

Drug-coated balloons for complex femoropopliteal lesions: two-year results of a real-world registry

DCB Schmidt complex fempop two-year results of a real-world registry study

Overview

Superiority of drug-coated balloon (DCB) compared with standard PTA for femoropopliteal interventions has been demonstrated for short lesions after one-year follow up. Long-term data for complex lesions in “real world” settings are scarce.

Objective

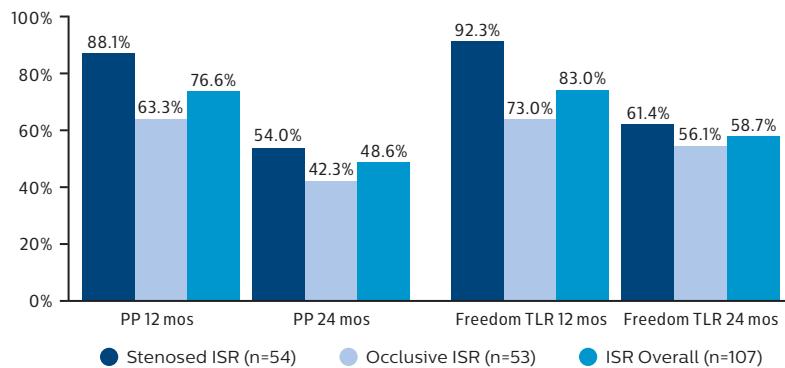
Purpose of study was to investigate whether DCB would improve patency for more complex femoropopliteal lesions, including ISR, and to assess the durability of results over an extended time, beyond one year.

Methods and results

Single center, retrospective study to analyze patency, target lesion revascularization (TLR) rate, clinical improvement, and safety endpoints of femoropopliteal lesions in 288 limbs (n=260 patients) treated with the In.Pact Pacific or Admiral DCB for up to two years of follow-up. Lesions were denovo (51.7%), restenosis (11.1%) and ISR (37.2%).

Key study results	DCB (N=260)
Mean lesion length (cm)	24.0
Occlusions	65.3%
ISR	37.2%
Overall primary patency at 12 months	79.2%
Overall primary patency at 24 months	53.7%
Overall freedom from TLR at 12 months	85.4%
Overall freedom from TLR at 24 months	68.6%
Amputation rate at 24 months	2.1%

Complex ISR results



Conclusions

Results suggest that DCBs are safe and effective in treating in long, complex lesions including ISR; however, patency rates dropped off after the first year, and may represent a late catch-up phenomenon.

Study summary

Key points

- The treatment of long and complex femoropopliteal lesions with DCB is associated with impressive patency results comparing favorably to historical, uncoated balloon angioplasty at one-year. However, patency rates drop off significantly after the first year, which may represent a late catch-up phenomenon.
- This finding also holds for complex ISR including diffuse and occlusive disease. The outcomes with DCB reported in this study are higher than other published datasets at 12 months within this population. A late catch-up effect, however, was observed by 24 months.
- In-stent occlusions were particularly challenging with 63.3% PP at 12 months falling to 42.3% by 24 months. Similarly, freedom from TLR in these lesions fell from 73% at 12 months to 56.1% by 24 months.
- This ISR late catch-up effect presented in this publication is consistent with other published data including the three-year outcomes published on DEBATE ISR.

Reference

Drug-coated balloons for complex femoropopliteal lesions: two-year results of a real-world registry
Schmidt A. et al.

Results from this case study are not predictive of future results.