

# Consensus ?

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- Pourquoi un consensus ?

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- Décalage entre les recommandations et les données de la science
- Cumul d'evidence
- Définir la bonne pratique médicale
- Soutenir la mise a disposition remboursée

# 2018 Guidelines Released Prior to Sham Controlled RCT Data

## Device-based therapies for hypertension

| Recommendation   | Class <sup>a</sup> | Level <sup>b</sup> |
|--|--------------------|--------------------|
| 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. <sup>367,368</sup> | III                | B                  |

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RCT = randomized controlled trial.

<sup>a</sup>Class of recommendation.

<sup>b</sup>Level of evidence.

## ESH Position Paper on Renal Denervation 2021<sup>2</sup>

### BOX 1: Position Statement in 2021

- On the basis of consistent results of several sham-controlled clinical trials, renal denervation represents an evidence-based option to treat hypertension, in addition to lifestyle changes and blood pressure lowering drugs.
- Renal denervation therefore expands therapeutic options to address the first objective of hypertension treatment, that is to effectively reduce an elevated blood pressure and achieve blood pressure targets.
- Renal denervation is considered a safe endovascular procedure without significant short-term or long-term adverse effects based on data available up to 3 years.
- Renal denervation is an alternative or additive, not a competitive treatment strategy.
- A structured pathway for clinical use of RDN in daily practice is recommended.
- Patients' perspective and preference as well as patients' stage of hypertensive disease including comorbidities should lead to an individualized treatment strategy in a shared decision-making process, that carefully includes the various options of treatment, including renal denervation.

1. Williams B, et al. Eur Heart J. 2018 Sep 1;39(33):3021-3104.

2. Schmieder R, et al. J Hypertens. 2021 Sep 1;39(9):1733-1741. doi: 10.1097/HJH.0000000000002933

# ESH Position Paper on Renal Denervation 2021

## Box 1: Position Statement in 2021

- RDN represents an **evidence-based option** to treat HTN,
  - in addition to lifestyle changes and BP lowering drugs.
- RDN **expands therapeutic options** to address the 1<sup>st</sup> objective of HTN treatment
  - to effectively reduce elevated BP and achieve BP targets.
- RDN is considered a **safe** endovascular procedure
  - without significant short-term or long-term adverse effects
  - based on data available up to **3 years**.
- RDN is an **alternative or additive**, not a competitive, treatment strategy.
- A **structured pathway** for clinical use of RDN in daily practice is recommended.
- **Patients’ perspective, preference** and stage of HTN disease (incl. comorbidities) should lead to an individualized treatment strategy in a **shared decision-making process**,
  - that carefully includes the various options of HTN treatment, including RDN.

Consensus Document

European Society of Hypertension position paper on renal denervation 2021

Rafael E. Schmieder\*, Felix Mahfouz\*, Giuseppe Marcia\*, Michael Azizif\*, Michael Böhm\*, Karakostas Dimitriadis\*, Kazumasa Kario\*, Abraham A. Kooze\*, Melvin D. Lubz\*, Christian Ott\*, Ashraf Pasha\*, Aleksandra Prasad\*, Filippo Scialoja\*, Markus Schillig\*, Bernhard Knäuper\*, Costas Tsioulfas\* on behalf of members of the ESH Working Group on Device-Based Treatment of Hypertension

This ESH Position Paper 2021 with updated proposed recommendations was drafted primarily after the publication of a set of high-level observational and clinical studies. It is not intended to provide information about the efficacy and safety of endovascular renal denervation (RDN) for hypertension treatment. RDN is effective in reducing or normalizing the sympathetic signal to the kidney and decreasing whole-body sympathetic activity (see Introduction, fully completed, non-validated RCTs) and achieving additional BP-lowering effects. However, the clinical benefit of RDN is significantly greater when compared to sham treatment. Moreover, there is a recent lack in patients with and without concomitant anti-hypertensive medication. The average decrease of diastolic BP is estimated to lower the incidence of cardiovascular events by 25–30% based on meta-analysis of RCTs using pharmacological treatment. Further pre-procedure, but also during and after the procedure, there is a need for a structured pathway for the use of RDN as an evidence-based option in the management of hypertension treatment. This structured process that ensures the appropriate performance of the endovascular RDN procedure, adequate selection of hypertension patients, should also encompass ongoing monitoring and evaluation of the procedure.

**Keywords:** hypertension, cardiovascular risk, sympathetic nervous system, lifestyle changes and pharmacotherapy, renal denervation

**Introduction**  
A renal hypertension is the most prevalent and important factor for death and disability worldwide, affecting more than one billion individuals and causing 10 million deaths annually. In addition to lifestyle changes and pharmacotherapy, renal denervation

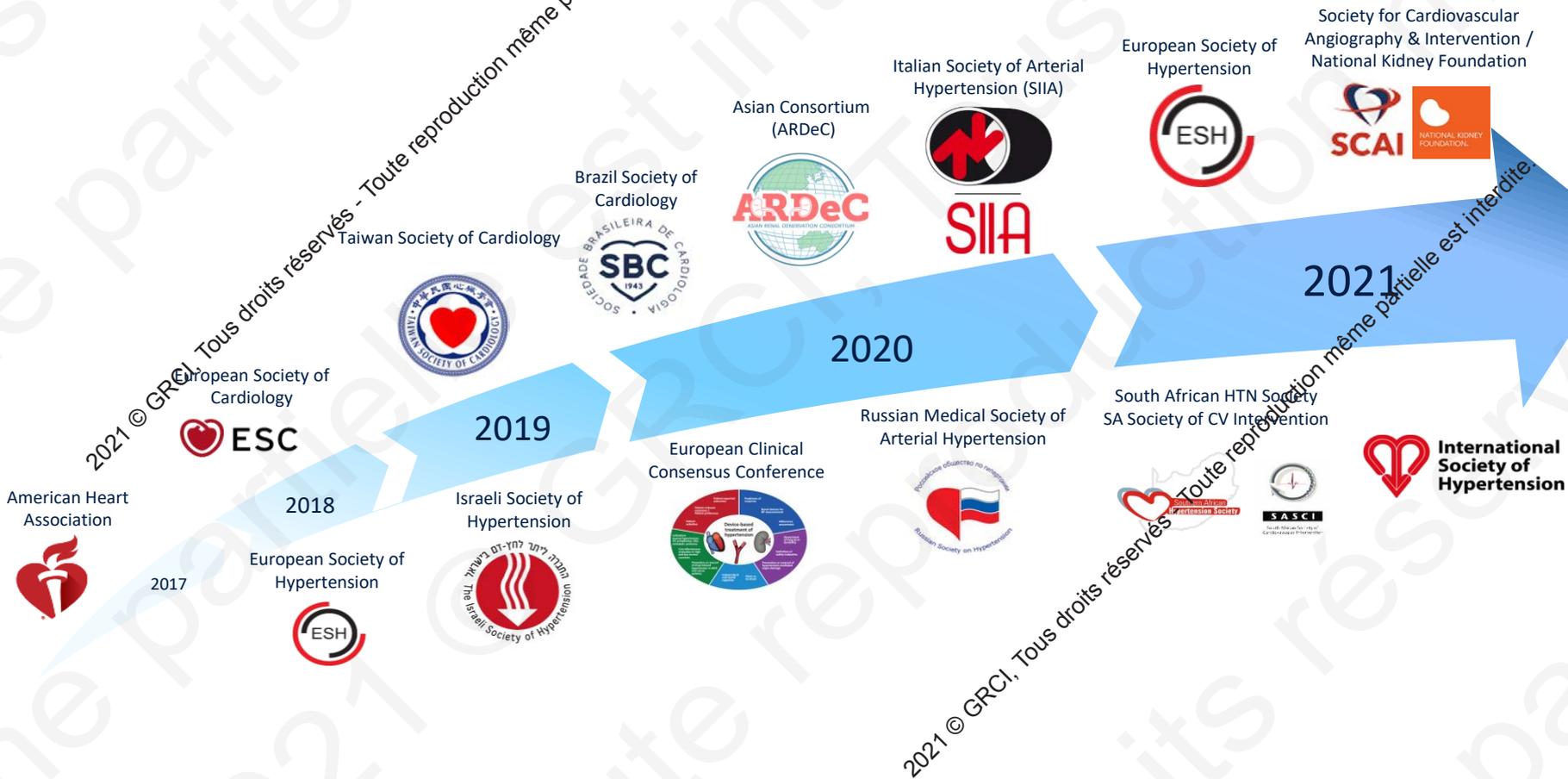
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**Introduction**  
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# Societies Provide Guidance Based on New Data

## RDN Consensus Statements Published in Multiple Countries



# Qui peut proposer la Denervation Rénale ?

- Centre de médecine interventionnelle ?
- Expertise en approche rénale
- Nombre d'actes ?
- Approche intégrée avec une équipe d'HTA

# Denervation rénale chez qui ?

- Comme dans les essais cliniques ?
  - Patients non contrôlés
  - Avec ou sans traitement ?
- Extrapolation des données des essais cliniques ?
  - Faible adhésion
  - Effets indésirables
  - Trop de traitement
  - Pas assez
  - Atteinte d'organes cibles
  - Situation à activité sympathique élevée

# RDN Patient Consideration Themes Across Consensus Statements



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**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 white coat

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

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- Que faire avant la denervation rénale ?

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- Bilan du RCV
- Evaluation du niveau de la TA
- Bilan d'HTA secondaire
- Optimisation pharmacologique
- Bilan avant Denervation Renale

# • Ou la dénervation rénale peut avoir lieu ?

- Centre expert en HTA ( centre d'excellence)
- Centre à volume
- Centre intégré dans un parcours de soins
- Avec un interventionnel
- Recours à la chirurgie de sauvetage

- Avec quelles techniques ?

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- RF

- US

- Alcool

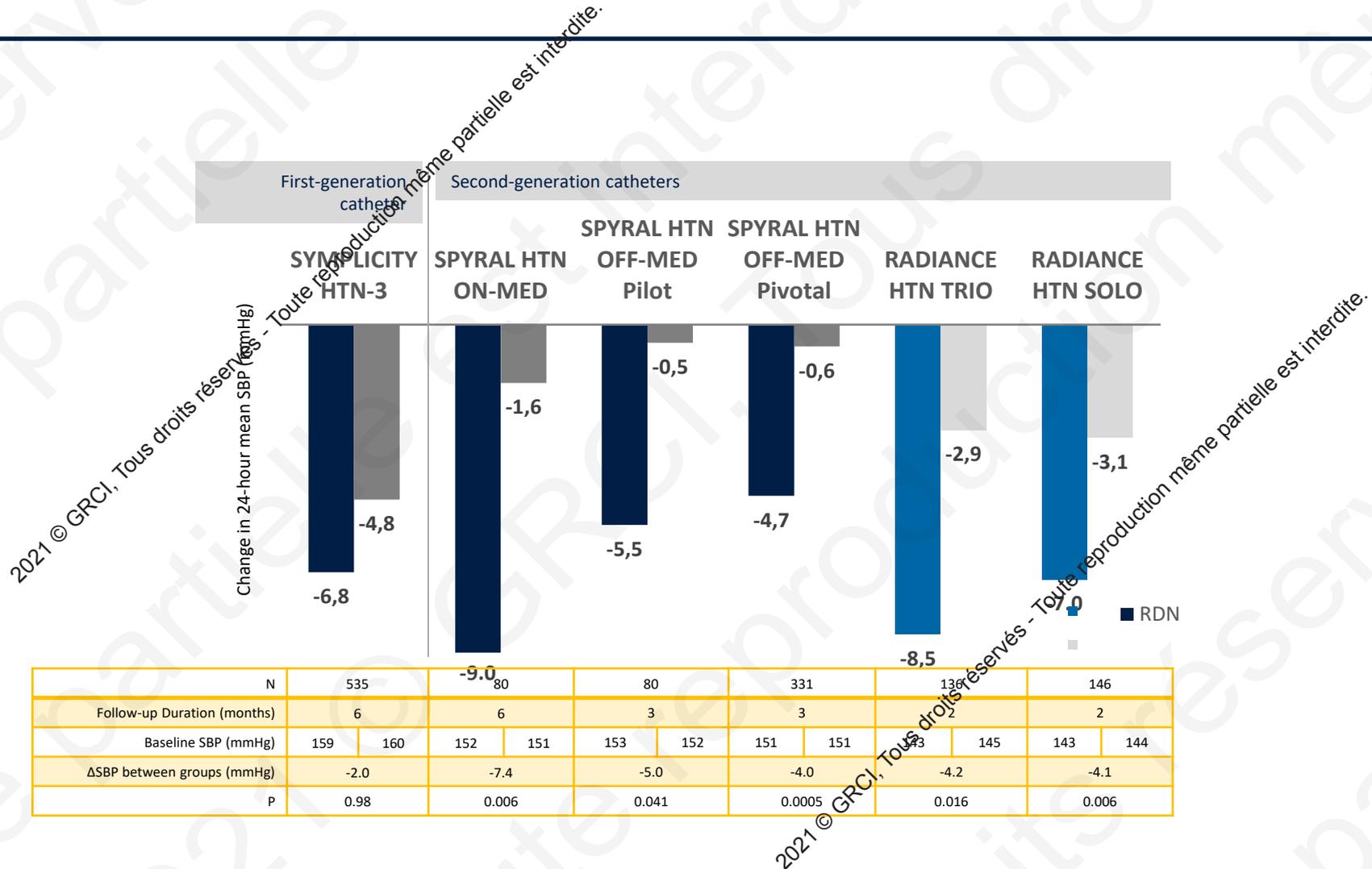
- Voie femorale? Radiale ?

- Cf topo Professeur Sapoval

# Quel suivi

- Efficacité
- Déescalade thérapeutique
- Complications
- Safety

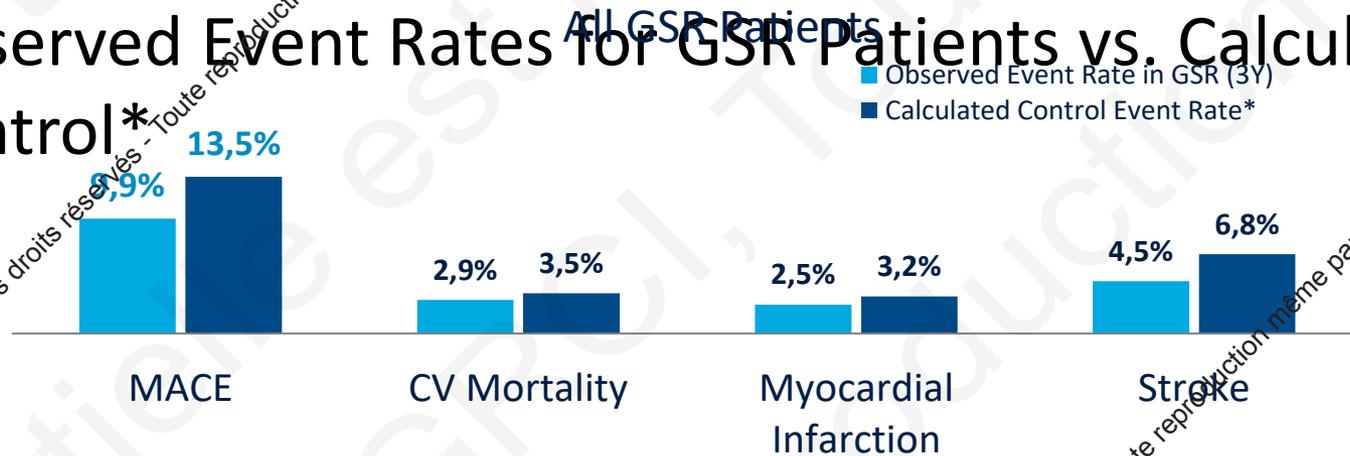
# Multiple Randomised Sham-Controlled Trials Demonstrate the Effectiveness of RDN With or Without Medications



|                                    |           |           |           |           |           |           |
|------------------------------------|-----------|-----------|-----------|-----------|-----------|-----------|
| N                                  | 535       | 80        | 80        | 331       | 136       | 146       |
| Follow-up Duration (months)        | 6         | 6         | 3         | 3         | 2         | 2         |
| Baseline SBP (mmHg)                | 159   160 | 152   151 | 153   152 | 151   151 | 143   145 | 143   144 |
| $\Delta$ SBP between groups (mmHg) | -2.0      | -7.4      | -5.0      | -4.0      | -4.2      | -4.1      |
| P                                  | 0.98      | 0.006     | 0.041     | 0.0005    | 0.016     | 0.006     |

# RDN Associated with 26% Relative Risk Reduction in MACE Over 3 Yrs<sup>1</sup>

## Observed Event Rates for GSR Patients vs. Calculated Control\*



|     |      |      |      |      |
|-----|------|------|------|------|
| RR  | 0.74 | 0.84 | 0.79 | 0.66 |
| NNT | 28   | 178  | 148  | 43   |

\*Analysis applied a previously published CV risk regression meta-analysis<sup>2</sup> to estimate the event rates of a modeled control group using the assumption the baseline blood pressure and anti-hypertensive drug prescription regimen remained unchanged for patients enrolled in GSR

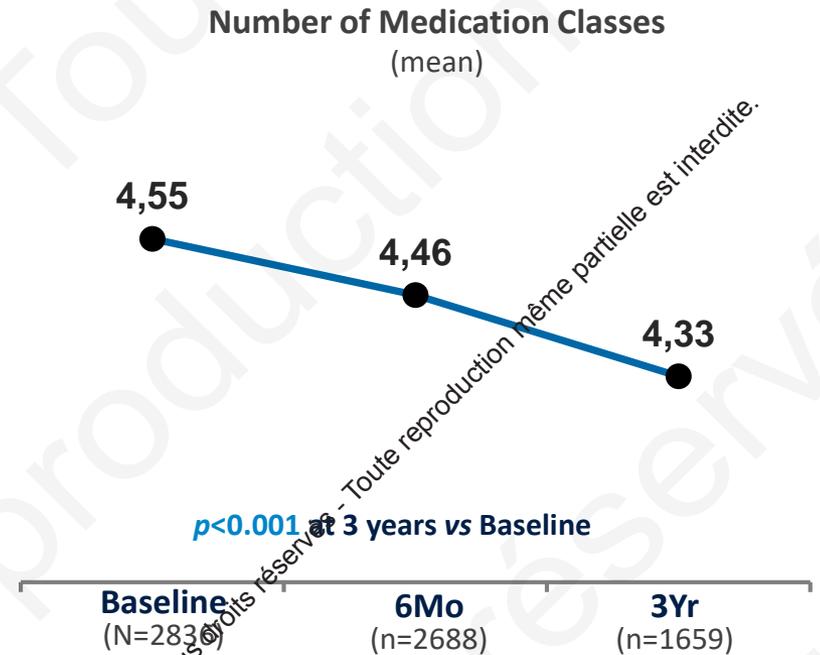
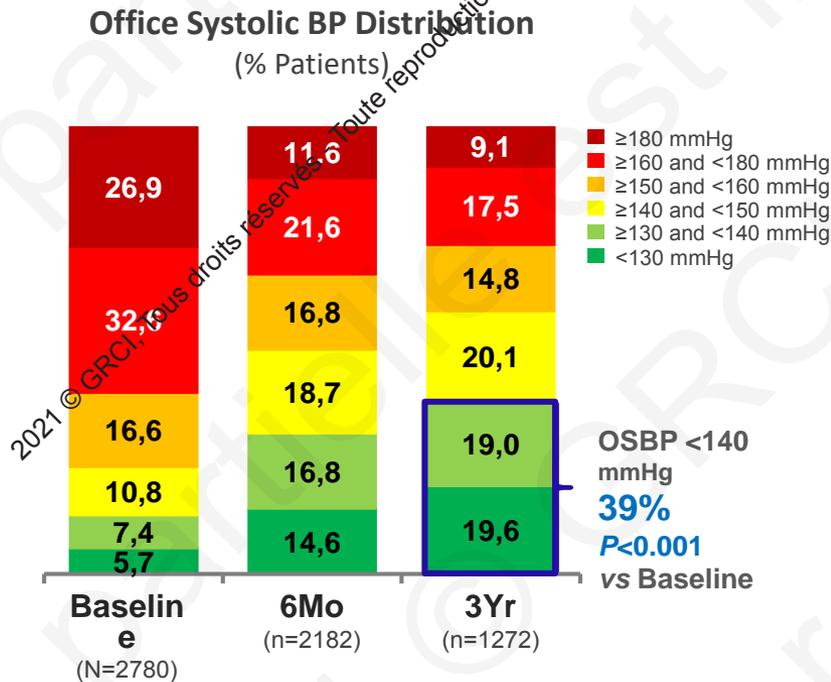
1. Schmierer RE, Pietzsch J et al. EuroPCR2021  
2. Thomopoulos C, et al. J Hypertension. 2014;32:2285-2295

MACE: major adverse cardiovascular events, calculated as composite of CV death, MI, and stroke

RR: relative risk; calculated from modeled control  
NNT: number needed to treat; calculated from modeled control

# RDN Lowered BP Without Increase in Medication Burden

## Three-fold Increase in % of Patients With BP <140 mmHg over 3 years



Mahfoud et al, EuroPCR 2021

- Nouveautés ?

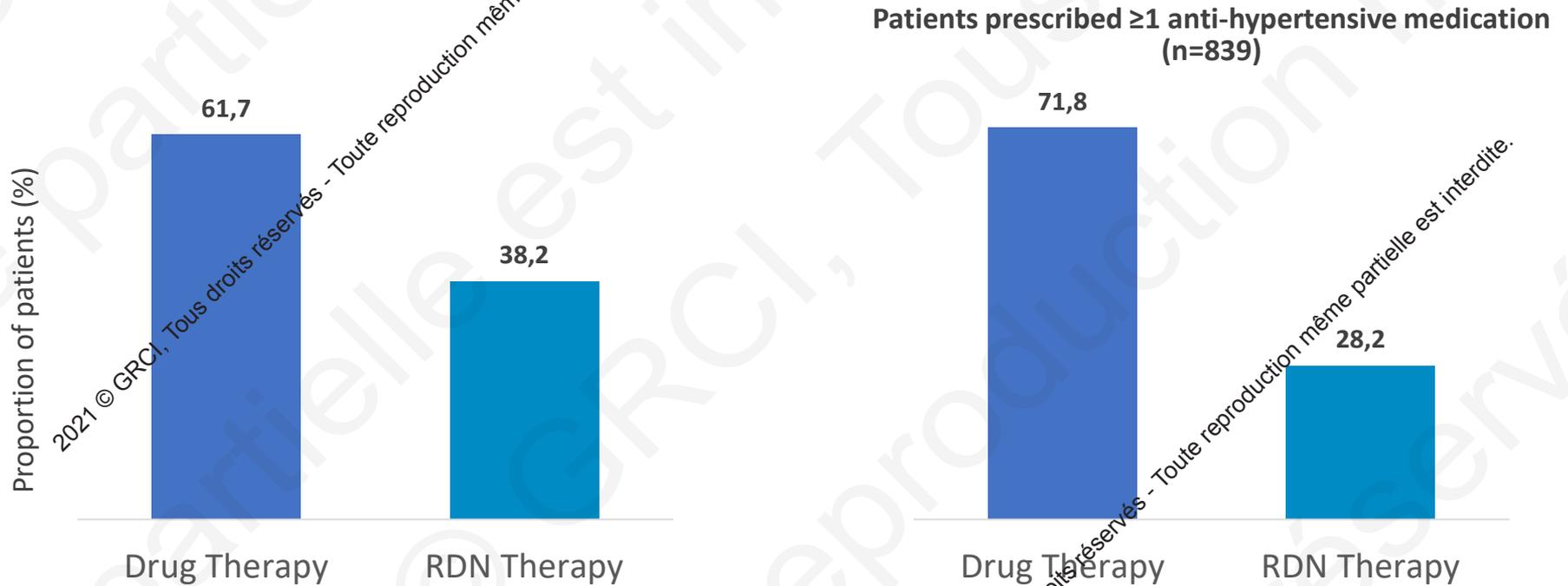
# Préférence Patient

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# Patient Preference for Drug Therapy vs. Renal Denervation

## Significant Proportion of Patients Interested in RDN



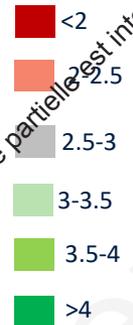
Questionnaire-based cross-sectional survey in patients with elevated blood pressure in Germany (N=1011)

# Physicians Recommend RDN Based on Higher BP, More Medications

**Referring Physicians**

| Systolic Blood Pressure (mmHg) | # of Medications |      |      |      |
|--------------------------------|------------------|------|------|------|
|                                | 0                | 1-2  | 3    | 4+   |
| <140                           | 1.10             | 1.23 | 1.76 | 2.60 |
| 140-160                        | 1.23             | 1.63 | 2.62 | 3.66 |
| >160                           | 1.50             | 2.17 | 3.57 | 4.54 |

Likert Score



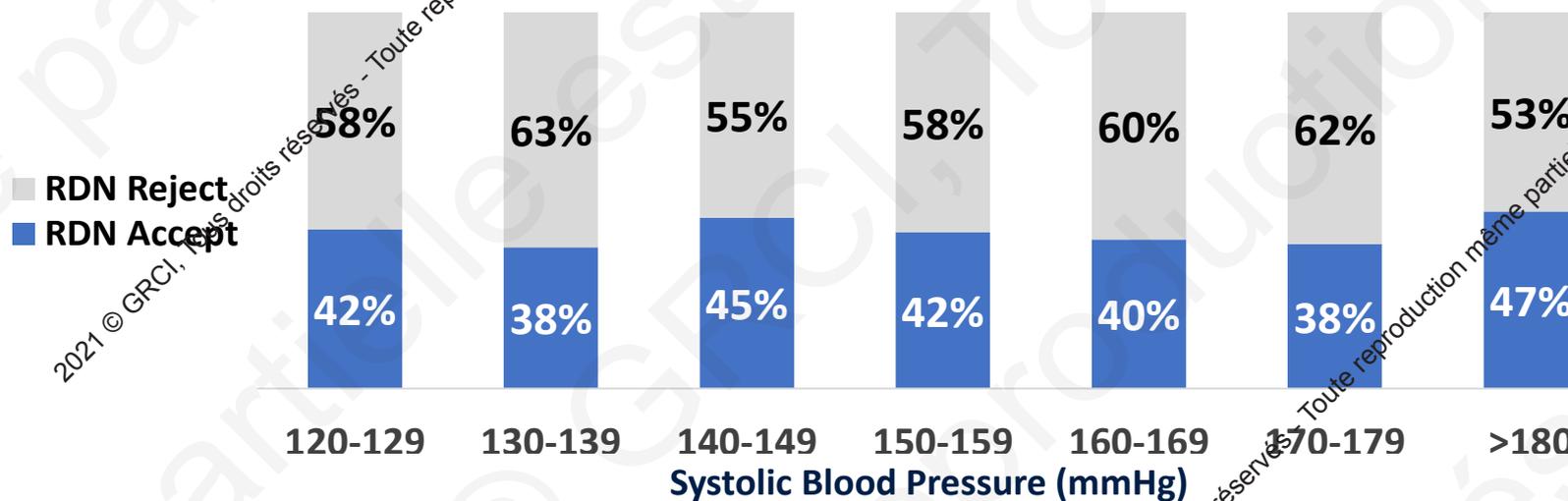
**Proceduralist**

| Systolic Blood Pressure (mmHg) | # of Medications |      |      |      |
|--------------------------------|------------------|------|------|------|
|                                | 0                | 1-2  | 3    | 4+   |
| <140                           | 1.12             | 1.45 | 2.22 | 2.98 |
| 140-160                        | 1.41             | 2.08 | 3.21 | 4.00 |
| >160                           | 1.85             | 2.84 | 4.08 | 4.64 |

*“On a scale of 1-5, how likely would you be to recommend/refer for/perform on patients with the following characteristics?”*

# Patient Willingness for RDN is Independent of BP Level

Patient preference to RDN across blood pressure ranges  
(N = 1,666)

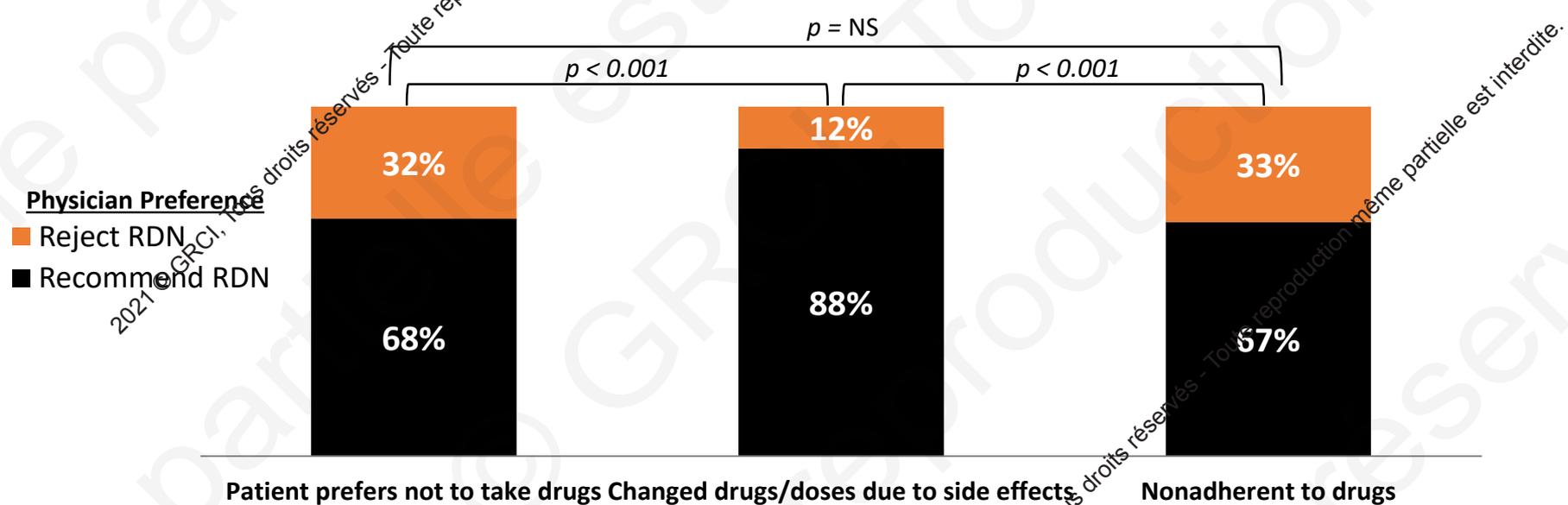


\*Differences between patients with SBP less than 130mmHg and those with SBP at least 130mmHg or at least 150mmHg were not significant ( $P > 0.7$  for both)

# Physicians More Likely to Recommend RDN for Patients with Side Effects

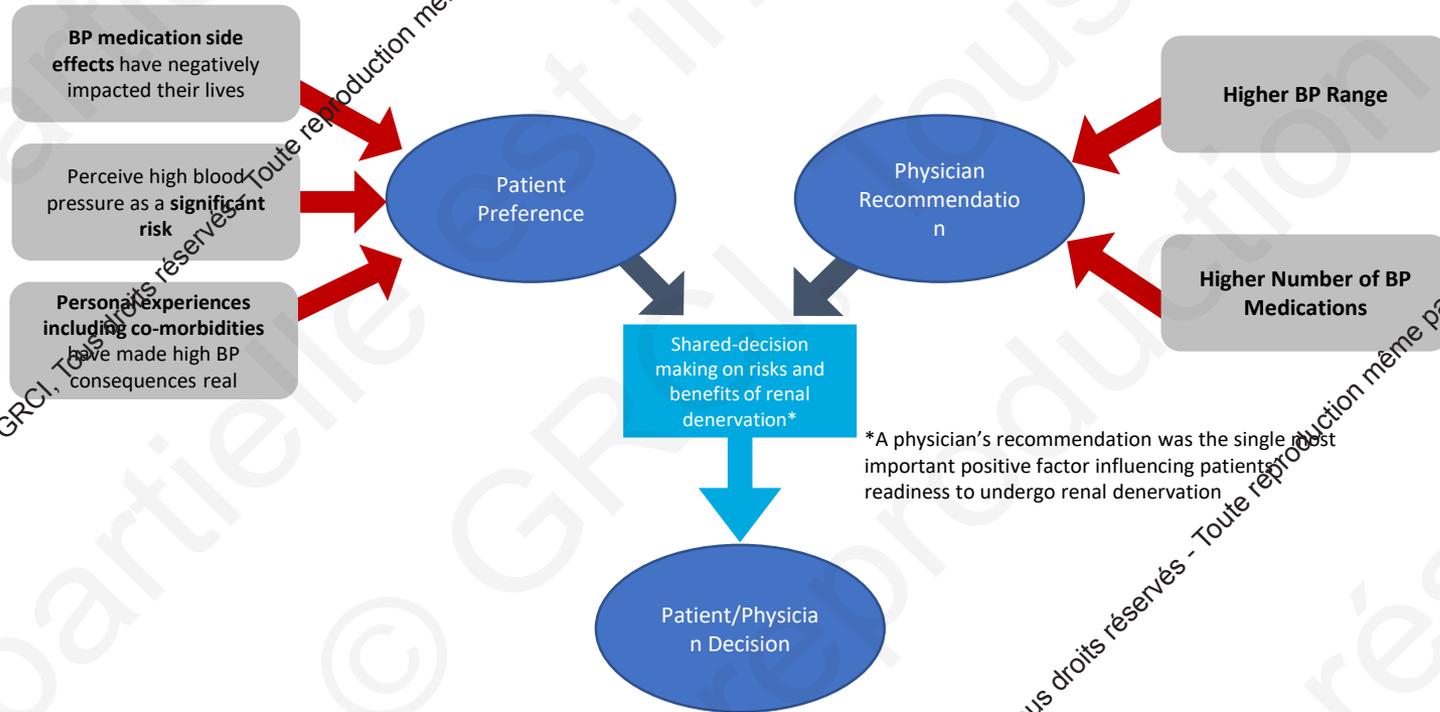
## 2/3 of Physicians Recommend RDN Regardless of Nonadherence Reason

**Influence of Patient Nonadherence Factors on Physician RDN Recommendation**  
(N = 501 Physicians Surveyed)



# Factors Influencing Patient and Physician Perspectives on Renal Denervation

## Shared-Decision Making is Key to RDN Recommendation



\*A physician's recommendation was the single most important positive factor influencing patients' readiness to undergo renal denervation

# Conclusions

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- New sham RCT data show RDN is an evidence-based treatment option for uncontrolled HTN
- Current HTN Guidelines were written without input from Multiple sham RCTs showing RDN Benefit
- Multiple local and global organizations have recently published consensus and position statements favoring RDN with very consistent themes
- New trial and registry data will continue to refine ideal patient populations
- Stay tuned French consensus coming soon