Coronary artery stents – some common questions and answers

What is NICE guidance?

The National Institute for Clinical Excellence (NICE) is part of the NHS. It produces guidance (recommendations) on the use of medicines, medical equipment, diagnostic tests and clinical and surgical procedures within the NHS in England and Wales. To produce this guidance, NICE looks at how well the medicine, equipment or procedure works and also how well it works in relation to how much it costs. This process is called an appraisal. The appraisal process involves the manufacturer of the medicine or equipment for which guidance is being produced and the organisations that represent the healthcare professionals, patients and carers who will be affected by the guidance.

NICE was asked to look at the available evidence on the use of coronary artery stents for patients with coronary artery disease (CAD). The resulting guidance was published in May 2001 (NICE Technology Appraisal Guidance No.4 The use of coronary artery stents in the Treatment of Ischaemic Heart Disease). As for all guidance NICE issues, this guidance has now been reviewed and updated. The use of drug eluting stents, which NICE was asked to look at after the publication of the original guidance on stents, was included as part of this review.

What is coronary artery disease (CAD)?

CAD (also called coronary heart disease or ‘CHD’) is the most common type of heart disease. It happens when a fatty substance, called atheroma, builds up on the inner walls of the arteries making them narrower. This process is called atherosclerosis and the resultant narrowing of the artery is called ‘stenosis’. Coronary artery stenosis may not cause any symptoms, or it may lead to angina, a chest pain that may be severe enough to restrict or prevent exertion. In severe cases, a narrowed artery becomes blocked and this can

cause a heart attack (also known as a myocardial infarction or MI). People with coronary artery disease are treated with medicines and are also given help and advice on lifestyle changes – for example, smoking cessation, losing weight and taking up exercise – that can improve their condition.

What are coronary artery stents?

Doctors may recommend an operation for some people with angina if medicines do not help with their symptoms. An operation may also be recommended for someone who has had an MI. Apart from a coronary artery bypass graft (CABG), the other type of operation is percutaneous transluminal coronary angioplasty (PCTA), or, as it is commonly referred to, balloon angioplasty. This involves the insertion of a thin catheter with a tiny balloon at its tip into a vein in the groin which is guided around the body until the tip reaches the narrowed coronary artery. The balloon is then inflated to open up the artery and then removed.

In most cases a stent is placed in the coronary artery during balloon angioplasty. Made of wire mesh, the stent is placed over the balloon and expands when the balloon is inflated. The stent keeps its shape when the balloon is removed, helping to keep the artery open and preventing the artery from re-narrowing (called ‘restenosis’). However, even with a stent in place restenosis of the artery can still occur, usually within six months of the procedure being carried out. To try to stop this happening some stents called drug-eluting stents are now coated with drugs that are slowly released into the artery.

What has NICE recommended about the use of coronary artery stents?

The guidance that NICE has produced recommends that a stent should be used routinely in people undergoing balloon angioplasty who have angina or who have had an MI.

The decision on which type of stent to use (ie either a conventional bare metal stent or a drug-eluting stent) depends on the person’s symptoms, how wide

the artery is and how long the narrowed part of the artery is. A drug-eluting stent should be used if the person has symptoms of angina and the artery is less than 3mm across, or the narrowed part (the 'lesion') is longer than 15mm.

If more than one artery is narrowed, doctors should make the decision on which type of stent to use for each artery separately.

The NICE guidance relates to two drug-eluting stents which are currently licensed in the UK: the Taxus stent, which elutes paxlitaxel to inhibit cell division; and the Cypher stent, which elutes sirolimus (previously known as rapamycin), an immunosuppressive agent that reduces inflammation.

The NICE guidance does not apply to people who have had an MI in the preceding 24 hours, or for people who have a blood clot ('thrombus') in the narrowed artery. The guidance also does not apply to people whose condition is being adequately managed with standard drug therapy.

Will NICE review its guidance?

Yes. The guidance will be reviewed in October 2004**.**

Who were the consultees involved in the appraisal?

The appraisal process involved the relevant manufacturers and organisations representing patients/carers, as well as health professionals treating patients. Those involved in this appraisal were:

- Abbott Vascular Devices Ltd
- Bard Ltd
- Biotronic Ltd
- Boston Scientific Ltd
- Cordis
- Guidant Ltd
- Jomed UK Ltd
- Kimal
- Medtronic Ltd

- Sorin Biomedica Ltd
- Terumo UK
- WL Gore & Associates
- Action Heart
- Association of British Health-Care Industries
- British Cardiac Industry Association
- British Cardiovascular Intervention Society
- British Cardiac Patients Association
- British Cardiac Society
- British Cardiovascular Industry Association
- British Heart Foundation
- Department of Health
- EUCOMED
- Heart UK
- National Collaborating Centre for Chronic Conditions
- NHS Quality Improvement Scotland
- Royal College of Nursing
- Royal College of Physicians
- Southwark PCT & South East Public Health Network
- Welsh Assembly Government

The following individuals were selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups. They participated in the Appraisal Committee discussions and provided evidence to inform the Appraisal Committee's deliberations. They gave their expert personal view on the use of coronary artery stents by attending the initial Committee discussion and/or providing written evidence to the Committee. They were also invited to comment on the ACD.

- Dr Mark de Belder, Assistant Secretary, British Cardiac Society & Consultant Cardiologist, The James Cook University Hospital, Middlesborough

- Dr Derek Connolly, Consultant Cardiologist, Heart UK & Sandwell and West Birmingham Hospitals NHS Trust, and Honorary Clinical Senior Lecturer, University of Birmingham
- Dr A H Gershlick, Consultant Cardiologist, Department of Cardiology, Glenfield Hospital NHS Trust, Leicester
- Mr S Livesey, Consultant Cardiac Surgeon, Southampton General Hospital
- Professor M Rothman, Consultant Cardiologist, London Chest Hospital

What will the guidance cost the NHS?

The total number of arteries requiring the more expensive drug-eluting stent could be as high as one-third of all stents. Based on this proportion, the additional cost of DES would be between £6 and £7.2 million per year, assuming the use of about 12,000 DES stents costing an additional £500 to £600 each. However, if the use of drug eluting stents reduced the restenosis rate by about 10%, the additional capacity generated could be used to increase the number of new stent procedures. This would have the effect of offsetting the cost of the BMS by about £4 million per year. Such cost savings, however, will often only be realised in the form of additional capacity.

Further information

The NICE website (www.nice.org.uk) has further information about NICE and the full guidance on the use of coronary artery stents that has been issued to the NHS. The guidance can also be requested from the NHS Response Line by phoning 0870 1555 455 and quoting reference N0341.

If you have access to the Internet, you can find more information coronary artery disease on the NHS Direct website (www.nhsdirect.nhs.uk). You can also phone NHS Direct on 0845 46 47.