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Standards and Guidelines

SCAI Position Statement on Renal Denervation for Hypertension: Patient Selection, Operator Competence, Training and Techniques, and Organizational Recommendations

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Table of Contents

Introduction 1
Patient selection 2
Procedural and technical considerations 3
Preprocedure evaluation and imaging 3
Anatomical considerations 3
Procedural technique 3
Procedural safety and postprocedure monitoring 4
Training and competency 4
Institutional requirements 5
Conclusions 6
Declaration of competing interest 6
Funding sources 6
Supplementary material 6
References 6

Introduction

Despite the availability of medications and advocacy for lifestyle interventions to address hypertension (HTN), more than one-half of individuals with high blood pressure do not achieve recommended treatment goals. Limitations of medical therapy include cost, adverse side effects, limited access, and poor adherence. Renal denervation (RDN) is a minimally invasive endovascular procedure targeting sympathetic nerves adjacent to the renal arteries. Disruption of these nerves has been shown in sham-controlled, randomized trials to produce clinically meaningful and safe short-term reductions in blood pressure, whereas both observational and limited randomized trial data[1] suggest longer term durability and safety. RDN may therefore represent a novel and important adjunct to lifestyle modification and antihypertensive medications for HTN.

In 2021, the Society for Cardiovascular Angiography & Interventions (SCAI) published an expert consensus roundtable statement cosponsored by SCAI and the National Kidney Foundation (NKF).[2] This document focused on the historical progress of HTN control, clinical trial data, the importance of multidisciplinary evaluation, and patient-centered treatment decision-making considerations for potential patients who may benefit from catheter-based RDN.

Pending US Food and Drug Administration approval, guidance on appropriate integration of RDN into clinical practice will be of paramount importance to ensure standardization of clinical protocols and optimization of procedural outcomes. This SCAI position statement will address patient selection, review optimal procedural and technical considerations, propose a roadmap for operator training and competency, and delineate institutional requirements for programmatic success. Detailed author disclosures are included as Supplemental Table S1.

Abbreviations: CTA, computed tomography angiography; eGFR, estimated glomerular filtration rate; HTN, hypertension; MRA, magnetic resonance angiography; RDN, renal denervation; rRDN, radiofrequency renal denervation.

Keywords: hypertension; renal denervation; resistant hypertension; uncontrolled hypertension.

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Patient selection

Defining the ideal candidate for RDN requires consideration of risk/benefit balance with a focus on patients with greatest clinical need in their hypertensive management, with important consideration for shared decision-making in determining patients' treatment options. Clinical trials have demonstrated the efficacy of RDN across a wide range of HTN severity, including patients with hypertension in whom medications have been withdrawn (RADIANCE-HTN SOLO, RADIANCE II, SPYRAL HTN-OFF MED), and patients with more severe and resistant HTN (SPYRAL HTN-ON MED, RADIANCE-HTN TRIO).[3-7] In these trials, confirmation of above-target, out-of-office blood pressure measurements was employed through either ambulatory blood pressure monitoring or home blood pressure monitoring to exclude patients with white coat HTN.[8] Since the prevalence of uncontrolled HTN is high, offering RDN to all patients with uncontrolled HTN would not currently be practical.

The 2021 SCAI/NKF expert consensus roundtable statement[2] previously established detailed patient selection criteria, including a description of patients with uncontrolled HTN, methods to confirm hypertension, exclusions of secondary causes of HTN, treatment priority placed on those with elevated cardiovascular risk, shared decision-making, specialty provider endorsement, and an experienced proceduralist performing the procedure. Notably, the current position statement is in alignment with the prior SCAI/NKF statement and briefly summarized in Table 1.

RDN was initially tested in patients with resistant HTN, where blood pressure control was elusive despite the use of at least 3 antihypertensive medications, 1 of which was a diuretic.[8-11] Assuming medication adherence, these patients have limited further medical treatment options and may benefit most from RDN. However, there are other populations who might also derive significant benefit, including those who are nonadherent.[12] Attenuation of medical adherence over long-term follow-up has been associated with forfeiting the clinical benefit of blood pressure lowering.[13] Many patients previously diagnosed with resistant HTN are now more appropriately recognized as having "apparent resistant HTN," as nearly half of these patients are not taking prescribed medications 1 year later.[14] The role that patient preference should play in choosing the most appropriate treatment strategy cannot be minimized.[15,16] For some patients, medication treatment is limited by side effects, whereas in others, nonadherence is explained by cost, fear, or lack of understanding of the benefit. Importantly, a high burden of antihypertensive medications is associated with high rates of nonadherence in a stepwise fashion.[17] Furthermore, a challenge for medication adherence among many younger hypertensive individuals is that HTN is often an asymptomatic condition until end-organ effects are manifest. Each of these factors should be considered when determining a patient's preference for alternative HTN treatment options.[12] Because providers and patients are not always aligned on which therapy to employ next for uncontrolled HTN, engaging in shared decision-making is critical.[15] Although RDN will eliminate the need for medication in only a minority of patients, experience suggests that medication burden can be reduced after successful RDN, and many patients and providers consider that a reasonable incentive to opt for RDN.[16] Finally, when considering RDN, priority might be given to patients with higher cardiovascular risk who may derive the greatest benefit from blood pressure reduction.

Table 1. Selection criteria appropriate for renal denervation.

Patients with resistant hypertension, defined by blood pressure >130/80 mm Hg despite being on 3 medications with maximally tolerated doses from classes with outcomes data (angiotensin-converting enzyme inhibitors or angiotensin II receptor blockers, calcium channel blockers, thiazide diuretics, and beta blockers)
Patients with uncontrolled hypertension despite attempting lifestyle modification and antihypertensive medication but who are either intolerant of additional medication or do not wish to be on additional medications and who are willing to undergo renal denervation after shared decision-making
Priority may be appropriately given to patients with higher cardiovascular risk (eg, comorbidities of coronary artery disease, diabetes, prior transient ischemic attack/cerebrovascular accident, or chronic kidney disease) who may have the greatest benefit from blood pressure reduction

Not all patients with HTN experience blood pressure reductions with RDN. Across the randomized data, the "non-responder" rate is approximately one-third. Therefore, it would be ideal if factors that predicted treatment response were identified. Unfortunately, predicting antihypertensive responses to RDN has been challenging. To date, the most reliable predictor for the magnitude of antihypertensive response has been higher levels of baseline systolic blood pressure, an observation known as Wilder's Principle.[18] This observation is particularly evident in sham-controlled randomized trials in which the magnitude of blood pressure reduction is proportional to baseline blood pressure in the RDN cohort but not among control subjects. Several studies have confirmed that higher starting blood pressures are associated with greater blood pressure reductions, both in standard medication-based trials and also with RDN.[19,20] It is also important to recognize that even modest reductions in systolic blood pressure (ie, 10 mm Hg) can lead to a 20% relative risk reduction in cardiovascular events.[21] Additional factors have been proposed to identify patients who would be more likely to experience a clinically meaningful reduction in blood pressure after undergoing RDN. These include hemodynamic markers of sympathetic activity including higher nocturnal blood pressures, greater variability of nocturnal blood pressure, higher resting heart rate, and orthostatic HTN.[20,22,23] Although some studies have shown an association with other markers like sleep apnea,[24] obesity, and plasma renin activity,[25] these results have not been replicated.[26]

Age has not proven to be a discriminator of response; studies have enrolled patients up to and beyond the age of 75 and found no lessening of effect in older patients.[27,28] Based on the hypothesis that hypertension associated with arterial stiffness may not respond as well to RDN, most randomized trials have only enrolled patients with combined (systolic and diastolic) hypertension. However, efficacy in isolated systolic HTN has been demonstrated in a randomized trial and in large numbers of registry patients.[27,29]

Future analyses, perhaps pooling data from multiple modalities or from new studies like SPYRAL AFFIRM[30] and the GPS Registry[31] may provide enough power to guide patient selection for RDN in the future. Postmarket RDN registries will also be valuable in further shaping patient selection and predicting efficacy.

There are patient subsets in whom RDN has not been studied well. For this reason, caution should be used when extrapolating results to these populations. The SPYRAL trials excluded patients with estimated glomerular filtration rate (eGFR) <45 mL/min/1.73 m^2, and the RADIANCE trials excluded patients with eGFR <40 mL/min/1.73 m^2; to date, most data about patients with lower eGFR comes from registries and postmarketing studies. A small, prospective, randomized trial evaluating the safety and efficacy of ultrasound RDN in patients with adult polycystic kidney disease (RDN-ADPKD)[32] is ongoing. RDN has not been studied in patients with a single functioning kidney, atrophic kidney, renal tumor, renal artery aneurysm, renal stent, renal transplantation, or significant renal artery stenosis from atherosclerotic disease, calcified lesions, or fibromuscular dysplasia.

To date, enrollment in clinical trials of RDN has been predicated on the absence of a secondary cause of HTN in patients with resistant HTN. Patients considered for RDN should undergo appropriate evaluation for secondary causes of HTN with specific treatment that may correct the etiology of their HTN.[2]

Procedural and technical considerations

Procedural planning and optimal technique are essential to safely achieving reductions in blood pressure with catheter-based RDN therapy. Thoughtful procedural review and methods are especially important because no reliable real-time biomarker or other measure of procedural success presently exists to confirm effectiveness and completeness of the RDN procedure.[33] Irrespective of the RDN method, standardization of the procedure is essential to ensure consistent and predictable results.

Preprocedure evaluation and imaging

As part of the preprocedure evaluation for uncontrolled HTN, noninvasive imaging is essential to exclude secondary causes of HTN that are anatomically ineligible for RDN, for example, renal artery stenosis or fibromuscular dysplasia. Imaging of the renal parenchyma may also identify conditions such as polycystic kidney disease or an atrophic kidney. The selection of imaging modality should be based on patient characteristics, availability, and local expertise.[34] Duplex ultrasound is a common screening method due to its widespread availability, low costs, and the avoidance of radiation and contrast, although alternative imaging methods may be used. Computed tomography angiography (CTA) or magnetic resonance angiography (MRA) offer greater precision regarding renal artery structural anatomy, vessel caliber, and identification of accessory renal arteries. Both CTA and MRA also permit a more detailed examination of the kidney and adrenal anatomy to exclude secondary causes of HTN. As a final confirmation of suitable renal artery anatomy, selective catheter-based renal angiography remains the standard prior to performance of RDN.

Anatomical considerations

Ablation site and method. A fundamental principle of RDN techniques is the need to ablate a threshold number of nerve fibers to achieve a reduction in sympathetic activity.[35] In a retrospective analysis of the SYMPLICITY HTN-3 trial using radiofrequency RDN,[36] both total number and circumferentiality of ablations were positively associated with greater blood pressure reductions. Although subsequent studies have demonstrated inconsistent results regarding number of treatments (which may be specific to RDN method), preclinical analyses consistently reinforced the concept that circumferential, perivascular RDN effectively ablates renal nerves while minimizing collateral damage to the vessel wall and adjacent anatomical structures using radiofrequency, ultrasound, or transarterial alcohol injection.[37-39]

Current histological and gross anatomy evaluations of renal innervation reinforce the spatial and anatomical relationship between vascular and nerve anatomy, which was not fully addressed with early RDN techniques. Specifically, renal nerves arise from multiple ganglia as well as the splanchnic and mesenteric nerves and may not form a true renal plexus surrounding the proximal or ostial vessel segments that were an early focus for RDN ablations.[40,41] Instead, numerous renal nerves converge to the renal artery at or beyond the distal segment of the main renal artery and its tributary branches.

Because the renal nerves always more closely approximate the vessel wall distally, greater efficacy of radiofrequency renal denervation (rRDN) in the distal segments of the renal vascular anatomy has made rRDN a solution to achieve more effective ablation.[42] In a preclinical study utilizing rRDN, targeted treatment of the distal main artery and renal artery branches achieved not only greater reductions in sympathetic activity but also reduced variability of treatment effect compared with rRDN of the main renal artery alone.[37]

Extension of RDN to distal branch vessels is device-specific. Ultrasound or ethanol-based ablations are performed in the main renal artery only. Data from RADIOSOUND-HTN, a 3-arm randomized trial of ultrasound RDN of the main artery, rRDN of the main artery, and rRDN of the main artery and distal branches, showed that ultrasound RDN of the main artery was superior to rRDN of the main artery only, and equivalent to rRDN of the main and distal branches at 3 months .[43]

An emerging focus is on overall area and distribution of ablation within the perivascular space.[44] Because surrounding structures (eg, lymph nodes, veins) may influence electrical, thermal, and drug distributions, bench models emphasizing lesion depth alone may represent an oversimplification of varied RDN technologies and may not accurately predict in vivo results. Furthermore, although increasing depth and circumferentiality of ablations or performing more distal ablations may achieve more extensive denervation, each could conceivably risk injury to adjacent perivascular structures. Inattention to spatial distancing of each ablation site could similarly lead to injury. To date, this has not been observed in carefully conducted clinical trials, but monitoring of these issues will be necessary when RDN is more widely used.

Accessory renal arteries. Accessory renal arteries are commonplace, identified in approximately one-third of individuals.[45] Similar to main renal arteries, nerves course farthest from the arterial lumen in the proximal artery segments and become closest in the distal segments when approaching the kidney parenchyma.[46] RDN of accessory arteries has been related to the magnitude of blood pressure reduction.[20] Provided that the vessel caliber is appropriate for current RDN technologies (3-8 mm) and meets device-specific instructions for use, treatment of clinically relevant accessory renal arteries is advocated and likely necessary to achieve a more complete denervation effect.[47]

Procedural technique

Femoral access is currently obtained using standard techniques with a 6F (rRDN) or 7F (ultrasound- and alcohol-mediated RDN) sheath. During the procedure, administration and monitoring of anticoagulation is necessary, generally with unfractionated heparin with an activated clotting time goal >250 seconds. Periprocedural aspirin load is recommended. In addition, administration of adequate analgesics for patient comfort is critical to successfully performing RDN. Familiarity with angiographic projections that best display the renal artery anatomy is imperative; for example, cranial or caudal projections and/or ipsilateral oblique positions may be useful in instances of vessel tortuosity and branch overlap. If preprocedure CTA is available, reconstructions of these images may allow for the identification of optimal invasive angiographic vessel projections. Angiography with diluted contrast is also recommended to confirm RDN catheter placement and apposition.

Prior to performing RDN procedures, operators should be familiar with the catheters, console devices, and troubleshooting, and treatment strategy should be completed with proper instruction that may include both didactic and simulation training. With rRDN, operators should be proficient with the generator's automated safety algorithm to monitor impedance and temperature changes and subselect distal branches. With ultrasound-mediated RDN, operators should be proficient with the generator's automated safety control of the cooling irrigation and energy emitter and have knowledge regarding balloon sizing. Protocols should also exist for routine maintenance and testing of equipment to ensure against device malfunction. Use of hydrophilic guidewires is not recommended, and careful attention to guidewire tip placement at all times is essential. Final angiography evaluating the renal arteries and parenchyma should be performed at completion of the RDN procedure to assess potential renal parenchymal or arterial injuries. Low-dose aspirin therapy for 1 month postprocedure may be considered.

Procedural safety and postprocedure monitoring

Proficiency at managing potential complications including perforation and dissection is necessary. In clinical trials, procedure-related complications were rare and almost exclusively associated with access site complications, underscoring the need for application of best practices for femoral artery access and hemostasis.[48] Development of technologies to permit radial artery approaches to RDN are underway. Patients are typically monitored following the procedure based upon best practices for femoral vascular access, and it is anticipated that same-day discharge will be the norm for RDN procedures. Post-procedural follow-up to assess blood pressure response should typically be performed at approximately 1 to 2 months postprocedure, and assessment of renal function should occur at approximately 3 to 6 months at a minimum. Although we would not advocate for routine imaging following an RDN procedure, renal duplex ultrasonography or cross-sectional imaging, if clinically indicated (eg, increase in blood pressure), could be considered in the months to years following an RDN procedure.

Training and competency

The 2023 ACC/AHA/SCAI Advanced Training Statement on Interventional Cardiology (Coronary, Peripheral Vascular, and Structural Heart Interventions) outlined standards for the operator knowledge base and procedural skill sets required for peripheral vascular intervention competencies.[49] Although there is only passing mention of RDN therein, these guidelines indicate that a curricular milestone for Level III training in peripheral vascular intervention includes skills to perform endovascular revascularization of the renal arteries and identify and manage complications of the procedure. The statement provides less granularity around volume requirements to achieve competence in renovascular procedures than its 2004 predecessor, the ACC/ACP/SCAI/SVMB/SVS Clinical Competence Statement on Vascular Medicine and Catheter-Based Peripheral Vascular Interventions.[50] The earlier statement, written at a time when renovascular procedures were more commonplace, proposed that trainees seeking competency in the renovascular bed alone perform no fewer than 30 diagnostic and 15 interventional procedures, half as primary operator, and that those already in interventional practice perform 20 diagnostic and 10 interventional procedures for that purpose. Given the declines in volume of renal angiography and renal interventions for atherosclerotic renovascular disease, this writing committee agreed that present day operators would not meet historical thresholds for competency in renovascular interventions nor are the higher procedural requirements from that era necessary for RDN procedures, which have been associated with very low complication rates and a favorable safety profile in contemporary clinical trials. Further, the committee acknowledged that the clinical trials, in which RDN safety was established, included both endovascular and coronary interventional operators with relatively low historical procedural volumes in the renal space.

To this end, the committee agreed that interventional cardiologists, with or without formal endovascular training, who seek to perform RDN should demonstrate proficiency in specific skillsets germane to RDN (Table 2). These skills can be obtained from various RDN clinical training pathways and (1) can be part of advanced endovascular training or (2) can entail development of expertise within a focused area of renovascular disease, with an emphasis on performing RDN. Dedicated RDN training programs incorporating didactic modules and simulation experience, procedural observerships at existing RDN centers, or initial procedural supervision from an experienced physician in the renal space are possible training pathways to achieve these skills. These skillsets should be obtained prior to entering a proctoring phase of each RDN device. The proctoring phase includes the first cases performed independently by the operator and can be accomplished by an experienced RDN physician operator or an industry-sponsored clinical representative.

Table 2. Skillsets and training modalities for physician operators performing renal denervation procedures.

Skillset	Training modality
- Arterial vascular access and hemostasis - Vascular access site complication management - Experience and knowledge of analgesia or sedation - Periprocedural hypertension management - Radiation and contrast-sparing measures	Prerequisite (current interventional or endovascular experience)
- Knowledge of aortic, renal, and visceral anatomy - Understanding of renal sympathetic nervous system anatomy and pathophysiology - Understand renal denervation indications - Know the risks and benefits of available renal denervation platforms	Didactic modules, simulation
- Understand catheter selection and technique for renal angiography - Know device-specific renal denervation set-up and technique - Recognize and treat potential renovascular complications, including balloon angioplasty and stenting	Simulation, observerships, and supervision

For interventional cardiologists who have prior endovascular training with active endovascular privileges, and can attest to proficiency of the required skillsets, we recommend a minimum of 5 proctored RDN cases with each approved device to be used at the center. The committee acknowledged that as RDN becomes more widespread, newer technology is developed, and operators become more familiar with performing procedures in the renovascular bed, proctoring thresholds could be reduced.

For interventional cardiologists who do not have endovascular privileges or renovascular expertise, the committee placed greater emphasis on completion of RDN training pathways to obtain the required RDN skillsets rather than on specific volume requirements, which should be established by local hospital privileging committees. Nevertheless, the committee suggested that 10 supervised cases of diagnostic/therapeutic renovascular procedures (stents and/or RDN), half as primary operator, are reasonable to attest to the required RDN skillset before moving to the proctorship phase, recognizing that there can be variability in this volume requirement based on baseline operator experience. The expectation is that an RDN operator will have interventional and endovascular skills to perform effective RDN treatments and manage potential complications, either themselves or with institutional support from colleagues that are immediately available to assist in emergent complication management. Institutional operators should be able to manage vascular perforations, vascular dissections, and have proficiency in placement of covered stents, catheter-based thrombectomy, and therapeutic embolization (eg, coils).

Institutional requirements

Institutions interested in providing RDN therapy for the management of systemic HTN will require several key programmatic components. First, a primary physician stakeholder with training in the management of HTN and resources for screening, testing, and treating HTN is required. It is recommended that this team member is a physician who has additional HTN training, whether through a certificate program, a dedicated HTN fellowship program, or advanced training in a subspecialty including cardiovascular disease or nephrology. This stakeholder will be charged

with the long-term management of the hypertensive patient referred for RDN, whether in a primary or consultative role.

Second, an institution interested in performing RDN will require a dedicated HTN program, or ensure appropriate expertise and services of such a program, designed to manage hypertensive patients. This comprehensive program will ensure the ability to perform or follow-up serial in-office, home, or ambulatory blood pressure measurements, perform serologic and imaging testing to rule out secondary causes of HTN, and have access to abdominal imaging to evaluate the renal artery anatomy and renal artery patency. HTN programs must have capabilities to provide intensive follow-up during the periprocedural period after RDN to monitor for both short-term postprocedural complications (eg, access site complications) as well as longitudinal follow-up after the RDN procedure, and to provide instructions on titration of antihypertensive therapy. Although obtaining American Heart Association Hypertension Center Certification is highly recommended, this may not be feasible for all interested institutions and thus is not a requirement.

Third, a multidisciplinary team should be identified that shares in the management of potential RDN patients. At the core of the team is an HTN navigator, which may be a physician, advanced practice provider, or registered nurse trained in program management. Stakeholders from both noninvasive and invasive specialties should be represented on the multidisciplinary team. Depending on geography and local practices, this may include additional specialists from nephrology, endocrinology, general cardiovascular medicine, vascular medicine, primary care, interventional cardiology, interventional radiology, vascular surgery, and/or (in some circumstances with appropriate training) invasive nephrology. The invasive partners need to have adequate training and privileges to perform RDN and should participate actively in decision-making and periprocedural management of patients. Finally, support staff (eg, triage nurses to follow-up home or ambulatory blood pressures, pharmacy specialist, and nutritionist) may be advantageous to provide patient-centered treatment and education. A suggested working algorithm for a patient referred into the HTN program is depicted in Figure 1.

Establishment as a referral center for RDN within a medical center's network of hospitals and practices should be in accordance with the following recommendations. First, the center should be experienced with using currently available, Food and Drug Administration-approved, RDN devices. The operators should have participated in previous clinical trials or received appropriate minimum proctoring as outlined in the preceding section on operator training and competency.

Second, the center should incorporate the multidisciplinary team within their HTN program to review suitability and appropriateness of patient selection, determination of additional testing or medical therapy, and ultimately, treating and managing patients referred for the procedure. The team concept embodies a collaboration across medical specialties, using their expertise in appropriate patient selection, management, and treatment. Referring centers may already have a collaborative HTN team and clinic, having provided the necessary evaluation, medical therapy, and management; thus, patients may have an expedited course to RDN treatment at the RDN center. The treatment plans should be communicated and outlined to the referring center or practice. Equally important, appropriate patient education should be provided to patients and their families of the potential benefits and risks for each of the technologies and in maintaining medical therapy. As further RDN studies are being conducted in other conditions that may benefit from the procedure, additional members from other disciplines may be incorporated in the team effort.

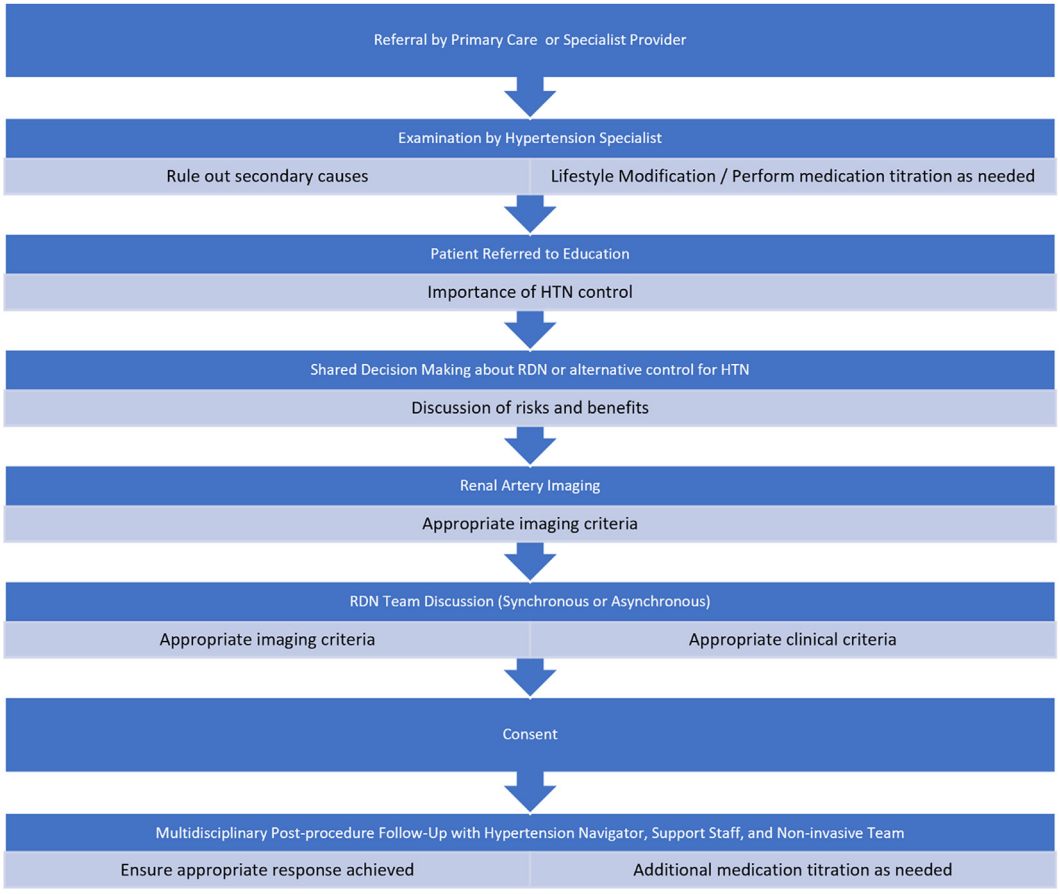

Figure 1.
Proposed care pathway for patients being considered for renal denervation. HTN, hypertension; RDN, renal denervation.

Third, the center offers appropriate and reasonable access to the procedure for patients within the medical center's network while maintaining quality outcomes. A minimum of maintaining an institutional quality registry of patients undergoing RDN is highly recommended and should at least include intra- and postprocedural adverse events (mortality, vascular events, acute renal injury, etc.), improvement in hypertensive control, and stability of renal function over a minimum of 6 months.

Fourth, the center performing RDN should have the appropriate infrastructure of necessary equipment in evaluating, treating, and managing patients. This should include the radiological services of CTA or MRA in defining the renal and other vascular anatomy and potential procedural complications; renal duplex ultrasound to directly image renal vessels and assess renal blood flow velocities; general vascular ultrasound to assess potential access site complications, including pseudoaneurysms and arteriovenous fistulas; and standard fluoroscopy equipment for image-guided therapy available within an interventional cardiology or radiology suite. Procedural equipment, as previously outlined, should be equally readily available. This includes appropriate diagnostic and guide catheters, whether from upper or lower extremity access to interventional guidewires, intravascular ultrasound, and imaging suite equipment capable of digital subtraction imaging and quantitative coronary angiography.

Conclusions

HTN is the leading cause of death and disability,[51] and the prevalence of uncontrolled HTN is increasing globally. In addition to inertia for lifestyle interventions, cost, side effects, and the impact of polypharmacy on quality-of-life limit access and adherence to pharmacotherapy. Device therapies targeting the renal sympathetic nervous system hold promise as adjuncts to abate or interventions to abolish HTN, depending upon the underlying severity of blood pressure elevation. Furthermore, RDN may have beneficial effects on several conditions beyond HTN that are likely to be manifestations of sympathetic imbalance including sleep apnea,[52] left ventricular hypertrophy,[53] albuminuria,[54] and atrial fibrillation.[55] Appropriate patient selection, preprocedure evaluation, careful procedural planning and technique, implementation of strict operator training standards, and facility requirements are paramount to programmatic success.

Declaration of competing interest

David E. Kandzari reports serving as a PI for Medtronic and Ablative Solutions; Ajay J. Kirtane reports serving as a PI for the RADIANCE II and RADIANCE-HTN trials and a consulting relationship with Medtronic; Taisei Kobayashi reports serving on the advisory boards and speakers bureaus and as a consultant for ReCor Medical and Medtronic; Eric Secemsky reports serving on the advisory board and speakers bureau and as a consultant for Medtronic. Naomi D. Fisher reports receiving consulting fees from ReCor Medical and Medtronic. The other authors report no competing interests.

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Supplementary material

To access the supplementary material accompanying this article, visit the online version of the *Journal of the Society for Cardiovascular Angiography & Interventions* at at 10.1016/j.jscai.2023.101121.

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