renovascular etiology and suggest an imaging algorithm according to the imaging findings.

## PATIENTS AND METHODS

In this prospective comparative study, 129 patients were submitted for imaging investigation due to hypertension during a four-year period (2002–2005). Fifty-eight of them (25 men, 33 women, age range 17–75 years, mean age 47.4 years), all patients with suspected renovascular hypertension, were included in our study. The suspicion of renovascular hypertension was based on the existence of at least one of the following clinical inclusion criteria:

- onset of hypertension before the age of 30 or after the age of 50,
- severe hypertension, refractory to standard medical treatment, associated with progressive renal failure,
- sudden onset of arterial hypertension, with predominant increase of diastolic pressure, or
- rapidly progressive arterial hypertension.

The exclusion criteria were:

- history of diabetes mellitus
- collagenoses, vasculitides or other systemic disease
- severe allergic reactions to contrast material, or
- contraindications for an MRI study

Only one of our patients was claustrophobic, but managed to undergo the MRA after oral administration of mild sedatives.

The mean baseline systolic blood pressure was 162 mmHg  $\pm$  21, and the mean diastolic blood pressure was 90 mmHg  $\pm$  14. The ethical review board of our hospital approved the study, and written informed consent was obtained from all participants.

Initially, all patients were examined with Doppler U/S of the renal arteries, followed by CTA, MRA, and finally DSA.

The Doppler ultrasound of the renal arteries was performed on an ATL HDI 3000 using a convex 2–4MHz transducer in the supine position. Doppler sonographic studies included imaging of the main renal arteries, and an effort was made to identify the accessory renal arteries, which was not possible in a few patients. The selected angle of insonation was between 30 and 60° and the age of the patient was taken into consideration in order to obtain meaningful measurements. The measurements included peak systolic velocities within main renal arteries, renal-aortic ratio (RAR), and intrarenal blood flow measurements. Peak systolic velocities <100 cm/sec have been considered as normal, those between 100–200 cm/sec as suggestive of mild stenosis (<50% narrowing), and those >200 cm/sec as suggestive of severe stenosis (50–99% narrowing). RAR greater than 3.0 was evidence of significant renal artery stenosis. Intrarenal vessel evaluation was performed with the patient in the lateral decubitus position, and an acceleration time greater than 0.07 seconds with a tardus-parvus waveform was considered diagnostic of severe stenosis of the extrarenal arteries.

Subsequently, all patients underwent renal CT angiography on a helical CT scanner (Tomoscan SR 5000 Philips, Eindhoven, The Netherlands). The acquisition started with a native low dose localizing dynamic scan to determine the level of the renal arteries, and the study was performed in a craniocaudal direction. The examination

protocol included axial images at the level of the renal arteries with a FOV 220 mm. A total volume of 150 mL non-ionic contrast material was then injected via a power injector at a rate of 4 mL/sec through an antecubital intravenous 18 G catheter. The slice thickness was 1.5 mm; pitch, 2 mm; scan time, 1.5 sec; kVp, 120; mA, 175; and the reconstruction index, 1 mm. A fixed delay time of 22 sec was used. Following the examination, the axial source images were analyzed on the Philips Easy Vision workstation (release 2.1) to obtain maximum intensity projection (MIP) and multiplanar reconstruction (MPR).

The MRAs of the renal arteries were performed on a 1.5 Tesla (Magnetom Vision, Siemens, Erlangen, Germany). A phased array body coil was used in all patients. After localizing the main renal arteries in the coronal and axial projections, a coronal 3D fast spoiled gradient-echo (Turbo-Flash, Siemens) breath-hold sequence with fat saturation was performed. The imaging parameters were TR, 4.0 ms; TE, 1.6; flip angle, 30°; slab thickness 64 mm, effect thickness, 1.78 mm; FOV, 360mm; and matrix, 256×156 acq time 19sec. Gadolinium chelate Magnevist®, Schering, Berlin, Germany was administered through a 20G antecubital venous catheter via a power injector at a rate of 2 mL/sec (0.2mmol/Kg). The delay time before the acquisition was determined by the detection of contrast in the renal arteries after injecting a bolus of 2 mL of gadolinium contrast, which was immediately followed by 20 ml saline. Image reconstruction was performed using MIP and image subtraction in all patients in an axial and coronal projection.

CTA and MRA image sets were separately analyzed by two experienced radiologists in a double-blind fashion. The number of identified renal arteries (main and accessory) and the presence and degree of renal artery stenosis or any other abnormal findings were recorded. The grading of renal stenosis was defined as mild when the reduction of the caliber was <50%, severe when the reduction was between 50–99%, and total occlusion. The digital subtraction angiography (DSA) of the renal arteries was performed on a V 3000 Integris (Philips, Eindhoven, the Netherlands). The examination protocol included an aortogram of the abdominal aorta using a 5F pigtail catheter (Cordis, Johnson & Johnson, Miami, Florida, USA) with transfemoral approach. Non-ionic contrast agent was injected into the aorta at a rate of 16 mL/sec (max. dose, 25 ml). Selective renal angiography was systematically performed with a hydrophilic catheter (Cobra SF, Terumo, Belgium) in the posteroanterior and lateral view. The volume of the contrast medium was 8 ml (3 mL/sec). The number of accessory renal arteries was determined and the presence of stenosis or other pathology was noted and graded according to the grading scheme used at MRA and CTA.

For the statistical analysis of the study, all findings of each method were separately and blindly evaluated prior to

the performance of DSA. In addition, sensitivity, specificity, and positive and negative predictive accuracy were calculated for each diagnostic modality individually. Statistical exact two-sided confidence intervals for binomial proportions at the 95% level for the above parameters were calculated.

## RESULTS

The results are summarized in Table 1 regarding the findings of all utilized imaging methods. DSA, which is considered the gold standard, revealed 132 arteries (116 main renal arteries and 16 accessory arteries) in the 58 patients examined. Moreover, multiple renal arteries were detected in 13 patients.

Color Doppler US was unable to detect the left main renal artery in one patient. In addition, US depicted two polar arteries, but it was inadequate to visualize 13 polar and one accessory renal artery. US detected a total of 117/132 (88.6%) renal arteries.

CT angiography was considered technically adequate related to the detection of all main renal arteries in all patients. Nevertheless, CTA failed to demonstrate 9 polar arteries out of 16 and missed two polar arteries with stenosis. A total of 123/132 (93.2%) renal arteries were detected by this method.

MR angiography missed two main renal arteries because they were superimposed with renal veins bilaterally due to a miscalculation of the delay time. The examination was repeated at a later date. MRA managed to demonstrate 9 polar arteries out of 16, and this is the second best estimation after DSA. A total of 123/132 (93.2%) renal arteries were detected by this method as well.

Color Doppler US findings were evaluated related to the ability to recognize stenosis or evidence of fibromuscular dysplasia in renal arteries. It was determined that there were 15 true positive, 10 false positive, 87 true negative, and 5 false negative results (see Figures 1 and 2). With respect to the true positive findings, Color Doppler US detected all four renal arteries with fibromuscular dysplasia and assessed 6 cases with mild stenosis and 5 cases with severe stenosis. These data corresponded to a sensitivity of 0.75 [95% CI: 0.56 < Se < 0.94], a specificity of

**Table 1**  
Distribution of findings among different methods

|     | TP | TN  | FP | FN |
|-----|----|-----|----|----|
| US  | 15 | 87  | 10 | 5  |
| CTA | 17 | 98  | 7  | 1  |
| MRA | 18 | 97  | 6  | 2  |
| DSA | 20 | 112 | —  | —  |



**Figure 1.** MRA shows a left renal artery that has been interpreted as stenotic.



**Figure 2.** DSA of the same patient that demonstrates normal patency of the left renal artery.

0.89 [95% CI: 0.836 < Sp < 0.957], a positive predictive accuracy of 0.6 [95% CI: 0.408 < pp < 0.792], and a negative predictive accuracy of 0.94 [95% CI: 0.857 < np < 1.035].

CT angiographic findings were determined as 17 true positive, 7 false positive, 98 true negative, and 1 false negative. With respect to the true positive findings, CTA detected all four renal arteries with fibromuscular dysplasia and assessed 1 case with mild stenosis and 12 cases with severe stenosis. These data corresponded to a sensitivity of

0.94 [95% CI: 0.839 < Se < 1.05], a specificity of 0.93 [95% CI: 0.886 < Sp < 0.981], a positive predictive accuracy of 0.71 [95% CI: 0.526 < pp < 0.89], and a negative predictive accuracy of 0.99 (98/99) [95% CI: 0.95 < np < 1.03].

The findings of MR GD-enhanced angiography were determined as 18 true positive, 6 false positive, 97 true negative, and 2 false negative (see Figures 1 and 2). With respect to the true positive findings, MRA detected all four renal arteries with fibromuscular dysplasia and assessed none of the cases with mild stenosis and 14 cases with severe stenosis (see Figures 3 and 4). These data corresponded to a sensitivity of 0.9 [95% CI: 0.769 < Se < 1.031], a specificity of 0.94 [95% CI: 0.897 < Sp < 0.987], a positive predictive accuracy of 0.75 [95% CI: 0.577 < pp < 0.923], and a negative predictive accuracy of 0.98 [95% CI: 0.924 < np < 1.036]. The above results are summarized in Tables 2–4.

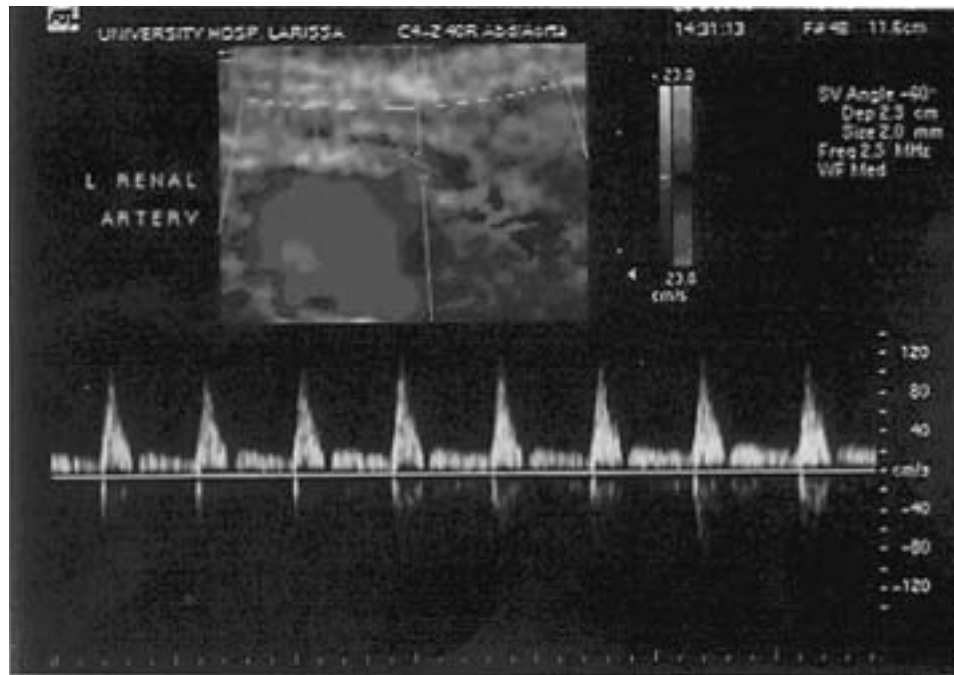
None of the above methods but DSA depicted the stenosis of the two polar arteries. In addition to that, US findings were considered normal in three cases of mild stenosis and in two cases of severe stenosis involving main renal arteries. Color Doppler US depicted both patients with bilateral findings suggestive of fibromuscular dysplasia, namely mid- to distal flow derangement and velocity augmentation. Both CTA and MRA depicted these two patients correctly. CTA was unable to detect one mild stenosis, and MRA failed to detect two mild stenotic main renal arteries.

## DISCUSSION

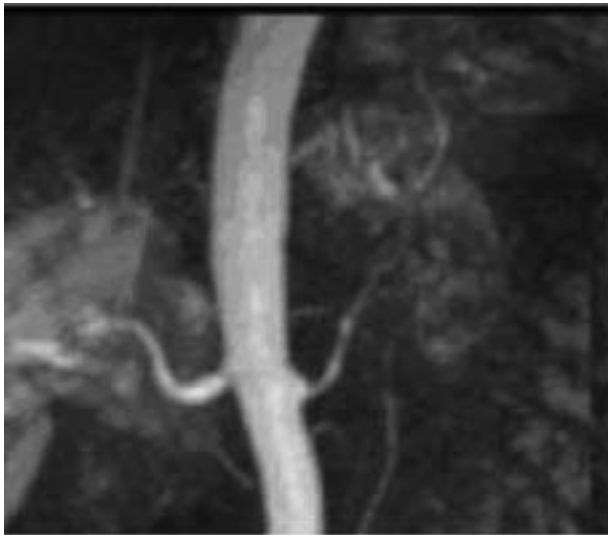
A large number of studies have been published comparing different imaging methods regarding renal artery stenosis. However, there is limited body of evidence comparing all four imaging modalities in a prospective way. In this current prospective clinical trial, the role of each imaging modality in the diagnostic approach of patients with medically refractory hypertension due to renovascular stenosis was assessed.

In this study, the specificity and sensitivity of color Doppler US regarding the detection rates of renal artery pathology were 75% and 89.6%, respectively. There was an overestimation of the severity of the stenosis in two cases. There were also some discrepancies related to the grading of stenosis in main renal arteries, with underestimation in two cases and non-visualization in three cases. Yet, there were 10 patients falsely reported as having stenosis, and there were five non-detected cases, although the findings involved polar arteries in two cases.

Color Doppler US has the advantage of being a widely available, inexpensive, well-tolerated, and reproducible method. Color Doppler US might be useful as the



**Figure 3.** Transverse color Doppler US image. The peak systolic velocity is below 100cm/sec, which is considered normal.



**Figure 4.** MRA demonstrates a severe stenosis, which was confirmed by DSA.

first screening method for suspected renal artery pathology and is considered a highly accurate method,<sup>[8]</sup> although there are a number of limitations involved with the application of this method.<sup>[12–15]</sup> An important drawback is the inability of US to reliably detect accessory renal arteries. Several authors agree that the detection rate is poor, although 25–30% of the population may have such an

**Table 2**

Imaging findings of US, CTA, MRA, and DSA

| Findings                                   | US  | CTA | MRA | DSA |
|--------------------------------------------|-----|-----|-----|-----|
| Normal renal artery                        | 90  | 92  | 90  | 98  |
| Normal polar artery                        | 2   | 7   | 9   | 13  |
| Normal (distal) accessory artery           | 0   | 0   | 0   | 1   |
| Atherosclerotic main renal artery stenosis | 21  | 20  | 20  | 14  |
| Atherosclerotic polar artery stenosis      | 0   | 0   | 0   | 2   |
| Fibromuscular dysplasia                    | 4   | 4   | 4   | 4   |
| Invisible main renal artery                | 1   | 0   | 2   | 0   |
| Invisible polar artery                     | 14  | 9   | 7   | 0   |
| Total number of examined arteries          | 117 | 123 | 123 | 132 |

anatomic variation. In this series, 2/16 (12.5%) polar renal arteries were depicted with US, which was normal, but 2 of the missing polar arteries were stenotic, as was depicted by DSA. It has recently been published that a stenosis of a polar artery may be the cause of hypertension, which might support the theory of a new syndrome.<sup>[16]</sup> It is therefore important to exclude stenosis not only in main but also in polar renal arteries.<sup>[16–18]</sup>

**Table 3**

Distribution of true positive findings related to mild and severe stenosis among different methods

|     | Stenosis <50% | Stenosis 50–99% | FMD | Total |
|-----|---------------|-----------------|-----|-------|
| US  | 6             | 5               | 4   | 15    |
| CTA | 1             | 12              | 4   | 17    |
| MRA | 0             | 14              | 4   | 18    |
| DSA | 4             | 12              | 4   | 20    |

**Table 4**

Results of diagnostic efficacy of all three methods compared with DSA

|     | Sensitivity | Specificity | Positive predictive accuracy | Negative predictive accuracy |
|-----|-------------|-------------|------------------------------|------------------------------|
| US  | 75%         | 89.6%       | 60%                          | 94.6%                        |
| CTA | 94%         | 93%         | 71%                          | 99%                          |
| MRA | 90%         | 94.1%       | 75%                          | 98%                          |

In this study, renal artery stenoses above 50% were graded as severe. Although possible, a more detailed classification of stenosis by color Doppler US was avoided. This somewhat crude grading system used in this study is most suitable because it facilitates the comparison of color Doppler US with the other methods, especially MRA and CTA, and also because it has been already validated in various previous comparative studies.<sup>[19,20]</sup>

Regarding CTA, in this series, sensitivity and specificity of CTA were 94% and 93%, respectively, which are suggestive of a satisfactory imaging modality.<sup>[7–9,21–24]</sup> According to our data, CTA managed to detect all main renal arteries with severe stenosis but missed one case with mild stenosis. In addition to that, CTA was unable to detect the two polar arteries with stenosis that were detected with DSA and also missed 9/16 polar arteries. CTA proved to be correct in the estimation of all cases of fibromuscular dysplasia. Nevertheless, it has been recently suggested that CTA may be not as reliable as previously reported when applied to large, non-selective clinical groups.<sup>[25]</sup> This argument, although controversial, does not challenge the present findings because the selection of these patients followed specific criteria.

There are several studies in the literature that investigate the diagnostic efficacy of this method comparing it with DSA and suggest that it represents an attractive, minimally invasive procedure in patients with renal artery stenosis.<sup>[21–23]</sup> The standard limitations of CTA include severe allergic reactions to iodinated contrast media and X-ray exposure. Imaging features of CTA include

increased spatial resolution and rapid acquisition time. Galanski et al.<sup>[5]</sup> were among the first authors to report their findings related to renal artery pathology utilizing CT angiography. Wittenberg et al.<sup>[21]</sup> reported that in a study group, CTA managed to demonstrate 30/33 polar arteries. According to recently reported data, multidetector CT scanners are able to achieve better detection rates related to the demonstration of accessory renal arteries.<sup>[23]</sup>

MR GD-enhanced angiography in the present study showed all main renal arteries with severe stenosis but missed two polar arteries with stenosis. MRA also overestimated the severity of stenosis in all four cases of mild stenosis and in two cases of severe stenosis. Moreover, it was unable to demonstrate two main renal arteries due to the superimposition of renal veins. Regardless of GD-enhanced MRA ability to depict the whole abdominal aorta, 7/16 polar arteries were not detected, possibly due to their very small caliber. On the other hand, there were 6 cases with false positive results in addition to two cases that were overestimated from mild to severe stenosis. The overall sensitivity and specificity were 90% and 94.1%, respectively.

MRA images may be influenced by motion artifacts or by rapid opacification of renal veins, which led to non-visualization of two renal arteries in this study group.<sup>[19–22]</sup> Contrast-enhanced MRA has been proposed as a reliable alternative to DSA in the detection of renal artery pathology, with reported sensitivity >96% and specificity >92%.<sup>[26–29]</sup> The limitations of this method include poor arterial phase timing, inability of the patients to maintain breath-hold, and small imaging volume. Advantages are that the method is noninvasive, there is no radiation, and no allergic reactions have been reported. Therefore, MRA is considered a good alternative to DSA in patients that are eligible for it, namely those without metallic implants or claustrophobia.

Compared to US, both MRA and CTA permitted the detection of hemodynamically insignificant stenosis, which is important in the progression of patients with renovascular disease and is reported to have greater sensitivity in patients with severe stenosis. In this study, CTA and MRA were unable to detect almost any of the accessory renal arteries that were found with DSA. Factors such as very small caliber, angulations of the vessels, and misinterpretation as the early division of the main renal artery could attribute to the above result. It is therefore important to take into consideration that not only US but also CTA and MRA may be unable to detect all cases of polar renal arteries.

Fibromuscular dysplasia of four renal arteries was detected correctly by all methods. Nevertheless, the small number of cases included in that study and the advanced pattern, which was clear and obvious by all methods, may

explain the excellent performance reported. The reported data vary significantly from the above.<sup>[23]</sup>

With regard to the positive predictive accuracy of the above methods, MRA results were best (75%). The positive predictive value of CTA and US were 71% and 60%, respectively. These low values were due to the high number of false positive results of our study group. This should be taken into consideration, because it is critical in cases that a patient needs to be further investigated with DSA. Nevertheless, negative predictive accuracy was very high for both CTA (99%) and MRA (98%). It seems that in terms of accuracy, CTA performs slightly better related to the exclusion of any underlying pathology in renal arteries. Both tests, however, can reliably exclude patients without renal artery pathology.

The present study supports both CTA and MRA as two non-invasive tests that may be used for imaging investigation of renal arteries with quite satisfactory results and well-known limitations. This comes into agreement with a previously reported meta-analysis<sup>[27]</sup> of all these three modalities, which concluded that GD-enhanced MRA and CTA could be the preferred methods applied in patients referred for the evaluation of renovascular hypertension. The study herein presented followed the careful selection of all patients included with the same criteria and recruitment methods. Thus, all patients were included consecutively, and heterogeneities that might influence the group study were kept to a minimum.

One limitation of this study was the fact that DSA was accepted as a gold standard method with 100% sensitivity and specificity. This is not always supported by the literature,<sup>[29]</sup> but the study group did not include cases with controversial DSA findings. Therefore, one can rely on the data provided from DSA studies, although imperfections have been reported.<sup>[29]</sup>

With respect to the clinical significance of a study like the one presented, it is very important to take into consideration some recently published data from the RADISH (Renal Artery Diagnostic Imaging Study in Hypertension) study group.<sup>[29,30]</sup> Theirs was a well-documented conclusion that revolutionized the whole concept of CTA and MRA utility due to unacceptably low detection rates in a large study cohort of 356 patients. Discrepancies among different study groups or study designs have been reported previously as well, but always with favorable results considering minimal invasive angiographies. Differences in patient selection criteria and recruitment methods (i.e., consecutive vs. non-consecutive) may explain the above results that are in disagreement with a great amount of reported data.

The emphasis of the imaging investigation in a patient with suspected renal artery pathology should be aimed mainly in the algorithm best suited for the single patient. Ultrasound would obviously be ineligible for an obese

patient but would serve as a reliable screening for a younger patient. CTA or MRA could serve as the second modality of choice, and according these data, CTA seems to perform slightly better regarding the accurate detection of renal arteries pathology and the demonstration of aberrant polar renal arteries. Therefore, it may be suggested that the combined agreement of US and either CTA or MRA is sufficient to demonstrate pathology of renal arteries and serve as a reliable non-invasive process that can be used in the routine clinical practice. The application of the above combination is particularly useful in cases of hemodynamically significant renal artery stenosis. DSA may be reserved for patients with major discordance between the two modalities, for those with negative imaging findings and unexplained hypertension and those suitable for angioplasty or stent placement.

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