

Optical coherence tomography to guide percutaneous coronary intervention

Interventional procedures guidance

Published: 23 February 2014

www.nice.org.uk/guidance/ipg481

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 Recommendations

- 1.1 The evidence on the safety of optical coherence tomography (OCT) to guide percutaneous coronary intervention (PCI) shows no major concerns. The evidence on efficacy is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to undertake OCT to guide PCI should take the following actions.
 - Inform the clinical governance leads in their NHS trusts.
 - Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
 - The National Institute for Cardiovascular Outcomes Research runs the UK Central Cardiac Audit Database (UKCCAD) and clinicians should enter details about all patients undergoing OCT to guide PCI onto this database and review local clinical outcomes.
- 1.3 NICE encourages further research into OCT to guide PCI compared against PCI with no intravascular imaging or PCI with intravascular ultrasound. Research outcomes should include data on medium- and long-term clinical outcomes, including the need for revascularisation.

2 Indications and current treatments

- 2.1 Optical coherence tomography (OCT) uses a catheter emitting near-infrared light to produce high-resolution images of blood vessel walls. It may be used to assess stenotic lesions in the coronary arteries and to image the result of stent deployment during percutaneous coronary interventions.
- 2.2 Coronary angiography is used to image coronary arteries immediately before angioplasty. Intravascular ultrasound or OCT may be used to provide additional and complementary information to coronary angiography.

3 The procedure

- 3.1 Optical coherence tomography (OCT) is usually performed using local anaesthesia. A guide wire and delivery sheath are introduced percutaneously into either the femoral or radial artery and passed into the target coronary artery using fluoroscopic image guidance. OCT imaging needs a blood-free field. This was first achieved by an occlusive technique, using an occlusion balloon with first-generation, time-domain OCT (TD OCT), but this technique is no longer used in clinical practice. A non-occlusive technique is now used, involving continuous flushing of contrast with frequency-domain OCT (FD OCT). For non-occlusive OCT, a guide wire through which contrast can be injected is used. The imaging catheter is delivered over this wire. Injection of contrast and imaging take place concurrently.
- 3.2 Second-generation FD OCT devices aim to improve image quality and, more importantly, increase the speed of image acquisition by a factor of 10. FD OCT has superseded TD OCT in the UK.
- 3.3 The resolution of coronary OCT is reported to be 10 times higher than that of intravascular ultrasound, and has rapid 3-dimensional reconstruction capability. The aim of providing more detailed images is to improve clinical outcome.

4 Efficacy

This section describes efficacy 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](#).

- 4.1 A retrospective case series compared 335 matched pairs of patients undergoing percutaneous coronary intervention (PCI) with either angiographic guidance alone or a combination of angiographic and frequency-domain optical coherence tomography (FD OCT) guidance. Cardiac death or myocardial infarction (MI) were less frequent in patients treated by PCI with a combination of angiographic and FD OCT guidance than in those treated by PCI with angiographic guidance alone over a follow-up period of 1 year. There were 15 cardiac deaths and 29 MIs in the angiography-only group, and 4 cardiac deaths and 18 MIs in the combined angiography and FD-OCT group; odds ratio 0.49; 95% confidence interval 0.25 to 0.96, $p=0.037$.
- 4.2 A randomised controlled trial comparing FD OCT against intravascular ultrasound for PCI optimisation in 70 patients reported that there was inferior stent expansion, both focal (65% versus 80%, $p=0.002$) and diffuse (84% versus 99%, $p=0.003$), when FD OCT had been used for guidance. PCI guided by FD OCT also showed a significant increase in residual stent-edge plaque burden (51% versus 42%, $p<0.001$). There were no significant differences in stent apposition.
- 4.3 In the retrospective case series comparing 335 matched pairs of patients undergoing PCI with either angiographic guidance or a combination of angiographic and FD OCT guidance, FD OCT led to additional interventions (further stenting and additional balloon dilation) in 116 patients (35%).
- 4.4 In a case series of 40 patients in whom OCT was performed to evaluate ambiguous or intermediate lesions, 60% (24 out of 40) were treated by PCI and 40% (16 out of 40) had PCI deferred. None of the patients for whom PCI was deferred had a coronary event within an average follow-up of 4.6 months.
- 4.5 The specialist advisers listed a key efficacy outcome as a change in diagnosis or management due to OCT imaging results. They cited as examples identifying culprit or non-culprit plaques in acute coronary syndromes, identifying

intracoronary or intra-stent thrombus, identifying dissections and complications after stenting, examining stent deformation and conformation, identifying modes of stent failure including neoatherogenesis, and documenting stent tissue coverage.

5 Safety

This section describes 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](#).

- 5.1 A large coronary perforation occurred (no further details of cause available) during optical coherence tomography (OCT) imaging in 1 patient presented in a case report, leading to reduced blood pressure and loss of consciousness. Surgical repair was done but the patient died of cardiac arrest after 7 days.
- 5.2 A minor type A coronary dissection occurred in 1 patient in the case series of 468 patients during time-domain OCT (TD OCT) imaging. Coronary blood flow was not impaired and further treatment was not needed.
- 5.3 Ventricular fibrillation occurred in 5 patients in a case series of 468 patients during TD OCT imaging, in 3 out of 256 during occlusive imaging and 2 out of 212 during non-occlusive imaging. In all cases, sinus rhythm was promptly restored after stopping OCT imaging and external defibrillation. Ventricular ectopic beats were noted in 3 patients in a case series of 90 patients undergoing 114 OCT image acquisitions.
- 5.4 Air embolism occurred in 3 patients in the case series of 468 patients during TD OCT imaging. All responded promptly to air aspiration, treatment with nitrates and, in 1 patient, nitroprusside administration.
- 5.5 Mechanical device failure occurred in 1 patient in the case series of 468 patients. The imaging wire became trapped within the struts of a stent and the tip fractured and remained within the stent. At 4-month follow-up there had been no clinical consequences and angiography showed no flow abnormalities.

- 5.6 Multiple thrombi were reported during OCT imaging in 3 patients presented in case reports. These formed during OCT imaging in the left anterior descending artery causing total occlusion in 1 patient and subtotal occlusion in 2 others. All resolved with appropriate management and all patients recovered uneventfully.
- 5.7 Vessel spasm during withdrawal of the OCT wire was reported in a single case report. This caused chest pain and ST elevation but resolved with an intracoronary injection of nitrate.
- 5.8 Self-limiting chest pain was reported by 48% of patients (225 out of 468) during TD OCT imaging in the case series of 468 patients. This was significantly more common when the occlusive rather than the non-occlusive technique was used (70% [180 out of 256] versus 21% [45 out of 212], $p < 0.001$).
- 5.9 Self-limiting QRS widening or ST depression and ST elevation occurred in 192 (46%) of 468 patients treated by occlusive or non-occlusive TD OCT. These were significantly more common when the occlusive rather than the non-occlusive technique was used (61% [139 out of 256] versus 27% [53 out of 212], $p < 0.001$).
- 5.10 The specialist advisers described the possibility that emergency revascularisation might be needed as a result of some of the complications of OCT which were reported in the literature.

6 Committee comments

- 6.1 The Committee was aware of the large numbers of patients in whom optical coherence tomography during percutaneous coronary interventions might be used. It considered that a high degree of certainty about the clinical utility of the procedure was therefore necessary, and this underpinned the recommendation in [section 1.1](#).

7 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

Information for patients

NICE has produced [information for the public on this procedure](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

ISBN: 978-1-4731-0442-6

Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).