

Vessel Prep Success: How to Know When Not to Take Another Pass or Crack at It

A strategy to evaluate endpoints for atherectomy and intravascular lithotripsy.

By Mike Watts, MD, FSIR

As the ability to treat more complex peripheral vascular lesions from a minimally invasive approach continues to advance, driven by the development of new technology and operator experience and expertise, it can be increasingly difficult to know with confidence how effectively each step of these interventions is being performed. Incremental increases in the available data have continued to showcase the value of atherectomy and intravascular lithotripsy (IVL) in certain clearly defined scenarios. However, reproducing the positive results of these data requires appropriate use of these technologies. It is incumbent upon the operator to use these technologies to their full potential to ensure the addition of value to the patient and justify any minimal increase in complication rates contingent upon adding these devices into the peripheral arterial care paradigm.

EVALUATING VESSEL PREP ENDPOINTS FOR ATHERECTOMY AND IVL

Lesion Evaluation With IVUS

The mainstay in lesion evaluation, both pre- and post-treatment, is direct intraluminal visualization. Since the sunseting of the Pantheris atherectomy system (Avinger), which used optical coherence tomography imaging, the most available and clinically practical device with which to accomplish direct intraluminal visualization is intravascular ultrasound (IVUS). Pretreatment lesion evaluation with IVUS should be used to direct further therapy. Circumferentially calcified arteries, long lesions with a calcium arc $> 270^\circ$, and lesions with calcium > 0.5 -mm thick may benefit from IVL. Lesions with less calcified plaque or eccentric calcifications, however, may benefit from debulking atherectomy in the appropriate circumstances.

The appearance of a lesion on IVUS after treatment can be just as important in deciding when the treatment has reached its full potential effectiveness. When comparing a lesion before and after treatment with IVL, definite calcium fractures or discontinuities can and should be seen. These fractures have been shown in the coronary literature to correlate with increased compliance and better stent expansion.¹ IVUS is also the only precise way to measure luminal gain to assess the effectiveness of an intervention after either IVL or atherectomy. Depending on the operator's choice in atherectomy, front or side cutting devices can achieve significantly improved luminal diameter. The accepted goal when measuring luminal gain pre- and posttreatment is for the residual stenosis to be $< 30\%$. This can be achieved with atherectomy or IVL alone but often requires further treatment with balloon angioplasty (including drug-coated or other specialty balloon angioplasty) or stenting. IVUS can help direct those therapies once the vessel has been maximally prepared.

Arterial Compliance

Whether the mechanism is via calcium modification or plaque debulking, the ultimate goal of native vessel prep is to increase the compliance of the artery to minimize the trauma delivered during delivery of the operator's choice of definitive therapy. The COMPLIANCE 360° trial showed that orbital atherectomy specifically lowered mean maximum balloon inflation pressures (4 atm vs 9.1 atm for percutaneous transluminal angioplasty [PTA] alone; $P < .001$), leading directly to significantly decreased adjunctive stenting (5.3% vs 77.8% for PTA alone; $P < .001$).² The endpoint of IVL or atherectomy regarding balloon expansion behavior should

be observable decreased waist formation of the balloon after vessel prep or complete expansion of the angioplasty balloon at nominal or subnominal inflation pressure. This change is dynamic and observable in real time with IVL. The IVL balloon waist at subnominal inflation pressures should improve under live fluoroscopy during delivery of the pulses. This will occur with corresponding decrease in balloon pressure indicated by loss of pressure measured by the insufflator. Assessing increased compliance after atherectomy involves a more iterative approach of attempting balloon inflation after each pass of the device to assess for lower balloon inflation pressures. This may require additional time and device exchanges but is essential to take advantage of the benefits offered by atherectomy.

Another common and practical use for vessel prep devices is to aid in the crossing of large devices through tight stenoses. There is a combination of tactile and visual feedback under fluoroscopy when a balloon or stent will not pass through the narrowed portion of the vessel. In this case, IVL or certain atherectomy devices may be used to debulk or increase compliance and allow for passage of the desired therapeutic device. Once the vessel prep has been completed, the result is binary: Either the stent or balloon crosses the previously obstructed lumen or it does not, indicating the need for further preparation.

Stent Expansion

Assuming preimaging with IVUS and appropriate vessel choice for the lesion in question, stenting is indicated for many of these complex calcified lesions. Because the goal of vessel prep is to increase arterial wall compliance for more effective definitive therapy, stent expansion is a marker for effectiveness similar to decreasing balloon inflation pressures. Once a stent is deployed in a previously prepped lesion and postdilated if necessary, further evaluation with IVUS is essential. Having appropriately sized the choice of stent with IVUS prior to its deployment, there should be optimal expansion with minimal residual stenosis. Postdeployment imaging gives the operator the chance to improve expansion with further IVL through the interstices of the stent. Although off-label, there are many reported cases of successful stent expansion in this manner.³ There is no role for atherectomy in this scenario.

Angiography for Vessel Prep

Traditionally, the method used to judge the effectiveness of treatment of complex lesions was angiography alone. Although contrast angiography with or without digital subtraction angiography is necessary, it is potentially inadequate to decide the endpoint of vessel preparation.

Current commercially available IVUS catheters cannot measure flow to any reliable extent, which is a strength of angiography. Angiography is also more efficient and accurate than IVUS at assessing recoil, which can occur shortly after treatment. However, when determining adequacy of vessel prep, arteriography cannot assess the status of the calcium, the change in compliance of the vessel, or the luminal gain with any accuracy.

SUMMARY

A growing body of evidence supports selective use of atherectomy and IVL in certain patient and lesion categories. Given the added expense and risk of these procedures, understanding how to effectively use them and appropriately evaluate their results is an essential part of their implementation. Knowing that the mechanism by which these technologies improve outcomes is by increasing arterial wall compliance via debulking plaque or fracturing calcium, angiography alone should not be relied upon to judge the result of a vessel prep intervention. For an operator to have full confidence that successful vessel preparation has been achieved, the lesion should be first evaluated with IVUS and treated with the selected device. If using IVL, the balloon waist will potentially resolve with loss of pressure in the balloon during the treatment. If it does not, postintervention IVUS should demonstrate longitudinal and multiplanar cracking of the calcium. If using atherectomy, postintervention IVUS should show luminal gain and balloon pressures should be minimized, thus decreasing trauma to the treated area. If these conditions are not met, further treatment with IVL, atherectomy, or possibly specialty balloon angioplasty should be considered. Finally, if a stent is chosen as definitive therapy after vessel prep, it should be evaluated with IVUS for full symmetrical expansion after deployment. The likelihood of this is maximized with effective prep, but further IVL would be possible at that point. ■

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