

Editorial



Should We Leave Something There?

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OPEN ACCESS

Received: Jun 24, 2024

Accepted: Jul 1, 2024

Published online: Jul 4, 2024

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Funding

The authors received no financial support for the research, authorship, and/or publication of this article.

Conflict of Interest

The authors have no financial conflicts of interest.

► See the article "Clinical Outcomes After Drug-Coated Balloon Treatment in Popliteal Artery Disease: K-POP Registry 12-Month Results" in volume 54 on page 454.

Although there have been recent advances in endovascular treatment modalities to treat peripheral artery disease, especially in the popliteal region, these treatment strategies have not yet shown satisfactory results and research is lacking.^{1,3)} The study titled "Clinical Outcomes after Drug-Coated Balloon Treatment in Popliteal Artery Disease: K-POP Registry 12-Month Results"⁴⁾ presents a detailed analysis of the 12-month clinical outcomes of IN.PACT drug-coated balloon (DCB) treatment in patients with symptomatic atherosclerotic popliteal artery disease (PoAD). The study reports a technical success rate of 100%, with a 12-month clinical primary patency rate of 76.0% and a target lesion revascularization (TLR)-free survival rate of 87.2%. Similar to these findings, a subgroup analysis of the IN.PACT Global Study reported a 3-year TLR-free survival rate of 76.5% for isolated PoAD.⁵⁾ This suggests that DCB treatment is highly effective for PoAD, offering an improvement over traditional treatment modalities.

However, to determine the clinical utility of these results, we should look at this current study from two different perspectives. Firstly, do the enrolled patients in this study represent a real-world spectrum of complex PoAD? Secondly, is effective comprehensive treatment possible with DCB treatment alone?

In this study, the mean lesion length was 93.7±53.7 mm, and chronic total occlusion and severe calcification were in 45% and 23% of patients, respectively. TASC II Type D lesions were identified in 21% of patients.⁴⁾ These lesion characteristics show that this study reflects actual real-world practice compared to a previous retrospective other study that shown a mean lesion length of 60±30 mm, long-segment occlusions of 18.5%, and severe calcification of 40.7%.⁶⁾ Additionally, the inclusion of combined atherectomy in 17% of cases and provisional stenting in 11% reflects a real-world scenario of clinical practice, can be considered a realistic parameter for the effectiveness of DCB.

Theoretically, combining DCB treatment with atherectomy for lesion modification could improve drug penetration and efficacy of DCB at the lesion site. Another study comparing DCB versus atherectomy and DCB angioplasty for PoAD showed favorable primary patency rate at 12 months (65% vs. 82%; hazard ratio, 2.64; 95% confidence interval, 1.09–6.37; p=0.021), while freedom from TLR did not differ between the 2 treatment strategies (82%

Data Sharing Statement

The data required to reproduce these findings cannot be shared as this is an editorial.

Author Contributions

Conceptualization: Lee CH, Kim W; Writing - original draft: Lee CH, Kim W; Writing - review & editing: Kim W.

The contents of the report are the author's own views and do not necessarily reflect the views of the *Korean Circulation Journal*.

vs. 94%, $p=0.072$).⁷⁾ Despite a thorough analysis of different subgroups who underwent atherectomy and provisional stenting, the single-arm design without a control group makes it difficult to clearly attribute the observed benefits to the DCB treatment alone in this study.

Interestingly, through multivariate Cox regression analysis, this study identifies female gender and long lesion length as independent predictors of loss of patency. In actual practice, these findings are important for selecting treatment modalities and determining which patients might consider DCB as first-line treatment for PoAD.

This multicenter study in real-world setting aims to fill the data gap regarding the efficacy of DCB in treatment of PoAD, which has traditionally been considered a "no-stent zone" due to biomechanical challenges resulting from knee joint movement. Despite the lack of a control group and the short-term follow-up period, this study highlights the potential of DCB to achieve high patency rates and reduce the need for revascularization, presenting a promising alternative to stenting. Randomized controlled trials with long-term follow-up are needed to verify these findings for PoAD.

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