Data Abstraction – Study Design Form

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.

METHODS: A total of 21 consecutive patients with refractory hypertension (daytime ambulatory blood pressure (BP) >/=150/100mmHg despite the use of 3 or more antihypertensive drugs), no evidence for secondary hypertension and normal renovascular anatomy were included. RSD was performed with the Medtronic Symplicity renal denervation catheter with an average of 4.2 (range 3-6) ablations per renal artery. To assess cardiac sympathetic activity, 123I-mIBG cardiac scintigraphy was performed before and 6weeks after. In addition, the effect of RSD on peripheral BP and cardiac hemodynamics were assessed non-invasively.

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.

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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? | 8. Specify units for Q7:

☐ 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 ▼]

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) [____]
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☐ Other (specify) [____]

18. Comments **(limit 250 characters)**
[____]

19. Comments **(limit 250 characters)**
[____]

20. Comments **(limit 250 characters)**
[____]

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