Background
Limited data is available regarding the safety and effectiveness of drug-coated balloon (DCB) vs uncoated balloon in the treatment of critical limb ischemia due to infrapopliteal peripheral arterial disease. We conducted an updated meta-analysis to assess the safety and efficacy of DCB in the treatment of infrapopliteal disease.

Methods
Database search of Pubmed/MEDLINE, EMBASE, and the Cochrane Library was performed by two reviewers from inception through November 15, 2021. Randomized trials that compared DCB with conventional PTA in treating infrapopliteal arterial disease were included. The risk ratios (RRs) and 95% confidence intervals (CIs) were reported.

Results
Nine trials were included (1,501 participants) in the study. The mean age was 71.1±10.2 years. Regarding the primary endpoints; treating infrapopliteal arterial disease with DCB had a lower incidence of re-stenosis (RR 0.48 [95% CI, 0.33-0.70]; P = 0.0001) with no significant difference regarding all-cause mortality (RR 1.11 [95% CI, 0.73-1.69]; P = 0.61), compared with uncoated balloon. With regards to the secondary endpoints, DCB usage was associated with a significant reduction in clinically driven target lesion revascularization (CDTLR) (RR 0.54 [95% CI, 0.35-0.84]; P = 0.006) with no significant difference with regards to major target limb amputation (MTLA) and major adverse cardiovascular events (P=0.05).

Conclusion
Among patients with critical limb ischemia secondary to infrapopliteal artery disease, using DCB was associated with a significantly lower number of restenosis and CDTLR compared with an uncoated balloon. There was no increase in all-cause mortality or MTLA with the use of DCB.

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References