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Original Research

Catheter-Based Radiofrequency Renal Denervation in the United States: A Cost-Effectiveness Analysis Based on Contemporary Evidence

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ABSTRACT

Background: Catheter-based radiofrequency renal denervation (RF RDN) has recently been approved as an adjunctive treatment for hypertensive patients without adequate blood pressure control. This study assessed the cost-effectiveness of RF RDN in the United States based on contemporary clinical evidence.

Methods: A decision-analytic Markov model projected costs, quality-adjusted life years (QALY), and clinical events for an active cohort treated with RF RDN and a control cohort treated with standard-of-care (defined as 1, 2, or 3 antihypertensive medications). Cohort demographics and therapy effect were derived from the SPYRAL HTN-ON MED study demonstrating an absolute 9.9 mm Hg reduction in office systolic blood pressure and 4.9 mm Hg reduction compared with sham control. Clinical event risk reduction from blood pressure lowering was based on a meta-regression of 47 hypertension trials. The incremental cost-effectiveness ratio was evaluated against willingness-to-pay thresholds of $50,000 per QALY (high value) and $150,000 per QALY (intermediate value). Extensive scenario and sensitivity analyses were conducted to assess robustness of the findings.

Results: RF RDN yielded a significant risk reduction in clinical events (0.80 for stroke, 0.88 for myocardial infarction, and 0.85 for cardiovascular death over 10 years). Over lifetime, RF RDN added 0.34 QALY at an additional cost of $11,275, leading to an incremental cost-effectiveness ratio of $32,732 per QALY. The cost-effectiveness of RF RDN was robust across a broad range of scenarios and sensitivity analyses.

Conclusions: Based on a lifetime projection, catheter-based RF RDN is a cost-effective, high-value intervention for hypertensive patients with uncontrolled hypertension.

Introduction

Hypertension affects nearly half of the American population and remains one of the most pressing public health challenges in the United States (US).[1,2] More than 75% of Americans with hypertension do not achieve societal or guideline-recommended treatment goals.[2] In November 2023, the Food and Drug Administration approved radiofrequency renal denervation (RF RDN), a minimally-invasive, catheter--based treatment that targets the sympathetic nervous system to lower systolic blood pressure (SBP), as an adjunct treatment in hypertensive patients without adequate blood pressure control.[3]

The safety and effectiveness of second-generation RF RDN devices were recently demonstrated in 2 randomized sham-controlled clinical trials—SPYRAL HTN-ON MED and SPYRAL HTN-OFF MED—which examined the effect of renal denervation (RDN) in the presence and absence of antihypertensive medications, respectively. In the SPYRAL HTN-ON MED study, a reduction in office SBP (OSBP) of 9.9 mm Hg and 5.0 mm Hg was reported in the active and sham cohorts respectively, yielding a 4.9 mm Hg reduction versus sham ($P = .001$).[4] In the SPYRAL HTN-OFF MED study, a reduction in OSBP of 9.6 mm Hg and 3.5 mm Hg was observed in the active and sham cohorts respectively, yielding a 6.5 mm Hg difference favoring RDN ($P < .001$).[5]

The cost-effectiveness of RF RDN has previously been assessed based on evidence from first-generation RF RDN device trials in 2012.[6] In response to novel developments within the fields of both RDN and the management of hypertension over the last decade, this study sought to build upon previous analyses using newly available,

Abbreviations: AP, angina pectoris; BP, blood pressure; CHD, coronary heart disease; ESRD, end-stage renal disease; HF, heart failure; ICER, incremental cost-effectiveness ratio; MI, myocardial infarction; OSBP, office systolic blood pressure; QALY, quality-adjusted life year; RF RDN, radiofrequency renal denervation.

Keywords: cost-effectiveness analysis; radio frequency ablation; resistant hypertension; United States.

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contemporary clinical and epidemiological evidence to assess the health-economic value of RF RDN in the US health care system.

Methods

Model structure and risk equations

The costs and effects of RDN were projected with a decision-analytic Markov model adapted from a prior report based on a health economic analysis from the United Kingdom.[7] In brief, this lifetime model for both interventional/pharmaceutical and pharmaceutical-only strategies tracked monthly transitions across 33 primary and secondary health states, representing cardiovascular sequelae from hypertension, including myocardial infarction (MI), stroke, heart failure, angina pectoris, and end-stage renal disease. The development of clinical sequelae was based on multivariate risk equations from large cohort study data, including the Framingham Heart Study for stroke, coronary heart disease (CHD) and heart failure, PROCAM for MI, and NHANES for end-stage renal disease.[8–12] Given all of these risk equations rely on OSBP as the blood pressure input, the current study adopted this parameter as the effectiveness measure. To facilitate sensitivity analyses and examine the effect of variation in baseline event risk, the multivariate risk functions could be further adjusted in the current analysis model. Relative risk reductions in clinical events resulting from OSBP reductions with RF RDN were calculated based on meta-regression data from 47 randomized controlled trials which explicitly examined the effects of blood pressure reduction in hypertensive patients.[13] The model schematic is shown in Figure 1.[6] The employed multivariate risk equations have been previously described.[7]

Clinical data

Treatment options, demographics, and reductions in OSBP were based on findings from the HTN-ON MED full cohort study.[4] The trial investigated the safety and efficacy of RF RDN (Symplicity SPYRAL system [Medtronic Inc]) in patients with uncontrolled hypertension despite a prescription of 1 to 3 antihypertensive medications. Participants in that study were on average 55 years old and had a baseline OSBP of 163 mm Hg. Per study protocol, both the active treatment and sham control groups were to maintain their blood pressure–lowering medication regimen without changes prior to ascertainment of the primary end point at 6 months. For purposes of the current analysis, this reduction in OSBP observed with RF RDN in this study was assumed to be maintained over lifetime, consistent with prior studies of RF RDN demonstrating sustained if not amplified blood pressure lowering over late-term follow-up and without escalation of medication burden.[14–17]

Costs and utilities

Health state-specific costs for the current analysis were derived from the published literature, while RF RDN therapy costs were estimated using a resource-based costing approach that considered periprocedural costs inclusive of 1 night of hospital stay, staff, device and facility costs, and was guided by expected grouping to an outpatient payment code.[18–27] Utilities were obtained from the published literature and age-adjusted.[28–37] Condition-specific mortality rates for the US population were obtained from published literature, and general mortality rates were obtained from US lifetables (Supplemental Table S1).[6,27,38,39–43] The model projected costs and effects with a lifetime horizon from a Medicare payer perspective. Costs and effects were discounted at the recommended rates of 3% per annum.[44] Table 1[4,18-27,29-37,44] displays key model inputs.

Model validation

The model was validated with real-world data using several approaches. First, projected clinical event rates assuming the same patient demographics and reduction in OSBP were compared with trial-observed event rates from a diverse range of landmark hypertension clinical trials for stroke, MI, cardiovascular, and all-cause death.[15,45–53] This led to the derivation of an "adjustment factor"—or relative risk—between study-reported and modeled event rates; an adjustment factor of 1 indicated perfect concordance, above 1 indicated underprojection by the model, and below 1 indicated overprojection by the model. Second, model-projected lifetime risk was compared with

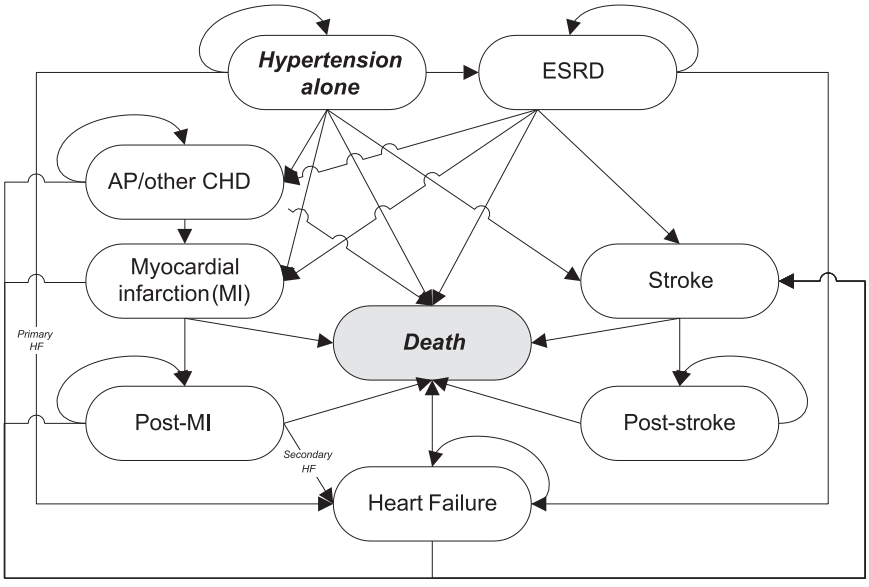


Figure 1.
Schematic representation of the Markov model (based on Geisler et al[6]). AP/other CHD, angina pectoris/other coronary heart disease; ESRD, end-stage renal disease; HF, heart failure; MI, myocardial infarction.

Table 1. Key input parameters.

Parameter	Value	Distribution	SE	Source
Age	55.0 y	Normal	0.53	SPYRAL HTN-ON MED full cohort, Kandzari et al,[4] 2023
Sex (% female)	19.9%	Beta	0.022	SPYRAL HTN-ON MED full cohort, Kandzari et al,[4] 2023
Baseline systolic BP	163 mm Hg	Normal	0.40	SPYRAL HTN-ON MED full cohort, Kandzari et al,[4] 2023
Treatment effect (OSBP reduction)	4.9 mm Hg	Normal	0.54	SPYRAL HTN-ON MED full cohort, Kandzari et al,[4] 2023
Discount rate (costs)	3.00% p.a.			Sanders et al,[44] 2016
Discount rate (effects)	3.00% p.a.			Sanders et al,[44] 2016
Costs (one-time/annual)				
Hypertension (Y1+)	$1038	Gamma	$104	Davis et al,[19] 2013
Stroke (acute)	$29,376	Gamma	$2938	Johnson et al,[18] 2016; Salata et al,[20] 2016
Stroke (Y1)	$39,046	Gamma	$3905	Johnson et al,[18] 2016
Stroke (Y2+)	$24,697	Gamma	$2470	Johnson et al,[18] 2016; Henk et al,[21] 2015
Myocardial infarction (acute)	$20,225	Gamma	$34	Krumholz et al,[24] 2014
Myocardial infarction (Y1+)	$6915	Gamma	$692	Ito et al,[25] 2015
Stable AP (Y1+)	$7357	Gamma	$210	Fearon et al,[22] 2018
Unstable AP (acute)	$10,240	Gamma	$1024	Nicholson et al,[23] 2016
Unstable AP (Y1+)	$7357	Gamma	$210	Fearon et al,[22] 2018
Heart failure (acute)	$2244	Gamma	$224	Urbich et al,[26] 2020
Heart failure (Y1+)	$26,924	Gamma	$2692	Urbich et al,[26] 2020
ESRD without diabetes (Y1+)	$90,226	Gamma	$9023	USRDS, 2021[27]
ESRD with diabetes (Y1+)	$101,118	Gamma	$10,112	USRDS, 2021[27]
RF RDN therapy utilities	$20,000	Gamma	$2000	Medtronic
Hypertension	0.96			
Stroke	0.63	Beta	0.06	Grosso et al,[32] 2011; Darlington et al,[30] 2007
Myocardial infarction (months 1-6)	0.76	Beta	0.08	Aasa et al,[29] 2010; Glasziou et al[31] 2007
Myocardial infarction (months 6+)	0.88	Beta	0.09	Grosso et al,[32] 2011; Pignone et al,[33] 2007
Stable AP	0.84	Beta	0.004	Sullivan et al,[34] 2006
Unstable AP	0.74	Beta	0.004	Glasziou et al,[31] 2007
Heart failure	0.71	Beta	0.07	Chen et al,[35] 2004; Fryback et al,[36] 2007
ESRD	0.63	Beta	0.06	Lee et al,[37] 2009

AP, angina pectoris; BP, blood pressure; ESRD, end-stage renal disease; OSBP, office systolic blood pressure; RF RDN, radiofrequency renal denervation; SE, standard error; USRDS, United States Renal Data System; Y1, year 1; Y2, year 2.

published analyses of lifetime risks observed for hypertensive populations.[54–58] Thirdly, model projections were compared against both the QRISK3, ACC/AHA pooled cohort equations (PCE), and the European SCORE risk charts.[59–63]

Analysis outcomes

Model analysis was completed by projecting cardiovascular clinical events, absolute risk reductions, numbers needed to treat, costs, quality-adjusted life years (QALY), and the incremental cost-effectiveness ratio (ICER), calculated by dividing lifetime incremental costs by incremental QALY gained. Cost-effectiveness was evaluated using the established cost-effectiveness thresholds of $50,000 per QALY gained (high value), and $150,000 per QALY (intermediate value), with all ICER below $150,000 per QALY considered cost-effective.[44,64]

Sensitivity and scenario analyses

Several analyses were completed to examine model robustness and uncertainty. First, input parameters were varied to their individual 95% confidence intervals for 1-way sensitivity analyses to examine which parameters the model was most sensitive to. Second, the effect of lower and higher baseline event incidence on analysis outcomes was studied by applying adjustment factors of 0.5 and 2.0 to the multivariate risk equations (this range is in part informed by the findings of validations reported in the Results section). Third, the ICER was calculated with an equal biological sex split at different ages, at different baseline OSBP, and for the base case age male and female. Fourth, the general population mortality rate was adjusted by 20% to assess the cost-effectiveness of RDN on lower- and higher-risk populations. Fifth, a multiway sensitivity analysis was completed using treatment effects representative of existing studies, ranging from 4 to 10 mm Hg OSBP reductions, and an adjustment factor range of 0.5 to 2.0, secondary to model validation. Sixth, ICER were calculated by utilizing data from the broader pool of RF RDN studies, including HTN-OFF MED trial data and meta-analysis data for 1st and 2nd generation RF RDN devices.[65] Seventh, a threshold analysis was completed to determine the therapy cost required to meet $50,000 and $150,000 per QALY. Finally, a probabilistic sensitivity analysis using 10,000 simulation runs was performed to systematically assess the effect of parameter uncertainty on the analysis outcomes, with results presented in cost-effectiveness scatterplots and cost-effectiveness acceptability curves for the base case and the explored scenarios of lower and higher baseline clinical event incidence. In line with recommendations for economic evaluation, clinical heterogeneity was not considered as it is inherently captured in the treatment effect.[66]

The model was constructed in Excel (Microsoft Corp), while statistical analyses and figures were generated with JMP Pro 16 (SAS Institute).

Results

Model validation

Adjustment factors between modeled and real-world trial data averaged 0.94 for stroke, 0.87 for MI, and 0.82 for all-cause death, indicating a marginal overprojection of clinical events when maintaining the original risk functions (Supplemental Table S2). The model-projected lifetime risks were in keeping with the data observed in epidemiological studies (Supplemental Appendix 1). Compared to the QRISK3, ACC/AHA PCE, and SCORE risk charts for composite measures, the model marginally overprojected for atherosclerotic cardiovascular disease and cardiovascular death (Supplemental Appendix 2). Due to model alignment with real-world data, and the relative underprojection compared to outcomes

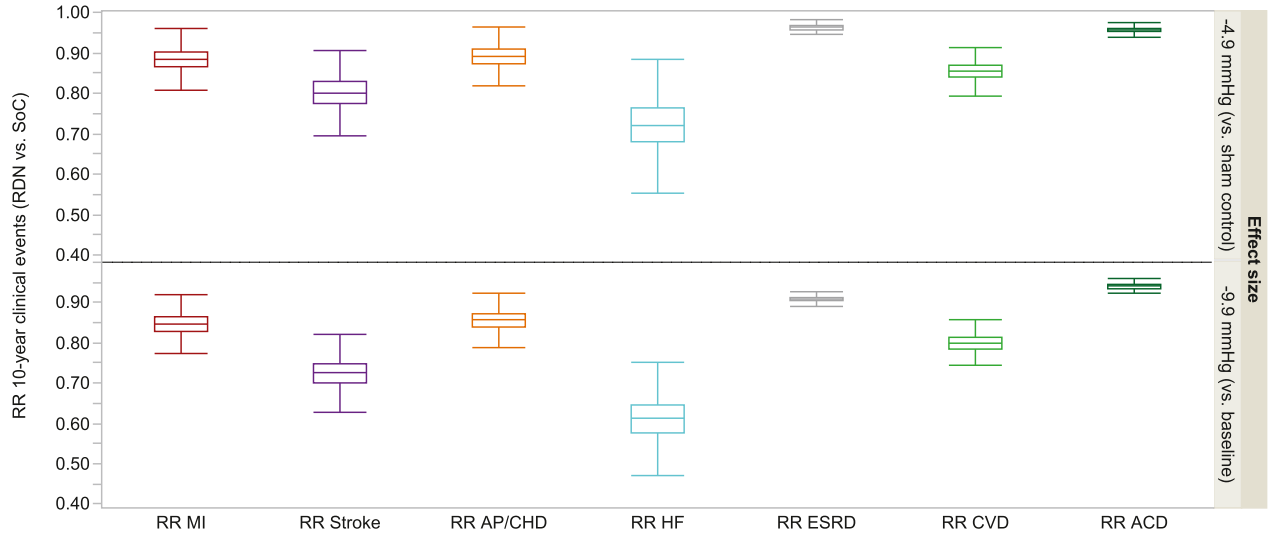


Figure 2.
Relative risks (RR) of clinical events at 10 years for radiofrequency renal denervation (RDN) effect size vs sham control (top) and vs baseline (bottom). The base case analysis relies on the effect observed vs sham. ACD, all-cause death; AP/CHD, angina pectoris/coronary heart disease; CVD, cardiovascular death; ESRD, end-stage renal disease; HF, heart failure; MI, myocardial infarction; SoC, standard of care.

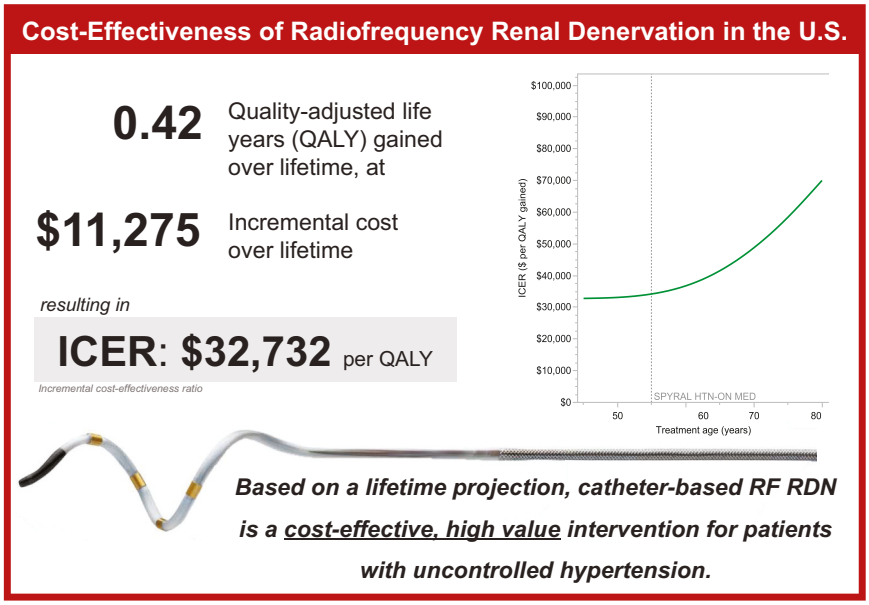
observed in RF RDN-treated patients in the GSR, the base case analysis maintained the original risk functions, while scenarios were calculated using adjustment factors of 0.5 and 2 (half to double the clinical event incidence) for CHD, MI, and stroke.

Base case analysis

Applying the OSBP reductions with RF RDN observed in the SPYRAL HTN-ON MED trial, the relative risk of MI, stroke, and cardiovascular death were respectively 0.88, 0.80, and 0.85 over a 10-year horizon (Figure 2 and Supplemental Table S3). The absolute risk reduction of MI, stroke, and cardiovascular death were respectively 0.8%, 1.7%, and 1.0% over 10 years and 1.7%, 3.3%, and 3.7% over 20 years (corresponding to a 20-year number needed to treat of 59, 31, and 27). Over lifetime, the incremental costs and QALY were $11,275 and 0.34, yielding an ICER of $32,732 per QALY in the base case (Central Illustration).

Sensitivity and scenario analysis

The model was most sensitive to RF RDN therapy costs, followed by adjustment factors for stroke and CHD baseline risk (Supplemental Figure S1). The ICER ranged from $33,040 to $70,846 per QALY for patients aged 45 to 80 years, and $31,884 to $41,524 per QALY for a baseline OSBP of 140 to 175 mm Hg (Figure 3A), with a higher ICER for older patients and lower baseline OSBP. The ICER was $32,013 and $39,251 for males and females, respectively, at 55 years of age. Varying the baseline mortality to 20% lower and higher yielded ICER of $28,779 and $36,725 per QALY gained, respectively. RF RDN was highly cost-effective for all tested OSBP reductions between 4 and 10



Central Illustration.
Cost-effectiveness of radiofrequency renal denervation (RF RDN) in the United States. Incremental cost-effectiveness ratio (ICER) related to patient age establishing radiofrequency renal denervation as a cost-effective, high-value therapy. QALY, quality-adjusted life-years.

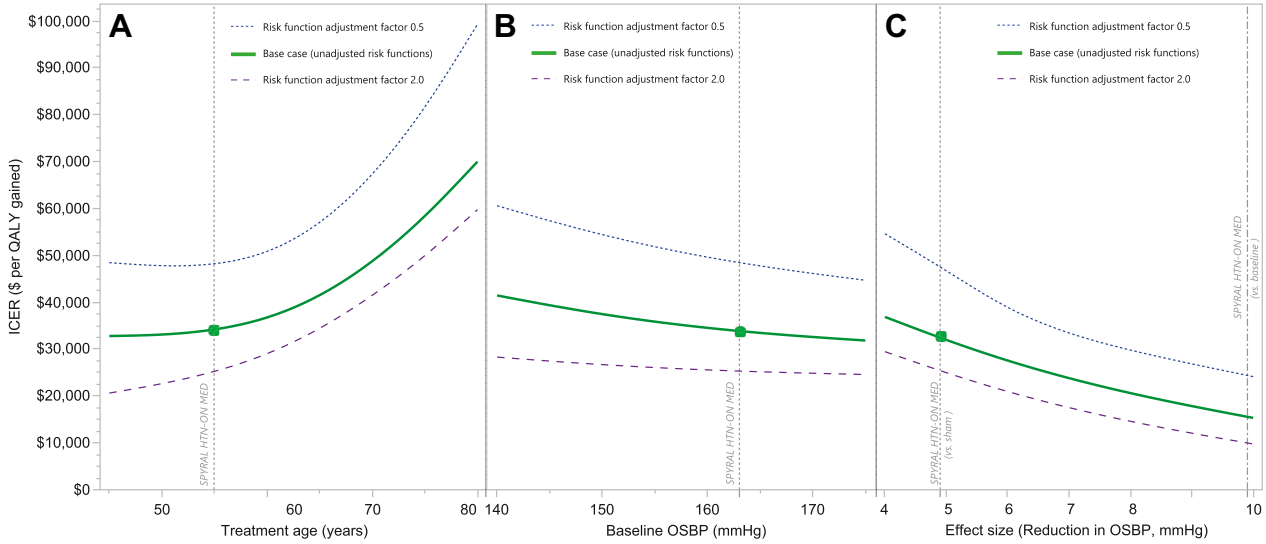


Figure 3.
Sensitivity analysis results: incremental cost-effectiveness ratio (ICER) dependent on treatment age (A), baseline office systolic blood pressure (OSBP) (B), and effect size (C). All scenarios shown for base case (unadjusted event risk functions), and down- and up-adjusted baseline event risk (factors 0.5 and 2.0, respectively). QALY, quality-adjusted life-years.

mm Hg, except for the scenario exploring a combined 4 mm Hg effect size and low baseline event incidence (adjustment factor 0.5), for which RF RDN was found cost-effective at intermediate value (Figure 3B, C). Over a 15-, 20-, and 30-year horizon, the ICER was respectively $130,656, $68,684, and $37,038 per QALY, reflecting the build-up of benefit over time.

For the effect size of 9.9 mm Hg observed versus baseline, an ICER of $15,838 per QALY gained was observed. Compared with sham control and assuming a reduction in OSBP of 4.81 mm Hg (meta-analysis of 1st and 2nd generation RDN devices), 5.73 mm Hg (meta-analysis of 2nd generation RF RDN devices only), and 6.6 mm Hg (HTN-OFF MED clinical trial), ICER of $33,173, $28,971, and $25,521 per QALY gained were obtained (Table 2).[4,5,65] Results from the threshold analysis suggest a therapy cost of $25,948 and $60,395 corresponded to ICER of $50,000 and $150,000 per QALY, respectively.

The conducted probabilistic sensitivity analysis yielded a 95% credibility interval for the ICER of $16,037 to $59,794 per QALY (Figure 4A), with 91.3% of simulations resulting in "high-value" (ICER below $50,000 per QALY gained) and 100% of simulations below the $150,000 per QALY threshold (Figure 4B). Higher baseline event risk was directionally associated with more favorable cost-effectiveness findings.

Discussion

Based on contemporary evidence from randomized trials and more than 10 years of clinical experience outside the US that support the therapy's maintained treatment effect, the current modeling study found RF RDN to be associated with meaningful projected reductions in clinical events over patients' lifetime that render it a cost-effective, high-value intervention in the US health care system. These findings provide an important perspective for clinical and policy decision-makers weighing the therapy's adoption following its recent approval by the US Food and Drug Administration as an adjunctive treatment in patients with uncontrolled hypertension despite attempts at lifestyle modification and the use of antihypertensive medications.[3]

The findings are directionally in line with those recently reported for the UK setting.[7,67] They also provide an important update to an earlier 2012 analysis conducted for the US which reported RDN to be cost-effective at an ICER of around $3000 per QALY gained.[6] That study, although instrumental to the new analyses and continuing to provide important methodological underpinnings, relied on the then-available evidence from the open-label Symplicity HTN-2 randomized controlled trial of resistant hypertension participants, with a baseline OSBP of 178 mm Hg and a treatment effect size of 32 mm Hg. This earlier model also relied on the epidemiological functions to project outcomes for both the treatment and control groups, which—as acknowledged in the earlier report—can be expected to underestimate the benefit of blood pressure reduction. For example, a treatment effect of 32 mm Hg corresponded to a 0.70 relative risk for stroke at a 10-year horizon, as opposed to a more pronounced relative risk of 0.47 according to the Thomopoulos risk equations.[13]

Among the important insights from the current study is the robustness of cost-effectiveness findings across patient risk profiles. Even with lower clinical event incidence, as might be suggested by atherosclerotic

Table 2. Base case and key scenario results over lifetime.

	Costs ($)		QALY		Δ Costs ($)	Δ QALY	ICER
	RF RDN	SoC	RF RDN	SoC			($ per QALY)
Base case (HTN-ON MED, OSBP, 4.9 mm Hg vs sham)[4]	96,416	85,141	12.83	12.49	11,275	0.34	32,732
HTN-ON MED (OSBP, 9.9 mm Hg vs BL)[4]	92,762	85,141	12.97	12.49	7621	0.48	15,838
Meta-analysis of 1st and 2nd generation RF RDN devices (OSBP, 4.81 mm Hg vs sham)[65]	96,484	85,141	12.83	12.49	11,343	0.34	33,173
Meta-analysis of 2nd generation RF RDN devices (OSBP, 5.73 mm Hg vs sham)[65]	95,793	85,141	12.86	12.49	10,652	0.37	28,971
HTN-OFF MED (OSBP effect size, 6.6 mm Hg vs sham)[5]	96,699	87,022	14.02	13.64	9677	0.38	25,521

ICER, incremental cost-effectiveness ratio; OSBP, office systolic blood pressure; QALY, quality-adjusted life-years; RF RDN, radiofrequency renal denervation; SoC, standard of care.

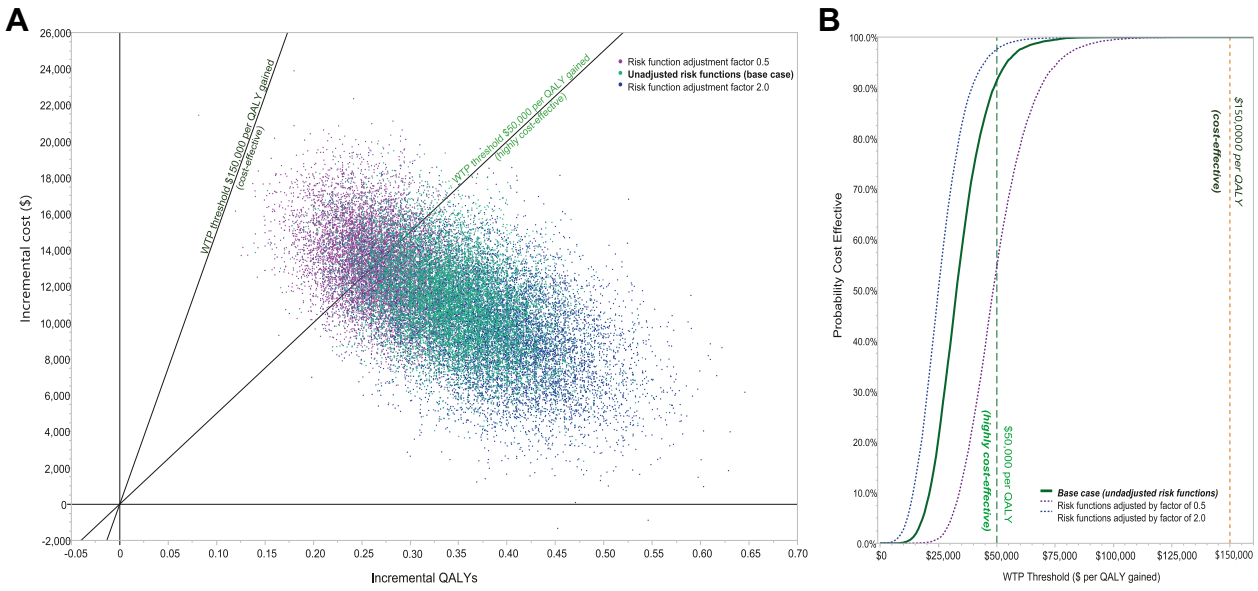


Figure 4.
Probabilistic sensitivity analysis results: incremental cost-effectiveness ratio scatterplot (A) and cost-effectiveness acceptability curve (B). Each graph shows results for base case (unadjusted event risk functions), and down- and up-adjusted baseline event risk (factors 0.5 and 2.0, respectively). QALY, quality-adjusted life-years; WTP, willingness-to-pay.

disease risk projections derived from PCE calculation, RF RDN remained highly cost-effective at an effect size of 4.9 mm Hg. Similarly, higher event incidence, as might be supported by 3-year data from actual RF RDN-treated patients in the GSR, led to somewhat improved cost-effectiveness, but not materially different ICER. Among the reasons for this dynamic is that lower event incidence implies longer cohort survival, with a prolonged lifetime over which blood pressure reductions achieved with RF RDN can continue to contribute to clinical benefit. These analyses, directionally, also provide perspective on the cost-effectiveness results expected in cohorts at lower and higher cardiovascular risk. Similarly, differences in the cost-effectiveness in younger versus older-aged cohorts receiving RF RDN treatment were identified, where cost-effectiveness decreased marginally as treatment age increased. Importantly, RF RDN remained highly cost-effective up to a mean cohort age of 70 years and remained cost-effective at attractive ICER even above that age (Figure 3A). Of note, short-term savings resulting from avoided events can be expected to be larger in older cohorts because of their elevated event risks, as opposed to younger cohorts where event risks are initially comparably low, though the longer time horizon in the young would subsequently compensate.

Cost-effectiveness in the current study, as outlined, was based on contemporary clinical evidence. Of note, the SPYRAL HTN-ON MED study underpinning the base case, with an effect size of 4.9 mm Hg versus sham control, provides the most conservative effect size among other evidence, including the SPYRAL HTN-OFF MED data. Assuming somewhat larger effect sizes, as supported by these studies—or alternatively considering the sustained absolute reductions from baseline following RF RDN in SPYRAL HTN-ON MED (~ 10 mm Hg)—would have led to further improved cost-effectiveness findings, largely due to the higher proportion of avoided clinical events. The robustness of cost-effectiveness findings in the current analysis was also underscored by the findings of the extensive deterministic and probabilistic sensitivity analyses.

This analysis has important limitations. First, the analysis assumes that the magnitude of treatment effect observed in trials at 6 months is sustained through late-term follow-up. This assumption is supported by a growing body of clinical evidence demonstrating durability of the RF RDN treatment effect up to and beyond 9 years.[14,16,68–70] Indeed, some studies have demonstrated sustained if not amplified blood pressure reductions following RF RDN that cannot be attributed to escalation in medication dose or number.[15,17] The assumed effect size versus sham control, as opposed to baseline, might also underestimate the real-world treatment effect size. However, use of the sham control-derived effect estimate is methodologically most appropriate for a base case. Larger effect sizes would have only further improved the already favorable "high value" cost-effectiveness finding documented in this study through sensitivity analyses. Second, although the analysis model tracks primary and secondary health states, it does not capture all potential clinical sequelae from hypertension, such as arrhythmias, vascular dementia, retinopathy, or peripheral vascular disease. Consideration of these clinical states may improve the projected therapeutic benefit of RDN. Third, condition-specific mortality data used in the model are at least 5 years old. However, even if there was some improvement in contemporary postevent survival, the effect on the analysis findings could be expected to be limited. Fourth, as RF RDN has only recently received regulatory approval in the US, little if any data exist that report on resource utilization and cost of RF RDN treatment. The cost assumption of $20,000 is higher than the $12,500 cost assumed in the 2012 analysis, and more than twice as high as the microcosting-derived UK analysis estimate of approximately £6800. The current estimate conservatively assumes an overnight stay following the RF RDN procedure. However, if facilities adopt a same-day discharge procedure that is common among many centers, the health economic value of RF RDN could be anticipated to further improve.[71] As real-world cost data for the US emerge, the current analysis framework and results can readily be used to evaluate implications for cost-effectiveness. Fifth, the analysis did not examine the cost-effectiveness of RDN from a private insurer perspective. Given the rising burden of uncontrolled hypertension in younger Americans, private insurance may be expected to represent a significant proportion of RF RDN procedures.[72] The upfront cost and downstream savings for private insurers might differ from the cost assumptions informing the current analysis. Nevertheless, guidelines for cost-effectiveness analysis are clear that true cost should inform analyses, with Medicare payments commonly considered a reasonable proxy for cost. Private payer audiences might particularly benefit from the reporting of short-term events avoided and NNT reported in the current study, an approach also adopted in an earlier analysis derived from 3-year outcomes from the GSR.[67] Sixth, the study did not

examine the cost-effectiveness of RF RDN for different ethnicities or socioeconomic status in which RF RDN has shown comparable safety and efficacy.[73–75] Such populations are disproportionately impacted by hypertension and possible variability in blood pressure with RF RDN among such subgroups may influence cost-effectiveness.[76–78] Finally, the analysis was based on RF RDN studies and may not be generalizable to other RDN methods.

Conclusion

Based on contemporary evidence and assumed maintained treatment benefit, catheter-based RDN is projected to achieve meaningful clinical event reductions in patients suffering from uncontrolled hypertension at incremental lifetime costs that render it a cost-effective, high-value intervention.

Declaration of competing interest

David E. Kandzari has received grants and consulting fees from Medtronic, Ablative Solutions, Boston Scientific, Abbott Vascular, OrbusNeich, and Cardiovascular Systems Inc, as well as travel and/or meeting support from Medtronic. Khoa N. Cao and Anne M. Ryschon report consulting fees from Medtronic (through Wing Tech Inc). Andrew S. P. Sharp has received honoraria and consulting fees and/or travel and research support from Medtronic, Boston Scientific, Philips, Recor Medical, and Penumbra. Jan B. Pietzsch reports consulting fees from Medtronic, Aktiia, Silk Road Medical, LimFlow, Philips, Endologix, Cardiovascular Systems Inc, and Abbott Vascular (all through Wing Tech Inc).

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Ethics statement and patient consent

This manuscript does not report on patients or patient data. The clinical trials, where underlying data were sourced from for the current analysis, were conducted in accordance with ethical standards.

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 10.1016/j.jscai.2024.102234.

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