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Revascularization and Patency in Lower Limb Peripheral Arterial Disease: A Systematic Review and Meta-analysis Comparing Paclitaxel-eluting with Bare Metal Stents

A. Bosworth Smith,[1] F. Distler,[1] S. Steiner,[2] Y. Goueffic,[3] J. Hafermann,[1] R. Saunders[1]
(1) Coreva Scientific GmbH & Co. KG, Königswinter, Germany; (2) Department of Internal Medicine II, Division of Angiology, Medical University Vienna, Vienna, Austria; (3) Hôpital Paris St Joseph, Vascular and Endovascular Surgical Center, Paris, France

Background

- Stent implantation is one of the treatment options for revascularization of symptomatic patients with lower limb peripheral arterial disease.[1]
- Common stent options used for management of femoropopliteal lesions include self-expanding bare metal stents (BMS) or paclitaxel-eluting or –coated stents.
- Given limited direct comparative data from randomized controlled trials, this analysis uses a meta-analysis of proportions to examine primary patency (PP) and target-lesion revascularization (TLR) across single arm and comparative studies.

Methods

- The systematic review (PROSPERO CRD42024528559) identified studies reporting on BMS or paclitaxel stents, as either polymer-based paclitaxel-eluting stents (PB-PES) or polymer-free paclitaxel-coated stents(PF-PCS).
- Analyzed studies were published between January 1st, 2009 and July 1st, 2024 and included ≥50 patients with femoropopliteal lesions.
- Data extracted included stent used, lesion length, PP, and TLR at 12 and 24 months.
- Study quality was assessed using the Downs and Black Quality Appraisal Tool.[2]
- As considerable between-study heterogeneity was expected, a random intercept logistic regression (generalized linear mixed model) in R was used to pool the data.[3,4]

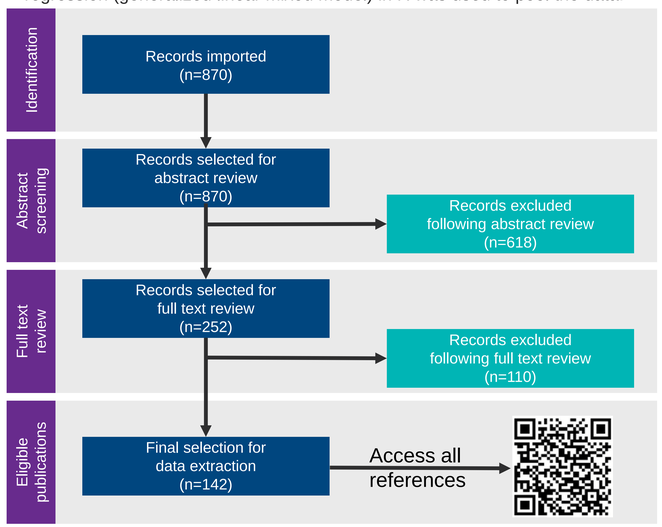

Figure 1 PRISMA diagram

References

1. Gerhard-Herman M.D., et al. (2017): 2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. In Circulation 135 (12), e726-e779. DOI: 10.1161/CIR.0000000000000471.
2. Downs, S. H.; Black, N. (1998): The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. In Journal of epidemiology and community health 52 (6), pp. 377–384. DOI: 10.1136/jech.52.6.377.
3. Viechtbauer, W. (2010): Conducting Meta-Analyses in R with the metafor Package. In J. Stat. Soft. 36 (3). DOI: 10.18637/jss.v036.i03.
4. Balduzzi, S. et al. (2019): How to perform a meta-analysis with R: a practical tutorial. In Evidence-based mental health 22 (4), pp. 153–160. DOI: 10.1136/ebmental-2019-300117.

Results

- Of 870 studies screened, 142 were included for data extraction (**Figure 1**).
- The pooled estimates of **TLR** and **primary patency** for each stent are reported in **Table 1**.
- For **primary patency** at 12 months, 51 paclitaxel stents studies (17 PB-PES and 34 PF-PCS) and 93 BMS studies were included. Fewer studies (86) report 24-month data (26 paclitaxel-eluting or -coated stents versus 60 BMS).
- For **TLR** at 12 months, 38 paclitaxel stent studies (14 PB-PES and 24 PF-PCS) and 59 BMS studies were included. This was reduced to 20 paclitaxel-eluting or -coated stent studies and 38 BMS at 24 months.
- The overall mean lesion length was 152.8 (range: 37-330) mm.
- When considering lesion length <150mm versus ≥150mm, PB-PES performed consistently in long and short lesions in regard to PP and TLR (**Figure 2 & 3**).

Table 1 Results of primary patency and target lesion revascularization

Stent type	12-month PP % (95% CI)	24-month PP % (95% CI)	12-month TLR % (95% CI)	24-month TLR % (95% CI)
PB-PES	86.99 (85.26 – 88.53)	77.92 (75.74 – 79.95)	7.30 (5.89 – 9.02)	14.16 (12.36 – 16.18)
PF-PCS	76.89 (73.40 – 80.05)	65.19 (60.40 – 69.69)	12.99 (9.98 – 16.74)	22.69 (17.43 – 28.97)
BMS	75.30 (72.90 – 77.55)	67.01 (62.91 – 70.87)	14.31 (12.50 – 16.34)	20.83 (17.61 –24.47)

PP: Primary patency; TLR: target-lesion revascularization; CI: confidence interval; PB-PES: polymer-based paclitaxel-eluting stents; PF-PCS: polymer-free paclitaxel-coated stents; BMS: bare metal stents

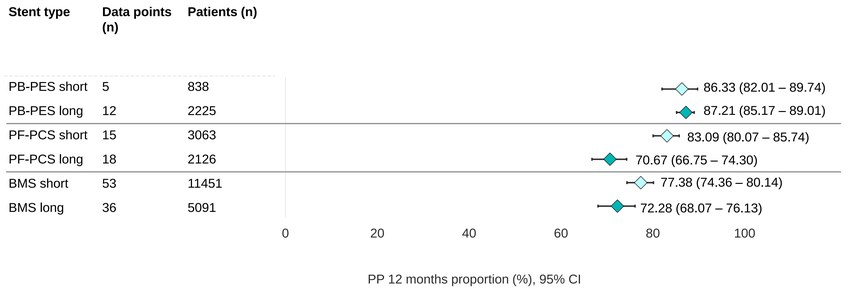

Figure 2 Lesion length: Primary patency
PB-PES: Polymer-based paclitaxel-eluting stents; PF-PCS: Polymer-free paclitaxel-coated stents; BMS: Bare metal stents; PP: Primary patency.

Conclusion

PB-PES showed higher primary patency and lower TLR rates than PF-PCS and BMS, both at 12 and 24 months of follow-up. This was true in both short and long lesions. This study provides an important overview and synthesis of data and insights into stent performance.

Discussion

- Stents tended to perform well in either short or long lesions, PB-PES performed consistently in both short and long lesions.
- As expected, performance tended to be worse at 24 months versus 12 months, and in more complex long lesions.
- This analysis used aggregated, cohort data from published studies.
- There were some inconsistencies in the definitions of primary patency and TLR.

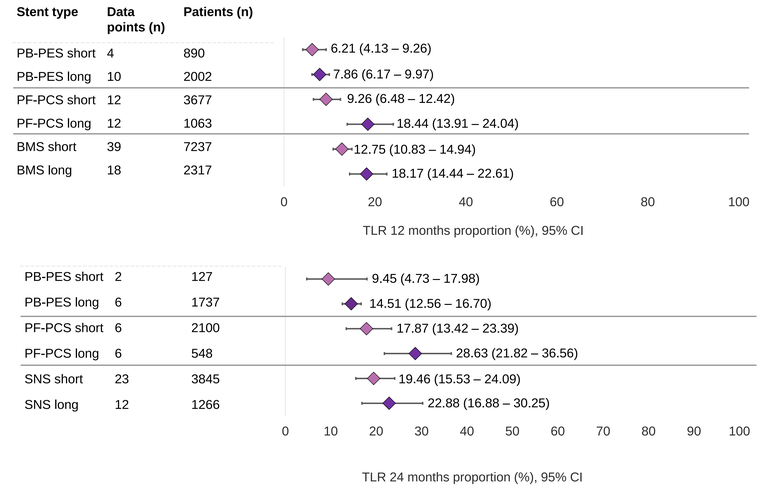

Figure 3 Lesion length: Target lesion revascularization
PB-PES: Polymer-based paclitaxel-eluting stents; PF-PCS: Polymer-free paclitaxel-coated stents; BMS: Bare metal stents; TLR: Target-lesion revascularization.

Disclaimer

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