

Patient Preferences and Devices for HTN

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Disclosure

- Consultancies or advisory Board memberships :
 - Medtronic, Recor, Saint Jude , Ablative Solution, Rox Medical
- Lecture fees paid by a commercial entity (honoraria)
 - Medtronic, Recor, Saint Jude , CVRx, Rox Medical, Ablative Solution
- Industry-sponsored grants (received or pending) including contracted research
 - Recor, CVRx, Medtronic
- Intellectual conflict of interest :
 - French Guidelines for Hypertension,
 - Vice President European Society for Patient Care and Therapeutic Education

Patient Preference and Drugs

- BP can be reduced by Life style Modification or Drugs

 - Adverse Drug Reaction

 - Very frequent (cough, leg oedema)

 - Recently , rare (skin cancer, lung cancer, valsartan story)

 - Different perception

 - Outcome data

 - Life long intervention

 - Length of the effect : length of the trial + observational data

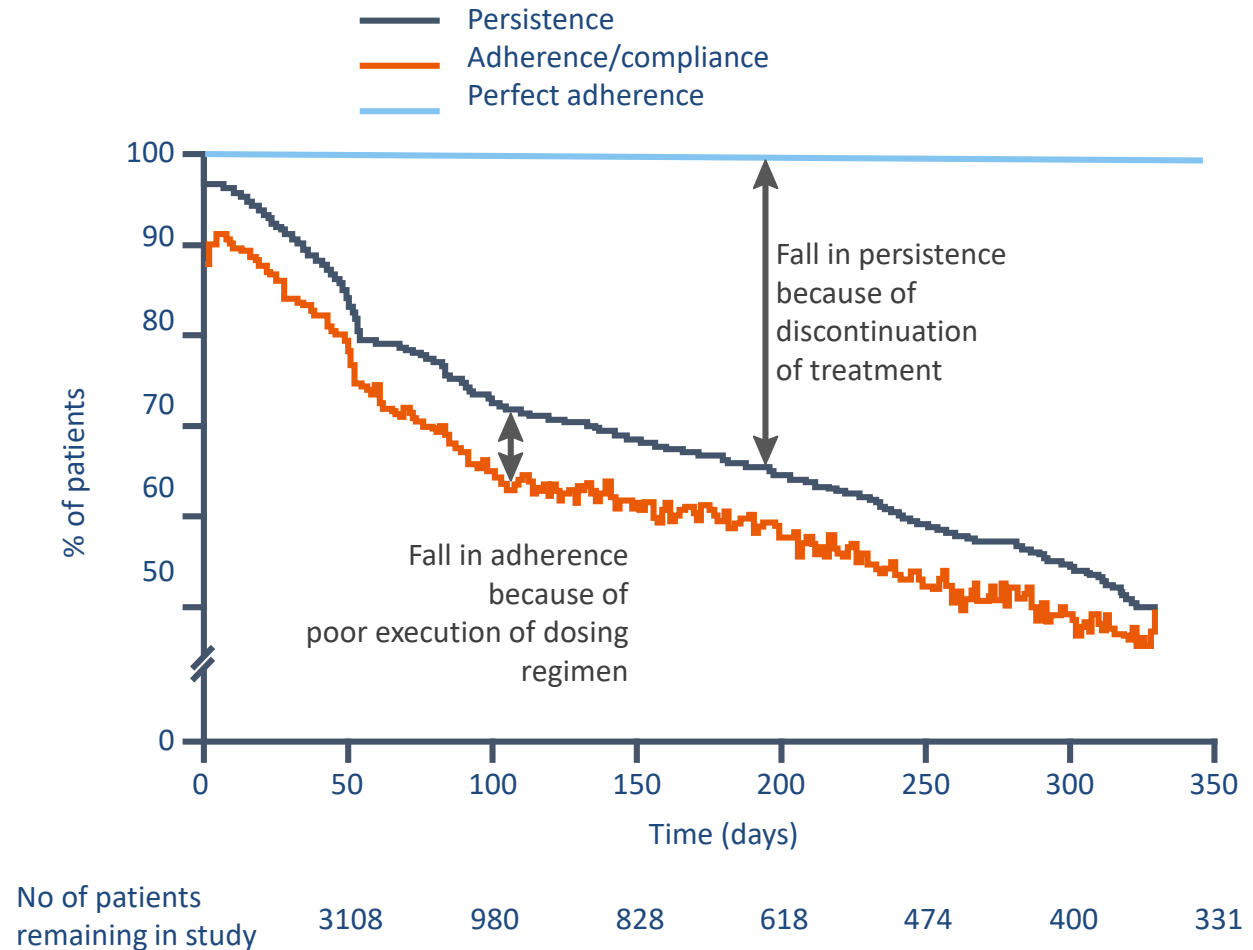
- Patient preference and shared medical decision

 - Choice of drug, switch, combination therapy

Patient prefer not to take Drugs!

Compliance and Persistence with Anti-HTN Therapy Typically Falls to <50% in One Year

- Study of hypertensive patients in clinical studies
- 4783 patients in 21 Phase IV trials
- Evaluated by medication event monitoring system



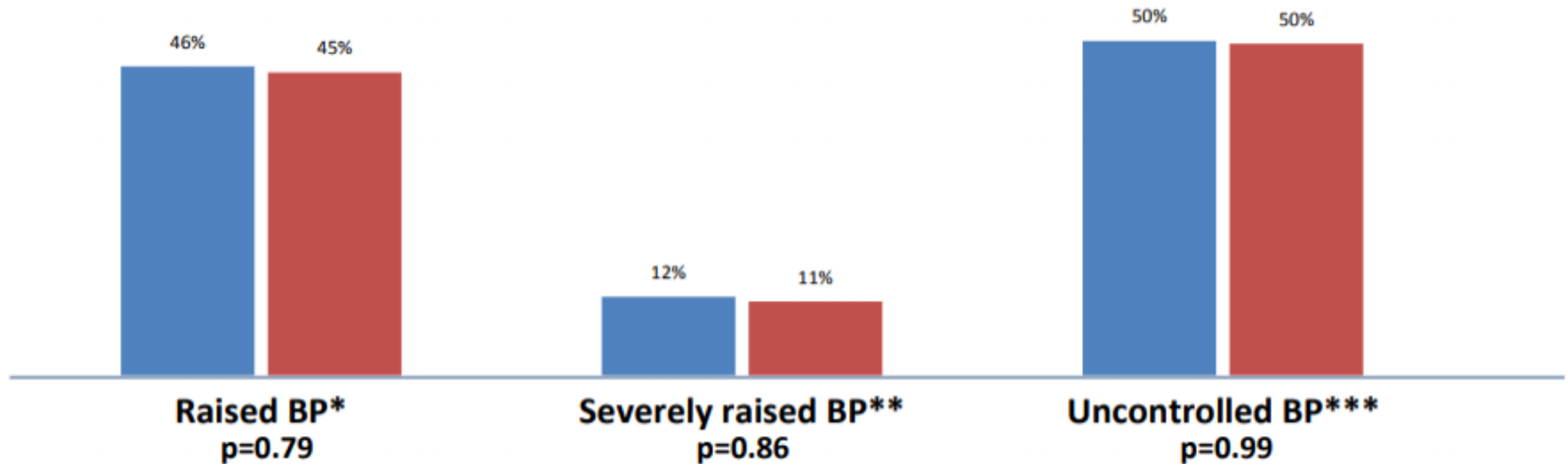


EUROASPIRE IV and V

Blood pressure

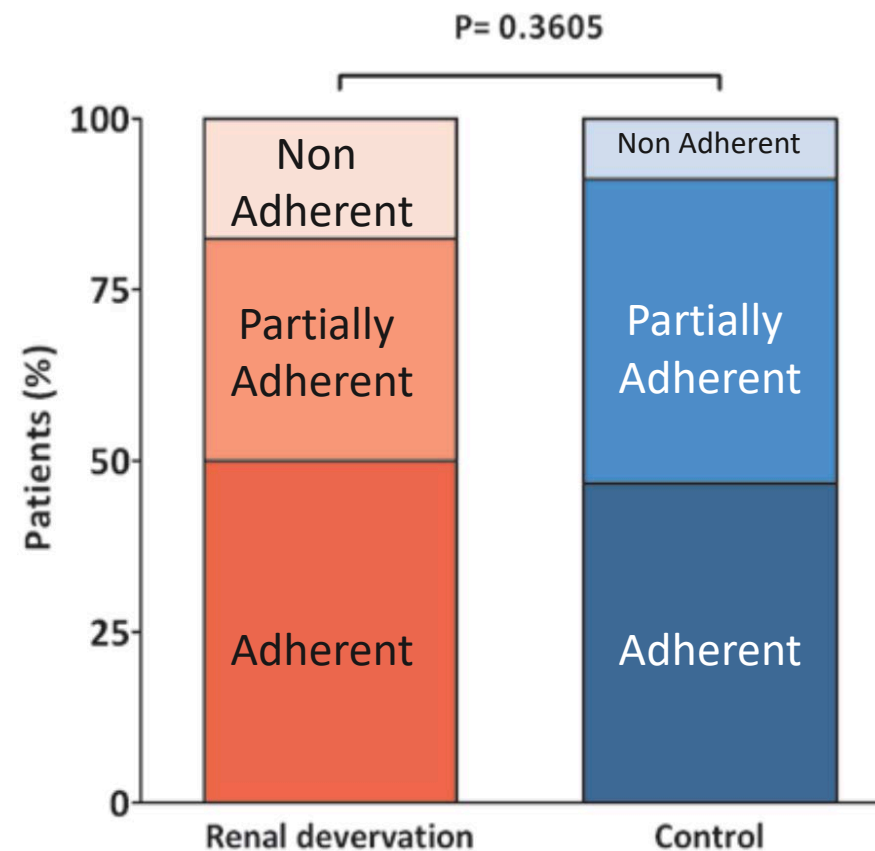


- EUROASPIRE IV (2012 – 2013)
- EUROASPIRE V (2016 – 2018)



Patient Adherence in RDN trials

Determinants of BP Lowering Drugs	Renal Denervation Group	
	Baseline (n=63)	6 mo (n=51)
No. of BP lowering drugs prescribed	3.7±1.5	4.0±1.7
No. of BP lowering drugs detected	1.8±1.4	2.0±1.5
Mean difference between prescribed and measured	1.8 (1.3 to 2.2)	1.9 (1.5 to 2.4)
<i>P</i> value	<0.001	<0.001

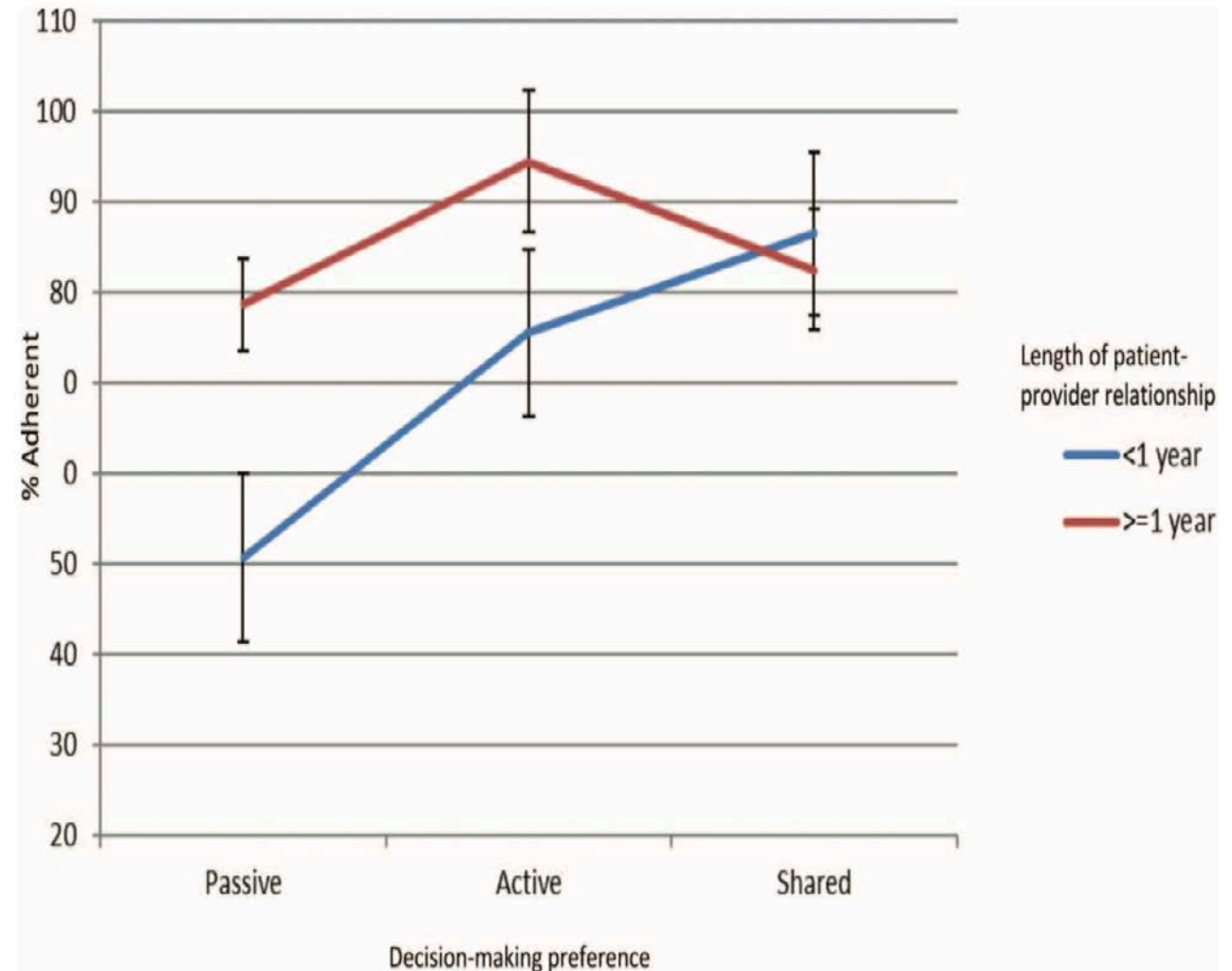


Medication adherence and decision making preference

Decision making preference has an impact on medication adherence

Length of patient provider relationship impact decision making preference

Patient preference influenced by:
Trust in physician,
satisfaction with care
confidence in decision



Patient Preference and Devices

- RDN able to reduce BP in patient (with or without treatment)
 - No Major Adverse Event
 - No outcome data
 - Single intervention
 - Length of the effect : at least some years
- Other devices able to reduce BP in patient on the top of treatment
 - BP reduction for a **Tolerable risk** ?
 - No outcome data
 - Single intervention
 - Length of the effect ?
- Patient preferences ?
 - Shared Medical Decision or Active Engagement versus Passive Decision

Patient Preference Information: added value in Hypertension

- Address burden of low adherence
- Perception of benefit and risk according to Drugs and Devices
 - Events are perceived differently (Heart attack valued more than Stroke)
 - Side Effect matters more than Benefits (lowering BP in an asymptomatic disease)
 - Risk of an intervention perceived differently
 - Importance of PRO (for asymptomatic disease)
 - Frequency and length of treatment
- Type of patient: PP studies reflect the preferences of patients from the full spectrum of disease for which the device is intended to be used (*Drug naive, mild to moderate HTN, uncontrolled HTN, history of HTN with ADR*)
- Impact of factors such as : Knowledge, personal belief, healthcare model, socio economic status, trust, satisfaction, confidence in decision

Patient preference and device trials

- **Before** trials to guide decision about endpoint and objectives
(Patients attribute different weight to individual clinical endpoints. This could have significant implications for the interpretation of clinical trial data).
- **During** the trial to reduce the impact of adherence to drugs or lifestyle modification (with PRO)
- **After** the trial : identify subgroups
- **Post market**: Patient preference needs to be reassessed (outcome data, new risks, optimize the benefit / risk ratio)

Conclusion

- It 's time for a Patient Preference Trial in Hypertension !
- Patient Preference will have an impact on Blood Pressure
- Patient preference instead of randomisation
 - To minimize impact of low adherence
 - Sham is not always possible, or at risk (ROX, carotid angiography)
 - The control arm will be a Device arm (Device vs Device trial)
 - Outcome trial difficult to perform