Intraoperative fluorescence angiography for the evaluation of coronary artery bypass graft patency

Interventional procedures guidance
Published: 27 October 2004

www.nice.org.uk/guidance/ipg98

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 Yellow Card Scheme.
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 assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Guidance

1.1 Current evidence on intraoperative fluorescence angiography suggests that the procedure is safe enough for routine use in the evaluation of coronary artery bypass graft patency.

1.2 There is limited evidence on the diagnostic utility (that is, the extent to which knowledge of its results improves patients' outcomes) of this procedure, and clinicians should therefore audit and review the clinical value of intraoperative fluorescence angiography in all patients having the investigation. The Institute may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

2.1.1 Coronary artery bypass grafting is one of the most common cardiac surgical interventions. In this procedure, a section of vessel from another part of the body is used to reroute (bypass) blood around a blocked coronary artery and improve blood flow to the heart. Early blockage of the graft and poor blood flow may be a significant cause of morbidity and mortality in patients who have undergone coronary artery bypass grafting.
2.1.2 Several techniques are used intraoperatively to assess graft patency. These include digital palpation, electromagnetic flow measurement, Doppler studies, and conventional and thermal coronary angiography techniques. A limitation with many of the imaging techniques is that they provide poor resolution and definition of the grafts.

2.2 Outline of the procedure

2.2.1 Intraoperative fluorescence angiography allows confirmation of the location of the coronary arteries and assessment of bypass graft function during coronary artery bypass procedures. The intraoperative fluorescence imaging system consists of a video camera and a laser diode that emits monochromatic light. The camera, guided by a range-detector diode, is positioned a safe distance above the heart. A small amount of indocyanine green (ICG) dye is then administered as a central venous injection. This dye fluoresces when illuminated using laser energy and the images are recorded digitally. Currently the technique is only semiquantitative, in that it permits assessment of graft flow as 'excellent', 'satisfactory' or 'poor' – it cannot provide an exact measure of graft flow. The penetrating depth of the laser beam is only around 1 mm, limiting the use of this technique to certain grafts. For more details, refer to the Sources of evidence section.

2.3 Efficacy

2.3.1 The evidence on efficacy is based on four case series studies, with three studies reporting on clinically relevant results. In one study, intraoperative graft patency was assessed in 200 patients: graft patency was confirmed in 192 patients (96%), and the additional information provided by the procedure resulted in graft revision of these eight patients. Similar results were reported in two other studies with 1.4% (4/290) to 3.7% (4/107) of grafts revised after the procedure. No other outcomes were reported. For more details, refer to the Sources of evidence section.

2.3.2 One Specialist Advisor considered there to be too little information available regarding efficacy.
2.4 Safety

2.4.1 Complications associated with this procedure appear to be uncommon. There were no reports of adverse events associated with the use of the ICG dye in evaluating the patency of coronary bypass grafts. Six additional papers were identified that described complications following the administration of ICG dye for indications other than coronary graft patency. Most of these were reports of patients developing anaphylactoid reactions, with an incidence ranging from 0.02% to 0.3%. For more details, refer to the Sources of evidence section.

2.4.2 One Specialist Advisor stated that anaphylactic/allergic reactions might occur very rarely as a result of this procedure.

Andrew Dillon
Chief Executive
October 2004

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

'Interventional procedures overview of intraoperative fluorescence angiography for the evaluation of coronary artery bypass graft patency', October 2003.

Information for patients

NICE has produced information on this procedure for patients and carers ('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.

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

Changes since publication

26 January 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 2004. All rights reserved. NICE
Intraoperative fluorescence angiography for the evaluation of coronary artery bypass graft patency (IPG98)

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 Healthcare Improvement Scotland.