View results

Respondent

2 Anonymous

08:28
Time to complete

Your information

1. Name: *

Ankur Thapar

2. Job title: *

Consultant vascular and endovascular surgeon

3. Organisation: *

Mid and South Essex NHS Trust

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

RCS Eng / ESVS

6. Nominated/ratified by (if applicable):

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

6103047

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with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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

8. 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.

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

   Are you familiar with the procedure/technology?

   Yes use it

10. 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.

    Cardiology use it

11. 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

12. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

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

Yes

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

Novel

15. 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.

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

Yes
Reduce stenting
Expand treatment possibilities beyond current standard

Current management

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

Stents
Iliac conduit

18. 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?

Atherectomy
Require filter and create more emboli

Potential patient benefits and impact on the health system

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

More patients can be treated
Less implants left in patients

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

Women with small iliacs requiring TEVAR
Heavily calcified iliac arteries where stents won't expand
No stent zones eg popliteal/tibial

21. 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

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

Generator

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

Yes training course

Safety and efficacy of the procedure/technology

24. 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

    Minimal
    Possible microembolisation

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

    Luminal gain
    Avoidance of stent
    Limb salvage

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

    Microembolisation

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

    No

28. 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

29. 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.

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

    Post market IVL registry NIHR funded

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

Other considerations

32. 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)?

5% of those with CLTI

33. 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.

Freedom from TLR
Maximum lumen gain
Limb salvage
Freedom from stenting
Amputation free survival

34. 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:

Embolisation

Further comments

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

catheters for tibial vessels are in development

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.

36. Type of interest: *

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

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

Na

38. 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

39. Name: *

    Ankur Thapar

40. Date: *

    03/03/2023

View results

Respondent

1 Anonymous

16:50
Time to complete

Your information

1. Name: *

Athanasios Diamantopoulos

2. Job title: *

Consultant Interventional Radiologist

3. Organisation: *

Guys and St Thomas NHS foundation trust

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

CIRSE, BSIR, RCR

6. Nominated/ratified by (if applicable):

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

7258346

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

8. 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.

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

   Are you familiar with the procedure/technology?

   Yes. Have performed cases using this specific device

10. 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.

    This is relatively knew but has been accepted by different vascular specialists in the field of peripheral vascular disease as a solution to a common problem when treating patients endovascular. Especially patients with calcified lesions.

11. 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

12. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

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

Yes

14. 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's quite innovative as it provides solution to a long standing known problem

15. 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.

16. 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 most likely be used as an additional to existing standard of care

Current management

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

Balloon angioplasty with the use of stents

18. 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?

Yes. ATherectomy. Different way to manage a similar problem however in my opinion with different day to day indications of use

Potential patient benefits and impact on the health system

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

Potentially best outcomes especially with the benefit of using less stents and better initial technical success

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

Patients with heavy calcified stenotc lesions in the peripheral that makes them poor candidates for only balloon angioplasty or only stent use. Also in these patients if a stent is used has the risk not to be able to fully expand due to the calcium. This device can potentially address this issue for a cohort of patients

21. 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 as it may improve the long term outcomes

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

none

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

minimal training is required as this is very straightforward

Safety and efficacy of the procedure/technology

24. 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

    This is considered relatively safe

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

    Reduction of calcium burden with immediate effect in the outcome of the angioplasty hand stent placement if required

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

    I am uncertain about the level of effectiveness.in occluded arteries and long lesions.

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

    Please see above

28. 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

29. 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.

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

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

Other considerations

32. 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)?

1000

33. 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.

Technical success
Amputation free survival
Limb salvage

34. 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:

Distal Embolization

Further comments

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

Cost of the device

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.

36. Type of interest: *

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

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

N/a

38. 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

39. Name: *

    Athanasios Diamantopoulos

40. Date: *

    02/03/2023

View results

Respondent

4 Anonymous

34:36
Time to complete

Your information

1. Name: *

Athanasios Saratzis

2. Job title: *

Associate Professor of Vascular Surgery and Consultant Vascular Surgeon

3. Organisation: *

University of Leicester & University Hospitals of Leicester NHS Trust

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

GMC - 7024328; Vascular Society of Great Britain and Ireland; Royal College of Surgeons (England).

6. Nominated/ratified by (if applicable):

Vascular Society of Great Britain and Ireland

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

7024328

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

8. 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.

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

   Are you familiar with the procedure/technology?

> Yes. I have used this technology in clinical practice more than 50 times in several patients with occluded or stenosed arteries. I have been using the technology regularly in the NHS for 2 years. I am familiar with the background of the technology and all relevant randomised trials / other research. In fact I am now leading a national prospective study in the UK (across 8 NHS hospitals) in the form of a registry, regarding the use of the technology in the NHS.

10. 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.

> This technology has been used in cardiology for many years in the NHS. It is now used (the last 3 years) regularly for calcified peripheral arteries i.e. in patient with peripheral arterial disease. The speed of uptake has been excellent across the NHS as this technology provides a solution to a difficult problem: angioplasty of very calcified arteries. It is now used in at least 12 NHS hospital that I know of by vascular surgeons and interventional radiologists. There are 2 clinical randomised trials published (testing efficacy) and long-term observational data.
> The technology is regularly used in peripheral arteries by vascular surgeons, radiologists and cardiologists (occasionally) across the NHS.
> I have experience in selecting patients across disciplines (radiology/vascular surgery) for use of this technology. MDTs across the NHS will regularly select patients for this technology, typically when their arteries are very calcified.

11. 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.
- [x] 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.
- [ ] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

12. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

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

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

The standard of care is simple angioplasty which does not work well in very calcified arteries. This procedure works better in calcified arteries by breaking down the calcium of the affected artery using ultrasonic waves. This has been shown in phase 2 / phase 3 trials and 2 randomised studies published in the last 2 years. The procedure is innovative in that it allows a doctor/operator to break down the artery's calcium, which is impossible usually with plain angioplasty. This procedure and technology has been used for years in cardiology (coronary arteries) and is now being used in peripheral arteries. This allows the treatment of calcified lesions which would not be amenable to plain angioplasty.

15. 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.

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

Addition to existing standard of care, when a patient's arteries are very calcified.

Current management

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

Plain angioplasty.

18. 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?

I am not aware of another device or technology which used ultrasonic energy to break down calcium. Some doctors will use atherectomy for very calcifies arteries, but this is a very different procedure altogether.

Potential patient benefits and impact on the health system

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

Minimally invasive treatment of very calcified arterial lesions which could not be treated with plain angioplasty. This procedure has also been shown to reduce the need for stents in these arteries in 2 randomised studies.

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

Patients with severely calcified arteries.

21. 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. It could lead to less invasive treatment of patients with severely calcified arteries, less hospital stay, less complications due to peripheral emboli (due to less use of atherectomy or plain angioplasty with high pressure balloons).

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

This procedure is already available in the NHS. The use of it is simple - it is identical to plain angioplasty. A doctor who already performs angioplasty would not need additional resources or training, apart from the consumables.

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

Not that I am aware of. The procedure involves a catheter which is identical to that of a balloon used during plain angioplasty.

Safety and efficacy of the procedure/technology

24. 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

Arterial rupture and peripheral emboli are the 2 main events that might occur. These have not occurred in my practice. In the 2 trials published so far, they are very rrare.
Relevant literature:

Stavroulakis K, Bisdas T, Torsello G, Tsilimparis N, Damerau S, Argyriou A. Intravascular Lithotripsy and Drug-Coated Balloon Angioplasty for Severely Calcified Femoropopliteal Arterial Disease. J Endovasc Ther. 2023 Feb;30(1):106-113. doi: 10.1177/15266028221075563. Epub 2022 Feb 7. PMID: 35130782; PMCID: PMC9896408.

Tepe G, Brodmann M, Werner M, Bachinsky W, Holden A, Zeller T, Mangalmurti S, Nolte-Ernsting C, Bertolet B, Scheinert D, Gray WA; Disrupt PAD III Investigators. Intravascular Lithotripsy for Peripheral Artery Calcification: 30-Day Outcomes From the Randomized Disrupt PAD III Trial. JACC Cardiovasc Interv. 2021 Jun 28;14(12):1352-1361. doi: 10.1016/j.jcin.2021.04.010. PMID: 34167675.

Madhavan MV, Shahim B, Mena-Hurtado C, Garcia L, Crowley A, Parikh SA. Efficacy and safety of intravascular lithotripsy for the treatment of peripheral arterial disease: An individual patient-level pooled data analysis. Catheter Cardiovasc Interv. 2020 Apr 1;95(5):959-968. doi: 10.1002/ccd.28729. Epub 2020 Jan 20. PMID: 31957955; PMCID: PMC7187419.

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

Lesion patency
Target lesion revascularisation rates

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

I do not have any major concerns about the safety and efficacy of this procedure. It is backed by randomised data in terms of safety and efficacy:

Tepe G, Brodmann M, Werner M, Bachinsky W, Holden A, Zeller T, Mangalmurti S, Nolte-Ernsting C, Bertolet B, Scheinert D, Gray WA; Disrupt PAD III Investigators. Intravascular Lithotripsy for Peripheral Artery Calcification: 30-Day Outcomes From the Randomized Disrupt PAD III Trial. JACC Cardiovasc Interv. 2021 Jun 28;14(12):1352-1361. doi: 10.1016/j.jcin.2021.04.010. PMID: 34167675.

Brodmann M, Holden A, Zeller T. Safety and Feasibility of Intravascular Lithotripsy for Treatment of Below-the-Knee Arterial Stenoses. J Endovasc Ther. 2018 Aug;25(4):499-503. doi: 10.1177/1526602818783989. Epub 2018 Jun 18. PMID: 29911480; PMCID: PMC6041733.

Virmani R, Finn AV, Kutyna M, Sato Y, Meess K, Smith C, Chisena RS, Gurm HS, George JC. Pulsatile intravascular lithotripsy: A novel mechanism for peripheral artery calcium fragmentation and luminal expansion. Cardiovasc Revasc Med. 2023 Jan 10:S1553-8389(23)00005-2. doi: 10.1016/j.carrev.2023.01.003. Epub ahead of print. PMID: 36697338.

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

Not that I am aware of.

28. 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

29. 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.

    We are running a national prospective registy in the NHS across 8 sites (hospitals). This finishes recruitment end of March 2023: https://www.isrctn.com/ISRCTN76218607

    I am not aware of any other conference proceedings.

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

    My own prospective cohort study in the NHS: https://www.isrctn.com/ISRCTN76218607

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

    Not applicable. See above.

    Please ensure that your literature review includes the PAD 2 and PAD 3 randomised trials:

    1. https://clinicaltrials.gov/ct2/show/NCT02923193

    2. https://www.jscai.org/article/S2772-9303(22)00325-8/fulltext

    3. https://www.jacc.org/doi/10.1016/j.jcin.2021.04.010.

Other considerations

32. 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)?

10,000
Angioplasties are the most common vascular procedures performed in the NHS. This technology addresses issues relating to performing angioplasty in very calcified arteries.

33. 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.

Short term: need for stenting, need for additional procedures, vessel patency, target lesion revascularisation.

34. 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:

Amputation (major i.e. above the ankle joint). Re-intervention (open and endovascular).

Further comments

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

The device is easy to use as it is based on the same principles as plain angioplasty. A healthcare professional who is trained in angioplasty can perform this procedure.
The need for further research as with any form of technology used in people with peripheral arterial disease relates to assessing clinical and cost effectiveness. This information is very difficult (if not impossible) to gather, given that several factors affect the performance of technologies aiming to improve the clinical effectiveness of PAD procedures.

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.

36. Type of interest: *

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

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

1) I have been paid to deliver lectures/presentations relating to this technology in 2022 at the Vascular Society of Great Britain and Ireland conference as well as an online education webinar. This was a lecture on my experience using this device in our vascular centre (I am a vascular surgeon).
2) I am the chief investigator of a study which is recruiting people treated with this technology in the NHS and finishes recruitment in March 2023. This is a national registry supported by the NIHR CRN portfolio, taking place in 8 NHS centres. The company which produces this device is paying for the study expenses i.e. the study co-ordinator, but I have no direct financial interests relating to this study (my salary is not paid by the industry partner/funder). All of my salary is paid by my employer and the University of Leicester / NIHR.
3) I use this device in my clinical practice, like other surgeons and radiologists in the NHS.

38. 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

39. Name: *

Athanasios Saratzis

40. Date: *

05/03/2023

View results

Respondent

5 Anonymous

14:13
Time to complete

Your information

1. Name: *

Bella Huasen

2. Job title: *

Endovascular and IR consultant

3. Organisation: *

LTHTR NHS

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

BSIR

6. Nominated/ratified by (if applicable):

BSIR

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

GMC 6157689

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

8. 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.

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

   Are you familiar with the procedure/technology?

   One of the first users internationally. Very familiar.

10. 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.

    Yes I maintain registry and data gathering within U.K. forum and within Europe.
    It's used by IR and vascular surgeons in the management of PAD or for access for TAVI/EVAR/TEVAR
    I use on my patients locally

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

- [ ] I have done bibliographic research on this procedure.
- [x] 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.
- [ ] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

12. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

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

Needs elaborating which I will share

14. 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 is no current other technology to compare. Lithotripsy is the only one of its kind currently produced by shockwave medical

15. 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.

16. 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 an addition as part of pathway in management of calcium in CLI / PAD
In use since 2019 in the U.K.
but used longer by cardiologists

Current management

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

No particular standards other than trying to improve flow and improve CLI and this is achieved via various ways

18. 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?

Not to IVL
Artherectomy is different

Potential patient benefits and impact on the health system

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

Improved vessel wall compliance, and reduced procedural complication compared to current devices

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

CLI - PAD - renal and diabetic patients

21. 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 less trash complications, less stent use so saves nhs money.

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

No change

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

Not really as it behaves like standard PTA prep

Safety and efficacy of the procedure/technology

24. 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

    No harm seen (behaves like our PTA balloons)

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

    For me reduction in complications: less dissection, less trash, less rupture.

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

    None for me

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

    Same as all CLI PTA

28. 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

29. 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.

    PAD3 disrupt RCT is latest and most useful

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

    On going work yes at leister university hospital

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

Other considerations

32. 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)?

70% of CLI cases (as due to calcifications)

33. 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.

Size of lesions in diameter and length
Size of IVL catheter used
What was used after
Complications
12-24 month follow up

34. 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:

Distal embolisation
Dissection
Rupture
Failure
Balloon rupture

Further comments

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

I see
Potential in visceral artery calcification

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.

36. Type of interest: *

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

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

On 20th Feb 2023 i attended lab in Verona where 15 key opinion leaders in Europe attended cadaver lab to work on shockwave catheters and expand our understanding of its role in CLI and aorto-iliac.
This trip was funded by shockwave medical.

38. 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

39. Name: *

Bella Huasen

40. Date: *

14/03/2023

View results

Respondent

8 Anonymous

23:01
Time to complete

Your information

1. Name: *

Conrad von Stempel

2. Job title: *

consultant Interventional Radiologist

3. Organisation: *

UCLH and Royal Free hospitals, London

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

RCR

6. Nominated/ratified by (if applicable):

n/a

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

7169882

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

8. 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.

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

   Are you familiar with the procedure/technology?

Yes I perform angioplasty regularly for PAD and use intravascular lithotripsy at least 1/month

10. 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.

Yes I am currently using intravascular lithotripsy.
It is gaining traction in large vascular centres as it has a profound positive effect on calcified arteries with potential resulting reduction in stent use and less aggressive ballooning strategies. Therefore it will gain rapid recognition in vascular centres across the uk over the next 6 months

Yes it is carried out by cardiologists doing TAVI (for iliac arteries) and vascular surgeons who are end-vascular trained.

I have 6 months experience of using IVL in iliac, femoral and crural disease.

11. 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

12. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

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

yes

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

Minor variation as it is essentially an angioplasty balloon

15. 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.

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

IVL will reduce the amount of stenting required in PAD which is of patient benefit as a stent has several drawbacks (for instance reocclusion of stent is more challenging to recanalise compared to a native artery). furthermore IVL reduces the angioplasty pressure required which reduces the risk of artery dissection - dissections lead to increased use of stents with associated drawbacks and cost implication.

Current management

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

Angioplasty with plain balloon+_ high pressure or cutting balloons +_ drug elution +_ atherectomy for recalcitrant lesions and use of metals stents to maintain patency (particularly in iliac arteries)

18. 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?

Not specifically - Boston are producing a laser device that is different to this. IVL is unique

Potential patient benefits and impact on the health system

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

1. Reduced need for repeat procedures
2. Reduced vessel dissection
3. Reduced need for stents which have high reintervention requirements

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

Elderly patients and dialysis patients who are poor candidates for open operations due to anaesthetic risks and comorbidities

21. 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?

Absolutely - evidence from DISRUPT-PAD study suggests reduced need for reintervention.
Reduced need to stent will reduce the requirement for future instent restenosis reintervention
Endovascular treatments have reduced morbidity.

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

A single additional generator box that is about the size of a laptop . Other than that it is an adaptation of the current angioplasty procedure.

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

Yes this should be carried out only by experienced endovascular interventional radiologists and trained vascular surgeons as the decision making requires an in-depth knowledge of calcium patterns in vessels on angiogram/ intravascular ultrasound imaging.

Safety and efficacy of the procedure/technology

24. 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

Potential risk of vessel dissection <5% (this is less than a standard plain balloon angioplasty)
Vessel rupture <1% (again very low risk as low pressure angioplasty)
Failure of device to work
Calcium dislodgement and embolisation <1% - this is unlikely as the calcium in PAD is medial and therefore covered by intimal layer that reduces risk of embolisation

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

Primary outcomes are reintervention rates at 30days, major amputation rates,
Secondary outcomes include appearances on angioplasty, WIFI score improvements and imaging follow up changes to calcium appearances

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

The safety of its use in carotid arteries

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

no

28. 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

29. 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.

    Y
    https://pubmed.ncbi.nlm.nih.gov/32869718/
    https://www.hmpgloballearningnetwork.com/site/jic/review/intravascular-lithotripsy-optimal-angioplasty-infrapopliteal-calcified-lesions
    https://pubmed.ncbi.nlm.nih.gov/30474206/
    https://www.jacc.org/doi/10.1016/j.jacc.2017.06.022
    https://www.jacc.org/doi/10.1016/j.jcin.2021.04.010
    https://www.jacc.org/doi/10.1016/j.jacc.2016.09.808
    Y
    https://journals.viamedica.pl/kardiologia_polska/article/view/85760
    Y
    https://pubmed.ncbi.nlm.nih.gov/35842260/
    https://pubmed.ncbi.nlm.nih.gov/32147133/
    https://pubmed.ncbi.nlm.nih.gov/35766412/
    https://pubmed.ncbi.nlm.nih.gov/35595607/
    Y
    https://pubmed.ncbi.nlm.nih.gov/34734559/
    https://pubmed.ncbi.nlm.nih.gov/31758362/
    Y

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

    DISRUPT-PAD

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

Other considerations

32. 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)?

25% of PAD population needing angioplasty (ie CLTI group)

33. 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.

Major and minor amputation rates - 30 days
WIFI scores (QoL, ABPI and ulcer assessments) over 30days
Reintervention rates 30days
Patient reported pain scores 6 months
Walking distance test 30 days

34. 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:

n/a

Further comments

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

In my opinion NICE should recommend IVL for the use as vessel preparation in angioplasty patients with heavy calcification to avoid vessel dissection

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.

36. Type of interest: *

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

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

I run a peripheral angioplasty course that includes use of IVL for which I am paid an honorarium

38. 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

39. Name: *

    Conrad von Stempel

40. Date: *

    02/04/2023

View results

Respondent

3 Anonymous

33:14

Time to complete

Your information

1. Name: *

HANY ZAYED

2. Job title: *

CONSULTANT VASCULAR SURGEON

3. Organisation: *

GUY'S AND ST. THOMAS' NHS FOUNDATION TRUST

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

GMC

6. Nominated/ratified by (if applicable):

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

6133112

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

8. 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.

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

   Are you familiar with the procedure/technology?

   I am familiar with the technology and have used it before.

10. 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 have used it and currently use it in my practice. This technology is used routinely in our trust. I am aware this technology is also being used in other NHS trust.

11. 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.
- [ ] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

12. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

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

Yes

14. 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 is a new modality used to prepare the vessels/ lesions for definitive treatment by balloons +/- stents

15. 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.

16. 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 could potentially be used as an addition to prepare the vessel/ lesion for definitive treatment

Current management

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

After crossing the lesions/blockages, the standard of care involves the use of balloons to extend/dilate the vessel +/- using a stent to keep the vessel open.

18. 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?

NA

Potential patient benefits and impact on the health system

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

This could potentially improve the response of the vessel/artery to definitive treatment with a balloon (coated or plain) and/or stenting, which could improve the overall outcome from these procedures

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

Patients with calcified arteries, such as those with diabetes or renal failure, are typically characterised by calcified blood vessels and could potentially be a group who would benefit from this technology

21. 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

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

The procedure require the special balloons (which contain the ultrasound emitters) which are connected to a special generator which generates the ultrasound pulses.

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

Minimal

Safety and efficacy of the procedure/technology

24. 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

    Assuming the operator follows the instructions for use of the device, I am not aware of significant adverse effects, apart from the fact that it might not work in very calcified/ challenging cases. Some reports of balloon rupture, dislodgement or device malfunction.

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

    Improvement of the vessel/lesion conformability/ compliance in preparation for the definitive treatment modality. This could potentially improve the technical/clinical outcomes of the procedures. Also could potentially reduce the need for the use of stents

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

    Not clear yet which lesion/vessel will have the best outcome
    Not clear yet if IVL improves the outcomes/ patency of stents if used for vessel prepartaion prior to stenting

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

    Cost effectiveness is still an area which needs further assessment

28. 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

29. 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.

    DISRUPT III study

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

    SHOCC is a multicentre trial, which we are taking part in, looking at the safety and efficacy of using IVL to treat PAD patients

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

NA

Other considerations

32. 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)?

If proved to be cost-effective, IVL could potentially be used in 25% to 30% of endovascular procedures for peripheral arterial disease roughly

33. 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.

Cost-effectiveness
Long-term clinical outcome data (limb salvage, amputation-free survival, Target lesion re-interventions)

34. 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 complications
Major amputations

Further comments

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

Level 1 evidence is still lacking. The published studies are industry sponsored. Ideally needs a randomised controlled trial for IVL + best endovascular treatment (Balloon + bail-out stenting) vs Best endovascular treatment (plain balloon angioplasty + bail-out stenting)

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.

36. Type of interest: *

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

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

Investigator in the SHOCC study, which is an industry-sponsored multi-centre study.
Honoraria for talks at workshops
Shockwave is currently a sponsor for an annual scientific meeting which I co-direct

38. 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

39. Name: *

hany zayed

40. Date: *

03/03/2023

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1973 Intravascular lithotripsy for calcified arteries in peripheral vascular disease

Your information

Name:	Mark James Portou
Job title:	Consultant Vascular Surgeon
Organisation:	Royal Free London NHS Foundation Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Royal College of Surgeons of England
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC 6122629

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?	I am familiar with this technology. I performed my first case with IVL Shockwave approximately 1 year ago and have become a regular user of it in my arterial peripheral vascular practice. My understanding is IVL has been rapidly adopted in the NHS by endovascular specialists across the country. The novel technology has led to considerable interest, and technical successes will likely lead ongoing and further rapid growth in adoption.
	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?	IVL based procedures for peripheral vascular disease are performed by interventional radiologists and vascular surgeons. The IVL technology was first adopted by interventional cardiologists however. They have a have a greater experience and caseload, and continue to use this technology with coronary artery specific balloons. My specialty (Vascular surgery) determines case selection for referral to interventional radiologists for procedure completion, however an increasing number of vascular surgeons (like myself) are also practitioners of endovascular surgery. For those surgeons who do not perform these procedures and use IR, the radiologist treating the patient would make the final decision on the treatment specifics, for example utilising IVL, although the surgeon may also have input.

	– 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 done bibliographic research on this procedure. Other (please comment)
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 the title reflects the procedure, although more commonly we are using peripheral arterial (or artery) disease (PAD) rather then peripheral vascular disease, as PVD also includes venous conditions. IVL is indicated for use in heavy medial wall calcification, the indication in the title more succinctly reflects that. A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. ***the benefit of IVL is an improvement in efficacy of angioplasty as an existing procedure. No suitable option reflected that.
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?	Both these options are possible in the wider broad topic of angioplasty. Current standard of care in heavy arterial medial wall calcium treatment may be conventional angioplasty PLUS the addition of a suitable stent if angioplasty response is suboptimal or vessel wall damage (dissection) occurs. IVL increases the vessel wall compliance which improves the response to subsequent conventional angioplasty, and in additional results in less arterial wall damage (dissections) due to

		the lower inflation pressures employed. It would therefore represent a new standard of care in its ability to reduce stent requirement. It is however also the case that in situations where stents are still required, the IVL deployment better prepares the diseased vessel for stent insertion by increasing vessel wall compliance and therefore reducing the extrinsic recoil of the vessel, and thus radial force exerted by the stent on the vessel. For territories such as the common femoral artery, the standard of care is clear in favour of open surgical endarterectomy and patch angioplasty. However this requires a certain level of perioperative fitness for surgery that may exclude many patients unfit for anaesthetic through medical co-morbidity. IVL has been increasingly shown to be efficacious in treating the common femoral artery and can now be offered as an alternative to surgery in this population utilising local anaesthesia. In this regard it will be used alongside existing standard of care.
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?	No substantial modifications have been made. The availability of the IVL devices for use in peripheral arterial procedures has been made possible by the increase in both the balloon diameter and length over those available for coronary IVL.

Current management

6	Please describe the current standard of care that is used in the NHS.	Patients undergoing revascularisation treatment for symptomatic PAD are offered either open surgery in the form of endarterectomy or bypass or are offered an endovascular procedure utilising angioplasty and/or percutaneous stent insertions, or a combination of both, in a ‘hybrid’ procedure utilising elements of both.

		The choice to offer one treatment modality vs the others involves several considerations. There are vascular territories where surgery has a clear superiority, such as in the common femoral artery. Most other anatomical considerations of disease distribution have options for either open or a suitable endovascular alternative. The patient's fitness, life expectancy, co-morbidity, infection status, availability of suitable autologous vein for conduit and previous interventions are all considered when choosing a suitable option/modality for the individual. Local experience, expertise and availability of required devices is also relevant.
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?	IVL is the first of its kind solution to arterial wall calcification. Other technologies available indicated for use in arterial calcification include atherectomy and stent insertion. Atherectomy involves essentially cutting a new flow channel through the diseased vessel and removing the debris liberated. Stenting utilises a metal cage, both without a plastic covering (bare metal stent) and with (covered stent). Stents can be balloon mounted or self expanding.

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?	The potential benefits of IVL are multiple. The first is that it represents a low inflation pressure option for vessel preparation, resulting in fewer dissections. As a consequence, less stents are required to repair the dissected vessel. Peripheral arterial stents are notorious for reduced patency and longevity in certain territories such as the common femoral, popliteal and below the knee vessels. (In certain territories such as iliac vessels clear evidence favours stent insertion).

		IVL therefore offers an effective means of achieving technical procedural success in the traditional 'no stent zones' listed above. Other benefits include better vessel preparation for the insertion of a stent. By reducing recoil of the vessel, the subsequent reduction in vessel wall reaction leads to improved stent patency. IVL has also provided a treatment option for patients unfit for conventional surgery by providing the first realistic means of treating the common femoral artery. In addition, IVL has the potential to improve the longer term outcomes of endovascular management of calcified vessels, and therefore reduce the requirement for repeat procedures and the risks/costs involved.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Specifically patients with calcified peripheral arterial disease requiring a revascularisation procedure.
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?	Yes. As I explained above all three of these possibilities apply. IVL provides a more efficacious treatment, particularly in the regions currently unsuitable for stenting with the benefit of reducing the need for repeat procedures. IVL also leads to a reduced number of bail-out stents used. In patients with high perioperative risk or deemed unfit for conventional open endarterectomy surgery, IVL offers a treatment option that removes the need for a high dependency or critical care bed. For cases done as day case or 23 hour stay, an inpatient bed is not required.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	IVL requires a portable lithotripsy emitter
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	It is possible that best practice training is industry provided in-lab supervision for at least the first case in the technicalities of balloon deployment and IVL delivery. However information regarding suitable case selection, balloon sizing and instructions for use could be provided through literature, meetings or online resources.

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: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	The standard recognised risks of angioplasty apply to IVL- such as: Access site complications (pseudoanerysm, haematoma, bruising) Arterial thrombosis/embolism Failure of procedure Balloon rupture Vessel perforation/rupture/spasm/dissection Risks specific to IVL Device malfunction There is a potential for development of aneurysms
14	Please list the key efficacy outcomes for this procedure/technology?	Improved vessel compliance Lumen gain Less recoil and restenosis Reduced stent requirement Superiority to stenting in hostile vascular territories such as CFA, popliteal and below the knee vessels
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	I have no concerns
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	No, but experience with IVL in the peripheral vasculature is still very limited compared to coronary artery usage. Its very recent introduction explains the lack of level 1 evidence, however this is of course common to most endovascular adjunctive technologies.

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. Potentially all hospitals that have arterial vascular surgery services. .

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 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.	1. Baig M, Kwok M, Aldairi A, *et al.* Endovascular intravascular lithotripsy in the treatment of calcific common femoral artery disease: a case series with an 18-month follow-up. *Cardiovasc Revasc Med*. 2022;43:80–4.
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Not in peripheral vascular use of IVL
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	This is extremely difficult to estimate as no reliable data exists for the population burden of arterial medial calcification amongst vascular patients undergoing endovascular treatment. My best estimation is somewhere between 10 and 15% of patients with symptomatic PAD would benefit from IVL

	estimated number, or a proportion of the target population)?	
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: Primary patency Secondary patency Freedom from clinically driven target lesion revascularisation Amputation free survival Stent free survival Adverse outcome measures: Late lumen loss Thrombosis rate Dissection rate Late complications (such as vessel aneurysm)

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	IVL is very easy to use and has become necessary to have as an instrument to reach for an for on-table decision-to-use. Pre-operative planning is possible with CT angiographic imaging, however with CLTI patients the benefit of rapid intervention is clear, therefore a duplex ultrasound is usually done instead as these can be obtained without significant delay to definitive treatment. This therefore requires an assessment of disease morphology using on table means such as angiography and intravascular ultrasound. A decision to use IVL therefore requires in lab availability of the relevant sized balloon.

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
Indirect	I have been asked to run a master-class teaching course on best practice management of severely calcified arterial lesions in PAD called 'coping with calcium'. The course is not specific to IVL but it is sponsored by shockwave.	**11th May 2023**	**11th May 2023**
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:	**Mark J Portou**
Dated:	**13/04/2023**

View results

Respondent

7 Anonymous

18:42
Time to complete

Your information

1. Name: *

Mo Hamady

2. Job title: *

Professor of Interventional Radiology and Image Guided Surgery

3. Organisation: *

Imperial College-London

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

British Society of Interventional Radiology

6. Nominated/ratified by (if applicable):

British Society of Interventional Radiology

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

GMC 5200780

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

8. 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.

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

   Are you familiar with the procedure/technology?

   Very familiar

10. 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 have been using this technology for more than 3 years. It is mainly used by Interventional Radiologists and few vascular surgeons. I expect the number of procedures will increase in the near future

11. 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.
- [ ] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

12. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

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

yes

14. 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 novel and new concept in peripheral vascular disease. It is well-known in coronary artery disease

15. 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.

16. 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 likely be used as an additional tool

Current management

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

The endovascular option is balloon angioplasty with or without stent.
bypass surgery remains the current gold standard

18. 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?

Atherectomy

Potential patient benefits and impact on the health system

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

reduce number of lesions that require stent insertion.
facilitate treatment of very calcified lesions

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

patients with calcified atherosclerotic plaques

21. 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

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

Minor modification

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

Minimal

Safety and efficacy of the procedure/technology

24. 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

    dissection
    failure to respond

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

    improve vessel elasticity and enhance angioplasty effect

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

    patient selection and additional treatment

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

    which lesion and which vessel

28. 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

29. 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.

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

    Yes

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

Other considerations

32. 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)?

In my centre (tertiary), around 100

33. 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.

length of lesions treated
residual stenosis
+/- stent insertion
+/- DEB
limb salvage
quality of life
re intervention rate
distal embolisation

34. 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:

restenosis
distal embolisation
major vs minor amputation

Further comments

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

There is definite need for further research to define the type of lesion , and the name of the vessel (common femoral artery , popliteal, etc) with the best technical and clinical response and to assess the reintervention rate. Direct comparison with other modalities such as atherectomy or open surgery should also be studied. It is also important to assess the cost effectiveness of this technology

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.

36. Type of interest: *

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

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

NA

38. 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

39. Name: *

Mo Hamady

40. Date: *

14/03/2023

View results

Respondent

6 Anonymous

59:32
Time to complete

Your information

1. Name: *

Narayanan Thulasidasan

2. Job title: *

Consultant Interventional Radiologist

3. Organisation: *

Guy's & St Thomas' NHS Foundation Trust

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

GMC

6. Nominated/ratified by (if applicable):

Vascular Society/British Society of Interventional Radiology

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

6164087

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

8. 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.

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

   Are you familiar with the procedure/technology?

   Yes, early adopter in the UK and use it once or twice a month.

10. 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.

    - procedure is used by either interventional radiologists or vascular surgeons who undertake endovascular treatment of peripheral arterial disease
    - anecdotally, the uptake of the technology in the UK has increased quite significantly in the past year. Although not required for most angioplasty procedures, the shallow learning curve and effectiveness seem to be attracting clinicians to using it in the setting of severely-calcified disease.

11. 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).
- [x] 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

12. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

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

to be more precise, it is for use to treat calcified atheroma causing narrowings in arteries.

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

- novel application of an old concept: lithotripsy for kidney stones has been around for decades, but this was the first product to allow delivery of lithotripsy to calcified plaque inside blood vessels
- a second product which works in a similar way but this is only just starting clinical trials

15. 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.

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

addition to existing standard of care with the aim of increasing both safety and efficacy

Current management

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

plain balloon angioplasty with or without stent insertion

18. 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?

    - atherectomy is currently available in the NHS which is also a vessel preparation tool to modify calcium prior to balloon angioplasty, however this works in a different way with a different risk profile and a steeper learning curve. atherectomy involves a catheter with high-speed rotating blades that functions like a drill through calcified plaque, removing some and modifying the remainder to allow it to respond better to angioplasty
    - intravascular lithotripsy works by using energy waves to cause microfractures in the calcified plaque which then allow it to respond better to angioplasty

Potential patient benefits and impact on the health system

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

    patients with calcified peripheral arterial disease

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

    diabetics and end-stage renal failure patients, who have the highest risk of having calcified arterial disease.

21. 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?

    whilst this will not change the pathway for patients, it could lead to more effective endovascular treatment in selected patients. This has two benefits:
    1. potentially reduced need for placement of expensive stents, which may require more complex procedures to manage if they block
    2. potentially open doors for more patients to have an endovascular treatment rather than open surgery for selected indications, which will save NHS theatre time and inpatient stay

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

    nil (small power unit and the balloon is a consumable)

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

    some training is needed, but all in all the device has a very shallow learning curve: if you can do angioplasty then you can do intravascular lithotripsy with just a little specific guidance early on

Safety and efficacy of the procedure/technology

24. 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

    Risks are very low; specifically one of the main benefits of the intravascular lithotripsy technology is its improved safety profile with reduced risk of vessel perforation, vessel dissection (injury/tearing to the inner lining of the artery) and distal embolisation (pieces of plaque breaking off and going down into the tiny arteries in the feet). From recent publication of the DISRUPT-PAD III observational study (i.e. real-world use of the technology) there was a 0.7% rate of flow-limiting dissections, 0.2% perforation and no distal embolisation.

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

    - reduced need for stent placement due to inadequate angioplasty result or significant dissection
    - significantly improved risk of distal embolisation
    - improved patency after angioplasty (to be confirmed long term in critical limb ischaemia patients)

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

    - long term patency rates in critical limb ischaemia patients

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

    none - longstanding use in coronary circulation

28. 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

29. 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.

1. DISRUPT PAD III randomised control trial and DISRUPT PAD III observational study.

2. Stavroulakis K, Torsello G, Chlouverakis G, Bisdas T, Damerau S, Tsilimparis N, Argyriou A. Intravascular Lithotripsy and Drug-Coated Balloon Angioplasty for Severely Calcified Common Femoral Artery Atherosclerotic Disease. J Endovasc Ther. 2023 Mar 10:15266028231158313. doi: 10.1177/15266028231158313. Epub ahead of print. PMID: 36896876.

3. Stavroulakis K, Bisdas T, Torsello G, Tsilimparis N, Damerau S, Argyriou A. Intravascular Lithotripsy and Drug-Coated Balloon Angioplasty for Severely Calcified Femoropopliteal Arterial Disease. J Endovasc Ther. 2023 Feb;30(1):106-113. doi: 10.1177/15266028221075563. Epub 2022 Feb 7. PMID: 35130782.

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

1. SHOCC registry in the UK (multicentre real-world registry with plaque analysis in a subgroup of patients)
2. DISRUPT PAD III observational study in the USA

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

nil

Other considerations

32. 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)?

5-10% of patients with peripheral arterial disease who require a revascularisation procedure

33. 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.

1. patency of treated artery and preservation of limb (measured over months/years)
2. improvement in ischaemic rest pain, walking distance and quality of life using questionnaires and objective walking tests
3. these could be captured by addition of intravascular lithotripsy to the National Vascular Registry core dataset

34. 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:

early complications: dissection, perforation, distal embolisation.
no late complications to this device

Further comments

35. 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.

36. Type of interest: *

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

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

I have received speaking fees from Shockwave Medical LLC for giving talks and delivering educational events on the subject of intravascular lithotripsy for the last two years, and also received sponsorship from them to cover travel and accommodation at some of these conferences (this is an ongoing arrangement). I will also receive a consulting fee for attending a "wet lab" session to evaluate their new pipeline devices in February 2023, along with having my travel and accommodation to Italy for this arranged by Shockwave. Finally, I have assisted in the production of educational content regarding intravascular lithotripsy for a trade magazine and received a consulting fee for my time in this matter.

I do not hold any Shockwave stock, and do not receive any financial compensation related to my own or my institution's use of the technology.

38. 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

39. Name: *

Narayanan Thulasidasan

40. Date: *

14/03/2023

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1973 Intravascular lithotripsy for calcified arteries in peripheral vascular disease

Your information

Name:	Paul Moxey
Job title:	Consultant Vascular Surgeon
Organisation:	St George's Hospital, Tooting, London
Email address:	[redacted]
Professional organisation or society membership/affiliation:	GMC 6057022
Nominated/ratified by (if applicable):	NA
Registration number (e.g. GMC, NMC, HCPC)	6057022

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?	I use this technology in my daily practice and have done for approximately 2 years I do not know exact figures but I would estimate approximately 10% of units that perform peripheral angioplasty have IVL on the shelf at present . It is gaining popularity and an increasing evidence base and therefore the number of units that use it will likely increase.
	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?	Cardiologist also perform the procedure on coronary arteries and indeed it was developed initially for heavily calcified coronary arteries and has moved from there to the peripheral arteries We select patients for the procedure based on CT angiography imaging that shows up heavy calcification. Most decisions are made in the multidisciplinary meeting but occasionally we decide to use IVL in a live case if a calcified lesion is not responding to plain balloon angioplasty

	− 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 done bibliographic research on this procedure. – I have read the current research but not authored any my self I have done research on this procedure in laboratory settings (e.g. device-related research). – I have performed the procedure on cadavers to test the efficacy on different types and patterns of calcification I have done clinical research on this procedure involving patients or healthy volunteers. – I was local PI for the SHOCC post market registry study of this procedure that has just finished recruiting I have published this research. - no I have had no involvement in research on this procedure. – no – see disclosures
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?	Yes, the title is accurate and the indication is heavily calcified arteries A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. – the technology is based on a standard angioplasty balloon platform which makes it easy to learn and angioplasty balloons have been around for many years. This is an adaptation of the standard balloon to allow it to deliver a pulse of ultrasound to break up calcium in the wall of the artery to improve compliance, reduce recoil and as a result reduce the need for stenting.

	Which of the following best describes the procedure (please choose one):	
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?	Would be used in addition, not all lesions are heavily calcified and need this technology so would not be expected to replace existing standard of care in non-calcified lesions
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?	Nothing substantial that I am aware of. The technology was designed initially for small calibre coronary arteries and based on a very thin 0.14 wire platform. Larger balloons have come to the market recently to allow larger leg arteries to be treated but is not a substantial modification Not that I am aware of

Current management

6	Please describe the current standard of care that is used in the NHS.	Balloon angioplasty is the current standard of care where a balloon is placed into a narrowed or blocked artery and the inflated to reopen the lumen and restore flow. This procedure is backed up by placing stents if the artery will not stay open or using atherectomy (drills) or IVL to break up calcium in the wall and help the artery stay open and not recoil shut or crush a stent

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?	No

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?	Less use of stents, less open surgical bypass procedures, potentially less re-occlusion or narrowing of previously treated blockages so less time in hospital
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients with heavily calcified arteries where current simple balloon angioplasty is not always enough to open the artery and keep it open
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?	Potentially yes and we await clinical trials to prove that it offers benefits to the groups of patients described above.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Interventional radiology suites or hybrid x-ray equipped operating theatres
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	As the technology is based on balloon angioplasty it is reasonably easy to learn. A short period of training and mentorship is needed as with all new devices but the learning curve is not steep

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:	Embolisation of calcium or clot within the artery being treated are a risk of any angioplasty procedure and therefore are a risk during IVL angioplasty. Bleeding from the puncture site and the area being treated are also a risk. To the best of my knowledge there is no evidence that IVL has a greater risk of these complications than current standard of care

	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?	Primary patency, assisted primary patency and secondary patency are the usual measures of angioplasty techniques. I also think more clinical outcomes like amputation free survival, wound healing and QoL scores are more useful for describing risks and benefits to patients and clinicians
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	No concerns I am aware of regards to safety. Still unclear exactly which group of patients benefit the most form the technology – circumferential calcium, partially calcified, occluded, stenosed and more research is needed to establish this but the effects of the IVL effect on calcification are clear
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Not that I am aware of
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.

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	The SHOCC trial has just finished recruiting and is a post market registry of the use of these balloons in multiple UK centres. It was based in Leicester but I am unsure when results will be published. Main publications are PADIII RCT and PADIII observational study (Stavroulakis et al 2021 JEVT)

	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.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	SHOCC registry has just finished recruiting and results awaited
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)?	30-40% of current patients needing an angioplasty are likely to be suitable for IVL based angioplasty
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	Beneficial outcome measures: Primary – Patency (all forms), wound healing, pain scores, QoL scores Secondary - Luminal gain as measured by intravascular ultrasound, proportion of cases that need bail out stenting Adverse outcome measures: Distal embolization, vessel rupture/perforation, limb loss Immediate, 30 day and 6 months

	procedure timescales over which these should be measured:	

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
Non-financial professional	Local PI for SHOCC IVL post market registry trial	**June 2022**	**On going**
Direct - financial	I have received remuneration from Shockwave (the manufacturer of current IVL balloons) for attending a national working group on IVL technology and for chairing a sponsored scientific session. This ceased in December 2023	**Nov 2021**	**Dec 2023**
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:	**Paul Moxey**
Dated:	**17th April 2023**

View results

Respondent

9 Anonymous

58:40
Time to complete

Your information

1. Name: *

Dr Peter Mezes

2. Job title: *

Consultant Interventional Radiologist

3. Organisation: *

North Bristol NHS Trust

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

BSIR, CIRSE

6. Nominated/ratified by (if applicable):

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

6148689

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

8. 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.

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

   Are you familiar with the procedure/technology?

I have done most of the cases in our department, including the first. We have done >10 cases.
Our department participated in the SHOCC trial.
I have no information on how widely this is currently used in the UK

10. 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.

Intravascular lithotripsy was already in use by cardiologist before we started using it in peripheral endovascular work. Some of the vascular surgeons are now also familiar and would be trained to use it
Pt selection for using this technology happens either during vascular MDT or often just before/during the procedure, left at the discretion of the operator

11. 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.
- [ ] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

12. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

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

yes

14. 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 and concept but was built on the old technology (standard plain angioplasty balloon)

15. 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.

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

currently there is insufficient data to answer this question, it is unlikley to completely replace the current standard of care, but has the potential to be a widely used adjunct technology

Current management

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

For iliac and femoropopliteal atherosclerotic disease, the current standard of care is either open surgical (bypass) or endovascular with plain balloon angioplasty and bail out stenting. Current standard endovascular treatment often insufficient in vessels with extensive calcification

18. 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?

There are many different approaches to handle intravascular calcium, but none of these so far has become widely accepted. These include atherectomy, various modification of angioplasty balloons (cutting/ scoring etc), stents

Potential patient benefits and impact on the health system

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

better primary patency of endovascular treatment, reduction in need for stent implantation

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

femoropopliteal or iliac arterial disease with severe/extensive mural calcification

21. 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, with improving vessel compliance by fragmenting mural calcification, it could improve outcome of endovascular treatment, and reduce the need for stent implantation

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

does not require anything extra to what is required for the current standard of care

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

minimal training required , very straightforward to use

Safety and efficacy of the procedure/technology

24. 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

    vessel dissection , perforation (very low) DIRUPT III study

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

    primary patency, limb salvage

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

    it remains uncertain which type of calcification would benefit the most from treatment. If lesion is long, the sue of multiple balloons would be required (cost effectiveness could be affected). Large eccentric plaques tend to respond less well

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

28. 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

29. 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.

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

    SHOCC

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

Other considerations

32. 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)?

33. 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 outcomes should be used to other peripheral lower limb interventions
    Reduction in the need for stenting

34. 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:

    30 days 1 year

Further comments

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

it is still not entirely clear how best to select patients, as the technology fails in larger eccentric plaque burden and how to assess if lithotripsy was effective for the treated calcified lesion

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.

36. Type of interest: *

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

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

none

38. 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

39. Name: *

    Peter Mezes

40. Date: *

    11/04/2023

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1973 Intravascular lithotripsy for calcified arteries in peripheral vascular disease

Your information

Name:	Raghuram Lakshminarayan
Job title:	Consultant Vascular Radiologist
Organisation:	Hull University Teaching Hospitals NHS Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Secretary, British Society of Interventional Radiology
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	6047755

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?	I am familiar with the technology and use it regularly.
	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?	Yes. This procedure is being adopted by many NHS trusts and I expect its use to increase over the next few years. Vascular Interventional Radiologists and vascular surgeons

	− 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 done bibliographic research on this procedure. I have been a part of a group that does clinical research on this procedure involving patients. This research will be published. I am working on a meta-analysis on one aspect of use of this technology, the protocol for this has been published (http://doi.org/10.54522/jvsgbi.2023.061)
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 It is appropriate if it is being stated that the procedure is used as an adjunct to treat calcified arteries with narrowing or occlusion with peripheral arterial disease. Definitely novel with developing information on safety and efficacy. The first in a new class of procedure.
4	Does this procedure/technology have the potential to replace current standard care or	It will act as an adjunct to standard care in the presence of specific indications

	would it be used as an addition to existing standard care?	
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?	No No

Current management

6	Please describe the current standard of care that is used in the NHS.	The present standard of care is percutaneous angioplasty and stenting for peripheral arterial disease when an endovascular approach is considered.
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?	There are no competing procedures. However, the other procedure which uses an entirely different technology to treat calcific disease in peripheral arteries is atherectomy (https://www.nice.org.uk/guidance/ipg380/chapter/1-Guidance) The technology of Intravascular lithotripsy uses technology to crack calcium unlike atherectomy which removes calcium. Both have their specific place in practise.

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?	It is a well-known fact that patients with calcific disease do badly with endovascular treatments (Angioplasty / Stent). This technology which causes micro fractures in calcium both intimal and medial can help increase luminal diameters, help drug penetration (if drug coated balloons or stents are used) and potentially have better long term outcomes. With the micro fractures, it is presumed that compliance of the vessel wall will improve.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Those with circumferential intimal or medial calcification will benefit the most 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?	I think it does in a way that this technology will be used as an adjunct in patients with calcification during endovascular treatment. It could reduce 'target vessel revascularisation' which essentially means re stenosis or occlusion of the treated vessel which has represented for treatment again (a primary failure).
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	None. The box that supplies the energy for the shockwave balloon is provided by the company. The balloon is like any other standard angioplasty balloon.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	The learning curve is steep and a short basic training for the nursing and other members of how to set up is all that is required.

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: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	We have not seen any distal embolization of calcific material as a result of use of this balloon. It is also not seen in the reported literature but could be a theoretical risk of procedure. Dissections are well known and tough to elucidate if the balloon dilatation of calcified lesion caused it or it was related to IVL. The incidence of severe dissections in studies have been to a lesser extent than plain balloon angioplasty. Other potential adverse events would include vessel perforation, thrombosis and vessel closure. We haven't experienced these events and the incidence in available literature is small or non existent.
14	Please list the key efficacy outcomes for this procedure/technology?	Comparison of vessel patency and target vessel revascularisation in patients who are treated with IVL to those treated with standard care (plain balloon / stent) over time.
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	As lot of technologies are used during a procedure which includes post IVL balloon dilatation, use of drug coated technology etc, the uncertainties of long term outcomes directly attributable to IVL will need studies with large number of patients.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	The controversy that most physicians face is the place of IVL in calcific disease and balancing this technology with atherectomy which uses a completely different method for calcium extraction.
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals and others who provide endovascular treatment of peripheral arterial disease.

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 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.	Use of Shockwave® Intravascular lithotripsy in the treatment of calcific peripheral vascular disease of the crural vessels: a protocol for a systematic review. Igwe C,Mohamed A,Nazir S,Smith G, Carradice D,Lakshminarayan R (http://doi.org/10.54522/jvsgbi.2023.061)
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Disrupt PAD II BTK study looking at safety and effectiveness of IVL in the BTK segment is ongoing with a plan to recruit 250 patients from 40 global sites (https://clinicaltrials.gov/ct2/show/NCT05007925)
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)?	Between 10-20% of patients undergoing angioplasty treatment for peripheral arterial disease.
22	Please suggest potential audit criteria for this procedure/technology. If known, please describe:	Beneficial outcome measures: long term outcomes for plain balloon angioplasty (POBA) vs IVL in peripheral arterial disease

	− 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:	Amputation rates, Ulcer healing, Target Vessel revascularisation & / or Patency over 2 years. Adverse outcome measures: Distal embolization requiring treatment; Restenosis / re-occlusion rates.

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	Calcific disease in the peripheral vascular tree in arterial disease is quite common. Deciding on patient selection for IVL and adjunct technologies along with IVL needs further work.

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
Direct - financial	Speaker fees	2/11/22	4/11/22
Direct - financial	Speaker fees	19/04/22	19/04/22
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:	**Raghu Lakshminarayan**
Dated:	**02-April-2023**