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Abstract:
Current recommendations on the use of bivalirudin in patients treated with percutaneous coronary intervention (PCI) are mostly based on trials comparing bivalirudin versus heparin plus planned glycoprotein IIb/IIIa inhibitor (GPI). Whether bivalirudin is also superior to heparin alone is still not well established. This meta-analysis investigates the efficacy and safety of bivalirudin versus heparin in patients treated with PCI without planned use of GPI. Scientific databases and websites were searched for randomised controlled trials. The primary efficacy and safety outcomes were the 30-day incidence of death and major bleeding, respectively. The secondary outcomes were the 30-day incidence of myocardial infarction (MI), definite stent thrombosis (ST), urgent target vessel revascularisation (TVR), and overall death at the longest available follow-up. Odds ratio (OR) and 95% confidence interval (95% CI) served as summary statistics. Ten trials were identified including a total of 18,065 PCI patients randomised to bivalirudin (n=9,033) versus heparin (n=9,032). At 30 days, bivalirudin versus heparin showed a comparable risk of death (1.09 [0.83-1.41], p=0.54), and MI (1.10 [0.83-1.46], p=0.50) with a trend towards a higher risk of urgent TVR (1.37 [0.96-1.96], p=0.08). The risk of major bleeding was lower with bivalirudin (0.57 [0.40-0.80], p=0.001)
and the bleeding reduction was more evident when high doses of heparin were used as comparator (p for interaction<0.001). The risk of definite ST (2.09 [1.26-3.47], p=0.005) and, in particular, the risk of acute ST (3.48 [1.66-7.28], p<0.001) was increased by bivalirudin. Patients undergoing PCI randomised to therapy with either bivalirudin or heparin display a similar mortality. Bivalirudin as compared to heparin appears to reduce the risk of major bleeding at the expense of a higher risk of acute ST.