



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.

Intraoperative fluorescence angiography for the evaluation of coronary artery bypass graft patency (IPG98)

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</u> 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.
- 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. NICE 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.

Intraoperative fluorescence angiography for the evaluation of coronary artery bypass graft patency (IPG98)

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, see the overview.

2.3 Efficacy

- 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 out of 290) to 3.7% (4 out of 107) of grafts revised after the procedure. No other outcomes were reported. For more details, see the overview.
- 2.3.2 One Specialist Advisor considered there to be too little information available regarding efficacy.

Intraoperative fluorescence angiography for the evaluation of coronary artery bypass graft patency (IPG98)

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, see the <u>overview</u>.
- 2.4.2 One Specialist Advisor stated that anaphylactic/allergic reactions might occur very rarely as a result of this procedure.

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: 978-1-4731-6227-3

Endorsing organisation

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