Image Guided Therapy

IVUS arterial compendium

IVUS evidence in peripheral arterial disease

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Introduction

Peripheral artery disease (PAD) includes disease of the aortoiliac, femoropopliteal (FP), and infrapopliteal arterial segments. It is estimated to affect 8.5 million people in the United States who are older than 40 years.[1] The prevalence of PAD worldwide is believed to approximately 202 million people.[2]

Diagnosis of PAD includes clinical history and physical examination findings in patients with multiple risk factors or claudication, even though only 10% of patients with PAD have classic claudication; others have atypical leg pain (50%) or are asymptomatic (40%).[3] Noninvasive studies such as the ankle-brachial index (ABI) and duplex ultrasound provide diagnostic and hemodynamic information of PAD.

Treatments for PAD span the full spectrum from conservative approaches of diet and exercise to drug therapy, minimally invasive therapy, and open surgery. An analysis of over 2 million hospital admissions for PAD between 2001 and 2007 showed that the choice of treatment dramatically changed, with a 78% increase in endovascular procedures and a concomitant decrease in open bypass surgery and amputations.[4]

Background

Imaging is an important tool for the diagnosis and treatment of PAD. It helps to localize the lesions targeted for revascularization, inform the choice of arterial access site, and aid in the selection of appropriate equipment or adjunctive devices for treatment.

Angiography/Digital Subtraction Angiography (DSA) remains the main imaging modality used worldwide for vascular imaging. It is primarily performed to determine anatomical indications for intervention, the extent of treatment required, and for assessing the adequacy of an intervention. Angiography is considered the clinical "gold standard" for defining peripheral arterial anatomy.[5] It can provide assessments of disease burden, lesion location/characteristics, and vessel sizing and is usually reserved for when an intervention (either endovascular or traditional open surgery) is planned.

Despite significant improvements in image acquisition using angiographic techniques, there are limitations. Conventional angiography provides a single plane "shadow" of the vascular lumen. Because an angiogram is only a two-dimensional (2D) image of a three-dimensional (3D) blood vessel, it has limited accuracy and reproducibility in vessel stenosis measurements and has limited ability to characterize plaque morphology. Further, it has been demonstrated that angiography underestimates vessel size in both coronary and peripheral arteries.[6,7] Not only can lesion severity be underestimated on angiography, but the 2D angiogram may also fail to identify significant obstructive lesions and the morphological characteristics of lesions.[8] Angiography has also been shown to have a low sensitivity in identifying intravascular thrombus.[9] Despite these weaknesses, most interventional peripheral arterial procedures performed utilize angiography as the only imaging modality during the intervention to guide therapy.

Recently, several adjunctive tools to angiography have been introduced to enhance vessel and plaque visualization, including intravascular ultrasound (IVUS). IVUS gained prominence as a novel vascular imaging technology in the 1990s when it was incorporated in modern invasive cardiology as the use of balloon angioplasty and atherectomy procedures increased.[10] IVUS imaging provides intraluminal information that supplements other imaging modalities such as angiography, CT angiography, and magnetic resonance imaging angiography.

IVUS uses a miniature ultrasound (piezoelectric) transducer mounted on the tip of a catheter that generates sound waves after electrical stimulation. The propagation of the waves into different tissues produces a reflection image based on the acoustic properties of each tissue. The ultrasound transducer emits and receives signals at 10-45 MHz, producing an axial image (or frame) similar to CT or MRI. 2D IVUS images are obtained from the ultrasound catheter passing over a guidewire in the area of investigation. Consecutive axial 2D images are aligned and stacked longitudinally during a pullback of the ultrasound catheter through the vessel. The axial view is a 360° real-time image obtained by rotating the ultrasound beam rapidly around the axis of the catheter. The 3D reconstruction is complete when all the stacked frames, including the Z-plane (third dimension), are put together. 3D reconstruction can assemble the stack of serial axial frames into both a longitudinal image and a transverse or volume image. For acquisition of high-quality longitudinal and transverse/volume views, a smooth pullback of the catheter at a steady rate is required. This may be done manually or using a motorized device.[11]

A variety of ultrasound characteristics offer advantages in the evaluation of the heterogenous pathology and histologic morphology of arterial disease. The radius of detection can be altered to suit the diameter of the vessel. A tomographic orientation allows for full circumference visualization of the vessel wall allowing for detailed characterization of lumen size and plaque morphology.[12] The high-definition, cross-sectional images of the arterial lumen and wall provided by IVUS gives detailed information that is not available with angiography. Additional software components, such as blood flow detection, allow for easy assessment of dissections and stent apposition. The versatility of IVUS allows for utilization from multiple access points including a contralateral, ipsilateral, antegrade, or pedal approach.

In a normal artery, the various vessel wall components reflect ultrasound waves differently depending on their composition. Reflections from collagen and elastin are stronger than smooth-muscle cells which allow for discernment of the three arterial wall layers: the tunica intima, the tunica media, and the tunica adventitia. Smooth muscle cells comprising the tunica media does not reflect ultrasound waves well and so this component appears dark in the gray-scale cross-sectional image, permitting easy identification. Using post-processing algorithms, IVUS also can characterize and quantify plaque using the echogenic signature of the image. IVUS assessment can distinguish between calcified plaque and lipid, sub-classifying plaque into four major categories: fibrous, fibro-fatty, necrotic-lipid and calcific.[13]

Current state of the role of IVUS in the management of peripheral arterial disease

IVUS use in aortic and aortoiliac interventions

IVUS has become an integral component of the endovascular management of aortic aneurysms. It represents an intra-operative adjunctive tool to plan for and assess the accuracy of endovascular repair. In endovascular aneurysm repair (EVAR) and thoracic endovascular aneurysm repair (TEVAR) procedures, IVUS is commonly being used to accurately size stent grafts and aid in their placement.[14]

IVUS enables a full evaluation of the ascending arch and thoracoabdominal aorta. It permits imaging of the vessel wall with identification of branch vessel landmarks and adequate sizing of the proximal and distal landing zones. In addition to sizing, IVUS can help assess the correct location of an aneurysm, it can detect the presence and extent of a dissection flap, the presence and volume of thrombus[14], and can differentiate between true and false lumen.15 IVUS has also been shown to reduce contrast agent load without radiation exposure during EVAR and TEVAR procedures, which is critical in patients with compromised renal function.[16,17,18,19] Because of the real-time and dynamic evaluation benefits of IVUS, several authors have proposed IVUS as the single diagnostic tool in EVAR procedures.[16,17,19]

Early studies have shown that IVUS may also aid in the endovascular treatment of atherosclerotic aortoiliac occlusive disease as well. Arko et al demonstrated that vessel diameter was underestimated 62% of the time by angiography and that 40% of stents placed in the iliac arterial system were under deployed, which might be related to treatment failure.[20,21,23] The use of IVUS may also improve long-term clinical outcomes. In patients treated with angioplasty and stenting for aortoiliac occlusive lesions, those who received IVUS and angiographic imaging to evaluate stent deployment had 100% Kaplan-Meier (KM) primary patency at 6 years compared to 69% in patients who received angiographic imaging alone ($P<0.001$).[22] Together, this data demonstrates that IVUS can provide valuable information related to diagnosis and treatment that can alter pre-procedure planning and subsequent conduct of endovascular procedures.

IVUS use in peripheral (infrainguinal) interventions

As with the aortic vasculature, IVUS has the capacity to define atherosclerotic plaque morphology and eccentricity with high precision in the infrainguinal vessels. IVUS can provide additional information such as accurate assessment of percent stenosis, thrombus, real time vessel diameters, presence and degree of dissection, and location of side branches.

Vessel sizing and lesion severity

Atherosclerotic plaque can accumulate in different shapes and lengths depending on spatial location and composition and can be classified as concentric or eccentric. Angiographic methods can misrepresent plaque shape and volume due to the limitations of 2D imaging.[24] Since most atherosclerotic lesions are eccentric within the vessel, multiplanar angiographic views would be needed to accurately evaluate the degree of stenosis, requiring higher amounts of contrast administration and radiation exposure. With the intraluminal images that IVUS produces, the true lumen can be assessed allowing for identification of plaque architecture and volume. This allows for a more accurate measure of the degree of stenosis compared with angiography.[7,8,25]

Calcium appraisal

The presence of severe calcification can increase the complexity of a procedure and yield a high rate of complications. Calcium patterns and distribution in the vessel wall and balloon sizing have been shown to play a factor in the amount of vessel damage after balloon angioplasty[27] which may affect long-term patency. Calcified plaque can be identified on IVUS images by highly echogenic areas which appear bright white in the gray scale ultrasound image.

There is evidence to suggest that calcification in peripheral arteries is more accurately assessed by IVUS than angiography alone. Kashyap et al demonstrated that angiography underestimated plaque calcification compared with histology specimens and that the inability of angiography to quantify calcification can lead to subjective interpretation.[7] When angiography and IVUS were used to assess calcium in 47 patients participating in a calcium study, IVUS detected calcium in 44/47 lesions (93.6%) while angiography only detected calcium in 26/47 lesions (55.3%, P<0.001).[26]

Adequate vessel sizing and calcium assessment with IVUS can help guide the treatment strategy which may contribute to improved outcomes.

Technical guidance during interventions

Beyond assessment of the vessel and lesion characteristics, IVUS can provide additional information related to the intravascular procedure that adds to the technical guidance for stenting, balloon angioplasty, and atherectomy.

The EPISODE study (Evaluation of Peripheral Intravascular Sonography on Dotter Effect) was designed to determine whether IVUS data on morphological and quantitative parameters can be predictive of outcomes.[28] In 39 patients who received IVUS imaging before and after PTA in the superficial femoral artery (SFA), IVUS measurements of the extent of dissection, lumen area and diameter were determined to be predictive factors of patency.[28]

Stenting of infrainguinal arterial lesions has been a critical component of PAD treatment. Immediate and long-term patency of stented lesions are directly related to proper stent deployment including full stent expansion, complete stent apposition, and full lesion coverage during stent placement.[29,30] If the stent is not fully apposed to the vessel wall, thrombus and fibrin can accumulate in this space which may result in acute stent thrombosis or lesion restenosis.[22] If drug coated balloons or stents are under-expanded or have incomplete apposition, this can lead to the delivery of sub-therapeutic drug concentrations and incomplete inhibition of smooth muscle cell proliferation. Conversely, stent oversizing can increase the potential for vessel perforation or rupture. In a retrospective analysis of 1645 limbs from 1329 consecutive PAD patients with TASC II class A to C lesions who received femoropopliteal stenting, the use of IVUS was associated with a significantly higher primary patency rate compared with those that did not have IVUS (P<0.001).[31] This difference persisted despite a more complex patient cohort receiving IVUS imaging compared to those without IVUS imaging.

IVUS can also be beneficial during atherectomy procedures. Angiography has limited ability to differentiate whether the increase in lumen diameter is due to plaque removal or vessel wall expansion. IVUS imaging can quantify area and thus can confirm the results of plaque removal during atherectomy.[32] IVUS is also able to provide guidance during atherectomy with respect to blade orientation to maximize plaque removal. It is also possible to assess the extent of vascular injury resulting from certain types of atherectomy, seen on IVUS as adventitial cuts. IVUS can also help mitigate vessel perforation and reduce inadequate debulking with its real-time imaging capability.[33]

Detection of dissection

Severe dissections (characterized as type C or greater by the NHLBI coronary artery dissection classification system) are associated with significantly increased rates of restenosis and target lesion revascularization (TLR).[34,35] Dissections have historically been assessed by angiography. However, angiography has been found to underestimate the number and severity of dissections and can fail identify deep dissections involving the media or adventitia.[36,37,38] It is suggested that deeper dissections are likely to trigger a cascade of restenosis and larger flaps can fall within the lumen and cause acute or subacute thrombotic events.[39] A study using the iDissection classification by Shammas et al, which combined both the depth of injury from intima to adventitia and the circumference of dissection as seen on IVUS, demonstrated that IVUS can identify 4–6 times more dissections than angiography.[38] Following angioplasty, the extent of dissections identified with IVUS is a predictive factor of patency.[28] Emerging evidence suggests that the identification of dissections after infrainguinal endovascular intervention may drive treatment strategy which can significantly impact clinical outcomes.

Despite the potential clinical benefits of IVUS, level 1 evidence supporting the use of IVUS in peripheral intervention is limited. However, a recent randomized controlled trial (RCT) in Australia was conducted to fill this information gap. In this RCT by Spark et al, 150 subjects were enrolled and randomized into two groups: a treatment group (those that had IVUS imaging performed with results available to the surgeon) and a control group (those who IVUS imaging performed but the results were not available to the surgeon and therefore treatment is based on angiography alone).[40] The primary endpoint was binary restenosis (defined as >50% stenosis according to established imaging criteria) at one year. Secondary endpoints included TLR and amputation. Preliminarily results in 91 patients suggest that angiographic and IVUS vessel size estimation vary, with angiography underestimating the overall extent of disease extent. Notably, these interim results have showed that the addition of IVUS imaging led to a change of treatment strategy in 79% of cases. Additionally, there was a significant difference in primary patency at 18 months between the treatment and control group, 83.0% vs 63.3%, respectively (P<0.015). There was also a difference in freedom from TLR between the two groups at 18 months with 93.6% in the treatment group compared to 84.1% in the control group, however this did not reach statistical significance (P<0.015). The interim results of this study suggest that IVUS provides a more accurate assessment of disease severity and vessel size, that the addition of IVUS information changes the treatment plan, and there are improved patency rates with combined IVUS and angiography.[40]

Impact of IVUS use on cost

At present, IVUS imaging during hospital-based procedures in the US is reimbursed under a bundled type of payment system (DRG, APC). However, IVUS imaging is paid as a separate procedure in office-based lab settings. Because the cost is additive to the hospital, there is a dis-incentive to utilize the device to protect profit margins.

A cost-effective analysis by Panaich et al that examined data from a nationwide inpatient sample on the use of IVUS in lower limb interventions showed that IVUS is predictive of lower post-procedural complications and amputation rates, while the hospital cost of using IVUS is non-significant.[41] Conversely, other studies have indicated IVUS may add a significant cost to a procedure.[42] For example, Buckley et al presented that the combined added cost-per-case at their center for IVUS (inclusive of technician and equipment) was approximately $1,080. Considering the current IVUS reimbursement at the time was less than the cost of the disposable catheter-delivered transducer, this would be a substantial added cost. However, Buckley hypothesized that if one considers that the expense associated with the salvage of an endovascular intervention once it has failed is estimated to be approximately $12,000 to $15,000, and if the use of IVUS could improve outcomes so that such failures would be less common, than the money saved from not performing additional interventions would have pay for itself.[22]

Limitations/barriers of IVUS use

IVUS is utilized infrequently in peripheral arterial interventions performed in the United States and EU. Several barriers of wider adoption of IVUS may include the following:

- Although observational and retrospective studies indicate a high rate of patency and freedom from revascularization with the use of IVUS as an adjunctive imaging modality, data from prospective, randomized trials linking clinical utility and cost-effectiveness of IVUS are lacking.
- A standard algorithm which encompasses IVUS use within peripheral interventions to optimize long-term outcomes has not been developed despite the availability of data that demonstrates significant improvement in acute procedural results and short- and mid-term outcomes.
- IVUS requires additional time, training, and resources. It requires a level of expertise in image interpretation that may not be available in all centers. Physicians, nurses, and technicians starting to use IVUS are subject to a learning curve to properly interpret the images generated and maximize the usefulness of the technology.
- A perceived limitation is time. However, with an experienced team, the additional time associated with IVUS use during an intervention is nominal.
- There can be substantial upfront cost comprising the cost of the system, disposable catheters, technician resources, and training. However, once the diagnostic competence, technical guidance and success rates are achieved, there may be a realized cost savings in the prevention of reintervention.

Final points

IVUS serves three important clinical purposes—diagnosis, guiding the interventional treatment, and optimizing the therapy in peripheral artery disease.

The assessment and visualization of plaque can help optimize the choice of vessel preparation and treatment strategy.

IVUS plays a critical role in identification of post-procedural dissections and other vascular injuries of concern that are not easily picked up by angiography alone.

IVUS use can lead to a decrease in the amount of contrast used and its associated complications in peripheral vascular procedures.

Comparison of imaging modalities in lower extremity artery disease

Imaging methods	Description	Availability	Cost	Strengths	Weaknesses	Risks/complication
Duplex ultrasound	Duplex ultrasonography uses the combination of gray scale (B-mode) for vessel morphology and color pulsed-wave Doppler techniques.	+++	+	Non-invasive Anatomic location/ degree of stenosis Hemodynamic information Restenosis Routine surveillance of patency	Multilevel stenosis Heavily calcified vessels Non visualization of iliac segments Differentiation of high-grade stenosis vs total occlusion	None
CTA (Computed Tomographic Angiography) / MD CTA (Multi-Detector Computed Tomographic Angiography)/MS CTA (Multi-Slice Computed Tomographic Angiography)	Non-invasive vessel imaging taken in multiple frames for a given time period with a contrast agent flowing (through vein) to allow visual differentiation from the surrounding anatomy. Rapid acquisition of <5min. Acquires volume data with 3D reconstructed images. Acquires multiple slices simultaneously and has more coverage of the patient and high spatial resolution.	++	++	Initial diagnostic modality for pre-procedure planning (Road mapping) Anatomic location of significant stenosis (≥50%) Eccentric lesions In-stent restenosis Calcified lesions Detection of unsuspected lesions (stenoses, aneurysms, or dissections)	Volume rendering and other parameters require time for processing Overestimate stenosis severity in presence of calcium	Contrast nephropathy Excessive radiation exposure Allergic reaction
MRA (Magnetic Resonance Angiography)	MRA compares the difference in T1 relaxation times of blood and the surrounding tissues following a rapid bolus infusion of a paramagnetic contrast agent. Infinite planes and orientations can be constructed. Acquisition time of >20min.	++	+++	Plaque morphology Plaque volume Anatomic location/ degree of stenosis	In-stent restenosis May overestimate degree of stenosis Some Pacemakers, cochlear implants, capped pacemaker leads, and other devices are absolute contraindications Heavily calcified vessels	Nephrogenic systemic fibrosis
DSA (Digital Subtraction Angiography)	Similar to conventional angiography, however it may require substantially more radiation. The computerized subtraction of the pre-contrast image from the post-contrast image results in an image with the contrast-filled vessels only.	+++	+++	Gold standard (Established modality) Initial diagnostic modality for pre-procedure planning (Road mapping) In-stent restenosis Hemodynamic information	Plaque morphology Eccentric lesions Underestimates degree of calcification Underestimates degree of stenosis Lumen characteristics	Access site complications Allergic reaction Contrast nephropathy Radiation exposure
IVUS (Intravascular Ultrasound)	IVUS uses a piezoelectric transducer located at the distal end of the catheter that generates sound waves when electrically stimulated. These waves propagate into different tissues and thus produce a reflection image based on the acoustic properties of that tissue.	++	++	Plaque morphology Vessel sizing Degree of stenosis Degree of calcium Stent deployment and apposition Lumen characteristics Dissections Potential for reduction of radiation exposure	Perceived increased procedure time Adoption curve for image interpretation	None Adjunct to angiography

Summary of current evidence for IVUS use in peripheral arterial disease

IVUS in PAD: stenting						
Author	**Journal**	**Objectives**	**Study design**	**Patients**	**Population**	**Conclusions**
Buckley (2002)[23]	J Vasc Surg	The purpose of this study was to determine whether the use of IVUS increased long-term patency of this intervention	Retrospective	N = 52 (36 IVUS)	Patients with symptomatic aortoiliac occlusive disease underwent balloon angioplasty with primary stenting.	IVUS significantly improved the long-term patency of iliac arterial lesions treated with balloon angioplasty and stenting by defining the appropriate angioplasty diameter endpoint and adequacy of stent deployment.
Iida (2014)[33]	J Endovasc Ther	To investigate whether use of intravascular ultrasound (IVUS) improves primary patency following nitinol stenting for TASC II (TransAtlantic Inter-Society Consensus) A-C femoropopliteal lesions	Retrospective	N = 468 (234 IVUS)	Patients with TASC II class A to C lesions who underwent EVT with provisional nitinol stent- ing	IVUS use in femoropopliteal stenting for TASC II A–C lesions appears to be associated with higher primary patency rate. IVUS use was associated with a significantly higher 5-year primary patency (65 ± 6% vs. 35 ± 6%, P < 0.001) rate, better freedom from any adverse limb event rate (P < 0.001) and better event-free survival rate (P < 0.001) IVUS resulted in significantly better assisted primary patency (p<0.001), secondary patency (p=0.004), and freedom from any reintervention (p <0.001). IVUS use in femoropopliteal stenting for TASC II A–C lesions appears to be associated with higher primary patency rate.
Kamakura (2015)[45]	JACC Cardiovasc Interv	To evaluate 15-year patency and life expectancy after EVT with primary stenting guided by IVUS for iliac artery lesions.	Prospective	N = 455	Patients receiving primary stenting for symptomatic aortoiliac lesions.	IVUS had favorable 15-year patency in all TASC categories. In Cox multivariate analysis, post-procedural minimal luminal area (MLA), in-stent thrombosis, discontinuation of antiplatelet therapy, and calcified lesions were independent predictors of primary patency. The high-resolution cross-sectional IVUS image clearly identifies in-stent thrombosis and calcification.
Mori (2015)[46]	J Endovasc Ther	To investigate the relationship between post-procedure IVUS findings and restenosis after placement of DES for femoropopliteal (FP) lesions.	Retrospective	N = 40	Patients treated with IVUS-guided DES for FP lesions	IVUS guidance of drug-eluting stent (DES) placement in FP lesions can offer useful predictors of restenosis at 1 year. With angiography, the measured vessel diameter varies according to the calibration point and X-ray source. Because IVUS measures the reference vessel diameter more accurately, this diameter becomes a useful predictor of restenosis.

Raney (2015)[47]	Catheter Cardiovasc Interv	To evaluate the outcomes of IVUS-directed endovascular exclusion of popliteal artery aneurysm (PAA) using stent grafts.	Retrospective	N = 7	Patients with stent treatment for PAAs	The use of IVUS for the endovascular treatment of PAA ensures excellent outcomes with minimal additional risk and time to the procedure. Authors were able to use IVUS successfully in all cases to accurately assess the dimensions and length of the PAA, as well as the diameter of the reference vessel/ desired landing zones. Co-registration of IVUS and fluoroscopic images was easily achieved using a simple radiopaque ruler. Additional information was obtained without any additional contrast administration or significant radiation.
Iida (2016)[48]	J Vasc Surg	To investigate the incidence and risk factors of the repetition of endovascular therapy (EVT) after DES implantation for FP lesions in patients with symptomatic PAD.	Prospective	N = 495	Patients with preoperative IVUS imaging before DES implantation for FP lesions	Small external elastic membrane area (as evaluated by IVUS) was independently associated with reintervention after DES implantation.
Miki (2016)[49]	Heart Vessels	To analyze IVUS predictors of long-term patency following stent implantation in the aorto-iliac artery lesion.	Retrospective	N= 122	Patients who underwent primary stenting for aortoiliac artery lesions	Small post-procedural minimal stent area (MSA) and the presence of stent edge dissection were strongly associated with TLR after self-expanding nitinol stent implantation for de novo iliac artery lesions. Only 19.5 % of IVUS-identified stent edge dissections were detected on angiography after stenting. This may suggest that IVUS-guided identification of stent edge dissection is useful in the clinical setting to prevent TLR.
Miki (2016)[61]	J Endovasc Ther	To identify IVUS measurements that can predict angiographic ISR following nitinol stent implantation in SFA lesions.	Retrospective	N = 78	Patients who received self-expanding BMS or DES as treatment for SFA lesions	IVUS-derived postprocedure MSA <15 mm2 can also predict angiographic restenosis following stent implantation for SFA lesions; no angiographic measurement emerged as a predictor of restenosis. These results might explain why IVUS-detected edge dissections had no impact on angiographic restenosis in the present study. Postprocedure MSA can predict ISR in SFA lesions, which suggests that adequate stent enlargement during angioplasty might be required for superior patency.
Kurata (2017)[50]	Circ J	To evaluate stent-to-vessel ratio in SFA lesions on IVUS, and to investigate the impact of this ratio on primary patency after sirolimus eluding stent (SES) implantation.	Retrospective	N = 117	Patients treated with IVUS-guided SES for symptomatic de novo SFA lesions	IVUS can provide the vessel diameter not only at the distal healthy site but also at the lesion site. An appropriate selection of stent size in reference to the vessel diameter would play an important role in ensuring better patency in de novo SFA intervention, and that the assessment of the vessel diameter at the lesion site would be more important than that at the distal healthy site.

Mori (2017)[51]	J Endovasc Thromb	To investigate the relationship between IVUS findings and restenosis after stent implantation for long, occlusive FP lesions using the intraluminal approach.	Retrospective	N = 45	Patients with 12-month follow-up after BMS implantation for long, occlusive FP lesions	If IVUS detects a proportion of the intramedial route within the chronic total occlusion (CTO) of 14.4% or a distal lumen CSA of 17.7 mm^2, restenosis is more likely.
Kurata (2019)[63]	J Vasc Interv Radiol	To investigate the rate and predictors of in-stent occlusion by intravascular ultrasound (IVUS) following femoropopliteal artery stent placement.	Retrospective	N = 162	Patients with peripheral artery disease who underwent endovascular therapy using self-expanding nitinol stents	Plaque burden >60% after stent placement as evaluated by IVUS was an independent predictor of in-stent occlusion and in-stent restenosis after fempop artery stent placement in symptomatic patients with PAD.
Miki (2020)[64]	J Endovasc Ther	To identify intravascular ultrasound (IVUS) findings that predict midterm stent patency in femoropopliteal (FP) lesions.	Retrospective	N = 274	Patients who had IVUS assessment before and after successful stent implantation	Patency rates in CTOs (80%) were in line with previously reported real-world registries. IVUS measurements can be considered a reasonable treatment option in FP lesions.

IVUS in PAD: CTO						
Author	**Journal**	**Objectives**	**Study design**	**Patients**	**Population**	**Conclusions**
Kawasaki (2008)[62]	Catheter Cardiovasc Interv	To demonstrate the safety and feasibility of IVUS-guided EVT for CTO of the iliac and/or FP arteries using Treasure 12, a stiff guidewirefor peripheral CTO in monodirectional approach setting.	Retrospective	N = 47	Patients with iliac or FP CTO undergoing EVT	IVUS-guided technique is helpful for saving the volume of contrast material. Authors' new technique dramatically reduced the volume of contrast material compared to the standard technique. IVUS-guided EVT should be useful, especially for patients complicated with renal insufficiency. IVUS-guided EVT is feasible and safe.
Takahashi (2017)[52]	J Endovasc Ther	To investigate the 1-year outcomes of transvenous IVUS-guided EVT for CTOs of the lower extremity arteries.	Retrospective	N = 44	Patients undergoing IVUS-guided EVT for peripheral CTOs (74% in the SFA)	Transvenous IVUS guidance is a safe technique and can provide optimal short-term results for CTO recanalization in the FP segment. IVUS-guided EVT facilitated intimal tracking and increased the potential for antegrade guidewire crossing. It visualized the occlusion from the SFA to the tibioperoneal trunk and optimized manipulation of the guidewire in the CTO. It would also appear to lower the risk of arterial perforation arising from subintimal balloon dilation or stent deployment. These results suggest that transvenous IVUS-guided EVT is useful even in cases with moderate or severe calcification.
Tomoi (2020)[53]	J Endovasc Ther	To examine with intravascular ultrasound (IVUS) the crossing pathways of the TruePath reentry device during primary antegrade recanalization of infrainguinal chronic total occlusions (CTOs)	Prospective	N = 143	Patients with CTOs treated in an antegrade approach using the TruePath reentry device with IVUS assessment of the crossing pathway	The intraplaque route was the primary pathway taken by the TruePath reentry device as it crossed infrainguinal CTOs. A longer CTO length and a failed revascularization history negatively affected the success rate.

Krishnamurthy (2010)[54]	Ann Vasc Surg.	To describe the benefits of using true lumen reentry devices to improve the success and safety of conventional subintimal recanalization for revascularization of CTO of the iliac arteries.	Retrospective	N = 11	Patients with CTO of the iliac arteries	True lumen entry devices greatly improve the technical success and safety of recanalization in CTO.
Saket (2004)[55]	J Endovasc Ther.	To report our experience using a commercially available catheter-based system equipped with an intravascular ultrasound (IVUS) transducer to achieve controlled true lumen re-entry in patients undergoing subintimal angioplasty for chronic total occlusions (CTO) or aortic dissections.	Prospective	N = 10	Patients with CTO	IVUS guidance of reentry in CTO's are feasible.
Baker (2015)[56]	Ann Vasc Surg	To describe the technical aspects and longitudinal follow-up after intravascular ultrasound-guided reentry of iliac and infrainguinal CTOs.	Retrospective	N=40 (20 IVUS)	Patients with lower extremity CTO treated with reentry devices (IVUS-RED)	Recanalization of CTO using IVUS-RED is safe and effective. Use of IVUS-RED does not adversely impact outcomes in conjunction with other endovascular techniques. Early follow-up demonstrates acceptable patency, especially in patients with claudication, and freedom from reintervention.
Miki (2020)[54]	J Endovasc Ther	To identify intravascular ultrasound (IVUS) findings that predict midterm stent patency in femoropopliteal (FP) lesions.	Retrospective	N = 274 CTO were present in 127 (38%) of enrolled patients	Patients who had IVUS assessment before and after successful stent implantation	Patency rates in CTOs (80%) were in line with previously reported real-world registries. IVUS measurements can be considered a reasonable treatment option in FP, including CTO lesions.
Sangera (2020)[69]	Cardiovasc Revasc Med	To examine the efficacy and safety of the facilitated intravascular ultrasound (IVUS)-guided balloon assisted-re-entry (FIBRE) technique in the treatment of complex, chronic total occlusion (CTO) peripheral arterial lesions.	Retrospective	N = 10	Patients with complex CTOs were identified using the FIBRE technique	Visualizing the inflated balloon on ultrasound imaging allows for a more precise puncture without repeated attempts which could potentially traumatize the vessel. Intravascular ultrasound guided re-entry catheter balloon rupture technique may offer a safe alternative for difficult lesions.

IVUS in PAD: Atherectomy						
Author	**Journal**	**Objectives**	**Study design**	**Patients**	**Population**	**Conclusions**
Yin (2017)[28]	J Endovasc Ther	To validate 3 angiographic scoring systems for peripheral artery calcification using IVUS as the gold standard.	Retrospective	N = 47	Patients with severely calcified peripheral lesions with preprocedural angiography and IVUS data	Because of the low sensitivity of angiographic calcium detection and limitations to assessment of calcium location, calcium evaluation by intravascular imaging is warranted to evaluate the true effect of treatment strategies. Although the presence of calcium on one or both sides of the artery wall can be assessed by angiography, angiography cannot accurately identify intimal vs medial calcification because it provides only 2-dimensional images. Conversely, using IVUS assessment of calcium location, the current study found that the presence of superficial calcium was dominant in PAD. The thickness of calcium that may influence both the angiographic classification and the procedure outcomes cannot be measured by IVUS because of calcium-induced acoustic shadowing; however, superficial calcium, by definition, can be thicker than deep calcium. These findings apply only for the FP arteries and need further study to be applied to the infrapopliteal arteries.
Shammas (2018)[40]	J Invasive Cardiol	To evaluate if angiography underestimates the presence of dissections post atherectomy of the infrainguinal arteries compared with IVUS	Prospective	N = 15	Patients evaluated by intravascular ultrasound (IVUS) following treatment of femoropopliteal de novo or non-stent restenosis using atherectomy	Dissections post atherectomy are grossly under-appreciated on angiogram when compared to IVUS. The identification of deeper injury that cannot be seen on angiography may offer an explanatory mechanism for the occurrence of restenosis in otherwise successful procedures as seen on angiography following atherectomy. These deeper injuries were identified on IVUS.
Krishnan (2018)[57]	J Endovasc Ther	To compare 1-year outcomes for patients with femoropopliteal in-stent restenosis using directional atherectomy guided by intravascular ultrasound (IVUS) versus directional atherectomy guided by angiography.	Retrospective	N = 114	Patients with femoro-popliteal in-stent restenosis using directional atherectomy	

IVUS in PAD: BTK						
Author	**Journal**	**Objectives**	**Study design**	**Patients**	**Population**	**Conclusions**
Shammas (2020)[66]	J Endovasc Ther	To investigate if imaging with intravascular ultrasound (IVUS) yields a more accurate estimate of vessel diameter and the presence of dissections after intervention when treating the infrapopliteal arteries.	Prospective	N = 20	Patients with de novo disease or native vessel restenosis of the infrapopliteal arteries	Compared to IVUS, angiography underestimates the presence/ severity of dissections following PTA and orbital atherectomy, as well as underestimating the infrapopliteal diameter by ~25%.
Fujihara (2020)[67]	J Endovasc Ther	To compare chronic limb threatening ischemia (CLTI) patients who underwent IVUS-guided vs angiography-guided balloon angioplasty.	Retrospective	N = 216	Patients with CLTI who underwent successful endovascular therapy (EVT) for below the knee (BTK) lesions	Technical success or complications rates were similar between IVUS-guided vs angiography-guided balloon angioplasty groups. Between propensity scored matching cohorts, the IVUS-guided group had a significantly shorter time to wound healing than the angiography-guided group, although there was no difference in freedom from clinically driven target lesion revascularization (CD-TLR) or limb salvage rates. IVUS guidance of endovascular procedures has the potential to influence better clinical outcomes than angiography-guided angioplasty. IVUS-guided interventions for BTK lesions are safe and effective in accurately assessing the lesions.
Soga (2020)[68]	Catheter Cardiovasc Interv	To estimate the impact of intravascular ultrasound (IVUS) in patients with chronic limb-threatening ischemia (CLTI) who underwent balloon angioplasty for isolated infrapopliteal lesion.	Retrospective	N = 155	Patients who primarily underwent balloon angioplasty for de novo isolated infrapopliteal atherosclerotic lesions	Limb salvage rate without any reintervention in IIVUS guided balloon angioplasty group was significantly higher than that in angio-guided balloon angioplasty group (p=0.028). Wound healing was significantly earlier (p=0.013) and time to wound healing was significantly shorter in the IVUS-guided group (84 ±55 days vs 135±118 days, p=0.007). IVUS use was an independent factor associated with better limb salvage without any reintervention (primary outcome) Study suggests that angiography underestimates vessel diameters in infrapopliteal arteries. Assessing the actual vascular diameter via IVUS makes it possible to select the optimal size of balloon diameter, thereby obtaining sufficiently safe gain which allows shortened wound healing period and better limb salvage without reinterventions.

IVUS in PAD: Contrast exposure						
Author	**Journal**	**Objectives**	**Study design**	**Patients**	**Population**	**Conclusions**
Kawasaki (2008)[62]	Catheter Cardiovasc Interv	To demonstrate the safety and feasibility of IVUS-guided endoluminal EVT for CTO of the iliac and/or FP arteries using Treasure 12, a stiff guidewire for peripheral CTO in monodirectional approach setting.	Retrospective	N = 47	Patients with iliac or FP CTO undergoing EVT	IVUS-guided technique is helpful for saving the volume of contrast material. Authors' new technique dramatically reduced the volume of contrast material compared to the standard technique. IVUS-guided EVT should be useful, especially for patients complicated with renal insufficiency. IVUS-guided EVT is feasible and safe.
Kawasaki (2011)[58]	Circ J	To perform without nephrotoxic contrast media both the preprocedural evaluation and endovascular therapy for stenotic or occlusive lesions of the iliac and/ or femoral arteries in patients with preexisting renal insufficiency.	Prospective	N = 36	Patients with chronic renal insufficiency and lower limb ischemia undergoing EVT in the iliofemoral segment	Authors' comprehensive EVT that includes duplex, MRA, and CT for preprocedural evaluation and an IVUS-guided procedure is feasible and may avoid intra-arterial contrast injection in selected patients deemed at high risk for renal failure from nephrotoxic contrast material. Caution should be exercised with IVUS-guided EVT until more data are collected. Meanwhile, patients who are severely allergic to contrast media or have renal insufficiency may benefit from proposed approach. There was no difference in fluoroscopic time and radiation exposure dose between the IVUS-guided EVT without contrast media and conventional IVUS-guided EVT with contrast media. IVUS-guided EVT allows constant real-time monitoring of the guidewire's location in the occluded arterial segment.

IVUS in PAD: Health economics						
Author	**Journal**	**Objectives**	**Study design**	**Patients**	**Population**	**Conclusions**
Makris (2017)[45]	Int Angiol	To explore the utility of IVUS in the guidance of lower limb revascularization procedures in patients with PAD and its potential contribution in prolonging the durability of this therapeutic approach.	Systematic review of PubMed and Scopus databases, according to PRISMA guidelines	N = 2,258 patients from 13 studies	Clinical studies evaluating IVUS as an adjunct to angiography during revascularization procedures in patients with PAD	2 studies suggested that IVUS adds additional cost to a revascularization procedure, with an increase that ranges between from $1080 to $1333; the medical costs were higher with IVUS guidance versus angiography alone during PAD procedures. The use of disposable catheter-delivered transducers, the expensive equipment and an experienced technician who may be necessary for the operation of IVUS system are the main factors responsible for the increased procedural costs of this technique. The cumulative costs [of using IVUS] are only slightly higher ranging from 1% to 7.8% due to the lower number of revascularizations and the decreased length of hospital stay in the IVUS guided endovascular interventions. IVUS used with reentry devices appear to be cost-effective since there is a reduction in the utilization of resources. Furthermore, the use of these devices lowers the risk of periprocedural complications that are related to prolonged operation times. In 5 studies that investigated the use of IVUS reentry devices, no significant periprocedural or postprocedural complications were reported. Further prospective clinical trials are required to elucidate the optimal role of IVUS in PAD as well as the cost effectiveness of this approach for routine use in the management of PAD.
Panaich (2016)[43]	Endovasc Ther	To evaluate the utility of IVUS in peripheral interventions in terms of amputation rates and postprocedural complications and to determine the impact of IVUS use on hospitalization costs.	Retrospective	N = 92,714 (1299 IVUS)	Patients who underwent lower limb endovascular interventions (with or without IVUS)	Patients who underwent lower limb endovascular interventions (with or without IVUS)
Buckley (2002)[23]	J Vasc Surg	The purpose of this study was to determine whether the use of IVUS influenced the long-term patency of aortoiliac occlusive lesions treated with balloon angioplasty and primary stenting.	Retrospective, single-center, review of a prospectively maintained registry.	N = 52	Patients with symptomatic aortoiliac occlusive disease	The use of IVUS adds additional cost to an endovascular procedure. The combined added cost-per-case for IVUS would then equal $1080. If intervention failure is estimated to be approximately $12,000 to $15,000, the use of IVUS to salvage early failures at the time of initial treatment, it would have paid for its use in all 52 patients.

Abstracts

Intravascular ultrasound predictors of restenosis after balloon angioplasty of the femoropopliteal artery

A van der Lugt , E J Gussenhoven, G Pasterkamp, T Stijnen, J A Reekers, F G van den Berg, A V Tielbeek, J L Seelen, H Pieterman

Eur J Vasc Endovasc Surg. 1998 Aug;16(2):110-9. doi: 10.1016/s1078-5884(98)80151-2. PMID: 9728429.

https://pubmed.ncbi.nlm.nih.gov/9728429/

Study design	Objectives	Patients	Population
Prospective Multi-Center Single arm	Determine the value of intravascular ultrasound restenosis following PTA of the femoropopliteal artery	N = 137	Patients referred for PTA of symptomatic obstructive disease of the femoropopliteal artery

Objective

To determine intravascular ultrasound parameters related to restenosis following percutaneous transluminal balloon angioplasty (PTA) of the femoropopliteal artery. Clinical, angiographic and intravascular ultrasound data obtained before and after PTA were evaluated to identify parameters associated with the outcome of PTA.

Methods

Patients were studies with intravascular ultrasound before and after angiographic successful PTA (n = 114). Intravascular ultrasound cross-sections obtained with 1 cm interval in the dilated segment were analyzed. A distinction was made between anatomic (duplex scanning) and clinical (Rutherford criteria) restenosis assessed within 1 month and at 6 months after PTA.

Results

Intravascular ultrasound predictors of 1 month anatomic outcome were lumen area stenosis after PTA, lumen area increase, plaque area decrease, and area stenosis decrease; predictor of 6 months anatomic outcome was area stenosis after PTA. Multivariate analysis revealed that area stenosis after PTA was the only independent predictor of both 1 and 6 months anatomic outcome. Intravascular ultrasound predictors of 1-month clinical outcome were the presence of hard lesion and the mean arc of hard lesion. Multivariate analysis revealed that the mean arc of hard lesion was the only independent predictor of 1-month clinical outcome. No predictors for 6 months clinical outcome was found

Conclusions

Intravascular ultrasound can elucidate parameters predictive of restenosis after PTA. The strongest intravascular ultrasound parameter predictive of anatomic restenosis was a large area stenosis after PTA.

Philips key takeaways

Most of the significant intravascular ultrasound predictors were related to 1-month outcome, while the predictive power of intravascular ultrasound parameters for outcome at 6 months was limited.

The independent intravascular ultrasound predictors of early restenosis (1-month) was smaller lumen area, larger residual area stenosis seen after PTA, extensive hard lesion (calcification) seen before PTA, media rupture and dissection.

However, the presence and extensive calcification were not predictors for late restenosis.

Dissections after PTA was significantly larger in procedures with late restenosis than in procedures with late success

The present study is limited by the absence of angiographic follow-up at 6 months.

Intravascular ultrasound validation of contemporary angiographic scores evaluating the severity of calcification in peripheral arteries

Da Yin, Akiko Maehara, Thomas M Shimshak Joseph J Ricotta 2nd , Venkatesh Ramaiah , Malcolm T Foster 3rd, Thomas P Davis, Mitsuaki Matsumura, Gary S Mintz , William A Gray

J Endovasc Ther. 2017 Aug;24(4):478-487. doi: 10.1177/1526602817708796. Epub 2017 May 15. PMID: 28504047.

https://pubmed.ncbi.nlm.nih.gov/28504047/

Study design	Objectives	Patients	Population
Retrospective Multi Center Review	To validate 3 angiographic scoring systems for peripheral artery calcification using intravascular ultrasound (IVUS) as the gold standard.	N=47	Patient who were treated with JetStream Atherectomy System in the treatment of symptomatic lower limb lesions (Rutherford category ≥1) with severe superficial calcification

Objective

To validate 3 angiographic scoring systems for peripheral artery calcification using intravascular ultrasound (IVUS) as the gold standard.

Methods

The study employed preprocedural angiography and IVUS data from 47 patients (median age 72 years; 34 men) in the 55-patient JetStream G3 Calcium Study (ClinicalTrials.govidentifier NCT01273623) to validate the 3 angiographic scoring systems [Peripheral Academic Research Consortium (PARC), Peripheral Arterial Calcium Scoring System (PACSS), and the DEFINITIVE Ca++ trial]. Preprocedural angiograms were analyzed using conventional quantitative vessel analysis software in 2 orthogonal views. Calcium length was evaluated by markers placed beside the artery during the procedure; calcium deposit(s) were assessed as being on one or both sides of the vessel wall. The 3 calcium scoring systems used these 2 basic angiographic elements to evaluate calcium severity. Based on these criteria, calcium severity varied from none to focal, mild, moderate, or severe in PARC; grade 0 to 4 in PACSS; and none, moderate, or severe in the DEFINITIVE Ca++ system. Calcium location on IVUS was classified as superficial, deep, or mixed. Lesion length was the segment between the most normal looking proximal and distal reference sites. Superficial, deep, and calcium length were based on motorized IVUS pullback.

Results

IVUS detected calcium in 44/47 (93.6%) lesions, and angiography detected calcium in 26/47 (55.3%) lesions (p<0.001). The sensitivity, specificity, positive predictive value, and negative predictive value of angiography relative to IVUS were 59%, 100%, 100%, and 14%, respectively. With increasing severity of angiographic calcium, there was a stepwise increase in the prevalence of IVUS superficial calcium and the maximum arc and length of superficial calcium. Using PARC criteria, with increasing severity of calcification, IVUS maximum calcium arc increased from 120° for none to 305° for severe (p<0.001); the length of calcium increased from 7 to 68 mm (p<0.001). Though a similar trend was seen in IVUS superficial calcium, it was not observed in IVUS deep calcium. Similar observations were seen when using the PACSS and DEFINITIVE Ca++ scoring systems.

Conclusions

IVUS confirmed that the PARC, PACSS, and DEFINITIVE Ca++ calcium scoring systems can be used to classify the degree of calcium in peripheral artery disease, especially superficial calcium.

Philips key takeaways

IVUS detected calcium in 44/47 (93.6%) lesions, and angiography detected calcium in 26/47 (55.3%) lesions ($p<0.001$).

With increasing severity of angiographic calcium, there was a stepwise increase in the prevalence of IVUS superficial calcium and the maximum arc and length of superficial calcium.

The sensitivity, specificity, positive predictive value, and negative predictive value of angiography relative to IVUS were 59%, 100%, 100%, and 14%, respectively.

IVUS confirmed that the PARC, PACSS, and DEFINITIVE Ca++ calcium scoring systems can be used to classify the degree of calcium in peripheral artery disease, especially superficial calcium.

Because of the low sensitivity of angiographic calcium detection and limitations to assessment of calcium location, calcium evaluation by intravascular imaging is warranted to evaluate the true effect of treatment strategies.

Philips key figures/tables

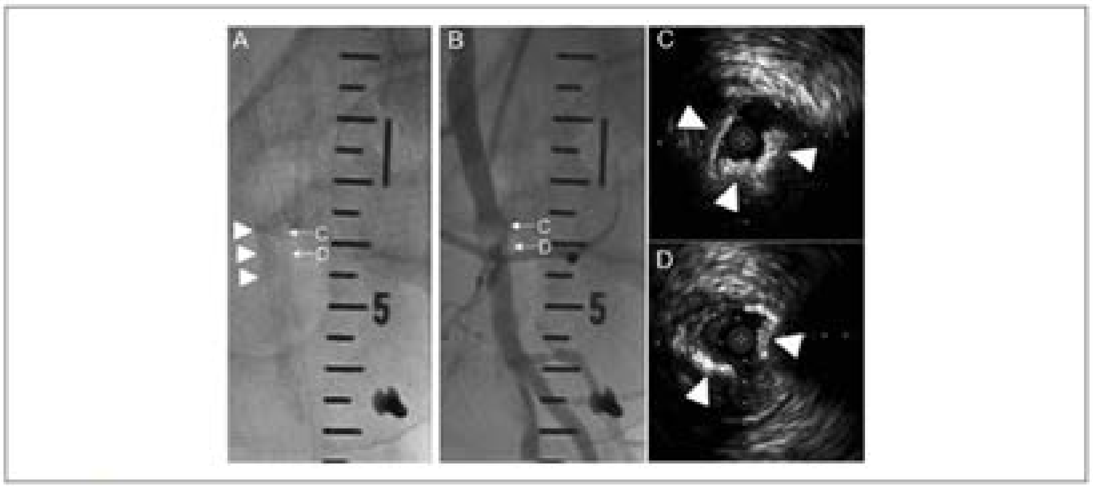


Figure 3. A representative case showing angiographic unilateral and bilateral calcification by intravascular ultrasound (IVUS). Angiography (A) with or (B) without contrast and (C, D) corresponding to IVUS images. Angiography showed unilateral calcification (white triangles), while IVUS showed 270° of calcium (white triangles) in (C) and 2 separate calcium deposits <90° (white triangles) in (D); both were defined as bilateral calcification by IVUS.

Efficacy of intravascular ultrasound in femoropopliteal stenting for peripheral artery disease with TASC II class A to C lesions

Osamu Iida, Mitsuyoshi Takahara, Yoshimitsu Soga, Kenji Suzuki, Keisuke Hirano, Daizo Kawasaki, Yoshiaki Shintani, Nobuhiro Suematsu, Terutoshi Yamaoka, Shinsuke Nanto, Masaaki Uematsu

J Endovasc Ther. 2014 Aug;21(4):485-92. doi: 10.1583/14-4721R.1. PMID: 25101575.

https://pubmed.ncbi.nlm.nih.gov/25101575/

Study design	Objectives	Patients	Population
Retrospective Multi-Center Review of REAL-FP database	To investigate whether use of intravascular ultrasound (IVUS) improves primary patency following nitinol stenting for TASC II (TransAtlantic Inter-Society Consensus) A–C femoropopliteal lesions.	N=965	All patients with TASC II A–C lesions (28% critical limb ischemia) treated by provisional stenting

Objective

To investigate whether use of intravascular ultrasound (IVUS) improves primary patency following nitinol stenting for TASC II (TransAtlantic Inter-Society Consensus) A-C femoropopliteal lesions.

Methods

Using a retrospective multicenter database of 1198 limbs from 965 patients (695 men; mean age 72±9 years) with TASC II A-C lesions (28% critical limb ischemia) treated by provisional stenting from April 2004 to December 2011, primary patency rate was compared between 234 propensity score-matched pairs with vs. without IVUS use.

Results

IVUS was used in 22% (n=268) of the overall population. It was more likely to be used in cases with generally more complicated femoropopliteal lesions (e.g., more severe TASC II class, longer lesion length, and narrower reference diameter). Analysis of the 234 propensity score-matched pairs (mean follow-up 1.9±1.5 years; 142 events) revealed higher 5-year primary patency with than without IVUS use (65%±6% vs. 35%±6%, $p<0.001$). IVUS resulted in significantly better assisted primary patency ($p<0.001$), secondary patency ($p=0.004$), freedom from any reintervention ($p<0.001$), freedom from any adverse limb event ($p<0.001$), and event-free survival ($p<0.001$).

Conclusions

IVUS use in femoropopliteal stenting for TASC II A-C lesions appears to be associated with higher primary patency rate.

Philips key takeaways

IVUS was used in 22% (268) of the overall population .

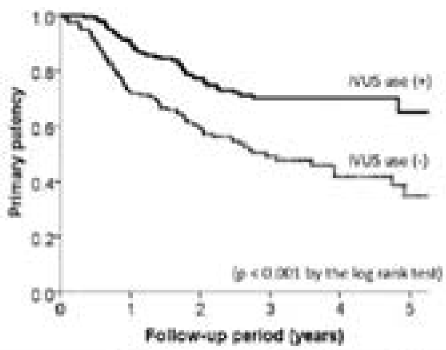
IVUS more likely to be used in cases with generally more complicated femoropopliteal lesions (e.g., more severe TASC II class, longer lesion length, and narrower reference diameter).

In the propensity score–matched groups, IVUS use was significantly associated with a higher primary patency rate in the lower limb arteries compared without IVUS. (65% vs. 35%, p<0.001).

IVUS resulted in significantly better assisted primary patency (p<0.001), secondary patency (p=0.004), freedom from any reintervention (p<0.001), freedom from any adverse limb event (p,0.001), and event-free survival (p<0.001).

IVUS use in femoropopliteal stenting for TASC II A–C lesions appears to be associated with higher primary patency rate.

Philips key figures/tables



		0 yr	1 yr	2 yr	3 yr	4 yr	5 yr
IVUS use(-)	No. at risk	234	126	74	37	20	9
	Rate±SE	100±0%	72±3%	60±4%	49±4%	42±5%	35±6%
IVUS use(+)	No. at risk	234	173	96	58	34	13
	Rate±SE	100±0%	90±2%	77±3%	70±4%	70±4%	65±6%

Figure 2 ◆ IVUS use was associated with a significantly higher primary patency rate than no IVUS use in TASC II class A–C femoropopliteal lesions (p<0.001 by log-rank test).

TABLE 2
Clinical Outcomes of Patients in the IVUS and No IVUS Groups

	No IVUS Use	IVUS Use	p
Primary patency	35%±6%	65%±6%	<0.001
Assisted primary patency	54%±6%	84%±3%	<0.001
Secondary patency	80%±7%	96%±2%	0.004
Freedom from surgical conversion	97%±1%	96%±4%	0.126
Freedom from any reintervention	54%±6%	84%±3%	<0.001
Freedom from major amputation	97%±2%	95%±2%	0.344
Freedom from MALE	95%±2%	91%±4%	0.839
Freedom from any adverse limb event	44%±6%	71%±5%	<0.001
Survival	79%±5%	84%±4%	0.321
Freedom from myocardial infarction	95%±2%	94%±3%	0.173
Freedom from stroke	93%±3%	97%±1%	0.316
Freedom from MACE	74%±5%	80%±4%	0.182
Amputation-free survival	78%±5%	82%±4%	0.443
MALE-free survival	76%±5%	79%±5%	0.280
Event-free survival	35%±5%	62%±5%	<0.001

Data are 5-year rate ± standard error as estimated by the Kaplan-Meier method; p values were calculated by the log-rank test.
MALE: major adverse limb events, MACE: major adverse cardiovascular events.

Evaluation of peripheral atherosclerosis: a comparative analysis of angiography and intravascular ultrasound imaging

Zachary M Arthurs, Paul D Bishop, Lindsay E Feiten, Matthew J Eagleton, Daniel G Clair, Vikram S Kashyap

J Vasc Surg. 2010 Apr;51(4):933-8; discussion 939. doi: 10.1016/j.jvs.2009.11.034. Epub 2010 Jan 15.

https://pubmed.ncbi.nlm.nih.gov/20080002/

Study design	Objectives	Patients	Population
Prospective Single-Center Case series	The goal of this study was to compare angiography to corresponding intravascular ultrasound (IVUS) imaging of the same vessels in patients with PAD	N=93	Patients undergoing angiography for PAD

Objective

Angiography remains a critical component for diagnostic imaging and therapeutic intervention in peripheral arterial disease (PAD). The goal of this study was to compare angiography with corresponding intravascular ultrasound (IVUS) imaging of the same vessels in patients with PAD.

Methods

From 2004 to 2008, 93 patients undergoing angiography for PAD were recruited in a prospective observational analysis. At the time of angiography, diseased lower extremities were interrogated using a 10-cm IVUS pullback with registration points. IVUS data were analyzed with radiofrequency techniques for vessel and lumen diameter, plaque volume, plaque composition, and cross-sectional area. Similarly, three vascular surgeons blinded to the IVUS data graded corresponding angiographic images according to vessel diameter, degree of stenosis, degree of calcification, and extent of eccentricity. Statistical analyses of matched IVUS images and angiograms were performed.

Results

The distribution of demographic and risk variables were typical for PAD: 54% male, 96% hypertension, 78% hyperlipidemia, 44% diabetic, 87% tobacco history, 65% coronary artery disease, and 10% end-stage renal disease. Symptoms precipitating the angiographic evaluation included claudication (53%), rest pain (18%), and tissue loss (29%). Angiographic and IVUS interpretation were similar for luminal diameters, but external vessel diameter was greater by IVUS imaging (7.0 +/- 0.7 vs 5.2 +/- 0.8 mm, $P < .05$). The two-dimensional diameter method resulted in a significant correlation for stenosis determination ($r = 0.84$); however, IVUS determination of vessel area stenosis was greater by 10% (95% confidence interval, 0.3%-21%, $P < .05$). IVUS imaging indicated that a higher proportion of plaques were concentric. Grading of calcification was moderate to severe in 40% by angiography but in only 7% by IVUS ($P < .05$).

Conclusions

In the evaluation of PAD, angiography and IVUS imaging provide similar luminal diameters and diameter-reducing stenosis measurements. Determination of overall vessel diameter and interpretation of plaque morphology by angiography are discordant from IVUS-derived data.

Philips key takeaways

Determination of overall vessel diameter, and interpretation of plaque morphology by angiography are discordant from IVUS derived data.

Angiographic and IVUS interpretation were similar for luminal diameters, but external vessel diameter was greater via IVUS (7.0 ± 0.7 vs.5.2 ± 0.8 mm, $P < 0.05$).

There was a significant correlation for stenosis determination ($r=0.84$) utilizing the two-dimensional diameter method; however, IVUS determination of vessel area stenosis was greater by 10% (95% confidence interval = 0.3–21%, $P<0.05$).

IVUS indicated that a higher proportion of plaques were concentric.

Grading of calcification was moderate/severe in 40% by angiography, but only 7% by IVUS ($P < 0.05$).

Philips key figures/tables

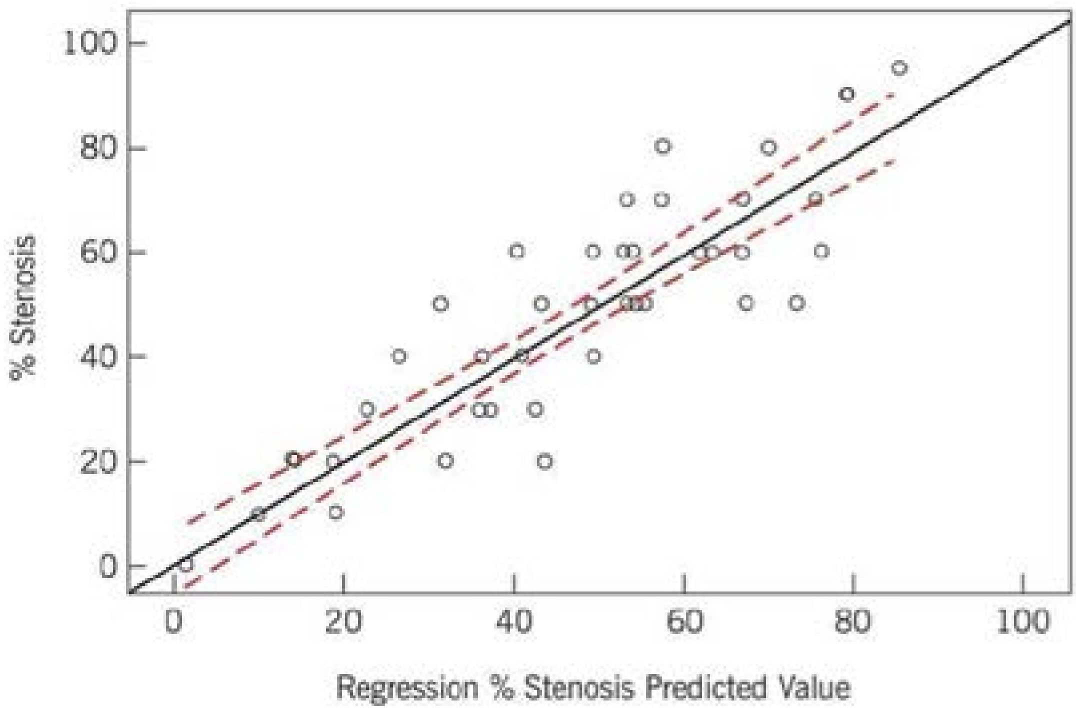


Figure 1 Inter-rater concordance among angiographic examiners for determining maximal percent stenosis. Open circles represent actual measured data points among examiners, and the solid black represents the linear regression through those points. The hashed red line represents the 95% confidence interval.

Table II A paired analysis of angiographic and intravascular ultrasound *(IVUS)* measurements in corresponding arterial vessel segments

Variable	Angiographic analysis	IVUS analysis		P [a]	r [b]
Proximal diameter, mm	5.5 ± 0.7	Lumen diameter	5.3 ± 0.9	.45	0.95
		Outer wall diameter	7.0 ± 0.7	<.05	0.28
Distal diameter, mm	5.2 ± 0.8	Lumen diameter	5.2 ± 0.9	.642	0.94
		Outer wall diameter	7.0 ± 0.7	<.05	0.31
Stenosis, %	46 ± 27	Diameter method	49 ± 25	.61	0.84
		Area method	55 ± 22	<.05	0.46

a Significance level of the paired *t* test for continuous variables and χ^2 analysis (or Fischer exact test where appropriate) for proportions.
b Correlation coefficient for the relationship between angiographic and IVUS measurements.

Table III A paired analysis of angiographic and intravascular ultrasound *(IVUS)* assessments of plaque characteristics in corresponding arterial vessel segments

Variable	Angiographic analysis	IVUS analysis		P [a]	r [b]
Length of stenosis, mm	14.3 ± 12	17.3 ± 13		<.05	0.60
Calcification				<.05	0.27
None	26%	Calcium 0%-5%	51%		
Mild	33%	5%-15%	42%		
Moderate	28%	15%-25%	7%		
Severe	12%	>25%	0%		

a Significance level of the paired *t* test for continuous variables and χ^2 analysis (or Fischer exact test where appropriate) for proportions.
b Correlation coefficient for the relationship between angiographic and IVUS measurements.

A prospective evaluation of using IVUS during percutaneous superficial femoral artery interventions

Elizabeth Hitchner, Mohamed Zayed, Vinit Varu , George Lee , Oliver Aalami , Wei Zhou

Ann Vasc Surg. 2015 Jan;29(1):28-33. doi: 10.1016/j.avsg.2014.07.026. Epub 2014 Sep 3. PMID: 25194552.

https://pubmed.ncbi.nlm.nih.gov/25194552/

Study design	Objectives	Patients	Population
Prospective Single-Center Case series	The aim of this study to determine whether intravascular ultrasound (IVUS) can help with residual disease assessment and procedure outcome.	N=95	Patients with primary SFA disease who underwent SFA intervention

Objective

The outcomes of endovascular interventions of the superficial femoral artery (SFA) are variable. Completion angiography is typically performed to confirm satisfactory outcomes after SFA angioplasty and/or stenting. However, two-dimensional angiography may not accurately reflect the extent of residual stenosis. We sought to determine whether intravascular ultrasound (IVUS) can help with residual disease assessment and procedure outcome.

Methods

Patients with anticipated SFA disease were prospectively recruited to the study. Patients with primary SFA disease on diagnostic angiography were included. After SFA endovascular intervention with angioplasty and/or stenting, a completion angiogram was performed to confirm satisfactory results before IVUS evaluation. IVUS-detected maximal residual stenosis, maximal residual lesion volume, and number of nonconsecutive posttreatment SFA segments with >50% residual stenosis were evaluated. Periprocedural ankle-brachial indexes (ABIs), Short Form 36 (SF-36) surveys, and Walking Impairment Questionnaires were also collected.

Results

Fifty-nine patients were prospectively enrolled. Thirty-three received angioplasty only, and 26 received angioplasty and stenting. All patients were men, mean age was 67 years, and major comorbidities included coronary artery disease (53%), active smoking (56%), hypertension (88%), and diabetes (68%). The angioplasty-only cohort had more nonconsecutive areas of >50% residual stenosis ($P = 0.004$), greater residual stenosis ($P = 0.03$), and smaller minimal lumen diameters after treatment ($P = 0.01$) than the angioplasty and stenting cohort. However, there was no significant difference in ABI between the 2 groups and no difference in ABI improvement after intervention. 64% of all patients demonstrated a >0.2 increase in postintervention ABI. Improvement in ABI at 1 month after procedure significantly correlated with postintervention SF-36 survey physical scores ($r = 0.435$, $P = 0.007$).

Conclusions

IVUS evaluation provides more accurate intraprocedural insight on the extent of residual stenosis after SFA interventions. Future studies are warranted to determine whether IVUS-guided postangioplasty and/or stenting can impact long-term interventional outcome.

Philips key takeaways

Significant residual disease was identified on IVUS in both the cohorts (Angioplasty and stenting) despite a satisfactory angiographic result.

Stenting patients demonstrated less residual stenosis on IVUS and better patient-reported outcomes (SF-36 mental subscore increase).

IVUS findings also highlight a potential cause for limited long-term benefit of endovascular interventions despite satisfactory angiographic outcomes after interventions.

Using IVUS in the SFA is feasible, low risk, and may provide the operating clinician with insightful information on residual disease of the artery after intervention and further guide intervention.

Philips key figures/tables

Table II. Stenting patients demonstrated greater patency on IVUS

IVUS parameter	Stent	Angioplasty	P value
Minimum lumen diameter, mm	3.1 (2–4.9)	2.6 (2–3.8)	0.01
Maximum residual stenosis, %	70 (53–84)	76 (50–90)	0.03
Areas of >50% residual stenosis	2.1 (0–7)	3.5 (0–7)	0.004

Table III. Stenting patients exhibited less residual stenosis on IVUS and better SF-36 outcomes after intervention, however, did not demonstrate greater ABI improvements compared with patients who underwent angioplasty

Variable	Stenting $N = 26$, n (%)	Angioplasty $N = 33$, n (%)	R^2 value	P value
IVUS residual stenosis >70%	14 (54)	26 (79)	−0.265	0.043
SF-36 mental subscore increase >50%	7 (33), $N = 21$	1 (6), $N = 16$	0.352	0.032
1-Month post-ABI improvement	24 (92)	29 (88)	0.073	0.584

Intravascular ultrasound in lower extremity peripheral vascular interventions: variation in utilization and impact on in-hospital outcomes from the nationwide inpatient sample (2006-2011)

Sidakpal S Panaich, Shilpkumar Arora, Nilay Patel, Nileshkumar J Patel, Chirag Savani, Achint Patel, Badal Thakkar, Vikas Singh, Samir Patel, Nish Patel, Kanishk Agnihotri, Parth Bhatt, Abhishek Deshmukh, Vishal Gupta, Ramak R Attaran, Carlos I Mena, Cindy L Grines, Michael Cleman, John K Forrest, Apurva O Badheka

J Endovasc Ther. 2016 Feb;23(1):65-75. doi: 10.1177/1526602815620780. Epub 2015 Dec 4

https://pubmed.ncbi.nlm.nih.gov/26637836/

Study design	Objectives	Patients	Population
	To examine the impact of intravascular ultrasound (IVUS) utilization during lower limb endovascular interventions as regards postprocedural complications and amputation.	N=92,714 N=1299 (IVUS)	

Objective

To examine the impact of intravascular ultrasound (IVUS) utilization during lower limb endovascular interventions as regards postprocedural complications and amputation.

Methods

The study cohort was derived from the Healthcare Cost and Utilization Project Nationwide Inpatient Sample database between the years 2006 and 2011. Peripheral endovascular interventions were identified using appropriate ICD-9 procedure codes. Two-level hierarchical multivariate mixed models were created. The co-primary outcomes were in-hospital mortality and amputation; the secondary outcome was postprocedural complications. Model results are given as the odds ratio (OR) and 95% confidence interval (CI). Hospitalization costs were also assessed.

Results

Overall, among the 92,714 patients extracted from the database during the observation period, IVUS was used in 1299 (1.4%) patients. IVUS utilization during lower extremity peripheral vascular procedures was independently predictive of a lower rate of postprocedural complications (OR 0.80, 95% CI 0.66 to 0.99, p=0.037) as well as lower amputation rates (OR 0.59, 95% CI 0.45 to 0.77, p<0.001) without any significant impact on in-hospital mortality. Multivariate analysis also revealed IVUS utilization to be predictive of a nonsignificant increase in hospitalization costs ($1333, 95% CI -$167 to +$2833, p=0.082).

Conclusions

IVUS use during lower limb endovascular interventions is predictive of lower postprocedural complication and amputation rates with a nonsignificant increase in hospitalization costs.

Philips key takeaways

IVUS was utilized in only a minority of the overall study population.

IVUS utilization during lower limb endovascular interventions was independently predictive of a lower rate of postprocedural complications (OR 0.80, 95% CI 0.66 to 0.99, p=0.037), as well as lower amputation rates (OR 0.59, 95% CI 0.45 to 0.77, p<0.001), with no significant difference between the study cohorts in terms of in-hospital mortality.

The hospitalization costs were higher in the group with IVUS use ($21,233±$417) compared to the cohort without IVUS ($20,646±$60). The IVUS derived increase of procedural costs is nonsignificant ($1333, 95% CI:- $167 to + $2833, P=0.082).

The nonsignificant increase in hospitalization costs with IVUS use should be weighed against the net clinical benefit. Study results provide supportive data for IVUS use, which should be particularly helpful as newer stents and DEBs are introduced.

Philips key figures/tables

Table 1. Baseline Data.[a]

	No IVUS (n=91,415; weighted 447,761)	IVUS (n=1299; weighted 6352)	Overall (n=92,714; weighted 454,113)	p
Amputation	9.8	5.3	9.7	<0.001
Below knee	2.1	1.4	2.1	<0.001
Above knee	1.3	0.5	1.3	<0.001
Minor amputation	7.0	3.8	6.9	<0.001
Mortality	1.3	1.1	1.3	0.34
Total charges, $	20,646±60	21,233±417	20,654±59	0.16

Abbreviations: CTO, chronic total occlusion; HMO, health maintenance organization; ICD-9, International Classification of Diseases, Ninth Revision; IVUS, intravascular ultrasound.

[a]Continuous data are presented as the means ± standard deviation; categorical data are given as the percentage.

[b]Charlson comorbidity index was calculated per the Deyo modification.

[c]This represents a quartile classification of the estimated median household income of residents in the patient's zip code. These values are derived from zip code demographic data obtained from Claritas. The quartiles are identified by values of 1 to 4, indicating the poorest to wealthiest populations. Because these estimates are updated annually, the value ranges vary by year. http://www.hcupus.ahrq.gov/db/vars/zipinc_qrtl/nisnote.jsp.

Impact of intravascular ultrasound findings on long-term patency after self-expanding nitinol stent implantation in the iliac artery lesion

Kojiro Miki, Kenichi Fujii, Masashi Fukunaga, Machiko Nishimura, Tetsuo Horimatsu, Ten Saita, Hiroto Tamaru, Takahiro Imanaka, Masahiko Shibuya, Yoshiro Naito, Tohru Masuyama

Heart Vessels. 2016 Apr;31(4):519-27. doi: 10.1007/s00380-014-0625-1. Epub 2015 Jan 21. PMID: 25605656.

https://pubmed.ncbi.nlm.nih.gov/25605656/

Study design	Objectives	Patients	Population
Retrospective Single-Center Review of database	To analyze IVUS predictors of long-term patency following stent implantation in the aorto-iliac artery lesion.	N=122	Patients who underwent endovascular therapy for de novo isolated aorto-iliac artery lesions

Objective

Although intravascular ultrasound (IVUS) predictors of stent patency for the coronary artery lesion have been established, little is known about IVUS predictors of stent patency for the aorto-iliac artery lesion.

Methods

We analyzed 154 lesions of 122 patients who underwent stent implantation for iliac artery lesions. Quantitative and qualitative IVUS analyses were performed for pre- and post-procedural IVUS imaging in all lesions. Target lesion revascularization (TLR) was defined as clinically driven revascularization with >50 % angiographic stenosis of the target lesion.

Results

The mean follow-up period was 39 ± 16 months. TLRs were performed in 13 lesions (8.4 %). Post-procedural minimum stent area (MSA) was significantly smaller in the TLR group compared to the no-TLR group (16.0 ± 5.8 vs. 25.6 ± 8.5 mm2, $p < 0.001$). Stent edge dissection was frequently observed in the TLR group compared to the no-TLR group (53.8 vs. 24.1 %, $p = 0.04$). Multivariate analysis revealed that post-procedural MSA (OR = 0.76, $p < 0.01$) and stent edge dissection (OR = 10.4, $p < 0.01$) were independent IVUS predictors of TLR. Receiver-operating characteristic analysis identified post-procedural MSA <17.8 mm(2) as the optimal cut-point for the prediction of TLR (AUC = 0.846).

Conclusions

Post-procedural MSA and stent edge dissection could predict long-term stent patency in the iliac artery lesion. Our results propose that adequate stent enlargement without edge dissection might be important to reduce TLR in the iliac artery lesion.

Philips key takeaways

Small post-procedural MSA and the presence of stent edge dissection were strongly associated with TLR after self-expanding nitinol stent implantation for de novo iliac artery lesions.

IVUS measurements of MLA at pre-procedure and MSA at post-procedure had excellent intra- and inter-observer reproducibility.

Plaque burden was larger in the TLR group compared to the no-TLR group.

Post-procedural MSA and stent edge dissection were independent predictors of TLR.

Philips key figures/tables

Table 4 Post-procedural IVUS findings

	No-TLR (n = 141)	TLR (n = 13)	P value
Reference segment			
Proximal EEM area (mm^2)	84.1 ± 26.1	69.4 ± 26.6	0.15
Proximal lumen area (mm^2)	49.1 ± 14.8	41.4 ± 13.7	0.19
Proximal plaque burden	38.4 ± 9.1	39.4 ± 8.2	0.79
Distal EEM area (mm^2)	56.5 ± 20.6	46.3 ± 13.1	0.08
Distal lumen area (mm^2)	38.5 ± 15.9	28.7 ± 10.0	0.03
Distal plaque burden	31.8 ± 11.3	38.4 ± 11.7	0.04
Stented segment			
MSA (mm^2)	25.6 ± 8.5	16.0 ± 5.8	<0.001
Stent expansion ratio	0.61 ± 0.14	0.52 ± 0.12	0.09
Radial stent symmetry index	0.69 ± 0.12	0.62 ± 0.10	0.04
Axial stent symmetry index	0.52 ± 0.15	0.44 ± 0.15	0.06
Abnormal findings			
ISA	50 (35)	2 (15)	0.22
Tissue protrusion	39 (28)	1 (8)	0.19
Stent edge dissection	34 (24)	7 (54)	0.04

Data given as mean ± SD or n (%)

IVUS intravascular ultrasound, *TLR* target lesion revascularization, *EEM* external elastic membrane, *MSA* minimum stent area, *ISA* incomplete stent apposition

Intravascular ultrasound-derived stent dimensions as predictors of angiographic restenosis following nitinol stent implantation in the superficial femoral artery

Kojiro Miki, Kenichi Fujii , Daizo Kawasaki , Masahiko Shibuya, Masashi Fukunaga, Takahiro Imanaka, Hiroto Tamaru, Akinori Sumiyoshi, Machiko Nishimura, Tetsuo Horimatsu, Ten Saita , Kozo Okada, Takumi Kimura, Yasuhiro Honda, Peter J Fitzgerald, Tohru Masuyama, Masaharu Ishihara

J Endovasc Ther. 2016 Jun;23(3):424-32. doi: 10.1177/1526602816641669. Epub 2016 Apr 4.

https://pubmed.ncbi.nlm.nih.gov/27044270/

Study design	Objectives	Patients	Population
Retrospective Single-Center Review of database	To identify intravascular ultrasound (IVUS) measurements that can predict angiographic in-stent restenosis (ISR) following nitinol stent implantation in superficial femoral artery (SFA) lesions.	N=97	Patients who underwent endovascular therapy for de novo isolated aorto-iliac artery lesions

Objective

To identify intravascular ultrasound (IVUS) measurements that can predict angiographic in-stent restenosis (ISR) following nitinol stent implantation in superficial femoral artery (SFA) lesions.

Methods

A retrospective review was conducted of 97 patients (mean age 72.9±8.9 years; 63 men) who underwent IVUS examination during endovascular treatment of 112 de novo SFA lesions between July 2012 and December 2014. Self-expanding bare stents were implanted in 46 lesions and paclitaxel-eluting stents in 39 lesions. Six months after stenting, follow-up angiography was conducted to assess stent patency. The primary endpoint was angiographic ISR determined by quantitative vascular angiography analysis at the 6-month follow-up. Variables associated with restenosis were sought in multivariate analysis; the results are presented as the odds ratio (OR) and 95% confidence interval (CI).

Results

At follow-up, 27 (31.8%) angiographic ISR lesions were recorded. The lesions treated with uncoated stents were more prevalent in the ISR group compared with the no restenosis group (74.1% vs 44.8%, p=0.02). Lesion length was longer (154.4±79.5 vs 109.0±89.3 mm, p=0.03) and post-procedure minimum stent area (MSA) measured by IVUS was smaller (13.9±2.8 vs 16.3±1.6 mm2, p<0.001) in the ISR group. Multivariate analysis revealed that bare stent use (OR 7.11, 95% CI 1.70 to 29.80, p<0.01) and longer lesion length (OR 1.08, 95% CI 1.01 to 1.16, p=0.04) were predictors of ISR, while increasing post-procedure MSA (OR 0.58, 95% CI 0.41 to 0.82, p<0.01) was associated with lower risk of ISR. Receiver operating characteristic analysis identified a MSA of 15.5 mm2 as the optimal cutpoint below which the incidence of restenosis increased (area under the curve 0.769).

Conclusions

Post-procedure MSA can predict ISR in SFA lesions, which suggests that adequate stent enlargement during angioplasty might be required for superior patency.

Philips key takeaways

IVUS-derived post-procedure MSA <15 mm2 can also predict angiographic restenosis following stent implantation for SFA lesions; no angiographic measurement emerged as a predictor of restenosis.

Bare stent use was also associated with an increasing incidence of restenosis in SFA lesions.

There were no differences in morphologic IVUS findings (incomplete stent apposition, tissue protrusion, or stent edge dissection) between the ISR and no restenosis groups.

IVUS measurements of minimum lumen area (MLA) pre-EVT and post-procedure MSA showed excellent intra- and interobserver reliability.

Post-procedure MSA was significantly smaller in the ISR group than in the no restenosis group and was also smaller in calcified lesions compared with non-calcified lesions.

Philips key figures/tables

Table 4. Intravascular Ultrasound Findings.[a]

	Total (n=85)	No ISR (n=58)	Restenosis (n=27)	p
Pre-EVT				
Lesion site				
MLA, mm^2	4.5±3.6	4.5±4.0	4.4±2.5	0.96
EEM area, mm^2	32.3±10.7	30.7±10.8	36.3±9.8	0.15
Plaque burden, %	85.4±12.0	84.5±13.7	87.7±5.8	0.46
Calcified lesion	28 (33)	16 (28)	12 (44)	0.12
Classification of non-calcified lesions				
Soft	8 (9)	6 (10)	2 (7)	>0.99
Fibrous	30 (35)	23 (40)	7 (26)	0.24
Mixed	19 (22)	14 (24)	5 (19)	0.78
Post-EVT				
Stented segment				
MSA, mm^2	15.6±2.3	16.3±1.6	13.9±2.8	<0.001
Stent expansion ratio	0.78±0.24	0.81±0.26	0.70±0.19	0.09
Stent eccentricity index	0.71±0.11	0.72±0.11	0.70±0.13	0.58
Incomplete stent apposition	22 (26)	12 (21)	10 (37)	0.11
Tissue protrusion	24 (28)	17 (29)	7 (26)	0.75
Reference segment				
Proximal EEM area, mm^2	39.0±13.8	38.9±14.3	39.0±12.9	0.98
Proximal lumen area, mm^2	23.3±9.0	23.2±9.6	23.3±7.6	0.97
Proximal plaque burden, %	40.2±8.6	40.5±8.5	39.7±8.9	0.73
Distal EEM area, mm^2	31.6±9.7	33.0±10.2	28.7±8.0	0.06
Distal lumen area, mm^2	19.0±6.4	20.0±6.4	17.1±6.0	0.06
Distal plaque burden, %	39.5±10.1	38.9±8.9	40.7±12.4	0.47
Stent edge dissection	38 (45)	24 (41)	14 (52)	0.37

Abbreviations: EEM, external elastic membrane; EVT, endovascular therapy; ISR, in-stent restenosis; MLA, minimum lumen area; MSA, minimum stent area.
[a]Continuous data are presented as the means ± standard deviation; categorical data are given as the counts (percentage).

Novel use of ultrasound guidance for recanalization of iliac, femoral and popliteal arteries

Daizo Kawasaki, Takeshi Tsujino, Kenichi Fujii, Motomaru Masutani, Mitsumasa Ohyanagi, Tohru Masuyama

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https://pubmed.ncbi.nlm.nih.gov/18412065/

Study design	Objectives	Patients	Population
Retrospective Single-Center Review	To demonstrate the safety and feasibility of (IVUS)-guided endoluminal endovascular therapy for chronic total occlusion (CTO) of the iliac and/or femoropopliteal arteries using Treasure 12, a stiff guidewire	N=47	Patients who under-went the endovascular therapy by monodirectional approach for CTO lesions of iliac and/or femoropopliteal arteries.

Objective

Endovascular therapy for CTO of the iliac and femoropopliteal arteries is still technically challenging. We attempted to demonstrate the safety and feasibility of intravascular ultrasound (IVUS)-guided endoluminal endovascular therapy for chronic total occlusion (CTO) of the iliac and/or femoropopliteal arteries using Treasure 12, a stiff guidewire for peripheral CTO of 0.018 in. in monodirectional approach setting.

Methods

Endovascular therapy was performed in 110 patients who were admitted to Hyogo College of Medicine Hospital with iliac and/or femoropopliteal artery disease from January 2006 to October 2007. We retrospectively analyzed the data of consecutive 47 patients who underwent the endovascular therapy by monodirectional approach for CTO lesions of the iliac and femoropopliteal arteries. From January 2006 to November 2006 (phase 1), standard technique was applied for the treatment of 21 lesions. From December 2006 to October 2007 (phase 2), IVUS-guided endovascular therapy was applied for the treatment of 31 lesions.

Results

Clinical and lesion characteristics in phase 1 were not significantly different from those in phase 2. The overall initial technical success rate improved from 81% in phase 1 to 97% in phase 2. There were no significant differences in radiation exposure time between phase 1 and phase 2. Total volume of contrast material was significantly smaller in phase 2 than in phase 1 ($P < 0.01$).

Conclusions

The IVUS-guided endovascular therapy for CTO using Treasure 12 guidewire is feasible and safe, minimizes contrast material, and has a high initial technical success rate.

Philips key takeaways

The overall initial technical success rate was improved from 81% of Phase 1 to 97% of Phase 2.

There were no differences in the total procedure times and radiation exposure time, whereas the total volume of contrast material was significantly smaller in Phase 2 (104 ml vs. 201 ml; $P<0.001$).

IVUS-guided technique is helpful for saving the volume of contrast material.

The role of intravascular ultrasound in lower limb revascularization in patients with peripheral arterial disease

Gregory C Makris, Pavlina Chrysafi, Mark Little, Rafiuddin Patel, Mark Bratby, andrew Wigham, Susan Anthony, Raman Uberoi

Int Angiol. 2017 Dec;36(6):505-516. doi: 10.23736/S0392-9590.17.03866-4. Epub 2017 Sep 11.

https://pubmed.ncbi.nlm.nih.gov/28895369/

Study design	Objectives	Patients	Population
Retrospective Multi-Center Meta-Analysis	The aim of this review is to explore the safety and effectiveness of intravascular ultrasound (IVUS) during lower limb endovascular interventions in patients with peripheral arterial disease (PAD).	N=2258	Patients having had IVUS for PAD intervention

Objective

The aim of this review is to explore the safety and effectiveness of intravascular ultrasound (IVUS) during lower limb endovascular interventions in patients with peripheral arterial disease (PAD).

Methods

A systematic review of the PubMed and Scopus databases was performed according to PRISMA guidelines. Clinical studies evaluating IVUS as an adjunct to angiography during revascularization procedures in patients with PAD were included.

Results

Thirteen studies were identified, with a total number of 2258 patients having had IVUS for PAD intervention. Seven investigated the role of IVUS for angioplasty and stenting, with the majority being retrospective cohorts. Technical success and patency rates ranged from 90-100% and 45-100%, respectively, with a follow-up that ranged from 4.3-63 months. Three of these studies compared IVUS and non-IVUS guided angioplasty and demonstrated a significant difference in the events of amputations or re-interventions in favor of the IVUS group. Furthermore, five studies evaluated IVUS use in true-lumen re-entry, with the technical success ranging between 97-100%. In one study, where IVUS was used for atherectomy, the technical success was 100% and the long-term patency was 90% during a 12-month follow-up. Overall, no significant peri/postoperative IVUS related complications were reported, whereas, 2 studies suggested an IVUS-associated increase in procedure costs that ranged from $1080-$1333.

Conclusions

There is limited and heterogeneous evidence regarding the use of IVUS for the management of PAD. Further research is required to elucidate the optimal role of IVUS in PAD as well as the cost effectiveness of this approach for routine use in the management of PAD.

Philips key takeaways

3 of the 4 studies that performed comparisons between IVUS and non IVUS guided angioplasties or stentings demonstrated lower rates of reinterventions and amputations in favor of the IVUS group.

Overall, no significant peri/postoperative IVUS related complications were reported.

2 studies suggested an IVUS-associated increase in procedure costs that ranged from $1080-$1333.

There is limited and heterogeneous evidence regarding the use of IVUS for the management of PAD.

Further research is required to elucidate the optimal role of IVUS in PAD as well as the cost effectiveness of this approach for routine use in the management of PAD.

Factors influencing in-stent occlusion after femoropopliteal artery stent placement with intravascular ultrasound evaluation

Naoya Kurata, Osamu Iida, Mitsutoshi Asai, Masaharu Masuda, Shin Okamoto, Takayuki Ishihara, Kiyonori Nanto, Toshiaki Mano

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https://pubmed.ncbi.nlm.nih.gov/31883937/

Study design	Objectives	Patients	Population
Retrospective Single-Center Review of a database	To evaluate the role of intravascular ultrasound (IVUS) during iliac stent deployment, with comparison of four major types of iliac stents.	N=162	Patients having had IVUS for de novo femoropopliteal artery intervention

Objective

To investigate the rate and predictors of in-stent occlusion by intravascular ultrasound (IVUS) following femoropopliteal artery stent placement.

Methods

From July 2012 to June 2016, this study retrospectively investigated 191 cases of de novo femoropopliteal artery lesions (lesion length, 170 ± 97 mm; chronic total occlusion, 51%) evaluated by IVUS in 162 patients with peripheral artery disease (with critical limb ischemia of 27%) who underwent endovascular therapy using self-expanding nitinol stents. Examination by IVUS was performed to record data for vessel characteristics immediately after wire crossing and at the end of the procedure. The primary outcome measurement was the occurrence of in-stent occlusion, defined as the absence of blood flow at the treatment site by duplex ultrasonography. Predictors for in-stent occlusion were also evaluated by multivariate analysis.

Results

In-stent occlusion was observed in 15% (n = 28) of lesions, and the mean follow-up time was 19 ± 13 months. After multivariate analysis, it was found that plaque burden ≥60% after stent placement ($P < .001$), female gender ($P = .002$), and Trans-Atlantic Inter-Society Consensus (TASC) II classification C and D lesions ($P = .047$) were significantly associated with the occurrence of in-stent occlusion.

Conclusions

Plaque burden ≥60% after stent placement, female gender, and TASC II classification C/D lesions were significantly associated with the occurrence of in-stent occlusion after femoropopliteal artery stent placement as evaluated by IVUS.

Philips key takeaways

Plaque burden ≥60% after stent placement as evaluated by IVUS was an independent predictor of in-stent occlusion and in-stent restenosis, as were female gender and TASC II classification of C/D lesions, after femoropopliteal artery stent placement in symptomatic patients with PAD.

Philips key figures/tables

Table 4. Predictors of In-Stent Occlusion after Stent Implantation in the Femoropopliteal Artery

	Unadjusted OR (95% CI)	*P* Value	Adjusted OR (95% CI)	*P* Value
Females	2.24 (1.06–4.75)	.035	4.13 (1.65–10.30)	.002
Age	0.98 (0.94–1.02)	.302		
BMI	0.91 (0.81–1.02)	.105		
Diabetes mellitus	1.59 (0.72–3.52)	.251		
Hemodialysis	0.70 (0.28–1.72)	.431		
Critical limb ischemia	3.15 (1.50–6.62)	.002	1.71 (0.70–4.15)	.236
Calcification	0.74 (0.35–1.58)	.441		
Poor runoff	2.18 (0.91–5.24)	.080		
TASC II grades C/D	11.66 (2.76–49.15)	.001	4.67 (1.02–21.38)	.047
DES used	0.62 (0.29–1.31)	.206		
Distal EEM area	1.00 (0.96–1.04)	.846		
Minimum stent area	0.92 (0.94–1.07)	.128		
Plaque burden ≥60% after stent placement	24.17 (9.16–63.79)	<.001	22.01 (7.59–63.80)	<.001

Note–Predictors associated with ISO were investigated using logistic regression analysis. Results are given as ORs and 95% CI. Factors demonstrating statistical significance in the univariate analysis were included in the subsequent multivariate analysis. The significance for all analyses was set at $P < .05$.
BMI = body mass index; CI = confidence interval; DES = drug-eluting stent; EEM = extra elastic membrane; ISO = in-stent occlusion; OR = odds ratio; SNS = self-expandable nitinol stent; TASC = Trans-Atlantic InterSociety Consensus.

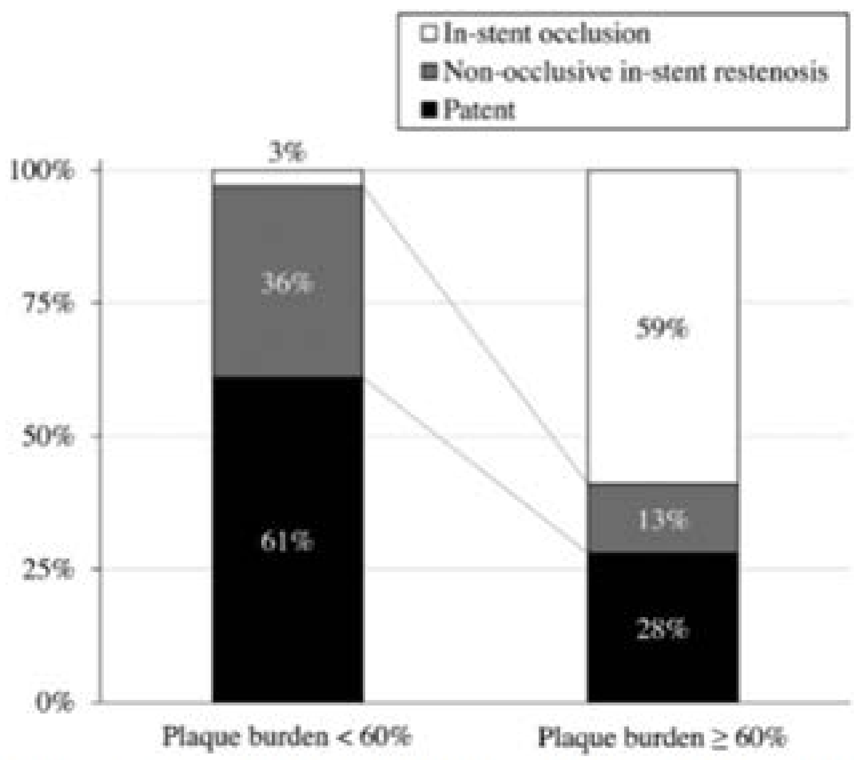

Figure 5. Percentage of stent patency, nonocclusive in-stent restenosis, and in-stent occlusion when classified by plaque burden with a cutoff of 60%. In the group with more than 60% plaque burden after stent placement, the incidence of in-stent occlusion was the greatest, accounting for 59% of the total lesions with in-stent occlusion.

Impact of IVUS-derived vessel size on midterm outcomes after stent implantation in femoropopliteal lesions

Kojiro Miki, Kenichi Fujii , Takamasa Tanaka , Koji Yanaka , Nagataka Yoshihara, Machiko Nishimura, Akinori Sumiyoshi, Tetsuo Horimatsu, Takahiro Imanaka, Masashi Fukunaga, Hirokuni Akahori, Tohru Masuyama, Masaharu Ishihara

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https://pubmed.ncbi.nlm.nih.gov/31948376/

Study design	Objectives	Patients	Population
Retrospective Single-Center Review of a database	To evaluate the role of intravascular ultrasound (IVUS) during iliac stent deployment, with comparison of four major types of iliac stents.	N=162	Patients having had IVUS for de novo femoropopliteal artery intervention

Objective

To identify intravascular ultrasound (IVUS) findings that predict midterm stent patency in femoropopliteal (FP) lesions.

Methods

A retrospective analysis was undertaken of 335 de novo FP lesions in 274 consecutive patients (mean age 72.4±8.2 years; 210 men) who had IVUS assessment before and after successful stent implantation. The mean lesion length was 13.2±9.8 cm. The primary outcome was primary patency at 24 months, defined as freedom from major adverse limb event (MALE) and in-stent restenosis (ISR). MALE was defined as major amputation or any target lesion revascularization (TLR). ISR was defined by a peak systolic velocity ratio >2.4 by duplex ultrasonography. Logistic regression analyses were performed to identify independent predictors of stent patency at 24 months; the results are presented as the odds ratio (OR) and 95% confidence interval (CI). Receiver operator characteristic (ROC) curve analysis was performed to determine the optimal threshold for prediction of stent patency at 24 months.

Results

Over the 24-month follow-up, 18 (7%) patients died and 43 (15%) of 286 lesions were responsible for MALE (42 TLRs and 1 major amputation). Primary patency was estimated at 82.5% (95% CI 78.1% to 86.9%) at 12 months and 73.2% (95% CI 67.9% to 78.5%) at 24 months. Multivariable analysis revealed that longer lesion length (OR 0.89, 95% CI 0.82 to 0.97, p<0.01) was an independent predictor of declining patency, while cilostazol use (OR 3.45, 95% CI 1.10 to 10.78, p=0.03) and increasing distal reference external elastic membrane (EEM) area (OR 1.18, 95% CI 1.02 to 1.37, p=0.03) were associated with midterm stent patency. ROC curve analysis identified a distal reference EEM area of 29.0 mm2 as the optimal cut-point for prediction of 24-month stent patency (area under the ROC curve 0.764). Kaplan-Meier estimates of 24-month primary patency were 83.7% (95% CI 78.3% to 89.2%) in lesions with a distal EEM area >29.0 mm2 vs 53.1% (95% CI 42.9% to 63.3%) in those with a distal EEM area ≤29.0 mm2 (p<0.001).

Conclusions

In FP lesions with a larger distal vessel area estimated with IVUS, stent implantation can be considered as a reasonable treatment option, with the likelihood of acceptable midterm results.

Philips key takeaways

12-month primary patency rate of 83% with a mean lesion length of 13.2 cm and 38% CTO patency rate is in line with previously reported data from real-world registries.

Longer lesion length was an independent predictor of a lower patency rate.

Small distal EEM area, similar to other studies, was also a risk factor for reduced stent patency.

IVUS utilization during EVT of FP lesions seems very helpful in identifying whether the lesion is suitable or not for a stenting option.

Philips key figures/tables

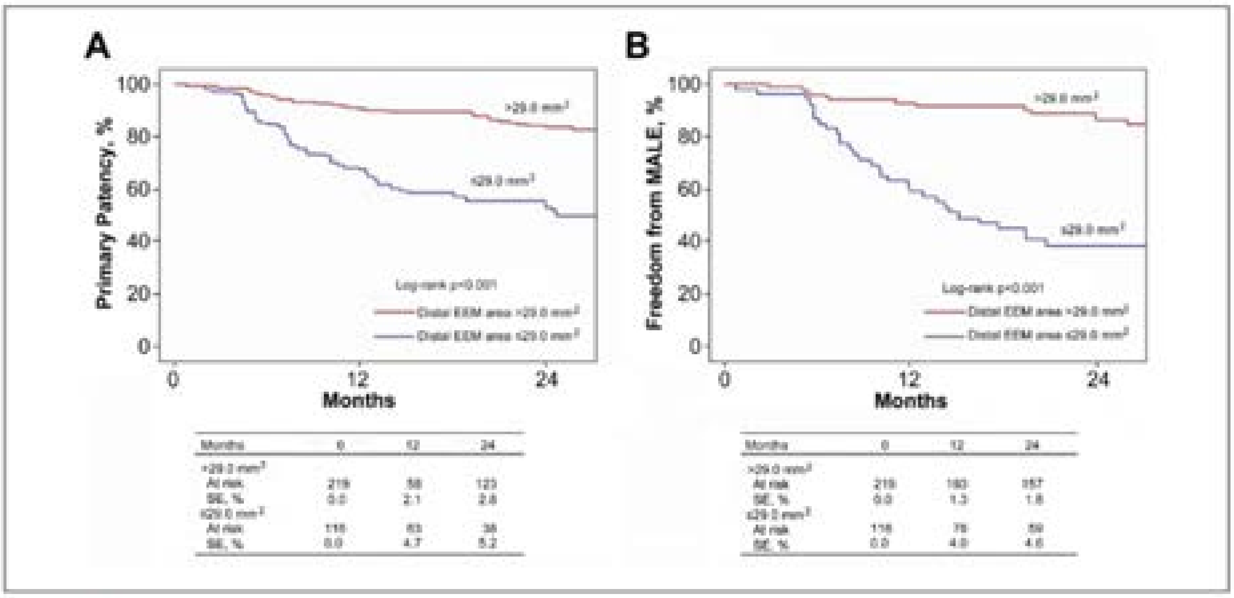

Figure 4. Kaplan-Meier curves estimating (A) primary patency and (B) freedom from major adverse limb events (MALE) in lesions with a distal reference external elastic membrane (EEM) area >29.0 mm² and ≤29.0 mm². Primary patency and MALE-free survival was significantly superior in lesions with distal reference EEM area >29.0 mm².

Utility of intravascular ultrasound in peripheral vascular interventions: systematic review and meta-analysis

Azfar Bilal Sheikh, Mahesh Anantha-Narayanan, Kim G Smolderen, Qurat-Ul-Ain Jelani, Sameer Nagpal, Marabel Schneider, Fiorella Llanos, Costin Ionescu, Christopher Regan, Robert Attaran, S Elissa Altin, Carlos Mena-Hurtado

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https://pubmed.ncbi.nlm.nih.gov/32338163/

Study design	Objectives	Patients	Population
Retrospective Multi-Center 2 Arm Meta-Analysis	To compare outcomes between intravascular ultrasound– (IVUS) versus angiography (AO)-guided peripheral vascular interventions (PVIs).	N=93,551	All studies that compared clinical outcomes, including primary patency, reinterventions, mortality, periprocedural complications, amputations, and myocardial infarction, following IVUS-guided peripheral vascular interventions versus angiography-guided peripheral vascular interventions

Objective

Intravascular ultrasound facilitates plaque visualization and angioplasty during PVIs for peripheral arterial disease. It is unclear whether IVUS may improve the durability of PVIs and lead to improved clinical outcomes. We sought to compare outcomes between intravascular ultrasound- (IVUS) versus angiography (AO)-guided peripheral vascular interventions (PVIs).

Methods

This is a study-level meta-analysis of observational studies. The primary end points of this study were rates of primary patency and reintervention. Secondary end points included rates of vascular complications, periprocedural adverse events, amputations, technical success, all-cause mortality, and myocardial infarction.

Results

Eight observational studies were included in this analysis with 93,551 patients. Mean follow-up was 24.2 ± 15 months. Intravascular ultrasound-guided PVIs had similar patency rates when compared with AO-guided PVIs (relative risk [RR]: 1.30, 95% confidence interval [CI]: 0.99-1.71, P = .062). There was no difference in rates of reintervention in IVUS-guided PVIs when compared to non-IVUS-guided PVIs (RR: 0.41, 95% CI: 0.15-1.13, P = .085). There is a lower risk of periprocedural adverse events (RR: 0.81, 95% CI: 0.70-0.94, P = .006) and vascular complications (RR: 0.81, 95% CI: 0.68-0.96, P = .013) in the IVUS group. All-cause mortality (RR: 0.76, 95% CI: 0.56-1.04, P = .084), amputation rates (RR 0.83, 95% CI: 0.32-2.15, P = .705), myocardial infarctions (RR: 1.19, 95% CI: 0.58-2.41, P = .637), and technical success (RR: 1.01, 95% CI: 0.86-1.19, P = .886) were similar between the groups.

Conclusions

Intravascular ultrasound-guided PVIs had similar primary patency and reintervention when compared with AO-guided PVIs with significantly lower rates of periprocedural adverse events and vascular complications in the IVUS-guided group.

Philips key takeaways

IVUS-guided PVI was associated with lower periprocedural adverse events and vascular complications without a significant difference in primary patency and reintervention rates when compared with AO-guided PVI.

When meta-regression was used to model the impact of extended follow-up time on reintervention rate, it revealed a significant effect which suggests that lower rates of reintervention at longer follow-up may have occurred in the IVUS-PVI group.

There was no difference in rates of technical success, amputations, all-cause mortality, or myocardial infarction between the two groups.

Limitations of the study: included studies were observational and only one was propensity-score matched, heterogeneity of some of the analyses were high, the largest study in this meta-analysis did not include lesion-level detail.

Philips key figures/tables

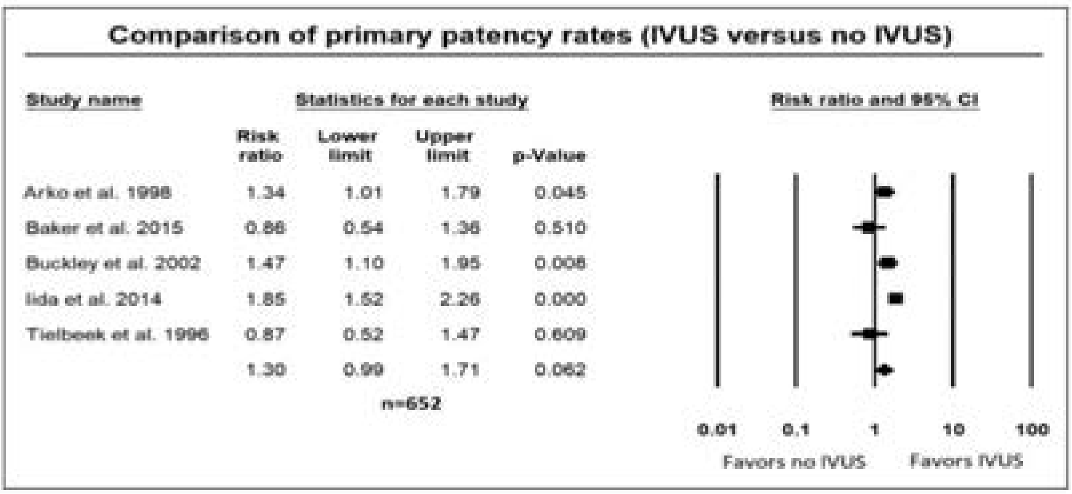


Figure 2. Forest plot and pooled analysis for primary patency rates. CI indicates confidence interval.

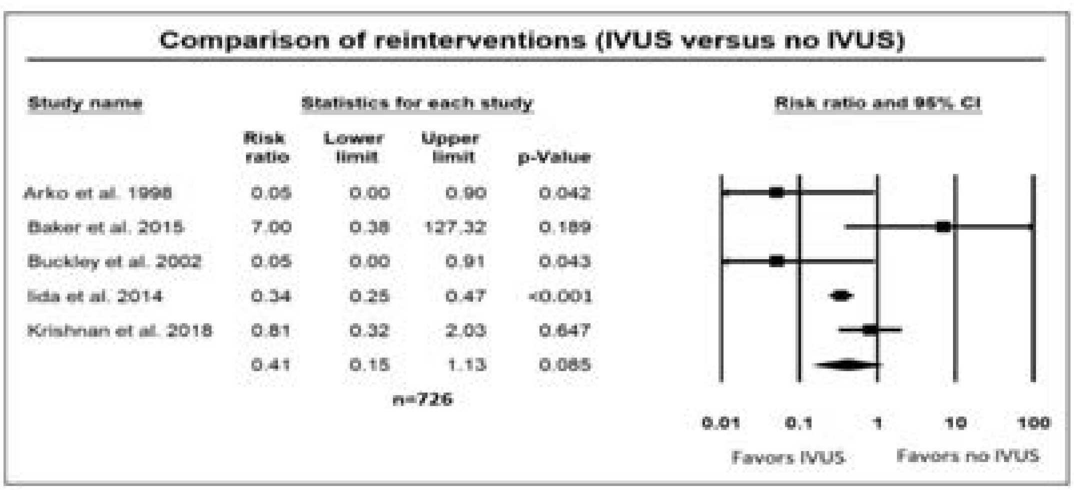


Figure 5. Forest plot and pooled analysis for reinterventions. CI indicates confidence interval.

Intravascular ultrasound imaging versus digital subtraction angiography in patients with peripheral vascular disease

George Pliagas, Fadi Saab, Konstantinos Stavroulakis, Theodosios Bisdas, Sara Finton, Carmen Heaney, Theresa McGoff, Kimberly Hardy, George Adams, Jihad A Mustapha

J Invasive Cardiol. 2020 Mar;32(3):99-103.

https://pubmed.ncbi.nlm.nih.gov/32123141/

Study design	Objectives	Patients	Population
Retrospective Single-Center 2 Arm Image Analysis	The objective was to compare predicted diameters of treated vessels utilizing angiographic imaging and compare these measurements with diameters obtained via IVUS imaging.	N=43	Patients who had angiography and IVUS utilized during an endovascular intervention

Objective

The evaluation of arterial plaque morphology and vessel diameter is a vital component of peripheral vascular interventions. Historically, digital subtraction angiography (DSA) has been considered the gold standard for vessel sizing and treatment. However, this modality has the limitation of providing a two-dimensional image of a three-dimensional luminal structure. Utilization of intravascular ultrasound (IVUS) has been incorporated into diagnostic and treatment algorithms to further characterize the arterial vessel. This study compared visual estimation of vessel diameter by angiographic imaging with IVUS measurements.

Methods

A retrospective analysis was conducted on a cohort of 43 patients who underwent an endovascular intervention utilizing DSA and IVUS imaging. Angiographic measurements were determined by an interventionalist blinded to the IVUS findings.

Results

Of the 43 patients, 58% were male, the majority (72%) were ages 60-89 years, 58% were Rutherford classification III, and 42% had critical limb ischemia (Rutherford classification IV or V). Arterial access sites were common femoral, posterior tibial, and anterior tibial in 37%, 37%, and 26%, respectively. Tibiopedal arterial minimally invasive (TAMI) retrograde revascularization was utilized in 63% of patients. Vessel sizing was consistently the same or smaller for female subjects with either imaging modality. Overall, measurements estimated from angiographic images were significantly smaller than those obtained from IVUS analysis.

Conclusions

IVUS appears to offer a greater degree of accuracy in measuring arterial lumen diameter. As measurements obtained from angiographic imaging consistently under-estimated vessel size, utilization of IVUS may aid in the determination of treatment algorithms and lead to improved endovascular outcomes.

Philips key takeaways

Tibial vessel diameters obtained via IVUS were significantly larger than diameters estimated by angiography across all segments.

IVUS appears to offer a greater degree of accuracy in measuring arterial lumen diameter.

IVUS may aid in the determination of treatment algorithms and lead to improved endovascular outcomes.

Philips key figures/tables

Table 1. Digital subtraction angiography versus intravascular ultrasound measurements of infrainguinal arteries.

Location	DSA (mm)	IVUS (mm)	P-Value[a]
Proximal superficial femoral	5.5 (1.0-6.5)	6.1 (4.1-7.8)	<.001
Mid superficial femoral	5.0 (1.0-6.0)	5.9 (3.8-7.9)	<.001
Distal superficial femoral	4.8 (0-6.0)	5.9 (4.2-7.7)	<.001
Proximal popliteal (P1)	5.0 (3.0-6.0)	5.8 (3.7-7.2)	<.001
Mid popliteal (P2)	4.5 (2.5-5.0)	5.6 (3.6-8.6)	<.001
Distal popliteal (P3)	4.0 (0-5.0)	5.3 (3.5-7.5)	<.001
Proximal anterior tibial	2.5 (1.0-4.0)	3.6 (3.0-4.0)	<.001
Mid anterior tibial	2.0 (0-3.0)	n/a[b]	n/a[b]
Distal anterior tibial	2.0 (0-2.5)	3.0 (2.7-3.6)	<.01
Tibioperoneal trunk	3 (1.5-3.5)	4 (2.3-5.5)	<.001
Proximal posterior tibial	2.5 (0-3.0)	3.4 (2.5-4.4)	<.001
Mid posterior tibial	2.0 (0-3.0)	n/a[b]	n/a[b]
Distal posterior tibial	2.0 (0-2.5)	3.2 (2.2-4.3)	<.001
Proximal peroneal	2.0 (1.0-2.5)	3.3 (2.6-3.4)	.03
Mid peroneal	1.5 (0-3.0)	n/a[b]	n/a[b]
Distal peroneal	1.0 (0-2.8)	n/a[b]	n/a[b]
Dorsalis pedis	0.5 (0-2.0)	n/a[b]	n/a[b]

Data presented as median (interquartile range).
[a]Wilcoxon test, distribution was checked by D'Agostino-Pearson test.
[b]Arterial segments were not evaluated via IVUS.
DSA = digital subtraction angiography; IVUS = intravascular ultrasound.

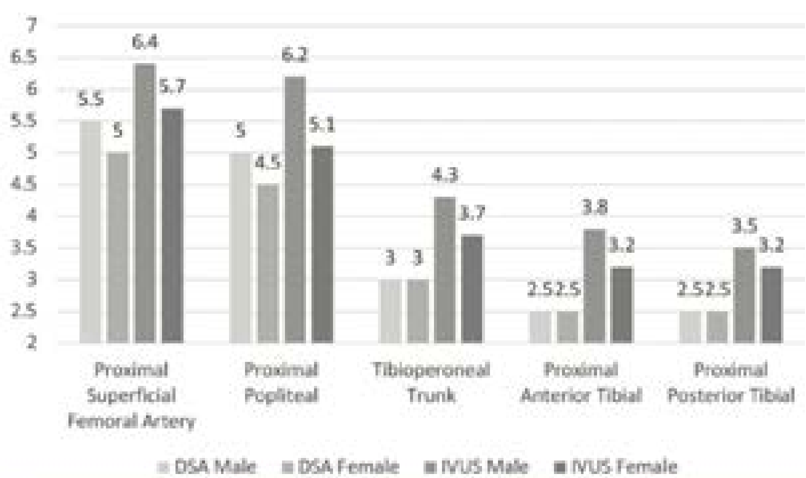


FIGURE 4. Digital subtraction angiography and intravascular ultrasound vessel sizing based on gender (median arterial diameter in millimeters).

Optimal vessel sizing and understanding dissections in infrapopliteal interventions: data from the Dissection below-the-knee study

Nicolas W Shammas, W John Shammas, Susan Jones-Miller, James T Torey, Ehrin J Armstrong, Qais Radaideh , Gail A Shammas

J Endovasc Ther. 2020 Aug;27(4):575-580. doi: 10.1177/1526602820924815. Epub 2020 May 18.

https://pubmed.ncbi.nlm.nih.gov/32419593/

Study design	Objectives	Patients	Population
Prospective Single-Center Case Series 2 Arm Image Analysis	To investigate if imaging with intravascular ultrasound (IVUS) yields a more accurate estimate of vessel diameter and the presence of dissections after intervention when treating the infrapopliteal arteries.	N=20	Patients with de novo disease or native vessel restenosis of the infrapopliteal arteries

Objective

To investigate if imaging with intravascular ultrasound (IVUS) yields a more accurate estimate of vessel diameter and the presence of dissections than angiography after intervention in the infrapopliteal arteries.

Methods

A prospective, single-center study enrolled 20 consecutive patients (mean age 74.1±12.4 years; 12 women) with infrapopliteal disease who were treated with percutaneous transluminal angioplasty (PTA; n=10) or orbital atherectomy (OA) followed by PTA (n=10). The majority of patients were hypertensive and half were diabetic. The overall lesion length was 7.3±6.3 cm, and the diameter stenosis was 80.3%±22.1%. The baseline characteristics did not differ between the groups. Vessel diameters were measured using IVUS from the internal elastic lamina (IEL) to the IEL. IVUS was performed at baseline, post PTA or OA, and post OA+PTA. Quantitative vascular angiography (QVA) and IVUS were analyzed by a core laboratory. Dissections on cine images were categorized based on the National Heart Lung and Blood Institute (NHLBI) classification, while the arc and depth were used to characterize dissections on IVUS images.

Results

Mean vessel diameter by QVA was 2.9±0.6 vs 4.0±1.0 mm by IVUS according to the core laboratory (mean difference 1.1±0.9, p<0.001). On angiography, there were 7 dissections after PTA (6 C, 1 D), 1 dissection after OA (1 B), and 2 dissections after OA+PTA (1 A, 1 B; p=0.028 vs post PTA). IVUS uncovered 3.8 times more dissections than seen on angiography. There were 23 dissections after PTA (18 intima, 3 media, 2 adventitia), 12 dissections after OA (8 intima, 1 media, 3 adventitia), and 11 dissections following OA+PTA (7 intima, 1 media, 3 adventitia; p=0.425 vs PTA). Bailout stenting (all due to angiographic dissections ≥C) was necessary in 6 of the PTA cohort and none of the OA+PTA group.

Conclusions

In addition to underestimating the infrapopliteal vessel diameter by ~25%, angiography underappreciated the presence and severity of post-intervention dissections vs IVUS, particularly in the OA+PTA group.

Philips key takeaways

Compared to IVUS, angiography underestimates the presence/severity of dissections following PTA and orbital atherectomy, as well as underestimating the infrapopliteal diameter by ~25%.

Philips key figures/tables

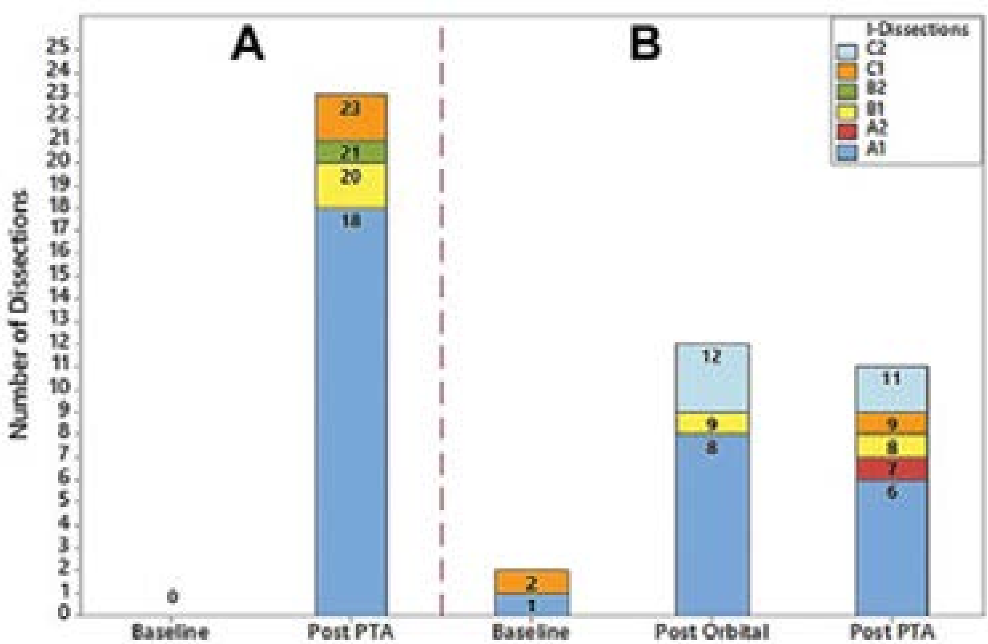
Table 2. Procedural Variables and Imaging Results.[a]

Variable	All	OA+PTA	PTA	p[b]
Balloon pressure, atm	9.1 ± 3.2	8.4 ± 2.5	9.8 ± 3.7	0.49
Inflation time, s	259.5 ± 116.8	292.6 ± 100.5	226.4 ± 127.6	0.12
Post OA stenosis, %	NA	38.0 ± 8.1	NA	
Final stenosis, %	21.5 ± 11.6	17.2 ± 7.7	26.2 ± 13.7	0.20
Bailout stent[c]	6	0	6	
Total stents	7	0	7	
Imaging				
Evaluated lesion length, cm	4.9 ± 2.5	4.8 ± 1.6	5.1 ± 3.2	0.94
Vessel diameter by QVA, mm	2.9 ± 0.6	NA	NA	
Vessel diameter by IVUS, mm[d]	4.0 ± 1.0	NA	NA	
Dissections on IVUS	34	11	23	
Dissections on angiography	9	2	7	
Dissection ratio (IVUS/angiography)	3.8	5.5	3.3	

Abbreviations: NA, not applicable; IVUS, intravascular ultrasound; OA, orbital atherectomy; PTA, percutaneous transluminal angioplasty; QVA, quantitative vascular analysis.
[a]Continuous data are presented as the mean ± standard deviation; categorical data are given as the number.
[b]Difference between OA+PTA vs PTA.
[c]For grade C or higher dissection.
[d]Internal elastic lamina to internal elastic lamina measurements.

Dissections on cine images were characterized based on the National Heart Lung and Blood Institute (NHLBI) classification

Figure 2. (A) Dissections seen after angioplasty (PTA) and (B) after orbital atherectomy without and with adjunctive angioplasty of the infrapopliteal arteries



Intravascular ultrasound-guided interventions for below-the-knee disease in patients with chronic limb-threatening ischemia

Masahiko Fujihara, MD , Yuko Yazu, CE, Mitsuyoshi Takahara, MD, PhD

J Endovasc Ther. 2020 Jun 26:1526602820935606. doi: 10.1177/1526602820935606.

https://pubmed.ncbi.nlm.nih.gov/32589120/

Study design	Objectives	Patients	Population
Retrospective Single-Center 2 Arm Comparison	Retrospective single-center study to compare CTLI patients who underwent IVUS-guided vs angiography-guided balloon angioplasty	N=216	Patients with CLTI

Objective

To assess the utility of intravascular ultrasound (IVUS) during below-the-knee (BTK) interventions for patients with chronic limb-threatening ischemia (CLTI).

Methods

This retrospective single-center study included 216 symptomatic patients (mean age 74.2±9.5 years; 167 men) with CLTI and BTK steno-occlusive disease who underwent successful balloon angioplasty between January 2016 and August 2018. Data from 88 vessels (58 patients) treated with IVUS-guided procedures were compared with corresponding values from 242 vessels (158 patients) treated with angiography-guided procedures. The primary outcomes included procedure-related variables of balloon size, contrast dose, and complication rates, as well as changes in ankle-brachial index (ABI) and skin perfusion pressure (SPP). Secondary outcomes included IVUS determination of vessel size, wire route, and calcification severity, as well as technical success and clinically-driven target lesion revascularization (TLR), limb salvage, and wound healing rates in the Rutherford category 5/6 patients as evaluated by propensity score matching analysis.

Results

The patient and lesion characteristics were similar in both groups. The mean balloon size for IVUS-guided procedures was significantly larger (2.45±0.4 mm) compared with that for angiography-guided procedures (2.23±0.4 mm; $p<0.001$). The technical success ($p=0.56$) and complication rates ($p=0.16$) were similar between the groups. The postprocedure dorsal and plantar SPP and change in dorsal SPP improved more in the IVUS-guided group ($p<0.001$, $p=0.015$, and $p=0.02$, respectively). The IVUS-guided group had a significantly better wound healing rate than the angiography-guided group ($p=0.006$), although the freedom from TLR and limb salvage rates were similar between the groups ($p=0.16$ and $p>0.99$, respectively).

Conclusions

IVUS-guided interventions for BTK lesions were safe and effective in accurately assessing the lesions. The results suggest that IVUS guidance of endovascular procedures has the potential to influence better clinical outcomes than angiography-guided angioplasty.

Philips key takeaways

Calcification of ≥180° by IVUS had the strongest correlation with postprocedure MLA compared with the other parameters and strongly associated with negative clinical outcomes.

Postprocedure MLA was significantly smaller in calcified lesions and connected with the loss of patency.

Accurate assessment of calcification patterns by IVUS is useful in maximizing the efficacy of endovascular therapy.

Philips key figures/tables

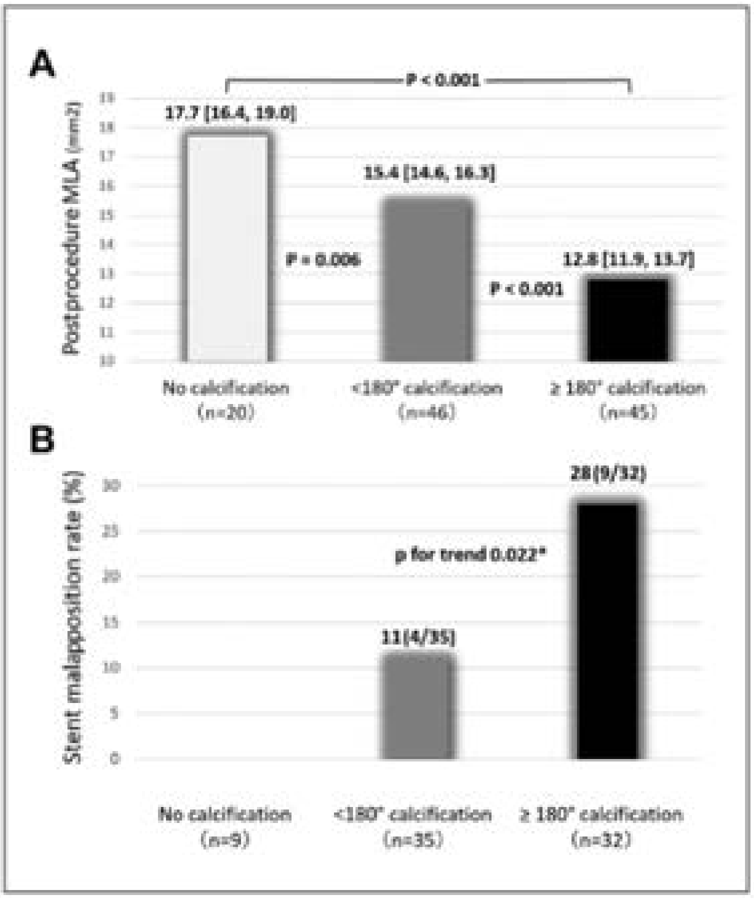


Figure 3. Correlations between a calcification arc ≥180° and (A) the postprocedure minimum lumen area (MLA) adjusted for distal vessel area (with or without stent implantation) and (B) stent malapposition.

Intravascular ultrasound assessment and correlation with angiographic findings demonstrating femoropopliteal arterial dissections post atherectomy: results from the iDissection study

Nicolas W Shammas, James T Torey, W John Shammas, Susan Jones-Miller, Gail A Shammas

J Invasive Cardiol. 2018 Jul;30(7):240-244.

https://pubmed.ncbi.nlm.nih.gov/29958175/

Study design	Objectives	Patients	Population
Prospective Single-Center Case series	Evaluation of dissections by angiography and intravascular ultrasound (IVUS) following treatment of femoropopliteal de novo or non-stent restenosis using atherectomy.	N=15	Patients undergoing atherectomy of the fem-oropopliteal arteries for de novo or restenotic disease (non-stent restenosis

Objective

Dissections occur post atherectomy of the infrainguinal arteries. We hypothesized that angiography underestimates their presence significantly.

Methods

In this prospective pilot study, a total of 15 patients were evaluated by intravascular ultrasound (IVUS) following treatment of femoropopliteal de novo or non-stent restenosis using atherectomy. Eagle Eye Platinum ST IVUS catheters (Philips) were used in this study. Thirteen Jetstream XC atherectomy devices (Boston Scientific) and 2 investigational B-laser atherectomy devices (Eximo Medical) were used. Cine and IVUS images were obtained at baseline, after atherectomy, and after adjunctive balloon angioplasty. Angiographic and IVUS core labs analyzed the images.

Results

Mean age was 70.6 ± 8.0 years. Diabetes and claudication were present in 60% and 73%, respectively. Mean baseline, post-atherectomy, and post-adjunctive angioplasty stenosis severity was 71.4%, 38.1%, and 19.7%, respectively (P<.001 for both baseline vs post atherectomy and post atherectomy vs adjunctive angioplasty). Lesion length was 108.5 ± 43.1 mm. Forty-six dissections were identified on IVUS post atherectomy vs 8 dissections on angiogram (P<.01) (ratio, 5.75 to 1). Post adjunctive angioplasty, there were 39 dissections on IVUS vs 11 on angiogram (P<.01) (ratio, 3.55 to 1). Of these dissections, 13% and 30.8% were ≥180° in circumference post atherectomy and adjunctive balloon angioplasty, respectively (P=.047). Also, 39.1% and 33.3% involved the media and/or adventitia as seen on IVUS post atherectomy and adjunctive balloon angioplasty, respectively (P=.58). Longer lesions correlated with more dissections post atherectomy on IVUS (P=.03), but not on angiogram (P=.28).

Conclusions

Dissections post atherectomy are grossly under-appreciated on angiogram when compared to IVUS. A multicenter registry correlating these findings with clinical outcomes is needed.

Philips key takeaways

There were significantly more dissections noted by IVUS when compared to cine angiography after atherectomy.

The contribution of these dissections (particularly the deeper and more extensive ones) to restenosis following DCB is unknown.

The role of IVUS in peripheral interventions

J Ian Spark and Richard Allan

Presentation at cx 2018. (No publication)

Study design	Objectives	Patients	Population
Prospective Single-Center RCT	To understand if the use of IVUS and angiography in combination improve outcomes compared to angiography alone in patients with peripheral vascular disease of the SFA or popliteal artery	N=91	Patients with a stenotic or occlusive lesion(s) in the SFA or popliteal artery in whom endovascular intervention with angioplasty +/- stenting is the most appropriate treatment

Objective

To understand if, with patients with peripheral vascular disease of the SFA or popliteal artery, does the use of IVUS and angiography in combination improve outcomes of EVT as measured by 1-year primary patency rates compared to angiography alone

Methods

A retrospective analysis was conducted on a cohort of 43 patients who underwent an endovascular intervention utilizing DSA and IVUS imaging. Angiographic measurements were determined by an interventionalist blinded to the IVUS findings.

Results

Of the 43 patients, 58% were male, the majority (72%) were ages 60-89 years, 58% were Rutherford classification III, and 42% had critical limb ischemia (Rutherford classification IV or V). Arterial access sites were common femoral, posterior tibial, and anterior tibial in 37%, 37%, and 26%, respectively. Tibiopedal arterial minimally invasive (TAMI) retrograde revascularization was utilized in 63% of patients. Vessel sizing was consistently the same or smaller for female subjects with either imaging modality. Overall, measurements estimated from angiographic images were significantly smaller than those obtained from IVUS analysis.

Conclusions

IVUS appears to offer a greater degree of accuracy in measuring arterial lumen diameter. As measurements obtained from angiographic imaging consistently under-estimated vessel size, utilization of IVUS may aid in the determination of treatment algorithms and lead to improved endovascular outcomes.

Philips key takeaways

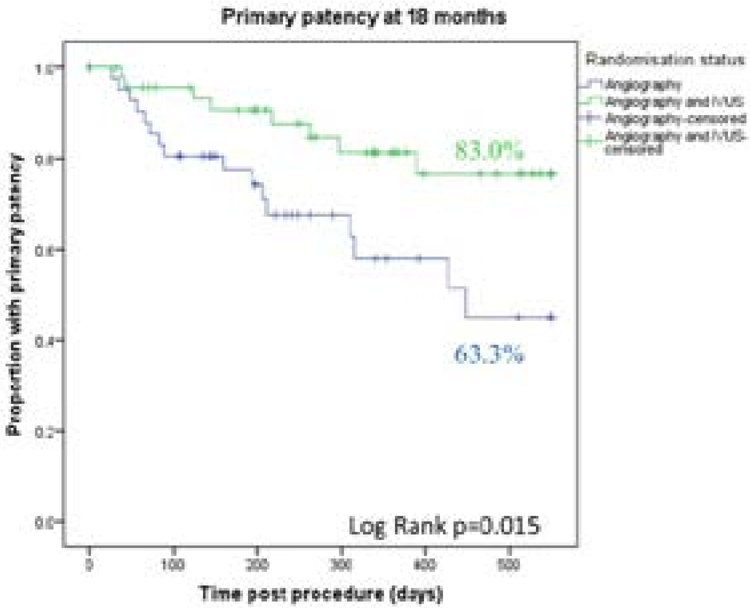
IVUS provides more accurate assessment of disease severity and vessel size

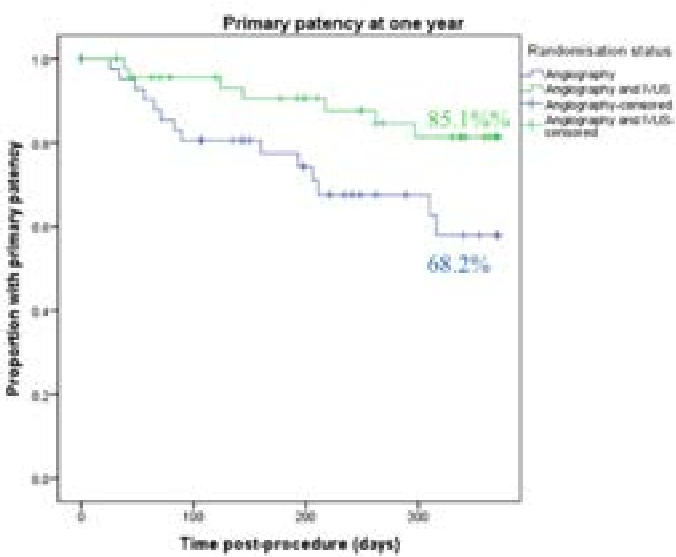
IVUS information changes treatment plan

Improved patency rates with combined IVUS and angiography

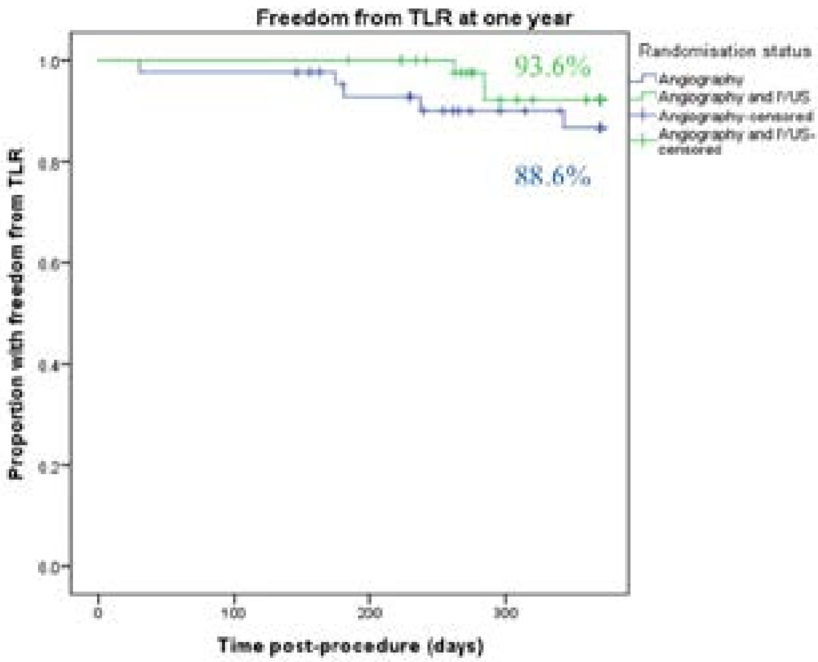
IVUS can assist in: (1) Appropriate balloon sizing for optimal DCB drug uptake (2) Adequate stent deployment; and (3) Guiding atherectomy

Philips key figures/tables

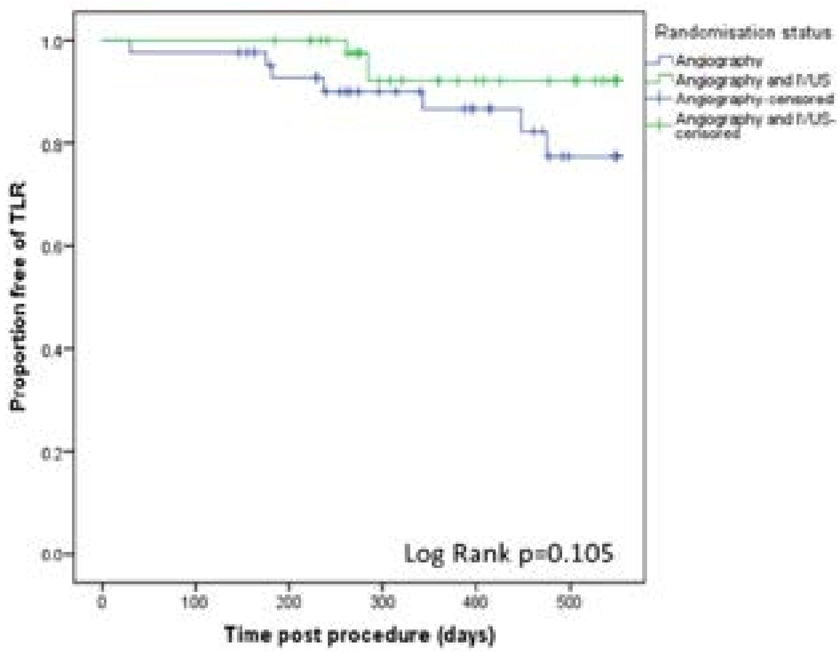




Number at risk	0 months	3 months	6 months	9 months	12 months
Angiography	44	33	25	15	10
Angiography and IVUS	47	39	35	26	19



Number at risk	0 months	3 months	6 months	9 months	12 months
Angiography	44	43	39	29	25
Angiography and IVUS	47	47	47	36	29



Clinical impact of intravascular ultrasound-guided balloon angioplasty in patients with chronic limb threatening ischemia for isolated infrapopliteal lesion

Yoshimitsu Soga, Mitsuyoshi Takahara, Nobuhiro Ito, Tomonori Katsuki, Kazuaki Imada, Seiichi Hiramori , Yusuke Tomoi, Kenji ando

Catheter Cardiovasc Interv. 2020 Oct 21. doi: 10.1002/ccd.29347.

https://pubmed.ncbi.nlm.nih.gov/33085185/

Study design	Objectives	Patients	Population
Retrospective Single-Center 2-Arm Analysis	To estimate the impact of intravascular ultrasound (IVUS) in patients with chronic limb-threatening ischemia (CLTI) who underwent balloon angioplasty for isolated infrapopliteal lesion.	N=155 (N=92 IVUS)	Patients with chronic limb-threatening ischemia (CLTI) who underwent balloon angioplasty for isolated infrapopliteal lesion

Objective

To estimate the impact of intravascular ultrasound (IVUS) in patients with chronic limb-threatening ischemia (CLTI) who underwent balloon angioplasty for isolated infrapopliteal lesion.

Methods

The study was performed as a single-center, prospective maintained database, retrospective analysis. Between January 2013 and December 2018, consecutive 155 CLTI patients (155 limbs) who primarily underwent balloon angioplasty for de novo isolated infrapopliteal atherosclerotic lesions with Rutherford category class 4 or 5 were identified (IVUS-guided: 92 patients, angio-guided: 63 patients) and included in the analysis. We compared clinical outcomes in IVUS-guided group with that in angio-guided group. The primary endpoint was limb salvage without any reintervention. The main secondary endpoints were wound healing rate and time to wound healing in the tissue loss group.

Results

Patient and limb characteristics were similar between the two groups. The IVUS-guided group was treated with a larger balloon size for all types of below-the-knee vessels ($p < .001$), although lesion characteristics, including the QVA-measured vessel diameter, were similar between the two groups. The IVUS-guided group had a higher rate of limb salvage without any reintervention than the angio-guided group ($p = 0028$). Whereas limb salvage and overall survival was not significantly different. Wound healing was significantly earlier and the time to wound healing was significantly shorter (84 ± 55 days vs. 135 ± 118 days, $p = .007$) in the IVUS-guided group.

Conclusions

Limb salvage rate without any reintervention in IVUS-guided balloon angioplasty group was significantly higher than that in angio-guided balloon angioplasty group in patients with CLTI due to isolated infrapopliteal disease.

Philips key takeaways

IVUS use was an independent factor associated with better limb salvage without any reintervention (primary outcome).

Study suggests that angiography underestimates vessel diameters in infrapopliteal arteries.

Assessing the actual vascular diameter via IVUS makes it possible to select the optimal size of balloon diameter, thereby obtaining sufficiently safe gain which allows shortened wound healing period and better limb salvage without reinterventions.

Philips key figures/tables

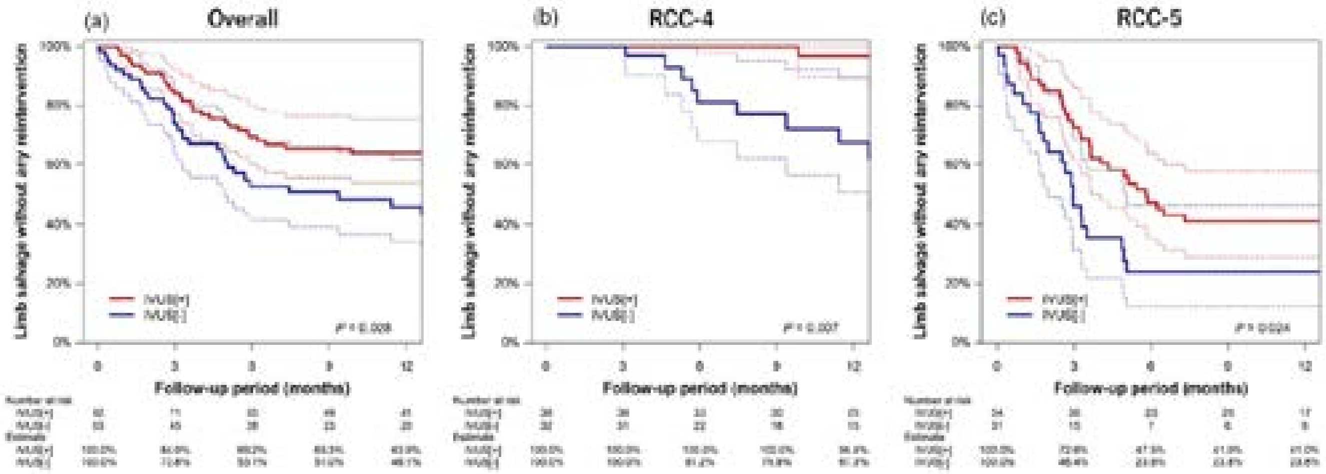


FIGURE 2 limb salvage without any reintervention. (a) Overall, (b) RCC-4, and (c) RCC-5. Error bars indicate 95% confidence intervals. Cumulative incidence rate of wound healing was assessed in the subgroup with tissue loss at baseline. RCC, Rutherford category class [Color figure can be viewed at wileyonlinelibrary.com]

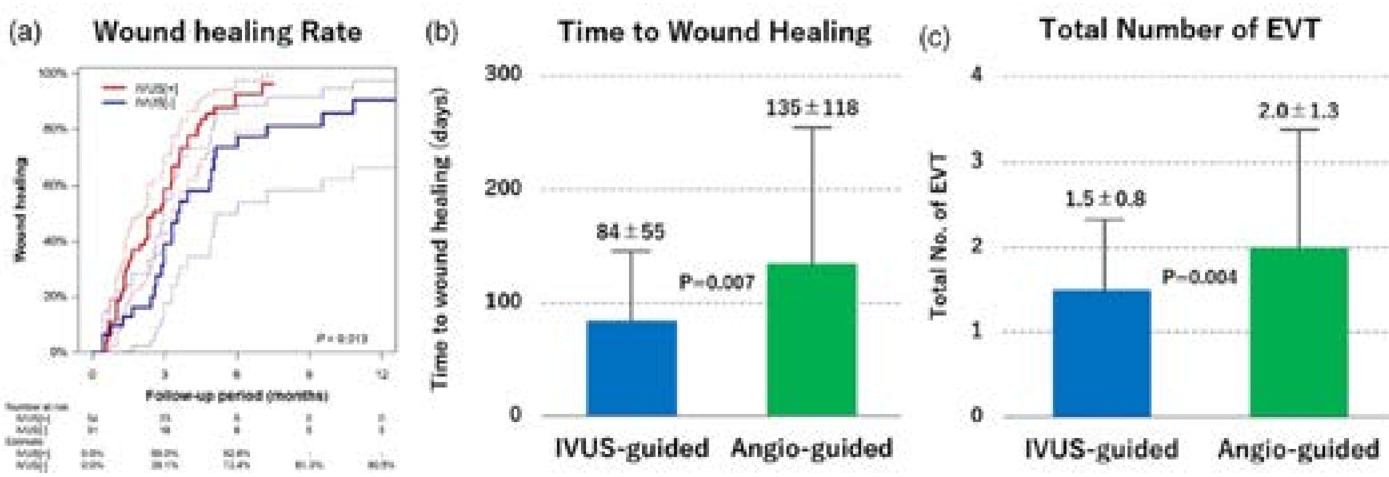


FIGURE 3 Subgroup analysis in Rutherford class 5. (a) Wound healing rate, (b) Time to wound healing, and (c) total number of endovascular therapy for complete healing. Error bars indicate 95% confidence intervals. Cumulative incidence rate of wound healing was assessed in the subgroup with tissue loss at baseline [Color figure can be viewed at wileyonlinelibrary.com]

Facilitated intravascular ultrasound-guided balloon-assisted re-entry technique for complex lower extremity chronic total occlusions: the FIBRE technique

Rajveer Sangera, Christopher Mercogliano, Jon C George, Vincent Varghese

Cardiovasc Revasc Med. 2020 Oct 3;S1553-8389(20)30579-0. doi: 10.1016/j.carrev.2020.09.030.

https://pubmed.ncbi.nlm.nih.gov/33051094/

Study design	Objectives	Patients	Population
Retrospective Multi-Center Case series	To examine the efficacy and safety of the facilitated intravascular ultrasound (IVUS)-guided balloon assisted-re-entry (FIBRE) technique in the treatment of complex, chronic total occlusion (CTO) peripheral arterial lesions.	N=10	Patients with complex, chronic total occlusion (CTO) peripheral arterial lesions undergoing FIBRE technique

Objective

To examine the efficacy and safety of the facilitated intravascular ultrasound (IVUS)-guided balloon assisted-re-entry (FIBRE) technique in the treatment of complex, chronic total occlusion (CTO) peripheral arterial lesions.

Methods

A retrospective analysis of 150 patients undergoing peripheral intervention for lower extremity CTO was performed from 2014 to 2017 at two institutions. From the selected population, 10 patients with complex CTOs were identified using the FIBRE technique. Procedural success, 30 day and 6 month patency rates, ankle brachial index improvement, and complications were analyzed.

Results

Ten out of 150 patients had the FIBRE technique utilized to attempt revascularization of a complex CTO of a femoropopliteal artery. Technical success was achieved in all 10 patients (100%). There were no intra-operative or peri-procedural complications reported including vessel perforation, bleeding, distal embolization, infrapopliteal vessel compromise, or infection. Arterial studies were obtained at 30 days and 6 months to assess patency in 9/10 patients (90%), with 1 patient being lost to follow up. Of the 9 patients, all 9 (100%) had documented arterial patency at both 30 days and 6 months. All patients reported improvement in symptoms. There were also no reports of re-intervention, amputation, or death at 6-month follow up.

Conclusions

The FIBRE technique is a safe and feasible strategy with excellent technical success in experienced hands for revascularization of complex lower extremity CTO when conventional modalities fail.

Philips key takeaways

Visualizing the inflated balloon on ultrasound imaging allows for a more precise puncture without repeated attempts which could potentially traumatize the vessel.

Intravascular ultrasound guided re-entry catheter balloon rupture technique may offer a safe alternative for difficult lesions.

Differences in intravascular ultrasound measurement values between treatment modalities for restenosis in femoropopliteal lesions

Hideaki Aihara , Michiaki Higashitani, Hideyuki Takimura, Kazuki Tobita, Kentaro Jujo, Koji Hozawa, Tetsuo Yamaguchi, Yo Iwata, Hideo Tokuyama, Masayuki Sakurai, Naotaka Murata, Yo Fujimoto, Arifumi Kikuchi, Hiroshi Koganei, Akira Sato, Yuichi Noguchi, Masaki Ieda

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Study design	Objectives	Patients	Population
Retrospective Multi-Center Case series	To examine the efficacy and safety of the facilitated intravascular ultrasound (IVUS)-guided balloon assisted-re-entry (FIBRE) technique in the treatment of complex, chronic total occlusion (CTO) peripheral arterial lesions.	N=10	Patients with complex, chronic total occlusion (CTO) peripheral arterial lesions undergoing FIBRE technique

Objective

The risk of restenosis after intervention is higher in femoropopliteal than in aortoiliac lesions. However, the appropriate endovascular therapy (EVT) for preventing restenosis after intervention for femoropopliteal lesions remains unknown. This study aimed to elucidate the relationship between lesion characteristics and patency after EVT using intravascular ultrasound (IVUS) measurement and to determine the predictors of restenosis on IVUS.

Methods

This prospective observational study was performed at 18 Japanese centers. We evaluated the lesion characteristics before and after EVT for femoropopliteal lesion using IVUS. Angiographic or duplex ultrasound follow-up was performed at 1 year after EVT.

Results

A total of 263 lesions underwent EVT between December 2016 and December 2017. In total, 20 lesions (8 cases of isolated common femoral artery lesion and 12 cases of restenosis lesion) were excluded, and 243 lesions were enrolled in this study. A total of 181 lesions were treated with stent placement, and 62 lesions were treated only with balloon angioplasty. In the case of stent use, a larger distal plaque burden was associated with restenosis, while a lower calcification angle was associated with higher patency in the case of balloon angioplasty alone.

Conclusions

The factors related to patency differed depending on the treating modality. The findings suggest that IVUS is a useful tool for predicting patency because it can provide a more accurate evaluation after EVT for femoropopliteal lesions.

Philips key takeaways

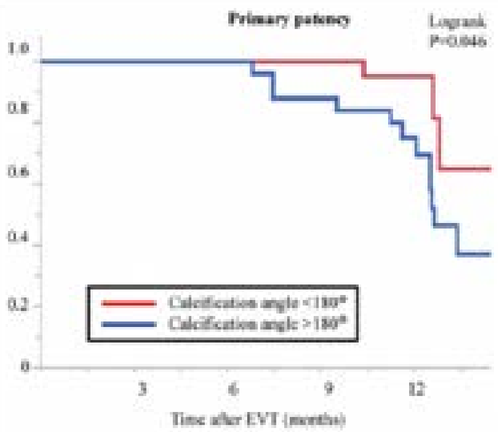
At 1 year after EVT, the primary patency rates were 67% and 74% in the stent and PTA groups, respectively.

Univariate analysis performed on the PTA group showed that the calcification angle of IVUS was the only significant factor.

Univariate analysis of IVUS parameters showed that distal plaque burden and stent edge dissection were significantly associated with restenosis.

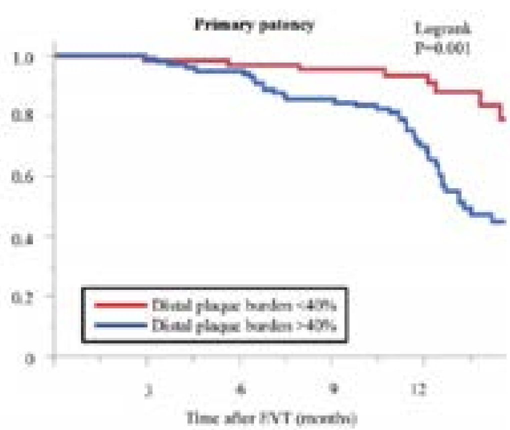
During stent deployment, IVUS should be used to find the site with a plaque burden of ≤40% on the distal side of the lesion, and stent placement should be performed from there.

Philips key figures/tables



months		0	3	6	9	12
No. at risk	Calcification angle <180°	[illegible]	[illegible]	21	23	12
	Calcification angle >180°	29	29	28	29	16
Patency (%)	Calcification angle <180°	100	100	100	100	[illegible]
	Calcification angle >180°	100	100	100	88.1	73.2
SE	Calcification angle <180°	0.00	0.00	0.00	0.00	0.04
	Calcification angle >180°	0.00	0.00	0.00	0.06	0.08

Figure 2. Primary patency rate of lesions with a calcification angle <180° or >180° by Kaplan-Meier analysis in the PTA group. The log-rank test showed that the primary patency rate of lesions with a calcification angle >180° was significantly lower than for lesions with a calcification angle <180°. EVT, endovascular therapy; PTA, percutaneous transluminal angioplasty; SE, standard error.



months		0	3	6	9	12
No. at risk	Distal plaque burden <40%	70	67	61	57	34
	Distal plaque burden >40%	111	97	91	80	44
Patency (%)	Distal plaque burden <40%	100	98.5	96.9	91.1	[illegible]
	Distal plaque burden >40%	100	89.0	83.8	81.1	47.2
SE	Distal plaque burden <40%	0.00	0.02	0.02	0.03	0.04
	Distal plaque burden >40%	0.00	0.03	0.02	0.03	0.05

Figure 1. Primary patency rate of lesions with distal plaque burden <40% or >40% by Kaplan-Meier analysis in the stent group. The log-rank test showed that the primary patency rate of lesions with distal plaque burden >40% was significantly lower than for lesions with distal plaque burden <40%. EVT, endovascular therapy; SE, standard error.

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Search methods

A comprehensive literature search strategy comprising 34 unique searches was conducted in PubMed on January 12, 2018. All searches were conducted with a date filter applied (1/1/1995 – 1/12/2018). A total of 713 papers were identified, of which 530 were duplicates and 183 were unique publications. On March 31, 2020, the search was rerun with 7 new operators and date filter applied (1/12/2018 – 3/31/2020) for the update. A total of 2,040 papers were identified, of which 1,558 were duplicates and 482 were unique publications. Full search strategy is detailed in Table 1.

A total of 158 papers underwent full paper review. The literature was surveyed to assess the objectives, study design, power, patient population, and conclusions regarding use of the IVUS device. Level of evidence of each publication was also graded per Oxford Centre for Evidence-based Medicine (http://www.cebm.net/oxford-centre-evidence-based-medicine-levels-evidence-march-2009) and Scottish Intercollegiate Guidelines Network (http://www.sign.ac.uk/guidelines/fulltext/50/annexoldb.html)

For this compendium, an abstract/presentation not published as well as an additional six (6) papers regarding IVUS use in peripheral arterial disease which were published after the date filters were also considered for inclusion. The top papers and one (1) presentation/abstract were chosen on the merits based on the following criteria: strength of study objectives of IVUS usage, level of evidence, study design and results.

Table 1. Full search strategy and output

	Terms/Operators	Search Results (1/12/2018)	Search Results (3/31/2020)	Total	Results
1	((“intravascular ultrasound”) and artery) and iliac	148	19	167	
2	((“intravascular ultrasound”) and artery) and femoral	202	46	248	
3	((“intravascular ultrasound”) and artery) and iliofemoral	14	4	18	
4	((“intravascular ultrasound”) and artery) and iliocaval	1	1	2	
5	((“intravascular ultrasound”) and artery) and popliteal	58	20	78	
6	((“intravascular ultrasound”) and artery) and femoropopliteal	38	16	54	
7	((“intravascular ultrasound”) and artery and tibial	7	3	10	
8	((“intravascular ultrasound”) and arterial) and iliac	147	11	158	
9	((“intravascular ultrasound”) and arterial) and femoral	195	21	216	
10	((“intravascular ultrasound”) and arterial) and iliofemoral	13	2	15	
11	((“intravascular ultrasound”) and arterial) and iliocaval	3	0	3	
12	((“intravascular ultrasound”) and arterial) and popliteal	55	11	66	
13	((“intravascular ultrasound”)) and arterial) and femoropopliteal	34	9	43	
14	((“intravascular ultrasound”)) and arterial) and tibial	7	1	8	
15	((IVUS) and artery) and iliac	98	4	102	
16	((IVUS) and artery) and femoral	133	20	153	
17	((IVUS) and artery) and iliofemoral	7	1	8	
18	((IVUS) and artery) and iliocaval	0	0	0	
19	((IVUS) and artery) and popliteal	41	9	50	
20	((IVUS) and artery) and femoropopliteal	28	10	38	
21	((IVUS) and artery) and tibial	4	2	6	
22	((IVUS) and arterial) and iliac	96	3	99	
23	((IVUS) and arterial) and femoral	131	16	147	
24	((IVUS) and arterial) and iliofemoral	7	0	7	
25	((IVUS) and arterial) and iliocaval	1	0	1	
26	((IVUS) and arterial) and popliteal	39	8	47	
27	((IVUS) and arterial) and femoropopliteal	26	7	33	

28	((IVUS) and arterial) and tibial	4	2	6
29	(“intravascular ultrasound”) and (“peripheral artery disease”)	24	15	39
30	(“intravascular ultrasound”) and (“peripheral arterial disease”)	58	10	68
31	(“intravascular ultrasound”) and (“critical limb ischemia”)	15	2	17
32	(“IVUS”) and (“peripheral artery disease”)	17	12	29
33	(“IVUS”) and (“peripheral arterial disease”)	36	8	44
34	(“IVUS”) and (“critical limb ischemia”)	9	2	11
35	((“intravascular ultrasound” OR “IVUS”) and (artery OR arterial) and (“non-thrombotic compression” OR “acute deep artery thrombosis” OR “post-thrombotic syndrome” OR “chronic arterial insufficiency”))	NA	5	5
36	(“intravascular ultrasound” OR “IVUS”) and (Artery OR Arterial) and (Vici OR “Zilver Vena” OR Venovo OR Abre)	NA	0	0
37	(“intravascular ultrasound” OR “IVUS”) and (Artery OR Arterial) and (VIRTUS OR VIVO OR VERNACULAR OR ABRE)	NA	36	36
38	(“intravascular ultrasound” OR “IVUS”) and (Artery OR Arterial) and cost) and (benefit OR effectiveness OR utilization)	NA	4	4
39	(“intravascular ultrasound” OR “IVUS”) and (Artery OR Arterial) and (health and economic)	NA	0	0
40	(“intravascular ultrasound” OR “IVUS”) and (Artery OR Arterial) and (expense)	NA	0	0
41	(“intravascular ultrasound” OR “IVUS”) and (Artery OR Arterial) and (reimbursement)	NA	0	0
Abstracts Identified	1700	340	2040	
	Deletion of Duplicates	1325	233	1558
Total Abstracts Reviewed	375	107	482	
	Exclusions after Review of Abstracts	237	87	324
Total Publications Included	138	20	158	

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Philips
3721 Valley Centre Drive, Suite 500
San Diego, CA 92130 USA
www.philips.com/IGTdevices

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