Barorezeptorstimulation oder renale Denervierung zur Behandlung der (resistenten) Hypertonie

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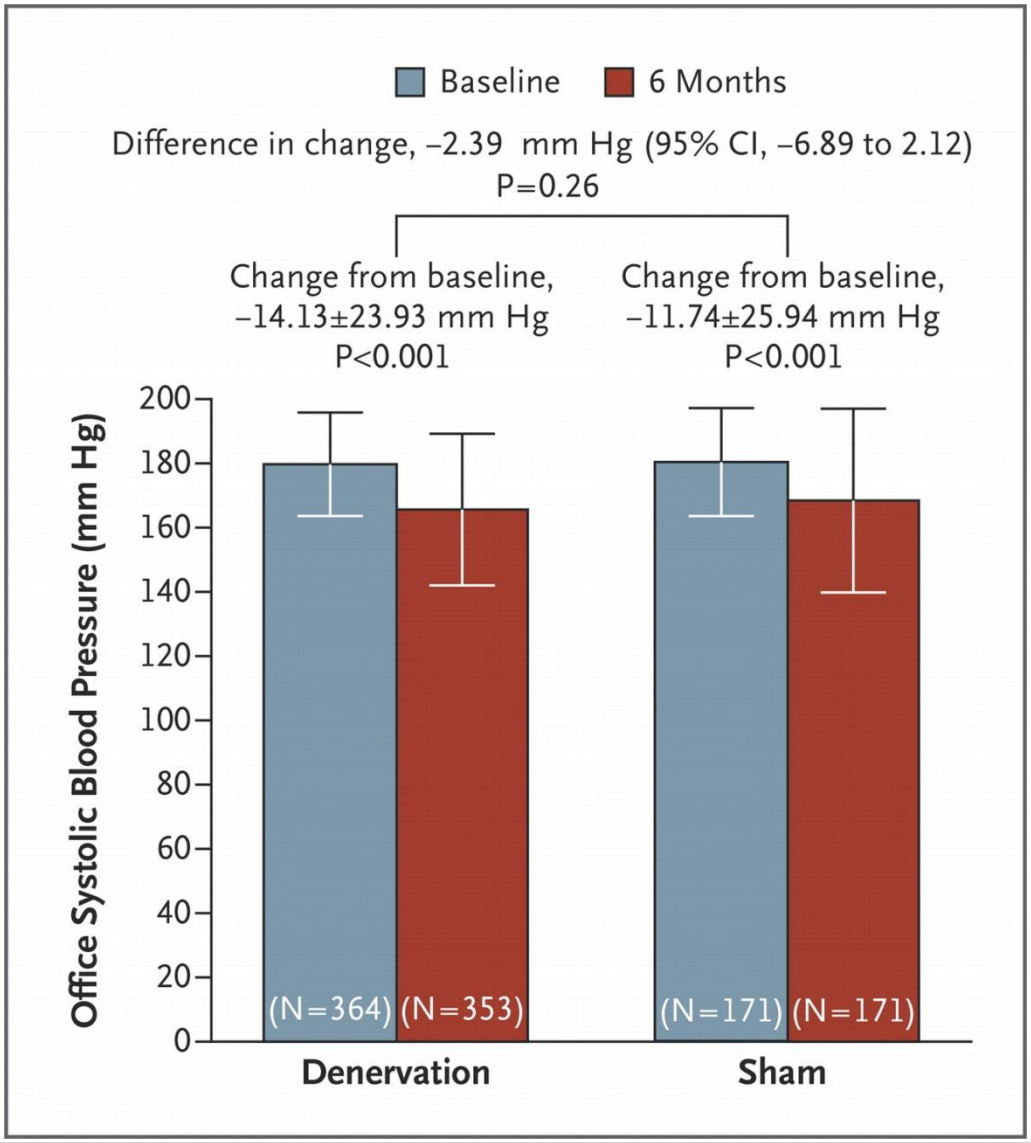
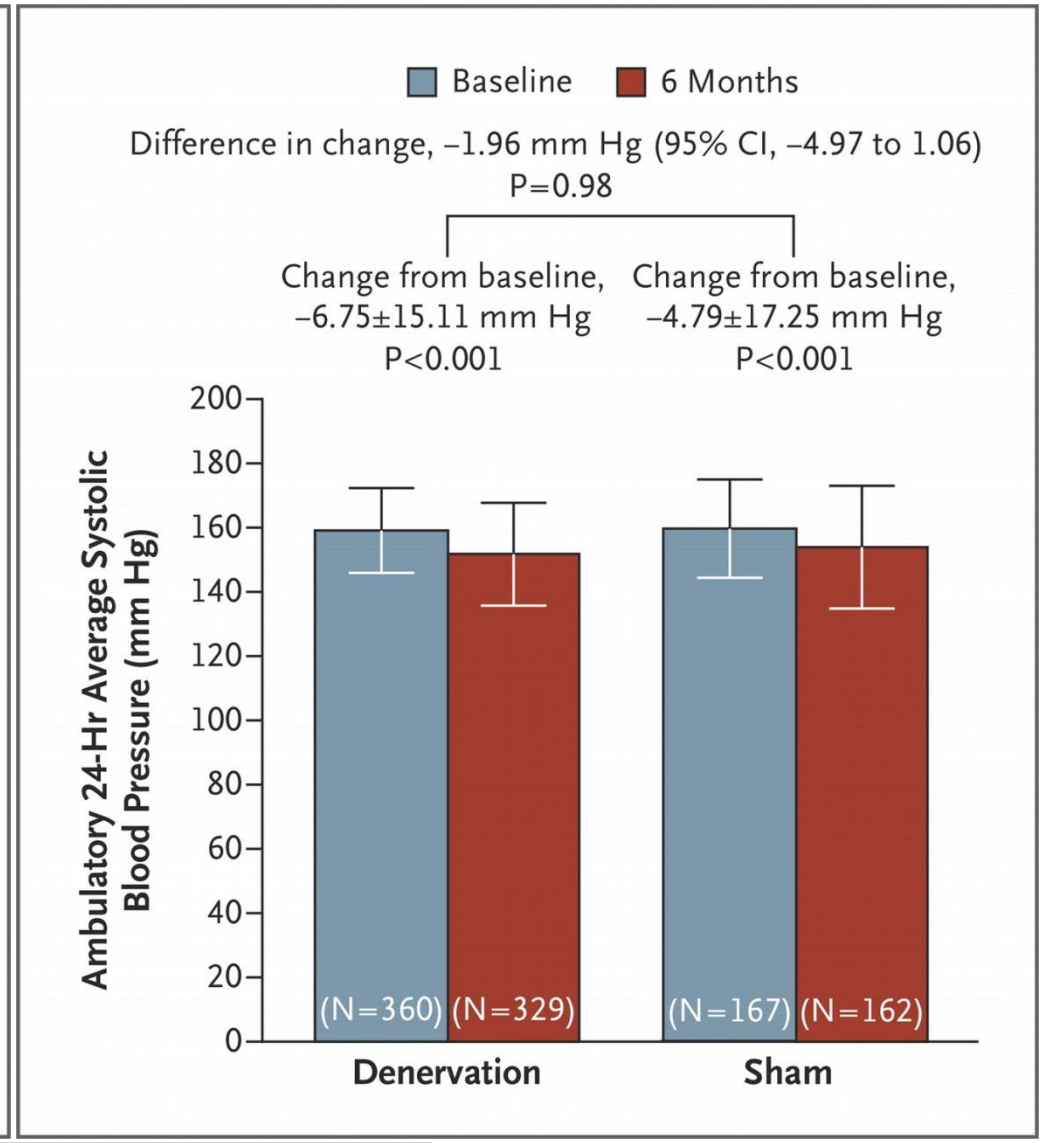
(Interessenkonflikt: Studienvergütungen [Klinikum St. Georg] und Sprecherhonorare von CVRx**)**

HTN-3 Results





Bhat, Bakris et. al. N Engl J Med 2014; 370:1393-1401

Editorial

Franz H. Messerli and Sripal Bangalore

… the medical community has been enamored with this procedure. Resistant hypertension evolved into a fashionable diagnosis …

Patients whose blood pressure is above their average … will be… enrolled. Blood-pressure measurements are prone to be lower regardless of whether there was an intervention.

… time has come to turn the page on renal denervation for hypertension but by all means, let's not close the book.

Häufigkeit in Deutschland / Leipzig

Ca. 20% der Bevölkerung (16 Mio/100.00)*

11 Mio /69.000 diagnostiziert

Dunkelziffer 5 Mio / 31.000

9 Mio / 56.000 unter Therapie

2 Mio / 12.000 ohne Therapie

Ca. 5 Mio / 31.000 nicht ausreichend therapiert

Ca. 4 / 25.000 Mio ausreichend therapiert

Ca. 0,4 Mio / 2.500 „Therapy – resistant"#
schwere Hypertonie
„schwer zu therapierende Hypertonie"

*Yoon S et al.: NCHS Data Brief. 2012 Oct;(107):1-8;
#Barochinger J et al. Clin Exp Hypertens. 2012 Nov 13.

Schwere Hypertonie

>= 140/90 mmHg unter
>= 3 optimal dosierten Antihypertensiva

AHA Scientific Statement

Resistant Hypertension: Diagnosis, Evaluation, and Treatment

A Scientific Statement From the American Heart Association Professional Education Committee of the Council for High Blood Pressure Research

David A. Calhoun, MD, FAHA, Chair; Daniel Jones, MD, FAHA; Stephen Textor, MD, FAHA; David C. Goff, MD, FAHA; Timothy P. Murphy, MD, FAHA; Robert D. Toto, MD, FAHA; Anthony White, PhD; William C. Cushman, MD, FAHA; William White, MD; Domenic Sica, MD, FAHA; Keith Ferdinand, MD; Thomas D. Giles, MD; Bonita Falkner, MD, FAHA; Robert M. Carey, MD, MACP, FAHA

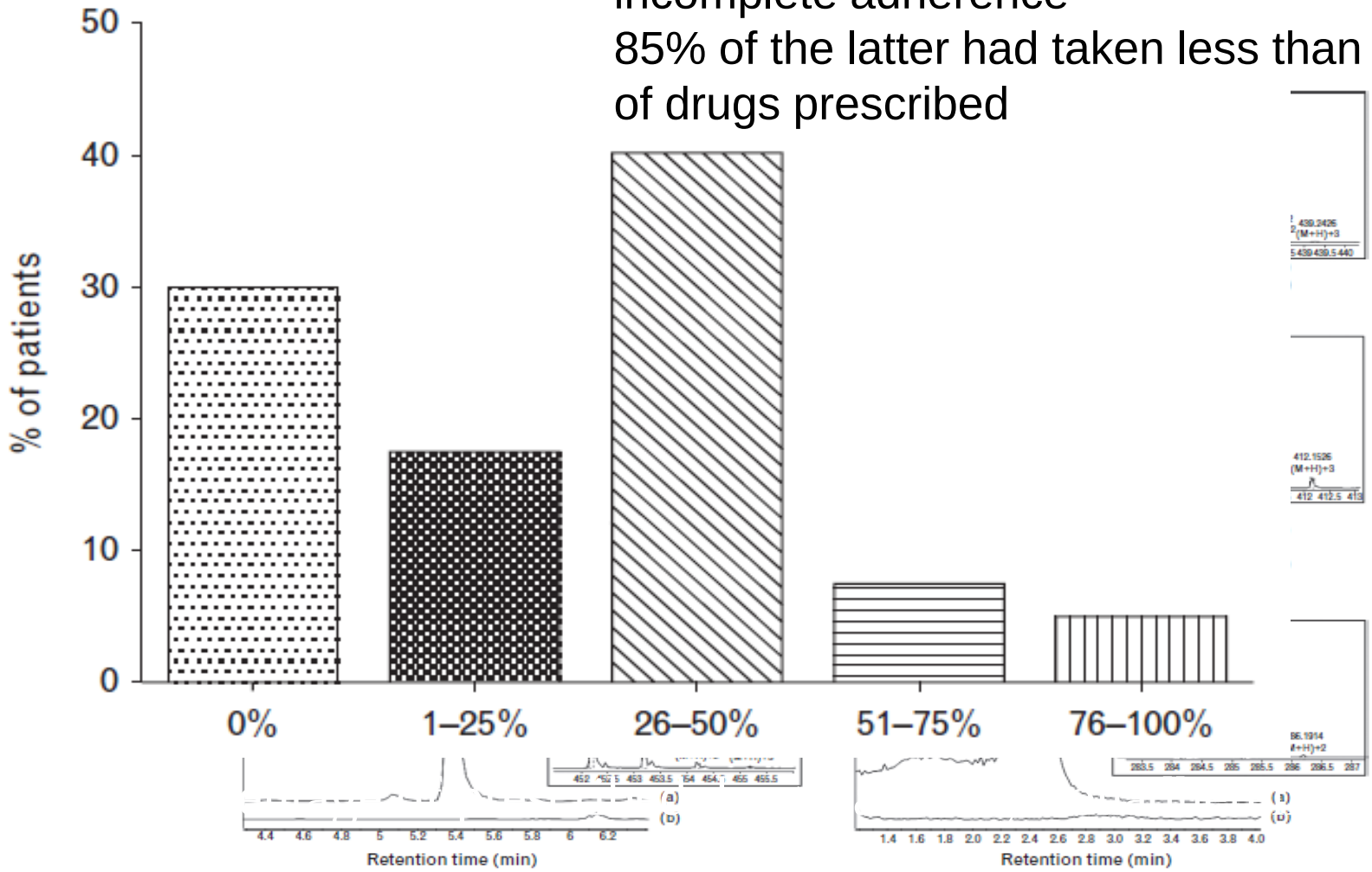
Abstract—Resistant hypertension is a common clinical problem faced by both primary care clinicians and specialists. While the exact prevalence of resistant hypertension is unknown, clinical trials suggest that it is not rare, involving perhaps 20% to 30% of study participants. As older age and obesity are 2 of the strongest risk factors for uncontrolled hypertension, the incidence

Hypertension. 2008;51:1403-1419

Incompliance !

40 of 76 patients (53%) were nonadherent !

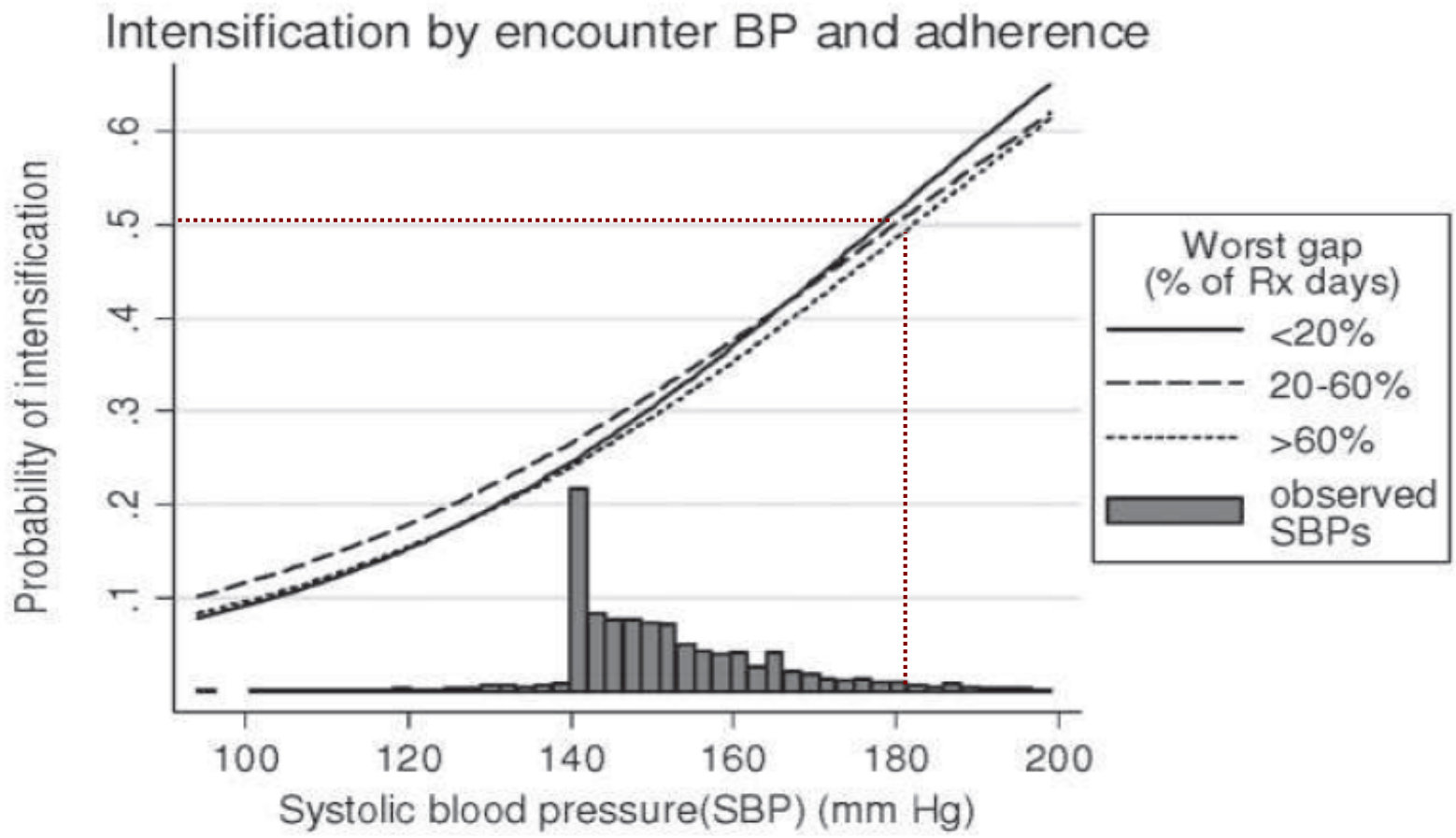
30% had complete and 70% had incomplete adherence
85% of the latter had taken less than 50% of drugs prescribed



Jung et al, Journal of Hypertension 2013, 31:766–774

Die Docs sind Teil des Problems !!!

Therapie-Intensivierung trotz SBP > 140mmHg nur in < 1/3 der Arztbesuche

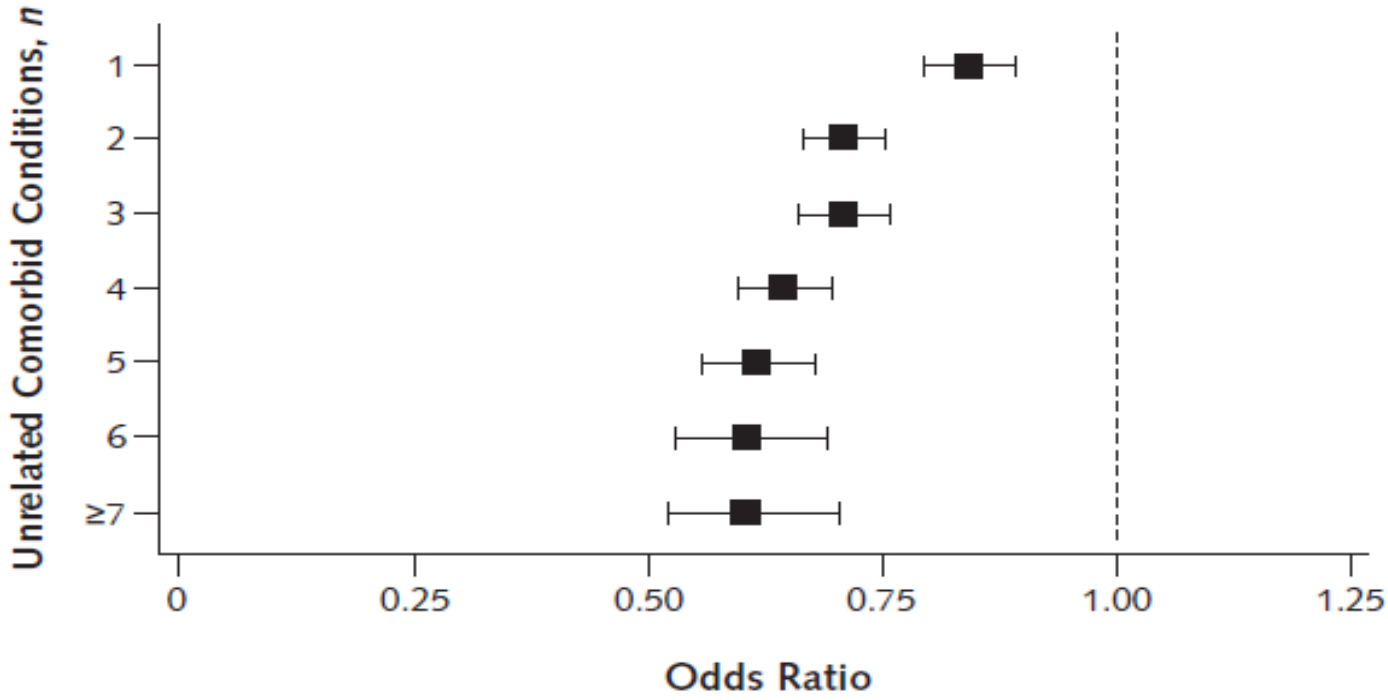


Circulation. 2008;117:2884-2892

Effect of Unrelated Comorbid Conditions on Hypertension Management

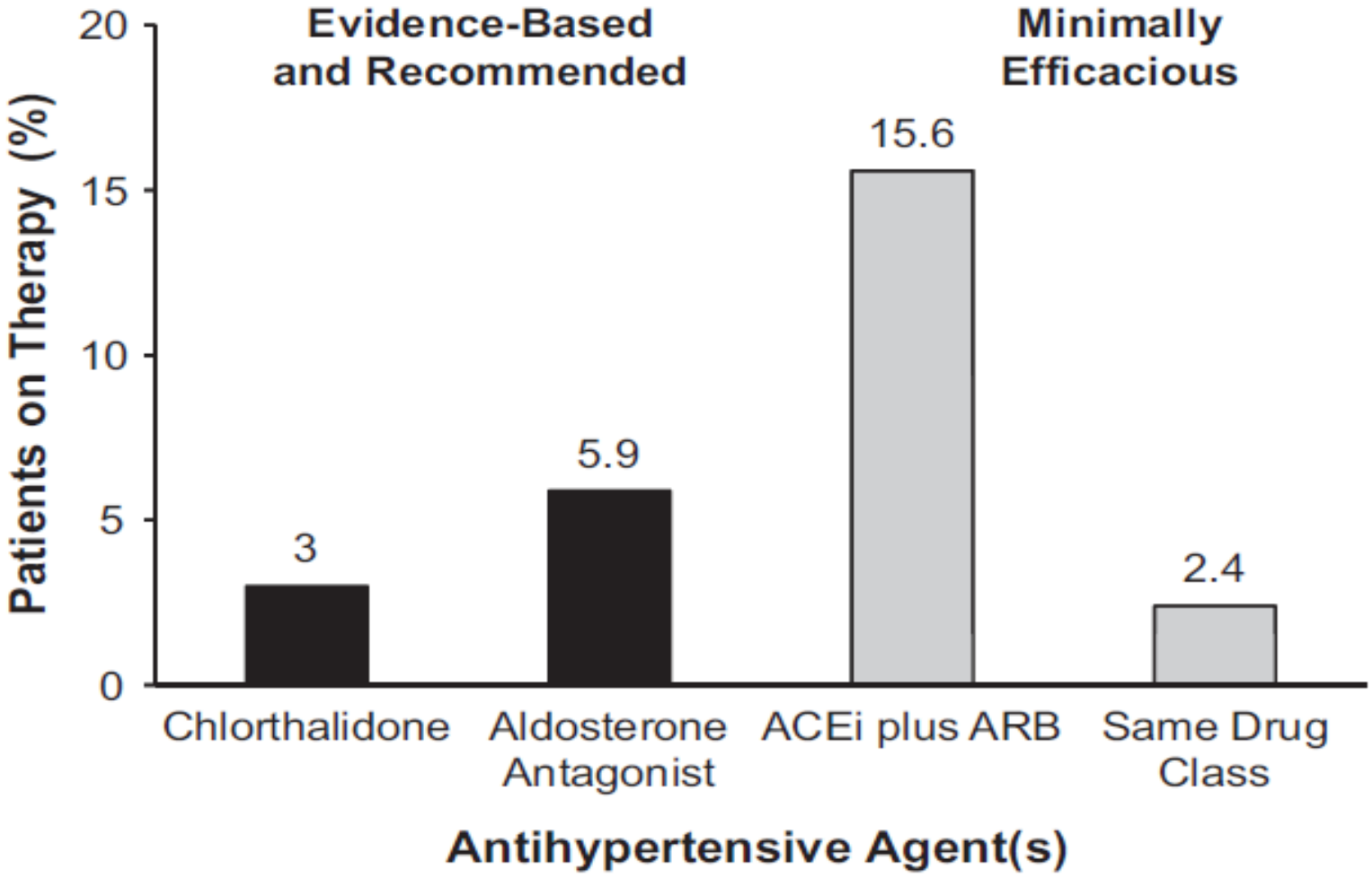
15 459 patients with uncontrolled hypertension who made 70 557 visits

Figure 2. **Adjusted association of unrelated comorbid conditions with management of uncontrolled hypertension.**



Ann Intern Med. 2008;148(8):578-586

Wie sind Patienten mit resistenter Hypertonie und >4 Medikamenten behandelt ?



5 442 410 patients
140 126 resistant hypertension and ≥4 antihypert. Agents

ACEI or ARB (96.2%)

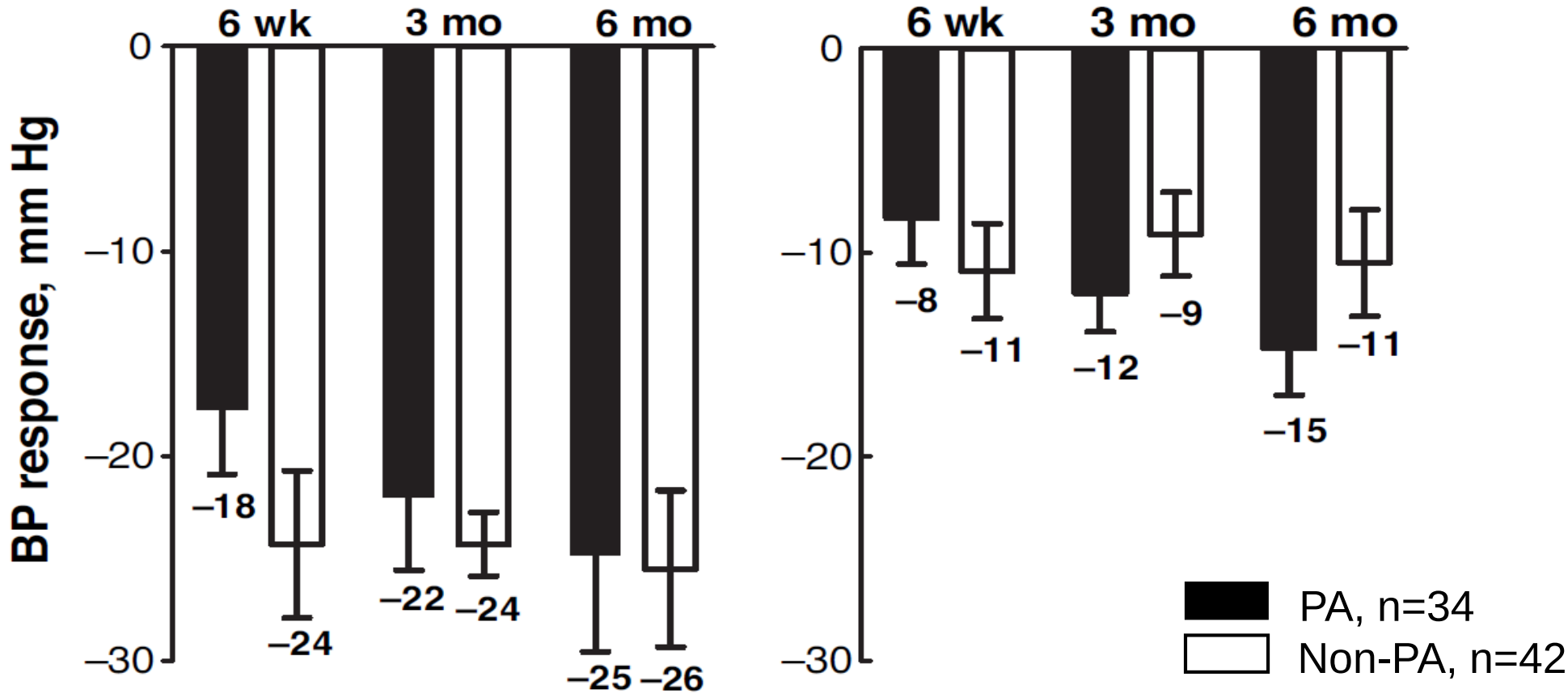
Diuretics (93.2%)

Calcium channel blockers (83.6%)

ß-blockers (80.0%)

Hypertension. 2011;58:1008-1013

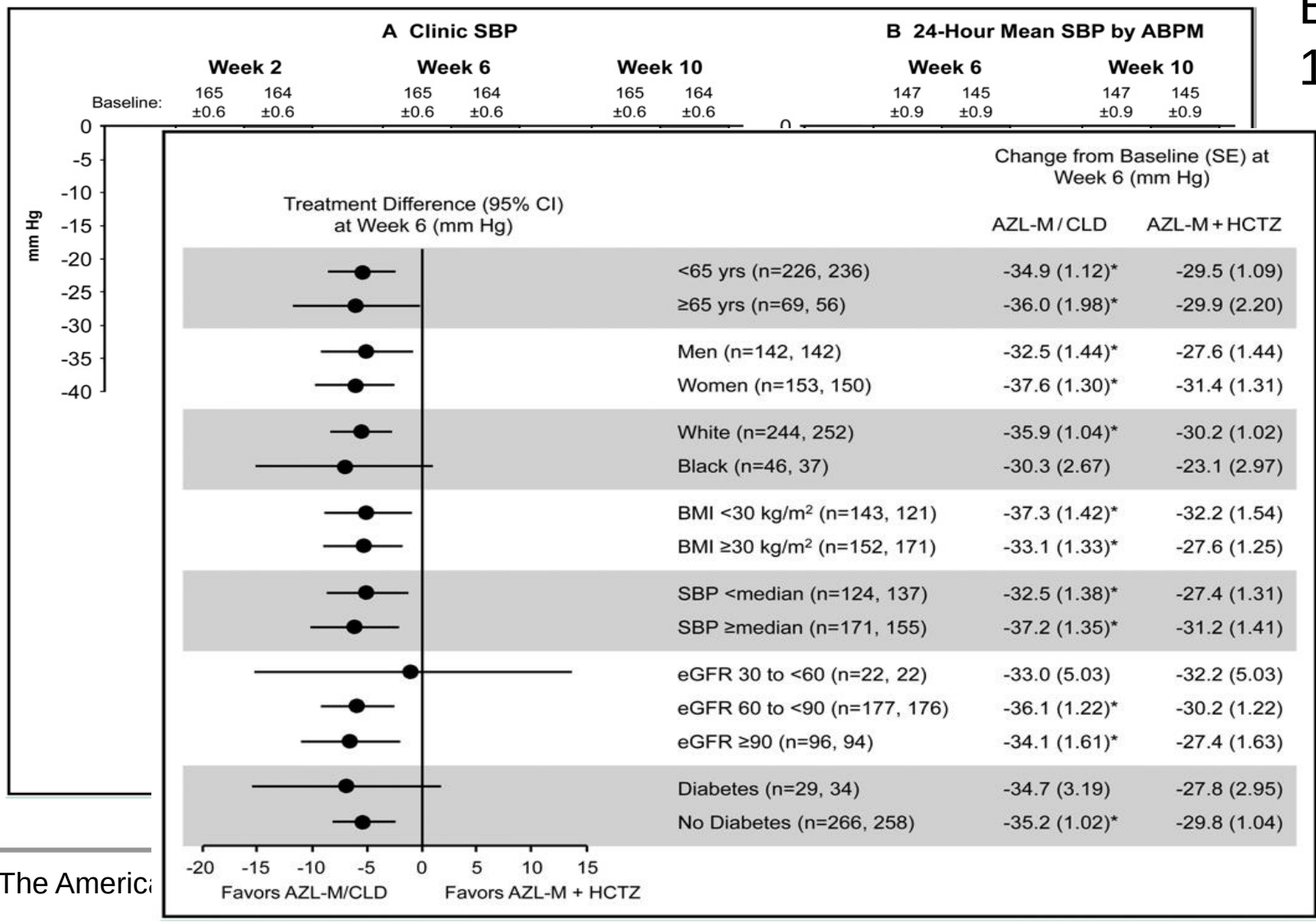
Effect of Low-Dose Spironolactone on Resistant Hypertension



Am J Hypertens 2003;16:925–930

Chlorthalidon vs. Hydrochlorothiazid (n=609)

BP *baseline*
164 / 95 mmHg



Minoxidil

Minoxidil for severe hypertension after failure of other hypotensive drugs

B L DEVINE, R FIFE, P M TRUST

British Medical Journal, 1977, **2**, 667-669

Summary

Forty-four patients with severe hypertension who were resistant to treatment with more conventional hypotensive drugs or could not tolerate the side effects were treated with minoxidil, a potent peripheral vasodilator. A beta-blocking drug and a diuretic were used routinely to control, respectively, the tachycardia and fluid retention caused by minoxidil. During treatment the outpatient supine blood pressure fell from a mean of 221/134 mm Hg to 162/98 mm Hg. Eleven patients required additional or alternative hypotensive agents before blood pressure was adequately controlled. Side effects were minor, although the invariable hirsuties caused by minoxidil was unacceptable to three women.

The possibility of cardiotoxic effects, raised by early

treating patients with severe hypertension in whom conventional treatment has failed to control blood pressure.[1] We describe here the use of minoxidil in 44 such patients.

Patients and methods

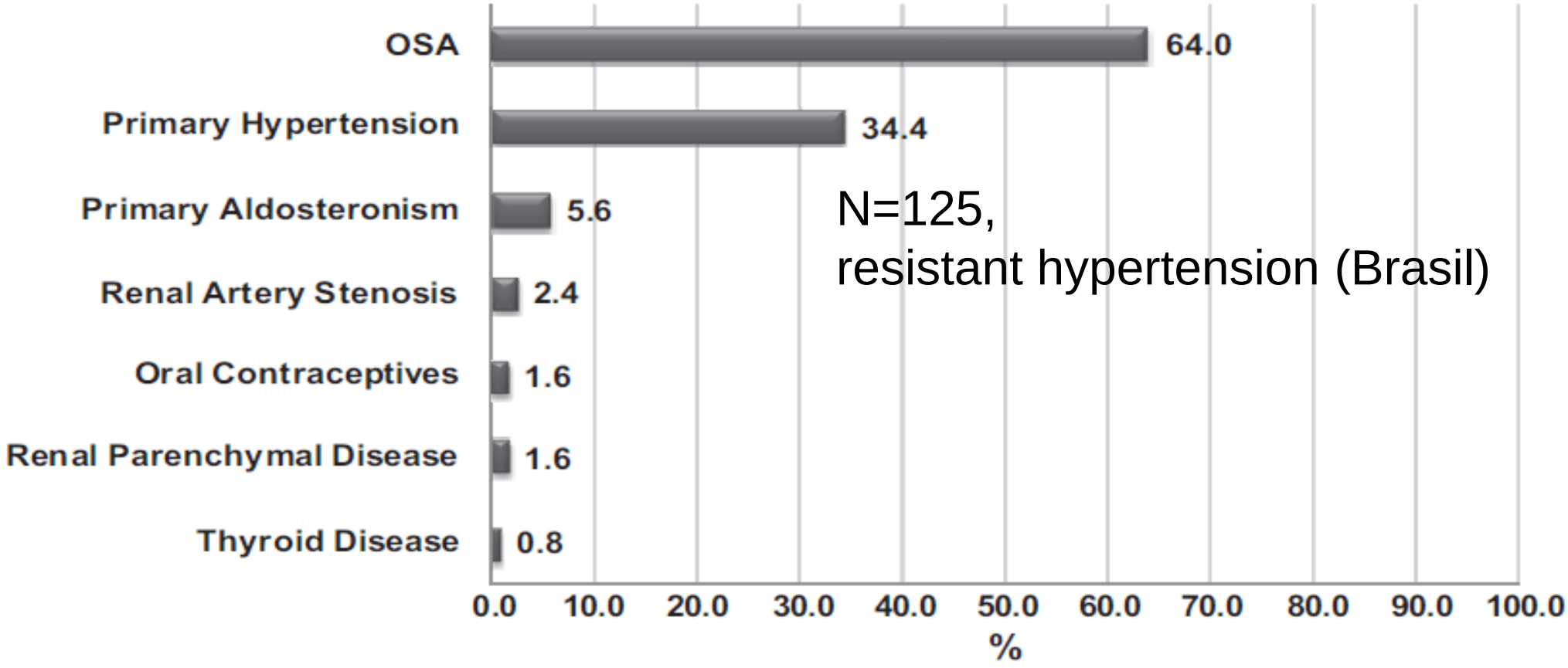
All the patients had diastolic blood pressures (fifth Korotkoff phase; the mean of the last three readings in the outpatient department, while sitting or lying) of over 120 mm Hg despite treatment with other hypotensive drugs. Previous hypotensive treatment (table I) had been given in full dosage or had produced intolerable side effects.

Ten patients had been in the malignant phase of hypertension, 14 had had a stroke, nine had had congestive cardiac failure, and five complained of angina of effort. Twenty-two patients had renal failure before starting minoxidil; their blood urea concentrations were consistently over 7 mmol/l (42 mg/100 ml) and serum creatinine concentrations over 120 μmol/l (1·4 mg/100 ml).

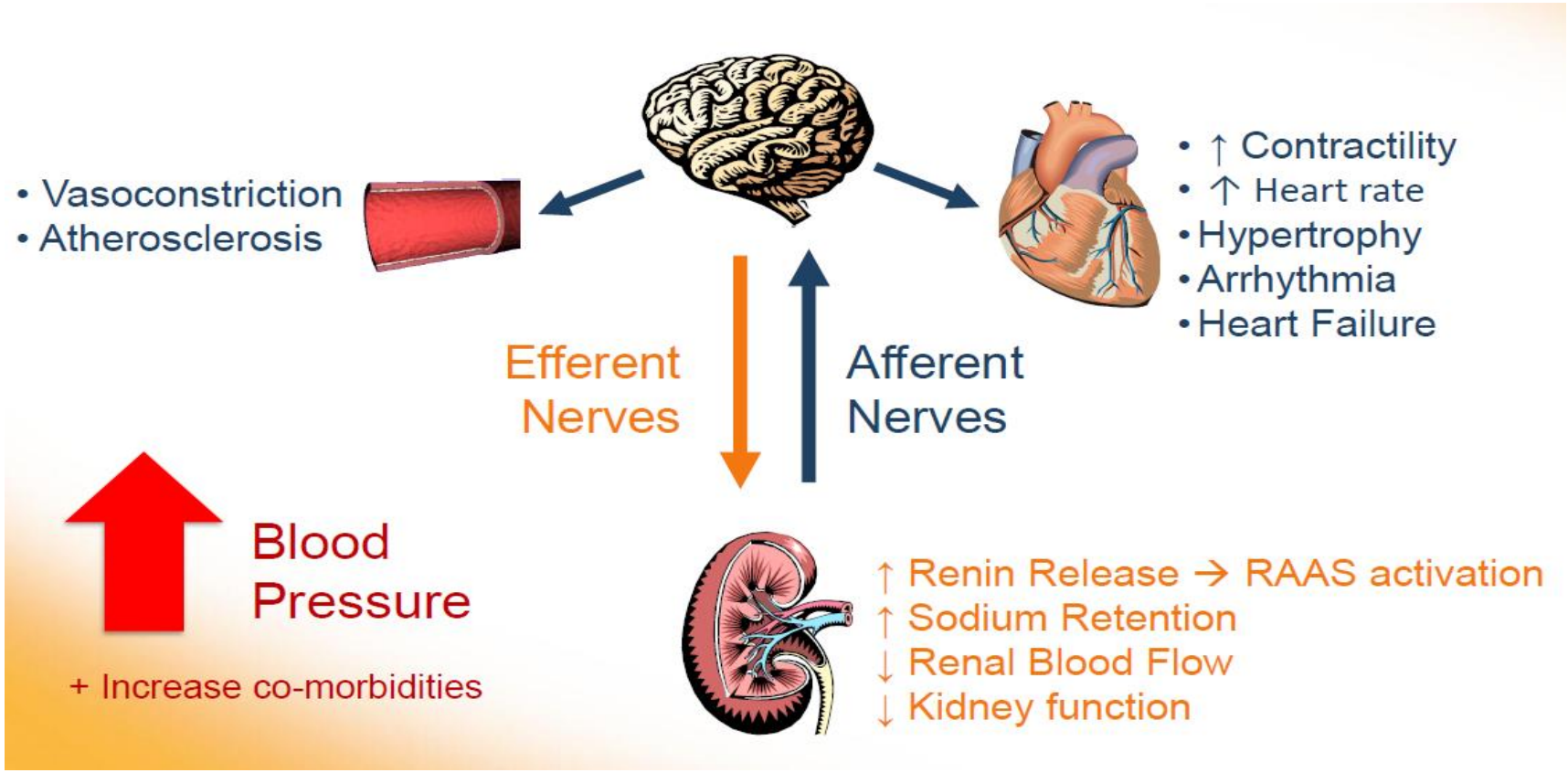
The patients were all admitted to hospital before starting minoxidil and the following values were measured: full blood count including

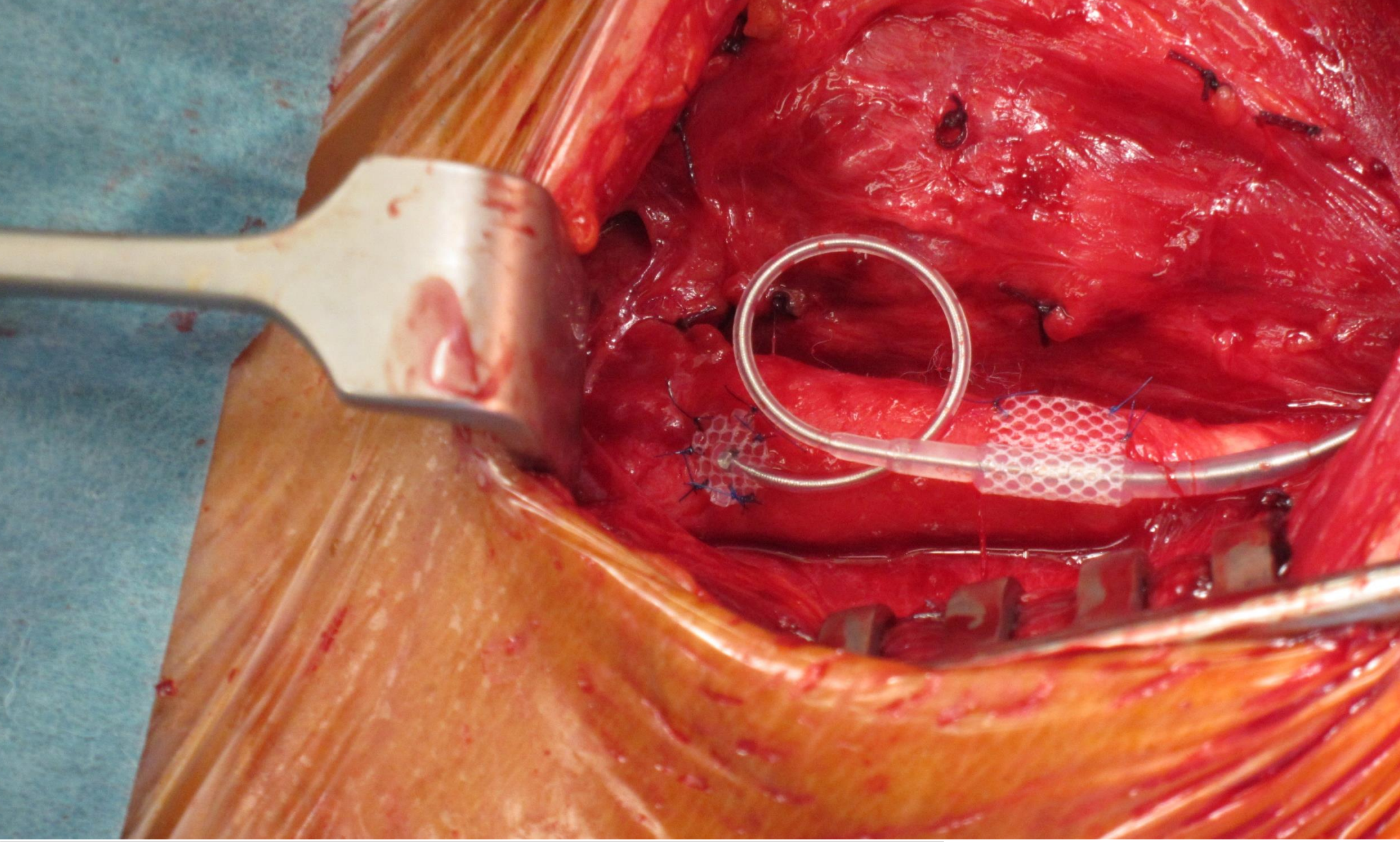
Case No	Age and sex	Diagnosis	Before minoxidil			During minoxidil			
			Urea (mmol/l)	Treatment	Mean outpatient blood pressure (mm Hg)	Minoxidil dose (mg/day)	Other drugs (and doses, mg/day)	Latest outpatient blood pressure (mm Hg)	Months on minoxidil
1	30 M	Glomerulonephritis	16·7	Pz	210/120	15	F (1000), Ox (80)	130/80	11
2	38 F	Essential hypertension	10·0	B, C, H, Meth, Ox, T	180/120	30	F (500), Ox (640)	155/90	2
3	52 F	,, ,,	7·7	B, C, Ox, Meth	220/145	10	F (120), P (120)	150/98	23
4	60 M	Chronic pyelonephritis	18·4	B, C, H, Meth, Ox, T	210/135	60	F (80), Ox (800)	170/95	16
5	57 M	,, ,,	19·7	C, Meth	218/130	10	T, P (240)	135/85	21
6	51 M	Essential hypertension	5·0	C, Dz, H, Meth	210/120	10	T, Ox (320)	130/90	11
7	45 M	,, ,,	14·0	Db, Ox, Pz, T	246/136	30	F (80), Ox (960)	180/100	16
8	55 M	,, ,,	26·1	C, Meth	248/138	30	F (160), P (80)	170/100	24
9	54 M	,, ,,	5·7	Db, C, Meth, Ox	240/130	30	T, P (320)	160/80	16
10	60 M	,, ,,	4·5	B, Meth, Ox, T	260/130	30	F (40), P (240)	160/105	22
11	40 M	Chronic pyelonephritis	19·5	—	240/160	50	F (500), P (320)	190/120	23
12	46 M	Hydronephrosis	9·4	B, C, Db, Meth, Pz	240/130	30	F (120), P (800)	120/70	16
13	37 F	Chronic pyelonephritis	15·0	B, Dz, H, Meth, Ox, T	180/120	35	F (1000), P (640)	140/90	12
14	53 M	Essential hypertension	7·0	B, C	225/115	50	T, P (960)	150/100	11
15	44 F	,, ,,	4·3	C, Meth,	250/148	35	F (40), P (320)	185/90	13
16	34 F	Chronic pyelonephritis	31·7	Dz, H, Meth, Ox, Pz, T	180/120	35	F (2000), Ox (1120)	145/90	16
17	66 F	Essential hypertension	6·7	B, C, Meth	230/130	25	F (160), P (120)	140/80	17 days
18	32 M	Chronic pyelonephritis	8·4	C, Meth, Pz	170/130	40	F (40), Ox (1920)	140/90	10
19	63 M	Essential hypertension	17·0	C, P	240/130	40	F (750), P (480)	170/105	23
20	52 M	Chronic pyelonephritis	8·4	B, Meth	210/110	45	F (500), P (320), S (100)	170/80	13
21	45 M	Pelvic kidney	9·1	C, Dz, H, P, Ph, T	270/150	30	T, P (320)	170/100	13
22	59 M	Essential hypertension	6·7	Am, B, F, L, Meth, S	217/137	20	Am (10), L (400)	166/92	11
23	52 M	,, ,,	16·0	C, L, P, T	237/143	20	T, L (1600)	170/100	12
24	69 F	,, ,,	5·0	B, Meth, P, T	223/119	2·5	T, P (480)	218/100	20
25	48 M	,, ,,	7·3	B, Meth, P, Pz, T	188/132	30	T, L (400)	142/90	16
26	46 M	,, ,,	6·0	B, Meth, P, T	221/134	20	T, P (480)	132/86	18
27	46 M	,, ,,	4·4	B, Meth, P, T	212/134	30	T, B (100), P (320)	140/88	18
28	54 M	,, ,,	4·2	C, Meth, Ox, T	190/133	30	S (200), L (800)	118/82	11
29	44 M	,, ,,	5·0	Meth, P, Pz, T	187/127	20	T, P (320)	146/100	5
30	51 M	,, ,,	10·0	B, C, Dz, G, P, Meth, S, T	212/129	30	T, P (400)	156/98	22
31	51 M	,, ,,	8·0	B, F, Meth, P, Pz, T	204/136	15	F (160), P (80)	148/90	4
32	50 M	,, ,,	14·8	F, L, Meth, P, T	243/169	30	F (160), P (160)	192/122	6
33	44 M	,, ,,	6·5	B, Meth, P, Pz, T	226/132	50	T, L (2400)	158/106	16
34	51 M	,, ,,	6·4	B, C, Dz, Meth, P, Pz, T	207/143	30	T, L (1600)	152/94	14
35	57 F	Renal artery stenosis	5·5	B, H, Meth, Met, T	228/136	2·5	F (40), Met (100), S (100)	196/114	2
36	48 F	Essential hypertension	15·5	B, L, Meth, P, S, T	240/150	20	F (120), P (40)	168/86	2
37	61 M	,, ,,	36·2	B, F, L, Meth, P, T	188/115	10	F (500), L (400)	200/120	1
38	49 F		4·9	L, Meth, T	222/144	5	T, P (80)	128/82	1

OSAS in resistant hypertension



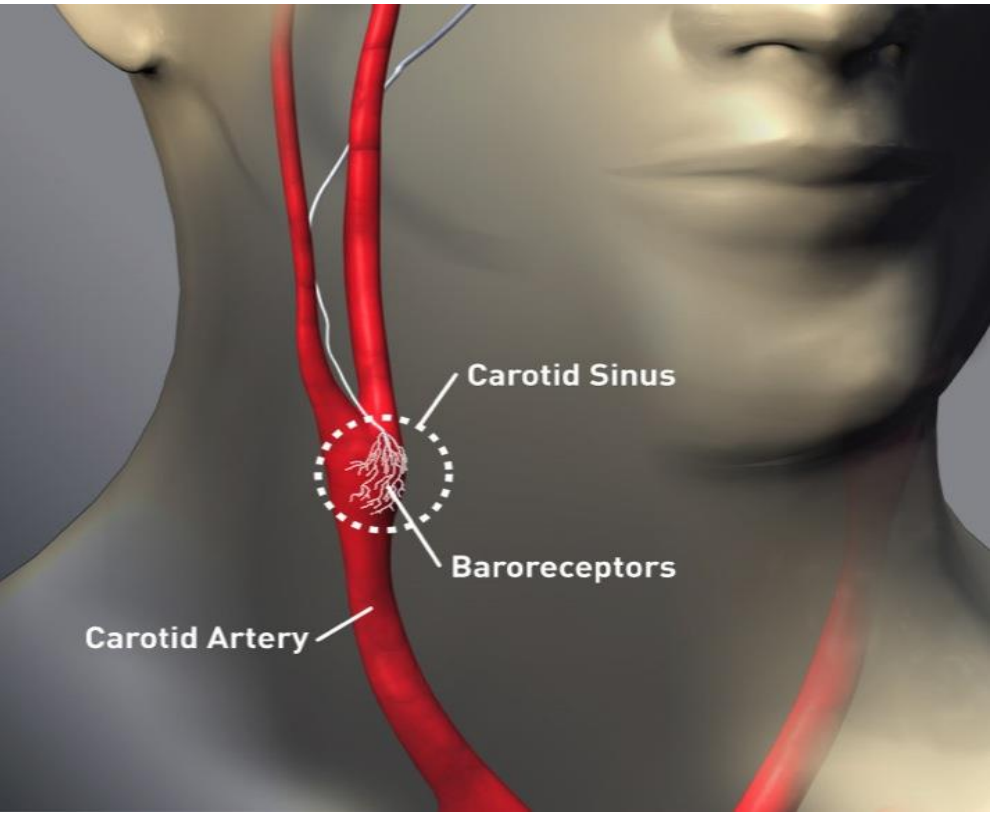
Hypertension. 2011;58:811-817


• Vasoconstriction
• Atherosclerosis
• ↑ Contractility
• ↑ Heart rate
• Hypertrophy
• Arrhythmia
• Heart Failure
Efferent Nerves
Afferent Nerves
Blood Pressure
+ Increase co-morbidities
↑ Renin Release → RAAS activation
↑ Sodium Retention
↓ Renal Blood Flow
↓ Kidney function



Dank an Dr. G. Hennig, Klinik f. Gefässchirurgie, Klinikum St. Georg

Baroreflex Activation Therapie (BAT)
Moduliert das autonome Nervensystem



Carotid Baroreceptor Stimulation

Brain

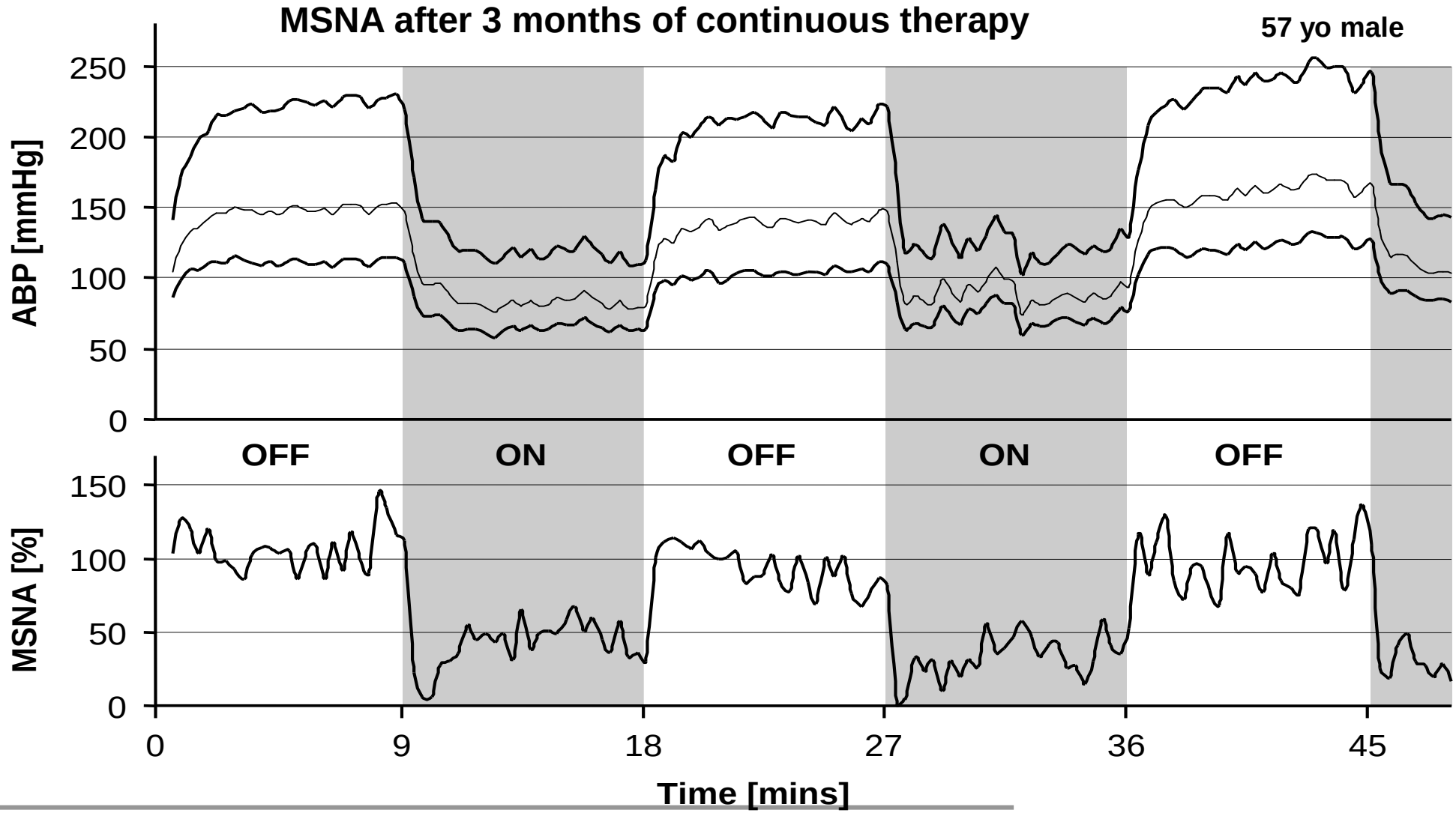
Autonomic Nervous System

Inhibited **Sympathetic** Activity

Enhanced **Parasympathetic** Activity

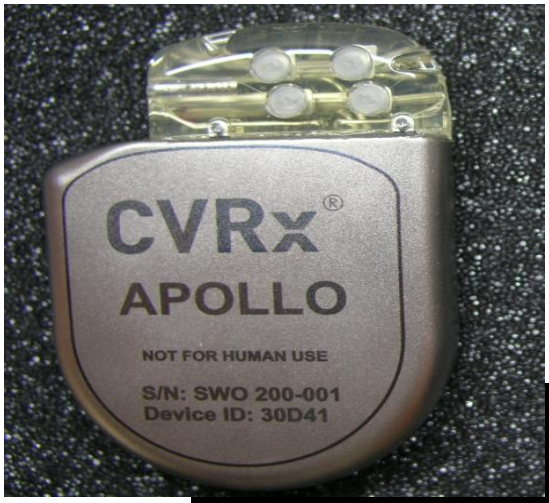
Heart	Vessels	Kidneys
↓ HR	↑ Vasodilation ↓ Stiffness	↑ Natriuresis ↓ Renin secretion

Muskel Sympathikusaktiviät nach 3 Monaten Hochdruckschrittmacher



Heusser et al. Hypertension 2010

neo (neu, Studie) vs Rheos („alt“)



Nach Barorezeptor-Stimulation

Langzeitblutdruckmessung

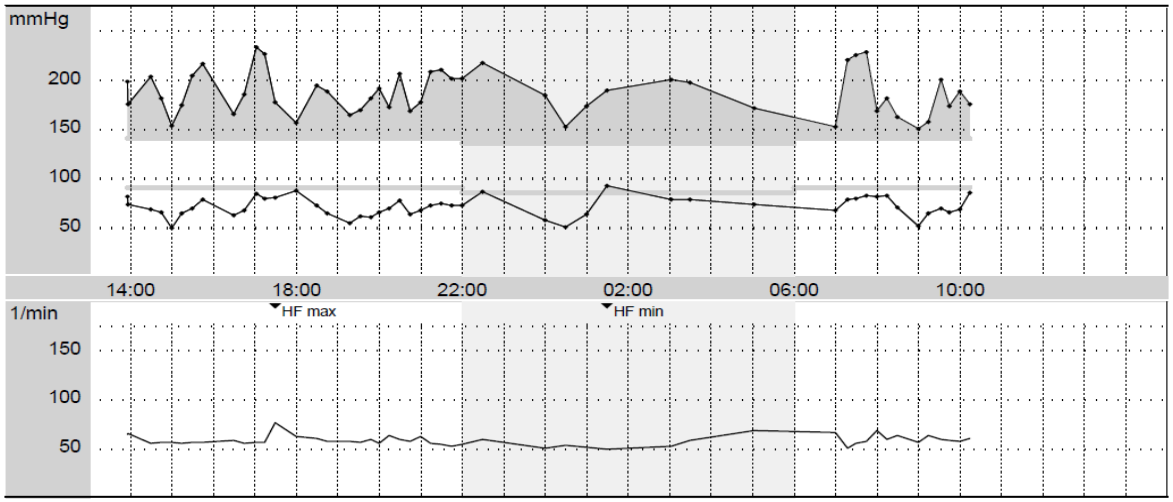
Auswertung	29.04.2011	Dauer	20:20 Std
Von	28.04.2011 (13:55)	Bis	29.04.2011 (10:15)

Messwert Tabelle

	Tag (06:00 - 22:00)	Nacht (22:00 - 06:00)	Gesamt	%-Abweichung
Blutdruck	185 / 71	189 / 75	186 / 72	2 / 5
Herzfrequenz	59	56	58	-6
Messungen	40	9	49	---

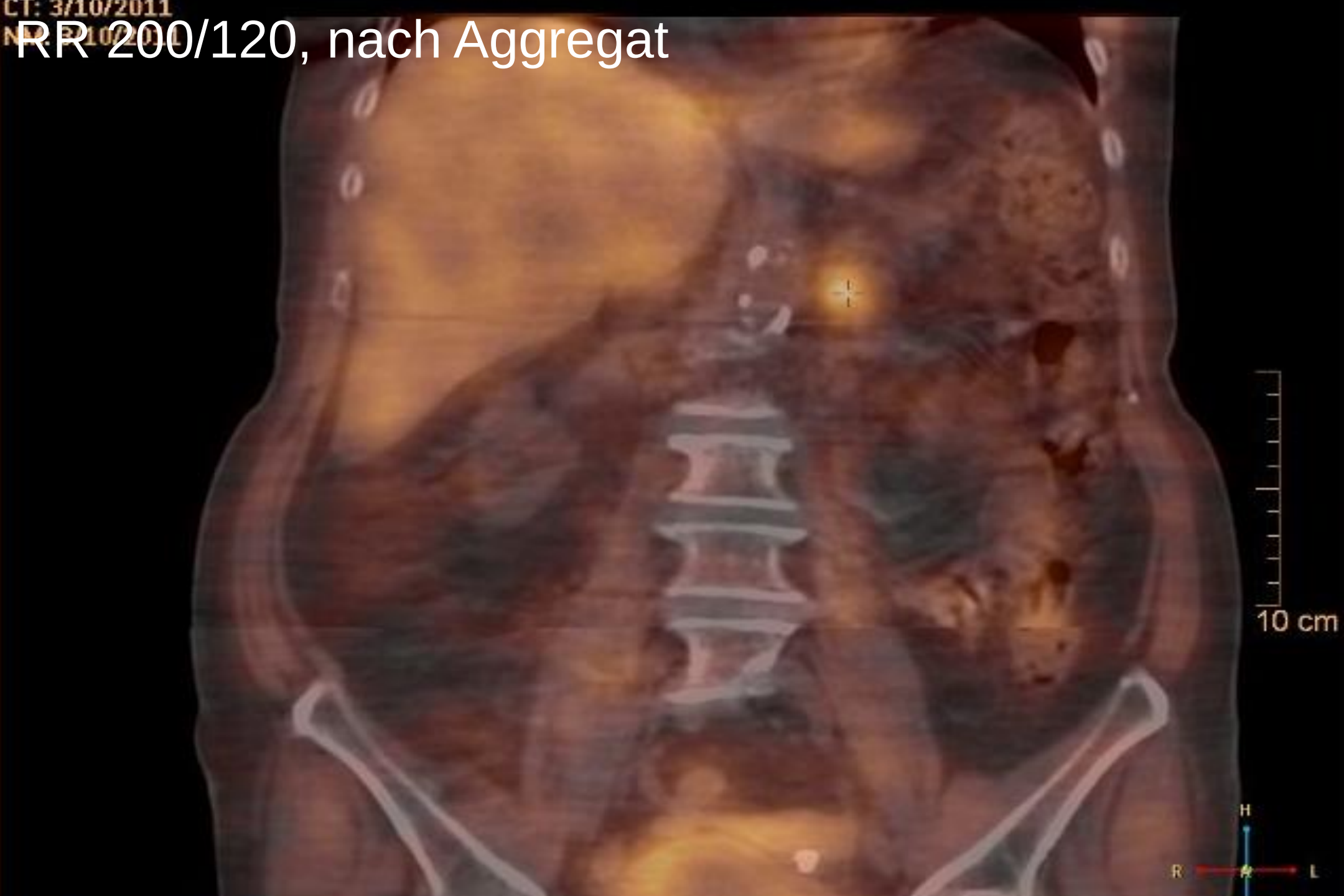
Grenzwert Tabelle

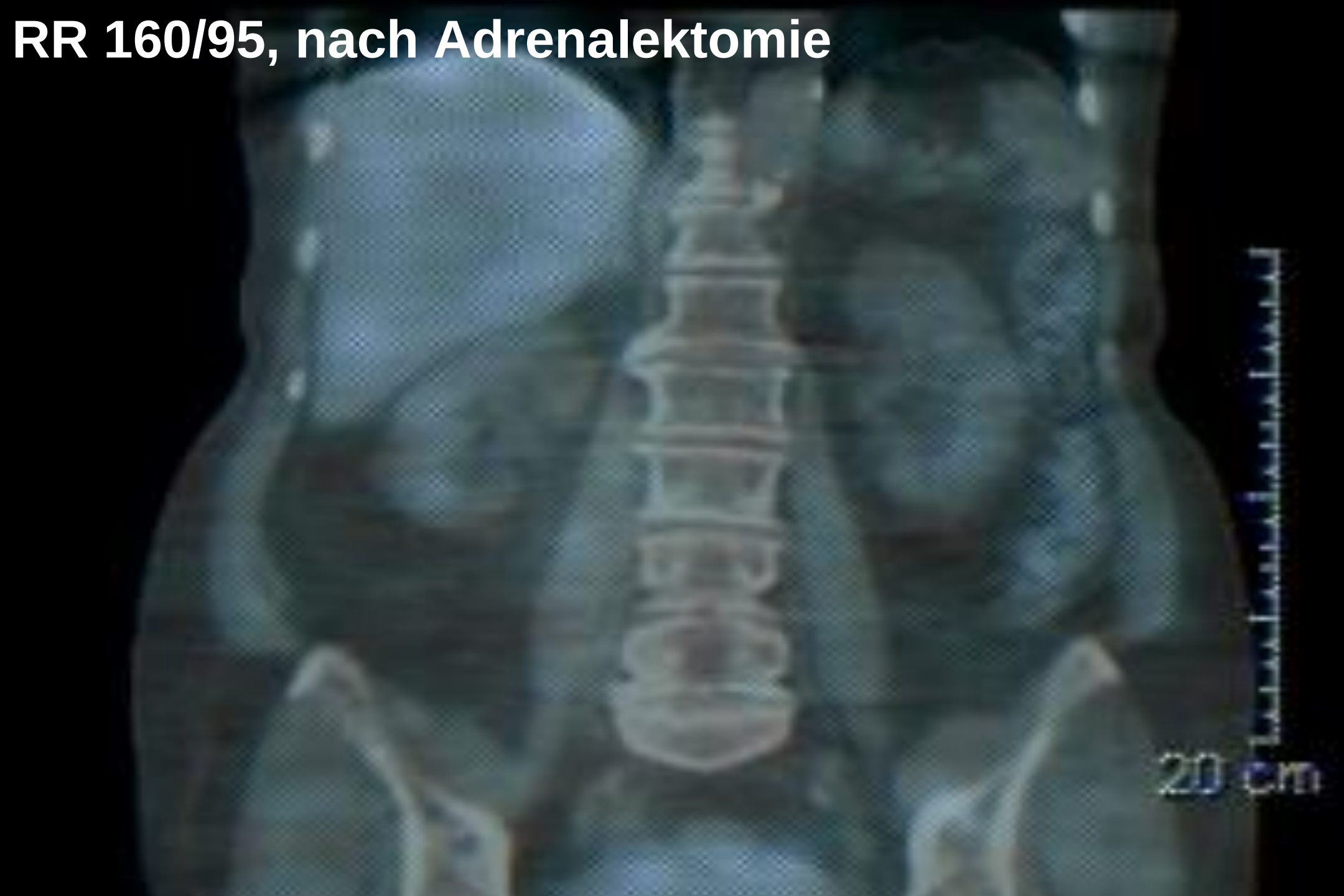
	Tag (140/90)					Nacht (135/85)					Gesamt	
	Min	Max	Mit	SD	%>GW	Min	Max	Mit	SD	%>GW	Mit	SD
Ps mmHg	150	233	185	23	100	152	217	189	19	100	186	22
Pd mmHg	49	87	71	9	---	50	92	75	13	22	72	10
Pm mmHg	83	133	109	12	---	84	129	113	14	---	110	12
PD mmHg	69	149	114	20	---	97	131	114	13	---	114	18
HF 1/min	50	76	59	5	---	49	68	56	6	---	58	5



20 mg Minoxidil
25 mg Aldactone
25 mg HCT
300 mg Aliskiren
320 mg Candesartan
20 mg Amlodipin
95 mg Metoprolol
8 mg Doxazosin

50 mg Citalopram


CT: 3/10/2011
RR 200/120, nach Aggregat
10 cm
H
R
A
L


RR 160/95, nach Adrenalektomie
20 cm

Nach Adrenalektomie

Gesamt-Auswertung 66 Messwerte

28.07.2011 09:38 – 29.07.2011 10:45

	Min	Mittelwert	Max	StdAbw
Sys	126	150,1	177	13,2
Dia	40	68,6	93	7,7
Puls	57	65,1	83	5,8
Systole > 140 mmHg		71,2 %		
Diastole > 90 mmHg		1,5 %		

Auswertung Tag 58 Messwer

07:00 – 21:59

	Min	Mittelwert	Max	StdAbw
Sys	126	151,4	177	13,4
Dia	40	69,3	93	7,9
Puls	57	65,4	83	6,0
Systole > 140 mmHg		75,9 %		
Diastole > 90 mmHg		1,7 %		

Tag-Nacht-Abweichung

Sys	7,0 %	Absenkung bei Nacht
Dia	8,0 %	Absenkung bei Nacht
Puls	4,1 %	Absenkung bei Nacht

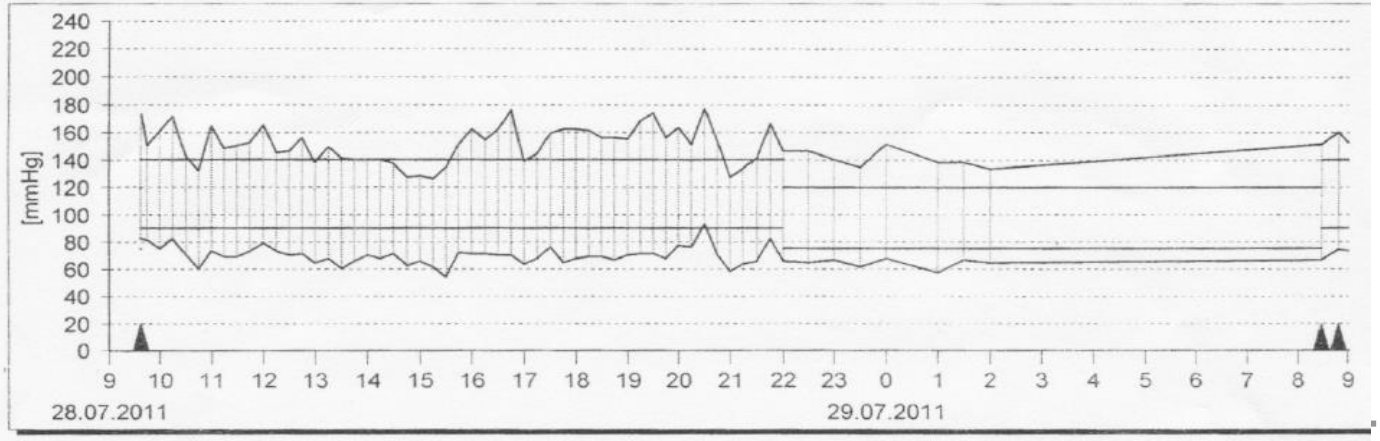
Auswertung Nacht 8 Messwe

22:00 – 06:59

	Min	Mittelwert	Max	StdAbw
Sys	133	140,8	151	6,3
Dia	57	63,8	67	3,3
Puls	58	62,8	68	3,0
Systole > 120 mmHg		100,0 %		
Diastole > 75 mmHg		0,0 %		

Profil

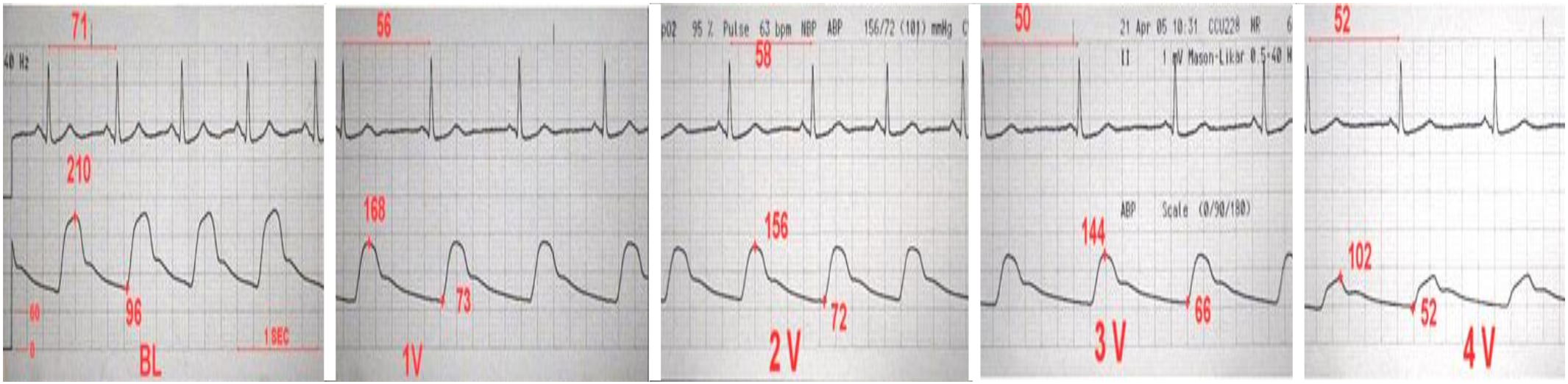
Sys/Dia



10 mg Minoxidil
25 mg Aldactone
12,5 mg HCT
150 mg Aliskiren
160 mg Candesartan
20 mg Amlodipin
95 mg Metoprolol
8 mg Doxazosin

Fallbericht Hämodialysepatientin, 38J., multiple Med. – Unverträglichkeiten, LvH, ABDM Tagesmittel 190/122

Intraoperativer Response



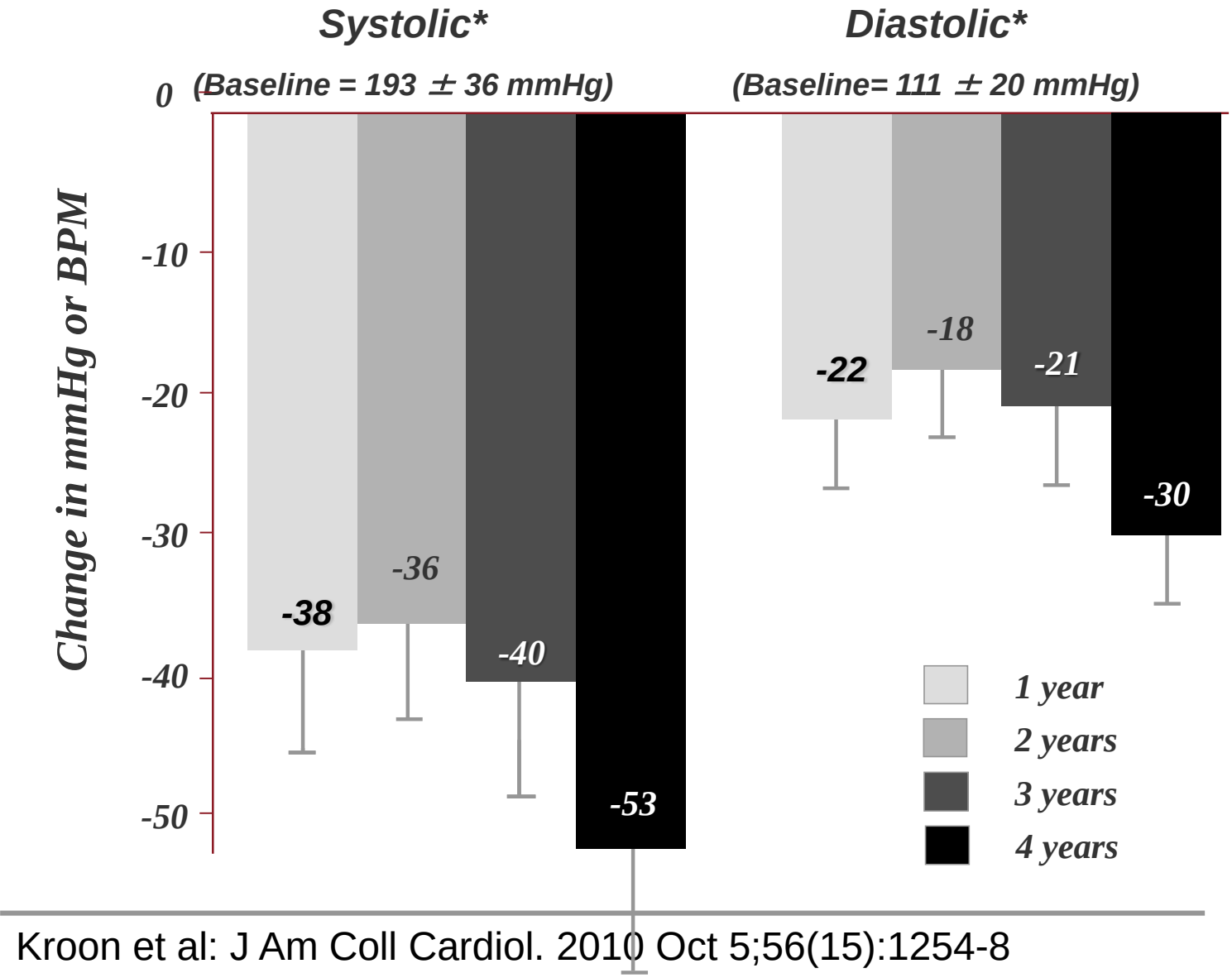
Fallbericht Hämodialysepatientin, 38J., multiple Med. – Unverträglichkeiten, LvH, ABDM Tagesmittel 190/122
Device Aktivierung Tag + 16

Patient Response Log

Log Time	Pathway	Width	Ampl.	Freq.	Dur/Int	Compliance	Battery Life	Imp.	Elapsed Time	BP	HR
2:11:54 PM	None	--- ---	--- ---	---	---/---	--- ---	-	942 4880	00:00	228/128	70
Notes: Therapy off Start programming											
2:15:28 PM	Right	140.625 ---	5.6 ---	60	---/---	Pass ---	33.1	788 4880	00:28	214/116	60
2:16:34 PM	Right	140.625 ---	5.6 ---	60	---/---	Pass ---	33.1	788 4880	01:34	199/117	59
2:18:21 PM	Right	140.625 ---	5.8 ---	60	---/---	Pass ---	31.7	777 4880	01:38	192/117	59
Notes: CNAP Cuff											
2:18:29 PM	Right	140.625 ---	5.8 ---	60	---/---	Pass ---	31.7	777 4880	01:45	187/117	59
Notes: CNAP Cuff											
2:19:36 PM	Right	140.625 ---	5.8 ---	60	---/---	Pass ---	32.2	777 4880	02:51	175/117	61

0,9 mg Moxonidin
10 mg Ramipril
25 mg HCT
20 mg Lercanidipin
5 mg Bisoprolol
150 mg Ebrantil
500 mg Furosemid

4-Jahres Ergebnisse Rheo Debut Studie



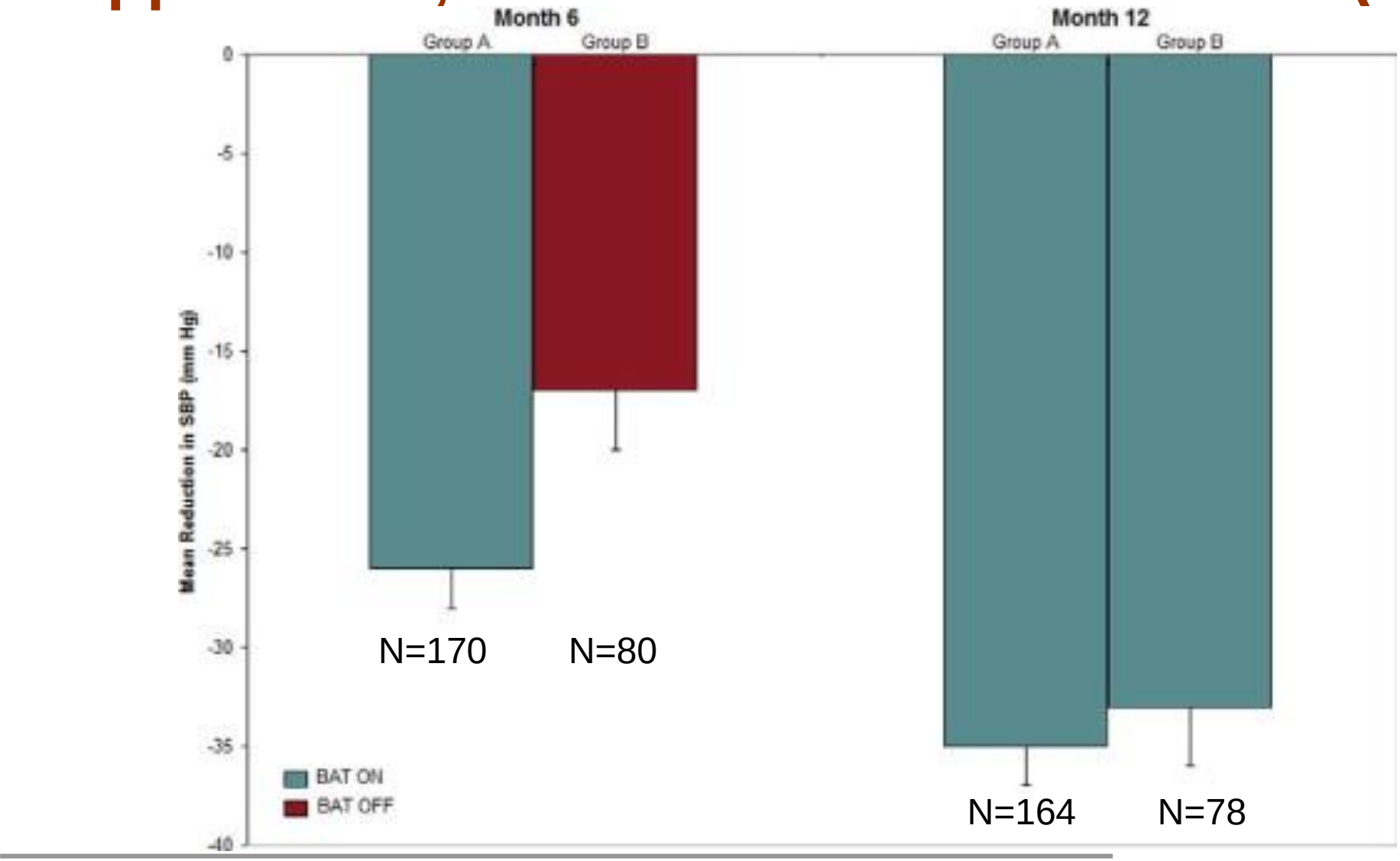
Anti-hypertensive Medications	
Baseline (n=45)	5.0 ± 1.3
1 year	-0.2 ± 0.3
2 years (n=17)	-0.7 ± 0.4
3 years	-0.8 ± 0.4
4 years**	-1.6 ± 0.5

* P < 0.01

** p = 0.02

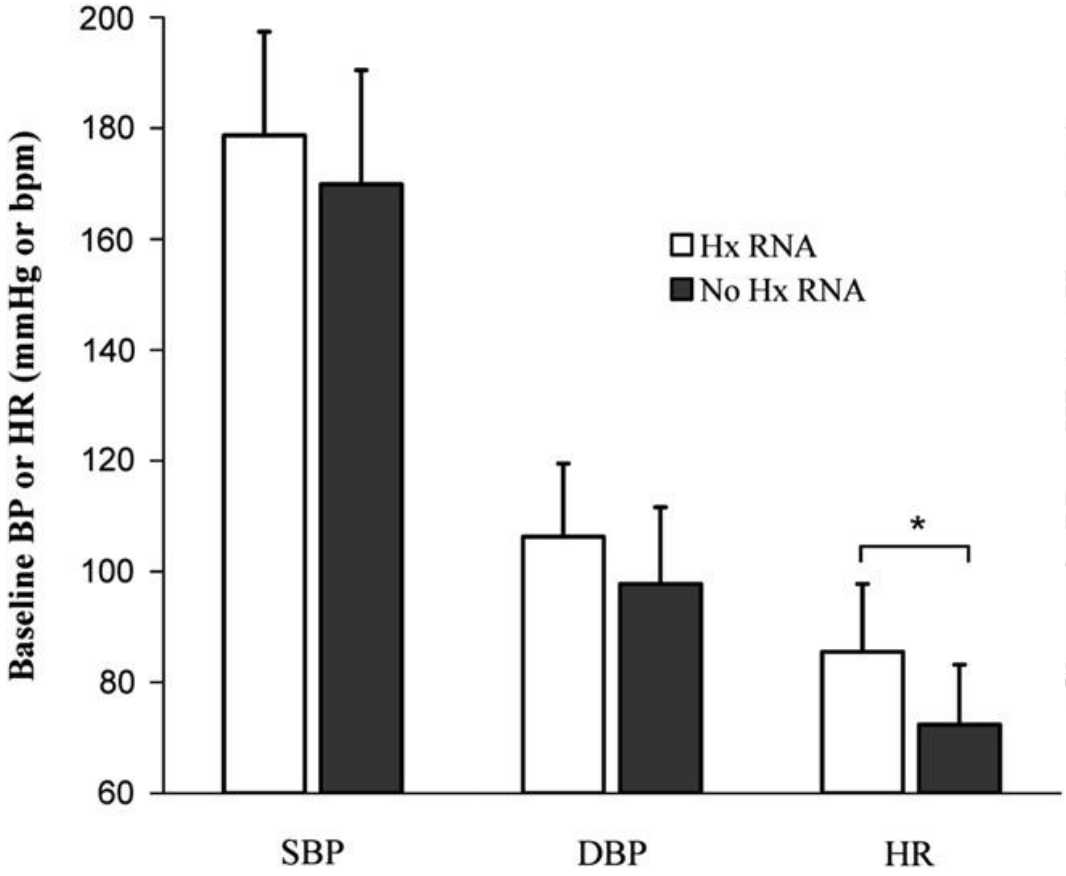
Kroon et al: J Am Coll Cardiol. 2010 Oct 5;56(15):1254-8

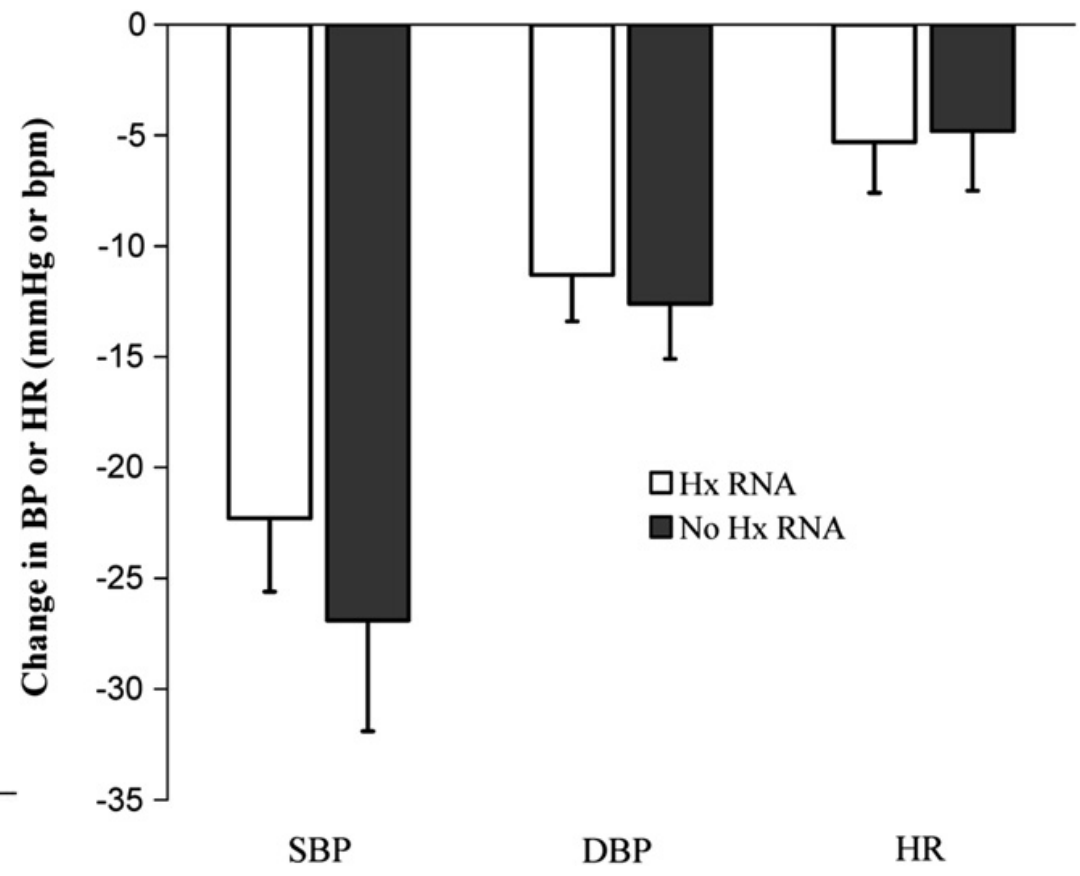
Doppelblinde, Placebo-kontrollierte Studie (n=265)



Bisognano et al: J Am Coll Cardiol. 59, (5), 31 Jan 2012, P.541

Barostim *neo* trial





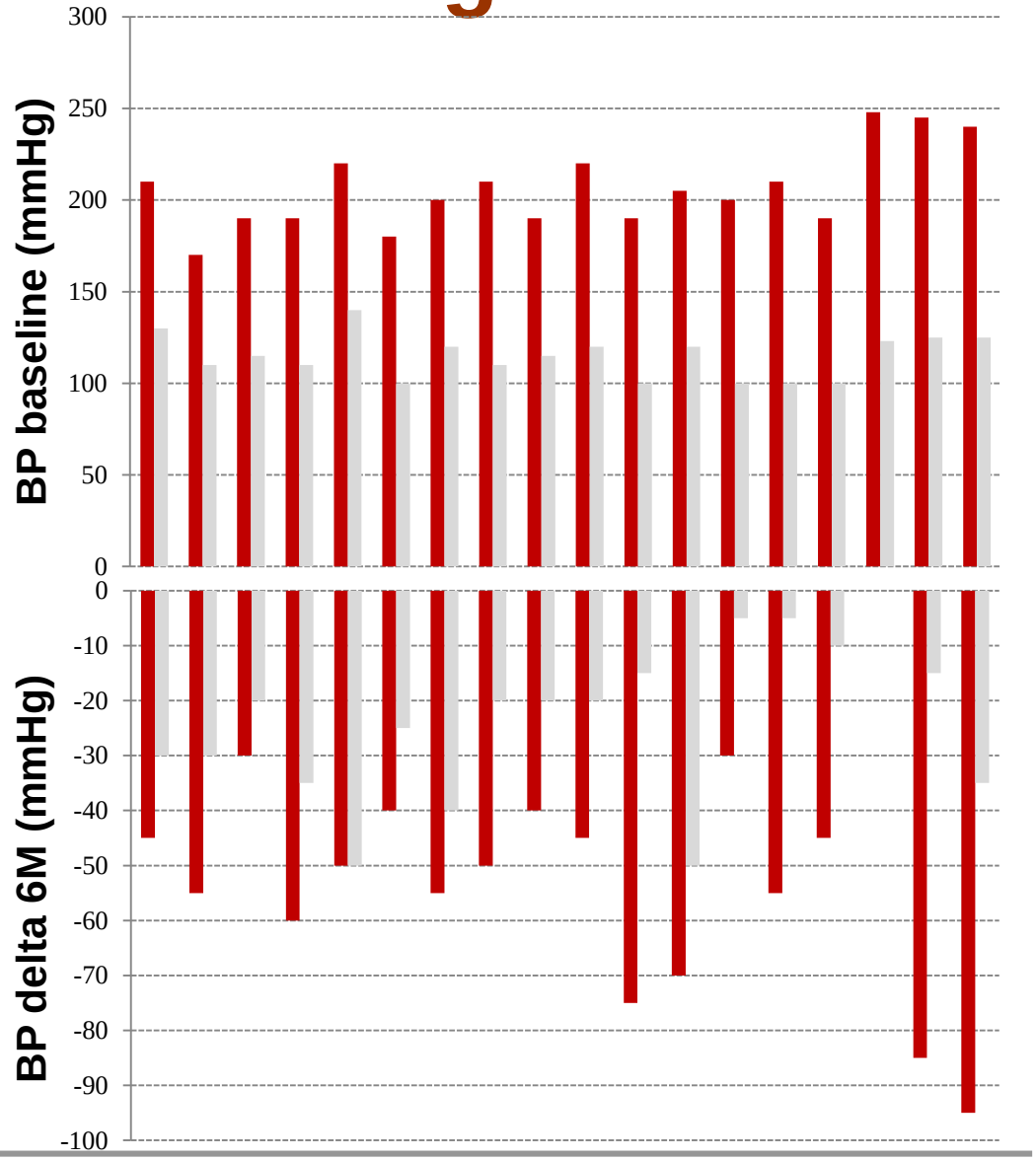
Hoppe, Beige et al.: JASH (2012) 1–7

Alle klinischen Studien BAT

Studientitel	Design	n	Endpunkt	Senkung (mmHg ± SD)
Rheos Pivotal	Doppel-Blind, randomisiert, Sham-kontrolliert	265	BPtrue	35/15; 10% *nonresponder*
Rheos Debut	Offen, prospektiv	45	BPtrue	21/12
XR-1	Offen, prospektiv	30	BPtrue	26/12
XR-1 und Rheos	Offen, prospektiv, Einzelzentrum	16	BPtrue	52±17 / 26±14

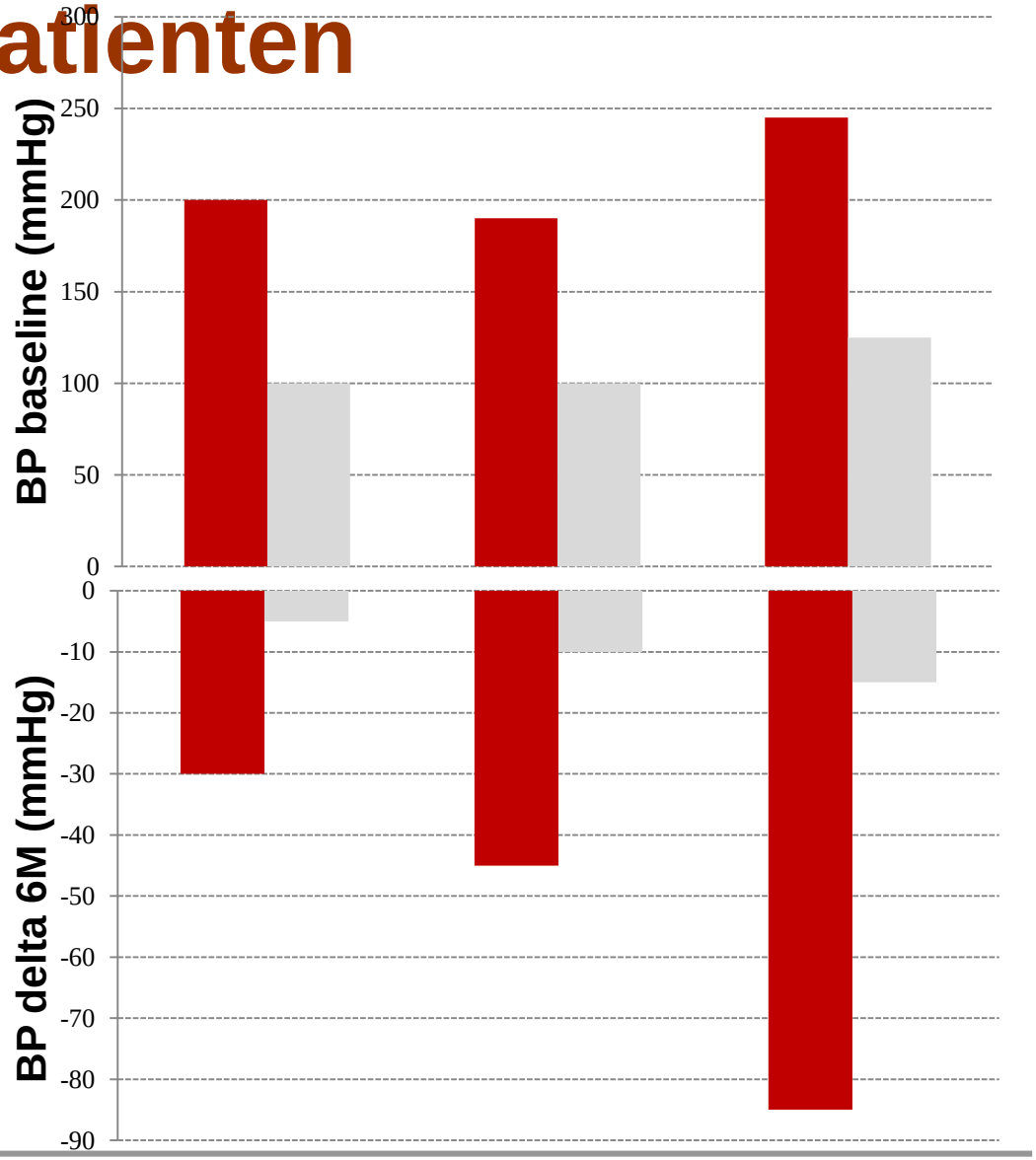
Beige et al.: Nieren- und Hochdruckkrankheiten, Nov. 2012; 41/11, 464-71

Leipziger Erfahrung Hochdruckschrittmacher



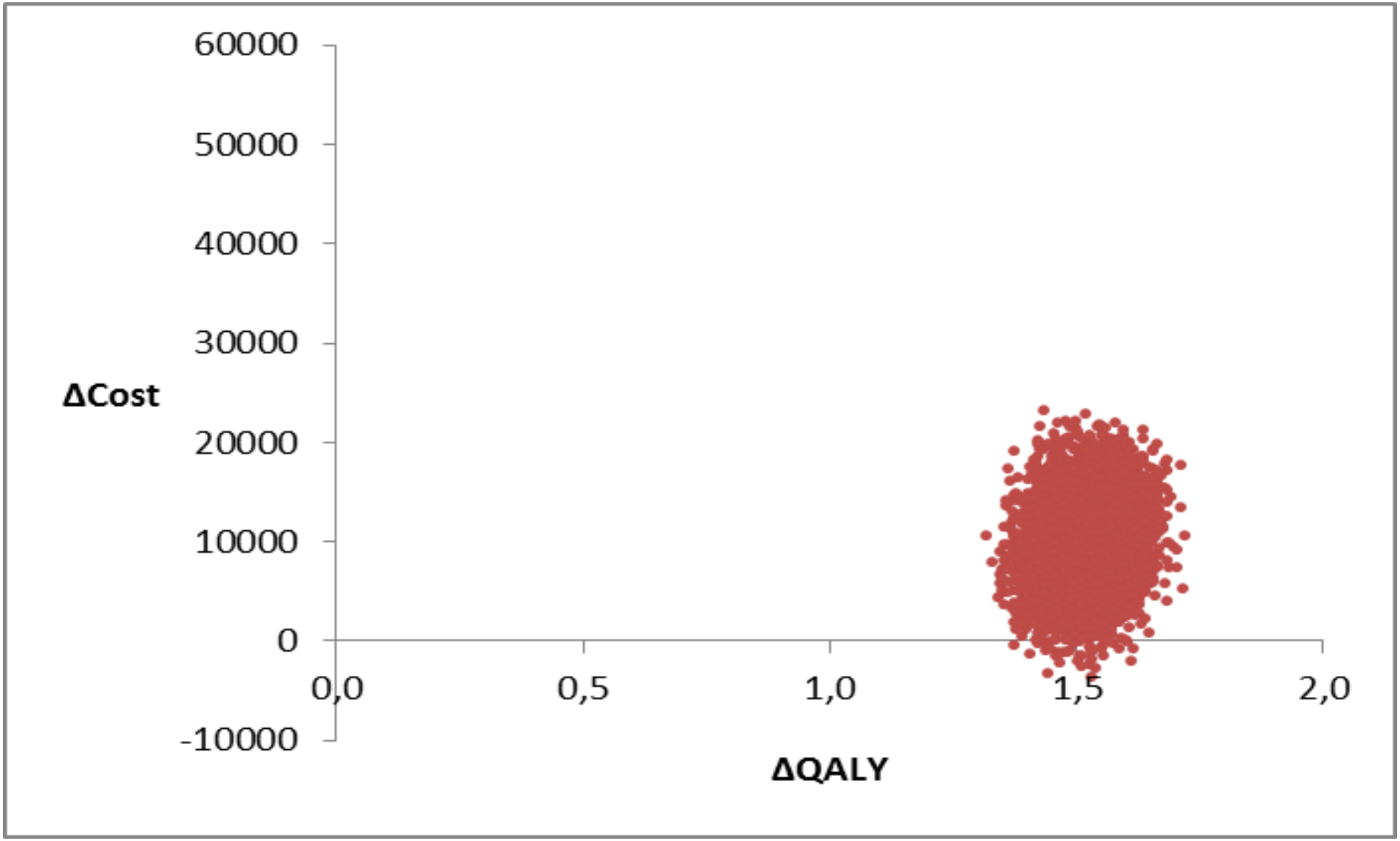
Beige et al.: Nieren- und Hochdruckkrankheiten, Nov. 2012; 41/11, 464-71

Leipziger Erfahrung Hochdruckschrittmacher Dialysepatienten



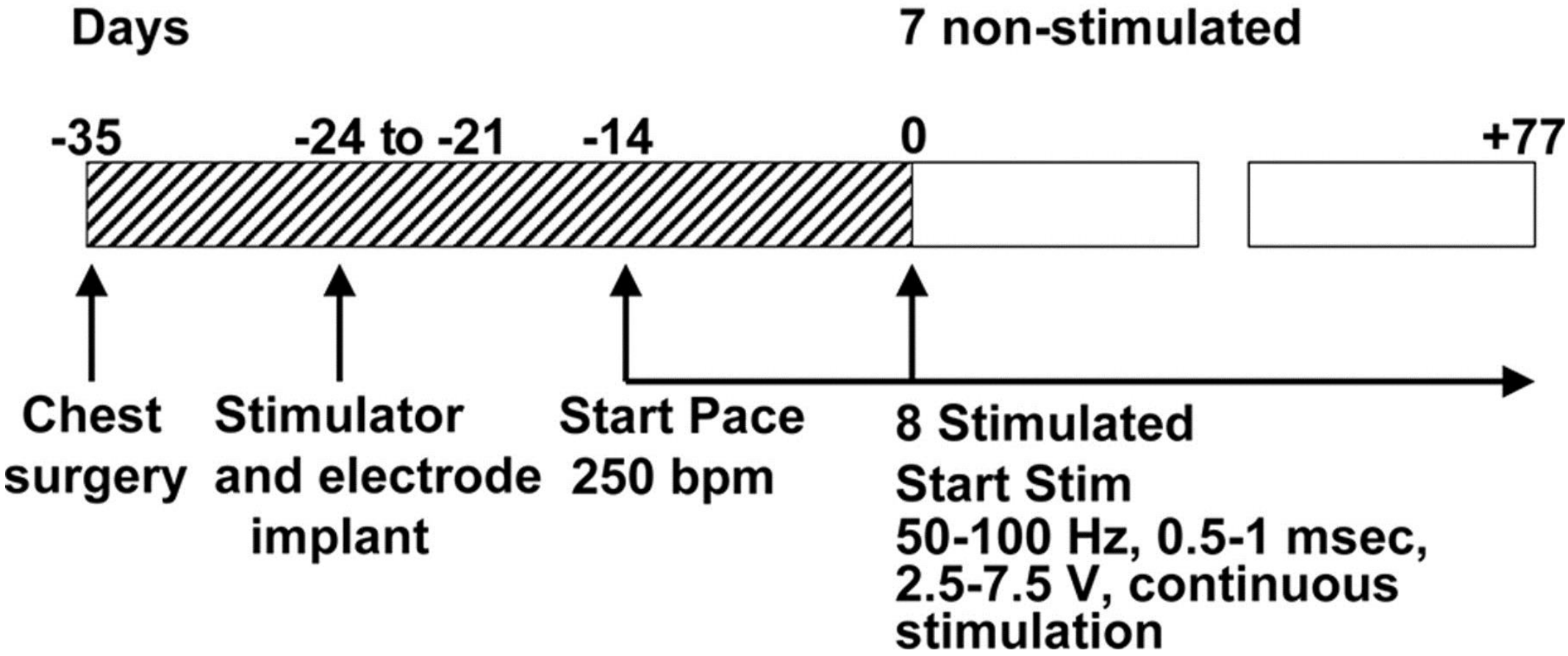
Beige et al.: Nieren- und Hochdruckkrankheiten, Nov. 2012; 41/11, 464-71

BAT Kosten pro QUALY (Registerdaten)



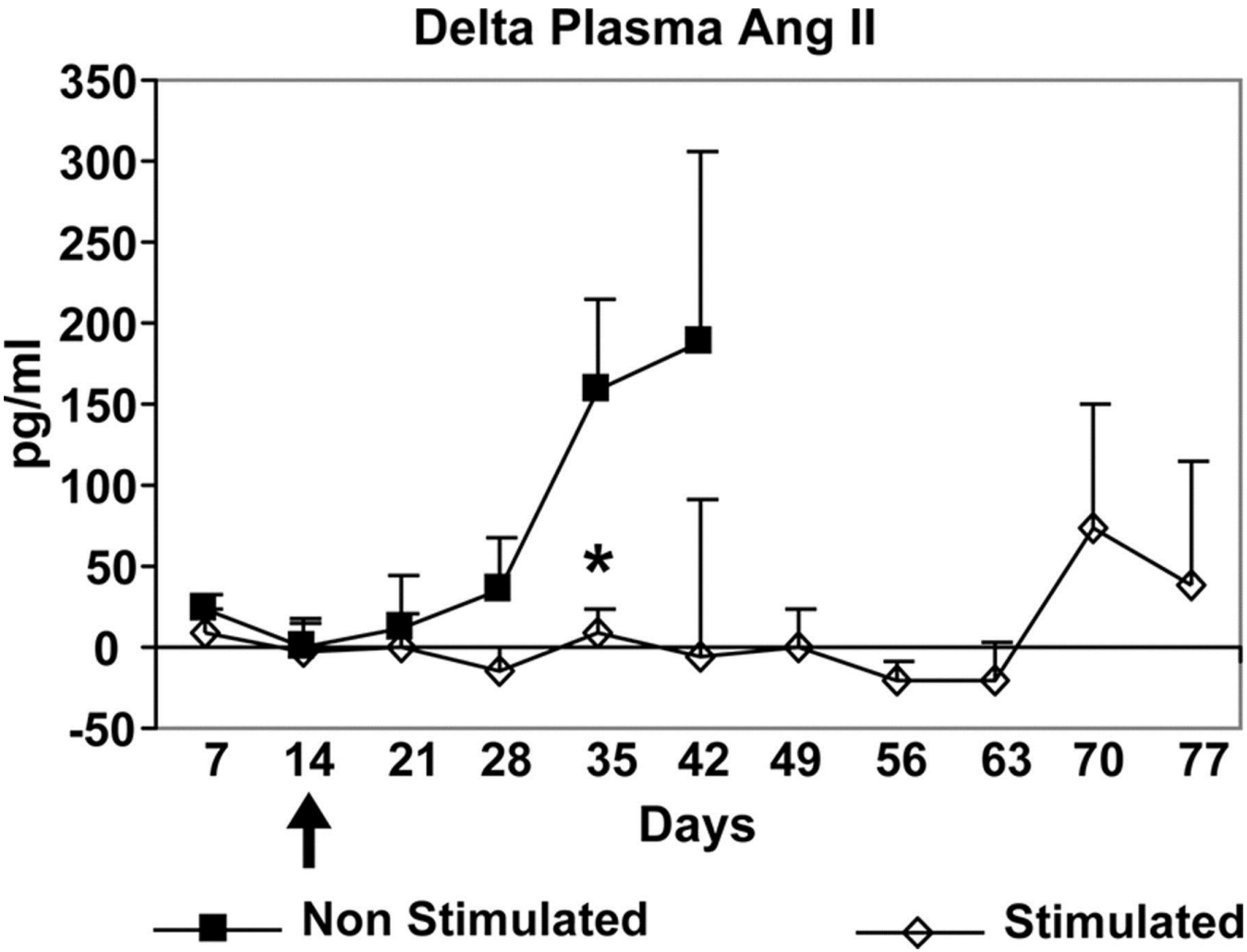
Borisenko, Beige et al.: JASH, 2013

Chronic Baroreceptor Activation Enhances Survival in Dogs With Pacing-Induced Heart Failure



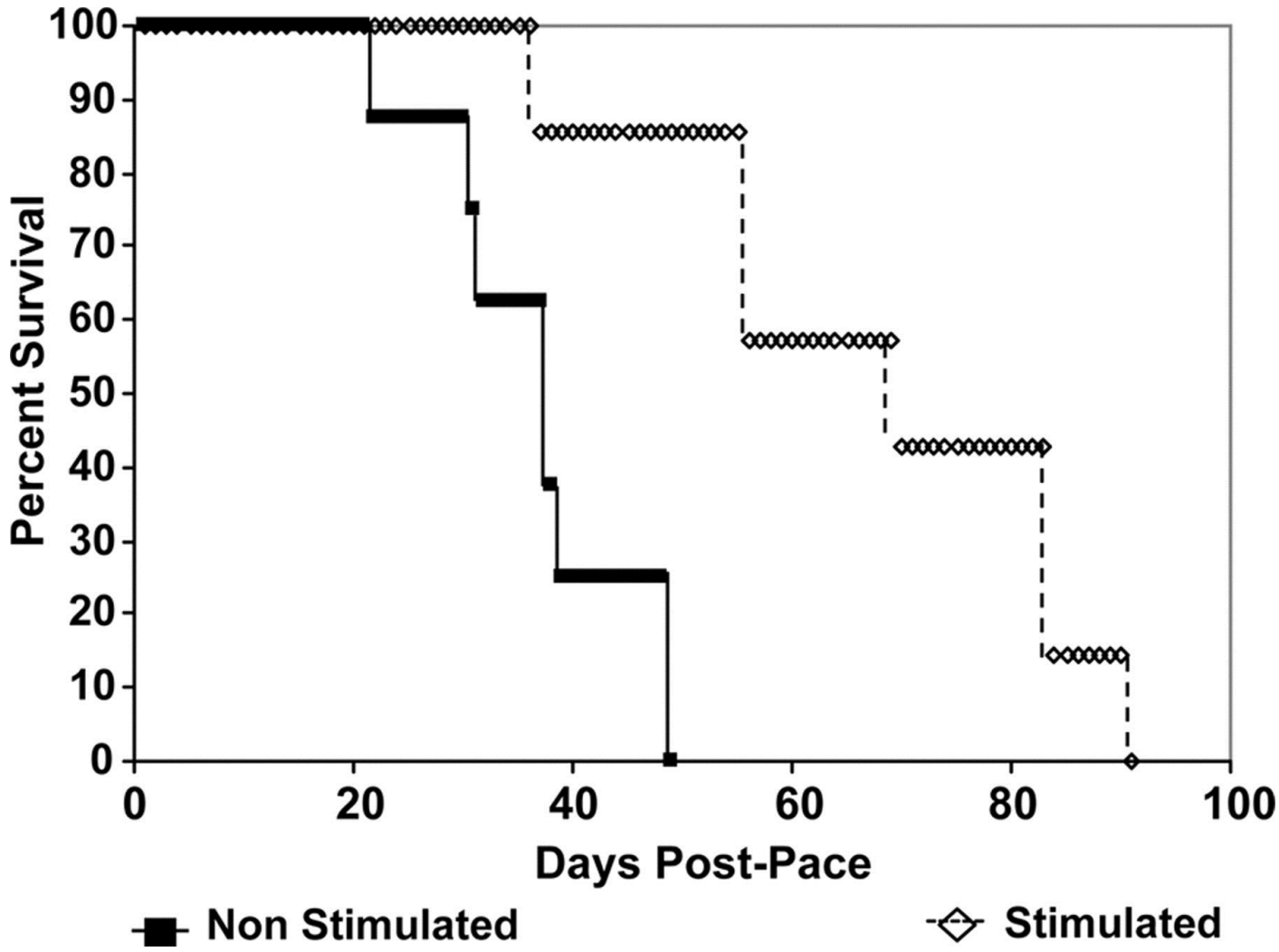
Zucker, Rossing A et al.: Hypertension. 2007 Nov;50(5):904-10

Chronic Baroreceptor Activation Enhances Survival in Dogs With Pacing-Induced Heart Failure



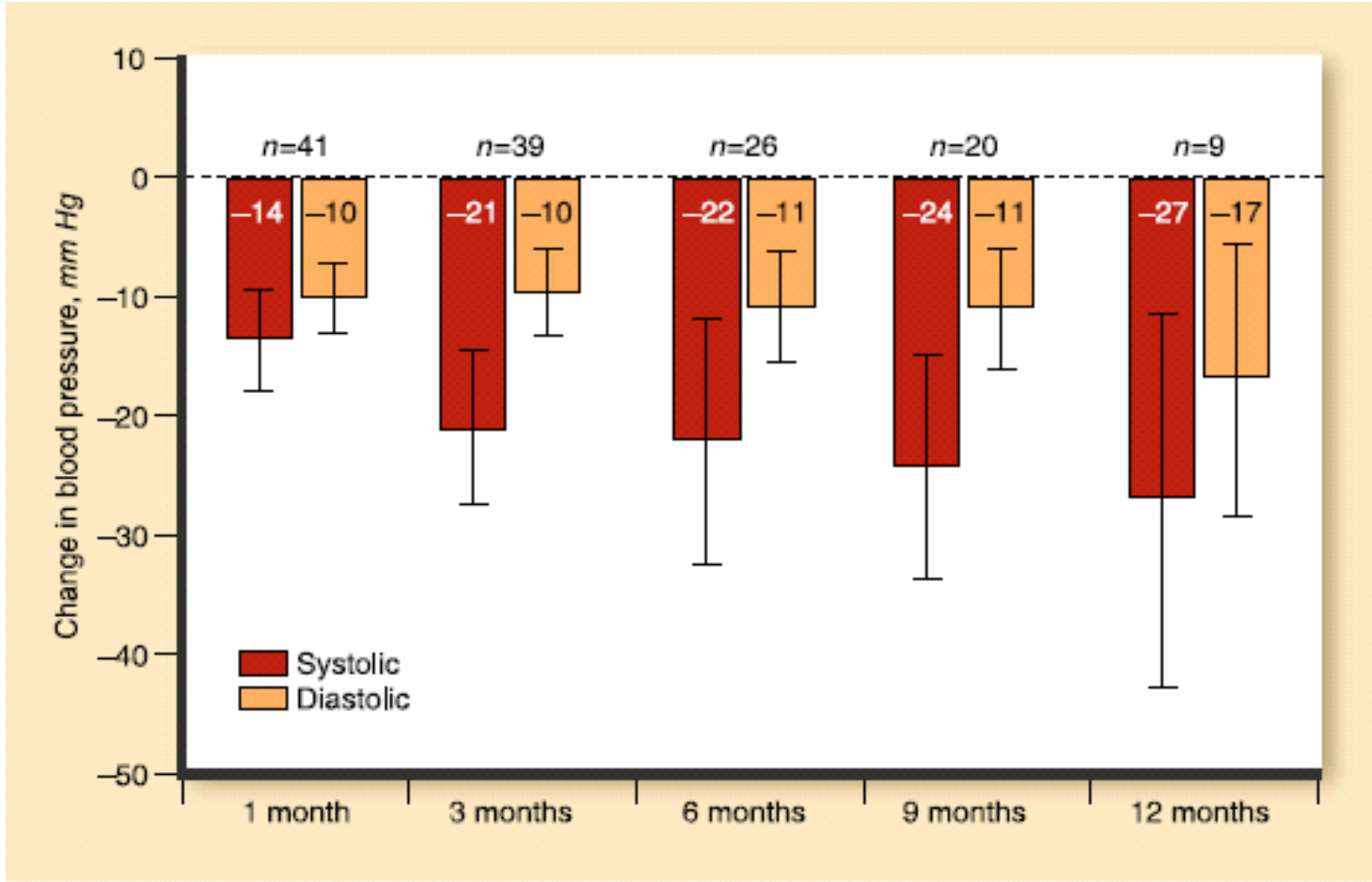
Zucker, Rossing A et al.: Hypertension. 2007 Nov;50(5):904-10

Chronic Baroreceptor Activation Enhances Survival in Dogs With Pacing-Induced Heart Failure

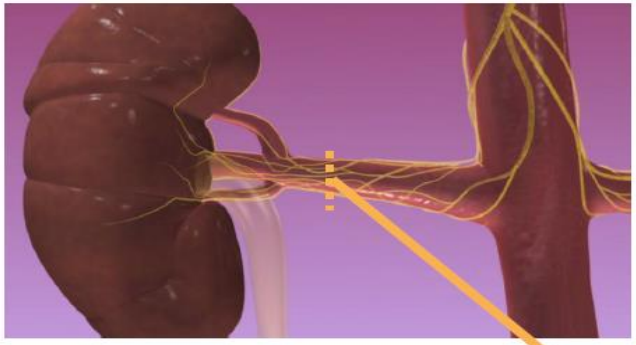


Zucker, Rossing A et al.: Hypertension. 2007 Nov;50(5):904-10

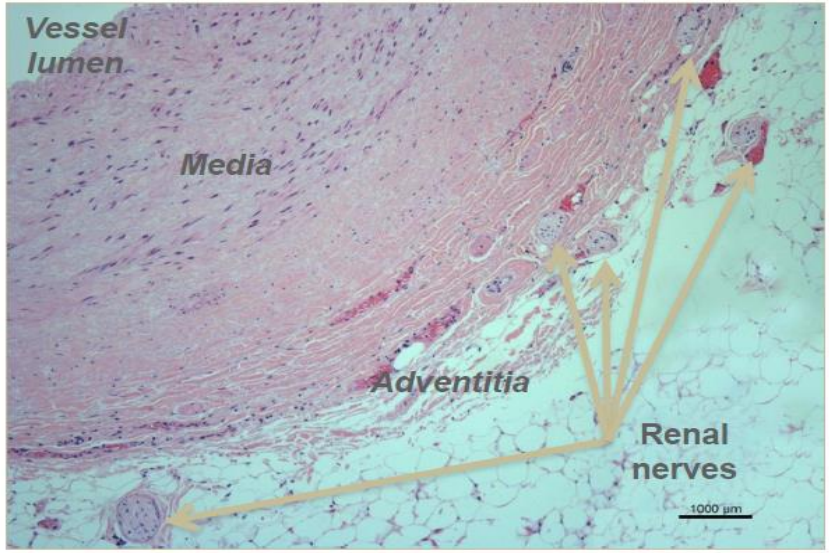
Renale Denervation (Simplicity 1)



Krum et al. Lancet. 2009 Apr 11;373(9671):1275-81.

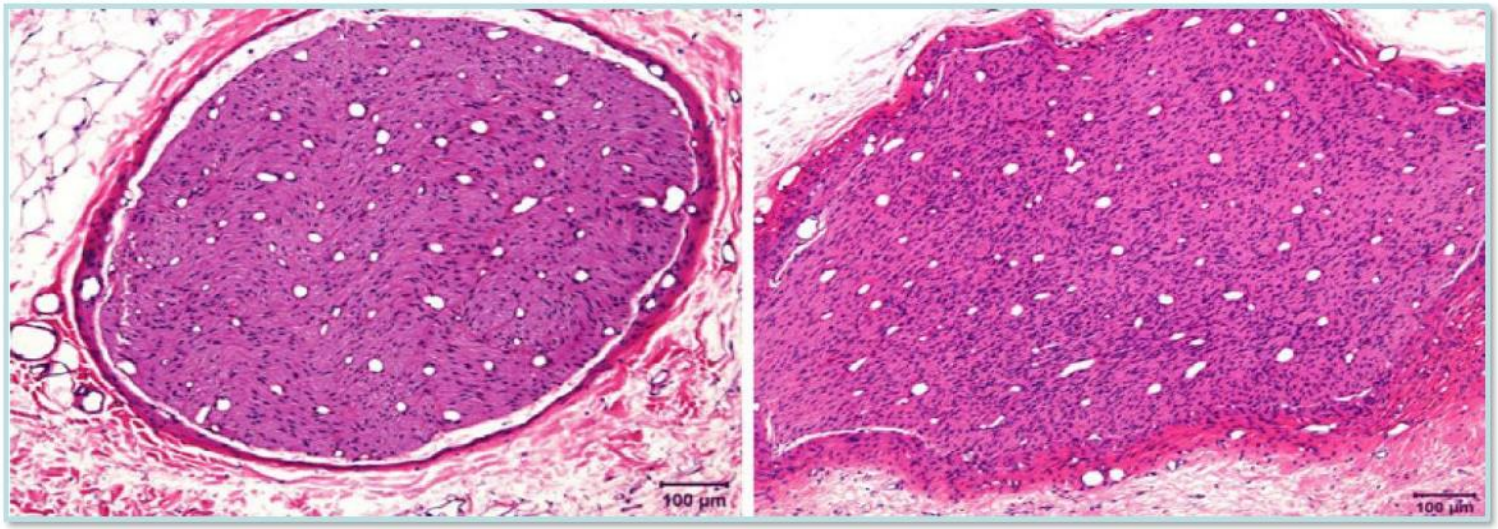


- Arise from T10-L2
- Follow the renal artery to the kidney
- Primarily lie within the adventitia
- The only location that renal efferent and afferent nerves travel together

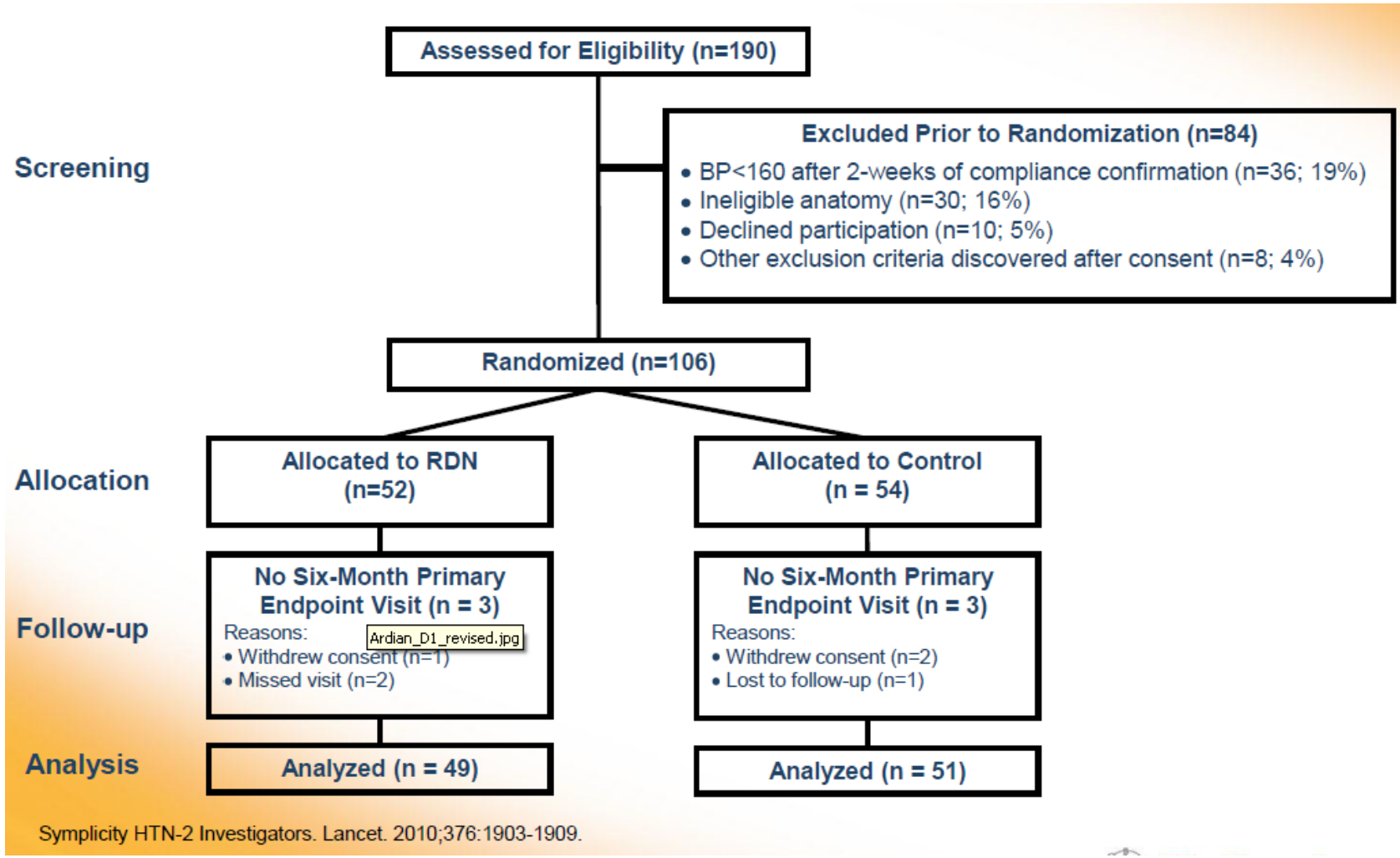


Nerv vor renaler Denervierung

Nerv nach renaler Denervierung



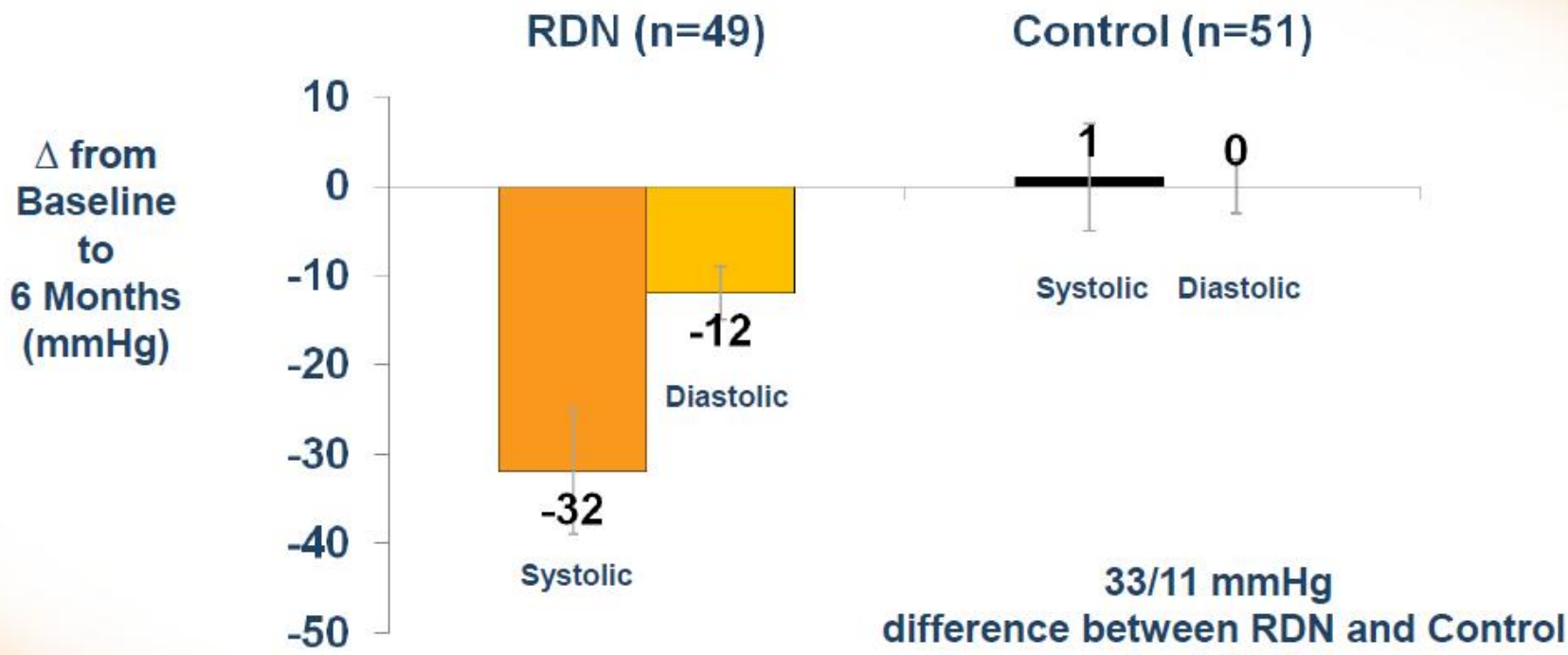
Renale Denervation (Simplicity 2)



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

Catheter-based Renal Sympathetic Denervation for resistant Hypertension Simplicity 2

Baseline: 178/97mmHg, 5.2 med.

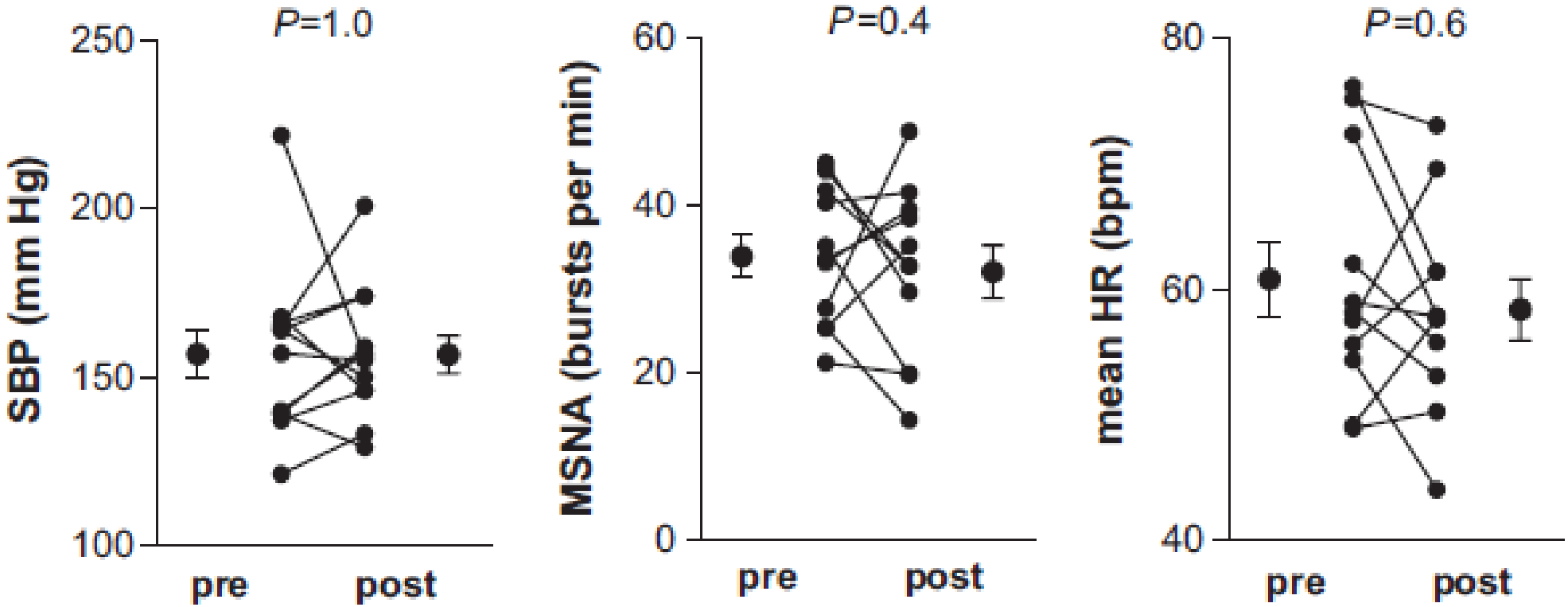


- 84% of RDN patients had ≥ 10 mmHg reduction in SBP
- 10% of RDN patients had no reduction in SBP

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

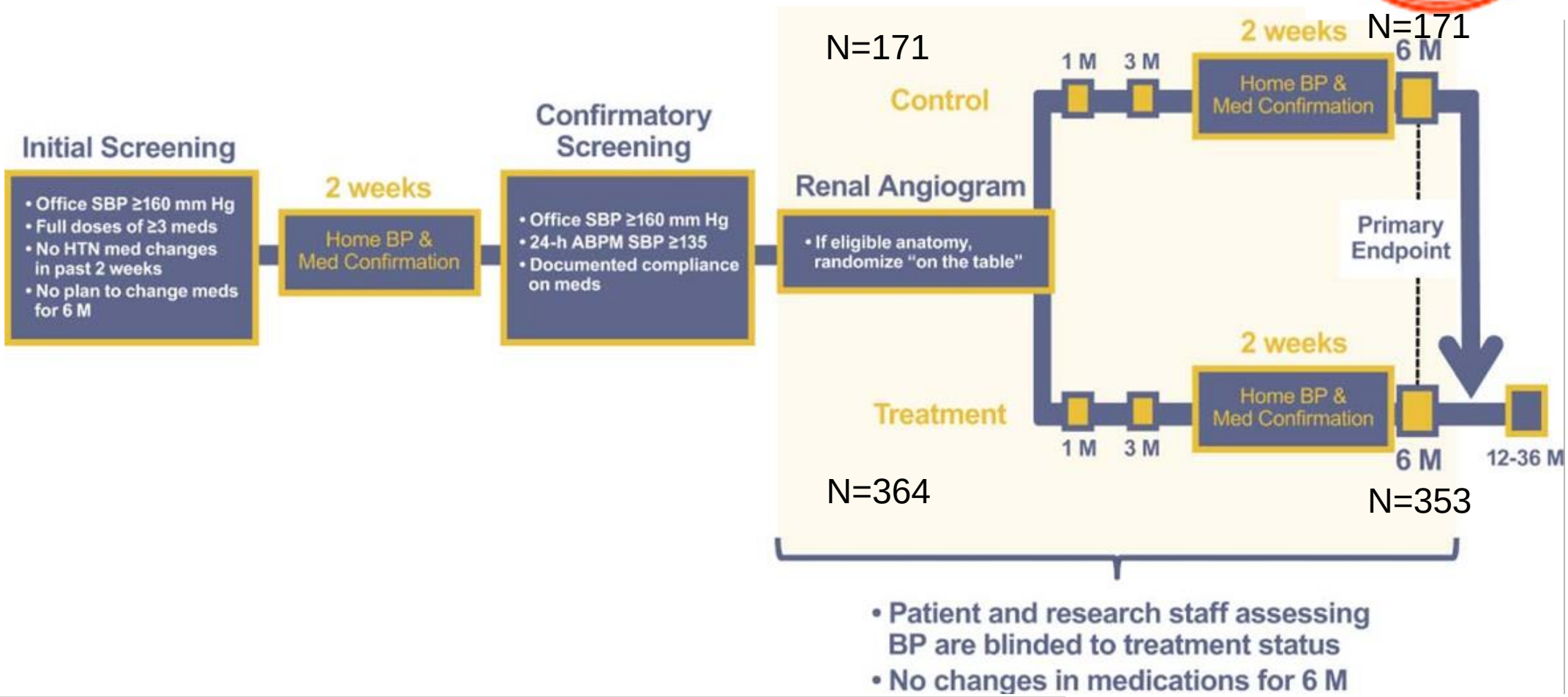
RNA and MSNA in Difficult-to-Control Hypertensive Patients

Sys BP, MSNA and HR before and after RND



Brinkmann, Heusser, Tank et al. Hypertension. 2012;60:00-00.

A Controlled Trial of Renal Denervation for Resistant Hypertension (HTN-3)



Bhat, Bakris et. al. N Engl J Med 2014; 370:1393-1401
Clin. Cardiol. 2012.

HTN-3 Population

Characteristic	Renal-Denervation Group (N=364)	Sham-Procedure Group (N=171)
Age — yr	57.9±10.4	56.2±11.2
Male sex — no. (%)	215 (59.1)	110 (64.3)
Body-mass index†	34.2±6.5	33.9±6.4
Race — no./total no. (%)‡		
Black	90/363 (24.8)	50/171 (29.2)
White	265/363 (73.0)	119/171 (69.6)
Asian	2/363 (0.6)	0/171
Other	6/363 (1.7)	2/171 (1.2)
Medical history — no. (%)		
Renal insufficiency§	34 (9.3)	17 (9.9)
Renal-artery stenosis	5 (1.4)	4 (2.3)
Obstructive sleep apnea	94 (25.8)	54 (31.6)
Stroke	29 (8.0)	19 (11.1)
Transient ischemic attack	28 (7.7)	13 (7.6)
Peripheral artery disease	19 (5.2)	5 (2.9)
Cardiac disease		
Coronary artery disease	101 (27.7)	43 (25.1)
Myocardial infarction	32 (8.8)	11 (6.4)
Diabetes		
Type 1	0	0
Type 2	171 (47.0)	70 (40.9)

Bhat, Bakris et. al. N Engl J Med 2014; 370:1393-1401

HTN-3 Safety

End point	Renal-Denervation Group	Sham-Procedure Group	Percentage-Point Difference (95% CI)
	no. of patients/total no. (%)		
Major adverse event†	5/361 (1.4)	1/171 (0.6)	0.8 (–0.9 to 2.5)
Composite safety end point at 6 mo‡	14/354 (4.0)	10/171 (5.8)	–1.9 (–6.0 to 2.2)
Specific event within 6 mo			
Death	2/352 (0.6)	1/171 (0.6)	0.0 (–1.4 to 1.4)
Myocardial infarction	6/352 (1.7)	3/171 (1.8)	0.0 (–2.4 to 2.3)
New-onset end-stage renal disease	0/352	0/171	—
Increase in serum creatinine of >50% from baseline	5/352 (1.4)	1/171 (0.6)	0.8 (–0.8 to 2.5)
Embolic event resulting in end-organ damage	1/352 (0.3)	0/171	0.3 (–0.3 to 0.8)
Renal-artery intervention	0/352	0/171	—
Vascular complication requiring treatment	1/352 (0.3)	0/171	0.3 (–0.3 to 0.8)
Hypertensive crisis or emergency	9/352 (2.6)	9/171 (5.3)	–2.7 (–6.4 to 1.0)
Stroke	4/352 (1.1)	2/171 (1.2)	0.0 (–2.0 to 1.9)
Hospitalization for new-onset heart failure	9/352 (2.6)	3/171 (1.8)	0.8 (–1.8 to 3.4)
Hospitalization for atrial fibrillation	5/352 (1.4)	1/171 (0.6)	0.8 (–0.8 to 2.5)
New renal-artery stenosis of >70%	1/332 (0.3)	0/165	0.3 (–0.3 to 0.9)

Bhat, Bakris et. al. N Engl J Med 2014; 370:1393-1401

HTN-3 Safety

End point	Renal-Denervation Group	Sham-Procedure Group	Percentage-Point Difference (95% CI)
	no. of patients/total no. (%)		
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Myocardial infarction	6/352 (1.7)	3/171 (1.8)	0.0 (–2.4 to 2.3)
New-onset end-stage renal disease	0/352	0/171	—
Increase in serum creatinine of >50% from baseline	5/352 (1.4)	1/171 (0.6)	0.8 (–0.8 to 2.5)
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Renal-artery intervention	0/352	0/171	—
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Hypertensive crisis or emergency	9/352 (2.6)	9/171 (5.3)	–2.7 (–6.4 to 1.0)
Stroke	4/352 (1.1)	2/171 (1.2)	0.0 (–2.0 to 1.9)
Hospitalization for new-onset heart failure	9/352 (2.6)	3/171 (1.8)	0.8 (–1.8 to 3.4)
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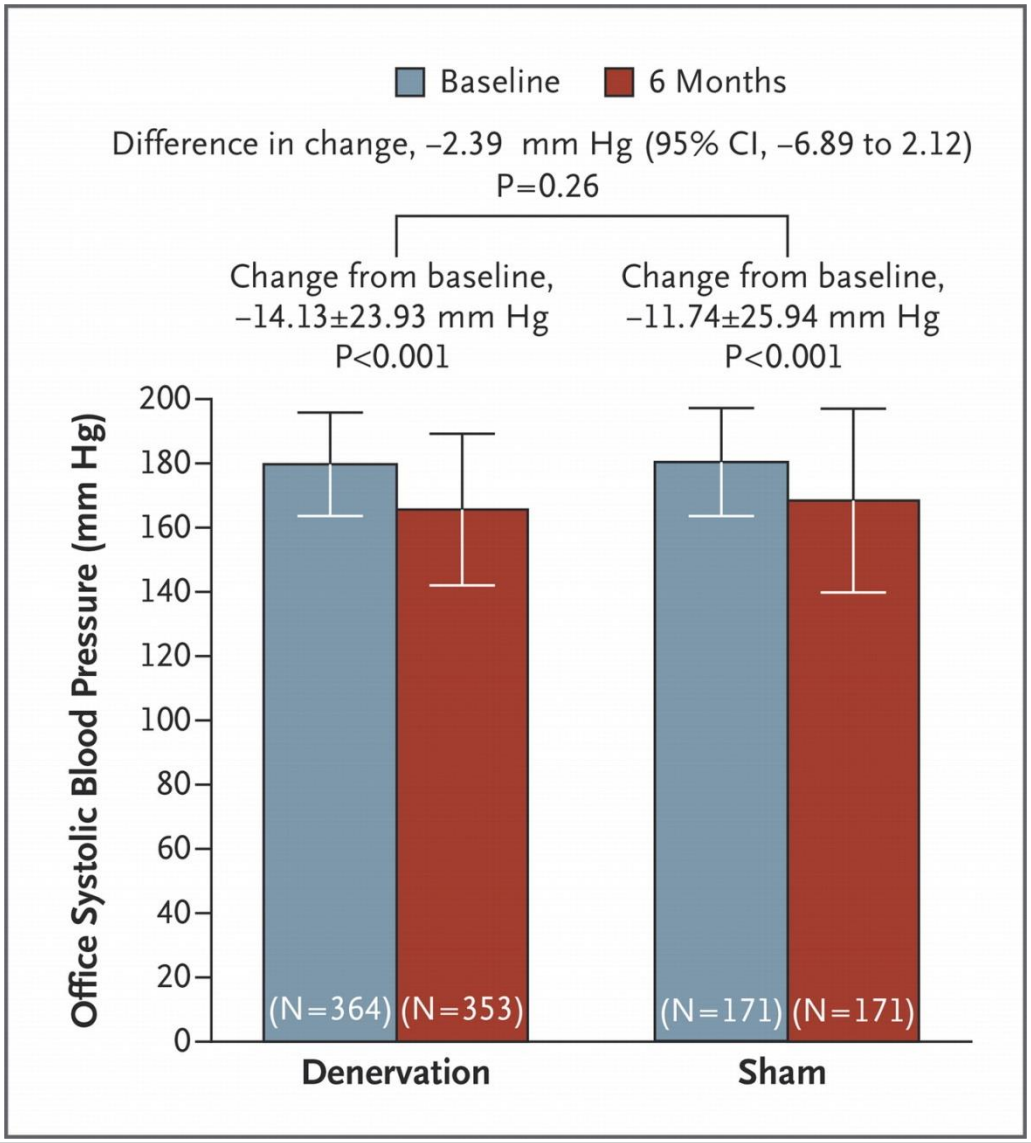
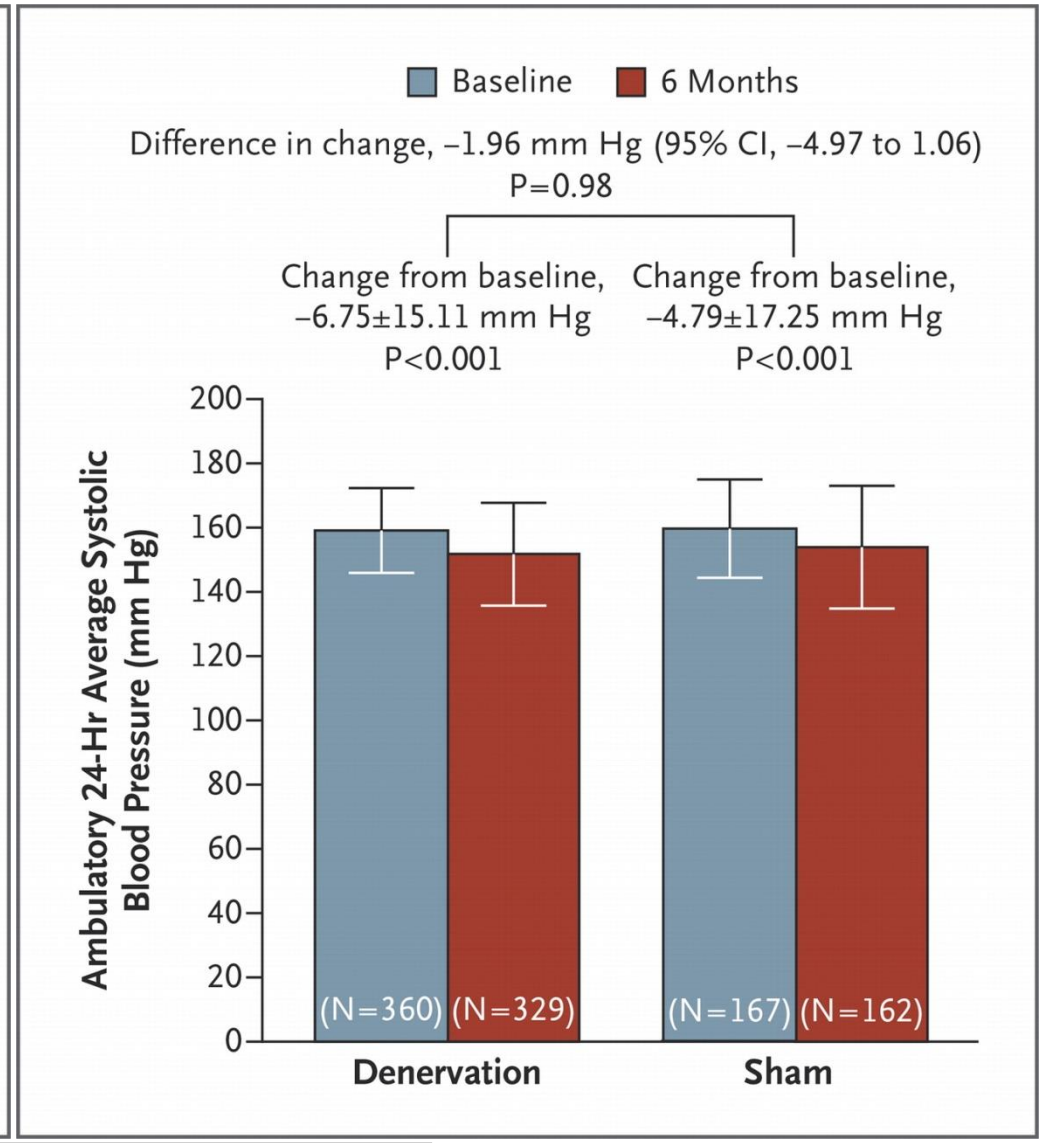
Bhat, Bakris et. al. N Engl J Med 2014; 370:1393-1401

HTN-3 Results





Bhat, Bakris et. al. N Engl J Med 2014; 370:1393-1401

	RND	Sham	
Baseline Office	N=364	N=171	
SBP	179.7 ± 16.1	180.2 ± 16.8	0.78
DBP	96.5 ± 16.6	98.9 ± 15.8	0.12
Baseline Ambulatory	N=360	N=167	
SBP	159.1 ± 13.2	159.5 ± 15.3	0.78
DBP	88.0 ± 14.0	90.9 ± 14.4	0.03
Baseline Home	N=364	N=171	
SBP	169.0 ± 15.9	169.1 ± 16.3	0.94
DBP	89.6 ± 15.9	92.9 ± 16.4	0.03
6 Months - Office	N=353	N=171	
SBP	165.6 ± 23.7	168.4 ± 28.6	0.26
DBP	89.5 ± 16.9	94.1 ± 17.7	0.01
DBP change	-6.6 ± 11.9	-4.6 ± 13.6	0.12
6 Months – Ambulatory	N=329	N=162	
SBP	151.8 ± 16.0	153.9 ± 19.1	0.24
DBP	83.1 ± 13.7	87.4 ± 14.6	<0.01
DBP change	-4.1 ± 9.2	-3.1 ± 10.1	0.28
6 Months - Home	N=343	N=166	
SBP	161.1 ± 19.2	162.8 ± 21.1	0.36
DBP	86.0±16.6	90.0 ± 16.4	0.01
DBP change	-2.9 ± 9.1	-2.8 ± 8.2	0.94

HTN-3 Results / Supp. Appendix

The average office, home, and ambulatory systolic blood pressure drops for the first renal denervation procedures of all operators

were close to or slightly higher

than the overall average for the study.

Medtronic

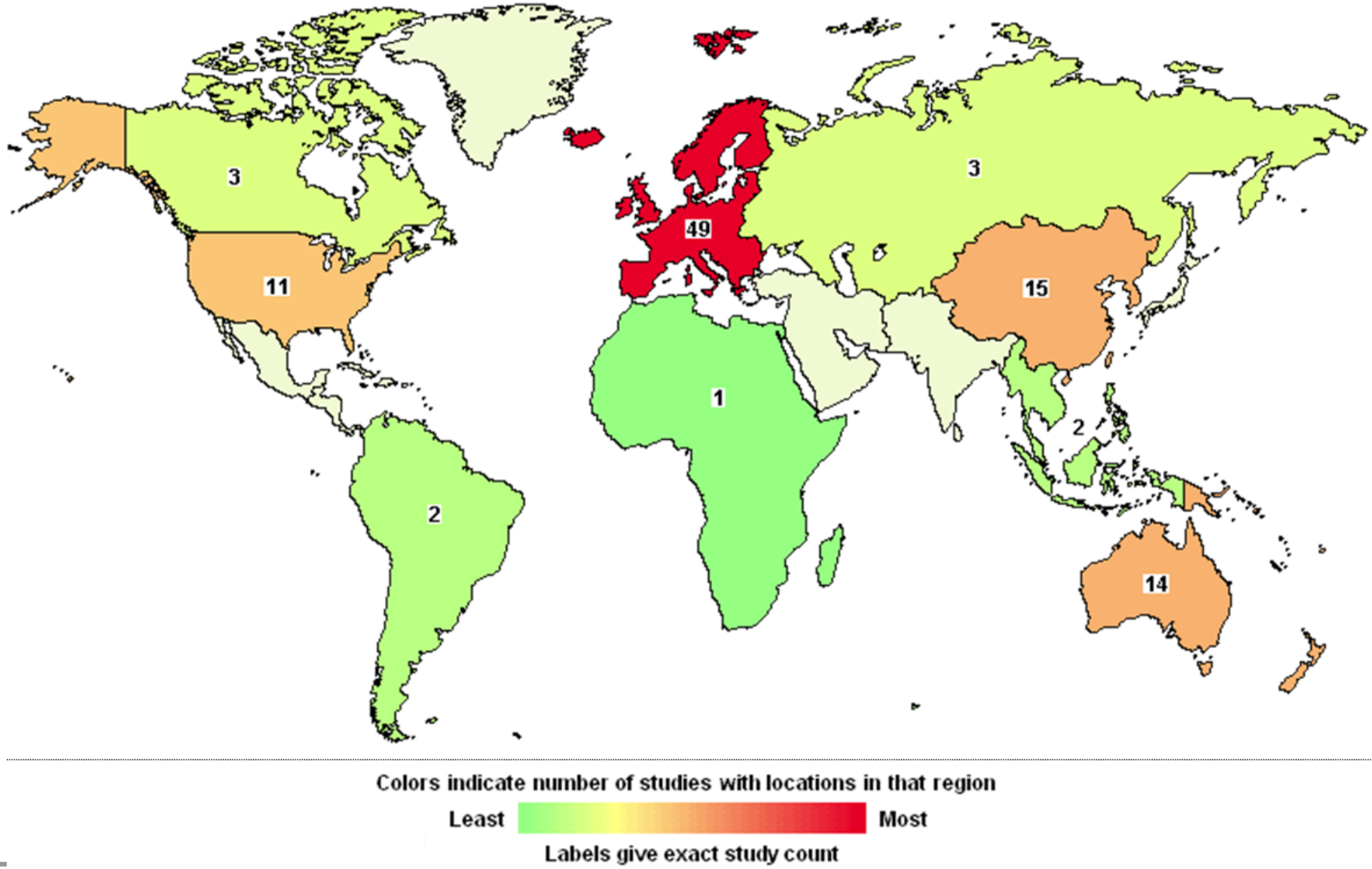
Suspend enrollment in the three countries where renal denervation hypertension trials are being conducted for regulatory approvals

Continue to ensure patient access to the Symplicity technology at the discretion of their physicians in markets where it is approved

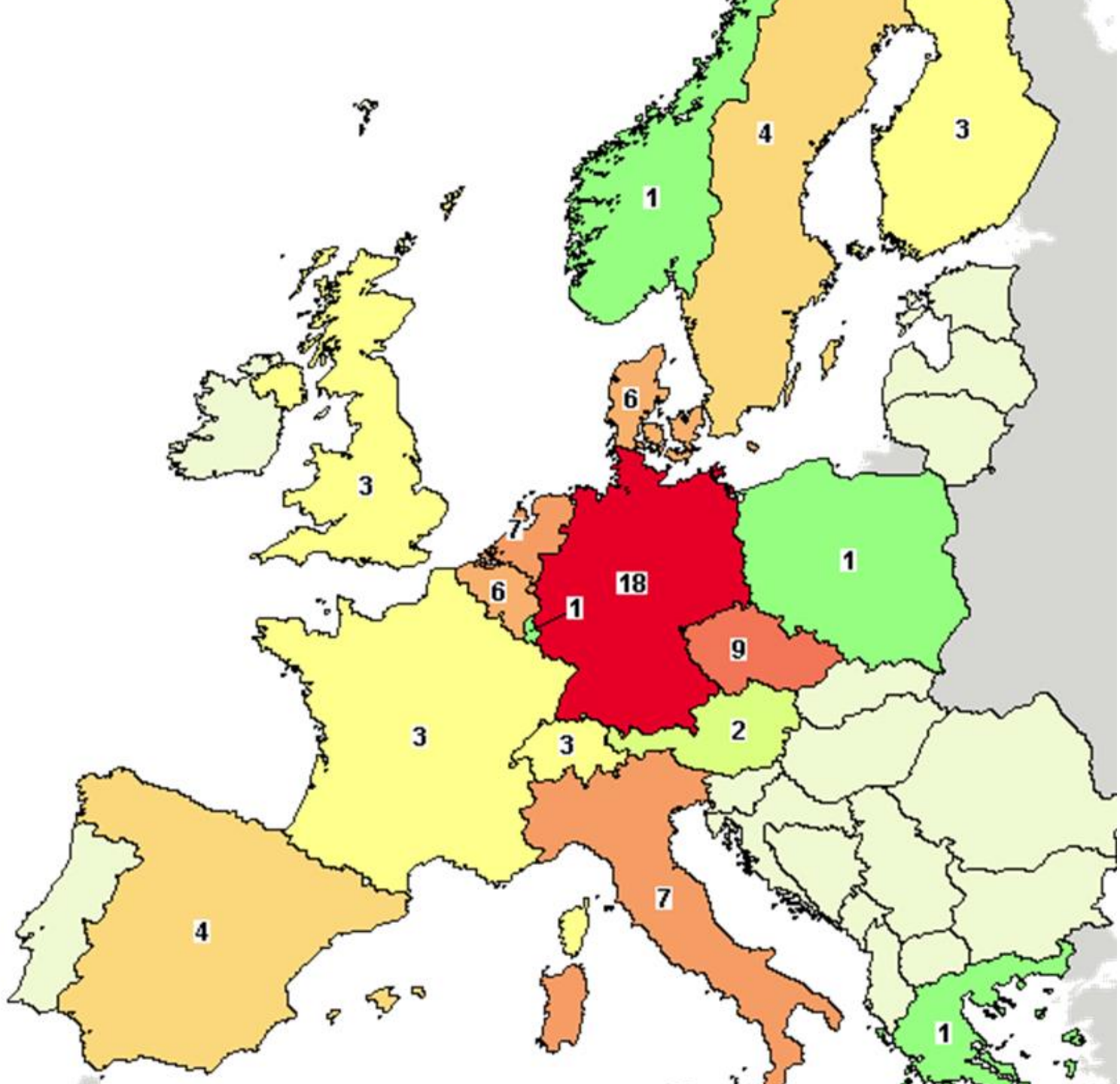
Continue the Global SYMPLICITY post-market surveillance registry and renal denervation studies evaluating other non-hypertension indications

http://www.ptca.org/news/2014/0109_MEDTRONIC_SYMPLICITY.html
accessed at June 4th 2014

Totgesagte leben länger …



http://clinicaltrials.gov/ct2/results/map?term=renal+denervation&recr=Open&no_unk=Y
Accessed at June4th, 2014

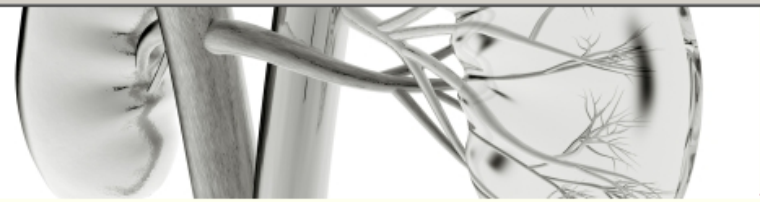

1
4
3
6
3
7
18
1
6
1
9
3
3
2
7
4
1

Ablation Catheter

- Multi-electrode
- Radiopaque electrodes
- 8 F compatible
- Deflectable, atraumatic tip
- Femoral access

Generator

- Default settings:
  - Power output (6 Watts)
  - Impedance (400Ω)
  - Electrode temperature (75 degrees C)
  - Time (90 seconds per ablation)
- Temperature controlled
  - Simultane Ablation in Vorbereitung



ST. GEORG UNTERNEHMENSGRUPPE

Infektiologie, Tropenmedizin und Nephrologie

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Nierensprechstunde
Patienteninformation Nephrologie
Schwere Hypertonie »
Neubau des Dialysezentrums
Notfallversorgung Nephrologie
Forschung Nephrologie
Alumni
Informations for international patients
Ambulanzen
Zentrenbeteiligung

Therapie der schweren Hypertonie

Von Bluthochdruck sind in Deutschland etwa 20 Mill. Menschen betroffen. 20 mmHg Blutdrucksteigerung führen zu einer Verdoppelung des kardiovaskulären Risikos. Bluthochdruck wird normalerweise medikamentös behandelt. Zielwert ist unter 140/90mmHg. Allerdings gelingt nur bei etwa einem Drittel der Betroffenen eine wirklich ausreichende Normalisierung. Für solche im ambulanten Umfeld nicht behandelbare Problemfälle stehen uns apparative Reserveverfahren zur Verfügung. Der schwere Bluthochdruck wird dabei bei uns in einem interdisziplinären Vorgehen gemeinsam von Nephrologen, Kardiologen und Gefässchirurgen behandelt, die über zertifizierte Spezialqualifikationen verfügen. Als eine von ganz wenigen Kliniken bundesweit verfügen wir über alle etablierten Techniken und können so die individuell geeignete Form für jeden Patienten auswählen.

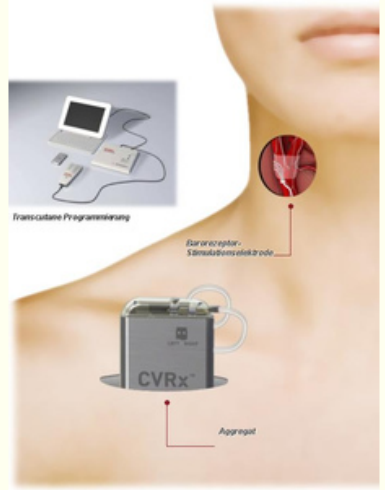
Apparative Barorezeptorstimulation (BAT, Hochdruckschrittmacher)

Die Gefässchirurgen unserer Klinik implantieren dazu eine kleine Elektrode an den Barorezeptor (Drucksensor) der Halsschlagader, die mit einem Schrittmacheraggregat stimuliert wird. Damit wird en nochmals erhöhter Blutdruck simuliert. Dieser Trick führt zu einer Gegenregulation des Organismus und damit zu einer Drucksenkung meistens in der Grössenordnung von 30 bis 50 mmHg.

Nierenarteriendenervation (RND)

Ein Teil der Blutdruckregulation erfolgt über das sympathische Nervengeflecht der Nierenarterien. Wenn diese Nerven durch Hitze "verkocht" werden, kommen Blutdruck -erhöhende Signale nicht mehr im Gehirn an. Deshalb kann auch diese apparative Technik zu einer Blutdrucksenkung im Sinne eines Reserveverfahrens beitragen.

Video Herstellerseite



Schematische Abbildung eines "Hochdruckschrittmacher"

Kontakt und Information