



PLATFORM OF LABORATORIES FOR ADVANCES IN CARDIAC EXPERIENCE

ROMA

Centro Congressi
di Confindustria
Auditorium
della Tecnica

9^a Edizione

30 Settembre
1 Ottobre
2022



Ipertensione arteriosa: terapia personalizzata

PRATICA CLINICA:

IL PERCORSO DIAGNOSTICO TERAPEUTICO

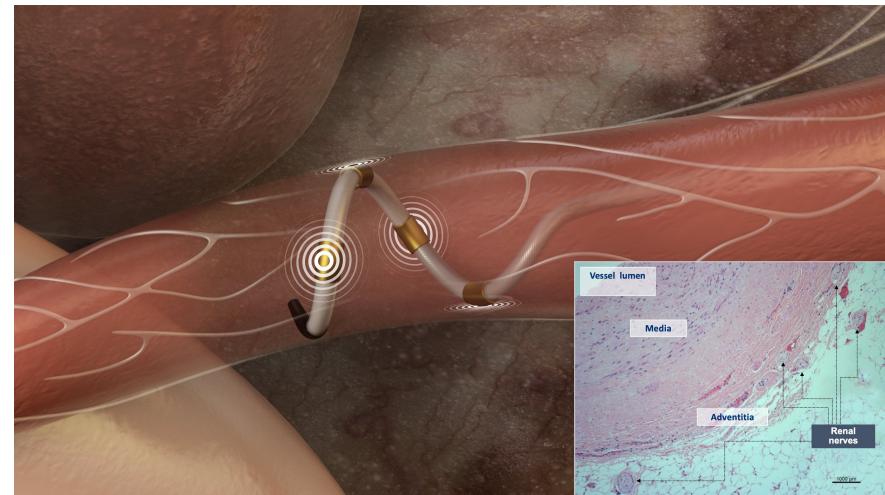
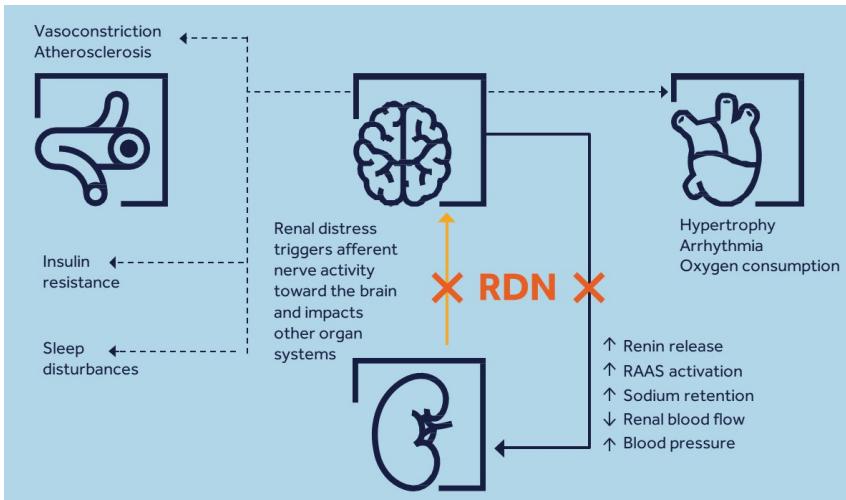
E LA TECNICA INTERVENTISTICA

Petrolini Alessandro

European Hospital - Aurelia Hospital , Roma



Nei casi di ipertensione resistente a terapia l'**ablazione transcatetere con radiofrequenza** dell'innervazione simpatica a livello delle arterie renali (RDN) si è dimostrata **efficace** e **sicura** nel ridurre la pressione arteriosa.




ESC/ESH GUIDELINES

2018 ESC/ESH Guidelines for the management of arterial hypertension

The Task Force for the management of arterial hypertension of the European Society of Cardiology (ESC) and the European Society of Hypertension (ESH)

Device-based therapies for hypertension

Recommendation	Class ^a	Level ^b
Use of device-based therapies is not recommended for the routine treatment of hypertension, unless in the context of clinical studies and RCTs, until further evidence regarding their safety and efficacy becomes available. ^{367,368}	III	B

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RDN Consensus Statements Published in Multiple Countries





Renal denervation: which patient?



Universal Patient Consideration themes across statements

Hypertensive BP

Blood pressure uncontrolled despite attempted hypertensive medications and lifestyle interventions

Confirm primary HTN

Rule out any secondary causes of hypertension

Patient voice

Emphasis must be placed on individualized treatment and patient preference given the challenges with medication adherence

Elevated CV risk

Global CV risk, hypertension-mediated organ damage, or established cerebro- or cardiovascular disease

Rule out whitecoat

Identify and rule out white coat hypertension with elevated out of office blood pressure



Causes, prevalence and diagnostic evaluation of secondary hypertension

Cause	Prevalence	Primary diagnostic evaluation	Confirmatory test
Hyperaldosteronism	1.4-10 %	Laboratory testing Aldosterone-renin quotient and absolute serum aldosterone concentration	- Sodium chloride tolerance test - CT or MRI of the adrenal glands - Selective adrenal venous sampling
Cushing syndrome	0.5 %	Cortisol in 24h urine sample	Dexamethasone suppression test
Pheochromocytoma	0.2-0.5 %	Metanephrines in plasma	- CT or MRI of the abdomen - ¹²³ I-MIBG scintigraphy
Thyroid diseases	1-2 %	Measurement of serum TSH, FT3, FT4	Thyroid ultrasonography or scintigraphy
Renal parenchymal disease	1.6-8 %	Renal ultrasonography Urinalysis	Detailed work-up for renal disease
Renal artery stenosis	1-8 %	Duplex ultrasonography of the kidneys and renal arteries	Contrast-enhanced CT or MRI of the renal arteries
Sleep apnea	>5-15 %	Polygraphy	Polysomnography
Aortic isthmus stenosis	< 1 %	Blood pressure difference right vs left arm and upper vs lower limb. Echocardiography	Contrast-enhanced CT or MRI of the thoracic aorta

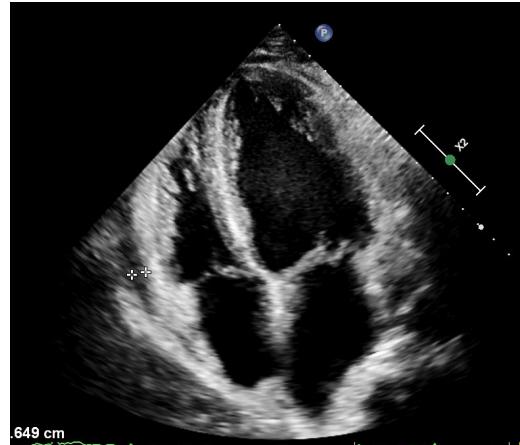


Anamnesi

- ✓ Uomo 71 anni, familiarità per MCV.
- ✓ Iipertensione arteriosa, dislipidemia, diabete mellito, obesità (BMI 31), lievi varici venose aa inferiori.
- ✓ Accessi in PS per crisi ipertensive, in un'occasione con manifestazione di TIA, ricoverato per alterazioni aspecifiche all'ECG con Ecocardiogramma normale tranne IVS, minimo incremento dei markers di miocitonecrosi.
- ✓ Pregressa scintigrafia miocardica da sforzo dubbia per deficit ischemici.
- ✓ Trasferito da altra struttura per eseguire coronarografia.



Ricovero in cardiologia

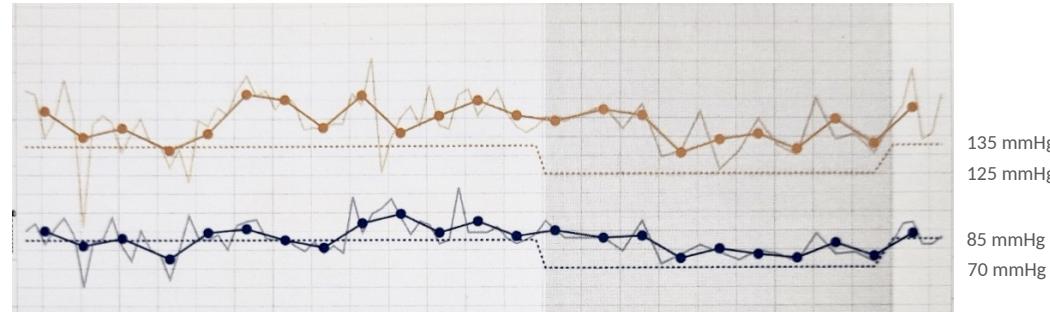


- TC e RM cranio negativa
- Esami ematochimici nei limiti (GFR 50, LDL 68, TpHS negativa, TSH nella norma)



Ricovero in cardiologia

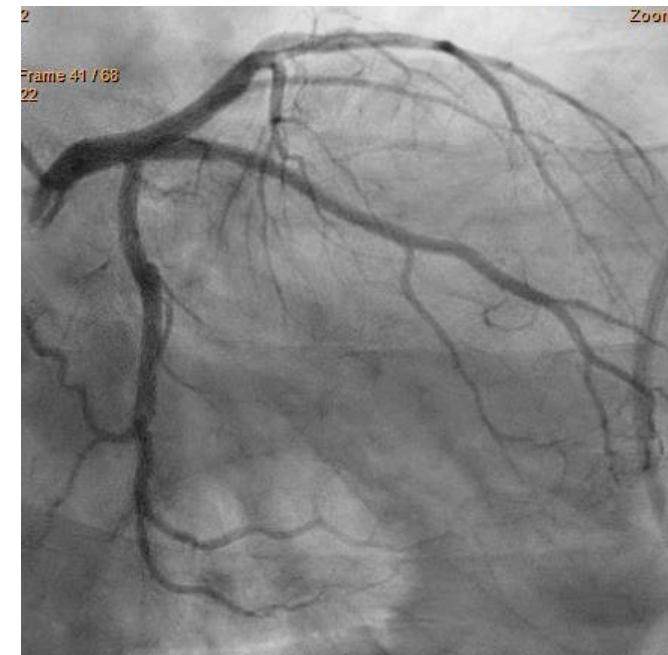
- Terapia domiciliare:
 - Olmesartan/HCT 40/25 mg
 - Atenololo 50 mg
 - Amlodipina 5 mg (?)
 - Metformina 1000 mg x 2
 - Atorvastatina 20 mg
 - Allopurinolo 150 mg
 - Cardioaspirin





Ricovero in cardiologia

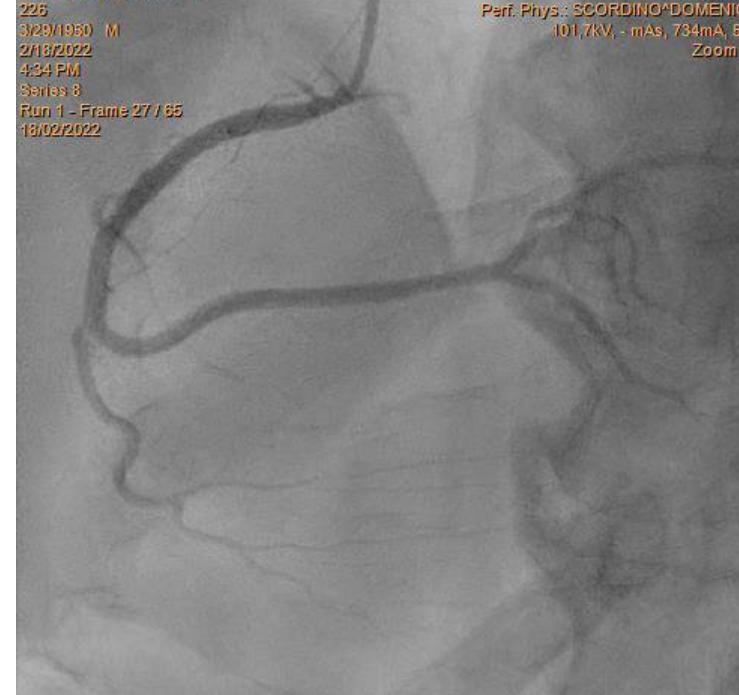
- Coronarografia (accesso radiale):





Ricovero in cardiologia

- Coronarografia (accesso radiale):





Ricovero in cardiologia

- Angiografia arterie renali (accesso radiale, PigTail o JR):
 - Controllo possibilità di accesso femorale.
 - Valutare fattibilità casi con stenosi dell'arteria renale, presenza di displasia fibromuscolare, aneurismi, calcificazioni, pregresso stenting.
 - Presenza di arterie renali accessorie.
 - Pianificazione della denervazione (catetere guida per la RDN, vasi target: 3-8mm, extraparenchimali).

Alternative all'angiografia sono angioTC, angioRM o anche ecocolorDoppler



Ricovero in cardiologia

- Angiografia arterie renali (accesso radiale):

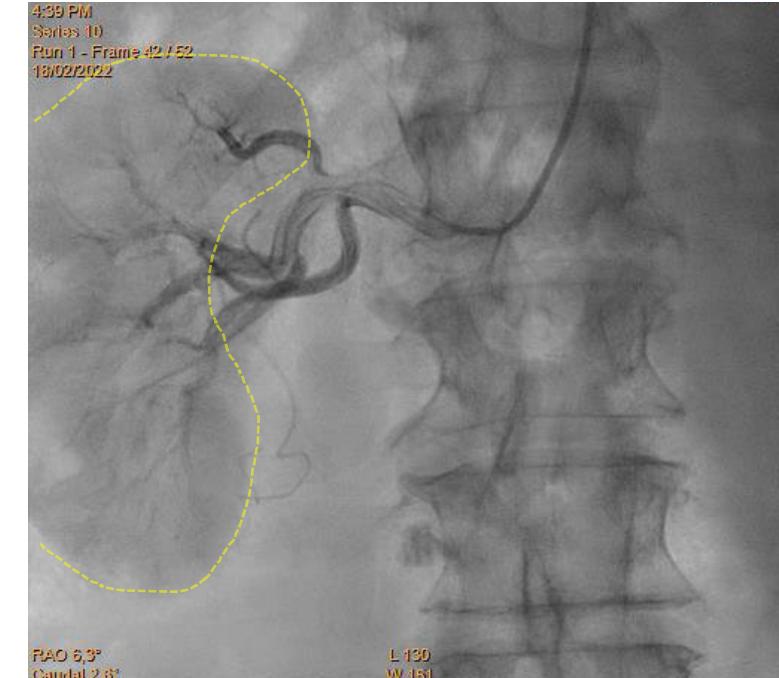


Renale sinistra



Ricovero in cardiologia

- Angiografia arterie renali (accesso radiale):



Renale destra



Ricovero in cardiologia

Asintomatico, incrementata la terapia ipotensiva durante la degenza ma paziente intollerante e poco compliant alla terapia con Amlodipina

- Olmesartan 40 mg
- Atenololo 50 mg
- Furosemide **50 mg**
- **Amlodipina 5 mg**
- Doxazosina 2 mg
- Metformina 1000 mg x 2
- Atorvastatina 20 mg
- Allopurinolo 150 mg
- Cardioaspirin



Ricovero in cardiologia

- Ripetuto Monitoraggio PA 24h dopo 3 giorni
- Screening per ipertensione secondaria



Persistono valori superiori a

140/85mmHg con ridotto Time to Target
Range



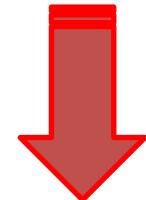
Negativ
o



Rischio CV elevato,
danno d'organo



Nota scarsa compliance del
paziente



Indicazione a Denervazione Renale



Procedura RDN

Select eligible patients
–
Informed consent

Renal Anatomy Assessment
(CTA, MRA, DUS)

Plan treatment areas

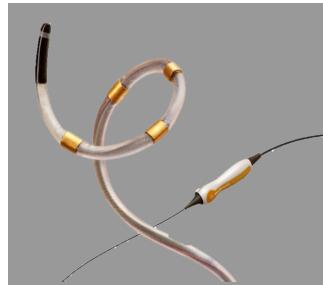
Sedation, selective angiography, guidewire positioning, RDN catheter deployment

Treat branches first and followed by main renal artery

Switch to opposite renal artery



Symplicity G3™



**Symplicity
Spyral™**

- Multi-electrode catheter with quadrantic vessel contact for simultaneous ablation in up to 4 electrodes
- Flexible catheter allows branch treatment
- 60-second simultaneous RF energy delivery
- Vessel diameter range: 3 – 8 mm
- 6F guide catheter 45–90 cm (IMA/LIMA or RDND1/RDC1)
- 0.014" guidewire (non-hydrophilic, supportive, with a floppy tip recommended)

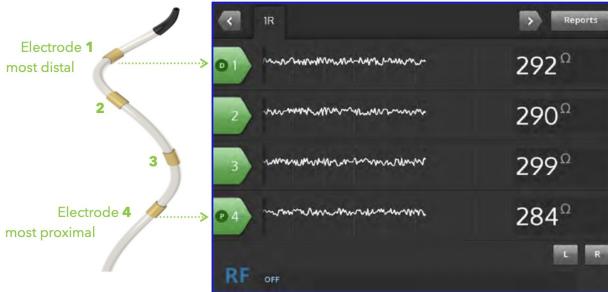
Patient preparation

- Morphine 10 mg i.m. 30' pre-procedure
- ASA
- Midazolam / Paracetamol
- Fentanyl 1 mg on arrival in Cath Lab
- Repeat fentanyl 1 mg in case of pain
- Contrast medium 50% diluted
- Echo-guided femoral access
- Heparin 70 U/kg (ACT 250")





Generator display

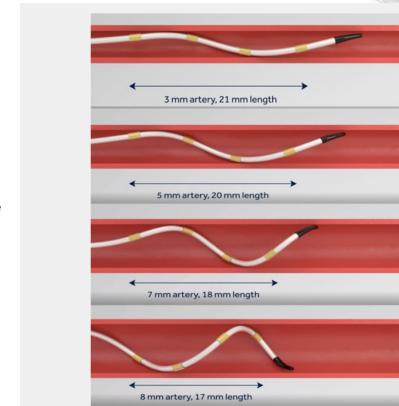


Example of Symplicity G3 generator display showing impedance at all four electrodes.

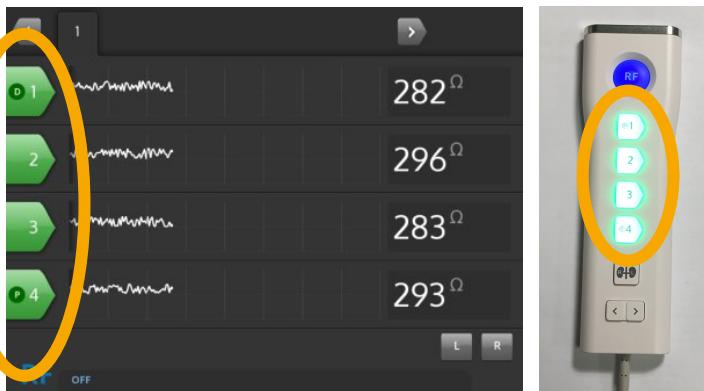
- Electrodes are numbered from distal to proximal and are independently selectable.
- Monitor each electrode on the Symplicity G3™ renal denervation RF generator's display.

One size fits arteries 3-8 mm¹

- Renal arteries from 3 to 8 mm in diameter can be treated with a single Symplicity Spyral™ catheter
- Symplicity Spyral catheter conforms to the vessel size and corresponding treatment length* depends on the vessel diameter.

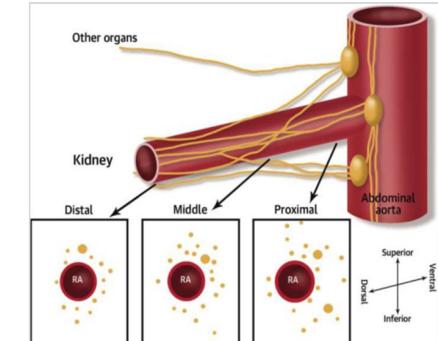
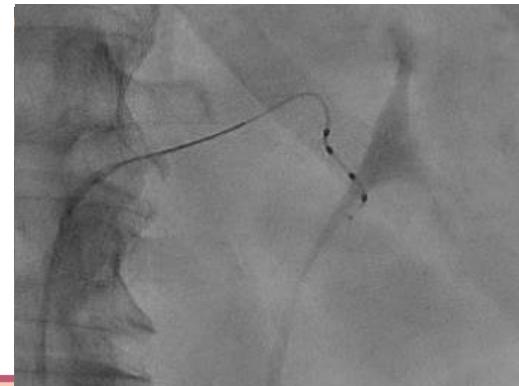
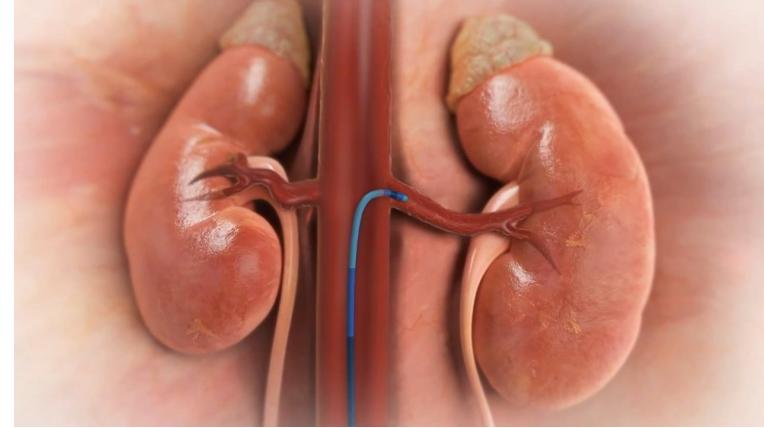
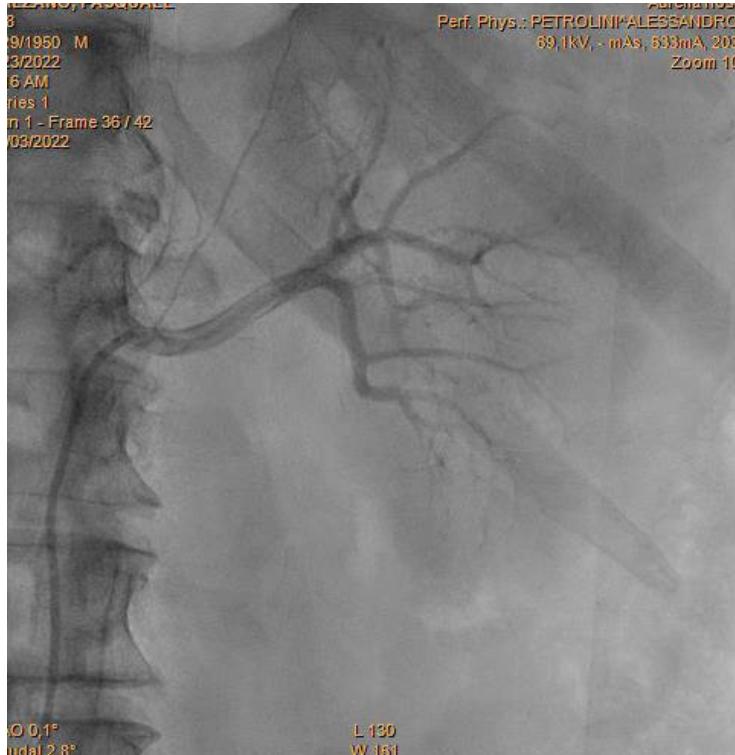


Close





Procedura RDN

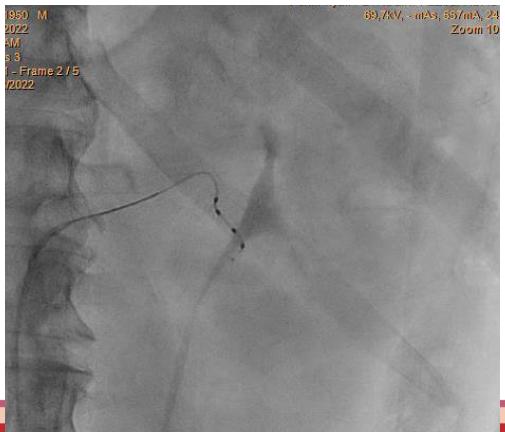
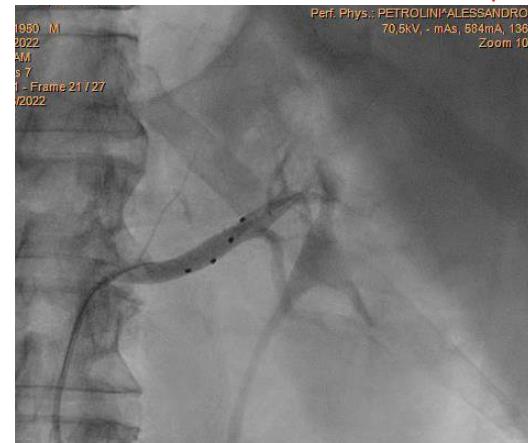
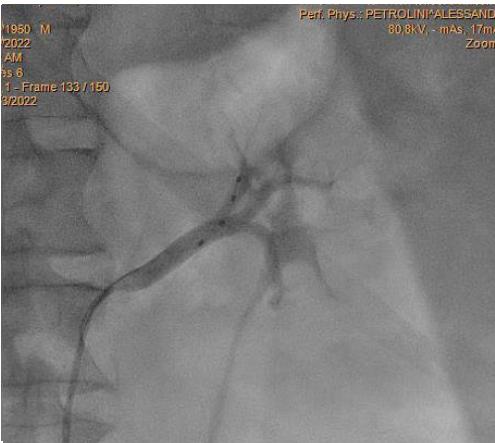
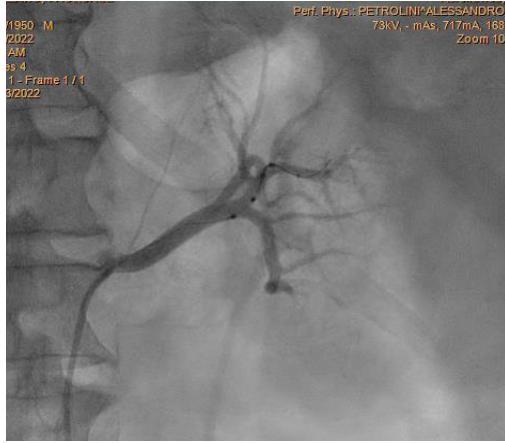


Iipertensione arteriosa: terapia personalizzata

PRATICA CLINICA: IL PERCORSO DIAGNOSTICO TERAPEUTICO E LA TECNICA INTERVENTISTICA

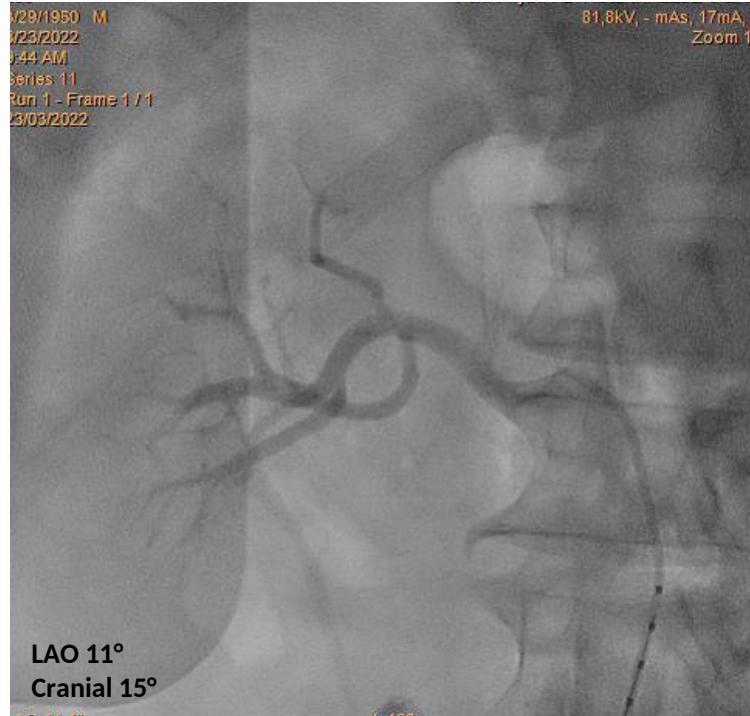
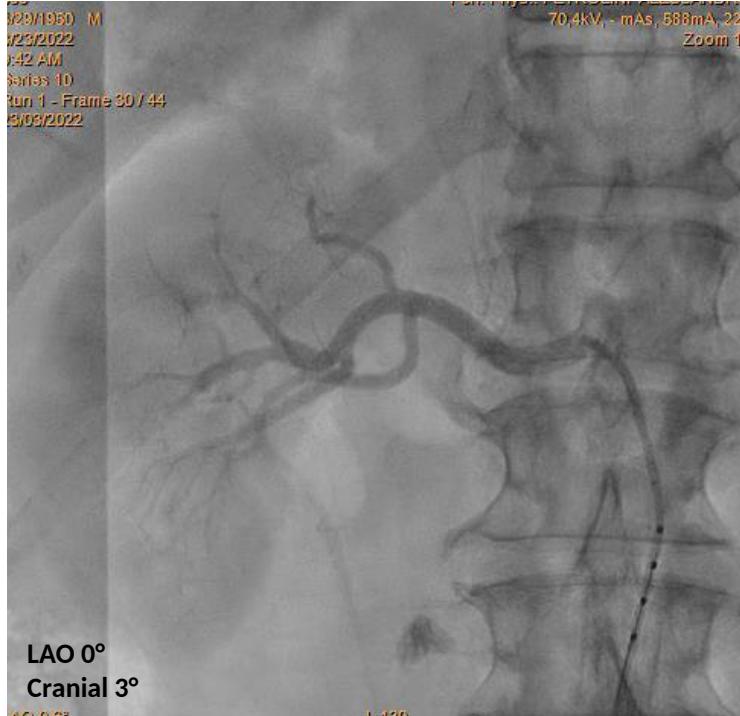


Procedura RDN sinistro



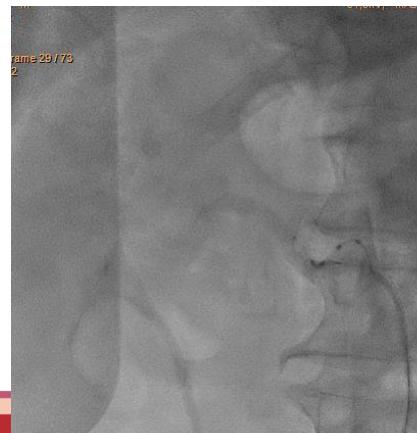
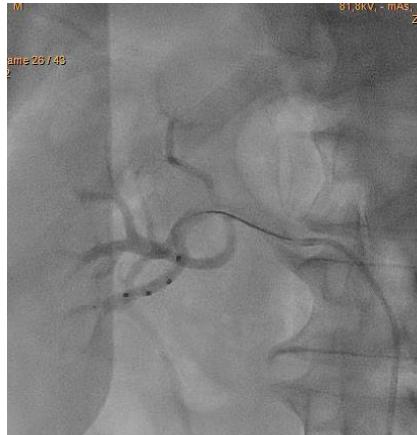
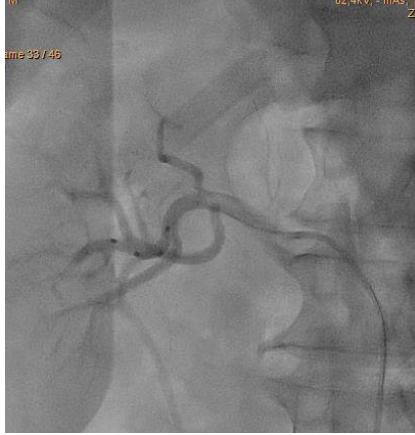


Procedura RDN destro





Procedura RDN destro




CASE REPORT
Renal Denervation
**UNCONTROLLED HTN UNIT FOR RENAL DENERVATION (RDN)**

Hospital	Aurelia Hospital
Proceduralist Name	Alessandro Petrolini, Stefano Migliaro
City	Roma
Procedure Date and Time	23/03/22 ; 08:00

PATIENT INFORMATION

Name and Surname	P.B.
Year of Birth	1950
Gender	Male
Previous Renal Interventions	None

PATIENT DATA**Baseline Office BP**

OSBP	150 mmHg
ODBp	80 mmHg

Pharmacological Treatment

N° Hypertension medications	4
Length of time	years of pharmacological treatment
Any known medication side effects and/or intolerance to HTN medications?	
(cough, rash, dizziness, light-headedness, inflammation, shortness of breath, constipation, salty metallic taste, chest pain, kidney failure)	
>	Intolerant to calcium channel blocker;
>	;
>	;

CARDIOVASCULAR RISKS
 prior MI, Stroke, CAD, HF, AF

- > Diabetes Mellitus;
- > Dyslipidemia;

ANATOMICAL FEATURES

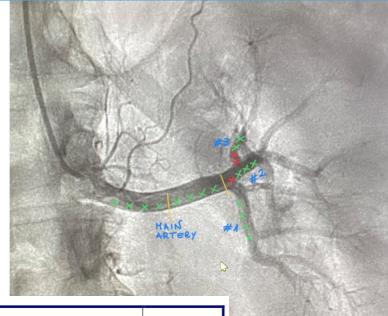
(complete with yes/no)

no	Vasculorenal Hypertension (Renal Artery Stenosis or Fibromuscular Dysplasia)
yes	Normal Renal US Doppler
yes	Normal Renal Angio – CT

OTHER CONSIDERATIONS

(not required/complete if known)

- > _____;
- > _____;
- > _____;

LEFT KIDNEY

- Activated Electrode;
- Non Activated Electrode;
- Detected Error;
- Successfully Repeated Ablation.

N° ABLATIONS		TOTAL
BRANCHES	9	17
MAIN ARTERY	8	

RIGHT KIDNEY

- Activated Electrode;
- Non Activated Electrode;
- Detected Error;
- Successfully Repeated Ablation.

N° ABLATIONS		TOTAL
BRANCHES	11	20
MAIN ARTERY	9	



Decorso e dimissione

- Nessuna complicanza vascolare
- Assenza di anemizzazione né alterazioni della funzionalità renale / elettroliti

Terapia alla dimissione

- Olmesartan 40 mg
- Atenololo 50 mg
- Furosemide 50 mg
- Amlodipina 5 mg
- Doxazosina 2 mg
- Metformina 1000 mg x 2
- Atorvastatina 20 mg
- Allopurinolo 150 mg
- Cardioaspirin
- Clopidogrel 75 mg per un mese

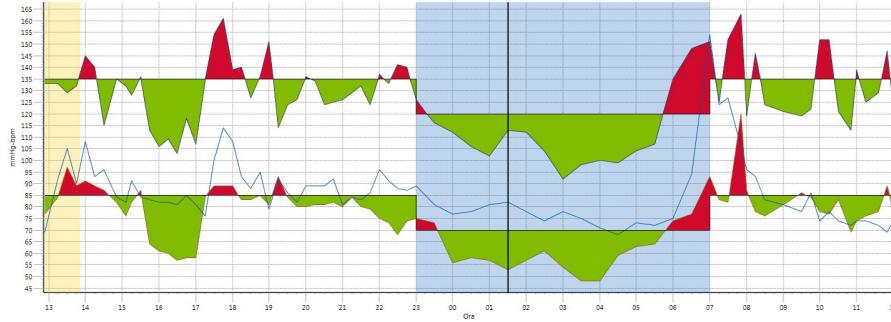
Programmato follow-up



Follow-up 3 mesi

- Nessun evento clinico
- Esami ematici nella norma
- Modificata la terapia:

- | | |
|----------------------------------|--|
| ○ Olmesartan HCT 40/25 mg | ○ Metformina 1000 mg x 2 |
| ○ Atenololo 50 mg | ○ Atorvastatina 20 mg |
| ○ Furosemide 50 mg | ○ Allopurinolo 150 mg |
| ○ Amlodipina 5 mg | ○ Cardioaspirin |
| ○ Doxazosina 2 mg (?) | ○ Clopidogrel 75 mg per un mese |



Data	Ora	Pressione max	Pressione min	Frequenza	Note
27/9/22	9 ^a	138	80	68	
"	19 ^a	130	80	60	
2/10/22	10 ^a	128	78	65	
"	19 ^a	133	85	72	
6/10/22	10 ^a	143	85	77	
"	21 ^a	134	78	68	
10/10/22	8 ³⁰	136	80	64	
"	18 ⁰⁰	131	78	61	
15/10/22	18 ^a	151	88	73	Poco Nocivo 5
16/10/22	8 ⁰⁰	132	78	68	
20/10/22	11 ^a	126	74	66	
"	18 ⁰⁰	128	76	70	Caduta gafie
23/10/22	8 ⁰⁰	129	78	63	
"	19 ⁰⁰	137	80	69	



Renal denervation: which patient?



Uncontrolled
hypertension
?

Resistant
hypertension
?

...what
about
diuretics ?

Refractory
hypertension
?

...what
about
adherence
?

Controlled
with 4
drugs ?

Uncontrolled
with 3
drugs ?





Renal denervation: which patient?

IL DOCUMENTO DI CONSENSO

Consensus Document

European Society of Hypertension position paper on renal denervation 2021

Roland E. Schmieder^a, Felix Mahfoud^b, Giuseppe Mancia^c, Michael Azizi^d, Michael Böhm^e, Kyriakos Dimitriadis^f, Kazuomi Kario^g, Abraham A. Kroon^h, Melvin D Loboⁱ, Christian Ott^{a,j}, Atul Pathak^k, Alexandre Persu^l, Filippo Scalise^m, Markus Schlaichⁿ, Reinhold Kreutz^o, Costas Tsoufis^p, on behalf of members of the ESH Working Group on Device-Based Treatment of Hypertension

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DOI:10.1097/HJH.0000000000002933

PUNTI PRINCIPALI

- «Sulla base di risultati ottenuti da trial clinici, la denervazione renale rappresenta un'opzione evidence-based per il trattamento dell'ipertensione, **che si aggiunge al corretto stile di vita ed ai farmaci per abbassare la pressione.**»
- «RDN è considerata una procedura endovascolare **sicura senza significativi effetti avversi** sia a breve che a lungo termine, sulla base di evidenze disponibili fino a 3 anni (GSR).»
- «RDN dovrebbe essere considerata un'opzione di trattamento anti-ipertensivo che riduce la pressione arteriosa e contribuisce a **migliorare la prognosi cardiovascolare dei pazienti ipertesi.**»
- «RDN è una strategia di trattamento alternativa o complementare, **non concorrenziale** (rispetto alle altre opzioni disponibili). Le preferenze del paziente, il livello di ipertensione (comorbidità incluse), dovrebbero portare ad una strategia di trattamento individualizzata in un processo di **shared decision-making**, che consideri attentamente le varie opzioni di trattamento, inclusa la RDN.»



Renal denervation: which patient?

POSITION PAPER



Società Italiana dell'Iipertensione Arteriosa
Lega Italiana contro l'Iipertensione Arteriosa

High Blood Pressure &
Cardiovascular Prevention

ISSN 1120-9879

High Blood Press Cardiovasc Prev
DOI 10.1007/s40292-020-00367-0

Italian Society of Arterial Hypertension (SIIA) Position Paper on the Role of Renal Denervation in the Management of the Difficult-to-Treat Hypertensive Patient

Rosa Maria Bruno^{1,2}  · Stefano Taddei¹ · Claudio Borghi³ · Furio Colivicchi⁴ · Giovambattista Desideri⁵ ·
Guido Grassi⁶ · Alberto Mazza⁷ · Maria Lorenza Muiesan⁸ · Gianfranco Parati^{9,10} · Roberto Pontremoli¹¹ ·
Bruno Trimarco¹² · Massimo Volpe^{13,14} · Claudio Ferri⁵

Received: 23 October 2019 / Accepted: 2 March 2020

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Renal Denervation in the management of Hypertension in adults, a Clinical Consensus
Statement of the ESC Council of Hypertension and the European Association of Cardiovascular
Interventions (EAPCI)
(in press)



Renal denervation: which patient?

1

RECOMMENDED

Essential hypertensive patient uncontrolled by an association

- RAS-blocker
- calcium-channel blocker
- diuretic

at maximally tolerated doses

Additional features:

- Adverse effects with spironolactone
- Poor drug adherence despite extensive counseling
- Systo-diastolic hypertension
- No extensive vascular damage
- High/very high lifetime cardiovascular risk
- Patient preferences

2

POSSIBLE

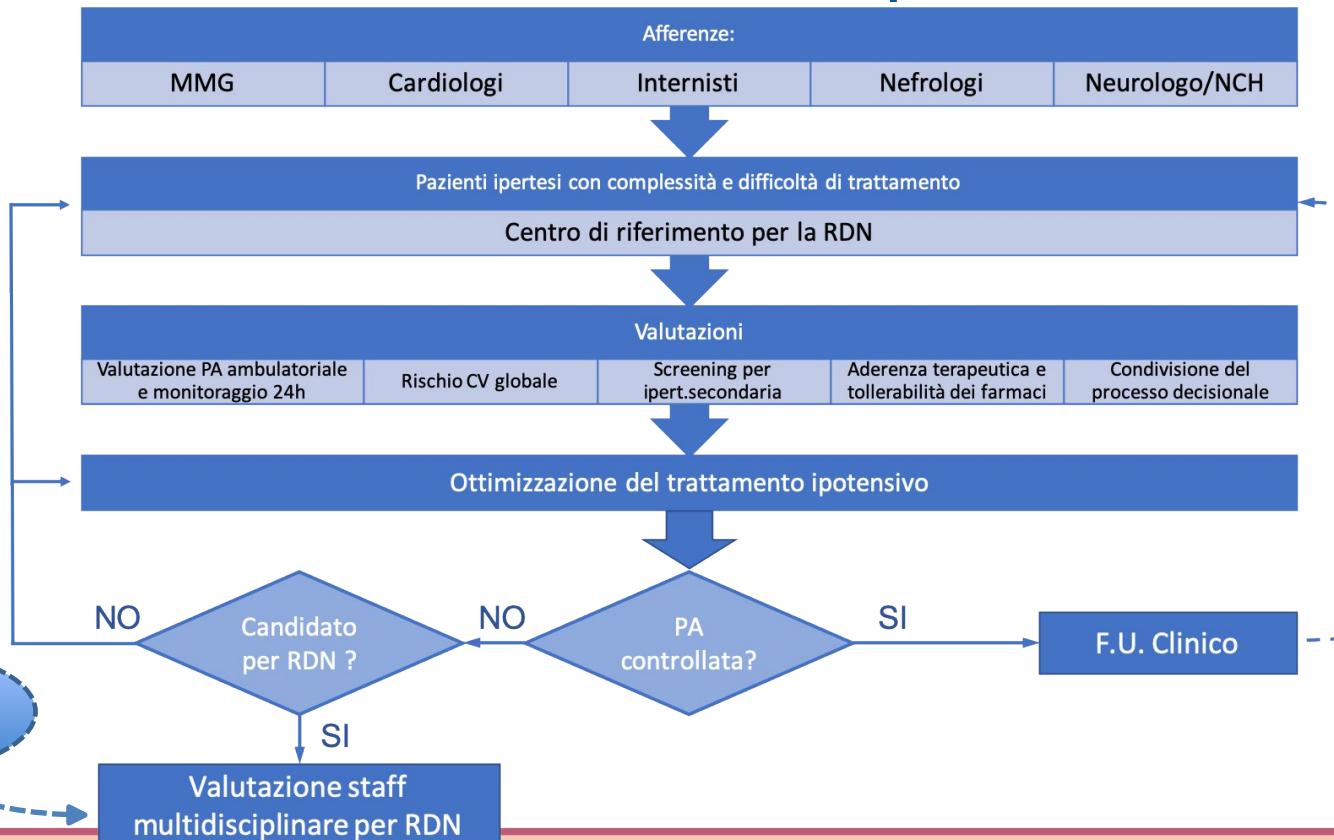
Grade 1–2, systo-diastolic, essential hypertensive patient, untreated or uncontrolled by 1–2 BP lowering drugs

Additional features:

- Multiple intolerance to BP-lowering drugs/adverse effects
- Poor drug adherence despite extensive counseling
- High/very high lifetime cardiovascular risk
- Paroxysmal atrial fibrillation and planned ablation
- Patient preferences



Renal denervation: which patient?





CONCLUSIONI

- ✓ La RDN è una metodica sicura ed efficace di trattamento interventistico dell'ipertensione arteriosa.
- ✓ Lo scopo è il miglior controllo dei valori pressori e non la riduzione della terapia.
- ✓ Procedura da eseguire correttamente (effetti non immediati!)
- ✓ Saper gestire le complicanze vascolari.
- ✓ Va migliorata l'informazione degli specialisti (e dei pazienti, da coinvolgere).
- ✓ Individuare percorsi specifici per l'indicazione a RDN.
- ✓ Cambiare la prospettiva da «ipertensione difficile da trattare» a «paziente difficile da curare».
- ✓ Verosimile ruolo terapeutico aggiuntivo nei pazienti con scompenso cardiaco.



Alessandro Petrolini

Cardiologia interventistica

European Hospital - Aurelia Hospital

Roma

petrolini@gmail.com





RDN Aurelia Hospital (March-May 2022)

5 patients: 4 with difficult to treat hypertension (taking at least 3 medications)

1 resistant patient (taking all available and tolerated medications)

CHARACTERISTICS	N (%) or Median (IQR)
Male sex	4 (80%)
Age, yrs	69 (58-75)
DM II	1 (20%)
Smoking Habit	2 (40%)
Previous Revascularization	2 (40%)
FE<50%	0
Stroke/TIA	1
Peripheral artery disease	0
CKD	1 (20%)

	Baseline Median	1 month	1 month Change
24 hr Sys BP mmHg	151 (136-160)	132 (113-140)	-12.6%
24 hr Dya BP mmHg	81 (80-82)	80 (70-92)	-1.2%
Pts taking HT drugs:			
- ACEi/ARB	5 (100%)	5 (100%)	=
- CCB	3 (60%)	2 (40%)	-30%
- Hzt	2 (40%)	1 (20%)	-50%
- Loop diuretics	2 (40%)	1 (20%)	-50%
- BB	5 (100%)	5 (100%)	=
- MRA	1 (20%)	1 (20%)	=
- Alfa blocker	2 (40%)	2 (40%)	=
Median number of drugs	4 (4-4)	4 (3-4)	=



RDN Aurelia Hospital (March-May 2022)

5 patients: 4 with difficult to treat hypertension (taking at least 3 medications)

	Median (IQR)	medications)
Num of ablation sites: RRA	23 (17-28)	Symplicity HTN-3 11 ± 3
Num of ablation sites: LRA	20 (16-26)	Spyral HTN OFF MED 44 ± 13
Num of ablation sites: Total	45 (33-49)	Spyral HTN ON MED 46 ± 14

No complications

GSR DEFINE Registry

Antiaggregazione e RDN

- ✓ SAPT pre-procedura
- ✓ ACT 250" durante procedura
- ✓ DAPT post-procedura durante degenza
- ✓ In dimissione DAPT 3-6 mesi se complicanze vascolari
- ✓ In dimissione DAPT 1 mese se basso rischio di sanguinamento
- ✓ In dimissione SAPT per 3 mesi se HBR
- ✓ Se in NAO/TAO valutare SAPT+NAO a breve termine o solo NAO.
- ✓ A 3 mesi valutazione SAPT / DAPT

- ✓ In realtà si va nella direzione della SAPT (1 mese?) (o NAO se il paziente è già in NAO) !



9^a Edizione

Iipertensione arteriosa: terapia personalizzata

PRATICA CLINICA: IL PERCORSO DIAGNOSTICO TERAPEUTICO E LA TECNICA INTERVENTISTICA





9^a Edizione

Iipertensione arteriosa: terapia personalizzata

PRATICA CLINICA: IL PERCORSO DIAGNOSTICO TERAPEUTICO E LA TECNICA INTERVENTISTICA



Caso clinico: Quale paziente iperteso trattare con denervazione renale percutanea?

Renal denervation: which patient?

Original Article

OPEN

Differences in patient and physician perspectives on pharmaceutical therapy and renal denervation for the management of hypertension

Roland E. Schmieder^a, David E. Kandzari^b, Tzung-Dau Wang^c, Ying-Hsiang Lee^d, Gabriel Lazarus^e, and Atul Pathak^f

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TABLE 1. Major physician-reported hurdles to greater uptake of renal denervation in Europe

Item indicated by physician	Interventional cardiologist (n = 347)	Referral cardiologist (n = 257)
Patient refuses procedure	38%	42%
Inadequate support in guidelines	30%	30%
Stronger supporting data needed	28%	29%
Needs more support from peer community	26%	32%
Cost concerns	33%	25%

TABLE 2. Perceived patient concerns about renal denervation as reported by physicians in Europe and the United States

Perceived patient concern reported by physician	Percentage of responders, Europe (n = 604)	Percentage of responders, United States (n = 201)
Invasiveness of procedure	65%	64%
Will still need to take pills	43%	30%
Unknown long-term effects	47%	61%
Concern about insufficient efficacy	42%	47%
Novelty of procedure	37%	52%
Irreversibility of procedure	29%	24%

Answers to the question 'Which would you consider the main barriers to recommending renal denervation along with a drug regimen? Select all that apply'.

Answers to the question 'What are some of the concerns your patients might have about renal denervation? Select all that apply'.

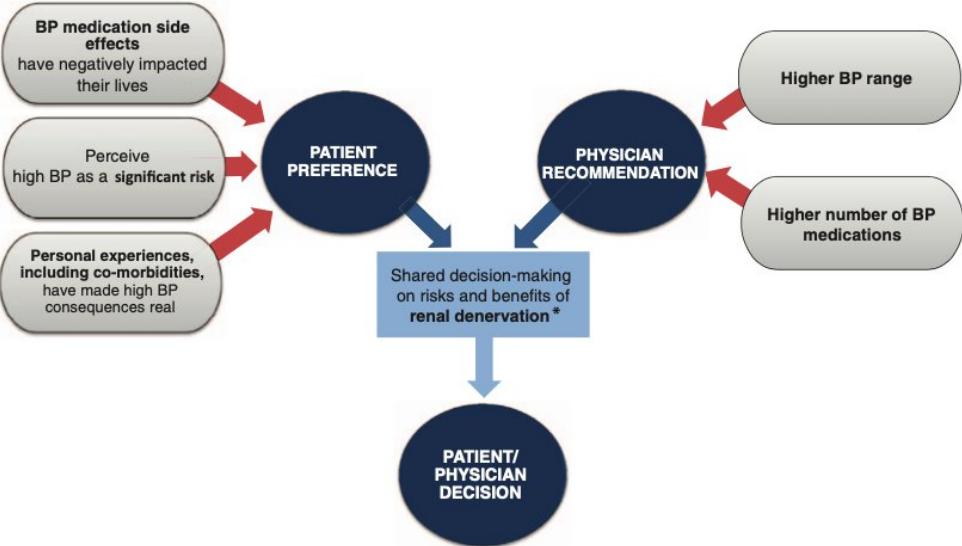


FIGURE 3 Factors influencing patient and physician perspectives on renal denervation. Patient preference for renal denervation is shaped by the perception of high blood pressure (BP) as a risk, having personally experienced the consequences of high BP (including comorbidities), or having suffered from medication side effects. BP levels and medication burden determine a physician's recommendation for renal denervation. *A physician's recommendation was the single most important positive factor influencing patients' readiness to undergo renal denervation.



THINKING AGAIN ABOUT YOUR
HYPERTENSIVE PATIENTS

HOW CAN YOUR HYPERTENSIVE **PATIENTS BENEFIT FROM RDN?**

Provides an option for patients who do not improve with lifestyle and medication changes alone

Helps reduce blood pressure in patients who are non-adherent

Prevents adding more medications to patients already on polypharmacy

Engage in shared decision related to RDN with your interventionalist, and discuss benefits of HTN therapies with your patients

ARDEC CONSENSUS STATEMENT ON RENAL DENERVATION IN ASIA

The Asia Renal Denervation Consortium (ARDeC) consensus conference was convened to achieve consensus recommendations¹ on renal denervation (RDN) and to help inform healthcare professionals in Asia.

Consider RDN as a way to reduce blood pressure in patients who are uncontrolled despite optimal medical therapy.

RDN could serve as a strategy for lowering blood pressure medication for Asian patients when blood pressure target is not achieved.

RDN should not necessarily be restricted to clinical trials or centers of excellence if proper procedural training is achieved.

ROLE OF RENAL DENERVATION SIIA CONSENSUS STATEMENT

Published by the Italian Society of Arterial Hypertension (SIIA), the Italian position paper flowchart to identify which difficult-to-treat patients should be considered for Renal Denervation.

What is the patient's cardiovascular risk profile?
RDN should be considered for hypertensive patients with higher cardiovascular risk, including those with resistant uncontrolled hypertension and intolerance of or nonadherence to drug therapy.

Is the patient taking antihypertensive medication?
RDN should be considered in uncontrolled morning hypertension and residual nocturnal hypertension treated with antihypertensive medication.

What is the patient's preference?
The decision to perform RDN should consider patient preference as part of the decision-making process between patient and physician.

Office and 24-h BP and HR
Global CV risk assessment
Screening for secondary hypertension
Drug adherence and tolerability assessment
Shared decision making

Optimization of BP-lowering treatment

Candidate for Renal Denervation?
Multidisciplinary staff evaluation for Renal Denervation

1. Koenen M, Byring K, Keay A, et al. Renal Denervation Asia: Consensus Statement of the Asia Renal Denervation Consortium. J Hypertens. 2020;38(1):170-179. doi:10.1097/HJH.0000000000002571

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PATIENT SELECTION CONSIDERATIONS FOR RENAL DENERVATION IN TAIWAN

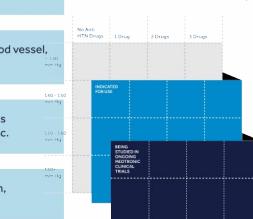
Clinicians Develop Patient Identification Tool for RDN

The Taiwan Hypertension Society published a consensus statement about renal denervation which included a helpful tool to identify RDN patients called RDN-i2.

RENAL DENERVATION INSIGHTS FROM ESC/ESH

Understanding Patient Selection for RDN

Renal denervation (RDN) is indicated for use in patients with uncontrolled hypertension.



Clinical Trial Perspective

The SPYRAL HTN Clinical Program is aligned with the ESC/ESH Guidelines² and ESH Statement on RDN,³ focusing on patients in the context of clinical studies and taking into account patient preference.

Key Takeaways from the ESH Position Paper² on Renal Denervation

1 Evidence provides biologic proof RDN lowers blood pressure (BP): "Sham subtracted reduction in ambulatory BP provides the clear message that RDN is effective in lowering BP in hypertensive patients without or with 1-3 anti-hypertensive medications."

2 RDN provides clinically meaningful BP reductions: "Although not definitely proven by a prospective outcome trial, we can expect that the 10-mmHg decrease in office BP achieved in RDN trials, if maintained long term, would be associated with a reduction in cardiovascular events by roughly 25%."

3 Evidence shows RDN is safe: "No major adverse events occurred in the three trials in the short term from 30 days to six months post procedure. There was no report of acute renal failure, renal artery dissection or perforation. eGFR remained stable throughout follow-up in the three studies."

4 Emphasis must be placed on individualized treatment and patient preference given the challenges with medication adherence. Discussions with the patient of treatment choice "need to take the patient's preference into account."

“ RDN should not be viewed as an anti-hypertensive treatment strategy for patients with resistant hypertension”

2019 THS and TSOC Consensus Statement

1 Wang TD, Lee YH, Cheng SS, et al. 2019 Consensus Statement of the Taiwan Hypertension Society and the Taiwan Society of Cardiology on Renal Denervation for the Management of Arterial Hypertension. Acta Cardiologica Sinica. 2019;35:219-230.

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Bravo RH, Tardif S, Bongi C, et al. Italian Society of Arterial Hypertension (SIIA) Position Paper on the Role of Renal Denervation in the Management of the Difficult-to-Treat Hypertensive Patient. High Blood Pressure Cardiovasc Prev. 2019;27:109-117.

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Medtronic Spiekers W, et al. 2018 ESC/ESH Guidelines for the management of arterial hypertension: The Task Force for the management of arterial hypertension of the European Society of Hypertension and the European Heart Journal. Volume 39, Issue 33, 01 September 2018, Pages 3023-3154. <https://doi.org/10.1093/europress/ezy033>

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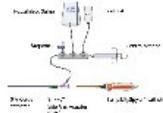
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Symplicity Spyral™

Multi-electrode Renal Denervation Catheter

PROCEDURE GUIDE

PREPARING FOR PROCEDURE



The following items should be available for equipment setup:

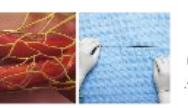
- Symplicity Spyral™ Multi-electrode renal denervation catheter
- Symplicity G3™ renal denervation RF generator with remote control
- Dispense electrode (jacket and pedestal) (part no. RFR-400-2-200) or Sympelab™ 7500
- Fracture catheter 45–90 cm(MA/IMA) or RONDU(RDC) or comparators
- 6 Fr introducer sheath
- 0.014" guidewires (from hydrophilic and support tow wire with a flexible tip recommended)
- Tufty™ side arm adapter (RHF)
- Nonionic contrast (dilute to 50:50)
- Hypersaline saline flush bag
- Sterile bag for remote control



- Turn on Symplicity G3 generator by pressing the On/Off switch 10 minutes before beginning procedure.
- Check dispense electrode connection.
- Assess renal anatomy.
- Remove Symplicity Spyral catheter from packaging.
- Connect Symplicity Spyral catheter cable to generator.
- Connect Tufty® side arm adapter (RHF).
- Administer pain medication approximately 5–10 minutes prior to ablation.



- Check ACT > 250 during procedure.
- Slide straightening tool over spiral portion of Symplicity Spyral catheter.
- Insert proximal end of guidewire through Symplicity Spyral catheter tips.
- Pass the guidewire through the Symplicity Spyral catheter until it exits through rapid exchange port.
- Return straightening tool to handle.



- Advance Symplicity Spyral catheter over guidewire through guide catheter until it is in the designated treatment area.
- Start treatment distally and move proximally toward the ostium.
- Deploy Symplicity Spyral catheter by retracting guidewire into sheath until guidewire tip is approximately 2 cm from proximal electrode.



- Adequate wall contact is achieved when deployment of the distal lead appears angiographically adequate.
- Impedance values are stated on each electrode through at least one respiratory cycle.
- Any electrode located in an unsuitable location (e.g., carina, adventitia) and/or area of dense tissue should be turned off by pressing the Electrode Number button on the remote control of Symplicity G3 generator or corresponding electrode icon in the G3 generator software.

PERFORMING ABLATION



- Consider administering nitroglycerin prior to start procedure.
- Deliver RF energy to treatment site by pressing the RF button on the remote control or Symplicity G3 generator.



- Once treatment is complete, reposition guide catheter in next vessel, repeat procedure, and deliver treatment, or retract it into the guide catheter if treatment of the renal artery is complete.
- Document vessel anatomy after completing its treatment.

REMOTE CONTROL FUNCTION



- 1. Pressing RF button will start ablation.
- 2. Each numbered button represents one of the 4 channels of Symplicity Spyral catheter. Number 1 is the most distal electrode. Each of the electrodes can be selected or deselected by pressing the corresponding button.
- 3. The kidney button provides an annotation in the ablation tab header of the display indicating whether the ablation was performed in a renal artery leading to the left or right kidney. The button can be selected only prior to performing an ablation.
- 4. Pressing the left arrow displays the previous treatment, and pressing the right arrow displays the latest treatment.

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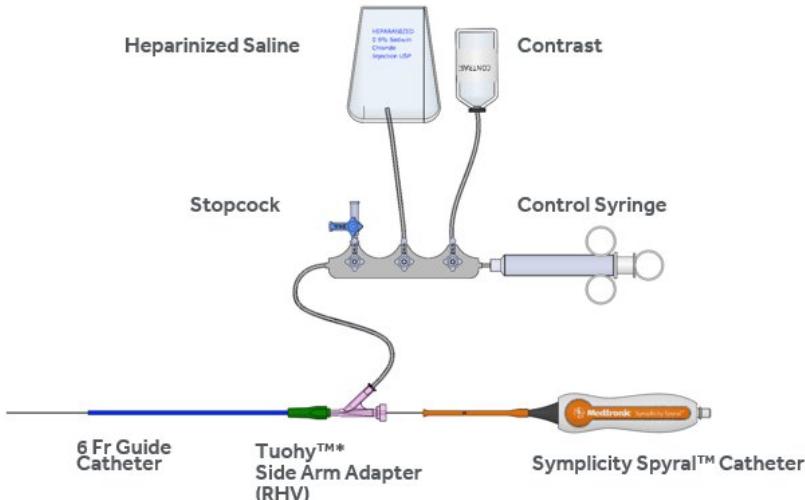
EQUIPMENT PREPARATION

Available Equipment for Procedure

The following items should be available for equipment setu

Common:

- 6-Fr introducer sheath
- Tuohy™* side arm adapter (RHV)
- Non-ionic contrast (dilute to 50:50)
- Heparinized saline flush bag



Specific:

- 6-Fr guide catheter 45–90 cm (IMA/LIMA or RDND1/RDC1 or comparable)
- 0.014" guidewire (non-hydrophilic, supportive, with a floppy tip recommended)
- Symplicity Spyral™ multi-electrode renal denervation catheter
- Symplicity G3™ renal denervation RF generator with remote control
- Dispersive Electrode (ground pad) (Conmed, REF 400-2100, Valleylab E 7506, Bovie ESRSC-1, Megadyne 0850C, 3M 1149C-LP or Baisheng Medical Co. LTD Greenpad 1030AC)
- Sterile bag for remote control
- Symplicity G3™ RF Generator Cart component (optional)

EQUIPMENT PREPARATION

Symplicity Spyral™ Catheter

Consider preparing Symplicity Spyral™ catheter after confirming eligibility of renal arteries for treatment.

1. Remove Symplicity Spyral™ catheter from sterile packaging.
2. Remove tray lid by pulling on the lid pull tab and then remove coiled catheter cable from packaging tray. Place on stable surface within sterile field. Then remove hooped catheter from tray and place next to coiled cable.
3. Pass cable connector outside sterile field and connect to Symplicity G3™ generator.
4. Cable should be secured to table using towel clamp, hemostats, or equivalent.

Notes

Do not flush the catheter while in the hoop or flush the catheter lumen prior to use.

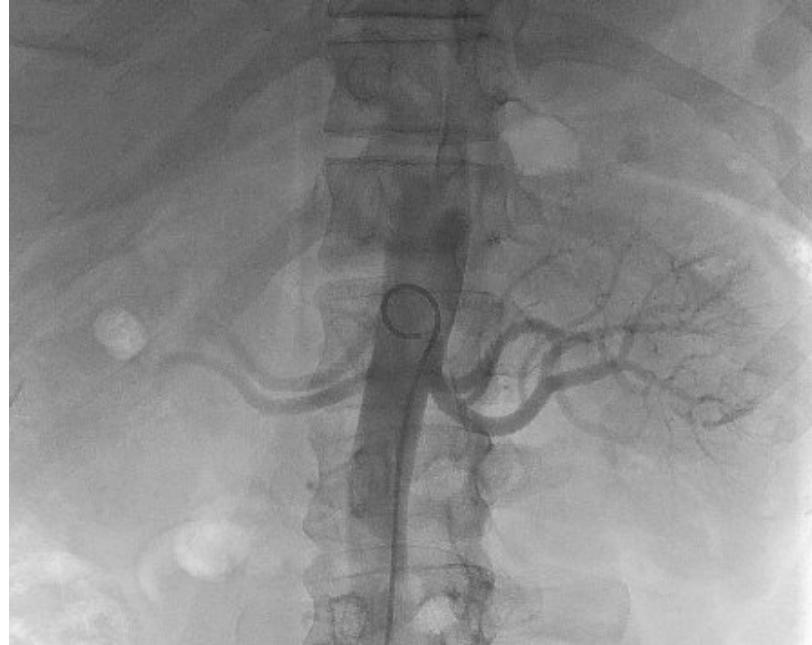
Do not wipe the spiral section of the catheter.



ASSESSING RENAL ANATOMY

Aortogram

In case pre-imaging is not available consider performing an aortogram for a complete assessment of renal anatomy

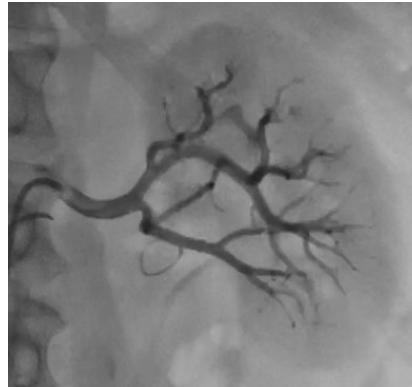


ASSESSING RENAL ANATOMY

Renal Arteries

Treatable diameter of vessel is 3–8 mm

Vessel Diameter (mm)	Treatment Length ¹ (mm)
3	21
4	20
5	20
6	19
7	18
8	17



Reminder

One single size Symplicity Spyral™ catheter is able to conform to any vessel size ranging from 3–8 mm in diameter width. There is no need to order different sizes.

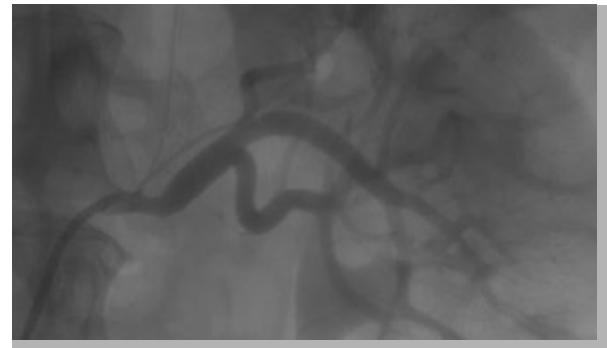
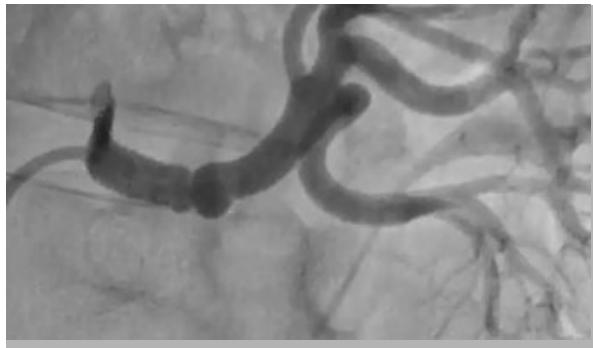
¹Treatment length: Distance between electrodes 1 and 4 as a function of deployed diameter.

ASSESSING RENAL ANATOMY

Renal Arteries

The following situations require thorough investigation whether the patient is suitable for renal denervation:

- Aneurysm
- Fibromuscular dysplasia (FMD)
- Stenosis



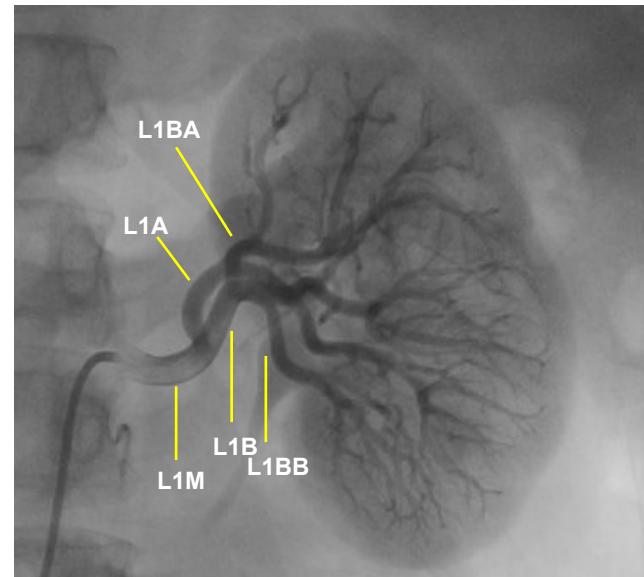
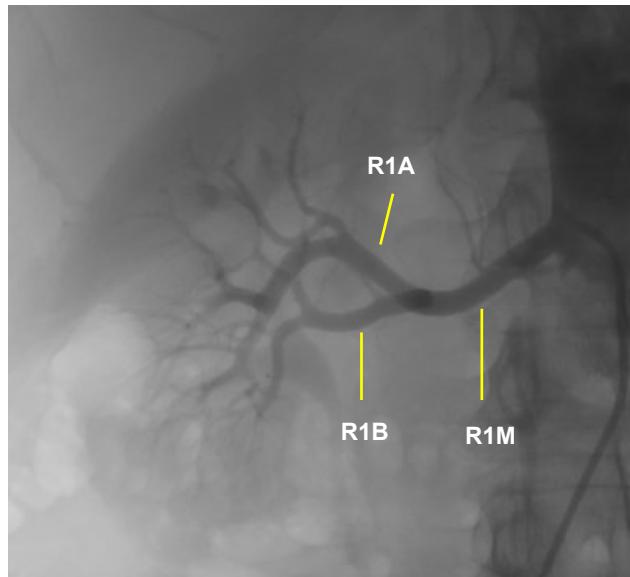
TREATMENT PLANNING

Example

Treatment should be outside the kidney parenchyma. For better artery assessment changing to a different projection may provide additional information. (Note: guide catheter is 6 Fr).

Example of Treatable/Non-treatable vessels:

- a) R1M/L1M (Main)
- b) R1A /L1A (branch)
- c) R1B /L1B (branch)
- d) L1BA and L1BB (sub-branches) are within the parenchyma and should NOT be treated.



RDN PATIENT SELECTION CONSIDERATIONS

RDN MAY BE CONSIDERED IN COMPLEX PATIENTS



Blood pressure **elevated ≥ 150 mmHg despite prescription** of guideline-based approaches, taking account individual patient condition



Rule out whitecoat and secondary cause of hypertension, with elevated out of office blood pressure



Intensive **discussion with patient on risks/benefits of renal denervation**, taking into consideration patient preference



RDN is indicated for use in uncontrolled hypertensive patients



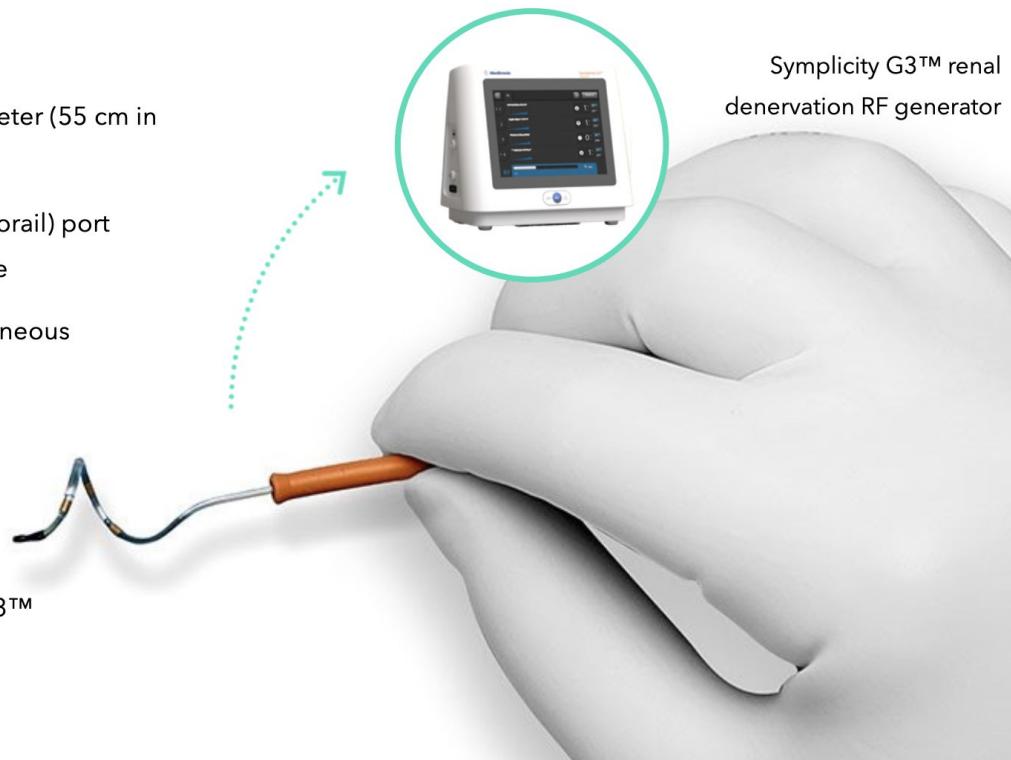
SPYRAL HTN Clinical Program aligns with the ESC/ESH Guidelines¹ and ESH Statement on RDN², focusing on patients in the context of clinical studies and taking into account patient preference



In addition, RDN is being studied in patients between 150 and 180 mmHg on 0 to 3 medications

Key features

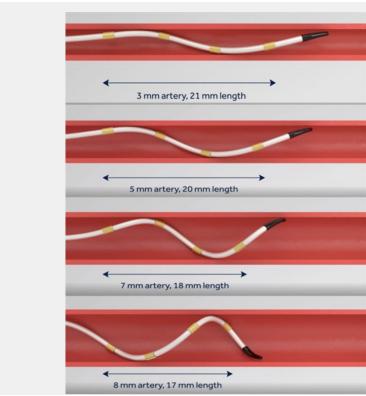
- Compatible with 6 Fr Guide Catheter (55 cm in length is recommended.)
- Features a Rapid Exchange (Monorail) port compatible with 0.014" guidewire
- Has 4 gold electrodes for simultaneous energy delivery
- Non-occlusive
- Works with radio frequency (RF) energy
- To be used with the Symplicity G3™ renal denervation RF generator
- Intended for single use



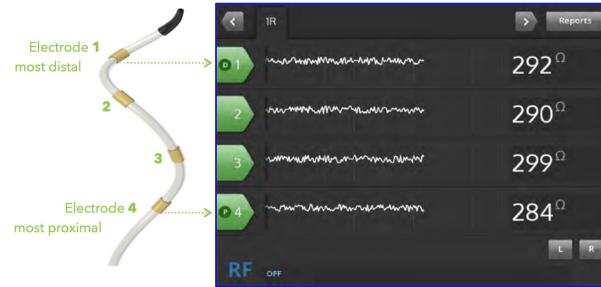
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One size fits arteries 3-8 mm¹

- Renal arteries from 3 to 8 mm in diameter can be treated with a single Symplicity Spyral™ catheter
- Symplicity Spyral catheter conforms to the vessel size and corresponding treatment length* depends on the vessel diameter.



Generator display



Example of Symplicity G3 generator display showing impedance at all four electrodes.

- Electrodes are numbered from distal to proximal and are independently selectable.
- Monitor each electrode on the Symplicity G3™ renal denervation RF generator's display.

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