The PANTHER Study

The real-world application of AngioSculpt in calcification. Can vessel preparation with a scoring balloon offset the detriment to patency caused by calcification?

BY ERWIN BLESSING, MD

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The impact of arterial calcification has not been well described, but early work suggests that calcification may decrease the effectiveness of drug-coated balloons (DCBs).[1] Fanelli et al assessed 60 patients with de novo superficial femoral artery (SFA) lesions who underwent angioplasty with a DCB.[1] The patients were categorized into groups based on the length and degree of circumferential calcification present in the treated lesion based on CT angiography axial images. In patients with circumferential (360º) calcification, the patency rate at 12 months was only 50%. Circumferential calcium distribution was a better predictor for loss of patency than longi-

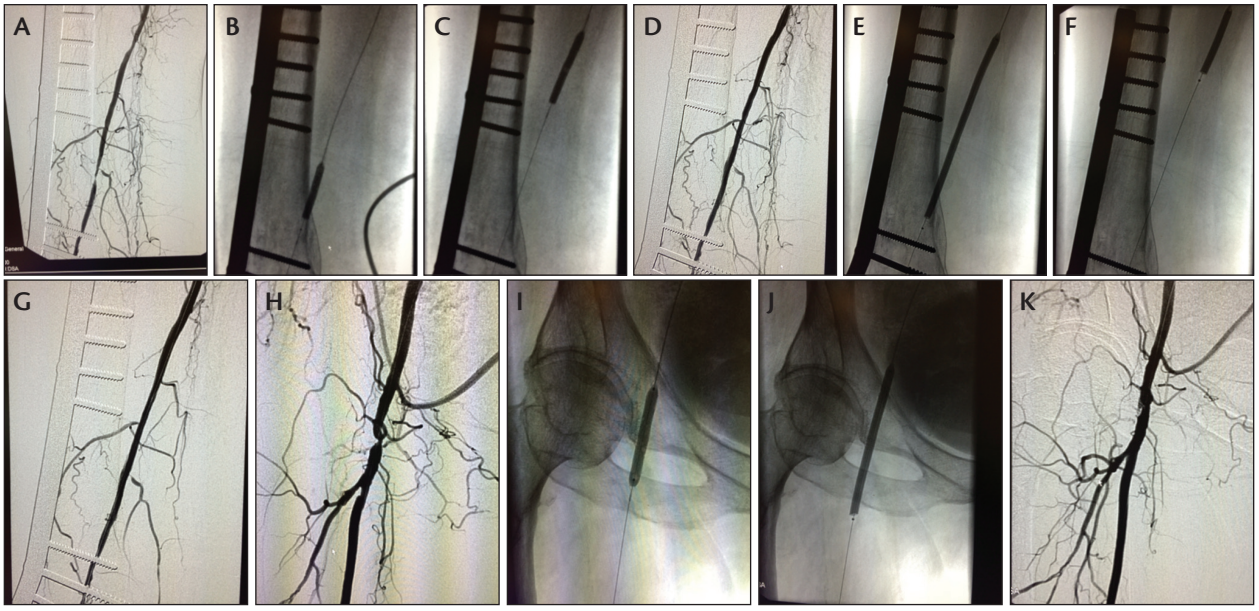

Figure 1. Baseline right SFA (A). AngioSculpt® scoring balloon (5 X 40 mm) inflation (B, C). Result after use of AngioSculpt® (D). Stellarex™ DCB (5 X 120 mm and 5 X 40 mm) inflations (E, F). Final result in the SFA (G). Baseline common femoral artery (H). AngioSculpt® scoring balloon (5 X 40 mm) inflation (I). Stellarex™ DCB (5 X 80 mm) inflation (J). Final result in the common femoral artery (K).

tudinal extension of vascular calcification. Because there was no control group treated with standard angioplasty, it remains speculative whether calcification really limits the benefits of antiproliferative therapy or whether calcification generally results in poorer long-term patency.

Is there inadequate penetration of paclitaxel into the media and adventitia? Would preparation of the lesion improve the drug absorption and, therefore, patency in calcified lesions? The PANTHER study was designed in part to address these questions.[2]

STUDY DESIGN

The PANTHER study enrolled 101 patients with 124 lesions. The majority of patients had hypertension (93.1%), and 34.7% presented with critical limb ischemia. The mean lesion length was 7.4 ± 5.9 cm, and the mean percent diameter stenosis was 85.5%; 16.1% were total occlusions. Calcification was present in all lesions and categorized as mild (21.8%), moderate (34.7%), and severe (43.5%).

An AngioSculpt® scoring balloon (Spectranetics Corporation) was used in each case, but adjunctive use of a bare-metal stent or DCB was at the discretion of the interventionist. In 40 lesions (32.3%), AngioSculpt® use was followed by inflation of a DCB, and in 38 cases (30.6%), a bare-metal stent was placed (Supera™, Abbott Vascular). In 46 lesions (37.1%), stand-alone AngioSculpt® use was the treatment of choice. At 12 months, the primary patency rate was 81.2%, and the secondary patency rate was 91.8%.

When stratified by calcification severity, there was no discernible difference between the patency rates (mild, 78.9%; moderate, 81.3%; and severe, 81.8%). Within the AngioSculpt® + DCB group, the mean lesion length was 5.9 cm, and 17.5% were chronic total occlusions. The primary patency rate was 83.9% at 12 months. Although limited in size, this study is encouraging for the use of scoring balloons in calcified lesions. Additional studies need to be conducted to define the role of scoring balloons and DCBs, but the future looks bright.

CASE PRESENTATION

Vessel Preparation With AngioSculpt® + Stellarex™ DCB

Recently, the Stellarex™ DCB became commercially available, and I have used it in conjunction with the AngioSculpt™ device with good acute outcomes. The patient was a 70-year-old woman with type 2 diabetes mellitus and hypertension. She presented with ischemic ulcers (Rutherford category 5) and a baseline ankle-brachial index of 0.46. Duplex ultrasound confirmed high-grade stenoses in the common femoral artery and distal SFA.

In this case, I used 5- X 40-mm AngioSculpt® scoring balloons to predilate the lesions prior to treatment

with the DCB. For predilatation before DCB use, I recommend undersizing by 1 mm whether using a plain angioplasty balloon or an AngioSculpt® scoring balloon. I followed-up with DCB treatment using the Stellarex™ DCB (Spectranetics Corporation).

During preparation, it is essential that contact with the DCB is avoided, in particular contact with fluid, which could lead to significant loss of the coating. I also believe it is crucial to minimize the time between insertion of the DCB into the sheath and final deployment. I try to keep this time to < 1 minute. It is important to use road mapping and radiopaque rulers to ensure that the final location of the DCB covers the length of the artery that was predilated, which is to say avoidance of "geographic miss." As far as sizing is concerned, I try to match the DCB diameter to the reference vessel diameter.

In this case, I used two Stellarex™ DCBs (5 X 120 mm and 5 X 60 mm) in the SFA, being careful to adequately overlap the balloons by at least 1 cm. One Stellarex™ DCB (5 X 80 mm) was used in the common femoral artery. An inflation time of 1 minute is the minimum, but I tend to keep the balloon inflated for approximately 3 minutes to ensure good mechanical dilatation of the artery (Figure 1).

The early data that are currently available have excited the medical community about the potential of DCBs. As more complex lesions are included in clinical trials and real-world use data are reported, we will learn more about the limitations and when vessel preparation is necessary to ensure good drug uptake and durable results. ■

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.
2. Blessing E. The role of vessel preparation–insights from the Heidelberg PANTHER registry. Presented at LINC 2015; Leipzig, Germany; January 27–30, 2015.