

Bioresorbable stent implantation to treat coronary artery disease

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg732

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.

This guidance replaces IPG492.

1 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 nicor.auditenquiries@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 the 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 happen 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 inside 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 13 sources, which was discussed by the committee. The evidence included 1 health technology assessment, 2 randomised controlled trials, 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.

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
- there are new generation devices being developed.

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Endorsing organisation

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