ROUNDTABLE DISCUSSION

SFA Vessel Prep in the Real World

A discussion on the current role of vessel preparation, when to use it and when not to use it, device selection, and data related to cost-effectiveness and algorithm creation.

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Prof. Brodmann: What do you feel is the current role of vessel preparation in the superficial femoral artery (SFA) space?

Prof. Zeller: There are different kinds of vessel preparation. According to the instructions for use for all certified devices, it is mandatory that all SFA lesions undergo vessel preparation prior to drug-coated balloon (DCB) inflation. The same holds true for the implantation of interwoven stents such as Supera (Abbott Vascular), in which aggressive predilatation is mandatory to guarantee proper stent expansion.

If vessel preparation is considered as a procedure beyond plain old balloon angioplasty (POBA) to reduce recoil and the likelihood of severe dissection, there are different technologies with specific indications. The main indication for vessel preparation is moderate or severe calcified SFA lesions because of insufficient luminal gain after balloon angioplasty or implantation of a slotted-tube nitinol stent. A variety of atherectomy devices are indicated for plaque removal. Another approach is the Lithoplasty system (Shockwave Medical, Inc.), where the aim is to fragment the calcium to improve vessel compliance and reduce vessel recoil. Another accepted vessel preparation indication is thrombus removal, either by thromboaspiration, mechanical thrombectomy, or local lysis.

Dr. Garcia: What is difficult here is the definition of vessel prep. This term is bantered about in all aspects of DCB technologies, atherectomy devices, and the "leave nothing behind" strategists in treating lower limb disease. The issue is that we still don't know—or at least I don't know—what that term means. It can imply certain things to certain individuals and completely other things to others. However, in its simplest sense, vessel prep is the process of changing arterial compliance to allow full dilation without aggressive balloon inflations for either DCB or nondrug (simple POBA) balloon technologies or stenting to effectively dilate the vessel. In this way, the vessel can expand to relieve the obstruction, and then a stent is or is not placed, depending on the operator's discretion.

Vessel prep in the DCB era has gained traction in the sense that it allows for full dilation of the lesion with the DCB, so that there is full coverage without significant dissections or frank perforations that mitigate the need for stents.

Dr. Armstrong: Vessel prep for SFA lesions has increasingly gained importance over the last 5 years. During all endovascular interventions, the goal is to minimize dissection and recoil and thereby optimize the results of angioplasty. Increasingly, however, new technologies have reemphasized the central role of vessel prep in optimizing these outcomes. The results have, in some cases, been surprising. For example, recent trials of DCB technologies have demonstrated that the patency of POBA is better than historically expected when attention is paid to long, low-pressure inflations. Similarly, the outcomes of nitinol stents are also likely better after adequate vessel preparation, as optimal preparation allows nominal stent deployment without areas of underexpansion or stent

elongation. For all of these reasons, I believe vessel prep is paramount, regardless of the final treatment strategy.

Prof. van den Berg: I agree with Dr. Garcia's point that a proper definition of vessel preparation is currently lacking. In the past, everybody performed predilation prior to stent placement or DCB angioplasty using standard angioplasty balloons, and this can be considered vessel preparation as well. Currently, when vessel preparation is discussed, it typically refers to more sophisticated techniques such as atherectomy and the use of specialty balloons such as scoring, focal force, and cutting balloons. This more specific vessel preparation is typically used prior to DCB angioplasty and use of nitinol-braided self-expanding stents (as advised by the manufacturer).

Prof. Tepe: First, there is lack of data on the role of vessel preparation. Studies should compare standard therapy (eg, with or without DCB) with the same procedure and vessel prep. Only the DEFINITIVE AR study suggests that atherectomy (with SilverHawk or TurboHawk [Medtronic]) in long lesions and very calcified vessels might add some benefit to DCBs only. Other than this, vessel prep can be performed with lithoplasty, scoring balloons, other atherectomy devices, or percutaneous transluminal angioplasty (PTA) with a slightly oversized balloon. Nevertheless, there is an unmet need in certain vessel conditions (eg, very calcified).

Prof. Brodmann: Vessel prep has quickly become a crowded space in the SFA market. How should operators who are not involved in clinical trials compare and select the options that are right for their practices?

Dr. Garcia: It is critical for any operator to review and understand the type of patient enrolled into any trial, regardless of whether it is a DCB, atherectomy, or stenting trial. What may become lost is that, in some trials, only those patients who were successfully predilated without dissections or perforations were enrolled into the trial. Therefore, if we presume that the outcomes are based on the device but also to a degree on the predilation, we have selected out a large number of patients who presumably did not have successful predilation. This is clearly not a real-world approach, given that in the real world, we treat whether the predilation was successful or not. Either way, many infer the outcomes based on the data without considering patient enrollment criteria such as predilation. This becomes critical to operators when reviewing the data and trying to maintain an evidence-based approach to their patients. Unfortunately, many infer an outcome that has never been tested.

In the end, the best approach for any operator is to review the enrollment criteria for any one trial they are interested in and follow that enrollment approach for the patients they are treating. For example, if their principal goal in the SFA is a DCB approach, then an aggressive stance on successful predilation would be warranted regardless of lesion length. If it is for a similar lesion with heavy calcification and their primary therapy is an atherectomy approach, then successful atherectomy with dedicated minimum lumen diameter may be something they need to attain before final PTA/DCB use.

Prof. Tepe: To choose a vessel prep device, two major considerations have to be made. The first is the question of whether data are available that show that the vessel prep device is safe and has the potential to add efficacy to the current standard. The second consideration should be based on whether the operator has experience using that vessel prep device. Because many vessel prep devices are a bit more difficult to handle compared to standard PTA balloons or standard nitinol stents, the operator needs to feel comfortable using such a device. There is also a learning curve with the different types of vessel prep devices.

Prof. van den Berg: It is still too early to give evidence-based advice in this respect. Trials are currently ongoing and should provide the answers on when and how to perform vessel preparation.

Dr. Armstrong: The decision to incorporate specific devices into individual practice is complex but should involve review of the specific types of cases that the operator commonly performs. In my practice, the majority of lesions that I treat have heavy calcification and are long-segment occlusions. I generally utilize a single type of specialty balloon but have access to multiple atherectomy devices. This access to multiple devices allows me to select a specific device based on whether the lesion is calcified, restenotic, thrombotic, or has other characteristics that might favor use of a specific device.

Prof. Zeller: Robust data about the true value of vessel preparation are sparse. The value of thrombectomy in local thrombotic occlusions prior to angioplasty or stenting is unquestioned even without large studies. Different thrombectomy devices are commercially available; the selection of a specific device is usually guided by individual operator preference and device availability in a specific country or region.

Regarding vessel preparation devices for calcified lesions, atherectomy devices are most widely used, and an upcoming new tool is lithotripsy. Some data are published for plaque excision with TurboHawk or HawkOne (Medtronic), which suggest a potential patency benefit for calcified and longer lesions prior to DCB inflation as compared to plain DCB angioplasty without atherectomy. The Diamondback atherectomy device (Cardiovascular Systems, Inc.) has shown reduced balloon pressures for postdilatation, but no data are available regarding the impact on patency. A small intravascular ultrasound–controlled study using the Jetstream device (Boston Scientific Corporation) in calcified short SFA lesions has shown substantial luminal gain after atherectomy, with limited longer-term technical follow-up. Lithotripsy resulted in impressive acute luminal gain comparable to stent implantation in calcified lesions, but longer-term patency is still limited. A study investigating the value of lithotripsy prior to DCB angioplasty (DISRUPT III) is still ongoing.

My personal recommendation would be to have access to a directional atherectomy device, specifically for treating eccentric lesions, and lithotripsy for more concentric calcified lesions.

Prof. Brodmann: What are your impressions of the learning curves for today's vessel prep options? Do you have any recommendations for first cases to select?

Dr. Armstrong: Most vessel preparation options are actually quite easy to utilize. Adequate vessel prep begins with paying attention to lesion characteristics such as calcification and location and then selecting the specific therapy. Specialty balloons in the SFA generally deliver with similar ease as a standard balloon, and the main technical approach with these balloons is to provide a prolonged low-pressure inflation, thereby allowing adequate plaque dilation and modification. In comparison, atherectomy devices have subtleties specific to each device, but can easily be incorporated into regular workflow.

In regard to first cases, nonoccluded severely calcified lesions would represent a good first group of cases for operators to select, as these lesions are generally easy to cross but may not respond well to standard balloon angioplasty.

Prof. Zeller: In general, each vessel prep device has an individual learning curve of about 10 cases. I would recommend on-site training by a proctor or participation in a hands-on workshop in a high-volume center.

Prof. van den Berg: Atherectomy as vessel prep option, whether you use directional, orbital, or rotational atherectomy devices, has some learning curve, both from a device handling point of view as well as a procedural point of view. It has been shown that one needs to go through a learning curve to be able to reduce deep vessel wall (adventitial) damage. The use of specialty balloons (eg, cutting balloons, AngioSculpt [Philips], Chocolate PTA dilatation catheter [Medtronic], and to a lesser extent lithoplasty) is much more straightforward and hardly requires any additional training. As with everything, I recommend starting with relatively easy cases that do not involve heavily calcified TransAtlantic Inter-Society Consensus (TASC) D lesions to gain confidence with the new devices.

Prof. Tepe: There is a learning curve for each vessel prep option. It would be ideal if a proctor is available to do the first cases. In general, I would recommend starting with easier lesions, such as short calcifications in the SFA or popliteal artery that are not occluded. Later, more demanding cases with long occlusions or the treatment of the common femoral artery could be done.

Dr. Garcia: All devices have a learning curve. However, and importantly, the simple POBA approach for many devices is relatively free from a learning curve. In cases where a device is needed to afford the "correct" vessel prep based on the trials and outcomes sought for any one patient, then the operator must become skilled with that device not only for patient safety but for the presumed patency outcome for the patient. Therefore, the learning curve could be one case or may be several, depending on the operator's experience. The operator may benefit from a clinical proctor or attending a workshop with that device. In this way, the operator may become an expert with the device not only in its use but also in troubleshooting, which will be necessary with any device from time to time.

Prof. Brodmann: In which cases are you certain to use a form of vessel prep prior to primary therapy?

Prof. van den Berg: I tend to use some kind of vessel preparation (that goes beyond predilation with a standard angioplasty balloon) in occlusions that are longer than 10 cm and in long stenotic lesions that are heavily calcified as a preparation for DCB angioplasty.

Prof. Zeller: I use vessel prep in all thrombotic occlusions, in-stent reocclusions, and severely calcified lesions.

Prof. Tepe: Vessel prep should be done in cases in which standard therapy is likely to fail (ie, severely calcified arteries).

Dr. Garcia: From its simplest form of POBA to more aggressive debulking strategies, we use vessel prep almost ubiquitously for any lower limb revascularization.

Dr. Armstrong: If a lesion has evidence of moderate to severe calcification on angiography, I will always use some type of vessel preparation before primary therapy. Data have consistently shown that calcified lesions are associated with higher rates of dissection and recoil after balloon angioplasty and that lesion calcification leads to higher rates of restenosis and target lesion revascularization (TLR). I believe that most of the limitations related to these lesions are due to inadequate lesion dilation and extensive dissection and that vessel preparation has the potential to improve the outcomes of these challenging lesions.

Prof. Brodmann: When is vessel prep not necessary?

Prof. Tepe: In approximately 90% of my SFA cases, dedicated vessel prep is not mandatory. Our standard therapy is DCB first. With DCB only, postdilatation and spot stenting (if necessary) can be done in most cases. In 10% of patients, vessel prep might be considered, and in the majority, the need for vessel prep is obvious by just analyzing the initial angiogram before performing the intervention.

Dr. Garcia: Simple, noncalcified, focal lesions may not benefit from aggressive vessel prep in the form of debulking devices. However, all would still benefit from predilation to any final device being used.

Prof. Zeller: In general, vessel prep is not necessary in lesions that are responsive to predilatation, mainly short fibrotic stenotic lesions (TASC II A and B).

Prof. van den Berg: There is probably no place for vessel preparation in short stenotic or occlusive lesions. There are no studies that support this opinion directly, but indirect evidence from the randomized DCB trials indicates that standard DCB angioplasty preceded by standard balloon angioplasty (as vessel preparation) is probably sufficient.

Dr. Armstrong: In my opinion, some type of vessel preparation is necessary in every endovascular case. I always perform predilation with some type of balloon before delivering definitive therapy with a DCB or stent. My rationale for this approach is that angiography alone does not always provide sufficient information regarding how a vessel will respond to angioplasty, and the initial predilation is important both for minimizing dissection and understanding what the best definitive therapy will be for that particular lesion.

Prof. Brodmann: With vessel prep in combination with drug delivery gaining popularity, but data somewhat scarce, how do we separate the results of one platform from the other?

Dr. Armstrong: This is a complex question related to the interplay between lesion preparation, drug delivery, and development of restenosis. All available atherectomy devices provide some benefit in optimizing luminal gain, either by modifying the compliance of the vessel or removing plaque before drug delivery. A larger biological question is whether these devices also improve the retention and/or depth of drug delivery to the lesion in question. Preliminary data from some devices, including laser atherectomy and orbital atherectomy, have suggested better paclitaxel penetration to the vessel wall after atherectomy. Whether these interventions reduce subsequent rates of restenosis remains to be seen, and randomized trials will be necessary to understand the potential clinical benefit of this combined approach.

Prof. van den Berg: Data are indeed very scarce, if not absent, and therefore it is impossible to give guidelines as to which platform works best or which platform to use in certain clinical scenarios.

Prof. Zeller: Basically, three different technologies exist: atherectomy devices, plaque modulation devices (eg, cutting balloon, scoring balloon, Flex scoring catheter [VentureMed Group, Inc.]), and lithotripsy. Short lesions can be best approached with atherectomy or a plaque modulation device, and eccentric lesions are preferentially approached with directional atherectomy. Longer lesions are easier to treat with the Flex catheter or with lithotripsy if they are calcified. Atherectomy for long lesions can become very time consuming, and the complication rate increases with lesion length.

Dr. Garcia: The combination of vessel prep with DCB has become a default strategy for many who treat the SFA. This is clearly driven by several trials and one pilot study suggesting combination therapy as a benefit in long or calcified lesions. Unfortunately, there are little data comparing devices, particularly in head-to-head trials. This difficulty makes the scientific pursuit of evidence-based medicine almost impossible. The nuance and heterogeneity of any one trial compared to another is unique and cannot be compared.

Prof. Tepe: Each platform and each device needs its own data because the efficacy varies. There is no one class of vessel prep and no one class of DCB. In addition, operator experience is a consideration.

Prof. Brodmann: Data on cost-effectiveness are also hard to come by, and reimbursement varies. What can be done to better explore and demonstrate that results with these devices offset their added costs?

Dr. Garcia: This may change with the REALITY trial, which will evaluate the use of directional atherectomy for debulking prior to DCB therapy in a core lab–adjudicated fashion. However, there is no comparator arm, and the trial is investigator-sponsored by the VIVA group. Notwithstanding these limitations, the trial will seek to determine many important answers regarding outcomes and cost analysis that have been severely lacking.

Prof. Tepe: My general remark is that each operator should make decisions based on the individual patient to achieve the best acute and long-term results. Patient selection is key. If vessel prep is cost-effective if it is chosen for those who really need it. Other than the additional costs of a device, additional procedural time is a consideration because vessel prep might increase the time needed for endovascular therapy. If the standard therapy fails (without vessel prep), all investments are lost.

Dr. Armstrong: There is a strong need for cost-effectiveness data with regard to both specialty balloons and atherectomy devices. The two major potential areas for cost offset include reducing the need for stent implantation (due to dissection or recoil that could have been prevented with improved vessel prep) and potentially reduced rates of TLR over time. In our own single-center analysis, we recently demonstrated that use of orbital atherectomy before DCB angioplasty in the SFA was associated with significantly lower rates of stent implantation despite severe lesion calcification.[1] If these data also show similar or lower rates of TLR during long-term follow-up, this could be one example of the cost-effectiveness of vessel preparation.

Prof. van den Berg: We need studies that will show a benefit of vessel preparation prior to DCB angioplasty or SFA stenting to justify the additional costs of the specialty devices. It is also important to perform head-to-head comparisons of various devices to be able to make scientifically based decisions.

Prof. Zeller: The only option is running comparative studies between plain application of standard techniques such as POBA, DCB, or stenting as compared to the use of these technologies after the use of a vessel preparation device. The combination therapy has to either prove a reduction in the TLR rate, improvement in patency rate, or equivalent outcomes with traditional therapies such as bare-metal stenting or drug-eluting stent implantation without the need for such an implant as a compensation of the additional costs for the vessel preparation device. If not, their use will not be cost-effective.

Prof. Brodmann: Do you think that we have enough data to create an algorithm for everyday procedures in the cath lab with regard to vessel prep?

Prof. Zeller: Yes, but only regarding the acute treatment success. For example, we know that lithotripsy and directional atherectomy result in excellent acute treatment success despite a reduced stent rate (DISRUPT I and II, DEFINITIVE AR, and DEFINITIVE LE studies). My personal algorithm is the following: Predilatation of a lesion with a plain balloon sized at least 1:1. If the result is satisfactory, the next step will be DCB use. If not, I consider either focal atherectomy or cutting balloon angioplasty in the area of the suboptimal angioplasty outcome, followed by DCB and provisional stent placement. For longer diffusely calcified lesions, I prefer lithotripsy as the first step of the treatment, followed either by DCB angioplasty or stent implantation.

Dr. Garcia: We have the basis for algorithms to be initiated. However, there are too many "what ifs" that make the algorithm extremely limited. Therefore, in my opinion, it remains left to operator discretion as to how to proceed with vessel prep in any one patient.

Prof. Tepe: No, we do not have enough data. Nevertheless, we have strong signs that vessel prep is needed in certain cases. The industry should be encouraged to support further studies of vessel prep with a real control group. It is not enough just to gain data on vessel prep devices without knowing how the patients would have done without using the vessel prep device.

Dr. Armstrong: I think we need more data to optimize current approaches to vessel preparation, but that certain principles apply. If a lesion is < 100 mm in length and does not appear calcified, vessel preparation with a standard balloon is reasonable. For longer,

noncalcified lesions, I prefer to use a specialty balloon to minimize dissection and recoil. If a lesion is calcified, I prefer to use atherectomy and a specialty balloon together as part of my vessel preparation algorithm.

Prof. van den Berg: It is still too early to create any kind of algorithm to provide guidance in clinical decision-making, and as previously mentioned, studies are needed to provide this proof. I think we all can agree that no DCB or stent should be used without prior (standard) balloon angioplasty (basic vessel preparation). Other devices certainly have their place in a treatment algorithm, but their role needs to be defined further. ■

1. Foley TR, Cotter RP, Kokkinidis DG, et al. Mid-term outcomes of orbital atherectomy combined with drug-coated balloon angioplasty for treatment of femoropopliteal disease. Catheter Cardiovasc Interv. 2017;89:1078–1085.

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