NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1858 Superficial venous arterialisation and selective venous occlusion for critical limb ischaemia**

Your information

Name:	Athanasios Saratzis
Job title:	Associate Professor of Vascular Surgery and Honorary Consultant Vascular and Endovascular Surgeon
Organisation:	University of Leicester and University Hospitals of Leicester NHS Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	General Medical Council, Royal College of Surgeons
Nominated/ratified by (if applicable):	British Society of Endovascular Therapy
Registration number (e.g. GMC, NMC, HCPC)	7024328

How NICE will use this information: the advice and views given in this questionnaire will form part of the information used by NICE and its advisory committees to develop guidance or a medtech innovation briefing on this procedure/technology. Information may be disclosed to third parties in accordance with the Freedom of Information Act 2000 and the Data Protection Act 2018, complying with data sharing guidance issued by the Information Commissioner's Office. 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interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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☐ I 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.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? − Is this procedure/technology performed/used by clinicians in specialities other than your own? − If your specialty is involved in patient selection or referral to another specialty for this	I am a vascular surgeon with a busy surgical and endovascular practice in peripheral arterial disease (mostly patients with chronic limb threatening ischaemia). At the same time, I am an academic surgeon being familiar with the relevant literature and latest advances. I am familiar with this procedure. **Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?** This procedure is very rarely used in the NHS. I cannot recall anyone using this technique in the Midlands region or in fact any regions where I practice and/or have trained. This is a very rare procedure in the UK. **Is this procedure/technology performed/used by clinicians in specialities other than your own?** No. This procedure might be performed by teams of vascular surgeons and radiologists; however, a vascular surgeon is needed in order to perform the procedure.

	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 not published or done any research on this procedure. I am recruiting patients in a study investigating deep venous arterialisation in this patient group (similar procedure).
3	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):	Definitely novel and of uncertain safety and efficacy.
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?	Not at the moment. Too limited evidence.

Current management

5	Please describe the current standard of care that is used in the NHS.	Angioplasty or surgical bypass to revascularise the occluded segment / arteries.

6	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 is a fairly similar procedure called LimFlow; however, it involves arterialisation of the deep rather than the superficial veins / venous system.

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Less invasive compared to traditional bypass (surgical reconstruction).
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients with chronic limb threatening ischaemia who have multiple co-morbidities (unfit for a long anaesthetic).
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	No at present. Too limited information. The literature consists only of cases series or case reports.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	About the same. Considerable resources would have to be invested in training staff for this new procedure, including both doctors and associated health care professionals.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	About same.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Training is the main issue.

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

Safety and efficacy of the procedure/technology

14	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	Bleeding. Peripheral embolization. Oedema due to venous hypertension. Amputation if the procedure is unsuccessful. These are theoretical adverse events. The literature is extremely limited.
15	Please list the key efficacy outcomes for this procedure/technology?	Patency of revascularisation (efficacy outcome measure).
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Uncertain about limb salvage and durability of this procedure.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	No.
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Cannot predict at present.

Abstracts and ongoing studies

19	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.	No. None that I can find.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	No. None.

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)?	>5,000
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Yes. This will require a lot of investment for training.
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	Cost and feasibility of use.

24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Yes. A randomised trial.
25	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: Amputation free survival. Adverse outcome measures: Bleeding, infection, recurrence, amputation(s) - major and minor.

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	None.

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Declarations of interests

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

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.	Primary investigator for an observational study called PROMISE UK – not paid for my participation in the study.	**10/10/2020**	**Ongoing**
Choose an item.	Honorarium paid by Abbott Medical – a company that produces devices used in treating similar patients (with peripheral arterial disease)	**07/05/2021**	**15/06/2021**
Choose an item.	Honorarium paid by Shockwave Medical – a company that produces devices used in treating similar patients (with peripheral arterial disease)	**11/06/2021**	**11/06/2021**

X 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:	**Athanasios Saratzis**
Dated:	**13/12/2021**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1858 Superficial venous arterialisation and selective venous occlusion for critical limb ischaemia**

Your information

Name:	Ankur THAPAR
Job title:	Consultant vascular surgeon
Organisation:	Mid and South Essex NHS Foundation Trust & Anglia Ruskin University
Email address:	[redacted]
Professional organisation or society membership/affiliation:	FRCS (Eng), FEBVS, PGCE, FHEA
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	6103047

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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.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example:	
	Are you familiar with the procedure/technology?	Yes
	Have you used it or are you currently using it?	I am a current practitioner of superficial venous arterialisation.
	− Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?	It is rarely performed e.g. 1-3 procedures / year / vascular network
	− Is this procedure/technology performed/used by clinicians in specialities other than your own?	No
	− If your specialty is involved in patient selection or referral to another specialty for this	Vascular selects the patient in MDT => based on age/ASA grade/great saphenous vein >3mm diameter and no target on angiography

	procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have had no involvement in research on this procedure. Other (please comment)
3	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):	It is a minor variation of a conventional femorodistal bypass. Established practice and no longer new.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	Addition to existing standard of care

Current management

5	Please describe the current standard of care that is used in the NHS.	Amputation/femorodistal bypass

6	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?	Endovascular deep venous arterialisation (Lim Flow)

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Limb salvage
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Age <70, ASA<4, great saphenous vein >3mm, no target on angiography
9	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?	Reduction in amputations
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	Same
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	Reduction in social care costs and earnings
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Hybrid theatre

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Training in valvulotomy

Safety and efficacy of the procedure/technology

14	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	Eur J Vasc Endovasc Surg (2017) 53, 387–402 REVIEW **Venous Arterialisation for Salvage of Critically Ischaemic Limbs: A Systematic Review and Meta-Analysis** M.A. Schreve [a,*], C.G. Vos [a], A.C. Vahl [b], J.P.P.M. de Vries [c], S. Kum [d], G.J. de Borst [e], Ç. Ünlü [a] Mortality 5% Limb loss 25% Steal syndrome ?unknown
15	Please list the key efficacy outcomes for this procedure/technology?	Limb salvage at 30 days Amputation free survival Wound healing
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Only case series review is available
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	It's efficacy

18	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

19	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.	Eur J Vasc Endovasc Surg (2017) 53, 387–402 REVIEW **Venous Arterialisation for Salvage of Critically Ischaemic Limbs: A Systematic Review and Meta-Analysis** M.A. Schreve [a,*], C.G. Vos [a], A.C. Vahl [b], J.P.P.M. de Vries [c], S. Kum [d], G.J. de Borst [a], Ç. Ünlü [a]
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Baylor University in the USA have a registry

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)?	100 / year / England

22	Are there any issues with the usability or practical aspects of the procedure/technology?	No
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	No
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	No
25	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: Limb salvage 30 days Amputation free survival Wound healing time Adverse outcome measures: Death within 30 days Reintervention rate

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	

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Choose an item.			
Choose an item.			

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Print name:	**Ankur THAPAR**
Dated:	**15/12/2021**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1858 Superficial venous arterialisation and selective venous occlusion for critical limb ischaemia

Your information

Name:	Pranav Somaiya
Job title:	Consultant Vascular Surgeon
Organisation:	Barts Health NHS Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	General Medical Council
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	6030489

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1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? − Is this procedure/technology performed/used by clinicians in specialities other than your own? − 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 done two cases of this in our practice now. It is relatively new technology for us so we have strict criteria for suitability and a small MDT which approves each of the cases. It is a very uncommon procedure and I do not know of any other hospital in the NHS that is doing it. It is being practiced across the rest of the world. No other specialty uses this procedure.

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 done research on this procedure in laboratory settings (e.g. device-related research). I have done clinical research on this procedure involving patients or healthy volunteers. I have published this research. I have had no involvement in research on this procedure. X Other (please comment)
3	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):	It is a variation of deep venous arterialisation but novel in that it arterialises the superficial venous system. It is a very novel procedure in that regard. 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. X
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?	It would be used as an addition to existing standard of care in that it will allow us to offer therapy for a patient with no surgical options of care left in peripheral vascular disease.

Current management

5	Please describe the current standard of care that is used in the NHS.	Angioplasty (proximal and distal), Bypass procedures, Deep Venous Arterialisation (DVA)
6	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?	DVA but SAVE Limb creates arterialisation of the superficial venous sytem. The benefits of it are that there is lower tissue oedema and is simpler surgery with potential for better long term outcomes.

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Limb salvage Lower tissue oedema post-revascularisation
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients with no distal targets for bypass or angioplasty Patients with microvascular angiopathy of diabetes Patients with extremely calcified digital vessels secondary to atherosclerosis In short, patients no more options for limb salvage
9	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 this new bypass it is hoped we will reduce the number of angioplasties needed in the future as well as help with wound healing in patients so they will need reduced visits to hospital
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	Less as if successful there will be an increase in the limb salvage rates, a reduction in reintervention rates and an an increase in wound healing rates
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	Same as standard care
12	What clinical facilities (or changes to existing facilities) are needed to do this	Same as existing facilities, no new facilities required

	procedure/technology safely?	
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, universal proctoring techniques will be employed to get the teams up to speed on the procedure. However these will be a small variation on the existing knowledge so there wont be a steep learning curve.

Safety and efficacy of the procedure/technology

14	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 main adverse event here is that of limb loss. However this procedure is being done on patients facing that as a potential outcome without it anyway. All other adverse events are in keeping with that of a hybrid vascular procedure, involving IR and Vascular Surgery
15	Please list the key efficacy outcomes for this procedure/technology?	Limb salvage is the key efficacy outcome for this procedure
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	We have only done two of these procedures so are unable to comment on the uncertainties.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	No
18	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. A minority of hospitals, but at least 10 in the UK. Fewer than 10 specialist centres in the UK.

		Cannot predict at present. X

Abstracts and ongoing studies

19	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.	Busato CR, Utrabo CAL, Lipinski LC, et al. Experimental model for the study of retrograde flow. *J Vasc Bras*. 2016;15(2):93-98. doi:10.1590/1677-5449.008915 Busato, Cesar Roberto, Utrabo, Carlos Alberto Lima, Gomes, Ricardo Zanetti, Hoeldtke, Eliziane, Housome, Joel Kengi, Costa, Dieyson Martins de Melo, & Busato, Cintia Doná. (2010). The great saphenous vein in situ for the arterialization of the venous arch of the foot. *Jornal Vascular Brasileiro*, *9*(3), 119-123. https://doi.org/10.1590/S1677-54492010000300004
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	None

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)?	Approx 1-2% of the patients with limb threatening ischaemia
22	Are there any issues with the usability or practical aspects of the procedure/technology?	No its just a variation of the established practice

23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	No
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Yes, it will need to evaluated and compared to other Deep Venous Arterialisation techniques
25	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: Limb salvage: @1month, 1yr Post-operative oedema: @1wk, 1mth Length of stay: days Wound healing times: @1mth,2mth,3mth Reintervention rates/times: @3mths, 6mths, 1yr Adverse outcome measures: Limb loss @1mth, 1yr Reintervention rates: @3mths, 6mths, 1yr Mortality: @1mth, 1yr, 5yrs

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	All our comments are contained within the SOP and other documents sent to you.

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

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Print name:	**Pranav Somaiya**
Dated:	**21/12/21**