



# Off-pump coronary artery bypass grafting

Interventional procedures guidance Published: 26 January 2011

www.nice.org.uk/guidance/ipg377

# 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 <u>Yellow Card Scheme</u>.

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 <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

This guidance replaces IPG35.

#### 1 Guidance

- 1.1 Current evidence on the safety and efficacy of off-pump coronary artery 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 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.
- Patient selection and treatment should be carried out by cardiac surgical teams who are skilled in both off-pump and on-pump surgery.
- 1.4 The National Institute for Cardiovascular Outcomes Research runs the UK Central Cardiac Audit Database (UKCCAD) and NICE encourages clinicians to submit data on patients having off-pump CABG to the database, with a view to ultimately providing information about longer-term outcomes by linking the database to national statistics records.

## 2 The procedure

#### 2.1 Indications and current treatments

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 coronary artery bypass grafting (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.

## 2.3 Efficacy

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 <u>overview</u>.

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 5,537 patients reported no significant difference in mortality rate between off-pump and on-pump CABG (relative risk 0.98, 95% [confidence interval] CI 0.66 to 1.44; follow-up not stated). A non-randomised controlled study of 3,014 patients treated by off-pump or on-pump CABG reported major adverse events (death, stroke or myocardial infarction) in 11% (72 out of 637) and 15% (367 out of 2,377) of patients respectively at 1-year follow-up (p=0.012). A randomised controlled trial (RCT) of 2,203 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 out of 1,104) and 7% (78 out of 1,099) 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).
- The meta-analysis of 5,537 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 out of 402) of patients in the off-pump group and in 46% (697 out of 1,518) of patients in the on-pump group at 12 to 18 months follow-up (p=0.75). An RCT of 2,203 patients treated by off-pump or on-pump CABG reported that fewer grafts were inserted than were planned preoperatively 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 on-pump CABG in 4% (12 out of 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 2,203 patients reported no significant difference in 30-day mortality between the off-pump group and the on-pump group (2% [18 out of 1,104] and 1% [13 out of 1,099] 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 onpump surgery (see the RCT of 2,203 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

#### Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the <u>overview</u>.

## Information for patients

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

ISBN: 978-1-4731-6369-0

# **Endorsing organisation**

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