NICE National Institute for Health and Care Excellence

NICE guidance

Intravascular lithotripsy to treat calcified coronary arteries during percutaneous coronary intervention

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg802

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.

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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.

This guidance replaces IPG673.

1 Recommendations

1.1 Use intravascular lithotripsy as an option to treat calcified coronary arteries during percutaneous coronary intervention with standard arrangements in place for clinical governance, consent and audit.

1.2 Clinicians should enter details about everyone having the procedure onto the National Institute for Cardiovascular Outcomes Research (NICOR) database and review local clinical outcomes.

Why the committee made these recommendations

There is good-quality evidence that this procedure is effective and safe. The evidence shows that calcification is reduced and blood vessel diameter is increased after this procedure, meaning a stent can be more easily inserted. People having this procedure already have a high risk of cardiovascular complications, but there is no evidence that intravascular lithotripsy increases this risk. This procedure is widely used and established in clinical practice.

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2 The condition, current treatments and procedure

The condition

2.1 Coronary artery calcification (intimal and medial calcifications) increases the complexity of percutaneous treatment strategies in coronary interventions. It contributes to:

- arterial wall stiffness
- suboptimal stent delivery and expansion
- in-stent restenosis
- high rates of stent thrombosis
- the need for subsequent target lesion revascularisation after endovascular interventions.

Current treatments

2.2 Standard endovascular treatment options for modifying calcium or plaque during percutaneous coronary intervention (PCI) include balloon angioplasty using standard or high-pressure non-compliant balloons; cutting or scoring balloons; and stenting with or without coronary atherectomy (such as rotational, orbital or laser atherectomy). These treatments aim to allow optimal stent expansion and achieve maximal luminal gain. But they may sometimes lead to localised wall injury, balloon rupture or the risk of coronary vessel dissections or perforation. Intravascular lithotripsy is another endovascular treatment option for PCI.

Unmet need

2.3 Addressing calcified coronary lesions during PCI presents a significant challenge.

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Calcified plaques can hinder stent deployment and expansion, increasing the risk of complications such as arterial dissection or inadequate stent expansion. Existing options for managing heavily calcified coronary arteries during PCI such as balloon angioplasty may not be effective in fracturing severe calcifications. By using sonic waves to fracture calcium deposits, intravascular lithotripsy may be an efficient approach to managing calcified coronary arteries and may lead to better stent placement and improved patient outcomes.

The procedure

2.4 In this procedure, intravascular lithotripsy is administered to the calcified coronary artery before the stent is placed during PCI.

2.5 A percutaneous guidewire is passed through a catheter inserted from the radial or femoral artery into the coronary artery. Then, an intravascular lithotripsy catheter with embedded emitters enclosed in an integrated angioplasty balloon is passed and connected to an external generator with a cable. The catheter is advanced to the target lesion guided by X-ray imaging of radio-opaque markers on the catheter. The balloon is then inflated with a saline and contrast solution to ensure contact with the vessel wall. The lithotripsy cycle is then started. For every cycle, the catheter emits localised, high-energy, pulsatile, unfocused, circumferential, sonic, pressure waves (lasting microseconds). These waves pass through the inflated balloon into the wall of the coronary artery. As the waves travel into the wall and the connective tissue, they disrupt calcium deposits (both intimal and medial) by micro-fracturing the calcified lesions. The balloon is then deflated to allow blood supply to return to the heart.

2.6 The cycle can be repeated until the lesion has expanded enough to allow optimal stent placement or the total pulses available are used.

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3 Committee considerations

The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 14 sources, which was discussed by the committee. The evidence included is based on about 8,300 people from 2 systematic reviews and meta-analyses, 1 small randomised controlled trial, 2 pooled analyses of prospective studies, 5 prospective studies, 2 retrospective cohort studies and 2 case reports. It is presented in the summary of key evidence section in the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: improved quality of life, reduced major cardiovascular events and coronary artery patency.

3.3 The professional experts and the committee considered the key safety outcomes to be: potential risk of coronary rupture and myocardial infarction.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 The committee noted that:

- the incidence of coronary artery calcification in people having percutaneous coronary intervention is increasing
- the importance of calcification is more recognised
- CT coronary angiography may show the presence of calcification so intravascular lithotripsy can be planned beforehand if the percutaneous coronary intervention is being done electively

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- the number of procedures recorded in the National Institute for Cardiovascular Outcomes Research (NICOR) database has increased rapidly over the past few years.

3.6 The committee was informed that:

- there is more research being done on using intravascular lithotripsy for eccentric calcified lesions
- this procedure may result in less distal embolisation than other procedures used to manage calcification.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

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