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Review

A call for uniform reporting standards in studies assessing endovascular treatment for chronic ischaemia of lower limb arteries

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Endovascular therapy is a rapidly evolving field for the treatment of patients with peripheral arterial disease, and a magnitude of studies reporting on various modern revascularization concepts have been recently published. Thus, studies assessing the efficacy of endovascular therapy of peripheral arteries do not operate with uniformly defined endpoints, rendering a direct comparison of studies difficult. The purpose of this consensus statement is to highlight differences in the terminology used in the current literature and to propose some standardized criteria that must be considered when reporting results of endovascular revascularization for chronic ischaemia of lower limb arteries.

Introduction

Endovascular therapy is a rapidly evolving field for the treatment of patients with peripheral arterial occlusive disease (PAD), and a magnitude of studies on technical improvements and innovative developments have been recently published. Studies assessing endovascular therapy of peripheral arteries, however, contain considerably smaller number of patients when compared with trials on coronary revascularization, and do not operate with uniformly defined endpoints, rendering a direct comparison of studies difficult.

A pivotal publication on standards to report results of peripheral revascularization has been published by Rutherford in 1986 and 1997.[1,2] Although these standards are widely accepted for surgical trials, this is by far less for trials assessing endovascular therapy. One reason is that some of the terminology needs adaptation.

The purpose of this consensus statement is to highlight differences in the terminology used in the current literature and to propose some standardized criteria that must be considered when reporting results of endovascular revascularization for chronic ischaemia of lower limb arteries, thereby partly reinforcing previously suggested reporting standards.[1–6]

Differences in endpoint definition in clinical trials

To identify differences in endpoint definitions in studies on peripheral arterial revascularization, a Medline research containing the following key words had been conducted: PAD, endovascular, balloon angioplasty, stent, claudication, critical limb ischaemia. Trials published within the last 10 years (1996–2006) were selected and most striking differences in endpoint selection were highlighted in our manuscript.

Studies reporting efficacy of endovascular therapy are characterized by heterogeneous definition of endpoints. Even more so, in landmark studies on endovascular therapy poor or no information regarding functional patient outcome is available.[7,8]

Immediate technical success is particularly relevant for a precise analysis of innovative endovascular techniques and

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represents the basis for clinical success. It is given as residual angiographic stenosis (diameter reduction) judged by visual estimation at the end of an intervention, but is variably defined as $<30\%$,[9–15] $<40\%$,[16] or $<50\%$[17] dependent on the author reporting the results. Moreover, as results are usually based on visual estimation, this is coupled with an intra- and interobserver variability as high as 23%.[18–20] For revascularization of the iliac arteries, technical success is also given as translesional pressure gradient <5 mmHg[21] or <10 mmHg.[22]

Procedural success is usually defined as technical success without procedural complications.

Definition of clinical success, often misleadingly called 'clinical patency',[10,12,13] varies significantly within different studies (*Table 1*). It seems obvious that 'freedom from target lesion revascularization (TLR)'[13] and 'outcome based on Rutherford categories'[1,2] are different endpoints, though in reports on endovascular therapy they are included under the same heading.[10–12,14,15,17,23] In trials assessing intermittent claudication, clinical success is assessed based on interrogation of patients' self-reported symptoms in some[10,11,13,14] or by standardized treadmill exercise testing in other studies.[7,9] In patients treated for critical limb ischaemia, limb salvage rates reflect the clinical achievement of preservation of a functional foot without requirement for a prosthesis,[24] but limb salvage is not synonymous with relief from clinical symptoms or healing of ischaemic lesions.

Table 1 Definition of clinical success in various studies assessing the efficacy of endovascular revascularization strategies in peripheral arterial disease

Author, year	Definition of clinical success
Minar *et al.*, 2000[10]	'Clinical patency': improvement of at least one category according to Rutherford *et al.*[2] (calculated according to Kaplan–Meier). No treadmill testing.
Scheinert *et al.*, 2001[9]	ABI measurements and non-cumulative comparison of Rutherford *et al.*[2] categorial upshift of $\geq$2 categories at baseline and follow-up. Treadmill testing (5 min at 2 mph on a 12% incline).
Duda *et al.*, 2002[8]	No clinical success given, ABI measurements and non-cumulative comparison of Rutherford *et al.*[2] class at baseline and follow-up. No treadmill testing.
Steinkamp *et al.*, 2002[17]	Clinical success: Composite of technical success (requiring a residual stenosis $\leq$50% according to angiography) and clinical improvement of $\geq$2 in limb status grading according to AHA criteria[3,4] that are comparable with the criteria proposed by Rutherford *et al.*[2] Treadmill testing (no details given).
Laird *et al.*, 2005[13]	Freedom from repeated TLR (calculated according to Kaplan–Meier). No treadmill testing.
Diehm *et al.*, 2005[11]	'Sustained clinical improvement': survival without repeated revascularization and with an increase in ABI $\geq$0.1 and/or an upward categorical shift of at least one category according to Rutherford *et al.*[2] (calculated according to Kaplan–Meier). No treadmill testing.
Dorffler-Melly *et al.*, 2005[14]	Clinical outcome based on Rutherford categories.[2] Comparison of baseline vs. end of follow-up. No treadmill testing.
Schillinger *et al.*, 2006[34]	Clinical outcome based on Rutherford categories. Standardized treadmill testing.

Undoubtedly, clinical success has little correlation with patency of the treated vessel. The term 'patency' derives from surgical revascularization literature and is used to describe the presence of uninterrupted flow. By definition, the term reflects the findings of objective imaging such as duplex ultrasound, digital subtraction angiography, computed tomographic or magnetic resonance angiography.[24] Applying the term 'patency' according to the surgical definition, high grade stenosis would still imply that the vessel is patent. According to the TASC document, primary patency implies uninterrupted patency following the revascularization procedure being evaluated.[24] Assisted primary patency expresses cases in which a revision of the revascularization method is applied to prevent impending occlusion or progression of stenosis. Secondary patency refers to patency of the initially treated vessel following a re-intervention to restore patency after occlusion.

As restenosis is a major drawback of endovascular therapy, it is mandatory to measure efficacy of various treatment approaches by exact quantification of restenosis.[8,10] In endovascular trials, the definition of patency ranges from absence of restenosis of $\geq$50% using objective imaging methods[10,14,25–27] or represents clinical assessment[9] (*Table 2*).

Furthermore, in studies reporting on patency rates as assessed by ultrasonography only, different definitions are implied regarding the flow-velocity criteria defined by Ranke *et al.*[28] (2–2.4 fold increase in flow velocity).[7,9,10,13]

The terms TLR and target vessel revascularization (TVR) rates refer to coronary trials but have rarely been used in studies assessing efficacy of endovascular therapy in PAD. Although TLR and TVR rates are influenced by many factors such as physician's preference or reimbursement policy, these rates set forth assists to differentiate restenosis from progression of atherosclerosis beyond the target lesion treated.

Suggested endpoint selection for trials assessing clinical and angiographic outcomes of endovascular therapy for chronic lower limb ischaemia

Definition of patients treated, immediate procedural results, procedure-related adverse events, functional outcomes and binary restenosis rates are the minimum information required to adequately report endovascular results in PAD.

Patient and lesion definition

Clinical and angiographic inclusion and exclusion criteria have to be stated in a dedicated paragraph. Demographic data including cardiovascular risk factors, co-morbidities, and classification of disease severity should be given at

Table 2 Definition of patency/restenosis in various studies assessing the efficacy of endovascular revascularization strategies in peripheral arterial disease

Author, year	Definition of patency/restenosis
Minar *et al.*, 2000[10]	Restenosis: angiographically verified stenosis of ≥50% narrowing of the luminal diameter within the recanalized segment compared with the diameters of normal segments of the vessel on the follow-up angiogram (calculated according to Kaplan-Meier). No quantitative vessel analysis.
Scheinert *et al.*, 2001[9]	Restenosis was assumed in case of: • >50% diameter restenosis according to angiography or transcutaneous duplex scans (no quantitative vessel analysis) or • >2-fold increment of the Doppler peak flow velocity within the target lesion when compared with the proximal reference value or • no change in the Doppler spectrum throughout the treated segment and in comparison with the proximal reference segment or • maintenance of achieved clinical improvement according to AHA limb status grading system[3] or • absence of ABI deterioration by >0.15 from the maximum post-interventional value.
Duda *et al.*, 2002[8]	'Binary restenosis' ≥50% stenosis. Quantitative vessel analysis after angiographical depection of the vessel in two planes.
Steinkamp *et al.*, 2002[17]	Primary patency: contrast limb status grading after successful primary recanalization. Primary assisted patency: patency of the target vessel regardless of secondary interventions performed to restore blood flow after restenosis. Secondary patency: patency of the target vessel regardless of secondary interventions performed to restore blood flow after reocclusions.
Laird *et al.*, 2005[13]	Primary patency was determined with use of duplex US, whereby restenosis was defined by a peak systolic velocity index greater than 2.0 at the target lesion.
Diehm *et al.*, 2005[11]	Angiographic patency: freedom from binary restenosis in the treated femoropopliteal target lesion.
Dorffler-Melly *et al.*, 2005[14]	Patency documented by means of colour-coded duplex sonography: <50% diameter reduction (peak systolic velocity index <2.4), 50% or more diameter reduction (peak systolic velocity index ≥2.4), and complete occlusion.
Schillinger *et al.*, 2006[34]	Angiographic patency: freedom from binary restenosis in the treated femoropopliteal target lesion by CTA or DSA. Ultrasound patency: restenosis was defined by a peak systolic velocity index greater than 2.4 at the target lesion

Table 3 Baseline patient characteristics and procedural details required in studies reporting outcomes of endovascular revascularization strategies

- Demographic data according to International Classification of Disease code[39]
  - Age
  - Gender
  - Hypertension
  - Hyperlipidaemia
  - Diabetes mellitus
  - Smoking
  - Ischaemic heart disease
  - Congestive heart failure
  - Renal insufficiency (creatinine level >2.0 mg/dL)
- Clinical inclusion criteria
  - Clinical stage according to Rutherford *et al.*[2]
- Morphological inclusion criteria
  - Lesion localization according to TASC guidelines[24]
  - Lesion length and lesion type (*de-novo* vs. recurrent lesion)
  - Lesion severity (stenosis vs. occlusion, quantification of stenosis)
  - Arterial in- and outflow situation
- Description of pre- and post-procedural imaging techniques
  - Angiography: angles and magnifications, amount of contrast medium administered, software used for quantitative vessel analysis
  - Duplex ultrasound: specifications of hardware used, cut-off flow velocities defining significant stenosis
- Vascular access specifications
  - Access routes
  - Size of introducer sheaths used
  - Specification of devices used (length and diameters of balloons/devices implanted)
- Device to artery ratio for balloons and implants, length of treated segment
- Pre-, peri- and post-procedural medication
- Clinical and technical follow-up monitoring strategies

baseline, as well as cardiovascular adverse events and death rates during follow-up to allow for correct classification of patients being treated (*Table 3*; appendix).

The Rutherford classification should be used for staging of the disease at baseline and during follow-up.[2] For uniform comparability, all data should be given separately for patients with intermittent claudication and critical limb ischaemia.

Procedural details

Besides morphological inclusion criteria characterizing the lesions treated (*Table 3*; appendix), detailed information of imaging methods applied should be provided. Furthermore, details on vascular access and post-procedural vascular morphometry as well as information about adjunctive drug treatment (statins, angiotensin-converting enzyme inhibitors, angiotensin-II antagonists, oral anticoagulation, anti-platelet-therapy, unfractionated or low molecular weight heparin, and glycoprotein IIb/IIIa inhibitors) have to be reported. Finally, clinical and technical monitoring strategies applied in the study should be stated.

Immediate procedural outcome

Data on immediate procedural outcome should include technical success rates and complications (*Table 4*; appendix). Technical success (based on an intention-to-treat analysis)

Table 4 Suggested outcome measures for studies reporting outcomes of endovascular revascularization strategies

Clinical outcome
- Morbidity and mortality: cumulative analysis of peri-procedural complications and in-hospital mortality and detailed information of procedure-related mortality according to SCVIR reporting standards[5] as well as mortality during follow-up
- Amputation: cumulative analysis of minor and major amputations (above the ankle) differentiating patients treated for claudication from patients treated for critical limb ischaemia, below-the-knee vs. above-the-knee amputation.
- Sustained clinical improvement: cumulative improvement of $\geq$1 class in case of claudication and of $\geq$2 classes in case of actual limb loss according to Rutherford *et al.*[2] and/or minimal haemodynamic improvement (ABI $>$ 0.15) without the need for repeated TLR in surviving patients. Incidence of critical limb ischaemia should be reported separately in trials for claudication and critical limb ischaemia
- Distribution of clinical stages at end of follow-up compared with baseline
- Use of standardized treadmill testing (12% treadmill incline at a speed of 3.2 km/h): ICD and ACD

Procedural outcome
- Technical success: successful access and deployment of the device and $\leq$30% diameter residual stenosis after revascularization
- Device success: exact deployment of stent or stentgraft as documented by two different projections
- The term 'patency' should be replaced by 'binary restenosis' as assessed by quantitative angiography (in case of head-to-head comparisons of medical devices) or by duplex ultrasound (defined as a peak velocity ratio of $<$2.4 at the target lesion) and calculated within a cumulative analysis. Furthermore, detailed description of findings from quantitative angiography providing reference vessel diameter, MLD, percent diameter stenosis, acute gain, late loss, and total occlusion rate is warranted
- Repeated TLR: cumulative analysis of endovascular or surgical target lesion redo-procedures in surviving patients with preserved limb
- Repeated TER: cumulative analysis of endovascular or surgical target extremity redo-procedures in surviving patients with preserved limb

Haemodynamic outcome
- Immediate haemodynamic improvement: ABI improvement of $\geq$0.15
- Sustained haemodynamic improvement: cumulative ABI improvement of $\geq$0.15 without the need for repeated TLR in surviving patients
- Mean or median ABI values at rest should be provided at every time point of follow-up
- Toe pressure and pulse waveform analysis (oscillometric reading) should be performed to measure haemodynamic changes in patients undergoing below-the-knee revascularization or in patients with falsely elevated ABI values

should be defined as successful vascular access and completion of the endovascular procedure as well as immediate morphological success with less than 30% residual diameter reduction as assessed by quantitative angiography. In case of iliac artery intervention, technical success should comprise the presence of a translesional mean pressure gradient $<$5 mmHg. Procedural success should be defined as technical success without periprocedural complications.

In case of application or deployment of endovascular stents or stentgrafts, device success should be defined as exact deployment of the device documented in at least two different projections.

Post-procedural outcome

Periprocedural complications including mortality and morbidity within 30 days following the intervention, in-hospital mortality as well as procedure- and device-related complications such as pseudoaneurysm, haematoma, bleeding or acute re-occlusion, and the rate of related re-interventions such as surgery or ultrasound-guided thrombin injection or compression for the management for iatrogenic pseudoaneurysms have to be reported. Procedural mortality rates including all in-hospital deaths should be specifically addressed. For this purpose, we propose to comply with proposed reporting standards of the Society of Cardiovascular & Interventional Radiology (SCVIR).[5] Minor complications contain those not requiring further treatment and being without further sequelae for the patient, or minor therapy including unplanned extend of hospital admission ($\leq$24 h) for observation. Major complications will refer to those requiring endovascular or surgical re-intervention or unplanned extend of hospitalization between 24 and 48 h or an unplanned increase in the level of care with prolonged hospitalization ($>$48 h), permanent sequelae, or death.

Follow-up

Evaluation of clinical, haemodynamic, and morphological efficacy of different endovascular treatment approaches, a minimum of 12 months of follow-up is recommended. For uniform comparability, we suggest assessment prior to discharge and at 1, 3, 6, and 12 months. To guarantee for the quality of data, complete follow-up of as many patients as possible should be obtained, with at least 90% of patients completing 12-month follow-up.

Clinical outcome

Clinical success describing functional outcomes after endovascular revascularization performed for intermittent claudication is of landmark importance and a major outcome criterion to achieve long-term credibility of endovascular therapy. Studies reporting solely morphological patency rates omitting clinical outcomes after endovascular revascularization are inappropriate.

Gauging clinical changes after surgical revascularization is well established applying the standards of reporting proposed by Rutherford *et al.*[2] in 1997. To adapt these standards to special requirements of trials assessing the efficacy of endovascular revascularization, we propose uniform endpoint definitions described in what follows.

Patient mortality after enrolment in a study has to be assessed during follow-up. Causes of death associated with the endovascular procedure (procedure related mortality) should be reported separately, as well as overall mortality.

Need for minor (below the ankle) and major (above the ankle) unplanned amputation have to be regarded as a major outcome criterion in trials, but should be reported separately for patients with intermittent claudication and chronic critical

limb ischaemia at entry. Major amputation should be reported as below-the-knee and above-the-knee amputations.

Sustained clinical improvement has to be regarded as a primary clinical endpoint. In patients treated for claudication, it is characterized as clinical improvement of at least one clinical category according to Rutherford *et al.*[2] assessed by standardized treadmill testing without the need for repeated TLR in surviving patients. Patients treated for critical limb ischaemia must demonstrate healing of all skin lesions and resolution of ischaemic rest pain to be considered improved.[2] Furthermore, in addition to providing the above-mentioned primary endpoint, distribution of clinical stages (according to Rutherford *et al.*[2]) during all follow-up visits should be given as compared to baseline. Erroneous endpoints such as 'clinical patency' or 'haemodynamic patency' must not be accepted.

In claudication trials, standardized treadmill testing (12% treadmill incline at a speed of 3.2 km/h) should be applied to measure the objective functional response to therapeutic interventions:[24] initial claudication distance (ICD) and absolute claudication distance (ACD) have to be reported. Patients who are not suitable to undergo standardized treadmill testing should not be included in claudication trials.

Morphological outcome

As restenosis is the major drawback of balloon angioplasty and its quantification is relevant for comparison of different revascularization methods, we suggest to replace the term 'patency' by 'binary restenosis', which equals $\geq$50% re-obstruction of the target lesion. We also suggest that independent core laboratory analysis of angiographic and duplex ultrasound images is mandatory for device approval.

Intra-arterial angiography remains the current gold standard for depiction of lesions in peripheral arteries.[6] Precise quantitative angiographic assessment of the target lesion with objective measures such as the percent diameter stenosis relative to the adjacent arterial segments is warranted. Especially in trials comparatively reporting on different peripheral endovascular revascularization strategies, i.e. using stents or other devices aiming at the prevention of restenosis, angiographic analysis using quantitative vessel analysis software derived from the methods established for coronary artery analysis is desirable.[8,12,29] It allows for objective evaluation of results of endovascular procedures as well as detailed insight in local phenomena such as edge effects and is current standard in coronary artery revascularization trials.[30]

Detailed information on arterial morphology should contain the following parameters obtained from quantitative angiography measurements:[8]

- reference vessel diameter (obtained from averaging 5-mm segments proximal and distal to the lesion);
- minimal luminal diameter (MLD);
- percent diameter stenosis;
- acute gain (change in MLD from baseline to post-intervention);
- late loss (change in MLD from the final angiogram to follow-up);
- total re-occlusion rate;
- binary ($\geq$50%) restenosis rate including the respective 95% confidence interval.

Owing to the less invasive character of the examination along with ethical considerations regarding serial intra-arterial angiography for study purposes, we recognize the accuracy of duplex ultrasonography for morphological follow-up and detection of binary restenosis. Unfortunately, duplex sonography can be associated with a considerable inter- and intraobserver variability especially in vessels as heterogenous as the femoropopliteal[31–34] and below-the-knee arteries.[19,35] Therefore, inter- and intra-observer variability of the performing ultrasound laboratory and core laboratory assessment should be included in the report. For uniform reporting standards, we suggest to define binary restenosis on duplex sonography by a peak systolic velocity index greater than 2.4 at the target lesion as initially proposed by Ranke *et al.*[36]

Especially in duplex sonography follow-up examinations of revascularization approaches, in which no endovascular landmark such as a stent is clearly visible (e.g. assessment of vessels after endovascular brachytherapy or deployment of biodegradable stents), separating *de-novo* obstructions from recurrent lesions can be a difficult task. We therefore recommend the use of rulers to document the exact distance of the lesion from anatomical landmarks (such as the patella or the iliac or femoral bifurcation) at baseline and during follow-up visits.

Magnetic resonance and computed tomography angiography might become valuable tools in morphological follow-up after endovascular interventions.

If non-angiographic modalities are used for follow-up, they must be compared with the same modality over time.

Since the terms primary patency, primary assisted patency, and secondary patency are mainly used in surgical trials[24] and its use may be confusing after endovascular therapy, we propose, in accordance to coronary trials, the following terminology to describe need for re-interventions. Rates of repeated TLR should be reported in surviving patients with preserved limb to express the frequency of the need for redo-procedures (endovascular or surgical) due to a problem arising from the lesion (+1 cm proximally and distally to include edge phenomena) initially treated. Repeated target extremity revascularization (TER) should be reported in surviving patients with preserved limb to express the frequency of the need for redo-procedures (endovascular or surgical) due to a problem arising outside the lesion initially treated. A subtraction of TLR from TER rates yields the rate of revascularizations performed due to progression of arteriosclerosis.

Haemodynamic outcome

According to definitions after surgical revascularization, immediate haemodynamic improvement after endovascular revascularization is defined as ankle brachial index (ABI) improvement of $\geq$0.15. Sustained haemodynamic improvement is defined as persistent ABI values $\geq$0.15 throughout follow-up when compared with baseline without the need for repeated TLR in surviving patients.[2] Desirable for review of data quality is the declaration of mean and median ABI at all follow-up visits when compared with baseline.

In patients undergoing below-the-knee endovascular revascularization or if ABI cannot be appropriately measured such as in case of medial arterial calcification (e.g. diabetes

mellitus or renal insufficiency), oscillometric reading or toe pressure measurement should be used.[2,6,24]

Statistical analysis

Except for results from registries, as well as feasibility and pilot trials, prospective randomized controlled study design should be preferred to reliably assess the efficacy of endovascular revascularization.

Except for analysis of technical success, periprocedural complications and quantitative angiographic outcomes, as already stated by Rutherford *et al.*,[2] and the above-mentioned endpoints should be calculated using cumulative analyses, i.e. according to the life-table method[37] or according to the method proposed by Kaplan–Meier.[38]

According to these statistical methods, patients in which defined endpoint has been reached (e.g. repeated TLR) have to be uncensored within the cumulative analysis and excluded from further follow-up assessments such as ABI comparisons or descriptions of clinical stage beyond the time of uncensoring.

Conclusion

Unique reporting standards as proposed within this manuscript and summarized in *Tables 3* and *4* are required to obtain comparability of studies dealing with endovascular therapy of peripheral arteries to further elucidate and to prove long-term credibility of this method.

Conflict of interest: none declared.

Appendix

	Item number	Descriptor	Reported on page number
Methods			
Demographic data	1	Age, gender, cardiovascular risk factor profile, spectrum of concomitant disease	
Clinical inclusion criterion	2	PAOD stage of patients according to Rutherford[2]	
Lesion morphology	3	Localization, length, type and severity of lesion; arterial in- and outflow specifications	
Imaging techniques	4	Detailed description of pre- and post-procedural imaging technique used to characterize lesion morphology	
Procedural specifications	5	Details on vascular access and devices used as well as pre-, peri-, and postprocedural medication administered	
Follow-up specifications	6	Detailed depiction of clinical and technical follow-up monitoring strategies	
Results			
Morbidity and mortality	7	Cumulative analysis of periprocedural complications, in-hospital mortality, and mortality throughout follow-up	
Amputation rates	8	Rates of minor and major amputations (provided separately for claudicants and patients with critical limb ischaemia). Major amputations separated in below-the-knee and above-the-knee amputation	
Sustained clinical improvment	9	Cumulative analysis of clinical improvement of $\geq$1 class in case of claudication and of 2 classes in case of actual limb loss according to Rutherford and/or minimal haemodynamic improvement (ABI $>$ 0.15) without need for repeated TLR in surviving patients	
Clinical stages	10	Distribution of Rutherford stages at end of follow-up as compared with baseline	

Continued

	Item number	Descriptor	Reported on page number
Claudication distance	11	ICD and ACD before revascularization and throughout follow-up	
Technical success	12	Successful completion of the procedure and ≤30% diameter residual stenosis after revascularization	
Device success	13	Exact deployment of implanted device as documented by two different projections	
Binary restenosis	14	Cumulative analysis of binary restenosis (≥50% re-obstruction of the target lesion) as assessed by quantitative angiography or by duplex ultrasound	
Repeated TLR/TER	15	Cumulative analysis of endovascular and surgical target lesion and target extremity redo-procedures in surviving patients with preserved limb	
Immediate haemodynamic improvement	16	Postprocedural rate of ABI improvement of ≥0.15 as compared to baseline	
Sustained haemodynamic improvement	17	Cumulative analysis of sustained ABI improvement of ≥0.15 throughout follow-up	
ABI values	18	Mean or median ABI values at rest at every time point of follow-up	
Toe pressure and oscillometric analysis	19	To measure haemodynamic changes in patients undergoing below-the-knee revascularization or in patients with falsely elevated ABI	

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