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Anatomical Eligibility of the Renal Vasculature for Catheter-Based Renal Denervation in Hypertensive Patients

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Objectives This study sought to determine the vascular anatomical eligibility for catheter-based renal artery denervation (RDN) in hypertensive patients.

Background Arterial hypertension is the leading cardiovascular risk factor for stroke and mortality globally. Despite substantial advances in drug-based treatment, many patients do not achieve target blood pressure levels. To improve the number of controlled patients, novel procedure- and device-based strategies have been developed. RDN is among the most promising novel techniques. However, there are few data on the vascular anatomical eligibility.

Methods We retrospectively analyzed 941 consecutive hypertensive patients undergoing coronary angiography and selective renal artery angiography between January 1, 2010, and May 31, 2012. Additional renal arteries were divided into 2 groups: hilar (accessory) and polar (aberrant) arteries. Anatomical eligibility for RDN was defined according to the current guidelines: absence of renal artery stenosis, renal artery diameter $\geq$4 mm, renal artery length $\geq$20 mm, and only 1 principal renal artery.

Results A total of 934 hypertensive patients were evaluable. The prevalence of renal artery stenosis was 10% (n = 90). Of the remaining 844 patients without renal artery stenosis, 727 (86%) had nonresistant hypertension and 117 (14%) had resistant hypertension; 62 (53%) of the resistant hypertensive and 381 (52%) of the nonresistant hypertensive patients were anatomically eligible for sympathetic RDN.

Conclusions The vascular anatomical eligibility criteria of the current guidelines are a major limiting factor for the utilization of RDN as a therapeutic option. Development of new devices and/or techniques may significantly increase the number of candidates for these promising therapeutic options. (J Am Coll Cardiol Intv 2014;7:187–92) © 2014 by the American College of Cardiology Foundation

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Arterial hypertension is the major cardiovascular risk factor worldwide (1). Despite substantial advances in drug-based treatment, arterial hypertension therapy remains a major challenge. According to recent surveys in the United States and Europe, only 26% to 63% of patients achieve target blood pressure (BP) values (2). To improve the number of well-controlled patients, novel procedure- and device-based strategies have been developed (3–5), particularly renal artery denervation (RDN).

See page 193

Exaggerated systemic sympathetic activity has been shown to be a major pathophysiological mechanism triggering the development, maintenance, and progression of arterial hypertension (6). Furthermore, recent preliminary studies suggest that RDN may also have favorable effects in other conditions associated with exaggerated sympathetic drive, such as obstructive sleep apnea syndrome, insulin resistance, and chronic renal or heart failure (7–9). Particularly, increased renal sympathetic activity has been shown to play an important role in the regulation of systemic BP (10). Consistent with this observation, surgical sympathectomy has been shown to significantly reduce BP in hypertensive patients (11). However, this procedure was accompanied by severe orthostatic hypotension and incontinence in some patients (12). To obviate these surgery-related complications, several minimally-invasive, catheter-based renal sympathetic denervation techniques have been developed in recent years (3,13). After placement of a catheter in the renal arteries, radiofrequency energy is applied endoluminally to induce thermal injury of the renal sympathetic fibers located in the adventitia of the renal arteries. To use this technique and to minimize the risk of complications (i.e., renal artery stenosis and dissection), several anatomical criteria of the renal arteries have to be fulfilled (Table 1). According to the guidelines (14,15), the diameter of the renal arteries should not be inferior to 4 mm, and the length before division should be ≥20 mm. Moreover, no renal artery stenosis (RAS) (≥30%) and no extrarenal artery should be present.

Abbreviations and Acronyms

BP = blood pressure

RAS = renal artery stenosis

RDN = catheter-based renal artery denervation

The SYMPLICITY (Renal Sympathetic Denervation in Patients With Treatment-Resistant Hypertension) study and others (16–18) reported 10% to 37% ineligibility among screened patients, because the anatomical criteria were not met. However, these data were limited due to the selected patient populations and the lack of detailed anatomical data.

In the present study, we aimed to determine the anatomical eligibility for RDN in a large population of consecutive patients with arterial hypertension undergoing renal angiography.

Table 1. Anatomical Eligibility Criteria of the Renal Vasculature

No renal artery stenosis (≥30%)
No extrarenal artery
Diameter of the renal artery: ≥4 mm
No early division: ≤20 mm

Methods

Patient selection and definitions. We retrospectively analyzed 941 consecutive hypertensive patients undergoing coronary angiography and concomitant selective renal arteriography between January 1, 2010, and May 31, 2012. Seven patients were excluded from the analysis, as their images were not suitable for evaluation (Fig. 1).

The study was approved by the institutional ethics committee, and informed consent was obtained from all patients.

Imaging of the renal arteries was performed by the invasive cardiologist performing coronary arteriography in patients with a history of (treated) hypertension, known hypertensive heart disease as diagnosed by echocardiography, or persistently elevated BP (>140/90 mm Hg), provided there was no previous assessment of the renal arteries.

Resistant hypertension was defined according to the current guidelines (19). Coronary artery disease and peripheral artery disease were defined as previously described (20). Impaired renal function was defined by a glomerular filtration rate of <60 ml/min/1.73 m^2, as estimated by the MDRD (Modification of Diet in Renal Disease) equations (21). Diagnosis of dyslipidemia and of diabetes mellitus were based on the 2013 European Society of Hypertension/European Society of Cardiology guidelines (19).

Significant RAS was defined as lumen narrowing ≥50% diameter, as previously described (20).

Selective and quantitative renal arteriography. Eight experienced staff cardiologists performed the 934 selective renal arteriographies considered in the study. The percutaneous femoral approach was used with standard 4- to 7-F Judkins or Amplatz catheters (Cordis, Miami Lakes, Florida). After coronary angiography, renal arteriography was performed by selectively injecting contrast medium into main and accessory renal arteries. All images were recorded digitally. The projection that best showed the anatomy was used for all analyses. Measurements were performed on cineangiograms. The contrast-filled, nontapered tip of the catheter was used for calibration. Digital angiograms were analyzed with the use of an automated edge-detection system (CAAS II, Pie Medical Imaging, Maastricht, the Netherlands), as previously described (22). Quantitative measurements included the diameter and length of the reference vessel. The intraobserver and interobserver variability of the quantitative measurements has been reported previously (23). The intraobserver (N.S.) and interobserver (N.S., S.F.R.) coefficients of variation for