Journal of the Society for Cardiovascular Angiography & Interventions 3 (2024) 101205

JSCAI

The official journal of the Society for Cardiovascular Angiography & Interventions

Standards and Guidelines

Intravascular Ultrasound Use in Peripheral Arterial and Deep Venous Interventions: Multidisciplinary Expert Opinion From SCAI/AVF/AVLS/SIR/SVM/SVS

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ABSTRACT

Percutaneous revascularization is the primary strategy for treating lower extremity venous and arterial disease. Angiography is limited by its ability to accurately size vessels, precisely determine the degree of stenosis and length of lesions, characterize lesion morphology, or correctly diagnose post-intervention complications. These limitations are overcome with use of intravascular ultrasound (IVUS). IVUS has demonstrated the ability to improve outcomes following percutaneous coronary intervention, and there is increasing evidence to support its benefits in the setting of peripheral vascular intervention. At this stage in its evolution, there remains a need to standardize the use and approach to peripheral vascular IVUS imaging. This manuscript represents considerations and consensus perspectives that emerged from a roundtable discussion including 15 physicians with expertise in interventional cardiology, interventional radiology, and vascular surgery, representing 6 cardiovascular specialty societies, held on February 3, 2023. The roundtable's aims were to assess the current state of lower extremity revascularization, identify knowledge gaps and need for evidence, and determine how IVUS can improve care and outcomes for patients with peripheral arterial and deep venous pathology.

Introduction

Percutaneous revascularization is often the primary interventional strategy for treating arterial and venous lesions of the lower extremities.[1] Although angiography is the dominant imaging modality in revascularization, this technology has inherent limitations. As angiography is a 2-dimensional projection of 3-dimensional structures, it has limited ability to accurately size vessels, determine stenosis severity and length of lesions precisely, characterize lesion morphology, and/or detect procedural complications such as dissections. Intravascular ultrasound (IVUS) can overcome these limitations by providing an intraluminal cross-sectional image of the vasculature. In addition, IVUS is a useful tool to limit radiation exposure as well as iodinated contrast use[2] in patients with significant renal impairment. IVUS has been used for decades during percutaneous coronary intervention, and numerous clinical trials and observational studies

Abbreviations: ASC, ambulatory surgical center; DRG, diagnosis-related group; IVUS, intravascular ultrasound; MALE, major adverse limb event; NIVL, nonthrombotic iliac vein lesion; OBL, office-based laboratory; PVD, peripheral vascular disease; RCT, randomized controlled trial.

Keywords: expert opinion; intravascular imaging; peripheral vascular disease.

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https://doi.org/10.1016/j.jscai.2023.101205
Received 1 June 2023; Received in revised form 21 September 2023; Accepted 3 October 2023
Available online 9 January 2024
This paper was jointly developed by Journal of the Society for Cardiovascular Angiography and Interventions, Journal of Vascular Surgery - Vascular Insights, Journal of Vascular and Interventional Radiology and jointly published by Elsevier Inc. The articles are identical except for minor stylistic and spelling differences in keeping with each journal's style. Either citation can be used when citing this article.

support its association with positive outcomes.[3–6] Evidence to support the benefits of IVUS for peripheral vascular intervention is mounting, and a standardized approach to peripheral vascular IVUS imaging is needed.

The present manuscript represents considerations and consensus perspectives from a roundtable discussion between 15 physicians with expertise in interventional cardiology, interventional radiology, and vascular surgery who are members of 6 professional societies that cosponsored the conference: Society for Cardiovascular Angiography & Interventions (SCAI), American Venous Forum (AVF), American Vein & Lymphatic Society (AVLS), Society of Interventional Radiology (SIR), Society for Vascular Medicine (SVM), and Society for Vascular Surgery (SVS); however, the content of this report represents solely the opinions of the consensus committee members. The aims of this roundtable were to assess the current state of lower extremity revascularization, identify knowledge gaps and need for evidence, and determine how IVUS can improve care and outcomes for patients with peripheral arterial and deep venous pathology.

IVUS vs angiography

IVUS uses omnidirectional ultrasound technology to produce cross-sectional images of the vessel. In contrast to single-plane angiography, IVUS reveals the full vessel wall circumference and a wider view of the interrogated vessel. This attribute increases its ability to assess vascular pathology and reduces the likelihood that errors in therapeutic decision making will be made. A comparison of the performance of IVUS vs angiography for evaluating vascular characteristics is provided in Table 1. The panel acknowledges the complimentary role of IVUS and angiography in all peripheral endovascular procedures.

Role of IVUS in peripheral arterial intervention

The high risk of complications and need for reintervention in peripheral artery disease is well documented.[8–11] In arterial interventions, IVUS outperforms angiography in evaluating the hemodynamic significance of a lesion,[12,13] lesion eccentricity, and the presence of calcification.[12,14] It also improves the assessment of vessel diameter, leading to more accurate sizing for various therapies.[15,16] Periprocedurally, IVUS can be used to identify situations in which vessel preparation or stent implantation may be needed.[17] Following intervention, IVUS can uncover inadequate apposition or expansion of stents,[18] as well as procedural complications, including arterial dissections for which angiography is of limited sensitivity.[19–24]

Table 1. Comparison of the performance of intravascular ultrasound (IVUS) vs angiography for evaluating vascular characteristics

Characteristics	IVUS	Angiography
Stenosis	+++	++
Plaque burden	+++	+
Plaque morphology (soft/fib/cal)	+++	+
Reference vessel diameter	+++	+
Lesion length	+++	++
Lesion eccentricity	+++	++
Guidewire orientation (sub/intra)	+++	−
Adherent thrombus	+++	+
Dissection	+++	++
Flow	±	+++
Stent sizing	+++	++
Stent apposition	+++	+
Extrinsic and dynamic compression	+++	+

+ Fair; ++ Good; +++ Excellent; − Not applicable; ± Under investigation. Adapted and reprinted with permission from Secemsky et al, 2022.[7]

Conversely, angiography has advantages in evaluating flow that make it complimentary to IVUS use.

Available data suggest that these advantages translate into improvements in procedural safety as well as in long-term outcomes.[25] A systematic review and meta-analysis of 8 observational trials with controlled comparisons between angiography-only interventions and those supplemented with IVUS found similar technical success, primary patency, reintervention, amputation, and mortality with both approaches. However, rates of periprocedural adverse events were significantly lower in the IVUS group.[26]

More recently, a retrospective analysis of Medicare beneficiaries undergoing peripheral arterial interventions from 2016 through 2019 demonstrated the association between IVUS use and improved long-term clinical outcomes.[27] Of 543,488 interventions, of which 63,372 (11.7%) used IVUS, IVUS use was associated with a 27% reduction in the risk for major adverse limb events (95% CI, 0.70-0.75; $P < .0001$) through a median follow-up of 514 days. There were similar reductions in the risk for acute limb ischemia (adjusted HR, 0.82; 95% CI, 0.78-0.87; $P < .0001$) and major amputation (adjusted HR, 0.69; 95% CI, 0.66-0.71; $P < .0001$)[28] (Figure 1). The observed differences in this administrative data set warrant further analyses in prospective studies to replicate these findings because association does not prove causation. Prospective studies may be able to tease out whether differences in other factors such as operator experience, clinical approach, or severity of disease may be responsible for these differences in outcomes.

Complementing the observational data, a recent randomized, prospective single-center trial enrolled 150 patients undergoing femoropopliteal endovascular intervention. Patients were randomized to angiography with or without adjunctive IVUS.[29] Although there were no significant differences between groups for clinically driven target lesion revascularization at 12 months (84.2% and 82.4%; $P = .78$), the prespecified powered end point, freedom from binary restenosis at 12 months, was significantly higher in the IVUS cohort (72.4% vs 55.4%; $P = .008$; Figure 2). Importantly, adjunctive IVUS use led to changes in the treatment plan in 78.9% of cases, mostly due to increases in treatment length and device sizes.

Data gaps

The panel reviewed the above data and agreed that the main evidence gap for arterial interventions was the need to determine whether greater incorporation of IVUS into clinical practice can result in improved overall procedural success. As an example, some have questioned whether greater use of IVUS in clinical trials, such as BEST-CLI,[27] might have translated into better procedural outcomes. Additional evidence gaps include the need to define what lesion severity warrants treatment to support procedural decision making. Furthermore, consensus on IVUS-guided sizing of devices for treatment is needed. The panel noted that the algorithm for employing IVUS-derived media-to-media diameter for coronary stent sizing is well established; however, this is not well defined for peripheral arteries. Future studies should be directed to reliably quantify how to size vessels to optimize luminal gain with balloons and for stent implantation. Finally, postintervention questions remain unanswered. For instance, IVUS is more sensitive than angiography for detecting procedure-related dissections, but there is no universal consensus on when to treat vs defer treatment of IVUS-detected dissection.[13]

Role of IVUS in venous intervention

Deep venous stent placement is widely used for the treatment of iliofemoral and iliocaval venous obstruction including both postthrombotic occlusions and nonthrombotic iliac vein lesions (NIVLs).

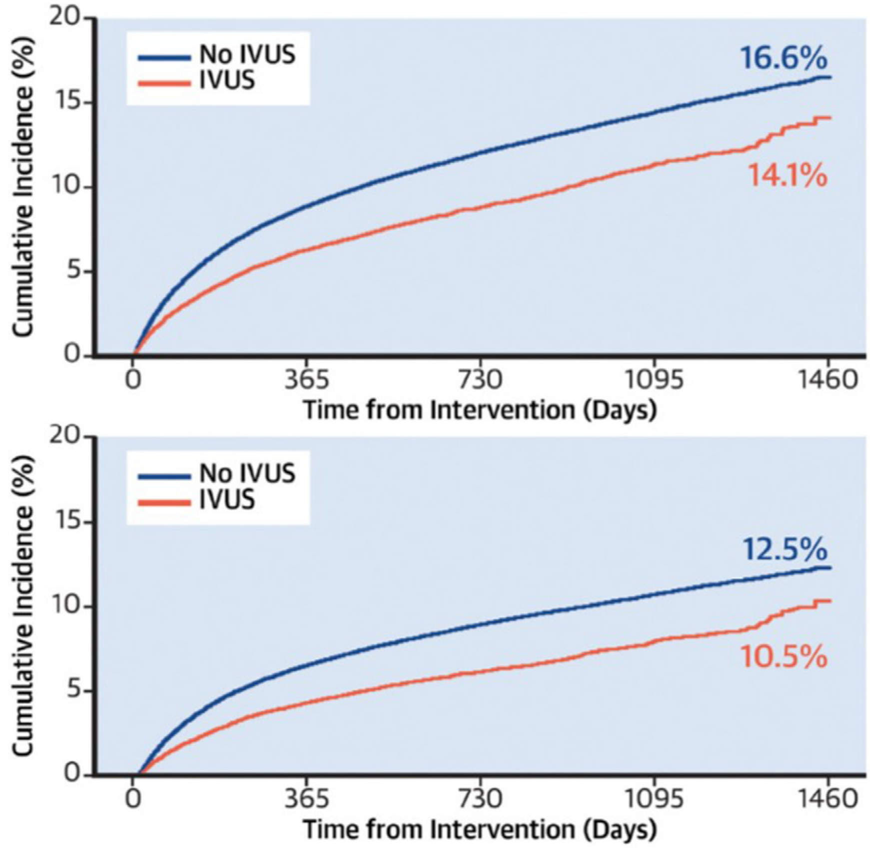

Figure 1.

Kaplan–Meier analysis of risk for major adverse limb events (MALE) (upper graph) and major amputation (lower graph) with interventions using IVUS (red) and not using IVUS (blue) in the Medicare data set. IVUS, intravascular ultrasound. Adapted and reprinted with permission from Divakaran et al, 2022.[28]

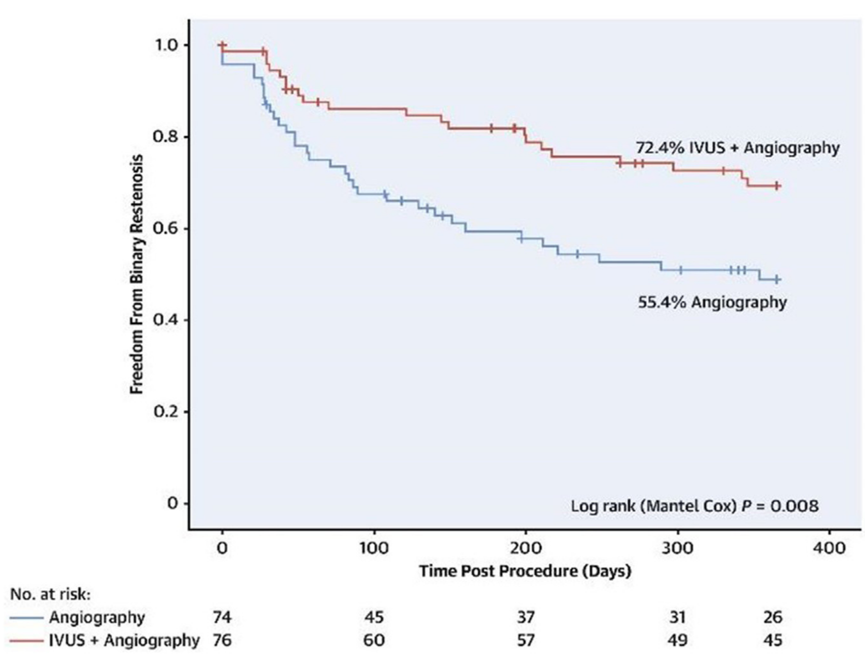

Figure 2.

Kaplan–Meier curve of 12-month freedom from binary restenosis after femoropopliteal endovascular intervention using angiography (blue) and intravascular ultrasound (IVUS) + angiography (red) in a single-center randomized trial. Reprinted with permission from Allan et al, 2022.[29]

Purpose-built stents for the iliofemoral venous segment are available, and purpose-built iliocaval venous scaffolds are in development.[30] With most venous interventions, the goal is to ameliorate venous hypertension, improve venous stasis symptoms, and increase overall quality of life. A meta-analysis from 2015 indicated a high technical success rate with restoration of antegrade flow and maintenance of patency following venous stent placement.[31] The long-term patency of iliofemoral stents was lower in patients with acute deep vein thrombosis and chronic occlusive disease related to postthrombotic syndrome than in those with NIVL.[31] For postthrombotic lesions, numerous prospective investigational device exemption studies have reported 2-year primary patency between 73% and 77%,[32–34] suggesting significant room for improvement.

The use of IVUS during deep venous intervention is increasingly considered vital to optimal outcomes.[35,36] Successful procedures are predicated on: (1) an adequate assessment of the location and degree of stenosis; (2) delineation of venous anatomy for an optimal landing zone; (3) assessment of reference vessels for appropriate stent sizing; and (4) postintervention assessment to ensure stent expansion, lesion coverage, and inflow. IVUS enhances clinical decision-making in venous interventions by providing more accurate evaluation of thrombus burden,[37–40] location and degree of venous obstruction,[41,42] as well as lesion length and vessel diameter[43–45] compared with venography alone. Compressive lesions can also be dynamic. IVUS detects changes associated with position, respiration, and cardiac activity to confirm the presence of true obstruction. IVUS has been shown to detect 30% more significant iliofemoral lesions than venography.[44,46] When assessing for >70% venous area stenosis, venography has poorer sensitivity (45%) and negative predictive value (49%) compared with IVUS.[47] Appropriate measurements of lesion and reference vessel diameter are paramount for accurate stent placement,[38,48] hence reducing the risk of complications, including migration and in-stent restenosis/occlusion.[46,49]

In patients with stent placement across the iliocaval confluence from the left common iliac vein, studies have shown a low but relevant 2% to 4% rate of contralateral iliac vein thrombosis.[50] This risk may be reduced by adjunctive IVUS, which permits clear identification of the lesion and carina, lending to more accurate stent deployment.[51–53] An observational study of 152 patients who underwent endovascular intervention for chronic iliofemoral vein stenosis found that venography missed a lesion in 51% of limbs ($P < .0001$).[46] Venography and IVUS concordance on location of the distal landing zone is 26%. Venography indicated a higher confluence in 74%, and IVUS identified a lower landing zone in 64% of limbs. The correlation between the modalities on the location of the iliocaval confluence was only 15%.[46]

Intravascular ultrasound is more accurate in determining appropriate stent diameter than venography. In a single-center observational setting, IVUS has been associated with increased stent size deployed compared with venography alone.[54] IVUS examination before stent deployment was associated with fewer stent reinterventions at 30 days and 2 years than use of multiplanar venography alone, which the investigators attributed to the use of larger size stents.[54] IVUS is also superior in identifying the appropriate length of vein to be stented by detecting the full extent of postthrombotic change. Complete coverage of all diseased vein segments is critical to successful treatment of postthrombotic obstructions.

Post procedure, IVUS can identify important complications, including grading severity of residual disease, thrombus layering, and assuring adequate stent apposition.[55–57] In the case of NIVLs, IVUS is also critical in identifying any residual venous compression and appropriate stent placement. An analysis of retrospective data on Medicare beneficiaries undergoing lower extremity deep venous stent placement procedures between 2017 and 2019 indicated that IVUS-guided stenting is associated with a reduced rate of reintervention and hospitalization, as well as with less stent migration, over 12 months follow-up.[58]

Data gaps

Despite the success of stent placement for iliofemoral venous outflow obstruction, questions remain. Importantly, there is no consensus on what constitutes a clinically significant degree of stenosis necessitating intervention, particularly in NIVLs. Among patients treated for NIVL, it has been reported that only 63% experienced a clinical treatment effect, 24% showed no clinical response, and in 14%, symptoms worsened.[59] Other studies have shown that a 54% cross-sectional area reduction after venous stent placement in NIVL rendered a positive predictive value to be as low as 46% for clinical improvement.[49] Left common iliac vein compression is a frequent anatomic variant in asymptomatic patients with no history of deep vein thrombosis; the natural history of such lesions is unclear, and treatment is frequently not required.[60] There are currently no validated hemodynamic tests to assess the relative influence of an iliac vein compression on lower extremity symptoms. In an analysis of computed tomography (CT) scans from 50 consecutive patients, 24% had >50% diameter compression, and 66% had >25% diameter compression.[60] A larger study of 300 subjects undergoing CT scanning demonstrated a mean 36.6% and 48.5% diameter reduction at the arterial crossing in comparison to the ipsilateral common iliac vein in men and women, respectively. A ≥50% stenosis was present in 33% of men and 53% of women. There was no difference in the severity of stenosis among patients with or without venous signs or symptoms.[61]

Whether diameter or area stenosis is the best predictor of clinical improvement in patients with NIVL remains a key unresolved question.[35] In the multicenter Venogram Versus Intravascular Ultrasound for Diagnosing and Treating Iliofemoral Vein Obstruction (VIDIO) trial, diameter stenosis was the only significant predictor of future improvement in clinical symptoms, with a threshold of >61% by IVUS.[49] IVUS area measurements estimated a similar threshold of stenosis as the overall cohort (>53%), but this measurement was not significantly predictive of later clinical improvement. The panel attributed this finding to variance in area measurements, which are difficult to perform due to a variety of factors including wire bias in the common iliac vein as well as incomplete luminal assessment at the compression site, where frequently not all margins of the vessel are visible. Most likely there is no single threshold for critical stenosis, and use of a single threshold and a single modality is clearly insufficient for predicting response in an individual patient. The problem is compounded by the sensitivity of IVUS measurements to respiration and position. The panel considered it less helpful to rely solely on the long-held dependence on area reduction >50% as it would probably lead to stent overuse. Until more reliable measures of hemodynamic significance are available, the decision to stent a NIVL currently requires good clinical judgment based on patient presentation in conjunction with imaging findings. Current data suggests that a greater than 61% diameter-reducing stenosis relative to a normal reference segment in the iliac vein yields the greatest symptom improvement following stent placement for nonthrombotic lesions of the iliac veins. Isolated imaging findings of significant venous compression/stenosis in the absence of an appropriate clinical context of associated symptoms should not lead to a decision to stent.

Lastly, venous inflow is an important factor when determining which patients will have a durable result, but reliable methods to assess inflow are lacking.[62–64] Inflow assessment, including as detected by IVUS, needs further investigation. The panel identified the common femoral, femoral, and profunda femoral veins as important components of inflow but acknowledge the lack of accepted definitions of normal inflow because it is currently determined by a variety of factors, including observations of contrast clearance during venography.

Contemporary trends in IVUS use during lower extremity arterial and venous intervention

The use of IVUS in peripheral interventions has grown significantly in recent years, but growth has varied across clinical settings and physician specialties. Two reports have analyzed Medicare records of peripheral interventions.[28,58] For arterial interventions, interventional radiologists were the greatest users of IVUS in 30% of procedures, with a 20% growth in use from early 2016 through the end of 2019. Cardiologists, surgeons, and other physician specialties used IVUS in 15% to 17% of procedures (Figure 3). The overall preference for IVUS use varied widely across individuals: physicians who used IVUS did so in a median of only 5.4% of cases (IQR, 2.2%-15%). Use was greatest in ambulatory surgery center (ASC) and office-based laboratory (OBL) settings, 40% of which used IVUS, with a 24% increase over the analyzed time period. By contrast, use of IVUS in inpatient or hospital outpatient procedures increased only marginally during the same time period and from a very low base of around 5% of procedures.[28] This may be due to hospital-based physicians not having ready access to developing technology due to the increased pressures from hospital administrators to not increase capital expenditures and the lack of additional reimbursement within the diagnosis-related group (DRG) system.

Uptake of IVUS is much higher for venous interventions.[58] Utilization rates are highest among cardiologists (89% of procedures) and surgeons (77%) with interventional radiologists utilizing IVUS in 41% of procedures (Figure 3). Among IVUS users, IVUS was used in a median 87.5% of venous procedures (IQR, 57.1%-100%). As with arterial procedures, use was highest in ASC/OBL settings and lowest in hospital inpatients (in 34% of procedures despite a recent increase). There is less of a trend toward increased use over time than observed for arterial interventions, largely due to the already higher rates of use.

Both findings provide important insights into where greater investment for IVUS growth is required. There is a need to ensure resources for IVUS utilization are not only focused on outpatient centers but also equally address barriers within the hospital setting.

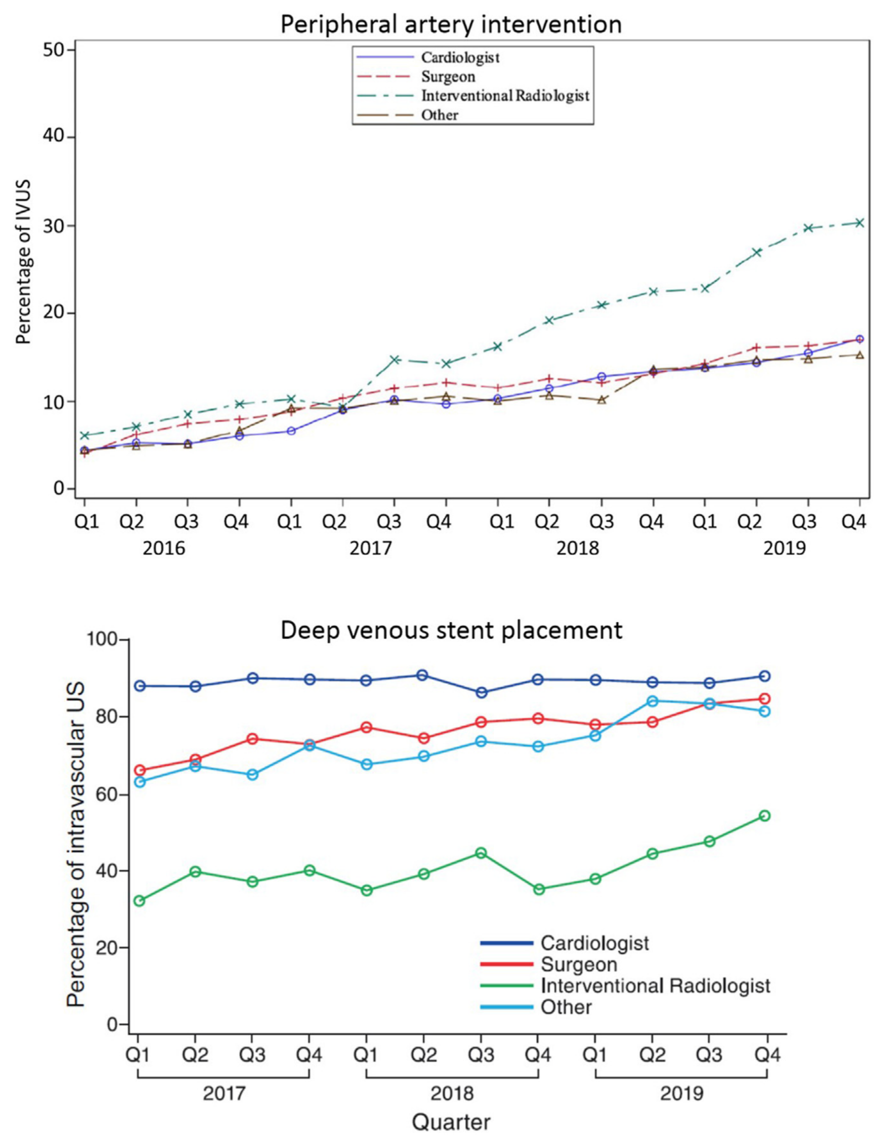

Figure 3.
Utilization of IVUS among different physician specialties up to the end of 2019. IVUS, intravascular ultrasound. Reprinted with permission from Divakaran et al, 2022[58] and Divakaran et al, 2022.[28]

Use of IVUS in other vascular beds

Outside of the lower extremities, IVUS plays an important role in other disease states. For instance, IVUS has been used routinely to assist in delineating aortic anatomy for more than 20 years.[65] Its use in the treatment of type B aortic dissection with thoracic endovascular aneurysm repair is associated with improved long-term survival.[66] The value of IVUS is also well established in interventions in coronary artery disease, where use of IVUS is associated with reduced rates of target vessel revascularization and stent-related events.[67,68]

There are several other vascular beds where adjunctive IVUS may contribute to improved diagnosis, procedural success, and outcomes. However, there are only sparse data and no systematic investigations available currently. Below are a few recent examples of this expanded use.

A single-center study added IVUS to standard angiography during endovascular interventions for failing hemodialysis access grafts and concluded that imaging of the arterial inflow vessel, arteriovenous graft conduit, and venous outflow vessel is feasible and may extend the time to the first reintervention. However, both groups experienced similar rates of one or more arteriovenous graft reinterventions or discontinuation at 3 months and 6 months.[69]

Renal arteriography and IVUS have been employed in renal infarction to improve the diagnostic process and evaluate secondary prevention treatment strategies. In a cohort of 25 patients, the use of imaging identified local artery disease in 14 patients, led to a diagnosis or change in diagnosis in 9 patients, and to a change in antithrombotic strategy in 14 patients.[70] Among the panel, there was agreement that IVUS may also play an important role in the application of novel technologies, such as ultrasound renal denervation for hypertension, where accurate assessment of vessel diameter and device choice are critical for successful outcomes as well as for follow-up monitoring.

IVUS-assisted venography has been reported in small studies to be valuable for determining and performing the optimal treatment strategy in selected patients with venous thoracic outlet syndrome.[71,72] Furthermore, IVUS has been used to aid in the successful deployment of inferior vena cava filters at the bedside.[73] Simultaneous IVUS imaging has been employed during transcatheter pulmonary embolectomy and was associated with improved thrombus visualization and catheter localization while minimizing contrast medium exposure and wire exchanges.[74,75] This may be particularly valuable for patients with pre-existing renal dysfunction.

The role of consensus documents and guidelines to support IVUS use in peripheral interventions

Despite the widespread use of adjunctive IVUS in peripheral interventions, few formal guideline recommendations are currently available. The European Society for Vascular Surgery 2022 Clinical Practice Guidelines on the management of chronic venous disease of the lower limbs[76] include a Class IIa recommendation for IVUS during endovascular procedures for iliac vein outflow obstruction, to determine the extent of the lesion and guide stent placement, mainly based on the VIDIO trial results. In the United States, IVUS is mentioned in the SVS/AVF [77] Clinical Practice Guidelines for early thrombus removal strategies for acute deep venous thrombosis as "likely a useful adjunct" to venography for the detection of chronic iliac obstruction but not formally recommended. The SIR Position Statement on treatment of acute iliofemoral deep vein thrombosis takes a similar view.[78] The use of IVUS in addition to venography was given a weak recommendation with a level of evidence C in "most patients" undergoing endovascular thrombus removal for acute iliofemoral deep vein thrombosis.

In 2022, Secemsky et al[79] developed and conducted a structured consensus survey to determine the appropriate use of peripheral IVUS. Covering both lower extremity arterial intervention and deep venous disease, the consensus document represented the views of an independent, global group of acknowledged experts across vascular disciplines. Experts were selected based on a 12-person steering committee with a priority to capture all specialties managing patients with peripheral vascular disease and incorporating viewpoints from across the globe. The experts, 15 each for arterial and venous interventions, graded the appropriateness of IVUS use in clinical scenarios for the preintervention, intraprocedure, and postintervention optimization stages. Grades from 7 to 9 were considered "appropriate"; 4 to 6, "may be appropriate"; and 1 to 3, "rarely appropriate" for the specific indication. Overall, the ratings (Figure 4) indicate consensus support for IVUS use at all procedural steps for tibial arteries and iliofemoral venous interventions. For revascularization of iliac and femoropopliteal artery disease, IVUS was graded as "may be appropriate" for several scenarios, particularly preintervention scenarios, but was otherwise deemed appropriate across remaining scenarios. The panel reviewed the appropriate use document in detail, and although they agreed with its design, execution, and findings in principle, they also acknowledged the need for further definitive cost-effectiveness and outcomes-based research to allow for more widespread adoption by all the societies. Future work remains needed to reach consensus on procedural and technical considerations with lower extremity IVUS imaging, including standardized approaches to pullback imaging acquisition and vessel measurements.

A similar exercise was recently conducted using the Delphi consensus method for IVUS use during deep venous interventions. These data were presented at AVF 2022[80] but are not published at the time of writing. Expert agreement and disagreement were solicited for a number of statements on the use of IVUS in venous interventions. Consensus, defined as >70% of respondents rating a statement as 7 to 9 on a 9-point scale, was reached on IVUS guidance in venous stenting procedures enabling accurate identification of lesion length and stent landing zones. There was also consensus on the use of IVUS to evaluate residual thrombus burden, lumen gain, lesion coverage, and stent expansion/apposition outcomes poststenting. Consensus was achieved on the use of a >60% cross-sectional area threshold for NIVL procedures.

The panel agreed on the need for formal incorporation of IVUS into peripheral guidelines, which can improve clinical practice, support reimbursement and improve access to training. Formal guidelines will depend on the same data as the current recommendations on surgical and endovascular peripheral interventions, most of which are based on evidence levels B and C, ie, consensus of expert opinion and/or small studies, retrospective studies, and registries.[81,82] This moderate strength evidence reflects the absence of randomized controlled trials (RCTs) and lack of hard end points, long-term follow-up data, and reproducible outcomes. Thus, retrospective studies and registries remain the strongest source of evidence evaluating the utilization of IVUS during lower extremity revascularization. Such data were recently aggregated and summarized in a systematic review in 2022 by Natesan et al.[25] The authors identified 29 studies in 95,000 patients deemed eligible to assess the use of IVUS in lower extremity peripheral arterial interventions and 19 eligible studies in iliofemoral venous interventions. Although no RCTs were included, 37 studies received a 2b evidence level rating on the Oxford Levels of Evidence scale.[83] The evidence consistently supported the value of IVUS in vessel characterization, vessel preparation, effective stent deployment, and monitoring for postprocedural complications during both arterial and venous peripheral interventions in appropriately selected patients.

	AUC Rating (Median Score)			
	Iliac Artery	**Femoropopliteal Artery**	**Tibial Arteries**	**Iliofemoral Vein**
Preintervention scenarios				
Lesion characteristics	N/A	N/A	N/A	A (8)
Occlusion	M (6)	M (6)	A (8)	N/A
Plaque morphology	M (6)	M (6)	A (8)	N/A
Ambiguous lesion/severity	A (7)	A (8)	A (7)	A(9)
Filling defects	M (6)	A (8)	A (8)	A (9)
Vessel sizing	A (7)	A (8)	A (8)	A (9)
Minimizing contrast	A (8)	A (8)	A (9)	A (9)
Intraprocedure scenarios				
Location of crossing track	A (9)	A (8)	A (8)	N/A
Determination of next therapeutic step	A (8)	A (9)	A (8)	A (9)
Vessel sizing for device	M (6)	A (7)	A (8)	A (9)
Postintervention optimization scenarios				
Residual stenosis/plaque after debulking	A (7)	A (7)	A (7)	N/A
Stent optimization/post-dilation	M (6)	A (7)	A (8)	A (9)
Dissection detection	A (8)	A(8)	A (8)	N/A

Figure 4.
Expert ratings for IVUS use by intervention phase and arterial segment and for iliofemoral veins. Green indicates scores 7 to 9 "Appropriate"; yellow indicates scores 4 to 6 "May be appropriate". A, appropriate; AUC, appropriate use criteria; IVUS**,** intravascular ultrasound; M**,** may be appropriate. Adapted and reprinted with permission from Secemsky et al, 2022.[79]

Key barriers to IVUS utilization

The panel identified a number of key barriers to increased IVUS use (Table 2).

Among technology-related issues are the limited maximal imaging diameter for lower profile catheters, the moderate quality and resolution of the image, and the lack of additional features such as vulnerable plaque determination, flow information on 0.035" catheters, angiography coregistration, and use of preprocedural axial imaging with technologies such as duplex ultrasound and CT and magnetic resonance angiography. Although IVUS is highly valuable for lesion and orifice localization and size measurements, it performs less well for vulnerable plaque identification. This is due to the relatively poor resolution, inaccurate tissue definition, and inconsistent border detection.[84] Higher frequency wavelengths improve image quality but at the cost of reduced depth of penetration and the resulting field of view. Technological developments and advances in our understanding of disease can be expected to reduce these barriers in the future.

In regard to operator comfort with use and with interpretation, in coronary applications, only 15% of recently surveyed cardiology trainees report independence in IVUS use.[85] For other interventions, where IVUS is less routinely used, this number can be expected to be lower. Peripheral IVUS training has never been standardized. The panel highlighted the need for continuing medical education modules covering all aspects: sizing, technique, set-up, interpretation, case flow, and more. Interdisciplinary collaboration will be invaluable, nationally and internationally; the vascular interventionists on the panel found much to be learned from how interventional cardiologists have approached training. Training is multifactorial, including data, guideline information, case studies, and expert clinical experience. Teaching libraries with archived cases should be made more widely available. Actively performing procedures are key to improving retention and quality, and hands-on training should be emphasized. Educational needs will differ between first-time users of IVUS and more experienced users (Figure 5). The panel recommended including a minimum number of IVUS cases into formal resident/fellow training curricula, including arterial and venous experience. A formal certification for physicians, as has been introduced for other devices like atherectomy, may improve the quality of decision making guided by IVUS. A further challenge is the need to train trainers, as there is a lack of experienced individuals available, particularly for peripheral procedures. Training programs run by industry should ideally focus on a range of levels including trainees, early career physicians, and more experienced practitioners.

Table 2. Major barriers to increased IVUS use

Limitations of the technology (ie, imaging quality)
Operator comfort with use and interpretation
Access/cost (ie, capital needed for technology in catheterization labs/angiography suites/operating rooms)
Additional time required for the integration of IVUS into standard procedures
Further need of evidence supporting use

IVUS, intravascular ultrasound.

Integration of IVUS into standard procedures may be associated with capital equipment cost and possibly increased procedure time. According to an analysis of IVUS use during inpatient peripheral arterial revascularization from 2006 to 2011, IVUS use was associated with a non-significant increase in hospitalization costs of \$1334 (95% CI, −\$167 to \$2833; $P = .082$).[86] Furthermore, longer-term studies outside the United States have supported cost reductions when IVUS was utilized, likely driven by a decreased event rate post hospitalization.[87] The financial impact may be greatest on independent practices, as independent physicians are directly responsible for managing the practice, staff recruitment and retention, and maintaining the financial viability of their practices. In an international survey of IVUS use in coronary procedures in 2018, cost was the major barrier, mentioned by 66% of

User	Arterial Training Needs	Venous Training Needs
Novice User	**Awareness**	
	Awareness of benefits of IVUS in improving long-term outcomes and the role of IVUS in vessel sizing, contrast minimalization, reducing radiation exposure and guiding intervention decisions	Awareness of the essential role of IVUS in iliocaval/ iliofemoral venous interventions, including the ability to evaluate disease severity, accurately size for stent placement and, reduce adverse events (i.e., stent migration)
	Basics of IVUS Implementation	
	Diagnostic • Determining lesion morphology/plaque characterization • Calculating vessel diameter and lesion length	**Diagnostic** • Understanding average venous anatomy • Calculating diameter and/or area reduction to determine lesion significance
	Procedural Planning • Evaluating need for plaque modification • Preparing for definitive treatment (i.e., drug-coated balloon treatment, stent implantation) through vessel sizing and identifying healthy landing zones	**Procedural Planning** • Determining the appropriate stent landing zones • Estimating the appropriate stent diameter and length • Identifying the iliocaval confluence
	Post-Intervention Assessment • Identifying the presence and severity of complications including dissection and vessel recoil • Evaluating for stent under expansion and malapposition	**Post-Intervention Assessment** • Assuring appropriate stent expansion and apposition • Evaluating for residual thrombus
Average/Experienced User	• Optimizing measurement and reporting standards • Classifying severity of lesions from mild/moderate to severe • Grading dissections by established IVUS-based criteria (e.g., iDissection criteria) • Incorporating IVUS with re-entry techniques for total occlusions	• Optimizing measurement and reporting standards • Understanding variations in anatomy • Understanding impact of positioning, hydration and underlying diagnosis on IVUS interpretation • Combining inflow assessment with disease severity

Figure 5.
Main training needs for novice and average users of IVUS in peripheral interventions. IVUS, intravascular ultrasound.

responders.[88] Additionally, coverage of IVUS outside the United States varies widely and has hampered growth and the ability to standardize international practices.

Added procedural time remains a theoretical concern slowing IVUS adoption. In a 2018 survey of coronary operators, prolongation of the diagnostic procedure or intervention was mentioned as a barrier to intravascular imaging by 35% of responders.[88] However, the panel pointed out that this is mostly a perceptual barrier. There is a clear upfront need for adequate training of personnel, incorporation of IVUS into standard procedural equipment, and operators becoming familiar with active imaging interpretation during use. But once the procedure has been established, the panel agreed that IVUS can improve the clinical, procedural, and workflow efficiency of peripheral interventions. For instance, in a coronary intravascular imaging study examining procedural workflows, a standardized imaging approach reduced procedural time, contrast utilization, radiation exposure, and device use.[89]

Procedural efficiency can also have positive financial implications. Although capital investments are relevant, a realistic assessment of the cost and resource impact of IVUS integration should ideally include personnel utilization and procedural time. Moreover, other potential advantages of IVUS incorporation are often omitted from cost assessments. There is demonstrated reduced use of contrast and reduced radiation exposure with IVUS,[90,91] which may be particularly beneficial to high-risk patients suffering from diabetes, chronic renal insufficiency, or contrast allergies.[92] Additionally, reduction in radiation to the operator and staff alone may justify use. In addition, a focus on total medical expense over 1 to 2 years after peripheral intervention would provide a more relevant measure of any economic benefits of IVUS related to the potential decreased need for reintervention and/or complications. Cost calculations are inextricably linked to the reimbursement landscape. In fact, the current DRG system disincentivizes proceduralists to adopt new technology with the potential to improve patient outcomes and decrease long-term total medical expense, since the short-term expense decreases already thin hospital margins. Technological improvements will not become widely implemented without updated reimbursement criterion. While the ability to be partially reimbursed for IVUS use may have led to earlier adoption of this beneficial technology in the outpatient setting, even this will be threatened with the cumulative projected 20% cuts to arterial revascularization and outpatient venous procedure reimbursement in the OBL setting.[93] Thus, the panel identified 3 major needs to further demonstrate the clinical utility of this technology: supporting additional prospective IVUS outcomes-based studies that also incorporate assessments for cost effectiveness; developing a closer collaboration with commercial partners to minimize capital equipment outlay; and working with societies and payers to strengthen reimbursement so that broader adoption is possible.

Future directions

Looking ahead, the panel highlighted a number of needs and desirable actions (Central Illustration).

Address data gaps

As discussed above, the evidence base for IVUS use in peripheral vascular interventions consists mostly of retrospective observational data, although prospective data do exist. A successful RCT would provide valuable level 1 evidence for IVUS-added versus standard imaging, but this may be challenging to perform on a large scale. The costs, existing high utilization and risk of inconclusive outcomes pose hurdles in the current healthcare landscape. For instance, during venous procedures, accurate sizing is difficult to achieve without the use of IVUS, which makes it ethically challenging to recruit a comparator group. The panel strongly supported the role of additional registries to augment clinical data. Registries today often do not include imaging data and need to improve data collection. Available data from retrospective studies and registries should be

Action Items to Advance the Use of Intravascular Imaging (IVUS) During Peripheral Interventions

	Needs	Desirable Actions
Data Gaps	• Arterial: Evidence supporting how technical and procedural success can be improved with IVUS • Arterial: Improved definitions of what lesion severity should be treated, and severity of dissection that warrants intervention • Venous: Definition of the most accurate predictor of clinical improvement with reliable cut-off points • All peripheral interventions: Health economic and comparative effectiveness studies	• Support the establishment of registries to augment clinical data • Increase the capture of imaging data in registries • Push for incorporation of available data from retrospective studies and registries into national and international guidelines • Greater use of IVUS during lower extremity revascularization clinical trials
Education	• Societal support for training on intravascular imaging in peripheral interventions • Standardized goals, content, and structure of training programs • Correlating IVUS findings with objective clinical metrics • Understanding differences in interventional therapies and modalities utilized across various economic, racial, and gender subgroups correlated with outcomes	• Introduce formal certification for physicians • Drive the inclusion of a minimum number of IVUS cases into curricula, including arterial and venous experience • Adapt learnings from how interventional cardiologists have approached intravascular imaging training • Ensure clinical indications for an intervention are part of physician training
Interdisciplinary Collaboration	• Appropriate reimbursement in the outpatient and inpatient settings • Inclusion of peripheral IVUS in society consensus documents and guidelines • Multispecialty society-led consensus on optimal use and role of IVUS during peripheral interventions • Consensus on value added with IVUS imaging despite increased cost at index procedure within diverse population subgroups	• Work closely with insurers and government agencies to develop treatment standards, guidelines, appropriateness criteria and global quality metrics • Adapt learnings from how interventional cardiologists have approached training • Collaborate on advocacy with regulatory and reimbursement agencies • Build upon professional societies' educational programs and adapt these for IVUS training • Work together to raise awareness on how IVUS can improve clinical care • Explore intra-society patient education, through e.g., Public Service Announcements

Central Illustration.
Action items to advance the use of intravascular imaging (IVUS) during peripheral interventions.

incorporated into guidelines, as was done in the European Society for Vascular Surgery guidelines,[76] coupled with expert opinion. It remains possible that artificial intelligence could facilitate interpretation of IVUS images collected during registry and clinical trial efforts and by doing so, better support clinical decision making and predict outcomes.

There is also an urgent need for health economic and comparative effectiveness studies, as appropriate reimbursement in the outpatient and inpatient settings is essential for IVUS uptake. Reimbursement systems are increasingly moving toward value-based approaches and appropriate health–economic analyses are fundamental to a favorable reimbursement environment.

Reinforce educational efforts and change perceptions of IVUS

Education is key to appropriate use and adoption of IVUS. For cardiovascular procedural training, recent guidelines recommend IVUS training,[94] but such support is lacking for peripheral interventions. Utilization will be driven by comfort with the technology and sophistication in imaging interpretation, and this education will ideally occur within physician training programs and continue into practice.

Efforts to raise awareness also need to be intensified, and perceptions of IVUS among physicians and reimbursement authorities changed. It is critical to note that an increase in technology use does not imply inappropriate use. Continued investment in the evidence supporting the role of this device and inclusion in guidelines will help deflect this unnecessary misinformation.

Interdisciplinary and intersociety collaboration

Physicians and organizations need to work closely together and with insurers and government agencies to develop treatment standards, guidelines, and appropriateness criteria and global quality metrics, which may in turn inform patient referral by primary care physicians and other specialists. Interdisciplinary and intersocietal collaboration and consensus documents are particularly important when the evidence base is in evolution, as is the case for peripheral interventions. What is more, professional societies have developed educational programs for physicians in many clinical areas, and the experiences can be built upon for IVUS training.

Deepened intersocietal collaboration and speaking in one voice can achieve a critical mass unreachable by single societies. This will increase the power of advocacy efforts with regulatory and reimbursement agencies. The need for societies to collaborate is instrumental in identifying and promoting standardized practices, such as appropriate patient selection.

Appropriate use

Some have raised concerns about the potential to overutilize IVUS in the outpatient OBL or ASC setting vs the inpatient setting because there is incremental physician reimbursement associated with use of this technology. Others have argued that there is potential for underutilization of this new technology on the inpatient side due to the increased costs of both capital equipment and lack of separate reimbursement for the disposable catheters because hospitals are paid based on a DRG system. These potential conflicts demonstrate the importance of generating more research related to patient outcomes and cost effectiveness with IVUS and the importance of creating mechanisms for reimbursement in both the inpatient and outpatient setting. While the authors believe that this will encourage further critical research in this area, they also recognize that reasonable practitioners may choose to wait for more definitive data before widely adopting this new technology.

Outlook

IVUS is an important tool for many aspects of peripheral vascular intervention, but its utilization remains low. Closer interdisciplinary collaboration at all levels will be crucial to ensure continued growth of IVUS utilization by appropriately trained and informed physicians, in a sustainable application of the latest data to patient identification and process optimization with supportive reimbursement. Patients with peripheral vascular disease will likely benefit from safer procedures and improved outcomes when IVUS is utilized, as agreed upon by all members of the panel.

Acknowledgments

Writing assistance was provided by Pelle Stolt, PhD, Basel, Switzerland.

Peer review statement

Journal of the Society for Cardiovascular Angiography & Interventions (JSCAI) Associate Editor Sahil A. Parikh had no involvement in the peer review of this article and had no access to information regarding its peer review. Full responsibility for the editorial process for this article was delegated to JSCAI Editor-in-Chief Alexandra J. Lansky.

Declaration of competing interest

Eric Secemsky receives research support to his institution from NIH/NHLBI K23HL150290, Food & Drug Administration, BD, Boston Scientific, Cook, CSI, Laminate Medical, Medtronic, Philips, and SCAI. He is a consultant for Abbott, Bayer, BD, Boston Scientific, Cook, Cordis, CSI, Heartflow, Inari, Infraredx, Medtronic, Philips, RapidAI, Shockwave Medical, and VentureMed. Herbert Aronow serves on the data safety monitoring board for the Philips ILLUMENATE trials, on the clinical events committee for Silk Road Medical's NITE Trial, and as a consultant for Medtronic and ReCor Medical. Patrick Muck has ownership interest and serves as a speaker for Penumbra, serves as a speaker and on the advisory board for Medtronic, serves on the advisory board for Boston Scientific and Abbott, and serves as a speaker for Becton Dickinson and Shockwave Medical. Christopher Kwolek is a principal investigator for Endologix and Silk Road Medical, serves as a consultant for Endologix, Silk Road Medical, and Philips (OBL design), and serves on the advisory board for Amsel Medical and Vasorum. He is chief medical officer for The Vascular Care Group. Sahil Parikh receives institutional research support from Abbott, Boston Scientific, Shockwave Medical, TriReme, Veryan, Surmodics, Reflow Medical, Concept Medical, and Acotec. He serves on advisory boards for Abbott, Boston Scientific, Medtronic, Cordis, and Philips. He is a consultant to Inari, Penumbra, Terumo, and Canon. He has equity in eFemoral, Encompass Vascular, and Advanced Nanotherapies. Ronald Winokur serves as a consultant for BD/Bard, Cordis, Inari Medical, Kalmaro Vascular, Medtronic, Mentice, Endovascular Engineering, VeinWay, Koya and serves as a speaker for Inari Medical, Medtronic, Tactile Medical, and Penumbra. Jon George receives consulting fees from Abbott, Avinger, Boston Scientific, Medtronic, Philips, and Siemens. Gloria Salazar is a consultant for Boston Scientific, Medtronic, Mentice, and Avail MedSystems and is part of the speaker bureau for BD, Boston Scientific, Medtronic, and Cook. Erin Murphy is a consultant for Boston Scientific, Bard/BD, Cook, Cordis, Gore, Medtronic, Philips, and Veryan, serves on the advisory board for Boston Scientific, Cordis, Medtronic, and Philips, and is a speaker for BD/Bard, Boston Scientific, Medtronic, and Philips. Mary Costantino has small ownership interest in Medtronic and Merit Medical and serves as a consultant for Abbott/Cardiovascular Systems, Inc, Siemens, Philips (not on IVUS), Merit, and Cordis. Jun Li serves on the advisory board for Boston Scientific, Inari Medical, and Medtronic and serves as a consultant for Abbott Vascular, Endovascular Engineering, and Philips. Robert Lookstein serves on the medical advisory board of Boston Scientific and Medtronic and serves as a consultant for Penumbra, Imperative Vascular, Cordis, Johnson and Johnson, Becton Dickinson, and Abbott Vascular. He is an equity stakeholder for Thrombolex, Innova Vascular, Summa Vascular, and Imperative Vascular. Kush Desai is a consultant and serves on the speaker's bureau for Cook Medical, Boston Scientific, Becton Dickinson/CR Bard, Medtronic, Penumbra, Tactile Medical, and Philips. He is also a consultant for W.L. Gore, Shockwave Medical, Asahi Intecc, Veryan, Cordis, and Surmodics. Mark Meissner and Wei Zhou reported no financial interests.

The authors were participants in a multisociety, multidisciplinary roundtable and were selected for their clinical expertise in IVUS and in consideration of constructing a diverse panel with respect to gender, race, and discipline. Of note, industry had no input in the selection of topics, roundtable participants/authors, or manuscript writing/editing. However, the authors acknowledge that while the majority of participants in this consensus document have significant clinical expertise and research experience with IVUS, many of them have also served as consultants to industry partners in the development of and training related to this new technology. This has the potential to introduce bias with respect to the recommendations being made. In addition, the potential for financial conflicts may also affect the decision to utilize IVUS.

Funding sources

The Expert Consensus Roundtable was supported by unrestricted grant support from Boston Scientific and Philips. Neither Boston Scientific nor Philips played any role in the drafting, review, or editing of this manuscript.

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