of 7

Off-pump coronary artery bypass grafting

Interventional procedures guidance Published: 26 January 2011

www.nice.org.uk/guidance/ipg377

This guidance replaces IPG35.

Guidance 1

This document replaces previous guidance on off-pump coronary artery bypass grafting (interventional procedure guidance 35).

- Current evidence on the safety and efficacy of off-pump coronary artery 1.1 bypass grafting (CABG) is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.
- During the consent process, patients should be informed that they will be 1.2 offered off-pump CABG rather than on-pump surgery, but that on-pump surgery may be a possibility. They should be informed about the uncertainties in relation to longer-term risks of graft occlusion and mortality, as well as the likely advantages of off-pump CABG, including

the lower incidence of stroke.

- 1.3 Patient selection and treatment should be carried out by cardiac surgical teams who are skilled in both off-pump and on-pump surgery.
- NICE encourages clinicians to submit data on patients having off-pump 1.4 CABG to the UK Central Cardiac Audit Database, with a view to ultimately providing information about longer-term outcomes by linking the database to national statistics records.

2 The procedure

Indications and current treatments 2.1

2.1.1 Coronary artery disease (CAD) refers to the hardening and narrowing of the coronary arteries as a result of atherosclerosis. It can cause angina, myocardial infarction and heart failure. One treatment option is CABG, most often performed 'on pump', maintaining the circulation and oxygenation of the blood extracorporeally using a cardiopulmonary bypass machine, while the heart is arrested (not beating).

2.2 Outline of the procedure

2.2.1 Off-pump CABG aims to avoid the potential hazards of cardiopulmonary bypass, mainly in relation to the risk of stroke. With the patient under general anaesthesia, after a thoracotomy, the heart is displaced and snares are placed around target coronary arteries to occlude them while bypass grafts are sutured in place. An immobilising device is used to minimise movement of the beating heart while the anastomoses are performed. Donor vessel harvesting is performed in the standard way.

> Sections 2.3 and 2.4 describe efficacy and 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 overview.

2.3 Efficacy

- 2.3.1 Some studies reported outcomes that could be interpreted as relating either to efficacy or to safety, depending on their timing, which was not documented. Outcomes with uncertain timing of occurrence have been considered as efficacy outcomes. It is assumed that these occurred after the immediate postoperative period because they were reported with long-term follow-up data.
- 2.3.2 A meta-analysis of 5537 patients reported no significant difference in mortality rate between off-pump and on-pump CABG (relative risk 0.98, 95% CI 0.66 to 1.44) (follow-up not stated). A non-randomised controlled study of 3014 patients treated by off-pump or on-pump CABG reported major adverse events (death, stroke or myocardial infarction) in 11% (72/637) and 15% (367/2377) of patients respectively at 1-year follow-up (p = 0.012). A randomised controlled trial (RCT) of 2203 patients treated by off-pump or on-pump CABG reported death, myocardial infarction or revascularisation between 1-month and 1-year follow-up in 10% (105/1104) and 7% (78/1099) of patients respectively (p = 0.04).
- 2.3.3 A UK national register report of 86,047 patients treated since 1999 reported that 1-year survival for patients treated in the period 2004 to 2008 was 97% for off-pump CABG and 96% for on-pump CABG. By 5-year follow-up (for patients who had reached that time point), survival was 89% for off-pump CABG and 89% for on-pump CABG (significance and absolute figures not stated).
- 2.3.4 The meta-analysis of 5537 patients and a meta-analysis of 297,000 patients reported no significant difference between off-pump and on-pump CABG in relative risk of revascularisation: 1.35 (95% CI 0.83 to 2.18) and 1.35 (95% CI 0.76 to 2.39) respectively (follow-up not stated).
- 2.3.5 The non-randomised controlled study of 3014 patients reported graft failure (≥ 75% stenosis) in 45% (181/402) of patients in the off-pump group and in 46% (697/1518) of patients in the on-pump group at 12 to 18 months follow-up (p = 0.75). An RCT of 2203 patients treated by off-pump or on-pump CABG reported that fewer grafts were inserted than were planned pre-operatively in 18% of patients in the off-pump group

and 11% in the on-pump group (p < 0.001) (absolute figures not stated).

- 2.3.6 In a case series of 312 patients, off-pump CABG was converted to onpump CABG in 4% (12/312) of patients.
- 2.3.7 The Specialist Advisers listed key efficacy outcomes as requirement for additional revascularisation, symptom relief and length of stay.

2.4 Safety

- A meta-analysis of 297,000 patients reported that 30-day mortality was significantly lower following off-pump rather than on-pump CABG (pooled odds ratio 0.72, 95% CI 0.66 to 0.78) (p < 0.00001). The RCT of 2203 patients reported no significant difference in 30-day mortality between the off-pump group and the on-pump group (2% [18/1104] and 1% [13/1099] respectively, p = 0.47).
- 2.4.2 Stroke occurred significantly less frequently following off-pump CABG than on-pump CABG in the meta analysis of 297,000 patients (pooled odds ratio 0.62, 95% CI 0.55 to 0.69) (p < 0.00001) (follow-up not stated).
- 2.4.3 The Specialist Advisers listed theoretical adverse events as infection, bleeding and renal dysfunction. They commented that inaccurate suturing may lead to graft failure.

2.5 Other comments

- 2.5.1 This review of existing guidance was precipitated by recent evidence of higher graft occlusion rates in the longer term after off-pump CABG compared with on-pump surgery (see the RCT of 2203 patients). The Committee considered this evidence carefully in the context of other evidence on large numbers of patients for whom off-pump CABG had shown advantages without additional safety concerns.
- 2.5.2 The Committee was advised that off-pump CABG may have a particular role in the management of patients with gross calcification of the

ascending aorta and those with low ejection fractions.

3 Further information

3.1 For related NICE guidance see our <u>website</u>.

Information for patients

NICE has produced <u>information on this procedure for patients and carers</u> ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 About this guidance

NICE interventional procedure 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. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

It updates and replaces NICE interventional procedure guidance 35.

We have produced a <u>summary of this guidance for patients and carers</u>. Information about the evidence it is based on is also <u>available</u>.

Changes since publication

8 May 2012: minor maintenance.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration

of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

Copyright

© National Institute for Health and Clinical Excellence 2011. All rights reserved. NICE copyright material can be downloaded for private research and study, and may be reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the written permission of NICE.

Contact NICE

National Institute for Health and Clinical Excellence Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT

www.nice.org.uk nice@nice.org.uk 0845 033 7780

Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.

Accreditation

