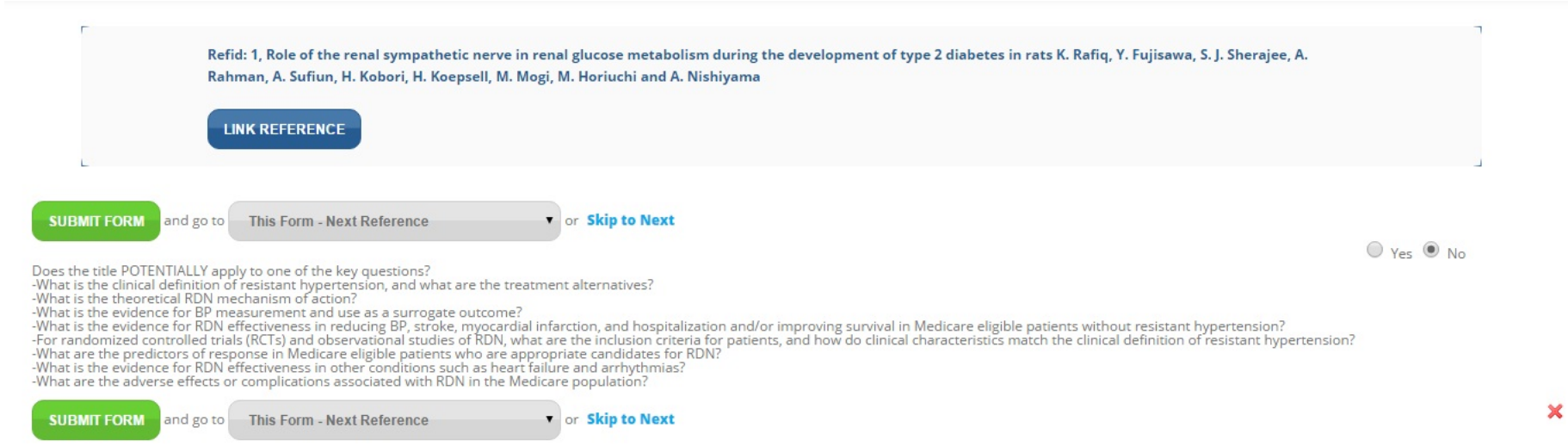
Appendix A. Detailed Electronic Database Search Strategies

Search #	Query	Hits
1	denervation[mh] AND (kidney[mh] OR “renal artery”[mh])	2247
2	“renal denervation”[tiab] OR “renal-artery denervation”[tiab] OR “renal artery denervation”[tiab] OR “renal sympathetic denervation”[tiab]	1796
3	#1 or #2 (denervation[mh] AND (kidney[mh] OR “renal artery”[mh])) OR (“renal denervation”[tiab] OR “renal-artery denervation”[tiab] OR “renal artery denervation”[tiab] OR “renal sympathetic denervation”[tiab])	2941
4	#3 AND (Addresses[ptyp] OR News[ptyp] OR Patient Education Handout[ptyp] OR Bibliography[ptyp] OR Dictionary[ptyp] OR Directory[ptyp] OR Legal Cases[ptyp] OR Legislation[ptyp] OR Newspaper Article[ptyp] OR Periodical Index[ptyp]) ((denervation[mh] AND (kidney[mh] OR “renal artery”[mh])) OR (“renal denervation”[tiab] OR “renal-artery denervation”[tiab] OR “renal artery denervation”[tiab] OR “renal sympathetic denervation”[tiab])) AND (Addresses[ptyp] OR News[ptyp] OR Patient Education Handout[ptyp] OR Bibliography[ptyp] OR Dictionary[ptyp] OR Directory[ptyp] OR Legal Cases[ptyp] OR Legislation[ptyp] OR Newspaper Article[ptyp] OR Periodical Index[ptyp])	7
5	#3 NOT #4 ((denervation[mh] AND (kidney[mh] OR “renal artery”[mh])) OR (“renal denervation”[tiab] OR “renal-artery denervation”[tiab] OR “renal artery denervation”[tiab] OR “renal sympathetic denervation”[tiab])) NOT (Addresses[ptyp] OR News[ptyp] OR Patient Education Handout[ptyp] OR Bibliography[ptyp] OR Dictionary[ptyp] OR Directory[ptyp] OR Legal Cases[ptyp] OR Legislation[ptyp] OR Newspaper Article[ptyp] OR Periodical Index[ptyp])	2934
6	#5 NOT (animal[mh] NOT human[mh]) (((denervation[mh] AND (kidney[mh] OR “renal artery”[mh])) OR (“renal denervation”[tiab] OR “renal-artery denervation”[tiab] OR “renal artery denervation”[tiab] OR “renal sympathetic denervation”[tiab])) NOT (Addresses[ptyp] OR News[ptyp] OR Patient Education Handout[ptyp] OR Bibliography[ptyp] OR Dictionary[ptyp] OR Directory[ptyp] OR Legal Cases[ptyp] OR Legislation[ptyp] OR Newspaper Article[ptyp] OR Periodical Index[ptyp])) NOT (animal[mh] NOT human[mh])	1266
7	#6 AND “2005/01/01”[pdat] : “2016/03/08”/[pdat] ((((denervation[mh] AND (kidney[mh] OR “renal artery”[mh])) OR (“renal denervation”[tiab] OR “renal-artery denervation”[tiab] OR “renal artery denervation”[tiab] OR “renal sympathetic denervation”[tiab])) NOT (Addresses[ptyp] OR News[ptyp] OR Patient Education Handout[ptyp] OR Bibliography[ptyp] OR Dictionary[ptyp] OR Directory[ptyp] OR Legal Cases[ptyp] OR Legislation[ptyp] OR Newspaper Article[ptyp] OR Periodical Index[ptyp])) NOT (animal[mh] NOT human[mh]))	1098

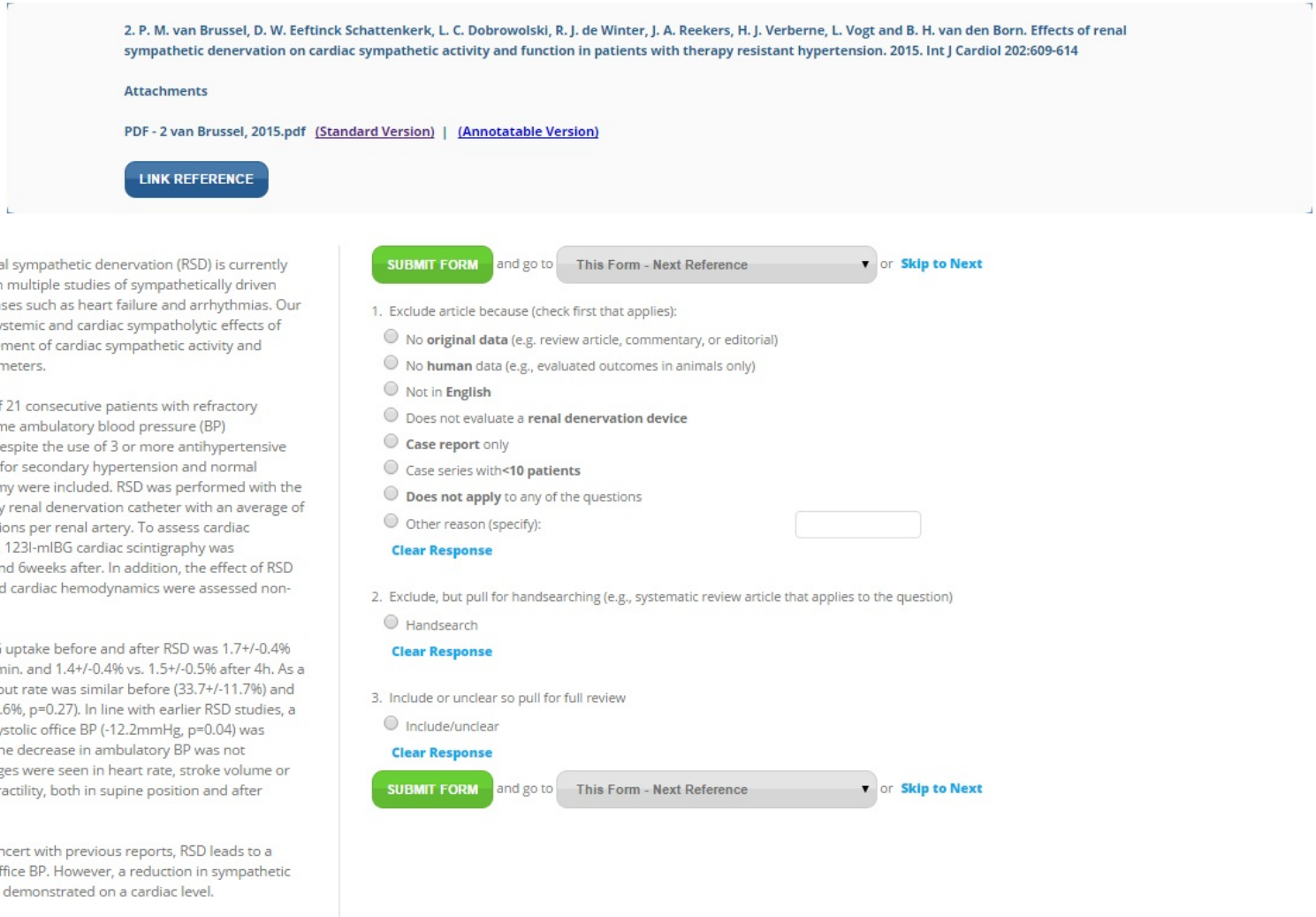
Search#	Query	Hits
7	((((denervation[mh] AND (kidney[mh] OR “renal artery”[mh])) OR (“renal denervation”[tiab] OR “renal-artery denervation”[tiab] OR “renal artery denervation”[tiab] OR “renal sympathetic denervation”[tiab])) NOT (Addresses[ptyp] OR News[ptyp] OR Patient Education Handout[ptyp] OR Bibliography[ptyp] OR Dictionary[ptyp] OR Directory[ptyp] OR Legal Cases[ptyp] OR Legislation[ptyp] OR Newspaper Article[ptyp] OR Periodical Index[ptyp])) NOT (animal[mh] NOT human[mh])) AND “2005/01/01”[pdat] : “2015/12/31”/[pdat]	11095

Appendix B. Forms

Title Review Form



Abstract Review Form



2. P. M. van Brussel, D. W. Eeftinck Schattenkerk, L. C. Dobrowolski, R. J. de Winter, J. A. Reekers, H. J. Verberne, L. Vogt and B. H. van den Born. Effects of renal sympathetic denervation on cardiac sympathetic activity and function in patients with therapy resistant hypertension. 2015. Int J Cardiol 202:609-614

Attachments

PDF - 2 van Brussel, 2015.pdf (Standard Version) | (Annotatable Version)

LINK REFERENCE

BACKGROUND: Renal sympathetic denervation (RSD) is currently being investigated in multiple studies of sympathetically driven cardiovascular diseases such as heart failure and arrhythmias. Our aim was to assess systemic and cardiac sympatholytic effects of RSD by the measurement of cardiac sympathetic activity and cardiovascular parameters.

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RESULTS: 123I-mIBG uptake before and after RSD was 1.7+/-0.4% vs. 1.7+/-0.5% at 15min. and 1.4+/-0.4% vs. 1.5+/-0.5% after 4h. As a consequence, washout rate was similar before (33.7+/-11.7%) and after RSD (30.1+/-12.6%, p=0.27). In line with earlier RSD studies, a significant drop in systolic office BP (-12.2mmHg, p=0.04) was detected, whereas the decrease in ambulatory BP was not significant. No changes were seen in heart rate, stroke volume or left ventricular contractility, both in supine position and after standing.

CONCLUSION: In concert with previous reports, RSD leads to a significant drop in office BP. However, a reduction in sympathetic activity could not be demonstrated on a cardiac level.

SUBMIT FORM and go to This Form - Next Reference or Skip to Next

1. Exclude article because (check first that applies):
   - No **original data** (e.g. review article, commentary, or editorial)
   - No **human** data (e.g., evaluated outcomes in animals only)
   - Not in **English**
   - Does not evaluate a **renal denervation device**
   - **Case report** only
   - Case series with**<10 patients**
   - **Does not apply** to any of the questions
   - Other reason (specify):

   Clear Response

2. Exclude, but pull for handsearching (e.g., systematic review article that applies to the question)
   - Handsearch

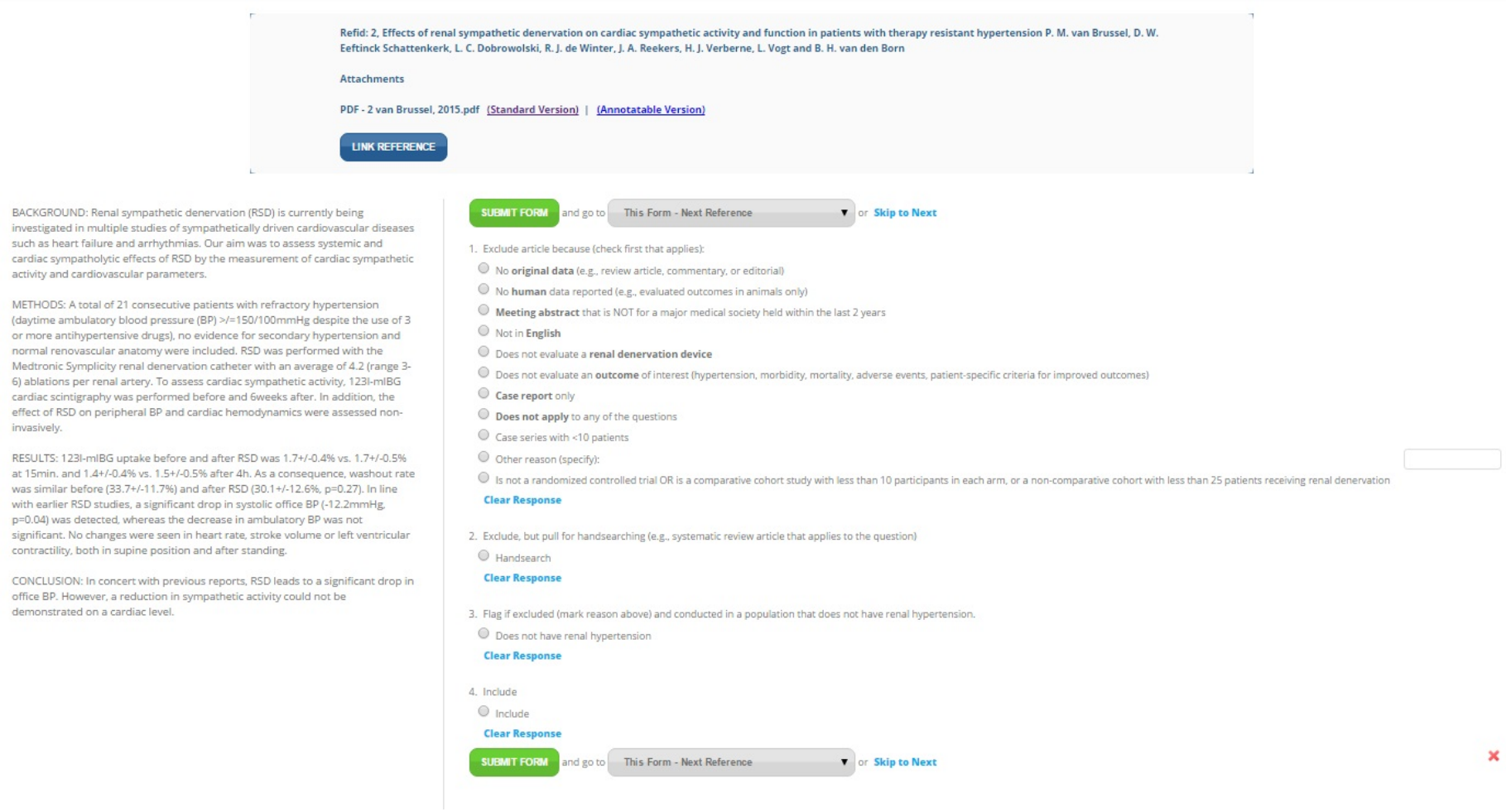
   Clear Response

3. Include or unclear so pull for full review
   - Include/unclear

   Clear Response

SUBMIT FORM and go to This Form - Next Reference or Skip to Next

Full Article Review Form



Refid: 2, Effects of renal sympathetic denervation on cardiac sympathetic activity and function in patients with therapy resistant hypertension P. M. van Brussel, D. W. Eeftinck Schattenkerk, L. C. Dobrowolski, R. J. de Winter, J. A. Reekers, H. J. Verberne, L. Vogt and B. H. van den Born

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SUBMIT FORM and go to This Form - Next Reference or Skip to Next

1. Exclude article because (check first that applies):
   - No **original data** (e.g., review article, commentary, or editorial)
   - No **human** data reported (e.g., evaluated outcomes in animals only)
   - **Meeting abstract** that is NOT for a major medical society held within the last 2 years
   - Not in **English**
   - Does not evaluate a **renal denervation device**
   - Does not evaluate an **outcome** of interest (hypertension, morbidity, mortality, adverse events, patient-specific criteria for improved outcomes)
   - **Case report** only
   - **Does not apply** to any of the questions
   - Case series with <10 patients
   - Other reason (specify):
   - Is not a randomized controlled trial OR is a comparative cohort study with less than 10 participants in each arm, or a non-comparative cohort with less than 25 patients receiving renal denervation

   Clear Response

2. Exclude, but pull for handsearching (e.g., systematic review article that applies to the question)
   - Handsearch

   Clear Response

3. Flag if excluded (mark reason above) and conducted in a population that does not have renal hypertension.
   - Does not have renal hypertension

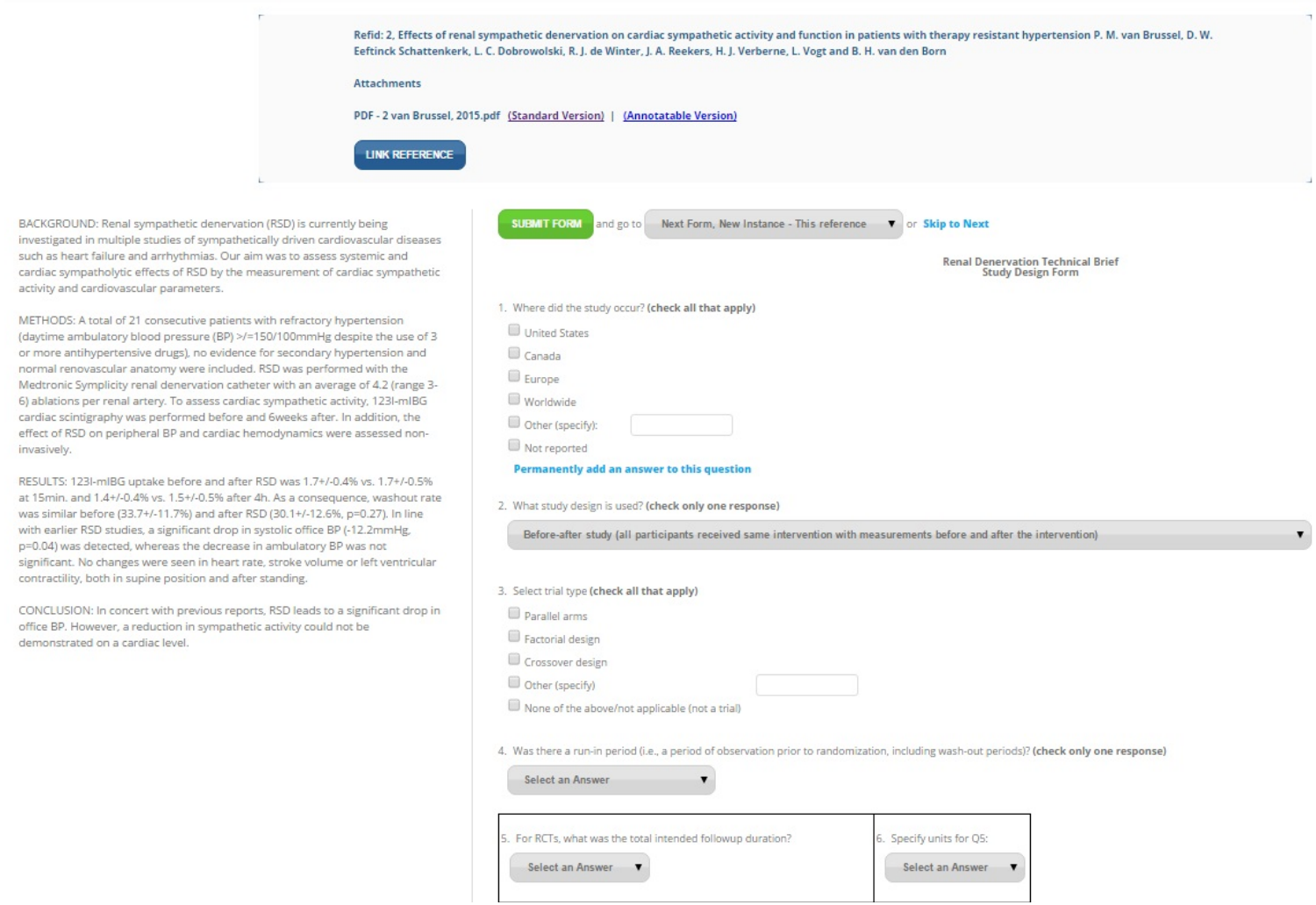
   Clear Response

4. Include
   - Include

   Clear Response

SUBMIT FORM and go to This Form - Next Reference or Skip to Next

Data Abstraction – Study Design Form



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CONCLUSION: In concert with previous reports, RSD leads to a significant drop in office BP. However, a reduction in sympathetic activity could not be demonstrated on a cardiac level.

SUBMIT FORM and go to Next Form, New Instance - This reference or Skip to Next

Renal Denervation Technical Brief
Study Design Form

1. Where did the study occur? **(check all that apply)**
   - United States
   - Canada
   - Europe
   - Worldwide
   - Other (specify):
   - Not reported

   Permanently add an answer to this question

2. What study design is used? **(check only one response)**

   Before-after study (all participants received same intervention with measurements before and after the intervention)

3. Select trial type **(check all that apply)**
   - Parallel arms
   - Factorial design
   - Crossover design
   - Other (specify)
   - None of the above/not applicable (not a trial)

4. Was there a run-in period (i.e., a period of observation prior to randomization, including wash-out periods)? **(check only one response)**

   Select an Answer

5. For RCTs, what was the total intended followup duration?	6. Specify units for Q5:
Select an Answer	Select an Answer

Other (specify)

Permanently add an answer to this question

14. Was the study funded wholly or partially by any of the following? **(check all that apply)**

- Manufacturer
- Government/non-profit
- Other
- Not reported

7. For observational studies, what was the mean/median followup duration?

- Mean followup
- Median followup
- Not reported
- Not applicable

8. Specify units for Q7:

Select an Answer

15. Did the study assess adherence during the run-in period?

- Yes, pill count
- Yes, diary
- Yes, other
- No
- Not reported
- Not applicable

Clear Response

9. What was the total number of patients screened?

Select an Answer

10. What was the total number at enrollment or cohort inception?

Select an Answer

16. Was adherence assessed?

Select an Answer

11. Does the study have a registered protocol (e.g., is registered in ClinicalTrials.gov)?

Select an Answer

17. Which subgroups were conducted?

- Age
- Other
- None
- Baseline blood pressure
- Diabetes status
- Kidney function
- Gender
- antihypertensive agent
- Body mass index

Permanently add an answer to this question

12. Does the study include patients with resistant hypertension?

Select an Answer

18. Comments **(limit 250 characters)**

13. Please specify the exclusion criteria. Any inclusion criteria should be entered as exclusion criteria.

- Age >
- Age <
- Number of antihypertensive medications: >
- Number of antihypertensive medications: <
- Blood pressure: >
- Blood pressure: <
- Duration of hypertension: >
- Duration of hypertension: <
- Other (specify)
- Other (specify)
- Other (specify)
- Other (specify)
- Other (specify)
- Other (specify)
- Other (specify)
- Other (specify)
- Other (specify)
- Other (specify)
- Other (specify)

19. Comments **(limit 250 characters)**

20. Comments **(limit 250 characters)**

SUBMIT FORM and go to Next Form, New Instance - This reference or Skip to Next

Data Abstraction – Population Form

Refid: 2, Effects of renal sympathetic denervation on cardiac sympathetic activity and function in patients with therapy resistant hypertension P. M. van Brussel, D. W. Eeftinck Schattenkerk, L. C. Dobrowolski, R. J. de Winter, J. A. Reekers, H. J. Verberne, L. Vogt and B. H. van den Born

Attachments

PDF - 2 van Brussel, 2015.pdf (Standard Version) | (Annotatable Version)

LINK REFERENCE

SUBMIT FORM and go to Next Form, New Instance - This reference or Skip to Next

Renal Denervation in the Medicare Population
Population Form – Baseline Characteristics

Instructions:
Only enter data for the first measure that you are able to for each row.

	Main Intervention	Comparison A	Comparison B	Comparison C	Comparison D
Total N at enrollment (i.e., at randomization or at beginning or exposure period) Total N not reported Clear Response	...	...	...	...	...
Age Age not reported Clear Response	Mean Median %>65	Mean Median %>65	Mean Median %>65	Mean Median %>65	Mean Median %>65
Male Male not reported Clear Response	%: N:	%: N:	%: N:	%: N:	%: N:
Race/Ethnicity Race/ethnicity not reported Clear Response	Caucasian, %: Caucasian, N: African American, %: African American, N: Other race/ethnicity, %: Other race/ethnicity, N:	Caucasian, %: Caucasian, N: African American, %: African American, N: Other race/ethnicity, %: Other race/ethnicity, N:	Caucasian, %: Caucasian, N: African American, %: African American, N: Other race/ethnicity, %: Other race/ethnicity, N:	Caucasian, %: Caucasian, N: African American, %: African American, N: Other race/ethnicity, %: Other race/ethnicity, N:	Caucasian, %: Caucasian, N: African American, %: African American, N: Other race/ethnicity, %: Other race/ethnicity, N:
Body mass index BMI not reported Clear Response	Mean: Median:	Mean: Median:	Mean: Median:	Mean: Median:	Mean: Median:

Estimated GFR or serum creatinine ○ eGFR ○ Serum creatinine ○ eGFR not reported **Clear Response**	☐ Mean: ☐ Median:	☐ Mean: ☐ Median:	☐ Mean: ☐ Median:	☐ Mean: ☐ Median:	☐ Mean: ☐ Median:
Chronic Kidney Disease Stages ○ CKD stages not reported **Clear Response**	☐ I, %: ☐ II, %: ☐ III, %: ☐ IV, %: ☐ V, %:	☐ I, %: ☐ II, %: ☐ III, %: ☐ IV, %: ☐ V, %:	☐ I, %: ☐ II, %: ☐ III, %: ☐ IV, %: ☐ V, %:	☐ I, %: ☐ II, %: ☐ III, %: ☐ IV, %: ☐ V, %:	☐ I, %: ☐ II, %: ☐ III, %: ☐ IV, %: ☐ V, %:
Diabetes status ○ Diabetes status not reported **Clear Response**	☐ % with diabetes: ☐ N with diabetes:	☐ % with diabetes: ☐ N with diabetes:	☐ % with diabetes: ☐ N with diabetes:	☐ % with diabetes: ☐ N with diabetes:	☐ % with diabetes: ☐ N with diabetes:
Left ventricular hypertrophy ○ LVH not reported **Clear Response**	☐ % with LVH: ☐ N with LVH:	☐ % with LVH: ☐ N with LVH:	☐ % with LVH: ☐ N with LVH:	☐ % with LVH: ☐ N with LVH:	☐ % with LVH: ☐ N with LVH:
Medication use ○ Medication use not reported **Clear Response**	☐ Mean # of BP medications: ☐ % on diuretics: ☐ N on diuretics:	☐ Mean # of BP medications: ☐ % on diuretics: ☐ N on diuretics:	☐ Mean # of BP medications: ☐ % on diuretics: ☐ N on diuretics:	☐ Mean # of BP medications: ☐ % on diuretics: ☐ N on diuretics:	☐ Mean # of BP medications: ☐ % on diuretics: ☐ N on diuretics:

Comments (limit 250 characters)

...

Comments (limit 250 characters)

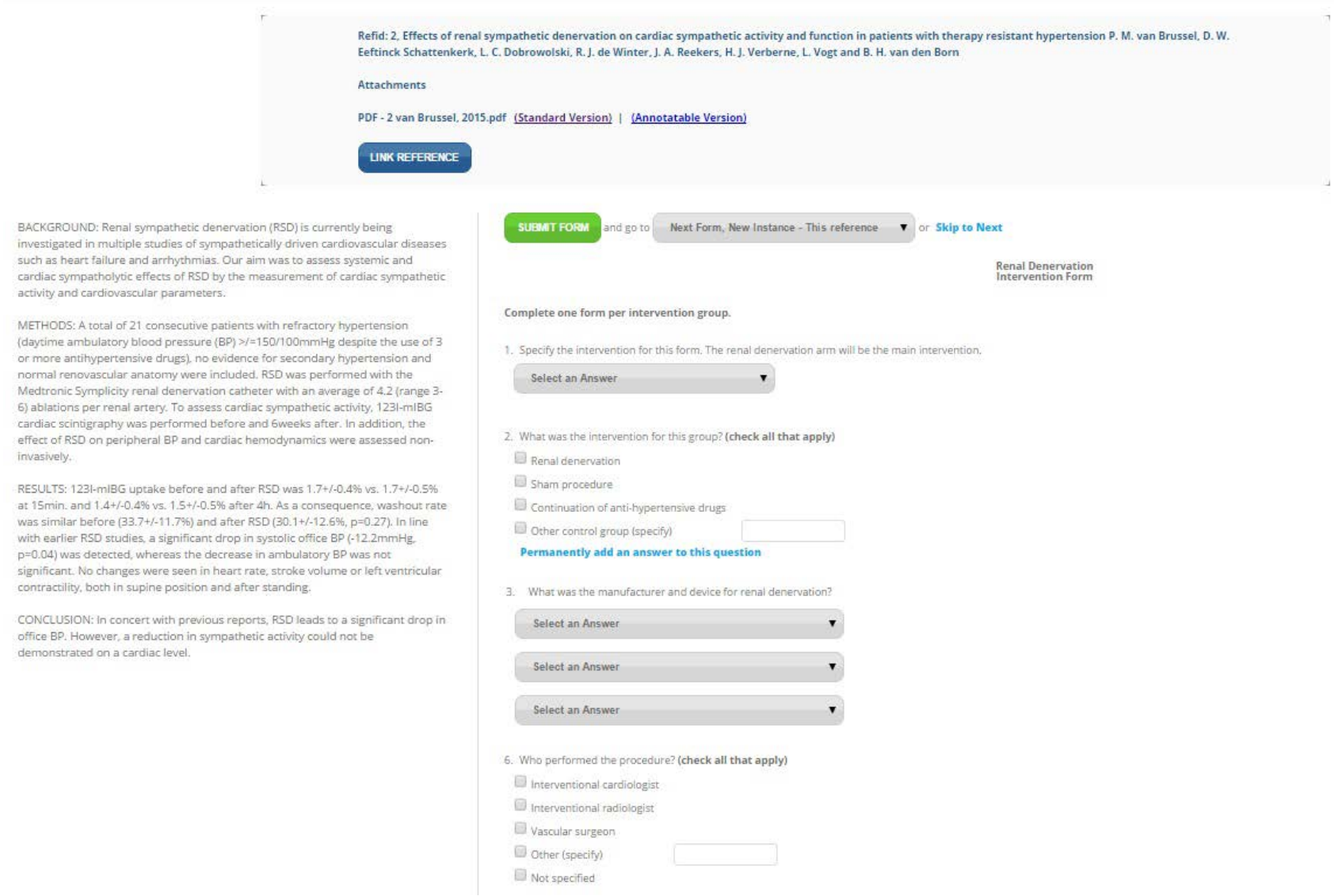
...

Comments (limit 250 characters)

...

SUBMIT FORM and go to Next Form, New Instance - This reference ▼ or **Skip to Next**

Data Abstraction – Intervention Form



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CONCLUSION: In concert with previous reports, RSD leads to a significant drop in office BP. However, a reduction in sympathetic activity could not be demonstrated on a cardiac level.

SUBMIT FORM and go to Next Form, New Instance - This reference or Skip to Next

Renal Denervation Intervention Form

Complete one form per intervention group.

1. Specify the intervention for this form. The renal denervation arm will be the main intervention.

Select an Answer

2. What was the intervention for this group? **(check all that apply)**

- Renal denervation
- Sham procedure
- Continuation of anti-hypertensive drugs
- Other control group (specify)

Permanently add an answer to this question

3. What was the manufacturer and device for renal denervation?

Select an Answer

Select an Answer

Select an Answer

6. Who performed the procedure? **(check all that apply)**

- Interventional cardiologist
- Interventional radiologist
- Vascular surgeon
- Other (specify)
- Not specified

7. Was there any training to perform the procedure? **(check all that apply)**

- ☐ Yes, simulation training
- ☐ Yes, animal model training
- ☐ Yes, prior experience
- ☐ Yes, but type of training was not specified
- ☐ Yes, other training (specify)
- ☐ No training
- ☐ Not reported

8. Was medication up titration allowed in the RDN arm?

Select an Answer ▼

9. What percent of patients did not receive their assigned treatment?

Select an Answer ▼

10. Comments **(limit 250 characters)**

11. Comments **(limit 250 characters)**

12. Comments **(limit 250 characters)**

SUBMIT FORM and go to Next Form, New Instance - This reference ▼ or Skip to Next

Data Abstraction – Outcomes Form

SUBMIT FORM and go to Next Form, New Instance - This reference or Skip to Next

Renal Denervation Outcomes Form

Instructions:
Only enter data for the first measure that you are able to for each row.

Please fill out on form for each outcome.

1. Outcome	2. Definition	3. Timing of outcome	4. Results reported for subgroup
Select an Answer	Select an Answer	Select an Answer	Subgroup (specify) Permanently add an answer to this question Clear Response

Continuous outcomes

Table 1. Mean difference from baseline to final measures of outcome (within-group difference)
(This should be Final - Baseline. If values decrease, be sure to indicate with a negative sign (-)).

Intervention group (Please be consistent with the labeling in the intervention form)	N for analysis	Point estimate (please specify negative/positive sign)	Measure of variability	95% CI or IQR	p-value (Record exact p-value)
		Mean Median Other (specify): Not reported Clear Response	SE SD Other (specify): Not reported Clear Response	95% CI IQR Not reported Clear Response	Not reported Clear Response
Main Intervention	N for analysis Baseline N Clear Response	...	...	Lower limit Upper limit	...
Comparison A	N for analysis Baseline N Clear Response	...	...	Lower limit Upper limit	...
Comparison B	N for analysis Baseline N Clear Response	...	...	Lower limit Upper limit	...
Comparison C	N for analysis Baseline N Clear Response	...	...	Lower limit Upper limit	...
Comparison D	N for analysis Baseline N Clear Response	...	...	Lower limit Upper limit	...
Comparison E	N for analysis Baseline N Clear Response	...	...	Lower limit Upper limit	...

Table 2. Mean difference from other intervention group measures of outcome (between-group difference). When filling out this table, please note that the point estimate should reflect this formula: (Final - Baseline for the intervention group) - (Final - Baseline for the reference group). You do not need to calculate this.

Intervention group (Please be consistent with the labeling in the intervention form)	N for analysis	Point estimate (please specify negative/positive sign)	Measure of variability	95% CI or IQR	p-value (Record exact p-value)	Indicate reference group
		○ Mean ○ Median ○ Other (specify): ○ Not reported Clear Response	○ SE ○ SD ○ Other (specify): ○ Not reported Clear Response	○ 95% CI ○ IQR ○ Not reported Clear Response	○ Not reported Clear Response	
Main Intervention	○ N for analysis ○ Baseline N Clear Response	...	...	☐ Lower limit ☐ Upper limit	...	Select an Answer
Comparison A	○ N for analysis ○ Baseline N Clear Response	...	...	☐ Lower limit ☐ Upper limit	...	Select an Answer
Comparison B	○ N for analysis ○ Baseline N Clear Response	...	...	☐ Lower limit ☐ Upper limit	...	Select an Answer
Comparison C	○ N for analysis ○ Baseline N Clear Response	...	...	☐ Lower limit ☐ Upper limit	...	Select an Answer
Comparison D	○ N for analysis ○ Baseline N Clear Response	...	...	☐ Lower limit ☐ Upper limit	...	Select an Answer
Comparison E	○ N for analysis ○ Baseline N Clear Response	...	...	☐ Lower limit ☐ Upper limit	...	Select an Answer

Table 3. Baseline measures of cohort

Intervention group (Please be consistent with the labeling in the intervention form)	N for analysis	Point estimate (please specify negative/positive sign) Mean Median Other (specify): Not reported Clear Response	Measure of variability SE SD Other (specify): Not reported Clear Response	95% CI or IQR 95% CI IQR Not reported Clear Response	p-value (Record exact p-value) Not reported Clear Response	Indicate reference group
Main Intervention	N for analysis Baseline N Clear Response	...	...	Lower limit Upper limit	...	Select an Answer
Comparison A	N for analysis Baseline N Clear Response	...	...	Lower limit Upper limit	...	Select an Answer
Comparison B	N for analysis Baseline N Clear Response	...	...	Lower limit Upper limit	...	Select an Answer
Comparison C	N for analysis Baseline N Clear Response	...	...	Lower limit Upper limit	...	Select an Answer
Comparison D	N for analysis Baseline N Clear Response	...	...	Lower limit Upper limit	...	Select an Answer
Comparison E	N for analysis Baseline N Clear Response	...	...	Lower limit Upper limit	...	Select an Answer

Table 4. Final measures of outcome

Intervention group (Please be consistent with the labeling in the intervention form)	N for analysis	Point estimate (please specify negative/positive sign) ○ Mean ○ Median ○ Other (specify): ○ Not reported Clear Response	Measure of variability ○ SE ○ SD ○ Other (specify): ○ Not reported Clear Response	95% CI or IQR ○ 95% CI ○ IQR ○ Not reported Clear Response	p-value (Record exact p-value) ○ Not reported Clear Response	Indicate reference group
Main Intervention	○ N for analysis ○ Baseline N Clear Response	...	...	☐ Lower limit ☐ Upper limit	...	Select an Answer ▼
Comparison A	○ N for analysis ○ Baseline N Clear Response	...	...	☐ Lower limit ☐ Upper limit	...	Select an Answer ▼
Comparison B	○ N for analysis ○ Baseline N Clear Response	...	...	☐ Lower limit ☐ Upper limit	...	Select an Answer ▼
Comparison C	○ N for analysis ○ Baseline N Clear Response	...	...	☐ Lower limit ☐ Upper limit	...	Select an Answer ▼
Comparison D	○ N for analysis ○ Baseline N Clear Response	...	...	☐ Lower limit ☐ Upper limit	...	Select an Answer ▼
Comparison E	○ N for analysis ○ Baseline N Clear Response	...	...	☐ Lower limit ☐ Upper limit	...	Select an Answer ▼

Dichotomous Outcomes

Table 5. Incidence of the outcome by intervention group

Intervention group (Please be consistent with the labeling in the intervention form)	N for analysis	Outcome measure/numerator	Denominator	p-value (Record exact p-value)	Indicate reference group
		Not reported Clear Response	Select an Answer	Not reported Clear Response	
Main intervention	N for analysis Baseline N Clear Response	# of patients with one or more events % of patients with one or more events # of events	...	...	Select an Answer
Comparison A	N for analysis Baseline N Clear Response	# of patients with one or more events % of patients with one or more events # of events	...	...	Select an Answer
Comparison B	N for analysis Baseline N Clear Response	# of patients with one or more events % of patients with one or more events # of events	...	...	Select an Answer
Comparison C	N for analysis Baseline N Clear Response	# of patients with one or more events % of patients with one or more events # of events	...	...	Select an Answer
Comparison D	N for analysis Baseline N Clear Response	# of patients with one or more events % of patients with one or more events # of events	...	...	Select an Answer
Comparison E	N for analysis Baseline N Clear Response	# of patients with one or more events % of patients with one or more events # of events	...	...	Select an Answer

Table 6. Measures of association for comparison of outcome between intervention groups

Intervention group (Please be consistent with the labeling in the intervention form)	N for analysis	Point estimate	Measure of variability	95% Confidence interval	p-value (Record exact p-value)	Indicate reference group
		○ Relative risk ○ Relative hazard ○ Odds ratio ○ Risk difference ○ Other: ○ Not reported Clear Response	○ SE ○ SD ○ Not reported Clear Response	○ Not reported Clear Response	○ Not reported Clear Response	
Main intervention	○ N for analysis ○ Baseline N Clear Response	...	...	☐ Lower limit ☐ Upper limit	...	Select an Answer
Comparison A	○ N for analysis ○ Baseline N Clear Response	...	...	☐ Lower limit ☐ Upper limit	...	Select an Answer
Comparison B	○ N for analysis ○ Baseline N Clear Response	...	...	☐ Lower limit ☐ Upper limit	...	Select an Answer
Comparison C	○ N for analysis ○ Baseline N Clear Response	...	...	☐ Lower limit ☐ Upper limit	...	Select an Answer
Comparison D	○ N for analysis ○ Baseline N Clear Response	...	...	☐ Lower limit ☐ Upper limit	...	Select an Answer
Comparison E	○ N for analysis ○ Baseline N Clear Response	...	...	☐ Lower limit ☐ Upper limit	...	Select an Answer

What were the results adjusted for in the final model?

- [ ] Results are not adjusted
- [ ] Age
- [ ] Sex
- [ ] Race/ethnicity
- [ ] Duration of disease
- [ ] Other (specify):
- [ ] Other (specify):
- [ ] Other (specify):
- [ ] Other (specify):
- [ ] Other (specify):
- [ ] Other (specify):
- [ ] Other (specify):
- [ ] Other (specify):

Permanently add an answer to this question

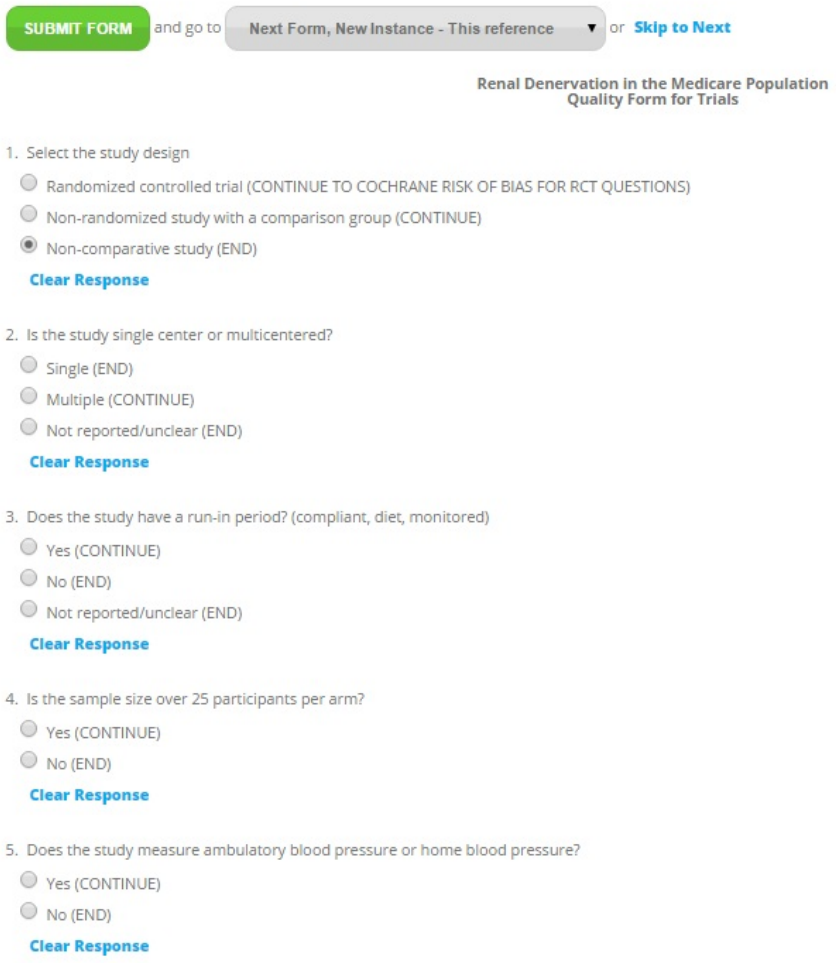
233. Comments **(limit 250 characters)**

234. Comments **(limit 250 characters)**

235. Comments **(limit 250 characters)**

SUBMIT FORM and go to Next Form, New Instance - This reference ▼ or **Skip to Next**

Data Abstraction – Quality Form



SUBMIT FORM and go to Next Form, New Instance - This reference or Skip to Next

Renal Denervation in the Medicare Population
Quality Form for Trials

1. Select the study design
   - ○ Randomized controlled trial (CONTINUE TO COCHRANE RISK OF BIAS FOR RCT QUESTIONS)
   - ○ Non-randomized study with a comparison group (CONTINUE)
   - ◉ Non-comparative study (END)

   Clear Response

2. Is the study single center or multicentered?
   - ○ Single (END)
   - ○ Multiple (CONTINUE)
   - ○ Not reported/unclear (END)

   Clear Response

3. Does the study have a run-in period? (compliant, diet, monitored)
   - ○ Yes (CONTINUE)
   - ○ No (END)
   - ○ Not reported/unclear (END)

   Clear Response

4. Is the sample size over 25 participants per arm?
   - ○ Yes (CONTINUE)
   - ○ No (END)

   Clear Response

5. Does the study measure ambulatory blood pressure or home blood pressure?
   - ○ Yes (CONTINUE)
   - ○ No (END)

   Clear Response

The Cochrane Collaboration's tool for assessing risk of bias

Sequence Generation

Was the allocation sequence adequately generated? Select an Answer

Criteria for a judgment of "YES" (i.e., low risk of bias)
The investigators describe a random component in the sequence generation process such as:
Referring to a random number table; Using a computer random number generator; Coin tossing; Shuffling cards or envelopes; Throwing dice; Drawing of lots; Minimization. Minimization may be implemented without a random element, and this is considered to be equivalent to being random.
Criteria for a judgment of "NO" (i.e., high risk of bias)
The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example:
Sequence generated by odd or even date of birth;
Sequence generated by some rule based on date (or day) of admission;
Sequence generated by some rule based on hospital or clinic record number.
Other non-random approached happen much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgment or some method of non-random categorization of participants, for example:
Allocation by judgment of the clinician;
Allocation by preference of the participant;
Allocation based on the results of a laboratory test or a series of tests.
Criteria for a judgment of "UNCLEAR" (i.e., uncertain risk of bias)
Insufficient information about the sequence generation process to permit judgement of "YES" or "NO."

Allocation Concealment

Was allocation adequately concealed? Select an Answer

Criteria for a judgment of "YES" (i.e. low risk of bias)
Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation:
Central allocation (including telephone, web-based, and pharmacy-controlled, randomization);
Sequentially numbered drug containers of identical appearance;
Sequentially numbered, opaque, sealed envelopes.
Criteria for a judgment of "NO" (i.e. high risk of bias)
Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on:
Using an open random allocation schedule (e.g. a list of random numbers);
Assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque or not sequentially numbered);
Alternation or rotation;
Date of birth;
Case record number;
Any other explicitly unconcealed procedure
Criteria for the judgment of "UNCLEAR" (i.e. uncertain risk of bias)
Insufficient information about the sequence generation process to permit judgment of "YES" or "NO".
This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgment – for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.

Blinding of Participants, Personnel, and Outcome Assessors

Was knowledge of the allocated interventions adequately prevented during the study? Select an Answer

Criteria for a judgment of "YES" (i.e. low risk of bias)
Any one of the following:
No blinding, but the review authors judge that the outcome and the outcome
Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken;
Either participants or some key study personnel were not blinded, but outcome assessment was blinded and the nonblinding of others unlikely to introduce bias.
Criteria for a judgment of "NO" (i.e. high risk of bias)
Any one of the following:
No blinding or incomplete blinding, and the outcome or outcome measurement is likely to be influenced by lack of blinding;
Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken;
Either participants or some key study personnel were not blinded, and the non-blinding of others likely to introduce bias.
Criteria for the judgment of "UNCLEAR" (i.e. uncertain risk of bias)
Any one of the following:
Insufficient information to permit judgment of 'Yes' or 'No';
The study did not address this outcome.

Incomplete Outcome Data

Select an Answer

Were incomplete outcome data adequately addressed?

Criteria for a judgment of "YES" (i.e. low risk of bias)
Any one of the following:
No missing outcome data;
Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias);
Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups;
For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate;
For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size;
Missing data have been imputed using appropriate methods.
Criteria for a judgment of "NO" (i.e. high risk of bias)
Any one of the following:
Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups;
For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate;
For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size;
'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomization;
Potentially inappropriate application of simple imputation
Criteria for the judgment of "UNCLEAR" (i.e. uncertain risk of bias)
Any one of the following:
Insufficient reporting of attrition/exclusions to permit judgment of 'Yes' or 'No' (e.g. number randomized not stated, no reasons for missing data provided);
The study did not address this outcome.

Selective Outcome Reporting

Are reports of the study free of suggestion of selective reporting?

Select an Answer ▼

Criteria for a judgement of "YES" (i.e. low risk of bias)
Any of the following:
The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way;
The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).
Criteria for a judgement of "NO" (i.e. high risk of bias)
Any one of the following:
Not all of the study'es pre-specified primary outcomes have been reported;
One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g., subscales) that were not pre-specified;
One or more reported primary outcomes were not pre-specified (unless clear jusitification for their reporting is provided, such as an unexpected adverse effect);
One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis;
The study report fails to include results for a key outcome that would be expected to have been reported for such a study.
Criteria for the judgement of "UNCLEAR" (i.e. uncertain risk of bias)
Insufficient information to permit judgement of "Yes" or "No". It is likely that the majority of studies will fall into this category.

Other sources of bias

Was the study apparently free of other problems that could put it at a high risk of bias? Select an Answer ▼

Criteria for a judgement of "YES" (i.e. low risk of bias)
The study appears to be free of other sources of bias
Criteria for a judgement of "NO" (i.e. high risk of bias)
There is at least one important risk of bias. For example, the study:
Had a potential source of bias related to the specific study design used; or
Stopped early due to some data-dependent process (including a formal-stopping rule); or
Had extreme baseline imbalance; or
Has been claimed to have been fraudulent; or
Had some other problem.
Criteria for the judgement of "UNCLEAR" (i.e. uncertain risk of bias)
There may be a risk of bias, but there is either:
Insufficient information to assess whether an important risk of bias exists; or
Insufficient rationale or evidence that an identified problem will introduce bias.

Downs and Black Quality Form

12. Have all important adverse events that may be a consequence of the intervention been reported?

- Yes
- No

Clear Response

13. Was compliance with the intervention/s reliable?

- Yes
- No
- Unable to determine

Clear Response

14. Were the main outcome measures used accurate (valid and reliable)?

- Yes
- No
- Unable to determine

Clear Response

15. Was the randomised internvetion assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?

- Yes
- No
- Unable to determine

Clear Response

16. Was there adequate for confounding in the analyses from which the main findings were drawn?

- Yes
- No
- Unable to determine

Clear Response

SUBMIT FORM and go to Next Form, New Instance - This reference or Skip to Next

Appendix C. List of Excluded Studies

. Renal sympathetic denervation for hypertension. Med Lett Drugs Ther. 2012 Jul 9;54(1394):55-6. PMID: 22777305.
No original data

Ahmed H, Neuzil P, Skoda J, et al. Renal sympathetic denervation using an irrigated radiofrequency ablation catheter for the management of drug-resistant hypertension. JACC Cardiovasc Interv. 2012 Jul;5(7):758-65. PMID: 22814781.
Does not meet study design criteria

Armaganijan L, Staico R, Abizaid A, et al. Unilateral renal artery sympathetic denervation may reduce blood pressure in patients with resistant hypertension. J Clin Hypertens (Greenwich). 2013 Aug;15(8):606. PMID: 23889725.
Case report

Armaganijan L, Staico R, Moraes A, et al. Renal denervation using an irrigated catheter in patients with resistant hypertension: a promising strategy? Arq Bras Cardiol. 2014 Apr;102(4):355-63. PMID: 24652055.
Does not meet study design criteria

Baroni M, Nava S, Giupponi L, et al. Effects of Renal Sympathetic Denervation on Arterial Stiffness and Blood Pressure Control in Resistant Hypertensive Patients: A Single Centre Prospective Study. High Blood Press Cardiovasc Prev. 2015 Dec;22(4):411-6. doi: 10.1007/s40292-015-0121-4. PMID: 26458940.
Does not meet study design criteria

Bartus K, Sadowski J, Kapelak B, et al. Denervation (ablation) of nerve terminalis in renal arteries: early results of interventional treatment of arterial hypertension in Poland. Kardiol Pol. 2013;71(2):152-8. PMID: 23575708.
Overlapping population

Bartus K, Sadowski J, Kapelak B, et al. Denervation of nerve terminals in renal arteries: one-year follow-up of interventional treatment of arterial hypertension. Kardiol Pol. 2014;72(5):425-31. PMID: 24408071.
Overlapping population

Bausback Y, Friedenberger J, Hertting K, et al. Renal denervation for hypertension refractory to renal artery stenting. J Endovasc Ther. 2014 Apr;21(2):181-90. PMID: 24754276.
Does not meet study design criteria

Benamer H, Mylotte D, Garcia-Alonso C, et al. [Renal denervation a treatment for resistant hypertension: a French experience]. Ann Cardiol Angeiol (Paris). 2013 Dec;62(6):384-91. PMID: 24182849.
Not in English

Berukstis A, Vajauskas D, Gargalskaite U, et al. Impact of renal sympathetic denervation on cardiac sympathetic nerve activity evaluated by cardiac MIBG imaging. EuroIntervention. 2016 Jan 22;11(9):1070-6. doi: 10.4244/eijv11i9a215. PMID: 26788709.
Does not meet study design criteria

Bilge M, Tolunay H, Kurmus O, et al. Percutaneous renal denervation in patients with resistant hypertension-first experiences in Turkey. Anadolu Kardiyol Derg. 2012 Feb;12(1):79-80. PMID: 22231942.
No original data; <10 patients

Bortolotto LA, Midlej-Brito T, Pisani C, et al. Renal denervation by ablation with innovative technique in resistant

hypertension. Arq Bras Cardiol. 2013 Oct;101(4):e77-9. PMID: 24217435.
Case report

Brandt MC, Mahfoud F, Reda S, et al. Renal sympathetic denervation reduces left ventricular hypertrophy and improves cardiac function in patients with resistant hypertension. J Am Coll Cardiol. 2012 Mar 6;59(10):901-9. PMID: 22381425.
Overlapping population

Brandt MC, Reda S, Mahfoud F, et al. Effects of renal sympathetic denervation on arterial stiffness and central hemodynamics in patients with resistant hypertension. J Am Coll Cardiol. 2012 Nov 6;60(19):1956-65. PMID: 23062529.
Overlapping population

Brinkmann J, Heusser K, Schmidt BM, et al. Catheter-based renal nerve ablation and centrally generated sympathetic activity in difficult-to-control hypertensive patients: prospective case series. Hypertension. 2012 Dec;60(6):1485-90. PMID: 23045466.
Does not meet study design criteria

Ciardetti M, Coceani M, Pastormerlo LE, et al. Renal denervation in resistant arterial hypertension: Effects on neurohormonal activation and cardiac natriuretic peptides. Int J Cardiol. 2015 Apr 1;184:574-5. PMID: 25767021.
<10 patients; Does not meet study design criteria

Courand PY, Dauphin R, Rouviere O, et al. [Renal denervation for treating hypertension: experience at the University Hospital in Lyon]. Ann Cardiol Angeiol (Paris). 2014 Jun;63(3):183-8. PMID: 24908520.
Not in English

Damascelli B, Patelli G, Ticha V, et al. Catheter-based radiofrequency renal sympathetic denervation for resistant hypertension. J Vasc Interv Radiol. 2013 May;24(5):632-9. PMID: 23622036.
Does not meet study design criteria

de Jager RL, Blankestijn PJ. Pathophysiology I: the kidney and the sympathetic nervous system. EuroIntervention. 2013 May;9 Suppl R:R42-7. PMID: 23732154.
No original data

Denolle T, Chamontin B, Doll G, et al. [Management of resistant hypertension. Expert consensus statement from the French Society of Hypertension, an affiliate of the French Society of Cardiology]. Presse Med. 2014 Dec;43(12 Pt 1):1325-31. PMID: 25459067.
Not in English

Diego-Nieto A, Cruz-Gonzalez I, Martin-Moreiras J, et al. Severe Renal Artery Stenosis After Renal Sympathetic Denervation. JACC Cardiovasc Interv. 2015 Sep;8(11):e193-4. PMID: 26404211.
Case report

Dobrowolski L, Schattenkerk DE, Krediet C, et al. 4A.08: ASSESSING MODULATIONS IN SYMPATHETIC NERVE ACTIVITY AFTER RENAL SYMPATHETIC DENERVATION USING RENAL 123I-MIBG SCINTIGRAPHY. J Hypertens. 2015 Jun;33 Suppl 1:e51. PMID: 26102844.
Does not meet study design criteria; Does not apply

Doltra A, Messroghli D, Stawowy P, et al. Potential reduction of interstitial myocardial fibrosis with renal denervation. J Am Heart Assoc. 2014 Dec;3(6):e001353. PMID: 25516438.

Does not meet study design criteria

Donazzan L, Mahfoud F, Ewen S, et al. Effects of catheter-based renal denervation on cardiac sympathetic activity and innervation in patients with resistant hypertension. Clin Res Cardiol. 2015 Oct 22doi: 10.1007/s00392-015-0930-4. PMID: 26493305.
Does not meet study design criteria; Protocol only

Donazzan L, Mahfoud F, Schirmer SH, et al. Renal nerve ablation. Heart. 2015 Feb;101(4):320-8. PMID: 25634313.
No original data

Dong H, Jiang X, Liang T, et al. One-year outcomes of percutaneous renal denervation for the treatment of resistant hypertension: the first Chinese experience. Chin Med J (Engl). 2014;127(6):1003-7. PMID: 24622425.
Does not meet study design criteria

Dores H, de Sousa Almeida M, de Araujo Goncalves P, et al. Renal denervation in patients with resistant hypertension: six-month results. Rev Port Cardiol. 2014 Apr;33(4):197-204. PMID: 24472425.
Not in English

Ewen S, Ukena C, Linz D, et al. The sympathetic nervous system in chronic kidney disease. Curr Hypertens Rep. 2013 Aug;15(4):370-6. PMID: 23737218.
No original data

Ezzahti M, Moelker A, Friesema EC, et al. Blood pressure and neurohormonal responses to renal nerve ablation in treatment-resistant hypertension. J Hypertens. 2014 Jan;32(1):135-41. PMID: 24131897.
Does not meet study design criteria

Fadl Elmula FE, Hoffmann P, Fossum E, et al. Renal sympathetic denervation in patients with treatment-resistant hypertension after witnessed intake of medication before qualifying ambulatory blood pressure. Hypertension. 2013 Sep;62(3):526-32. PMID: 23836798.
Does not meet study design criteria

Fischell TA, Fischell DR, Ghazarossian VE, et al. Next generation renal denervation: chemical "perivascular" renal denervation with alcohol using a novel drug infusion catheter. Cardiovasc Revasc Med. 2015 Jun;16(4):221-7. PMID: 25979565.
Does not meet study design criteria

Fontenla A, Garcia-Donaire JA, Hernandez F, et al. Management of resistant hypertension in a multidisciplinary unit of renal denervation: protocol and results. Rev Esp Cardiol (Engl Ed). 2013 May;66(5):364-70. PMID: 24775818.
Does not meet study design criteria

Ghadri JR, Gaehwiler R, Jaguszewski M, et al. Impact of local vascular lesions assessed with optical coherence tomography and ablation points on blood pressure reduction after renal denervation. Swiss Med Wkly. 2015;145:w14102. PMID: 25658048.
Does not meet study design criteria

Grassi G, Seravalle G, Brambilla G, et al. Blood pressure responses to renal denervation precede and are independent of the sympathetic and baroreflex effects. Hypertension. 2015 Jun;65(6):1209-16. PMID: 25824245.
Does not meet study design criteria

Grassi G, Seravalle G, Trevano FQ, et al. Asymmetric and Symmetric Dimethylarginine and Sympathetic Nerve Traffic after Renal Denervation in Patients with Resistant Hypertension. Clin J Am Soc

Nephrol. 2015 Sep 4;10(9):1560-7. PMID: 26138262.
Does not meet study design criteria

Hayek SS, Abdou MH, Demoss BD, et al. Prevalence of resistant hypertension and eligibility for catheter-based renal denervation in hypertensive outpatients. Am J Hypertens. 2013 Dec;26(12):1452-8. PMID: 23934709.
Does not apply; No renal denervation device

Hering D, Lambert EA, Marusic P, et al. Renal nerve ablation reduces augmentation index in patients with resistant hypertension. J Hypertens. 2013 Sep;31(9):1893-900. PMID: 23697964.
Overlapping population

Hering D, Mahfoud F, Walton AS, et al. Renal denervation in moderate to severe CKD. J Am Soc Nephrol. 2012 Jul;23(7):1250-7. PMID: 22595301.
Does not meet study design criteria

Hering D, Marusic P, Walton AS, et al. Sustained sympathetic and blood pressure reduction 1 year after renal denervation in patients with resistant hypertension. Hypertension. 2014 Jul;64(1):118-24. PMID: 24732891.
Overlapping population

Heusser H, Tank J, Brinkmann J, et al. Response to catheter-based renal nerve ablation and centrally generated sympathetic activity in difficult-to- control hypertensive patients. Hypertension. 2013 Feb;61(2):e9-10. PMID: 23444459.
No original data

Heusser K, Tank J, Brinkmann J, et al. Response to blood pressure and sympathetic nervous system response to renal denervation. Hypertension. 2013 Feb;61(2):e14. PMID: 23444460.
No original data

Id D, Kaltenbach B, Bertog SC, et al. Does the presence of accessory renal arteries affect the efficacy of renal denervation? JACC Cardiovasc Interv. 2013 Oct;6(10):1085-91. PMID: 24156968.
Overlapping population

Ierna S, Biondi-Zoccai G, Bachis C, et al. Transcatheter renal sympathetic ablation for resistant hypertension: in vivo insights in humans from optical coherence tomography. Int J Cardiol. 2013 May 10;165(2):e35-7. PMID: 23164587.
No original data; <10 patients

Jin Y, Jacobs L, Baelen M, et al. Rationale and design of the Investigator-Steered Project on Intravascular Renal Denervation for Management of Drug-Resistant Hypertension (INSPiRED) trial. Blood Press. 2014 Jun;23(3):138-46. PMID: 24742341.
No original data

Johns EJ, Abdulla MH. Renal nerves in blood pressure regulation. Curr Opin Nephrol Hypertens. 2013 Sep;22(5):504-10. PMID: 23872675.
No original data

Johns EJ. Autonomic regulation of kidney function. Handb Clin Neurol. 2013;117:203-14. PMID: 24095127.
No original data

Johns EJ. The neural regulation of the kidney in hypertension and renal failure. Exp Physiol. 2014 Feb;99(2):289-94. PMID: 23955311.
No original data

Jordan J, Heusser K, Brinkmann J, et al. Response to catheter-based renal nerve ablation and centrally generated sympathetic activity in difficult-to- control hypertensive patients: prospective case series. Hypertension. 2013 Feb;61(2):e18. PMID: 23444462.
No original data

Judd E, Calhoun DA. Apparent and true resistant hypertension: definition, prevalence and outcomes. J Hum Hypertens. 2014 Aug;28(8):463-8. PMID: 24430707.
No original data

Kaczmarek K, Ptaszynski P, Krekora J, et al. An electrophysiological approach using 3D electroanatomical mapping system for catheter-based renal denervation: the first Polish experience. Kardiol Pol. 2013;71(9):990. PMID: 24065279.
Case report

Kaltenbach B, Franke J, Bertog SC, et al. Renal sympathetic denervation as second-line therapy in mild resistant hypertension: a pilot study. Catheter Cardiovasc Interv. 2013 Feb;81(2):335-9. PMID: 22807098.
Does not meet study design criteria

Kaltenbach B, Id D, Franke JC, et al. Renal artery stenosis after renal sympathetic denervation. J Am Coll Cardiol. 2012 Dec 25;60(25):2694-5. PMID: 23141482.
No original data

Karanasos A, Van Mieghem N, Bergmann MW, et al. Multimodality Intra-Arterial Imaging Assessment of the Vascular Trauma Induced by Balloon-Based and Nonballoon-Based Renal Denervation Systems. Circ Cardiovasc Interv. 2015 Jul;8(7):e002474. PMID: 26156150.
Overlapping population

Kario K, Bakris GL, Bhatt D. 4A.10: PREFERENTIAL REDUCTION IN MORNING/NOCTURNAL HYPERTENSION BY RENAL DENERVATION FOR DRUG-RESISTANT HYPERTENSION: A NEW ABPM ANALYSIS OF SYMPLICITY HTN-3 AND HTN-JAPAN. J Hypertens. 2015 Jun;33 Suppl 1:e52. PMID: 26102846.
No original data

Kario K, Bhatt DL, Brar S, et al. Effect of Catheter-Based Renal Denervation on Morning and Nocturnal Blood Pressure: Insights From SYMPLICITY HTN-3 and SYMPLICITY HTN-Japan. Hypertension. 2015.
No original data

Kario K, Ikemoto T, Kuwabara M, et al. Catheter-Based Renal Denervation Reduces Hypoxia-Triggered Nocturnal Blood Pressure Peak in Obstructive Sleep Apnea Syndrome. J Clin Hypertens (Greenwich). 2015 Dec 31doi: 10.1111/jch.12759. PMID: 26718924.
<10 patients

Kiuchi MG, Graciano ML, de Queiroz Carreira MA, et al. Effects of renal sympathetic denervation in left ventricular hypertrophy in CKD refractory hypertensive patients. Int J Cardiol. 2015 Aug 29;202:121-3. PMID: 26386937.
Does not meet study design criteria

Kiuchi MG, Maia GL, de Queiroz Carreira MA, et al. Effects of renal denervation with a standard irrigated cardiac ablation catheter on blood pressure and renal function in patients with chronic kidney disease and resistant hypertension. Eur Heart J. 2013 Jul;34(28):2114-21. PMID: 23786861.
Does not meet study design criteria

Kiuchi MG, Mion D, Jr., Graciano ML, et al. Proof of concept study: Improvement of echocardiographic parameters after renal sympathetic denervation in CKD refractory hypertensive patients. Int J Cardiol. 2016 Mar 15;207:6-12. doi: 10.1016/j.ijcard.2016.01.088. PMID: 26788816.
No outcome

Korovesis S, Giazitzoglou E, Pantos I, et al. Renal denervation for resistant hypertension: acute results and long-term follow-up. Hellenic J Cardiol. 2014 May-Jun;55(3):211-6. PMID: 24862613.
Does not meet study design criteria

Krum H, Schlaich M, Whitbourn R, et al. Catheter-based renal sympathetic denervation for resistant hypertension: a multicentre safety and proof-of-principle cohort study. Lancet. 2009 Apr 11;373(9671):1275-81. PMID: 19332353.
Overlapping population

Kucherov VV, Fursov AN, Chernetsov VA, et al. [The first experience with the use of catheter denervation of renal arteries in patients with refractory hypertension]. Klin Med (Mosk). 2014;92(11):72-4. PMID: 25796951.
Not in English

Lambert GW, Dhar AK, Schlaich MP. Cognitive performance in patients with resistant hypertension following renal sympathetic denervation. EuroIntervention. 2013 Oct;9(6):665-7. PMID: 24169126.
No original data

Lepor NE, Karns A. Hypertension. Left ventricular hypertrophy and cardiac function in patients with resistant hypertension. Rev Cardiovasc Med. 2013;14(1):69-71. PMID: 23651989.
No original data

Lobo MD, de Belder MA, Cleveland T, et al. Joint UK societies' 2014 consensus statement on renal denervation for resistant hypertension. Heart. 2015 Jan;101(1):10-6. PMID: 25431461.
No original data

Lu Y, Zhang L, Zhou X, et al. Renal sympathetic denervation: A potential alternative strategy for managing patients with heart failure. Int J Cardiol. 2015 Dec 15;201:140-1. PMID: 26298357.
No original data; No human data

Luetkens JA, Wilhelm K, Dusing R, et al. Renal denervation: results of a single-center cohort study. Rofo. 2015 Jan;187(1):36-41. PMID: 25188311.
Does not meet study design criteria

Luo D, Zhang X, Lu CZ. Renal sympathetic denervation for the treatment of resistant hypertension with chronic renal failure: first-in-man experience. Chin Med J (Engl). 2013 Apr;126(7):1392-3. PMID: 23557581.
Case report

Mabin T, Sapoval M, Cabane V, et al. First experience with endovascular ultrasound renal denervation for the treatment of resistant hypertension. EuroIntervention. 2012 May 15;8(1):57-61. PMID: 22580249.
Does not meet study design criteria

Mahfoud F, Bohm M, Rump LC, et al. Catheter-based renal nerve ablation and centrally generated sympathetic activity in difficult-to-control hypertensive patients: prospective case series. Hypertension. 2013 Feb;61(2):e17. PMID: 23248153.
No original data

Mahfoud F, Cremers B, Janker J, et al. Renal hemodynamics and renal function after catheter-based renal sympathetic

denervation in patients with resistant hypertension. Hypertension. 2012 Aug;60(2):419-24. PMID: 22733462.
Overlapping population

Mahfoud F, Schlaich M, Kindermann I, et al. Effect of renal sympathetic denervation on glucose metabolism in patients with resistant hypertension: a pilot study. Circulation. 2011 May 10;123(18):1940-6. PMID: 21518978.
Overlapping population

Mahfoud F, Ukena C, Schmieder RE, et al. Ambulatory blood pressure changes after renal sympathetic denervation in patients with resistant hypertension. Circulation. 2013 Jul 9;128(2):132-40. PMID: 23780578.
Overlapping population

Mahfoud F, Urban D, Teller D, et al. Effect of renal denervation on left ventricular mass and function in patients with resistant hypertension: data from a multi-centre cardiovascular magnetic resonance imaging trial. Eur Heart J. 2014 Sep 1;35(33):2224-31b. PMID: 24603307.\
Overlapping population

Manakshe G, Chakravarthi R, Hussaini S, et al. Renal sympathetic denervation for treatment of resistant hypertension - indigenous technique. Indian Heart J. 2013 May-Jun;65(3):239-42. PMID: 23809374.
Does not meet study design criteria

Matous D, Jiravsky O, Nykl I, et al. Effect of renal denervation on glucose metabolism after a 12 month follow-up. Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub. 2015 Jun;159(2):246-50. PMID: 26077005.
No outcome

McArdle MJ, deGoma EM, Cohen DL, et al. Beyond blood pressure: percutaneous renal denervation for the management of sympathetic hyperactivity and associated disease states. J Am Heart Assoc. 2015 Mar;4(3):e001415. PMID: 25801757.
No original data

McLellan AJ, Schlaich MP, Taylor AJ, et al. Reverse cardiac remodeling after renal denervation: Atrial electrophysiologic and structural changes associated with blood pressure lowering. Heart Rhythm. 2015 May;12(5):982-90. PMID: 25638699.
Does not meet study design criteria

Middlekauff HR. A mechanistic explanation for the minimal impact of renal denervation on 24-h ambulatory blood pressure in SIMPLICITY HTN-3. J Am Coll Cardiol. 2015 Mar 10;65(9):959. PMID: 25744017.
No original data

Miller MA, Gangireddy SR, Dukkipati SR, et al. Renal sympathetic denervation using an electroanatomic mapping system. J Am Coll Cardiol. 2014 Apr 29;63(16):1697. PMID: 24613336.
Case report

Miroslawska A, Solbu M, Skjolsvik E, et al. Renal sympathetic denervation: effect on ambulatory blood pressure and blood pressure variability in patients with treatment-resistant hypertension. The ReShape CV-risk study. J Hum Hypertens. 2016 Mar;30(3):153-7. doi: 10.1038/jhh.2015.69. PMID: 26134621.
Does not meet study design criteria

Mortensen K, Franzen K, Himmel F, et al. Catheter-based renal sympathetic denervation improves central hemodynamics and arterial stiffness: a pilot study. J Clin Hypertens (Greenwich). 2012 Dec;14(12):861-70. PMID: 23205753.
Does not meet study design criteria

Murai H, Okuyama Y, Sakata Y, et al. Different responses of arterial blood pressure to electrical stimulation of the renal artery in patients with resistant hypertension. Int J Cardiol. 2015 Jul 1;190:296-8. PMID: 25932812.
Case report

Olsen LK, Kamper AL, Svendsen JH, et al. High incidence of secondary hypertension in patients referred for renal denervation--the Copenhagen experience. Blood Press. 2014 Aug;23(4):233-9. PMID: 24437697.
No outcome; No renal denervation device

Ong PJ, Foo D, Ho HH. Successful treatment of resistant hypertension with percutaneous renal denervation therapy. Heart. 2012 Dec;98(23):1754-5. PMID: 22821275.
Case report

Oparil S. Can catheter-based renal denervation be used safely and effectively to substantially reduce blood pressure in treatment-resistant hypertensive patients? Curr Cardiol Rep. 2011 Dec;13(6):478-80. PMID: 21845443.
No original data

Ott C, Janka R, Schmid A, et al. Vascular and renal hemodynamic changes after renal denervation. Clin J Am Soc Nephrol. 2013 Jul;8(7):1195-201. PMID: 23559677.
Does not meet study design criteria

Patane S. Sympathetic and Autonomic Effects of Renal Denervation on Atrial Remodeling and Atrial Arrhythmias. JACC Cardiovasc Interv. 2015 Oct;8(12):1638. doi: 10.1016/j.jcin.2015.07.014. PMID: 26493256.
No original data

Persu A, Durand-Zaleski I, Renkin J, et al. Quality of life after renal denervation. Hypertension. 2013 Apr;61(4):e38. PMID: 23460289.
No original data

Persu A, Jin Y, Azizi M, et al. Blood pressure changes after renal denervation at 10 European expert centers. J Hum Hypertens. 2014 Mar;28(3):150-6. PMID: 24067345.
No original data

Persu A, Renkin J, Thijs L, et al. Renal denervation: ultima ratio or standard in treatment-resistant hypertension. Hypertension. 2012 Sep;60(3):596-606. PMID: 22851728.
No original data

Prochnau D, Heymel S, Otto S, et al. Renal denervation with cryoenergy as second-line option is effective in the treatment of resistant hypertension in non-responders to radiofrequency ablation. EuroIntervention. 2014 Sep;10(5):640-5. PMID: 25256203.
Does not meet study design criteria

Prochnau D, Lucas N, Kuehnert H, et al. Catheter-based renal denervation for drug-resistant hypertension by using a standard electrophysiology catheter. EuroIntervention. 2012 Jan;7(9):1077-80. PMID: 21959556.
Does not meet study design criteria

Qiu M, Shan Q, Chen C, et al. Renal sympathetic denervation improves rate control in patients with symptomatic persistent atrial fibrillation and hypertension. Acta Cardiol. 2016 Feb;71(1):67-73. doi: 10.2143/ac.71.1.3132100. PMID: 26853256.
Does not meet study design criteria

Ricke J, Seidensticker M, Becker S, et al. Renal Sympathetic Denervation by CT-Guided Ethanol Injection: A Phase II Pilot

Trial of a Novel Technique. Cardiovasc Intervent Radiol. 2016 Feb;39(2):251-60. doi: 10.1007/s00270-015-1261-6. PMID: 26634740.
Does not meet study design criteria; Protocol only

Rimoldi SF, Scheidegger N, Scherrer U, et al. Anatomical eligibility of the renal vasculature for catheter-based renal denervation in hypertensive patients. JACC Cardiovasc Interv. 2014 Feb;7(2):187-92. PMID: 24440022.
Does not apply; No outcome

Roleder T, Skowerski M, Wiecek A, et al. Long-term follow-up of renal arteries after radio-frequency catheter-based denervation using optical coherence tomography and angiography. Int J Cardiovasc Imaging. 2016 Feb 16doi: 10.1007/s10554-016-0853-9. PMID: 26883432.
No outcome

Rong S, Zhu H, Liu D, et al. Noninvasive Renal Denervation for Resistant Hypertension Using High-Intensity Focused Ultrasound. Hypertension. 2015 Oct;66(4):e22-5. PMID: 26238444.
Does not meet study design criteria

Rosa J, Zelinka T, Petrak O, et al. Importance of thorough investigation of resistant hypertension before renal denervation: should compliance to treatment be evaluated systematically? J Hum Hypertens. 2014 Nov;28(11):684-8. PMID: 24500722.
No outcome; Does not meet study design criteria

Rundqvist B, Volz S, Manhem K, et al. [Catheter-based renal denervation: a new method for resistant hypertension. Initial experiences of the procedure shows significant decrease in blood pressure]. Lakartidningen. 2013 Jan 16-22;110(3):86-8. PMID: 23424985.
Not in English

Sanders MF, Blankestijn PJ, Voskuil M, et al. Safety and long-term effects of renal denervation: Rationale and design of the Dutch registry. Neth J Med. 2016 Jan;74(1):5-15. PMID: 26819356.
Protocol only

Savard S, Frank M, Bobrie G, et al. Eligibility for renal denervation in patients with resistant hypertension: when enthusiasm meets reality in real-life patients. J Am Coll Cardiol. 2012 Dec 11;60(23):2422-4. PMID: 23141491.
Does not apply; Does not meet study design criteria

Scherlag MA, Scherlag BJ. A randomized comparison of pulmonary vein isolation with versus without concomitant renal artery denervation in patients with refractory symptomatic atrial fibrillation and resistant hypertension. J Am Coll Cardiol. 2013 Sep 17;62(12):1129-30. PMID: 23810880.
No original data

Schirmer SH, Sayed MM, Reil JC, et al. Atrial Remodeling Following Catheter-Based Renal Denervation Occurs in a Blood Pressure- and Heart Rate-Independent Manner. JACC Cardiovasc Interv. 2015 Jun;8(7):972-80. PMID: 26003031.
Overlapping population

Schirmer SH, Sayed MM, Reil JC, et al. Improvements in left ventricular hypertrophy and diastolic function following renal denervation: effects beyond blood pressure and heart rate reduction. J Am Coll Cardiol. 2014 May 13;63(18):1916-23. PMID: 24315919.
Overlapping population

Schlaich M, Hering D, Lambert G, et al. Blood pressure and sympathetic nervous system response to renal denervation. Hypertension. 2013 Feb;61(2):e13. PMID: 23248152.
No original data

Schlaich MP, Bart B, Hering D, et al. Feasibility of catheter-based renal nerve ablation and effects on sympathetic nerve activity and blood pressure in patients with end-stage renal disease. Int J Cardiol. 2013 Oct 3;168(3):2214-20. PMID: 23453868.
Does not meet study design criteria

Schmieder RE, Ott C, Schmid A, et al. Adherence to Antihypertensive Medication in Treatment-Resistant Hypertension Undergoing Renal Denervation. J Am Heart Assoc. 2016;5(2)doi: 10.1161/jaha.115.002343. PMID: 26873693.
No outcome

Schmieder RE, Ott C, Veelken R, et al. 7B.01: FINAL ANALYSIS ON ADHERENCE TO ANTIHYPERTENSIVE MEDICATION IN TREATMENT RESISTANT HYPERTENSION (TRH) UNDERGOING RENAL DENERVATION (RDN). J Hypertens. 2015 Jun;33 Suppl 1:e92. PMID: 26102969.
Overlapping population

Seravalle G, Dell'Oro R, Trevano FQ, et al. 4A.04: EFFECTS OF RENAL DENERVATION ON ASYMMETRIC DIMETHYLARGININE AND SYMPATHETIC NERVE TRAFFIC IN RESISTANT HYPERTENSIVE PATIENTS. J Hypertens. 2015 Jun;33 Suppl 1:e50. PMID: 26102840.
Does not meet study design criteria; Does not apply

Sridhar GS, Watson T, Han CK, et al. Profound Sustained Hypotension Following Renal Denervation: A Dramatic Success? Arq Bras Cardiol. 2015 Aug;105(2):202-4. PMID: 26352181.
Case report

Stabile E, Ambrosini V, Squarcia R, et al. Percutaneous sympathectomy of the renal arteries: the OneShot Renal Denervation System is not associated with significant vessel wall injury. EuroIntervention. 2013 Oct;9(6):694-9. PMID: 24169131.
Does not meet study design criteria

Staessen JA, Jin Y, Thijs L, et al. First-in-man randomized clinical trial of renal denervation for atrial arrhythmia raises concern. J Am Coll Cardiol. 2013 Nov 19;62(21):e445-6. PMID: 24060455.
No original data

Tank J, Heusser K, Brinkmann J, et al. Spike rate of multi-unit muscle sympathetic nerve fibers after catheter-based renal nerve ablation. J Am Soc Hypertens. 2015 Jul 31doi: 10.1016/j.jash.2015.07.012. PMID: 26324745.
Does not meet study design criteria

Taylor J. CardioPulse: ESC recommends patients and centres for renal denervation: recommendations on catheter-based renal denervation for treatment resistant hypertension should guide reimbursement. Eur Heart J. 2013 May;34(17):1245-6. PMID: 23776956.
No original data

Templin C, Jaguszewski M, Ghadri JR, et al. Vascular lesions induced by renal nerve ablation as assessed by optical coherence tomography: pre- and post-procedural comparison with the Simplicity catheter system and the EnligHTN multi-electrode renal denervation catheter. Eur Heart J. 2013 Jul;34(28):2141-8, 8b. PMID: 23620498.
Does not meet study design criteria

Tofield A. Recurrent atrial fibrillation reduced after renal denervation with pulmonary vein ablation in select patients. Eur Heart J. 2015 Feb 1;36(5):257. PMID: 25763437.
No original data

Tsioufis C, Papademetriou V, Dimitriadis K, et al. Long-term effects of multielectrode renal denervation on cardiac adaptations in resistant hypertensive patients with left ventricular hypertrophy. J Hum Hypertens. 2016 Jan 28doi: 10.1038/jhh.2015.127. PMID: 26818805.
Does not meet study design criteria; No outcome

Tsioufis C, Papademetriou V, Dimitriadis K, et al. 8B.08: SUSTAINED BENEFICIAL EFFECTS OF MULTI-ELECTRODE RENAL DENERVATION ON CARDIAC ADAPTATIONS IN RESISTANT HYPERTENSION: A 24-MONTHS FOLLOW-UP STUDY. J Hypertens. 2015 Jun;33 Suppl 1:e109. PMID: 26102674.
Does not meet study design criteria

Tsioufis C, Papademetriou V, Tsiachris D, et al. Drug-resistant hypertensive patients responding to multielectrode renal denervation exhibit improved heart rate dynamics and reduced arrhythmia burden. J Hum Hypertens. 2014 Oct;28(10):587-93. PMID: 24621623.
Does not meet study design criteria

Tuohy ST, Kyvelou SG, Gleeson PJ, et al. The effect of renal sympathetic denervation on nocturnal dipping in patients with resistant hypertension; observational data from a tertiary referral centre in the Republic of Ireland. Ir J Med Sci. 2015 Jun 19PMID: 26089291.
Does not meet study design criteria

Ukena C, Mahfoud F, Kindermann I, et al. Cardiorespiratory response to exercise after renal sympathetic denervation in patients with resistant hypertension. J Am Coll Cardiol. 2011 Sep 6;58(11):1176-82. PMID: 21884958.
Does not meet study design criteria

Ukena C, Mahfoud F, Spies A, et al. Effects of renal sympathetic denervation on heart rate and atrioventricular conduction in patients with resistant hypertension. Int J Cardiol. 2013 Sep 10;167(6):2846-51. PMID: 22917547.
Overlapping population

van Brussel PM, Eeftinck Schattenkerk DW, Dobrowolski LC, et al. Effects of renal sympathetic denervation on cardiac sympathetic activity and function in patients with therapy resistant hypertension. Int J Cardiol. 2016 Jan 1;202:609-14. doi: 10.1016/j.ijcard.2015.09.025. PMID: 26447672.
Does not meet study design criteria

Vemulapalli S, Ard J, Bakris GL, et al. Proceedings from Duke resistant hypertension think tank. Am Heart J. 2014 Jun;167(6):775-88 e1. PMID: 24890525.
No original data

Verloop WL, Vink EE, Voskuil M, et al. Eligibility for percutaneous renal denervation: the importance of a systematic screening. J Hypertens. 2013 Aug;31(8):1662-8. PMID: 23743806.
No outcome; No renal denervation device

Vink EE, Blankestijn PJ. Catheter-based renal nerve ablation and centrally generated sympathetic activity in difficult-to-control hypertensive patients. Hypertension. 2013 Feb;61(2):e8. PMID: 23213193.
No original data

Vink EE, Verloop WL, Siddiqi L, et al. The effect of percutaneous renal denervation on muscle sympathetic nerve activity in hypertensive patients. Int J Cardiol. 2014 Sep;176(1):8-12. PMID: 25027168.
Does not meet study design criteria

Vonend O, Antoch G, Rump LC, et al. Secondary rise in blood pressure after renal denervation. Lancet. 2012 Aug 25;380(9843):778. PMID: 22920752.
Case report

Voskuil M, Verloop WL, Blankestijn PJ, et al. Percutaneous renal denervation for the treatment of resistant essential hypertension; the first Dutch experience. Neth Heart J. 2011 Aug;19(7-8):319-23. PMID: 21567219.
Does not meet study design criteria

Waksman R, Barbash IM, Chan R, et al. Beta radiation for renal nerve denervation: initial feasibility and safety. EuroIntervention. 2013 Oct;9(6):738-44. PMID: 24169134.
No human data; Does not meeting study design criteria

Wang L, Lu CZ, Zhang X, et al. [The effect of catheter based renal synthetic denervation on renin-angiotensin-aldosterone system in patients with resistant hypertension]. Zhonghua Xin Xue Guan Bing Za Zhi. 2013 Jan;41(1):3-7. PMID: 23651959.
Not in English

Weber MA, Kirtane A, Mauri L, et al. Renal Denervation for the Treatment of Hypertension: Making a New Start, Getting It Right. Clin Cardiol. 2015 Aug;38(8):447-54. PMID: 26216107.
No original data

White WB, Turner JR, Sica DA, et al. Detection, evaluation, and treatment of severe and resistant hypertension: proceedings from an American Society of Hypertension Interactive forum held in Bethesda, MD, U.S.A., October 10th 2013. J Am Soc Hypertens. 2014 Oct;8(10):743-57. PMID: 25418497.
No original data

Witkowski A, Prejbisz A, Florczak E, et al. Effects of renal sympathetic denervation on blood pressure, sleep apnea course, and glycemic control in patients with resistant hypertension and sleep apnea. Hypertension. 2011 Oct;58(4):559-65. PMID: 21844482.
Does not meet study design criteria

Wu B, Hong M, Wu H, et al. Renal sympathetic denervation might be an adjunctive treatment approach for managing ventricular arrhythmia. Int J Cardiol. 2015 Apr 1;184:257-8. PMID: 25726902.
No original data

Wybraniec MT, Czerwienska B, Lelek M, et al. Plasma renalase concentration before and after radiofrequency renal denervation in patients with resistant hypertension. J Hum Hypertens. 2015 Aug 27PMID: 26310184.
Does not meet study design criteria; No outcome

Yang WY, Staessen JA. Hypertension: Renal denervation-promising data from the DENERHTN trial. Nat Rev Nephrol. 2015 May;11(5):258-60. PMID: 25752835.
No original data

Zaman S, Pouliopoulos J, Al Raisi S, et al. Novel use of NavX three-dimensional mapping to guide renal artery denervation. EuroIntervention. 2013 Oct;9(6):687-93. PMID: 24169130.
Does not meet study design criteria

Zhao MM, Tan XX, Ding N, et al. [Comparison of efficacy between continuous

positive airway pressure and renal artery sympathetic denervation by radiofrequency ablation in obstructive sleep apnea syndrome patients with hypertension]. Zhonghua Yi Xue Za Zhi. 2013 Apr 23;93(16):1234-7. PMID: 23902614.
Not in English

Zheng XX, Li XY, Lyu YN, et al. Possible mechanism by which renal sympathetic denervation improves left ventricular remodelling after myocardial infarction. Exp Physiol. 2016 Feb 1;101(2):260-71. doi: 10.1113/ep085302. PMID: 26556551.
No human data

Ziakas A, Gossios T, Doumas M, et al. The pathophysiological basis of renal nerve ablation for the treatment of hypertension. Curr Vasc Pharmacol. 2014 Jan;12(1):23-9. PMID: 23905601.
No original data

Ziegler AK, Bertog S, Kaltenbach B, et al. Efficacy and safety of renal denervation in elderly patients with resistant hypertension. Catheter Cardiovasc Interv. 2015 Aug;86(2):299-303. PMID: 23983010.
Does not meet study design criteria

Zuern CS, Rizas KD, Eick C, et al. Effects of Renal Sympathetic Denervation on 24-hour Blood Pressure Variability. Front Physiol. 2012;3:134. PMID: 22590460.
Does not meet study design criteria

Appendix D: Studies Excluded for Overlapping Populations

Bartus K, Sadowski J, Kapelak B, et al. Denervation (ablation) of nerve terminalis in renal arteries: early results of interventional treatment of arterial hypertension in Poland. Kardiol Pol. 2013;71(2):152-8. PMID: 23575708.

Bartus K, Sadowski J, Kapelak B, et al. Denervation of nerve terminals in renal arteries: one-year follow-up of interventional treatment of arterial hypertension. Kardiol Pol. 2014;72(5):425-31. PMID: 24408071.

Brandt MC, Mahfoud F, Reda S, et al. Renal sympathetic denervation reduces left ventricular hypertrophy and improves cardiac function in patients with resistant hypertension. J Am Coll Cardiol. 2012 Mar 6;59(10):901-9. PMID: 22381425.

Brandt MC, Reda S, Mahfoud F, et al. Effects of renal sympathetic denervation on arterial stiffness and central hemodynamics in patients with resistant hypertension. J Am Coll Cardiol. 2012 Nov 6;60(19):1956-65. PMID: 23062529.

Hering D, Lambert EA, Marusic P, et al. Renal nerve ablation reduces augmentation index in patients with resistant hypertension. J Hypertens. 2013 Sep;31(9):1893-900. PMID: 23697964.

Hering D, Marusic P, Walton AS, et al. Sustained sympathetic and blood pressure reduction 1 year after renal denervation in patients with resistant hypertension. Hypertension. 2014 Jul;64(1):118-24. PMID: 24732891.

Id D, Kaltenbach B, Bertog SC, et al. Does the presence of accessory renal arteries affect the efficacy of renal denervation? JACC Cardiovasc Interv. 2013 Oct;6(10):1085-91. PMID: 24156968.

Karanasos A, Van Mieghem N, Bergmann MW, et al. Multimodality Intra-Arterial Imaging Assessment of the Vascular Trauma Induced by Balloon-Based and Nonballoon-Based Renal Denervation Systems. Circ Cardiovasc Interv. 2015 Jul;8(7):e002474. PMID: 26156150.

Krum H, Schlaich M, Whitbourn R, et al. Catheter-based renal sympathetic denervation for resistant hypertension: a multicentre safety and proof-of-principle cohort study. Lancet. 2009 Apr 11;373(9671):1275-81. PMID: 19332353.

Mahfoud F, Cremers B, Janker J, et al. Renal hemodynamics and renal function after catheter-based renal sympathetic denervation in patients with resistant hypertension. Hypertension. 2012 Aug;60(2):419-24. PMID: 22733462.

Mahfoud F, Schlaich M, Kindermann I, et al. Effect of renal sympathetic denervation on glucose metabolism in patients with resistant hypertension: a pilot study. Circulation. 2011 May 10;123(18):1940-6. PMID: 21518978.

Mahfoud F, Ukena C, Schmieder RE, et al. Ambulatory blood pressure changes after renal sympathetic denervation in patients with resistant hypertension. Circulation. 2013 Jul 9;128(2):132-40. PMID: 23780578.

Mahfoud F, Urban D, Teller D, et al. Effect of renal denervation on left ventricular mass

and function in patients with resistant hypertension: data from a multi-centre cardiovascular magnetic resonance imaging trial. Eur Heart J. 2014 Sep 1;35(33):2224-31b. PMID: 24603307.

Schirmer SH, Sayed MM, Reil JC, et al. Atrial Remodeling Following Catheter-Based Renal Denervation Occurs in a Blood Pressure- and Heart Rate-Independent Manner. JACC Cardiovasc Interv. 2015 Jun;8(7):972-80. PMID: 26003031.

Schirmer SH, Sayed MM, Reil JC, et al. Improvements in left ventricular hypertrophy and diastolic function following renal denervation: effects beyond blood pressure and heart rate reduction. J Am Coll Cardiol. 2014 May 13;63(18):1916-23. PMID: 24315919.

Ukena C, Mahfoud F, Spies A, et al. Effects of renal sympathetic denervation on heart rate and atrioventricular conduction in patients with resistant hypertension. Int J Cardiol. 2013 Sep 10;167(6):2846-51. PMID: 22917547.

Appendix E: Evidence Tables

Table 1. Characteristics of studies evaluating renal denervation devices

Author, year Country Study design Registered protocol	Run-in period	Adherence during the run-in and adherence during the study	Follow-up duration	Number screened/ enrolled	Funding source	Exclusion criteria
Azizi, 2015[1] Europe RCT NCT01570777	Yes run-in	Adherence during the run-in not reported Other adherence during the study	RCT follow-up: 6 months	N screened: 1416 N enrolled: 106	Govt./ non-profit	Ages <18 and >75; blood pressure <140 mmHg / 90 mmHg; <3 antihypertensive medications; does not have suitable renal artery anatomy on CT angiogram, magnetic resonance angiogram, or renal angiogram performed within the previous year; secondary hypertension (ruled out by standardized screening in the past 2 years); eGFR < 40 mL/min/1.73 m2; Ambulatory BP <135/85
Bhatt, 2014[2] United States RCT NCT01418261	Yes run-in	Pill count	RCT follow-up: 6 months	N screened: 1441 N enrolled: 535	Manufact.	Ages <18 and >80; blood pressure <160; <3 antihypertensive medications; 24-hr Systolic ABPM <135; Clinical exclusion criteria were known secondary causes of hypertension and more than one hospitalization for a hypertensive emergency in the previous year; anatomical: renal-artery stenosis > 50%, renal-artery aneurysm, prior renal-artery intervention, multiple renal arteries, renal artery < 4 mm in diameter, treatable segment <20 mm length
Bohm, 2015[3] Worldwide Before-after study NCT01534299	Not applicable	Other adherence during run-in Other adherence during the study	Mean obs follow-up: 6 months	N screened not reported N enrolled: 998	Govt./ non-profit Manufact.	Ages <18; not eligible for RDN as defined by local regulations
Burchell, 2016[4] Before-after study No registered protocol	Yes run-in	Other adherence during run-in Other adherence during the study	Mean obs follow-up: 12 months	N screened: 321 N enrolled: 29	Govt./ non-profit	Unsuitable renal artery anatomy; eGFR <45 ml/min/1.73m²; secondary causes of hypertension; pseudoresistant hypertension; poor medication adherence
de Sousa Almeida, 2016[5] Before-after study No registered protocol	Yes run-in	Other adherence during run-in No adherence during the study	Mean obs follow-up: 12 months	N screened: 318 N enrolled: 31	None	Ages <18; <3 antihypertensive medications; OSBP <160 mmHg; <1 diuretic; secondary causes for hypertension; 1-year followup with 24-hour ABPM and transthoracic echocardiogram

Table 1. Characteristics of studies evaluating renal denervation devices (continued)

Author, year Country Study design Registered protocol	Run-in period	Adherence during the run-in and adherence during the study	Follow-up duration	Number screened/ enrolled	Funding source	Exclusion criteria
Desch, 2015[6] Europe RCT NCT01656096	No	Other adherence during run-in Other adherence during the study	RCT follow-up: 6 months	N screened: 1597 N enrolled: 71	Govt./ non-profit	Ages <18 and >75; <3 antihypertensive medications; ABPM values below or above the predefined ranges ((2) mean daytime systolic BP on 24-hour ambulatory BP measurement (ABPM) between 135 and 149 mmHg or mean day-time diastolic BP between 90 and 94 mmHg); unsuitable anatomy for RSD; severe renal artery stenosis; estimated glomerular filtration rate <45 mL/min per 1.73 m2 (modification of diet in renal disease formula); change in BP medication in the 4 weeks preceding randomization; unwillingness to adhere to unchanging BP medication during the study period of 6 months; pregnancy, and severe comorbidities with limited life expectancy
Dorr, 2013[7] Europe Before-after study No registered protocol	No	Adherence during run-in not reported Adherence during the study not reported	Mean obs follow-up: 3 months	N screened not reported N enrolled: 62	Not reported	Does not have resistant hypertension (undefined)renal artery stenosis; secondary causes of hypertension
Dorr, 2015[8] Europe Before-after study No registered protocol	Not applicable	Adherence during run-in not reported Adherence during the study not reported	Mean obs follow-up: 6 months	N screened not reported N enrolled: 150	Not reported	Blood pressure <140; <3 antihypertensive medications; not on stable antihypertensive drug regimen; secondary, treatable causes of hypertension
Dorr, 2015[9] Europe Before-after study No registered protocol	Not applicable	Adherence during run-in not reported Adherence during the study not reported	Mean obs follow-up: 6 months	N screened not reported N enrolled: 100	Not reported	Blood pressure <160 mmHg (150 for type 2 diabetics) or ABPM >135 mmHg; <3 antihypertensive medications; does not have secondary causes of secondary origins of hypertension; not on a stable antihypertensive regimen; systemic infections; rheumatoid diseases; malignancies
Dorr, 2015[10] Europe Before-after study No registered protocol	No	Adherence during run-in not reported Adherence during the study not reported	Mean obs follow-up: 6 months	N screened not reported N enrolled: 60	Govt./ non-profit	Blood pressure -140; <3 antihypertensive medications; secondary origins of hypertension; patients with systemic infections; rheumatoid diseases; malignancies

Table 1. Characteristics of studies evaluating renal denervation devices (continued)

Author, year Country Study design Registered protocol	Run-in period	Adherence during the run-in and adherence during the study	Follow-up duration	Number screened/ enrolled	Funding source	Exclusion criteria
Eikelis, 2015[11] Australia Non-randomized trial No registered protocol	No	Adherence during run-in not reported Adherence during the study not reported	Mean obs follow-up: 12 months	N screened not reported N enrolled: 69	Govt./ non-profit	Secondary hypertension; does not meet criteria for hypertension using the European Society of Hypertension guidelines
Ewen, 2014[12] Europe Prospective cohort No registered protocol	No	Adherence during run-in not applicable Adherence during the study not reported	Mean obs follow-up: 12 months	N screened not reported N enrolled: 60	Manufact.	Ages <18; blood pressure <140/90 mmHg; <3 antihypertensive medications; not using a diuretic; not on a stable antihypertensive drug regimen; secondary causes of hypertension
Ewen, 2015[13] Europe Before-after study NCT01888315	No	Adherence during run-in not applicable Other Adherence during the study	Mean obs follow-up: 6 months	N screened not reported N enrolled: 100	Govt./ non-profit	Ages <18 and >140; <3 anti-hypertensive medications; not on a diuretic; not on a stable antihypertensive regimen; secondary, treatable causes of hypertension
Ewen, 2015[14] Europe Before-after study NCT01888315	No	Adherence not reported	Mean obs follow-up: 12 months	N screened not reported N enrolled: 126	Govt./ non-profit	Ages <18; blood pressure <140; <3 antihypertensive medications; not on a diuretic; not on a stable antihypertensive drug regimen; secondary, treatable causes of hypertension
Ewen, 2015[15] Before-after study NCT01888315	Not applicable	Adherence during run-in not applicable Other adherence during the study	Mean obs follow-up: 6 months	N screened not reported N enrolled: 30	Govt./ non-profit	Ages <18; <3 antihypertensive medications; OSBP <140 mmHg; <1 diuretic; secondary, treatable causes of hypertension; not on a stable antihypertensive drug regimen; ejection fraction < 50%

Table 1. Characteristics of studies evaluating renal denervation devices (continued)

Author, year Country Study design Registered protocol	Run-in period	Adherence during the run-in and adherence during the study	Follow-up duration	Number screened/ enrolled	Funding source	Exclusion criteria
Ewen, 2015[16] Before-after study NCT01888315	Not applicable	Adherence during run-in not applicable No adherence during the study	Mean obs follow-up: 6 months	N screened not reported N enrolled: 84	Deutsche Forschungsgemeinschaft (KFO 196), Deutsche Gesellschaft fu¨r Kardiologie, and Deutsche Hochdruckliga	Ages <18; <3 antiphyertensive medications; OSBP <140 mmHg and ASBP <135 mmHg; <1 diuretic; unstable antihypertensive drug regimen; secondary, treatable causes of hypertension
Fadl Elmula, 2014[17] Europe RCT NCT01673516	No	Other Adherence during run-in Adherence during the study not reported	RCT follow-up: 6 months	N screened: 65 N enrolled: 20	Govt./ non-profit	Ages <18 and >80; blood pressure <140; <3 antihypertensive medications; secondary or spurious hypertension or high serum aldosterone levels that responded to treatment with spironolactone; drug treatment changed in last 2 weeks; no change in treatment preplanned for the next 6 months; abnormal renal arteries at computed tomography or MRI within last 2 years; eGFR < 45 ml/min/1.73 m2; urine albumin/creatinine ratio >50 mg/mmol; type 2 diabetes; mean ambulatory daytime SBP <135 mm Hg immediately after investigator witnessed intake of their antihypertensive morning drugs
Hameed, 2015[18] Europe Before-after study No registered protocol	Not applicable	Adherence during the run-in not applicable Other Adherence during the study	Mean obs follow-up: 6 months	N screened not applicable N enrolled: 34	Not reported	Blood pressure -160, with confirmed daytime average BP > 150 mmHg on ABPM or >140 mmHg on ABPM in patients with type 2 diabetes--3-eGFR < 45 mL/min/1.73 m2 (but those with a lower eGFR could be considered after discussion with a nephrologist); non-adherence; white-coat hypertension; secondary causes of hypertension; non-suitable renal artery anatomy

Table 1. Characteristics of studies evaluating renal denervation devices (continued)

Author, year Country Study design Registered protocol	Run-in period	Adherence during the run-in and adherence during the study	Follow-up duration	Number screened/ enrolled	Funding source	Exclusion criteria
Hamza, 2014[19] Egypt Before-after study No registered protocol	No	Adherence during run-in not applicable Adherence during the study not reported	Mean obs follow-up: 6 months	N screened not reported N enrolled: 55	Not reported	Ages <18; blood pressure <160; <3 antihypertensive medications; not on a diuretic; pregnant; secondary causes of hypertension; type 1 diabetes; eGFR < 45 mL/min/1.73 m2; hemodynamically significant valvular disease; implantable cardioverter defibrillators; renal artery problems or stenosis or small accessory renal artery
Hering, 2015[20] Australia Before-after study No registered protocol	No	Other adherence	Mean obs follow-up: 6 months	N screened not reported N enrolled: 91	Govt./ non-profit Manufact.	Did not have successful 24-hr ABPM at baseline, 3-, and 6-months after RDN
Honarvar, 2013[21] Iran Before-after study IUMS.ac.ir #391001	Yes run-in	Adherence during run-in: diary Adherence during the study not reported	Mean obs follow-up: 6 months	N screened: 45 N enrolled: 30	Not reported	Ages <15; Blood pressure-160/90 mmHg (>=150 mmHg in patients with type 2 diabetes); <3 antihypertensive medications; unsuitable renal artery anatomy; known secondary hypertension; eGFR < =45 mL/min/1.73 m2; history of unstable angina or cerebrovascular accident in past 6 months; pregnant; blood pressure measurements below the enrolment criteria for blood pressure in 24-hr BP Holter monitoring
Id, 2015[22] Europe Before-after study No registered protocol	Not applicable	Adherence during run-in not reported Adherence during the study: diary	Mean obs follow-up: 6 months	N screened: 221 N enrolled: 101	Not reported	Ages <18; <140 mmHg; <3 antihypertensive medications; does not have bilateral single renal arteries; systolic 24-hr ABPM < 130 mmHg; secondary causes of hypertension; renal artery abnormalities
Kaiser, 2014[23] Europe Before-after study No registered protocol	No	Adherence during run-in not applicable Other adherence during the study	Mean obs follow-up: 6 months	N screened not reported N enrolled: 93	Not reported	Ages <40 and >85; blood pressure <160; <3 antihypertensive medications

Table 1. Characteristics of studies evaluating renal denervation devices (continued)

Author, year Country Study design Registered protocol	Run-in period	Adherence during the run-in and adherence during the study	Follow-up duration	Number screened/ enrolled	Funding source	Exclusion criteria
Kario, 2015[24] Japan RCT NCT01644604	Yes run-in	Adherence during run-in: diary Adherence during the study not reported	RCT follow-up: 6 months	N screened: 84 N enrolled: 41	Manufact.	Ages <20 and >80; Blood pressure <160; <3 antihypertensive medications; not on a diuretic; 24-hour average ambulatory SBP < 135 mm Hg; eGFR < 45 mL/min/1.73 m2; main renal arteries < 4mm in diameter or <20 mm treatable length; multiple renal arteries for which the main renal artery was estimated to supply <75% of the kidney; renal artery stenosis >50% or renal artery aneurysm; history of prior renal artery intervention; >1 inpatient hospitalization for a hypertensive crisis not related to confirmed non-adherence to medication within the last year; type 1 diabetes mellitus; >=1 episodes of orthostatic hypotension not related to medication changes; secondary causes of hypertension
Kim, 2015[25] Korea Before-after study NCT01534299	No	Adherence not applicable	Mean obs follow-up: 12 months	N screened not reported N enrolled: 534	Manufact.	OSBP < 160 mmHg (or 150 mmHg if type 2 diabetes); <3 antihypertensive medications; prior renal intervention; main renal arteries < 4 mm in diameter or < 20 mm in length and hemodynamically or anatomically significant renal artery abnormalities; eGFR < 45 mL/min/1.73 m2; type 1 diabetes; stenotic valvular heart disease; myocardial infarction, unstable angina, or cerebrovascular accident within 6 months; possible secondary hypertension; not of African descent
Kiuchi, 2014[26] Brazil Before-after study No registered protocol	No	Adherence during run-in not applicable Adherence during the study: diary	Mean obs follow-up: 12 months	N screened not reported N enrolled: 27	Govt./ non-profit	Ages <18 and >70; Blood pressure 160 mmHg (or <150 mmHg for type 2 diabetics); <3 antihypertensive medications; eGFR <15 and >89 mL/min/1.73 m2; pregnancy; valvular heart disease with significant hemodynamic consequences; stenotic valvular heart disease for which the reduction in BP could be dangerous; acute myocardial infarction, unstable angina, or transitory ischemic attack within the previous 6 months; renovascular anomalies; type 1 diabetes; secondary cause for hypertension; not on a diuretic
Kiuchi, 2015[27] Brazil Before-after study No registered protocol	No	Adherence during run-in not applicable Adherence during the study not reported	Mean obs follow-up: 12 months	N screened not reported N enrolled: 30	Not reported	Did not have CKD stages 1 or 5

Table 1. Characteristics of studies evaluating renal denervation devices (continued)

Author, year Country Study design Registered protocol	Run-in period	Adherence during the run-in and adherence during the study	Follow-up duration	Number screened/ enrolled	Funding source	Exclusion criteria
Kiuchi, 2015[28] Before-after study No registered protocol	Yes	Adherence during run-in not reported Other adherence during the study	Mean obs follow-up: 24 months	N screened: 33 N enrolled: 30	Hospital Regional Darcy Vargas	Ages <18 and >70; <3 antihypertensive medications (including a diuretic); SBP <160 mmHg or <150 mmHg for patients with type 2 diabetes; eGFR <15 ml/min/1.73m^2 and >89 ml/min/1.73m²; pregnancy; valvular heart disease with significant hemodynamic consequences; use of warfarin; stenotic valvular heart disease; acute myocardial infarction; unstable angina; stroke; transient ischaemic attack within the previous 6 months; renovascular anomalies; diabetes mellitus type 1; secondary causes of hypertension
Krum, 2014[29] Europe, Australia, United States Before-after study NCT00483808, NCT00664638, and NCT00753285	No	Adherence during run-in not applicable Adherence during the study not reported	Mean obs follow-up: 36 months	N screened not reported N enrolled: 150	Manufact.	Blood pressure -160; <3 antihypertensive medications; not on a diuretic; eGFR < 45 mL/min/1.73 m2; renovascular abnormalities (renal-artery stenosis, previous renal stent or angioplasty, dual renal arteries, or polar arteries)
Kyvelou, 2013[30] Europe Before-after study No registered protocol	No	Adherence during run-in not applicable Adherence during the study not reported	Mean obs follow-up: 6 months	N screened not reported N enrolled: 31	Not reported	Did not fulfill criteria for resistant hypertension; secondary causes of hypertension
Lambert, 2012[31] Australia Prospective cohort No registered protocol	No	No adherence during run-in No adherence during the study	obs-duration-not reported	N screened: 62 N enrolled: 62	Govt./ non-profit Manufact.	<3 antihypertensive medications; History of CV disease; Known psychiatric disorders

Table 1. Characteristics of studies evaluating renal denervation devices (continued)

Author, year Country Study design Registered protocol	Run-in period	Adherence during the run-in and adherence during the study	Follow-up duration	Number screened/ enrolled	Funding source	Exclusion criteria
Lambert, 2014[32] Europe Before-after study No registered protocol	No	Adherence during run-in not reported No adherence during the study	Mean obs follow-up: 6 months	N screened not applicable N enrolled: 86	Not reported	Ages <18; <3 antihypertensive medications; pregnant; eGFR of <45 mL/min/1.73 m^2; renal artery diameter <4 mm; renal artery length <20 mm; non-diabetic
Lambert, 2015[33] Europe Before-after study No registered protocol	No	Adherence during run-in not reported Adherence during the study not reported	Mean obs follow-up: 6 months	N screened not applicable N enrolled: 76	Not reported	Ages <18; systolic office BP <160 mmHg; <3 antihypertensive medications; secondary causes of hypertension; <1 diuretic; pregnancy; eGFR<45 ml/min/1.73; artery diameter <4 mm; artery length <20 mm; renal artery stenosis
Lambert, 2015[34] Europe Before-after study No registered protocol	No	No adherence during run-in No adherence during the study	Mean obs follow-up: 24 months	N screened not applicable N enrolled: 32	Not reported	Ages <18; blood pressure <160 mmHg; <3 antihypertensive medications; -<1 diuretic; pregnant; eGFR<45 ml/min/1.73 m^2; renal artery anatomy < 4mm diameter; renal artery anatomy <20 mm long
Lambert, 2015[35] Australia Retrospective cohort NCT01865240, NCT01865253, NCT02016573	No	No adherence during run-in No adherence during the study	Mean obs follow-up: 12 months	N screened not reported N enrolled: 97	Manufact.	----
Lambert, 2015[36] Europe Before-after study No registered protocol	No	No adherence during run-in No adherence during the study	Mean obs follow-up: 6 months	N screened not applicable N enrolled: 106	Not reported	Ages <18; Blood pressure <160 mmHg and systolic office BP; <3 antihypertensive medications; <1 diuretic; pregnancy; eGFR < 45 ml/min/1.73 m^2; secondary causes of hypertension; artery diameter < 4 mm; artery length < 20 mm

Table 1. Characteristics of studies evaluating renal denervation devices (continued)

Author, year Country Study design Registered protocol	Run-in period	Adherence during the run-in and adherence during the study	Follow-up duration	Number screened/ enrolled	Funding source	Exclusion criteria
Lenski, 2013[37] Europe Before-after study	No	No adherence during run-in No adherence during the study	Mean obs follow-up: 6 months	N screened not applicable N enrolled: 119	Govt./ non-profit	Ages <18 and >85; SBP 160 mmHg; <3 antihypertensive medications; eGFR < 45 mL/min/1.73 m; type 1 diabetes; contraindications to MRI; substantial stenotic valvular heart disease; pregnancy or planned pregnancy during study; history of myocardial infarction; unstable angina; cerebrovascular accident in previous 6 months
Lenski, 2013[38] Europe Before-after study No registered protocol	No	No adherence during run-in No adherence during the study	Mean obs follow-up: 3 months	N screened not applicable N enrolled: 36	Govt./ non-profit	Ages <18 and >85; SBP 160 mmHg; <3 antihypertensive medications; eGFR <45 mL/min/1.73; type 1 diabetes; contraindications to MRI; substantial stenotic valvular heart disease; pregnancy or planned pregnancy during study; history of myocardial infarction; unstable angina; cerebrovascular accident in the previous 6 months
Lobo, 2015[39] Not reported Before-after study No registered protocol	No	Adherence during run-in not reported Adherence during the study not reported	Mean obs follow-up: 12 months	N screened not applicable N enrolled: 129	Not reported	Blood pressure <160; <3 antihypertensive medications; <1 diuretic; eGFR < 45 mL/min/1.73 m2
Ott, 2013[40] Europe Before-after study NCT01687725	No	Adherence during run-in not reported Adherence during the study not reported	Mean obs follow-up: 6 months	N screened not applicable N enrolled: 54	Not reported	OBP 140/90 mmHg; "white coat" or pseudo resistant hypertension; unchanged antihypertensive drug regimen for at least 2 months; main renal arteries <4 mm in diameter or < 20 mm in length; hemodynamically or anatomically significant renal artery abnormality or stenosis in either renal artery; history of renal artery intervention including balloon angioplasty or stenting; multiple main renal arteries in either kidney; secondary cause of hypertension

Table 1. Characteristics of studies evaluating renal denervation devices (continued)

Author, year Country Study design Registered protocol	Run-in period	Adherence during the run-in and adherence during the study	Follow-up duration	Number screened/ enrolled	Funding source	Exclusion criteria
Ott, 2014[41] Europe Before-after study NCT01687725	No	Adherence during run-in not reported Adherence during the study not reported	Mean obs follow-up: 6 months	N screened not reported N enrolled: 59	Manufact.	OBP 140/90 mmHg; <3 antihypertensive medications; <1 diuretic; nephrotic syndrome or active renal disease defined as being unstable within the last 3 months; renal artery diameter of <4mm and <20 mm in length; hemodynamically or anatomically significant renal artery abnormality or stenosis in either renal artery; history of prior renal artery intervention including balloon angioplasty or stenting; secondary cause of hypertension
Ott, 2015[42] Europe Before-after study NCT01687725	Not applicable	Adherence during the run-in not reported Other adherence during the study	Mean obs follow-up: 6 months	N screened not applicable N enrolled: 63	Not reported	OBP 140/90 mmHg; <3 antihypertensive medications; unstable drug regime for less than 4 weeks prior to study inclusion; renal artery diameter <4mm; renal artery length <20mm; hemodynamically or anatomically significant renal artery abnormality or stenosis in either renal artery; history or prior renal artery intervention including balloon angioplasty or stenting; secondary cause of hypertension; eGFR <15 ml/min/1.73m^2
Ott, 2015[43] Europe Before-after study NCT01442883	Not applicable	No adherence during run-in Other adherence during the study	Mean obs follow-up: 6 months	N screened not applicable N enrolled: 27	Not reported	eGFR <15 ml/min/1,73 m^2; unstable drug regimen; renal artery diameter <4mm; renal artery length <20mm; hemodynamically or anatomically significant renal artery abnormality or stenosis in either renal artery; history of prior renal artery intervention including balloon angioplasty or stenting; secondary cause of hypertension
Ott, 2015[44] Europe Before-after study NCT01687725	Not applicable	Adherence during run-in not reported Other adherence during the study	Mean obs follow-up: 12 months	N screened not applicable N enrolled: 51	Not reported	office BP 140/90 mmHg and daytime ABPM 135/85 mmHg; <3 antihypertensive medications; <1 diuretic; secondary causes of hypertension; eGFR <15 ml/min/1.73 m^2; renal artery diameter <4mm/<20 mm in length; hemodynamically or anatomically significant renal artery abnormality or stenosis in either renal artery; history of prior renal artery intervention including balloon angioplasty or stenting
Papademetriou, 2014[45] Europe, Australia Before-after study NCT01438229	Not applicable	No adherence during run-in No adherence during the study	Mean obs follow-up: 12 months	N screened not applicable N enrolled: 46	Manufact.	Ages <18 and >80; office SBP 160 mmHg (150 for type 2 diabetes); <3 antihypertensive medications; <1 diuretic; evidence of renal artery stenosis in either renal artery; multiple main arteries in either kidney; main renal arteries are <4mm in diameter; main renal arteries are <20mm in length; eGFR <45 mL/min/1.73m; type 1 diabetes; identified secondary cause of hypertension; chronic fibrillation/atrial flutter

Table 1. Characteristics of studies evaluating renal denervation devices (continued)

Author, year Country Study design Registered protocol	Run-in period	Adherence during the run-in and adherence during the study	Follow-up duration	Number screened/ enrolled	Funding source	Exclusion criteria
Persu, 2014[46] Europe Retrospective cohort No registered protocol	Not applicable	Adherence during the run-in not applicable Adherence during the study not applicable	Mean obs follow-up: 6 months	N screened not applicable N enrolled: 109	Not reported	----
Pokushalov, 2012[47] Not reported RCT NCT01117025	No	Adherence during run-in not applicable Adherence during the study not reported	RCT follow-up: 1 Year	N screened not reported N enrolled: 27	Manufact.	Blood pressure -160; <3 antihypertensive medications; does not have symptomatic drug-refractory AF (with history of failure of _>=2 class I or III antiarrhythmic drugs) in patients referred for catheter ablation of AF; does not have paroxysmal AF with _1 monthly episodes or Pers; AF in patients who had already undergone _3 electrical cardioversions; not on a diuretic; eGFR<45 ml/min/1.73 m2; secondary cause of hypertension; severe renal artery stenosis or dual renal arteries; CHF with NYHA functional class II to IV symptoms; left ventricular ejection fraction <35%; transverse left atrial diameter _>60 mm on transthoracic echocardiography; previous AF ablation procedure; treatment with amiodarone; previous renal artery stenting or angioplasty or type 1 diabetes
Poss, 2014[48] Europe Prospective cohort No registered protocol	No	Other adherence during run-in Other adherence during the study	Mean obs follow-up: 6 months	N screened not applicable N enrolled: 101	Manufact.	Ages <18; office SBP 160 mmHg; <3 antihypertensive medications; eGFR 45 ml/min/1.73 m^2; using a vitamin D supplement
Poss, 2015[49] Europe Before-after study No registered protocol	No	Adherence during run-in not applicable Adherence during the study not applicable	Mean obs follow-up: 6 months	N screened not reported N enrolled: 137	Govt./ non-profit Manufact.	Ages <18; SBP 140 mmHg; <3 antihypertensive medications; GFR < 15 ml/min/1.73 m; hemodialysis; <1 diuretic

Table 1. Characteristics of studies evaluating renal denervation devices (continued)

Author, year Country Study design Registered protocol	Run-in period	Adherence during the run-in and adherence during the study	Follow-up duration	Number screened/ enrolled	Funding source	Exclusion criteria
Prochnau, 2012[50] Not reported Before-after study No registered protocol	No	No adherence during run-in No adherence during the study	Mean obs follow-up: 12 months	N screened not applicable N enrolled: 30	Not reported	<4 antihypertensive medications
Prochnau, 2013[51] Europe Before-after study No registered protocol	No	No adherence during run-in No adherence during the study	Mean obs follow-up: 6 months	N screened not applicable N enrolled: 43	Not reported	AMP 140 mmHg--4-reversible causes of HTN; previous renal angioplasty
Ripp, 2015[52] Before-after study NCT01499810	Not applicable	Adherence during run-in not applicable No adherence during the study	Mean obs follow-up: 24 weeks	N screened not reported N enrolled 60	Not reported	Ages <18 and >80; <3 antihypertensive medications; OBP <160/100 mmHg; <1 diuretic; eGFR < 30 ml/min/1.73 m²; daily arterial blood pressure less than 135/85 mmHg according to 24-h monitoring; renal diseases; blood disorders; gastrointestinal diseases; neurological disorders; metabolic syndromes; other conditions with the signs of insufficiency of any system; symptomatic arterial hypertension; pregnancy or planned pregnancy during the period of observation; refusal to sign the informed consent form to enroll in the study
Rohla, 2016[53] Before-after study No registered protocol	Not applicable	Adherence during run-in not applicable No adherence during the study	Mean obs follow-up: 12 months	N screened not reported N enrolled 103	Govt./ non-profit	Ages <18; <3 antihypertensive medications; OSBP <160 mmHg (<150 mmHg in patients with diabetes); <1 diuretic; secondary causes of hypertension; pregnancy; eGFR <45 ml/min/1.73 m²; renal artery diameter <4 mm and a length <20 mm
Rosa, 2015[54] Europe RCT NCT01560312	No	Adherence during run-in not applicable Adherence during the study not reported	RCT follow-up: 6 months	N screened not reported N enrolled: 106	Govt./ non-profit	Blood pressure -140 mmHg; <3 antihypertensive medications; secondary hypertension; 24-hour ABPM (average systolic BP ,130 mm Hg); assessment of treatment compliance (quantitative plasma drugs level measurements)

Table 1. Characteristics of studies evaluating renal denervation devices (continued)

Author, year Country Study design Registered protocol	Run-in period	Adherence during the run-in and adherence during the study	Follow-up duration	Number screened/ enrolled	Funding source	Exclusion criteria
Scheurig-Muenkler, 2013[55] Europe Before-after study No registered protocol	Not applicable	Adherence during run-in not reported Adherence during the study not reported	Obs-duration – not reported	N screened not reported N enrolled: 53	Not reported	Implanted pacemakers or cardioverter defibrillators and a vessel diameter below 4 mm, assessed in pre-interventional computed tomography or magnetic resonance angiography
Schmid, 2013[56] Europe Before-after study NCT01687725	Not applicable	Adherence during run-in not reported Adherence during the study not reported	Mean obs follow-up: 6 months	N screened not reported N enrolled: 53	Not reported	Blood pressure <140; common and rare causes of secondary hypertension; drug-induced hypertension and obstructive sleep apnea; renal artery anatomy making the patient ineligible for treatment (main renal arteries <4 mm in diameter or <20 mm in length; hemodynamically or anatomically significant renal artery abnormality or stenosis [>50 %] in either renal artery)
Schmid, 2015[57] Europe Before-after study NCT 01442883	Not applicable	Adherence during run-in not applicable Adherence during the study not reported	Not reported Months	N screened: 89 N enrolled: 51	Manufact.	Blood pressure <140/90; <3 antihypertensive medications; true TRH (office systolic BP >/= 140/90 mmHg and 24-h ambulatory BP monitoring >/=130/80 mmHg; at least three antihypertensive drugs at maximum tolerated dose including one diuretic agent
Schneider, 2015[58] Europe RCT NCT01899456	No	Adherence during run-in not applicable Adherence during study: diary	RCT follow-up: 6 months	N screened: 109 N enrolled: 18	None	Ages <18 and >85; Blood pressure <140; <3 anti-hypertensive medications; have not had a renal transplant or were transplanted within the last 6 months; not on a diuretic; eGFR <= 30 mL/min/1.73 m2
Schwerg, 2014[59] Not reported Before-after study No registered protocol	Not applicable	Adherence during run-in not reported Adherence during the study not reported	Mean obs follow-up: 6 months	N screened not applicable N enrolled: 41		SBP 135 mmHg; <3 antihypertensive medications; pseudo resistance; secondary causes of hypertension; history of renal stenting or nephrectomy; eGFR < 50 ml/min/1.73 m^2

Table 1. Characteristics of studies evaluating renal denervation devices (continued)

Author, year Country Study design Registered protocol	Run-in period	Adherence during the run-in and adherence during the study	Follow-up duration	Number screened/ enrolled	Funding source	Exclusion criteria
Sharp, 2015[60] Not reported Before-after study No registered protocol	Not applicable	Adherence during run-in not reported Adherence during the study not reported	Mean obs follow-up: 10 months	N screened not applicable N enrolled: 246	Not reported	----
Sharp, 2016[61] Before-after study No registered protocol	Not applicable	Adherence during run-in not applicable No adherence during the study	Mean obs follow-up: 11 months	N screened not reported N enrolled 253	None	<3 antihypertensive medications; OSBP < 160 and systolic ASBP <150; white-coat or secondary hypertension; patient selection by multidisciplinary teams of hypertension specialists and interventionists
Sievert, 2015[62] Europe, Australia, New Zealand Before-after study No registered protocol	No	Adherence during run-in not reported Adherence during the study not reported	Mean obs follow-up: 6 months	N screened not reported N enrolled: 146	Manufact.	Ages <18 and >75; OSBP 160 and ODBP 90 mmHg; <3 antihypertensive medications; no changes to antihypertensive medication regimen within 2 weeks prior to enrollment; eGFR < 45 ml/min/1.73 m^2; secondary hypertension; contraindication for intravascular contrast material or medications required for an interventional procedure; bleeding or hyper coagulation disorders; type 1 diabetes; myocardial infarction, unstable angina pectoris, uncompensated heart failure, or cerebrovascular accident within 6 months prior to screening; widespread atherosclerosis with documented intravascular thrombosis or unstable plaques; hemodynamically significant valvular heart disease for which reduction of BP would be considered hazardous; implantable cardioverter defibrillator or pacemaker or a clinically significant abnormal electrocardiogram at time of screening; pregnant, nursing or planning to become pregnant; currently taking oestrogen or any oestrogen like compound

Table 1. Characteristics of studies evaluating renal denervation devices (continued)

Author, year Country Study design Registered protocol	Run-in period	Adherence during the run-in and adherence during the study	Follow-up duration	Number screened/ enrolled	Funding source	Exclusion criteria
Symplicity, 2010[63] Worldwide RCT NCT00888433	Yes run-in	Adherence during run-in: diary Adherence during the study: diary	RCT follow-up: 36 months	N screened: 190 N enrolled: 106	Manufact.	Ages <18 and >85; 160 mmHg (or 150 mmHg for patients with type 2 diabetes); <3 antihypertensive medications; eGFR < 45 mL/min/1.73 m2; type 1 diabetes; contraindications to MRI; substantial stenotic valvular heart disease; pregnancy or planned pregnancy during the study; history of myocardial infarction, unstable angina, or cerebrovascular accident in previous 6 months; hemodynamically significant renal artery stenosis, previous renal artery intervention, or renal artery anatomy that precluded treatment
Symplicity, 2011[64] Europe, Australia, United States Before-after study No registered protocol	Not applicable	Adherence not reported	Mean obs follow-up: 24 months	N screened not applicable N enrolled: 153	Manufact.	Ages <18; SBP <160 mmHg; <3 antihypertensive medications; <1 diuretic; eGFR <45 ml/min/1.73 m^2; type 1 diabetes mellitus; secondary cause of hypertension; significant renovascular abnormalities
Tiroch, 2015[65] Before-after study NCT01875809	Not applicable	Adherence during run-in not applicable No adherence during the study	Mean obs follow-up: 6 months	N screened: 53 N enrolled: 50	Not reported	Ages <18 and >85; <3 antihypertensive medications; SBP <160 mmHg; <1 diuretic; renal artery stenosis; solitary kidney; obstructive sleep apnea; thyroid disorders; elevated cotrisol levels; elevated aldosterone/renin ratio; acromegaly; elevated plasma metanephrine; anaemia; extensive use of alcohol, drugs**;** extensive use of liquorice or NSAIDS
Tsioufis, 2015[66] Europe, Australia Prospective cohort NCT01438229	No	No adherence during run-in No adherence during the study	Mean obs follow-up: 6 months	N screened not applicable N enrolled: 31	St. Jude Medical Inc.	Ages <18 and >80; office SBP 160 mmHg; <3 antihypertensive medications; -<1 diuretic; evidence of renal artery stenosis in either renal artery; multiple main renal arteries in either kidney; main renal arteries diameter <4mm; main renal arteries length <20mm; eGFR of < 45mL/min/1.73m; type 1 diabetes; identified secondary cause of hypertension; chronic atrial fibrillation/atrial flutter

Table 1. Characteristics of studies evaluating renal denervation devices (continued)

Author, year Country Study design Registered protocol	Run-in period	Adherence during the run-in and adherence during the study	Follow-up duration	Number screened/ enrolled	Funding source	Exclusion criteria
Tsioufis, 2015[67] Not reported Other study design NCT01438229	Not applicable	No adherence during run-in No adherence during the study	Mean obs follow-up: 24 months	N screened not applicable N enrolled: 46	St. Jude Medical Center	Ages <18 and >80; office SBP <160 mmHg; <3 anti-hypertensive medications; <1 diuretic; evidence of renal artery stenosis; multiple main renal arteries in either kidney; renal artery diameter <4mm; renal artery length <20mm; eGFR <45 mL/min/1,73m; type 1 diabetes; identified secondary causes of hypertension; chronic atrial fibrillation/atrial flutter
Tsioufis, 2015[68] Europe, Australia Prospective cohort NCT01438229	Not applicable	No adherence during run-in No adherence during the study	Mean obs follow-up: 6 months	N screened not applicable N enrolled: 30	St. Jude Medical Inc.	Ages <18 and >80; office SBP 160 mmHg; <3 antihypertensive medications; -<1 diuretic; evidence of renal artery stenosis in either renal artery; multiple renal arteries in either kidney; main renal arteries are <4mm diameter; renal arteries are <20mm in length; eGFR <45mL/min/1.73m; type 1 diabetes; identified secondary cause of hypertension; chronic atrial fibrillation/atrial flutter
Tsioufis, 2015[69] Europe, Australia Other study design NCT01438229	Not applicable	No adherence during run-in No adherence during the study	Mean obs follow-up: 24 months	N screened not applicable N enrolled: 46	St. Jude Medical Inc.	Ages <18 and >80; office SBP 160 mmHg; <3 antihypertensive medications; evidence of renal artery stenosis in either renal artery; multiple renal arteries in either kidney; renal artery diameter <4mm; renal artery length <20mm; eGFR <45 mL/min/1.73m; type 1 diabetes; identified secondary cause of hypertension; chronic atrial fibrillation/atrial flutter
van Brussel, 2015[70] Europe Before-after study No registered protocol	Yes run-in	Adherence during run-in not reported Adherence during the study not reported	Mean obs follow-up: 6 weeks	N screened not applicable N enrolled: 21	Govt./ non-profit	Ages <40 and >70: Blood pressure 150/100; <3 anti-hypertensive medications; Secondary causes of hypertension; abnormal renal artery anatomy; renal insufficiency (eGFR<45); proteinuria (?1 g/24 h); Pacemaker; Implantable cardiac defibrillator; fibrillation; type 1 diabetes
Verheye, 2015[71] Europe, New Zealand Before-after study NCT01520506	Not applicable	No adherence during run-in Other adherence during the study	Mean obs follow-up: 12 months	N screened not applicable N enrolled: 50	Manufact.	Ages <18 and >85; SBP 160 mmHg; <3antihypertensive medications; <1 diuretic; unstable antihypertensive regimen 14 days prior to enrollment; renal artery diameter <4mm <7mm; renal artery length <20mm; ESRD; eGFR <45 ml/min/1.73 m^2; type 1 diabetes mellitus; bleeding disorders; myocardial infarction, unstable angina, coronary events or stroke within six months of the treatment; serious renal abnormalities including severe renal artery stenosis; evidence of prior renal stenting; more than one main renal artery

Table 1. Characteristics of studies evaluating renal denervation devices (continued)

Author, year Country Study design Registered protocol	Run-in period	Adherence during the run-in and adherence during the study	Follow-up duration	Number screened/ enrolled	Funding source	Exclusion criteria
Verloop, 2014[72] Europe Before-after study No registered protocol	No	No adherence during run-in No adherence during the study	Mean obs follow-up: 6 months	N screened not reported N enrolled: 69	Not reported	OSBP <160 mmHg; <3 antihypertensive medications; eGFR <30 ml/min/1.73 m^2; severe comorbidity; renal artery diameter < 4mm; renal artery length < 20mm; renal artery stenting or stenosis
Verloop, 2015[73] Not reported Before-after study NCT01465724	Not applicable	Adherence during run-in not reported No adherence during the study	Mean obs follow-up: 12 months	N screened not reported N enrolled: 29	Manufact.	Ages <18; SBP 130 mmHg; high fasting glucose <5.6 mmol/L; <1 antidiabetic or 1 antihypertensive drug at baseline
Verloop, 2015[74] Not reported Before-after study NCT01427049	Not applicable	Adherence during run-in not reported Adherence during the study not reported	Mean bs follow-up: 12 months	N screened not applicable N enrolled: 46	Govt./ non-profit	SBP 160 mmHg; <3 antihypertensive medications; eGFR <30 ml/min/1.73 m^2; secondary causes of hypertension; history of renal artery stenting
Vink, 2014[75] Europe Before-after study No registered protocol	Not applicable	Adherence during run-in not reported Adherence during the study not reported	Mean obs follow-up: 6 months	N screened not applicable N enrolled: 67	Not reported	SBP 160 mmHg; <3 antihypertensive medications; eGFR < 30 ml/min/1.73 m^2; secondary causes of hypertension; history of renal artery stenting or severe comorbidity
Vink, 2015[76] Not reported Before-after study NCT01427049	No	No adherence during run-in No adherence during the study	Mean obs follow-up: 12 months	N screened not reported N enrolled: 46	Manufact.	SBP <160 mmHg; <3 antihypertensive medications; eGFR < 30 ml/min/1.73 m^2; secondary causes of hypertension; history of renal artery stenting; severe comorbidity
Vogel, 2014[77] Europe Before-after study No registered protocol	No	No adherence during run-in Adherence during the study not reported	Mean obs follow-up: 12 months	N screened not reported N enrolled: 63	Not reported	Blood pressure -160 or 150 mmHg in diabetics; <3 antihypertensive medications

Table 1. Characteristics of studies evaluating renal denervation devices (continued)

Author, year Country Study design Registered protocol	Run-in period	Adherence during the run-in and adherence during the study	Follow-up duration	Number screened/ enrolled	Funding source	Exclusion criteria
Volz, 2014[78] Sweden Non-randomized trial No registered protocol	No	No adherence during run-in No adherence during the study	Mean obs follow-up: 6.7 months	N screened: 60 N enrolled: 38	Not reported	<3 antihypertensive medications; Secondary form of hypertension; OBP < 140/90 mmHg in the sitting position; ABPM < 135/85 mmHg; hemodynamically significant valve disease; significant renal dysfunction (eGFR < 45 ml/min/1,73m); lack of drug compliance; diabetes type 1; previously being subject to renal artery or abdominal aortic stenting
Whitbourn, 2015[79] Australia Before-after study NCT01699529	No	No adherence during run-in No adherence during the study	Mean obs follow-up: 12 months	N screened not applicable N enrolled: 50	Manufact.	OSBP < 160 mmHg; <3 antihypertensive medications; eGFR < 45 mL/min/1.73 m; type 1 diabetes; renal artery stenosis of >50%; renal artery aneurysm; prior renal artery intervention; artery length < 22mm
Worthley, 2013[80] Europe, Australia Before-after study NCT01438229	Yes run-in	No adherence during run-in No adherence during the study	Mean obs follow-up: 6 months	N screened: 62 N enrolled: 47	Manufact.	Ages <18 and >80; OSBP 160 mmHg; <3 antihypertensive medications; <1 diuretic; evidence of renal stenosis; multiple main renal arteries in either kidney; main renal artery diameter <4mmmain renal artery length <20mm; eGFR < 45 ml/min/1.73m^2; type 1 diabetes; identified secondary cause of hypertension; chronic atrial fibrillation/atrial flutter
Worthley, 2015[81] Europe, Australia Other study design NCT01438229	No	Adherence during run-in not reported Adherence during the study not reported	Mean obs follow-up: 6 months	N screened: 62 N enrolled: 40	St. Jude Medical Inc.	Ages <18 and >80; office SBP 160 mmHg; <3 antihypertensive medications; <1 diuretic; evidence of renal artery stenosis in either renal artery; multiple renal arteries in either kidney; main renal artery diameter <4mm; main renal artery length <20mm; eGFR < 45 mL/min/1.73m; type 1 diabetes; identified secondary cause of hypertension; chronic atrial fibrillation/atrial flutter
Zhang, 2014[82] China Case-control No registered protocol	No	No adherence during run-in No adherence during the study	Mean obs follow-up: 12 months	N screened not reported N enrolled: 81	Govt./ non-profit	Ages <18; OSBP 160 mmHg; <3 antihypertensive medications; <1 diuretic; secondary hypertension; type 1 diabetes; multiple renal arteries with diameter <4mm; renal artery length of <20mm; dual renal artery systems; renal artery stenosis >50% or patients who had received renal artery balloon angioplasty or stenting; eGFR <45 ml/min/1.73m^2

Table 1. Characteristics of studies evaluating renal denervation devices (continued)

Author, year Country Study design Registered protocol	Run-in period	Adherence during the run-in and adherence during the study	Follow-up duration	Number screened/ enrolled	Funding source	Exclusion criteria
Zuern, 2013[83] Not reported Before-after study No registered protocol	No	No adherence during run-in No adherence during the study	Mean obs follow-up: 6 months	N screened not reported N enrolled: 50	Not reported	Ages <18; OSBP 160 mmHg; <3 antihypertensive medications with no changes in medication for a minimum of 2 weeks before enrollment; eGFR <45 ml/min/1.73m^2; secondary cause of hypertension other than sleep apnea or chronic kidney disease

ABPM = ambulatory blood pressure monitor; AF = atrial fibrillation; BP = blood pressure; CHF = congestive heart failure; CT = computed tomography; CV = cardiovascular; eGFR = estimated glomerular filtration rate; ESRD = End Stage Renal Disease; Govt. = government; hr = hour; HTN = hypertension; m = meters; manufact. = manufacturer; min = minute; mL = milliliters; mm = millimeters; mmHg = millimeter of mercury; mmol/L = millimoles per litre; MRI = magnetic resonance imaging; N = total population; NYHA = New York Heart Association; OBP = office blood pressure; obs = observation; RCT = randomized controlled trial; RDN = renal denervation; RSD = reflex sympathetic dystrophy

Table 2. Population characteristics of studies evaluating renal denervation devices

Author, year	Intervention	Total N	Mean age	Male, %	Race, %	Mean BMI	Mean eGFR/serum creatinine	CKD stages	DM, % and LVH, %	Mean # of medications and diuretics, %
Azizi, 2015[1]	Renal denervation	53	55.2	64.2	Caucasian: 79.2	30.7	Mean eGFR: 88	CKD stages not reported	DM, %: 17 LVH not reported	Diuretics, %: 100
Azizi, 2015[1]	Continuation of anti-hypertensive drugs	53	55.2	60.4	Caucasian: 77.4	29.7	Mean eGFR: 90	CKD stages not reported	DM, %: 26.4 LVH not reported	Diuretics, %: 100
Bhatt, 2014[2]	Renal denervation	364	57.9	59.1	African American: 24.8 Caucasian: 73 Other race: 2.3	34.2	Kidney function not reported	CKD stages not reported	DM, %: 47 LVH not reported	Mean # of BP meds: 5.1 Diuretics, %: 99.7
Bhatt, 2014[2]	Sham procedure	171	56.2	64.3	African American: 29.2 Caucasian: 69.6 Other race: 1.2	33.9	Kidney function not reported	CKD stages not reported	DM, %: 40.9 LVH not reported	Mean # of BP meds: 5.2 Diuretics, %: 100
Bohm, 2015[3]	Renal denervation	998	61	59.9	Race/ethnicity not reported	30.6	Kidney function not reported	CKD stages not reported	DM, %: 41.40% LVH, %: 17.10%	Mean # of BP meds: 4.5 Diuretics, %: 80.1
Burchell, 2016[4]	Renal denervation	29	55.4	48	Race/ethnicity not reported	30.2	Mean eGFR: 74	CKD stages not reported	DM, %: 17 LVH not reported	Mean # of BP meds: 5.2 Diuretics, %: 76
de Sousa Almeida, 2016[5]	Renal denervation	31	65	48.4	Caucasian: 100	31.8	Mean eGFR: 76.4	CKD stages not reported	DM, %: 71 LVH, %: 87	Mean # of BP meds: 5.8 Diuretics, %: 87.1
Desch, 2015[6]	Renal denervation	35	64.5	77	Race/ethnicity not reported	31.9	Mean eGFR: 79	CKD stages not reported	DM, %: 54 LVH not reported	Mean # of BP meds: 4.4
Desch, 2015[6]	Sham procedure	36	57.4	69	Race/ethnicity not reported	31.2	Mean eGFR: 84	CKD stages not reported	DM, %: 36 LVH not reported	Mean # of BP meds: 4.3
Dorr, 2013[7]	Renal denervation	62	67.8	51.6		29.3	Kidney function not reported	CKD stages not reported	Diabetes status not reported LVH not reported	Mean # of BP meds: 5.4

Table 2. Population characteristics of studies evaluating renal denervation devices (continued)

Author, year	Intervention	Total N	Mean age	Male, %	Race, %	Mean BMI	Mean eGFR/serum creatinine	CKD stages	DM, % and LVH, %	Mean # of medications and diuretics, %
Dorr, 2015[8]	Renal denervation	150	64.9	71.2	Race/ethnicity not reported	BMI not reported	Kidney function not reported	CKD stages not reported	DM, %: 35 LVH not reported	Mean # of BP meds: 4.9 Diuretics, %: 97
Dorr, 2015[9]	Renal denervation	100	65.4	57	Race/ethnicity not reported	BMI not reported	Kidney function not reported	CKD stages not reported	DM, %: 40 LVH not reported	Mean # of BP meds: 5.2 Diuretics, %: 99
Dorr, 2015[10]	Renal denervation	60	67.9	62	Race/ethnicity not reported	28.7	Kidney function not reported	CKD stages not reported	DM, %: 42 LVH not reported	Mean # of BP meds: 5.3 Diuretics, %: 93
Eikelis, 2015[11]	Renal denervation	69	69	65	Race/ethnicity not reported	32.2	Kidney function not reported	CKD stages not reported	Diabetes status not reported LVH not reported	Mean # of BP meds: 4.6
Ewen, 2014[12]	Renal denervation	50	64.7	77	Race/ethnicity not reported	30.7	Kidney function not reported	CKD stages not reported	DM, %: 50 LVH not reported	Mean # of BP meds: 5.1 Diuretics, %: 84
Ewen, 2014[12]	Unspecified	10	68.4	80	Race/ethnicity not reported	28.6	Kidney function not reported	CKD stages not reported	DM, %: 30 LVH not reported	Mean # of BP meds: 4 Diuretics, %: 50
Ewen, 2015[13]	Renal denervation	100	62.7	67	Race/ethnicity not reported	30.8	Mean kidney function: 74.5	CKD stages not reported	DM, %: 44 LVH not reported	Mean # of BP meds: 5.2 Diuretics, %: 86
Ewen, 2015[14]	Renal denervation	126	66.7	55	Race/ethnicity not reported	29.5	Mean eGFR: 68.5	CKD stages not reported	DM, %: 40 LVH not reported	Mean # of BP meds: 5.1 Diuretics, %: 92
Ewen, 2015[15]	Renal denervation	30	61.9	60	Race/ethnicity not reported	30.4	Mean eGFR: 59	CKD stages not reported	DM, %: 32 LVH not reported	Mean # of BP meds: 5 Diuretics, %: 92
Ewen, 2015[16]	Renal denervation	84	65	73	Race/ethnicity not reported	31	Kidney function not reported	CKD stages not reported	DM, %: 37 LVH not reported	Mean # of BP meds: 5 Diuretics, %: 86
Fadl Elmula, 2014[17]	Renal denervation	9	57	78	Race/ethnicity not reported	29	Kidney function not reported	CKD stages not reported	DM, %: 22 LVH, %: 56	Mean # of BP meds: 5.1 Diuretics, %: 100

Table 2. Population characteristics of studies evaluating renal denervation devices (continued)

Author, year	Intervention	Total N	Mean age	Male, %	Race, %	Mean BMI	Mean eGFR/serum creatinine	CKD stages	DM, % and LVH, %	Mean # of medications and diuretics, %
Fadl Elmula, 2014[17]	Continuation of anti-hypertensive drugs	10	62.7	100	Race/ethnicity not reported	30	Kidney function not reported	CKD stages not reported	DM, %: 30 LVH, %: 60	Mean # of BP meds: 5 Diuretics, %: 100
Hameed, 2015[18]	Renal denervation	34	56	58.8	African American: 14.7 Caucasian: 82.4 Other race: 2.9	32.2	Mean serum creatinine: 90	CKD stage 2, %: 64.7 CKD stage 3, %: 26.5 CKD stage 4, %: 8.8	DM, %: 26.5 LVH not reported	Mean # of BP meds: 4.5 Diuretics, %: 91.2
Hamza, 2014[19]	Renal denervation	55	58	69	Race/ethnicity not reported	28.9	Kidney function not reported	CKD stages not reported	DM, %: 40 LVH not reported	Mean # of BP meds: 3.95 Diuretics, %: 100
Hering, 2015[20]	Renal denervation	65	63	63	Race/ethnicity not reported	31	Mean eGFR: 72	CKD stages not reported	DM, %: 37 LVH not reported	Mean # of BP meds: 4.5 Diuretics, %: 72
Hering, 2015[20]	Renal denervation	16	63	75	Race/ethnicity not reported	31	Mean eGFR: 71	CKD stages not reported	DM, %: 44 LVH not reported	Mean # of BP meds: 4.6 Diuretics, %: 81
Hering, 2015[20]	Renal denervation	10	67	40	Race/ethnicity not reported	31	Mean eGFR: 71	CKD stages not reported	DM, %: 10 LVH not reported	Mean # of BP meds: 4.9 Diuretics, %: 70
Honarvar, 2013[21]	Renal denervation	30	52	56.7	Race/ethnicity not reported	30.6	Kidney function not reported	CKD stages not reported	DM, %: 17.7 LVH not reported	Mean # of BP meds: 3.6 Diuretics, %: 63.3
Id, 2015[22]	Renal denervation	101	62.8	60.4	Race/ethnicity not reported	30.6	Mean eGFR: 71.1	CKD stages not reported	DM, %: 32.4 LVH not reported	Mean # of BP meds: 4.2 Diuretics, %: 82.4
Kaiser, 2014[23]	Renal denervation	93	68	45	Race/ethnicity not reported	BMI not reported	Mean kidney function: 71	CKD Stage 3, %: 1 CKD Stage 4, %: 3	DM, %: 47 LVH not reported	Diuretics, %: 83
Kario, 2015[24]	Renal denervation	22	59.5	68.2	Race/ethnicity not reported	27	Kidney function not reported	CKD stage 3, %: 4.5	DM, %: 36.4 LVH not reported	Mean # of BP meds: 4.9 Diuretics, %: 100

Table 2. Population characteristics of studies evaluating renal denervation devices (continued)

Author, year	Intervention	Total N	Mean age	Male, %	Race, %	Mean BMI	Mean eGFR/serum creatinine	CKD stages	DM, % and LVH, %	Mean # of medications and diuretics, %
Kario, 2015[24]	Continuation of anti-hypertensive drugs	19	56	84.2	Race/ethnicity not reported	28	Kidney function not reported	CKD stage 3, %: 15.8	DM, %: 63.2 LVH not reported	Mean # of BP meds: 4.9 Diuretics, %: 100
Kim, 2015[25]	Renal denervation	93	55.9	72	Race/ethnicity not reported	27.5	Mean eGFR: 88.9	CKD stages not reported	DM, %: 46.2 LVH not reported	Mean # of BP meds: 3.7 Diuretics, %: 83.9
Kim, 2015[25]	Renal denervation	169	61.8	62.7	Race/ethnicity not reported	31.2	Mean eGFR: 80.9	CKD stages not reported	DM, %: 36.3 LVH not reported	Mean # of BP meds: 4.7 Diuretics, %: 78.1
Kiuchi, 2014[26]	Renal denervation	27	54.8	40.7	Caucasian: 70.4	31.4	Mean eGFR: 62.2	CKD stage 2, %: 66.7 CKD stage 3, %: 14.8 CKD stage 4, %: 18.5	DM, %: 37 LVH not reported	Mean # of BP meds: 4.6 Diuretics, %: 100
Kiuchi, 2015[27]	Renal denervation	30	55	43	Other race: 70	30.8	Mean eGFR: 61.9	CKD stage 2, %: 63 CKD stage 3, %: 20 CKD stage 4, %: 17	DM, %: 37 LVH not reported	Mean # of BP meds: 4.6
Kiuchi, 2015[28]	Renal denervation	30	55	43	Caucasian: 30 Other race: 70	30.8	Mean eGFR: 61.9	CKD stage 2, %: 63 CKD stage 3, %: 20 CKd stage 4, %: 17	DM, %: 37 LVH not reported	Mean # of BP meds: 4.6 Diuretics, %: 100
Krum, 2014[29]	Renal denervation	150	57.1	62	Caucasian: 95 Other race: 5	BMI not reported	Mean eGFR: 83.4	CKD stages not reported	DM, %: 31 LVH not reported	Mean # of BP meds: 5 Diuretics, %: 92
Kyvelou, 2013[30]	Renal denervation	31	45	Male not reported	African American: 3 Caucasian: 97	BMI not reported	Mean serum creatinine: 91	CKD stages not reported	Diabetes status not reported LVH not reported	Medication use not reported

Table 2. Population characteristics of studies evaluating renal denervation devices (continued)

Author, year	Intervention	Total N	Mean age	Male, %	Race, %	Mean BMI	Mean eGFR/serum creatinine	CKD stages	DM, % and LVH, %	Mean # of medications and diuretics, %
Lambert, 2012[31]	Renal denervation	62	61.9	65	Race/ethnicity not reported	31.9	Kidney function not reported	CKD stages not reported	Diabetes status not reported LVH not reported	Mean # of BP meds: 4.8
Lambert, 2012[31]	Un-medicated normotensive subjects	63	62	63	Race/ethnicity not reported	30.8	Kidney function not reported	CKD stages not reported	Diabetes status not reported LVH not reported	Mean # of BP meds: 0
Lambert, 2012[31]	Hypertensive patient data	68	65.4	68	Race/ethnicity not reported	31.6	Kidney function not reported	CKD stages not reported	Diabetes status not reported LVH not reported	Mean # of BP meds: 1.3
Lambert, 2014[32]	Renal denervation	81	Age not reported	59.3	Race/ethnicity not reported	BMI not reported	Mean eGFR: 80.5	CKD stages not reported	DM, %: 100 LVH not reported	Diuretics, %: 100
Lambert, 2015[33]	Renal denervation	76	64	57	Race/ethnicity not reported	BMI not reported	Kidney function not reported	CKD stages not reported	DM, %: 30 LVH not reported	Medication use not reported
Lambert, 2015[34]	Renal denervation	32	Age not reported	53.1	Race/ethnicity not reported	BMI not reported	Kidney function not reported	CKD stages not reported	DM, %: 28.1 LVH not reported	Medication use not reported
Lambert, 2015[35]	Renal denervation	97	64	61	Race/ethnicity not reported	31.1	Mean eGFR: 70	CKD stages not reported	Diabetes status not reported LVH not reported	Mean # of BP meds: 5
Lambert, 2015[36]	Renal denervation	106	Age not reported	58.5	Race/ethnicity not reported	BMI not reported	Mean eGFR: 79.6	CKD stages not reported	DM, %: 25.5 LVH not reported	Medication use not reported
Lenski, 2013[37]	Renal denervation	119	61.8	55	Race/ethnicity not reported	30.3	Mean kidney function: 78.2	CKD stages not reported	DM, %: 40.3 LVH, %: 21.8	Mean # of BP meds: 5.7
Lenski, 2013[38]	Renal denervation	36	65	75	Race/ethnicity not reported	30.2	Mean kidney function: 75.2	CKD stages not reported	DM, %: 56 LVH not reported	Mean # of BP meds: 4.8

Table 2. Population characteristics of studies evaluating renal denervation devices (continued)

Author, year	Intervention	Total N	Mean age	Male, %	Race, %	Mean BMI	Mean eGFR/serum creatinine	CKD stages	DM, % and LVH, %	Mean # of medications and diuretics, %
Lobo, 2015[39]	Renal denervation	129	62	Male not reported	Race/ethnicity not reported	BMI not reported	Kidney function measure: eGFR	CKD stages not reported	Diabetes status not reported LVH not reported	Mean # of BP meds: 4.22
Ott, 2013[40]	Renal denervation	54	63.6	70	Race/ethnicity not reported	31.1	Mean kidney function: 69.5	CKD stages not reported	DM, %: 50 LVH not reported	Mean # of BP meds: 5.1
Ott, 2014[41]	Renal denervation	59	63	69	Race/ethnicity not reported	31.6	Mean kidney function: 67.2	CKD stages not reported	DM, %: 53 LVH not reported	Mean # of BP meds: 5.5
Ott, 2015[42]	Renal denervation	63	Age not reported	71	Race/ethnicity not reported	BMI not reported	Kidney function not reported	CKD stages not reported	DM, %: 44 LVH not reported	Medication use not reported
Ott, 2015[43]	Renal denervation	27	63.4	81	Race/ethnicity not reported	31.2	Mean kidney function: 48.5	CKD stages not reported	DM, %: 56 LVH not reported	Mean # of BP meds: 6.2
Ott, 2015[44]	Renal denervation	51	59.1	71	Race/ethnicity not reported	31.2	Kidney function measure: eGFR	CKD stages not reported	DM, %: 43 LVH not reported	Mean # of BP meds: 5.7
Papademetriou, 2014[45]	Renal denervation	46	60	67	Caucasian: 98	32	Mean eGFR: 87	CKD stages not reported	DM, %: 33 LVH not reported	Mean # of BP meds: 4.7 Diuretics, %: 98
Persu, 2014[46]	Renal denervation	21	58.9	28.6	Race/ethnicity not reported	27.5	Mean eGFR: 80.9	CKD stages not reported	DM, %: 14.3 LVH not reported	Mean # of BP meds: 4.2
Persu, 2014[46]	Renal denervation	22	62	63.6	Race/ethnicity not reported	27.7	Mean eGFR: 66.5	CKD stages not reported	DM, %: 13.6 LVH not reported	Mean # of BP meds: 4.7
Pokushalov, 2012[47]	Renal denervation pulmonary vein isolation	13	57	85	Race/ethnicity not reported	28	Mean eGFR: 78	CKD stages not reported	DM, %: 7.7 LVH not reported	Mean # of BP meds: 3.8 Diuretics, %: 100

Table 2. Population characteristics of studies evaluating renal denervation devices (continued)

Author, year	Intervention	Total N	Mean age	Male, %	Race, %	Mean BMI	Mean eGFR/serum creatinine	CKD stages	DM, % and LVH, %	Mean # of medications and diuretics, %
Pokushalov, 2012[47]	Pulmonary vein isolation	14	56	71	Race/ethnicity not reported	28	Mean eGFR: 80.2	CKD stages not reported	DM, %: 14.2 LVH not reported	Mean # of BP meds: 3.6 Diuretics, %: 92
Poss, 2014[48]	Renal denervation	101	61.9	58.3	Race/ethnicity not reported	31	Mean kidney function: 82.7	CKD stages not reported	DM, %: 38.8 LVH not reported	Mean # of BP meds: 5.3
Poss, 2015[49]	Renal denervation	137	63	63	Race/ethnicity not reported	30.4	Kidney function not reported	CKD stages not reported	DM, %: 39 LVH not reported	Mean # of BP meds: 5.2
Prochnau, 2012[50]	Renal denervation	30	62.4	67	Race/ethnicity not reported	32.4	Kidney function not reported	CKD stages not reported	DM, %: 50 LVH not reported	Mean # of BP meds: 6
Prochnau, 2013[51]	Renal denervation	43	63	63	Race/ethnicity not reported	31.5	Mean eGFR: 67.3	CKD stages not reported	DM, %: 51 LVH not reported	Mean # of BP meds: 5.8
Ripp, 2015[52]	Renal denervation	60	Age not reported	Male not reported	Race/ethnicity not reported	BMI not reported	Kidney function not reported	CKD stages not reported	Diabetes status not reported LVH not reported	Medication use not reported
Rohla, 2016[53]	Renal denervation	103	63	56	Race/ethnicity not reported	BMI not reported	Kidney function not reported	CKD stages not reported	DM, %: 23 LVH not reported	Mean # of BP meds: 4.1 Diuretics, %: 86
Rosa, 2015[54]	Renal denervation	52	56	77	Race/ethnicity not reported	31.2	Mean serum creatinine: 87	CKD stages not reported	DM, %: 22 LVH not reported	Mean # of BP meds: 5.1
Rosa, 2015[54]	Continuation of anti-hypertensive drugs	54	59	63	Race/ethnicity not reported	33.4	Mean serum creatinine: 84	CKD stages not reported	DM, %: 17 LVH not reported	Mean # of BP meds: 5.4
Scheurig-Muenkler, 2013[55]	Renal denervation	53	59	66	Race/ethnicity not reported	30.5	Mean eGFR: 76.4	CKD stages not reported	DM, %: 23 LVH not reported	Medication use not reported
Schmid, 2013[56]	Renal denervation	53	Age not reported	77	Race/ethnicity not reported	BMI not reported	Kidney function not reported	CKD stages not reported	Diabetes status not reported LVH not reported	Medication use not reported

Table 2. Population characteristics of studies evaluating renal denervation devices (continued)

Author, year	Intervention	Total N	Mean age	Male, %	Race, %	Mean BMI	Mean eGFR/serum creatinine	CKD stages	DM, % and LVH, %	Mean # of medications and diuretics, %
Schmid, 2015[57]	Renal denervation	51	61.3	76	Race/ethnicity not reported	30.8	Mean eGFR: 73.5	CKD stages not reported	DM, %: 76 LVH not reported	Mean # of BP meds: 5.9
Schneider, 2015[58]	Renal denervation	9	62	78	Caucasian: 89 Other race: 11	31	Mean eGFR: 40.8	CKD stages not reported	DM, %: 89 LVH not reported	Mean # of BP meds: 5.1 Diuretics, %: 100
Schneider, 2015[58]	Continuation of anti-hypertensive drugs	9	60	89	Caucasian: 89 Other race: 11	33	Mean eGFR: 42	CKD stages not reported	DM, %: 33 LVH not reported	Mean # of BP meds: 4.3 Diuretics, %: 89
Schwerg, 2014[59]	Renal denervation	40	63	60	Race/ethnicity not reported	30	Mean kidney function: 96	CKD stages not reported	DM, %: 35 LVH not reported	Mean # of BP meds: 5
Sharp, 2015[60]	Renal denervation	246	56.7	13	Caucasian: 87	BMI not reported	Kidney function not reported	CKD stages not reported	DM, %: 27 LVH not reported	Mean # of BP meds: 4.7
Sharp, 2016[61]	Renal denervation	253	57	47	Caucasian: 88.1	32	Mean eGFR: 69	CKD stages not reported	DM, %: 26.5 LVH not reported	Mean # of BP meds: 5 Diuretics, %: 95
Sievert, 2015[62]	Renal denervation	146	58.6	61	Race/ethnicity not reported	BMI not reported	Mean serum creatinine: 82	CKD stages not reported	DM, %: 28.1 LVH not reported	Mean # of BP meds: 5.3
Symplicity, 2010[63]	Renal denervation	52	58	65	Caucasian: 98	31	Mean eGFR: 77	CKD stage 3, %: 21	DM, %: 40 LVH not reported	Mean # of BP meds: 5.2 Diuretics, %: 89
Symplicity, 2010[63]	Unspecified, but allowed to crossover to RDN after 6 months	54	58	50	Caucasian: 96	31	Mean eGFR: 86	CKD stage 3, %: 11	DM, %: 28 LVH not reported	Mean # of BP meds: 5.3 Diuretics, %: 91
Symplicity, 2011[64]	Renal denervation	153	57	61	Race/ethnicity not reported	BMI not reported	Mean eGFR: 83	CKD stages not reported	DM, %: 31 LVH not reported	Mean # of BP meds: 5.1

Table 2. Population characteristics of studies evaluating renal denervation devices (continued)

Author, year	Intervention	Total N	Mean age	Male, %	Race, %	Mean BMI	Mean eGFR/serum creatinine	CKD stages	DM, % and LVH, %	Mean # of medications and diuretics, %
Tiroch, 2015[65]	Renal denervation	46	65.3	50	Race/ethnicity not reported	32	eGFR: 69	CKD stages not reported	DM, %: 41 LVH not reported	Mean # of BP meds: 5.1 Diuretics, %: 100
Tsioufis, 2015[66]	Renal denervation	31	61.1	61.3	Race/ethnicity not reported	32	Kidney function not reported	CKD stages not reported	DM, %: 35.5 LVH not reported	Mean # of BP meds: 4.5
Tsioufis, 2015[66]	No-renal denervation	12	58	66.7	Race/ethnicity not reported	33.5	Kidney function not reported	CKD stages not reported	DM, %: 25 LVH not reported	Mean # of BP meds: 4.2
Tsioufis, 2015[67]	Renal denervation	46	60	67	Caucasian: 98	32	Mean Kidney Function: 84.7	CKD stages not reported	DM, %: 33 LVH not reported	Mean # of BP meds: 4.7
Tsioufis, 2015[68]	Renal denervation	18	56	67	Race/ethnicity not reported	33.6	Kidney function not reported	CKD stages not reported	DM, %: 33 LVH, %: 100	Mean # of BP meds: 4.5
Tsioufis, 2015[68]	Sham procedure	10	54	60	Race/ethnicity not reported	31.8	Kidney function not reported	CKD stages not reported	DM, %: 30 LVH, %: 100	Mean # of BP meds: 4.6
Tsioufis, 2015[69]	Renal denervation	46	60	Male not reported	Race/ethnicity not reported	32	Kidney function not reported	CKD stages not reported	Diabetes status not reported LVH not reported	Mean # of BP meds: 4.7
van Brussel, 2015[70]	Renal denervation	21	58.7	71	Caucasian: 76	27.9	Mean kidney function: 73	CKD stage 4, %: 67	DM, %: 0 LVH, %: 29	Mean # of BP meds: 4.7
Verheye, 2015[71]	Renal denervation	50	63	58	Race/ethnicity not reported	32.6	Mean eGFR: 75.8	CKD stages not reported	DM, %: 42 LVH, %: 12	Mean # of BP meds: 5.1
Verloop, 2014[72]	Renal denervation	126	59	58	Race/ethnicity not reported	29.1	Mean eGFR: 74	CKD stages not reported	DM, %: 17 LVH not reported	Mean # of BP meds: 4
Verloop, 2015[73]	Renal denervation	29	60	59	Race/ethnicity not reported	31.5	Mean kidney function: 85	CKD stages not reported	DM, %: 17 LVH not reported	Mean # of BP meds: 1.2
Verloop, 2015[74]	Renal denervation	54	58	50	Race/ethnicity not reported	29.2	Mean eGFR: 75	CKD stages not reported	DM, %: 15 LVH not reported	Mean # of BP meds: 6.1
Vink, 2014[75]	Renal denervation	67	59	49	Race/ethnicity not reported	29.1	Mean eGFR: 74	CKD stages not reported	DM, %: 18 LVH not reported	Mean # of BP meds: 4

Table 2. Population characteristics of studies evaluating renal denervation devices (continued)

Author, year	Intervention	Total N	Mean age	Male, %	Race, %	Mean BMI	Mean eGFR/serum creatinine	CKD stages	DM, % and LVH, %	Mean # of medications and diuretics, %
Vink, 2015[76]	Renal denervation	46	57	50	Race/ethnicity not reported	29.1	Mean kidney function: 76	CKD stages not reported	DM, %: 17 LVH not reported	Mean # of BP meds: 4
Vogel, 2014[77]	Renal denervation	63	64	56	Race/ethnicity not reported	30	Kidney function not reported	CKD stages not reported	DM, %: 37 LVH not reported	Mean # of BP meds: 4.6
Volz, 2014[78]	Renal denervation	22	61	46	Race/ethnicity not reported	30	Mean eGFR: 98	CKD stages not reported	DM, %: 23 LVH not reported	Mean # of BP meds: 4
Volz, 2014[78]	Continuation of anti-hypertensive drugs	22	63	68	Race/ethnicity not reported	29	Mean eGFR: 95	CKD stages not reported	DM, %: 27 LVH not reported	Mean # of BP meds: 4
Whitbourn, 2015[79]	Renal denervation	50	63	64	Caucasian: 90	31.1	Mean eGFR: 85.1	CKD stages not reported	DM, %: 46 LVH not reported	Mean # of BP meds: 4.5
Worthley, 2013[80]	Renal denervation	46	59.9	67.3	Race/ethnicity not reported	32.4	Kidney function not reported	CKD stages not reported	DM, %: 32.6 LVH not reported	Mean # of BP meds: 4.1
Worthley, 2015[81]	Renal denervation	40	Age not reported	Male not reported	Race/ethnicity not reported	BMI not reported	Kidney function not reported	CKD stages not reported	Diabetes status not reported LVH not reported	Medication use not reported
Zhang, 2014[82]	Renal denervation	39	58.6	62	Race/ethnicity not reported	29.9	Mean serum creatinine: 89.6	CKD stages not reported	DM, %: 18 LVH not reported	Mean # of BP meds: 5.3
Zhang, 2014[82]	Continuation of anti-hypertensive drugs	38	62.9	53	Race/ethnicity not reported	30.1	Mean serum creatinine: 92.6	CKD stages not reported	DM, %: 16 LVH not reported	Mean # of BP meds: 4.9
Zuern, 2013[83]	Renal denervation	50	60.3	56	Race/ethnicity not reported	30.7	Mean serum creatinine: 0.9	CKD stages not reported	DM, %: 36 LVH not reported	Mean # of BP meds: 5.4

BMI = body mass index; BP = blood pressure; CKD = chronic kidney disease; DM = diabetes mellitus; eGFR = estimated glomerular filtration rate; LVH = left ventricular hypertrophy; N = total population

Table 3. Intervention characteristics

Author, year	Type of intervention	Manufacturer /device	Performed procedure	Training	Medication up titration in RDN arm	Did not receive assigned treatment, %
Azizi, 2015[1] RCT	Renal denervation	Medtronic Simplicity	Interventionalist	Not reported	Not reported	13.2%
Azizi, 2015[1] RCT	Continuation of anti-hypertensive drugs	Not applicable	Not applicable	Not applicable	Yes	Not reported
Bhatt, 2014[2] RCT	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Yes	0%
Bhatt, 2014[2] RCT	Sham procedure	Not applicable	Not applicable	Not applicable	Not applicable	Not reported
Bohm, 2015[3] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Not reported	Not reported
Burchell, 2016[4] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Yes	0%
de Sousa Almeida, 2016[5] Before-after study	Renal denervation	Medtronic Simplicity, St. Jude Medical EnligHTN, Covidien OneShot System	Not specified	Not reported	Not reported	0%
Desch, 2015[6] RCT	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Not reported	8.6%
Desch, 2015[6] RCT	Sham procedure		Not specified	Not reported	Not reported	2.9%
Dorr, 2013[7] Before-after study	Renal denervation	Unspecified	Not specified	Not reported	Not reported	Not reported
Dorr, 2015[8] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Yes, prior experience	Yes	Not reported
Dorr, 2015[9] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Yes, prior experience	Yes	Not reported
Dorr, 2015[10] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Not reported	Not reported
Eikelis, 2015[11] Non-randomized trial	Renal denervation	Unspecified	Not specified	Not reported	Yes	Not reported

Table 3. Intervention characteristics (continued)

Author, year	Type of intervention	Manufacturer /device	Performed procedure	Training	Medication up titration in RDN arm	Did not receive assigned treatment, %
Ewen, 2014[12] Prospective cohort	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Yes	Not reported
Ewen, 2014[12] Prospective cohort	Unspecified	Not applicable	Not applicable	Not applicable	Not applicable	Not reported
Ewen, 2015[13] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Yes, prior experience	Yes	Not reported
Ewen, 2015[14] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Yes, prior experience	Yes	Not reported
Ewen, 2015[15] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Yes, prior experience	Yes	0%
Ewen, 2015[16] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	No	0%
Fadl Elmula, 2014[17] RCT	Renal denervation	Medtronic Simplicity	Interventional radiologist	Yes, prior experience	No	10%
Fadl Elmula, 2014[17] RCT	Continuation of anti-hypertensive drugs	Not applicable	Not applicable	Not applicable	Not applicable	Not reported
Hameed, 2015[18] Before-after study	Renal denervation	Medtronic Simplicity	Interventional cardiologist Interventional radiologist	Not reported	Yes	Not applicable
Hamza, 2014[19] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Not reported	Not applicable
Hering, 2015[20] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Yes	Not applicable
Hering, 2015[20] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Yes	Not applicable
Hering, 2015[20] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Yes	Not applicable
Honarvar, 2013[21] Before-after study	Renal denervation	Steerable catheter with radiofrequency energy electrode tip	Interventional fellow	Not reported	Yes	Not applicable
Id, 2015[22] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Yes	Not applicable

Table 3. Intervention characteristics (continued)

Author, year	Type of intervention	Manufacturer /device	Performed procedure	Training	Medication up titration in RDN arm	Did not receive assigned treatment, %
Kaiser, 2014[23] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Not reported	Not applicable
Kario, 2015[24] RCT	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Not reported	Not reported
Kario, 2015[24] RCT	Continuation of anti-hypertensive drugs	Not applicable	Not applicable	Not applicable	Not applicable	Not reported
Kim, 2015[25] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Not reported	Not applicable
Kim, 2015[25] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Not reported	Not applicable
Kiuchi, 2014[26] Before-after study	Renal denervation	Unspecified	Not specified	Not reported	Yes	Not applicable
Kiuchi, 2015[27] Before-after study	Renal denervation	Unspecified	Not specified	Not reported	Not reported	Not applicable
Kiuchi, 2015[28] Before-after study	Renal denervation	AlCath Flux eXtra Gold Full Circle 2708	Not specified	Not reported	No	0%
Krum, 2014[29] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Yes	Not reported
Kyvelou, 2013[30] Before-after study	Renal denervation	Unspecified	Not specified	Not reported	Not reported	Not applicable
Lambert, 2012[31] Prospective cohort	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Not reported	Not reported
Lambert, 2012[31] Prospective cohort	Un-medicated normotensive subjects	Unspecified	Not specified	Not reported	Not reported	Not reported
Lambert, 2012[31] Prospective cohort	hypertensive patient data	Unspecified	Not specified	Not reported	Not reported	Not reported
Lambert, 2014[32] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	No	0%
Lambert, 2015[33] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Not reported	0%
Lambert, 2015[34] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Not reported	0%

Table 3. Intervention characteristics (continued)

Author, year	Type of intervention	Manufacturer /device	Performed procedure	Training	Medication up titration in RDN arm	Did not receive assigned treatment, %
Lambert, 2015[35] Retrospective cohort	Renal denervation	Symplicity Flex	Not specified	Not reported	Not reported	0%
Lambert, 2015[36] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Not reported	0%
Lenski, 2013[37] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Not reported	0%
Lenski, 2013[38] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Not reported	0%
Lobo, 2015[39] Before-after study	Renal denervation	St. Jude Medical EnligHTN	Not specified	Not reported	Not reported	0%
Ott, 2013[40] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	No	0%
Ott, 2014[41] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Not reported	0%
Ott, 2015[42] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Not reported	0%
Ott, 2015[43] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Not reported	0%
Ott, 2015[44] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	No	0%
Papademetriou, 2014[45] Before-after study	Renal denervation	St. Jude Medical EnligHTN	Not specified	Not reported	Not reported	0%
Persu, 2014[46] Retrospective cohort	Renal denervation	Medtronic Simplicity	Not specified	Not reported	No	Not applicable
Persu, 2014[46] Retrospective cohort	Renal denervation	Medtronic Simplicity	Not specified	Not reported	No	Not applicable
Pokushalov, 2012[47] RCT	Renal denervation pulmonary vein isolation	Unspecified	Not specified	Not reported	Yes	0%

Table 3. Intervention characteristics (continued)

Author, year	Type of intervention	Manufacturer /device	Performed procedure	Training	Medication up titration in RDN arm	Did not receive assigned treatment, %
Pokushalov, 2012[47] RCT	Pulmonary vein isolation	Not applicable	Not applicable	Not applicable	Not applicable	0%
Poss, 2014[48] Prospective cohort	Renal denervation	Medtronic Simplicity	Not specified	Not reported	No	0%
Poss, 2015[49] Before-after study	Renal denervation	Medtronic Simplicity	Interventionalist	Not reported	Not reported	Not reported
Prochnau, 2012[50] Before-after study	Renal denervation	7-French Marinr Medtronic	Not specified	Not reported	No	0%
Prochnau, 2013[51] Before-after study	Renal denervation	7-French Marinr Medtronic	Not specified	Not reported	Not reported	0%
Ripp, 2015[52] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Not reported	0%
Rohla, 2016[53] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Not reported	Not applicable
Rosa, 2015[54] RCT	Renal denervation	Medtronic Simplicity	Interventional cardiologist Electrophysiologists	Yes, prior experience	Yes	Not reported
Rosa, 2015[54] RCT	Continuation of anti-hypertensive drugs	Not applicable	Not applicable	Not applicable	Not applicable	Not reported
Scheurig-Muenkler, 2013[55] Before-after study	Renal denervation	Boston Scientific Natick	Not specified	Not reported	Not reported	Not reported
Schmid, 2013[56] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Not reported	Not reported
Schmid, 2015[57] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Not reported	1.9%
Schneider, 2015[58] RCT	Renal denervation	Medtronic Flex	Not specified	Not reported	Yes	Not reported
Schneider, 2015[58] RCT	Continuation of anti-hypertensive drugs	Not applicable	Not applicable	Not applicable	Not applicable	Not reported
Schwerg, 2014[59] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Not reported	0%

Table 3. Intervention characteristics (continued)

Author, year	Type of intervention	Manufacturer /device	Performed procedure	Training	Medication up titration in RDN arm	Did not receive assigned treatment, %
Sharp, 2015[60] Before-after study	Renal denervation	Unspecified	Not specified	Not reported	Not reported	0%
Sharp, 2016[61] Before-after study	Renal denervation	Symplicity Flex; Medtronic Spyra; Boston Scientific Vessix V2 Renal Denervation System	Not specified	Yes, prior experience	Yes	0%
Sievert, 2015[62] Before-after study	Renal denervation	Boston Scientific Vessix V2 Renal Denervation System	Not specified	Not reported	Not reported	0%
Symplicity, 2010[63] RCT	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Yes	
Symplicity, 2010[63] RCT	Unspecified, but allowed to crossover to RDN after 6 months	Not applicable	Not applicable	Not applicable	Not applicable	Not reported
Symplicity, 2011[64] Before-after study	Renal denervation	Ardian Symplicity	Not specified	Not reported	Yes	0%
Tiroch, 2015[65] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Yes, prior experience	Not reported	Not reported
Tsioufis, 2015[66] Prospective cohort	Renal denervation	St. Jude Medical EnligHTN	Not specified	Not reported	Not reported	0%
Tsioufis, 2015[66] Prospective cohort	No-renal denervation	Not applicable	Not specified	Not reported	Not reported	Not applicable
Tsioufis, 2015[67] Prospective cohort, 1 study group	Renal denervation	St. Jude Medical EnligHTN	Not specified	Not reported	Not reported	0%

Table 3. Intervention characteristics (continued)

Author, year	Type of intervention	Manufacturer /device	Performed procedure	Training	Medication up titration in RDN arm	Did not receive assigned treatment, %
Tsioufis, 2015[68] Prospective cohort	Renal denervation	St. Jude Medical EnligHTN	Not specified	Not reported	Not reported	0%
Tsioufis, 2015[68] Prospective cohort	Sham procedure	Not applicable	Not specified	Not reported	Not reported	Not applicable
Tsioufis, 2015[69] Retrospective, 1 study group	Renal denervation	St. Jude Medical EnligHTN	Not specified	Not reported	Not reported	0%
van Brussel, 2015[70] Before-after study	Renal denervation	Medtronic Simplicity	Interventional radiologist	Yes, prior experience	No	Not applicable
Verheye, 2015[71] Before-after study	Renal denervation	Covidien OneShot System	Not specified	Not reported	Not reported	0%
Verloop, 2014[72] Before-after study	Renal denervation	Symplicity Flex, Medtronic St. Jude Medical EnligHTN Covidien OneShot System	Not specified	Not reported	Not reported	0%
Verloop, 2015[73] Before-after study	Renal denervation	Symplicity Flex, Medtronic	Not specified	Not reported	Not reported	0%
Verloop, 2015[74] Before-after study	Renal denervation	Symplicity Flex, Medtronic St. Jude Medical EnligHTN Covidien OneShot System	Not specified	Not reported	Not reported	0%
Vink, 2014[75] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Not reported	0%

Table 3. Intervention characteristics (continued)

Author, year	Type of intervention	Manufacturer /device	Performed procedure	Training	Medication up titration in RDN arm	Did not receive assigned treatment, %
Vink, 2015[76] Before-after study	Renal denervation	Symplicity Flex, Medtronic St. Jude Medical EnligHTN Covidien OneShot System	Not specified	Not reported	Not reported	0%
Vogel, 2014[77] Before-after study	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Yes	Not reported
Volz, 2014[78] Non-randomized trial	Renal denervation	Medtronic Simplicity	Not specified	Not reported	Not reported	Not reported
Volz, 2014[78] Non-randomized trial	Continuation of anti-hypertensive drugs	Not applicable	Not specified	Not reported	Not reported	Not reported
Whitbourn, 2015[79] Before-after study	Renal denervation	Medtronic Spyra	Not specified	Not reported	No	0%
Worthley, 2013[80] Before-after study	Renal denervation	St. Jude Medical EnligHTN	Not specified	Not reported	Not reported	0%
Worthley, 2015[81] retrospective cohort, 1 group	Renal denervation	EnligHTN multielectrode radiofrequency ablation catheter	Not specified	Not reported	Not reported	Not reported
Zhang, 2014[82] Case-control	Renal denervation	IBI, St. Jude Medical	Not specified	Not reported	Not reported	0%
Zhang, 2014[82] Case-control	Continuation of anti-hypertensive drugs	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Zuern, 2013[83] Before-after study	Renal denervation	Symplicity Flex, Medtronic/Ardian	Not specified	Not reported	No	0%

RDN = renal denervation

Table 4. Results of controlled studies evaluating blood pressure outcomes

Author, year Study design	Outcome	Mean follow-up	RDN, n	Control, N	Mean change from baseline in RDN group	Mean change from baseline in control group	Mean between group difference
Azizi, 2015[1] RCT	Night ambulatory systolic blood pressure	6 months	RDN (Medtronic Simplicity), 48	Continuation of anti-hypertensive drugs, 53	-13.9 (-18 to -9.8)	-7.6 (-11.4 to -3.7)	-6.3 (-11.9 to -0.7) P=0.0296
Azizi, 2015[1] RCT	Change in meds	6 months	RDN (Medtronic Simplicity), 53	Continuation of anti-hypertensive drugs, 53	NR	NR	NR
Azizi, 2015[1] RCT	Office systolic blood pressure	6 months	RDN (Medtronic Simplicity), 48	Continuation of anti-hypertensive drugs, 53	-15.1 (-20.6 to -9.5)	-9.5 (-14.7 to -4.2)	-5.6 (-13.2 to 2) P=0.1491
Azizi, 2015[1] RCT	Daytime ambulatory systolic blood pressure	6 months	RDN (Medtronic Simplicity), 48	Continuation of anti-hypertensive drugs, 53	-15.8 (-19.7 to -11.9)	-9.9 (-13.6 to -6.2)	-5.9 (-11.3 to -0.5) P=0.0329
Bhatt, 2014[2] RCT	Daytime ambulatory systolic blood pressure	6 months	RDN (Medtronic Simplicity), 361	Sham procedure, 168	-7.2 (-8.9 to -5.5) P=<0.001	-6.1 (-8.9 to -3.3) P=<0.001	-1.1 (-4.4 to 2.2) P=0.52
Bhatt, 2014[2] RCT	Night ambulatory systolic blood pressure	6 months	RDN (Medtronic Simplicity), 362	Sham procedure, 168	-5.6 (-7.6 to -3.7) P=<0.001	-2.4 (-5.2 to 0.5) P=0.1	-3.3 (-6.8 to 0.2) P=0.06
Bhatt, 2014[2] RCT	Change in meds	6 months	RDN (Medtronic Simplicity), 364	Sham procedure, 171	-0.1 (-0.1 to -0.1)	0 (0 to 0)	-0.1 (-0.5 to 0.3)
Bhatt, 2014[2] RCT	Office systolic blood pressure	6 months	RDN (Medtronic Simplicity), 364	Sham procedure, 171	-14.13 (-16.6 to -11.6)	-11.74 (-18 to -10.2)	-2.39 (-7 to 2.2) P=0.26
Bhatt, 2014[2] RCT	Office systolic blood pressure	12 months	RDN (Medtronic Simplicity), 319	Sham procedure, 48	-18.9 (-21.7 to -16.1)	-21.4 (-24.5 to -13.3)	2.5 (-3.8 to 8.8)
Bhatt, 2014[2] RCT	Office systolic blood pressure	6 months	RDN (Medtronic Simplicity),	Sham procedure,	NR	NR	NR
Bhatt, 2014[2] RCT	Overall ambulatory systolic blood pressure	6 months	RDN (Medtronic Simplicity), 360	Sham procedure, 167	-6.75 (-8.4 to -5.1)	-4.79 (-9.4 to -4.1)	-1.96 (-5.1 to 1.2) P=0.98
Bhatt, 2014[2] RCT	Overall ambulatory systolic blood pressure	12 months	RDN (Medtronic Simplicity), 247	Sham procedure, 20	-7.6 (-7.9 to -7.3)	-6.1 (-13.9 to -1.3)	-1.5 (-7.8 to 4.8)

Table 4. Results of controlled studies evaluating blood pressure outcomes (continued)

Author, year Study design	Outcome	Mean follow-up	RDN, n	Control, N	Mean change from baseline in RDN group	Mean change from baseline in control group	Mean between group difference
Desch, 2015[6] RCT	Overall ambulatory systolic blood pressure	6 months	RDN (Medtronic Simplicity),	Sham procedure,	-8.3 (-11.7 to -5)	-3.5 (-6.8 to -0.2)	-4.8 (-9.5 to -0.1)
Desch, 2015[6] RCT	Overall ambulatory systolic blood pressure	6 months	RDN (Medtronic Simplicity),	Sham procedure,	-7 (-10.8 to -3.2)	-3.5 (-6.7 to -0.2)	-3.5 (-8.5 to 1.5)
Desch, 2015[6] RCT	Overall ambulatory systolic blood pressure	6 months	RDN (Medtronic Simplicity),	Sham procedure,	-9.5 (-13.1 to -5.9)	-13.1 (-6.1 to -0.3)	3.6 (-1 to 8.2)
Desch, 2015[6] RCT	Daytime ambulatory systolic blood pressure	6 months	RDN (Medtronic Simplicity),	Sham procedure,	-9.9 (-13.4 to -6.5)	-3.7 (-7.1 to -0.2)	-6.2 (-11.1 to -1.3)
Ewen, 2014[12] Prospective cohort	Office systolic blood pressure	6 months	RDN (Medtronic Simplicity), 50	unspecified, 10	-26 (-27.4 to -24.6) P=<0.001	-2 (-6.8 to 2.8) P=0.75	-24
Fadl Elmula, 2014[17] RCT	Daytime ambulatory systolic blood pressure	6 months	RDN (Medtronic Simplicity), 9	Continuation of anti-hypertensive drugs, 10	-10 (-17.8 to -2.2) P=<0.05	-19 (-17.4 to -2.6) P=<0.0005	-9 (-19.8 to 1.8) P=NS
Fadl Elmula, 2014[17] RCT	Office systolic blood pressure	6 months	RDN (Medtronic Simplicity), 9	Continuation of anti-hypertensive drugs, 10	-8 (-17.8 to 1.8) P=0.12	-28 (-16.1 to 0.1) P=<0.0005	-20 (-32.7 to -7.3) P=0.008
Kario, 2015[24] RCT	Office systolic blood pressure	6 months	RDN (Medtronic Simplicity), 22	Continuation of anti-hypertensive drugs, 19	-16.6 (-24.3 to -8.9) P=<0.001	-7.9 (-26 to -7.2) P=0.117	-8.6 (-20.8 to 3.6) P=0.169
Kario, 2015[24] RCT	Overall ambulatory systolic blood pressure	6 months	RDN (Medtronic Simplicity), 22	Continuation of anti-hypertensive drugs, 19	-7.5 (-12.5 to -2.5) P=0.008	-1.4 (-12.1 to -2.9) P=0.563	-6.2 (-13 to 0.6) P=0.087
Lambert, 2012[31] Prospective cohort	Office systolic blood pressure	3	RDN (Medtronic Simplicity), 62	Unmedicated normotensive subjects, 63	NR	NR	-16 (-16.7 to -15.3) P=0.01
Lambert, 2012[31] Prospective cohort	Office systolic blood pressure	3	RDN (Medtronic Simplicity), 62	hypertensive patient data, 68	NR	NR	-16 (-16.7 to -15.3) P=0.01

Table 4. Results of controlled studies evaluating blood pressure outcomes (continued)

Author, year Study design	Outcome	Mean follow-up	RDN, n	Control, N	Mean change from baseline in RDN group	Mean change from baseline in control group	Mean between group difference
Lambert, 2012[31] Prospective cohort	Office systolic blood pressure	3	RDN (Unspecified), 63	hypertensive patient data, 68	NR	NR	NR
Pokushalov, 2012[47] RCT	Change in meds	1 year	RDN (Unspecified), 13	pulmonary vein isolation, 14	-0.5 (-0.6 to -0.4)	0.2 (0.1 to 0.3)	-0.7 (-1.4 to 0)
Pokushalov, 2012[47] RCT	Office systolic blood pressure	6 months	RDN (Unspecified), 13	pulmonary vein isolation, 14	-28 (-30.7 to -25.3)	-5 (-29.3 to -26.7)	-23 (-26 to -20)
Pokushalov, 2012[47] RCT	Office systolic blood pressure	1 year	RDN (Unspecified), 13	pulmonary vein isolation, 14	-25 (-27.7 to -22.3)	-5 (-27.6 to -22.4)	-20 (-23.8 to -16.2) P=<0.001
Rosa, 2015[54] RCT	Daytime ambulatory systolic blood pressure	6 months	RDN (Medtronic Simplicity), 52	Continuation of anti-hypertensive drugs, 54	-9 (-13.2 to -4.7) P=<0.001	-8.2 (-12.4 to -4) P=<0.001	-0.8 (-6.8 to 5.2) P=0.79
Rosa, 2015[54] RCT	Night ambulatory systolic blood pressure	6 months	RDN (Medtronic Simplicity), 52	Continuation of anti-hypertensive drugs, 54	-8.1 (-12.7 to -3.6) P=<0.001	-7.6 (-12.1 to -3.1) P=0.001	-0.5 (-6.9 to 5.9) P=0.87
Rosa, 2015[54] RCT	Change in meds	6 months	RDN (Medtronic Simplicity), 52	Continuation of anti-hypertensive drugs, 54	-0.02 (-0.2 to 0.1) P=0.81	0.3 (0.2 to 0.5) P=<0.001	-0.3 (-0.6 to -0.1) P=<0.01
Rosa, 2015[54] RCT	Office systolic blood pressure	6 months	RDN (Medtronic Simplicity), 52	Continuation of anti-hypertensive drugs, 54	-12.4 (-17 to -7.8) P=<0.001	-14.3 (-19.7 to -8.9) P=<0.001	1.9 (-5.2 to 9) P=0.6
Rosa, 2015[54] RCT	Overall ambulatory systolic blood pressure	6 months	RDN (Medtronic Simplicity), 52	Continuation of anti-hypertensive drugs, 54	-9 (-11.8 to -5.3) P=<0.001	-8.1 (-12.7 to -3.4) P=0.001	-0.5 (-6.2 to 5.2) P=0.87
Rosa, 2015[54]	Office systolic blood pressure	12 months	RDN (Medtronic Simplicity), 51	Continuation of anti-hypertensive drugs, 50	NR (-18.9 to -7.9) P = <0.001	-11.3 (-17.1 to -5.5) P = <0.001	-2.1 (-10.1 to 5.9) P = 0.61
Rosa, 2015[54]	Overall ambulatory systolic blood pressure	12 months	RDN (Medtronic Simplicity), 51	Continuation of anti-hypertensive drugs, 50	NR (-10.1 to -2.7) P = 0.001	-8.2 (-13.3 to -3.3) P = 0.002	1.9 (-4.3 to 8.1) P = 0.54
Rosa, 2015[54]	Change in meds	12 months	RDN (Medtronic Simplicity), 51	Continuation of anti-hypertensive drugs, 50	0.1 (-0.06 to 0.3) P = 0.2	0.2 (-0.2 to 0.6) P = 0.33	-0.1 (-0.5 to 2) P = 0.69

Table 4. Results of controlled studies evaluating blood pressure outcomes (continued)

Author, year Study design	Outcome	Mean follow-up	RDN, n	Control, N	Mean change from baseline in RDN group	Mean change from baseline in control group	Mean between group difference
Schneider, 2015[58] RCT	Night ambulatory systolic blood pressure	6 months	RDN (Medtronic Flex),	Continuation of anti-hypertensive drugs,	-10.38 (-18.7 to -2) P=0.06	1.97 (-18.4 to -2.4) P=0.64	-12.35 (-23.9 to -0.8) P=0.18
Schneider, 2015[58] RCT	Office systolic blood pressure	6 months	RDN (Medtronic Flex), 9	Continuation of anti-hypertensive drugs, 9	-23 (-32.5 to -13.5) P=0.003	1 (-31.5 to -14.5) P=0.77	-24 (-36.7 to -11.3) P=<0.001
Schneider, 2015[58] RCT	Overall ambulatory systolic blood pressure	6 months	RDN (Medtronic Flex), 9	Continuation of anti-hypertensive drugs, 9	-2.88 (-10.1 to 4.4) P=0.49	-5 (-10.1 to 4.4) P=0.21	2.1 (-8.2 to 12.4)
Schneider, 2015[58] RCT	Daytime ambulatory systolic blood pressure	6 months	RDN (Medtronic Flex),	Continuation of anti-hypertensive drugs,	1.5 (-7.3 to 10.3) P=0.76	-5.18 (-6.7 to 9.7) P=0.25	6.68 (-5.3 to 18.7)
Symplicity, 2010[63] RCT	Office systolic blood pressure	6 months	RDN (Medtronic Simplicity), 49	unspecified, but allowed to crossover to RDN after 6 months, 51	-32 (-38.4 to -25.6) P=<0.001	1 (-37.8 to -26.2) P=0.77	-33 (-41.6 to -24.4) P=<0.001
Symplicity, 2010[63] RCT	Change in meds	36 months	RDN (Medtronic Simplicity), 40	unspecified, but allowed to crossover to RDN after 6 months,	-0.5 (-0.6 to -0.4) P=0.02	NR	NR
Symplicity, 2010[63] RCT	Office systolic blood pressure	12 months	RDN (Medtronic Simplicity), 49	unspecified, but allowed to crossover to RDN after 6 months,	-28.1 (-35.4 to -20.7) P=<0.001	NR	NR
Symplicity, 2010[63] RCT	Office systolic blood pressure	36 months	RDN (Medtronic Simplicity), 52	unspecified, but allowed to crossover to RDN after 6 months,	-33 (-40 to -25) P=<0.001	NR	NR
Symplicity, 2010[63] RCT	Overall ambulatory systolic blood pressure	6 months	RDN (Medtronic Simplicity),	unspecified, but allowed to crossover to RDN after 6 months,	-11 (-17.6 to -4.4) P=0.006	-3 (-18.4 to -3.6) P=0.51	-8 (-17.9 to 1.9)
Tsioufis, 2015[66] Prospective cohort	Daytime ambulatory systolic blood pressure	6	RDN (St. Jude Medical EnligHTN), 31	no-renal denervation, 12	-9.9 (-11.4 to -8.4)	0.7 (-1 to 2.4)	-10.6 (-20.7 to -0.5)

Table 4. Results of controlled studies evaluating blood pressure outcomes (continued)

Author, year Study design	Outcome	Mean follow-up	RDN, n	Control, N	Mean change from baseline in RDN group	Mean change from baseline in control group	Mean between group difference
Tsioufis, 2015[66] Prospective cohort	Night ambulatory systolic blood pressure	6	RDN (St. Jude Medical EnligHTN), 31	no-renal denervation, 12	-10.5 (-12.1 to -8.9)	-2.2 (-4.3 to -0.1)	-8.3 (-19.6 to 3)
Tsioufis, 2015[66] Prospective cohort	Overall ambulatory systolic blood pressure	6	RDN (St. Jude Medical EnligHTN), 31	no-renal denervation, 12	-10.2 (-11.5 to -8.9)	-0.6 (-2.2 to 1)	-9.6 (-18.9 to -0.3)
Tsioufis, 2015[68] Prospective cohort	Office systolic blood pressure	6	RDN (St. Jude Medical EnligHTN), 18	Sham procedure, 10	-42 (-45.1 to -38.9)	0 (-3 to 3)	-42 (-58.4 to -25.6)
Tsioufis, 2015[68] Prospective cohort	Overall ambulatory systolic blood pressure	6	RDN (St. Jude Medical EnligHTN), 18	Sham procedure, 10	-20 (-22.7 to -17.3)	0 (-2.8 to 2.8)	-20 (-34.6 to -5.4)

n = sample size; N = total population; NR = not reported; NS = not specified; RCT = randomized controlled trial; RDN = renal denervation

Table 5. Results of controlled studies evaluating clinical outcomes

Author, year Study design	Mean follow-up	Outcome definition	RDN	Control group	n/N (%) in RDN group	n/N (%) in control group	Absolute risk difference
Azizi, 2015[1] RCT	6 months	Stroke (Not specified)	Medtronic Simplicity	Continuation of anti-hypertensive drugs	1 / 46 (2.2)	0 / 53 (0)	2.2 (-2 to 6.4)
Azizi, 2015[1] RCT	6 months	Myocardial infarction (Not specified)	Medtronic Simplicity	Continuation of anti-hypertensive drugs	1 / 46 (2.2)	1 / 53 (1.9)	0.3 (-5.3 to 5.9)
Bhatt, 2014[2] RCT	6 months	Mortality (Not specified)	Medtronic Simplicity	Sham procedure	2 / 352 (0.6)	1 / 171 (0.6)	0 (-1.4 to 1.4)
Bhatt, 2014[2] RCT	6 months	Stroke (Not specified)	Medtronic Simplicity	Sham procedure	4 / 352 (1.1)	2 / 171 (1.2)	-0.1 (-2.1 to 1.9)
Bhatt, 2014[2] RCT	6 months	Hospitalization (hospitalization for new-onset heart failure)	Medtronic Simplicity	Sham procedure	9 / 352 (2.6)	3 / 171 (1.8)	0.8 (-1.8 to 3.4)
Bhatt, 2014[2] RCT	6 months	Hospitalization (hospitalization for atrial fibrillation)	Medtronic Simplicity	Sham procedure	5 / 352 (1.4)	1 / 171 (0.6)	0.8 (-0.9 to 2.5)
Bhatt, 2014[2] RCT	12 months	Mortality (Not specified)	Medtronic Simplicity	Sham procedure	6 / 355 (1.8)	2 / 69 (3.6)	-1.8 (-6.4 to 2.8)
Bhatt, 2014[2] RCT	6 months	Myocardial infarction (Not specified)	Medtronic Simplicity	Sham procedure	6 / 352 (1.7)	3 / 171 (1.8)	-0.1 (-2.5 to 2.3)
Desch, 2015[6] RCT	6 months	Mortality (Not specified)	Medtronic Simplicity	Sham procedure	0 / 32 (0)	0 / 35 (0)	0 (0 to 0)
Fadl Elmula, 2014[17] RCT	6 months	Myocardial infarction (myocardial infarction)	Medtronic Simplicity	Continuation of anti-hypertensive drugs	1 / 9 (11.1)	NR	NR
Rosa, 2015[54] RCT	6 months	Stroke (ischemic stroke)	Medtronic Simplicity	Continuation of anti-hypertensive drugs	1 / 52 (1.9)	NR	NR
Rosa, 2015[54] RCT	6 months	Mortality (Not specified)	Medtronic Simplicity	Continuation of anti-hypertensive drugs	0 / 52 (0)	0 / 54 (0)	0 (0 to 0)
Rosa, 2015[54] RCT	6 months	Myocardial infarction (MI without ST elevations)	Medtronic Simplicity	Continuation of anti-hypertensive drugs	1 / 52 (1.9)	NR	NR

Table 5. Results of controlled studies evaluating clinical outcomes (continued)

Author, year Study design	Mean follow-up	Outcome definition	RDN	Control group	n/N (%) in RDN group	n/N (%) in control group	Absolute risk difference
Rosa, 2015[54] RCT	12 months	Mortality (Not specified)	Medtronic Simplicity	Continuation of anti-hypertensive drugs	0 / 52 (0)	0 / 54 (0)	0 (0 to 0)
Rosa, 2015[54] RCT	12 months	Myocardial infarction (MI without ST elevations)	Medtronic Simplicity	Continuation of anti-hypertensive drugs	1 / 52 (1.9)	NR	NR
Rosa, 2015[54] RCT	12 months	Stroke (Ischemic stroke)	Medtronic Simplicity	Continuation of anti-hypertensive drugs	1 / 52 (1.9)	NR	NR
Symplicity, 2010[63] RCT	6 months	Hospitalization (hospitalization for hypertensive emergency)	Medtronic Simplicity	unspecified, but allowed to crossover to RDN after 6 months	3 / 52 (5.8)	2 / 54 (3.7)	2.1 (-6 to 10.2)
Symplicity, 2010[63] RC	6 months	Hospitalization (hospital admission for nausea and edema)	Medtronic Simplicity	unspecified, but allowed to crossover to RDN after 6 months	1 / 52 (1.9)	NR	NR
Symplicity, 2010[63] RCT	6 months	Hospitalization (hospitalization with hypertension crisis after abrupt stopping of clonidine)	Medtronic Simplicity	unspecified, but allowed to crossover to RDN after 6 months	1 / 52 (1.9)	NR	NR
Symplicity, 2010[63] RCT	6 months	Hospitalization (hospitalization due to transient ischemic attack)	Medtronic Simplicity	unspecified, but allowed to crossover to RDN after 6 months	1 / 52 (1.9)	2 / 54 (3.7)	-1.8 (-8.1 to 4.5)
Symplicity, 2010[63] RCT	6 months	Hospitalization (hospitalization for hypotensive episode)	Medtronic Simplicity	unspecified, but allowed to crossover to RDN after 6 months	1 / 52 (1.9)	NR	NR
Symplicity, 2010[63] RCT	6 months	Hospitalization (hospitalization for coronary stent for angina)	Medtronic Simplicity	unspecified, but allowed to crossover to RDN after 6 months	1 / 52 (1.9)	1 / 54 (1.9)	0 (-5.2 to 5.2)

Table 5. Results of controlled studies evaluating clinical outcomes (continued)

Author, year Study design	Mean follow-up	Outcome definition	RDN	Control group	n/N (%) in RDN group	n/N (%) in control group	Absolute risk difference
Symplicity, 2010[63] RCT	6 months	Hospitalization (hospitalization because of a hypotensive episode)	Medtronic Simplicity	unspecified, but allowed to crossover to RDN after 6 months	NR	1 / 35 (2.9)	NR
Symplicity, 2010[63] RCT	6 months	Hospitalization (hospitalization for hypertensive event)	Medtronic Simplicity	unspecified, but allowed to crossover to RDN after 6 months	NR	2 / 35 (5.7)	NR
Symplicity, 2010[63] RCT	from 12 to 36 months	Hospitalization (hospitalization due to hypertensive events)	Medtronic Simplicity	unspecified, but allowed to crossover to RDN after 6 months	5 / 69 (7.2)	NR	NR
Symplicity, 2010[63] RCT	between 12 and 36 months	Hospitalization (hospitalization with atrial fibrillation)	Medtronic Simplicity	unspecified, but allowed to crossover to RDN after 6 months	2 / 69 (2.9)	NR	NR
Symplicity, 2010[63] RCT	between 12 and 36 months	Mortality (Not specified)	Medtronic Simplicity	unspecified, but allowed to crossover to RDN after 6 months	3 / 69 (4.3)	NR	NR

MI = myocardial infarction; n = sample size; N = total population; NR = not reported; RCT = randomized controlled trial; RDN = renal denervation; ST = segment

Table 6. Results of controlled studies evaluating adverse events

Author, year Study design	Mean follow-up	Outcome definition	RDN	Control group	n/N (%) in RDN group	n/N (%) in control group	Absolute risk difference
Azizi, 2015[1] RCT	6 months	hypertension crisis	Medtronic Simplicity	Continuation of anti-hypertensive drugs	3 / 46 (6.5)	3 / 53 (5.7)	0.8 (-8.7 to 10.3)
Azizi, 2015[1] RCT	6 months	syncope	Medtronic Simplicity	Continuation of anti-hypertensive drugs	0 / 46 (0)	1 / 53 (1.9)	-1.9 (-5.6 to 1.8)
Azizi, 2015[1] RCT	6 months	lumbar pain	Medtronic Simplicity	Continuation of anti-hypertensive drugs	2 / 46 (4.3)	0 / 53 (0)	4.3 (-1.6 to 10.2)
Azizi, 2015[1] RCT	6 months	hypokalemia	Medtronic Simplicity	Continuation of anti-hypertensive drugs	1 / 46 (2.2)	0 / 53 (0)	2.2 (-2 to 6.4)
Azizi, 2015[1] RCT	6 months	hyperkalemia	Medtronic Simplicity	Continuation of anti-hypertensive drugs	1 / 46 (2.2)	0 / 53 (0)	2.2 (-2 to 6.4)
Azizi, 2015[1] RCT	6 months	pancreatitis	Medtronic Simplicity	Continuation of anti-hypertensive drugs	1 / 46 (2.2)	0 / 53 (0)	2.2 (-2 to 6.4)
Azizi, 2015[1] RCT	6 months	groin hematoma	Medtronic Simplicity	Continuation of anti-hypertensive drugs	1 / 46 (2.2)	0 / 53 (0)	2.2 (-2 to 6.4)
Bhatt, 2014[2] RCT	6 months	new-onset end-stage renal disease	Medtronic Simplicity	Sham procedure	0 / 352 (0)	0 / 171 (0)	0 (0 to 0)
Bhatt, 2014[2] RCT	6 months	increase in serum creatinine >50% from baseline	Medtronic Simplicity	Sham procedure	5 / 352 (1.4)	1 / 171 (0.6)	0.8 (-0.9 to 2.5)
Bhatt, 2014[2] RCT	6 months	embolic event resulting in end-organ damage	Medtronic Simplicity	Sham procedure	1 / 352 (0.3)	0 / 171 (0)	0.3 (-0.3 to 0.9)
Bhatt, 2014[2] RCT	6 months	renal-artery intervention	Medtronic Simplicity	Sham procedure	0 / 352 (0)	0 / 171 (0)	0 (0 to 0)
Bhatt, 2014[2] RCT	6 months	vascular complication requiring treatment	Medtronic Simplicity	Sham procedure	1 / 352 (0.3)	0 / 171 (0)	0.3 (-0.3 to 0.9)
Bhatt, 2014[2] RCT	6 months	hypertensive crisis or emergency	Medtronic Simplicity	Sham procedure	9 / 352 (2.6)	9 / 171 (5.3)	-2.7 (-6.4 to 1)
Bhatt, 2014[2] RCT	6 months	new renal-artery stenosis of >70%	Medtronic Simplicity	Sham procedure	1 / 332 (0.3)	0 / 165 (0)	0.3 (-0.3 to 0.9)

Table 6. Results of controlled studies evaluating adverse events (continued)

Author, year Study design	Mean follow-up	Outcome definition	RDN	Control group	n/N (%) in RDN group	n/N (%) in control group	Absolute risk difference
Bhatt, 2014[2] RCT	12 months	new-onset end-stage renal disease	Medtronic Simplicity	Sham procedure	1 / 355 (0.3)	0 / 70 (0)	0.3 (-0.3 to 0.9)
Bhatt, 2014[2] RCT	12 months	significant embolic event resulting in end-organ damage	Medtronic Simplicity	Sham procedure	1 / 355 (0.3)	0 / 69 (0)	0.3 (-0.3 to 0.9)
Bhatt, 2014[2] RCT	12 months	vascular complication	Medtronic Simplicity	Sham procedure	1 / 355 (0.3)	0 / 69 (0)	0.3 (-0.3 to 0.9)
Bhatt, 2014[2] RCT	12 months	renal artery re-intervention	Medtronic Simplicity	Sham procedure	2 / 355 (0.6)	0 / 69 (0)	0.6 (-0.2 to 1.4)
Bhatt, 2014[2] RCT	12 months	hypertensive crisis/emergency	Medtronic Simplicity	Sham procedure	17 / 355 (4.8)	4 / 69 (5.5)	-0.7 (-6.5 to 5.1)
Bhatt, 2014[2] RCT	12 months	new renal artery stenosis > 70%	Medtronic Simplicity	Sham procedure	NR	0 / 69 (0)	NR
Fadl Elmula, 2014[17] RCT	6 months	mild-to-moderate hematomas at the femoral access site	Medtronic Simplicity	Continuation of anti-hypertensive drugs	4 / 9 (44.4)	NR	NR
Fadl Elmula, 2014[17] RCT	6 months	bradycardia	Medtronic Simplicity	Continuation of anti-hypertensive drugs	1 / 9 (11.1)	NR	NR
Fadl Elmula, 2014[17] RCT	6 months	symptomatic hypotension	Medtronic Simplicity	Continuation of anti-hypertensive drugs	1 / 9 (11.1)	4 / 10 (40)	-28.9 (-65.5 to 7.7)
Fadl Elmula, 2014[17] RCT	6 months	sexual dysfunction	Medtronic Simplicity	Continuation of anti-hypertensive drugs	NR	2 / 10 (20)	NR
Fadl Elmula, 2014[17] RCT	6 months	detectable change in renal function	Medtronic Simplicity	Continuation of anti-hypertensive drugs	0 / 9 (0)	0 / 10 (0)	0 (0 to 0)
Kario, 2015[24] RCT	6 months	major adverse event	Medtronic Simplicity	Continuation of anti-hypertensive drugs	0 / 22 (0)	0 / 19 (0)	0 (0 to 0)
Kario, 2015[24] RCT	6 months	50% increase in serum creatinine	Medtronic Simplicity	Continuation of anti-hypertensive drugs	1 / 22 (4.5)	0 / 19 (0)	4.5 (-4.2 to 13.2)
Pokushalov, 2012[47] RCT	1 yr	procedure-related complications	Unspecified	pulmonary vein isolation	0 / 13 (0)	0 / 14 (0)	0 (0 to 0)

Table 6. Results of controlled studies evaluating adverse events (continued)

Author, year Study design	Mean follow-up	Outcome definition	RDN	Control group	n/N (%) in RDN group	n/N (%) in control group	Absolute risk difference
Pokushalov, 2012[47] RCT	6 months	renal artery stenosis	Unspecified	pulmonary vein isolation	0 / 13 (0)	0 / 14 (0)	0 (0 to 0)
Rosa, 2015[54] RCT	6 months	unstable angina	Medtronic Simplicity	Continuation of anti-hypertensive drugs	NR	1 / 54 (1.9)	NR
Rosa, 2015[54] RCT	6 months	spasms after application of radiofrequency energy	Medtronic Simplicity	Continuation of anti-hypertensive drugs	4 / 52 (8)	NR	NR
Rosa, 2015[54] RCT	6 months	dissection of renal artery	Medtronic Simplicity	Continuation of anti-hypertensive drugs	1 / 52 (2)	NR	NR
Rosa, 2015[54] RCT	6 months	Post-punctual pseudo aneurysm	Medtronic Simplicity	Continuation of anti-hypertensive drugs	1 / 52 (2)	NR	NR
Rosa, 2015[54] RCT	6 months	arterio-venous fistula	Medtronic Simplicity	Continuation of anti-hypertensive drugs	1 / 52 (2)	NR	NR
Rosa, 2015[54] RCT	6 months	laryngospasm after analgosedation	Medtronic Simplicity	Continuation of anti-hypertensive drugs	1 / 52 (2)	NR	NR
Rosa, 2015[54] RCT	6 months	asymptomatic bradycardia after procedure	Medtronic Simplicity	Continuation of anti-hypertensive drugs	2 / 52 (4)	NR	NR
Rosa, 2015[54] RCT	6 months	phlebitis associated with peripheral line	Medtronic Simplicity	Continuation of anti-hypertensive drugs	1 / 52 (2)	NR	NR
Rosa, 2015[54] RCT	6 months	hyperkalemia	Medtronic Simplicity	Continuation of anti-hypertensive drugs	NR	6 / 54 (11)	NR
Rosa, 2015[54] RCT	6 months	worsening of renal function	Medtronic Simplicity	Continuation of anti-hypertensive drugs	NR	1 / 54 (2)	NR
Rosa, 2015[54] RCT	6 months	antiandrogen effect of spironolactone	Medtronic Simplicity	Continuation of anti-hypertensive drugs	NR	7 / 54 (13)	NR

Table 6. Results of controlled studies evaluating adverse events (continued)

Author, year Study design	Mean follow-up	Outcome definition	RDN	Control group	n/N (%) in RDN group	n/N (%) in control group	Absolute risk difference
Rosa, 2015[54] RCT	6 months	refusal to continue treatment with spironolactone because of symptomatic blood pressure reduction	Medtronic Simplicity	Continuation of anti-hypertensive drugs	NR	5 / 54 (9)	NR
Rosa, 2015[54] RCT	6 months	refusal to start spironolactone treatment	Medtronic Simplicity	Continuation of anti-hypertensive drugs	NR	2 / 54 (4)	NR
Rosa, 2015[54] RCT	12 months	Refusal to start spironolactone treatment	Medtronic Simplicity	Continuation of anti-hypertensive drugs	NR	2 / 52 (4)	NR
Rosa, 2015[54] RCT	12 months	Refusal to continue treatment with spironolactone because of symptomatic blood pressure reduction	Medtronic Simplicity	Continuation of anti-hypertensive drugs	NR	5 / 54 (10)	NR
Rosa, 2015[54] RCT	12 months	Antiandrogen effect of spironolactone	Medtronic Simplicity	Continuation of anti-hypertensive drugs	NR	7 / 54 (14)	NR
Rosa, 2015[54] RCT	12 months	Worsening of renal function	Medtronic Simplicity	Continuation of anti-hypertensive drugs	NR	1 / 54 (2)	NR
Rosa, 2015[54] RCT	12 months	Hyperkalemia	Medtronic Simplicity	Continuation of anti-hypertensive drugs	NR	6 / 54 (12)	NR
Rosa, 2015[54] RCT	12 months	Phlebitis associated with peripheral line	Medtronic Simplicity	Continuation of anti-hypertensive drugs	1 / 52 (2)	NR	NR
Rosa, 2015[54] RCT	12 months	Asymptomatic bradycardia after procedure	Medtronic Simplicity	Continuation of anti-hypertensive drugs	2 / 52 (4)	NR	NR
Rosa, 2015[54] RCT	12 months	Laryngospasm	Medtronic Simplicity	Continuation of anti-hypertensive drugs	1 / 52 (2)	NR	NR
Rosa, 2015[54] RCT	12 months	Arterio-venous fistula	Medtronic Simplicity	Continuation of anti-hypertensive drugs	1 / 52 (2)	NR	NR

Table 6. Results of controlled studies evaluating adverse events (continued)

Author, year Study design	Mean follow-up	Outcome definition	RDN	Control group	n/N (%) in RDN group	n/N (%) in control group	Absolute risk difference
Rosa, 2015[54] RCT	12 months	Postpunctual pseudoaneurysm	Medtronic Simplicity	Continuation of anti-hypertensive drugs	2 / 52 (4)	NR	NR
Rosa, 2015[54] RCT	12 months	Dissection of renal artery	Medtronic Simplicity	Continuation of anti-hypertensive drugs	1 / 52 (2)	NR	NR
Rosa, 2015[54] RCT	12 months	Spasms after application of radiofrequency energy	Medtronic Simplicity	Continuation of anti-hypertensive drugs	4 / 52 (8)	NR	NR
Rosa, 2015[54] RCT	12 months	Unstable agina	Medtronic Simplicity	Continuation of anti-hypertensive drugs	NR	1 / 54 (1.9)	NR
Schneider, 2015[58] RCT	6 months	Pseudo aneurysm at the femoral vascular access site	Medtronic Flex	Continuation of anti-hypertensive drugs	2 / 9 (22.2)	NR	NR
Symplicity, 2010[63] RCT	6 months	serious complications related to device or procedure	Medtronic Simplicity	unspecified, but allowed to crossover to RDN after 6 months	0 / 52 (0)	NR	NR
Symplicity, 2010[63] RCT	6 months	femoral artery pseudo aneurysm	Medtronic Simplicity	unspecified, but allowed to crossover to RDN after 6 months	1 / 52 (1.9)	NR	NR
Symplicity, 2010[63] RCT	6 months	post-procedural drop in blood pressure resulting in a reduction in antihypertensive drugs	Medtronic Simplicity	unspecified, but allowed to crossover to RDN after 6 months	1 / 52 (1.9)	NR	NR
Symplicity, 2010[63] RCT	6 months	urinary tract infection	Medtronic Simplicity	unspecified, but allowed to crossover to RDN after 6 months	1 / 52 (1.9)	NR	NR

Table 6. Results of controlled studies evaluating adverse events (continued)

Author, year Study design	Mean follow-up	Outcome definition	RDN	Control group	n/N (%) in RDN group	n/N (%) in control group	Absolute risk difference
Symplicity, 2010[63] RCT	6 months	extended hospital admission for assessment of paraesthesias	Medtronic Simplicity	unspecified, but allowed to crossover to RDN after 6 months	1 / 52 (1.9)	NR	NR
Symplicity, 2010[63] RCT	6 months	back pain	Medtronic Simplicity	unspecified, but allowed to crossover to RDN after 6 months	1 / 52 (1.9)	NR	NR
Symplicity, 2010[63] RCT	6 months	bradycardia	Medtronic Simplicity	unspecified, but allowed to crossover to RDN after 6 months	7 / 52 (13)	NR	NR
Symplicity, 2010[63] RCT	6 months	progression of atherosclerotic lesion	Medtronic Simplicity	unspecified, but allowed to crossover to RDN after 6 months	1 / 43 (2.3)	NR	NR
Symplicity, 2010[63] RCT	6 months	renal artery dissection	Medtronic Simplicity	unspecified, but allowed to crossover to RDN after 6 months	NR	1 / 35 (2.9)	NR
Symplicity, 2010[63] RCT	between 12 and 36 months	acute renal failure	Medtronic Simplicity	unspecified, but allowed to crossover to RDN after 6 months	1 / 69 (1.4)	NR	NR
Symplicity, 2010[63] RCT	between 12 and 36 months	acute renal failure	Medtronic Simplicity	unspecified, but allowed to crossover to RDN after 6 months	1 / 69 (1.4)	NR	NR
Symplicity, 2010[63] RCT	between 12 and 36 months	renal vascular events	Medtronic Simplicity	unspecified, but allowed to crossover to RDN after 6 months	0 / 69 (0)	NR	NR

n = sample size; N = total population; NR = not reported; RCT = randomized controlled trial; RDN = renal denervation

Table 7. Results of non-controlled studies evaluating blood pressure outcomes

Author, year	Outcome	Participants, n	Mean follow-up	Change from baseline
Bohm, 2015[3]	Office systolic blood pressure	998	6 months	-11.6
Bohm, 2015[3]	Office systolic blood pressure	740	1 year	-13
Bohm, 2015[3]	Overall ambulatory systolic blood pressure	998	6 months	-6.6
Bohm, 2015[3]	Overall ambulatory systolic blood pressure	390	1 year	-8.3
Bohm, 2015[3]	Change in meds	998	6 months	-0.1
Burchell, 2016[4]	Office systolic blood pressure	29	6 months	-13
Burchell, 2016[4]	Office systolic blood pressure	21	1 year	-22.4
Burchell, 2016[4]	Overall ambulatory systolic blood pressure	13	6 months	-12
Burchell, 2016[4]	Daytime ambulatory systolic blood pressure	13	6 months	-14
Burchell, 2016[4]	Nighttime ambulatory systolic blood pressure	12	6 months	-9
de Sousa Almeida, 2016[5]	Office systolic blood pressure	31	1 year	-27
de Sousa Almeida, 2016[5]	Overall ambulatory systolic blood pressure	31	1 year	-18
de Sousa Almeida, 2016[5]	Change in meds	31	1 year	-0.8
Dorr, 2013[7]	Office systolic blood pressure	62	3 months	-26
Dorr, 2013[7]	Office systolic blood pressure	47	3 years	-23.4
Dorr, 2015[8]	Office systolic blood pressure	150	6 months	-23
Dorr, 2015[8]	Overall ambulatory systolic blood pressure	150	6 months	-9.5
Dorr, 2015[9]	Office systolic blood pressure	100	6 months	-24.3
Dorr, 2015[9]	Overall ambulatory systolic blood pressure	100	6 months	-11.4
Dorr, 2015[10]	Office systolic blood pressure	60	6 months	-26.4
Dorr, 2015[10]	Overall ambulatory systolic blood pressure	60	6 months	-14.1
Dorr, 2013[7]	Change in meds	62	3 years	-1.3
Eikelis, 2015[11]	Office systolic blood pressure	69	6 months	-14.8
Eikelis, 2015[11]	Office systolic blood pressure	69	1 year	-21.3
Ewen, 2014[12]	Office systolic blood pressure	45	6 months	-26
Ewen, 2014[12]	Office systolic blood pressure	10	6 months	-2
Ewen, 2015[13]	Office systolic blood pressure	100	6 months	-15
Ewen, 2015[13]	Overall ambulatory systolic blood pressure	84	6 months	-8
Ewen, 2015[13]	Change in meds	100	6 months	-0.2
Ewen, 2015[14]	Office systolic blood pressure	63	6 months	-27

Table 7. Results of non-controlled studies evaluating blood pressure outcomes (continued)

Author, year	Outcome	Participants, n	Mean follow-up	Change from baseline
Ewen, 2015[14]	Office systolic blood pressure	63	12 months	-30
Ewen, 2015[14]	Office systolic blood pressure	63	12 months	-17
Ewen, 2015[14]	Office systolic blood pressure	63	6 months	-18
Ewen, 2015[14]	Overall ambulatory systolic blood pressure	63	6 months	-8
Ewen, 2015[14]	Overall ambulatory systolic blood pressure	63	NR	7
Ewen, 2015[14]	Overall ambulatory systolic blood pressure	63	NR	-13
Ewen, 2015[14]	Overall ambulatory systolic blood pressure	63	NR	-15
Ewen, 2015[14]	Change in meds	63	6 months	-0.1
Ewen, 2015[14]	Change in meds	63	6 months	-0.1
Ewen, 2015[14]	Change in meds	63	12 months	-0.1
Ewen, 2015[14]	Change in meds	63	12 months	0
Ewen, 2015[15]	Office systolic blood pressure	30	6 months	-19
Ewen, 2015[15]	Overall ambulatory systolic blood pressure	30	6 months	-10
Ewen, 2015[16]	Overall ambulatory systolic blood pressure	84	6 months	-19
Ewen, 2015[16]	Daytime ambulatory systolic blood pressure	84	6 months	-15
Ewen, 2015[16]	Nighttime ambulatory systolic blood pressure	84	6 months	-11
Hameed, 2015[18]	Office systolic blood pressure	34	6 months	-15.1
Hameed, 2015[18]	Daytime ambulatory systolic blood pressure	34	6 months	-5.4
Hameed, 2015[18]	Night ambulatory systolic blood pressure	34	6 months	-1.7
Hamza, 2014[19]	Office systolic blood pressure	55	6 months	-24
Hamza, 2014[19]	Change in meds	55	6 months	-0.28
Hering, 2015[20]	Office systolic blood pressure	65	6 months	-12
Hering, 2015[20]	Office systolic blood pressure	16	6 months	-2
Hering, 2015[20]	Office systolic blood pressure	10	6 months	-19
Hering, 2015[20]	Overall ambulatory systolic blood pressure	65	6 months	-6
Hering, 2015[20]	Overall ambulatory systolic blood pressure	16	6 months	-4
Hering, 2015[20]	Overall ambulatory systolic blood pressure	10	6 months	-11

Table 7. Results of non-controlled studies evaluating blood pressure outcomes (continued)

Author, year	Outcome	Participants, n	Mean follow-up	Change from baseline
Hering, 2015[20]	Daytime ambulatory systolic blood pressure	65	6 months	-7
Hering, 2015[20]	Daytime ambulatory systolic blood pressure	16	6 months	-5
Hering, 2015[20]	Daytime ambulatory systolic blood pressure	10	6 months	-10
Hering, 2015[20]	Night ambulatory systolic blood pressure	65	6 months	-5
Hering, 2015[20]	Night ambulatory systolic blood pressure	16	6 months	-3
Hering, 2015[20]	Night ambulatory systolic blood pressure	10	6 months	-14
Honarvar, 2013[21]	Office systolic blood pressure	30	6 months	-14.4
Honarvar, 2013[21]	Overall ambulatory systolic blood pressure	23	6 months	-17.3
Id, 2015[22]	Office systolic blood pressure	101	6 months	-14.7
Id, 2015[22]	Overall ambulatory systolic blood pressure	71	6 months	-6.8
Id, 2015[22]	Change in meds	101	6 months	0.1
Kaiser, 2014[23]	Office systolic blood pressure	53	6 months	-46
Kaiser, 2014[23]	Office systolic blood pressure	16	6 months	-33
Kaiser, 2014[23]	Office systolic blood pressure	24	6 months	-1
Kaiser, 2014[23]	Overall ambulatory systolic blood pressure	15	6 months	-20
Kaiser, 2014[23]	Overall ambulatory systolic blood pressure	14	6 months	-12
Kaiser, 2014[23]	Overall ambulatory systolic blood pressure	9	6 months	20
Kim, 2015[25]	Office systolic blood pressure	93	12 months	-27.2
Kim, 2015[25]	Office systolic blood pressure	93	6 months	-19.4
Kim, 2015[25]	Office systolic blood pressure	169	12 months	-20.1
Kim, 2015[25]	Office systolic blood pressure	169	6 months	-20.9
Kim, 2015[25]	Change in meds	93	6 months	-0.1
Kim, 2015[25]	Change in meds	93	12 months	-0.1
Kim, 2015[25]	Change in meds	163	6 months	0
Kim, 2015[25]	Change in meds	169	12 months	0
Kiuchi, 2014[26]	Office systolic blood pressure	27	6 months	-52.6
Kiuchi, 2014[26]	Office systolic blood pressure	22	12 months	-58.2
Kiuchi, 2015[27]	Office systolic blood pressure	30	6 months	-53
Kiuchi, 2015[27]	Office systolic blood pressure	30	12 months	-54

Table 7. Results of non-controlled studies evaluating blood pressure outcomes (continued)

Author, year	Outcome	Participants, n	Mean follow-up	Change from baseline
Kiuchi, 2015[28]	Office systolic blood pressure	27	24 months	-54
Kiuchi, 2015[28]	Office systolic blood pressure	27	6 months	-48
Kiuchi, 2015[28]	Office systolic blood pressure	30	1 year	-53
Kiuchi, 2015[28]	Overall ambulatory systolic blood pressure	27	24 months	-20
Kiuchi, 2015[28]	Overall ambulatory systolic blood pressure	30	6 months	-18
Kiuchi, 2015[28]	Overall ambulatory systolic blood pressure	30	1 year	-19
Kiuchi, 2015[28]	Change in meds	27	24 months	-1.4
Krum, 2014[29]	Office systolic blood pressure	144	6 months	-22
Krum, 2014[29]	Office systolic blood pressure	132	12 months	-26.5
Krum, 2014[29]	Office systolic blood pressure	88	36 months	-32
Krum, 2014[29]	Change in meds	150	6 months	0.1
Krum, 2014[29]	Change in meds	150	36 months	0.2
Kyvelou, 2013[30]	Office systolic blood pressure	24	6 months	-6
Kyvelou, 2013[30]	Overall ambulatory systolic blood pressure	24	6 months	-4
Kyvelou, 2013[30]	Change in meds	24	6 months	NR
Lambert, 2012[31]	Office systolic blood pressure	62	3	NR
Lambert, 2012[31]	Office systolic blood pressure	63	3	NR
Lambert, 2012[31]	Office systolic blood pressure	68	3	NR
Lambert, 2014[32]	Office systolic blood pressure	81	6	-8.4
Lambert, 2014[32]	Overall ambulatory systolic blood pressure	81	6	-4.4
Lambert, 2014[32]	Daytime ambulatory systolic blood pressure	81	6	-4.9
Lambert, 2014[32]	Night ambulatory systolic blood pressure	81	6	-5.2
Lambert, 2015[33]	Office systolic blood pressure	76	6	-15
Lambert, 2015[33]	Overall ambulatory systolic blood pressure	76	6 months	-5
Lambert, 2015[34]	Office systolic blood pressure	32	24 months	-1.3
Lambert, 2015[34]	Overall ambulatory systolic blood pressure	32	24 months	-5.8
Lambert, 2015[34]	Daytime ambulatory systolic blood pressure	32	24 months	-7
Lambert, 2015[34]	Night ambulatory systolic blood pressure	32	24 months	-1.8
Lambert, 2015[35]	Office systolic blood pressure	97	NR	NR

Table 7. Results of non-controlled studies evaluating blood pressure outcomes (continued)

Author, year	Outcome	Participants, n	Mean follow-up	Change from baseline
Lambert, 2015[35]	Daytime ambulatory systolic blood pressure	86	NR	NR
Lambert, 2015[35]	Night ambulatory systolic blood pressure	86	NR	NR
Lambert, 2015[36]	Overall ambulatory systolic blood pressure	106	6	-5.3
Lenski, 2013[37]	Office systolic blood pressure	119	6	-20
Lenski, 2013[38]	Office systolic blood pressure	36	3	-17
Lenski, 2013[38]	Overall ambulatory systolic blood pressure	36	3	-11
Lobo, 2015[39]	Office systolic blood pressure	64	12 months	-17.2
Lobo, 2015[39]	Office systolic blood pressure	103	6 months	-18.2
Lobo, 2015[39]	Daytime ambulatory systolic blood pressure	64	12 months	-7.6
Lobo, 2015[39]	Daytime ambulatory systolic blood pressure	103	6 months	-7.9
Ott, 2013[40]	Office systolic blood pressure	54	6	-13
Ott, 2013[40]	Overall ambulatory systolic blood pressure	54	6	-14
Ott, 2013[40]	Daytime ambulatory systolic blood pressure	54	6	-14
Ott, 2013[40]	Night ambulatory systolic blood pressure	54	6	-13
Ott, 2014[41]	Office systolic blood pressure	59	6	-18
Ott, 2014[41]	Overall ambulatory systolic blood pressure	59	6	-11
Ott, 2015[42]	Office systolic blood pressure	33	6	-23
Ott, 2015[42]	Office systolic blood pressure	30	6	-12
Ott, 2015[42]	Overall ambulatory systolic blood pressure	33	6	-11
Ott, 2015[42]	Overall ambulatory systolic blood pressure	33	6	-3
Ott, 2015[43]	Office systolic blood pressure	27	NR	-20
Ott, 2015[43]	Overall ambulatory systolic blood pressure	27	NR	-8
Ott, 2015[44]	Office systolic blood pressure	51	NR	-19
Ott, 2015[44]	Overall ambulatory systolic blood pressure	51	NR	-12
Papademetriou, 2014[45]	Office systolic blood pressure	45	NR	-27

Table 7. Results of non-controlled studies evaluating blood pressure outcomes (continued)

Author, year	Outcome	Participants, n	Mean follow-up	Change from baseline
Papademetriou, 2014[45]	Overall ambulatory systolic blood pressure	35	NR	-7
Persu, 2014[46]	Office systolic blood pressure	21	6	-52
Persu, 2014[46]	Office systolic blood pressure	22	6	12
Persu, 2014[46]	Overall ambulatory systolic blood pressure	21	6	-31
Persu, 2014[46]	Overall ambulatory systolic blood pressure	22	6	14
Poss, 2014[48]	Office systolic blood pressure	85	6	-34.2
Poss, 2014[48]	Office systolic blood pressure	16	6	1.9
Poss, 2015[49]	Office systolic blood pressure	137	6	-18
Poss, 2015[49]	Change in meds	137	6	0
Prochnau, 2012[50]	Overall ambulatory systolic blood pressure	30	6 weeks	-15
Prochnau, 2013[51]	Overall ambulatory systolic blood pressure	43	6	-17
Ripp, 2015[52]	Office systolic blood pressure	60	6 months	-26.94
Rohla, 2016[53]	Overall ambulatory systolic blood pressure	103	6 months	-3.7
Rohla, 2016[53]	Overall ambulatory systolic blood pressure	79	1 year	-8
Rohla, 2016[53]	Change in meds	103	1 year	0
Schmid, 2013[56]	Office systolic blood pressure	32	6 months	-18
Schmid, 2013[56]	Office systolic blood pressure	21	6 months	-17
Schmid, 2015[57]	Office systolic blood pressure	43	NR	-15
Schmid, 2015[57]	Overall ambulatory systolic blood pressure	38	NR	-9
Schwerg, 2014[59]	Overall ambulatory systolic blood pressure	40	6	-7
Sharp, 2015[60]	Office systolic blood pressure	246	10 months	-22
Sharp, 2015[60]	Daytime ambulatory systolic blood pressure	246	10 months	NR
Sharp, 2015[60]	Night ambulatory systolic blood pressure	246	10 months	NR
Sharp, 2016[61]	Office systolic blood pressure	253	11 months	-22
Sharp, 2016[61]	Daytime ambulatory systolic blood pressure	177	8.5 months	-12

Table 7. Results of non-controlled studies evaluating blood pressure outcomes (continued)

Author, year	Outcome	Participants, n	Mean follow-up	Change from baseline
Sharp, 2016[61]	Nighttime ambulatory systolic blood pressure	186	8.5 months	-9
Sievert, 2015[62]	Office systolic blood pressure	146	6	-24.7
Sievert, 2015[62]	Overall ambulatory systolic blood pressure	103	6	-6
Symplicity, 2011[64]	Office systolic blood pressure	153	24 months	-32
Symplicity, 2011[64]	Change in meds	153	24 months	-0.1
Tiroch, 2015[65]	Office systolic blood pressure	40	6 months	-13
Tiroch, 2015[65]	Overall ambulatory systolic blood pressure	37	6 months	-6
Tiroch, 2015[65]	Change in meds	46	6 months	-0.1
Tsioufis, 2015[66]	Overall ambulatory systolic blood pressure	31	6	-10.2
Tsioufis, 2015[66]	Overall ambulatory systolic blood pressure	12	6	-0.6
Tsioufis, 2015[66]	Daytime ambulatory systolic blood pressure	31	6	-9.9
Tsioufis, 2015[66]	Daytime ambulatory systolic blood pressure	12	6	0.7
Tsioufis, 2015[66]	Night ambulatory systolic blood pressure	31	6	-10.5
Tsioufis, 2015[66]	Night ambulatory systolic blood pressure	12	6	-2.2
Tsioufis, 2015[67]	Office systolic blood pressure	44	24 months	-29
Tsioufis, 2015[67]	Overall ambulatory systolic blood pressure	44	24 months	-13
Tsioufis, 2015[67]	Change in meds	46	24 months	0.1
Tsioufis, 2015[68]	Office systolic blood pressure	18	6	-42
Tsioufis, 2015[68]	Office systolic blood pressure	10	6	0
Tsioufis, 2015[68]	Overall ambulatory systolic blood pressure	18	6	-20
Tsioufis, 2015[68]	Overall ambulatory systolic blood pressure	10	6	0
Tsioufis, 2015[69]	Office systolic blood pressure	46	24 month	-29
Tsioufis, 2015[69]	Overall ambulatory systolic blood pressure	46	24 months	-13
van Brussel, 2015[70]	Office systolic blood pressure	21	6 weeks	-14.1

Table 7. Results of non-controlled studies evaluating blood pressure outcomes (continued)

Author, year	Outcome	Participants, n	Mean follow-up	Change from baseline
van Brussel, 2015[70]	Overall ambulatory systolic blood pressure	21	6 weeks	-5
Verheye, 2015[71]	Office systolic blood pressure	41	NR	-8
Verheye, 2015[71]	Overall ambulatory systolic blood pressure	41	NR	-9.1
Verheye, 2015[71]	Daytime ambulatory systolic blood pressure	41	NR	-9.5
Verheye, 2015[71]	Night ambulatory systolic blood pressure	41	NR	-7.1
Verloop, 2014[72]	Office systolic blood pressure	83	6	7
Verloop, 2014[72]	Office systolic blood pressure	43	6	9
Verloop, 2014[72]	Daytime ambulatory systolic blood pressure	83	6	2
Verloop, 2014[72]	Daytime ambulatory systolic blood pressure	43	6	5
Verloop, 2015[73]	Office systolic blood pressure	29	NR	-7
Verloop, 2015[73]	Overall ambulatory systolic blood pressure	29	NR	-6
Verloop, 2015[73]	Change in meds	29		0.1
Verloop, 2015[74]	Overall ambulatory systolic blood pressure	54	NR	-7
Verloop, 2015[74]	Change in meds	54		-1
Vink, 2014[75]	Office systolic blood pressure	67	6	-30
Vink, 2014[75]	Daytime ambulatory systolic blood pressure	67	6	NR
Vink, 2014[75]	Change in meds	67	6	-1
Vink, 2015[76]	Overall ambulatory systolic blood pressure	46	NR	-9
Vink, 2015[76]	Daytime ambulatory systolic blood pressure	46	NR	-10
Vink, 2015[76]	Change in meds	46		-0.7
Vogel, 2014[77]	Office systolic blood pressure	24	NR	-26
Volz, 2014[78]	Overall ambulatory systolic blood pressure	11	6	-5
Volz, 2014[78]	Daytime ambulatory systolic blood pressure	22	6	-9
Volz, 2014[78]	Daytime ambulatory systolic blood pressure	22	NR	-6

Table 7. Results of non-controlled studies evaluating blood pressure outcomes (continued)

Author, year	Outcome	Participants, n	Mean follow-up	Change from baseline
Volz, 2014[78]	Daytime ambulatory systolic blood pressure	22	6	0
Volz, 2014[78]	Night ambulatory systolic blood pressure	22	NR	0
Whitbourn, 2015[79]	Office systolic blood pressure	50	NR	-19.2
Whitbourn, 2015[79]	Overall ambulatory systolic blood pressure	41	NR	-7.6
Whitbourn, 2015[79]	Change in meds	50	NR	0
Worthley, 2013[80]	Office systolic blood pressure	46	6	-26
Worthley, 2013[80]	Overall ambulatory systolic blood pressure	46	6	-10
Worthley, 2015[81]	Office systolic blood pressure	46	6	-26
Zhang, 2014[82]	Office systolic blood pressure	39	NR	-27.3
Zhang, 2014[82]	Office systolic blood pressure	38	NR	-5.3
Zuern, 2013[83]	Office systolic blood pressure	50	6	-8
Zuern, 2013[83]	Office systolic blood pressure	50	6	-23
Zuern, 2013[83]	Change in meds	50	6	-0.1

n = sample size; NR = not reported

Table 8. Results of non-controlled studies evaluating clinical outcomes

Author, year Study design	Mean follow-up	Outcome definition	n/N (%) in RDN group
Bohm, 2015[3]	6 months	Cardiovascular mortality	0 / 997 (0)
Bohm, 2015[3]	1 year	Cardiovascular mortality	7 / 1000 (0.7)
Bohm, 2015[3]	6 months	Hospitalization	4 / 997 (0.4)
Bohm, 2015[3]	6 months	Hospitalization	6 / 997 (0.6)
Bohm, 2015[3]	6 months	Hospitalization	5 / 997 (0.5)
Bohm, 2015[3]	6 months	Mortality	0 / 997 (0)
Bohm, 2015[3]	6 months	Stroke	7 / 997 (0.7)
Bohm, 2015[3]	6 months	Myocardial infarction	7 / 997 (0.7)
Kim, 2015[25]	12 months	Hospitalization	2 / 91 (2.2)
Kim, 2015[25]	12 months	Hospitalization	1 / 91 (1.1)
Kim, 2015[25]	12 months	Hospitalization	1 / 165 (0.6)
Kim, 2015[25]	12 months	Hospitalization	2 / 165 (1.1)
Kim, 2015[25]	12 months	Mortality	0 / 91 (0)
Kim, 2015[25]	12 months	Mortality	0 / 165 (0)
Kim, 2015[25]	12 months	Stroke	2 / 91 (2.2)
Kim, 2015[25]	12 months	Stroke	1 / 165 (0.6)
Kim, 2015[25]	12 months	Myocardial infarction	0 / 91 (0)
Kim, 2015[25]	12 months	Myocardial infarction	1 / 165 (0.6)
Krum, 2014[29]	36 months	Cardiovascular mortality	3 / 153 (2)
Krum, 2014[29]	36 months	Hospitalization	3 / 153 (2)
Krum, 2014[29]	36 months	Hospitalization	13 / 153 (8.5)
Krum, 2014[29]	36 months	Mortality	3 / 153 (2)
Symplicity, 2011[64]	24 months	Mortality	2 / 153 (1.3)
Whitbourn, 2015[79]	NR	Hospitalization	0 / 49 (0)
Whitbourn, 2015[79]	NR	Hospitalization	0 / 49 (0)
Whitbourn, 2015[79]	NR	Mortality	0 / 49 (0)
Whitbourn, 2015[79]	NR	Stroke	0 / 49 (0)
Whitbourn, 2015[79]	NR	Myocardial infarction	1 / 49 (2)

n = sample size; N = total population; NR = not reported; RDN = renal denervaton

Table 9. Results of non-controlled studies evaluating adverse events

Author, year Study design	Mean follow-up	Outcome definition	n/N (%) in RDN group
Bohm, 2015[3]	6 months	new renal artery stenosis >70%	1 / 997 (0.1)
Bohm, 2015[3]	6 months	renal artery re-intervention	2 / 997 (0.2)
Bohm, 2015[3]	1 year	renal artery stenosis >70%	2 / 1000 (0.2)
Bohm, 2015[3]	6 months	new-onset end-stage renal disease	2 / 997 (0.2)
Bohm, 2015[3]	6 months	serum creatinine elevation >50%	3 / 997 (0.3)
Bohm, 2015[3]	1 year	new-onset end-stage renal disease	3 / 1000 (0.3)
Bohm, 2015[3]	6 months	vascular complication	3 / 997 (0.4)
de Sousa Almeida, 2016[5]	1 year	mild hematoma	1 / 31 (3.2)
de Sousa Almeida, 2016[5]	1 year	Femoral pseudoaneurysm	1 / 31 (3.2)
Dorr, 2015[9]	6 months	procedural complications	0 / 100 (0)
Ewen, 2015[13]	6 months	renal artery stenosis	0 / 100 (0)
Ewen, 2015[13]	6 months	serious adverse events (undefined)	0 / 100 (0)
Ewen, 2015[14]	6 months	hemodynamically significant renal artery stenosis	0 / 126 (0)
Ewen, 2015[14]	12 months	hemodynamically significant renal artery stenosis	0 / 126 (0)
Ewen, 2015[14]	6 months	syncope	1 / 126 (0.8)
Hameed, 2015[18]	6 months	hematoma at the femoral artery puncture site	1 / 34 (2.9)
Hameed, 2015[18]	6 months	Pseudo aneurysm of the femoral artery	0 / 34 (0)
Hameed, 2015[18]	6 months	abdominal pain	2 / 34 (5.9)
Hameed, 2015[18]	6 months	persistent nausea and vomiting	1 / 34 (2.9)
Hamza, 2014[19]	6 months	Peri-procedural (access site) complications and/or complications	0 / 55 (0)
Hamza, 2014[19]	6 months	Procedure-related endovascular complications at final angiography	0 / 55 (0)
Hering, 2015[20]	6 months	intra- or peri-procedural complications	0 / 65 (0)
Hering, 2015[20]	6 months	intra- or peri-procedural complications	0 / 16 (0)
Hering, 2015[20]	6 months	intra- or peri-procedural complications	0 / 10 (0)
Honarvar, 2013[21]	6 months	renal artery irregularities	4 / 30 (13.3)
Honarvar, 2013[21]	6 months	vascular damage on angiography	0 / 30 (0)
Honarvar, 2013[21]	6 months	per-procedural complications	0 / 30 (0)
Id, 2015[22]	6 months	serious adverse events related to the device or procedure	0 / 101 (0)
Id, 2015[22]	6 months	coronary intervention	2 / 101 (2.6)
Kaiser, 2014[23]	6 months	renal artery stenosis	0 / 93 (0)
Kaiser, 2014[23]	6 months	kidney infarct	1 / 93 (1.1)
Kim, 2015[25]	12 months	serum creatinine elevation > 50%	0 / 91 (0)

Table 9. Results of non-controlled studies evaluating adverse events (continued)

Author, year Study design	Mean follow-up	Outcome definition	n/N (%) in RDN group
Kim, 2015[25]	12 months	renal failure	1 / 91 (1.1)
Kim, 2015[25]	12 months	procedure-related vascular complications	0 / 93 (0)
Kim, 2015[25]	12 months	vascular complications	0 / 91 (0)
Kim, 2015[25]	12 months	serum creatinine elevation > 50%	0 / 165 (0)
Kim, 2015[25]	12 months	renal failure	0 / 165 (0)
Kim, 2015[25]	12 months	procedure-related vascular complications	0 / 169 (0)
Kim, 2015[25]	12 months	vascular complications	2 / 165 (1.1)
Kiuchi, 2015[27]	12 months	bruising or aneurismal formation	0 / 30 (0)
Kiuchi, 2015[27]	6 months	complication or change in blood flow in the renal arteries as detected by doppler ultrasound	0 / 30 (0)
Kiuchi, 2015[28]	24 months	bleeding at the puncture site	1 / 30 (3.3)
Kiuchi, 2015[28]	6 months	stenosis	0 / 30 (0)
Krum, 2014[29]	36 months	renal-artery dissection	1 / 153 (0.7)
Krum, 2014[29]	36 months	renal-artery stenosis	4 / 153 (2.6)
Krum, 2014[29]	36 months	acute renal failure	1 / 153 (0.7)
Krum, 2014[29]	36 months	access-related complications in the groin	3 / 153 (2)
Krum, 2014[29]	36 months	Bradycardia associated with ablation procedure	8 / 153 (5.2)
Krum, 2014[29]	36 months	orthostatic hypotension	0 / 153 (0)
Kyvelou, 2013[30]	6 months	major complications during or after the procedure	0 / 31 (0)
Papademetriou, 2014[45]	12 months	renal artery dissections, perforations, or occlusions	0 / 46 (0)
Papademetriou, 2014[45]	12 months	worsening renal artery stenosis	2 / 46 (4.3)
Papademetriou, 2014[45]	12 months	access site complications	0 / 46 (0)
Papademetriou, 2014[45]	12 months	hypotension	1 / 46 (2.2)
Papademetriou, 2014[45]	12 months	hypertensive renal disease progression	1 / 46 (2.2)
Scheurig-Muenkler, 2013[55]	Peri-procedural	Renal artery spasm	1 / 53 (1.9)
Scheurig-Muenkler, 2013[55]	periprocedural	imminent respiratory and cardiocirculatory depression	1 / 53 (1.9)

Table 9. Results of non-controlled studies evaluating adverse events (continued)

Author, year Study design	Mean follow-up	Outcome definition	n/N (%) in RDN group
Schwerg, 2014[59]	6 months	Renal Artery Stenosis	NR
Symplicity, 2011[64]	24 months	Pseudo aneurysm/hematoma in the femoral access site	3 / 153 (2)
Symplicity, 2011[64]	24 months	renal artery dissection on placement of the treatment catheter	1 / 153 (0.7)
Symplicity, 2011[64]	24 months	preexisting renal artery stenosis in the proximal portion of the renal artery	1 / 153 (0.7)
Tsioufis, 2015[67]	24 months	renal artery stenosis	2 / 46 (4.3)
Tsioufis, 2015[67]	24 months	hypertension renal disease progression	1 / 46 (2.2)
Tsioufis, 2015[67]	24 months	hypotension	1 / 46 (2.2)
Verheye, 2015[71]	NR	renal artery injury (renal artery stenosis)	1 / 41 (2.4)
Verheye, 2015[71]	NR	flank pain	1 / 41 (2.4)
Verheye, 2015[71]	NR	cardiac complication (bradyarrhythmia)	1 / 41 (2.4)
Whitbourn, 2015[79]	NR	renal artery re-intervention due to perforation or dissection	0 / 49 (0)
Worthley, 2013[80]	6	hematoma	8 / 46 (17.4)
Worthley, 2013[80]	6	progression of pre-existing real artery stenosis	1 / 46 (2.2)
Worthley, 2013[80]	6	hypertensive renal disease progression	1 / 46 (2.2)
Worthley, 2013[80]	6	hypertensive renal disease progression (non-serious)	1 / 46 (2.2)
Worthley, 2013[80]	6	hypotension	1 / 46 (2.2)
Worthley, 2013[80]	6	vasopasm	7 / 46 (15.2)
Worthley, 2013[80]	6	hypotension (non-serious)	3 / 46 (6.5)
Worthley, 2013[80]	6	bradycardia	2 / 46 (4.3)

n = sample size; N = total population; NR = not reported; RDN = renal denervation

Table 10. Study quality of randomized controlled trials evaluating renal denervation devices

Author, year	Sequence generation	Allocation concealment	Incomplete outcome data	Selective outcome reporting	Other sources of bias
Azizi, 2015[1]	Yes	Yes	Yes	Yes	No
Bhatt, 2014[2]	Unclear	Unclear	Yes	Yes	Yes
Desch, 2015[6]	Yes	Yes	Unclear	Yes	Yes
Fadl Elmula, 2014[17]	Yes	Yes	Unclear	No	Yes
Kario, 2015[24]	Unclear	Unclear	Yes	Yes	Yes
Pokushalov, 2012[47]	Unclear	Yes	Yes	Yes	Yes
Rosa, 2015[54]	Unclear	Unclear	Unclear	Yes	Yes
Schneider, 2015[58]	Yes	Yes	Unclear	Yes	No
Symplicity, 2010[63]	Unclear	Yes	No	No	Yes

Appendix F: References

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