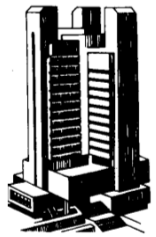
Catheter- Based Renal sympathetic Denervation

Uri Rosenschein MD

Bnai Zion Medical Center

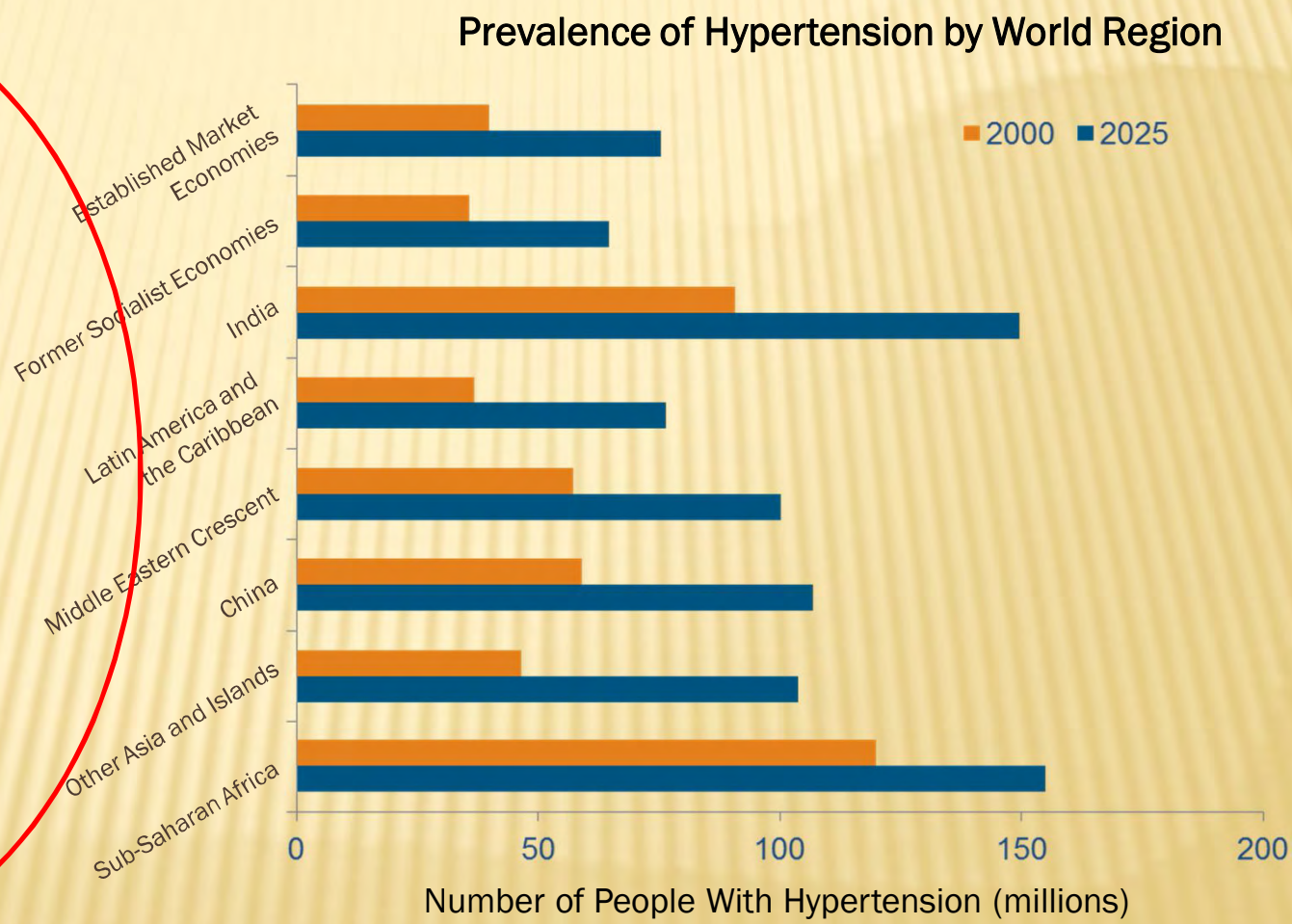
Technion




THE NEED
MITAKE

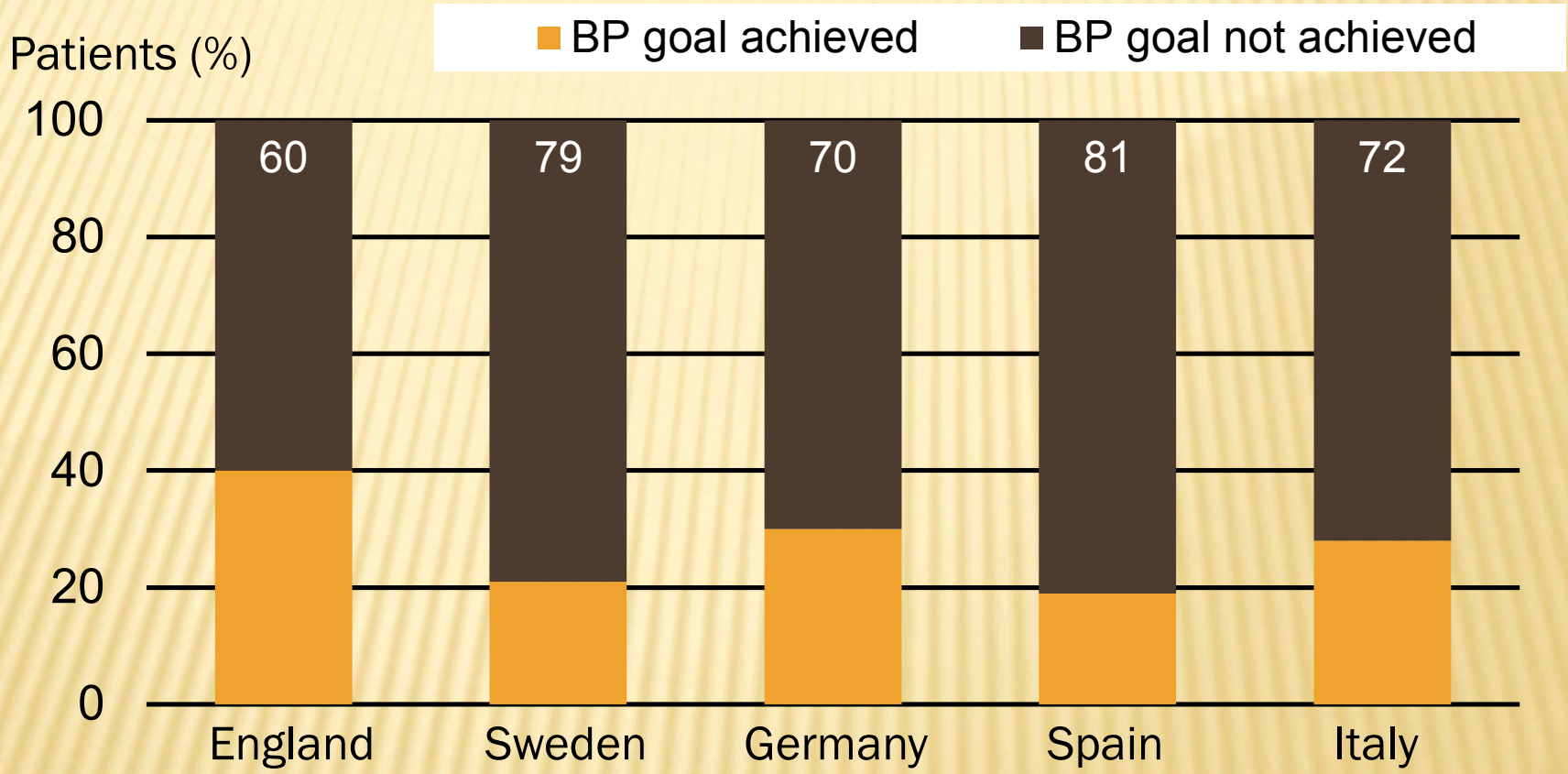
WORLDWIDE PREVALENCE OF HYPERTENSION IS INCREASING

- In 2000, 972 million (26%), of the adult population had hypertension
- By year 2025, 1.56 billion (29%) will have hypertension



Kearney PM, et al. *Lancet.* 2005;365:217-223.

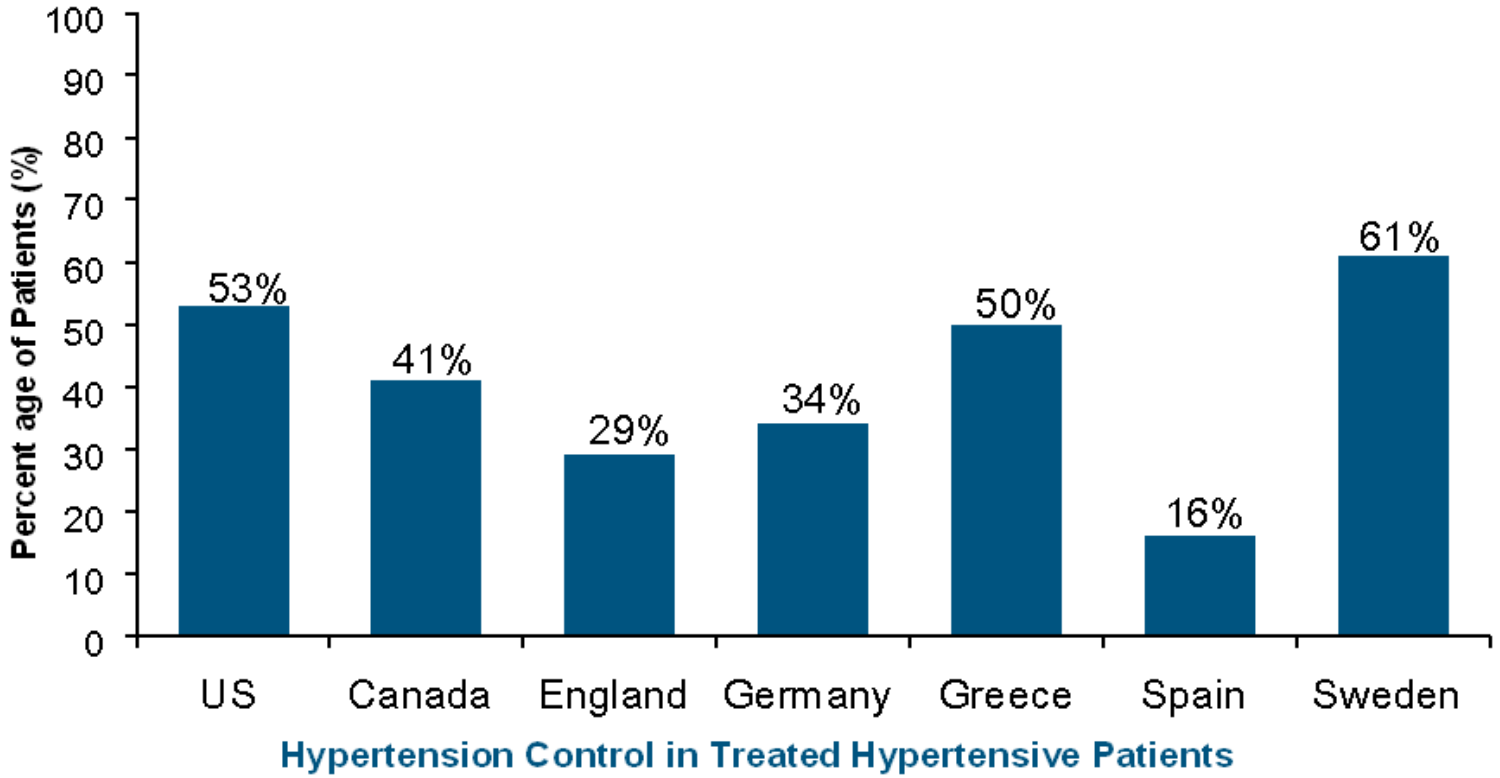
APPROXIMATELY 70% OF PATIENTS* IN EUROPE DO NOT REACH BP GOAL



*Treated for hypertension
BP goal is <140/90 mmHg

Wolf-Maier et al. Hypertension 2004;43:10–17

REAL LIFE HYPERTENSION CONTROL

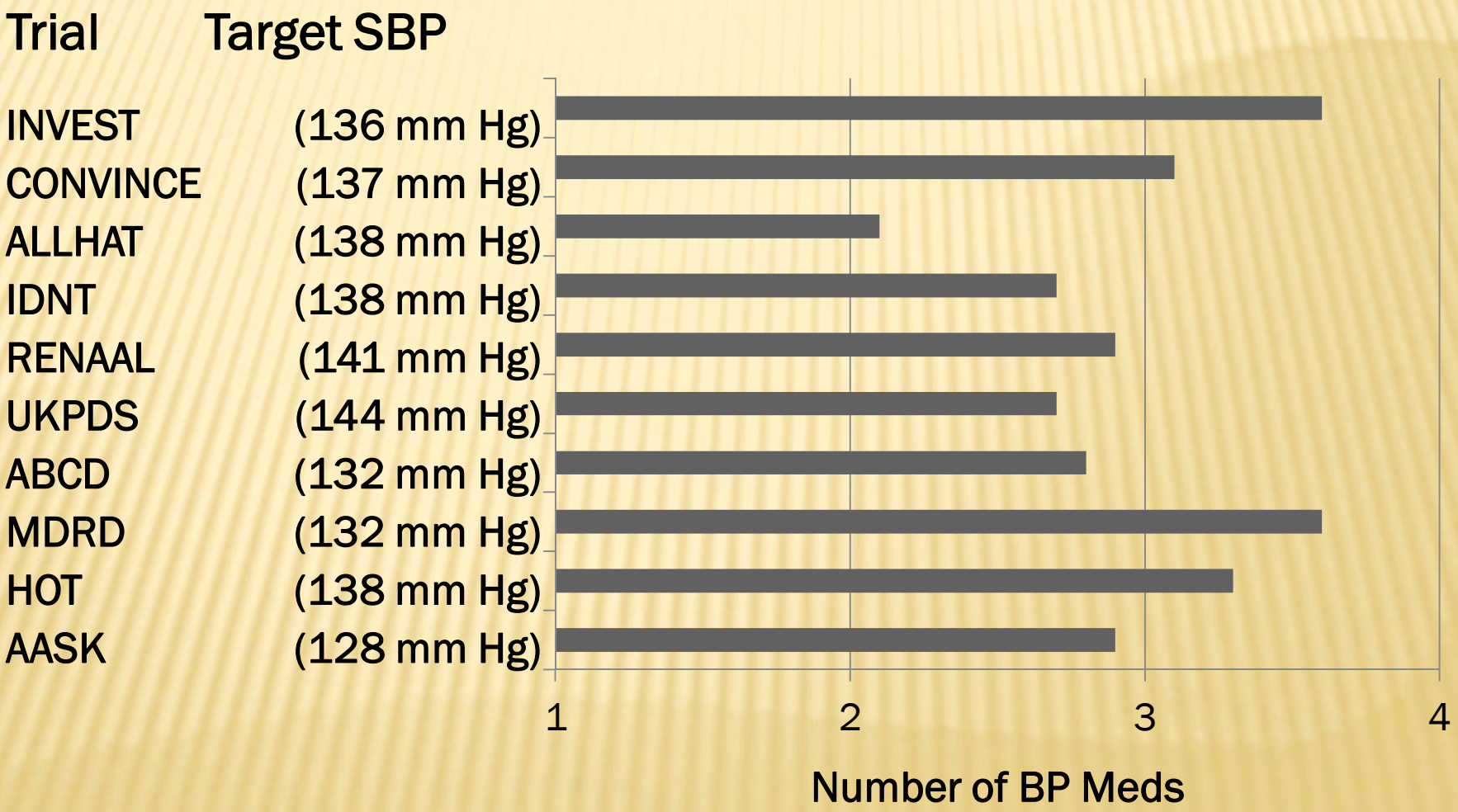


Source: Kearney PM, et al. *J Hypertens*. 2004; 22:11-19.

BNAI ZION ADMISSIONS TO CARDIOLOGY

- Hypertensive 88%
- Of the hypertensive group
  - Uncontrolled by Meds 38%
  - 2 classes of Meds 26%
  - 3 classes of Meds 15%

2.7 BP MEDS/PATIENT TO ACHIEVE TARGET BP



Bakris GL, et al. *Am J Kidney Dis*. 2000;36(3):646-661.

ADHERENCE TO COMMON CV MEDICATIONS

Medication	Self-Reported Adherence, %	Consistent Adherence, %*
Aspirin	83	71
Lipid-lowering agents	63	46
β-blockers	61	44
Aspirin + β-blocker	54	36
Aspirin + β-blocker + lipid-lowering agent	39	21

*More than 2 consecutive follow-up surveys over 6±12 months.

Baroleti et al Circ 2010:121;1455

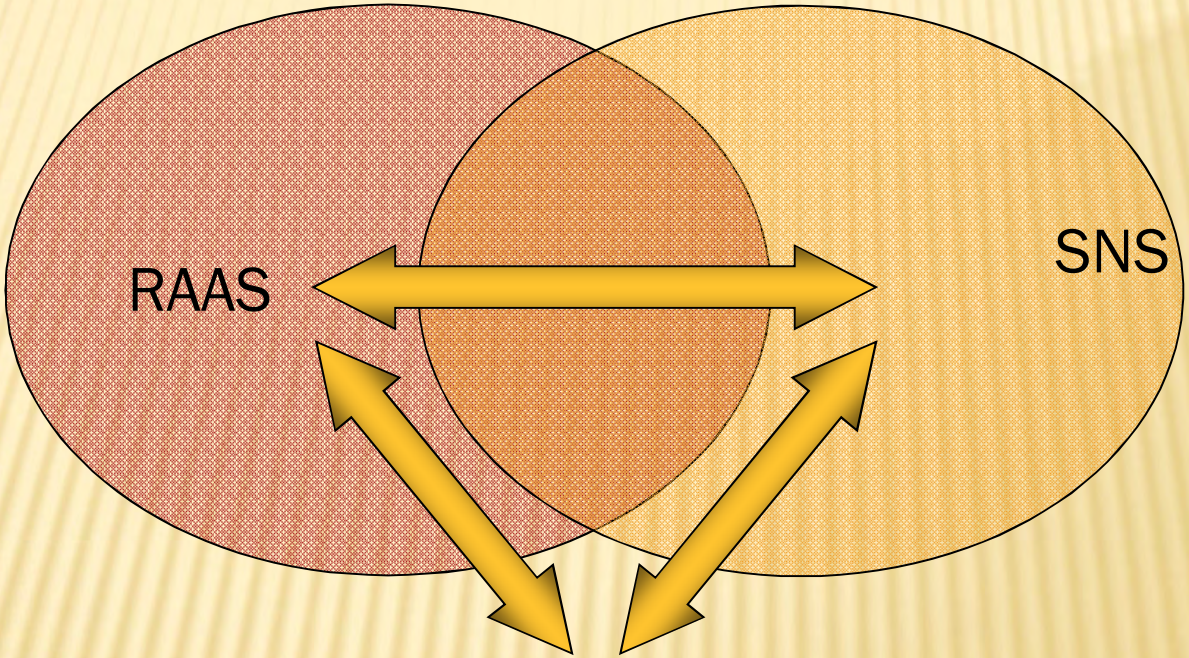
IMPACT OF A 5 MMHG SBP REDUCTION

	Overall Reduction
Stroke	14%
Coronary Heart Disease	9%
All Cause Mortality	7%

Hypertension 2003;289:2560-2572.

MAJOR INFLUENCERS IN HYPERTENSION

In human and animal models there are 2 basic, well-defined contributors to the pathophysiology of HBP

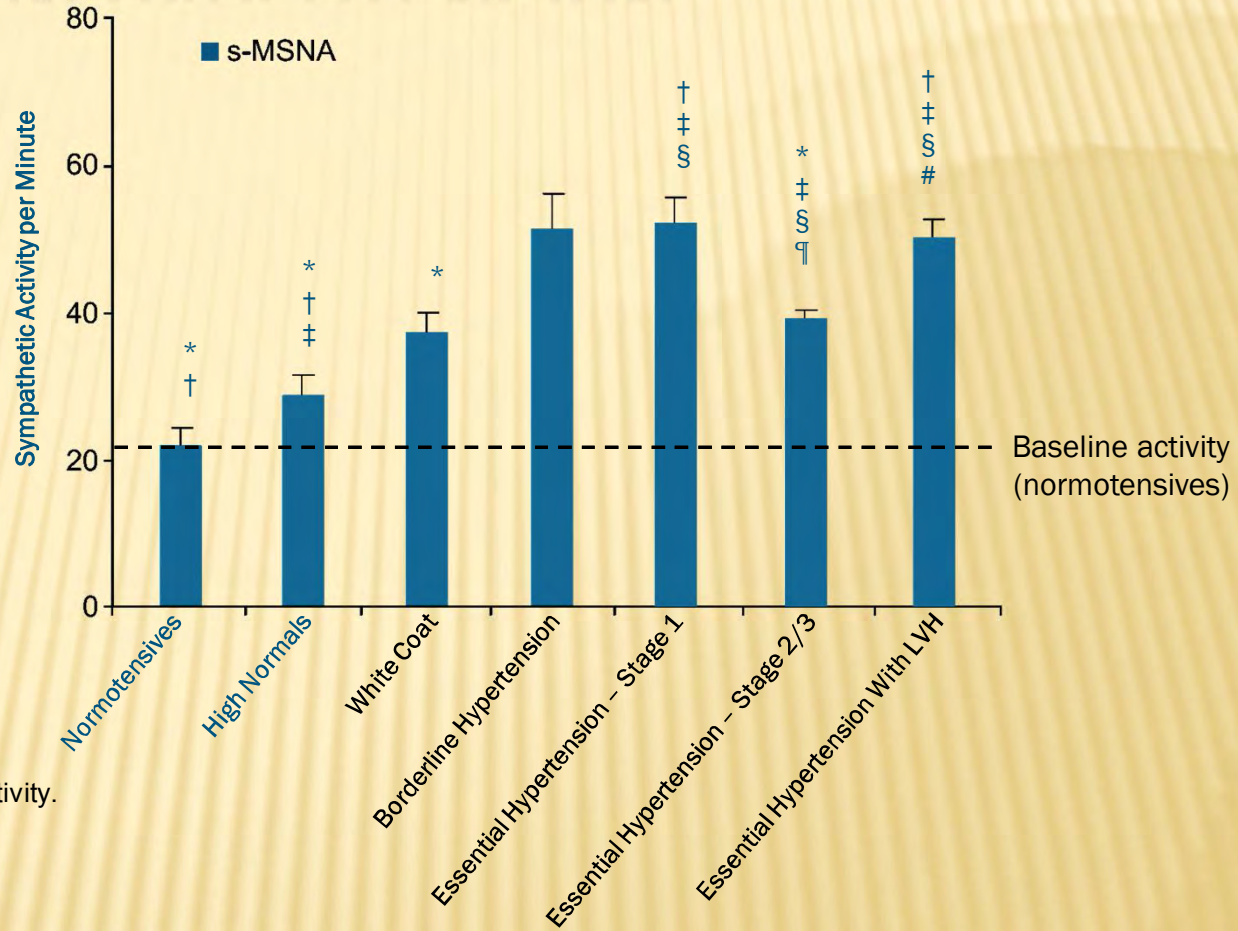


Other influencers include:
- Na & Water retention
- Co morbidities
- Genetic Factors

Laragh JH, Sealey JE. Am J Hypertens. 2003;16:407-415

INCREASED CENTRAL SYMPATHETIC DRIVE IN HYPERTENSION

- Sympathetic drive is elevated in multiple types of hypertension

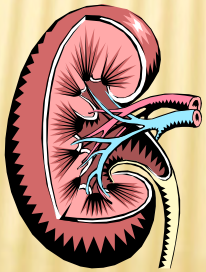


s-MSNA=single-unit efferent sympathetic nerve activity.
LVH=left ventricular hypertrophy.
*P<0.05 Compared with borderline hypertension.
†P<0.05 Compared with white coat hypertension.
‡P<0.05 Compared with normal pressure.
§P<0.05 Compared with high-normal pressure.
¶P<0.05 Compared with essential hypertension–stage 1.
#P<0.05 Compared with essential hypertension–stage 2/3.

Adapted from Smith P, et al. *Am J Hypertens.* 2004; 17:217-222.

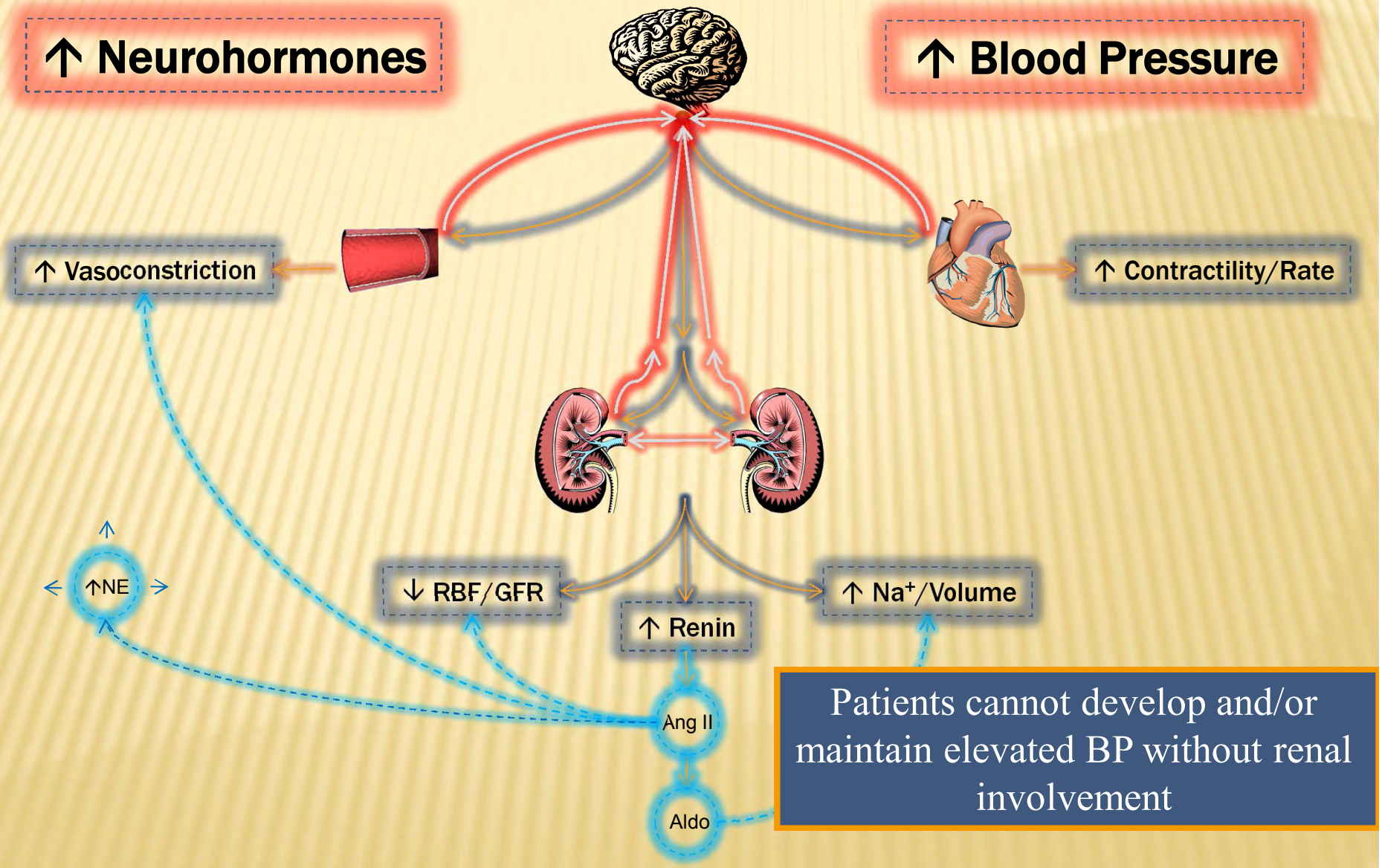
CLASSICAL NEURO-HORMONAL AXIS:
KIDNEY AS A PASSIVE RECIPIENT OF SYMPATHETIC SIGNALS

Renal Efferent Nerves



↑ Renin Release → RAAS activation
↑ Sodium Retention
↓ Renal Blood Flow

CROSSTALK BETWEEN KIDNEYAND CNS



PRECEDENT SURGICAL THORACOLUMBAR SYMPATHECTOMY

THE EFFECTS OF PROGRESSIVE SYMPATHECTOMY ON BLOOD PRESSURE

BRADFORD CANNON

From the Laboratories of Physiology in the Harvard Medical School

Received for publication March 24, 1931

THE BRITISH JOURNAL OF SURGERY

1952

SYMPATHECTOMY IN THE TREATMENT OF BENIGN AND MALIGNANT HYPERTENSION*

A REVIEW OF 76 PATIENTS

By C. J. LONGLAND and W. E. GIBB

THE JOURNAL

of the American Medical Association

Published Under the Auspices of the Board of Trustees

VOL. 152, NO. 16 — CHICAGO, ILLINOIS — AUGUST 15, 1953

SPLANCHNICECTOMY FOR ESSENTIAL HYPERTENSION

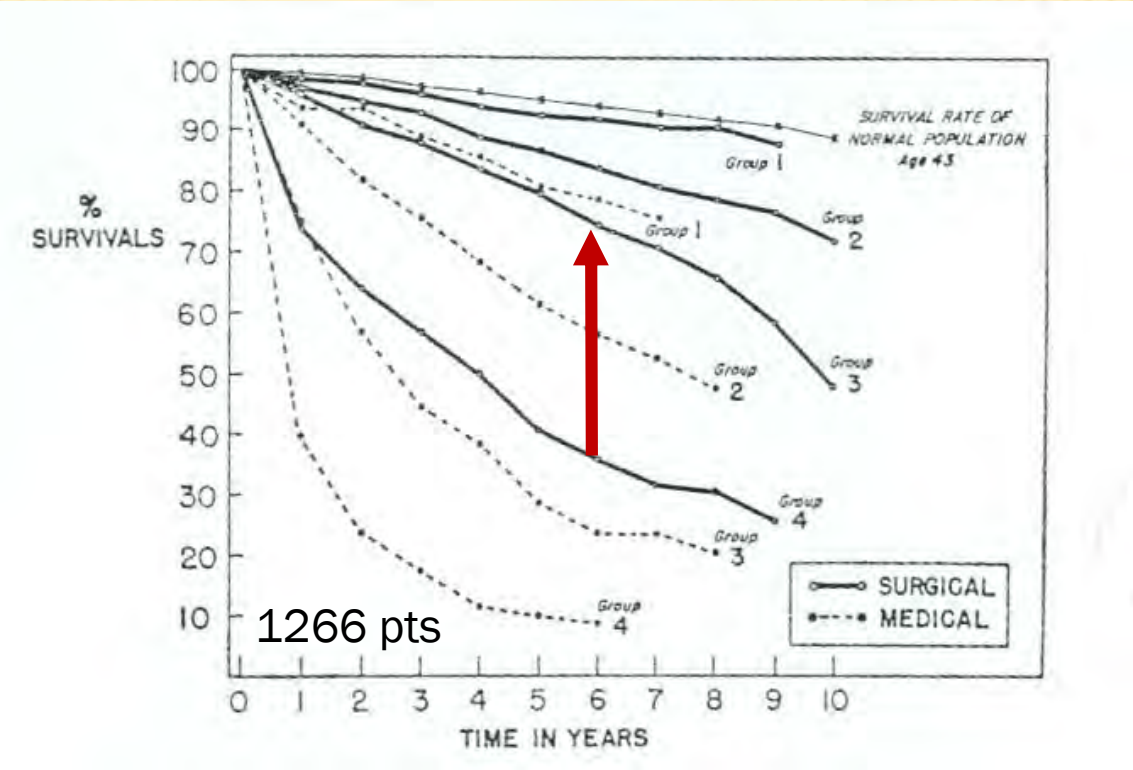
RESULTS IN 1,266 CASES

Reginald H. Smithwick, M.D.
and
Jesse E. Thompson, M.D., Boston

Dr. Reginald H. Smithwick

14

SYMPATHECTOMY IN HYPERTENSION:



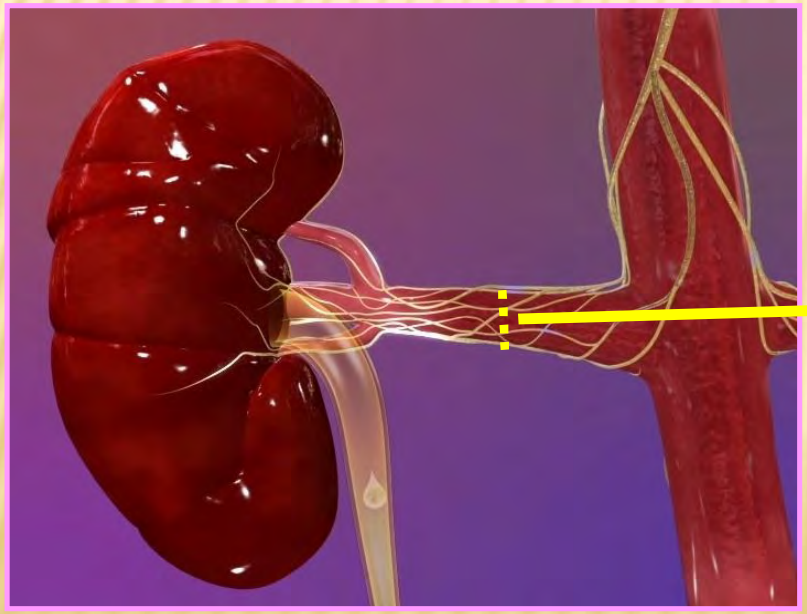
Denervating lower half of the body produced:

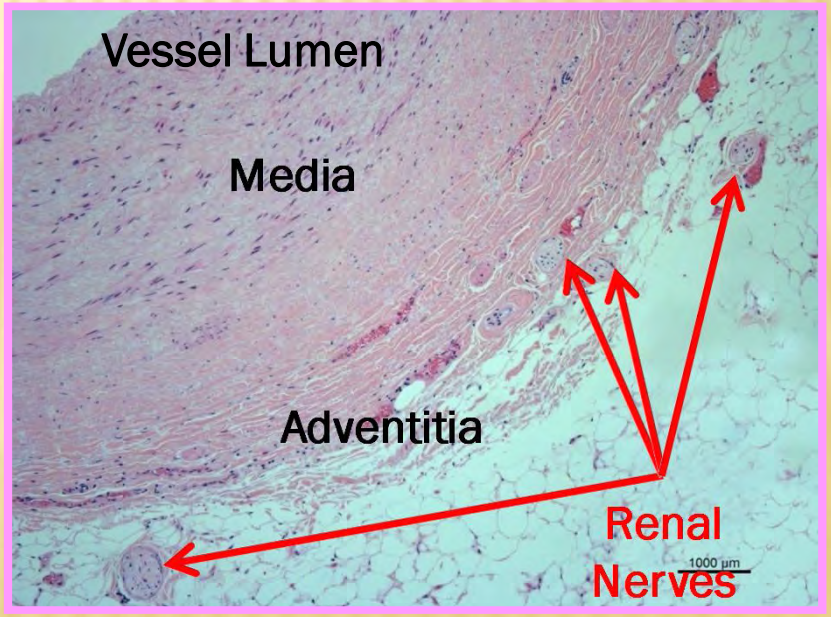
- Mortality benefit
- Inconsistent BP results
- Significant morbidity including orthostatic hypotension, bowel & bladder dysfunction

Smithwick RH, *J Am Med Assoc.* 1953;152:1501-1504

THE SYMPATHETIC RENAL NERVES

- Follow the renal artery to the kidney
- Primarily lie within the adventitia
- ≈ 70% within 15mm of the ostium
- ≈ 95% are within 2.5mm of the vessel lumen

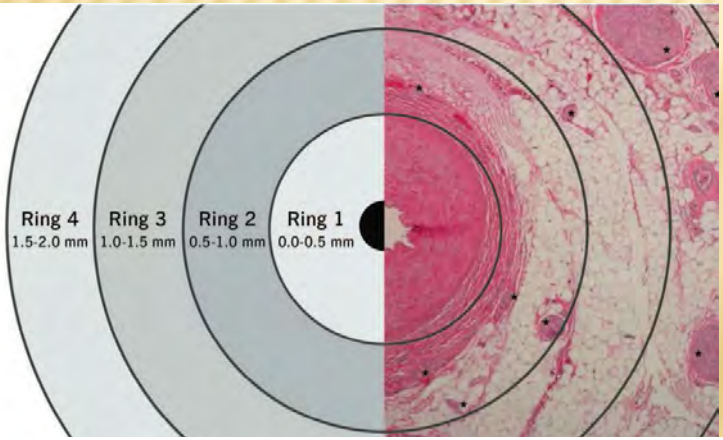




HUMAN RENAL ARTERY:

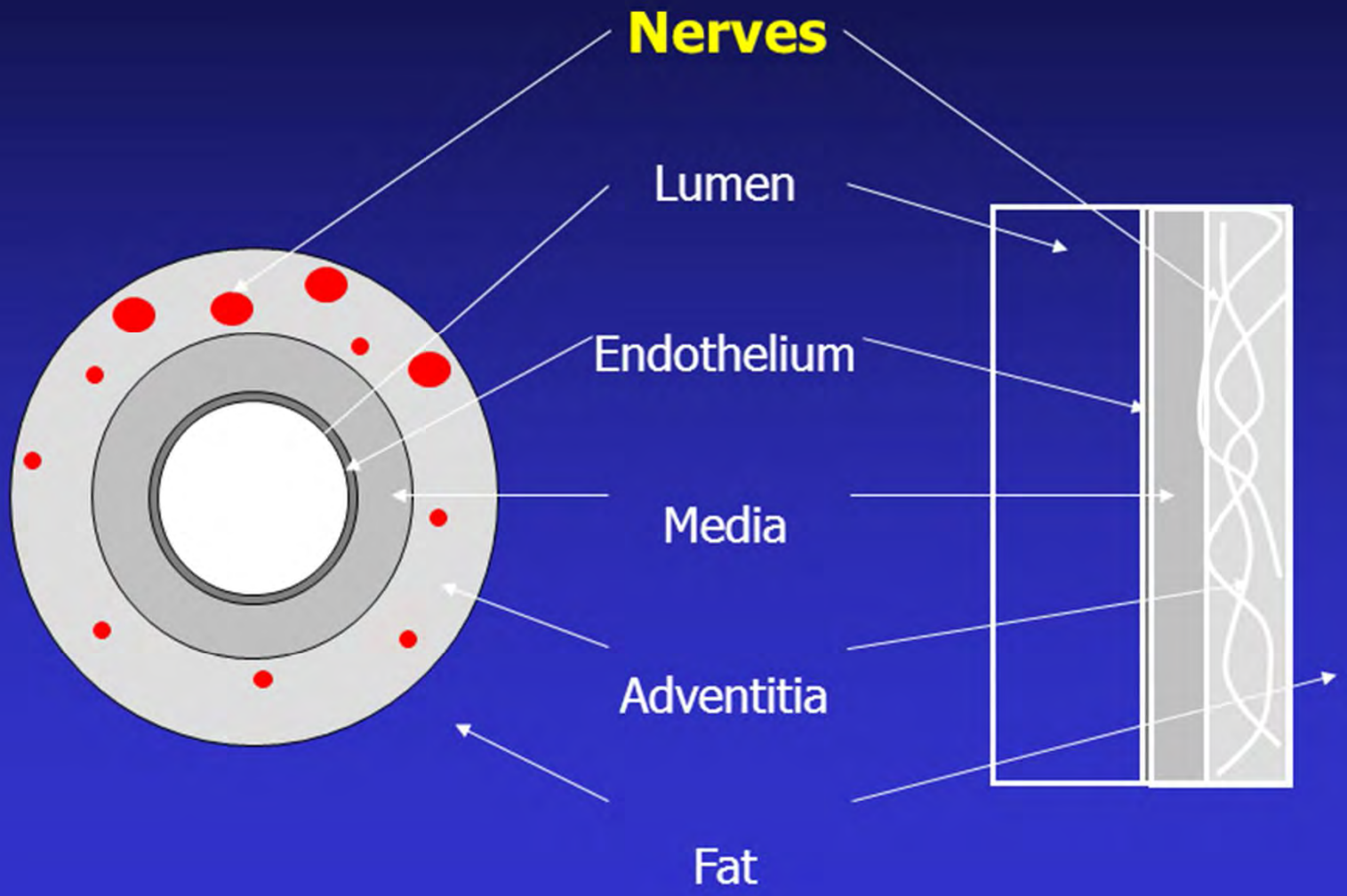
TOTAL NUMBER (%) OF NERVES PER RING (0-0.5 TO 2.0-2.5 MM) AND PER SEGMENT (PROXIMAL TO DISTAL) IN NON-PERFUSION FIXED ARTERIES

Ring	Segment			
	Proximal	Middle	Distal	Total
0 – 0.5	2 (0.2%)	2 (0.2%)	6 (0.6%)	10
0.5 – 1.0	87 (9.1%)	152 (15.9%)	223 (23.3%)	462
1.0 – 1.5	65 (6.8%)	86 (6.0%)	94 (9.8%)	245
1.5 – 2.0	43 (4.5%)	47 (4.9%)	58 (6.1%)	148
2.0 – 2.5	19 (2.0%)	36 (3.8%)	36 (3.8%)	91
Total	216 (22.6%)	323 (33.8%)	417 (43.6%)	956



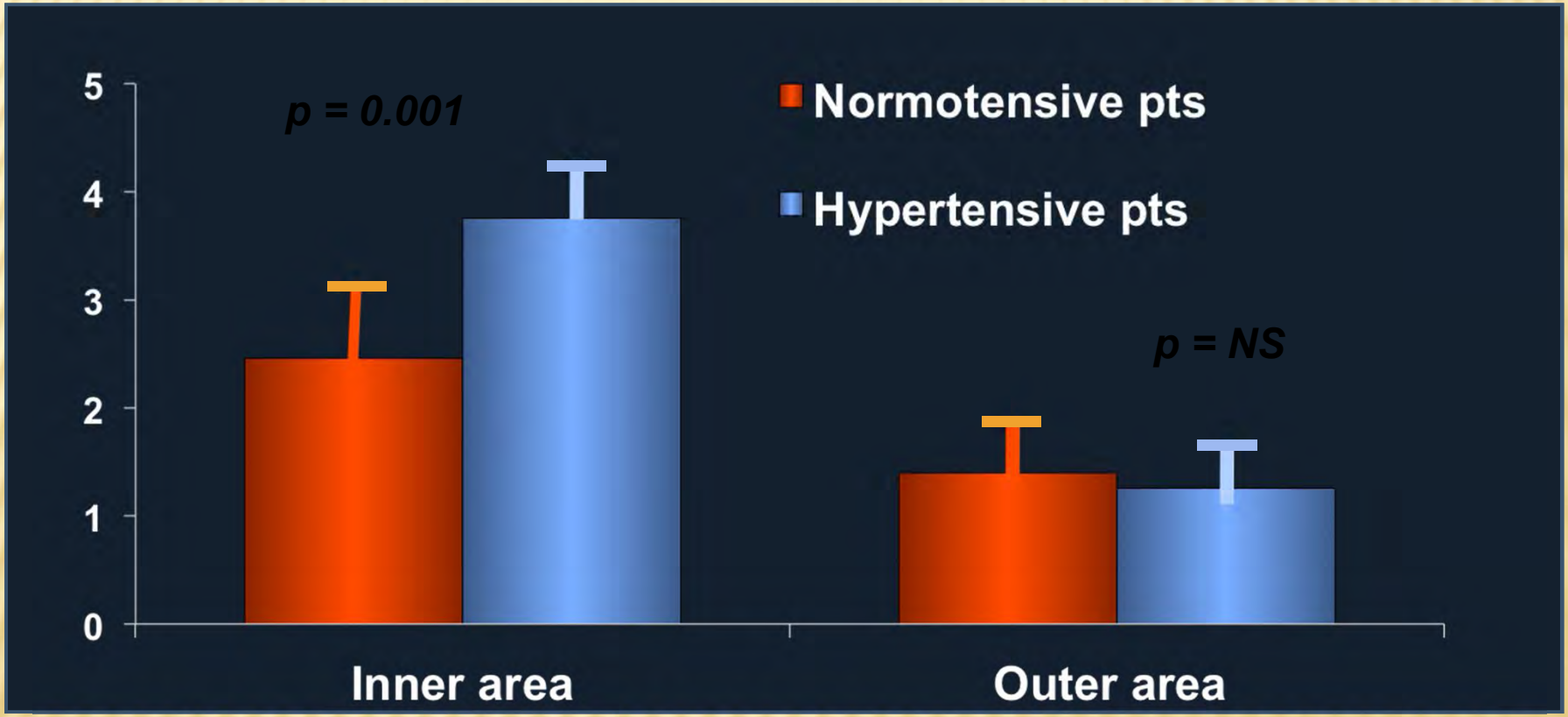
Atherton DS, et al., Clin Anat 2012;25:628-633

Anatomy of Renal Artery



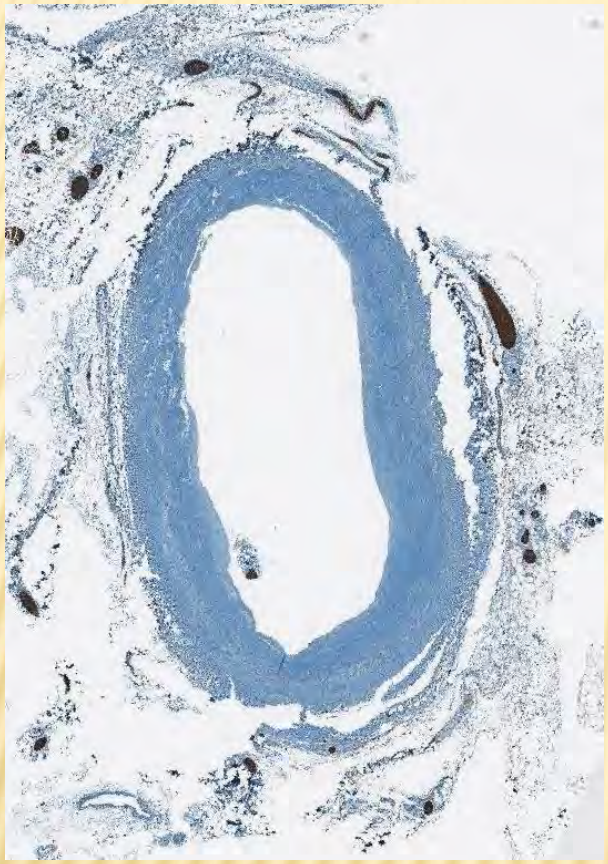
NUMBER OF NERVES IN PERIADVENTITIAL FAT

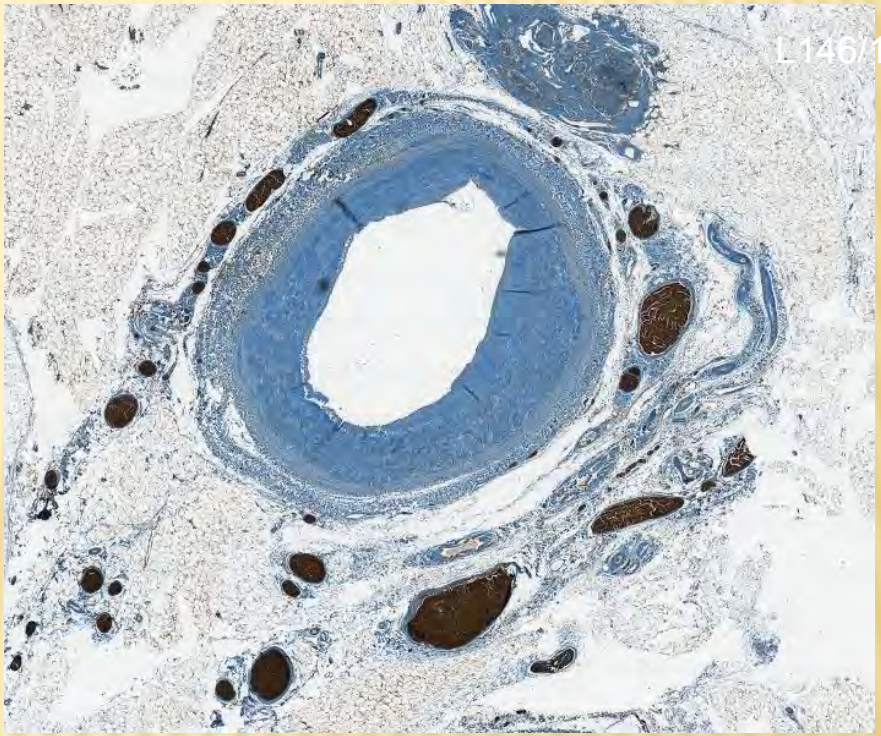
(Nerves x mm2)



Sangiorgi et al TCT 2012

Renal Artery Sypmathetic Nerves
Hypertensive vs. Normotensive Pts



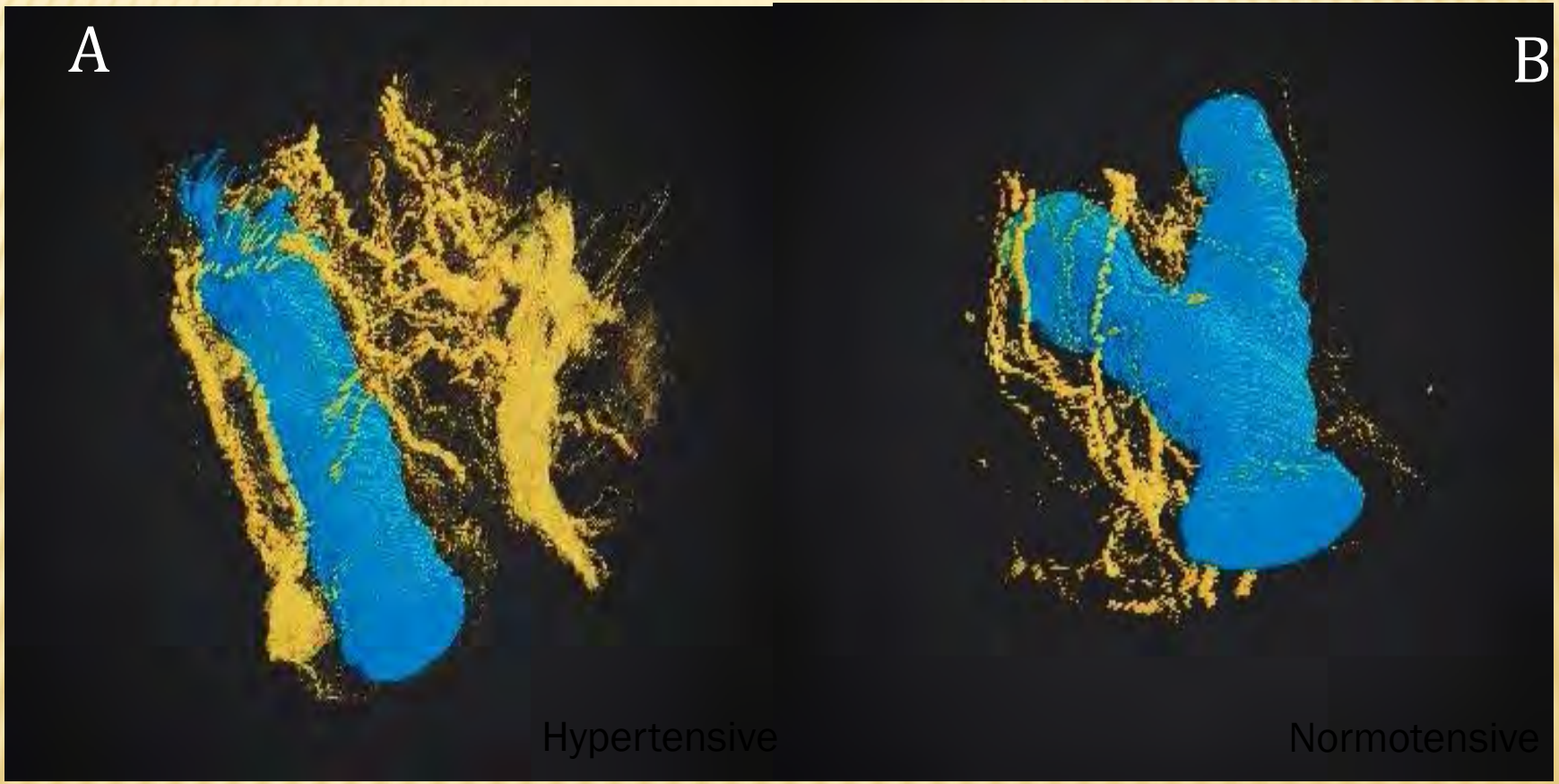


Normotensive

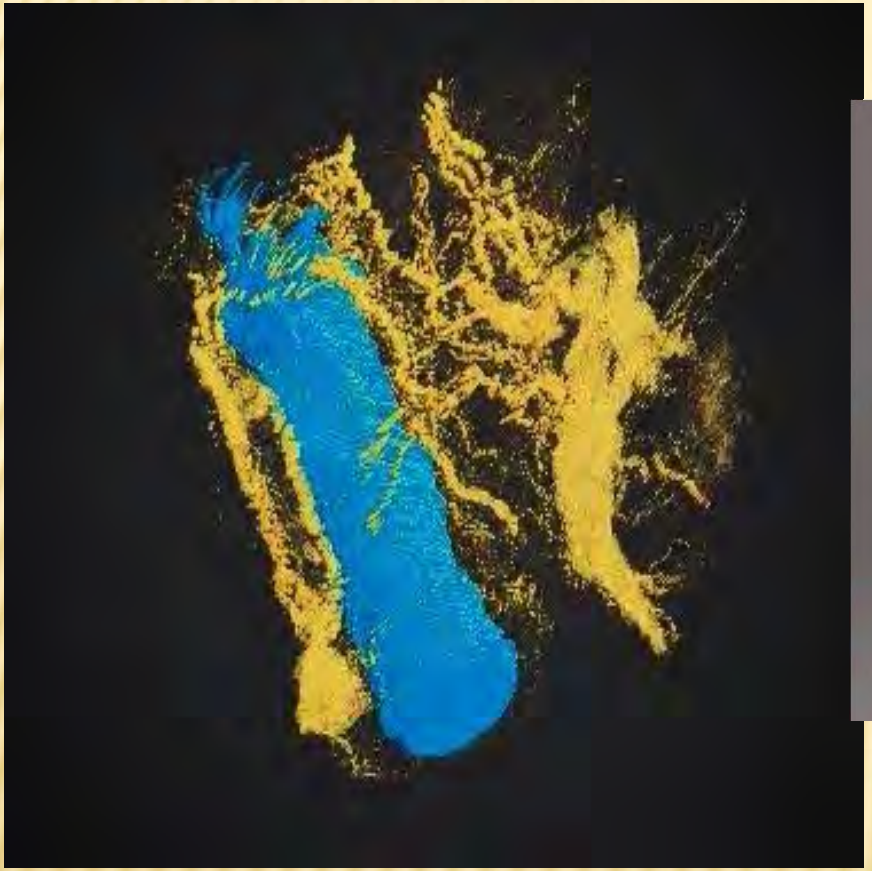
Hypertensive

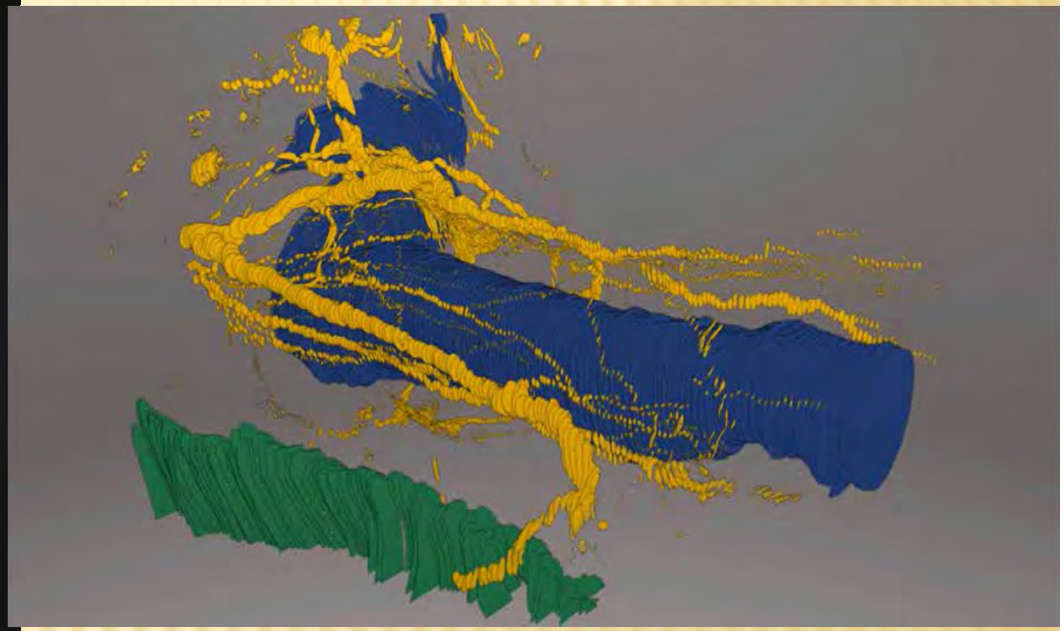
Sangiorgi et al TCT 2012

3D Reconstruction
Hypertensive vs. Normotensive



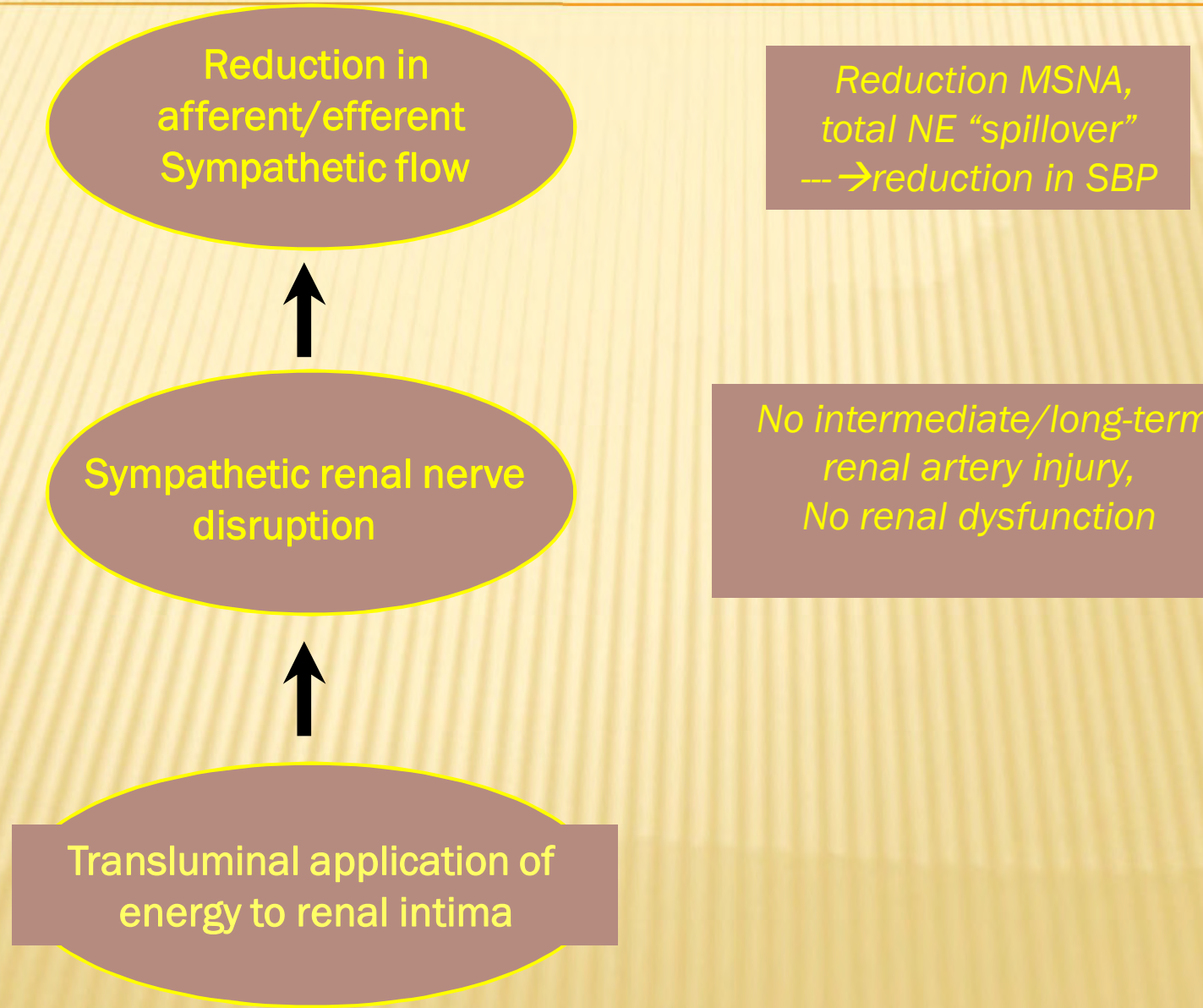
Hypertesive patients
3D Reconstruction





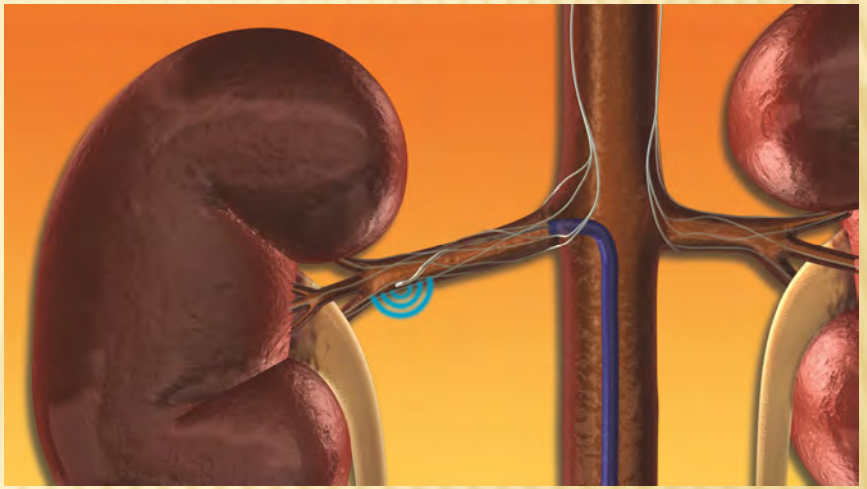
Sangiorgi et al TCT 201

BASIC PRINCIPLES OF RDN

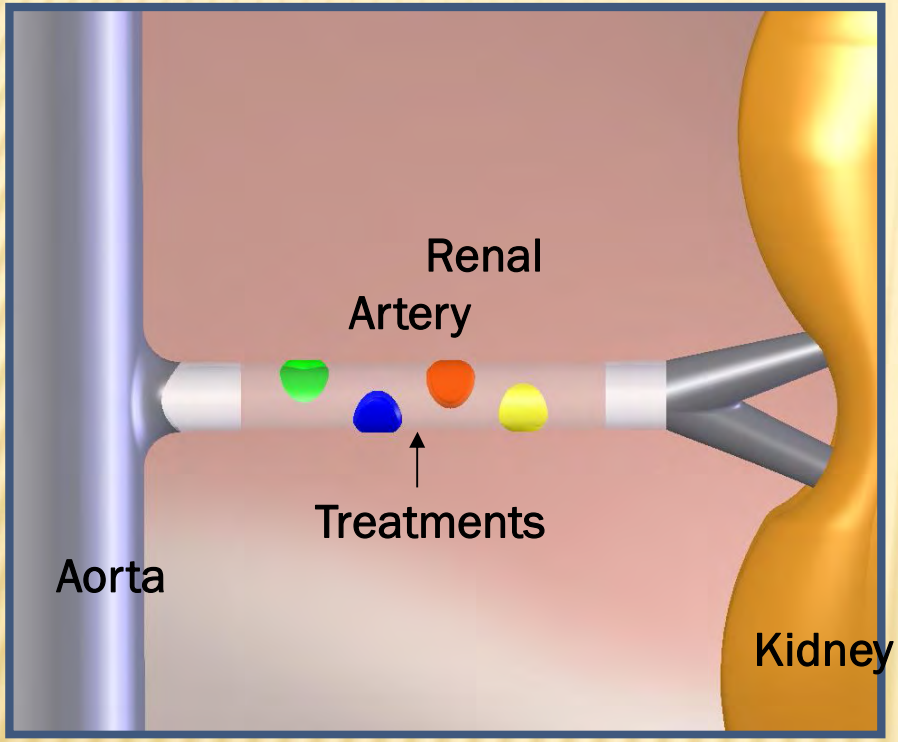


CATHETER-BASED RENAL DENERVATION

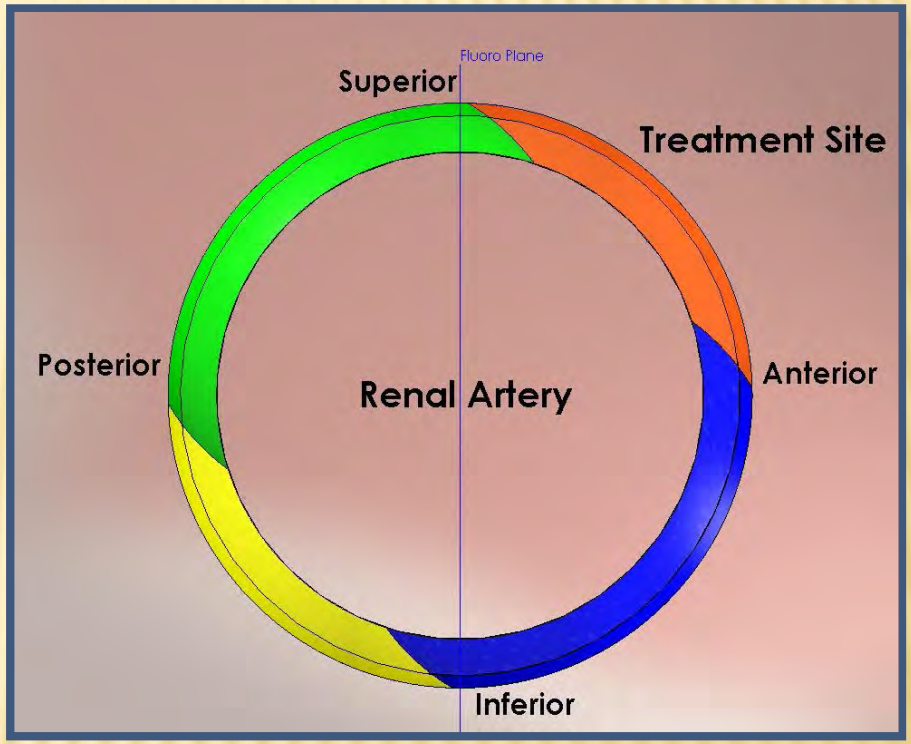
- Semi-standard interventional technique
- Dedicated ablation catheter
- RF Generator
  - Automated
  - Low-power
  - Built-in safety algorithms



TREATMENT STRATEGY

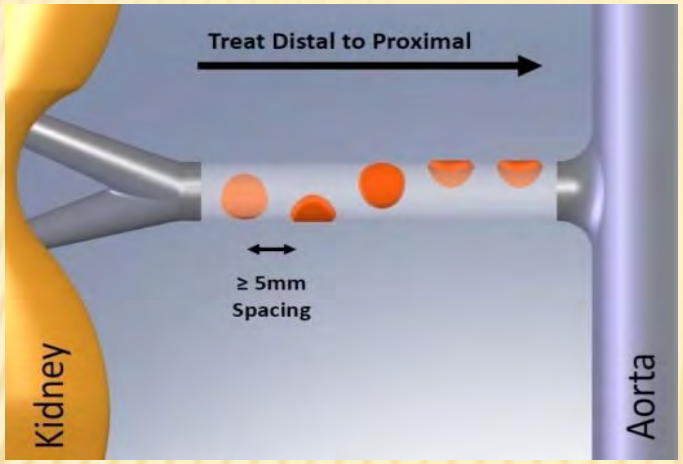


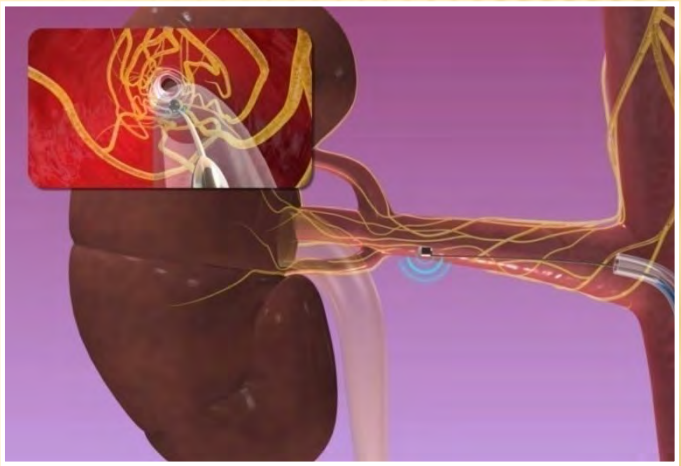
Multiple focal ablations
spaced along vessel

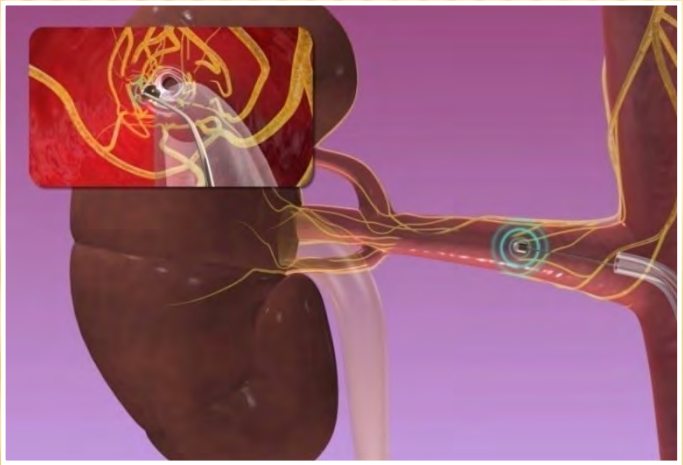


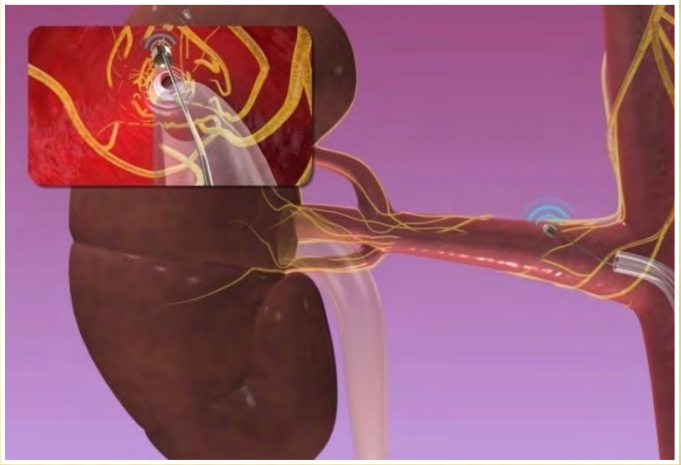
↑ circumferential coverage

SELECTIVE DENERVATION OF THE RENAL SYMPATHETIC NERVES BY RF ABLATION

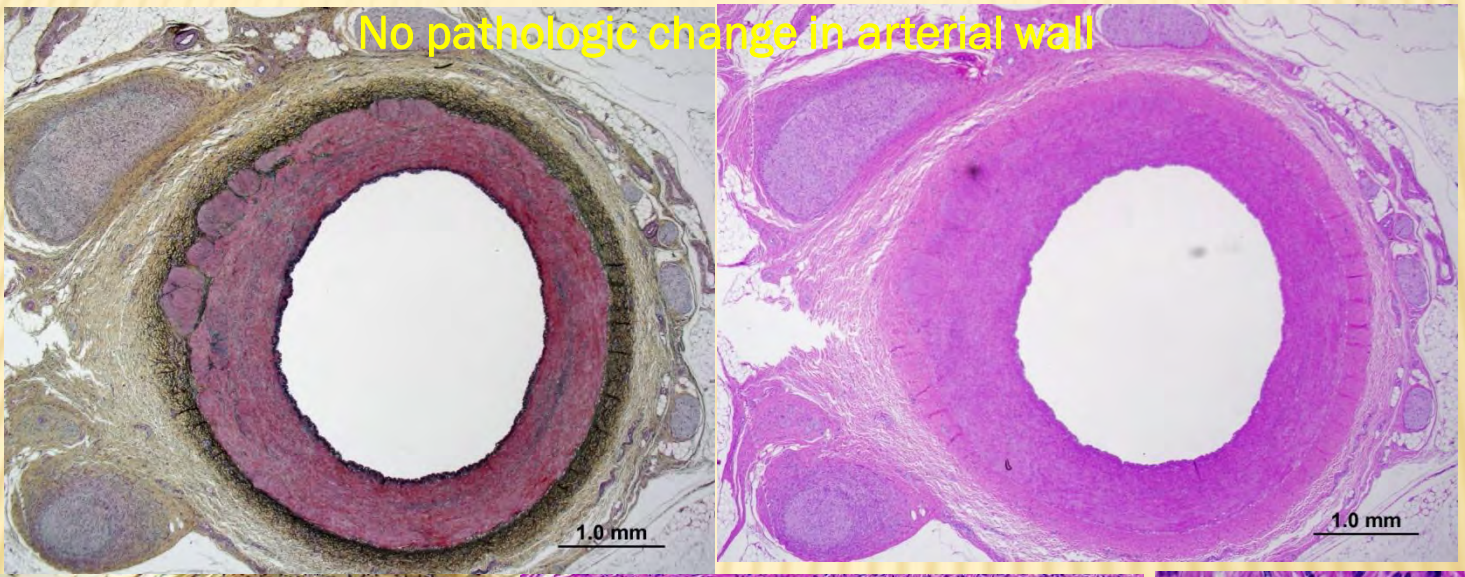


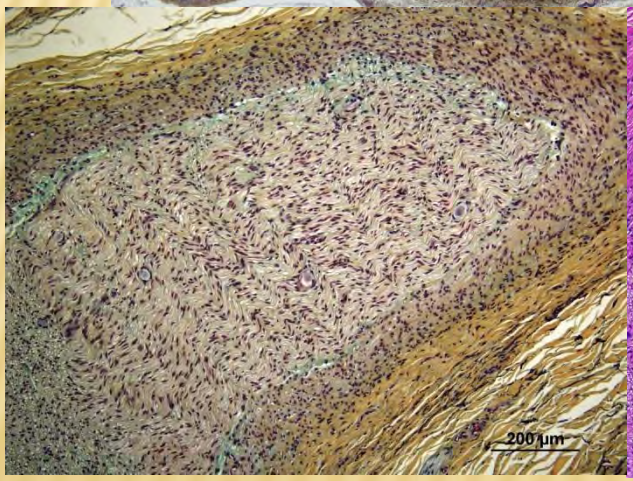


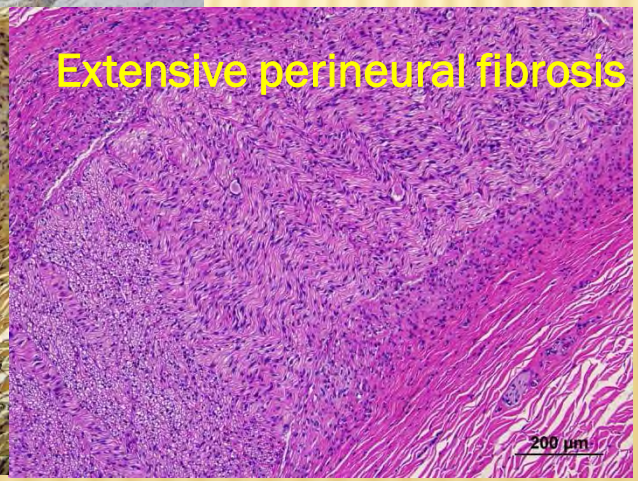


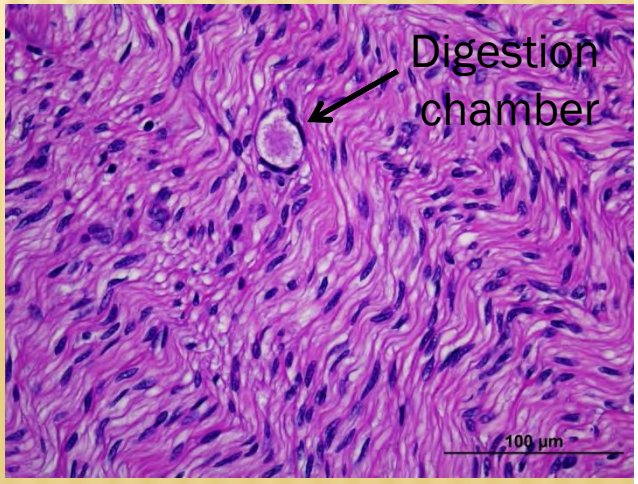


RF ABLATION AT 6 MONTHS

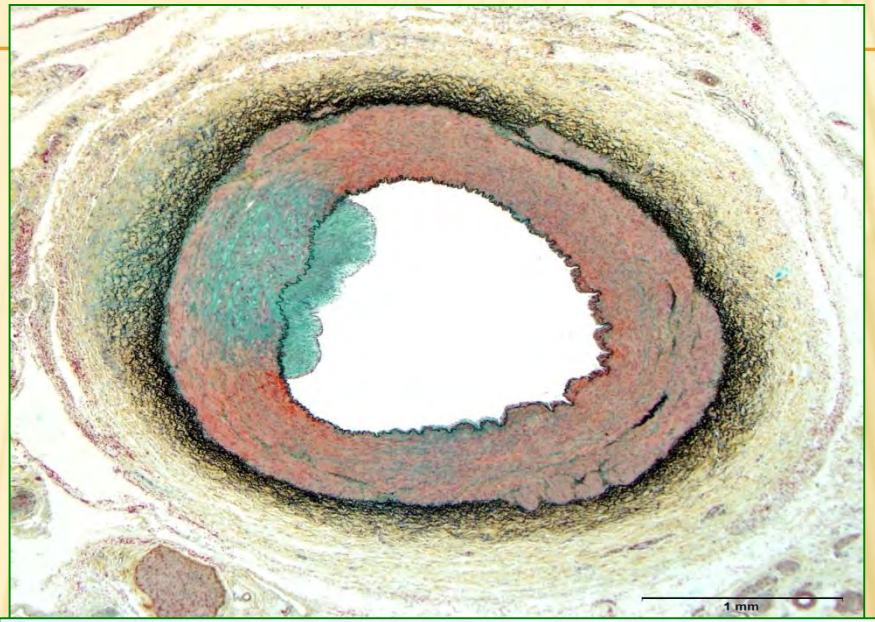


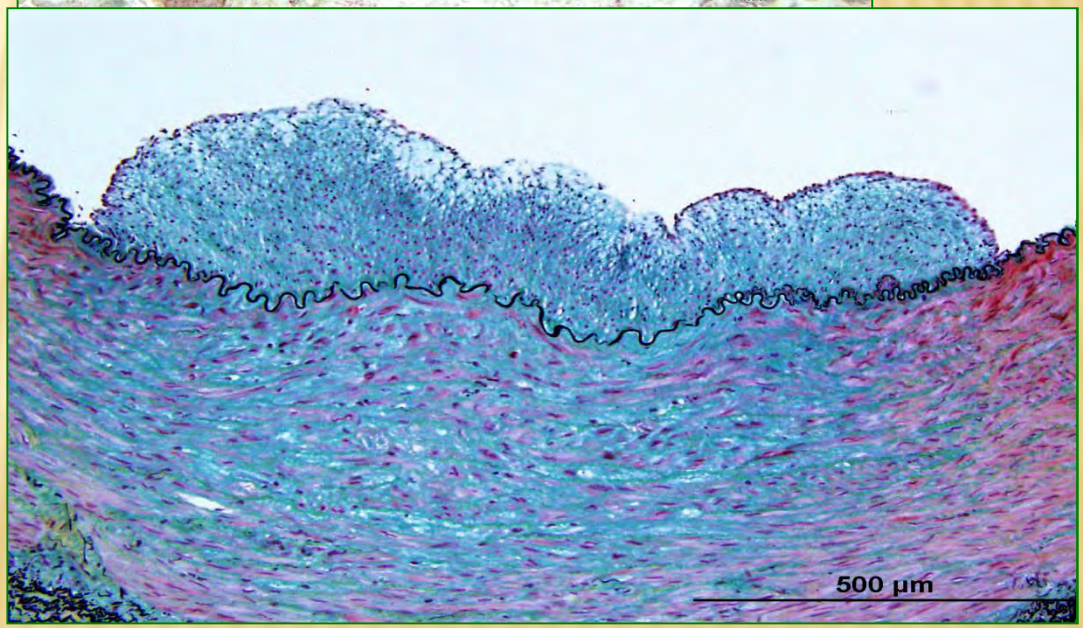




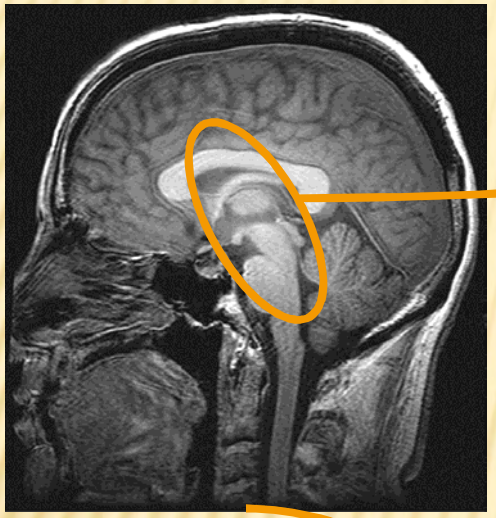


NEOINTIMAL THICKENING IS UNCOMMONLY OBSERVED IN ANIMALS EVEN IN THE PRESENCE OF SEVERE INJURY TO MEDIA

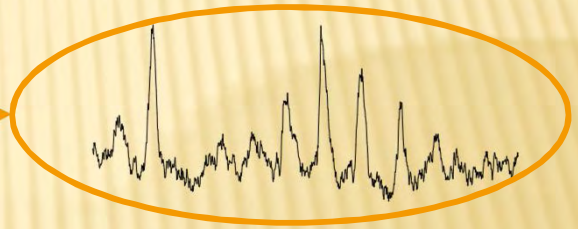




QUANTIFYING HUMAN SNS ACTIVITY



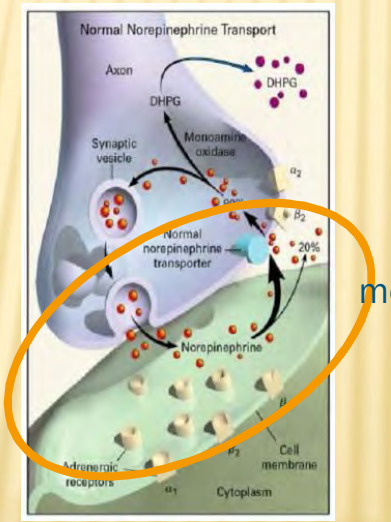
Central Sympathetic Nerve Activity



Muscle Sympathetic Nerve Activity (MSNA)

records postganglionic nerve traffic

Renal Sympathetic Nerve Activity



NE "spillover"

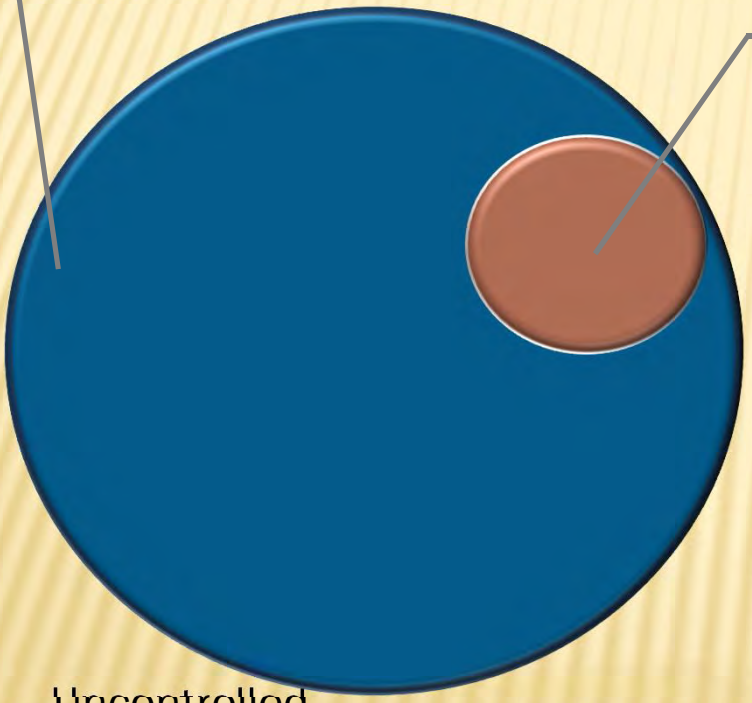
measures amount of transmitter from sympathetic nerves that escapes neuronal uptake and local metabolism and "spills over" into circulation

Esler M. *J Appl Physiol*. 2010;108:227-237.

DEFINITION OF RESISTANT HYPERTENSION

Uncontrolled Hypertension

- N □BP control on treatment –including those on inadequate treatment regimens, those with poor adherence, those with undetected secondary hypertension, as well as those with true treatment resistance[1]



Uncontrolled Hypertension

Resistant Hypertension

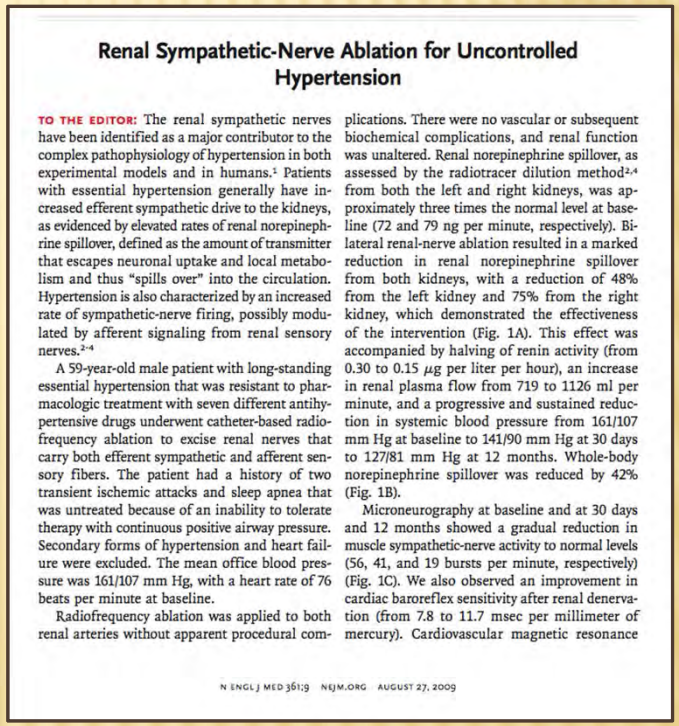
- **BP above goal**
- **Compliance with full doses of ≥3 antihypertensive medications of different classes; ideally, 1 of the 3 agents should be a diuretic[1]**
- **Includes those patients who achieve BP control but require ≥4 antihypertensive agents to do so[1]**

Calhoun DA, et al. *Circulation*. 2008;117:e510-e526. .1
Mancia G, et al. *Eur Heart J*. 2007;28:1462-1536. .2

RENAL SYMPATHETIC NERVE ABLATION FOR UNCONTROLLED HYPERTENSION

NEW ENGL J MED CASE STUDY[1]

- 59-year-old patient
- Resistant hypertension
- Renal sympathetic nerve activity modulated by catheter-based radiofrequency(RF) ablation



Renal Sympathetic-Nerve Ablation for Uncontrolled Hypertension

TO THE EDITOR: The renal sympathetic nerves have been identified as a major contributor to the complex pathophysiology of hypertension in both experimental models and in humans.[1] Patients with essential hypertension generally have increased efferent sympathetic drive to the kidneys, as evidenced by elevated rates of renal norepinephrine spillover, defined as the amount of transmitter that escapes neuronal uptake and local metabolism and thus "spills over" into the circulation. Hypertension is also characterized by an increased rate of sympathetic-nerve firing, possibly modulated by afferent signaling from renal sensory nerves.[2-4]

A 59-year-old male patient with long-standing essential hypertension that was resistant to pharmacologic treatment with seven different antihypertensive drugs underwent catheter-based radiofrequency ablation to excise renal nerves that carry both efferent sympathetic and afferent sensory fibers. The patient had a history of two transient ischemic attacks and sleep apnea that was untreated because of an inability to tolerate therapy with continuous positive airway pressure. Secondary forms of hypertension and heart failure were excluded. The mean office blood pressure was 161/107 mm Hg, with a heart rate of 76 beats per minute at baseline.

Radiofrequency ablation was applied to both renal arteries without apparent procedural complications. There were no vascular or subsequent biochemical complications, and renal function was unaltered. Renal norepinephrine spillover, as assessed by the radiotracer dilution method[2,4] from both the left and right kidneys, was approximately three times the normal level at baseline (72 and 79 ng per minute, respectively). Bilateral renal-nerve ablation resulted in a marked reduction in renal norepinephrine spillover from both kidneys, with a reduction of 48% from the left kidney and 75% from the right kidney, which demonstrated the effectiveness of the intervention (Fig. 1A). This effect was accompanied by halving of renin activity (from 0.30 to 0.15 μg per liter per hour), an increase in renal plasma flow from 719 to 1126 ml per minute, and a progressive and sustained reduction in systemic blood pressure from 161/107 mm Hg at baseline to 141/90 mm Hg at 30 days to 127/81 mm Hg at 12 months. Whole-body norepinephrine spillover was reduced by 42% (Fig. 1B).

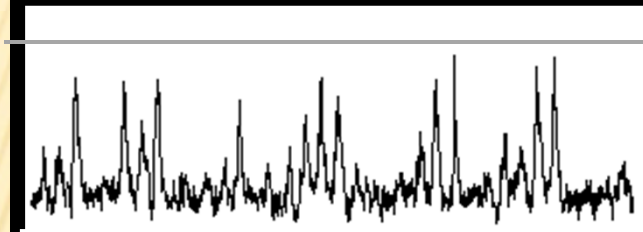
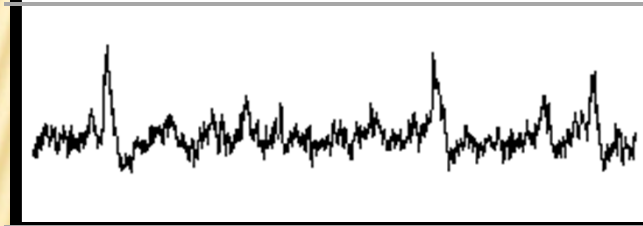
Microneurography at baseline and at 30 days and 12 months showed a gradual reduction in muscle sympathetic-nerve activity to normal levels (56, 41, and 19 bursts per minute, respectively) (Fig. 1C). We also observed an improvement in cardiac baroreflex sensitivity after renal denervation (from 7.8 to 11.7 msec per millimeter of mercury). Cardiovascular magnetic resonance

N ENGL J MED 361;9 NEJM.ORG AUGUST 27, 2009

Schlaich MP, et al. *New Engl J Med*. 2009;361:932-934.

↓ of Renal Contribution to Central Sympathetic Drive: MSNA in Resistant Hypertension Patient

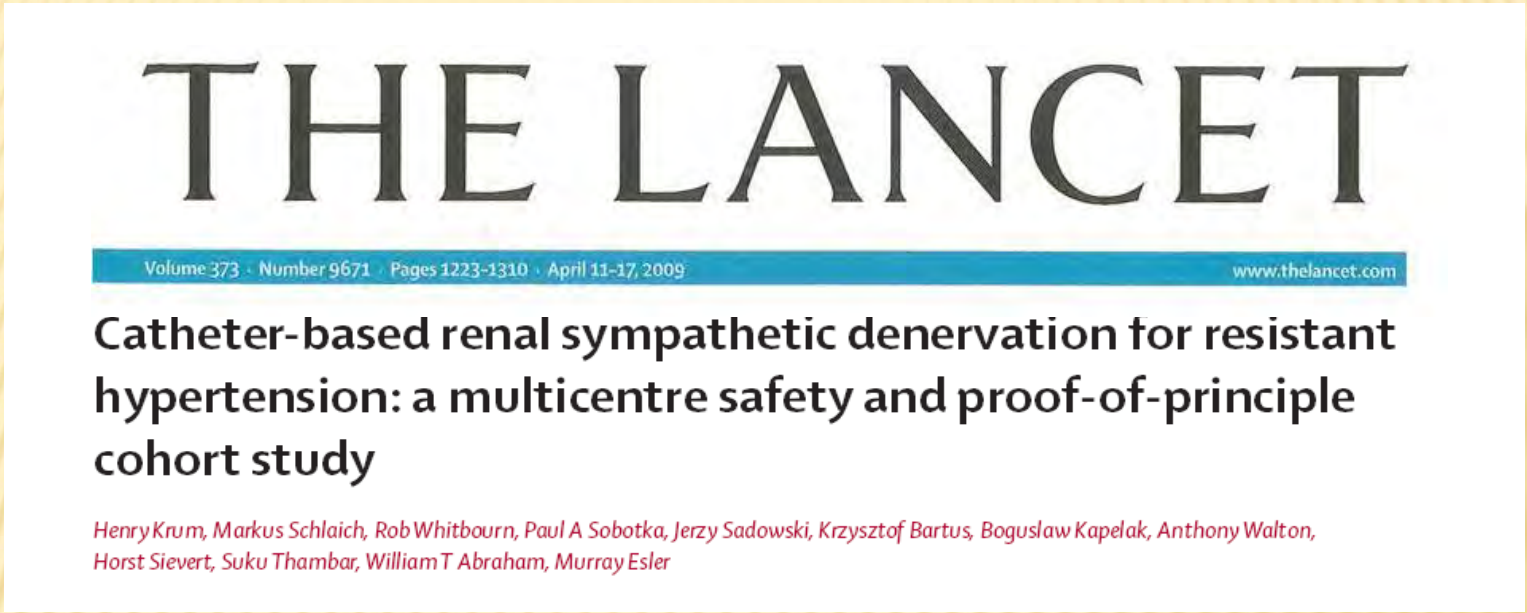
* 59 year old male on 7 HTN meds

		MSNA (burst/min)		BP (mmHg)
Baseline		56	→	161/107
1 mo		41 (-27%)	→	141/90 (-20/-17)
12 mo		19 (-66%)	→	127/81 (-34/-26)

* Improvement in cardiac baroreflex sensitivity after renal denervation (7.8 →11.7 msec/mmHg)

Schlaich et al. NEJM. 2009; 36(9): 932-934.

Symplicity HTN I: FIM



THE LANCET

Volume 373 · Number 9671 · Pages 1223-1310 · April 11-17, 2009 www.thelancet.com

Catheter-based renal sympathetic denervation for resistant hypertension: a multicentre safety and proof-of-principle cohort study

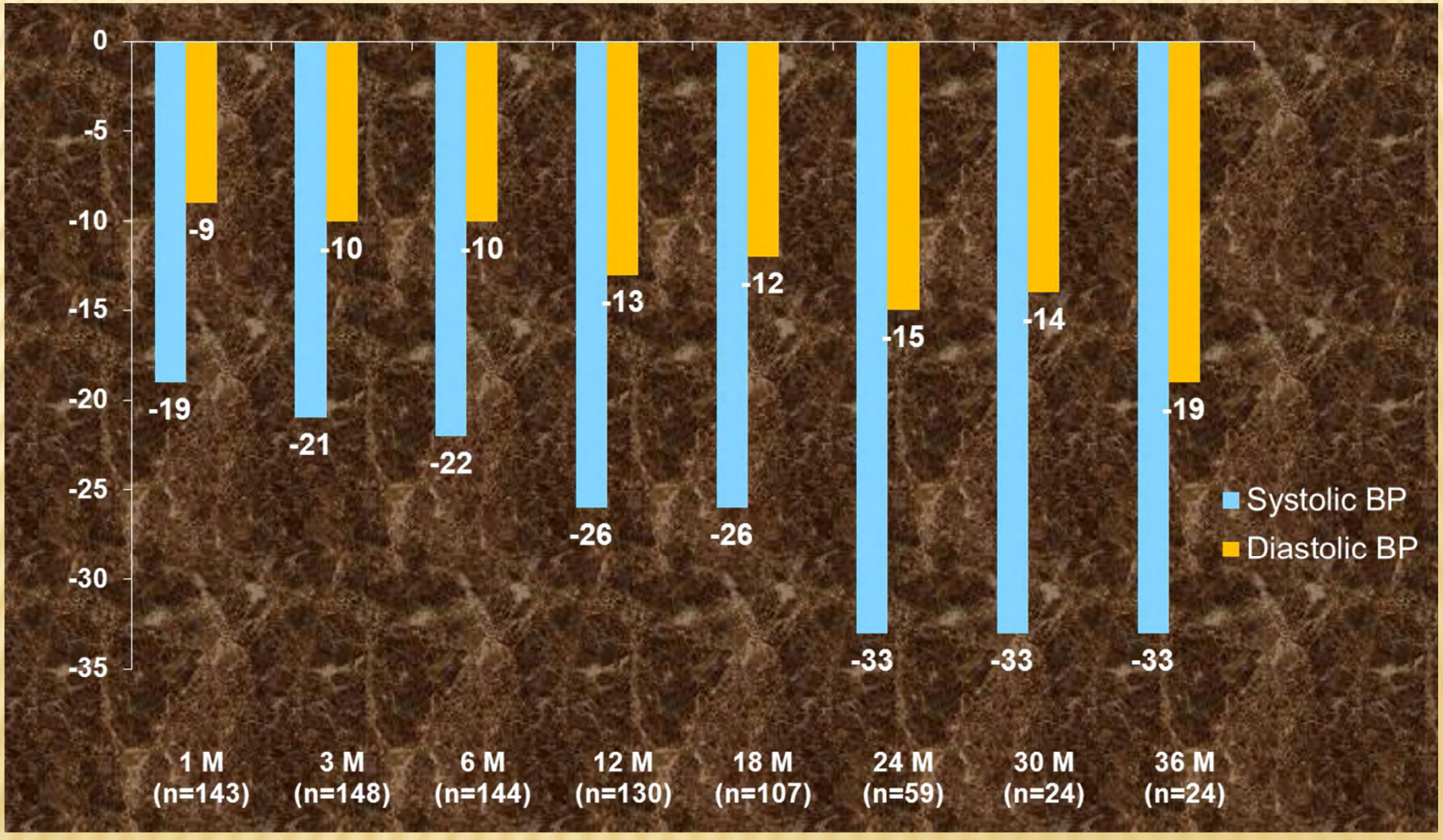
Henry Krum, Markus Schlaich, Rob Whitbourn, Paul A Sobotka, Jerzy Sadowski, Krzysztof Bartus, Boguslaw Kapelak, Anthony Walton, Horst Sievert, Suku Thambar, William T Abraham, Murray Esler

<u>Study Aims:</u>

First-in-man 12-month safety and BP-lowering efficacy of percutaneous renal sympathetic denervation in patients with resistant hypertension

Krum et al. *Lancet*. 2009;373(9671):1275-1281

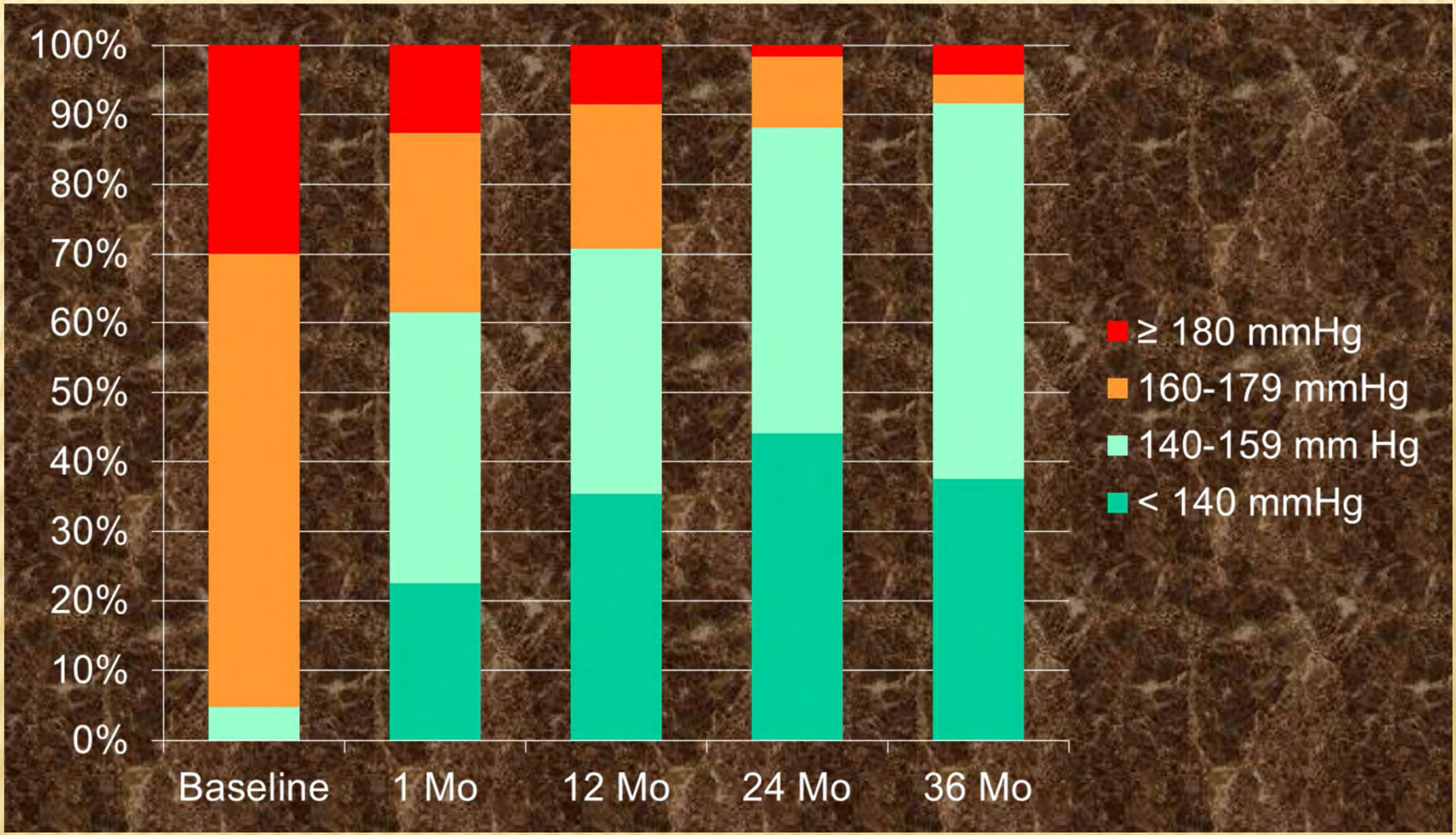
CHANGE IN OFFICE BLOOD PRESSURE THROUGH 36 MONTHS



P<0.01 for Δ from BL for all time points

Sobotca et at ACC 2012

DISTRIBUTION OF SBP CHANGE AT BL, 1, 12, 24, AND 36 MONTHS

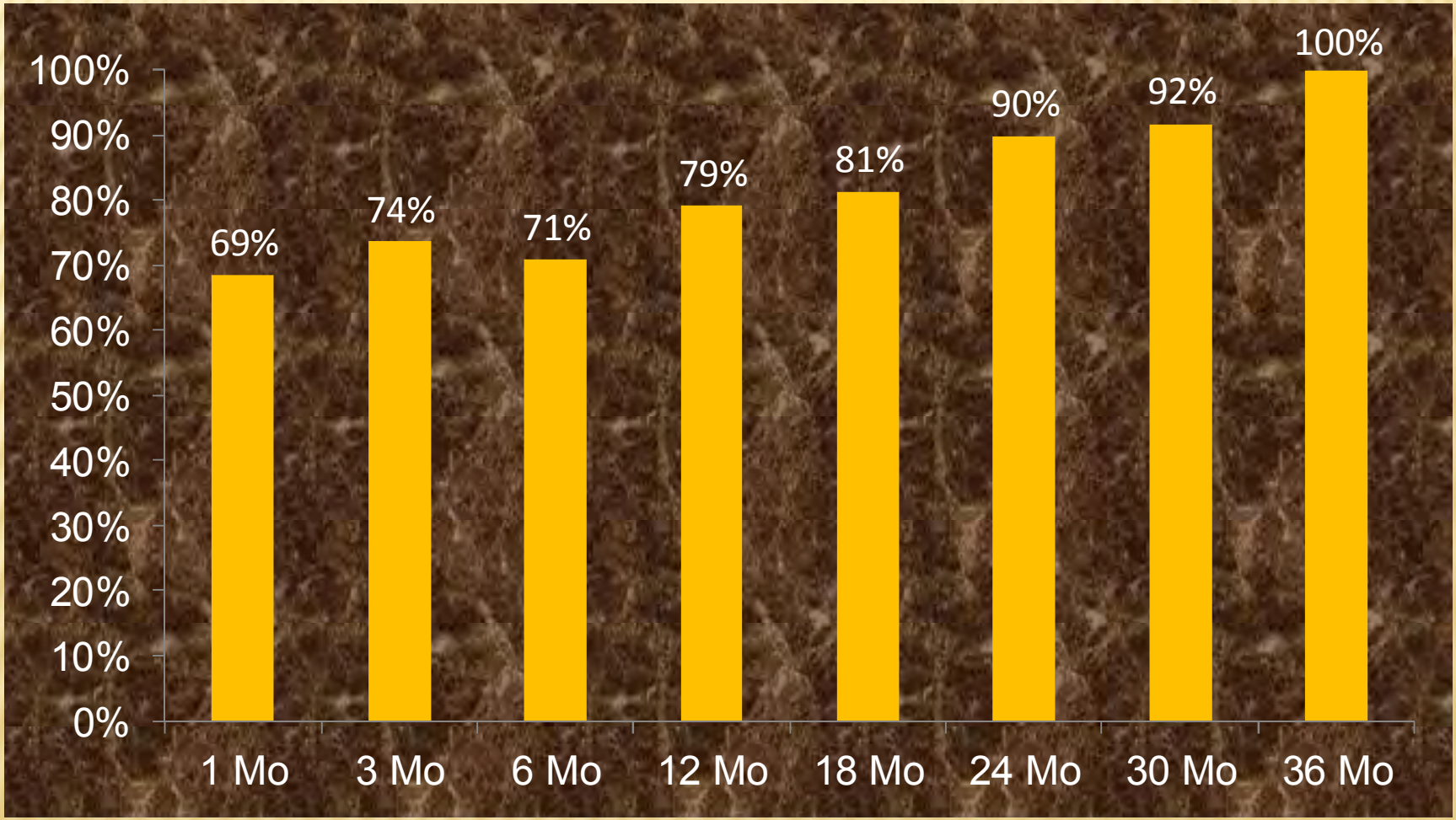


(N=150) (N=143) (N=130) (N=59) (N=24)

Sobotca et at ACC 2012

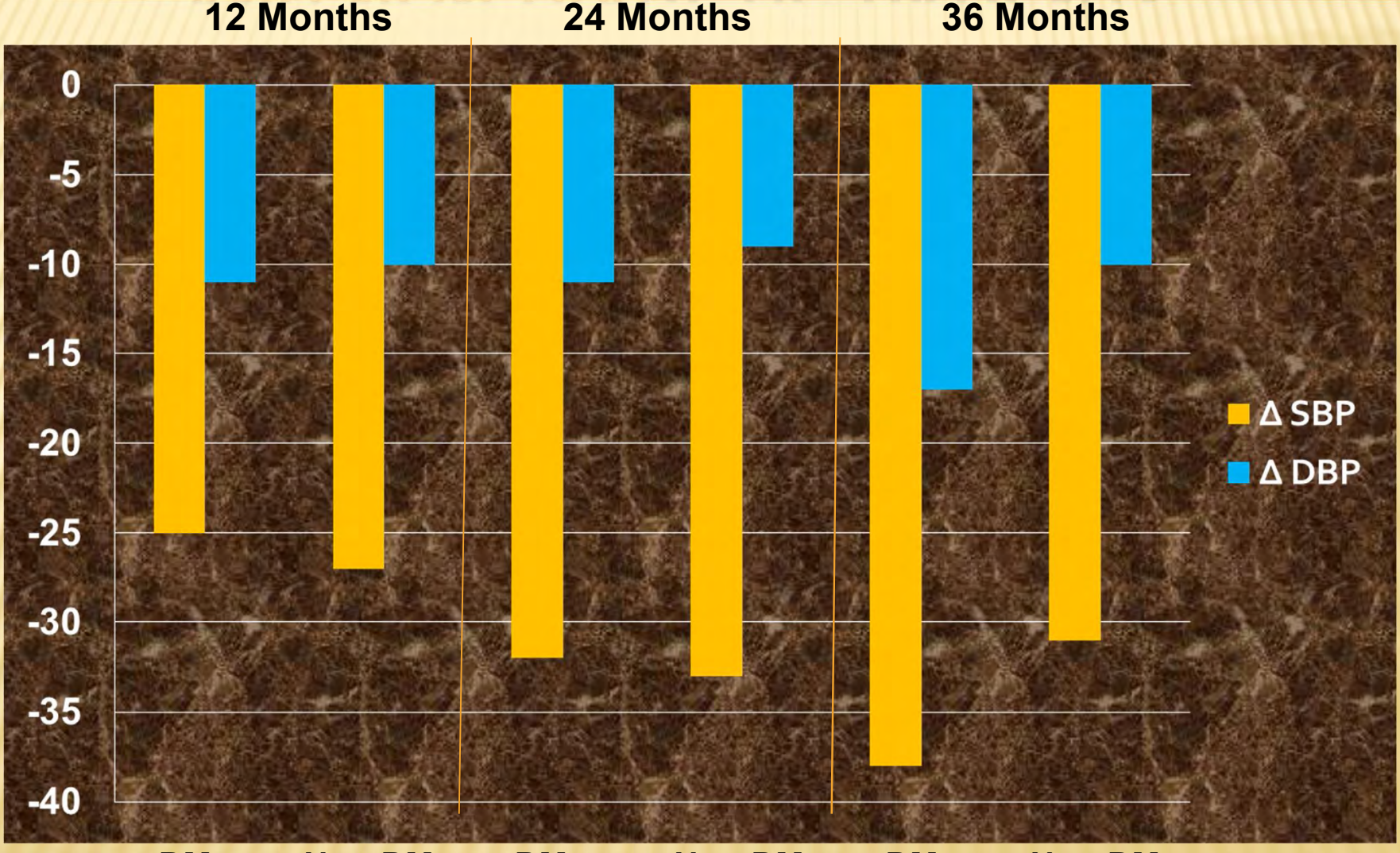
% RESPONDERS OVER TIME

Responder was defined as an office SBP reduction ≥10 mm Hg

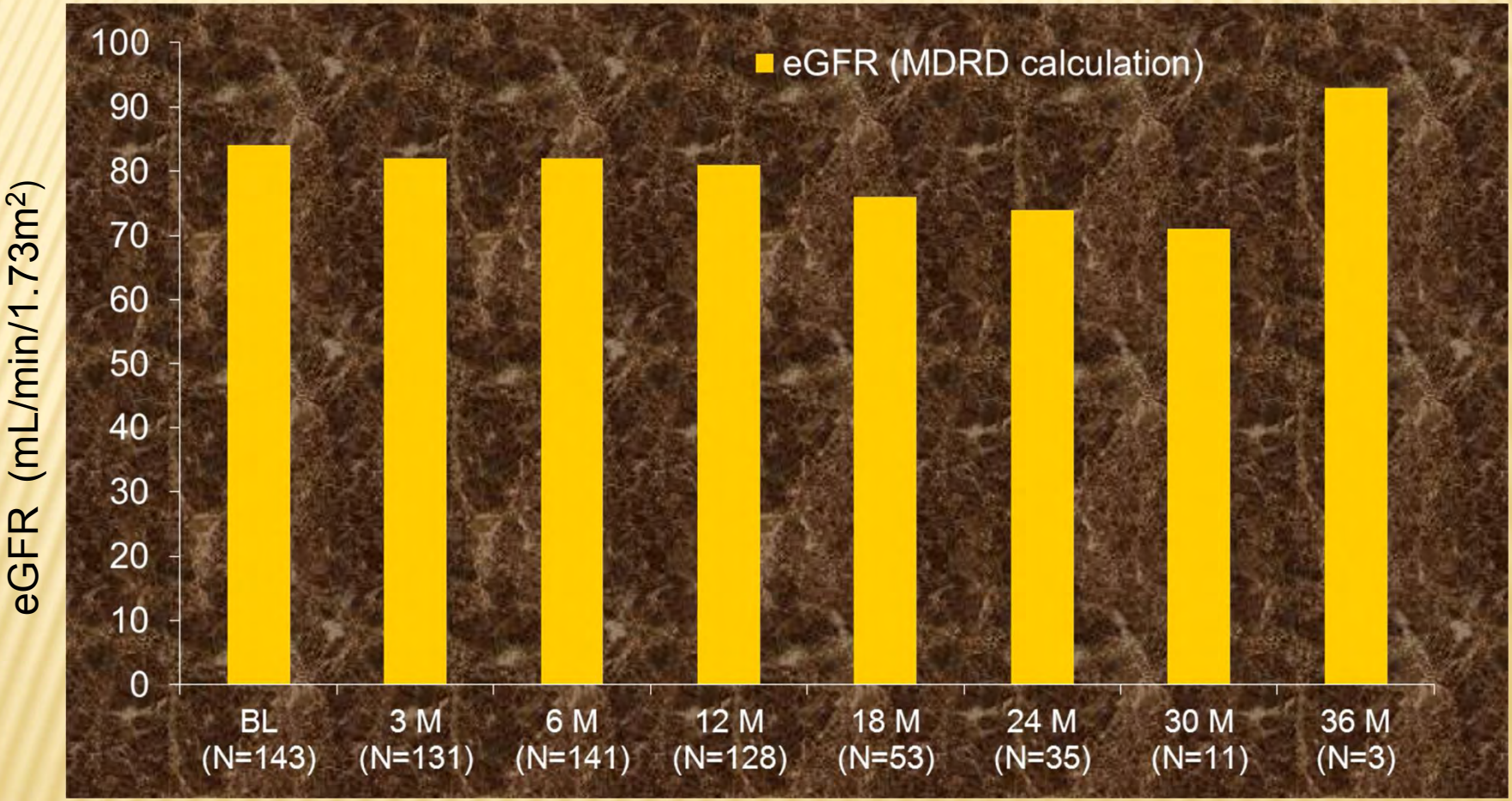


Sobotca et at ACC 2012

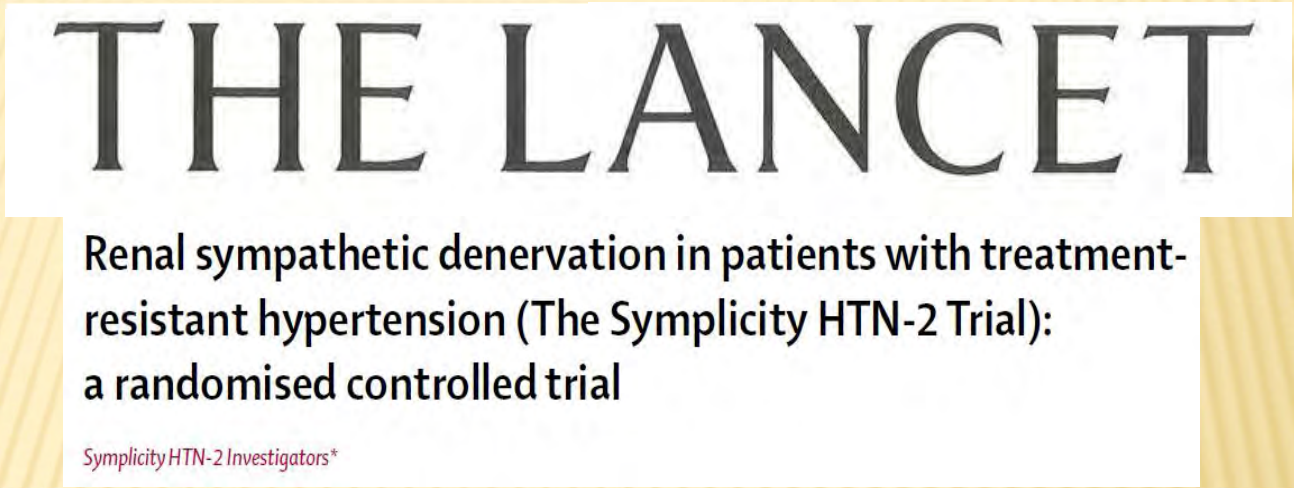
CHANGE IN OFFICE BP IN DIABETIC AND NON-DIABETIC PATIENTS



RENAL FUNCTION OVER TIME



SYMPLICITY HTN-2


THE LANCET

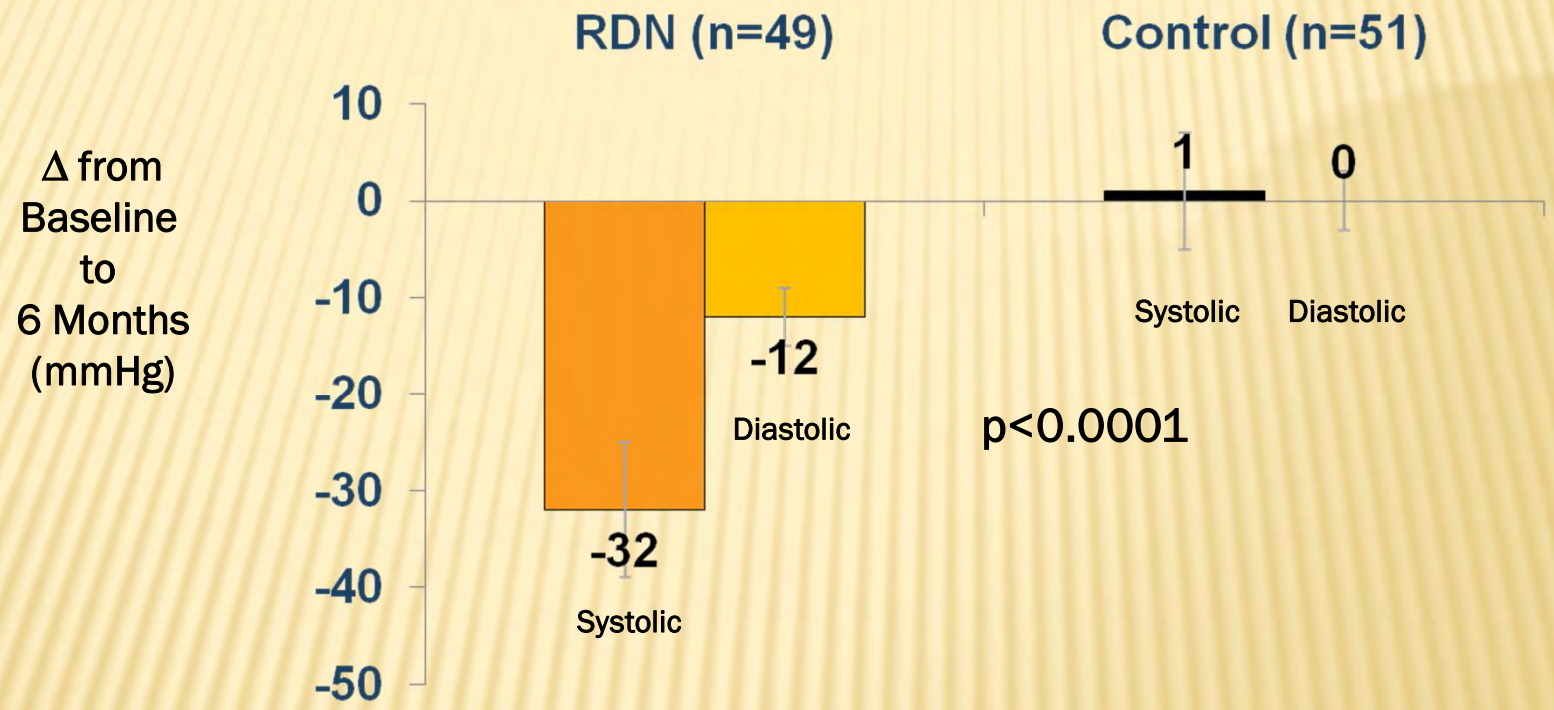
Renal sympathetic denervation in patients with treatment-resistant hypertension (The Symplicity HTN-2 Trial): a randomised controlled trial

Symplicity HTN-2 Investigators*

- **Purpose**: Prospective CRT, Effectiveness of catheter-based renal denervation for reducing BP in patients with uncontrolled hypertension
- **Patients:** 106 patients, 1:1 randomization, RDN vs. control

Symplicity HTN-2 Investigators. The Lancet 2010: 376:1903-1909

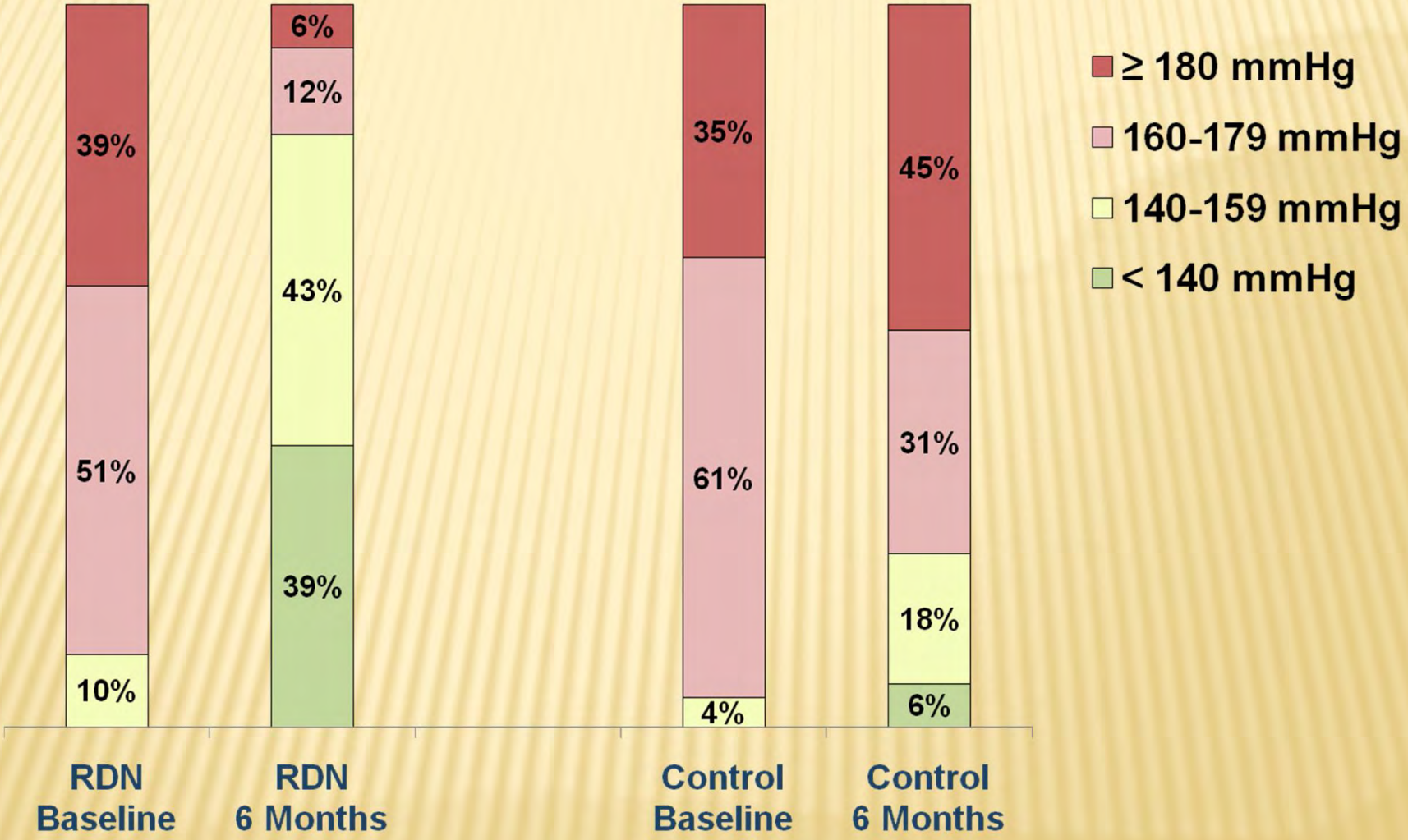
PRIMARY ENDPOINT: 6-MONTH OFFICE BP



- 33/12 mmHg difference between RDN and Control
- 84% of RDN patients had ≥ 10 mmHg reduction in SBP
- 10% of RDN patients had no reduction in SBP

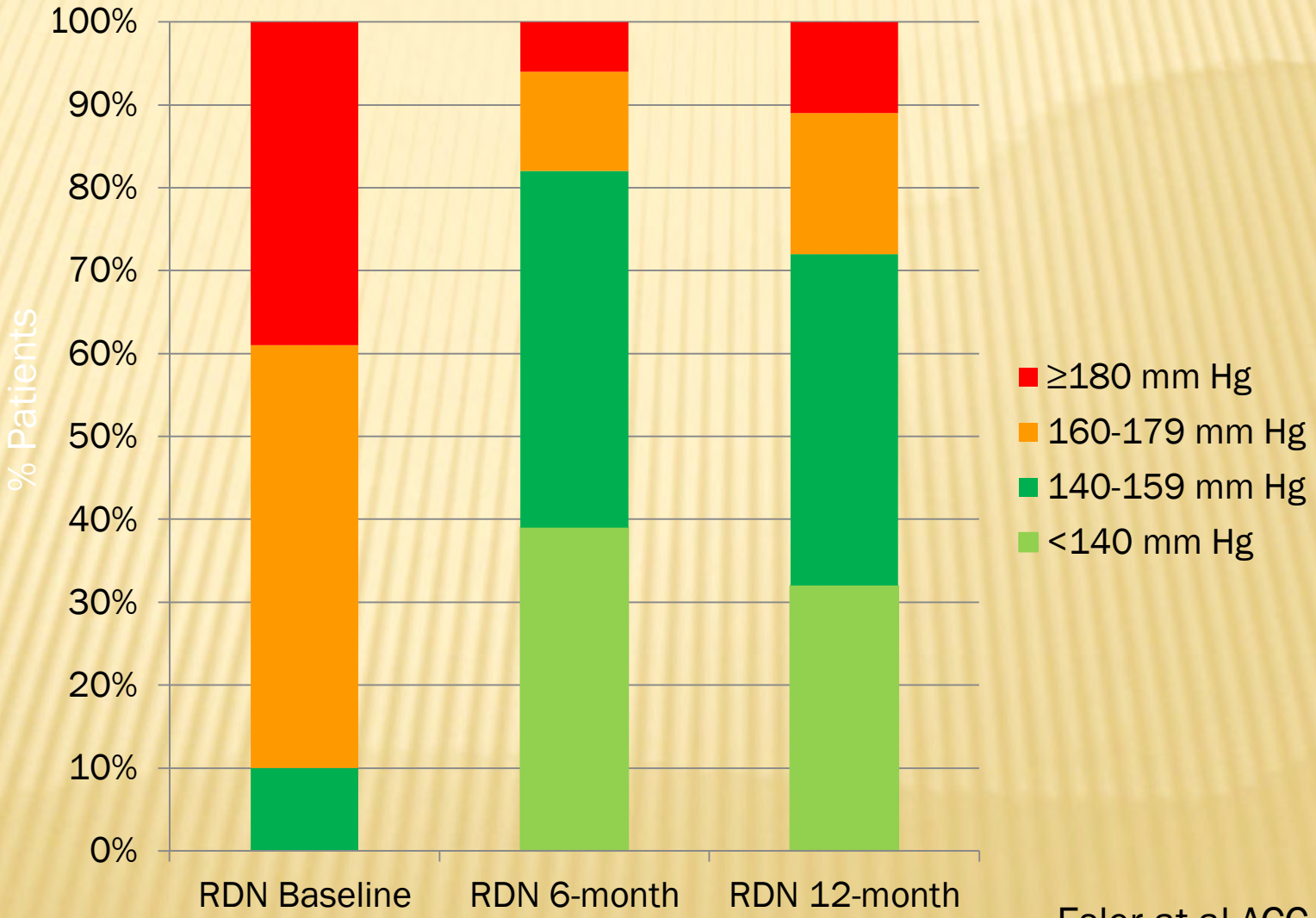
Symplicity HTN-2 Investigators. The Lancet 2010: 376:1903-1909

OFFICE SYSTOLIC BP DISTRIBUTION @ 6 MONTHS



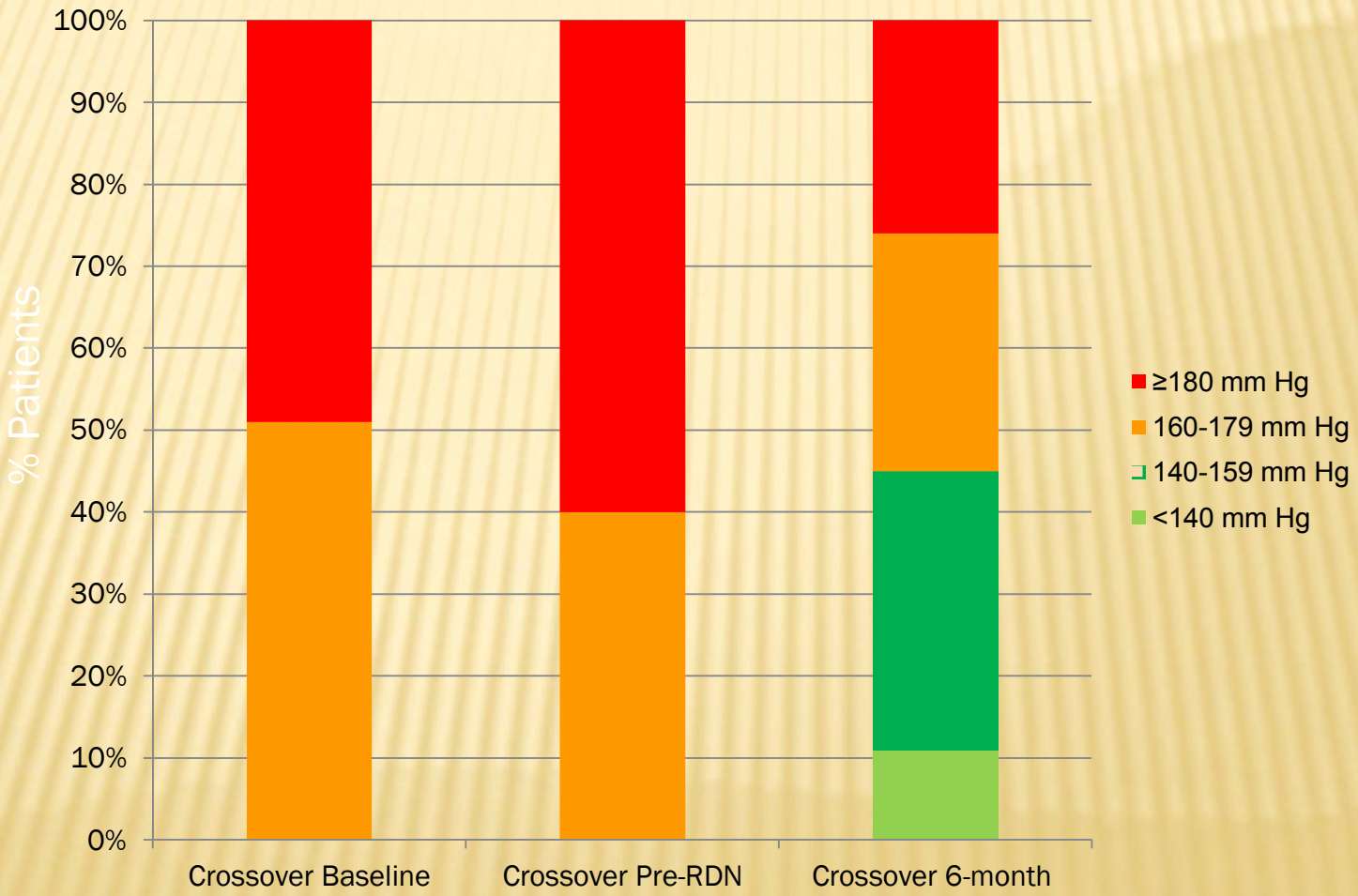
Symplicity HTN-2 Investigators. Lancet. 2010;376:1903-1909.

DISTRIBUTION OF OFFICE SBP FOR RDN GROUP @12 MONTHS F/U



Esler at al ACC 2012

DISTRIBUTION OF OFFICE SBP FOR CROSSOVER GROUP



AIM

To describe our initial experience with Renal Denervation (RDN) on Blood Pressure in patients with resistant Hypertension

METHODS

1. Team approach
2. Screening by Nephrologist (SS)
3. Procedure by Interventional Cardiologist
4. Follow-up by Nephrologist
5. F/U
    1. Office/ABP measurements of BP
    2. Clinical F/U

BP MEASUREMENT TECHNIQUES

Method	Brief Description
In-office	Two readings, 5 minutes apart. Sitting in chair, not on exam table. Confirm elevated reading in contralateral arm.
Ambulatory BP monitoring	Indicated for evaluation of “white-coat” HTN. Can be used to confirm self-measurement when inconsistent with in-office measurement. Reimbursable.

http://hin.nhlbi.nih.gov/nhbpep_slds/menu.htm; Accessed October 20, 2003; 8:15AM

METHODS

Inclusion Criteria: (Based on HTN-1, HTN-2 studies)

1. Office SBP ≥ 160 mmHg (≥ 150 mmHg with Type II Diabetes Mellitus)
2. Drug regimen: ≥ 3+ anti-HTN medications,
4. Renal artery: diameter ≥ 4 mm,
   length≥ 20mm
5. eGFR of ≥45
6. Age >18years

METHODS

Exclusion Criteria: (Based on HTN-1, HTN-2 studies)

1. Significant renal artery abnormalities
2. Type 1 Diabetes Mellitus
3. Valvular heart disease
4. AMI, unstable angina, or CVA in the prior 6 months
5. ICD or pacemaker
6. Pregnant, nursing or planning to be pregnant

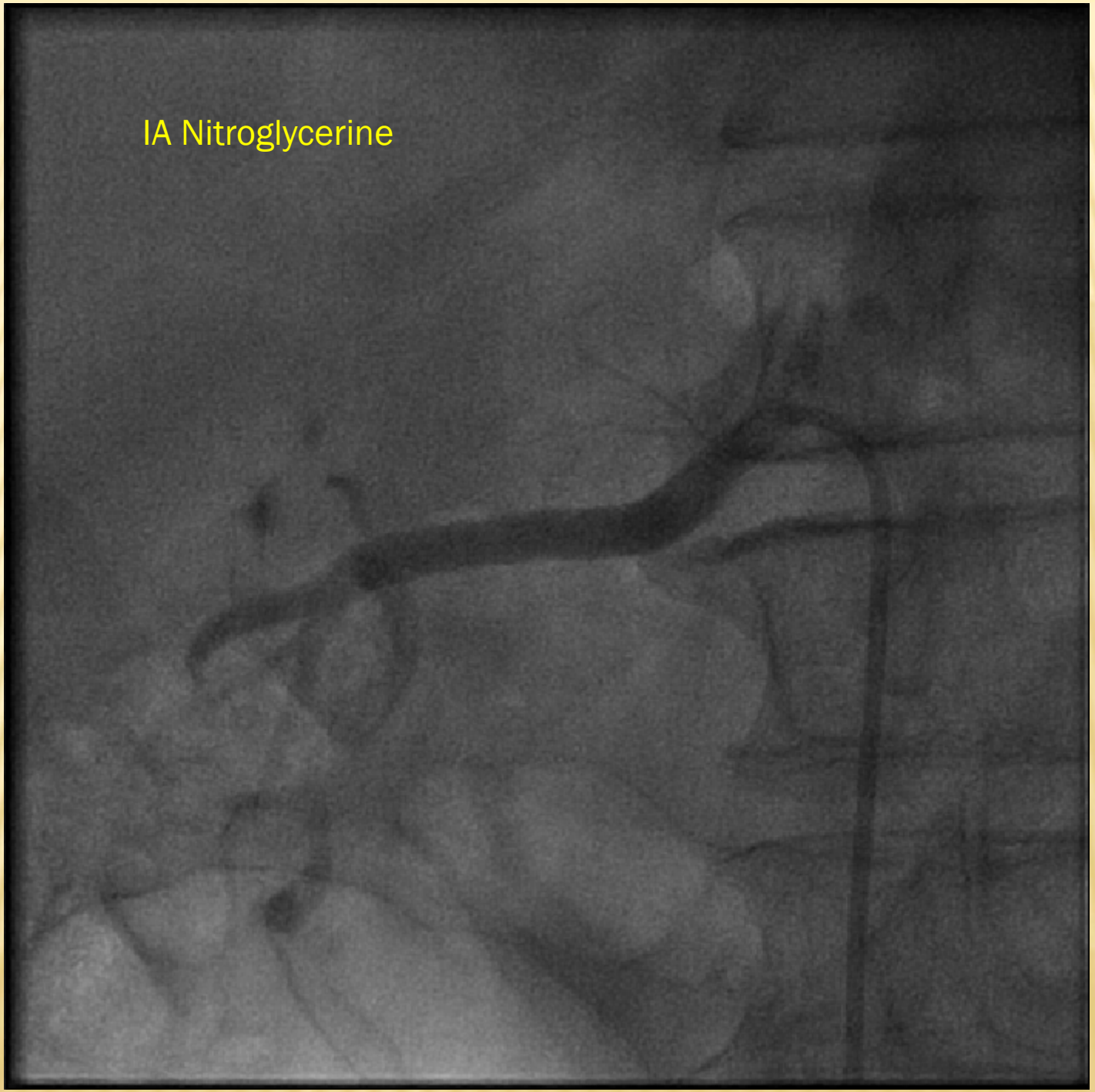
RESULTS

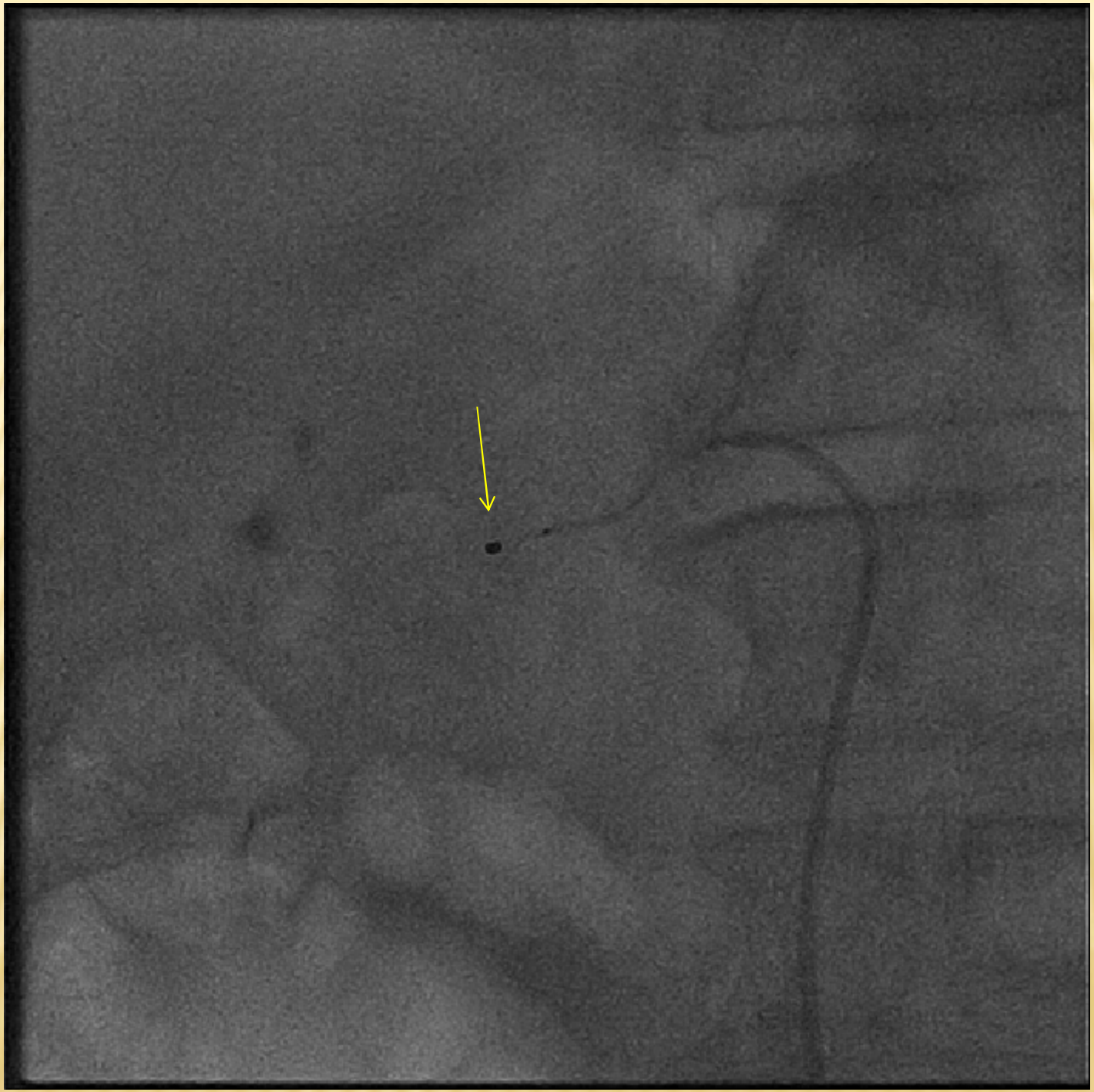
Demographics (n=19)

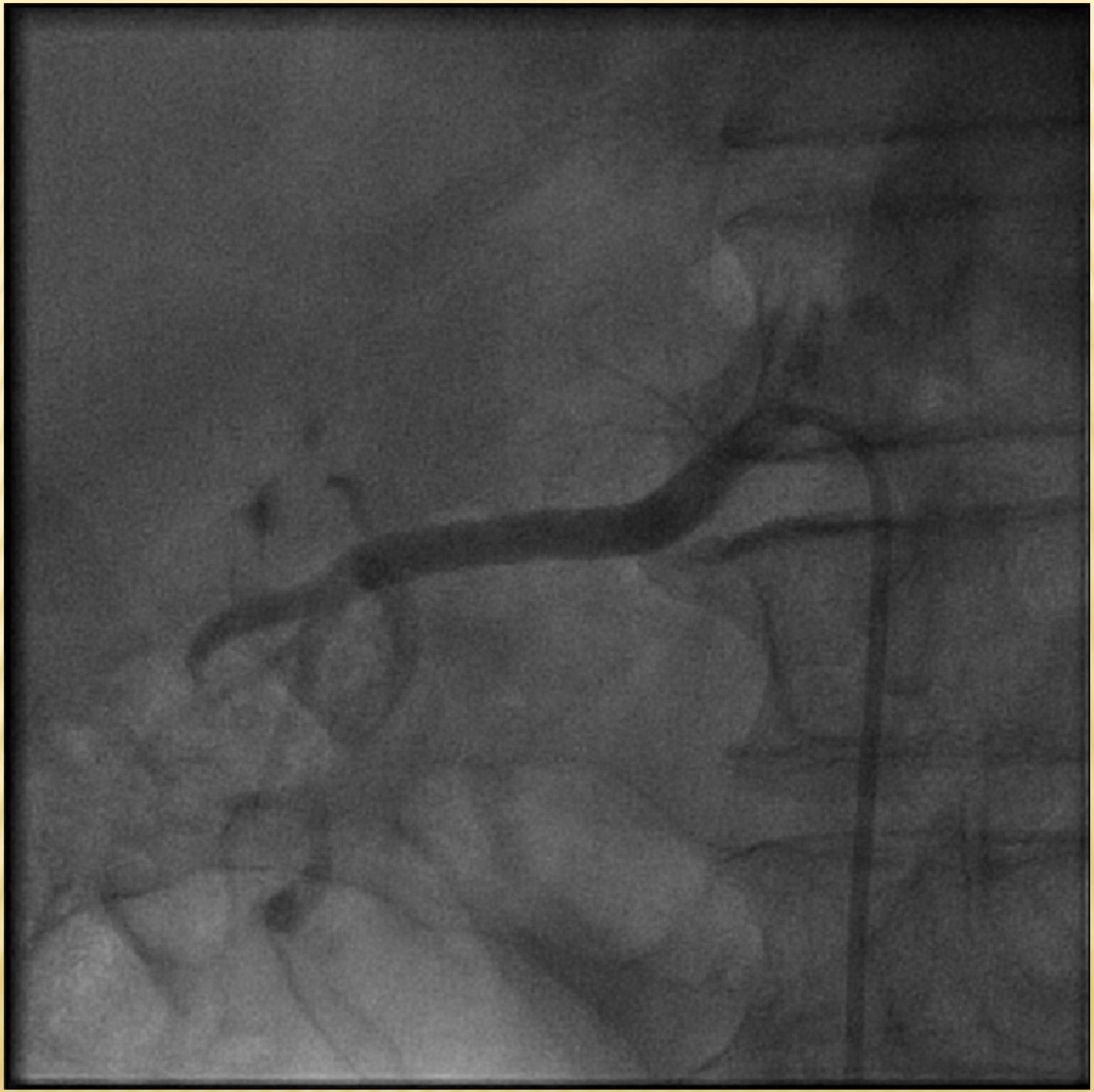
Male	57%
Age	60 +/- 7.1 yrs
DM	63%
Hyperlipidemia	73%
Smokers	63%
CAD	57%
PVD	9%
eGFR	89 +/- 25

RESULTS

No of Antihypertensive Rx	3.75
Diuretics	11
ACEI and/or ARB	11
Beta Blockers	8
Ca Channel Blockers	7
Central Activity (Clonidine)	2


IA Nitroglycerine





LEARNING CURVE

- Procedure Time
  First 3 pts 101min
  Last 3 pts 70min (-Δ44%)

- Fluoroscopy Time
  First 3 pts 17min
  Last 3 pts 11min (-Δ35%)

- Contrast (1:2 diluted)
  First 3 pts 155ml
  Last 3 pts 70ml (-Δ55%)

RESULTS

Procedure Details:

Ablations/Artery 5-7

IV Pain Management

Midazolam 2mg

Fentanyl 0.25mg

RESULTS

Procedure Success :

Device introduction and energy application without complications - 95%

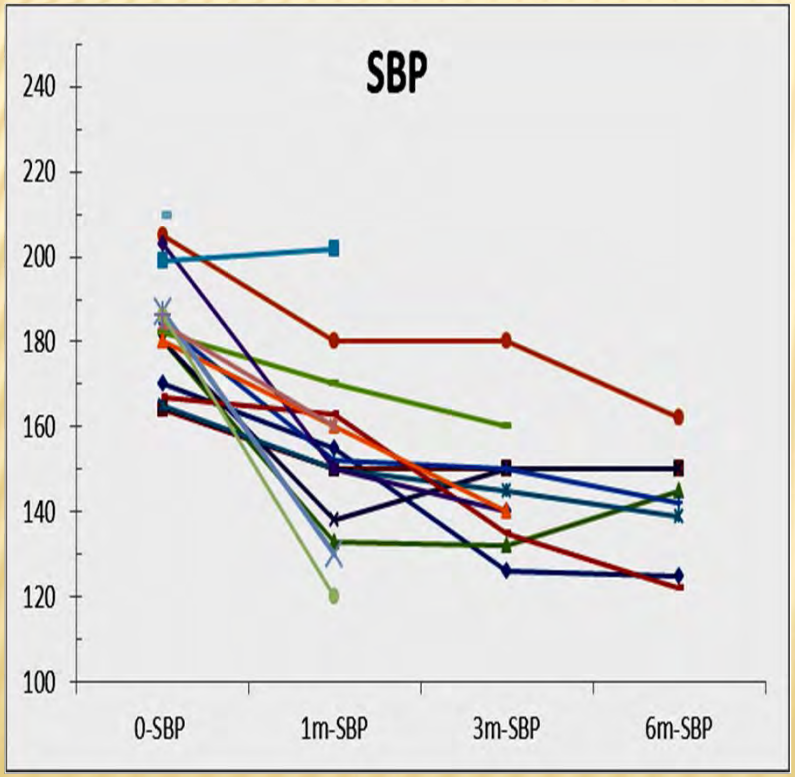
1 severe spasm

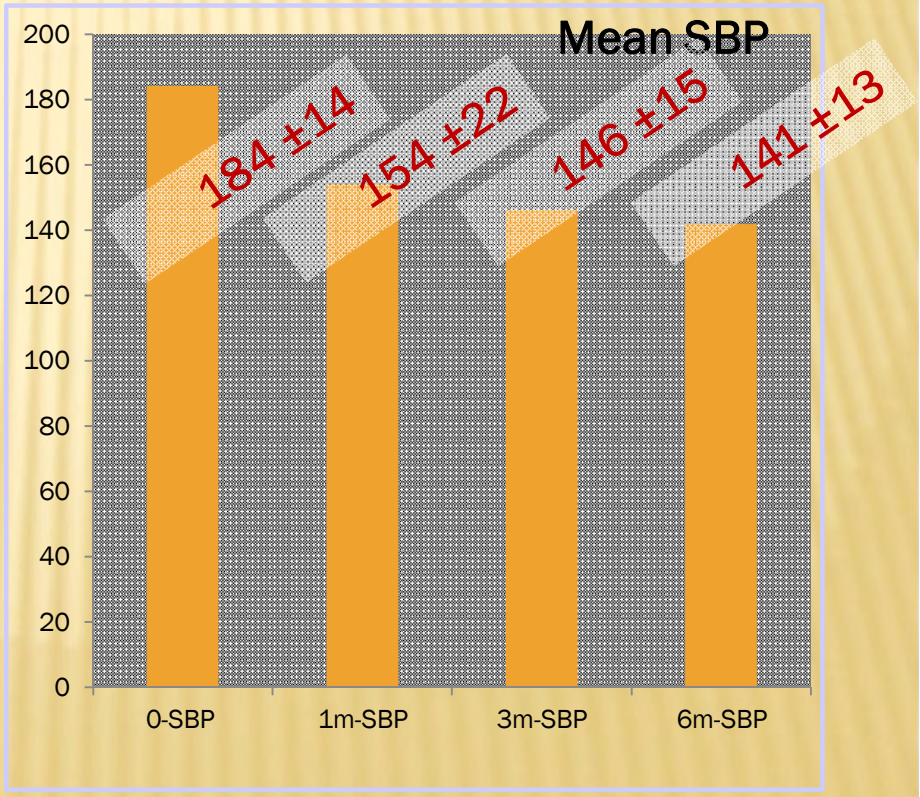
CHANGES IN SYSTOLIC BP POST RDN (N=19)

SBP decreased significantly in 18 of 19 patients

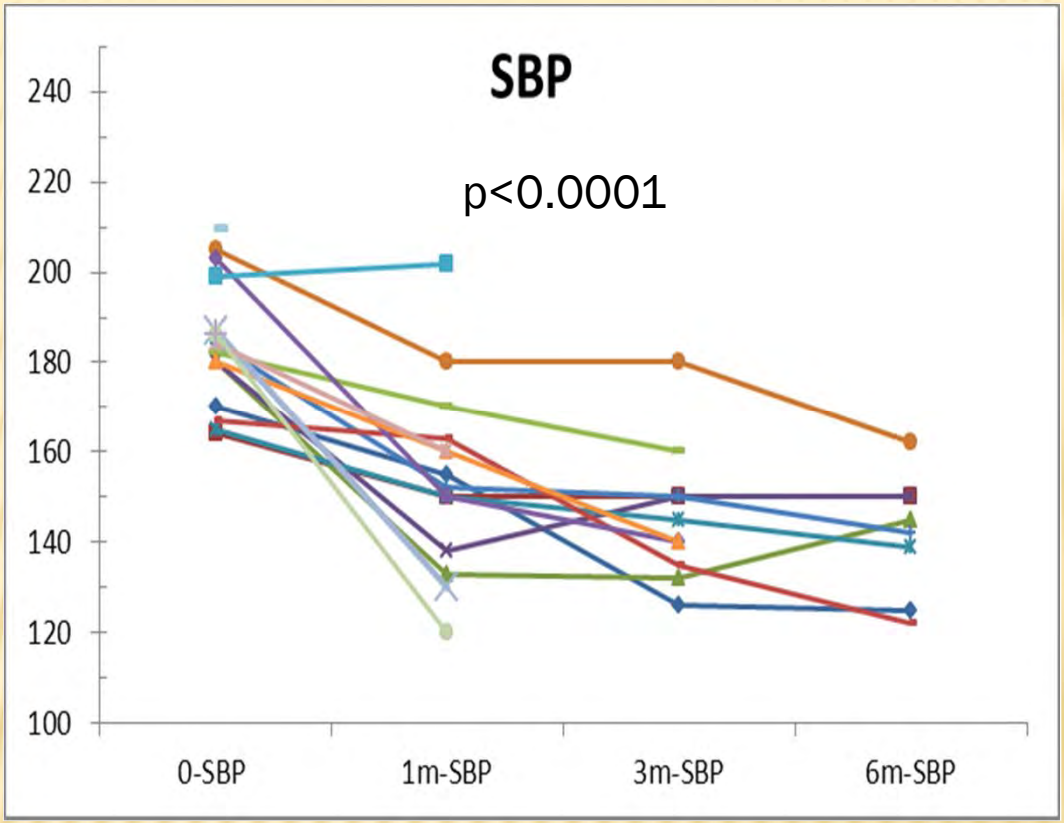
Baseline SBP was 184 ±14

Post RDN- 154 ±22, 146 ±15 , 141 ±13 @ 1, 3, 6 mnths, p<0.0001





CHANGES IN SYSTOLIC BP POST RDN (N=17)



- Baseline SBP = 184 ±14mmHg
- Decreased to 154 ±20, 146 ±15 & 141 ±13 @ 1, 3 & 6mont, respectively

RESULTS

Procedure Safety

No early major/minor complication

One severe spasm after RF delivery

No change in renal function or electrolyte disturbances

הצגת מקרה

- ע.ס. גבר בן 66 נשוי +4 רתך במקצועו
- עודף משקל- BMI-36
- העדר פעילות גופנית סדירה
- סוכרתי - 25 שנה, תלויי אינסולין -8 שנים
- עישון - 45 שנות קופסא - COPD
- יתר לחץ דם - 21 שנה

הצגת מקרה

רשימת תרופות ללחץ דם :

- EXFORGE 160/5 MG X1
- CARDILOC 10 MG X1
- CADEX 2 MG X2
- FUSID 40 MG X1
- DIOVAN 160 MG X1

הצגת מקרה

- **טרשת עורקים**
  - CABG 2004–CAD
  - CVA-2004
  - RT CAROTID PTA 2004
- **דום נשימה בשינה- מטופל ב** CPAP

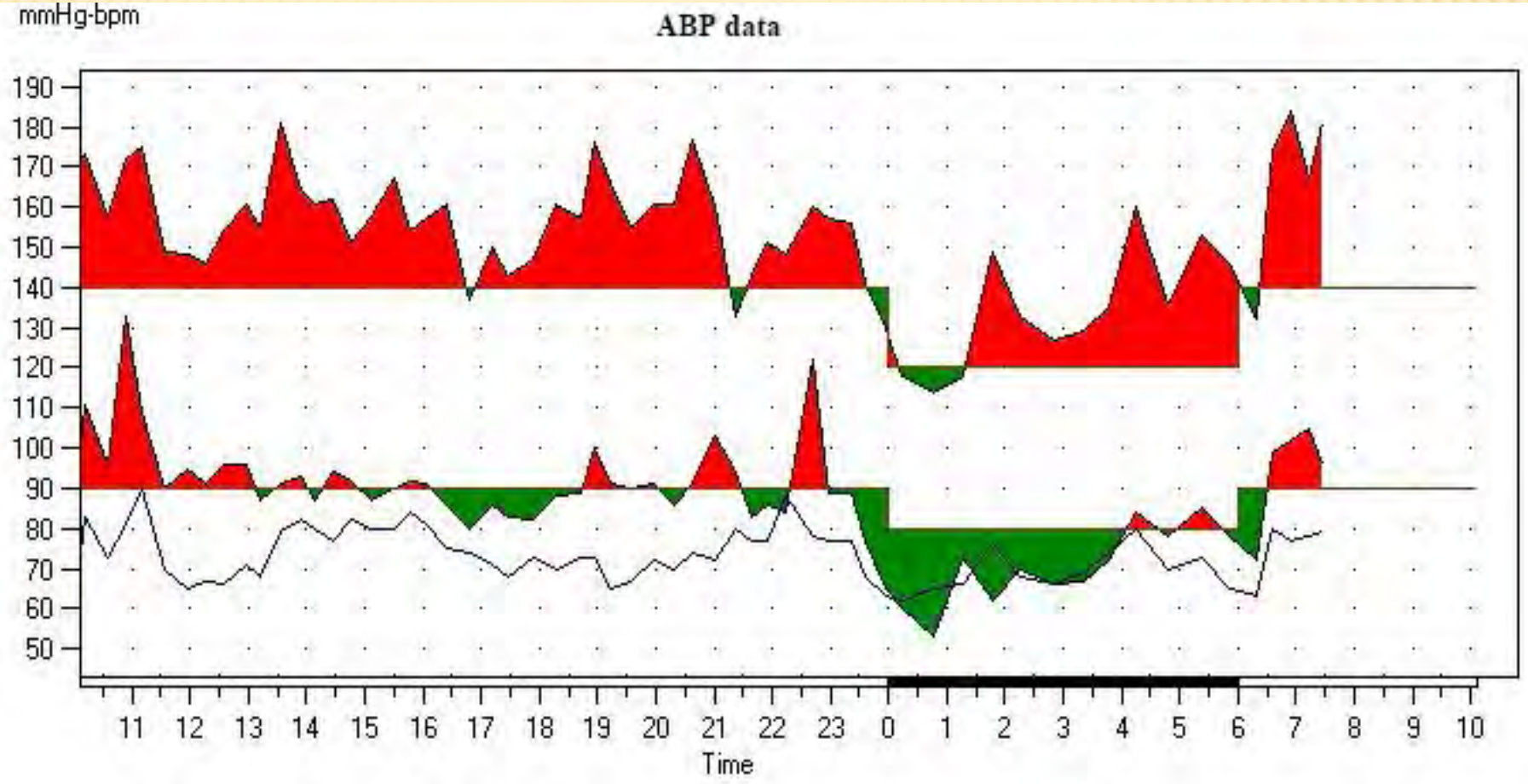
הצגת מקרה

- DOE– 5.2011. ללא תעוקת חזה
  - מיפוי לב : פגם מילוי חולף תחתון בזאלי.
  - צנתור כלילי : מעקפים פתוחים

    עורקים כליליים חסומים.

    - לחצי דם גבוהים במהלך אשפוז

הולטר לחצי דם ל24 שעות 5.2011

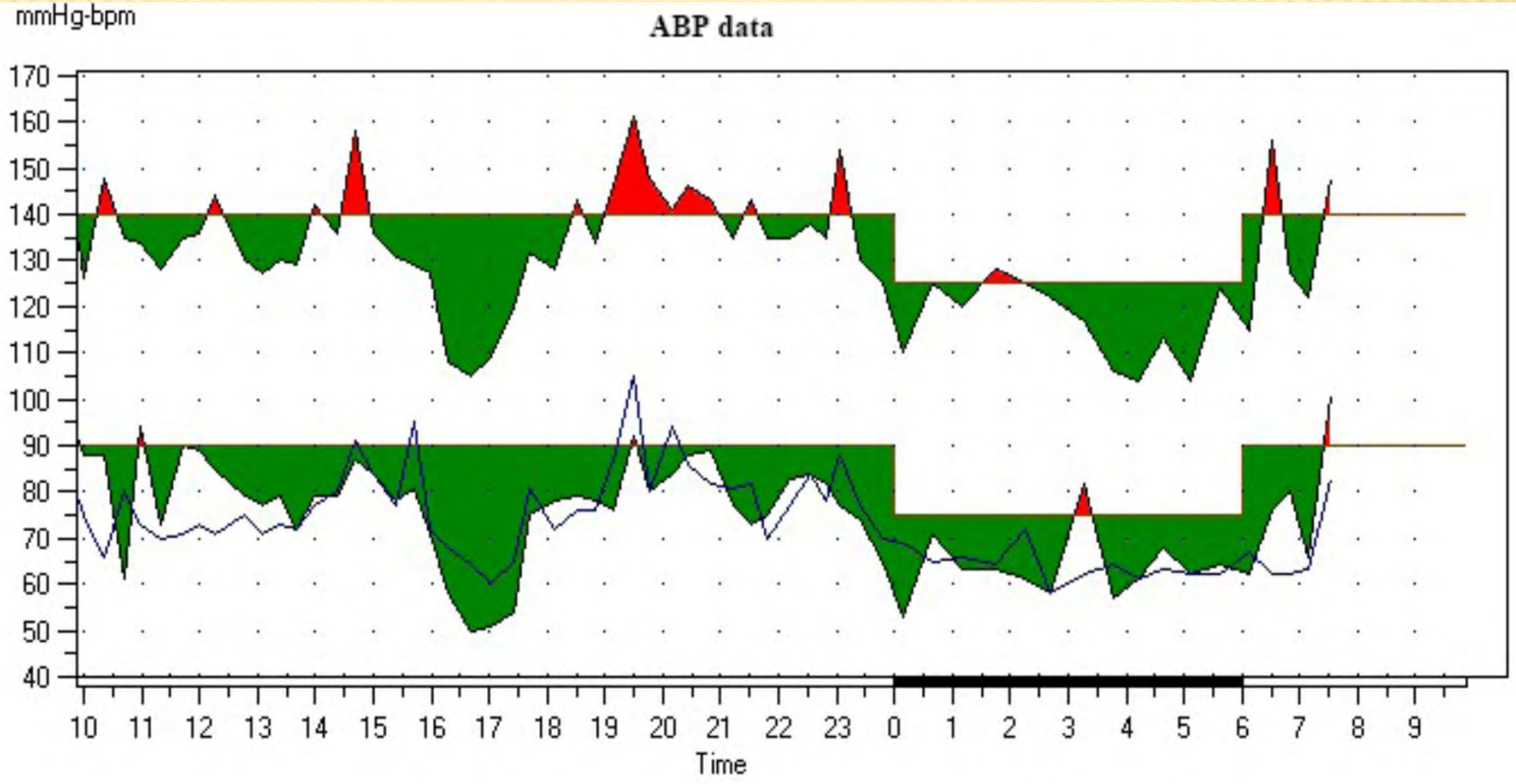


Average day = 168/92 HR = 75 night = 135/71 HR = 70

הצגת מקרה

- 10.2011 קוצר נשימה עם גודש ריאתי
  - לחץ דם סיסטולי >200ממ"כ.
  - RENAL DENERVATION
  - (6 אבלציות משמאל 5 מימין).

הולטר לחצי דם אחרי 6 חודשים



Average day = 132/75 HR = 66 night = 122/73 HR = 59

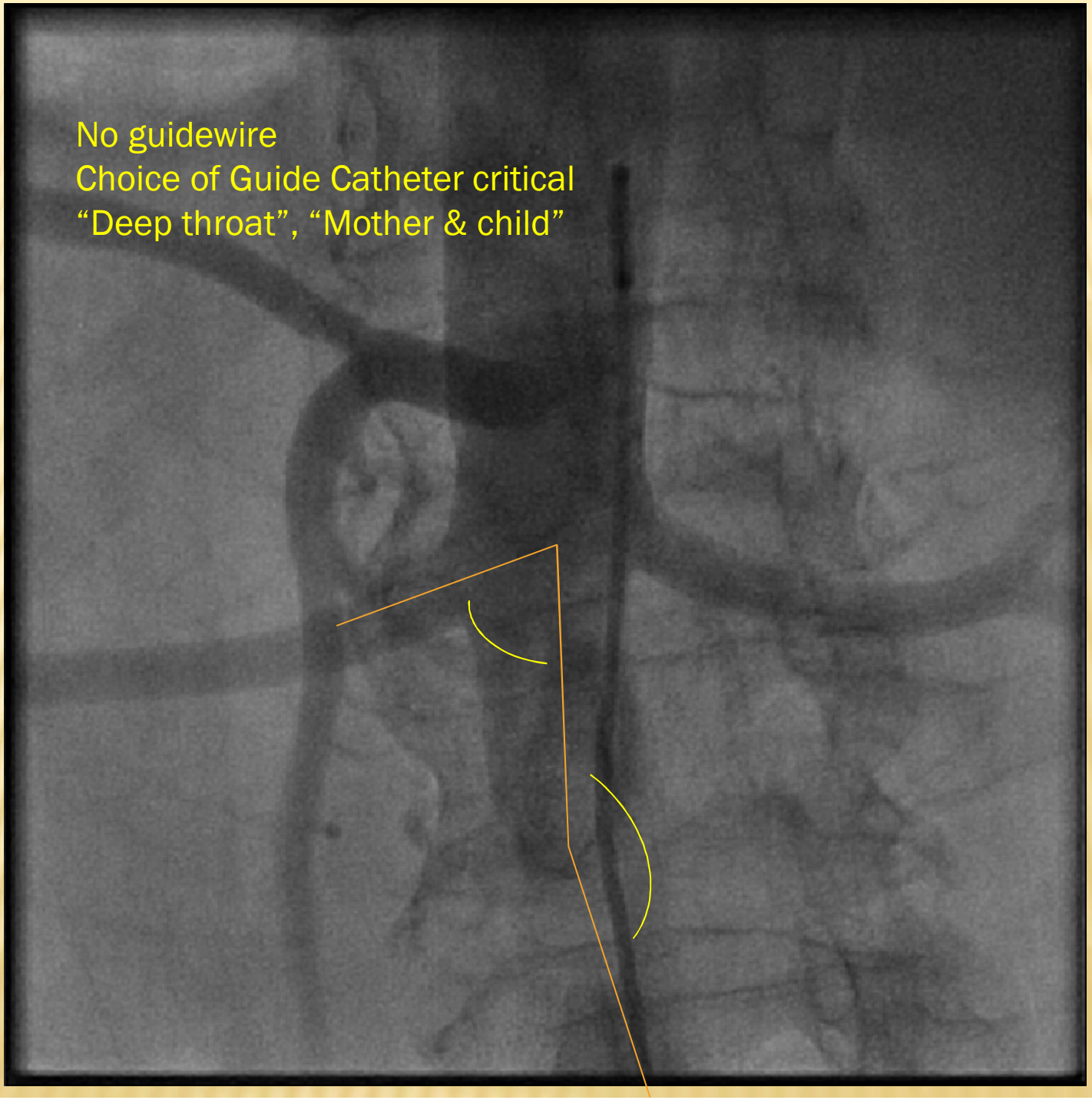
הצגת מקרה

רשימת תרופות חודש לאחר הRDN :

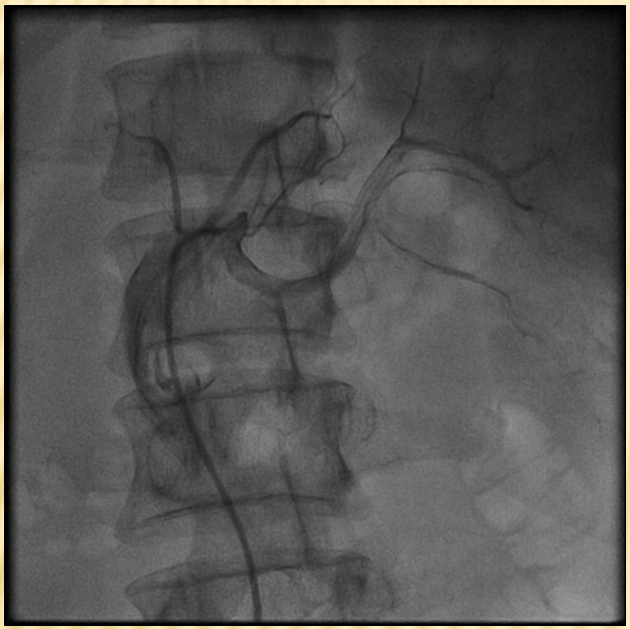
- LOTAN 100 MG X1
- NORVASC 10 MG X1
- CARDILOC 10 MG X1

LIMITATIONS OF CURRENT TECHNOLOGY

- Technology is limited
  - Not guide wire based
  - Wide variance in ablation geometry
  - Variance in energy delivered
- Ablation
  - No obvious target during procedure
  - No way to measure effect (e.g. change in sympathetic activity on line)


No guidewire
Choice of Guide Catheter critical
“Deep throat”, “Mother & child”

UNFAVORABLE ANATOMY



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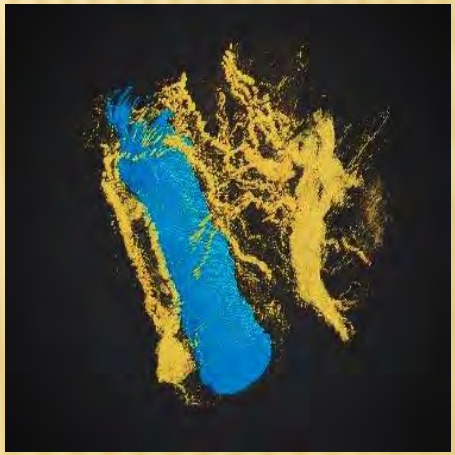
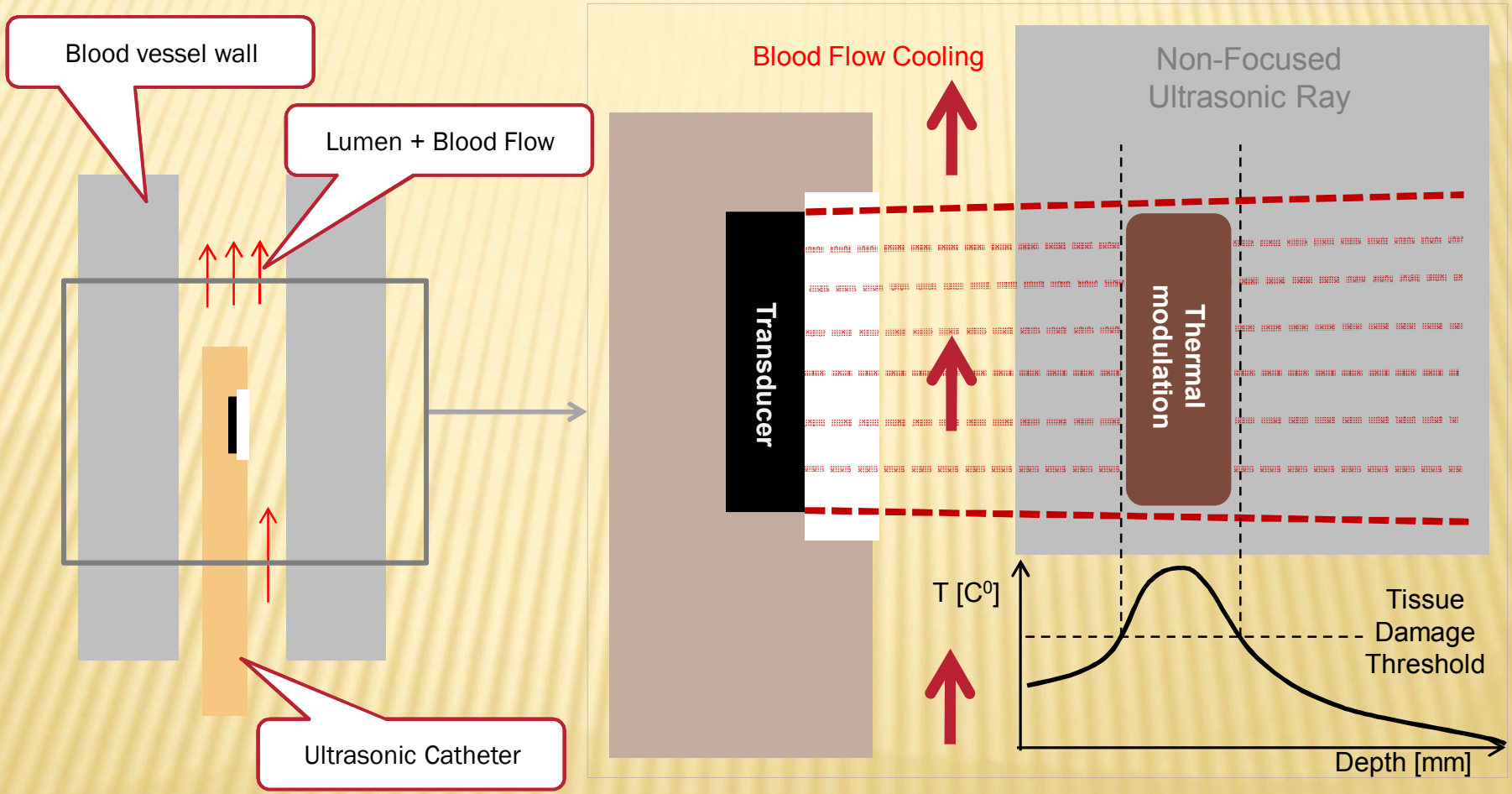


TIVUS™ CORE TECHNOLOGY

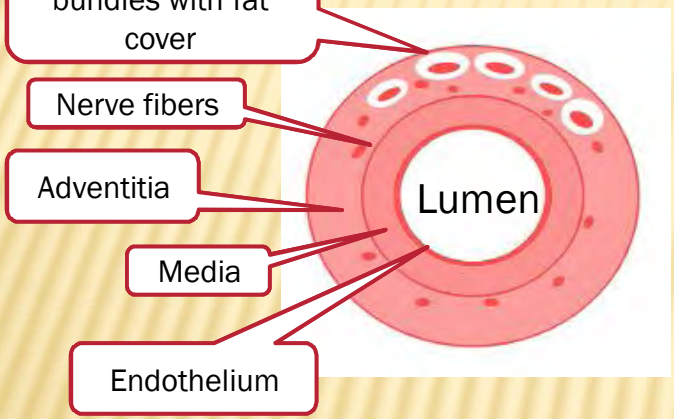
- High-intensity, ultrasonic catheter (0.014” OTW)
- Selective thermal modulation
- No contact with the vessel intima
- Short, total treatment:5-10 min/artery

TIVUS™ CORE TECHNOLOGY:
NON-FOCUSED HIGH INTENSITY ULTRASONIC CATHETER

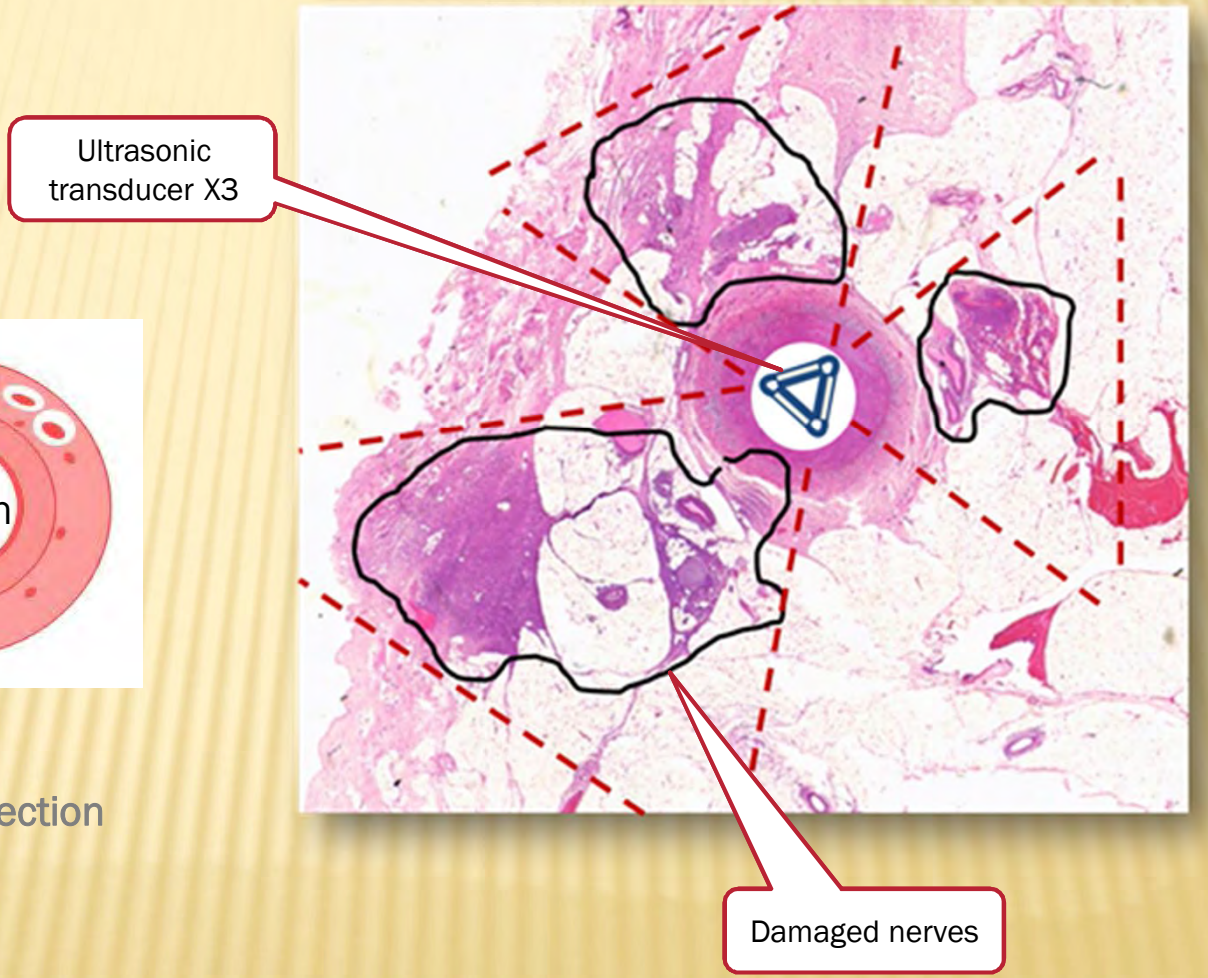


MULTIDIRECTIONAL TIVUS™

Histological Analysis



Renal Artery Cross-Section

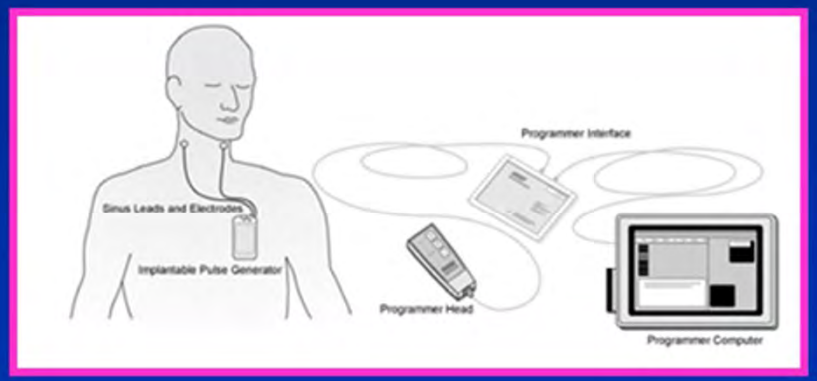


STUDY OVERVIEW

- Prospective, single arm study
- RDN in pts with resistant hypertension
- 50-75 patients at up to 15 sites:
  - Europe, Australia & Israel
- Follow-up through 12 months
- Eligibility:
  - Systolic OBP ≥160
  - Systolic 24h ABP ≥135
  - Stable drug regimen, >3 drugs classes, one diuretic

Device-Based Approaches to Autonomic Modulation

Baroreflex Sensitisation

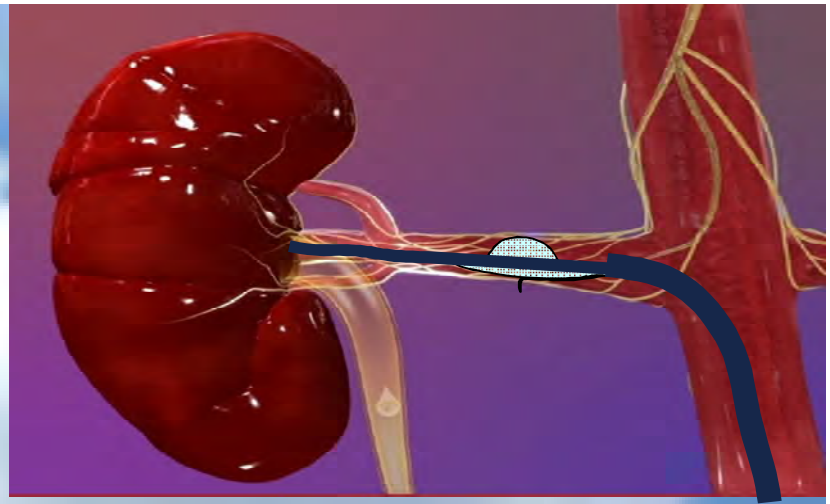


Renal Sympathetic Denervation

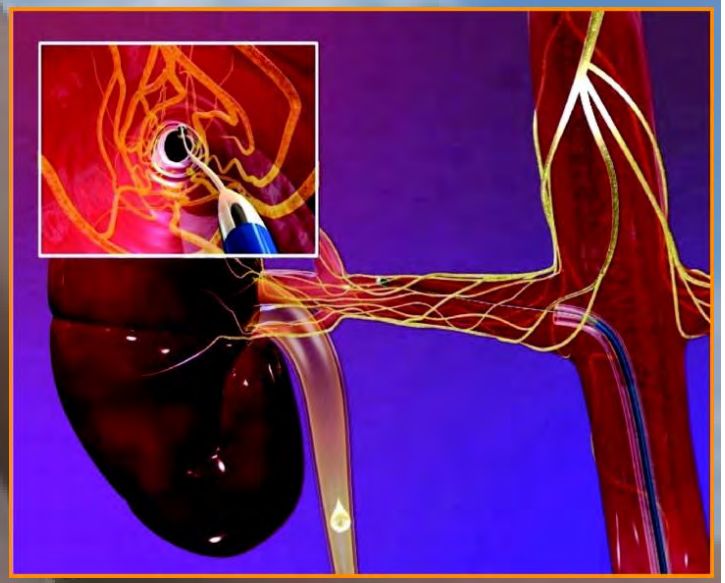
CONCLUSIONS

1. Encouraging initial experience
2. Exciting new treatment strategy targeting the renal artery adventitial autonomic nervous system
3. New exciting technologies on the horizon

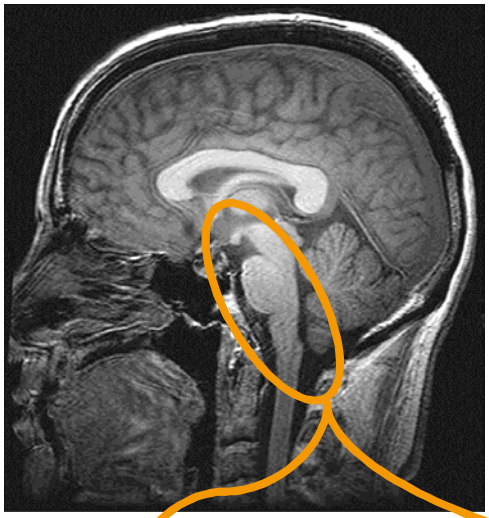
עידן חדש!!

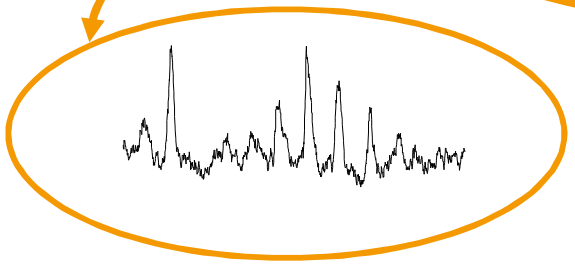



Baroreflex
Activation Leads
Programming
System
Implantable
Pulse Generator

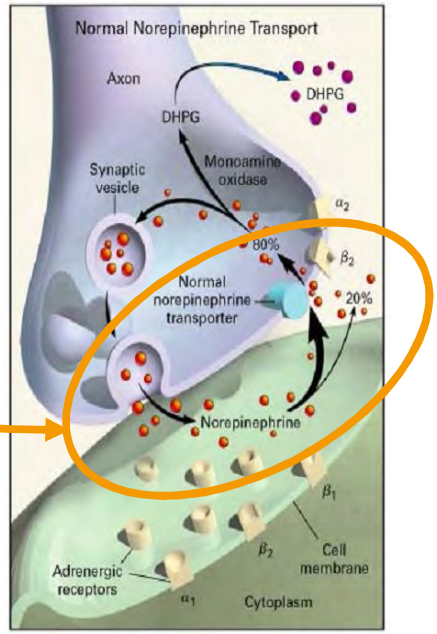


Quantification of human sympathetic activity





Sympathetic
Nerve Traffic

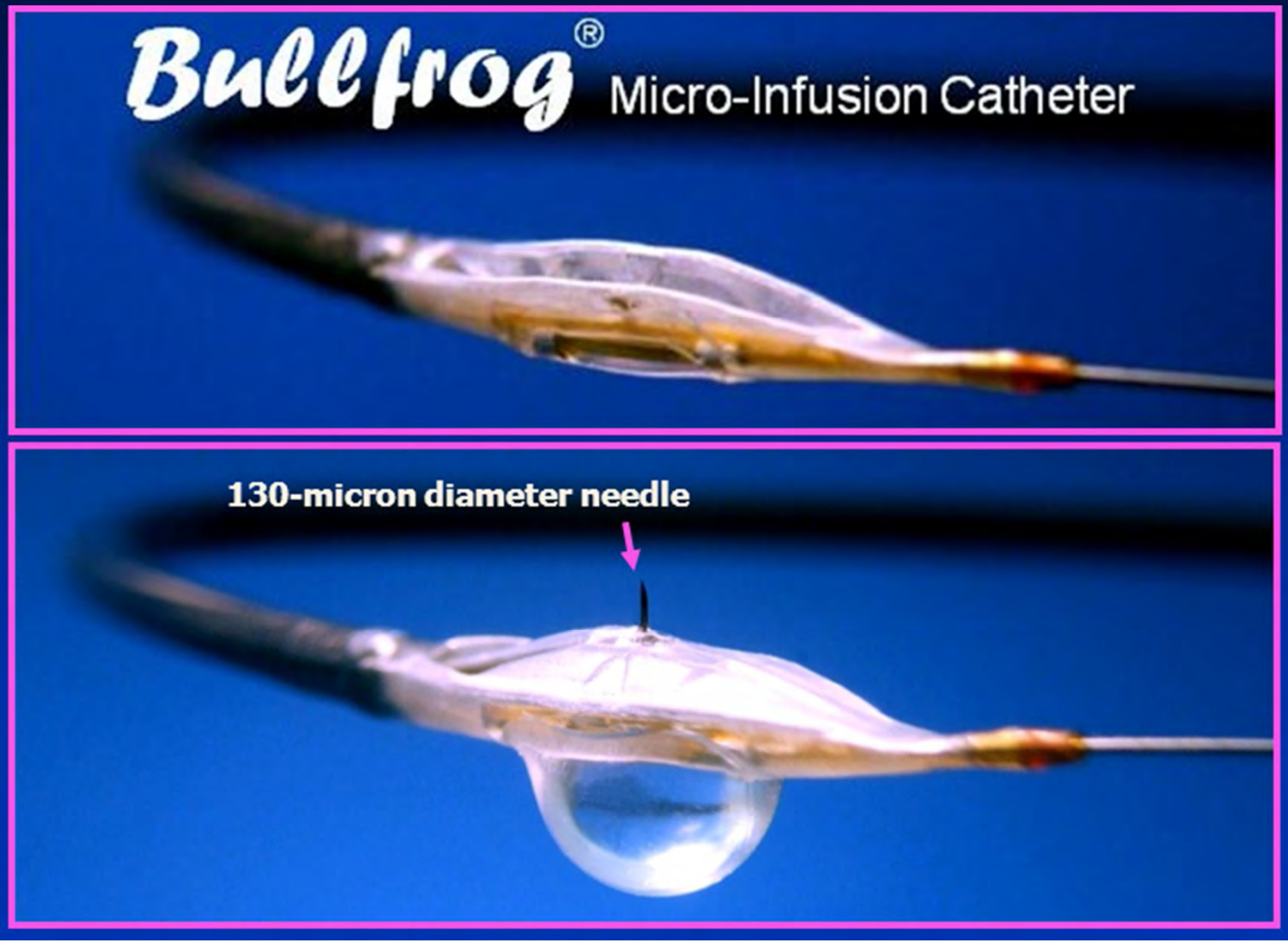


Noradrenaline

Muscle sympathetic nerve activity
(MSNA)
(Peroneal nerve activity)

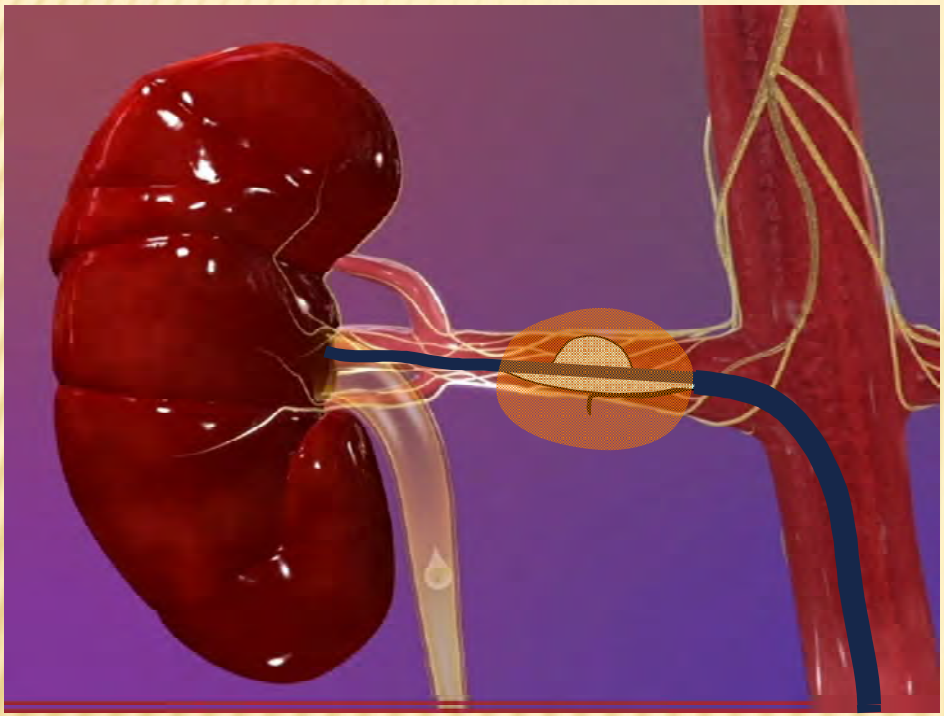
Measuring transmitter release from sympathetic nerves to plasma
(noradrenaline “spillover”)

Treatment by Micro-Infusion Catheter



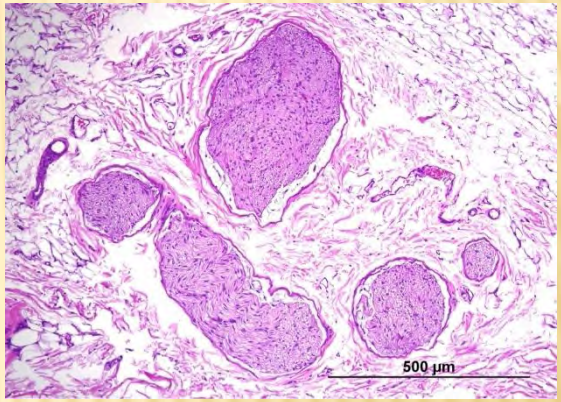
NEW TECHNOLOGIES ARE UNDERWAY
LOCALIZED *GUANETHIDINE* SYMPATHECTOMY

Bullfrog® Micro-Infusion Catheter (Mercator MedSystems)

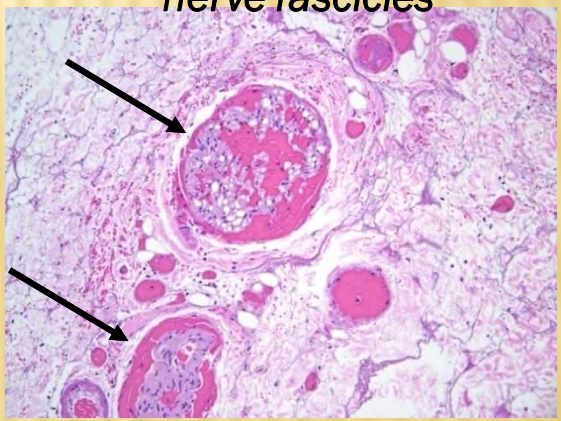


Drugs can be targeted directly to adventitial nerves with the Bullfrog Catheter

TCT 2010

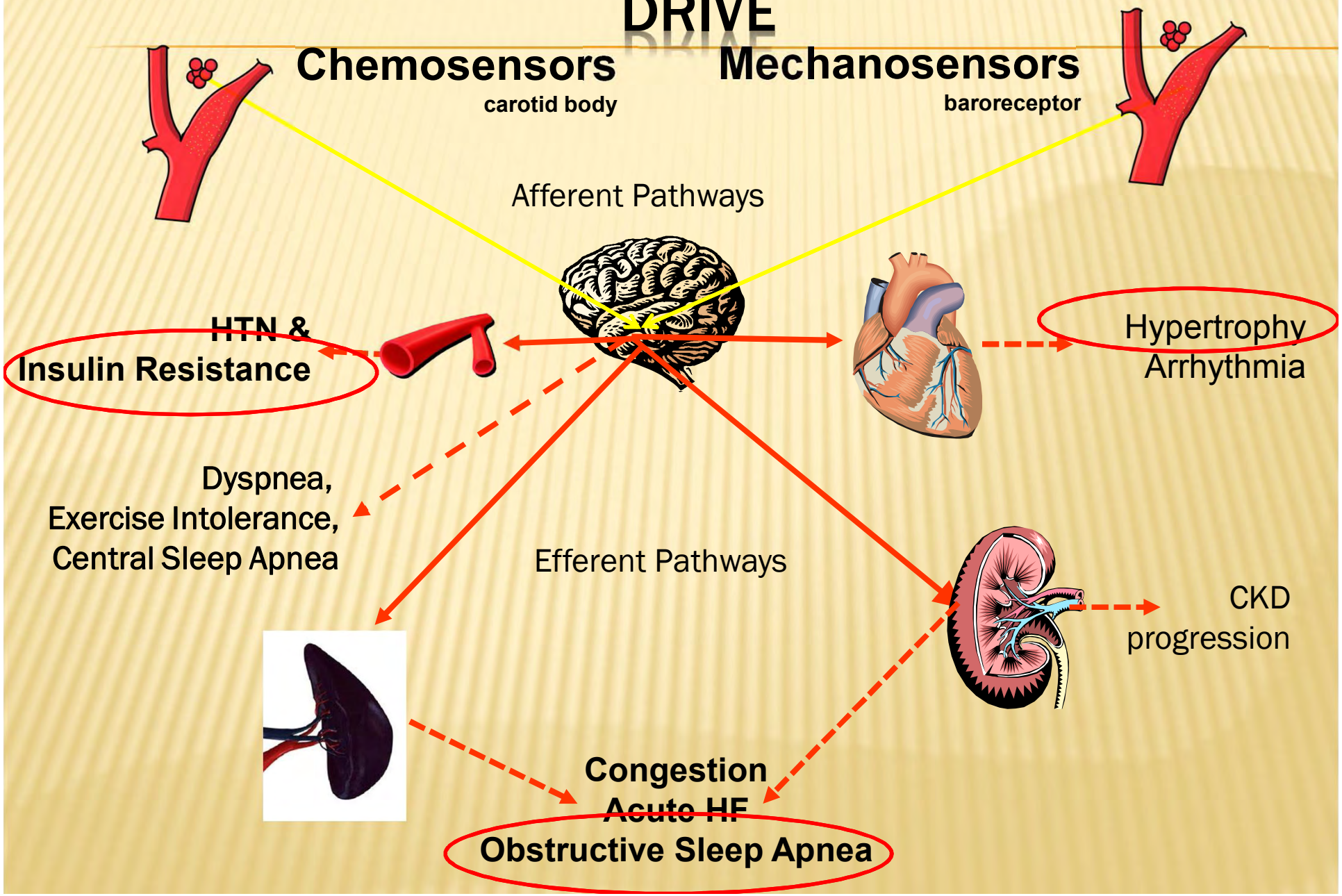


Control Porcine renal adventitial nerve fascicles



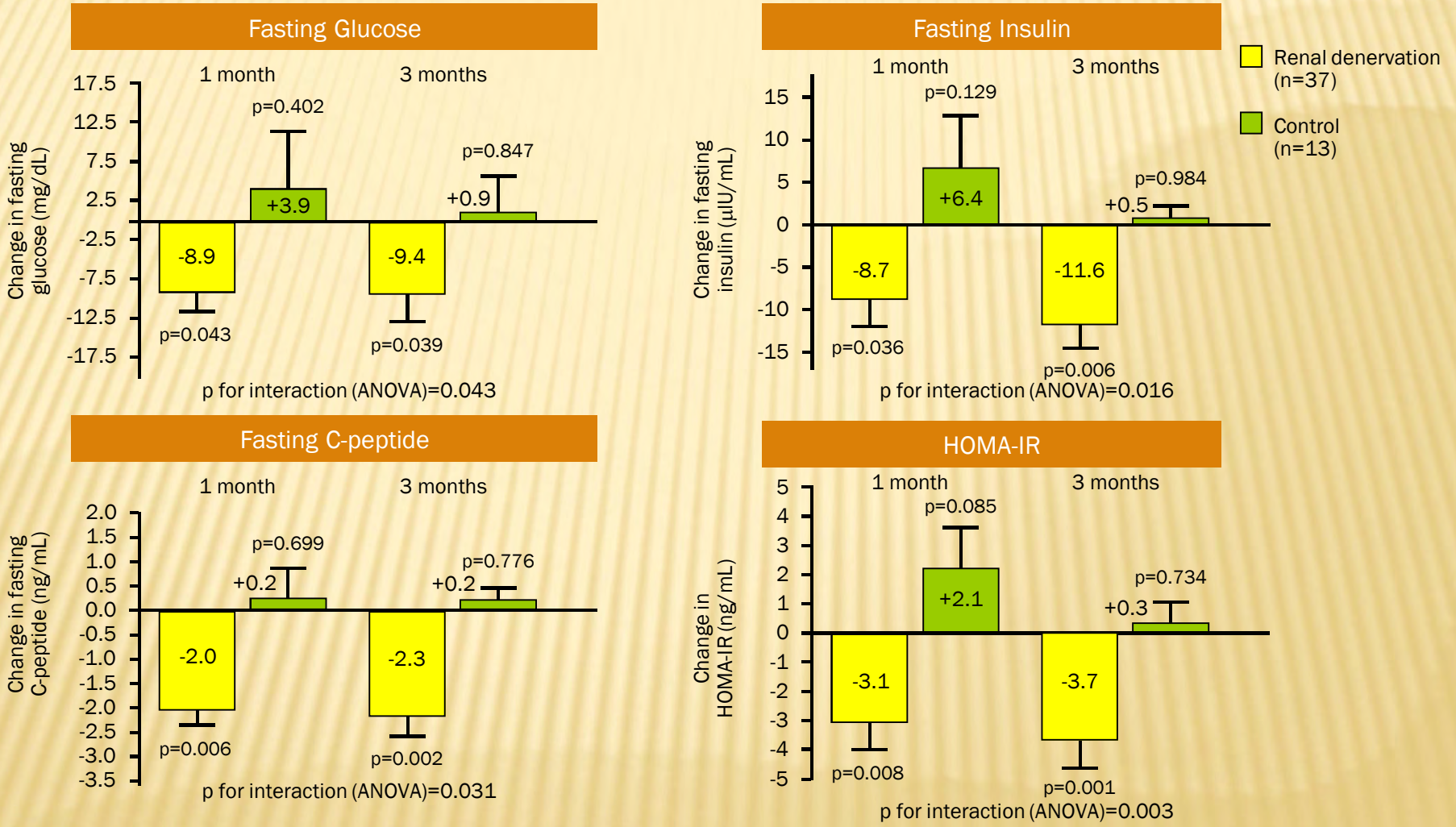
24 hrs after delivery of guanethidine: Injured interstitial nerve fascicles

CONTROL OF CENTRAL SYMPATHETIC DRIVE



DIABETES MELLITUS

RDN GROUP SHOWED IMPROVEMENTS IN SEVERAL KEY INSULIN RESISTANCE MARKERS



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CLINICAL RESEARCH — Interventions in Hypertension

Renal Sympathetic Denervation Reduces Left Ventricular Hypertrophy and Improves Cardiac Function in Patients With Resistant Hypertension

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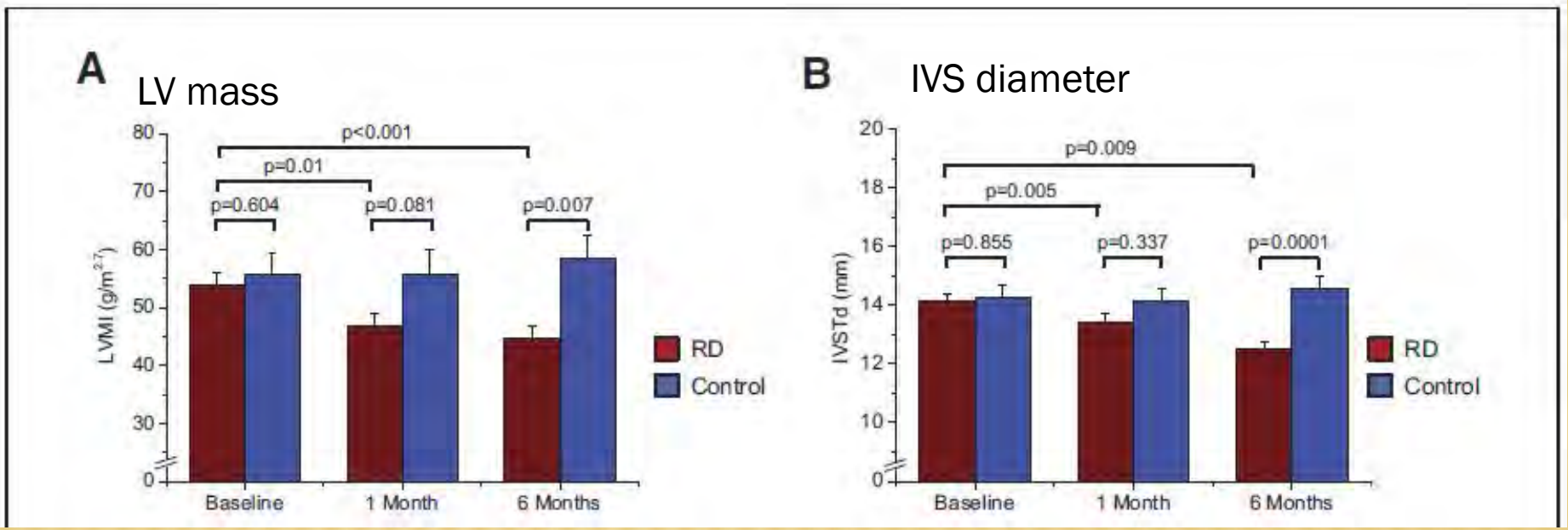

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Effects of Renal Sympathetic Denervation on Blood Pressure, Sleep Apnea Course, and Glycemic Control in Patients With Resistant Hypertension and Sleep Apnea

Adam Witkowski, Aleksander Prejbisz, Elbieta Florczak, Jacek K dziela, PaweB ZliwiDski, PrzemysBaw BieleD, Ilona MichaBowska, Marek Kabat, Ewa WarchoB,

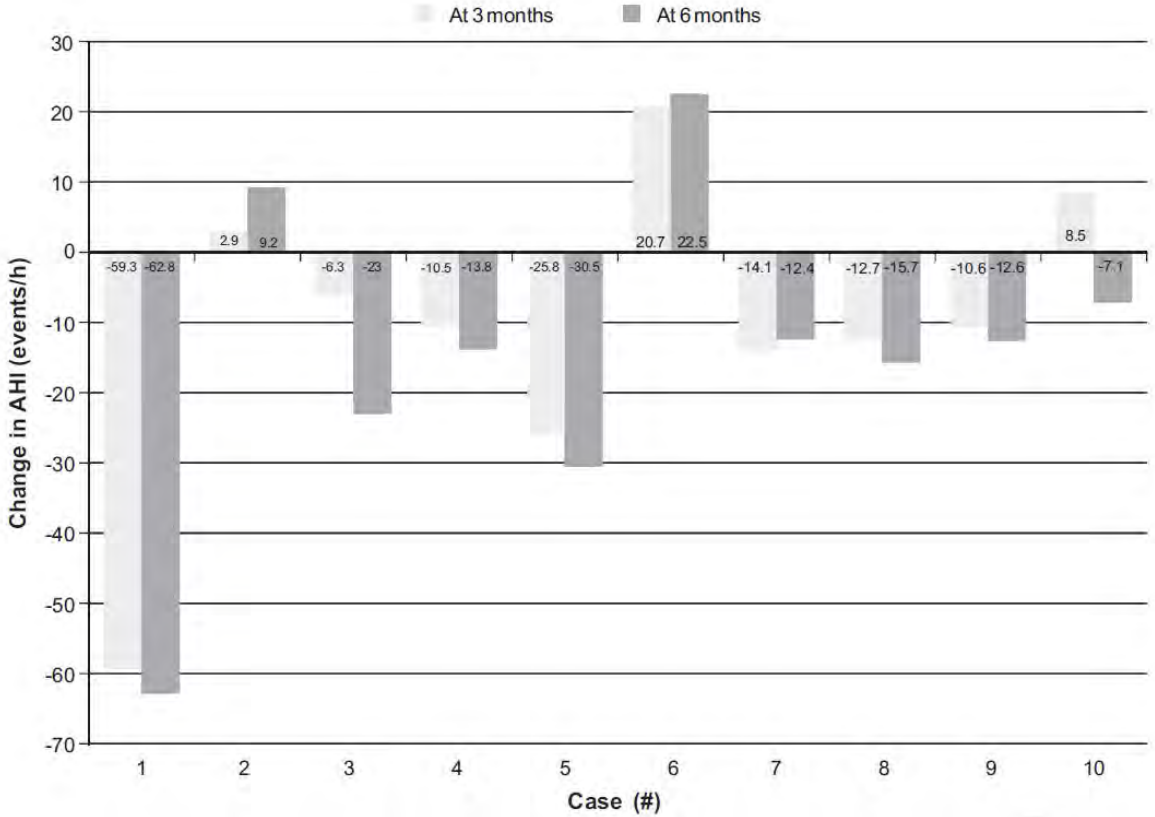

Figure 2. Changes of apnea/hypopnea index (AHI) at 3 and 6 months after denervation. Data of individual cases.