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ORIGINAL ARTICLE

Catheter-based radiofrequency renal sympathetic denervation for resistant hypertension; initial Egyptian experience

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KEYWORDS

Sympathetic;
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Abstract *Objectives:* To evaluate the feasibility, efficacy, and safety of catheter-based radiofrequency renal sympathetic denervation for treatment of resistant hypertension.
Background: In a subpopulation of patients with essential hypertension, therapeutic targets are not met, despite the use of multiple types of medication. In this paper we describe our first experience with a novel percutaneous treatment modality using renal artery radiofrequency (RF) ablation.
Methods: Thirty patients with essential hypertension unresponsive to at least three types of antihypertensive medical therapy (baseline office systolic blood pressure $\geqslant$160 mmHg) were selected between March and September 2012 and received percutaneous RF ablation. Patients were followed up for 6 months after treatment. The primary effectiveness endpoint was change in seated office-based measurement of systolic blood pressure at 6 months. Another thirty patients were taken as control.
Results: A reduction of mean office blood pressure was seen from 170/102 ± 9/5 mmHg at baseline to 151/91 ± 8/6 mmHg at 6 months follow-up ($p = 0.001$). Also, we noted a significant decrease in plasma renin activity (3.66 ± 0.64 versus 3.37 ± 0.47 ng/mL/h; $p = 0.003$). No periprocedural complications, adverse events or change in renal function were noted during follow-up.
Conclusion: Catheter-based renal denervation seems an attractive minimally invasive treatment option in patients with resistant hypertension, with a low risk of serious adverse events.

1. Introduction

Successful treatment of raised blood pressure has proven elusive despite availability of various drugs, combination pharmaceutical products, and resources to assist patients' adherence and lifestyle changes. In about half of hypertensive patients, blood pressure remains higher than accepted treatment targets despite the broad availability of effective pharmaceutical agents.[1,2]

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Thus, the development of new approaches for the management of hypertension is a priority. These considerations are especially relevant to patients with drug-resistant hypertension and/or patients with severe intolerance to medication.

Renal sympathetic nerves contribute to development and perpetuation of hypertension, and sympathetic outflow to the kidneys is activated in patients with essential hypertension.[3] Efferent sympathetic outflow stimulates renin release, increases tubular sodium reabsorption, and reduces renal blood flow.[4] Afferent signals from the kidney modulate central sympathetic outflow and thereby directly contribute to neurogenic hypertension.[5–7]

Radical surgical methods for sympathetic denervation have been successful in lowering blood pressure in severely hypertensive patients. However, these methods were associated with high perioperative morbidity and even mortality and also long-term complications.[4]

Recently, a percutaneous, catheter-based approach using radiofrequency energy (RF) was developed to disrupt renal sympathetic nerves. This resulted in no severe (long-term) vascular or renal injury. Importantly, catheter-based renal nerve ablation was associated with a significant reduction in both systolic and diastolic blood pressure on top of maximal medical therapy, which persisted throughout 12 months follow-up in the first-in-man study.[5]

The Symplicity HTN-2 Trial was recently published, which was the first randomised controlled study using this technique of renal denervation, confirming the findings of the first-in man study.[6]

Here, we report the results of the Egyptian experience regarding this novel treatment modality.

2. Materials and methods

2.1. Study design and patients

Patients were eligible if they have an office systolic blood pressure of 160 mmHg or more, despite being compliant with at least three antihypertensive drugs, or confirmed intolerance to medication. Blood pressure measurements were performed in a seated position in at least two subsequent visits in both arms. Blood pressure check was performed before intervention and at 6 months follow-up.

Also, renal function and changes in plasma renin level were obtained at baseline and during follow-up.

The renal artery anatomy was considered suitable in case of a vessel diameter of $\geqslant 4$ mm, no prior renal angioplasty/stenting and no significant stenosis or other abnormalities.

Exclusion criteria for this treatment modality were pregnancy, age below 18 years, patients with any known secondary cause of hypertension and a glomerular filtration rate estimated at <45 mL/min/1.73 m^2 Also, patients with type 1 diabetes, haemodynamically significant valvular disease or implantable cardioverter defibrillators were excluded from intervention.

Thirty patients underwent renal denervation and another thirty patients with resistant hypertension were considered as control.

2.2. Procedure

The baseline activated clotting time (ACT) was determined, the renal artery was catheterized via standard femoral access, and renal angiography was then performed, after which 70 mg/kg of heparin sodium was administered. When an ACT of 250–300 s had been achieved, a Symplicity electrode was introduced through a renal double-curve, left internal mammary artery, or renal short standard guiding catheter at least 6F in diameter. The radiopaque tip of the electrode was brought into contact with the endothelium, initially at the most distal point of the renal trunk.

When the impedance was stable we applied RF energy for 2 min, automatically regulated to 8 W with a maximum temperature of 70 °C. If the impedance value recorded at the time of RF application was too high, indicating the presence of calcium, the electrode was moved to a more favorable position. If the bifurcation was early, RF could be applied in the branches, provided they were of adequate diameter (i.e., $\geqslant 4$ mm).

A bilateral treatment of the renal arteries was performed with the use of series of 2-min RF energy deliveries along each artery, aiming at 4–6 treatment points per artery. These treatment points are made with a minimum of 5 mm distance in between and with a pullback from distal to proximal in a circumferential way. A control angiography was performed after the procedure.

2.3. Statistical analysis

We assessed continuous variables between groups, including the primary endpoint, with Student's two-sample *t* test unless otherwise specified. We compared categorical variables with Fisher's exact test. For within group paired data, a paired *t* test was used unless otherwise specified. A two-sided alpha level of 0.05 was used for all superiority testing. All statistical analyses were done using SPSS software statistical computer package version 16.

3. Results

The baseline characteristics of the patient groups are listed in Table 1. The mean time of the procedure (i.e. from puncture of the femoral artery to closure) was 74 ± 9 min. Mean fluoroscopy time was 14 ± 5 min. The ACT time achieved was 288 ± 44 s. The mean use of contrast was 208 ± 35 ml.

Table 1 Baseline patient characteristics.

Demographic information	
Age, yrs	56 ± 6
Men,%	80
BMI, kg/m^2	28.9 ± 3.3
Relevant medical history	
Duration of hypertension, yrs	9.8 ± 2
Diabetes mellitus	18(60%)
CAD	12(40%)
Antihypertensive drugs	
ACEI/ARB	28(93.3%)
Calcium channel blocker	28(93.3%)
B-blocker	22(73.3%)
Diuretic	30(100%)
α-blocker	2(6.7%)
Centrally acting drug	0(0%)

Values are mean ± SD or *n* (%).
ACEI = angiotensin-converting enzyme inhibitor; CAD = coronary artery disease.