

Coronary sinus narrowing device implantation for refractory angina

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg712

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful

discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Recommendations

- 1.1 Evidence on the safety of coronary sinus narrowing device implantation for refractory angina shows well-recognised complications. Evidence on efficacy is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.
- 1.2 Clinicians wanting to do coronary sinus narrowing device implantation for refractory angina should:
 - Inform the clinical governance leads in their healthcare organisation.
 - Give patients (and their families and carers as appropriate) clear written information to support shared decision making, including NICE's information for the public.
 - Ensure that patients (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
 - Audit and review clinical outcomes of all patients having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).
 - Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

- 1.3 Healthcare organisations should:
- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for every patient having this procedure.
 - Regularly review data on outcomes and safety for this procedure.
- 1.4 Patient selection should be done by a multidisciplinary team.
- 1.5 The procedure should only be done in specialist centres by interventional cardiologists with specific training in the technique.
- 1.6 Report any problems with a medical device using the [Medicines and Healthcare products Regulatory Agency's Yellow Card Scheme](#).
- 1.7 NICE encourages further research into coronary sinus narrowing device implantation for refractory angina. This should report details of patient selection and long-term patient outcomes, including survival.

2 The condition, current treatments and procedure

The condition

- 2.1 Angina is pain or constricting discomfort that typically occurs in the front of the chest (but may radiate to the neck, shoulders, jaw or arms). It is brought on by physical exertion or emotional stress. Some people can have atypical symptoms, such as gastrointestinal discomfort, breathlessness or nausea. Angina is the main symptom of myocardial ischaemia. It is usually caused by atherosclerotic obstructive coronary artery disease restricting blood flow and therefore oxygen delivery to the heart muscle. Being diagnosed with angina can have a significant effect on a person's quality of life, restricting daily work and leisure activities.

Current treatments

- 2.2 [NICE's guideline on stable angina](#) describes recommendations on managing stable angina. Options include lifestyle advice, drug treatment and revascularisation using percutaneous or surgical techniques.
- 2.3 Coronary sinus narrowing device implantation is indicated for angina when other treatment options (medical or surgical) have failed or are not possible (refractory angina). The aim is to reduce symptoms and to improve quality of life.

The procedure

- 2.4 The coronary sinus is a large venous structure formed by the merging of veins that drain blood away from the myocardium. It receives most of the cardiac venous blood, which then flows into the right atrium (along with deoxygenated blood from the superior and inferior venae cavae).
- 2.5 This procedure uses a percutaneously inserted, balloon-expandable device to narrow the coronary sinus. In current practice, an hourglass-shaped device made of stainless steel mesh is used. The device is put into the main vessel of the coronary sinus by a catheter in the right side of the heart, typically through the right or left jugular vein. To define and measure the most suitable position for the device, injected contrast is used to visualise the anatomy of the coronary sinus. A guiding catheter is then used to advance the device to the implantation site. The device is mounted on a balloon, which is inflated to expand it. Once the device is correctly placed, the balloon is deflated and the catheter pulled back. Imaging is used to confirm that there is 'hour-glass' device expansion in the coronary sinus.
- 2.6 Over time, endothelialisation occurs, which creates a functional stenosis. This leads to an increase in postcapillary venous pressure and redistribution of blood from the less ischaemic epicardium to the more ischaemic endocardium.

3 Committee considerations

The evidence

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 10 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial and 8 case series, 1 of which is reported in 2 publications. It is presented in the [summary of key evidence section in the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.
- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: symptomatic relief, reduction in medications for angina and improved quality of life.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: vascular perforation, device migration, worsening of symptoms and procedure related mortality.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 The committee noted that the exact mechanism of action is unclear.
- 3.6 The committee noted that the intention of the procedure is to improve symptoms and quality of life, rather than to improve survival.
- 3.7 The committee was informed that the procedure is indicated for angina that is refractory to medication or further coronary artery intervention.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).