The Future of Renal Denervation for the Treatment of Resistant Hypertension
Every Decision Backed by Research
HYPERTENSION TREATMENT

Hypertension is defined as a systolic blood pressure (SBP) of greater than or equal to 140 mmHG and a diastolic blood pressure (DBP) of greater than or equal to 90 mmHg.

This complex disorder affects over 1 billion people worldwide and approximately 44.2% of people in Europe.

Uncontrolled hypertension (i.e. the inability to maintain blood pressure (BP) below 140/90 mmHg) is a major risk factor for cardiovascular morbidity and mortality and represents a significant burden on the healthcare system. Despite advances in the pharmacological treatment of hypertension, the percentage of patients achieving BP control remains low.

The prevalence and impact of hypertension on clinical outcomes strongly suggests the need for improvement in the management of hypertension. The following pages discuss the prevalence, related risks, and current treatment programs for hypertension. The final pages introduce studies that are investigating the potential benefits of renal denervation for the management of resistant hypertension.

References:

For the data above, hypertension is defined as an average systolic blood pressure 140 mmHg or greater, diastolic blood pressure 90 mm Hg or greater, or use of antihypertensive medication. The data in the chart above is from Kearney PM, et al. 2005.

** Definitions: Established market economies: USA, Canada, Spain, England, Germany, Greece, Italy, Sweden, Australia, and Japan; Former socialist economies: Slovakia; Latin America and the Caribbean: Mexico, Paraguay, and Venezuela; Middle Eastern Crescent: Egypt and Turkey; Other Asia and Islands: Korea, Thailand, and Taiwan; Sub-Saharan Africa: South Africa, Cameroon, Tanzania, and Zimbabwe.
HYPERTENSION IS A RISK FACTOR FOR CARDIOVASCULAR MORBIDITY AND MORTALITY

- Chronic uncontrolled hypertension is related to cardiovascular conditions such as stroke and heart failure²
- The risk of cardiovascular death increases with rising blood pressure, every 20 mmHg rise in SBP doubles the risk of cardiovascular death (See Figure)³-⁵

![Cardiovascular Mortality Risk Increases as Blood Pressure Rises***](image)

*** Measurements taken in individuals aged 40-69 years, beginning with a blood pressure of 115/75 mm Hg, the data in this graph is from Lewington et al.2002³

References
5. The graph on this page includes data from sources 3 and 4 and was adapted from www.hypertensiononline.org.
TRADITIONAL TREATMENT OF HYPERTENSION FOLLOWS A PROGRESSIVELY MORE AGGRESSIVE PHARMACOLOGIC REGIMEN

The goal of pharmacotherapy is to reach a blood pressure of < 140/90 mmHg (goal pressure for diabetic and chronic kidney disease patients is < 130/80 mmHg) (See Figure).¹

- Patients with stage I hypertension are generally initiated on at least one anti-hypertension drug
- Patients with stage II hypertension are generally initiated on a combination drug therapy comprising of 2 or more anti-hypertension drugs

* Hypertension may exist in association with other high-risk conditions in which there are compelling indications for use of a particular treatment. These additional treatments must be considered when managing BP.¹
UP TO 12.8% OF HYPERTENSIVE PATIENTS ARE RESISTANT TO PHARMACOLOGICAL TREATMENT

Data from the NHANES* shows that 12.8% of drug-treated hypertension patients (n=539) meet the criteria for resistant hypertension

DEFINITIONS FOR RESISTANT HYPERTENSION

JNC7¹

- Failure to reach blood pressure (BP) <140/90 mmHg with at least 3 antihypertension agents of different classes, including a diuretic or
- Blood pressure is controlled but requires 4 or more medications to do so

ESH/ESC³

- When lifestyle measures and combination of at least three drugs in adequate doses have failed to lower systolic and diastolic BP sufficiently

References


*National Health and Nutrition Examination Survey (NHANES)
Renal sympathetic nerves play a critical role in the initiation and maintenance of systemic hypertension. Efferent and afferent renal sympathetic nerves form the renal plexus located in the outer wall of the renal artery.¹

Activation of the **efferent** renal sympathetic nerves leads to:²
- Renal insufficiency by decreasing renal blood flow and function
- Hypertension by increasing vasoconstriction, heart rate, and heart contractility

Activation of the **afferent** renal sympathetic nerves leads to:²
- Hypertension by increasing the activity of the sympathetic nervous system
RENAL SYMPATHETIC DENERVATION FOR CONTROL OF RESISTANT HYPERTENSION

Renal denervation is a catheter based ablation procedure in which lesions are delivered along the walls of the renal arteries to disrupt the sympathetic nerve network located within the arterial adventitia.

References:
CATHETER BASED RENAL DENERVATION* CAN REDUCE BLOOD PRESSURE

Symplicity HTN-2 six month data:

- Patients who underwent the renal denervation procedure had a significant reduction in SBP (p<0.0001). This reduction was significantly greater than the reduction in SBP for the control group (p<0.0001) (See Figure).
- Patients in the renal denervation group had no serious complications
  - Stable renal function
  - No new stenosis at the location of procedure.
ST. JUDE MEDICAL: FURTHER EVALUATING THE USE OF ABLATION TECHNOLOGY FOR RESISTANT HYPERTENSION

With a history of expertise in ablation devices and tools, St. Jude Medical is conducting research to evaluate new approaches to renal denervation

ENLIGHTN-I: ABLATION INDUCED RENAL SYMPATHETIC DENERVATION TRIAL

The objective of this feasibility study is to demonstrate the safety and efficacy of the St. Jude Medical Renal Denervation System in treatment of patients with resistant hypertension (see chart below for study design)

**Patients with resistant hypertension and office systolic blood pressure ≥160 mmHg (≥150 mmHg for patient with type 2 diabetes)**

**ESTIMATED ENROLLMENT:** 60 patients

**Inclusions and Exclusions**

**RENAL DENERVATION PERFORMED**

**DATA COLLECTED:** Medication, Office BP, Home-Based BP, 24-hour Ambulatory BP, Blood and Urine Collection, 12-lead ECG, Renal Artery Anatomy Evaluation, Adverse Events, Protocol Deviation

Follow-up visits: Pre-discharge, Months – 1, 3, 6, 12, 18, 24

References

2. ClinicalTrials.gov Identifier: NCT01438229.
St. Jude Medical is focused on reducing risk by continuously finding ways to put more control into the hands of those who save and enhance lives.