Sensing renal nerve activity before, during and after denervation

Dr García Touchard

Hospital Puerta de Hierro Majadahonda

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Background

Clinical RDN studies demonstrated a large variability in blood pressure response:

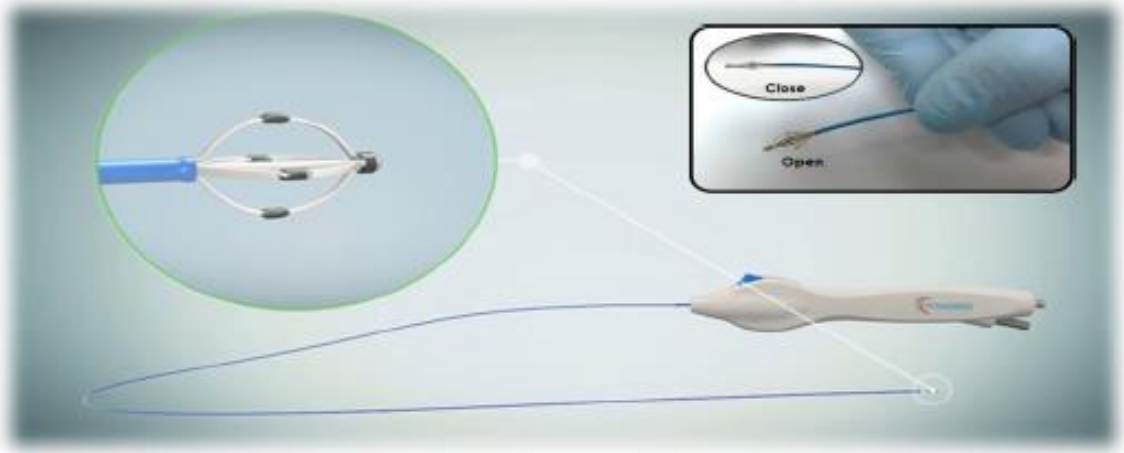
- **Inappropriate patient selection**
- **Inaccurate nerve targeting, "blind nature" of the procedure**
- **Inability to verify real time treatment success**

- **Identify responders and non-responders**
- **Optimize RDN therapy sites ("Hot Spots" for ablation) and support an evidence-based treatment**
- **Provide real time feedback on ablation success**

ConfidenHT™ System

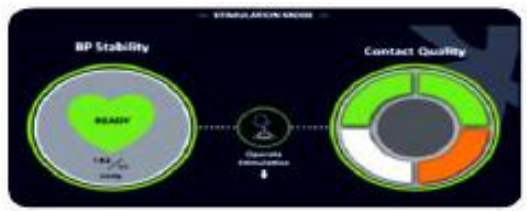
Catheter

- Multi-electrode
- Flexible design
- Adjustable basket size
- 8F GC/ 0.014” GW compatible
- Femoral access approach



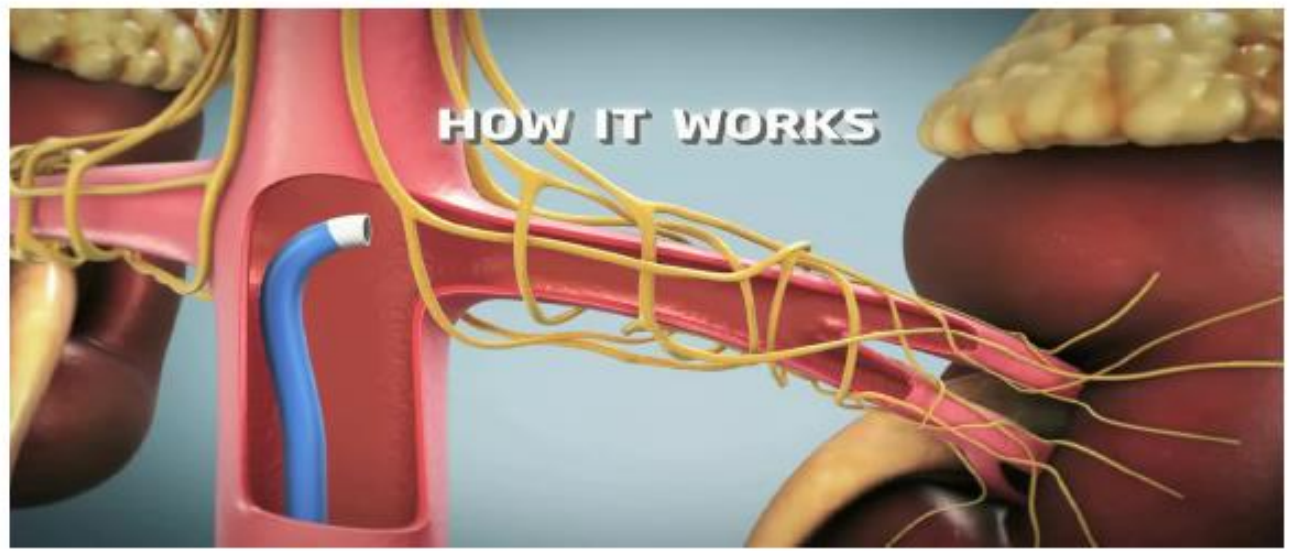
Console

- Multi channel generator
- Real time physiological signal analysis using a proprietary algorithm
- Instant monitoring in change of blood pressure



ConfidenHT™ Mechanism of Action

Electrical stimulation evokes action potential in the adjacent nerves and provides an immediate noticeable change in physiological markers (BP)



ConfidenHT FIM Study design

Study Design	Prospective, Feasibility, open-label, single-arm, study
Aim	To evaluate the safety and performance of the ConfidenHT™ System for diagnostic mapping of renal nerves
Patient Population	Hypertensive patients and/or potential candidates for renal sympathetic denervation (RDN)
Number of patients / Clinical sites	20 patients / 3 EU sites: ▪ Dr. Konstantinos Tsioufis, Athens, Greece ▪ Dr. Joost Daemen, Rotterdam, the Netherlands ▪ Dr. Michiel Voskuil, Utrecht, the Netherlands
Primary safety endpoint	The occurrence of serious adverse events and 1 and 3 month FU
Primary performance endpoint	Arterial blood pressure changes to renal nerve stimulation

Baseline characteristics

	(N=20)
Age (years ± SD)	60± 11
Male (%)	45
Race	
▪ Caucasian (%)	95
▪ Other (%)	5
Diabetes Type II, %	5
Mean office blood pressure	
▪ Systolic (mmHg ± SD)	156 ± 23
▪ Diastolic (mmHg ± SD)	89 ± 15
▪ MAP (mmHg ± SD)	115 ± 18
GFR mean ± SD (ml/min)	81± 19

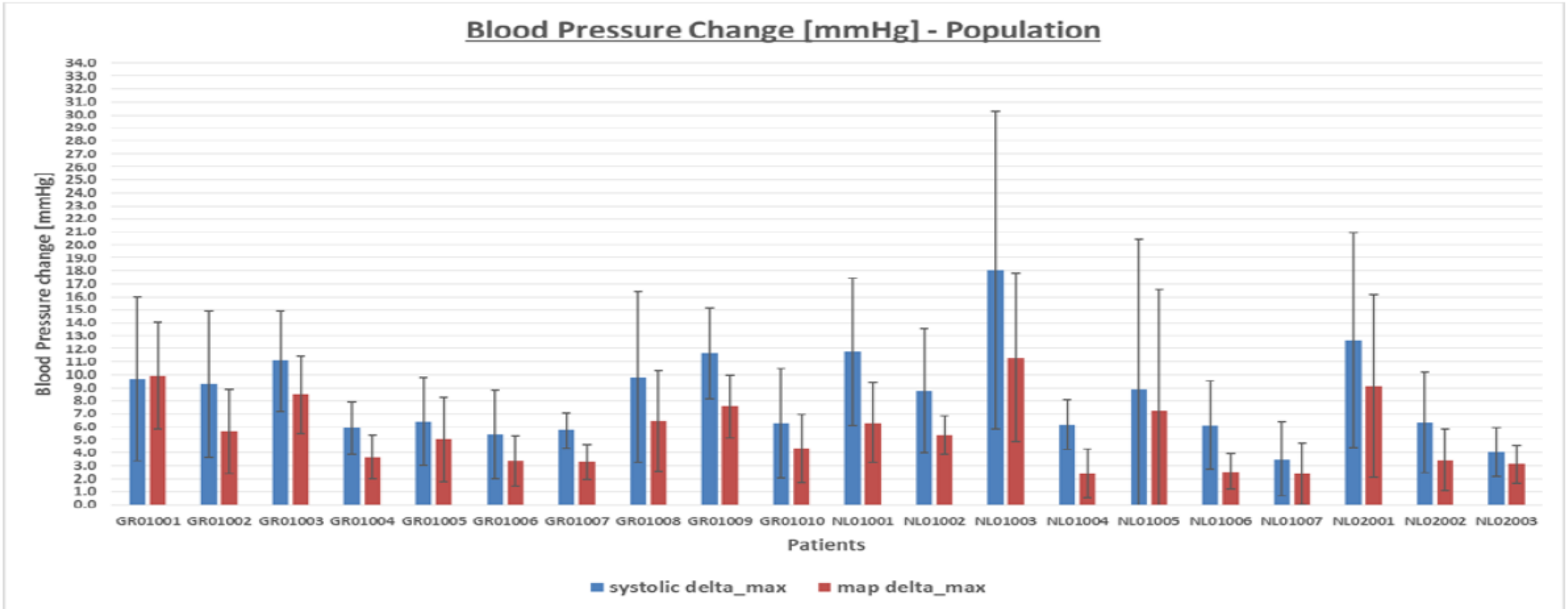
Procedure

- Stimulations in right and left renal arteries
- 3-4 sites per artery, including branches
- 2 and 4 mA stimulation amplitude at chosen sites
- Total of 6-8 mapped sites per patient

Color code	ΔSBP [mmHg]	ΔMAP [mmHg]
Green	0-4	0-2.5
Orange	4-8	2.5-5.5
Red	≥8	≥5.5

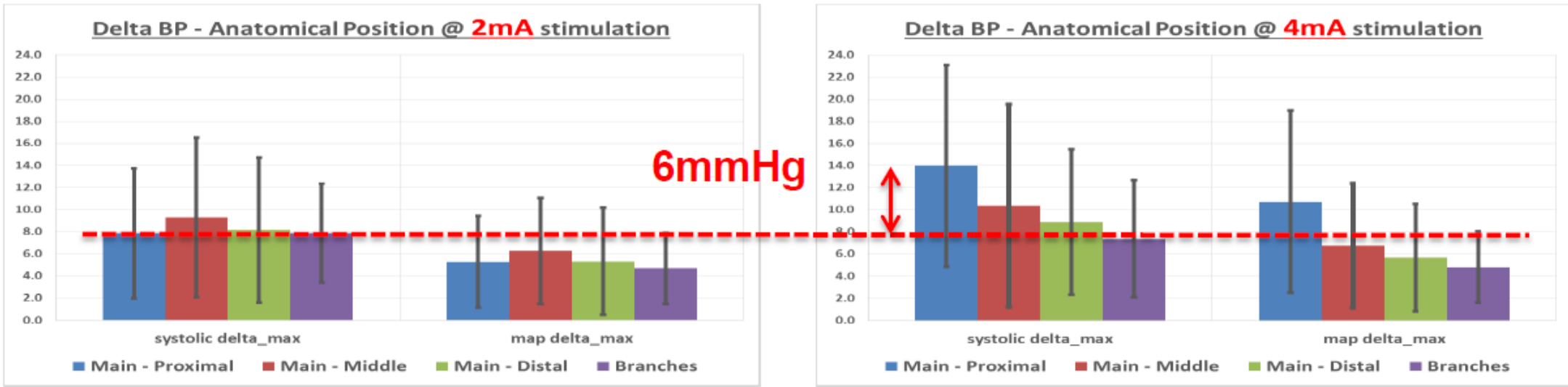
Blood pressure response (per patient)

- Mean individual SBP responses varied between 3.5 and 18 mmHg
- Mean individual MAP responses varied between 2.4 and 11.3 mmHg
- Large variation in patient response



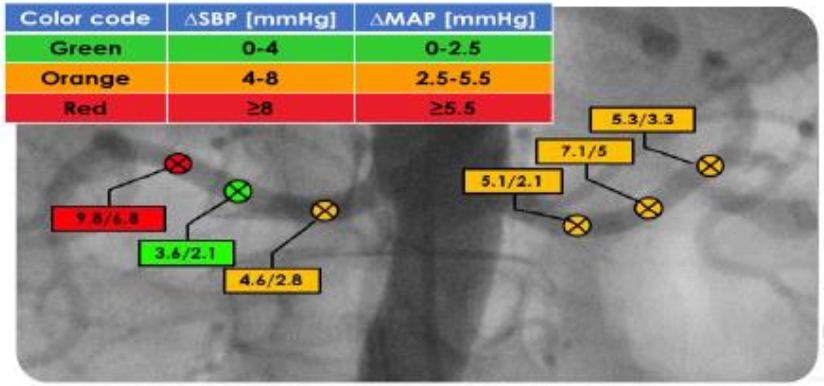
Nerve depth?

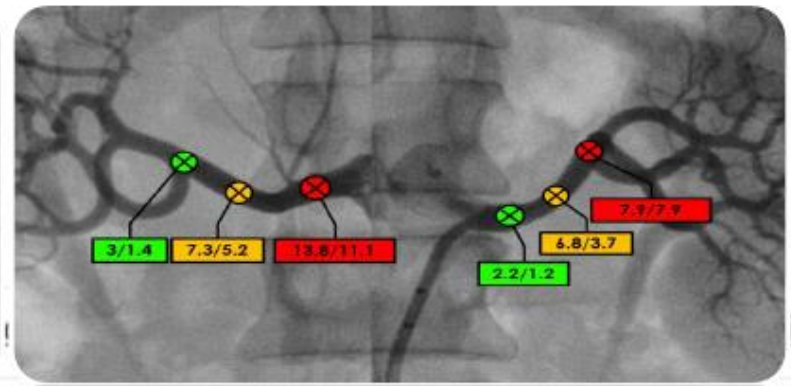
Distance to the nerves deeper at proximal locations?

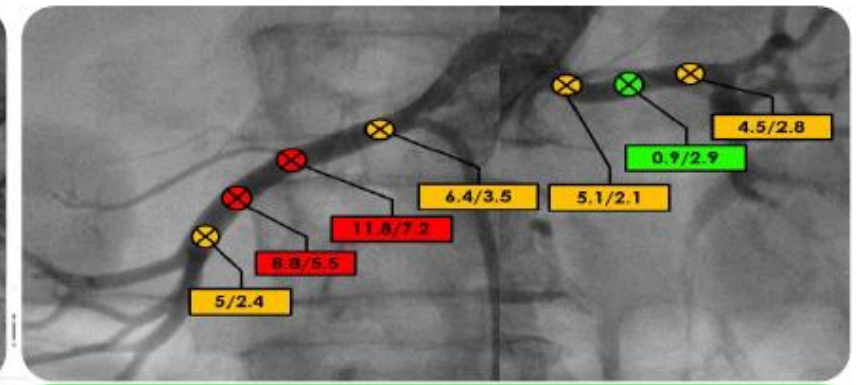


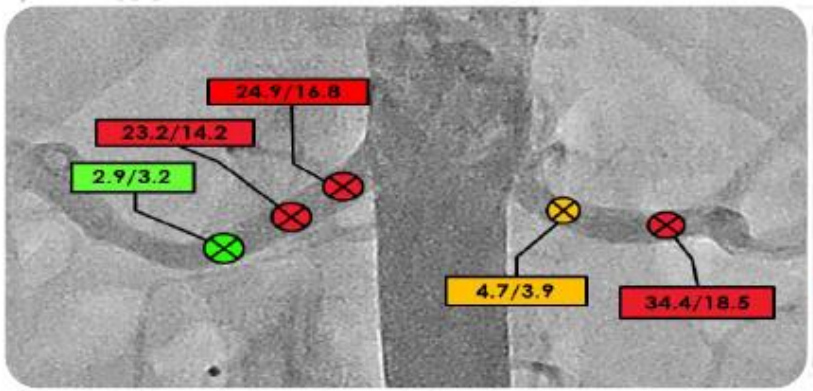
Response variation

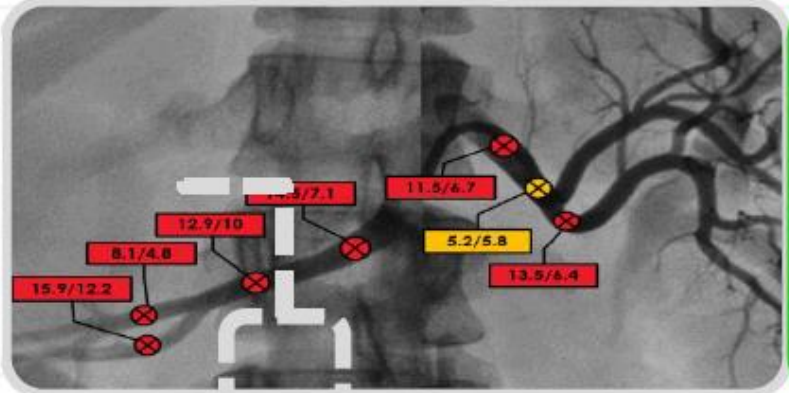
Color code	ΔSBP [mmHg]	ΔMAP [mmHg]
Green	0-4	0-2.5
Orange	4-8	2.5-5.5
Red	≥8	≥5.5

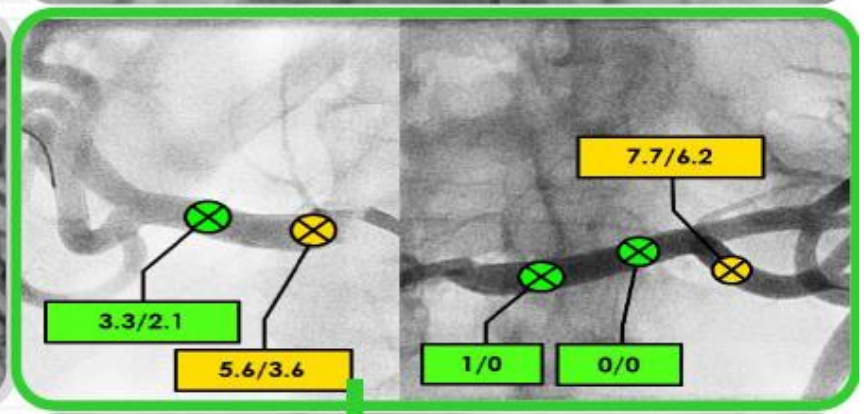


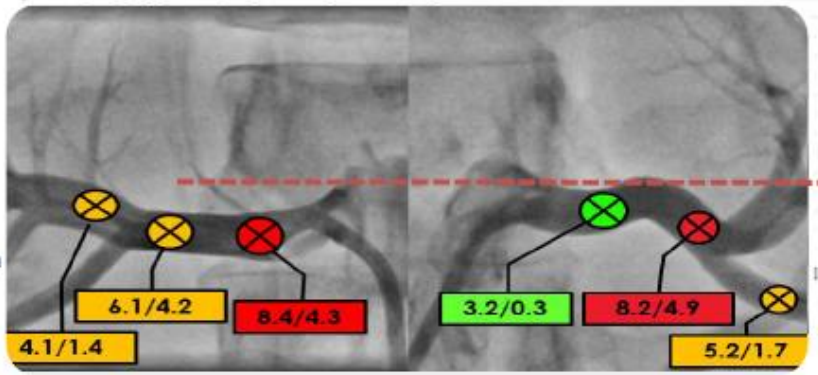


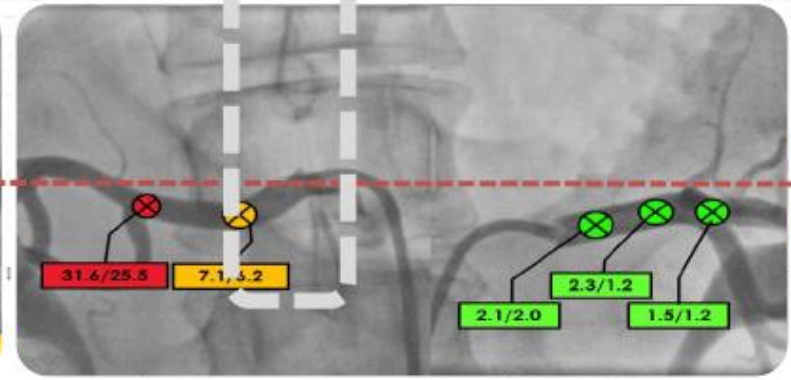


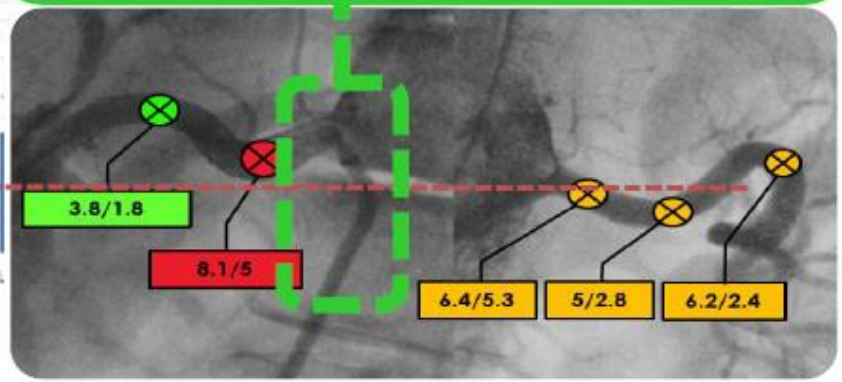






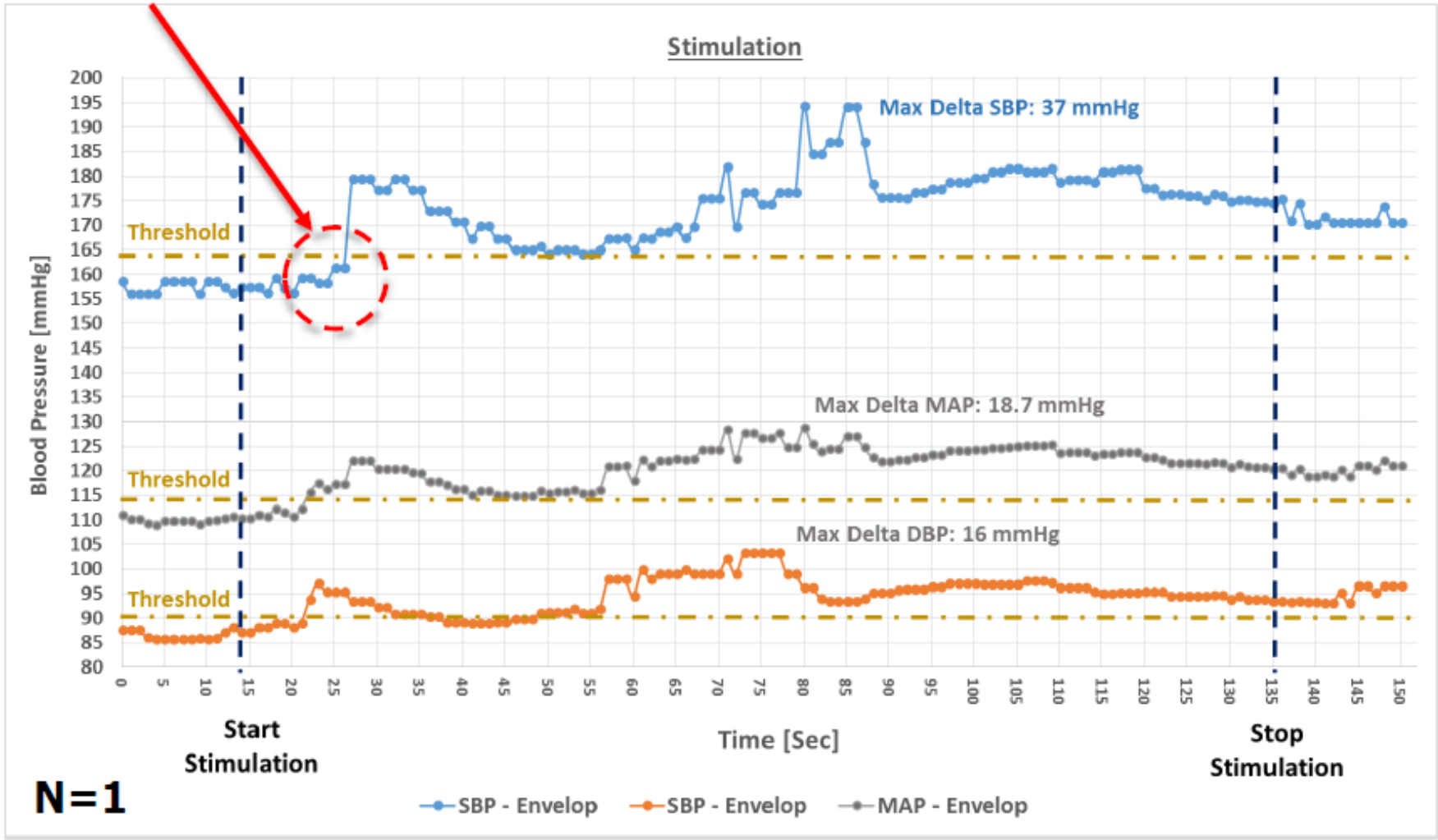






Speed of Mapping

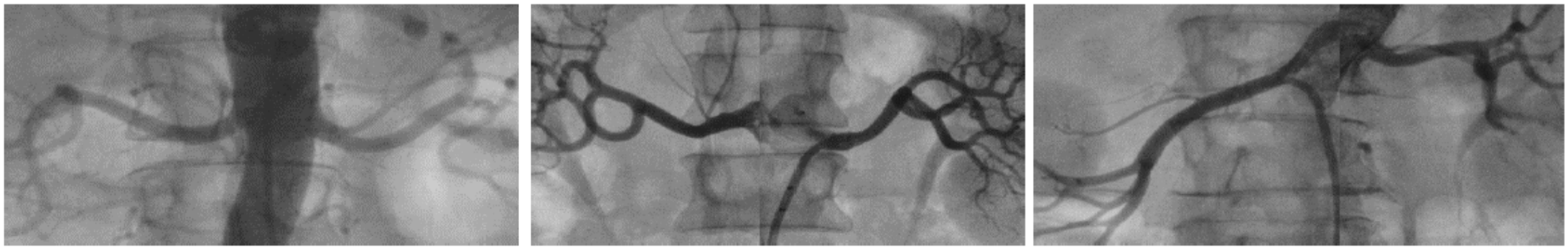
Time to crossing SBP threshold: 13 sec



Safety

- No peri-procedural adverse events
- No SAE at 1 month (N=20) and 3 months (N=13) follow up
- No signs of angiographically visible spasms/thrombus or dissection post procedure
- Creatinine levels remained within the normal range

Baseline



Post Proc.

Conclusions

- **The ConfidenHT system is safe and effective in identifying potential nerve hotspots along the renal artery**
- **Large variation in response per patient and per location**
- **Promising new technology to identify potential responders to renal denervation**
- **Potential real time feedback to RDN effect**
- **Can be integrated with any existing ablation system**
- ***Although CE marked the company stopped the program last year***