Commentary

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The Liberal Versus Selective Use of Drug-Coated Balloon Angioplasty in Femoropopliteal Disease

Ali F AbuRahma*

Department of Vascular and Endovascular Surgery, West Virginia University, West Virginia, USA

***Corresponding author:** Ali F AbuRahma

ali.aburahma@camc.org

Department of Vascular and Endovascular Surgery, West Virginia University, West Virginia, USA

Tel: 304-388-4887
Fax: 304-388-4879

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Stents were originally utilized to prevent elastic recoil of arteries after percutaneous transluminal angioplasty (PTA). However, they have been hypothesized to increase neointimal hyperplasia by increasing inflammatory reaction and inducing trauma. Therefore, drug-coated balloons (DCBs) were designed to deliver large doses of anticell proliferating agent directly to the injured vessel in order to decrease the neointimal hyperplastic process.

Several studies have reported somewhat satisfactory results of paclitaxel DCBs in primary and restenotic femoral-popliteal lesions. Over the past few years, three DCBs have been approved for use in the United States: IN.PACT Admiral (Medtronic, Dublin, Ireland), Lutonix 0.35 (Bard, Tempe, Arizona) and Stellarex (Philips, Amsterdam, The Netherlands). Most of the results of clinical data came from industry sponsored multicenter clinical trials and includes mainly patients with lower Rutherford classes (claudication) as opposed to critical limb ischemia (CLI) patients.

These studies showed that when compared to conventional PTA, DCBs had improved patency rates when used to treat popliteal and SFA lesions. However, they were limited by heterogeneous patient populations, shorter follow-up and smaller sample size.

In the LEVANT 1 trial, 101 patients were randomized to uncoated balloons vs Lutonix DCB and found that primary patency rates were significantly better with DCB at 12 months (74% vs 57%, P<0.001). Additionally, major adverse events (death/target lesions thrombosis/reintervention/amputation) at 24 months were 46% for conventional PTA vs 39% for DCB (P=0.45).

The largest DCB trial was the LEVANT 2 trial which randomly assigned 476 patients with Rutherford Class 2, 3 and 4 to POBA vs Lutonix DCB in a 1:2 ratio. The mean total lesions length was 101.2±84 mm, 31% of these lesions had total occlusion and only 22% were longer than 150 mm. Compared with conventional PTA, the primary patency at 12 and 24 months was superior in patients who had Lutonix DCB (85% and 76%).

A few single center studies have been published to verify the outcome from real world experience. We recently analyzed 228 patients who were treated with DCB angioplasty (Lutonix 0.35). Treated lesions were primarily TASC C and D. Indications included critical limb ischemia (CLI) (Rutherford Class 4 and 5) in 60% and Rutherford Class 2 and 3 (claudication) in 40%. 64% of patients obtained symptom relief (improvement of ≥ one Rutherford Class). Primary patency rates at 1 and 2 years were 56% and 39%, while limb salvage rates were 92% and 83%, respectively. Symptom improvement was 49% for CLI vs 0% for claudication (P<0.001). Major amputation rate was 13% for CLI vs 0% for claudications (P<0.001). Primary patency rates at 1 and 2 years were 54% and 37% for CLI vs 59% and 41% for claudication (P=0.307). TASC A-C lesions had a primary patency rate of 82% and 71% at 1 and 2 years vs 29% and 14% for TASD D lesions (P<0.001) while limb salvage rates were 85% and 74% for CLI vs 100% and 100% for claudication at 1 and 2 years, respectively.

To be noted that, in our study the mean lesion length was much longer (20 cm) than the LEVANT 1 and 2 trials, 23% (47 lesions) were >30 cm and 66% (138 lesions) were >15 cm. 45% of the lesions in our series were also TASC D lesions and 40% had chronic total occlusions.

For patients with TASC D femoropopliteal lesions, the optimal therapy remains ill-defined. If patients have a low operative risk and favorable anatomy, the current SVS Practice Guidelines for Management of Claudication Patients, recommend surgical bypass as an initial strategy particularly in patients with small caliber artery (<5 mm), extensive calcification of SFA or femoropopliteal occlusive disease (TASC D lesions).

With the recent meta-analysis/systematic review of randomized controlled trials which analyzed paclitaxel coated stents/paclitaxel coated balloon angioplasty in the femoropopliteal arterial location found that mortality was significantly higher using these devices. Therefore, doctors should be cautious when using these devices. For shorter femoropopliteal lesions, data suggests that selective use of DCBs would be a better choice.

