Patient Preferences and Devices for HTN

Professor Atul PATHAK, MD, PhD.

Head of Clinical Research
Director Hypertension, Dyslipidemia and Heart Failure unit
Director of Hi-LAB (Health Innovation Lab)
Clinique Pasteur, Toulouse
INSERM 1048
FRANCE
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

---

Azoulay L et al. BMJ 2018;363:k4209
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)

- **Raised BP**: 46% vs 45% (p=0.79)
- **Severely raised BP**: 12% vs 11% (p=0.86)
- **Uncontrolled BP**: 50% vs 50% (p=0.99)

*SBP/DBP ≥140/90 (≥140/80 for patients with diabetes);**SBP/DBP ≥160/100 mmHg;***Raised blood pressure in patients using blood pressure lowering drugs.
### Patient Adherence in RDN trials

<table>
<thead>
<tr>
<th>Determinants of BP Lowering Drugs</th>
<th>Renal Denervation Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline (n=63)</td>
</tr>
<tr>
<td>No. of BP lowering drugs prescribed</td>
<td>3.7±1.5</td>
</tr>
<tr>
<td>No. of BP lowering drugs detected</td>
<td>1.8±1.4</td>
</tr>
<tr>
<td>Mean difference between prescribed and measured</td>
<td>1.8 (1.3 to 2.2)</td>
</tr>
</tbody>
</table>

| P 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

Study in Progress, Medtronic
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