

## **Patient information – Renal sympathetic nerve ablation (RSNA), St George Hospital – Departments of Cardiology and Renal Medicine**

### **Introduction**

Your Doctor has recommended Renal Sympathetic Nerve Ablation for treatment of resistant hypertension. This means that your high blood pressure (hypertension) has not responded to the usual combination of at least 3 blood pressure medications and that your Doctor has not found another treatable or reversible cause for your hypertension.

### **Description of the procedure**

RSNA is a relatively new treatment for hypertension. It has been shown to lower blood pressure (in addition to usual medication) by a single treatment. This treatment involves a renal angiogram performed at STGH (as an overnight or day only stay). The angiogram is almost always done through a small needle in the groin under local anaesthetic and a catheter fed into the aorta and then the renal arteries. The catheter has a probe on its tip and this tip is allowed to sit on the wall of the renal artery (the artery supplying the kidney). The tip then emits a radio frequency wave which heats the wall of the artery and damages the renal nerves which run in the wall of the artery. The temperature of the procedure is monitored by the equipment to ensure safety. This procedure takes about 120 seconds, and then is repeated in 5-7 places in the same artery (so the total time for each artery is about 15-20 min). Both the left and the right arteries are treated. The catheter is then removed and the procedure is complete. There is a small hole left in the artery in groin as a consequence of this procedure which will require some pressure or a small stitch or plug to close and allow it to heal.

### **How it works**

It is believed the RSNA damage to the renal nerves prevents the kidneys from sending signals to the brain to raise blood pressure and possibly also prevents the kidneys from responding to the brain's messages to raise blood pressure. By lowering blood pressure, ideally to the target level, the risk of stroke, heart attack, and other cardiovascular problems is lowered. Also, you may need to take less medication as a consequence of this procedure.

### **Safety**

This procedure is very safe and you will be under the care of experienced staff. There are known complications from having a catheter introduced into the artery in the groin including bleeding into the area (in < 3% cases) which may require further pressure or even a minor surgical procedure to control the bleeding. There is always a risk of damaging the kidney artery by introducing a catheter into it (the rate is approximately 1/150). There appears to be no significant risk per se of the radio frequency treatment from the available studies around the world. There have been no deaths attributed to the procedure.

## Effects on the kidneys

There do not appear to be any significant deleterious effects on the kidneys in a study with follow up to 2 years post-procedure.

## Likelihood of Benefit

The studies to date suggest that about 85% of patients who undergo this procedure will have a beneficial lowering of BP of around 30/15 mmHg in the first few months. However it appears that the benefit may apply to nearly all patients in studies that have followed patients for at least 2 years.

## Cost to you

This procedure will be performed at St George Public Hospital. The only potential cost could relate to Private Health Insurance excess payments in the event you are privately insured and choose to use the policy.

## Potential Risks of the Procedure

### Complications from catheter insertion site in the groin, catheter advancement and radiological imaging of the arteries to the kidneys:

- Pain, bruising, bleeding, infection, nausea and vomiting, vascular complications requiring surgery, contrast allergy and reactions, circulatory disturbances and death.
- There are additional risks that could possibly be associated with the denervation procedure. These potential risks have not yet been quantified, but may include:
- Pain, Injury to the kidneys or their arteries - if severe enough may require dialysis or further (e.g. arterial stenting), Rapid reduction of blood pressure causing dizziness or fatigue, Electrolyte disturbances, Haematuria & Skin burn

## 4. Minimization of Risk:

### The following measures will also be taken to minimize risk to participants:

1. Physicians and staff have received specific and appropriate training in using the Medtronic Ardian system.

2. The system's design and software include several safety mechanisms to reduce risk to the patient (limitations on temperature, time, impedance, and power delivered to the patient).

### **Minimization of Risk**

The following measures will also be taken to minimize risk to participants:

1. Physicians and staff will receive appropriate training by Medtronic Ardian prior to using the system.
2. *Instructions for Use* are provided with each catheter and a *User's Manual* is provided with each generator.
3. The system's design and software include several safety mechanisms to reduce risk to the patient (limitations on temperature, time, impedance, and power delivered to the patient).
4. Patients will be closely monitored during the procedure and at regularly scheduled intervals.
5. Physicians will employ usual and customary clinical technique (*e.g.*, sterile technique during catheter use and aseptic wound care procedures).

### **Data Collection**

St George Hospital is involved in a national registry. The registry is aiming to document the long-term safety and effectiveness of renal denervation in patients with hypertension and other diseases characterized by elevated sympathetic drive.

Patient data will be collected and reported in a de-identified manner.