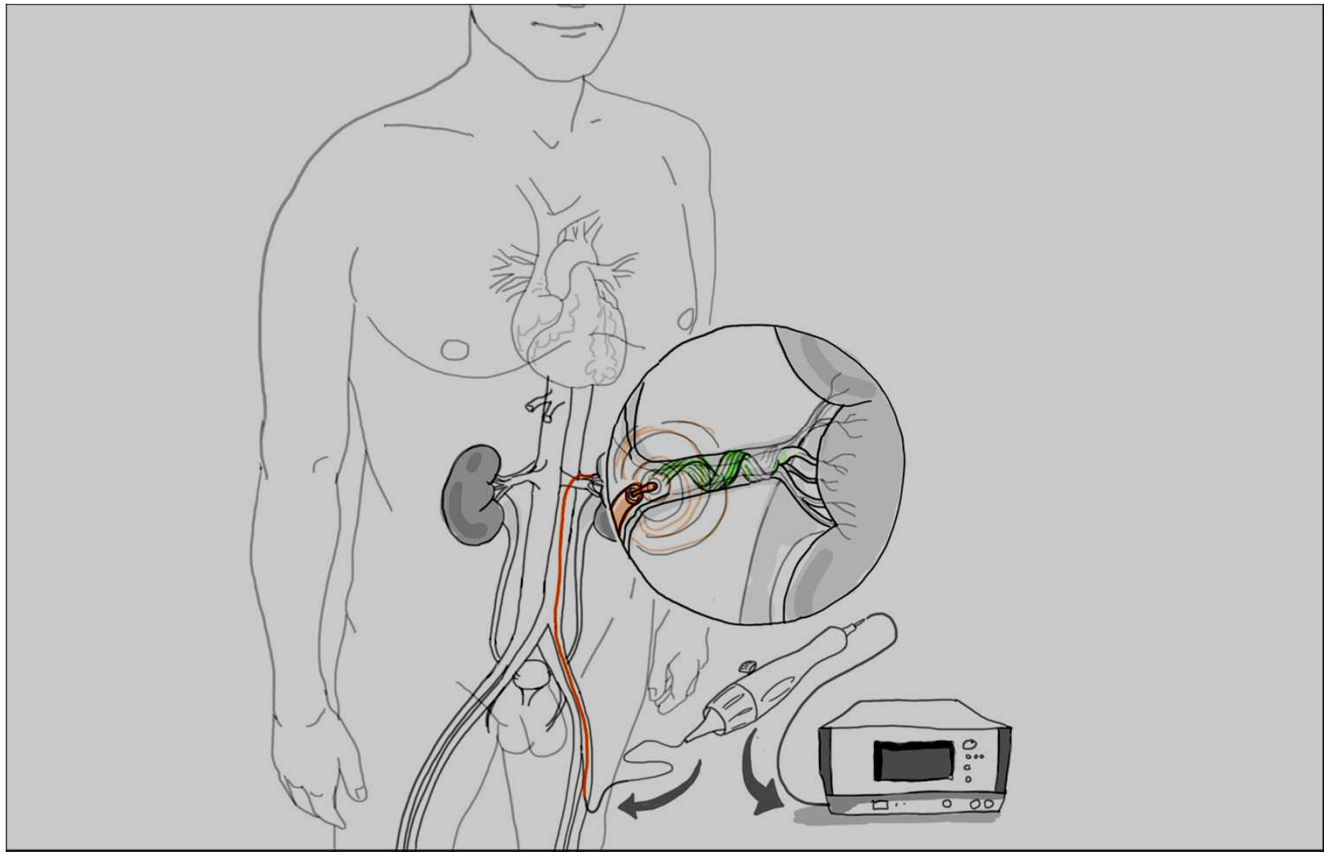
La technologie Radiance un dispositif endocavitaire à Ultra sons pour une denervation rénale circonférentielle et controlée

- M Sapoval, C Del Giudice
- Radiologie Interventionnelle HEGP

Il ne s’agit pas d’une technologie générique



Challenge technique ????

- Détruire les nerfs sympathiques
  - Fiable
  - Puissante
  - complète
- Sans léser la paroi artérielle
- Challenge technique car
  - Les nerfs sont profonds
  - La source d'énergie est endovasculaire…

Renal Nerve Distribution along the Main Renal Artery

TABLE 2 Distribution of Nerves Stratified According to Total Number and Distance From Lumen in Relative Proximal, Middle, and Distal Location

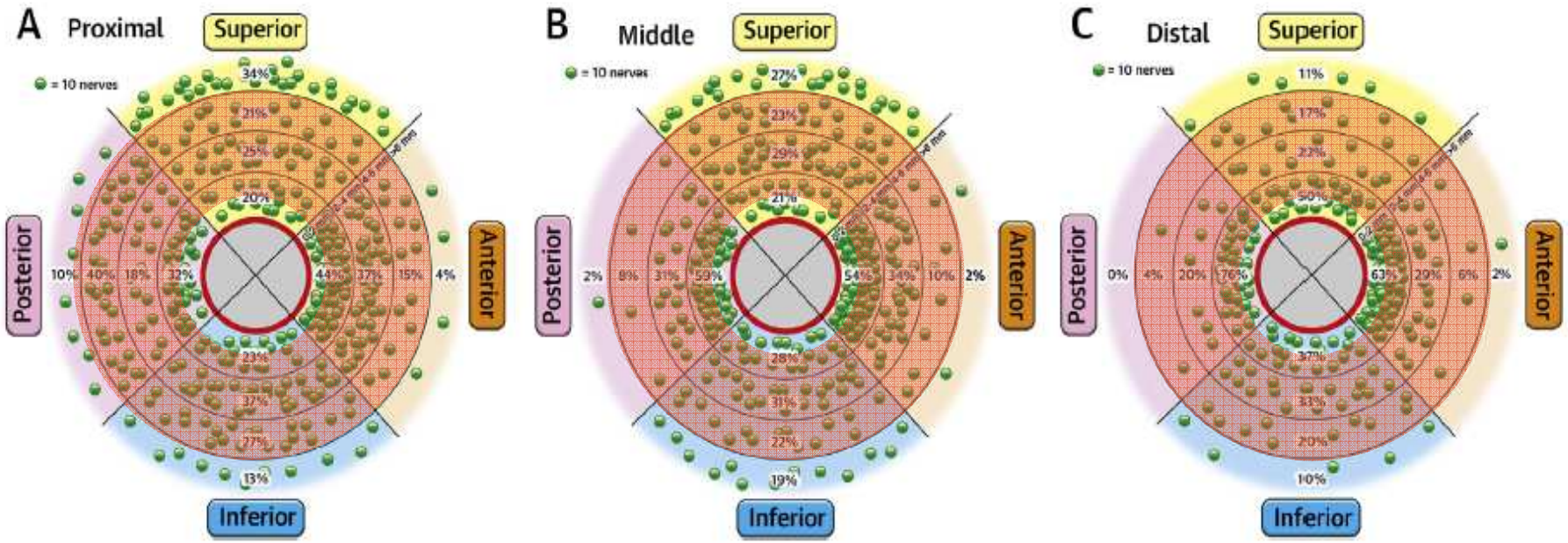
	Whole Distribution (n = 8,030 nerves)			
	Proximal	Middle	Distal	Total
Distance from lumen to nerve, mm				
0-<1	218	244	227	689 (8.6)
1-<2	831	892	877	2,579 (32.1)
2-<3	549	553	324	1,426 (17.8)
3-<4	469	372	213	1,054 (13.1)
4-<5	314	284	133	731 (9.1)
5-<6	249	203	115	567 (7.1)
6-<7	163	169	39	371 (4.6)
7-<8	120	86	36	242 (3.0)
8-<9	91	71	29	191 (2.4)
9-<10	58	71	14	143 (1.8)
≥10	8	7	1	16 (0.2)
Total no. of nerves	3,070	2,952	2,008	8,030
No. of arterial section	82	76	62	220

~80%

Ablation depth goal: 1mm - 6mm
1mm Near Field Ensures Arterial Wall Safety
6mm Far Field Ensures ~80% Nerve Target
& Regional Structure Safety

* Sakakura et al, JACC Vol. 64, NO. 7, 2014

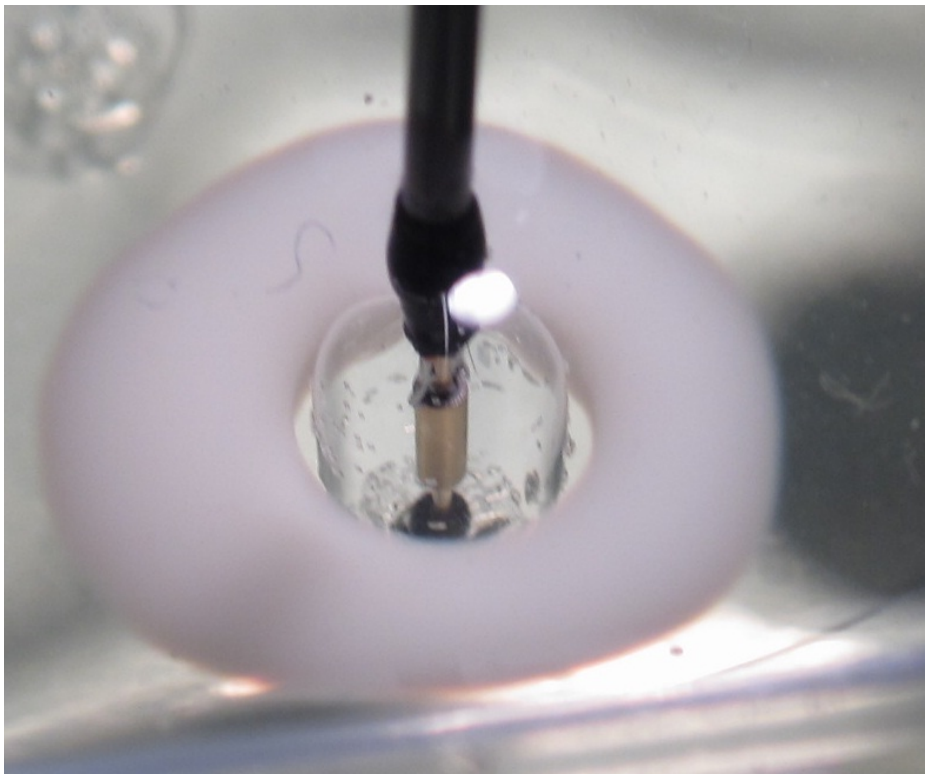
Circumferential Energy Delivery Ensures Consistent Nerve Ablation



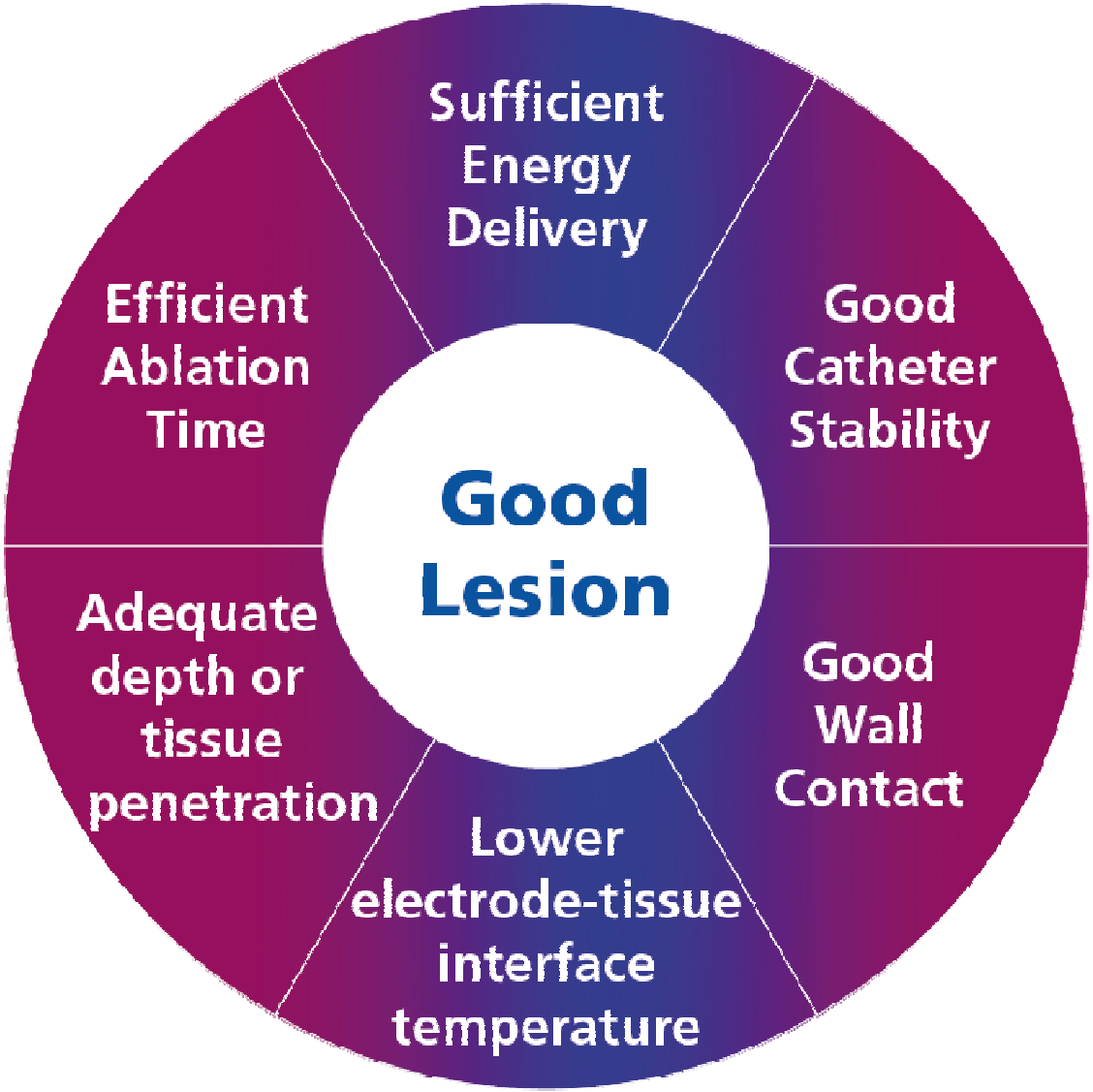
Ablation depth goal: 1mm - 6mm
Protect Arterial Wall / Target 80% Nerves / Protect Regional Structures

*** Source: Sakakura et al. JACC 2014; Mahfoud et al, JACC 2014**

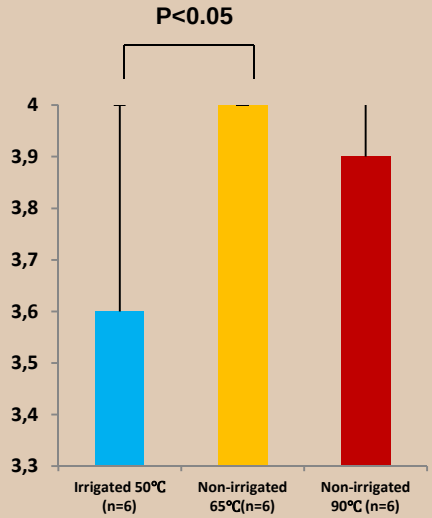
Il ne s’agit pas d’une technologie générique ?



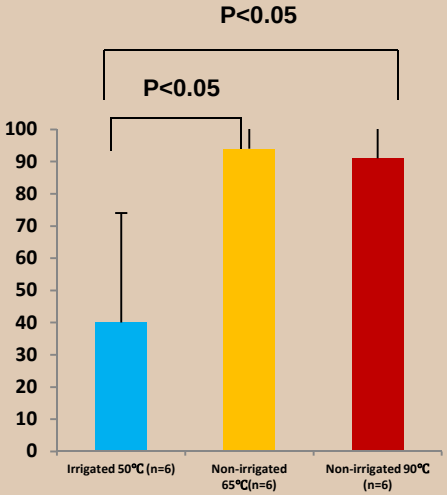
What is an optimal RF lesion?



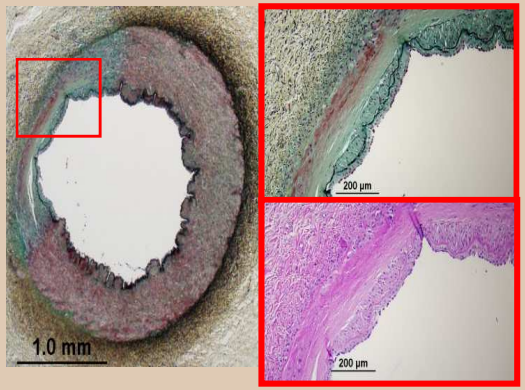
Media damage (depth)
(score 0-4)
P=0.03

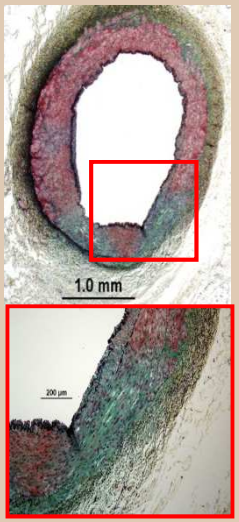


Media thinning
(%)
P=0.001

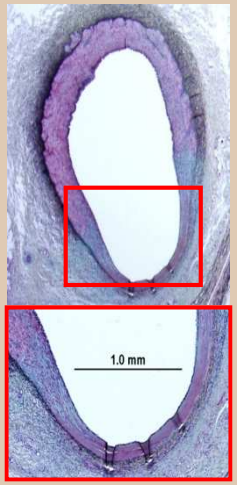


Media thinning:
Media thickness < 50% of unaffected Media thickness

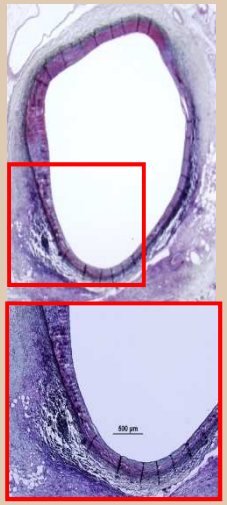




Irrigated 50℃

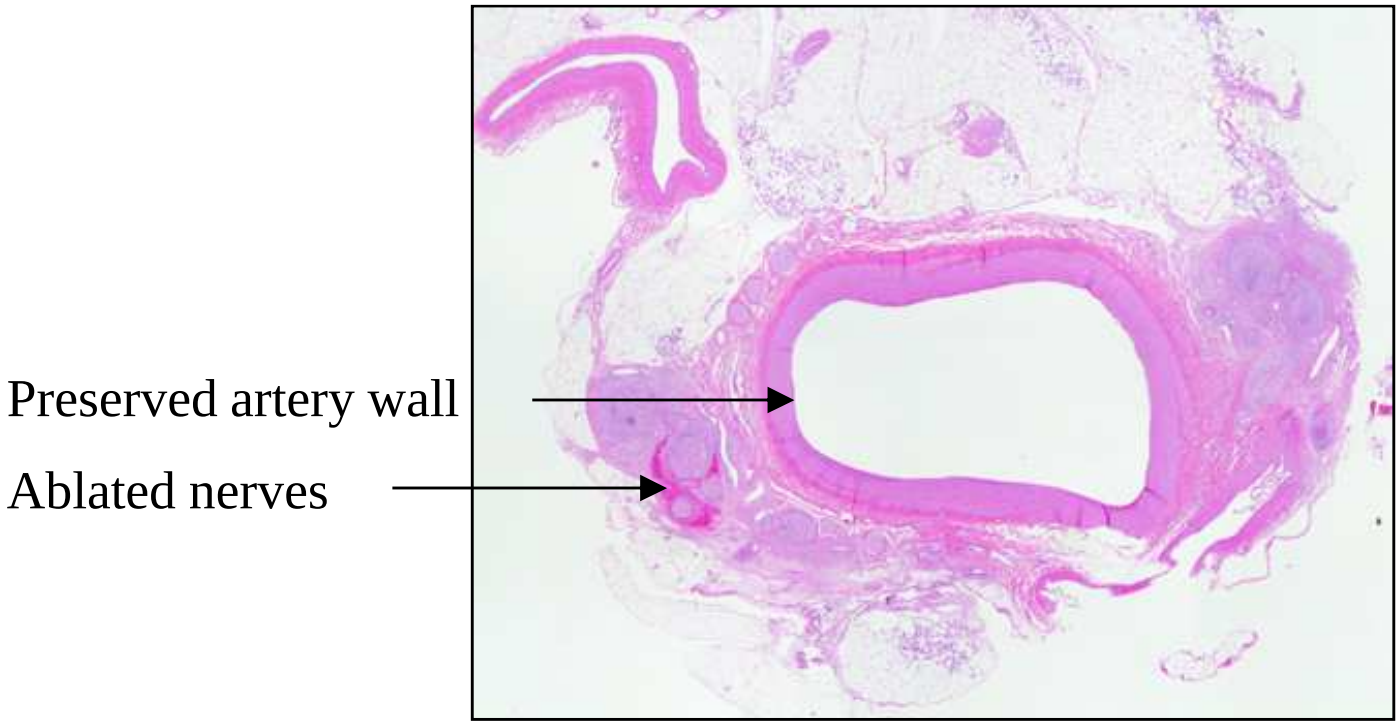


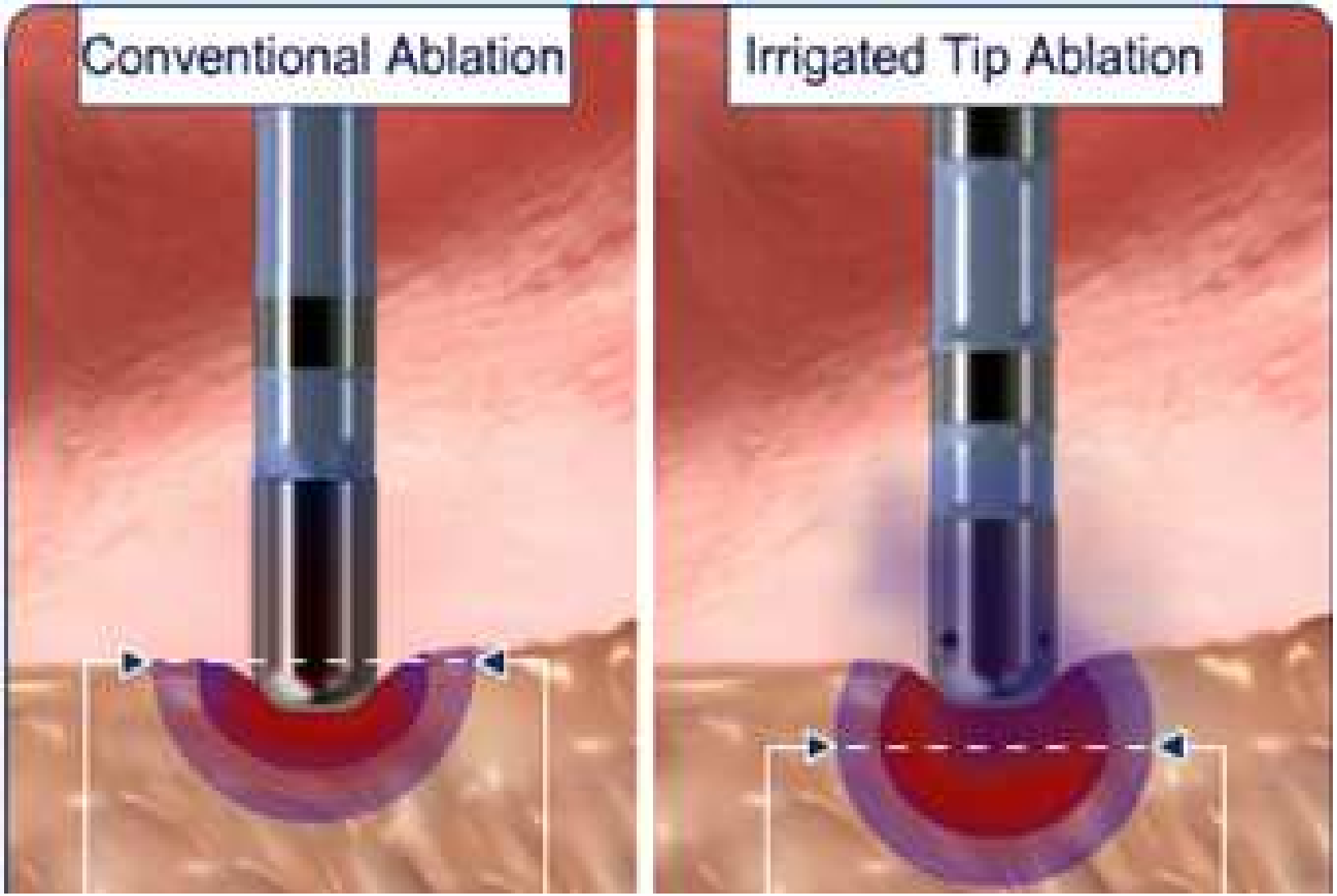
Non-irrigated 65℃



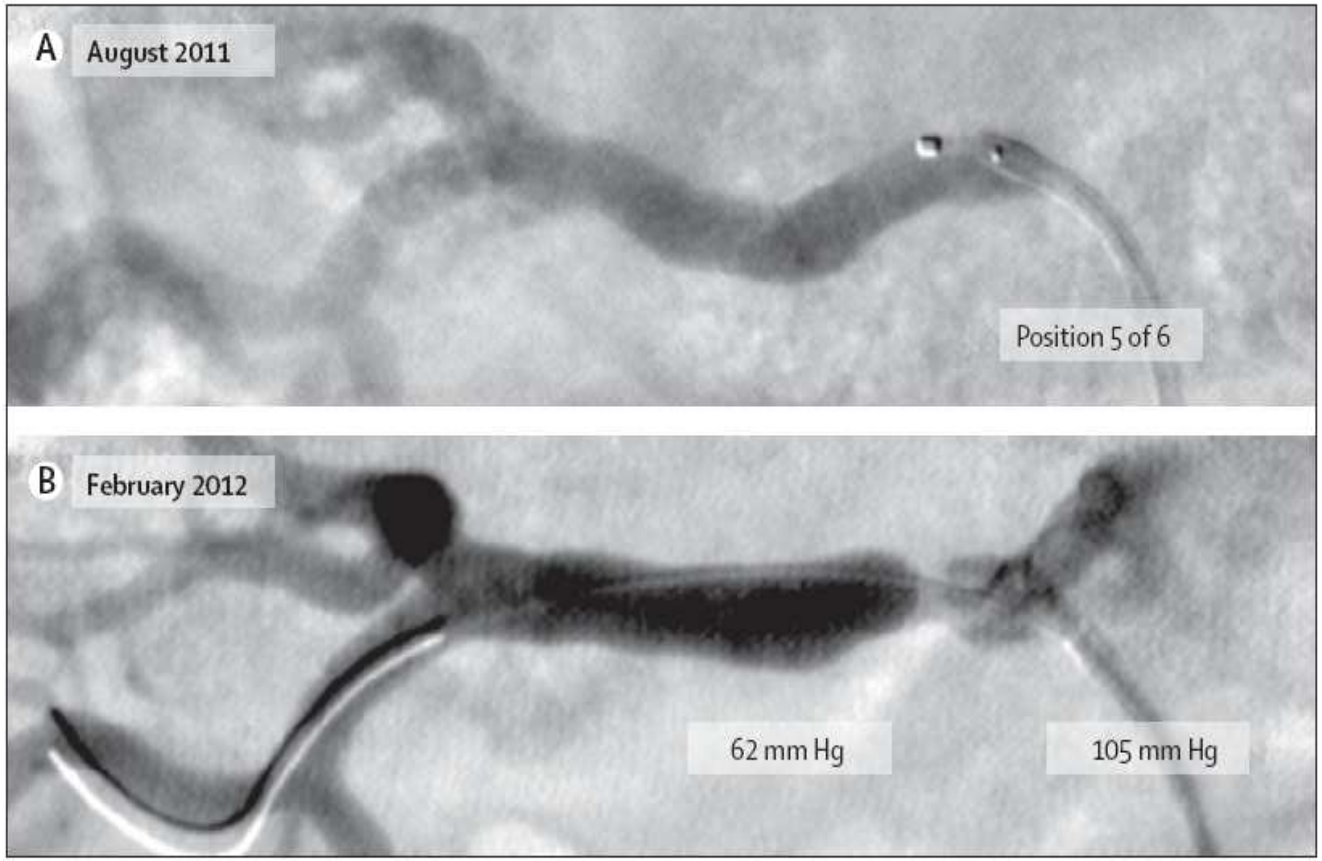
Non-irrigated 90℃

Preclinical Background




Conventional Ablation
Irrigated Tip Ablation

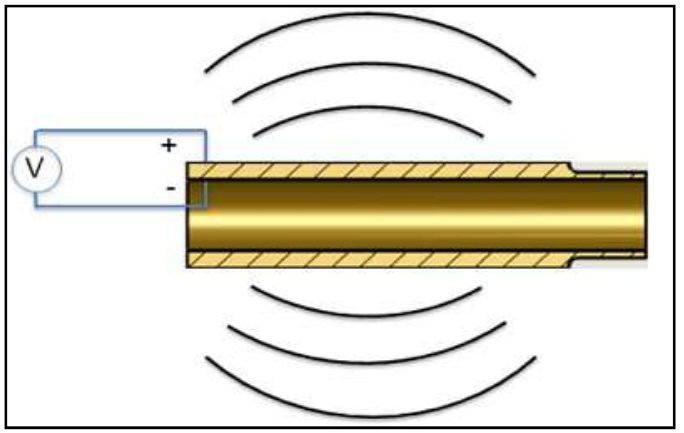
Long term safety



Vonend O et al. Lancet 2012; 380: 778

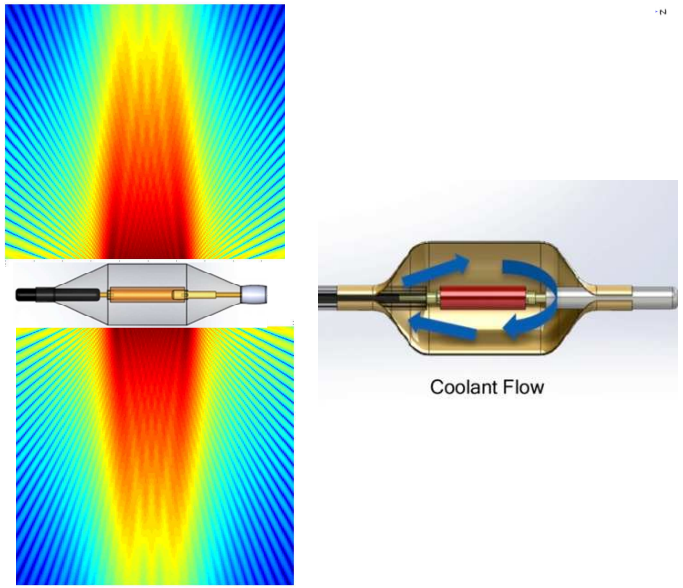
Ultrasound Technology for Renal Denervation

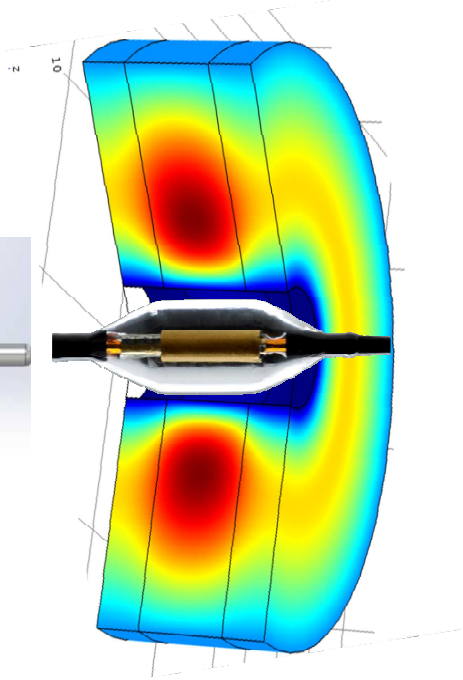
- Therapeutic ultrasound energy consists of high-frequency sound waves that generate frictional heating in soft tissues
    - Direct tissue contact with the ultrasound source is not required for energy transmission
- Cylindrical ultrasound source creates uniform toroidal lesions
- Piezoelectric Ultrasound Transducer
    - expands and contracts when a voltage is applied, create acoustic pressure waves.
    - Acoustic pressure waves generate heat in tissue



Paradise System:
Unique Ultrasound Technology

Ultrasonic Heating + Water Cooling → Paradise Thermal Profile





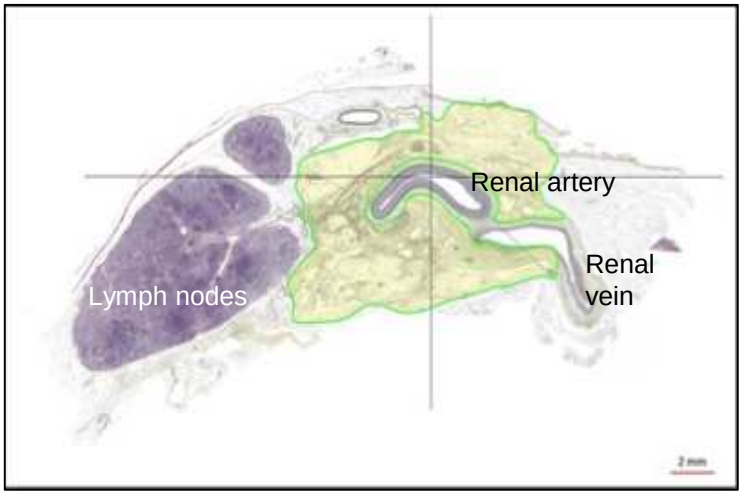
Paradise Thermal Profile:
Protect Renal Arteries & Ablate Renal Nerves

VIDEO

Paradise System Ablation Target

- Target ablation depth: 1mm – 6mm
  - 0-1mm protect arterial wall
  - 1mm-6mm to achieve 80% nerve ablation*
  - 6mm depth avoids regional non-target tissues
- Pre-Clinical Porcine Model (7-day):
  - 7-second ultrasound emission
  - Renal Arterial Wall protected from thermal injury
  - Significant Renal Nerve Injury at each ultrasound emission
  - Achieves target ablation region of 1mm-6mm

Swine Renal Histology

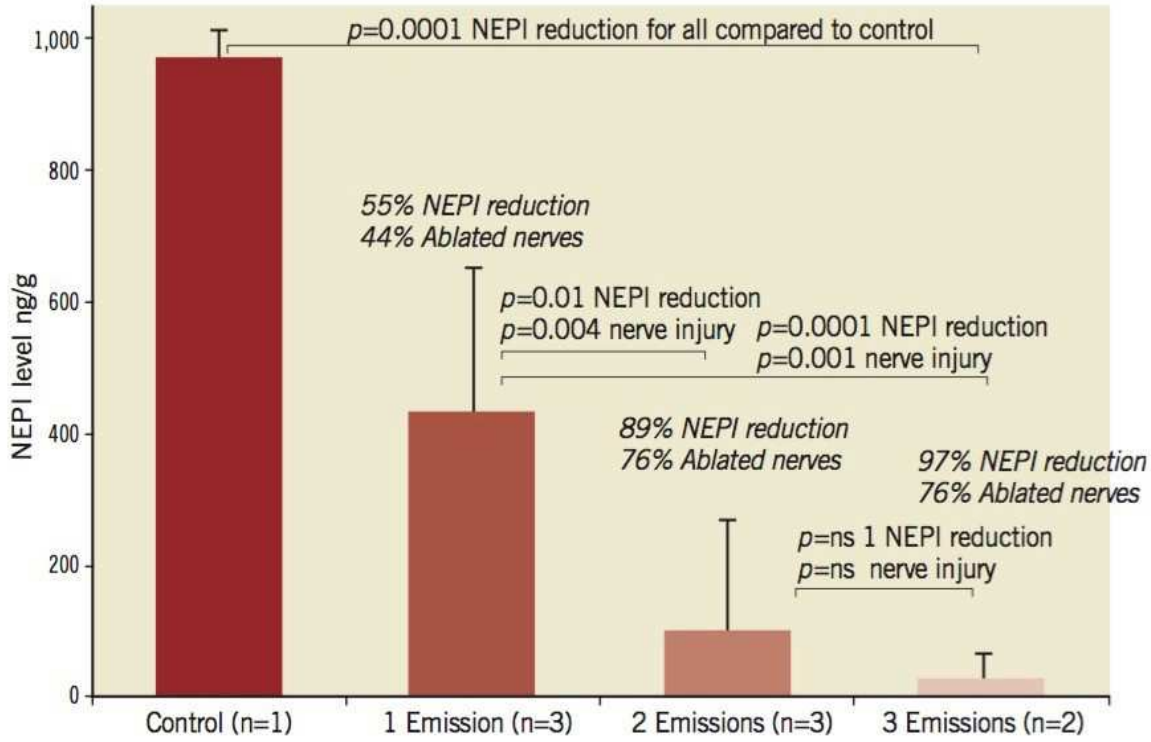


Ablation region indicated in yellow

Paradise Renal Denervation System Protects Renal Arterial Wall and Creates Circumferential Ablative Injury of Renal Nerves

* Sakakura et al, JACC Vol. 64, NO. 7, 2014

Pre-clinical Data Highlights Arterial Wall Protection and NEPI Reduction

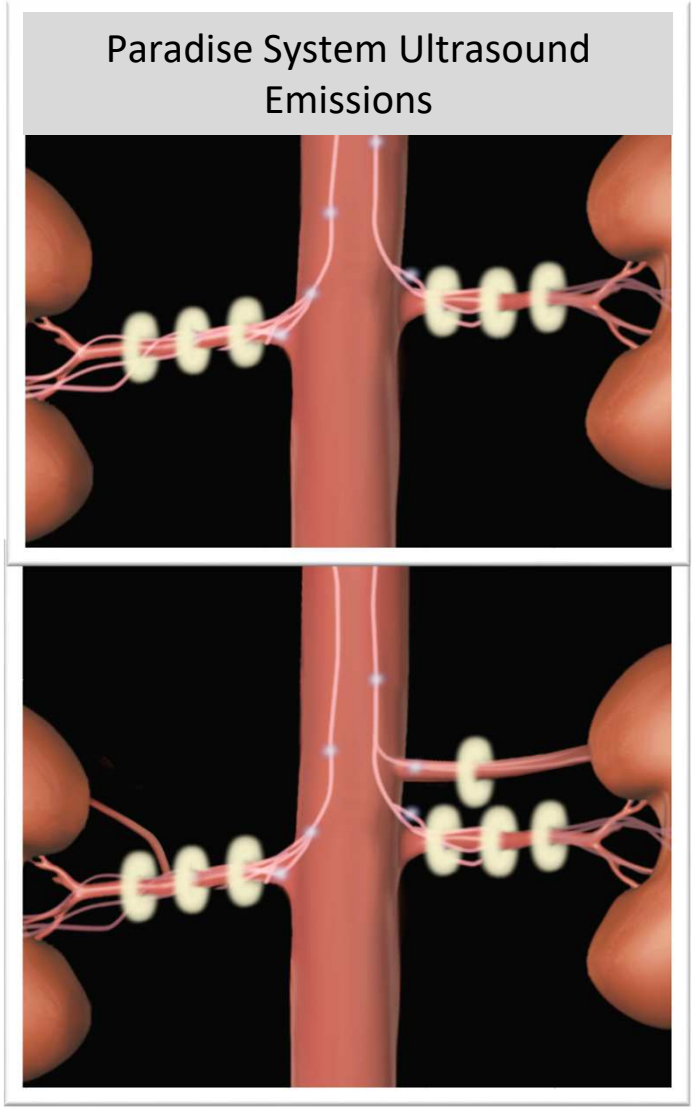


Significant reduction in kidney norepinephrine levels at 7 days with 2-3 ultrasound ablations in the main renal artery

*Pathak A, Eurointervention 2015

RADIANCE-HTN & REQUIRE: Treatment Strategy

- Ablation Strategy
  - Protect the renal artery with cooling
  - Injure up to 80% of the renal nerves
- Target Ablation for each ultrasound emission
  - Target depth of 1mm-6mm
  - No ablation of tissues in 0-1mm
- Treatment Strategy
  - Two to three emissions along each main renal artery
  - A minimum of one emission proximal to side branches off main
  - Treat accessory arteries ≥ 4mm diameter



RADIANCE-HTN & REQUIRE: Treatment Consistency

3mensio MEDICAL IMAGING

Report Details

Creation Date:	2/12/2016	**Physician:**	M. Sapoval
Created By:	Leslie and Shawn	**Hospital:**	Hopital Europeen Georges Pompidou
Received Date:	09Feb2016	**City:**	Paris
Reviewed Date:	09Feb2016	**Country:**	France

Patient Information

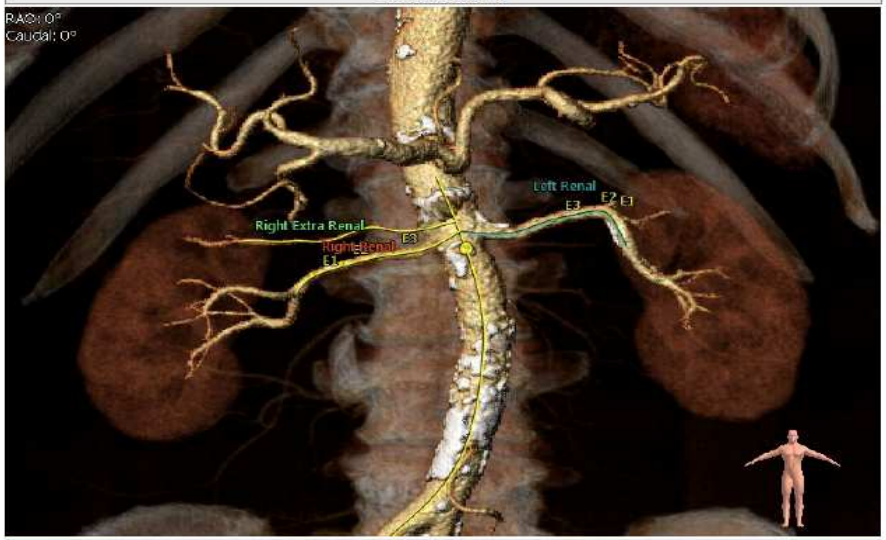
Name:	Paris pt	**Study Description:**	Renal CTA assessment for Paradise treatment
Sex:	Male	**Study Date:**	TBD
Year Of Birth (Age):	1939 (76)		

Comments: Subject has R renal accessory artery. Diameter measured by CTA >2 mm and <4 mm, which would make the subject ineligible for RADIANCE-HTN. Please confirm by angiogram.

If eligible by renal angio, recommended treatment stategy is 3 bilateral emisions in the main renal arteries. See below for details on emission location (E1, E2, E3).

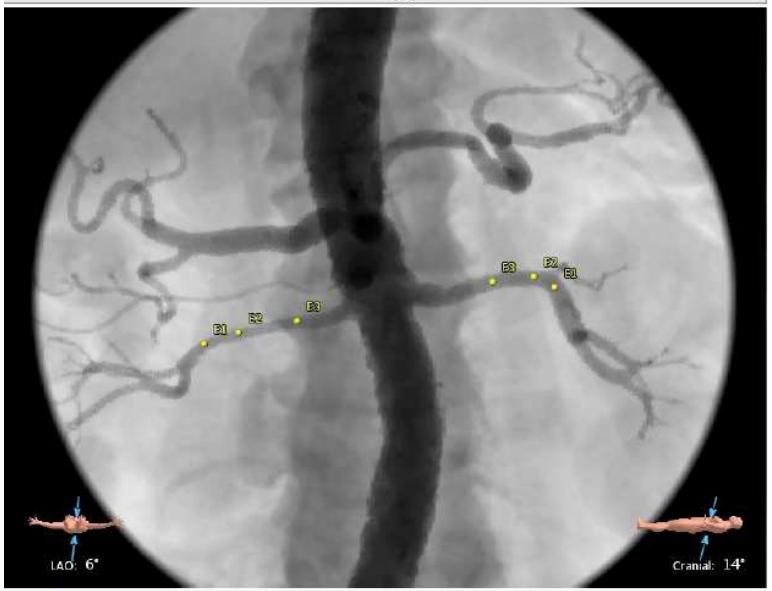
Screenshots

3D volume rendering



- Pre-procedure imaging (CTA/MRA) for anatomical assessment during screening phase
- Treatment strategy recommended centrally for consistency

R Renal C-arm projection



Right renal artery C-arm projection. LAO 6 deg, Cranial 14 deg

Paradise System Conclusion

- Le système Paradise est
  - Simple
  - Fiable
  - Efficace
  - Sécuritaire
- On attend les preuves cliniques qui seront apportées peut-être par les études Solo et Trio