

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Intravascular lithotripsy for calcified coronary arteries during percutaneous coronary intervention

Coronary arteries (the main blood vessels supplying blood to the heart) can become narrowed or blocked with fatty deposits. At times, the fatty deposits contain calcium and the arteries become stiff (calcified). Usually, a thin wire is passed down the affected artery (percutaneously, that is, via an artery in the groin or arm), and a small balloon is inflated to widen the narrowed artery, squashing the fatty deposits against the arterial wall so that blood can flow freely. Sometimes a small wire mesh tube (stent) is also inserted and left in place to keep the artery open. In this procedure, the balloon used to stretch the artery contains a device that delivers ultrasound shock waves. These break up the hard deposits (lithotripsy) to make it easier to insert the stent and to avoid damaging the artery.

NICE is looking at intravascular lithotripsy for calcified coronary arteries during percutaneous coronary intervention.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants with knowledge of the procedure.

This document contains the draft guidance for [consultation](#). Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a [resolution](#) process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 25 March 2020

Target date for publication of guidance: June 2020

1 Draft recommendations

1.1 Evidence on the safety and efficacy of intravascular lithotripsy for calcified coronary arteries during percutaneous coronary intervention 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 percutaneous coronary intervention 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 percutaneous coronary intervention onto the [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). These treatments aim 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 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.

Tom Clutton-Brock

Chair, interventional procedures advisory committee

February 2020

ISBN: