NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

Health Technology Appraisal

Coronary artery stents for the treatment of ischaemic heart disease (Update to guidance No. 71)

Draft scope

Appraisal objective

To appraise the clinical and cost effectiveness of newer drug eluting coronary artery stents for the prevention of ischaemic heart disease and to provide guidance to the NHS in England and Wales[1].

Background

Ischaemic heart disease (IHD) (otherwise known as coronary artery disease (CAD)) is caused by an insufficient supply of oxygen to the heart muscle, due to narrowing (occlusion) of the arteries by atheromatous plaques, a process known as stenosis. CAD can be 'silent' or can present as angina, unstable angina, myocardial infarction or sudden death. CAD may affect one or more arteries, which may be of different calibres. Occlusion may be partial or total.

CAD causes about 2100 deaths annually per million of the population in England and Wales (about 110,000 deaths in total) and is also the cause of considerable morbidity and loss of ability to lead a normal life. Approximately 1.4 million people in England and Wales suffer from angina, the most common form of such morbidity.

The symptoms and health risks that are associated with a stenosed artery may be treated either by modification of risk factors (for example, smoking cessation and diet) and/or by drug treatment (for example, beta-adrenergic blockers, nitrates, calcium channel blockers, antiplatelet agents and statins).

If these treatments do not adequately control the symptoms of CAD or are inappropriate, two invasive therapies are available. The first, coronary artery bypass grafting (CABG), involves major cardiac surgery. The second, known as balloon angioplasty, or percutaneous transluminal coronary angioplasty (PTCA), involves a nonsurgical widening from within the artery using a balloon catheter. When inflated, the balloon increases the calibre of the artery.

The major problem with PTCA is restenosis (re-narrowing) of the artery. This may occur acutely, requiring emergency CABG to prevent MI in a small proportion of cases, or subsequently during the first 6 months,

[1]The Department of Health and Welsh Assembly government remit to the Institute (20.05.02): "As part of the planned review of guidance on coronary artery stents, to appraise the clinical and cost effectiveness of drug eluting stents compared with conventional stents for the primary prevention of restenosis following PTCA".

requiring a repeat procedure in approximately 20% of patients. This rate of re-intervention is much higher (up to 50%) for arteries with small diameters, saphenous vein grafts, long lesions, total occlusions and in people with diabetes.

The technology

Stents are thin wire-mesh structures that act as permanent prosthetic artery linings to keep the artery inflated and maintain its patency. The aim of using a stent following PTCA is to reduce the likelihood of restenosis. In 2001, 86% of PTCAs undertaken in England and Wales were carried out using a stent.

Two types of stent exist – bare-metal and drug-eluting stents (DES). DES are coated with a drug that is temporarily held in place with a polymer that is 'painted' onto the bare metal. The drug is slowly released over a period of several months.

A number of drugs have been tested in the context of DES, but at the time of the last review in October 2003, only three DES had been granted a CE (Conformite Europeene) marking. These were:

- Cypher (manufactured by Cordis) which elutes sirolimus (formerly known as rapamycin), an immunosuppressive agent that reduces inflammation.
- Taxus (manufactured by Boston Scientific) which elutes paclitaxel, a cell division inhibitor
- BiodivYsio stent (manufactured by Abbott/Biocompatibles) which elutes dexamethasone, a synthetic adrenocortical steroid that reduces inflammation. (Note that as there was no reported randomised controlled trial of this product, it was not appraised in the guidance issued in October 2003).

Since the publication of technology appraisal number 71, the following developments have occurred:

- The structure of the Cypher stent has been changed and the new version of this stent is known as Cypher Select.
- Biotronic is to seek CE marking for its paclitaxel-eluting Costar stent.
- Guidant is to seek CE marking for its everolimus-eluting Xience stent.

This scope of this appraisal is therefore restricted to those DES not included in Technology Appraisal 71.

Intervention(s)	Cypher Select BiodivYsio Costar Xience
Population(s)	People with coronary artery disease requiring PTCA.
Standard comparators	(1) Bare-metal stents (2) DES
Outcomes	The outcome measures to be considered include: • health-related quality of life • restenosis • major adverse coronary events, including MI and the need for further revascularisation procedures • overall survival • adverse effects of treatment
Economic analysis	Ideally, the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. Costs should be considered from an NHS and Personal Social Services perspective.
Other considerations	• The role of concurrent therapies (e.g. antiplatelets or anticoagulants) will be explored where the evidence permits. • If the evidence allows, sub-groups involving narrow arteries, long lesions, complicated lesions (such as bifurcation lesions), saphenous vein grafts, partial versus total occlusion, and people with diabetes should be investigated. • The different types of DES should be compared with each other where evidence permits • Guidance will only be issued for DES that have been awarded an appropriate CE mark by September 30th 2005, and for which data have been supplied by 8th June 2005.

Related NICE recommendations	Related Technology Appraisals: • Acute coronary syndromes - clopidogrel (No. 80), July 2004 • Acute coronary syndromes - glycoprotein IIb/IIIa inhibitors (review) (No. 47) Sept 2002 • Angina and myocardial infarction - myocardial perfusion scintigraphy (No. 73) Nov 2003 • Ischaemic heart disease -coronary artery stents (No. 71) Oct 2003 • Myocardial infarction - thrombolysis (No. 52) Oct 2002

Questions for consultation

The main reason for carrying out the review is to appraise new technologies, particularly in the area of DES. For that reason, the scope of this update is restricted to the new DES that are/will be available. The Institute seeks the views of consultees on the appropriateness of the scope of the appraisal. The Institute would also welcome comments on whether there have been any other significant advances that they believe would potentially lead to a change in the existing guidance (No 71).