

Consensus ?

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- Pourquoi un consensus ?

- 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 ^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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RCT = randomized controlled trial.

^aClass of recommendation.

^bLevel of evidence.

ESH Position Paper on Renal Denervation 2021²

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

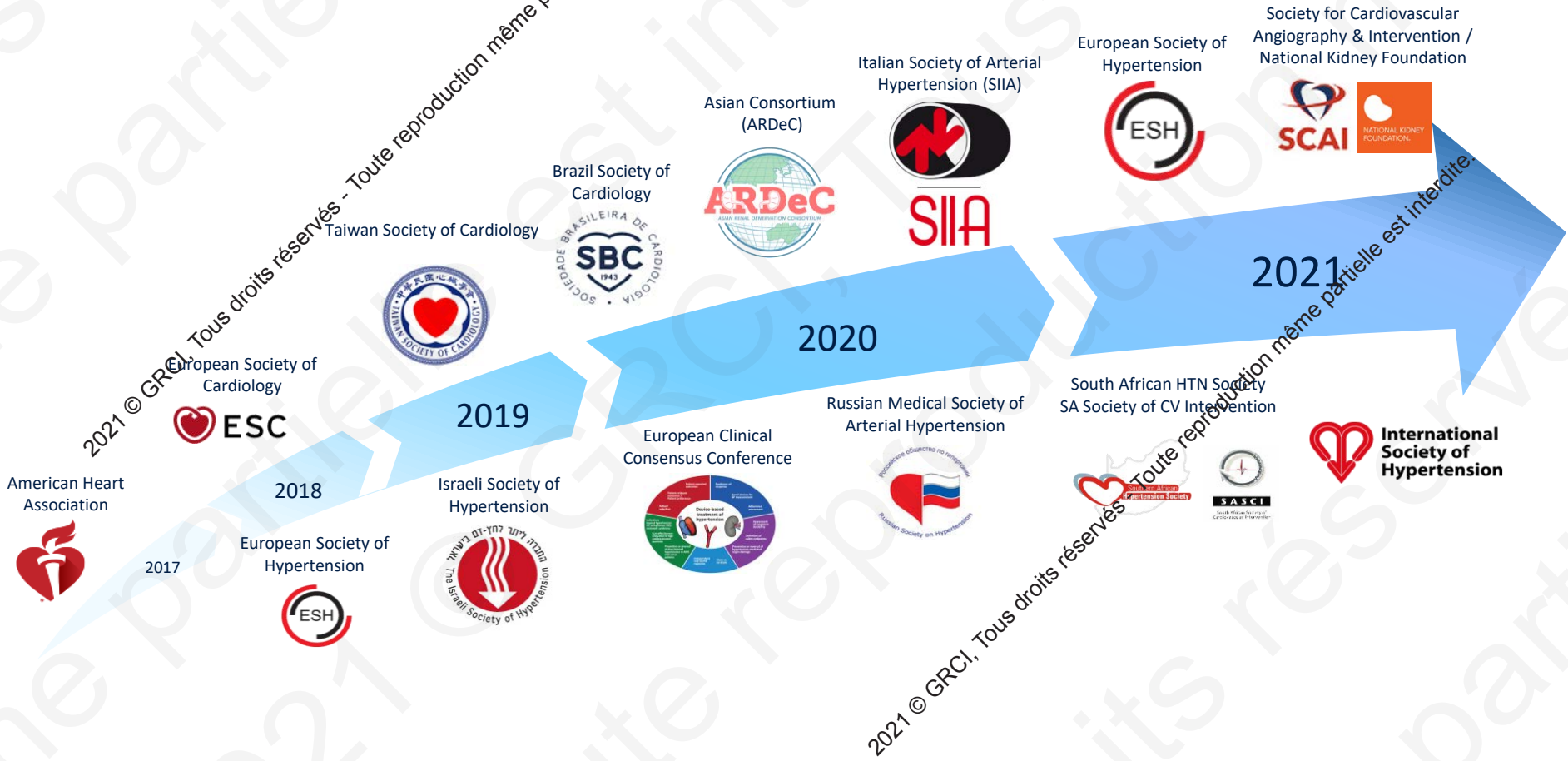
Box 1: Position Statement in 2021

- 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 1st 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.



Societies Provide Guidance Based on New Data

RDN Consensus Statements Published in Multiple Countries



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Qui peut proposer la Dénervation 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 ?

- 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 ?

- RF

- US

- Alcool

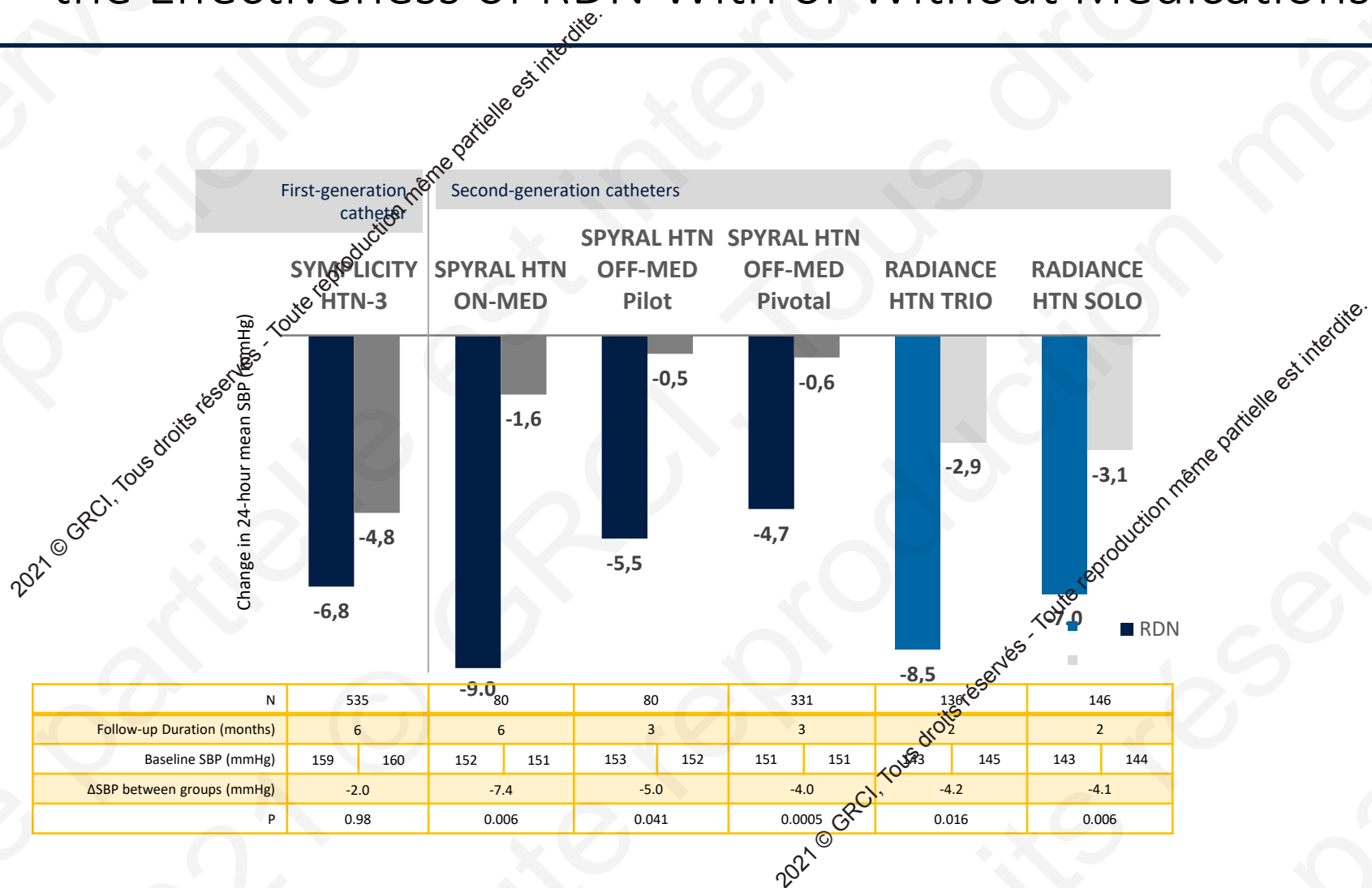
- Voie femorale? Radiale ?

- Cf topo Professeur Sapoval

Quel suivi

- Efficacité
- Déescalade thérapeutique
- Complications
- Safety

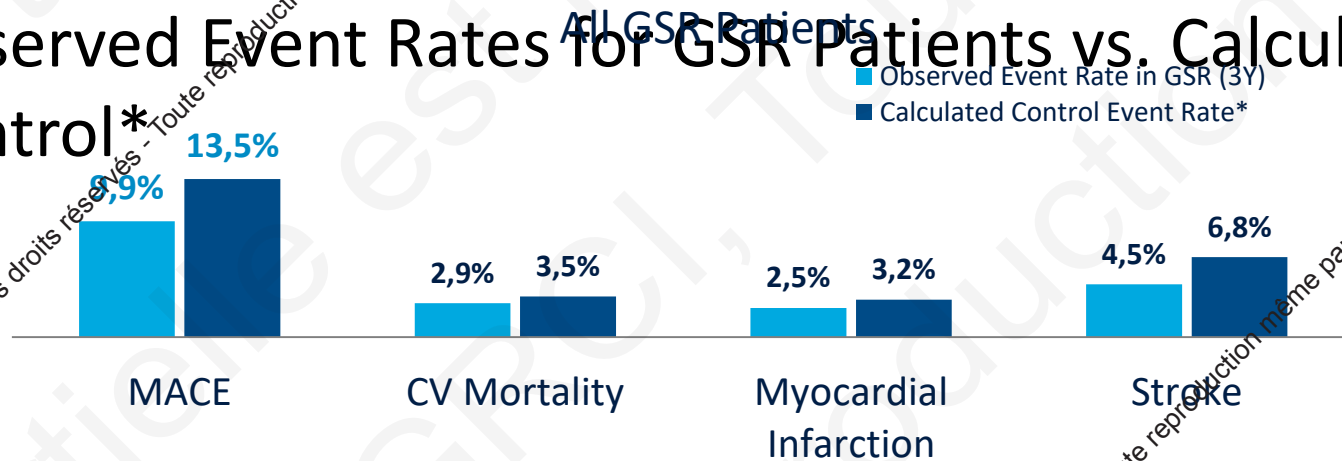
Multiple Randomised Sham-Controlled Trials Demonstrate the Effectiveness of RDN With or Without Medications



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
ΔSBP 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 Yrs¹

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-analysis² 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

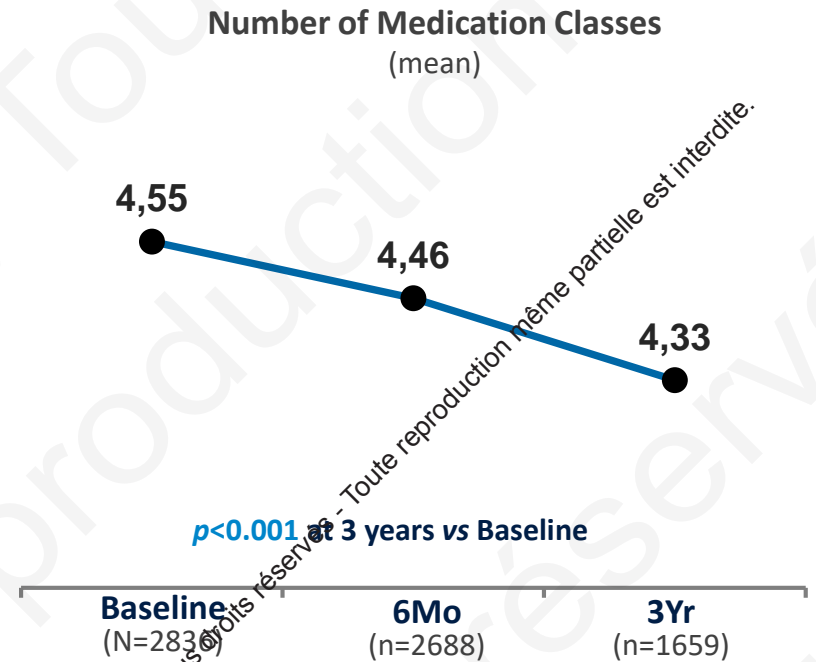
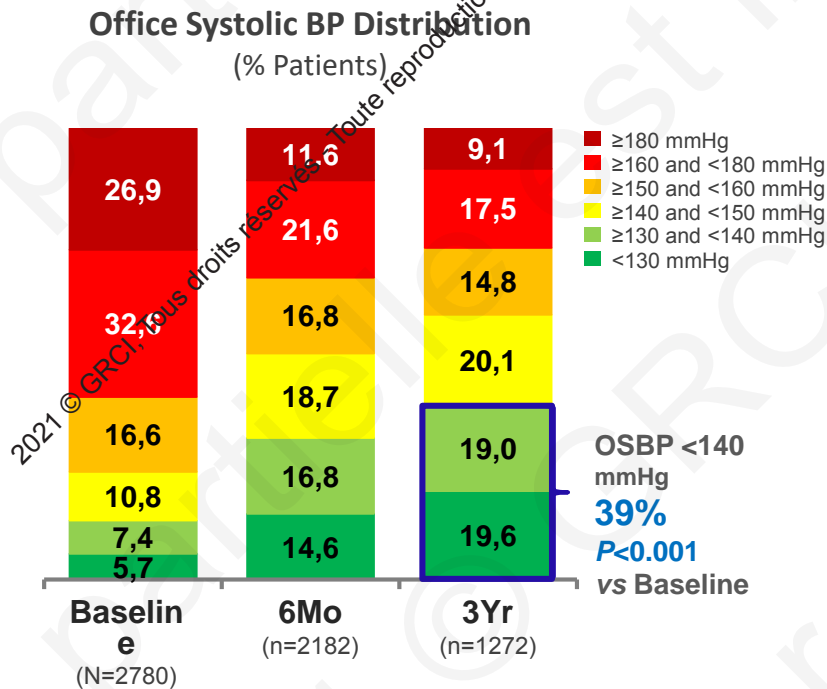
1. Schmierer RE, Pietzsch J et al. EuroPCR2021
2. Thomopoulos C, et al. J Hypertension. 2014;32:2285-2295

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 ?

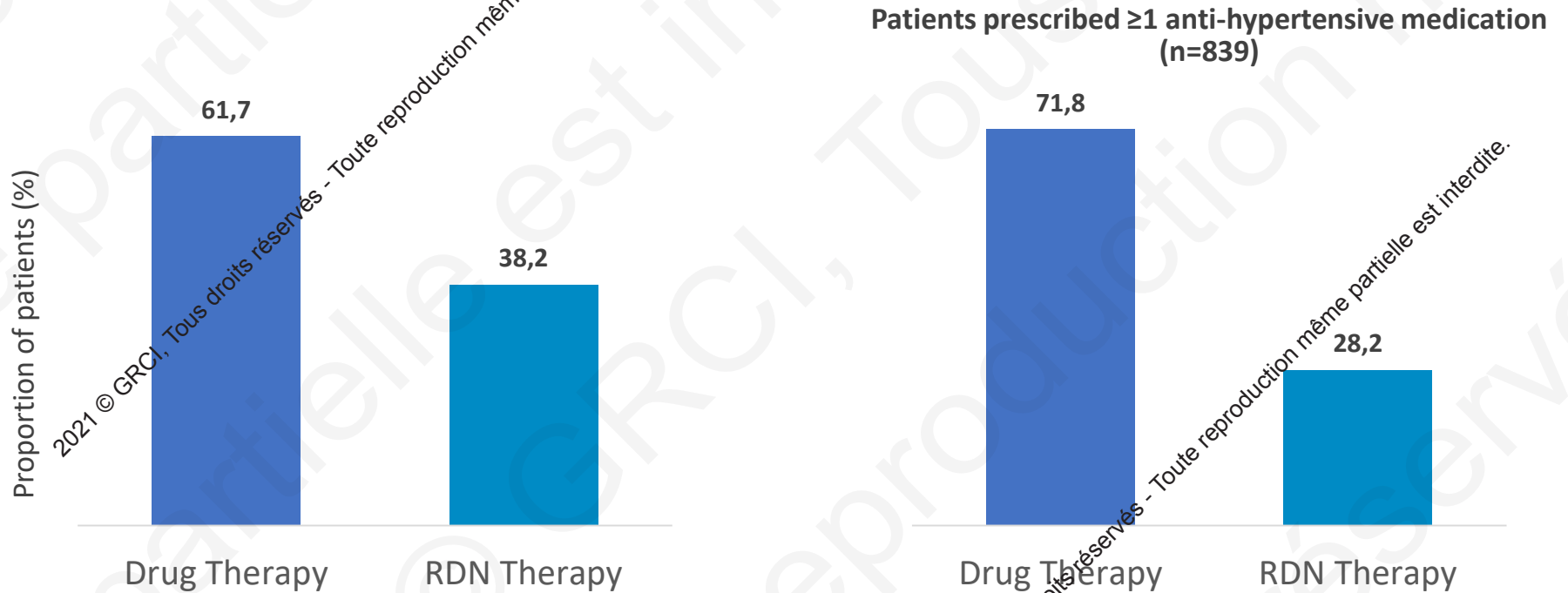
Préférence Patient

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Patient Preference for Drug Therapy vs. Renal Denervation

Significant Proportion of Patients Interested in RDN



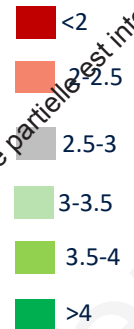
Questionnaire-based cross-sectional survey in patients with elevated blood pressure in Germany (N=1011)

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



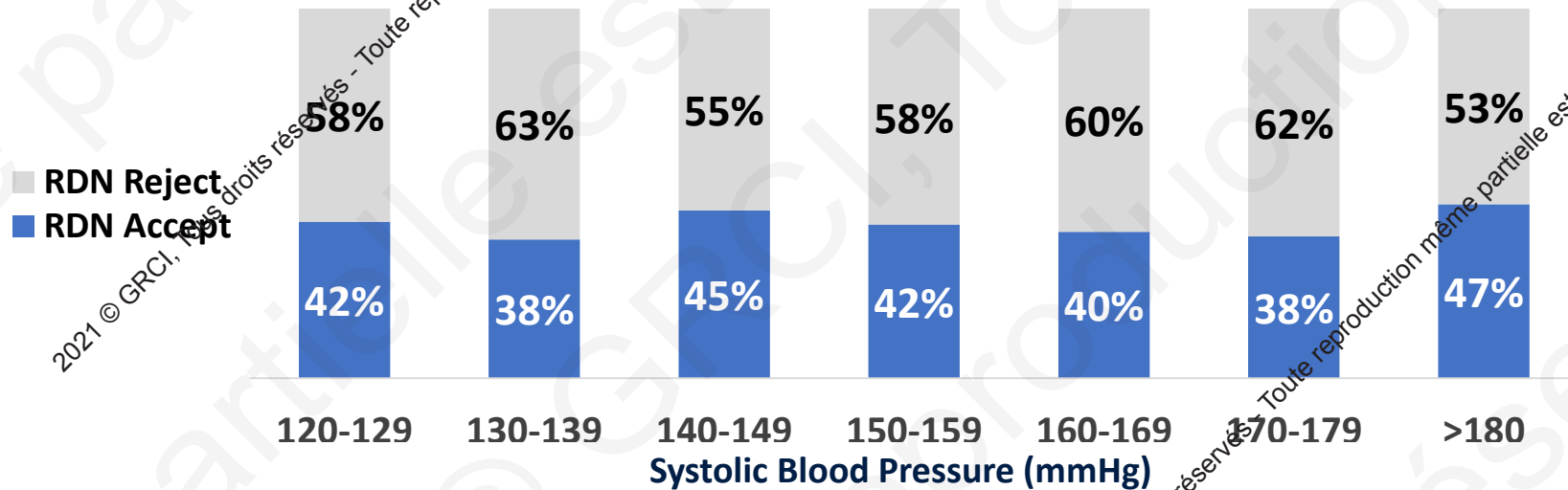
Proceduralist

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)

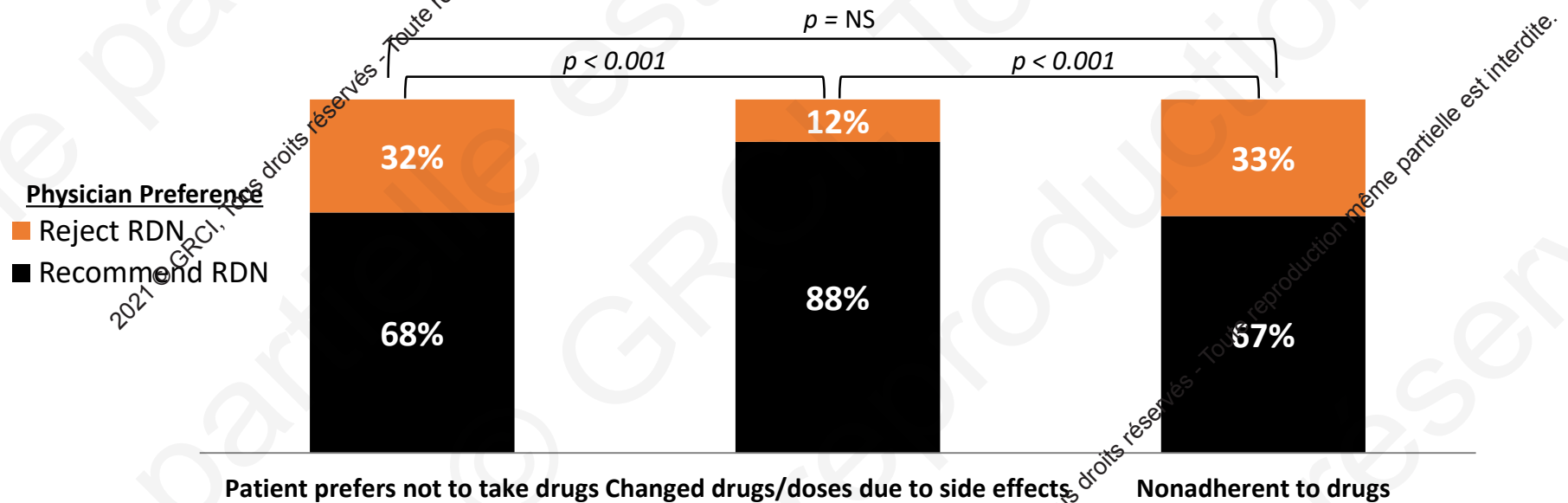


*Differences between patients with SBP less than 130mmHg and those with SBP at least 130mmHg or at least 150mmHg were not significant ($P > 0.7$ for both)

Physicians More Likely to Recommend RDN for Patients with Side Effects

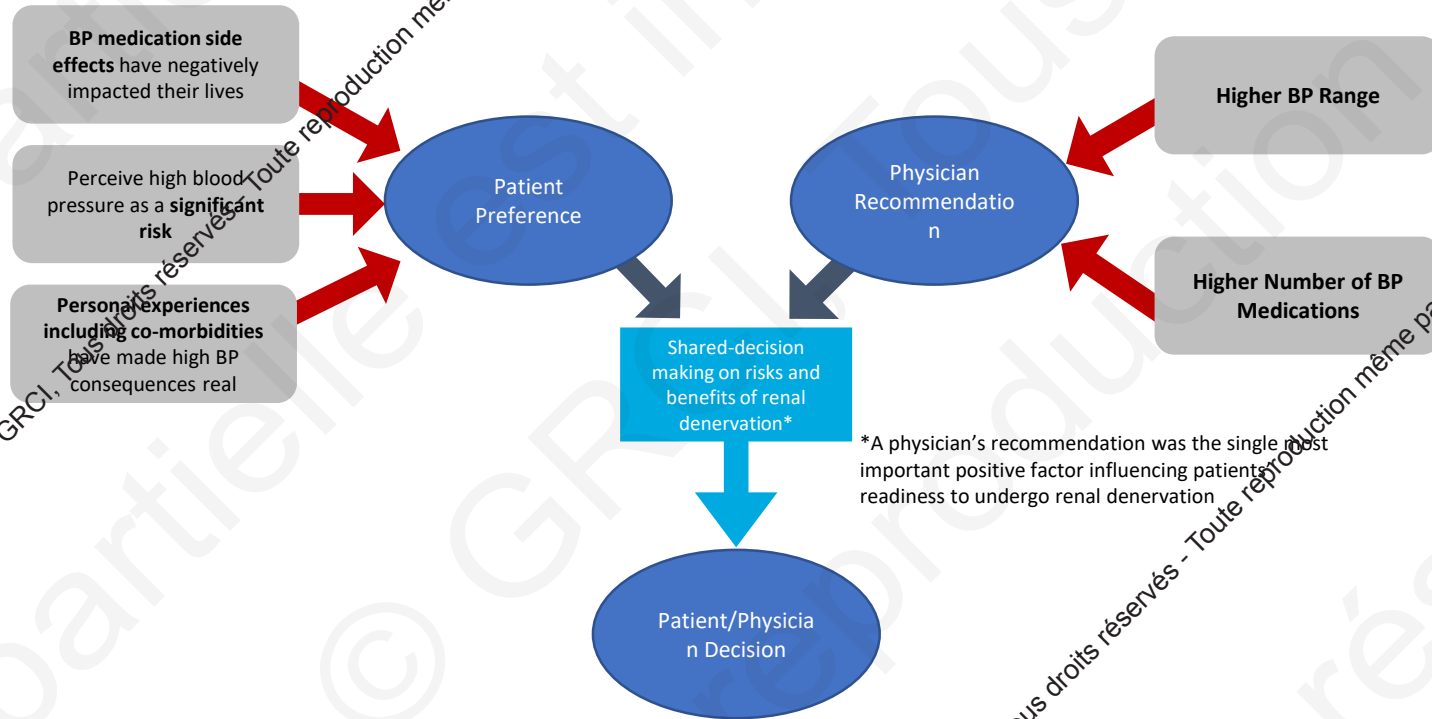
2/3 of Physicians Recommend RDN Regardless of Nonadherence Reason

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

- 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