NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Bioresorbable stent implantation to treat coronary artery disease

The coronary arteries supply blood to the heart muscle. In coronary artery disease, they become narrowed with fatty material. This can cause chest pain on exertion and increases the risk of heart attacks. In this procedure, a stent (small tube) is implanted into a narrowed artery to widen it. Unlike permanent metal stents, bioresorbable stents slowly dissolve over a few months. The aim is to increase blood flow to the heart, while reducing the risk of longer term complications.

NICE is looking at bioresorbable stent implantation to treat coronary artery disease. This is a review of NICE's interventional procedures guidance on bioresorbable stent implantation to treat coronary artery disease.

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This document contains the draft guidance for consultation.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 The draft guidance may change after this consultation.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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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: 17 March 2022

Target date for publication of guidance: July 2022

1 Draft recommendations

1.1 Evidence on the efficacy of bioresorbable stent implantation to treat coronary artery disease is inadequate. Evidence on its safety has shown an increased risk of serious complications in the longer term. This includes an increased risk of myocardial infarction and death with some types of bioresorbable stents. Therefore, this procedure should only be used in the context of research. Find out what only in research means on the NICE interventional procedures guidance page.

1.2 Clinicians should enter details about everyone having bioresorbable stent implantation to treat coronary artery disease into the National Institute for Cardiovascular Outcomes Research's National Audit of Percutaneous Coronary Interventions. Contact bartshealth.nicor-generalenquiries@nhs.net for details.

1.3 Further research should include randomised controlled trials reporting details of patient selection and choice of bioresorbable stent. It should also include long-term outcomes.

2 The condition, current treatments and procedure

The condition

2.1 Stenosis of the coronary arteries is usually caused by deposition of atherosclerotic plaque. This reduces blood flow to the heart muscle and is usually progressive. Symptoms of coronary artery disease typically include angina (chest pain that is exacerbated by exertion). A critical reduction of the blood supply to the heart may result in myocardial infarction or death.

Current treatments

2.2 The symptoms from a stenosed artery may be treated medically. This includes modifying risk factors (for example, smoking, hyperlipidaemia, obesity, hyperglycaemia) and treatment with medicines (for example, beta blockers, nitrates, calcium-channel blockers, antiplatelet agents, statins).

2.3 If medical management fails or is inappropriate, the usual options are coronary artery bypass grafting, or percutaneous transluminal coronary angioplasty followed by stent insertion to maintain the patency of coronary artery.

The procedure

2.4 Bioresorbable stents are designed to be absorbed by the body over time. One aim is to reduce the risk of late complications such as thrombosis, which may occur after using metal stents. The other is to reduce the need for long-term antiplatelet medicines, with their risk of bleeding complications.

2.5 The procedure is done under local anaesthesia. A guidewire is passed into the target coronary artery, usually from the radial or femoral artery under fluoroscopic image guidance. A balloon angioplasty catheter passed over the guidewire is used to dilate the coronary artery stenosis. A bioresorbable stent mounted on a balloon catheter is passed over the guide wire into the relevant segment of the artery. Then, it is expanded by inflation of the balloon within it. The balloon is then deflated and removed with the guide wire. The stent acts as a scaffold to hold the vessel open. Additional imaging, such as intravascular ultrasound and optical coherence tomography, is sometimes used to guide the procedure. This is to optimise positioning and deployment of the stent in the target coronary artery.

2.6 Bioresorbable stents are absorbed over time. Most bioresorbable stents are also drug-eluting, with a view to reducing the risk of restenosis. Antiplatelet medicines such as aspirin and clopidogrel are usually prescribed for at least 6 months after the procedure.

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 12 sources, which was discussed by the committee. The evidence included 1 health technology assessment, 1 randomised controlled trial, 3 systematic reviews with meta-analysis, 5 case series and 2 case reports. 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: reduced coronary insufficiency symptoms, maintenance of coronary patency, a reduced myocardial infarction rate and reduced mortality.

3.3 The professional experts and the committee considered the key safety outcomes to be: death, myocardial infarction, in-stent thrombosis and need for further intervention.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 The committee noted that most of the evidence came from a single device, which has now been withdrawn from the market. This device was associated with an increased risk of complications in the longer term, including myocardial infarction and death.

NICE interventional procedures consultation document, February 2022

3.6 The committee was informed that the rate of stent bioresorption varies between people who have had a stent implanted and also between different types of device.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
February 2022

ISBN: