

Intravascular lithotripsy for calcified coronary arteries during percutaneous coronary intervention

Interventional procedures guidance
Published: 24 June 2020

www.nice.org.uk/guidance/ipg673

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 Evidence on the safety and efficacy of intravascular lithotripsy for calcified coronary arteries during percutaneous coronary intervention (PCI) 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 do intravascular lithotripsy for calcified coronary arteries during PCI should:
 - Inform the clinical governance leads in their NHS trusts.
 - Give patients clear information to support shared decision making, including NICE's information for the public.
 - Ensure that patients understand the procedure's safety and efficacy, as well as any uncertainties about these.
 - Enter details about all patients having intravascular lithotripsy for calcified coronary arteries during PCI onto the National Institute for Cardiovascular Outcomes Research (NICOR) database, and review local clinical outcomes.
- 1.3 The procedure should only be done by an experienced interventional cardiologist with specific training in the procedure.
- 1.4 Research could be a randomised controlled trial, comparing the procedure with current standard therapies, or an observational cohort study, including using

registry data. Studies should include details of patient selection, the size and shape of the lesion, procedural success, minimal stent area and longer-term outcomes including survival.

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 and the need for subsequent target lesion revascularisation after endovascular interventions.

Current treatments

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

The procedure

- 2.3 In this procedure, shockwave intravascular lithotripsy is administered to the calcified coronary artery before stent deployment during PCI.

- 2.4 A percutaneous guidewire is passed from the radial or femoral artery into a 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 connector cable. The catheter is advanced to the target lesion guided by radiopaque 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 activated. For every cycle, the catheter emits localised, high-energy, pulsatile, unfocused, circumferential, acoustic, sonic, pressure waves (lasting microseconds). These waves pass through the inflated balloon into the wall of the coronary artery. As the waves travel along the wall and the connective tissue, they disrupt calcium deposits (both intimal and medial calcium) by microfracturing the calcified lesions.
- 2.5 The cycle can be repeated until the lesion has been expanded sufficiently to allow optimal stent placement. Intravascular lithotripsy during PCI may improve stent delivery and expansion and modify focal intravascular calcium, while limiting localised injury to the endovascular surface.

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 6 sources, which was discussed by the committee. The evidence included 6 case series. It is presented in [table 2 of 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: coronary artery patency, reduced cardiac-related symptoms, survival and improved quality of life.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: major adverse cardiovascular events, coronary artery rupture or dissection,

coronary thrombosis, distal embolisation and balloon rupture.

- 3.4 One patient organisation representing patients who have had this procedure provided [submissions](#) and these were discussed by the committee.

ISBN: 978-1-4731-3791-2

Endorsing organisation

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