NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Coronary sinus stent insertion for refractory angina

Angina is chest pain caused by reduced blood flow to the heart muscle. It is refractory when it cannot be controlled using medication, by inserting a small wire-mesh device (stent) to widen or unblock an artery that supplies the heart or with conventional open-heart surgery. In this procedure, a stent is inserted through a vein in the neck. It is guided into the vessel that drains blood from the heart muscle into 1 of the right heart chambers (the coronary sinus) and expanded using a balloon. The device narrows the coronary sinus, which is thought to increase the blood to flow into the heart muscle. The aim is to reduce chest pain and improve quality of life.

NICE is looking at coronary sinus stent insertion for refractory angina.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 22 July 2021

Target date for publication of guidance: November 2021

1 Draft recommendations

1.1 Evidence on the safety of coronary sinus stent insertion 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 wishing to do coronary sinus stent insertion 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.

- Enter details about all patients having coronary sinus stent insertion for refractory angina onto UCL's Central Cardiac Audit Database and review local clinical outcomes.
- 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 stent insertion for refractory angina, which 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), and 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 impact 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 For patients with refractory angina, these treatments do not control symptoms or are not clinically suitable. Coronary sinus stent insertion is indicated for those patients in whom other treatment options (medical or surgical) have failed or are not possible. The aim is to reduce symptoms, and to improve quality of life and long-term morbidity and mortality.

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 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 stent device to narrow the coronary sinus. In current practice the device used is a stainless-steel mesh hourglass-shaped device. The stent device is usually inserted via the right jugular vein or femoral vein under local anaesthesia. A catheter is introduced through the vein, then the superior or inferior vena cava to the right atrium and into the main vessel of the coronary sinus. Injected

contrast is used to visualise the anatomy of the coronary sinus, to define and measure the most suitable position for implanting the stent device. 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. Imaging is used to confirm full occlusion of the coronary sinus by the balloon which is then deflated and the catheter pulled back.

2.6 The device becomes the sole path for blood flow through the coronary sinus, leading to development of an upstream pressure gradient that results in redistribution of blood from the less ischaemic epicardium to the 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 7 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial and 6 case series. 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.

Committee comments

3.4 The committee noted that the exact mechanism of action is unclear.

3.5 The committee noted that the intention of the procedure is to improve symptoms and quality of life, rather than to improve survival.

3.6 The committee noted that the procedure is indicated for angina that is refractory to medication or further coronary artery intervention.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
June 2021

ISBN: