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Case Report

Catheter-Based Renal Denervation Using the Symplicity Spyral™ System for Resistant Hypertension: Initial Single-Center Experience and Two Case Reports

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Abstract

Background: Resistant hypertension remains a major clinical challenge despite advances in pharmacological therapy. Catheter-based renal denervation has re-emerged as a promising adjunctive treatment following the development of second-generation devices and positive evidence from recent randomized sham-controlled trials.

Case Presentation: We report the initial single-center experience with bilateral radiofrequency renal denervation using the Symplicity Spyral™ system in two patients with long-standing resistant hypertension. Both patients had persistent severe hypertension despite treatment with at least four antihypertensive medications and had no angiographically significant renal artery stenosis.

Methods: Bilateral renal denervation was performed via right femoral access using the Symplicity Spyral™ multielectrode radiofrequency catheter. Radiofrequency applications were delivered to the upper, middle, and lower segmental branches of both renal arteries according to the standard procedural technique.

Results: Technical success was achieved in both procedures without vascular or angiographic complications. Renal artery patency was preserved, and renal function remained stable throughout hospitalization. During early follow-up, office blood pressure decreased from values up to 240/130 mmHg and 230/120 mmHg to approximately 120–130/80 mmHg in both patients while continuing antihypertensive therapy.

Conclusion: Our initial experience suggests that catheter-based renal denervation using the Symplicity Spyral™ system is a safe and technically feasible adjunctive treatment for carefully selected patients with resistant hypertension. Larger studies with long-term follow-up are required to confirm the durability of these encouraging early results.

Keywords: Resistant hypertension, Renal denervation, Symplicity Spyral, Radiofrequency ablation, Sympathetic nervous system, Catheter intervention

Introduction

Arterial hypertension remains the leading modifiable risk factor for cardiovascular morbidity and mortality worldwide, affecting more than one billion people and contributing substantially to ischemic heart disease, stroke, heart failure, chronic kidney disease, and premature death [1,2]. Despite the widespread availability of

effective antihypertensive medications and evidence-based treatment strategies, blood pressure control remains suboptimal in a considerable proportion of patients. Contemporary registries indicate that fewer than half of treated hypertensive patients achieve the recommended blood pressure targets, leaving a substantial residual cardiovascular risk [3,4].

Among hypertensive patients, resistant hypertension represents one of the greatest therapeutic challenges. According to current European and American guidelines, resistant hypertension is defined as persistently elevated blood pressure despite treatment with at least three antihypertensive agents of different classes, including a diuretic, prescribed at maximally tolerated doses, or blood pressure requiring four or more medications to achieve adequate control [5,6]. The prevalence of true resistant hypertension is estimated to range between 5% and 15% of treated hypertensive patients after exclusion of pseudo-resistance, poor medication adherence, white-coat hypertension, and secondary causes of hypertension [7]. Patients with resistant hypertension carry a markedly increased risk of myocardial infarction, stroke, heart failure, atrial fibrillation, chronic kidney disease progression, and cardiovascular mortality compared with patients whose blood pressure is adequately controlled [8].

The pathophysiology of resistant hypertension is complex and multifactorial. One of the central mechanisms is persistent overactivation of the sympathetic nervous system. Increased renal sympathetic efferent activity stimulates renin secretion, enhances sodium and water retention, reduces renal blood flow, and contributes to sustained vasoconstriction. Simultaneously, renal afferent sympathetic fibers transmit signals from the kidneys to central autonomic regulatory centers, further amplifying systemic sympathetic activation and maintaining elevated blood pressure [9,10]. This bidirectional interaction between the kidneys and the central nervous system has established the renal sympathetic nerves as an attractive therapeutic target (Figure 1).

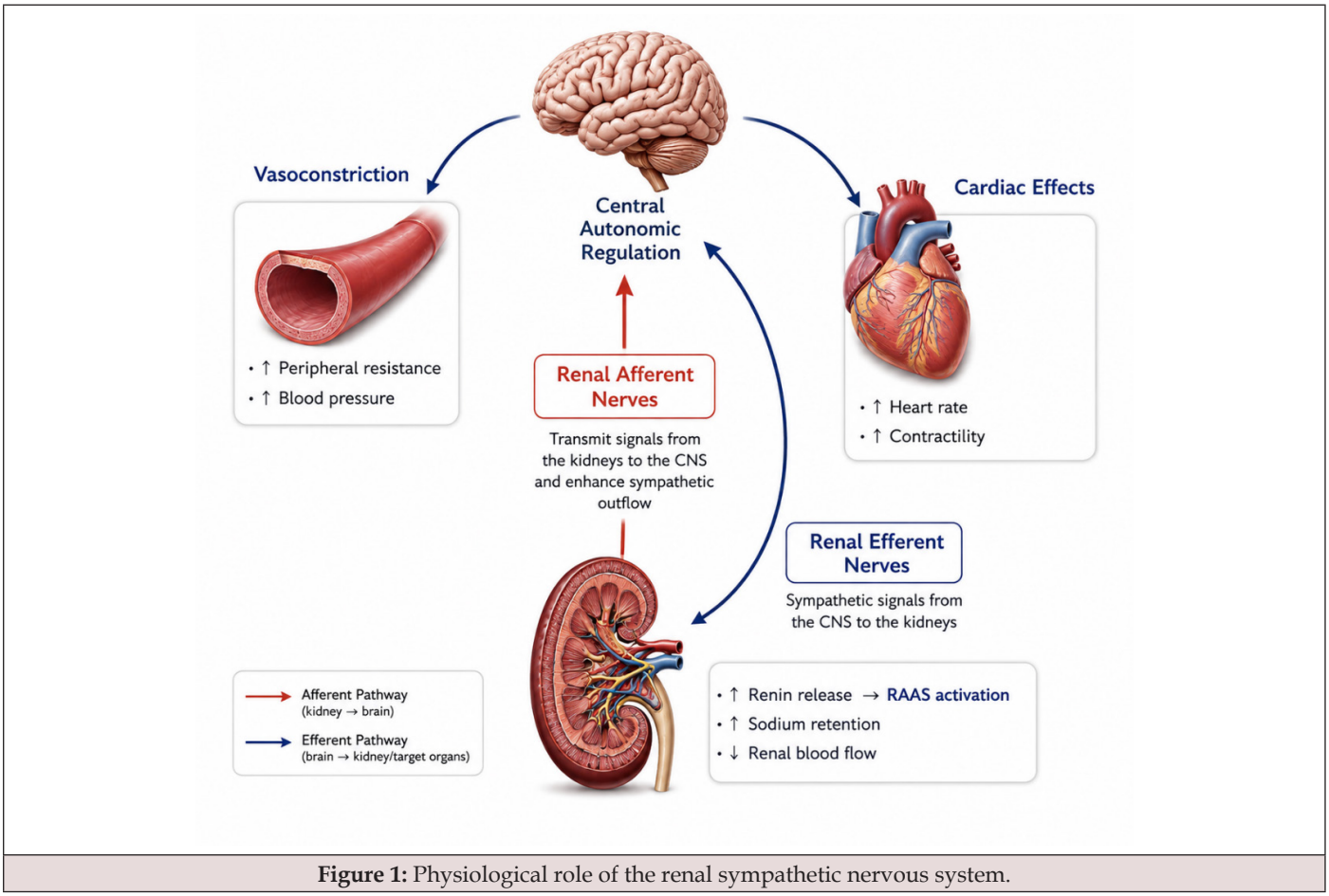

Figure 1: Physiological role of the renal sympathetic nervous system.

Catheter-based renal denervation (RDN) was developed to interrupt these sympathetic pathways through endovascular ablation of the periarterial renal sympathetic nerves. Initial proof-of-concept studies demonstrated promising reductions in blood pressure; however, enthusiasm declined following the publication of the SYMPLICITY HTN-3 trial, which failed to meet its primary efficacy endpoint [11]. Subsequent analyses identified several important limitations of the study, including medication changes during follow-up, incomplete circumferential ablation, operator experience, and first-generation catheter technology [12]. These findings led to substantial refinements in patient selection, procedural technique, trial design, and device technology.

The development of second-generation multielectrode renal denervation systems, particularly the Symplicity Spyral™ radiofrequency catheter (Medtronic, Minneapolis, MN, USA), enabled a more comprehensive circumferential ablation strategy involving both the main renal arteries and their distal branches, where sym-

pathetic nerve fibers are located closer to the arterial lumen [13]. A series of well-designed sham-controlled randomized clinical trials, including the SPYRAL HTN-OFF MED, SPYRAL HTN-ON MED, SPYRAL HTN-PIVOTAL, and RADIANCE programs, consistently demonstrated clinically meaningful and durable reductions in both office and ambulatory blood pressure with an excellent procedural safety profile [14-18]. These data have re-established renal denervation as a valuable adjunctive treatment option for carefully selected patients with uncontrolled or resistant hypertension.

Consequently, contemporary European Society of Cardiology (ESC) and European Society of Hypertension (ESH) recommendations recognize catheter-based renal denervation as a therapeutic option for appropriately selected patients with uncontrolled or resistant hypertension following multidisciplinary evaluation and shared decision-making [5,6].

In this report, we present the first two patients with resistant hypertension treated with bilateral radiofrequency renal denervation using the Symplicity Spyral™ system at our institution. In addition to describing the procedural technique and early clinical outcomes, we review the current evidence supporting renal denervation as an emerging interventional treatment for resistant hypertension.

Materials and Methods

Patient Selection

This report presents the initial single-center experience with catheter-based renal denervation (RDN) using the Symplicity Spyral™ radiofrequency system (Medtronic, Minneapolis, MN, USA) in two consecutive patients with resistant hypertension treated at the Department of Cardiology, Heart and Brain Hospital, Pleven, Bulgaria.

Both patients had long-standing arterial hypertension with persistently elevated blood pressure despite treatment with multiple antihypertensive medications at maximally tolerated doses. Before consideration for renal denervation, all patients underwent comprehensive clinical evaluation, including detailed medical history, physical examination, laboratory investigations, echocardiography, and assessment of medication adherence. Secondary causes of hypertension were actively investigated according to current clinical practice, and both patients were evaluated by a multidisciplinary Heart Team before the final therapeutic decision.

Renal artery anatomy was assessed angiographically immediately before the intervention. Both patients demonstrated bilateral renal arteries of adequate diameter without angiographically significant stenosis or anatomical abnormalities precluding renal denervation.

Renal Denervation Procedure

All procedures were performed in the cardiac catheterization laboratory under local anesthesia with conscious intravenous sedation (Morphine 2.5mg, Midazolam 5-8 mg)

Following right common femoral arterial access, a 6-Fr vascular sheath was introduced. Selective renal angiography was performed to confirm renal artery anatomy and exclude significant renal artery stenosis.

A 6-Fr 45-cm Internal Mammary (IM) guiding catheter was advanced sequentially into each main renal artery. A 0.014-inch Sion Blue XS guidewire (Asahi Intecc, Japan) was advanced distally into the target vessel to facilitate delivery of the Symplicity Spyral™ multielectrode radiofrequency catheter.

Radiofrequency ablations were delivered in a circumferential spiral pattern within the upper, middle, and lower segmental branches of each renal artery, according to the manufacturer's recommendations and contemporary procedural practice. The multielectrode design of the Symplicity Spyral catheter allowed sequential ablations without repeated catheter exchanges, enabling treatment of both the main renal arteries and distal branch vessels (Figures 2-4).

Figure 2: Symplicity Spyral™ multielectrode radiofrequency catheter.

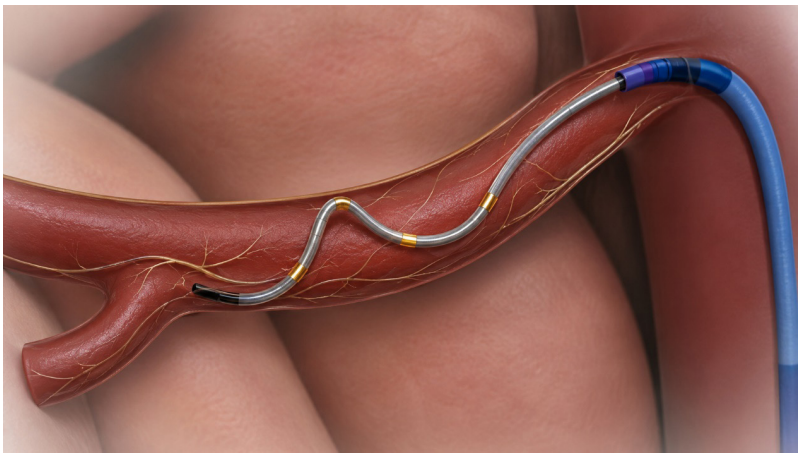

Figure 3: Schematic illustration of the Symplicity Spyral™ catheter.

Figure 4: Radiofrequency generator used during renal denervation.

During the procedure, all patients received intravenous unfractionated heparin (8,000 IU). Conscious sedation and analgesia were achieved using intravenous midazolam and morphine, while local anesthesia was performed with lidocaine infiltration at the vascular access site.

At completion of the procedure, final renal angiography confirmed preserved renal artery patency without evidence of dissection, thrombosis, perforation, vasospasm, or distal embolization. Femoral hemostasis was achieved by Obtura vascular closure device (Meril).

Postprocedural Management and Follow-up

Following renal denervation, all patients remained under continuous electrocardiographic and hemodynamic monitoring during hospitalization. Serum creatinine, estimated glomerular filtration rate (eGFR), and serum electrolytes were reassessed before discharge to evaluate procedural safety and renal function.

Antihypertensive therapy was continued after the intervention

without immediate reduction of medication burden. Aspirin 100 mg daily was prescribed for one month following the procedure according to the institutional protocol.

Clinical follow-up included assessment of blood pressure control, vascular access-site complications, renal function, and procedure-related adverse events. Early follow-up demonstrated stable renal function and improved office blood pressure control in both patients.

Case Presentations

Case 1

A 61-year-old woman was referred to our department because of long-standing resistant hypertension with persistently uncontrolled blood pressure despite treatment with multiple antihypertensive medications. She had a history of arterial hypertension since 2005, while since 2019 blood pressure control had progressively deteriorated despite optimization of medical therapy. Repeated hypertensive crises with blood pressure values reaching 240/130 mmHg were documented. The patient also reported exertional dyspnea, easy fatigability, and episodes of chest discomfort.

Her cardiovascular risk profile included advanced age, active smoking (>20 cigarettes daily), and a positive family history of severe hypertension. Home antihypertensive treatment consisted of moxonidine, nebivolol/hydrochlorothiazide, doxazosin, and molsidomine. Despite adherence to therapy, blood pressure remained poorly controlled.

Transthoracic echocardiography demonstrated severe concentric left ventricular hypertrophy with preserved left ventricular size, mildly reduced left ventricular systolic function (left ventricular ejection fraction approximately 50%), grade I diastolic dysfunction, and mild mitral and tricuspid regurgitation. Laboratory investigations revealed preserved renal function (serum creatinine 68 μmol/L; eGFR 83 mL/min/1.73 m^2) without significant electrolyte abnormalities. Renal angiography demonstrated bilateral renal arteries of normal caliber without angiographically significant stenosis.

Following multidisciplinary evaluation, the patient was considered an appropriate candidate for catheter-based renal denervation.

The procedure was performed via right femoral arterial access using the Symplicity Spyral™ radiofrequency renal denervation system. Sequential radiofrequency ablations were delivered within the upper, middle, and lower segmental branches of both renal arteries according to the standard procedural protocol. Completion angiography confirmed preserved renal artery patency without evidence of vascular injury, dissection, thrombosis, or perforation (Figures 5,6).

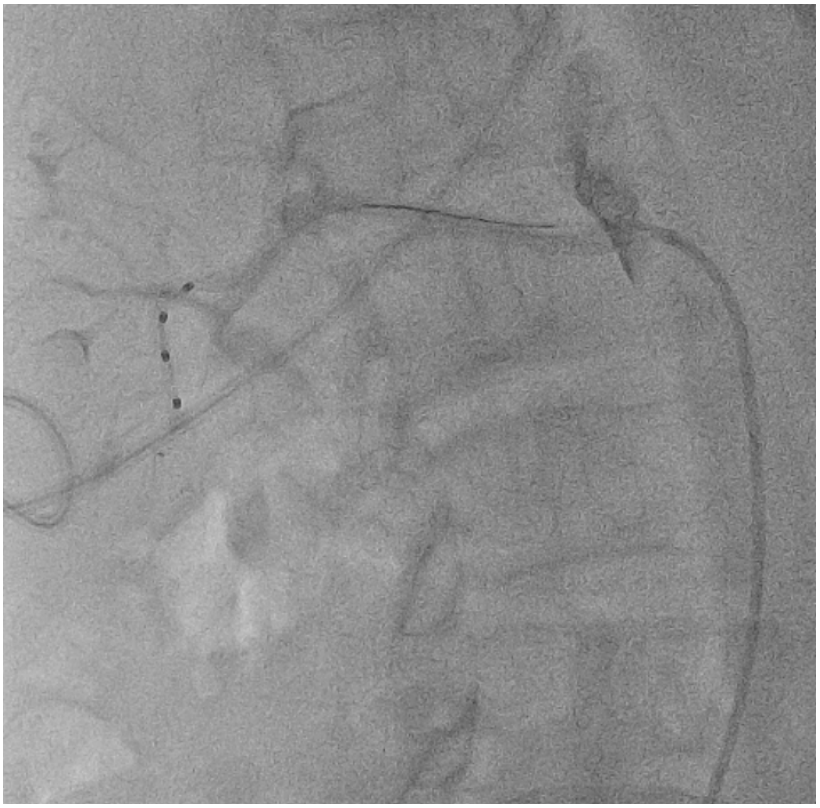

Figure 5: Right renal artery during renal denervation.

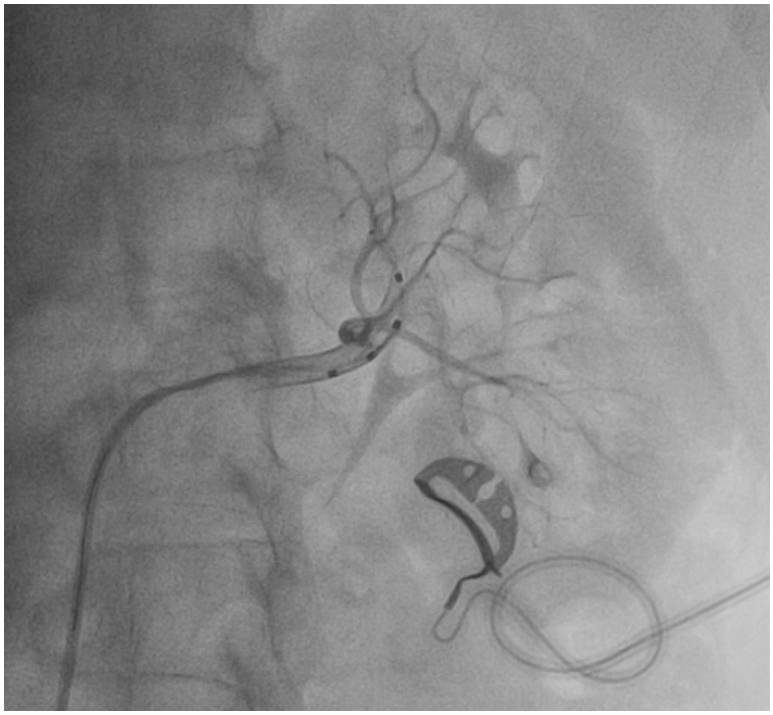

Figure 6: Left renal artery during renal denervation.

The postprocedural course was uncomplicated from a vascular and renal standpoint. Serum creatinine remained stable, and no deterioration of renal function was observed. During early follow-up, office blood pressure decreased to approximately 120–130/80 mmHg, while antihypertensive therapy was continued.

Case 2

A 68-year-old man with long-standing resistant hypertension was referred for consideration of catheter-based renal denervation because of persistent severe blood pressure elevation despite treatment with multiple antihypertensive medications. Blood pressure had repeatedly reached 230/120 mmHg, frequently accompanied by severe occipital and frontal headaches. The patient also reported exertional dyspnea, profuse sweating, and episodes of chest tightness.

His medical history included type 2 diabetes mellitus, dyslipidemia, abdominal aortic aneurysm, bilateral renal cysts, adrenal incidentaloma, panic disorder, chronic heart failure with preserved ejection fraction, and non-obstructive coronary artery disease documented during previous coronary angiography.

At admission, blood pressure was adequately controlled under intensive medical therapy; however, the long-term history clearly fulfilled the criteria for resistant hypertension. Echocardiography demonstrated concentric left ventricular hypertrophy with preserved systolic function (left ventricular ejection fraction 65%) and no hemodynamically significant valvular disease. Renal function was mildly impaired but stable (baseline serum creatinine 110 µmol/L; eGFR 59 mL/min/1.73 m^2). Selective renal angiography demonstrated anatomically suitable bilateral renal arteries without significant stenosis.

The patient subsequently underwent bilateral radiofrequency renal denervation using the Symplicity Spyral™ system via right femoral access. Radiofrequency applications were delivered to the upper, middle, and lower segmental branches of both renal arteries following the standard ablation protocol. Final angiography demonstrated preserved vessel integrity without dissection, thrombosis, perforation, or other angiographic complications (Figures 7,8).

The postprocedure recovery was uneventful. Renal function remained stable throughout hospitalization, with no evidence of procedure-related deterioration. At early clinical follow-up, office blood pressure was consistently maintained at approximately 120–130/80 mmHg while continuing antihypertensive therapy (Table 1).

Table 1: Baseline and follow-up blood pressure.

Patient	Baseline BP	Follow-up BP
Case 1	240/130 mmHg	125/80 mmHg
Case 2	230/120 mmHg	125/80 mmHg

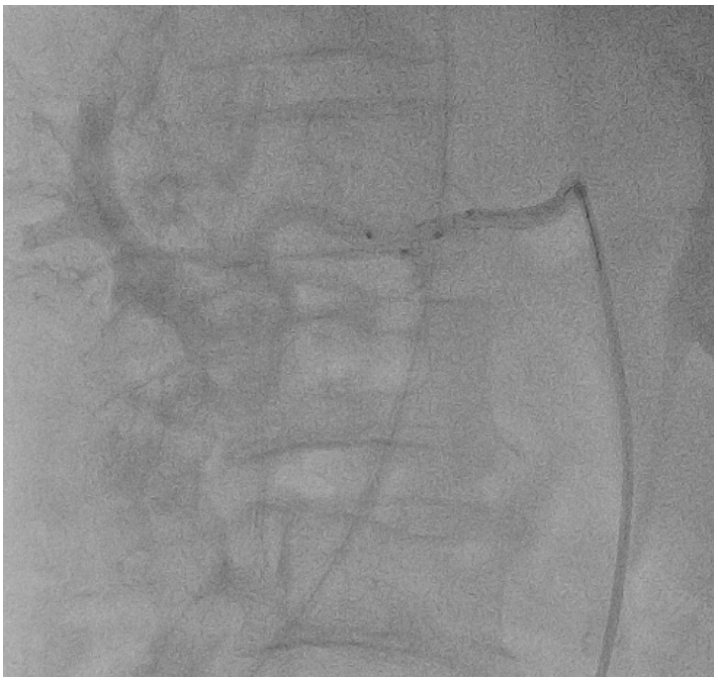

Figure 7: Right renal artery with the Symplicity Spyral™ catheter.

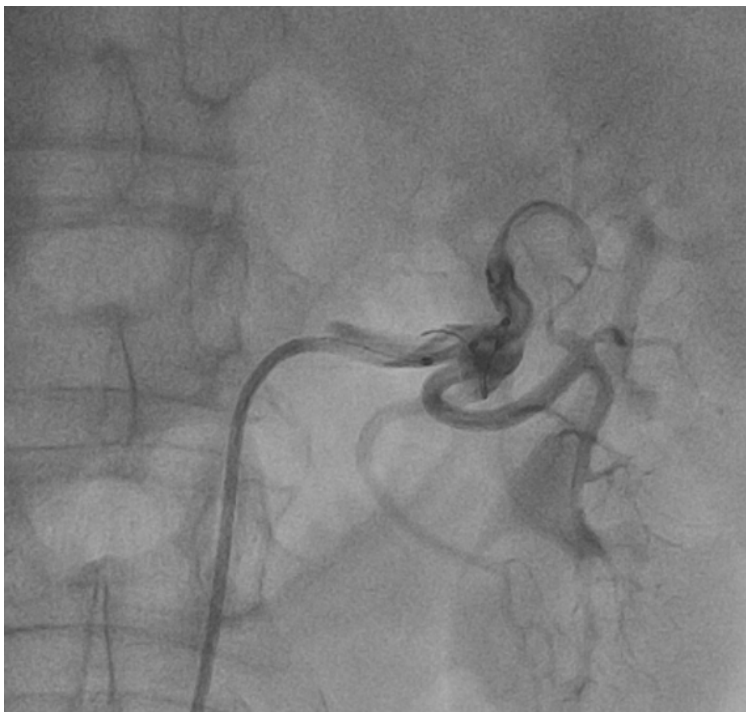

Figure 8: Left renal artery with the Symplicity Spyral™ catheter.

Results

Two consecutive patients with long-standing resistant hypertension successfully underwent bilateral catheter-based radiofrequency renal denervation using the Symplicity Spyral™ system. In both cases, preprocedural renal angiography demonstrated anatomically suitable bilateral renal arteries without significant stenosis or anatomical abnormalities.

Technical success was achieved in 100% (2/2) of procedures. Bilateral renal denervation was completed as planned in both patients without the need for additional devices or procedural mod-

ifications. Final angiography demonstrated preserved renal artery patency with no evidence of renal artery dissection, thrombosis, perforation, flow-limiting vasospasm, or distal embolization.

No access-site complications, major bleeding, or other procedure-related adverse events occurred during hospitalization. Renal function remained stable in both patients, with no clinically significant deterioration in serum creatinine concentration or eGFR rate following the intervention.

At early clinical follow-up, both patients demonstrated a marked improvement in office blood pressure control. Blood pressure decreased from documented preprocedural values of up to 240/130 mmHg and 230/120 mmHg, respectively, to approximately 120–130/80 mmHg, while continuing antihypertensive therapy. Neither patient required rehospitalization during the early follow-up period. The principal procedural and clinical characteristics of both patients are summarized in Table 1 (Table 2).

Table 2: Baseline characteristics and procedural outcomes.

	Case 1	Case 2
Age (years)	61	68
Sex	Female	Male
Maximum documented BP	240/130 mmHg	230/120 mmHg
Resistant hypertension	Yes	Yes
Number of antihypertensive drugs	≥4	≥4
Renal artery stenosis	No	No
Procedure	Bilateral RDN	Bilateral RDN
Device	Symplicity Spyral™	Symplicity Spyral™
Technical success	Yes	Yes
Angiographic complications	None	None
Renal function deterioration	No	No
Office BP at early follow-up	120–130/80 mmHg	120–130/80 mmHg

Discussion

Resistant hypertension remains one of the most challenging clinical conditions in cardiovascular medicine. Despite the availability of multiple effective antihypertensive drug classes, a considerable proportion of patients fail to achieve adequate blood pressure control, resulting in a substantially increased risk of myocardial infarction, stroke, heart failure, chronic kidney disease, and cardiovascular mortality [19,20]. Although optimization of pharmacological therapy remains the cornerstone of treatment, long-term blood pressure control is frequently compromised by medication intolerance, poor adherence, therapeutic inertia, and persistent sympathetic nervous system activation.

The kidneys play a pivotal role in blood pressure regulation through both efferent and afferent sympathetic innervation. Increased efferent sympathetic activity promotes renin release, sodium retention, renal vasoconstriction, and reduced renal blood flow, whereas afferent renal fibers transmit excitatory signals to central autonomic centers, further augmenting systemic sympathetic activity. This bidirectional neurohumoral pathway contributes significantly to the maintenance of resistant hypertension and represents the physiological rationale for catheter-based renal denervation [9,10].

Radiofrequency renal denervation was initially introduced more than a decade ago, with the first SYMPLICITY HTN studies reporting remarkable reductions in blood pressure. However, enthusiasm declined after the publication of the SYMPLICITY HTN-3 trial, which failed to demonstrate superiority over a sham procedure [11]. Subsequent analyses identified several important limitations, including the use of first-generation single-electrode technology, incomplete circumferential ablation, limited treatment of distal renal artery branches, operator inexperience, and substantial changes in antihypertensive therapy during follow-up [12]. Rather than disproving the concept of renal denervation, these findings highlighted the importance of appropriate patient selection, procedural standardization, and improved device technology.

The introduction of the Symplicity Spyral™ multielectrode radiofrequency catheter represented a major technological advancement. Unlike the first-generation system, the Spyral catheter is specifically designed to perform simultaneous circumferential ablations while allowing treatment of both the main renal arteries and their distal segmental branches. Histological studies have demonstrated that sympathetic nerve fibers become progressively closer to the arterial lumen within distal branches, supporting the concept that more distal ablation may improve procedural efficacy [13].

Evidence supporting renal denervation has substantially strengthened over the past several years. The SPYRAL HTN-OFF MED trial demonstrated significant reductions in both office and ambulatory blood pressure in patients not receiving antihyperten-

sive medications, confirming the intrinsic antihypertensive effect of renal denervation independent of pharmacological treatment [13]. Subsequently, the SPYRAL HTN-ON MED trial confirmed clinically meaningful blood pressure reductions in patients receiving standardized antihypertensive therapy [14]. The sham-controlled SPYRAL HTN-PIVOTAL trial further demonstrated durable reductions in ambulatory systolic blood pressure together with an excellent safety profile [15]. Similar findings were reported in the ultrasound-based RADIANCE SOLO, RADIANCE TRIO, and RADIANCE II trials, indicating that the antihypertensive benefit is reproducible across different denervation technologies [16,17].

Equally important is the favorable safety profile consistently demonstrated across randomized clinical trials and large international registries. Major vascular complications, clinically significant renal artery stenosis, deterioration of renal function, and procedure-related mortality have remained uncommon. Long-term data from the Global SYMPLICITY Registry have confirmed sustained blood pressure reduction for several years after treatment without evidence of progressive renal impairment or excess cardiovascular events attributable to the procedure [20].

Our initial experience is consistent with these observations. Both patients fulfilled accepted clinical criteria for resistant hypertension despite treatment with multiple antihypertensive medications. Bilateral renal denervation was technically successful in both procedures without angiographic complications, vascular injury, or deterioration of renal function. During early follow-up, office blood pressure decreased to approximately 120–130/80 mmHg in both patients while continuing antihypertensive therapy. Although the present report includes only two patients and follow-up remains short, our findings demonstrate that renal denervation using the Symplicity Spyral™ system is technically feasible, safe, and capable of achieving meaningful early blood pressure reduction in carefully selected patients.

Current international recommendations increasingly recognize catheter-based renal denervation as an adjunctive treatment option for appropriately selected patients with uncontrolled or resistant hypertension after exclusion of secondary causes and confirmation of adherence to pharmacological therapy [5,6,18]. The procedure should not be considered a replacement for antihypertensive medication but rather an additional therapeutic modality integrated into a comprehensive multidisciplinary management strategy.

The present report has several limitations. First, it represents the initial experience of a single center and includes only two patients, precluding any statistical analysis or conclusions regarding efficacy. Second, follow-up is currently limited to the early post-procedural period, and long-term blood pressure control remains to be established. Finally, ambulatory blood pressure monitoring was not available at the time of this early analysis, although future follow-up will include standardized ambulatory blood pressure assessment.

Nevertheless, these first clinical experiences illustrate that contemporary radiofrequency renal denervation can be safely incorporated into routine interventional cardiology practice following appropriate patient selection, meticulous procedural technique, and multidisciplinary evaluation. As the evidence base continues to expand and longer-term data accumulate, renal denervation is expected to become an increasingly important component of the therapeutic armamentarium for resistant hypertension.

Conclusions

Catheter-based radiofrequency renal denervation using the Symplicity Spyral™ system represents a safe and technically feasible adjunctive treatment option for carefully selected patients with resistant hypertension. In our initial single-center experience, bilateral renal denervation was successfully performed in two consecutive patients without procedural or vascular complications and without deterioration of renal function. Both patients demonstrated substantial early improvement in office blood pressure control while continuing guideline-directed antihypertensive therapy.

Although limited by the small number of patients and short follow-up, our findings are consistent with the growing body of evidence supporting renal denervation as an effective complementary treatment for resistant hypertension. Continued prospective follow-up and larger patient cohorts will be essential to evaluate the durability of blood pressure reduction, long-term renal safety, and the impact on cardiovascular outcomes.

Acknowledgments

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Ethics Statement

Written informed consent for publication of anonymized clinical information was obtained from both patients. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Conflicts of Interest

The authors declare no conflict of interest.

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