Background

Blood pressure is measured in millimeters of mercury (mmHg). A person can be said to have hypertension if the blood pressure is consistently above 140 mmHg when the heart is pumping (systolic) and/or over 90 mmHg as the heart is refilling (diastolic), i.e. 140/90 mmHg. For more than 95% of people the cause of their high blood pressure is unknown and so is called 'primary' or 'essential hypertension'.

The risk of death from ischaemic heart disease and stroke increases almost linearly with increasing blood pressure. For every 20/10 mmHg increase in blood pressure the risk of mortality from ischaemic heart disease and stroke doubles. On top of this, as blood pressure increases so does the chance of developing heart failure and kidney disease.

In the adult population around 32% of men and 29% of women are thought to have high blood pressure. The risk of developing high blood pressure increases with age with around 2 in 3 of those aged 65 years or older being affected.

Current Practice

The current treatment pathways for hypertension in adults are provided by the National Institute for Health and Clinical Excellence (NICE) and the British Hypertension Society. Initial treatment for slightly elevated blood pressure may include advice about lifestyle changes, but if the blood pressure still remains high the patient may be given an anti-hypertensive drug, with more being added if the first is unsuccessful, up to a total of three concurrent medications. If a person’s blood pressure still remains elevated after receiving three concurrent anti-hypertensive drugs of different classes at their optimal dose the person can be described as having resistant hypertension. Although the exact prevalence of resistant hypertension is unknown, clinical trials suggest that it is not rare, involving perhaps 20% to 30% of study participants. Treatment of resistant hypertension is almost always multifactorial and centres on identification and reversal of lifestyle factors contributing to treatment resistance. More specialised drugs may be given to lower blood pressure in resistant hypertension, but these may have severe side effects. Many of the earliest agents developed for blood pressure control blocked the activation of the sympathetic nervous system, part of which supplies the kidneys, but due to their severe side effects, are no longer used.

Simplicity® Catheter System for renal sympathetic denervation in resistant hypertension

Simplicity® is a device designed to treat a form of drug resistant, persistent high blood pressure (hypertension). Used in a specialised clinic that performs catheterisation, the tip of the Simplicity® device is fed into the renal artery via the femoral artery in the groin. Once in place, a burst of radio waves destroys the nerve supply to the renal artery which is intended to decrease blood pressure in some patients who are resistant to anti-hypertensive drugs.
New Technology

Developed by Ardian Limited, which is now part of Medtronic, the Symplicity® Catheter System™ consists of a catheter fed in turn into each of the arteries that supply the kidneys through the major artery in the groin. Once in place, radio waves are emitted from the tip of the catheter which deactivates the nerve supply to each renal artery. Deactivation of the sympathetic nerve supply to the arteries of the kidney may lead to a sustainable reduction in blood pressure in some patients with resistant hypertension. Symplicity® was CE marked in February 2008, and is currently available in a limited number of specialised centres in the UK.

Other interventional procedures under development for resistant hypertension include chronic carotid baroreflex stimulation using CVRx’s Incorporated Rheos system®, and deep brain stimulation.

Clinical Studies and Research Questions

A number of multicentre early phase trials have been published.

A multicentre safety and proof of principle cohort study of the Symplicity® Catheter System™ was performed on 45 patients with resistant hypertension. A further five patients who were not suitable to undergo the treatment acted as controls. Blood pressure was measured in these groups at intervals up to 12 months post-procedure. 41 patients who had received treatment with the Symplicity® Catheter System™ were followed up at 1 month post procedure where it was found that their systolic blood pressure had fallen by 14 mmHg and their diastolic pressure by 10 mmHg. Over this period the systolic blood pressure of the five patients who had not been treated with Symplicity® increased by 3 mmHg. Twenty patients who had received treatment with Symplicity® were followed up at nine months where their systolic and diastolic blood pressure was reported to have fallen by 24mmHg and 11mmHg respectively. The blood pressure of two control patients who were followed up at this point increased by 26 and 17 mmHg respectively. The decrease in blood pressure in the treatment group was reported to be maintained at 12 months following treatment.

A follow up multicentre study of the Symplicity® Catheter System™ was performed on 117 people (including the 45 patients recruited for the trial outlined above) whose blood pressure was recorded at intervals up to 24 months post-procedure. At one month, of the 105 people followed up, average systolic blood pressure had decreased by 20 mmHg (systolic) and 11mmHg (diastolic). This lowered blood pressure was maintained at 6 and 12 months in those followed up (72 and 58 people respectively). Of the 11 people who were followed up for two years, the average fall in blood pressure from pre-treatment levels was 33 mmHg (systolic) and 14 mmHg (diastolic).

There is an ongoing multicentre prospective randomised controlled study of the Symplicity Catheter System examining the role of this treatment in 110 patients with uncontrolled hypertension. If assigned to the treatment group patients receive renal denervation and are maintained on baseline anti-hypertensive drugs for six months, whilst people in the control group will be maintained on baseline anti-hypertensive medications alone and followed for six months, after which they have the option to
undergo the renal denervation procedure. These patients will be followed up for a period of three years. With enrolment completed in 2010, the trial is due to report sometime in 2014.

**Addendum (July 2011)**

Since writing this news brief (September 2010), two clinical trials have been published:

Esler MD, Krum H, Sobotka PA *et al.* Renal sympathetic denervation in patients with treatment resistant hypertension (The Symplicity HTN-2 Trial): a randomised controlled trial. The Lancet 2010;376:1903-1909 (described in this publication as an ongoing trial)


A consultation document on this procedure has also been issued by NICE. [http://www.nice.org.uk/nicemedia/live/13340/54644/54644.pdf](http://www.nice.org.uk/nicemedia/live/13340/54644/54644.pdf)

**Potential Impact**

If proved to be effective the Symplicity® Catheter System™ may offer a new option for treatment of those with high blood pressure that is resistant to drugs or lifestyle change. This is a group of people for whom current therapeutic options are limited and an effective treatment would offer benefits in terms of reduction of the risks of serious consequences of hypertension, such as stroke and renal failure.

If used, the Symplicity® Catheter System™ would be an addition to the current treatment pathway for hypertension and so would require additional healthcare resources in terms of the cost of the device itself and the use of specialist staff and hospital radiology resources during the procedure. The cost must be weighed against the potential healthcare resource benefits of reduced morbidity from the consequences of hypertension.

**References**


