

Transcatheter Renal Denervation

The 3 Stages of RND

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Renal Denervation

Is It Magic Therapy??

Attitude for the RND

Just like The Five Stages of Grief

**Denial -> Angry -> Bargaining
-> Depression -> Acceptance**

2008 ESH LBCT

SYMPPLICITY HTN 1 Trial

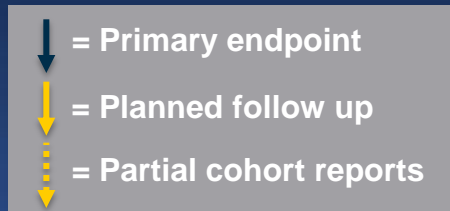
Symplicity HTN-1
First-in-Man, and Expanded
Cohort (N=153)^{1,2}



Symplicity HTN-2
Randomized,
Controlled Trial
(N=106)³



Symplicity HTN-3
Randomized,
Blinded,
Controlled Trial
(N~530)⁴



2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016

Shading on bars indicates clinical trial enrollment periods.
Enrollment period for HTN-3 is estimated.

1. Krum H, et al. *Lancet*. 2009;373:1275-1281.
2. Symplicity HTN-1 Investigators. *Hypertension*. 2011;57:911-917.
3. Esler et al. *Lancet*. 2010;376:1903-1909.
4. Data on file, Medtronic.



The First Impression

DENIAL

My Response : Can't Believe

AMC First Case with Dr. Sievert in TCT AP 2012

- 57/ F, 152cm, 76kg
- HTN, DM, breast cancer
- General edema after CCB (adalat oros 60)
- Lorsartan 100mg, bisoprolol 2.5mg, dichlozid 12.5mg
- Initial BP: 225/104
- Cr 1.0

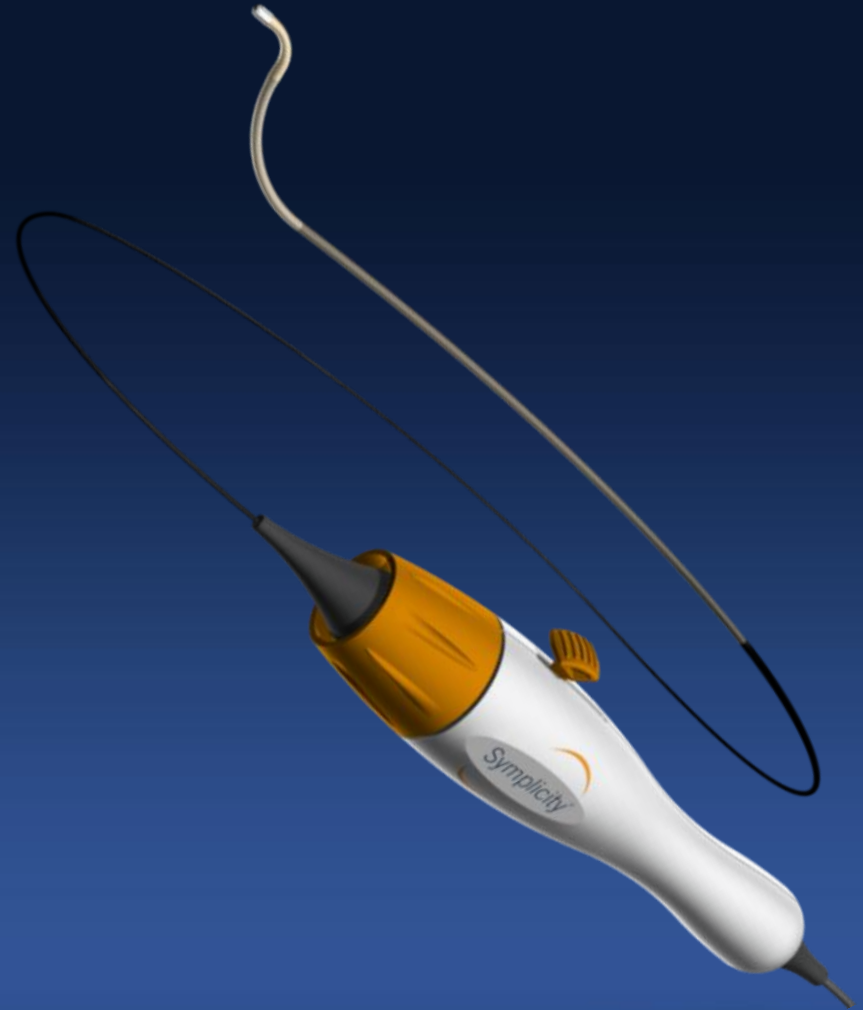
Generator

- Energy maximum 8 Watt
- It automatically switches off if
 - temperature increases too fast or too slowly
 - temperature is higher than 75 °C
 - Impedance does not decrease sufficiently

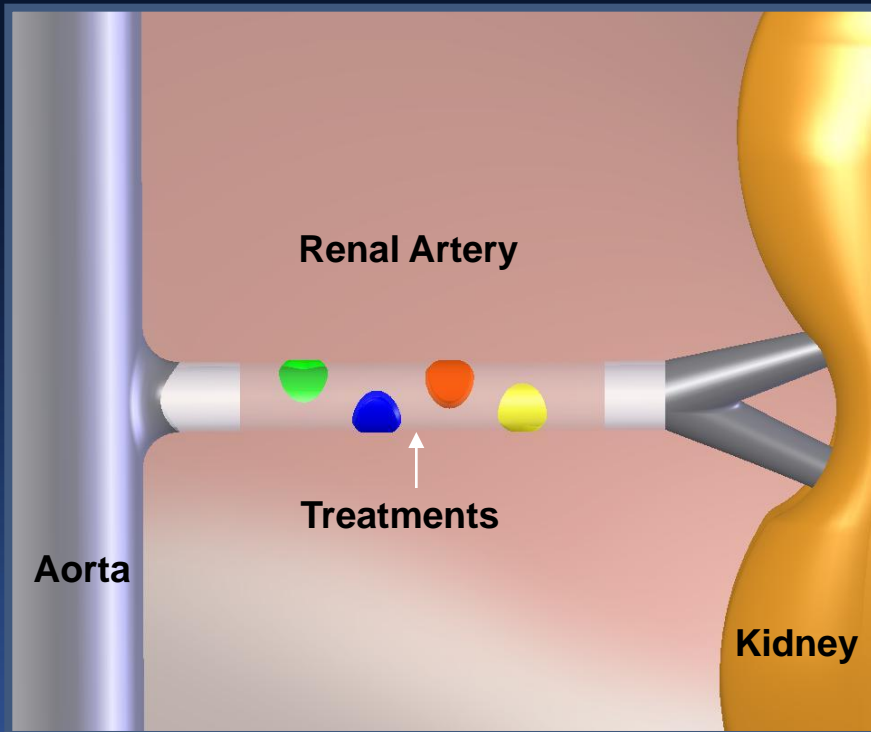


Simplicity™ Catheter

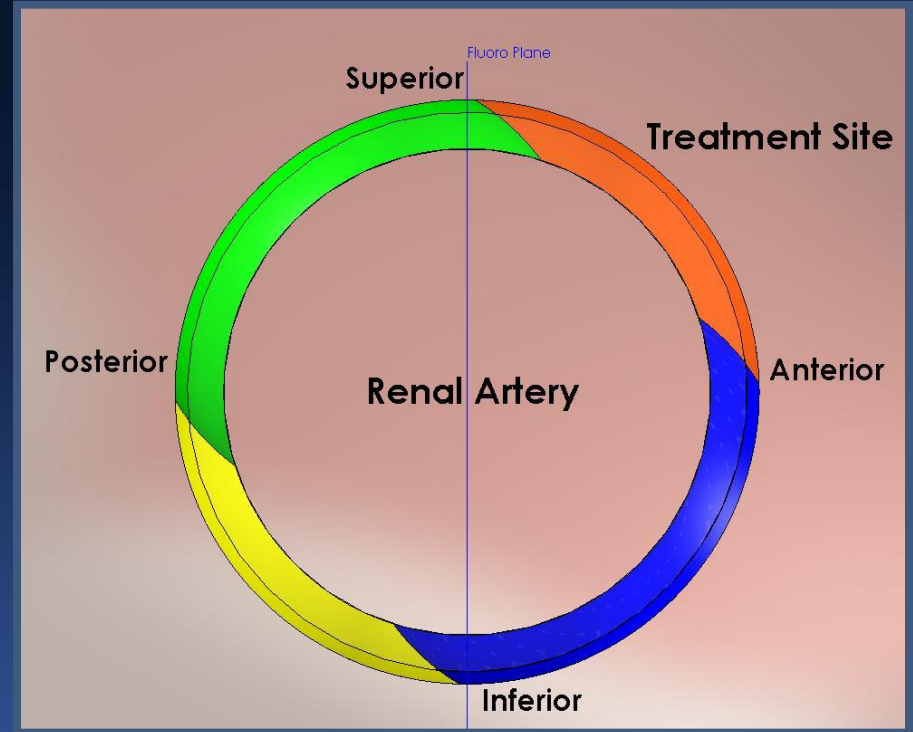
- Radiofrequency electrode tip
- Handle allows bending of the tip and rotation
- Compatible with a 6 F guiding catheter



Treatment Strategy



Focal ablations
spaced along vessel

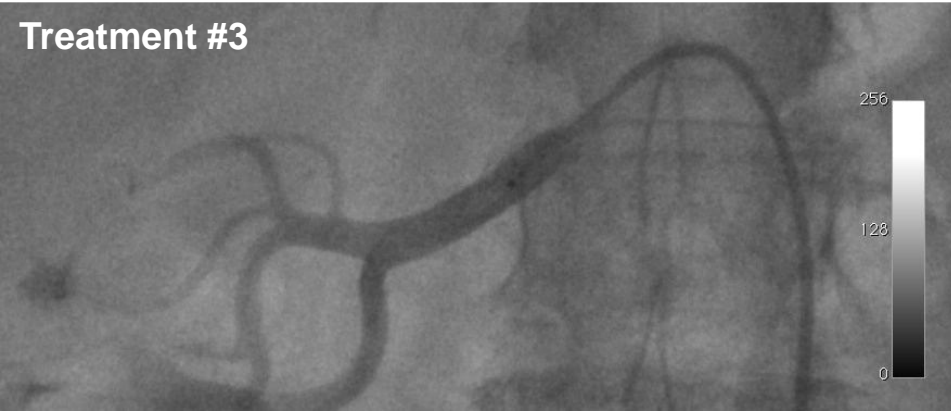
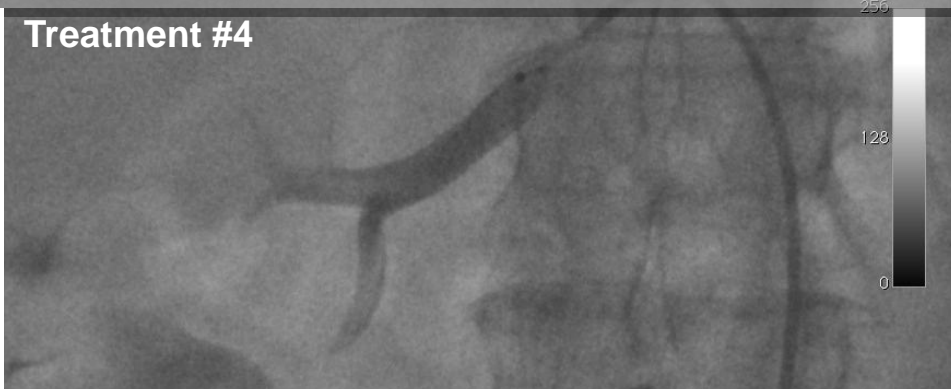


Multiple focal ablations
↑ circumferential coverage

Procedural details

- Premedication
 - Aspirin 100 mg/day (to be continued for 1 week)
 - 10-20 mg morphin + sedatives
 - 5,000 U heparin
 - Nitro i.a.
- 6 F femoral sheath
- 6 F renal guiding catheter
- Angiography of all renal arteries
- Introduce radiofrequency catheter
- 8 ablations, 2 min each, total procedure time (1hr)
- Contrast : Visipaque, 100cc

Example Treatment Locations in a Right Renal Artery



AMC First Case with Dr. Sievert

- No procedure related complication
- Discharge 1 day later
- 1 month follow up : 172/93 mmHg, HR 119
- 3 months : 150/92 mmHg, HR97
- 6 months : 190/100 mmHg, HR 77
- Dose escalation with CCB
- 1 year : 142/79 mmHg, HR 71

2nd Period

BARGAINING

My Response : 50:50

AMC Cases

- 53/ M, 165cm, 88kg
- HTN, CAD, spinal stenosis, CVA
- CCB, BB, Diuretics, ARB, alpha blocker, vasodilator, etc (>10 drugs)
- Initial BP: 170/95
- Cr 0.65
- Procedure time; 70 min
- Contrast medium ; Visipaque, 50 cc
- 1 month FU ; 135/95 (exforge 5/80mg, concor 2.5mg)

Procedural details

- Premedication
 - Aspirin 100 mg/day (to be continued for 1 week)
 - 10-20 mg morphin + sedatives
 - 5,000 U heparin
 - Nitro i.a.
- 6 F femoral sheath
- 6 F renal guiding catheter
- Angiography of all renal arteries
- Introduce radiofrequency catheter
- 12 ablations, 2 min each, total procedure time (1.5hr)
- Contrast : Visipaque, 60cc

AMC First Case with Dr. Sievert

- No procedure related complication
- Discharge 1 day later
- 1 month follow up : 135/95 mmHg, HR 70
- 3 months : 130/80 mmHg, HR68
- Reduction in medication (CCB, BB, ARB)
- 6 months : 125/75 mmHg, HR 77
- Reduction in medication (CCB, BB)

Final Period

ACCEPTANCE

My Response : 90:10

AMC Last Case

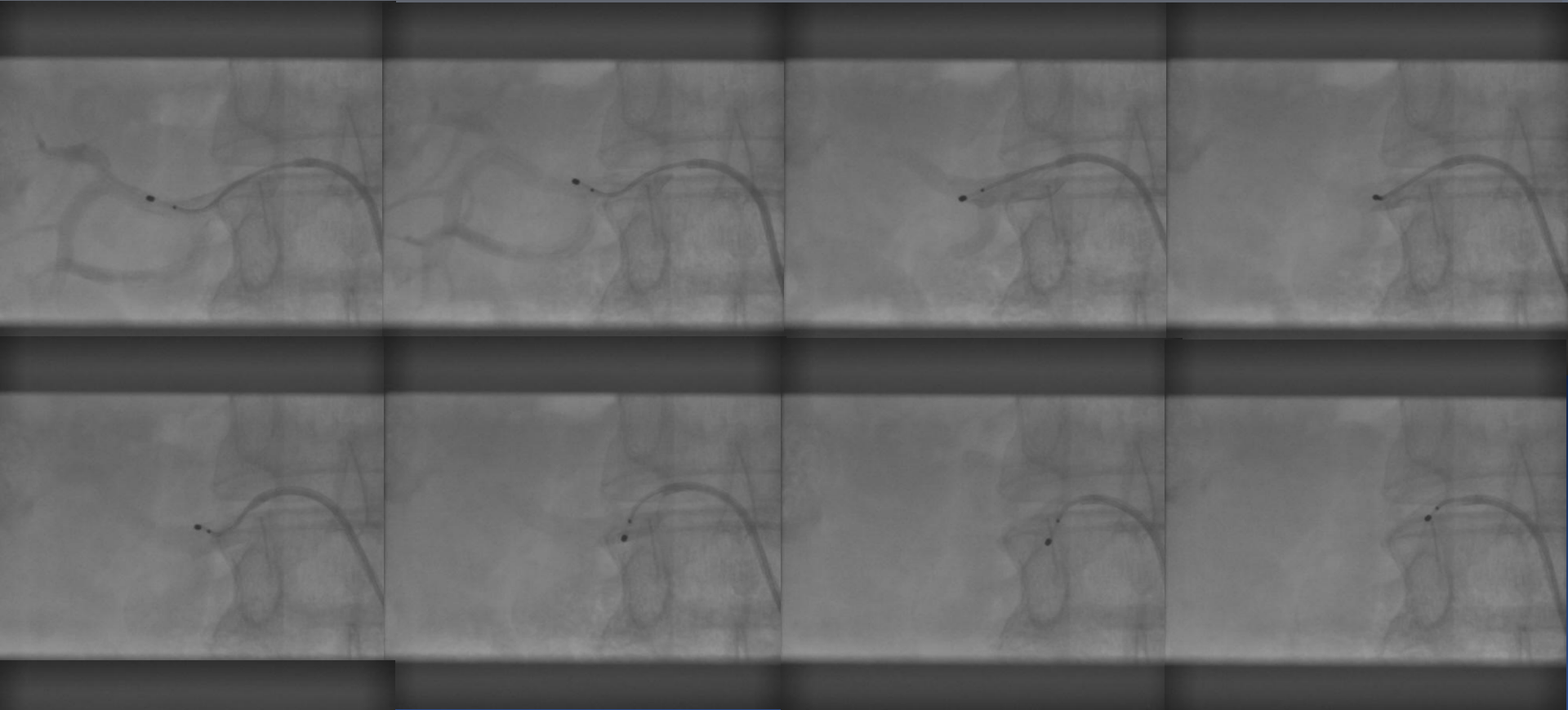
- 61/ F, 167cm, 78kg
- Drug adverse effect: rash, edema d/t CCB
- Dichlozid 25mg, tenormin 50mg, olmetec 40mg
- Initial BP: 200/120 with severe headache
- Cr 0.66
- Procedure time; 70min
- Contrast medium ; Visipaque, 50 cc
- 1 month FU ; 133/80 without medication

Challenging Cases

AMC Cases - RAS

- 65/ M, 170cm, 68kg
- HTN, variant angina
- Exforge 5/160mg, dilatrend 25mg, atacand plus 1T qd.
- Initial BP: 178/122, HR 87/min
- Cr 0.9
- Procedure time; 120 min
- Contrast medium ; Visipaque, 90 cc

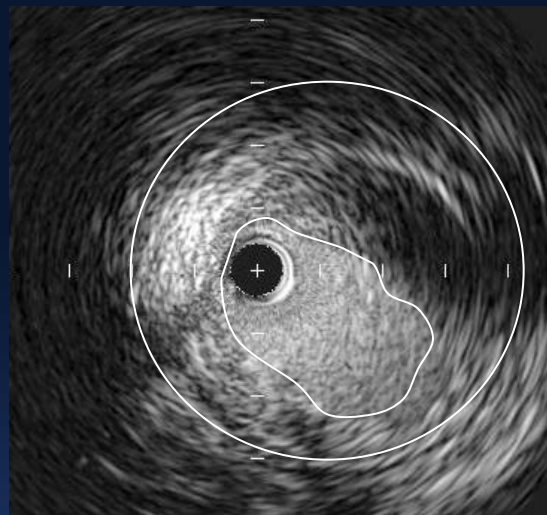
Successful Ablation in Right Renal Artery



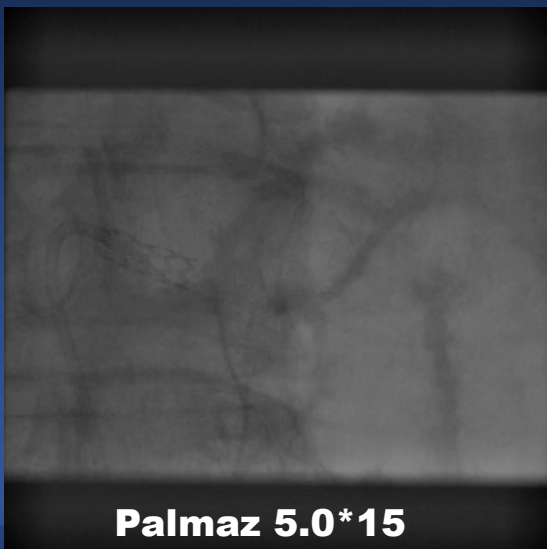
**Totally, 14 ablations were done
in Right Renal Artery**



And Then, Left Renal Artery....



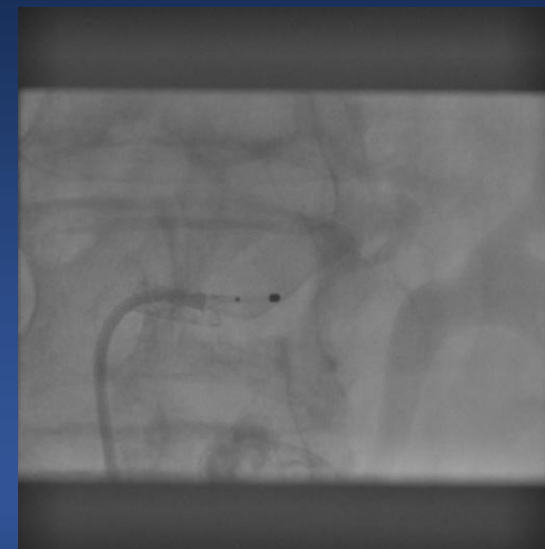
Stering 4.0*20



Palmaz 5.0*15



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Additionally, 14 ablations were done in Left Renal Artery

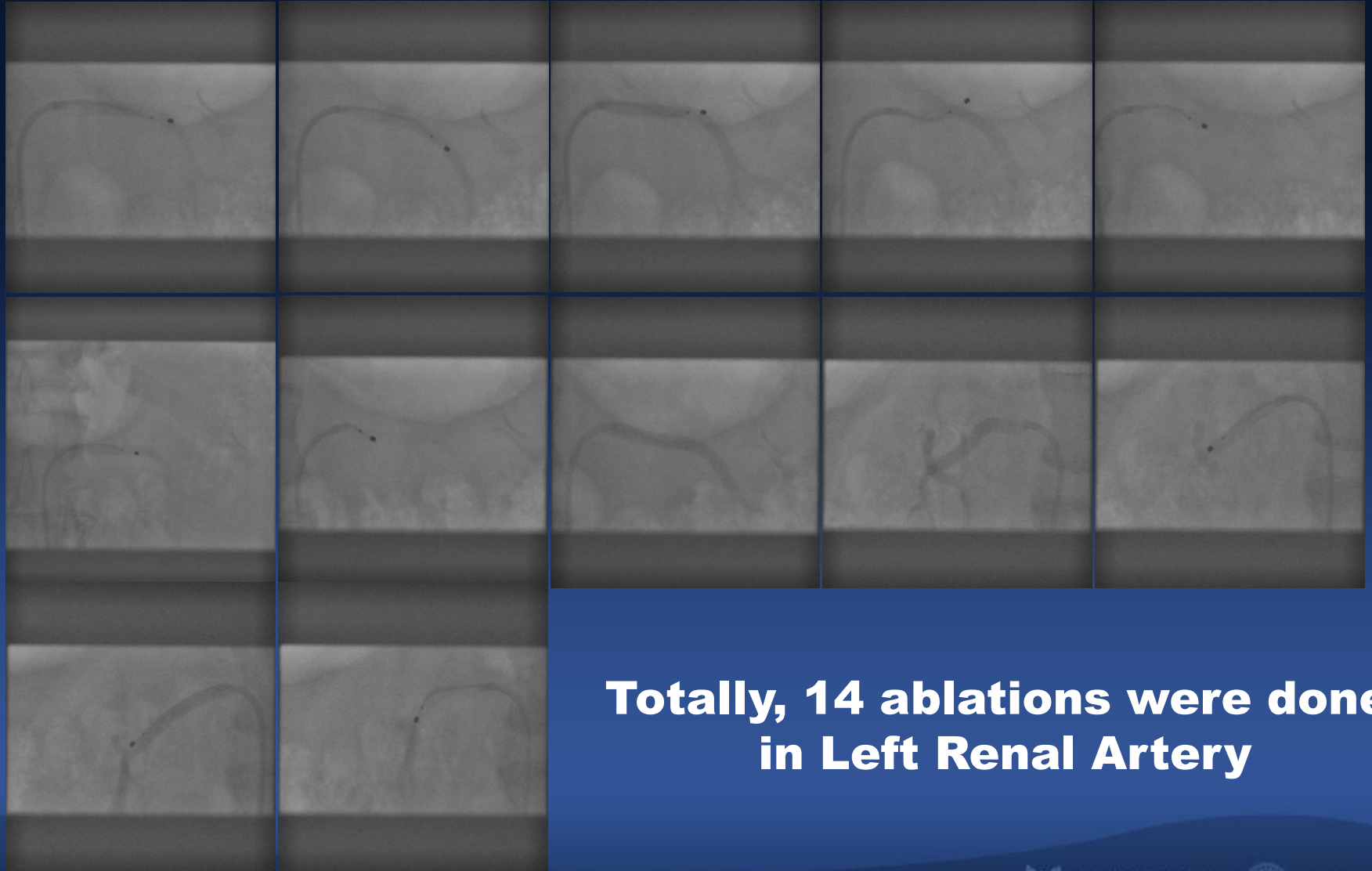
Follow Up

- No procedure related complication
- Discharge 1 day later
- 1 month follow up : 140/80 mmHg, HR 70
- 3 months : 139/89 mmHg, HR68

AMC Cases

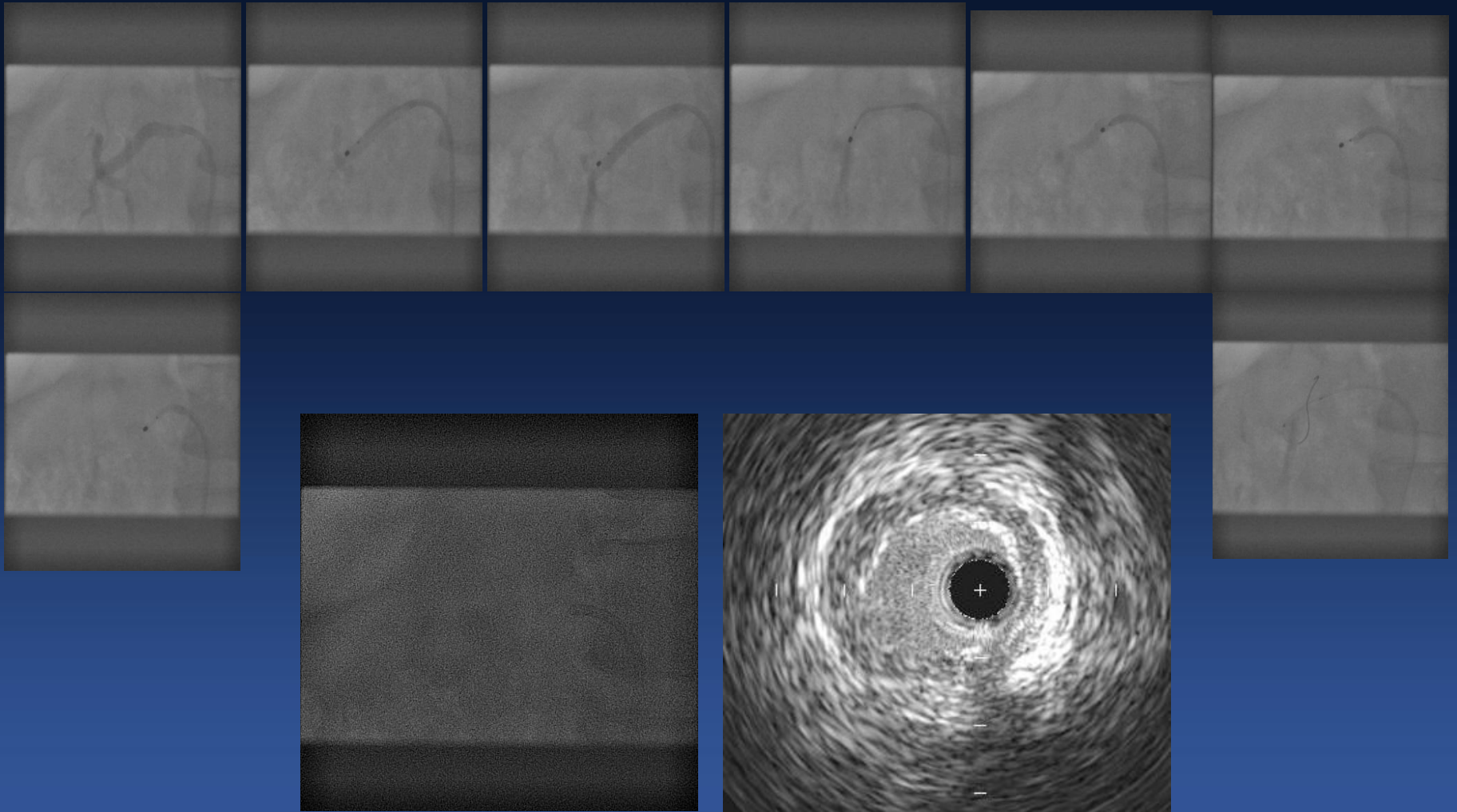
- 53/ M, 171cm, 78kg
- HTN, DM
- Caduet 5/20mg, cadura XL 1T, dichlozid 25mg, exforge 5/160mg, tenormin 50mg qd
- Initial BP: 167/88
- Cr 0.97
- Procedure time; 80min
- Contrast medium ; Visipaque, 70 cc

Successful Ablation in Left Renal Artery



**Totally, 14 ablations were done
in Left Renal Artery**

And Then, Right Renal Artery....



Additionally, 14 ablations were done in Right Renal Artery

Follow Up

- No procedure related complication
- Discharge 1 day later
- 1 month follow up : 155/85 mmHg, HR 78
- 3 months : 145/85 mmHg, HR 77
- 6 months : 135/78 mmHg, HR 65

Unmet Needs in RND?

- No Sham Control Group – Symplicity HTN-3
- 24 ABPM was available in a small portion
- Long term effect during nerve regeneration
- Exclusion : dual renal artery, accessory artery, no data on unilateral RND
- Lack of preprocedural marker
- No clinical applicable technique
- No data ; less severe HTN, hard end points
- Cost-benefit studies
- Standardized certification of RND centers

ESH recommendation 2012

- 1st Exclude : 24 ABPM, 2nd HTN, sleep apnea, high salt diet, BP raising drugs, severe obesity
- 2nd Optimize anti-HTN drug with 3-4 (diuretics, anti-aldosterone drug)
- 3rd *consider anatomic contraindications or eGFR*
- Overall
 - very experienced hospital centers
 - use device which have demonstrate efficacy and safety in clinical studies

Conclusions

- Transcatheter Renal Denervation results in significant reductions in BP
- The procedure seems to be very safe
- The effect is sustained up to 3 years
- It may also be beneficial in patients with diabetes, sleep apnea, heart failure and other diseases
- However, we still need to be under the strict indication, such as true resistant hypertension