

Royal Papworth Hospital

NHS Foundation Trust

Coronary sinus reducer Patient information sheet

Why have I been chosen?

You have been identified as having refractory angina. This affects 5-10% of patients with coronary artery disease. As you are aware, there is no straightforward treatment option available. Your arteries are not suitable for bypass surgery or routine coronary angioplasty with stents to open the blockages within the coronary arteries. Up until now the mainstay of treatment has been anti angina medications. Despite this many patients continue to experience refractorys angina, which is why this new technology has been developed.

What does the procedure involve?

The coronary sinus reducer is a stainless steel balloon expandable stent that is designed to create a narrowing in the coronary sinus, which is the final pathway of cardiac venous drainage. We believe this redistributes blood and improves the blood supply to the heart, in particular to areas that need it most.

The stent is implanted via a small tube inserted into the internal jugular vein in the neck or femoral vein in the groin. This is performed using ultrasound guidance under local anaesthetic plus sedation if required. The balloon expandable coronary sinus stent is correctly positioned under X-ray guidance in the cardiac catheter laboratory. The implantation procedure takes about one hour to complete. The neck or femoral vein tube will be removed at the end of the procedure and compression applied to achieve haemostasis.

Following expansion of the stent blood flow is redistributed to the narrowed diseased coronary arteries, improving blood supply to the heart muscle in order to reduce your symptoms of angina. This procedure is new to Royal Papworth Hospital and will be performed by Dr Hoole assisted by expert colleagues.

What are the risks/ side effects of the procedure?

Bruising, bleeding and haematoma formation around the access site of the neck or leg vein may occur after implantation (1/100). If you are taking oral anticoagulation (eg warfarin or similar drug) we may ask this to be interrupted to mitigate the bleeding risk. If we use the neck vein as the access site there is a 1/500 chance of a pneumothorax (deflated lung). We will minimise this risk by using ultrasound guidance to place the sheath in the neck vein. Although not reported in the literature, we believe there is a small risk (<1/500) that the device may embolise (fall out) into the right atrium during implantation.

In most circumstances this can be retrieved with a snare via the neck or femoral vein but rarely open heart surgery may be required to retrieve the lost device. Blood may also collect around the heart during the procedure (<1/500) if the coronary vein is damaged and this may need a drain to remedy the problem. There is also a small risk (<1/1000) of heart attack/ stroke.

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Large print copies and alternative language versions of this leaflet Collaboration can be made available on request.

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Implantation of the coronary sinus reducer has not been associated with any significant increase in long term risk when compared to placebo.

What are the possible benefits of this procedure?

In a small clinical trial of 104 patients, implantation of the coronary-sinus reducing device was associated with significant improvement in symptoms and quality of life in patients with refractory angina who were not candidates for bypass surgery or coronary angioplasty. The number needed to treat to significantly improve angina was five, compared to placebo. However, almost three quarters of patients receiving a coronary sinus reducer experienced an improvement in their angina symptoms.

How long do I need to stay in hospital?

We will keep you in overnight for observation and we will arrange a post-implantation ECG and chest x-ray. We aim to discharge you home the next morning.

What will happen after the procedure?

We will contact you a week later by telephone to see how you are getting on. We will also review you in clinic at six to eight weeks and six months following the procedure. You will be required to take aspirin 75mg once a day and clopidogrel 75mg once a day for six months. These are blood thinning medications required to keep the stent patent and functioning well while it heals.

What if there is a problem?

If you experience any side effects or problems you think may be related to the procedure then please contact the team via Dr Hoole's secretary, Mrs Sarah Barrett, at sarah.barrett11@nhs.net or 01223 639758.

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