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Treatment Algorithm: How DCB Evidence Has Changed My Practice

With Marcus Treitl, MD, MBA, EBIR

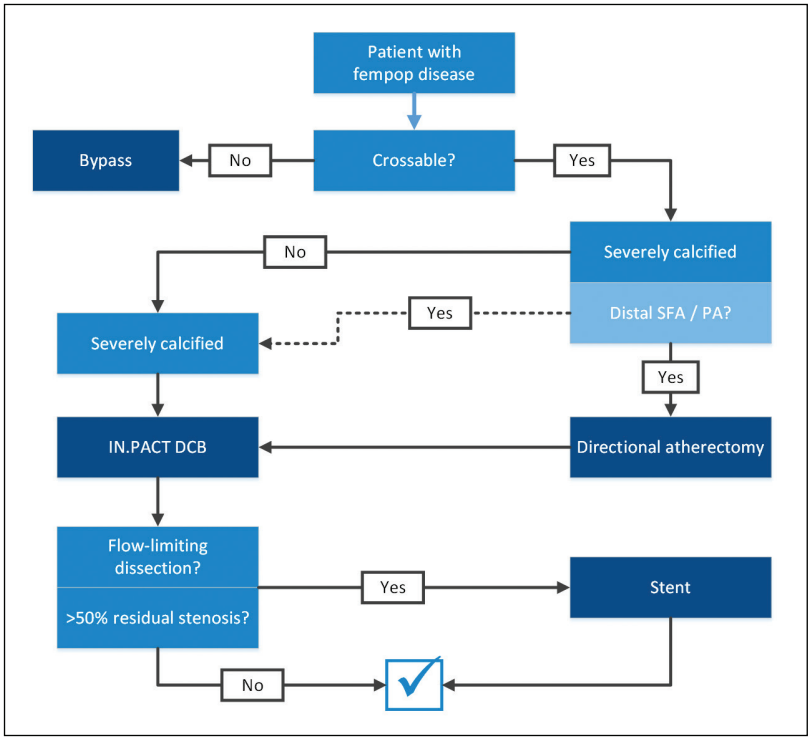
With the use of predilatation or atherectomy in combination with a drug-coated balloon (DCB), Marcus Treitl, MD, MBA, EBIR, who is with the Radiological Section of the Center for Vascular Diseases of the University of Munich, Germany, has reduced the stent rate for femoropopliteal lesions from 30% to 10% over the last 2 years at his center. In this interview, he reveals his rationale for vessel preparation and DCB use and shares his treatment strategy (Figure 1) in the popliteal and superficial femoral arteries (SFA).

WHAT ARE THE FACTORS THAT INFLUENCE YOUR TREATMENT CHOICE IN THE SFA AND POPLITEAL ARTERIES?

Dr. Treitl: The main factors influencing my treatment choice are lesion crossability, the type of crossing (subintimal vs luminal), the degree of calcification, and lesion site, especially its distance to the femoral bifurcation or the peroneal trunk.

CAN YOU PLEASE DESCRIBE YOUR TREATMENT ALGORITHM FOR SFA DISEASE?

Dr. Treitl: The first milestone is crossability of the lesion. Of course, in the case of a noncrossable lesion, the patient is then referred for bypass surgery. But before that, I try antegrade and retrograde options to cross the lesion and, if successful, I carefully evaluate how the lesion was crossed before I select my treatment tool. For example, in the subintimal space I would rarely use atherectomy and would always use standard angioplasty, followed by a DCB. In the case of luminal crossing, the calcification of the lesion and the exact location are the next factors influencing my choice of treatment. If there is visible or severe calcification, I perform lesion preparation with directional atherectomy or, if unfeasible because of lesion location, I use scoring-balloon angioplasty, followed by the use of a DCB. In certain locations such as the distal popliteal artery, the combined use of a directional atherectomy device and a filter can be hindered by the short distance between the lesion and the trunk. In this case, I prefer to use plain angioplasty instead of atherectomy.



But all lesions are postdilated with a DCB. Stenting is, from my point of view, still a bailout strategy for otherwise untreatable residual stenosis > 30% or flow-limiting dissection. With the routine use of predilation or atherectomy in combination with a DCB, our stent rate has decreased dramatically from 30% to 10% over the last 2 years.

WHAT EVIDENCE HAS GUIDED YOUR DECISION-MAKING IN DEVICE SELECTION?

Dr. Treitl: Our decision-making process has been based mainly on personal experience. We have been using directional atherectomy and DCB from the very beginning and have made some important observations. Firstly, DCB technology does work; however, there are remarkable differences between the available products deriving from manufacturing process and excipient used. We have tried out seven different DCB systems, and at least three of them did not show drug effect or increased patency. In addition, the combination of atherectomy and DCB has further decreased stent use and improved results even for complex lesions such as calcified ones.

Secondly, the amount of data supporting DCB use in the femoropopliteal axis has increased dramatically over the past 3 years. Of note, the encouraging results from the IN.PACT trials and the IN.PACT global study have contributed a lot to this fact and now allow us to use DCB technology in more demanding lesions like long lesions, chronic total occlusions, and in-stent restenosis.

WHAT IS THE ROLE OF PREDILATATION? DO YOU ALWAYS USE IT?

Dr. Treitl: Predilatation and other measures for lesion preparation for DCB usage, from my point of view, are always recommended if there is an occlusion or severe calcification, because there is potential drug loss during lesion crossing. In case of a high degree of stenosis, I also prefer to perform predilatation before DCB use. In all other cases, with a degree of stenosis between 70% and 90%, I use the DCB directly.

WHAT ARE THE SIZING RULES FOR DCBs (LESION COVERAGE, SIZE OF PREDILATATION BALLOON, SIZE OF DCB, INFLATION TIME)?

Dr. Treitl: In my daily practice for predilatation, I use a balloon 1 mm smaller than the estimated or measured luminal diameter of the target vessel, followed by a DCB the same size as the target vessel. During predilatation, I mark the margins of the treated vessel segment on the viewing monitor and after that, I use, without changing the position of my C-arm, a DCB that is longer than the treated segment, and covers more than the predilated vessel area. This is important to avoid geographic miss. The inflation time depends on the manufacturer's instructions for use but is typically located between 1 to 3 minutes.

WHAT ARE THE BENEFITS OF USING DIRECTIONAL ATHERECTOMY AS A VESSEL PREPARATION STEP BEFORE THE USE OF DCB? AND FOR WHAT TYPE OF LESION IS THIS COMBINATION THERAPY MOST APPROPRIATE?

Dr. Treitl: Directional atherectomy has two major benefits. It reduces the risk of inducing a flow-limiting dissection that requires stent implantation to almost zero. This makes directional atherectomy the ideal tool in all so-called no-stent zones like the femoral bifurcation, most parts of the adductors canal, and the popliteal artery. Second, directional atherectomy removes major amounts of the atherosclerotic material that could hinder the drug activity in the vessel wall. This is especially true for severely calcified lesions, as we know from the trial from Fanelli et al[1]; they discovered that the drug action diminishes when the vessel wall is covered with calcium. The ideal targets for directional atherectomy are no-stent zones and calcified lesions.

DO YOU ALWAYS USE A FILTER WITH DIRECTIONAL ATHERECTOMY?

Dr. Treitl: I always use a filter when using directional atherectomy, even for noncalcified lesions. There is always a risk of losing small particles downstream during directional atherectomy and because this is not thrombus but tissue, there is no possibility of treating distal embolizations after directional atherectomy with thrombolysis. So, the only options are leaving it as it is or trying catheter aspiration. The latter poses the risk of damaging the crural vessels and inducing new lesions. Therefore, I prefer to use a filter in all cases.

WHAT IS THE ROLE OF STENTING IN THE TREATMENT OF SFA DISEASE GOING FORWARD?

Dr. Treitl: I think stenting was, is, and will remain a bailout treatment for femoropopliteal lesions. The results for stenting have improved during the last decade, without a doubt. However, it still represents a mechanical implant in a zone of high physical stress for both the stent material and the vessel wall.

We have not yet completely understood the pathophysiology of in-stent restenosis and therefore are still looking for the perfect implant. Given the fantastic results of DCB technology in almost all types of femoropopliteal lesions, there is not an increasing role for stenting in this vessel region. And as I mentioned earlier, the stent rate has decreased dramatically in our daily routine.

FOR THOSE PHYSICIANS WHO OPT FOR STENTING AS THEIR PREFERRED TREATMENT OPTION, WHAT RECOMMENDATION DO YOU HAVE FOR THEM TO ADJUST THEIR PRACTICE TO STENT LESS?

Dr. Treitl: They should try the combination of lesion preparation with plain angioplasty or directional atherectomy and DCB technology. This alone has led to a drop in stent use at our department and I expect the same for many others who are doing this as well. But we should also remember the accepted indications for stenting: flow-limiting dissection or residual stenosis. I quite often see that the term "flow-limiting dissection" is replaced by "dissection," which means that sometimes stents are also used for more benign dissections that are not flow-limiting—this is something we should avoid.

1. Fanelli F, Cannavale A, Gazzetti M, et al. Calcium burden assessment and impact on drug-eluting balloons in peripheral arterial disease. Cardiovasc Intervent Radiol. 2014;37:898–907.

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IN.PACT™ Admiral™ Brief Statement
Indications for Use:
- The IN.PACT™ Admiral™ Paclitaxel-Coated PTA Balloon catheter is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, of de novo, restenotic, or in-stent restenotic lesions with lengths up to 360 mm in superficial femoral or popliteal arteries with reference vessel diameters of 4-7 mm.
- Contraindications
- The IN.PACT™ Admiral™ DCB is contraindicated for use in:
- Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries
- Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system
- Patients with known allergies or sensitivities to paclitaxel
- Women who are breastfeeding, pregnant or are intending to become pregnant or men intending to father children. It is unknown whether paclitaxel will be excreted in human milk and whether there is a potential for adverse reaction in nursing infants from paclitaxel exposure.

Warnings
- Use the product prior to the Use-by Date specified on the package.
- Contents are supplied sterile. Do not use the product if the inner packaging is damaged or opened.
- Do not use air or any gaseous medium to inflate the balloon. Use only the recommended inflation medium (equal parts contrast medium and saline solution).
- Do not move the guidewire during inflation of the IN.PACT™ Admiral™ DCB.
- Do not exceed the rated burst pressure (RBP). The RBP is 14 atm (1419 kPa) for all balloons except the 200 and 250 mm balloons. For the 200 and 250 mm balloons the RBP is 11 atm (1115 kPa). The RBP is based on the results of in vitro testing. Use of pressures higher than RBP may result in a ruptured balloon with possible intimal damage and dissection.
- The safety and effectiveness of using multiple IN.PACT™ Admiral™ DCBs with a total drug dosage exceeding 34,854 µg of paclitaxel in a patient has not been clinically evaluated.

Precautions
- This product should only be used by physicians trained in percutaneous transluminal angioplasty (PTA).
- This product is designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- Assess risks and benefits before treating patients with a history of severe reaction to contrast agents.
- The safety and effectiveness of the IN.PACT™ Admiral™ DCB used in conjunction with other drug-eluting stents or drug-coated balloons in the same procedure or following treatment failure has not been evaluated.
- The extent of the patient's exposure to the drug coating is directly related to the number of balloons used. Refer to the Instructions for Use (IFU) for details regarding the use of multiple balloons and paclitaxel content.
- The use of this product carries the risks associated with percutaneous transluminal angioplasty, including thrombosis, vascular complications, and/or bleeding events
- Vessel preparation using only pre-dilatation was studied in the clinical study. Other methods of vessel preparation, such as atherectomy, have not been studied clinically with IN.PACT™ Admiral™ DCB.
- This product is not intended for the expansion or delivery of a stent

Potential Adverse Effects
- The potential adverse effects (e.g. complications) associated with the use of the device are: abrupt vessel closure; access site pain; allergic reaction to contrast medium, antiplatelet therapy, or catheter system components (materials, drugs, and excipients); amputation/loss of limb; arrhythmias; arterial aneurysm; arterial thrombosis; arteriovenous (AV) fistula; death; dissection; embolization; fever; hematoma; hemorrhage; hypotension/hypertension; inflammation; ischemia or infarction of tissue/organ; local infection at access site; local or distal embolic events; perforation or rupture of the artery; pseudoaneurysm; renal insufficiency or failure; restenosis of the dilated artery; sepsis or systemic infection; shock; stroke; systemic embolization; vessel spasms or recoil; vessel trauma which requires surgical repair.
- Potential complications of peripheral balloon catheterization include but are not limited to the following: balloon rupture; detachment of a component of the balloon and/or catheter system; failure of the balloon to perform as intended; failure to cross the lesion.
- Although systemic effects are not anticipated, potential adverse events that may be unique to the paclitaxel drug coating include but are not limited to: allergic/immunologic reaction; alopecia; anemia; gastrointestinal symptoms; hematologic dyscrasia (including leucopenia, neutropenia, thrombocytopenia); hepatic enzyme changes; histologic changes in vessel wall, including inflammation, cellular damage, or necrosis; myalgia/arthralgia; myelosuppression; peripheral neuropathy.
- Refer to the Physician's Desk Reference for more information on the potential adverse effects observed with paclitaxel. There may be other potential adverse effects that are unforeseen at this time.
- Please reference appropriate product Instructions for Use for a detailed list of indications, warnings, precautions and potential adverse effects. This content is available electronically at www.manuals.medtronic.com.

CAUTION:
Federal law (USA) restricts this device to sale by or on the order of a physician.