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Intravascular Ultrasound in Endovascular Interventions for Peripheral Artery Disease

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Abstract

Purpose of review This article reviews the contemporary evidence for the use of intravascular ultrasound (IVUS) for peripheral arterial disease (PAD) endovascular interventions.
Recent findings Earlier observational studies have shown that IVUS use for endovascular interventions is associated with improved patency rates and freedom from restenosis. Recently, a randomized trial demonstrated that IVUS was associated with a significantly larger mean vessel diameter than angiography, higher freedom from binary restenosis at 12 months. Recent large observational studies have suggested that IVUS is also associated with improved clinical outcomes. One study of 543,488 Medicare beneficiaries showed that IVUS use was associated with lower risk of major adverse limb events, including amputation and arterial thrombosis. Another Japanese analysis of 85,649 showed that the IVUS was associated with lower incidence of amputation at 12 months.
Summary The benefit of IVUS use in coronary interventions is well established, but the translation of these benefits to endovascular interventions has lagged behind, with a growing body of evidence supporting its use, mainly observational studies. Randomized trials are emerging to better document the benefit of IVUS in endovascular interventions.

Opinion statement

The evidence supporting IVUS use for endovascular interventions is mostly driven from retrospective observational studies. IVUS use for endovascular interventions is controversial given the availability of other less expensive imaging modalities—unlike coronaries—to assess lesion morphology and provide help with preprocedural planning. Future randomized trials establishing the role of IVUS for endovascular interventions are encouraged.

Introduction

Peripheral arterial disease (PAD) is the third leading cause of atherosclerotic morbidity, following coronary heart disease and stroke, with a prevalence of approximately 5% at age 40–44 and 12% at age 70–74 [1], and it has been estimated that 238 million people were living with PAD in 2015 [2].

The use of percutaneous endovascular approaches to treat PAD has increased over the years [3] with new advances in technology, wires, stents, balloons, and improved imaging modalities [4]. That led to an increased number of endovascular interventions, including balloon angioplasty, atherectomy, and stenting [5]. However, patency rates in the lower extremity are not durable [6, 7]. Digital subtraction angiography (DSA) remains the imaging modality during endovascular peripheral procedures. However, it has the limitation of providing a two-dimensional image of a three-dimensional luminal structure, and the images can be confounded by vessel tortuosity and complex luminal irregularities [4, 8].

Intravascular ultrasound (IVUS) is an invasive vascular imaging modality that was first introduced in the early 1990s. It has been used as an adjunctive modality to angiography overcoming its two-dimensional imaging limitation. It acquires images perpendicular to the axis of imaging catheter. Once the IVUS catheter is at the desired location, imaging is performed by a slow pullback which can be performed manually or automatically with rates of pullback of 0.5 or 1.0 mm/s depending on the type of catheter.

IVUS can guide adequate lesion preparation by providing information regarding lesion severity, morphology, plaque burden, and vessel dimensions, which will help to ensure appropriate stent sizing. It can also provide information about adequate stent expansion and strut apposition as well as identifying complications such as dissections. Furthermore, IVUS provides potential benefits in reducing iodinated contrast and radiation exposure [9]. For these reasons, IVUS has been increasingly used in coronary interventions and has been associated with better clinical outcomes [10, 11]. The main objective of this review is to provide an update on the use of IVUS in endovascular interventions for PAD.

Clinical outcomes with IVUS-guided endovascular interventions for PAD

The data on clinical outcomes with IVUS-guided interventions for PAD are scarce and mostly driven from observational studies with limited prospective studies or clinical trials comparing the outcomes between IVUS-guided and angiography-guided endovascular interventions.

In a systematic review, Natesan et al. identified 29 studies comparing IVUS with angiography alone during endovascular interventions for PAD [12]. The majority were retrospective cohorts with a total number of 95,192 patients. Among29 studies, 18 evaluated the utility of IVUS for device sizing, placement, and optimization. Six studies examined the utility of IVUS in the evaluation of lesion characteristics, 3 studies evaluated IVUS utility in cases of arterial dissections, and 2 studies evaluated IVUS use in reentry of chronic total occlusions. IVUS-guided endovascular interventions were associated with accurate reference vessel diameter measurements, larger balloons and stents sizes, and better wound healing rates compared with angiography alone.

Allan et al. [13] performed a single-center randomized trial of 150 patients undergoing femoropopliteal endovascular intervention and demonstrated that IVUS was associated with a significantly larger mean vessel diameter than angiography (5.60 mm vs. 5.10 mm; $p<0.001$), higher freedom from binary restenosis at 12 months (72.4% vs. 55.4%; $p=0.008$), and lower binary restenosis for cases treated with drug-coated balloons (9.1% vs. 37.5%; $p=0.001$). There was a high grade (82%) of disagreement between IVUS and angiographic findings, with a change in treatment strategies with IVUS in 79% of cases.

In a recent analysis by Divakaran et al. [14], among 543,488 Medicare beneficiaries (i.e., aged > 65 years) between 2016 and 2019 treated for endovascular interventions, IVUS use has marginally increased. IVUS was associated with a lower risk of major adverse limb events, including amputation and arterial thrombosis (adjusted hazard ratio, 0.73; 95% confidence interval (CI) 0.70–0.75; $p<0.0001$). A recent Japanese analysis of 85,649 patients showed that IVUS was associated with a significantly lower incidence of amputation at 12 months (6.9% in the IVUS group versus 9.3% in the non-IVUS group; hazard ratio, 0.80 [95% CI, 0.72–0.89]). IVUS was also associated with a lower incidence of bypass surgery and stent grafting, but a higher incidence of reintervention and readmission. Iida et al. in a cohort study of 965 patients with PAD undergoing femoropopliteal artery stenting showed that IVUS was associated with higher 5-year primary patency rate (65% ± 6% vs. 35% ± 6%, $p<0.001$), better freedom from any adverse limb event rate ($p<0.001$), and better event-free survival rate ($p<0.001$) [15]. Similar results were demonstrated by Kumakura et al. [16] who showed a 5-, 10-, and 15-year patency of 89, 83, and 75%, respectively, among 455 patients undergoing IVUS-guided primary stenting for iliac artery disease. Miki et al. [17] in a retrospective analysis of 274 patients showed that IVUS-guided stenting was associated with a primary patency rate of 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. Other observational studies reported on the clinical outcomes of IVUS-guided peripheral endovascular procedures [16–20].

Tsujimura et al. investigated the effect of IVUS on clinical outcomes after aortoiliac stenting in patients with PAD, with a total of 803 patients (IVUS,

Table 1. Summary of characteristics of the main studies assessing IVUS use in peripheral endovascular interventions

References	Study design	No. of patients	Arterial level	Follow-up
Allan et al. [13]	Randomized prospective	150	Femoropopliteal	12 months
Divakaran et al. [14]	Retrospective	543,488	All peripheral interventions	17 months
Kurata et al. [23]	Retrospective	165	Femoropopliteal	17 ± 9 months
Tsujimura et al. [21]	Retrospective	803	Aortoiliac	12 months
Soga et al. [24]	Retrospective	155	Infrapopliteal	12 months
Fujihara et al. [25]	Retrospective	216	Below knees	12 months
Miki et a. [17]	Retrospective	274	Femoropopliteal	24 months
Shammas et al. [26]	Prospective	15	Femoropopliteal	Procedure day
Krishnan et al. [18]	Retrospective	114	Femoropopliteal	12 months
Baker et al. [27]	Retrospective	40	Iliac and infrainguinal arteries	4.3 months
Kumakura et al. [16]	Prospective	455	Iliac	63 months
Iida et al. [15]	Retrospective	965	Femoropopliteal	1.9 ± 1.5 years
Araki et al. [20]	Retrospective	82	Iliac	27.6 months
Buckley et al. [28]	Retrospective	52	Aortoiliac	62.1 ± 7.3 months

545; no IVUS, 258). In 138 matched pairs, they found no significant difference in the 12-month restenosis rate between the 2 groups (10.2% (95% CI 6.9 to 14.9%) vs. 10.3% (95% CI 5.4 to 18.6%), $p = 0.99$) [21]. These findings were similar to another study with1,091 patients undergoing drug-eluting stent implantation for femoropopliteal lesions There was no significant difference in the rate of 1-year restenosis the 2 groups (11.5% (95% CI 9.1–14.0%) vs. 15.5% (95% CI 10.9–20.1%); $p = 0.22$), with a significantly higher incidence of aneurysmal degeneration in the IVUS group [22].

Tables 1 and 2 summarize the characteristics and outcomes of the main studies evaluating IVUS in the endovascular management of PAD.

IVUS for evaluation of lesion characteristics and severity

The proper evaluation of plaque morphology and accurate vessel sizing is a major component for peripheral endovascular procedures. IVUS provides detailed information not only about the vessel lumen but also about plaque morphology and composition, with a high degree of accurate measurements of the vessel diameter. Several studies showed that IVUS is superior than angiography in terms of accurate vessel measurements [29–33]. In a study by Yin et al., IVUS detected calcium in 44/47 (93.6%) lesions, while angiography detected calcium in only 26/47 (55.3%) [34].

Iida et al. in a prospective multicenter study including 1725 patients undergoing femoropopliteal interventions for symptomatic PAD showed that IVUS-assessed RVD (reference vessel diameter) was significantly larger than angiography-assessed RVD (6.0 ± 1.0 mm vs. 5.0 ± 1.0 mm; $p < 0.001$), with

Table 2. Summary of main outcomes of the main studies assessing IVUS use in endovascular interventions

References	Main outcomes
Allan et al. [13]	IVUS was associated with higher freedom from binary restenosis at 12 months (72.4% vs 55.4%; $p=0.008$), with a significantly lower binary restenosis for cases treated with drug-coated balloons (DCBs) (9.1% vs. 37.5%; $p=0.001$)
Divakaran et al. [14]	IVUS use was associated with lower MALE than non-IVUS use (14.1% vs. 16.6%)
Kurata et al. [23]	Lesions treated with a DCB of IVUS-EEM size had a lower 2-year restenosis rate than those treated with a DCB over/under IVUS-EEM size (19.7 ± 5.7% vs. 34.5 ± 4.7%, $p=0.02$ by the log-rank test)
Tsujimura et al. [22]	The 12-month restenosis rate was not significantly different between IVUS and no-IVUS groups (10.2% (95% CI 6.9 to 14.9%) vs. 10.3% (95% CI 5.4 to 18.6%), $p=0.99$)
Soga et al. [24]	The IVUS-guided group had a higher rate of limb salvage without any re-intervention than the angio-guided group ($p=0028$), whereas limb salvage and overall survival were not significantly different. Wound healing was significantly earlier in the IVUS-guided group
Fujihara et al. [25]	Freedom from TLR and limb salvage rates was similar between the groups ($p=0.16$ and $p>0.99$). The technical success ($p=0.56$) and complication rates ($p=0.16$) were also similar between the groups. Wound healing rate was better with IVUS-guided group than the angiography-guided group ($p=0.006$)
Miki et a. [17]	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
Shammas et al. [26]	IVUS was better able to identify the dissections than angiography
Krishnan et al. [18]	IVUS-guided atherectomy patients had a clinically driven target lesion revascularization (CD-TLR) rate of 17.9% compared with angiographic-guided DA with a CD-TLR rate of 51% at 1 year ($p=0.03$)
Baker et al. [27]	Primary patency for the IVUS-guided reentry device group was 62% at 12 months
Kumakura et al. [16]	The 5-, 10-, and 15-year primary patencies were 89%, 83%, and 75% for primary stenting guided by IVUS
Iida et al. [15]	Five-year primary patency rates are higher with IVUS use than angiography alone (65% ± 6% vs. 35% ± 6%, $p<0.001$)
Araki et al. [20]	The primary patency rate was 96.5% at 2 years
Buckley et al. [28]	Three- and 6-year primary patency rates were 100% and 100% in the IVUS group and 82% and 69% in the non-IVUS group, respectively

IVUS intravascular ultrasound, *MALE* major adverse limb events, *DCB* drug-coated balloon, *CD-TLR* clinically driven target lesion revascularization

a mean difference of 0.98 mm (95% CI 0.94–1.03 mm). About half of the study cohort had ΔRVD ≥ 1 mm. IVUS measurements were more likely to be different by angiography in cases with small vessels, chronic total occlusion (CTO), bilateral calcification, and history of stent implantation [35]. A retrospective study of 165 patients showed that drug-coated balloon (DCB) sizing according to IVUS-measured external elastic membrane (EEM) size, but not of angio-lumen size or IVUS-lumen size, was associated with a reduced risk of restenosis after femoropopliteal interventions [23].

IVUS for device sizing, placement, and optimization

Five observational studies with a total number of 1,133 patients compared IVUS use versus angiography alone during percutaneous transluminal angioplasty (PTA) and stenting [15, 27, 28, 36, 37]. Long-term patency rates ranged from 57 to 100% with IVUS use vs. 64 to 83.4% without IVUS use. Four studies reported that IVUS identified more under-deployed stents and provided improved vessel sizing information compared to angiography [28, 37–39].

Hitchner et al. in their observational study of 59 patients undergoing superficial femoral artery interventions showed that IVUS was able to detect residual stenosis and 80% of patients underwent additional treatment after identification of significant residual stenosis by IVUS [40]. IVUS provides optimal measurements, identify under-deployed stents, and detect residual stenosis.

IVUS for below-the-knee (BTK) interventions

IVUS use in below-the-knee (BTK) interventions was studied in few observational studiess. A recent consensus document on the appropriate use of IVUS in various phases of peripheral arterial and venous interventions in which thirty international vascular experts anonymously completed a survey showed that IVUS was rated appropriate especially in all interventional phases for the tibial arteries [41].

In a single-center retrospective analysis of 155 CLI patients [24], IVUS was associated with larger balloon size ($p < 0.001$). Wound healing was significantly earlier, whereas limb salvage and overall survival were not significantly different. Another observational study by Fujihara et al. [25] of 33 propensity score-matched pairs of patients who underwent successful balloon angioplasty treated with IVUS-guided versus angiography-guided procedures, demonstrating a significantly larger maximal balloon size in the IVUS group (2.45 ± 0.4 mm vs. 2.23 ± 0.4 mm; $p < 0.001$). There was no significant difference in limb salvage rates, complication rate, or technical success ($p > 0.99$, $p = 0.16$, and $p = 0.56$, respectively). In a small observational study of 20 patients, Kuku et al. [32] compared mean reference vessel diameter (RVD) between IVUS and angiography during BTK interventions and found that IVUS use was associated with larger mean RVD (3.27 ± 0.68 mm vs. 2.81 ± 1.19 mm; $p = 0.15$). They also found a greater correlation between IVUS measurements and the nominal balloon diameters (IVUS: balloon, $R^2 = 0.45$ vs. QVA: balloon, $R^2 = 0.34$). Interestingly, there was a greater degree of acute gain (defined by the difference between pre- and post-intervention minimal lumen diameters) in cases where the treatment balloon size correlates with IVUS-measured reference size. These findings of larger mean vessel diameter were also shown in a study by Shammas et al. [33].

The main findings of the aforementioned studies of larger balloons being used with IVUS measurements, leading to favorable wound healing rates, shed the light on the importance of proper measurements of BTK vessel beds. Assessing the true lumen diameter would help with optimal balloon sizing and stenting, which will probably shorten the healing period and lower the likelihood of re-intervention.

IVUS for diagnosis of arterial dissections

Dissections are common complications with endovascular interventions. Dissections can be classified by angiography based on the NHLBI classification [42] or by IVUS based on the iDissection classification [43]. Some pathologic studies have shown that deeper dissections into the media and adventitia correlate with patency loss [44]. Angiography under appreciates the presence, extent, and depth of dissections and often can be misleading. Multiple studies have confirmed the superiority of IVUS in detecting dissections [26, 37, 45–47], which can correlate with clinical outcomes and improved patency rates. In a prospective study by Shammas et al. [26] of 15 patients undergoing treatment of femoropopliteal de novo or non-stent restenosis using atherectomy, forty-six dissections were identified on IVUS post atherectomy vs. 8 dissections on angiogram ($p < 0.01$) (ratio, 5.75 to 1). For post adjunctive angioplasty, IVUS identified 39 dissections vs. 11 by angiogram. There are similar findings to another study [46], in which IVUS detected 49 dissections post adjunctive angioplasty vs. 6 on angiogram. In BTK interventions, IVUS detected more dissections than seen on angiography (34 on IVUS vs. 9 dissection on angiography) [33]. Interestingly, IVUS can also be a useful tool to undercover extraluminal diseases, as in the case report of an adventitial cystic disease that was misdiagnosed as PAD in which IVUS was a useful tool to reach proper diagnosis [48].

IVUS for chronic total occlusion interventions

Chronic total occlusions (CTOs) are encountered in around 40–50% of patients undergoing endovascular interventions [49]. Long occlusion with heavy calcification can be technically challenging; thus, failure to cross such lesions can be as high as 30% [49] and is associated with a higher risk of complications [50]. Percutaneous subintimal recanalization is the most common endovascular revascularization technique for CTO of the iliac arteries. The primary reason for failure of this technique is failure to reenter the true lumen [51–53]. Some studies evaluated the use of IVUS for true lumen reentry during subintimal angioplasty and showed very promising results with technical success rates of almost 100%. The real-time imaging of IVUS allows the operator to create a subintimal tract and direct the needle deployment. IVUS also confirms vessel patency at the point of the needle due to its color flow capabilities. The controlled reentry offered by IVUS catheters reduces the risk of complications, such as dissections or perforations caused by wire or catheter misplacements [52, 54–58]. Kawasaki et al. [55] compared true lumen reentry with and without IVUS and showed that technical success was higher in the IVUS group (97% vs. 81%).

IVUS and contrast exposure

It was proposed that with IVUS guidance contrast injection could be reduced or completely avoided. Kawasaki et al. [55] evaluated IVUS use in reentry and demonstrated that the total volume of contrast material was less with IVUS than without IVUS guidance (104 ± 56 mL vs. 201 ± 100 mL ($p < 0.01$). Essa et al. [30] also showed that IVUS was associated with a lower overall mean contrast utilization compared to computed tomography angiography (CTA) (29 vs. 100 cc; $p < 0.001$). The lower contrast media used with IVUS guidance decreases the risk of complications as contrast-induced acute kidney injury and can be very important especially for patients suffering from diabetes, chronic renal disease, or contrast allergies.

IVUS and cost

The incorporation of IVUS catheters in endovascular interventions adds additional cost to the overall procedure with an increase that ranges from $1,080 to $1,333 [28, 59]. Schiele et al. [59] reported that acute procedural costs can be 18% higher with IVUS compared to non-IVUS use. Interestingly, they reported a higher number of revascularization procedures in the control group (31 in the control group vs. 20 in the IVUS group), then analyzed the cumulative medical costs at 18 months which was slightly higher in the IVUS group (4535 ± 2020 Euros vs. 4679 ± 1471 Euros in the IVUS group). The higher acute costs in the group with IVUS guidance were partially offset by the lower number of re-interventions. This observation sheds the light to that; the use of IVUS can be cost effective when properly used.

Barriers to IVUS use

Many operators and researchers are opposed to the use of IVUS for peripheral endovascular interventions. There is paucity of data driven from randomized controlled trials demonstrating the long-term clinical outcomes of IVUS use as almost all studies are retrospective observational, so there is a risk for unmeasured confounding. Most of the studies did not account for the operator's experience. IVUS being a morphologic assessment tool that cannot provide information about the hemodynamic significance of stenosis is a concern [60]. The use of larger balloons and stents based upon IVUS outer vessel diameter measurements may cause complications as dissections as reported by Tsujimura et al. [21] with a significantly higher frequency of aneurysmal degeneration at 1 year in the IVUS group than in the non-IVUS group (19.8% (95% CI 16.3–23.4%) vs. 7.1% (95% CI 3.3–11.0%); $p < 0.001$). Similar results by Iida et al. [61] showed that IVUS was associated with a high rate of superficial femoral artery degeneration with a 1-year occurrence of aneurysmal degeneration of 16.8% (95% CI 13.9–19.6%). Unlike coronaries, there are other modalities to assess lesion characteristics regarding reference vessel size and plaque composition non-invasively as preprocedural duplex ultrasound or computed tomographic angiography which can reduce the total procedure time without additional cost to the procedure.

Conclusion

IVUS was shown in multiple observational studies to provide better vessel diameter measurements and ensure optimal stent sizing and proper deployment with some studies reporting better long-term patency rates, which was confirmed by a recent randomized trial. Accordingly, some data indicate that there has been a marginal increase in IVUS use for PAD. In addition, large observational studies suggest that IVUS is associated with lower risk of major adverse limb events, including amputation. Future randomized trials to further establish the role of IVUS during endovascular interventions are encouraged.

Compliance with Ethical Standards

Conflict of Interest
Mohamed Khedr declares that he has no conflict of interest. Michael Megaly declares that he has no conflict of interest. Islam Y. Elgendy declares that he has no conflict of interest.

Human and Animal Rights and Informed Consent
This article does not contain any studies with human or animal subjects performed by any of the authors.

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