Pacitaxel-coated balloon or primary bare nitinol stent for revascularization of femoropopliteal artery: a meta-analysis of randomized trials versus uncoated balloon and an adjusted indirect comparison.

The performance of paclitaxel-coated balloon (PCB) or primary bare nitinol stent (BNS) versus uncoated balloon angioplasty (UCB) for femoropopliteal artery disease and the relative efficacy and safety of PCB versus BNS are still debated. A meta-analysis of trials in which patients were randomly assigned to PCB versus UCB or BNS versus UCB was performed, as well as an indirect comparison of PCB versus BNS, with UCB common comparator. The primary endpoint was target lesion revascularization (TLR); secondary endpoints were restenosis, death and amputation. In total, 1464 patients were assigned to revascularization with PCB versus UCB (n = 441) or BNS versus UCB (n = 1023). Treatment with PCB versus UCB reduced the risk of TLR (odds ratio [95% confidence interval] = 0.29 [0.15-0.56], p < 0.001) and restenosis (0.31 [0.19-0.51], p < 0.001) without affecting mortality (1.05 [0.41-2.71], p = 0.92) or amputation (0.68 [0.04-10.31], p = 0.78). BNS versus UCB therapy reduced the risk of TLR (0.46 [0.27-0.80], p = 0.006) and restenosis (0.51 [0.34-0.77], p = 0.02) without affecting mortality (2.08 [0.93-4.66], p = 0.07) or amputation (0.84 [0.30-2.35], p = 0.74). The indirect comparison found no difference with PCB versus BNS in the risk of TLR (0.63 [0.26-1.48] p = 0.29),
restenosis (0.60 [0.32-1.15], p = 0.13) death (0.50 [0.05-4.82], p = 0.55) or amputation (0.80 [0.04-15.63], p = 0.66). In atherosclerotic disease of femoropopliteal artery, both PCB and BNS therapy have superior antirestenotic efficacy to UCB, without safety issues. At indirect comparison, PCB and BNS may have comparable antirestenotic efficacy and safety.