

Infrapopliteal treatment with drug coated balloon versus plain old balloon in patients presenting chronic limb-threatening ischemia

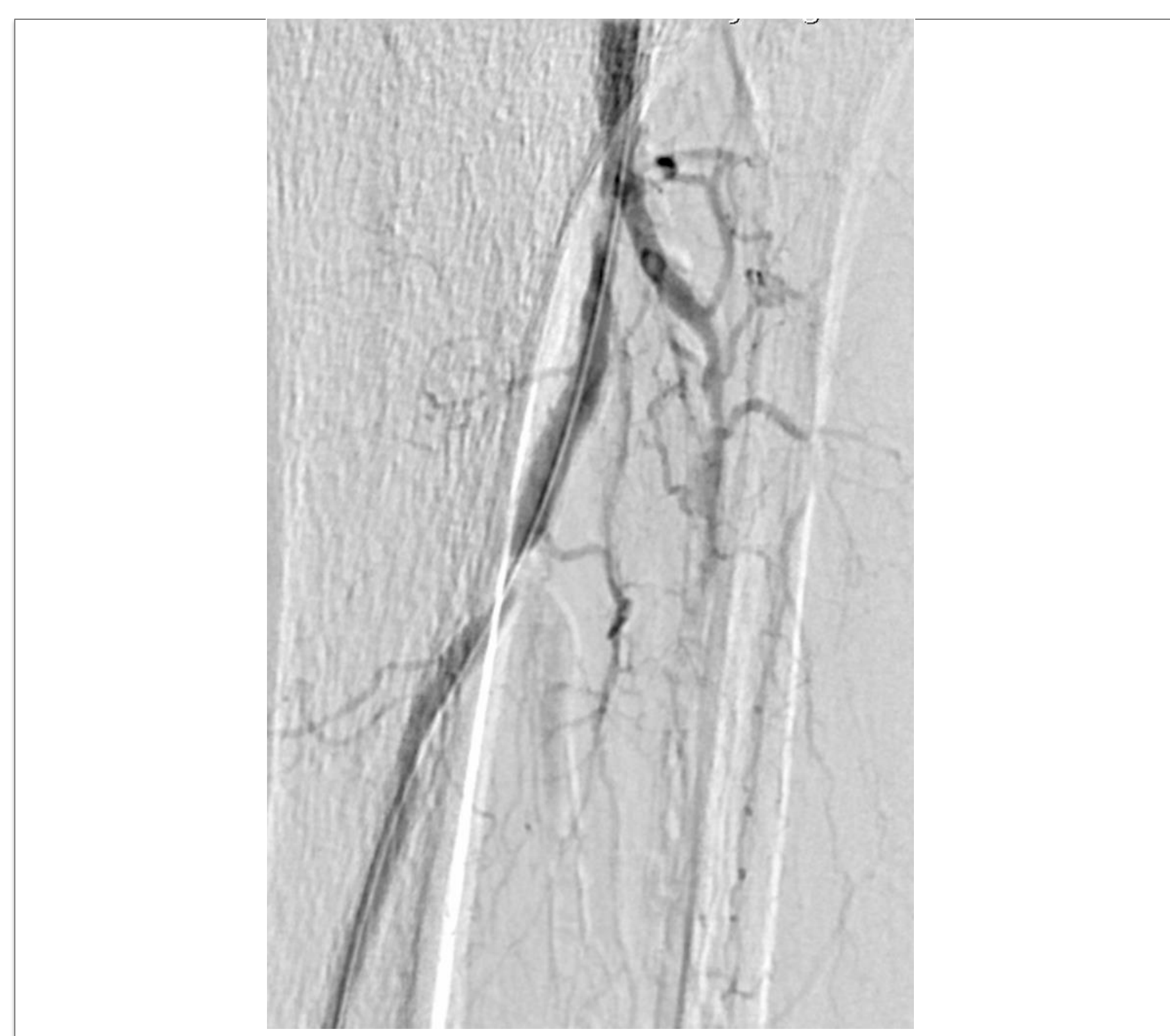
Felice Pecoraro,¹ Salvatore Buno,² Domenico Mirabella,² Martina Giambra,³ Ettore Dinoto,² Pierfrancesco Veroux.³

¹ University of Palermo, Italy; Vascular Surgery Unit, AOU Policlinico 'P. Giaccone' Palermo, Italy; ² Vascular Surgery Unit, AOU Policlinico 'P. Giaccone' Palermo, Italy; ³ University of Catania, Italy; Vascular Surgery and Organ Transplant Unit, AOU Policlinico 'G. Rodolico - San Marco' Catania, Italy

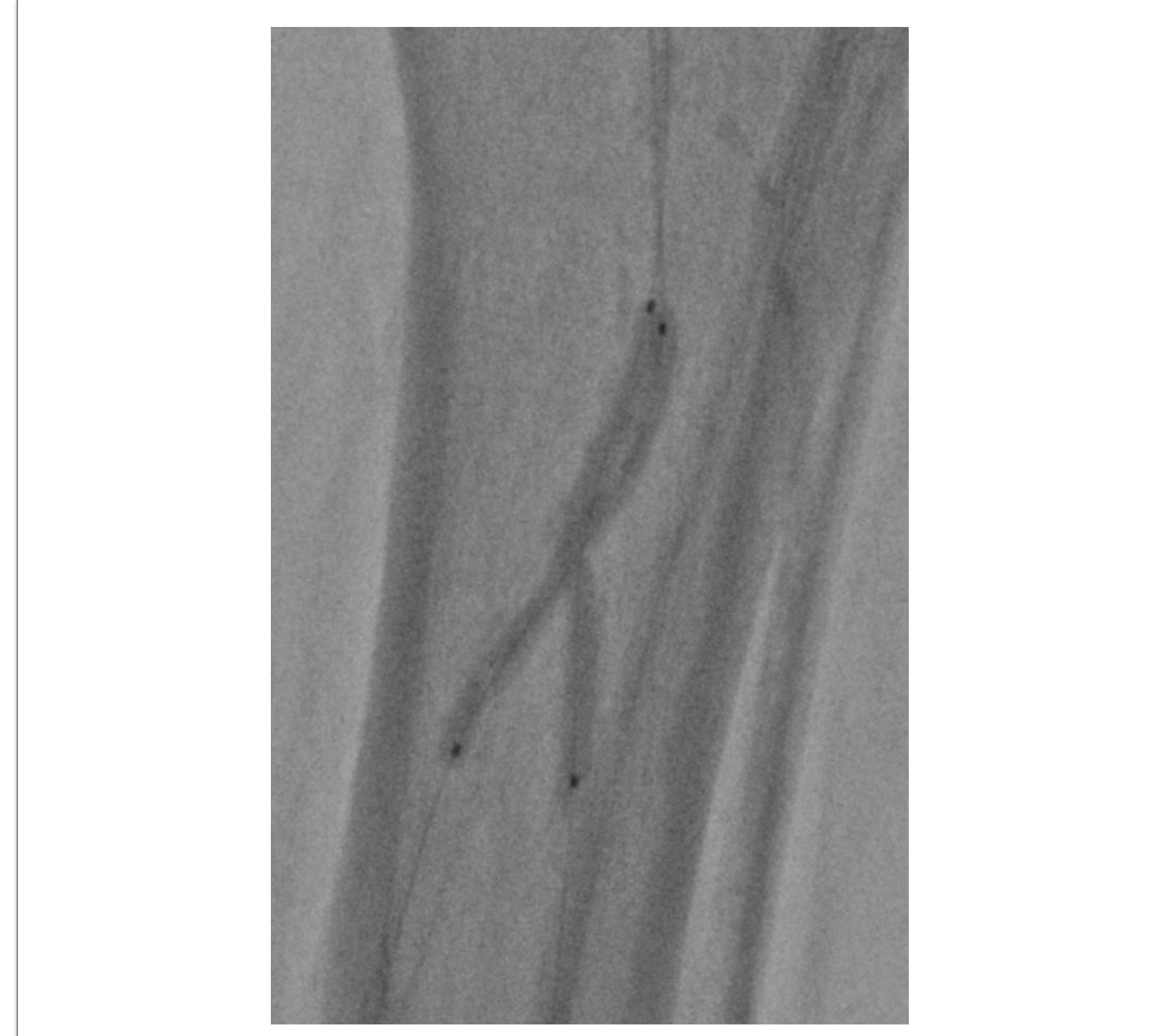
AIM

This study aims to compare safety and efficacy of drug coated balloon (DCB) vs plain old balloon angioplasty (POBA) in the treatment of infrapopliteal lesions in patients with chronic limb-threatening ischemia (CLTI).

Complex below the knee lemultilevel lesion



Treatment with kissing balloon treatment BTK



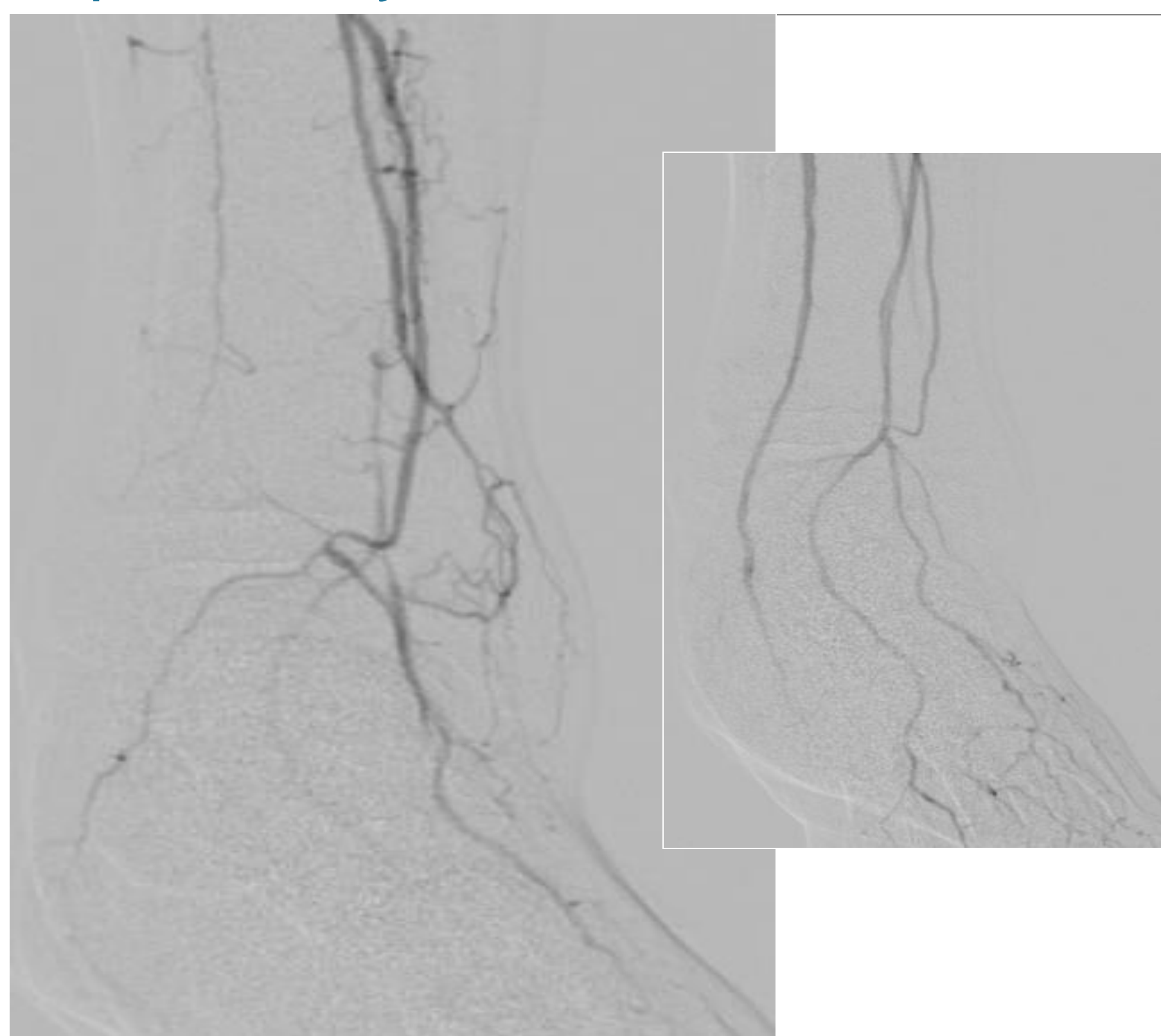
Final outcome



METHODS

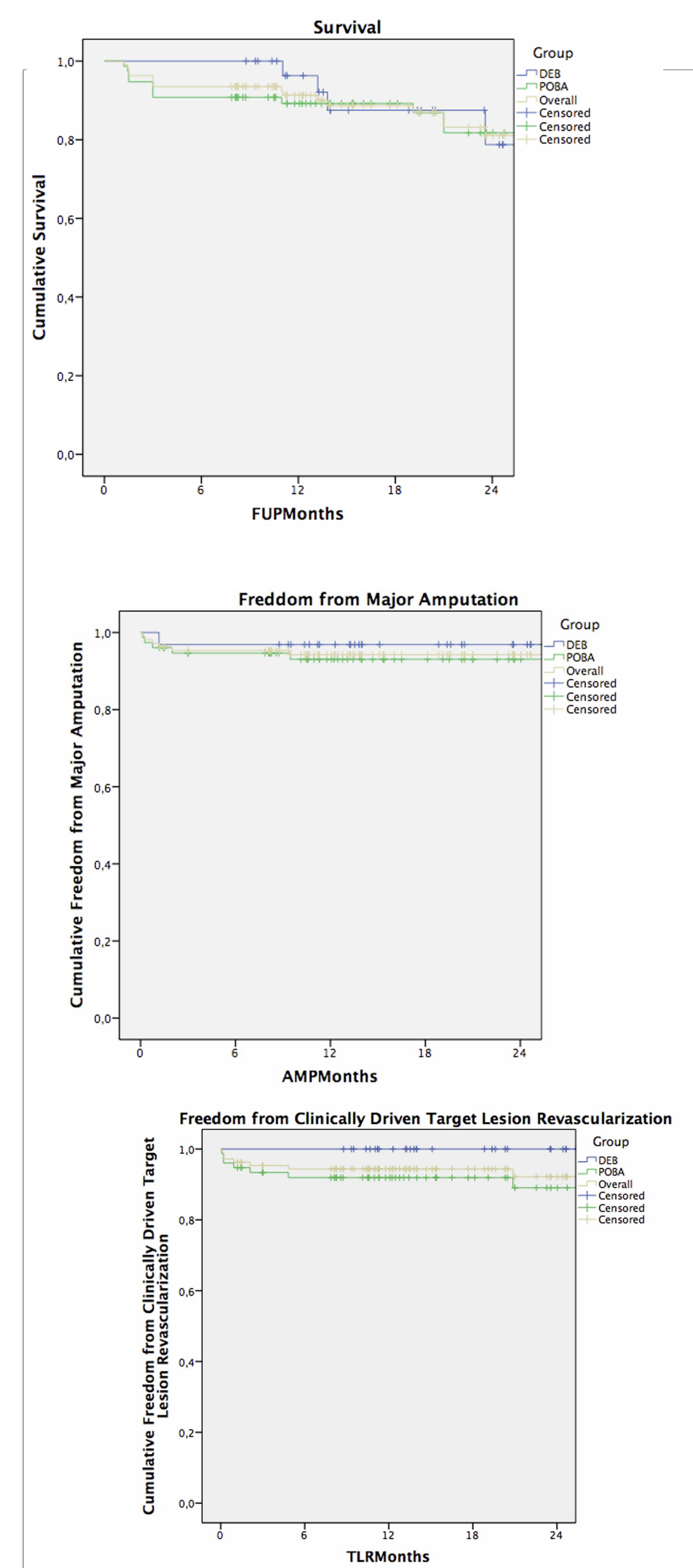
The single-center, retrospective, non-randomized study included 108 patients from January 2019 to December 2023 who underwent endovascular treatment using DCB (n=32, 29.6%) or POBA (n=76, 70.4%). Patients who were candidated to primary amputation were excluded from the cohort. Significant difference was observed in baseline for age (DCB 73.5 ± 13 yrs; POBA 70.7 ± 10 yrs; p=0.004) and chronic kidney disease (CKD) (DCB n= 7, 21.9%; POBA n=25, 32.9%; p=0.013). No differences were found in target lesion characteristics between the groups. Mean lesion length was 123.4 ± 75.6 mm in DCB group and 114.9 ± 72.1 mm in POBA group with lesions almost equally distributed in stenoses and occlusions. A total of 238 vessels (DCB n=67, 28.1%; POBA n=171, 71.9%) were treated during the study period with a mean device per lesion of 1.9 (DCB 2.13; POBA 1.8). Primary endpoints were technical success, primary patency and freedom from amputation. Mortality, clinically-driven target lesion revascularization (CD-TLR) and major adverse events were also considered as secondary endpoints.

Complex foot artery disease



RESULTS

Technical success was 100% and 97.4% for DCB and POBA groups respectively, while primary patency at 12 months was 100% for DCBs and 94.7% for POBAs (p<0.001). No major amputations occurred in DCB group during follow-up, conversely, freedom from amputation in POBA group was 94.7% at 24 months (p<0.001). Freedom from CD-TLR at 24 months was 100% for DCB and 93.4% for POBA (p<0.001).



CONCLUSIONS

DCBs use for treatment of infrapopliteal CLTI seems safe and effective with better outcomes than POBAs regarding primary patency, freedom from amputation and CD-TLR.

BIBLIOGRAPHY

- Gouëffic Y, Brodmann M, Deloose K, Dubosq-Lebaz M, Nordanstig J. Drug-eluting devices for lower limb peripheral arterial disease. *EuroIntervention*. 2024 Sep 16;20(18):e1136-e1153. doi: 10.4244/EIJ-D-23-01080.
- Cawich I, Armstrong EJ, George JC, Golzar J, Shishebor MH, Razavi M, Lee V, Ouriel K. Temozolimus Adjuvant Delivery to Improve ANGIOGRAPHIC Outcomes Below the Knee. *J Endovasc Ther*. 2024 Aug;31(4):562-575. doi: 10.1177/15266028221131459.
- Wittig T, Schmidt A, Kabelitz M, Hukauf M, Pflug T, Scheinert D, Steiner S. Safety and Efficacy of All Comers Treated with a Paclitaxel Coated Balloon for Below Knee Intervention. *Eur J Vasc Endovasc Surg*. 2022 Nov;64(5):516-525. doi: 10.1016/j.ejvs.2022.08.004.
- Cai H, Dong J, Ye Y, Song Q, Lu S. Safety and Efficacy of Drug-Coated Balloon in the Treatment of Below-the-Knee Artery: A Meta-analysis. *J Surg Res*. 2022 Oct;278:303-316. doi: 10.1016/j.jss.2022.04.055.