Drug-Coated Balloons for Long Superficial Femoral Artery Disease
Leaving Nothing Behind in the Real-World*

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The optimal endovascular strategy for treatment of superficial femoral artery (SFA) atherosclerotic disease is an evolving area of research and clinical practice. Initial randomized trials demonstrated a benefit of nitinol self-expanding stent placement in this region when compared to standalone balloon angioplasty (1). However, observational studies subsequently raised concerns regarding the risk of stent fracture and significant restenosis due to the unique mechanical forces in the SFA and popliteal artery (2). Further refinements in stent technology have resulted in lower rates of stent fracture, but most currently available nitinol stent platforms continue to demonstrate a linear relationship between stent length and restenosis (3). The longer lesion lengths frequently encountered in clinical practice may thus be susceptible to lower long-term patency with multiple overlapping nitinol stents.

The development of paclitaxel-based drug-eluting stents (DES) and drug-coated balloons (DCB) represents an evolution in the endovascular treatment of peripheral artery disease. Paclitaxel-eluting nitinol stents have been shown to be superior to both balloon angioplasty and primary nitinol stenting, with outcomes data now available up to 5 years (4). Recent randomized clinical trials have also demonstrated that angioplasty with a DCB is superior to standard balloon angioplasty for moderate length lesions in the femoropopliteal region (5,6). Although direct comparative effectiveness studies have not been performed, these results suggest that treatment with a DCB may result in comparable or superior outcomes to those observed in the nitinol stenting trials. Contemporary multicenter registries have confirmed these findings, demonstrating excellent primary patency of DCB in anatomically simple (e.g., Trans-Atlantic Inter-Society Consensus [TASC] A or B) SFA disease (7).

The promising results in observational studies and randomized clinical trials may suggest that DCBs should be the standard therapy for the treatment of atherosclerotic disease in the SFA. However, the treatment of anatomically complex lesions (e.g., TASC C and D) with longer lengths that are frequently encountered in clinical practice had not yet been evaluated. In this issue of JACC: Cardiovascular Interventions, Micari et al. (8) provide the first evidence evaluating the efficacy of DCBs in longer lesions treated in a real-world setting. As described, the SFA-Long (Superficial Femoral Artery-Long) study was a prospective multicenter observational cohort that included 105 patients with long (>150 mm) femoropopliteal lesions. The enrolled cohort had significant anatomic complexity, with a mean lesion length of 251 mm and a significant proportion of lesions (50%) with total occlusions. Despite the high burden of disease, the authors report impressively low rates of bailout stenting (10.9%) and an excellent primary patency rate (83%) at twelve months of follow-up, as assessed by duplex ultrasound. Further, the clinically driven target lesion revascularization rate remained remarkably low (4%) with a concomitant improvement in the functional status of the population studied.

The results of the SFA-Long cohort are impressive, with low rates of bailout stenting and outstanding primary patency at 1 year. While the lack of head-to-head data makes it difficult to directly compare

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technologies, the reported patency rates in this cohort are comparable or superior to published studies of nitinol stents for similar lesion lengths (49% to 55%) as well as currently available DES for longer lesions (78%). The results are also similar to or surpass the reported patency of covered self-expanding stents (67% to 71%) and interwoven nitinol stents (81%) (3,9–14). Observational cohorts have supported these findings, with a recent propensity weighted analysis demonstrating similar patency rates between DES and DCB among patients with longer femoropopliteal disease, with a mean lesion length of 194 mm (15). Taken together, the available observational data suggest that treatment with a DCB may provide similar or superior 1-year patency when compared to currently available stent technologies.

With this in mind, should treatment with a DCB be the new standard therapy for long atherosclerotic lesions in the SFA? The concept of “leaving nothing behind” is certainly compelling, especially in longer lesions that would require multiple overlapping stents in a region of repetitive mechanical stress. Before concluding this, several caveats should be considered when interpreting the currently available data. First, the longer-term patency rates of long, complex femoropopliteal disease treated with a DCB remain ambiguous. The currently available observational studies only provide patency data after 2 years of follow-up (16). It is possible that increasing lesion lengths predispose patients to restenosis despite treatment with a DCB, and thus additional data will be necessary to better understand vessel patency after this time period. Second, the rates of bailout stenting (10.9%) in the SFA-Long cohort are much lower than previously reported in observational studies and randomized trials of longer lesion lengths. Additional investigations incorporating larger cohorts should be performed to determine if this low bailout stenting rate can be replicated by other groups. Third, the Micari et al. (8) analysis did not include a large percentage of patients with severe calcific disease (13%). Prior investigations have demonstrated decreased patency rates with increasing calcification of the SFA (17). Because of this, further evaluation of DCBs in severely calcified vessels with or without concomitant atherectomy will be necessary to understand the efficacy of this treatment strategy for these patients.

Overall, the SFA-Long analysis demonstrates that treatment of long atherosclerotic lesions in the femoropopliteal region can be safely and effectively performed with DCBs. Further studies incorporating longer follow-up periods will ultimately determine if the complex lesions frequently encountered in the real world can be treated with this strategy, moving us 1 step closer to leaving nothing behind.

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REFERENCES


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