Expert Opinion on When to Use DCBs

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Percutaneous transluminal angioplasty (PTA) remains the standard of care of treatment in superficial femoral artery (SFA) and below-the-knee (BTK) lesions. It has been the only proven treatment modality but, with growing lesion length and new tools to improve our success and patency rate, the use of adjunctive therapy beyond stenting, such as drug-coated balloons (DCBs) and atherectomy is growing. Nowadays, primary stenting is a rare case in SFA and BTK lesions, but it is the primary approach in iliac arteries in our cath lab. Adjunctive treatment modalities, such as DCBs or atherectomy, do not yet play a role in the iliac arteries. In Germany, even though a lot of DCBs have CE Mark approval and our health care system is reimbursing the use of DCBs, we still have to justify their use.

STRATEGIES OF TREATMENT

Strategies in the treatment algorithm of stenosis or occlusions in SFA lesions do not differ all that much—lesion length, grade of calcification, and location of the lesion strongly influence our modalities.

In cases of an ostial SFA lesion or a lesion of the common femoral artery, as well as in the popliteal artery, or the areas known as "no-stent zones," we would primarily start with the atherectomy or scoring PTA in combination with DCBs. Twelve-month data presented at VIVA 2014 indicated that atherectomy in combination with DCBs may lead to better results in complex femoropopliteal lesions.

In these areas, we know that stenting with nitinol stents faces restrictions and requires special technolo-

gies. There are stents on the market that qualify (more for mechanical stress and their use in areas of flexion), but everybody would agree that the native artery without any mechanical implant inside is superior in terms of flexibility and behavior during motion.

Mostly, we try to achieve intraluminal wire passage followed by vessel preparation and plaque removal with atherectomy followed by a PTA with a DCB. If we run into a subintimal route, we probably would not opt for atherectomy.

In cases of flow-limiting dissection, we would not hesitate to use a dedicated stent in these areas, except in the common femoral artery, because we still believe that open surgery is a valid alternative with robust data in terms of patency and durability.

In noncalcified SFA lesions, if the wire passage is performed successfully, we currently would start with a gentle predilation by using an undersized balloon. If the primary result looks promising in terms of good flow and the absence of major dissections and thrombus, the next step would be a DCB sized properly to match the reference vessel diameter. Inflation time would be at least 3 to 5 minutes. If the lesion length exceeds the balloon length of a single DCB, several may be used. In such cases, we are careful to ensure that the entire length of the lesion and predilated area is treated with a DCB. If the result is good, the patient would be set on dual-antiplatelet therapy for at least 3 months, and an early follow-up by duplex ultrasound would be scheduled.

If the result does not look good, we would go for stenting of the dissected/subintimal area.

In stenoses or occlusions located within a stent, we use DCBs in 100% of cases.

In calcified lesions, we would use atherectomy or scoring technology as a primary treatment to prepare the vessel for a DCB or stenting. If atherectomy was not effective in reducing the calcified plaque burden, a DCB would play a limited role. In such cases, we would opt for PTA with a short, noncompliant balloon with high inflation pressure or for a scoring/cutting balloon to prepare the vessel for final stenting. DCBs are probably not as effective in severely calcified lesions as they are normally,[1] but further study and data are needed.

In BTK lesions, we still believe that the concept of local drug delivery is promising, although the IN.PACT DEEP trial brought significant drawbacks to the interventional community.[2] The data from the Biolux P-II trial showed safety data without any increase in amputation rates after 6 months. However, the same as for IN.PACT DEEP, in this randomized trial of Biotronik DCB versus PTA, the primary efficacy endpoint was not met.[3] It seems as if the right choice of DCB for treatment below the knee is more crucial than in the SFA, and this is probably driven by the excipient used on the balloon and the coating technology.

To date, we do not treat CLI BTK cases with DCBs, and we are waiting for more robust data to help determine optimal therapy. In these cases, we opt for a long inflation time with a standard PTA balloon and, for spot stenting, a drug-eluting stent. The treatment of patients with severe claudication with concomitant BTK lesions is probably safe with use of a DCB, and we administer local drugs at ostial or bifurcation lesions in such cases.

The data supporting the use of DCBs for SFA de novo lesions are robust and a little less robust for in-stent restenosis. If we look for predictors of restenosis in general, the following were identified: long lesions (TASC C and D), small arteries and areas of flexion such as the common femoral artery, the popliteal artery, and the SFA proximally and distally.

These indications qualify more for DCB use with or without adjunctive therapy; however, there remain unanswered questions.

Dialysis access has the highest restenosis rate reported so far; these arterialized veins qualify for DCBs, as indicated by some preliminary small trials.

SUMMARY

For clinical practice, we need DCB technology that addresses dialysis challenges, such as shunt veins, and safe DCB technology for BTK lesions. There is a lack of data for long SFA and popliteal lesions because in all trials presented so far, the lesion length is approximately 6 to 8 cm. Most clinical cases we treat to date exceed this lesion length.

Future trials and registries should primarily address long lesions and combination therapy with scoring technology and debulking devices. Data from the DEFINITIVE AR trial concerning the combination of atherectomy and DCBs are showing promising results, but the cohort of this pilot trial was too small to produce evidence. ■

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