Abstract:

In disease of the femoropopliteal artery, paclitaxel-coated balloon (PCB) therapy improved angiographic outcomes as compared with uncoated balloon (UCB) angioplasty. Nevertheless, it remains uncertain whether PCB may reduce the need for reintervention. We searched Medline, EMBASE, the Cochrane Central Register of Controlled Trials (CENTRAL), scientific session abstracts, and relevant web sites for trials of PCB versus UCB angioplasty. Key words were: "superficial femoral artery," "popliteal artery," "angioplasty," "drug-eluting balloon," "paclitaxel-eluting balloon," and "randomized trial." Inclusion criteria were: (1) randomized design; (2) intention-to-treat analysis; and (3) ≥6-month follow-up. Exclusion criteria were: (1) vessel treated other than femoropopliteal artery; (2) device used other than PCB/UCB; and (3) irretrievable or duplicated data. No restrictions (language, publication date, or status) were applied. The primary end point was target lesion revascularization. Secondary end points were: angiographic binary restenosis and late lumen loss and all-cause mortality. A total of 381 patients enrolled in 4 randomized trials were included (PCB, n=186 versus UCB, n=195). Median follow-up was 10.3 months. Angioplasty with PCB versus UCB reduces target lesion revascularization (12.2% versus
27.7%; OR, 0.22; 95% CI, 0.13-0.38; P<0.0001), angiographic restenosis (18.7% versus 45.5%; OR, 0.26; 95% CI, 0.14-0.48; P<0.0001), and late lumen loss (range, -0.05 to 0.50 mm versus 0.61-1.7 mm; weighted mean difference, -0.75 mm; 95% CI, -1.06 to -0.45; P<0.00001). No mortality difference was observed for PCB versus UCB (2.1% versus 3.2%; OR, 0.99; 95% CI, 0.39-2.49; P=0.98). In femoropopliteal arterial disease, PCB therapy is associated with superior antirestenotic efficacy as compared with UCB angioplasty with no evidence of a differential safety profile.