

ANGIOPLASTY SUMMIT-TCTAP 2012
Seoul, Korea, April 24-27, 2012

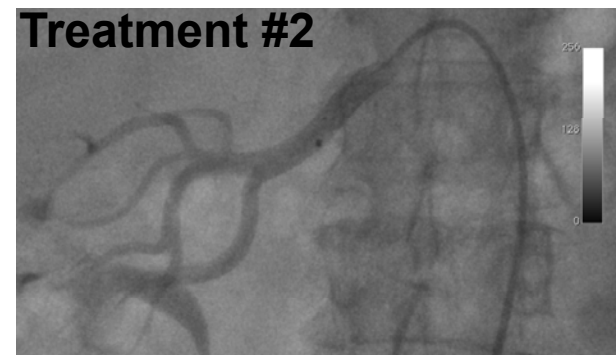
Transcatheter Renal Denervation Therapy: A Breakthrough for Refractory Hypertension?

Horst Sievert, Ann-Kathrin Ziegler, Benjamin
Kaltenbach, Ilona Hofmann, Undine Pittl
CardioVascular Center Frankfurt,
Frankfurt, Germany

What is renal denervation?

- Catheter based interruption of renal nerves
- Reduces central sympathetic drive
- This results in blood pressure reduction
- It may have other beneficial effects in heart failure and diabetes

Simplicity, Ardian, Medtronic Radiofrequency



Techniques on the Horizont

- Other radiofrequency approaches
- Heat
- Cryo
- Radiation
- Ultrasound
- Drugs

So is this a
"Breakthrough"?

The answer is "yes"

I believe that renal denervation
may become as important as PCI
or PTA

... and I am not the only one

> 500 attendees!



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CSI Focus
Workshop

February 18, 2012 | Frankfurt, Germany

TREND 2012

TRANSCATHETER RENAL DENERVATION



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Neuro-Humoral Interventions
Catheter and Device Based Treatment of Hypertension and Heart Failure
Transcatheter Renal Denervation

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Which interventional procedure can become a "breakthrough"?

- The disease should be important
- Interventionalists should have direct access to the patients
- Should be doable without huge infrastructure
- The procedure should be
 - effective
 - safe
 - durable
 - easy to learn

With renal denervation we
can treat hypertension

Needless to say that
hypertension is important

But hypertension is much
more frequent and much more
important than you may think

How important is hypertension?

- 30-40% of the adult population in the US/Europe has hypertension
- The prevalence is expected to increase with the aging population
- 65% of hypertensive patients are either untreated or have a blood pressure above the recommended goal

Please look around in this room!

How many candidates do you see
for renal denervation compared to
TAVI, TEVAR or flow diverters?

Actually, you may be one of the
candidates

How important is hypertension?

- Associated with an increased risk of:
 - Stroke
 - Myocardial infarction
 - Renal insufficiency
 - Congestive heart failure
 - Peripheral arterial disease
 - Death
- 20mmHg increase in BP doubles cardiovascular mortality
- According to the WHO hypertension is the most frequent cause of death worldwide

Hypertension is a huge financial burden

- Estimated costs associated with hypertension in 2009 in the US: \$73.4 billion

Limitations of BMT

- 60-80% of hypertensive patients are either untreated or have suboptimal blood pressure control despite optimal medical therapy
- Many patients are troubled by medication side-effects

Do you have
direct patient access?

Everybody has access to patients
– even dentists

Infrastructure?

- Cath lab
- Generator
- Catheter

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Symlicity HTN-2 THE LANCET

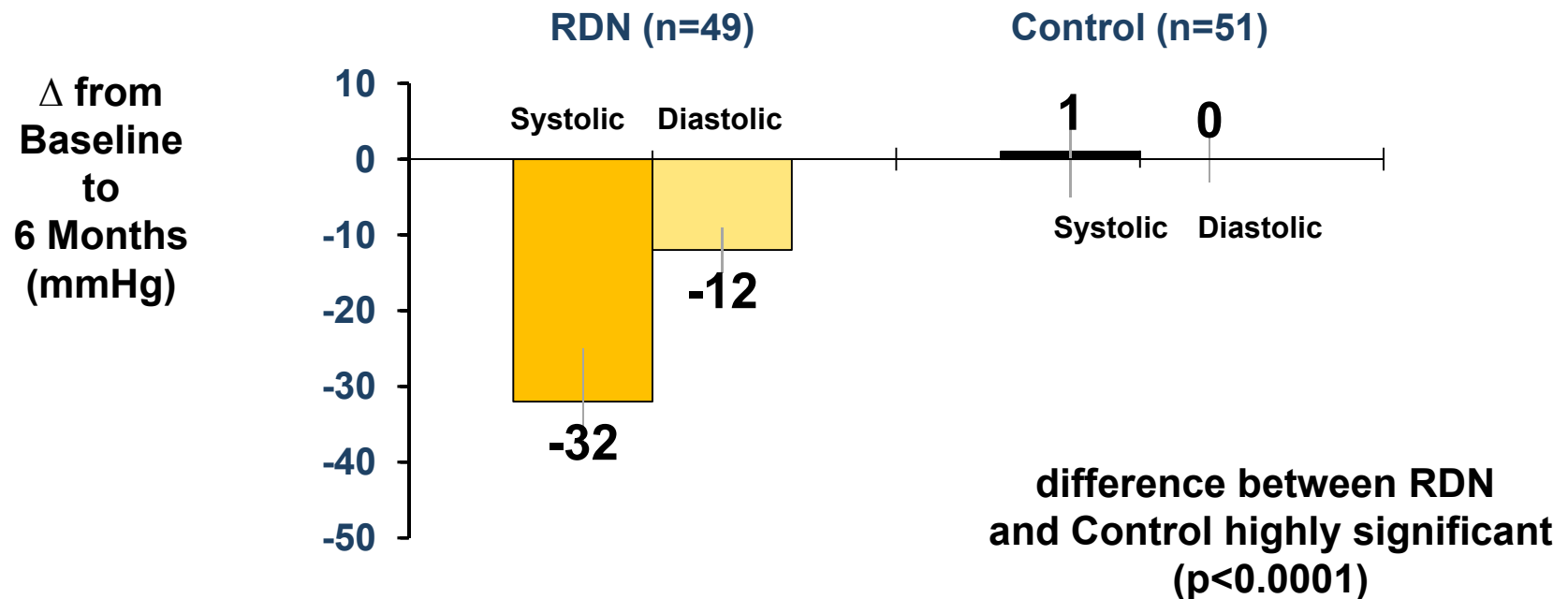
Renal sympathetic denervation in patients with treatment-resistant hypertension (The Symlicity HTN-2 Trial): a randomised controlled trial

*Symlicity HTN-2 Investigators**

Lancet. 2010;376:1903-1909

- Randomized, controlled, clinical trial
- **Patients:**
 - 106 patients with resistant hypertension randomized 1:1 to treatment with renal denervation vs. control
 - Office SBP $\geq$ 160 mmHg
 - 3+ more anti-HTN medications

Primary Endpoint: 6-Month Office BP

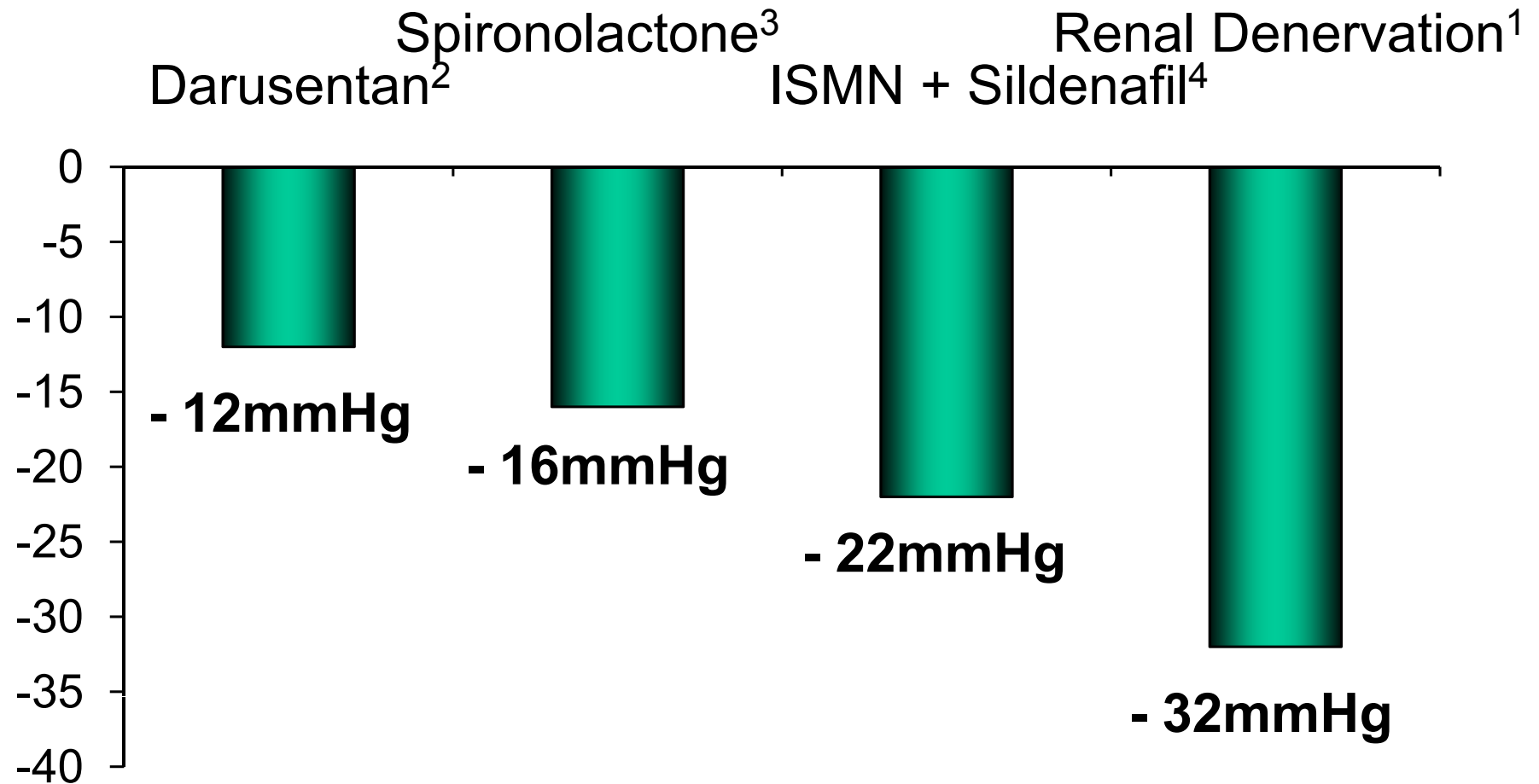


- 84% of RDN patients had ≥ 10 mmHg reduction in SBP
- Only 10% of RDN patients had no reduction in SBP

How does this compare
to medical treatment?

Randomized Trials in Resistant Hypertension

Mean Reduction in Systolic BP



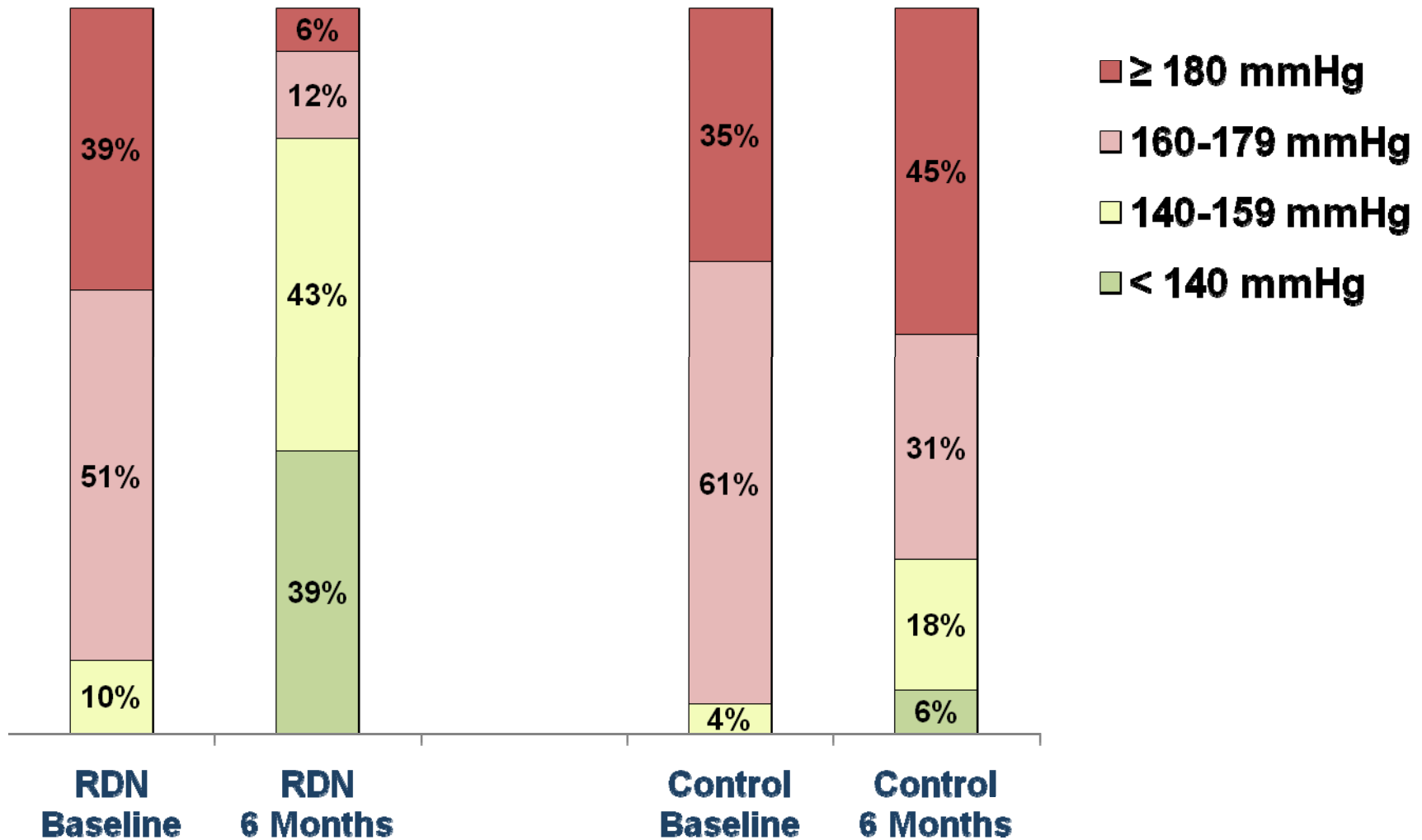
¹Lancet. 2010

²Curr Hypertens Rep. 2008 Dec;10(6):429-31.

³Hypertension. 2010 Jan;55(1):147-52

⁴Hypertension. 2010 Jul;56(1):22-3.

Office Systolic BP Distribution



Is it safe?

HTN-1: Chronic Safety Out to 3 Years

- One progression of a pre-existing stenosis unrelated to RF treatment (stented without further sequelae)
- One new moderate stenosis which was not hemodynamically relevant and no treatment
- 3 deaths within the follow-up period; all unrelated to the device or therapy
- No hypotensive events that required hospitalization
- There were no observed changes in mean electrolytes or eGFR

Subgroup analyses

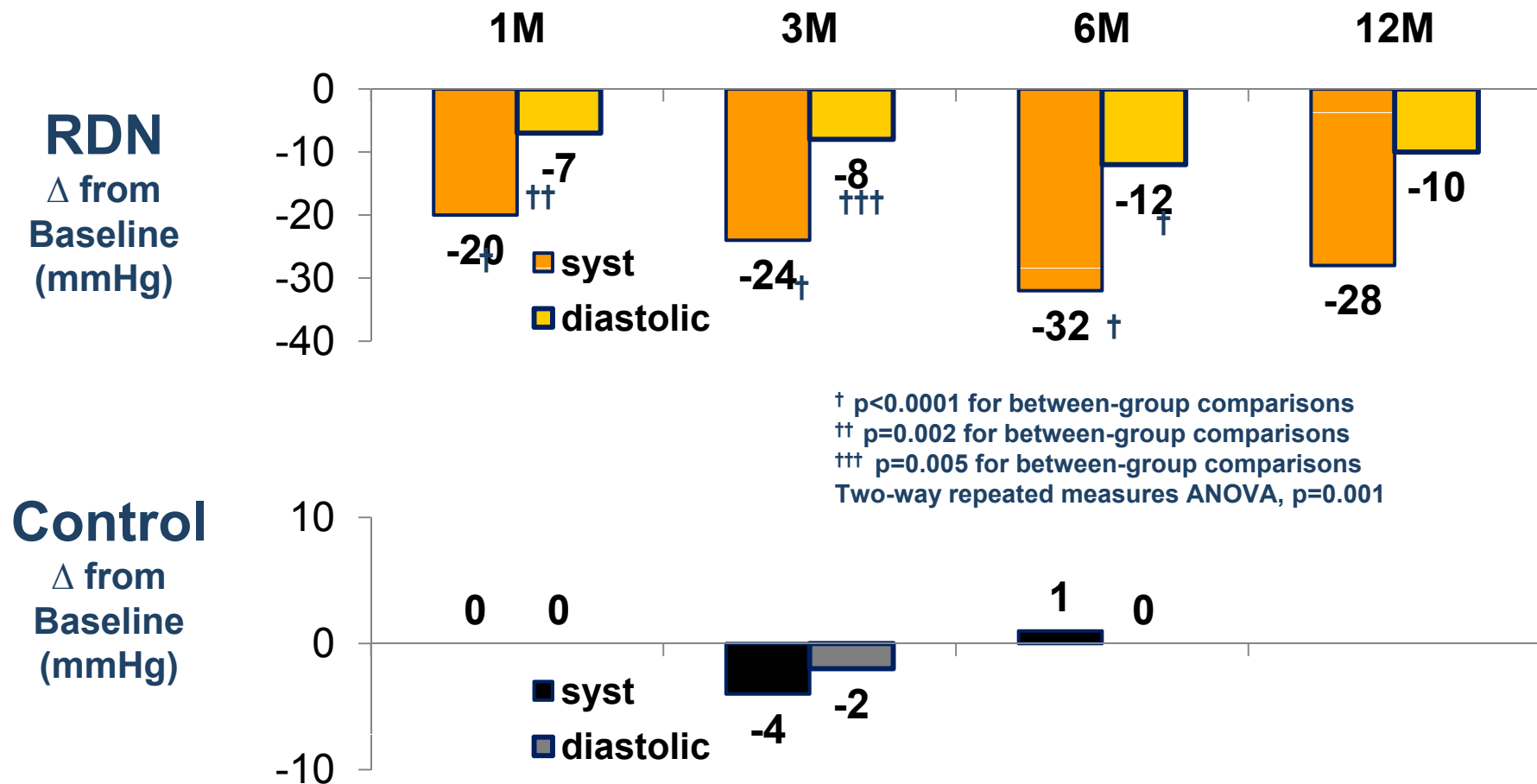
- Age
- Gender
- Diabetes

————→ no differences

Is the effect durable?

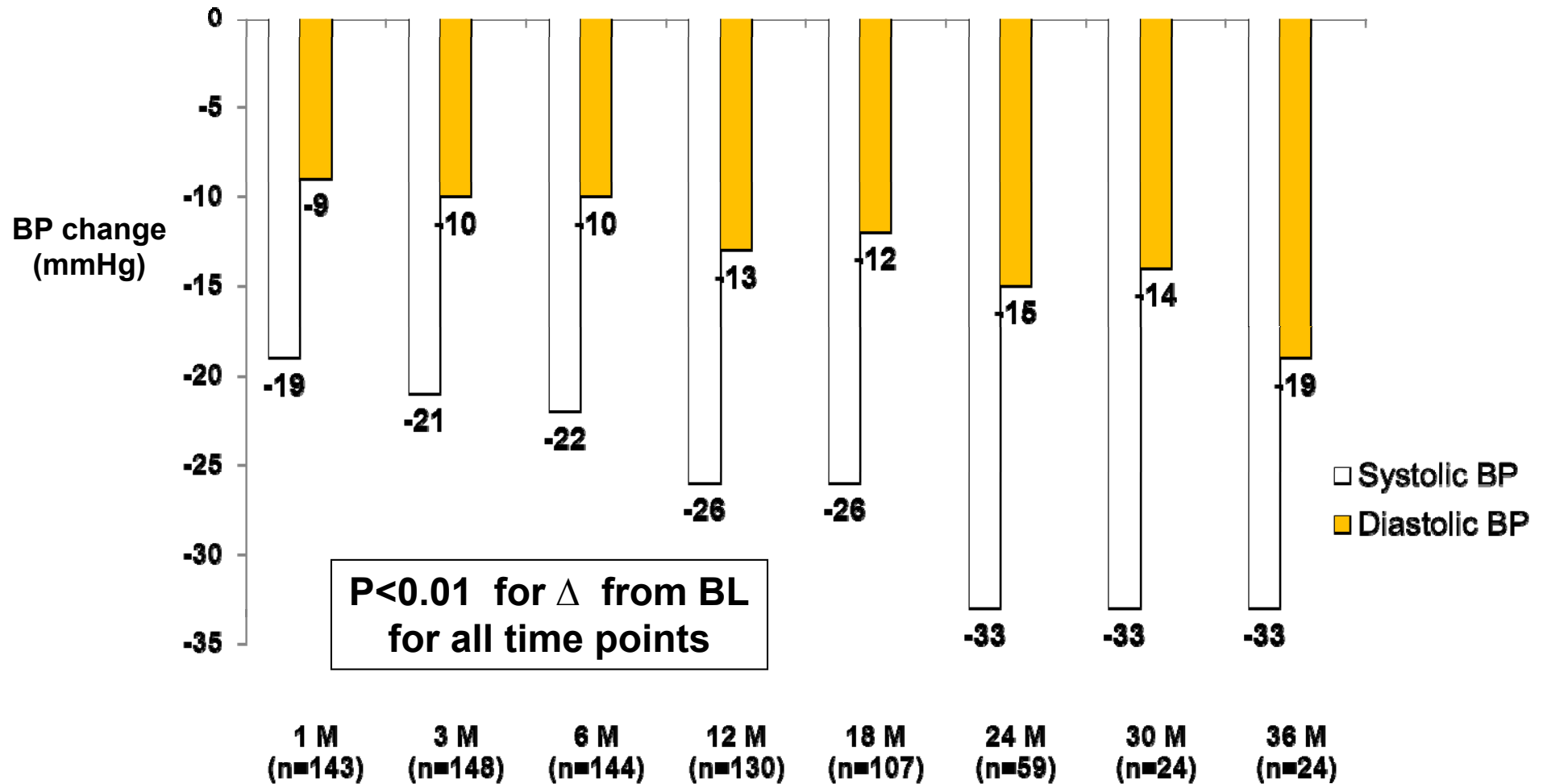
Symlicity HTN-2

Time Course of Office BP Change



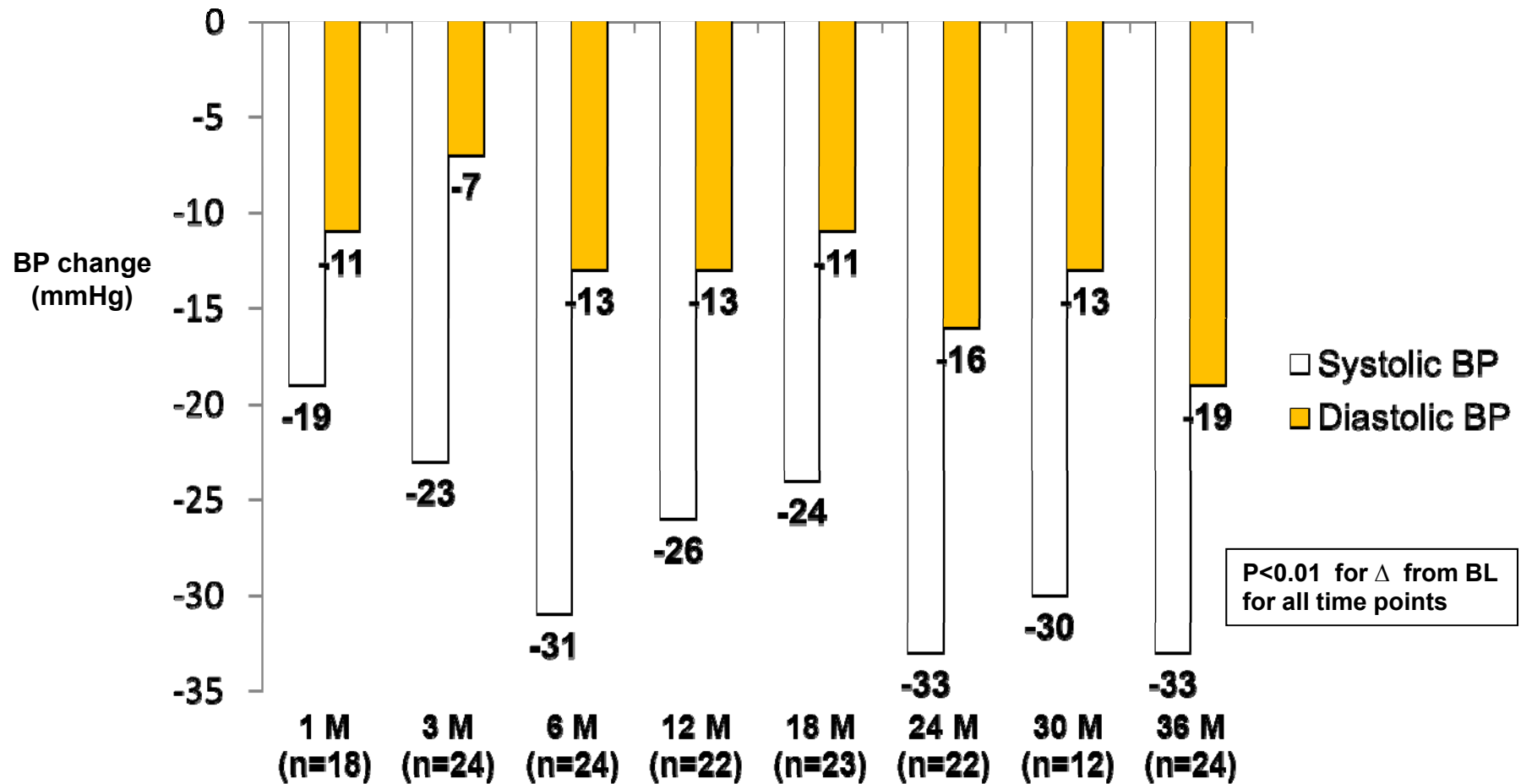
Symlicity HTN-1

Significant, Sustained BP Reduction through 3 yrs

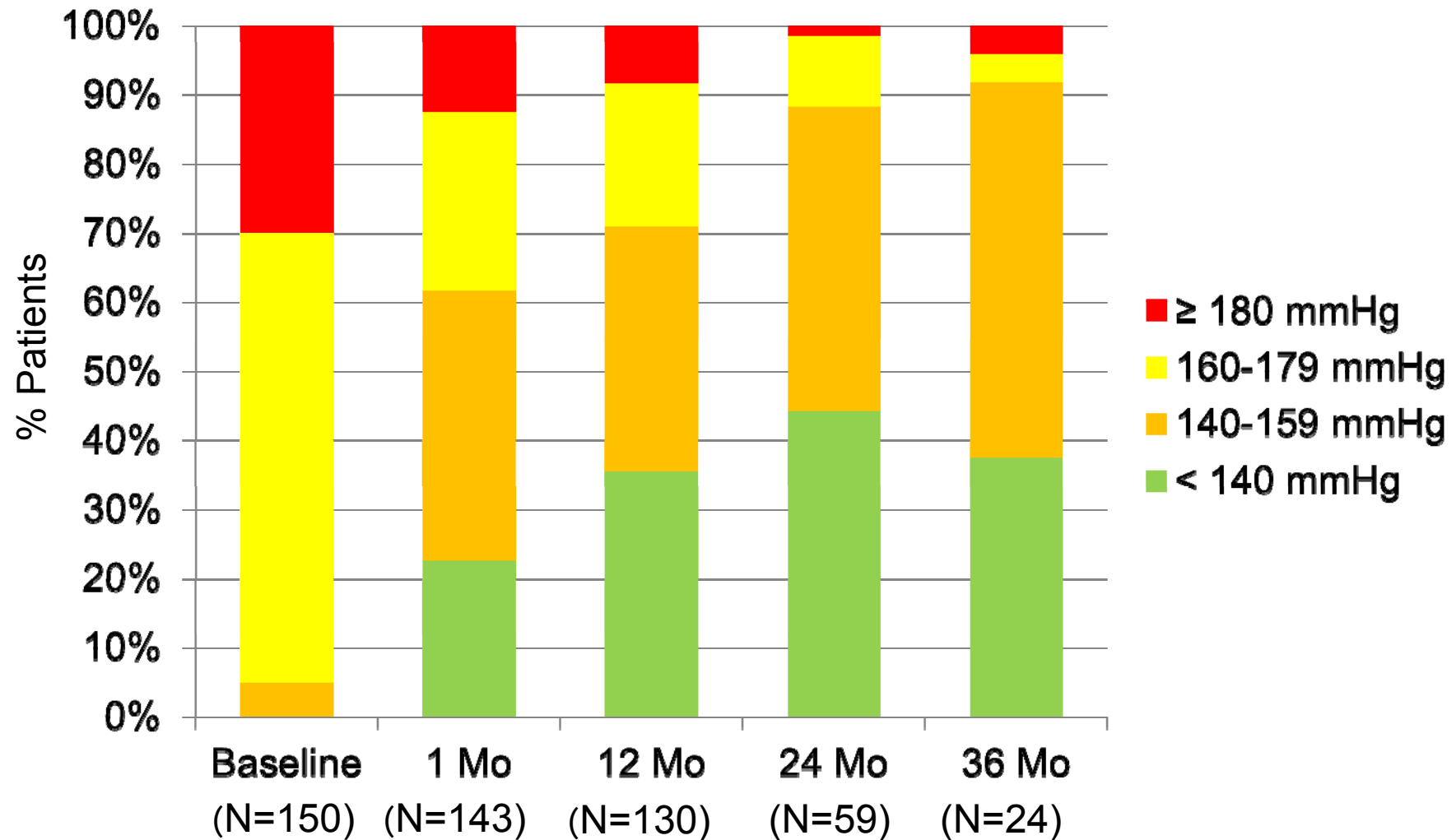


Symlicity HTN-1

Change in Office Blood Pressure for 24 Pts with 3 yrs Follow-up

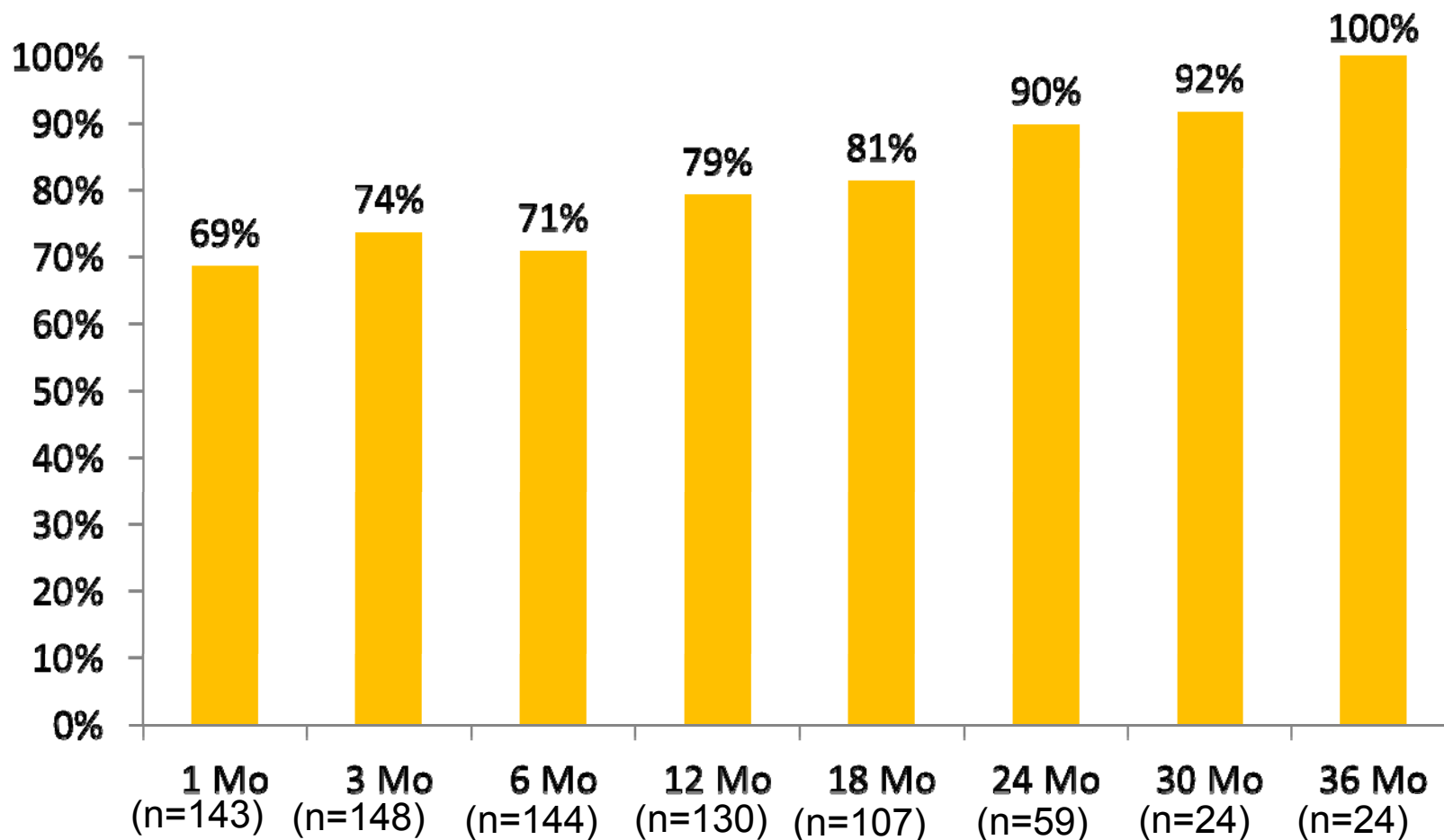


Distribution of SBP Change at BL, 1, 12, 24, and 36 Months



Percentage Responders Over Time

Responder was defined as an office SBP reduction ≥ 10 mmHg



Caution: The Symplicity® Catheter System™ is an Investigational Device. Limited by U.S. law to investigational use.
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