View results

Respondent

16 Anonymous

39:02
Time to complete

1. Project Number - (Can be found on email - IPXXX)

1758/1

Your information

2. Name: *

Ian Purcell

3. Job title: *

Consultant interventional cardiologist

4. Organisation: *

Freeman Hospital Newcastle upon Tyne

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

British Cardiovascular Intervention Society (BCIS)

7. Nominated/ratified by (if applicable):

8. Registration number (e.g. GMC, NMC, HCPC) *

3492622

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice

9. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

10. Please describe your level of experience with the procedure/technology, for example:

    Are you familiar with the procedure/technology?

    Yes

11. Have you used it or are you currently using it?

    - Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

    - Is this procedure/technology performed/used by clinicians in specialities other than your own?

    - If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.

    I am currently using this technology as part of routine clinical practice. It is used by interventional cardiologists for treatment of coronary artery disease, and interventional radiologists for treatment of peripheral arterial disease.

12. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [ ] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [x] I have had no involvement in research on this procedure.
- [ ] Other

13. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

14. Is the proposed indication appropriate? If not, please explain

Yes

15. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

There are are already several methods available to treat calcific coronary artery disease but it is an innovative and novel design. The technique is already in wide use in interventional centres in the UK.

16. Which of the following best describes the procedure:

- (●) Established practice and no longer new.
- ( ) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- ( ) Definitely novel and of uncertain safety and efficacy.
- ( ) The first in a new class of procedure.

17. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

Both. This may be used as a replacement for existing adjunctive therapy such as high-speed rotational atherectomy. Given the ease of use and short learning curve, intravascular lithotripsy may be used more widely than current calcium modification technology de facto becoming an extension to existing standard care.

18. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

No substantial modifications yet.

19. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

More case series but no randomised data to the best of my knowledge. What has changed is that the device is now widely used. NICOR will have national data on the number used but I expect this to have increased significantly.

Current management

20. Please describe the current standard of care that is used in the NHS.

I believe that intravascular lithotripsy has become part of standard care in a number of interventional centres for calcific coronary artery disease.

21. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

    If so, how do these differ from the procedure/technology described in the briefing?

Other technology includes: ultra high-pressure balloon inflation, high-speed rotational atherectomy, orbital atherectomy, cutting and scoring balloons, laser angioplasty.

Potential patient benefits and impact on the health system

22. What do you consider to be the potential benefits to patients from using this procedure/technology?

Improved lesion preparation to allow better stent expansion. Effective treatment of calcific coronary stenosis where existing therapies are ineffective. Lower risk of repeat revascularisation/in stent re stenosis.

23. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Patients with calcific coronary artery disease, more common in patients with conditions including
diabetes mellitus, renal impairment /failure, older patients, patients following bypass graft surgery.

24. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

    Adjunctive therapy to treat calcific coronary artery disease already exists. However IVL is simple to use and may have benefits in patients with, for example, large diameter coronary arteries were existing treatment is suboptimal. It has the potential to improve revascularisation outcomes both short and long-term in patients with calcific coronary artery disease.

25. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

    No additional facilities or change to existing PCI facilities required. Intra coronary imaging is essential. This should already be available in all interventional labs. The device works with existing PCI equipment.

26. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

    Yes. Instruction on lesion selection, equipment use, awareness of complications is required. However the technique itself is well within the training spectrum of interventional cardiologists in the UK.

Safety and efficacy of the procedure/technology

27. What are the potential harms of the procedure/technology?

    Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

    - Adverse events reported in the literature (if possible, please cite literature)
    - Anecdotal adverse events (known from experience)
    - Theoretical adverse events

    Includes complications typical of all interventions, particularly in calcific lesions, such as vessel dissection, perforation, balloon rupture. Ventricular arrhythmia noted as a specific complication relating to ventricular capture.

28. Please list the key efficacy outcomes for this procedure/technology?

    Immediate revascularisation success, complication rate, minimum lumen / stent area obtained. Requirement for repeat revascularisation, vessel/lesion failure.

29. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

    Equivalence or superiority to current adjunctive therapies for calcific disease including high-speed rotational atherectomy.

30. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

    No randomised data but given relatively low volume use, it is likely to be difficult to conduct a sufficiently large randomise study.

31. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ○ Most or all district general hospitals.
- ◉ A minority of hospitals, but at least 10 in the UK.
- ○ Fewer than 10 specialist centres in the UK.
- ○ Cannot predict at present.

Abstracts and ongoing studies

32. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

33. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

34. Please list any other data (published and/or unpublished) that you would like to share.

Other considerations

35. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

Depending on the population, perhaps 5% of patients undergoing PCI.

36. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Beneficial outcome measures.

These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

Similar short and long-term outcomes to any interventional cardiology study. Emphasis on successful revascularisation, minimum stent area. Quality of life angina scales.

37. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Similar early and late complications to any interventional cardiology study. Procedural complications should include ventricular arrhythmia, revascularisation failure, perforation and dissection.

Further comments

38. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

There is great enthusiasm for this technique in the interventional community. The use of the device has increased rapidly due to ease of use and perceived procedural success.

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

39. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

40. Description of interests, including relevant dates of when the interest arose and ceased. *

None

41. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

    Please note, all declarations of interest will be made publicly available on the NICE website. *

    - (●) I agree
    - ( ) I disagree

Signature

42. Name: *

    Ian Purcell

43. Date: *

    10/05/2023

View results

Respondent

17 Anonymous

21:38
Time to complete

1. Project Number - (Can be found on email - IPXXX)

1758/1

Your information

2. Name: *

Mohammad Alkhalil

3. Job title: *

Consultant

4. Organisation: *

Newcastle Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

6152959

7. Nominated/ratified by (if applicable):

8. Registration number (e.g. GMC, NMC, HCPC) *

6152959

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

10. Please describe your level of experience with the procedure/technology, for example:

    Are you familiar with the procedure/technology?

    Yes- I have been using this technology for 4 years

11. Have you used it or are you currently using it?

    - Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

    - Is this procedure/technology performed/used by clinicians in specialities other than your own?

    - If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.

    IVL is increasingly been used in the NHS. It has been used in coronary as well as peripheral calcified arteries.

12. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [ ] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [x] I have done clinical research on this procedure involving patients or healthy volunteers.
- [x] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

13. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

14. Is the proposed indication appropriate? If not, please explain

yes

15. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

It is a novel application/ approach compared to current standard of care.

16. Which of the following best describes the procedure:

- (●) Established practice and no longer new.
- ( ) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- ( ) Definitely novel and of uncertain safety and efficacy.
- ( ) The first in a new class of procedure.

17. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

It will be used in addition to standard clinical care.

18. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

No

19. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

No

Current management

20. Please describe the current standard of care that is used in the NHS.

For calcified arteries, rotational atherectomy is used.

21. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

    If so, how do these differ from the procedure/technology described in the briefing?

    Rotational/orbital atherectomy. However, the difference in calcium distribution and ability to cross with devices dictate the use of these approaches.

Potential patient benefits and impact on the health system

22. What do you consider to be the potential benefits to patients from using this procedure/technology?

    Easy and simple to use. Less likely to cause no-/ slow reflow. Patients will tolerate this technology better than other calcium modification modalities

23. Are there any groups of patients who would particularly benefit from using this procedure/technology?

    Impaired LV function

24. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

    No

25. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

It could be performed in any PCI lab

26. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

The learning curve is not steep and the use of IVL is straightforward

Safety and efficacy of the procedure/technology

27. What are the potential harms of the procedure/technology?

Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

IVL use is similar to any balloon angioplasty balloon with risks of balloon rupture, artery dissection or perforation. There is a risk of causing malignant arrhythmia although this risk is very small and only reported in single cases
(https://academic.oup.com/ehjcr/article/4/6/1/6006377)
(https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7891254/)

28. Please list the key efficacy outcomes for this procedure/technology?

Optimal lesion preparation
Stent expansion
Lower risk of stent failure

29. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

30. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

No

31. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- (●) Most or all district general hospitals.
- ( ) A minority of hospitals, but at least 10 in the UK.
- ( ) Fewer than 10 specialist centres in the UK.
- ( ) Cannot predict at present.

Abstracts and ongoing studies

32. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

Distrupt III

33. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

COIL registry

34. Please list any other data (published and/or unpublished) that you would like to share.

Other considerations

35. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

36. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Beneficial outcome measures.

These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

Intra-vascular imaging data

37. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Procedural outcomes including successful stent implantation

Further comments

38. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

None

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

39. Type of interest: *

- [ ] Direct: financial
- [x] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [ ] No interests to declare

40. Description of interests, including relevant dates of when the interest arose and ceased. *

None

41. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website. *

- (●) I agree
- ( ) I disagree

Signature

42. Name: *

Mohammad Alkhalil

43. Date: *

12/05/2023

View results

Respondent

52 Anonymous

39:21
Time to complete

1. Project Number and Name - (Can be found on email) *

IP1758/2 Intravascular lithotripsy for calcified coronary arteries during percutaneous coronary intervention

Your information

2. Name: *

Sergio Nabais de Araujo

3. Job title: *

Consultant Cardiologist

4. Organisation: *

Salisbury NHS Foundation Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

Salisbury NHS Foundation Trust

7. Nominated/ratified by (if applicable):

8. Registration number (e.g. GMC, NMC, HCPC) *

GMC 7353691

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, as communicated by the coordinator/administrator.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

How NICE will use this information:

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10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further in formation about the procedure/technology and/or your experience.

11. Please describe your level of experience with the procedure/technology, for example:

    Are you familiar with the procedure/technology?

I am extremely familiar with intravascular lythotripsy. I have performed this procedure in 108 patients since 2019 (11, 10, 19, 30, 38)

12. Have you used it or are you currently using it?

    - Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

    - Is this procedure/technology performed/used by clinicians in specialities other than your own?

    - If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.

All interventional cardiologists should have access to intravascular lythotripsy if performing PCI as part of their job. This is an essential piece of equipment for PCI at present, for the safe treatment of patients with calcified coronary lesions. Calcified lesions are common. The technology has spread across most NHS hospitals since 2019. We were one of the earliest adopters of this technology.
It can also be used by specialists performing vascular intervention in the peripheral arteries.

13. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [x] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [x] Presented clinical outcomes data at EuroPCR

14. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

15. Is the proposed indication appropriate? If not, please explain

Yes

16. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

This was a disruptive technology when it appeared in 2018. The alternatives of rotablation, high pressure balloon dilatation, orbital atherectomy, cutting balloon atherectomy for the treatment of calcified lesions present higher risk and are more complex to use. Even if rotablation is needed to cross a lesion, IVL is complementary to those treatments. IVL can also replace those alternatives as a safer treatment in many cases.
IVL is now an established practice during PCI for the treatment of calcified lesions.

17. Which of the following best describes the procedure:

- [x] Established practice and no longer new.
- [ ] A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- [ ] Definitely novel and of uncertain safety and efficacy.
- [ ] The first in a new class of procedure.

18. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

As paragraph 16

19. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

No significant changes in the way it is used since 2018. However, its use is now more widespread as it has moved on from bailout technique in non-expandable lesions to the elective treatment of calcified lesions to achieve better stent expansion and improve outcomes (reduction in ISR, TVR, stent thrombosis).

20. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

There is now more RWL data that this procedure is safe and effective

21. Do you think the guidance needs updating?

Yes. IVL is now established practice and an essential piece of equipment in every cath lab for safe and effective PCI practice.

Current management

22. Please describe the current standard of care that is used in the NHS.

IVL is part of the current standard of care in PCI of very calcified lesions in most NHS hospitals.

23. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

    If so, how do these differ from the procedure/technology described in the briefing?

Rotablation, orbital atherectomy, high pressure balloon dilatation, and cutting balloon atherectomy are alternative/complementary treatments

Potential patient benefits and impact on the health system

24. What do you consider to be the potential benefits to patients from using this procedure/technology?

Adequate and safe preparation of calcified coronary lesions during PCI in order to achieve better stent expansion and improved outcomes. Reduction of the risk of coronary perforation and death during PCI. Reduction of the risk of instent restenosis, and stent thrombosis.

25. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Those patients with angina or heart attack caused by blockages in calcified coronary arteries. This is more common in elderly patients, diabetic patients, those with kidney dysfunction.

26. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

    Yes. Improved outcomes, fewer readmissions or visits to hospital, less need for CABG surgery that is much more invasive. Less need for rotablation that is riskier and technically more demanding

27. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

    Cath labs only need the generator and a stock of IVL balloons.

28. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

    Operators with experience in PCI should watch the procedure once and go through the technical aspects. There really isn't a learning curve.

Safety and efficacy of the procedure/technology

29. What are the potential harms of the procedure/technology?

    Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

    - Adverse events reported in the literature (if possible, please cite literature)
    - Anecdotal adverse events (known from experience)
    - Theoretical adverse events

    There is a risk of coronary dissection but it is rare and usually easy to treat.
    I had a case of ventricular tachycardia induced by the shock-related ventricular ectopics out of 108 patients.

30. Please list the key efficacy outcomes for this procedure/technology?

Coronary perforation, PCI success, target vessel revascularisation, target lesion revascularisation, death, myocardial infarction, instent restenosis, stent thrombosis

31. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

No concerns.

32. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

Not really in my view

33. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- (●) Most or all district general hospitals.
- ( ) A minority of hospitals, but at least 10 in the UK.
- ( ) Fewer than 10 specialist centres in the UK.
- ( ) Cannot predict at present.

Abstracts and ongoing studies

34. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

    The evidence available is vast

35. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

    Yes, there is a trial in women I believe, by Roxanna Menran

36. Please list any other data (published and/or unpublished) that you would like to share.

    Our data published at EuroPCR 2013 showing the technology to be safe and effective in a local registry over 4 years.

Other considerations

37. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

    up to 15-20% of all PCIs performed in the country, more in areas with older population

38. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Beneficial outcome measures.

    These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

    Less angina, less risk with PCI, less risk of heart attack after PCI, less need for CABG

39. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Adverse outcome measures.

    These should include early and late complications. Please state the post procedure timescales over which these should be measured:

    death, ISR, MI, TVR, TLR

Further comments

40. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

    NA

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

41. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

42. Description of interests, including relevant dates of when the interest arose and ceased. *

NA

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Please note, all declarations of interest will be made publicly available on the NICE website. *

- (●) I agree
- ( ) I disagree

Signature

44. Name: *

Sergio Nabais de Araujo

45. Date: *

18/04/2024

View results

Respondent

61 Anonymous

17:01
Time to complete

1. Project Number and Name - (Can be found on email) *

Intravascular lithotripsy for calcified coronary arteries during percutaneous coronary intervention (IP1758/2)

Your information

2. Name: *

Keith

3. Job title: *

Robertson

4. Organisation: *

NHS Golden Jubilee

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

Member of Royal College of Physicians and Surgeons (Glasgow). Member of British Cardiovascular Intervention Society (BCIS), British Cardiovascular Society (BCS) and Scottish Cardiac Society (SCS).

7. Nominated/ratified by (if applicable):

Royal College of Physicians and Surgeons Glasgow

8. Registration number (e.g. GMC, NMC, HCPC) *

6077025

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, as communicated by the coordinator/administrator.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

11. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

As a high-volume interventional cardiologist in a large tertiary Percutaneous Coronary Intervention (PCI) centre, I have extensive experience in the use of intravascular lithotripsy (IVL) for the treatment of coronary calcification. The presence of clinically important calcium in lesions requiring PCI is rising with more elderly and co-morbid patients undergoing revascularisation procedures. IVL has become an important tool in achieving successful stent implantation within calcified diseased segments.

12. Have you used it or are you currently using it?

- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

- Is this procedure/technology performed/used by clinicians in specialities other than your own?

- If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.

Since IVL became commercially available its use has increased in our centre. For year 2019/20 we performed 21 cases. This has risen steadily to 129 cases in year 2022/23. For comparison, the British Cardiovascular Interventional Society (BCIS) dataset showed 11 cases being performed during year 2018/19 in England, rising to 2453 in year 2022/23.
Within our centre the vast majority of IVL is used for coronary cases, however it is also used by our structural operators to assist in the delivery of trans-femoral (TF) TAVI (Transcatheter Aortic Valve Implantation) in patients with severe calcified peripheral vascular disease. This has been seen to be associated with high levels of successful valve delivery and low complication rates in a large multi-centre registry.
There is a building body of evidence for the use of IVL in femoropopliteal and below-the-knee disease and it is therefore also used by our Vascular Surgery and Interventional Radiology colleagues.
During PCI, patient selection for coronary IVL should be based on appropriate lesion suitability and this is best identified by the use of adjuvant intravascular imaging, either intravascular ultrasound (IVUS) or optical coherence tomography (OCT). This is the practice in our institution to ensure appropriate use of what remains an expensive technology. For TF-TAVI the potential need for IVL is identified on routine pre-procedural CT scanning as part of normal work-up.

13. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [x] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

14. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

15. Is the proposed indication appropriate? If not, please explain

Yes

16. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

It is a novel approach to managing calcium in arteries although the technique of lithotripsy is very well established for the treatment of kidney stones, for example.

17. Which of the following best describes the procedure:

- (●) Established practice and no longer new.
- ( ) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- ( ) Definitely novel and of uncertain safety and efficacy.
- ( ) The first in a new class of procedure.

18. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

I would consider it an addition to existing care. There are some lesions which are balloon uncrossable and therefore cannot be treated with IVL. These lesions require rotational or orbital atherectomy. There are also complex anatomies that require multiple calcium modification techniques such as atherectomy followed by IVL to achieve adequate stent results. It is however easier to learn and use than atherectomy techniques potentially allowing adoption and better overall results in lower volume PCI centres who do not have access to, or lack experience in, atherectomy techniques. The ability to use IVL to optimise stents that are underexpanded due to underprepared calcium or have calcific in-stent restenosis (ISR) is a further useful indication.

19. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

Yes. In 2023 a new Shockwave C2+ catheter became available. The main modification is the ability to deliver 120 lithotripsy pulses rather than the 80 achievable with the C2 catheter. This additional available energy allows for better modification of long areas of disease or calcific nodules, a subset of lesions that cause difficulty in achieving adequate stent expansion and are associated with a higher rate of adverse events. There have been no significant alterations to the procedural technique other than recent expert consensus that the previously recommended post pulse delivery inflation to 6 atm is not required and may increase the risk of balloon rupture. (SCAI Expert Consensus Statement 2024).

20. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

Yes. Disrupt CAD III, a prospective, single-arm, multicenter study of 384 patients showed that IVL delivery was successful in 95% of cases, and procedural complication rates were low, with no cases of slow flow/no-reflow and only isolated incidents of dissection, perforation, and abrupt closure. Low rates of stent thrombosis (0.8%) and target lesion failure (7.6%) were observed at 30 days. Major Adverse Cardiovascular Events (MACE) at 1 year occurred in 14% of patients, with myocardial infarction in 10.5%, ischemia-driven Target Lesion Revascularisation (TLR) in 4.3%, and target lesion failure in 12%. A pooled analysis of the Disrupt CAD I-IV studies suggested that these results are widely reproducible. Initially it was believed that IVL would be most effective in the presence of concentric calcium, but intravascular imaging data has suggested the efficacy and safety to be consistent whether calcium was concentric, eccentric, or nodular. There is also some data suggesting that IVL may be a safer calcium modification technique than atherectomy in female patients.

21. Do you think the guidance needs updating?

Yes

Current management

22. Please describe the current standard of care that is used in the NHS.

Prior to the advent of IVL, standard calcium modification techniques included non-compliant balloons, scoring balloons, cutting balloons, high pressure inflation balloons and atherectomy techniques (rotational, rarely laser and more recently orbital).

23. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

    If so, how do these differ from the procedure/technology described in the briefing?

No. IVL has a unique mechanism of action compared with the methods described above.

Potential patient benefits and impact on the health system

24. What do you consider to be the potential benefits to patients from using this procedure/technology?

With an ageing and co-morbid population, PCI procedures involving severely calcified coronary artery lesions are becoming increasingly common and are associated with higher procedural risk and an increase in short-term and long-term adverse events. A major cause of this is stent under-expansion due to residual calcium which is a strong predictor of re-stenosis and stent thrombosis.
The DISRUPT CAD III Study met its safety and effectiveness targets with a less than 30% residual stenosis achieved in 99.5% of enrolled patients. Serious angiographic complications occurred in 0.5% of cases and 92.2% of enrolled patients were free of major cardiovascular events at 30 days. Overall procedure success was achieved in >90% of cases. Importantly as this is a balloon technology there appeared to be no significant learning curve with >80% of operators taking part in the study having no prior IVL experience.
IVL is therefore an important additional tool for calcium modification allowing better stent expansion, better clinical outcomes and lower risks of long term adverse events in patients with severe calcific coronary artery disease.

25. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Previous reports with atherectomy have shown that females with calcified coronary disease are more susceptible to adverse procedural outcomes compared to males. Despite often being more challenging to treat, female patients are under-represented in published data. Early retrospective analyses have suggested comparable favourable outcomes in female and male patients with IVL and specific research in this area is ongoing. It is hypothesised that IVL may help bridge some of the disparity gap in PCI treatment and outcomes between genders.
Although data suggests IVL is best for modifying circumferential calcium in balloon-crossable lesions, increasing evidence supports IVL therapy in eccentric and nodular calcium, although more pulse delivery may be required in these lesions. The new balloon with increased capacity supports this.
IVL can be used synergistically with atherectomy devices, especially in longer lesions where there is often more heterogeneity in vessel size and the pattern of calcification allowing a more tailored approach for patients with the most complex and diffuse disease patterns.

26. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

As above, data suggests that when IVL is used appropriately in severely calcified lesions that improved stent area and patient outcomes are achieved. This reduction in the risk of stent failure could lead to a lower risk of future procedures due to failure of the target lesion.

27. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

For appropriate use of IVL, intravascular imaging (IVUS or OCT) should be used in the vast majority of cases. It helps to assess that IVL is the most appropriate first or second line calcium modification device, it allows identification of fractures and luminal expansion to establish treatment efficacy and in longer lesions helps determine where the pulses are best used. Sites using IVL should have access to imaging modalities. Intravascular imaging was used in 24% of PCI cases during year 2022/23 based on BCIS dataset.

28. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

As previously mentioned, data from DISRUPT CAD III suggests a shallow learning curve. As a balloon technology it is easy to learn and requires no new skillset for most PCI operators. Training/proctoring from other interventional consultants is freely available and case presentations of IVL use are common at national and international meetings. In my opinion it is much easier to use than atherectomy techniques.

Safety and efficacy of the procedure/technology

29. What are the potential harms of the procedure/technology?

Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

The data from DISRUPT CAD III suggests a low risk of adverse procedural complications (0.5%). These include coronary artery dissection, vessel perforation and acute vessel closure. There appears to be no risk of no or slow flow. Low rates of stent thrombosis (0.8%) and target lesion failure (7.6%) were observed at 30 days. Major Adverse Cardiovascular Events (MACE) at 1 year occurred in 14% of patients, with myocardial infarction in 10.5%, ischemia-driven Target Lesion Revascularisation (TLR) in 4.3%, and target lesion failure in 12%.
When treating areas that subtend large myocardial distributions (eg, left main lesions) then haemodynamic compromise can occur. Being aware of this and using longer rest periods between therapies can help mitigate cardiovascular collapse.
Ballloon rupture rarely occurs, recent expert consensus suggests that no longer dilating the balloon to nominal pressure (6 atmospheres) after a set of pulse delivery reduces this risk (SCAI Expert Consensus Statement JSCAI Feb 24).
Improper use – it is an expensive technology and carries an increased procedural cost when used (~£1200/balloon). If used inappropriately in lesions that could be successfully treated with cheaper alternatives (e.g. NC balloons, cutting/scoring balloons) then there could be an economic impact.

30. Please list the key efficacy outcomes for this procedure/technology?

- Improved procedural success – increased stent delivery and minimal stent area (MSA)
- Reduced MACE rate
- Reduced rate of stent thrombosis, in-stent restenosis, target lesion/vessel failure

31. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

None. Easy to use, effective and data suggests safe.

32. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

No

33. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- (●) Most or all district general hospitals.
- ( ) A minority of hospitals, but at least 10 in the UK.
- ( ) Fewer than 10 specialist centres in the UK.
- ( ) Cannot predict at present.

Abstracts and ongoing studies

34. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

EURO PCR 2024 "Clinical Experience with IVL in ACS" (Sponsored session). Useful data that IVL is effective in the setting of ACS with similar gains in MSA compared to chronic coronary disease patients but with a higher MACE rate associated with higher risk presentation and more complex disease than in the DISRUPT studies for example. Growing area of use in clinical practice.

EURO PCR 2024 – initial results of PINNACLE I trial using a new IVL system LithiX™ Hertz Contact Intravascular Lithotripsy System (Elixir Medical). Delivers multiple discrete points of IVL and designed to amplify treatment over a long area. Small study suggests safety and efficacy with similar outcomes to those with common commercially available catheter. More work will be required.

35. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

EMPOWER CAD (Equity in modifying plaque of women with undertreated calcified CAD; NCT05755711)
Intravascular Balloon Lithotripsy in Left Main Stem Percutaneous Coronary Intervention (NCT04319666)
Short-Cut (Shockwave Lithoplasty Compared to Cutting Balloon Treatment in Calcified Coronary Disease Trial; NCT06089135)
DECALCIFY (Prospective, Randomized, Controlled, Multicenter Study for the Treatment of Calcified Coronary Artery Lesions With Rotational Atherectomy vs. Intravascular LithotripsY; NCT04960319)
SONAR (Shockwave Balloon or Atherectomy With Rotablation in Calcified Coronary Artery Lesions; NCT05208749)
BALI (Balloon Lithoplasty for Preparation of Severely Calcified Coronary Lesions Before Stent Implantation; NCT04253171)
VICTORY (Value of IVL Compared to OPN Noncompliant Balloons for Treatment of Refractory Coronary Lesions; NCT05346068)
ROLLING-STONE study (IVL and/or Mechanical Debulking for Severely Calcified Coronary Artery Lesions; NCT05016726)
ROLLERCOASTR trial (Rotational Atherectomy, Lithotripsy, or Laser for the Treatment of Calcified Stenosis; NCT04181268)

36. Please list any other data (published and/or unpublished) that you would like to share.

None currently

Other considerations

37. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

Calcified coronary lesions are estimated to be present in up to one-third of patients undergoing PCI. During 2022/23 our centre performed 129 IVL procedures out of 2789 PCI cases (~5%). Numbers have progressively increased over the last 4 years. In my opinion it's use in 5-15% of PCI procedures is conceivable over the next few years.

38. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Beneficial outcome measures.

    These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

Already covered in the BCIS Audit data set.
• Procedural numbers per centre

Beneficial outcome measures:
• Procedural success (Was stent/Drug Coated Balloon delivered successfully)
• Minimal stent area and luminal gain (measured during procedure by intravascular imaging)
• Symptom improvement (30 days, 1 year, Questionnaire)

39. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Most research measures MACE at 30 days. 1 year and 5 year follow up is reasonable to look for late failure signals
• Myocardial Infarction (MI)
• Need for further revascularisation – Target vessel or lesion failure (measured by clinical re-presentation and repeat angiography

Further comments

40. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

Nothing that isn't covered above.

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

41. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

42. Description of interests, including relevant dates of when the interest arose and ceased. *

N/A

43. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website. *

- (●) I agree
- ( ) I disagree

Signature

44. Name: *

Keith Robertson

45. Date: *

21/05/2024

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1758/2 Intravascular lithotripsy for calcified coronary arteries during percutaneous coronary intervention**

Your information

Name:	Professor Robert F. Storey on behalf of the British Cardiovascular Society
Job title:	Professor of Cardiology and Honorary Consultant Cardiologist
Organisation:	University of Sheffield and Sheffield Teaching Hospitals NHS Foundation Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	British Cardiovascular Society
Nominated/ratified by (if applicable):	British Cardiovascular Society Guidelines and Practice Committee
Registration number (e.g. GMC, NMC, HCPC)	3431447

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

☐ Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice.

☒ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own?	I am a consultant interventional cardiologist with 22 years experience as a consultant participating in a primary PCI on-call rota. I am familiar with intravascular lithotripsy and have used this to good effect in the treatment of calcified coronary arteries. The technology is simple to adopt for an experienced interventional cardiologist and is used routinely across the NHS. Occasionally the technology is used in the treatment of calcified arteries other than coronary arteries, including peripheral leg arteries. It can be used to facilitate the passage of devices via the femoral artery, such as during transcutaneous aortic valve implantation/replacement (TAVI/TAVR) via the femoral route. Consequently it might be used by other vascular interventionists.

	– If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have had no involvement in research on this procedure.
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Yes Yes The technology is an important adjunct to standard coronary interventional techniques. It has allowed successful treatment of calcified arteries in instances where previously treatment would have failed or led to serious complication such as coronary/stent thrombosis. Established practice and no longer new.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	As above, it is an addition to the existing standard of care. However, there are instances where it could be used more widely instead of alternative approaches for initial management of calcified coronary arteries, such as the use of standard or 'cutting' balloons to disrupt segments of heavy calcification. More evidence may be required to demonstrate benefits of more widespread use beyond its use as a bail-out technology when standard and/or cutting balloon dilatation has failed.

5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	The underpinning technology has not been substantially modified. There has been extensive use within the interventional community globally which has led to much greater experience in use and application of the technology.

Current management

6	Please describe the current standard of care that is used in the NHS.	Percutaneous coronary intervention is a standard procedure used in the treatment of coronary stenoses in patients with either acute or chronic coronary syndromes. Techniques for treating calcified coronary arteries include use of either standard or cutting balloons, standard or orbital rotational atherectomy, intracoronary laser and intravascular lithotripsy, with or without the guidance of intravascular imaging technologies (optical coherence tomography and intravascular ultrasound).
7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	The competing technologies are, as listed above, either standard or cutting balloons, standard or orbital rotational atherectomy, and intracoronary laser, with or without the guidance of intravascular imaging technologies. These have different benefits and risks compared to intravascular lithotripsy and ideally the choice of technology is highly individualised in order to optimise clinical outcomes.

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	This technology is able to transform treatment from being unsuccessful and/or associated with serious complication to being successful without serious complication in individual cases so it represents an important advance in the armamentarium available to interventional cardiologists.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients with heavily calcified coronary stenoses may particularly benefit from this technology.
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	The technology has the potential to allow percutaneous coronary intervention in some individuals who would otherwise require open-heart coronary artery bypass graft surgery and therefore may facilitate less invasive treatment and shorter hospital stays. Alternatively the technology may facilitate revascularisation of patients who would otherwise not be eligible for a revascularisation procedure and therefore continue to suffer from refractory and limiting angina symptoms with more hospital visits.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	The technology is simply accommodated within existing cardiac facilities.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Specific training is required for interventional cardiologists using this technology and is simple to organise.

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:	The harms are those associated with treatment of calcified coronary arteries, particularly coronary rupture/perforation but also usual complications such as coronary thrombosis, coronary dissection, embolization, and balloon rupture. There is no evidence that the technology increases the risk of these complications relative to other standard techniques for dealing with coronary calcification.

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	
14	Please list the key efficacy outcomes for this procedure/technology?	Most evidence is anecdotal, including conversion of a coronary revascularisation outcome from unsuccessful when no other options are available to successful. This is most obvious in the case of a calcified coronary stenosis that cannot be dilated with standard balloon dilatation techniques.
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	The efficacy and safety of the procedure outside of the treatment of non-dilatable lesions remain to be established in comparison with other techniques for treating calcified coronary artery stenoses.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Most of the uncertainty relates to case selection and whether the technology should be used prophylactically in patients with heavy coronary calcification rather than as a bail-out option. Prophylactic use guided by intravascular imaging could potentially prove very expensive for the NHS and cost-effectiveness of this approach has not been established.
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	“A minority of hospitals, but at least 10 in the UK” i.e. all PCI centres in the UK

Abstracts and ongoing studies

18	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which	Numerous case and observational presentations on the use of intravascular lithotripsy are made at all national and international meetings that encompass coronary intervention. The abstracts of the EuroPCR 2024 meeting (May 2024, Paris, France) may be used as a source of emerging evidence.

	might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	The ShOckwave ballooN or Atherectomy With Rotablation in Calcified Coronary Artery Lesions, the SONAR Trial (SONAR) (ClinicalTrials.gov ID NCT05208749) is an ongoing study of 170 patients comparing intravascular lithotripsy with rotational atherectomy in coronary stenoses that are non-dilatable with standard balloon dilatation. The ongoing Balloon Lithoplasty for Preparation of Severely Calcified Coronary Lesions (BALI) (ClinicalTrials.gov ID NCT04253171) is comparing the use of intravascular lithotripsy in preparing calcified coronary stenoses with standard preparation techniques in 200 patients. The Value of IVL Compared To OPN Non-Compliant Balloons for Treatment of RefractorY Coronary Lesions (VICTORY) Trial (VICTORY) (ClinicalTrials.gov ID NCT05346068) is comparing intravascular lithotripsy with an ultra-high-pressure balloon system in 280 patients. Newer versions of the Shockwave system are also being assessed (Shockwave C2+ 2Hz Coronary IVL Catheter).
20	Please list any other data (published and/or unpublished) that you would like to share.	

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	About 5% of patients undergoing PCI.

22	Please suggest potential audit criteria for this procedure/technology. If known, please describe: – Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. – Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Rate of conversion from failed to successful revascularisation procedure Rates of stent thrombosis and target vessel revascularisation Adverse outcome measures: Rate of coronary perforation

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	

NICE National Institute for Health and Care Excellence

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.			
Choose an item.			
Choose an item.			

☒ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Professor Robert Storey**
Dated:	**22 April 2024**