Specialist Referral for Lower Limb Issues & Leg Ulcers

The State of the Art

Mr Lukla Biasi, PhD
Consultant Vascular Endovascular Surgeon
Lead for Lower Limb Revascularisation

Guy's and St Thomas' NHS Foundation Trust
King's Health Partners and Tunbridge Wells Hospital

Guy's and St Thomas' NHS Foundation Trust

ESC European Society of Cardiology

European Heart Journal (2018) **39**, 763–821
doi:10.1093/eurheartj/ehx095

ESC GUIDELINES

2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS)

Document covering atherosclerotic disease of extracranial carotid and vertebral, mesenteric, renal, upper and lower extremity arteries

Endorsed by: the European Stroke Organization (ESO)

The Task Force for the Diagnosis and Treatment of Peripheral Arterial Diseases of the European Society of Cardiology (ESC) and of the European Society for Vascular Surgery (ESVS)

Authors/Task Force Members: Victor Aboyans* (ESC Chairperson) (France), Jean-Baptiste Ricco*[1] (Co-Chairperson) (France), Marie-Louise E. L. Bartelink (The Netherlands), Martin Björck[1] (Sweden), Marianne Brodmann (Austria), Tina Cohnert[1] (Austria), Jean-Philippe Collet (France), Martin Czerny (Germany),

* Corresponding authors: Victor Aboyans, Department of Cardiology CHRU Dupuytren Limoges, 2 Avenue Martin Luther King, 87042 Limoges, France. Tel: +33 5 55 05 63 10, Fax: +335 55 05 63 34, Email: vaboyans@live.fr. Jean-Baptiste Ricco, Department of Vascular Surgery, University Hospital, rue de la Miletrie, 86021 Poitiers, France. Tel: +33 549443846, Fax: +33 5 49 50 05 50, Email: jeanbaptistericco@gmail.com

ESC Committee for Practice Guidelines (CPG) and National Cardiac Societies (NCS) document reviewers: listed in the Appendix

[1]Representing the European Society for Vascular Surgery (ESVS)

[2]Representing the European Stroke Organisation (ESO)

ESC entities having participated in the development of this document:
Associations: European Association of Preventive Cardiology (EAPC), European Association of Cardiovascular Imaging (EACVI), European Association of Percutaneous Cardiovascular Interventions (EAPCI).
Councils: Council for Cardiology Practice (CCP), Council on Cardiovascular Primary Care (CCPC), Council on Hypertension (CHT).
Working Groups: Atherosclerosis and Vascular Biology, Cardiovascular Pharmacotherapy, Cardiovascular Surgery, Peripheral Circulation, Thrombosis.

Disclaimer. The ESC Guidelines represent the views of the ESC and were produced after careful consideration of the scientific and medical knowledge and the evidence available at the time of their publication. The ESC is not responsible in the event of any contradiction, discrepancy and/or ambiguity between the ESC Guidelines and any other official recommendations or guidelines issued by the relevant public health authorities, in particular in relation to good use of healthcare or therapeutic strategies. Health professionals are encouraged to take the ESC Guidelines fully into account when exercising their clinical judgment, as well as in the determination and the implementation of preventive, diagnostic or therapeutic medical strategies; however, the ESC Guidelines do not override, in any way whatsoever, the individual responsibility of health professionals to make appropriate and accurate decisions in consideration of each patient's health condition and in consultation with that patient and, where appropriate and/or necessary, the patient's caregiver. Nor do the ESC Guidelines exempt health professionals from taking into full and careful consideration the relevant official updated recommendations or guidelines issued by the competent public health authorities, in order to manage each patient's case in light of the scientifically accepted data pursuant to their respective ethical and professional obligations. It is also the health professional's responsibility to verify the applicable rules and regulations relating to drugs and medical devices at the time of prescription.

Eur J Vasc Endovasc Surg (2019) 58, S1—S109

CLINICAL PRACTICE GUIDELINE DOCUMENT

Global Vascular Guidelines on the Management of Chronic Limb-Threatening Ischemia

Michael S. Conte, MD, Co-Editor [a,*], Andrew W. Bradbury, MD, Co-Editor [b], Philippe Kolh, MD, Co-Editor [c], John V. White, MD, Steering Committee [d], Florian Dick, MD, Steering Committee [e], Robert Fitridge, MBBS, Steering Committee [f], Joseph L. Mills, MD, Steering Committee [g], Jean-Baptiste Ricco, MD, Steering Committee [h], Kalkunte R. Suresh, MD, Steering Committee [i], M. Hassan Murad, MD, MPH [j], Victor Aboyans [k], Murat Aksoy [l], Vlad-Adrian Alexandrescu [m], David Armstrong [n], Nobuyoshi Azuma [o], Jill Belch [p], Michel Bergoeing [q], Martin Bjorck [r], Nabil Chakfé [s], Stephen Cheng [t], Joseph Dawson [u], Eike S. Debus [v], Andrew Dueck [w], Susan Duval [x], Hans H. Eckstein [y], Roberto Ferraresi [z], Raghvinder Gambhir [aa], Mauro Gargiulo [ab], Patrick Geraghty [ac], Steve Goode [ad], Bruce Gray [ae], Wei Guo [af], Prem C. Gupta [ag], Robert Hinchliffe [ah], Prasad Jetty [ai], Kimihiro Komori [aj], Lawrence Lavery [ak], Wei Liang [al], Robert Lookstein [am], Matthew Menard [an], Sanjay Misra [ao], Tetsuro Miyata [ap], Greg Moneta [aq], Jose A. Munoa Prado [ar], Alberto Munoz [as], Juan E. Paolini [at], Manesh Patel [au], Frank Pomposelli [av], Richard Powell [aw], Peter Robless [ax], Lee Rogers [ay], Andres Schanzer [az], Peter Schneider [ba], Spence Taylor [bb], Melina V. De Ceniga [bc], Martin Veller [bd], Frank Vermassen [be], Jinsong Wang [bf], Shenming Wang [bf]: GVG Writing Group for the Joint Guidelines of the Society for Vascular Surgery (SVS), European Society for Vascular Surgery (ESVS), and World Federation of Vascular Societies (WFVS)

[a] Division of Vascular and Endovascular Surgery, University of California, San Francisco, CA, USA
[b] Department of Vascular Surgery, University of Birmingham, Birmingham, United Kingdom
[c] Department of Biomedical and Preclinical Sciences, University Hospital of Liège, Wallonia, Belgium
[d] Department of Surgery, Advocate Lutheran General Hospital, Niles, IL, USA
[e] Department of Vascular Surgery, Kantonsspital St. Gallen, St. Gallen, and University of Berne, Berne, Switzerland
[f] Department of Vascular and Endovascular Surgery, The University of Adelaide Medical School, Adelaide, South Australia, Australia
[g] Division of Vascular Surgery and Endovascular Therapy, Baylor College of Medicine, Houston, TX, USA
[h] Department of Clinical Research, University Hospitalof Poitiers, Poitiers, France
[i] Jain Institute of Vascular Sciences, Bangalore, India
[j] Mayo Clinic Evidence-Based Practice Center, Rochester, MN, USA
[k] Department of Cardiology, Dupuytren, University Hospital, France
[l] Department of Vascular Surgery American, Hospital, Turkey
[m] University of Liège CHU Sart-Tilman Hospital, Belgium
[n] University of Southern California, USA
[o] Asahikawa Medical University, Japan
[p] Ninewells Hospital University of Dundee, UK
[q] Escuela de Medicina Pontificia Universidad, Catolica de Chile, Chile
[r] Department of Surgical Sciences, Vascular Surgery, Uppsala University, Sweden
[s] University Hospital of Strasbourg, France
[t] The University of Hong Kong, Hong Kong
[u] Royal Adelaide Hospital & University of Adelaide, Australia
[v] University Heart Center Hamburg, University Hospital Hamburg-Eppendorf, Germany
[w] Schulich Heart Centre, Sunnybrook Health, Sciences Centre, University of Toronto, Canada
[x] Cardiovascular Division, University of, Minnesota Medical School, USA
[y] Technical University of Munich, Germany
[z] Interventional Cardiovascular Unit, Cardiology Department, Istituto Clinico, Città Studi, Milan, Italy
[aa] King's College Hospital, London, UK
[ab] Diagnostica e Sperimentale, University of Bologna, Italy

Endorsed by the American Podiatric Medical Association, British Cardiovascular Society, British Society for Endovascular Therapy, British Society of Interventional Radiology, Circulation Foundation, College of Podiatry, Society of Interventional Radiology, Society for Vascular Nursing, the Society for Vascular Technology of Great Britain and Ireland, and the Vascular Society of Great Britain and Ireland

Additional material for this article may be found online at https://doi.org/10.1016/j.ejvs.2019.05.006.

Independent peer-review and oversight has been provided by members of the ESVS Guideline Committee (Drs Gert Jan de Borst, Guidelines Committeechair, Jos van den Berg, Frederico Bastos Goncalves, Stavros Kakkos, IgorKoncar, Jes Lindholt, Henrik Sillesen), SVS Document Oversight Committee (Drs Thomas L. Forbes, chair, Ali AbuRahma, Kwame Anankwah, Neal Barshes, Ruth Bush, Ronald L. Dalman, Mark Davies, Alik Farber, Anil Hingorani, Mahmoud Malas, J. Sheppard Mondy, Eva Rzucidlo, Marc Schermerhorn), and the Council of the World Federation of Vascular Societies (Drs Alberto Muñoz, Vidyasagaran Thiruvengadam, Martin Björck, Peter Subramaniam, P Rajaruthnam, Varinder Bedi, Thanyani Mulaudzi, Kimihiro Komori, T. Vidyasagaran, Nobuyoshi Azuma, John Henry Nicholas Wolfe, John Wolfe, Arkadiusz Jawien, Pramook Mutirangura, Bernie Bourke, Arkadiusz Jawien, Alvaro Balcazar, Juan Esteban Paolini, Douglas Cavaye, Nelson de Luccia, Marcelo Diamant).

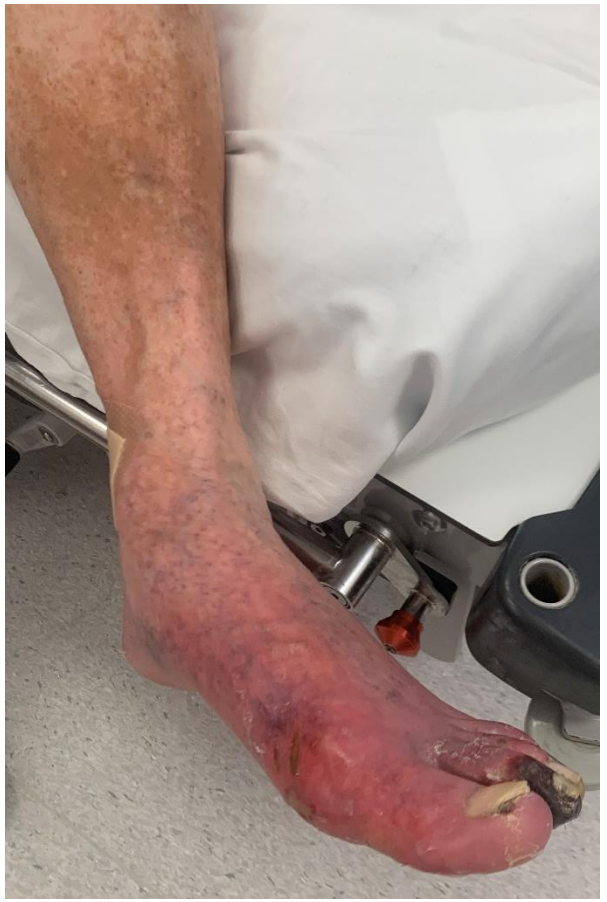
* Correspondence: Michael Conte, MD, Division of Vascular and Endovascular Surgery, University of California San Francisco, 400 Parnassus Ave, Ste A581, San Francisco, CA 94143-2202.
E-mail address: michael.conte2@ucsf.edu (Michael S. Conte).

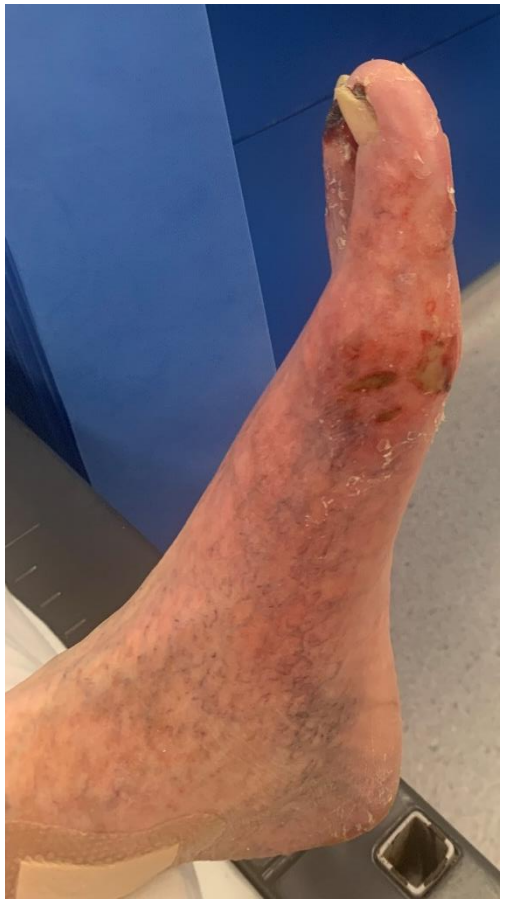
https://doi.org/10.1016/j.ejvs.2019.05.006

Chronic Limb-Threatening Ischaemia - CLTI / Critical Limb Ischaemia - CLI

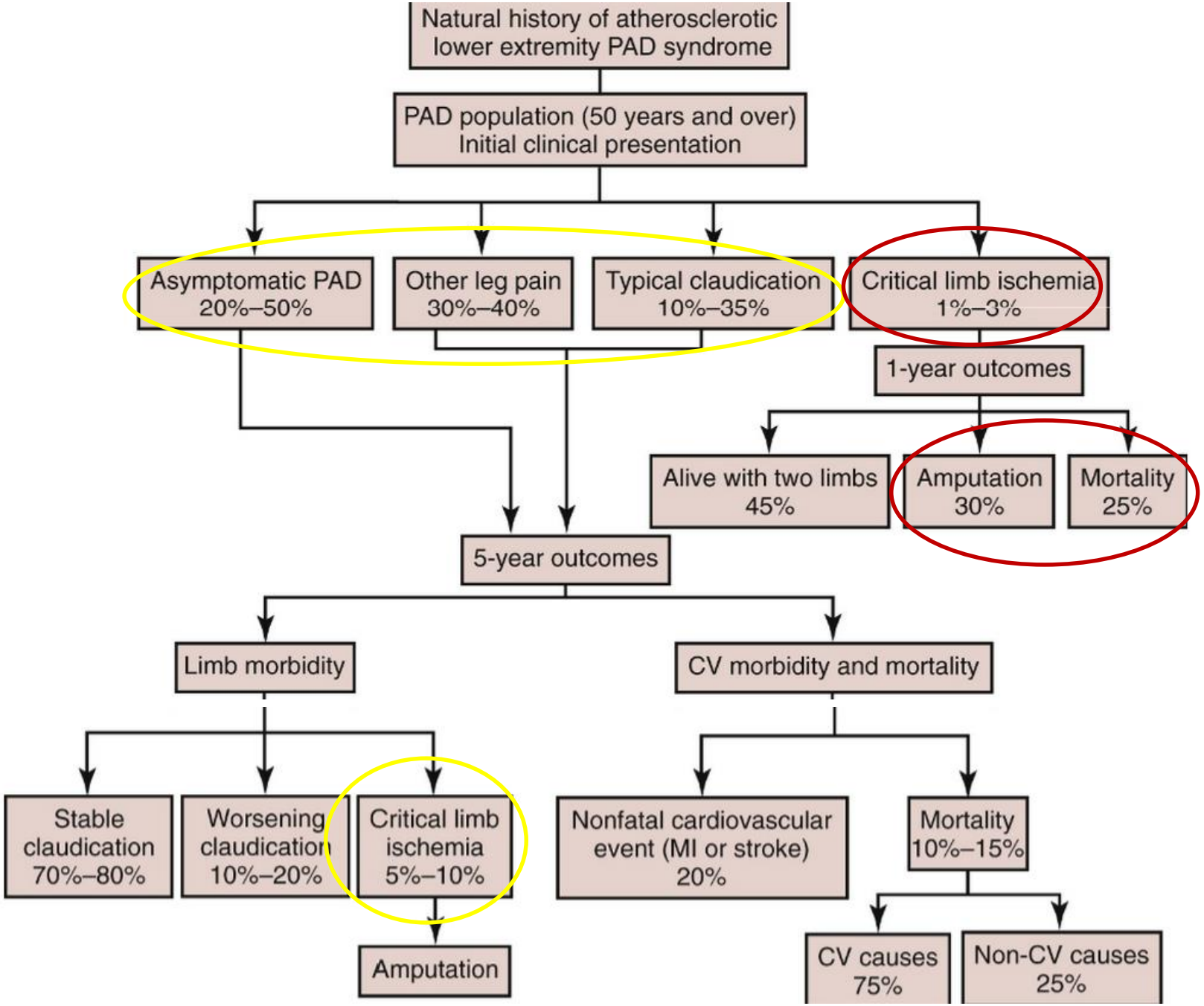
Fontaine Grade	Rutherford Category	Clinical Description	Objective Criteria
0	0	Asymptomatic	Normal treadmill or reactive hyperemia test
	1	Mild Claudication	Completes treadmill exercise*; AP after exercise >50 mm Hg but at least 20 mm Hg lower than resting value
I	2	Moderate Claudication	Between categories 1 and 3
	3	Severe Claudication	Cannot complete standard treadmill exercise*; AP after exercise <50 mm Hg
II†	4	Ischemic Rest Pain	Resting AP <40 mm Hg; ankle or metatarsal PVR flat or barely pulsatile; TP <30 mm Hg
III†	5	Minor Tissue Loss	Resting AP <60 mm Hg; ankle or metatarsal PVR flat or barely pulsatile; TP <40 mm Hg
	6	Major Tissue Loss‡§	Same as 5

AP, ankle pressure; PVR, pulse volume recording; TP, toe pressure.

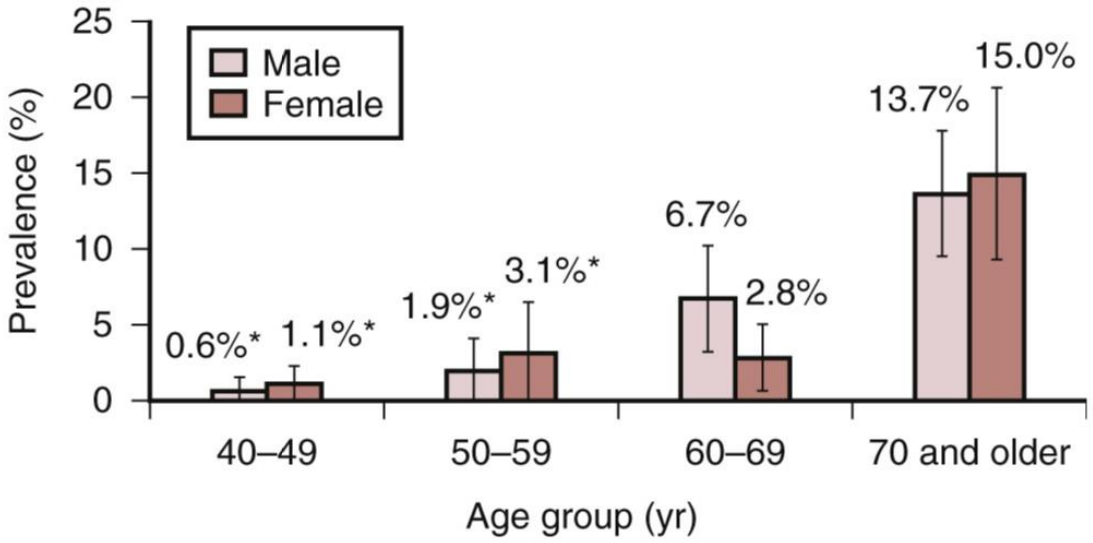




Rutherford RB, Baker JD, Ernst C, et al. Recommended standards for reports dealing with lower extremity ischemia: revised version. *J Vasc Surg*. 1997;26(3):517-538


Natural history of atherosclerotic lower extremity PAD syndrome
PAD population (50 years and over) Initial clinical presentation
Asymptomatic PAD 20%–50%
Other leg pain 30%–40%
Typical claudication 10%–35%
Critical limb ischemia 1%–3%
1-year outcomes
Alive with two limbs 45%
Amputation 30%
Mortality 25%
5-year outcomes
Limb morbidity
CV morbidity and mortality
Stable claudication 70%–80%
Worsening claudication 10%–20%
Critical limb ischemia 5%–10%
Amputation
Nonfatal cardiovascular event (MI or stroke) 20%
Mortality 10%–15%
CV causes 75%
Non-CV causes 25%

Prevalence of Peripheral Arterial Disease by age and gender



Global (ESVS, SVS, WFVS) Vascular Guidelines on CLTI Management

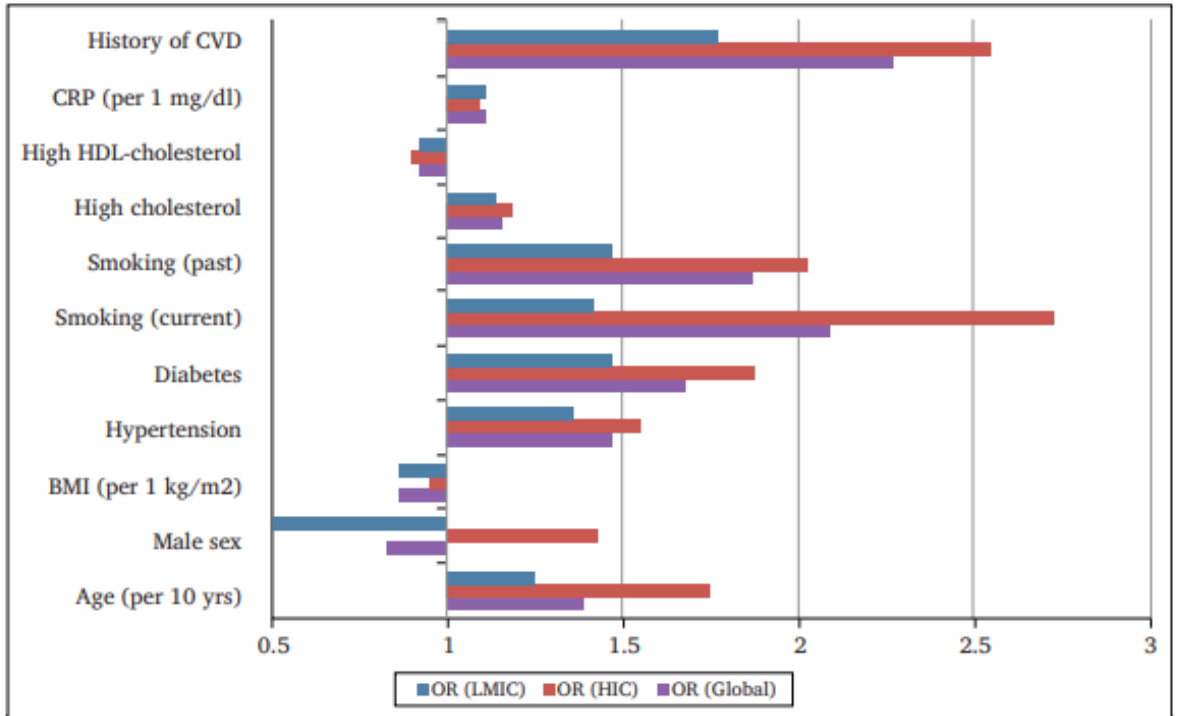


Figure 2.2. Odds ratios (*ORs*) for peripheral artery disease (PAD) in high-income countries (*HICs*) and low- and middle-income countries (*LMICs*). BMI = Body mass index; CRP = C-reactive protein; CVD = cardiovascular disease; HDL = high-density lipoprotein. (Reprinted from Criqui MH, Aboyans V. Epidemiology of peripheral artery disease. Circ Res 2015;116:1509-26.)

Primary Care – Diagnosing and Limb Staging in CLTI

Recommendations 3		
3.1 Perform a detailed history to determine symptoms, past medical history, and cardiovascular risk factors in all patients with suspected CLTI.		
Grade	**Level of evidence**	**Key references**
Good practice statement		-
3.2 Perform a complete cardiovascular physical examination of all patients with suspected CLTI.		
Grade	**Level of evidence**	**Key references**
Good practice statement		-
3.3 Perform a complete examination of the foot, including an assessment of neuropathy and a probe-to-bone test of any open ulcers, in all patients with pedal tissue loss and suspected CLTI.		
Grade	**Level of evidence**	**Key references**
Good practice statement		-

Recommendations 3 (continued)		
3.4 Measure AP and ABI as the first-line noninvasive test in all patients with suspected CLTI.		
Grade	**Level of evidence**	**Key references**
1 (Strong)	B (Moderate)	Lijmer,[19] 1996 Dachun,[20] 2010
3.5 Measure TP and TBI in all patients with suspected CLTI and tissue loss (Fig 3.1).		
Grade	**Level of evidence**	**Key references**
1 (Strong)	B (Moderate)	Aboyans,[21] 2008 Salaun,[169] 2018
3.6 Consider using alternative methods for noninvasive assessment of perfusion, such as PVR, transcutaneous oximetry, or skin perfusion pressure, when ankle and toe pressures, indices, and waveforms cannot be assessed.		
Grade	**Level of evidence**	**Key references**
2 (Weak)	C (Low)	Aboyans,[21] 2008 Shirasu,[23] 2016 Saluan,[169] 2018

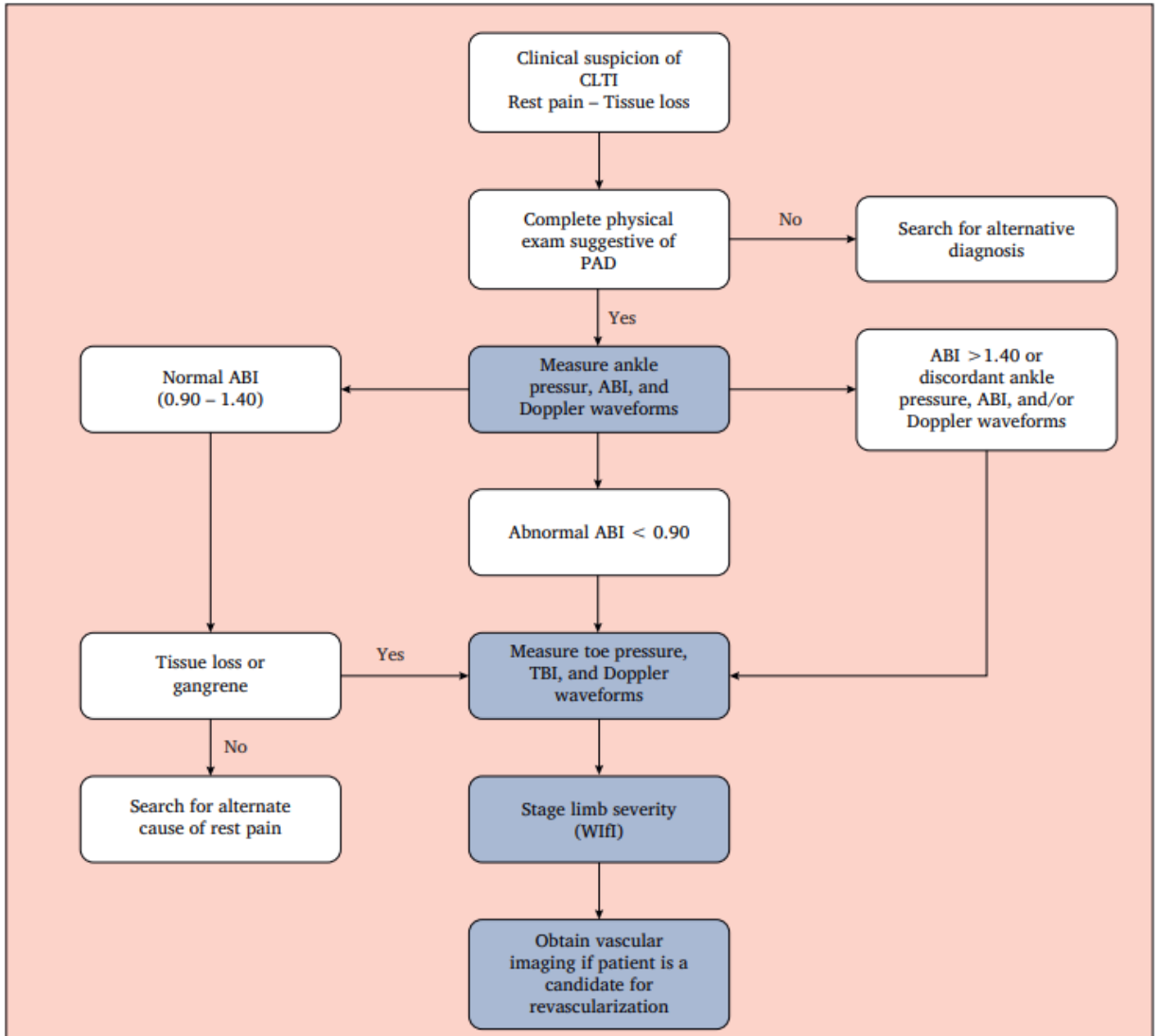


Figure 3.1. Flow diagram for the investigation of patients presenting with suspected chronic limb-threatening ischemia (CLTI). ABI = Ankle-brachial index; PAD = peripheral artery disease; TBI = toe-brachial index; WIfI = Wound, Ischemia, and foot Infection.

Primary Care – Medical Management[1]

Recommendations 4		
4.1 Evaluate cardiovascular risk factors in all patients with suspected CLTI.		
Grade	**Level of evidence**	**Key references**
1 (Strong)	B (Moderate)	I.C.A.I. group,[30] 1997
4.2 Manage all modifiable risk factors to recommended levels in all patients with suspected CLTI.		
Grade	**Level of evidence**	**Key references**
1 (Strong)	B (Moderate)	Armstrong,[224] 2014 Faglia,[32] 2014

Recommendations 4 (continued)		
4.3 Treat all patients with CLTI with an antiplatelet agent.		
Grade	**Level of evidence**	**Key references**
1 (Strong)	A (High)	Antithrombotic Trialists' Collaboration,[33] 2002 Antithrombotic Trialists' Collaboration,[34] 2009
4.4 Consider clopidogrel as the single antiplatelet agent of choice in patients with CLTI.		
Grade	**Level of evidence**	**Key references**
2 (Weak)	B (Moderate)	CAPRIE,[35] 1996 Hiatt,[36] 2017
4.5 Consider low-dose aspirin and rivaroxaban, 2.5 mg twice daily, to reduce adverse cardiovascular events and lower extremity ischemic events in patients with CLTI.		
Grade	**Level of evidence**	**Key references**
2 (Weak)	B (Moderate)	Anand,[37] 2018
4.6 Do not use systemic vitamin K antagonists for the treatment of lower extremity atherosclerosis in patients with CLTI.		
Grade	**Level of evidence**	**Key references**
1 (Strong)	B (Moderate)	Anand,[38] 2007

Randomized Controlled Trial > Lancet. 2018 Jan 20;391(10117):219-229.
doi: 10.1016/S0140-6736(17)32409-1. Epub 2017 Nov 10.

Rivaroxaban with or without aspirin in patients with stable peripheral or carotid artery disease: an international, randomised, double-blind, placebo-controlled trial

Findings: Between March 12, 2013, and May 10, 2016, we enrolled 7470 patients with peripheral artery disease from 558 centres. The combination of rivaroxaban plus aspirin compared with aspirin alone reduced the composite endpoint of cardiovascular death, myocardial infarction, or stroke (126 [5%] of 2492 vs 174 [7%] of 2504; hazard ratio [HR] 0·72, 95% CI 0·57-0·90, p=0·0047), and major adverse limb events including major amputation (32 [1%] vs 60 [2%]; HR 0·54 95% CI 0·35-0·82, p=0·0037). Rivaroxaban 5 mg twice a day compared with aspirin alone did not significantly reduce the composite endpoint (149 [6%] of 2474 vs 174 [7%] of 2504; HR 0·86, 95% CI 0·69-1·08, p=0·19), but reduced major adverse limb events including major amputation (40 [2%] vs 60 [2%]; HR 0·67, 95% CI 0·45-1·00, p=0·05). The median duration of treatment was 21 months. The use of the rivaroxaban plus aspirin combination increased major bleeding compared with the aspirin alone group (77 [3%] of 2492 vs 48 [2%] of 2504; HR 1·61, 95% CI 1·12-2·31, p=0·0089), which was mainly gastrointestinal. Similarly, major bleeding occurred in 79 (3%) of 2474 patients with rivaroxaban 5 mg, and in 48 (2%) of 2504 in the aspirin alone group (HR 1·68, 95% CI 1·17-2·40; p=0·0043).

Interpretation: Low-dose rivaroxaban taken twice a day plus aspirin once a day reduced major adverse cardiovascular and limb events when compared with aspirin alone. Although major bleeding was increased, fatal or critical organ bleeding was not. This combination therapy represents an important advance in the management of patients with peripheral artery disease. Rivaroxaban alone did not significantly reduce major adverse cardiovascular events compared with asprin alone, but reduced major adverse limb events and increased major bleeding.

Funding: Bayer AG.

Primary Care – Medical Management[2]

Tertiary Prevention

Supra-inguinal

- **single antiplatelet**

Femoro-popliteal

- **Plain balloon /BMS → single antiplatelet**
- **Drug eluted technology → DAPT**
- **Fem-pop bypass → SAPT or DAPT** *(surgeon choice)*

Infra-popliteal / tibial

Fem – Distal bypass

- **DAPT**
- **DOAC + Aspirin**

VOYAGER Trial

Rivaroxaban in Peripheral Artery Disease after Revascularization

Marc P. Bonaca, M.D., M.P.H., Rupert M. Bauersachs, M.D., Sonia S. Anand, M.D., E. Sebastian Debus, M.D., Ph.D., Mark R. Nehler, M.D., Manesh R. Patel, M.D., Fabrizio Fanelli, M.D., Warren H. Capell, M.D., Lihong Diao, M.D., Nicole Jaeger, M.S., Connie N. Hess, M.D., M.H.S., Akos F. Pap, M.Sc., John M. Kittelson, Ph.D., Ivan Gudz, M.D., Ph.D., Lajos Mátyás, M.D., Dainis K. Krievins, M.D., Rafael Diaz, M.D., Marianne Brodmann, M.D., Eva Muehlhofer, M.D., Lloyd P. Haskell, M.D., Scott D. Berkowitz, M.D., and William R. Hiatt, M.D.

ABSTRACT

BACKGROUND

Patients with peripheral artery disease who have undergone lower-extremity revascularization are at high risk for major adverse limb and cardiovascular events. The efficacy and safety of rivaroxaban in this context are uncertain.

METHODS

In a double-blind trial, patients with peripheral artery disease who had undergone revascularization were randomly assigned to receive rivaroxaban (2.5 mg twice daily) plus aspirin or placebo plus aspirin. The primary efficacy outcome was a composite of acute limb ischemia, major amputation for vascular causes, myocardial infarction, ischemic stroke, or death from cardiovascular causes. The principal safety outcome was major bleeding, defined according to the Thrombolysis in Myocardial Infarction (TIMI) classification; major bleeding as defined by the International Society on Thrombosis and Haemostasis (ISTH) was a secondary safety outcome.

RESULTS

A total of 6564 patients underwent randomization; 3286 were assigned to the rivaroxaban group, and 3278 were assigned to the placebo group. The primary efficacy outcome occurred in 508 patients in the rivaroxaban group and in 584 in the placebo group; the Kaplan–Meier estimates of the incidence at 3 years were 17.3% and 19.9%, respectively (hazard ratio, 0.85, 95% confidence interval [CI], 0.76 to 0.96; P=0.009). TIMI major bleeding occurred in 62 patients in the rivaroxaban group and in 44 patients in the placebo group (2.65% and 1.87%; hazard ratio, 1.43; 95% CI, 0.97 to 2.10; P=0.07). ISTH major bleeding occurred in 140 patients in the rivaroxaban group, as compared with 100 patients in the placebo group (5.94% and 4.06%; hazard ratio, 1.42; 95% CI, 1.10 to 1.84; P=0.007).

CONCLUSIONS

In patients with peripheral artery disease who had undergone lower-extremity revascularization, rivaroxaban at a dose of 2.5 mg twice daily plus aspirin was associated with a significantly lower incidence of the composite outcome of acute limb ischemia, major amputation for vascular causes, myocardial infarction, ischemic stroke, or death from cardiovascular causes than aspirin alone. The incidence of TIMI major bleeding did not differ significantly between the groups. The incidence of ISTH major bleeding was significantly higher with rivaroxaban and aspirin than with aspirin alone. (Funded by Bayer and Janssen Pharmaceuticals; VOYAGER PAD ClinicalTrials.gov number, NCT02504216.)

N ENGL J MED 382;21 NEJM.ORG MAY 21, 2020

The New England Journal of Medicine

Primary Care – Medical Management[3]

Recommendations 4 (continued)

4.7 Use moderate- or high-intensity statin therapy to reduce all-cause and cardiovascular mortality in patients with CLTI.

Grade	Level of evidence	Key references
1 (Strong)	A (High)	Leng,[39] 2000 Heart Protection Study Group,[40] 2002 Meade,[41] 2002 Aung,[42] 2007 Mills,[43] 2011 Rodriguez,[44] 2017

Recommendations 4 (continued)

4.8 Control hypertension to target levels of <140 mm Hg systolic and <90 mm Hg diastolic in patients with CLTI.

Grade	Level of evidence	Key references
1 (Strong)	B (Moderate)	ACCORD Study Group,[45] 2010 Bavry,[46] 2010 Wright,[47] 2015 Moise,[48] 2016

Recommendations 4 (continued)

4.12 Offer smoking cessation interventions (pharmacotherapy, counseling, or behavior modification therapy) to all patients with CLTI who smoke or use tobacco products.

Grade	Level of evidence	Key references
1 (Strong)	A (High)	Dagenais,[58] 2005 Athyros,[59] 2013 Blomster,[60] 2016

4.13 Ask all CLTI patients who are smokers or former smokers about status of tobacco use at every visit.

Grade	Level of evidence	Key references
1 (Strong)	A (High)	Kondo,[61] 2011 Newhall,[62] 2017

Recommendations 4 (continued)

4.14 Prescribe analgesics of appropriate strength for CLTI patients who have ischemic rest pain of the lower extremity and foot until pain resolves after revascularization.

Grade	Level of evidence	Key references
Good practice statement		-

4.15 In CLTI patients with chronic severe pain, use paracetamol (acetaminophen) in combination with opioids for pain control.

Grade	Level of evidence	Key references
Good practice statement		-

Recommendations 4 (continued)

4.9 Consider control of type 2 DM in CLTI patients to achieve a hemoglobin $A1_c$ of <7% (53 mmol/mol [International Federation of Clinical Chemistry]).

Grade	Level of evidence	Key references
2 (Weak)	B (Moderate)	Selvin,[49] 2004 Nathan,[50] 2005 van Dieren,[51] 2014 Fox,[52] 2015 American Diabetes Association,[53] 2018

4.10 Use metformin as the primary hypoglycemic agent in patients with type 2 DM and CLTI.

Grade	Level of evidence	Key references
1 (Strong)	A (High)	Palmer,[54] 2016

4.11 Consider withholding metformin immediately before and for 24 to 48 hours after the administration of an iodinated contrast agent for diabetic patients, especially those with an estimated glomerular filtration rate <30 mL/min/1.73 m^2.

Grade	Level of evidence	Key references
2 (Weak)	C (Low)	Nawaz,[55] 1998 Goergen,[56] 2010 Stacul,[57] 2011

Surgical Wound
Lower Limb
#Stop the Pressure

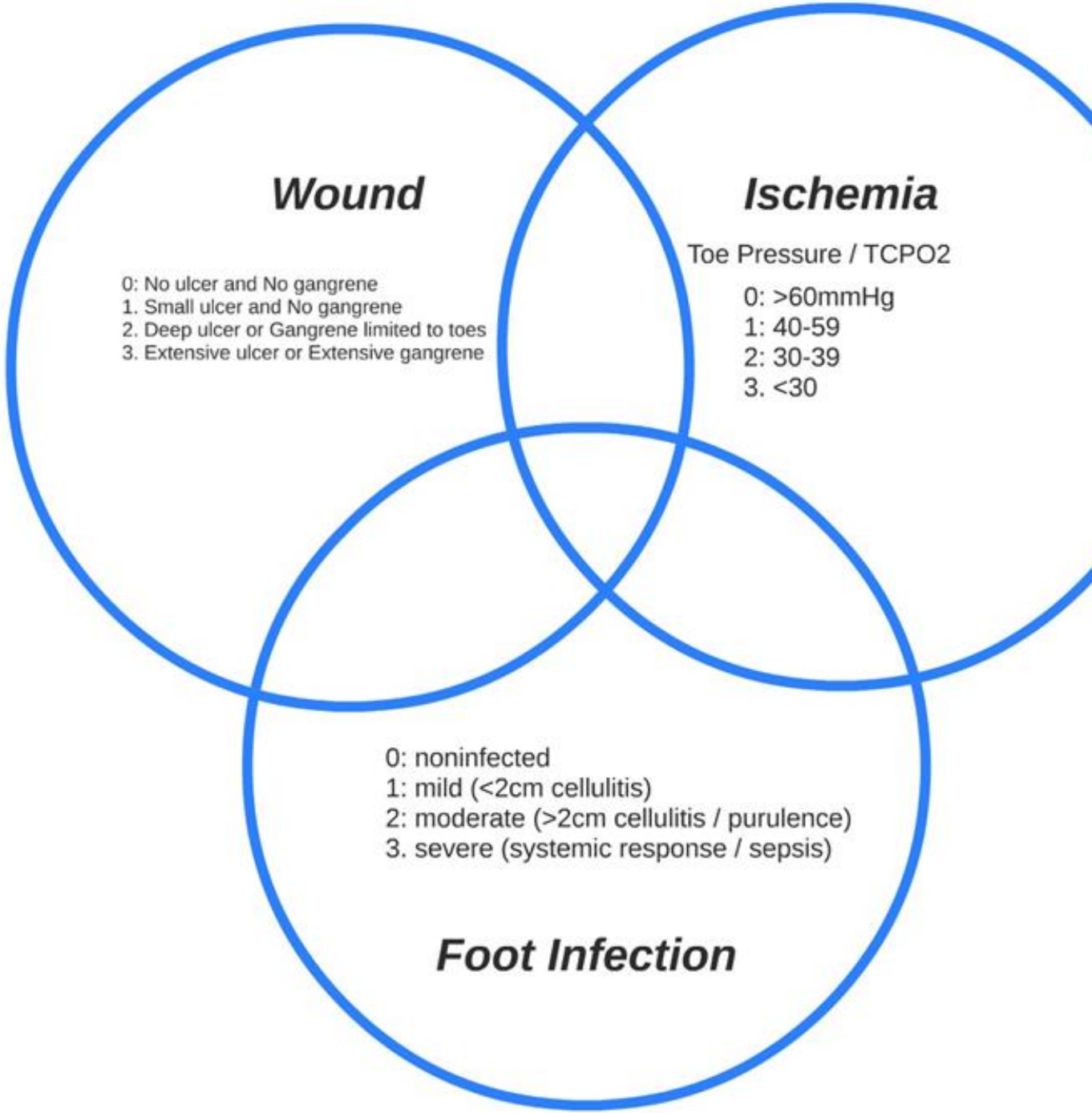
National Wound Care Strategy Programme

Excellence. Every Patient. Every Time.

SOCIETY FOR VASCULAR SURGERY® DOCUMENT

The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk stratification based on Wound, Ischemia, and foot Infection (WIfI)

Joseph L. Mills, Sr, MD,[a] Michael S. Conte, MD,[b] David G. Armstrong, DPM, MD, PhD,[a] Frank B. Pomposelli, MD,[c] Andres Schanzer, MD,[d] Anton N. Sidawy, MD, MPH,[e] and **George Andros, MD,[f] on behalf of the Society for Vascular Surgery Lower Extremity Guidelines Committee,** *Tucson, Ariz; San Francisco and Van Nuys, Calif; Brighton and Worcester, Mass; and Washington, D.C.*



Limitations of Classification Systems

- Born in 1948
- White British male
- Millionaire
- Live in a castle
- Like tea

Quality Improvement Framework

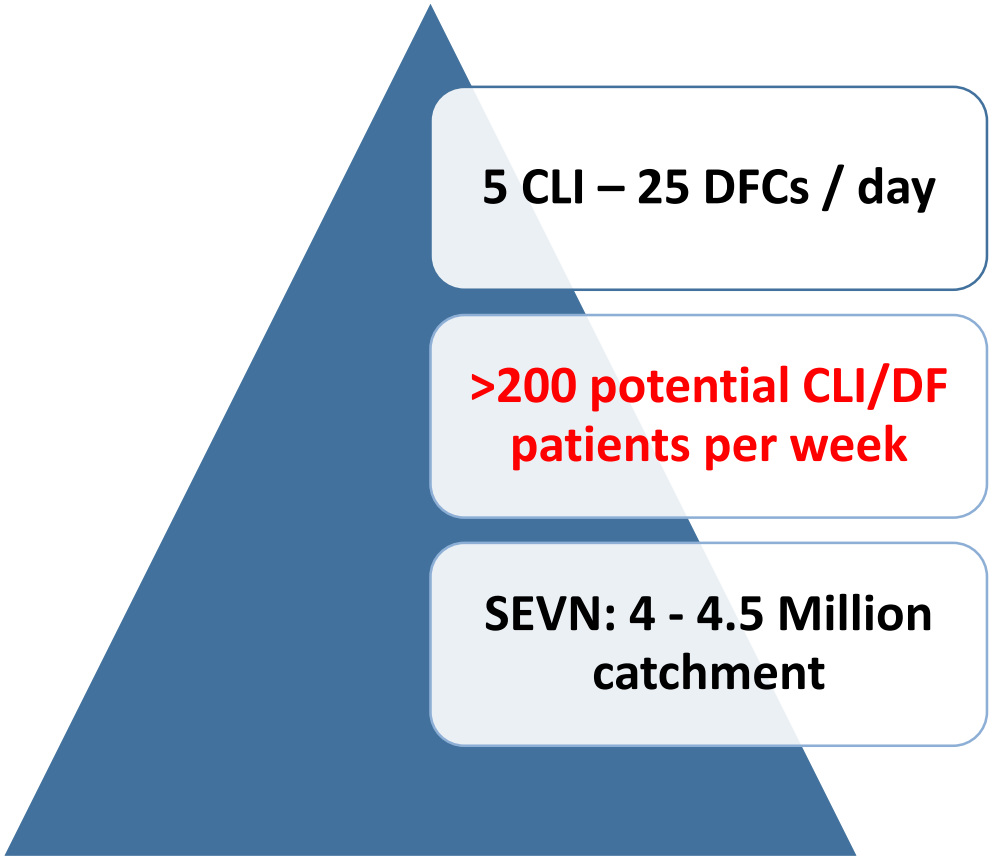
VASCULAR SOCIETY
THE VASCULAR SOCIETY OF GREAT BRITAIN AND IRELAND

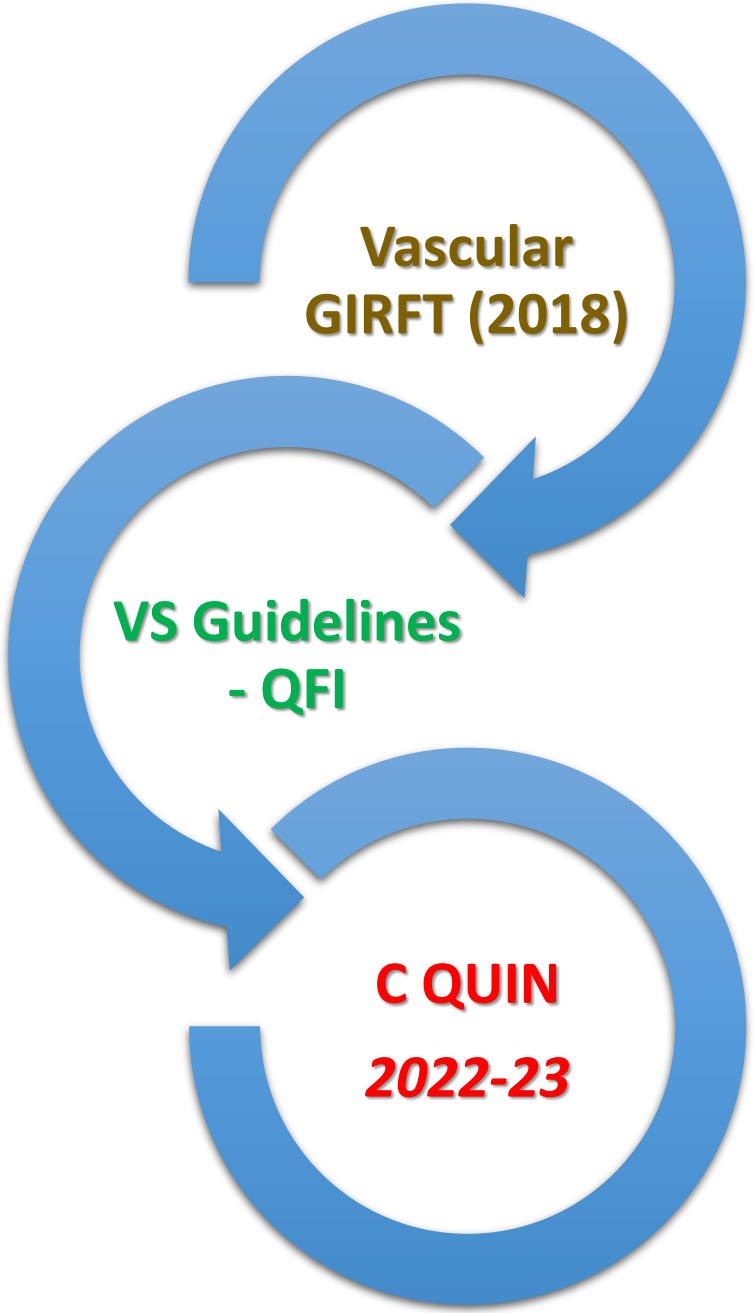
A Best Practice Clinical Care Pathway for **Peripheral Arterial Disease**

April 2019

CONTEXT


PAD incidence 1 in 5 people aged >60
Prevalence: a population of 800,000 should see 1 CLI and 5 DFCS every day
23,000 LL revascularisation / year in the UK
GIRFT: inconsistent deliver of CLI surgery


5 CLI – 25 DFCs / day
>200 potential CLI/DF patients per week
SEVN: 4 - 4.5 Million catchment



Commissioning for Quality and Innovation (CQUIN)

The Commissioning for Quality and Innovation (**CQUIN**) payment **framework** enables commissioners to link a proportion of providers' income to the achievement of quality improvement goals.

CQUIN schemes equate to 2.5% of the total contract value for providers.

QUI Standards / Targets: MANAGEMENT

QIF standards

Management of people with peripheral arterial disease	Target
Commissioned stop smoking services for people diagnosed with PAD	100%
Commissioned supervised exercise therapy for people diagnosed with IC [1]	> 90%
Peripheral MDT core team (see page 5) quorate at formal MDT meetings (*over 12 months*)	> 95%
WIfI, or equivalent, classification system documented in patient medical record for CLI	> 80%
Peripheral MDT discussion documented in patient medical record	100%
Evidence of shared decision making in patient medical record	> 80%
Written patient information provided	100%
Consultant anaesthetist pre-assessment before open surgical procedures	100%
Consultant in care of elderly and frailty assessment of frail or elderly patients	> 80%
Open bypass surgery performed at arterial centre	100%
Major (above ankle) amputation performed at arterial centre	> 95%
Revascularisation on planned surgical or interventional radiology list	> 75%
Consultant vascular specialist, surgeon or interventional radiologist, present at procedure	100%
Consultant anaesthetist, or post FRCA trainee, present for general anaesthetic procedure	100%
Post revascularisation assessment of procedural success	100%
NVR submission for bypass, angioplasty and major amputation procedure	100%

[1] *Within 1 hours travel time, except in remote rural areas of the UK and Ireland.*

QUI Standards / Targets

Admitted patient - severe critical limb ischaemia and/or foot sepsis

Non-admitted patient - stable disease, such as mummified toes

These pathways apply to all referrals, including from network emergency departments, networked non-arterial hospitals, and for acute diabetic foot problems with ischaemia.

Referral to secondary care for critical limb ischaemia	Timescale Compliance > 80%	Source
Referral to vascular specialist Triage of referral by vascular specialist	**Same day** **One working day**	POVS NHSE

'Admitted' patient pathway

CLI with rapid progression, deep tissue injury and/or infection, and/or or uncontrolled pain.

From receipt of referral

Admission or transfer to network arterial centre	**≤ 2 days** [1]	StAMP POVS

From hospital admission

Cross-sectional imaging with CTA or MRA Vascular surgeon 'face to face' review	**≤ 12 hours** **≤ 14 hours**	NHSE NCEPOD
Revascularisation	**≤ 5 days** [3]	POVS

'Non-admitted' patient pathway

CLI with ulcer, minor necrosis, mummified toes, superficial infection or controlled pain.

From receipt of referral

Vascular surgeon 'face to face' review	**≤ 7 days** [2]	POVS

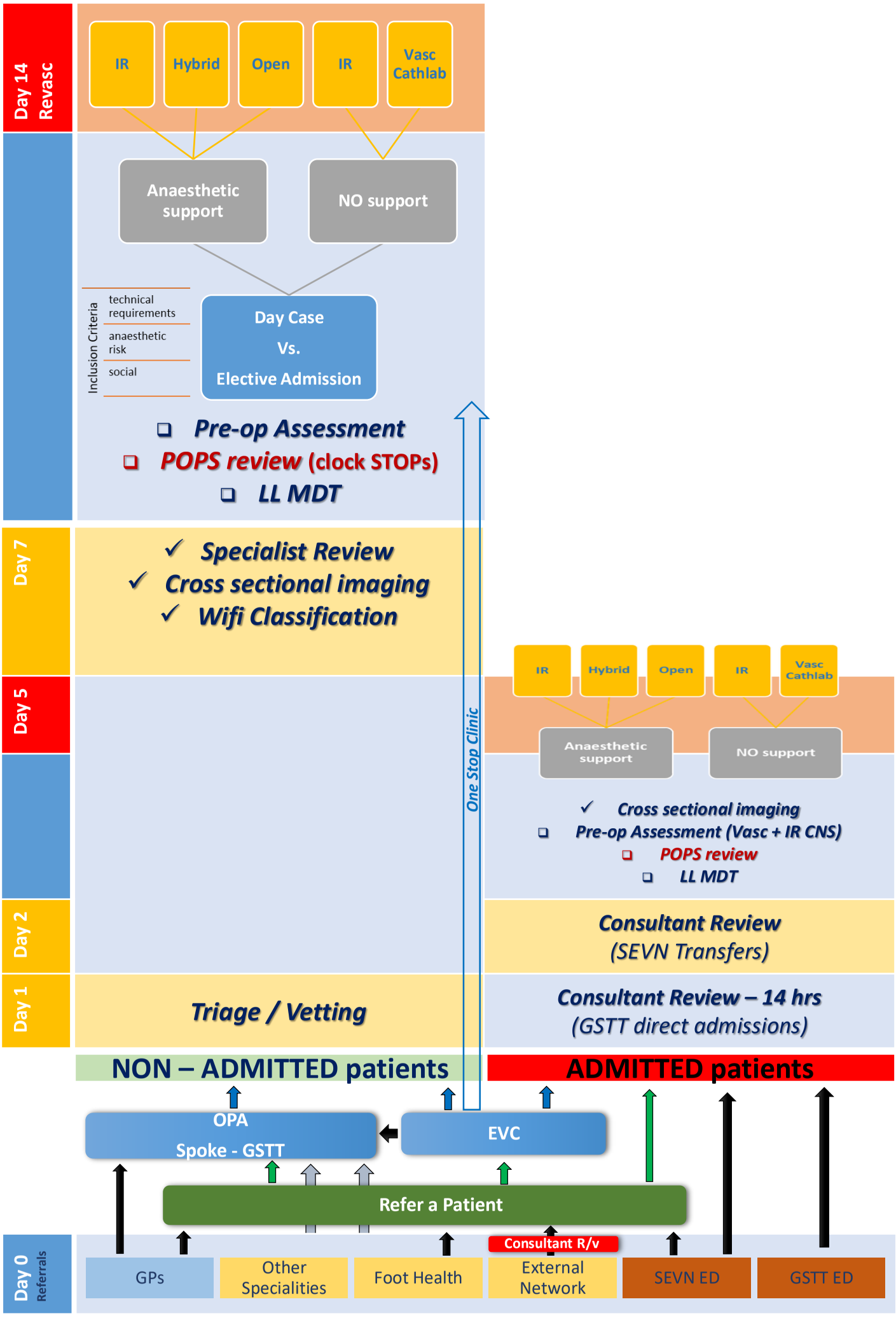
From review by specialist

Cross-sectional imaging (CTA or MRA)	**≤ 7 days**	POVS
Revascularisation	**≤ 14 days** [3]	POVS

[1] *Achieving this target necessitates 48 hourly specialist vascular presence, consultant or specialist nurse, at networked hospitals or a written pathway of care for transfer patients to arterial centre for review.*

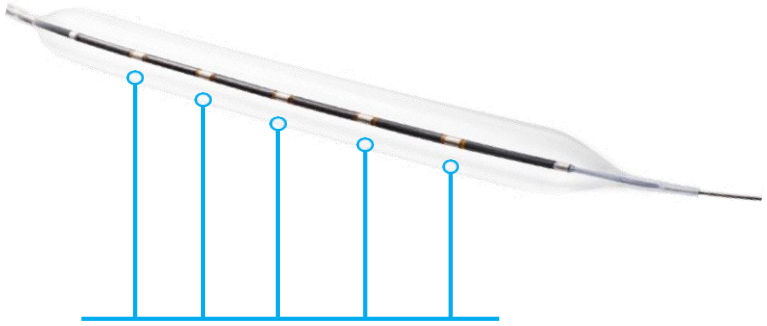
[2] *Achieving this target requires the provision of urgent ('hot') outpatient appointments with clearly defined pathways for urgent imaging, admission and revascularisation if indicated.*

[3] *Intervention should not be deferred more than once for non-medical reasons.*


Day 14 Revasc
IR
Hybrid
Open
IR
Vasc Cathlab
Anaesthetic support
NO support
Inclusion Criteria
technical requirements
anaesthetic risk
social
Day Case
Vs.
Elective Admission
Pre-op Assessment
POPS review (clock STOPs)
LL MDT
Day 7
Specialist Review
Cross sectional imaging
Wifi Classification
Day 5
One Stop Clinic
IR
Hybrid
Open
IR
Vasc Cathlab
Anaesthetic support
NO support
Cross sectional imaging
Pre-op Assessment (Vasc + IR CNS)
POPS review
LL MDT
Day 2
Consultant Review
(SEVN Transfers)
Day 1
Triage / Vetting
Consultant Review – 14 hrs
(GSTT direct admissions)
NON – ADMITTED patients
ADMITTED patients
OPA
Spoke - GSTT
EVC
Refer a Patient
Day 0 Referrals
Consultant R/v
GPs
Other Specialities
Foot Health
External Network
SEVN ED
GSTT ED

Intravascular Lithotripsy – IVL Shockwave

Miniaturized and arrayed Lithotripsy Emitters for localized lithotripsy at the site of the vascular calcium



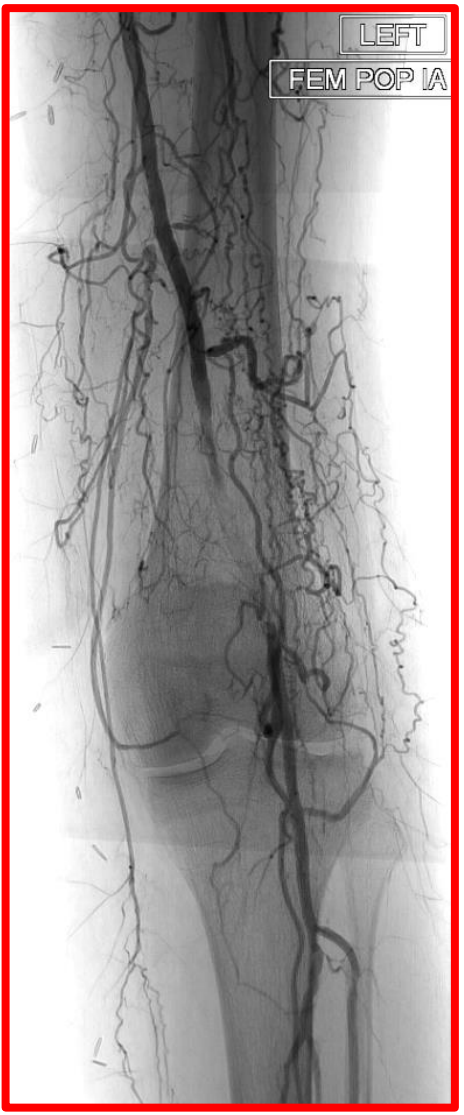
Expanding and collapsing vapor bubble creates a short burst of **sonic pressure waves**

Sonic pressure waves travel through the vessel with an effective pressure of **~50 atm**

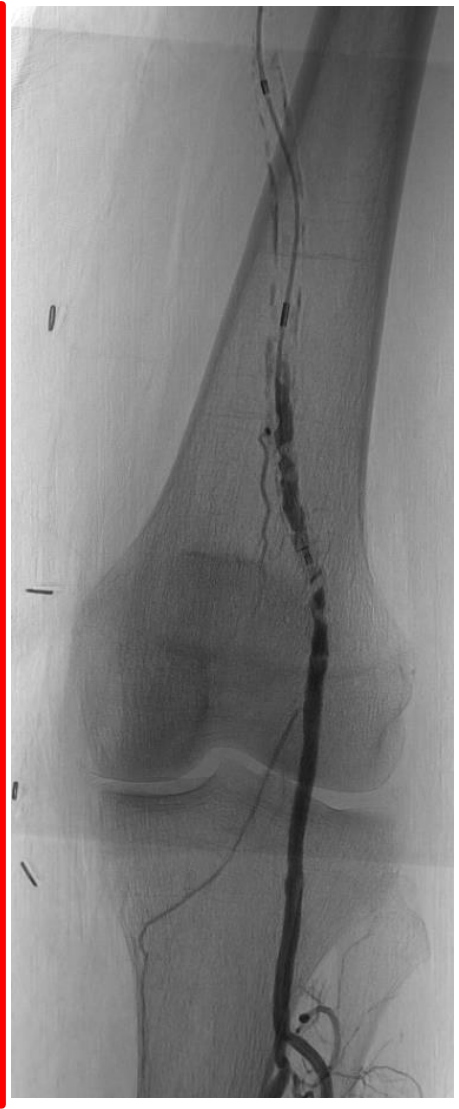
A **localized field effect** within the vessel fractures both **intimal and medial calcium**

Femoropopliteal Segment – “stand alone” approach

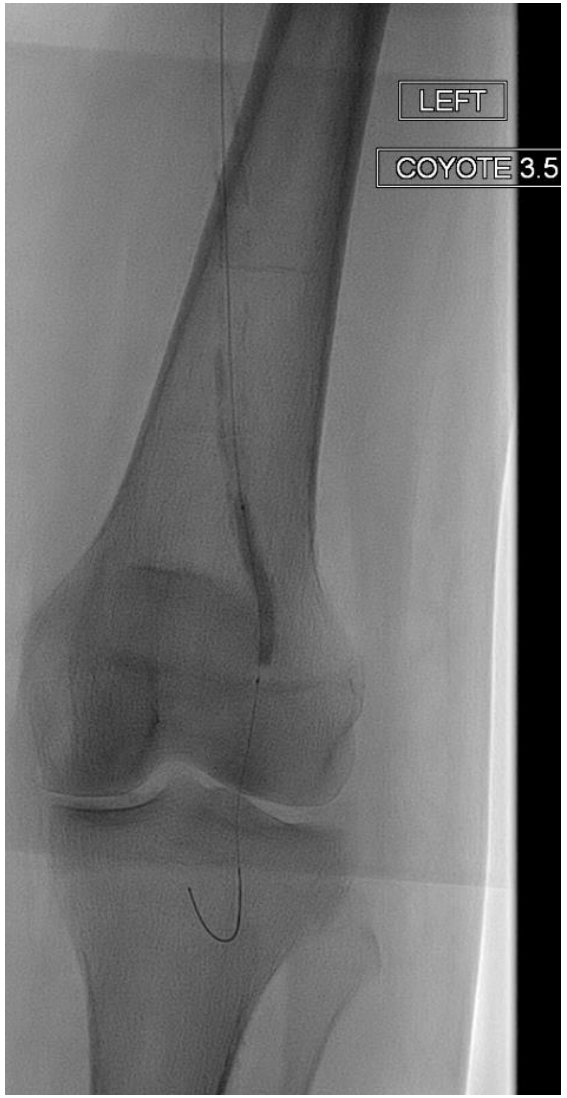
Diagnostic Angiogram



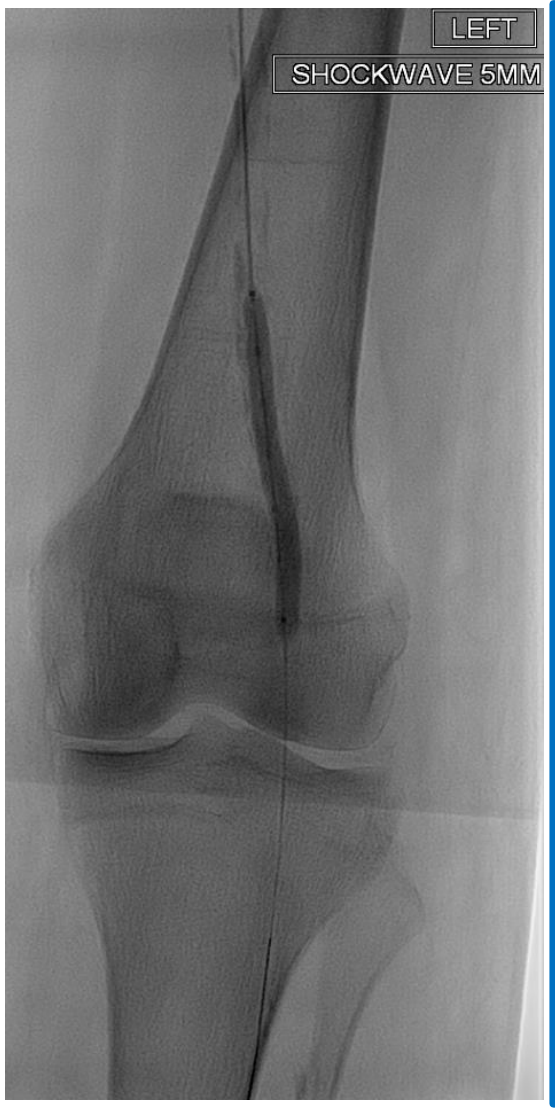
intraluminal crossing



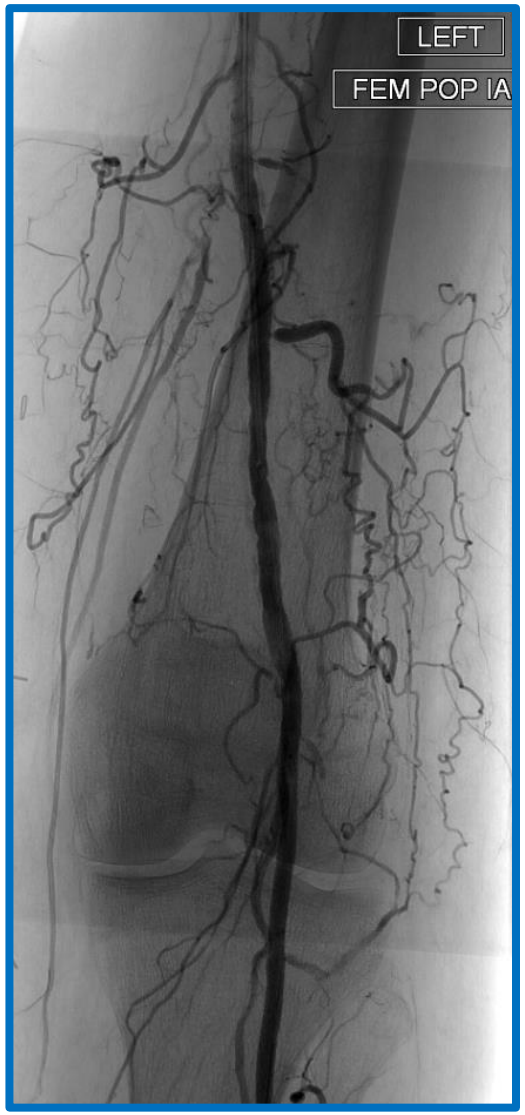
pre-dilatation



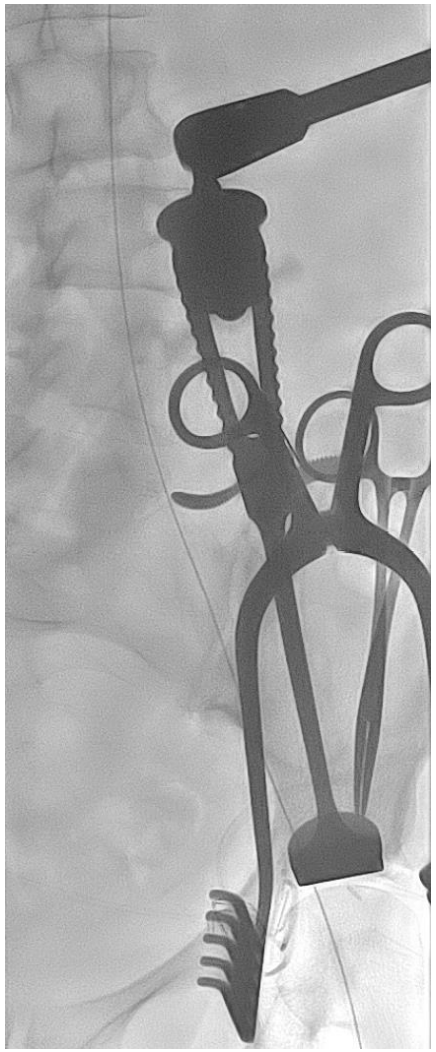
Shockwave 3 cycles (4atm)

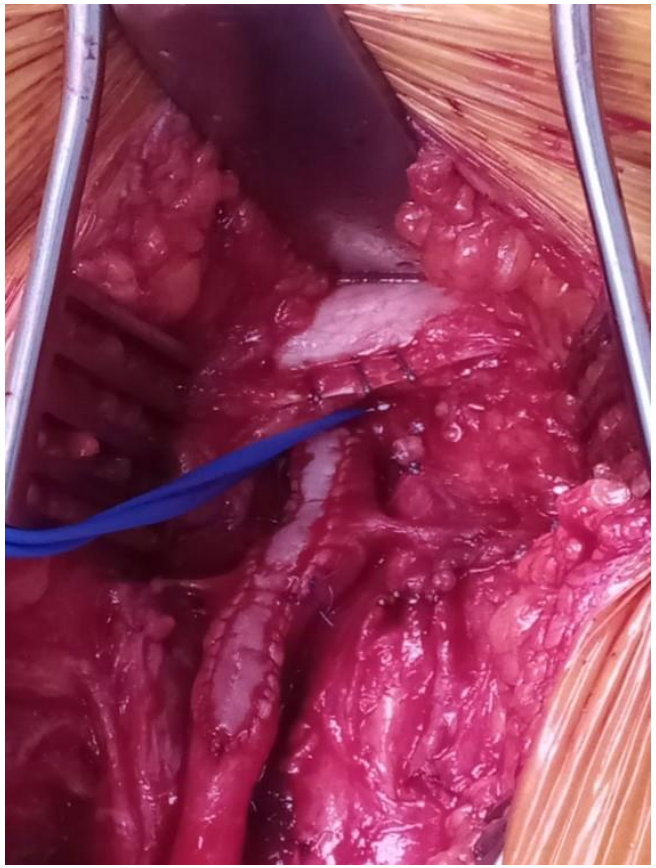


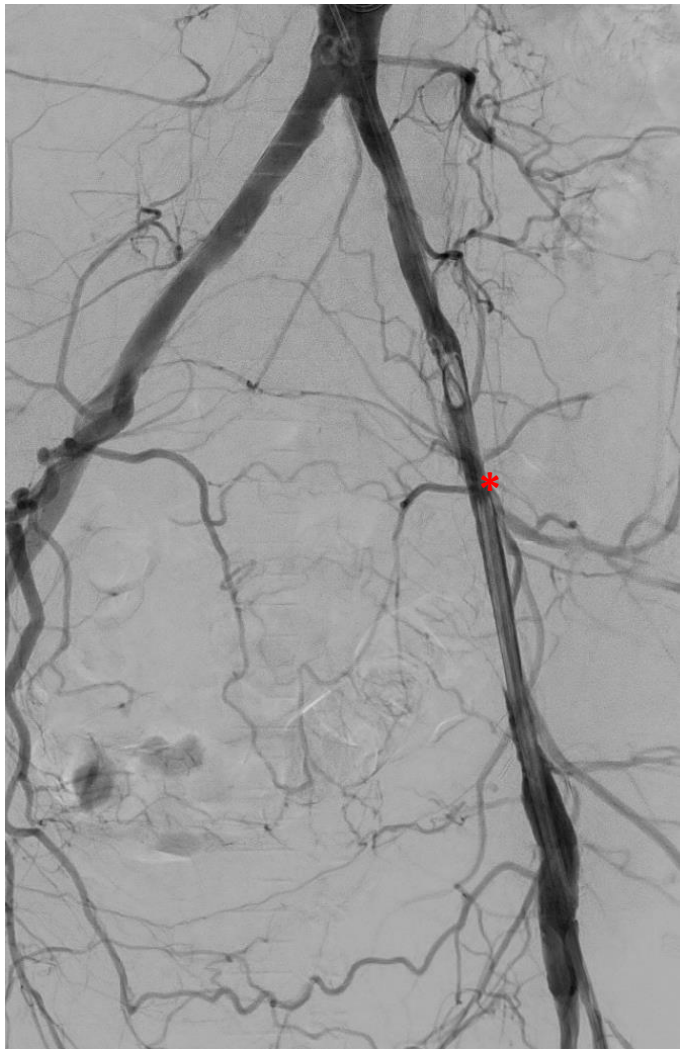
Completion Angiogram

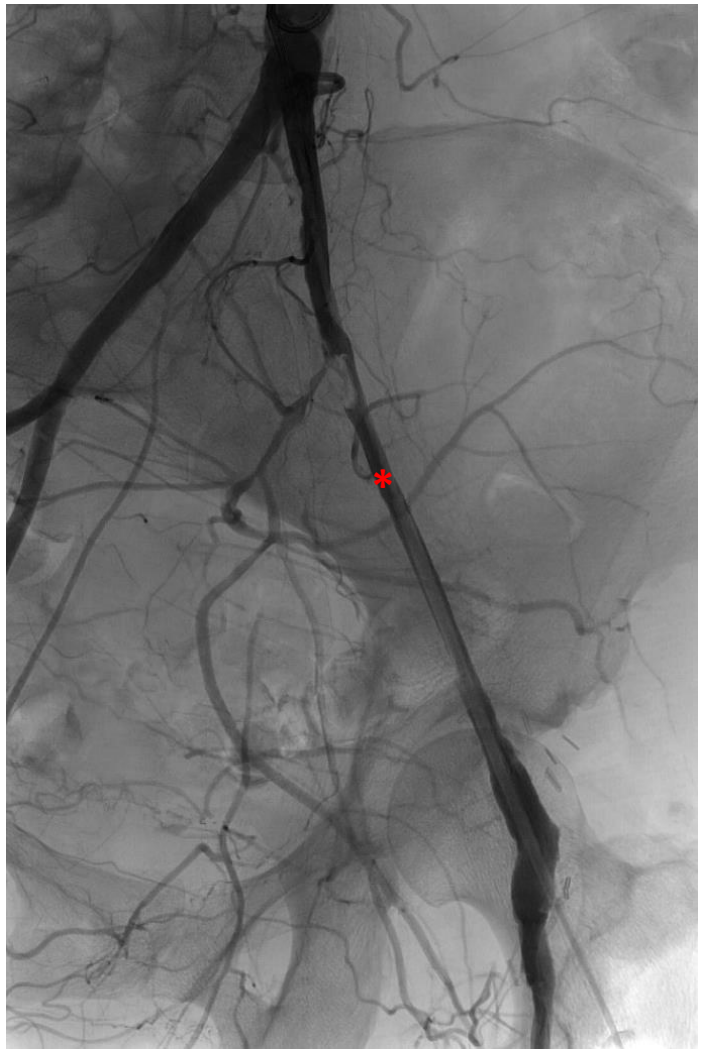


Hybrid Shockwave



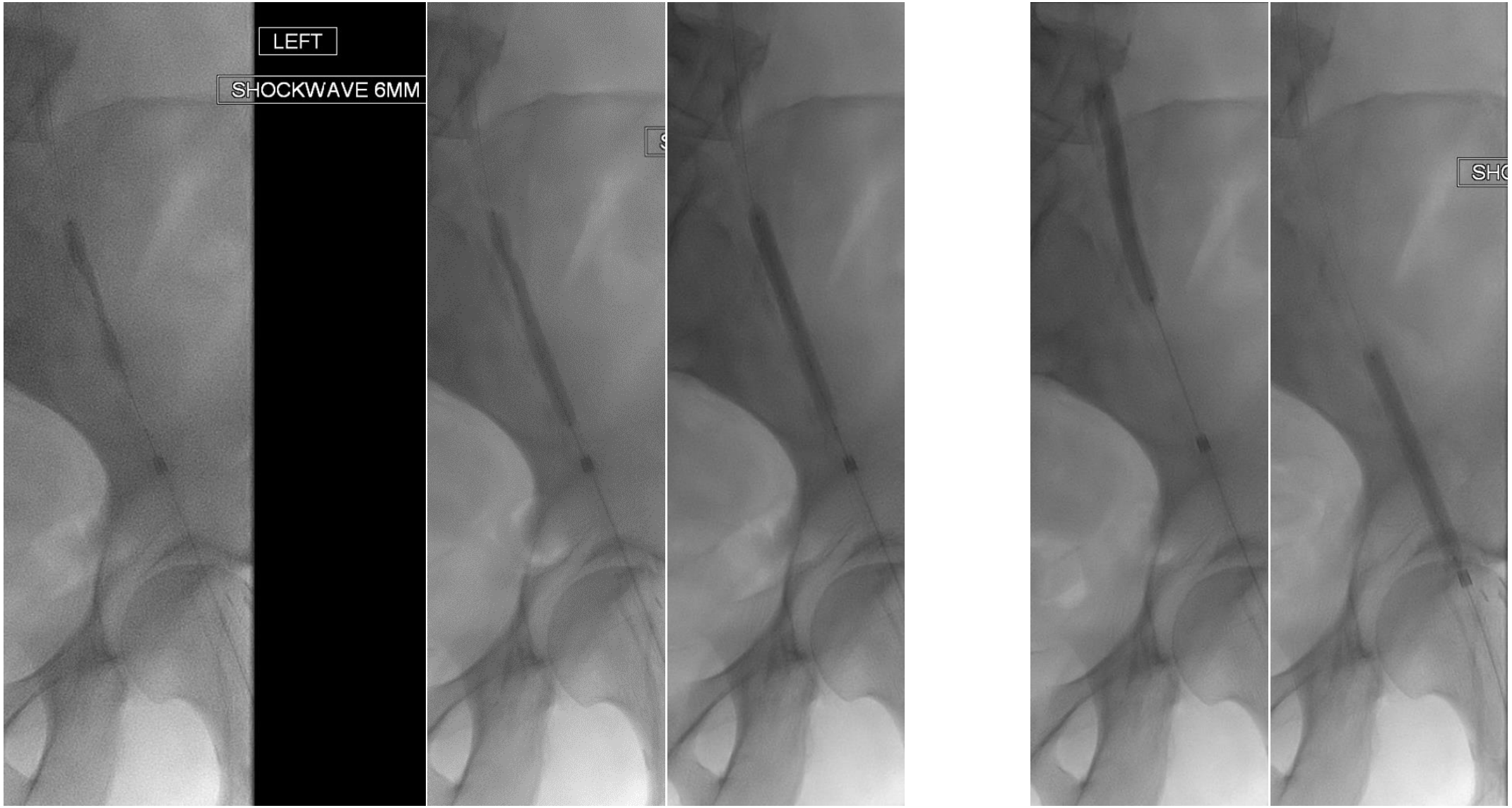




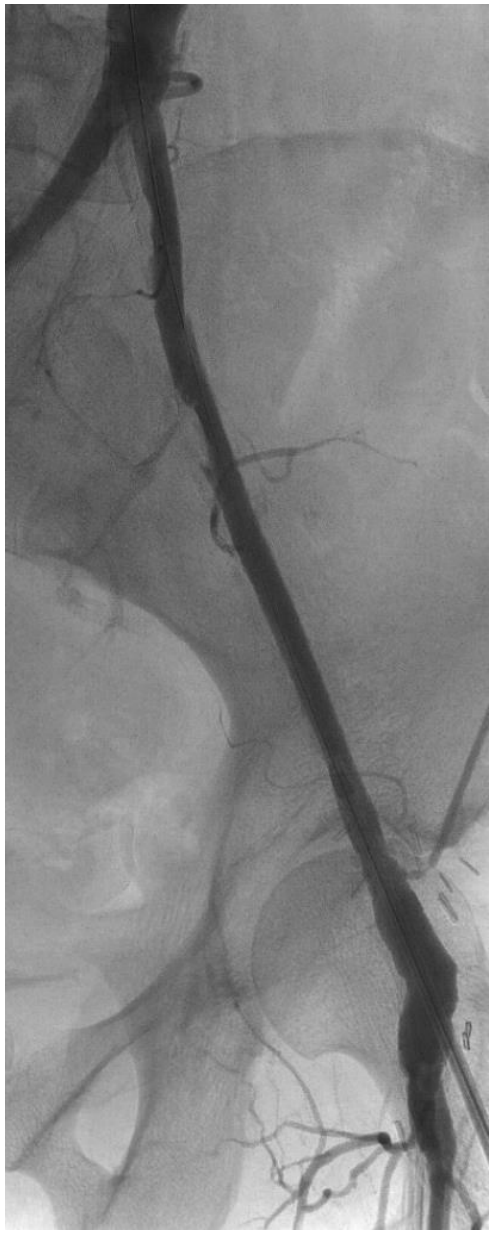


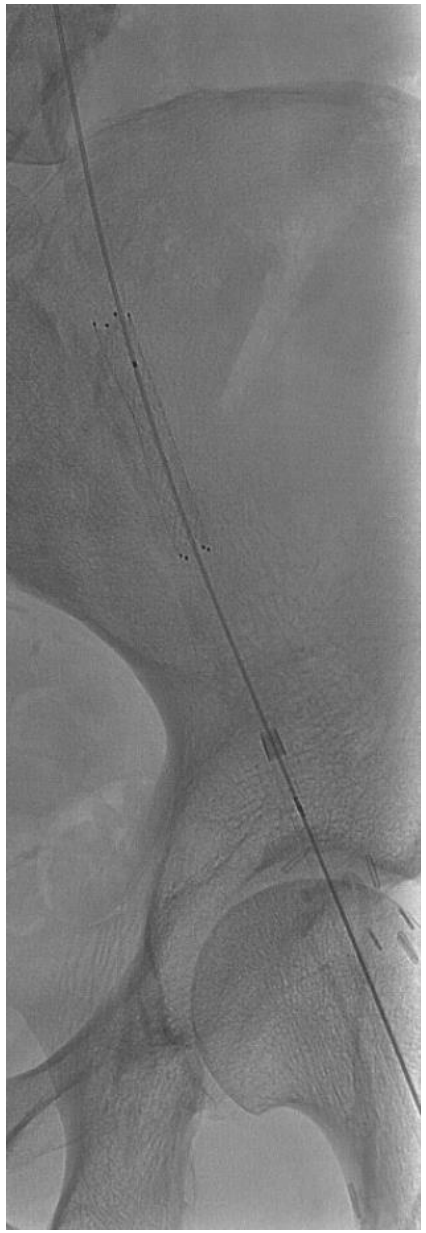
Iliac vessel-prep

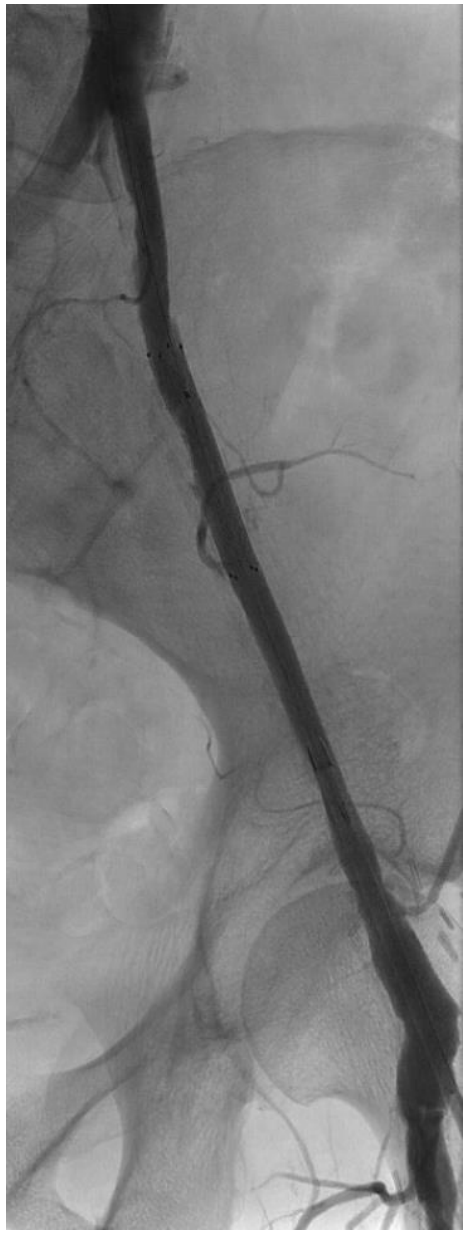
Cycle 1 | Cycle 2 | Cycles 3+4 | Cycles 5+6 | Cycles 7+8



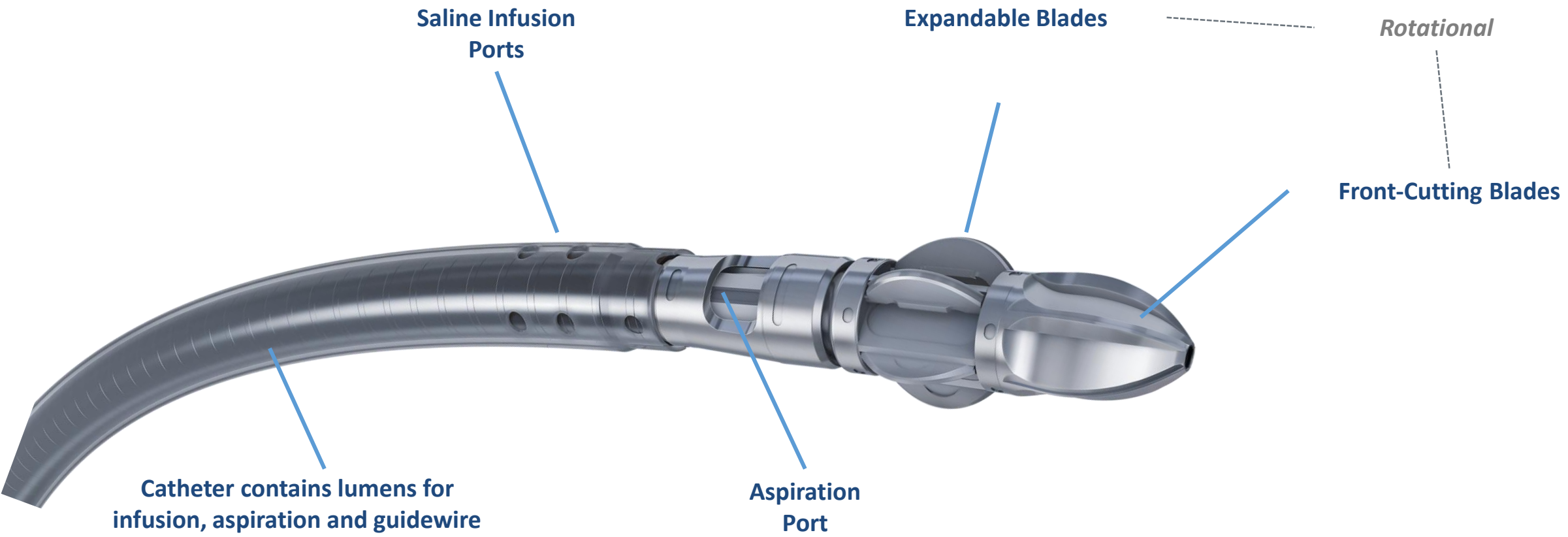
vessel treatment: "spot stenting" (nitinol self expanding)







Jetstream Catheter Components

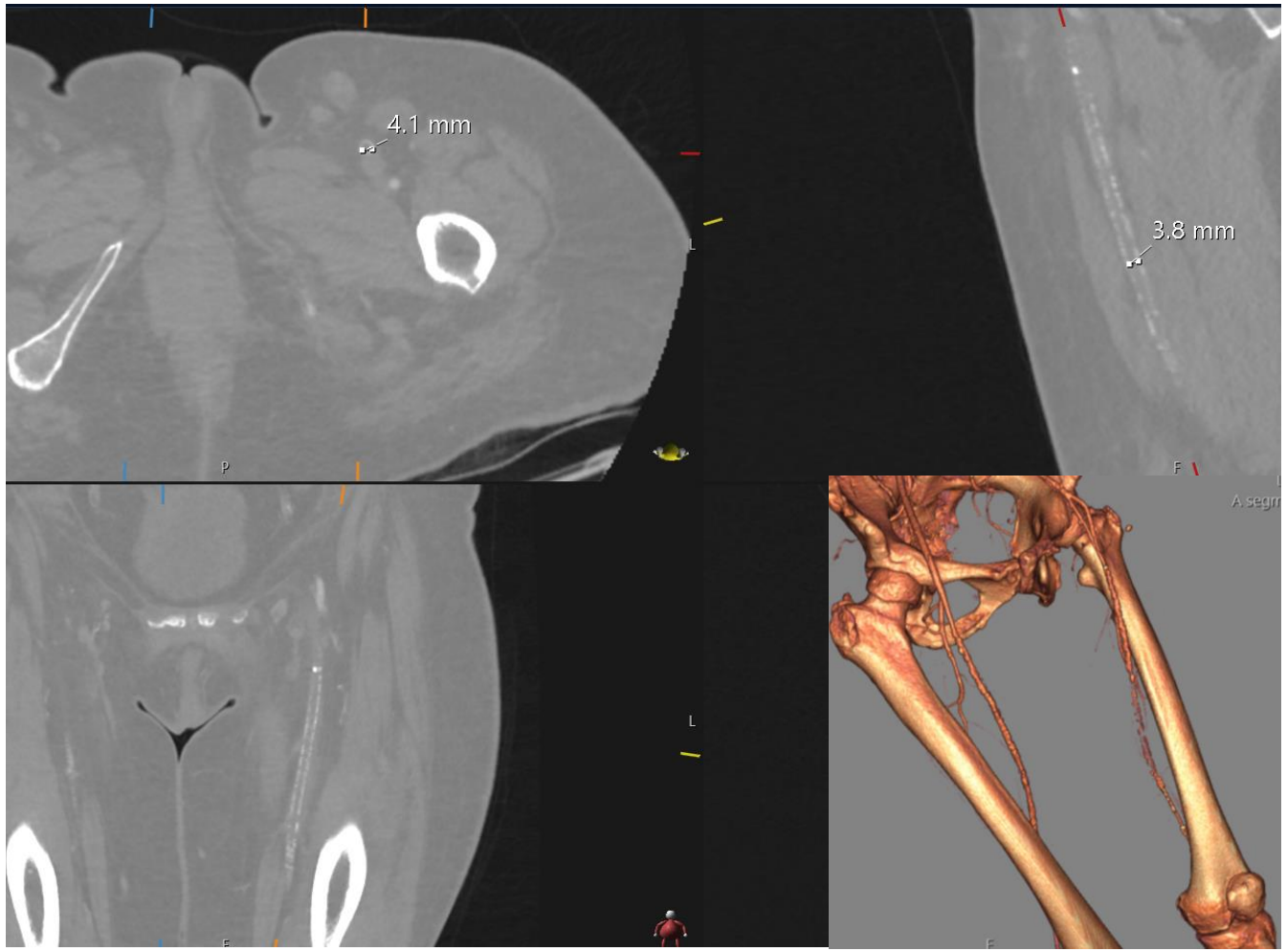


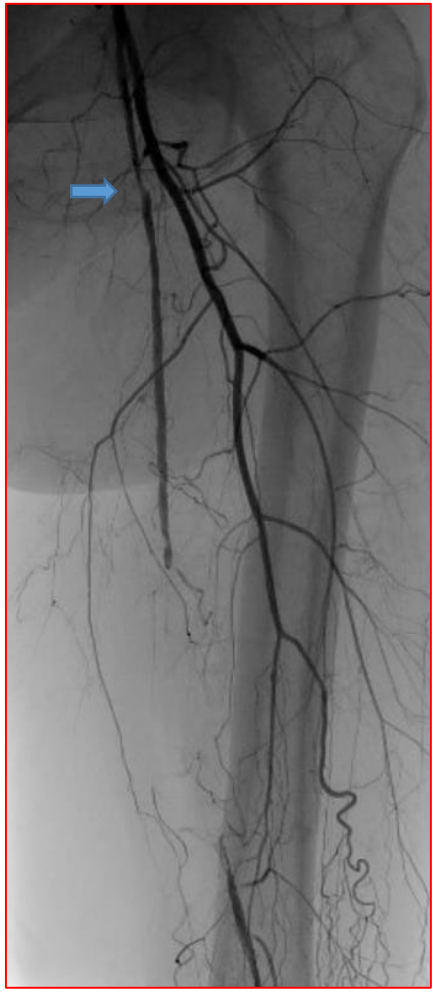
Complex JETSTREAM revascularisation

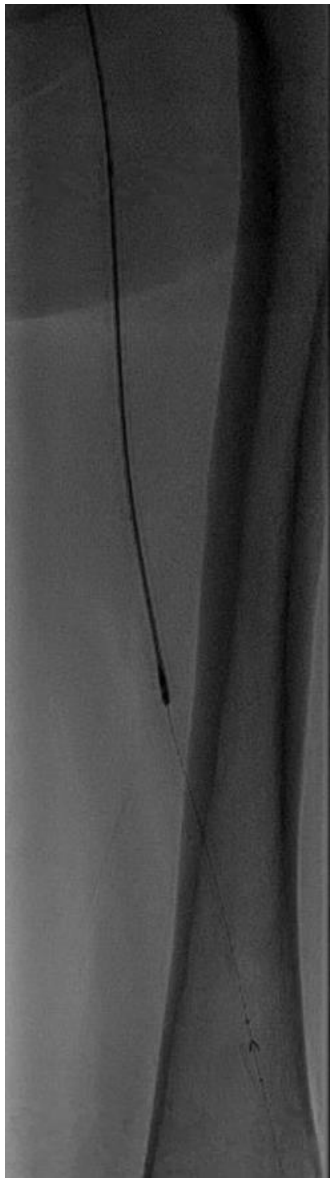
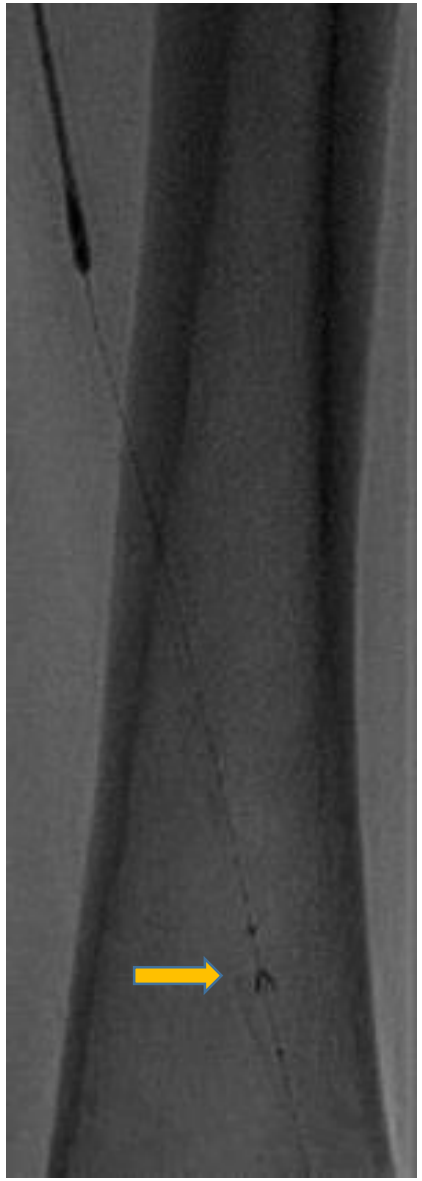
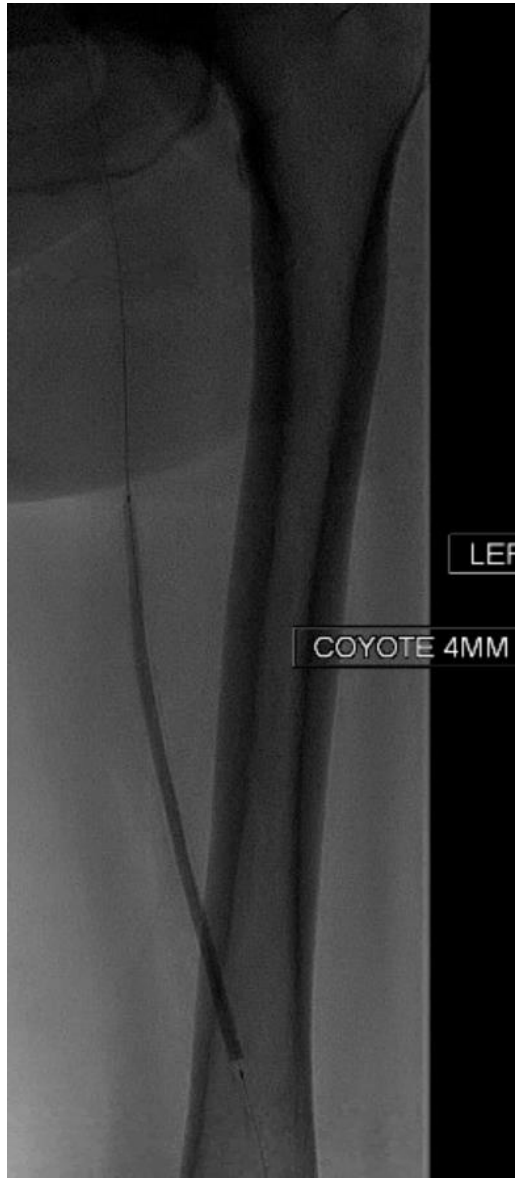
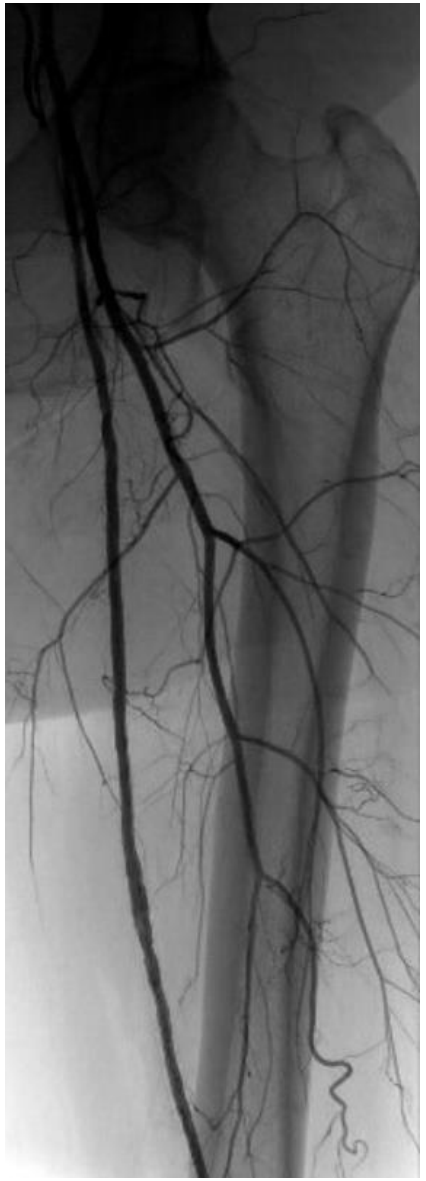
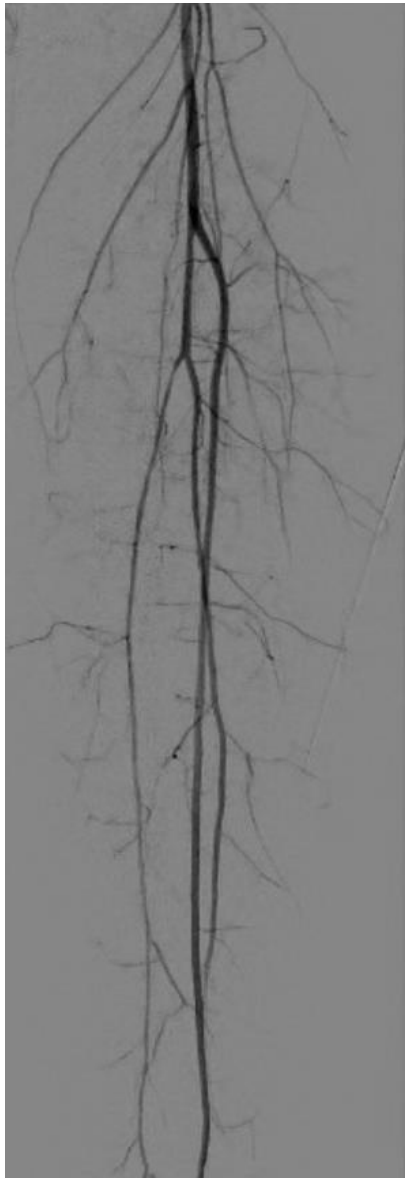
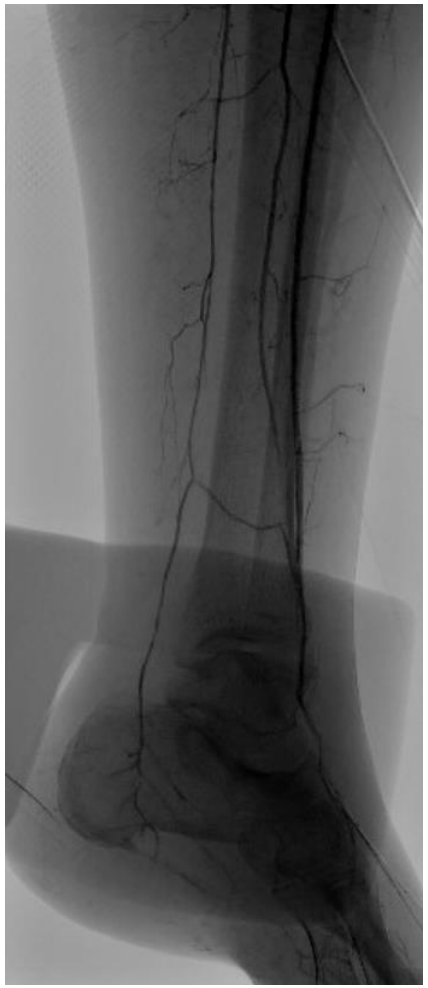
✓ *small diameter vessels*

- ✓ *unsuitable for stenting*
- ✓ *high-risk of dissection / recoiling / thrombosis*

Mr Lukla Biasi - GSTT

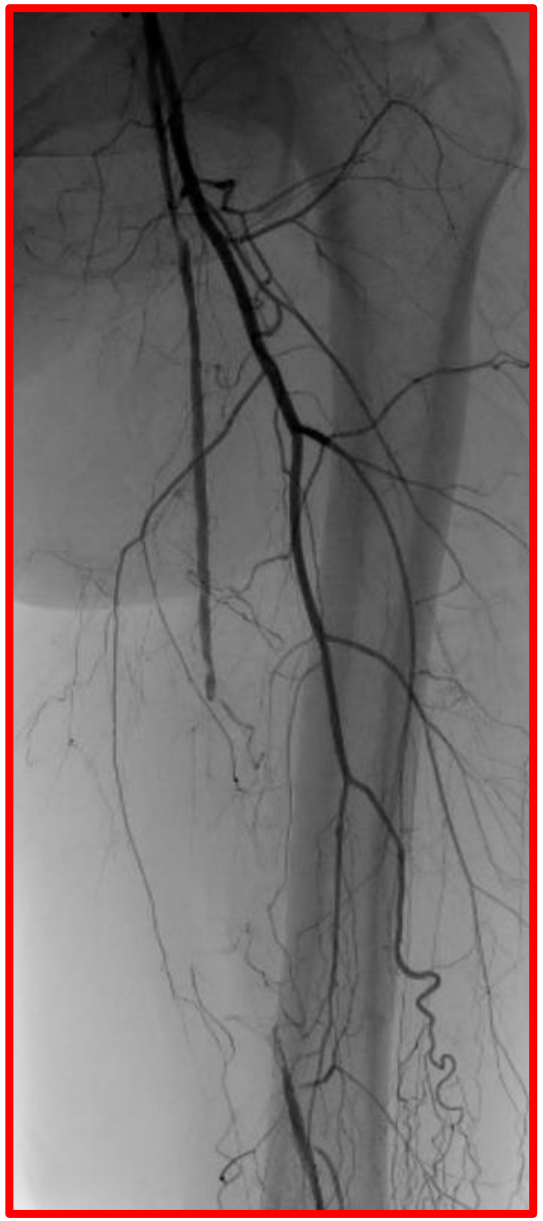


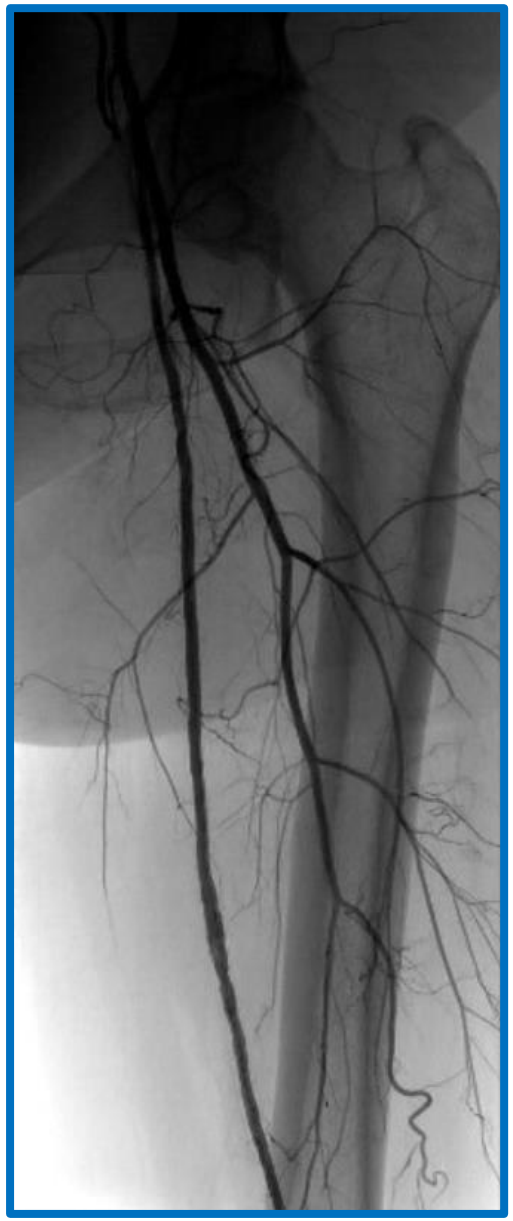





COYOTE 4MM




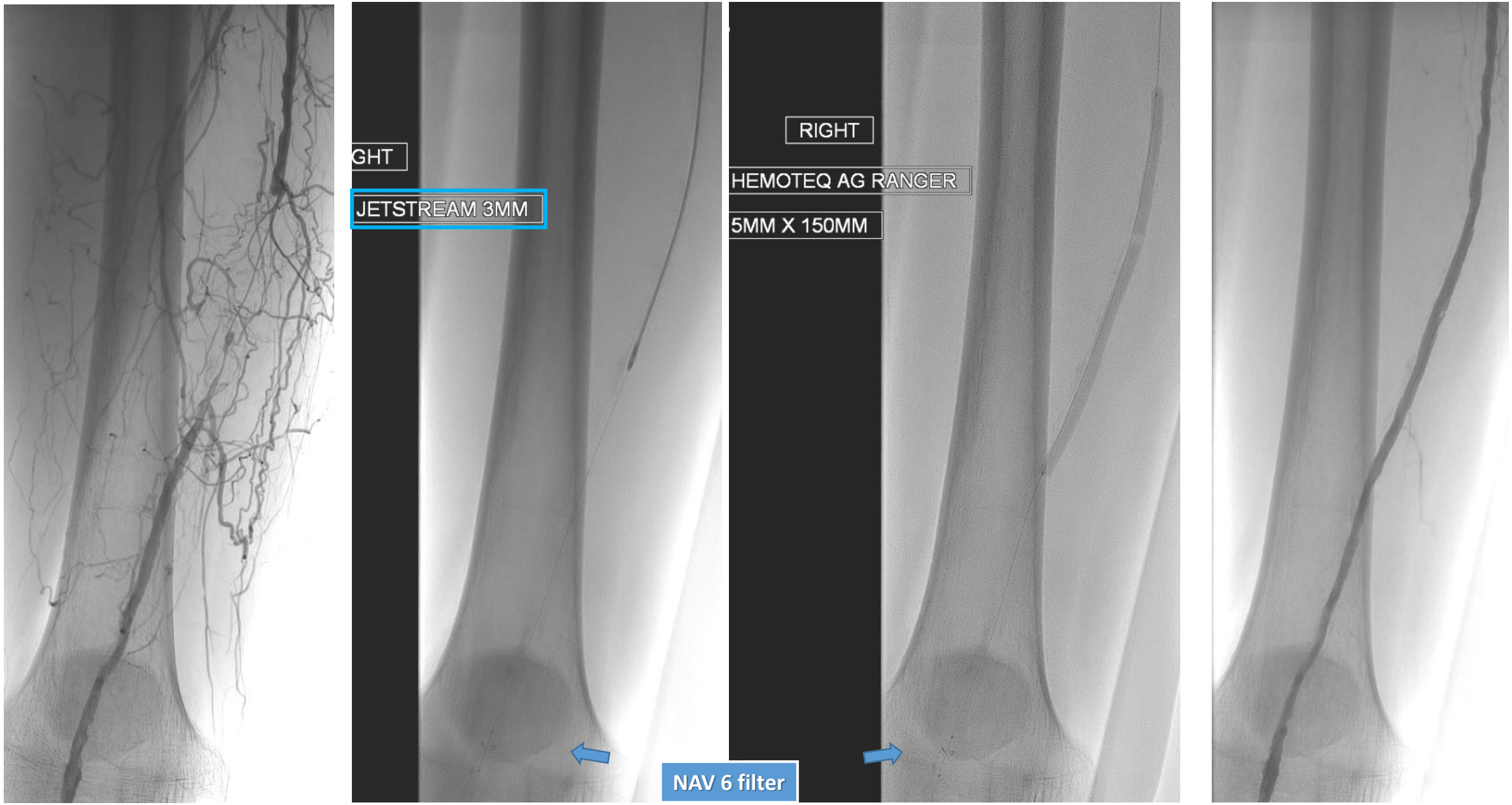
Pre

Post - Jetstream

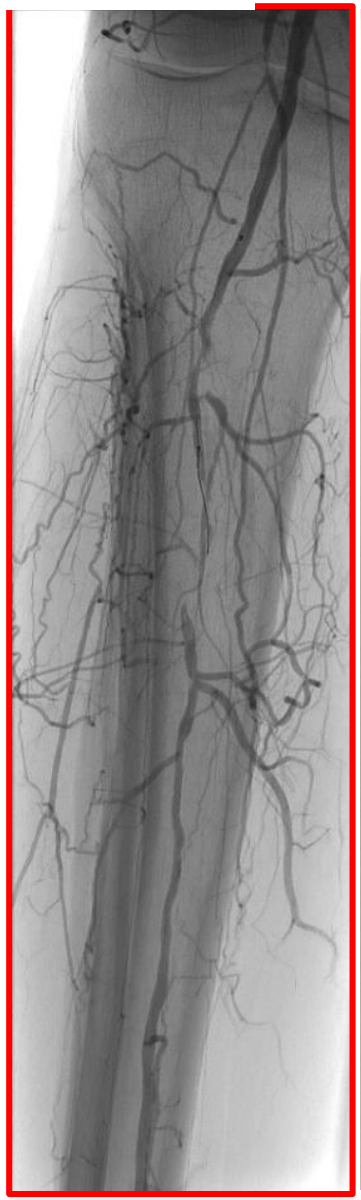




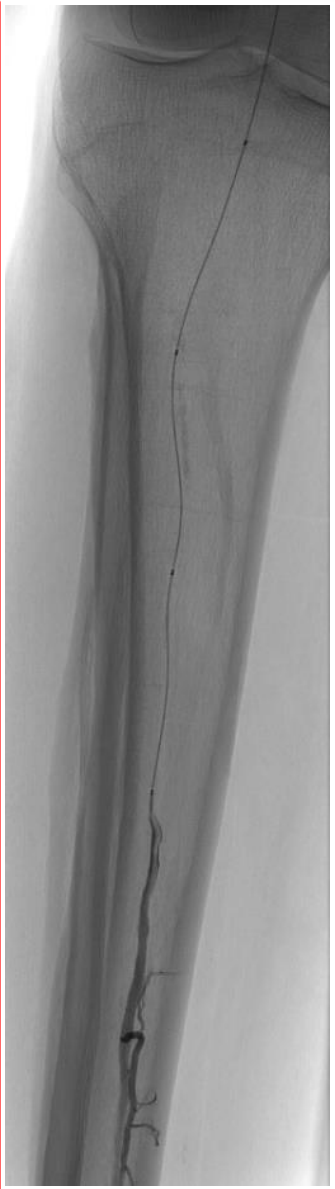
Stage 1: Rotational Atherectomy



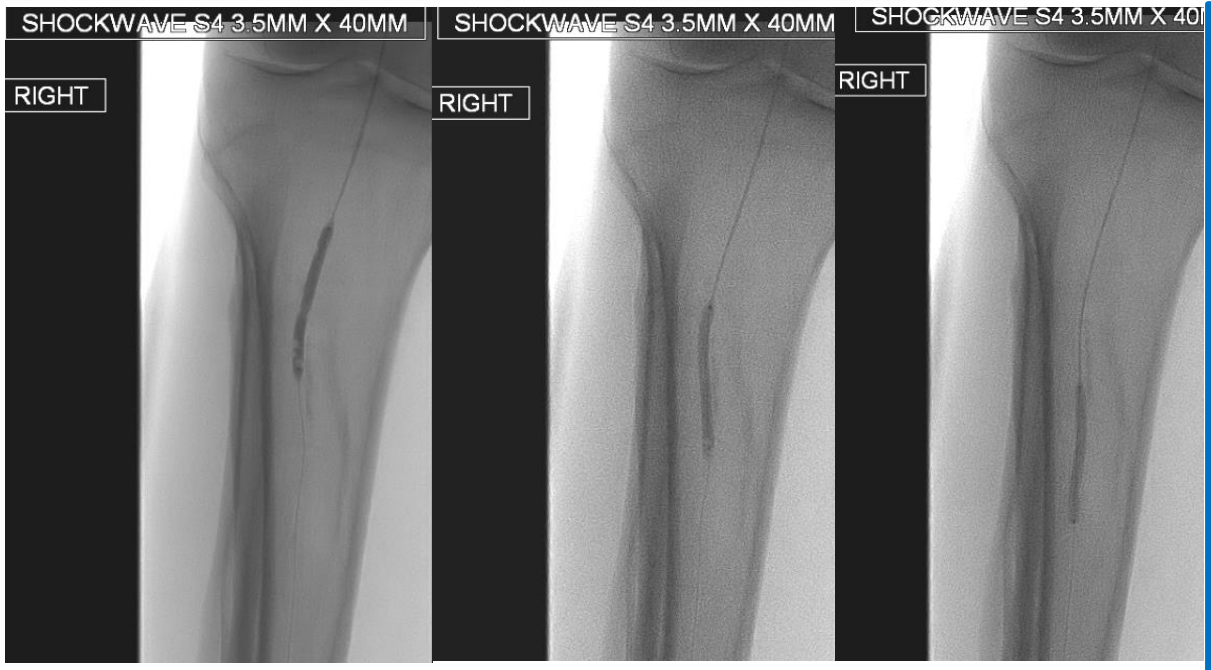
Stage 2: Shockwave *(TPT – Peroneal Art)*



Pre

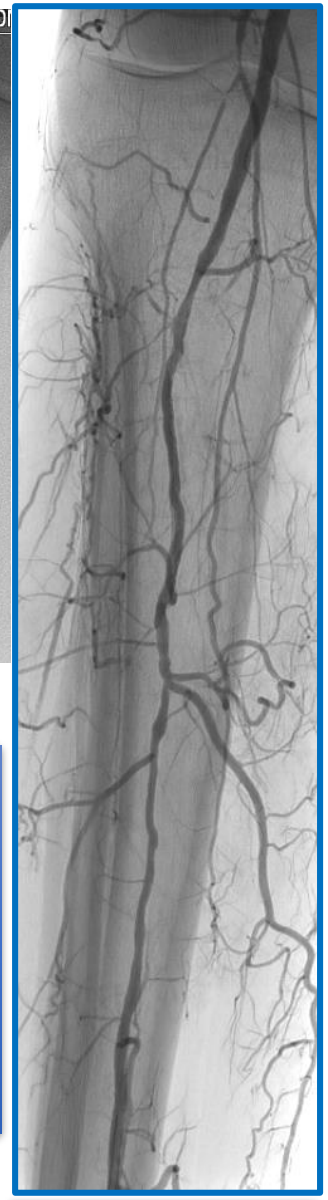


intraluminal crossing



IVL – Shockwave S4

- ***3.5mm X 40 mm***
- ***20 pulses / cycles***
- ***2 cycles / segment***
- ***3 segments***
- ***Tot: 120 pulses***



Post

Referrals Pathway – NHS Vascular Service

Routine	• Varicose Veins (CEAP C4 – C5) • PAD - Intermittent Claudication
Soon	• Uncomplicated venous leg ulcer • Varicobleeding • PAD - occasional night time pain / cramps
Urgent	• CLTI Rutherford 4 (ischaemic rest pain) • CLTI Rutherford 5-6 (arterial leg ulcer)
Diabetic Foot *(within 2/52)*	• MDT Foot Clinic

Guy's and St Thomas' NHS
NHS Foundation Trust