The Taiwan Renal Denervation Registry: A Prospective Nationwide Multicenter Study Evaluating Real-World Efficacy and Safety in Patients with Hypertension

Li-Chih Wu[1,2], Chang-Yi Lin[2,3], Po-Lin Lin[1,2], Jung-Cheng Hsu[4], Wei-Chung Tsai[5,6], Shih-Hsien Sung[7,8,9,10], Tzung-Dau Wang[11,12], Ying-Hsiang Lee[2,3,13]

[1]Division of Cardiology, Department of Internal Medicine, Hsinchu MacKay Memorial Hospital, Hsinchu, Taiwan
[2]Department of Medicine, MacKay Medical University, New Taipei, Taiwan
[3]Cardiovascular Medicine, MacKay Memorial Hospital, Taipei, Taiwan
[4]Department of Cardiology, Far Eastern Memorial Hospital, New Taipei, Taiwan
[5]Division of Cardiology, Department of Internal Medicine, Kaohsiung Medical University Hospital, Kaohsiung Medical University, Kaohsiung, Taiwan
[6]Faculty of Medicine, College of Medicine, Kaohsiung Medical University, Kaohsiung, Taiwan
[7]Institute of Emergency and Critical Care Medicine, College of Medicine, National Yang Ming Chiao Tung University, Taipei, Taiwan
[8]Cardiovascular Research Center, College of Medicine, National Yang Ming Chiao Tung University, Taipei, Taiwan
[9]Division of Cardiology, Department of Medicine, Taipei Veterans General Hospital, Taipei, Taiwan
[10]General Clinical Research Center, Taipei Veterans General Hospital, Taipei, Taiwan
[11]Cardiovascular Center and Division of Cardiology, Department of Internal Medicine, National Taiwan University Hospital, Taipei, Taiwan
[12]College of Medicine and Smart Health Technology Research and Development Center, National Taiwan University, Taipei, Taiwan
[13]Department of Artificial Intelligence and Medical Application, MacKay Junior College of Medicine, Nursing, and Management, Taipei, Taiwan

Abstract

Objectives: The Taiwan RDN Registry has been established to evaluate the real-world efficacy and safety outcomes of renal denervation (RDN) in patients with hypertension.

Methods: This prospective, multicenter, observational registry enrolls adults with resistant hypertension who are eligible for RDN across medical centers in Taiwan. Baseline demographics, office and 24-hr ambulatory BP, antihypertensive medication use, renal function and procedural parameters are systematically recorded at baseline and at discharge, and at 1, 3, 6, and 12 months post-procedure. The primary endpoints are changes in blood pressure and the incidence of procedure-related adverse events.

Results: Approximately 150 patients are expected to be enrolled, with extended follow-up for long-term safety and efficacy. Statistical analyses will include paired and longitudinal

Received: Received : Nov. 03, 2025; Accepted: Dec. 22, 2025
Address for correspondence: Ying-Hsiang Lee, MD.
Cardiovascular Medicine, MacKay Memorial Hospital, Taipei, Taiwan
E-mail: speakerlee@gmail.com

comparisons, correlation analyses and multivariable logistic regression to identify independent predictors of response.

Conclusions: The Taiwan RDN Registry will evaluate long term outcomes in an Asian population with hypertension.

Keywords: renal denervation, resistant hypertension, registry, blood pressure, real-world evidence, antihypertensive therapy.

1. Background and Rationale

Resistant hypertension is defined as persistently elevated blood pressure (BP) despite adherence to guideline-directed medical therapy comprising at least three antihypertensive agents of different classes, including a diuretic, all administered at optimal or maximally tolerated doses[1]. Patients with hypertension carry a markedly increased cardiovascular risk and often require multidrug regimens to achieve BP control[2]. Renal denervation (RDN) has emerged as a minimally invasive, catheter-based procedure designed to attenuate sympathetic overactivity by ablating renal sympathetic nerves[3]. Randomized controlled trials and observational studies have demonstrated meaningful reductions in BP following RDN[4,5]. However, data from large, real-world populations remain essential to clarify its long-term efficacy and safety.

To address this evidence gap, the Taiwan RDN Registry has been established to provide real world evidence on the clinical effect of RDN among patients with hypertension in Taiwan, in order to evaluate longitudinal outcomes, identify predictors of treatment response, and offer insight into the integration of RDN within routine clinical practice in Asian populations.

2. Study Objectives

The primary objectives of the registry are to quantify changes in office/home/24-hour ambulatory systolic and diastolic BP at follow-up intervals up to 12 months and compare with baseline values, and to determine the incidence, nature and severity of adverse events related to the RDN procedure, including vascular complications and renal function deterioration. Secondary objectives include the assessment of longitudinal changes in antihypertensive medication, exploration of its interaction with BP response, and the identification of baseline demographic or clinical variables that can independently predict treatment efficacy or safety outcomes.

3. Study Design

3.1 Overview

The Taiwan RDN Registry is a prospective, multicenter, observational registry enrolling patients with hypertension deemed suitable for RDN by their physicians. Each participant provides written informed consent, which is reviewed by the local IRB of each participating hospital. The study adheres to the principles outlined in the Declaration of Helsinki and follows Good Clinical Practice standards.

3.2 Participating Centers

The Taiwan RDN Registry involves multiple tertiary medical centers and cardiovascular institutes across Taiwan. All participating centers are led by experienced interventional cardiologists trained in performing RDN procedures.

3.3 Eligibility Criteria

Eligible participants are adults aged ≥18 years with documented hypertension — defined as uncontrolled BP despite treatment. Patients must be willing and able to comply with scheduled follow-up assessments and provide written

informed consent. Patients are excluded if there are structural abnormalities such that they are judged unsuitable by the operator. Additional exclusion criteria mirror those employed in major global RDN registries to ensure comparability.

4. Intervention

4.1 Renal Denervation Procedure

Pre-procedural evaluation includes review of imaging to confirm anatomical feasibility, baseline laboratory studies (including serum creatinine and estimated glomerular filtration rate), electrocardiography, and hemodynamic assessment. RDN is performed using commercially available radiofrequency systems — primarily the Symplicity™ and Symplicity Spyral™ renal denervation catheters (Medtronic, Minneapolis, MN, USA). Both systems are radiofrequency-based platforms designed to achieve circumferential ablation of renal sympathetic nerves located within and adjacent to the adventitia of the renal arteries. During the procedure, patients receive local or general anesthesia according to institutional preference. Under fluoroscopic guidance, the ablation catheter is advanced into each renal artery, and energy is applied at multiple circumferential sites. The number and distribution of ablation points are determined by vessel length and diameter, but generally follow device-specific recommendations. After the procedure, patients are routinely observed for 24-48 hours to monitor for early complications such as vascular access bleeding, renal artery injury, or acute renal function decline. Imaging or Doppler ultrasound is performed when clinically indicated. All procedural details — including device type, ablation count, duration, energy delivered and contrast usage — are captured in the registry database for subsequent analysis.

5. Outcome Measures

5.1 Primary Outcomes

The primary efficacy endpoint is the change in systolic and diastolic BP (office, home and 24-hour ambulatory) from baseline to each follow-up visit (at discharge, and at 1, 3, 6, and 12 months after the procedure). Office blood pressure is obtained using validated automated sphygmomanometers after the patient has rested in a seated position for five minutes with back supported and feet flat on the floor. An appropriately sized cuff is placed at heart level. Home blood pressure monitoring is performed twice daily — morning and evening — for seven consecutive days prior to each follow-up visit. Patients are instructed to obtain two readings at each session, and the mean of all readings, excluding the first day, is recorded. 24-hour ambulatory blood pressure monitoring (ABPM) is performed using validated devices programmed to operate at 20-30-minute intervals during the day and at 30-60-minute intervals at night. A dataset is considered valid if at least 70% of programmed readings are successful. Mean 24-hour, daytime, and nighttime values are then used for the analyses. This measurement protocol is provided to all sites and is intended to minimize inter-center variability and enhance reproducibility of BP-related endpoints.

Safety outcomes are prespecified to ensure consistent reporting across centers. Renal function deterioration is defined as a decline of at least 30% in estimated glomerular filtration rate compared with baseline, confirmed by repeat measurement within two weeks. Renal artery complications include angiographically verified dissection, perforation, intramural hematoma, or pseudoaneurysm. Access-site complications include hematoma requiring transfusion, pseudoaneurysm necessitating intervention, or bleeding that prolongs hospitalization for at least 24 hours. Contrast-induced nephropathy is defined as an increase in serum creatinine of at least 0.3 mg/dL or a relative rise of 50% within 48-72 hours after the procedure. All adverse events and serious adverse events are entered into the electronic registry and reviewed at the coordinating center.

5.2 Secondary Outcomes

Secondary endpoints include changes in dosage of each antihypertensive agent. Variations in dosage of each antihypertensive agent from baseline until each follow-up time are recorded. In addition, 24-hour ABPM data — comprising mean daytime, nighttime, and overall SBP/DBP — are analyzed where available. The registry also records home BP measurements, heart rate trends, and renal function, enabling comprehensive assessment of RDN's clinical impact. Because changes in antihypertensive therapy may influence blood pressure outcomes, adjustments to antihypertensive agents are permitted when clinically necessary — such as the development of symptomatic hypotension, uncontrolled hypertension, or electrolyte disturbances — and investigators are encouraged to adjust medication as standard practice after RDN. All modifications of the therapy regimen, including dose escalations, reductions, class substitutions or discontinuations, are recorded in the registry. Medication burden is quantified and incorporated into longitudinal analyses to account for pharmacological influences on BP trajectories. This structured approach ensures transparency and minimizes variability introduced by post-procedural medical management.

6. Data Collection and Management

At baseline and at each follow-up visit (discharge, 1, 3, 6 and 12 months), investigators record comorbidities, office and home BP readings, ABPM parameters, heart rate, laboratory indices, and detailed medication profiles. Data entry is performed via a secure, cloud-based electronic case-report system that assigns unique anonymized identifiers to each participant. Access to the database is restricted to authorized study personnel, and all data are stored on password-protected servers compliant with local data-protection legislation. Before analysis, all records are fully de-identified to preserve confidentiality. Regular investigator meetings are held to ensure consistency across participating sites.

7. Statistical Analysis

7.1 Sample Size Considerations

A target enrollment of approximately 150 patients is expected to provide adequate statistical precision to describe clinical outcomes and explore subgroup effects. Continued enrollment is permitted to capture broader patient diversity and enhance generalizability.

7.2 Analytic Plan

Candidate predictors include demographic characteristics, baseline office and ambulatory blood pressure, renal function, comorbidities such as diabetes or chronic kidney disease, the medication burden, and procedural parameters including device type, ablation points and completeness of bilateral ablation. Continuous variables such as SBP, DBP and heart rate will be summarized as mean ± standard deviation or median depending on distribution; categorical variables will be expressed as counts and percentages. Changes in BP over time will be evaluated using paired t-tests or Wilcoxon signed-rank tests as appropriate, and longitudinal analyses will employ repeated-measures ANOVA or mixed-effects models. Correlations between early post-procedure BP changes and 12-month outcomes will be examined using Pearson or Spearman coefficients. Multivariable logistic regression models will identify independent predictors of response, adjusting for demographic and clinical covariates such as age, sex, baseline BP, comorbidities and medication burden. All analyses will be two-sided, with $p < 0.05$ considered statistically significant. All analyses will be performed using SAS 9.4 or equivalent statistical software.

8. Safety Monitoring

All adverse events and serious adverse events are documented in the electronic database

and reported in accordance with national and institutional requirements. Events of special interest include renal vascular complications, contrast-induced nephropathy, and access-site bleeding. Investigators must notify their IRBs and the registry coordinating center within the timelines mandated by regulatory authorities. Periodic on-site and remote data audits verify adherence to the protocol and ensure the consistency of safety oversight.

9. Ethical Considerations

The registry protocol has been approved by the IRB or ethics committee at each participating site. Written informed consent is obtained from every participant prior to any study procedure. All aspects of the study conform to the Declaration of Helsinki and relevant Good Clinical Practice guidelines. Patient confidentiality is strictly maintained by de-identifying all records throughout data collection, storage, and analysis. Any substantive protocol modifications will be submitted for IRB approval as formal amendments before implementation.

10. Expected Impact

The Taiwan RDN Registry is expected to provide real-world evidence regarding the long-term safety and sustained efficacy of RDN among Asian patients with resistant hypertension. Through this registry, we also hope to better understand the effect of RDN in different subgroups of patients with comorbidities. Insights derived from this dataset may guide clinicians in optimizing patient selection, procedural standardization, and long-term management strategies within interventional hypertension therapy.

11. Conclusion

This registry protocol demonstrates a prospective, multicenter, real-world investigation designed to evaluate the clinical utility of renal denervation for hypertension in Taiwan. We hope to further determine the magnitude of BP reduction, characterize safety outcomes, and describe changes in antihypertensive medication use following RDN. Our experience may help shape future recommendations and regional guidelines governing the use of RDN for patients with hypertension in Asia.

12. Reference

1. Jones DW, Ferdinand KC, et al. *Hypertension* 2025;82(10):e212-e316.
2. Carey RM, Calhoun DA, Bakris GL, et al. *Hypertension* 2018;72(5):e53-e90.
3. Lauder L, Fisher NDL, Böhm M, et al. *JACC Cardiovasc Interv* 2025;18(15):1833-1847. doi:10.1016/j.jcin.2025.06.022
4. Mahfoud F, Kandzari DE, Kario K, et al. *Lancet* 2022;399(10333):1401-1410.
5. Bhatt DL, Vaduganathan M, Kandzari DE, et al. *Lancet* 2022;400(10361):1405-1416.