

# Bioresorbable stent implantation for treating coronary artery disease

Interventional procedures guidance

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[www.nice.org.uk/guidance/ipg492](http://www.nice.org.uk/guidance/ipg492)

## 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. However, 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.

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.

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 Current evidence on the short-term safety and efficacy of bioresorbable stent

implantation for treating coronary artery disease is adequate, but the quantity of evidence on the safety and efficacy of the procedure in the long term is inadequate. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

- 1.2 Clinicians wishing to undertake bioresorbable stent implantation for treating coronary artery disease should take the following actions.
- Inform the clinical governance leads in their NHS trusts.
  - Ensure that patients understand the uncertainty about the procedure's safety and efficacy in the longer term and provide them with clear written information. In addition, the use of NICE's [information for the public](#) is recommended.
  - Enter details about all patients undergoing bioresorbable stent implantation for treating coronary artery disease onto the [UK Central Cardiac Audit Database](#) and review clinical outcomes locally.
- 1.3 NICE encourages further research into bioresorbable stent implantation for treating coronary artery disease and may review the procedure on publication of further evidence. Details of subsequent antiplatelet therapy should be reported and outcomes should include major adverse cardiac events (MACE) and target vessel revascularisation (defined as any repeat percutaneous intervention or surgical bypass of any segment of the treated vessel), particularly in the long term (at least 2–3 years). Studies on the safety and efficacy of the procedure compared with other types of coronary stent implantation would be useful.

## 2 Indications and current treatments

- 2.1 Coronary artery disease is narrowing (stenosis) of the coronary arteries 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.
- 2.2 The symptoms and health risks associated with a stenosed artery may be treated medically, by modifying risk factors (for example, smoking,

hyperlipidaemia, obesity and hyperglycaemia) and by drug treatment (for example, with beta-adrenergic blockers, nitrates, calcium-channel blockers, antiplatelet agents and statins).

- 2.3 If medical management fails or is inappropriate, the usual options are surgical coronary artery bypass grafting or percutaneous transluminal coronary angioplasty (usually with insertion of a bare-metal or drug-eluting stent). Stents are inserted with a view to maintaining the patency of coronary arteries after balloon dilatation.

## 3 The procedure

- 3.1 Bioresorbable stents are designed to be absorbed by the body over time. The aim is to reduce the risk of late complications such as thrombosis that may occur after the use of metal stents, and to reduce the need for long-term antiplatelet drugs, with their risk of bleeding complications.
- 3.2 The procedure is usually done under local anaesthesia with fluoroscopic image guidance. The target coronary artery stenosis is dilated, using a percutaneous approach (typically balloon angioplasty over a guide wire via the femoral or radial artery). A bioresorbable stent mounted on a balloon catheter is then passed over the guide wire into the relevant segment of the artery. The stent is expanded by inflation of the balloon within it. The balloon is then deflated and removed with the guide wire. The stent is left in place to act as a scaffold holding the vessel open. Additional imaging, such as intravascular ultrasound and optical coherence tomography, is sometimes used to guide the procedure to optimise positioning and deployment of the stent in the target coronary artery.
- 3.3 Bioresorbable stents are absorbed over time (for example, over 2 years). Some bioresorbable stents are also drug-eluting, with a view to reducing the risk of restenosis. Dual antiplatelet agents (for example, aspirin and clopidogrel) are usually prescribed for at least 6 months following the procedure.

## 4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the

evidence, see the [interventional procedure overview](#).

- 4.1 In a case series of 30 patients treated by drug-eluting bioresorbable stents, device success (defined as 'successful stent delivery and deployment at the intended target lesion with attainment of a final residual stenosis of less than 50%') was reported in 94% of patients (29/31 attempts). The bioresorbable stent dislodged (needing bailout stenting) in 2 patients. Procedure success (defined as 'clinical device success with any adjunctive device without the occurrence of major adverse cardiac events [MACE] related to ischaemia up to 7 days after the index procedure') was reported in 100%.
- 4.2 In a case series of 50 patients treated by non-drug eluting bioresorbable stents, survival rates free of all-cause death, cardiac death and MACE at 10 years were 87%, 98% and 50% respectively. Cumulative rates of MACE (defined in this series as including both cardiac and non-cardiac death) during the 10-year follow-up period were 4% (2/50) scaffold thrombosis (1 sub-acute and 1 very late at 10 years), 14% (7/50) deaths (1 cardiac death, 6 non-cardiac deaths), 8% (4/50) myocardial infarctions, and 38% (21/50) target vessel revascularisations.
- 4.3 In a case series of 63 patients treated with drug-eluting bioresorbable stents, MACE (defined as cardiac death, Q wave myocardial infarction and need for revascularisation of the target lesion) were reported in 24% (15/63) of patients at 4 months follow-up. The overall MACE rate was 27% (16/60) at 12 months follow-up and these were all target lesion revascularisations. There were no deaths or myocardial infarctions.
- 4.4 A comparative case series of 253 patients (150 treated with drug-eluting bioresorbable stents and 103 treated with drug-eluting stents) reported that in-hospital, 30-day and 6-month cumulative MACE rates were similar between both groups (all  $p > 0.5$ ), with most complications occurring during the first 10 days.
- 4.5 In the case series of 30 patients, 52% (15/29) of patients were on dual antiplatelet therapy at 1 year. At 5 years clopidogrel had been discontinued in all but 1 patient.
- 4.6 The specialist advisers listed key efficacy outcomes as successful deployment of the device, a reduced need for dual antiplatelet therapy (leading to a reduced

risk of bleeding complications), rates of stent thrombosis and target vessel revascularisation 'at intervals' greater than 12 months.

## 5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [interventional procedure overview](#).

- 5.1 Cardiac death from cardiogenic shock after the procedure was reported in 1 patient in a case series of 11 patients despite percutaneous coronary intervention (PCI) and inotropic support.
- 5.2 Definite or probable in-stent/scaffold thrombosis occurred in 2 patients with bioresorbable stents and 1 patient with a drug-eluting stent during the index procedure, and in another patient in each group within 30 days after stent implantation, in the comparative case series of 253 patients.
- 5.3 Sub-acute scaffold thrombosis was observed in 2 patients (1 on day 6 at the site of overlapping scaffolds, and 1 on day 27 after discontinuation of dual antiplatelet therapy) in a case series of 450 patients. Late scaffold thromboses occurred in 2 patients (1 on day 75 in a patient with resistance to clopidogrel and 1 on day 239) in the same case series.
- 5.4 Scaffold dislodgement was reported in 3 patients in the case series of 450 patients. All scaffold dislodgements occurred in the left circumflex, and in 2 patients dislodgement was observed after reinsertion of the same device.
- 5.5 Destruction of scaffold after balloon dilatation (not apparent on cineangiography) was reported in 1 patient in a case series of 44 patients. Further details were not reported.
- 5.6 The specialist advisers stated that theoretical adverse effects are the same as for other forms of PCI and include dissection, perforation of coronary vessels, acute myocardial infarction, late or very late thrombosis and restenosis. One adviser stated that there is a theoretical possibility of device hypersensitivity with polymer-based stents.

## 6 Committee comments

- 6.1 The Committee noted that there are different types of bioresorbable stents, which may vary in safety and efficacy. It also noted that the technology for this procedure continues to evolve.
- 6.2 The Committee noted that majority of the evidence is from drug-eluting bioresorbable stents.
- 6.3 The Committee noted that there are several ongoing trials on bioresorbable stent implantation for treating coronary artery disease.

## 7 Further information

### Information for patients

NICE has produced information on this procedure for patients and carers ([information for the public](#)). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

### About this guidance

NICE interventional procedures guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

This guidance was developed using the NICE [interventional procedures guidance process](#).

We have produced a [summary of this guidance for patients and carers](#). Information about the evidence the guidance is based on is also [available](#).

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

## Accreditation

