

NICE interventional procedures consultation document, September 2024

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Interventional procedures consultation document

# Intravascular lithotripsy to treat calcified coronary arteries during percutaneous coronary intervention

The main blood vessels that supply blood to the heart (coronary arteries) can be narrowed by fatty deposits. These can become hard (calcified). Usually in percutaneous coronary intervention, a small tube (stent) is placed inside the narrowed artery (intravascular). This keeps the artery open and allows blood to flow more freely. Before the stent is inserted, a balloon is inflated to widen the narrowed artery. Calcified fatty deposits can make placing the stent difficult. To make this easier and to avoid damaging the artery, a device in the balloon produces ultrasound shockwaves. These waves break up the hard deposits (lithotripsy) before the balloon is fully inflated.

This is a review of NICE's interventional procedures guidance on 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 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This document contains the [draft guidance for consultation](#).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 The draft guidance may change after this consultation.**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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance

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NICE interventional procedures consultation document, September 2024

- 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: 07 October 2024

Target date for publication of guidance: February 2025

NICE interventional procedures consultation document, September 2024

## 1 Draft 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.

## 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.

## The procedure

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

2.4 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 along the wall and the connective tissue, they disrupt calcium deposits (both intimal and medial calcium) by micro-fracturing the calcified lesions. The balloon is then deflated to allow blood supply to return to the heart.

NICE interventional procedures consultation document, September 2024

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

### **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 8 sources, which was discussed by the committee. The evidence included is based on about 4,300 people from 2 systematic reviews and meta-analyses, 4 prospective studies, and 2 retrospective cohort studies. 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

NICE interventional procedures consultation document, September 2024

- 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
- 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.

Tom Clutton-Brock, Chair

Interventional procedures advisory committee

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