Intravascular Ultrasound is Critical to Insuring Long-Term Stent Performance

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Introduction

In 1972, Bom and colleagues described the application of miniaturized ultrasound transducers to the tips of flexible intravascular catheters.1,2 These intravascular ultrasound (IVUS) catheters were initially used to obtain high-resolution ultrasound imaging of cardiac and vascular structures. This technology was slow to find clinical relevance. In 1987, catheter-delivered B-mode ultrasonography for transluminal imaging of blood vessels was introduced to provide supplemental imaging information for the endovascular treatment of arterial occlusive disease.3,4

Historically, arteriography has been regarded as the “gold standard” for defining the arterial anatomy, pathology and adequacy of intravascular treatment. Arteriography certainly defines basic arterial anatomy but fails to fully define vessel pathology. As the endovascular therapist used IVUS as a part of the evaluation and treatment of arterial occlusive disease, its value in defining vessel wall architecture, morphology of the occlusive lesions and measurements of true lumen and overall vessel diameter have been shown to be superior to arteriography.5–7 The use of IVUS in peripheral angioplasty and stent procedures has been shown to have a direct effect on the long-term outcome of these procedures.7,8

Equipment

There are two major IVUS consoles that are used for peripheral interventions. Volcano Corporation (Rancho Cordoba, California) (Figure 1) and Boston Scientific Corporation (Natick, Massachusetts) are the manufacturers of these devices. The Boston Scientific IVUS imaging system is more commonly used for coronary interventions, while the Volcano equipment is mainly used in peripheral interventions. IVUS catheters are available in various lengths, French-size diameters, MHz frequency and guidewire compatibilities. The larger-diameter lower-frequency IVUS devices are typically used with a 0.035/0.038 inch guidewire and 9 Fr introducer sheath in the aorto-ilio-femoral arterial system. The smaller French-size diameter IVUS catheters of higher frequency, longer catheter lengths and 0.014-/0.018-inch guidewire compatibilities are used in the femoral-popliteal and tibial arterial systems. The 0.018-inch compatible systems may be used with a 6 Fr introducer sheath and are useful in the renal and brachiocephalic arteries. The 0.014-compatible systems are 2.9 Fr in diameter and may be used with a 5 Fr sheath. These are useful in the carotid, femoral-popliteal and tibial vessels. The Volcano version of this small IVUS catheter system is called “Eagle Eye” and provides a color-coded image named “virtual histology,”

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Figure 1. Volcano Corporation’s s5 Tower and s5 Integrated Intravascular Ultrasound system.

Normal Vessel

Intima

Media

Adventitia

Figure 2. Intravascular ultrasound image of normal vessel showing the intima, media and adventitia.
Buckley

which can identify fibrous, calcified, lipid-laden and necrotic components of an atherosclerotic plaque. This plaque morphology information is useful in determining which treatment would be best for a specific arterial occlusive lesion.

Clinical Application

IVUS provides excellent pretreatment blood vessel and lesion evaluations. Multiplane arteriographic views would be required to adequately evaluate the degree of stenosis at any given lesion site because of the eccentrically located nature of the atherosclerotic lesion. Real-time 360° cross-sectional imaging of an artery provided with IVUS permits an accurate measurement of both diseased and true lumen diameters of vessels (Figure 2). IVUS is estimated to be accurate within 0.5 mm when measuring vessel diameter. When combined with intraoperative fluoroscopy, IVUS will accurately localize an occlusive lesion and define the extent of the lesion within the vessel using pull-back of the catheter while tracking the movement of the transducer under fluoroscopy. The distance the catheter is pulled back while still visualizing the occlusive lesion with IVUS is measured with a ruler and gives a very accurate measurement of lesion length (the extent of vessel wall which must be treated with a stent (Figure 3). If the manufacturer of IVUS catheters would put 1-cm increment radio-opaque markers on their imaging catheters, this procedure would be greatly facilitated. IVUS is also useful in locating important vessel side branches so that they may be preserved during endovascular treatment. It identifies structural changes in the adventitia, media and intimal layers of blood vessels.

IVUS will show the integrity of the fibrous cap of an atherosclerotic plaque and the severity of any plaque ulcerations. Four types of plaque morphology are commonly identified and many lesions possess combinations of these morphologic types. The first type, a hypoechoic image, is often described as “soft” plaque and is typical for lipid deposits. The IVUS image is displayed as a dark area covered by a bright reflection, which is the fibrous cap. Fibromuscular tissue, responsible for intimal thickening, produces a soft, gray, homogenous image with granular or speckled characteristics and has no acoustic shadowing. The third type, which produces a bright echo, is a collagen-rich fibrous tissue seen in more advanced or older atherosclerotic lesions typically found in an area of restenosis. The fourth type, indicative of heavily calcified tissue or hard plaque, produces the brightest echos with acoustic shadowing — a black void seen behind the bright echo. Plaque morphology information provided by IVUS can have direct influence on the type of endovascular treatment selected for a specific problem (Figure 4).

Figure 3. Measuring lesion length by the pull-back technique.

Figure 4. Soft plaque represented by soft grays (isoechoic) with no shadowing. Calcified plaque is represented by bright white plaques (hyperechoic) with noticeable far-field shadowing. Sometimes, reverberations occur equidistantly in shadows of dense calcifications.

Plaque Composition

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<th>Soft</th>
<th>Fibrous</th>
<th>Calcified</th>
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IVUS CRITICAL FOR LONG-TERM STENT PERFORMANCE

IVUS is used to assess the effectiveness of therapeutic interventions. It readily identifies treatment-related complications. IVUS shows and measures the degree of residual stenosis after an intervention and shows unstable changes that are produced in the vessel wall adjacent to the lumen, such as highly mobile fragmented segments of plaque, luminal thrombi or dissections.

When adjunctive remote atherectomy or other forms of lesion debulking are used in conjunction with transluminal angioplasty to increase overall lumen diameter, IVUS will determine the effectiveness of this therapy and whether additional debulking is required. Studies have shown that as much as 48–74% of residual bulk volume can remain after apparent “arteriographically successful” mechanical atherectomy.3 This modality will also identify those patients who might benefit from placement of an intravascular stent.

Common indications for intravascular stent placement after transluminal angioplasty are dissections, elastic recoil, residual stenosis, a significant residual pressure gradient across the lesion, or plaque ulceration with local thrombus accumulation. Certain lesions, especially those located in the common iliac or renal arteries, are typically treated with primary stenting. Intravascular stents have been shown to increase the patency of arterial occlusive lesions that have undergone angioplasty by reducing technical procedure-related failure and possibly affecting restenosis.3,12 Stent placement is not without its own inherent risks. Inadequate stent expansion can lead to early thrombosis or stent migration. Critics of IVUS suggest that routine overdistention of a stented lesion will prevent stent underexpansion and its associated problems. However, overexpansion of a stent can result in excessive intimal hyperplasia or vessel rupture. Colombo and associates found that after routinely overdistending stented coronary lesions, 30% of stents were still underdeployed when IVUS was used for evaluation.13

IVUS true diameter vessel wall measurement has been helpful in avoiding stent and vessel overdistention for both coronary and peripheral lesions. Improved outcomes were documented when IVUS was used to identify dissections that were significant enough to require stents (> 60% residual stenosis14) (Figure 5). Further proof of the utility of IVUS for intravascular stent placement is that IVUS was able to demonstrate adequate stent expansion in only 13–20% of treated coronary lesions (satisfactory result by angiography), which required additional stent expansion by balloon dilatation.13,15 In peripheral vessels, angiography-guided stent deployment results in incorrect positioning or incomplete expansion in as many as 20–40% of cases (Figure 6).12,16 In our practice, commonly used self-expanding stents have a greater propensity for underexpansion than balloon-expandable stents. Therefore, we routinely post-dilate all self-expanding stents to the true vessel wall diameter as determined by IVUS.

IVUS Information Enhances the Effectiveness of Intravascular Stent Procedures

The use of intraluminal stenting as an adjunct to balloon angioplasty for the treatment of arterial occlusive lesions has become commonplace. The United States Food and Drug Administration (FDA) has approved the use of selected stents in both the common and external iliac arteries, renal arteries, femoral-popliteal arteries and the carotid arteries. Other stents have been used “off label” or on a “compassionate” basis in the brachial-cephalic and tibial vessels.

Two studies were undertaken by the Division of Vascular Surgery at Scott & White Healthcare System to determine the usefulness of IVUS in the endovascular treatment of atherosclerotic aorto-iliac occlusive disease. In the first study, 32 consecutive patients with aorto-iliac occlusive disease were evaluated with IVUS before and after balloon angioplasty and stenting of 40 separate iliac arterial lesions. Measurements of stenosed and non-stenosed vessel lumen diameters, location and morphology of occlusive lesions, results of endovascular treatment and identification of complications were studied and comparisons made between IVUS and angiographic evaluations. Sixty-two percent of vessel diameters were underestimated by angiographic criteria from 1 mm to 4 mm (mean 2.8 mm), which affected the size of the balloon catheters that were selected to perform angioplasty of a particular lesion. Angiography also inaccurately assessed the degree of residual stenosis after treatment.15,17

Figure 5. Intravascular ultrasound images of significant dissection and subsequent repair with stent.
Most importantly, this study showed that 40% of the stents used in treating these 40 lesions were underdeployed by IVUS criteria but appeared adequately expanded when evaluated with arteriography. Underdeployed stents are believed by many endovascular therapists to be a possible cause for failure of an endovascular intervention.12,14,15,18,19 These underdeployed stents were incompletely applied to the adjacent vessel wall and required further stent expansion with larger angioplasty balloons to achieve accurate stent-to-vessel wall apposition. This proved to be statistically significant ($p < 0.01$; 95% confidence interval [CI]).12 Other investigators have made similar observations in both coronary and peripheral use of arterial stents.7,15

The effect of the use of IVUS on the long-term patency of balloon DILATED and stented iliac arterial occlusive lesions was evaluated in a second Scott & White Health Care System study. This study included 52 patients who underwent balloon angioplasty and stenting of 71 limbs with iliac occlusive lesions that were followed for 24–60 months (mean 40 months) after treatment. The treatment of 16 of these patients (22 limbs) was evaluated by arteriography alone, and the treatment of 36 patients (49 limbs) was evaluated by both arteriography and IVUS. This study found no restenosis or occlusions in the treated vessel segments in the arteriography plus IVUS group; however, in the group evaluated by arteriography alone, restenosis or occlusion of a treated arterial segment occurred in 25%, or 4 of 16 patients ($p < 0.01$) (Figure 7). These 4 failures occurred within 12 months of treatment and were managed with either transluminal thrombolysis ($n = 3$) with urokinase infusion or direct Fogarty catheter thrombectomy ($n = 1$). All lesions were then evaluated with IVUS. Underdeployed stents were identified in all 4 of these cases; subsequent treatment consisted of adequate redeployment of the existing stents with IVUS criteria for complete stent expansion and apposition to the vessel wall. All salvaged reconstructions have remained patent during continued follow-up evaluations. The findings of this study have been substantiated in clinical practice on multiple occasions and apply to stented lesions in both the iliac and femoral-popliteal arterial systems.8

**Specialized IVUS**

Refinements in catheter technology have allowed treatment of chronic total occlusions in the aorto-iliac, femoral-popliteal
and tibial arterial systems. Traversing such lesions requires either maintaining catheter position in the thrombosed lumen or, more commonly, entering and traversing the subintimal plane and then re-entering the true lumen beyond the area of total occlusion. The success of these procedures depends solely on being able to re-enter the true lumen distally. Failure rates for these recanalizations have ranged from 13–26%. IVUS has been helpful in facilitating and defining the true lumen re-entry. It has also been useful in assessing the composition of the occluding plaque and defining the location of the guidewire as it traverses either the intraluminal or subintimal space. Medtronic Vascular (Santa Rosa California) has developed an IVUS-guided true lumen re-entry system (Pioneer) to facilitate lumen re-entry after crossing a total occlusion. This catheter has been used with a high degree of success (95%+) in both the aorto-iliac and femoral-popliteal arteries. It reduces the total procedure time and radiation exposure times for these difficult procedures.

As described previously, specialized forms of IVUS, color flow and virtual histology, provide additional information regarding lumen size and specific aspects of plaque composition (Figure 8). This information can alter treatment, both with respect to the type of stent used — open cell, closed cell or covered — to minimize embolization risk and restenosis. It will also provide guidance as to whether additional dilatation is required to optimize the lumen diameter. These enhanced forms of IVUS can be obtained only with the higher-frequency, smaller-diameter catheters. Clinical experience with virtual histology in the carotid artery has shown improved patency and reduced overall procedure-related complications including stroke21–23 (Figure 9).

Conclusion

IVUS provides valuable diagnostic information relative to blood vessel wall architecture and plaque morphology that...
many endovascular therapists use as the basis for formulating endovascular therapy plans. IVUS should be considered an essential component of endovascular therapy when intraluminal arterial stents are used to ensure adequacy of stent deployment and detection of complications not readily identified by arteriography or other diagnostic means. Experience has shown that the use of IVUS has had a direct positive effect on the long-term clinical outcome of stented arterial occlusive lesions.

References