

Renal denervation system trial gives positive result

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Bangalore: Preliminary data from a study has demonstrated that St. Jude Medical's EnligHTN renal denervation system is safe and effective for treatment of resistant hypertension. The study demonstrated a systolic blood pressure reduction of 28 points after 30 days on average patients with resistant hypertension experience. St. Jude Medical is a global medical device company.

Renal denervation is a specialized ablation procedure that has been clinically proven to reduce blood pressure in patients with hypertension that is resistant to medical therapy. A typical normal blood pressure is below 120 systolic (the first number) and 80 diastolic (the second number) and is expressed as 120/80 mmHg. Hypertension, or high blood pressure, is a blood pressure greater than 140/90 mmHg.

Patients that enrolled in the trial had an average of 176 / 96 mmHg baseline blood pressure despite being on multiple medications to help control blood pressure. "The risk of cardiovascular death doubles with every 20 point increase in systolic blood pressure, so an average blood pressure reduction of 28 points is quite significant and demonstrates just how effective the technology is," said Prof Stephen Worthley of Royal Adelaide Hospital in Australia who is the primary investigator in the trial. "From other clinical trials studying the impact of renal denervation, we have learned that blood pressure continues to be reduced over time, so I would not be surprised to see this trend continue and see an even greater benefit for patients."

Results from other clinical trials for competitive technologies studying the safety and efficacy of renal denervation demonstrated that results improve over time. After 30 days, a 14 point reduction in systolic blood pressure was noted in a competitor's study, but this number improved to a reduction of 27 points of systolic blood pressure after one year. Compared to this competitive technology, the average 30-day results from the EnligHTN renal denervation trial showed double the reduction in blood pressure at 30 days. Further, the renal denervation treatment was successfully delivered with no serious complications related to the procedure or device.

Forty seven patients enrolled in the multi-center study. To be considered for enrollment, patients were required to have a

systolic blood pressure above 160 (150 for patients with type 2 diabetes) and take at least three anti-hypertensive medications concurrently at maximally tolerated doses, including a diuretic.

"Hypertension accounts for millions of deaths every year, so it is encouraging that just ahead of World Hypertension Day, new data demonstrate that there is a safe and effective solution to help reduce blood pressure in patients where other treatments aren't working," said Mr Frank J Callaghan, president of the St. Jude Medical Cardiovascular Division. "The EnligHTN system is truly a unique technology that we believe has the potential to reduce a root cause of some of the world's most burdensome cardiovascular diseases and help patients around the world live more healthy lives."

Hypertension is a root cause of various life-threatening health problems, including heart disease, stroke, and kidney failure. It impacts more than 1 billion people globally, many of whom do not respond to conventional treatment with medication.