Bivalirudin vs. Unfractionated Heparin during PCI in High Risk Patients for Bleeding. ACRIPAB Trial

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In low to medium risk population undergoing PCI Bivalirudin (BIV) exhibited significantly lower rate of bleeding compared to unfractionated heparin (UFH). However, clinical outcome and bleeding complications in high risk population was not established yet.
We performed randomized double blinded prospective trial comparing efficacy and safety of BIV vs. UFH on top of dual antiplatelet therapy during PCI among patients with NSTEMI or angina pectoris and with high risk for bleeding. There were 100 consecutive patients (66.6±12.3 years old, 69% males) enrolled in our study with 1:1 distribution between BIV and UFH groups. The study end points were: major, minor bleeding, port of entry complications, MACE in-hospital and after 30 days follow up. There were 87% patients with diabetes mellitus, 98% with hypertension, 22% with chronic renal failure, 30% older than 75 years, 21% with haemoglobin plasma level < 11 mg% and 58% with systolic blood pressure > 180 mm Hg. 24% of participants were catheterized due to NSTEMI. Femoral approach was used in 16% of patients. There were significantly more PCIs accomplished via radial approach in BIV group (90% vs. 78%, p=0.05). BIV group was represented with higher male's rate (78% vs. 60%, p=0.05).
Results: There was 1 case of major GI bleeding in BIV group and 7% rate of minor bleeding complications in both categories. There was twice higher rate of periprocedural AMI in BIV group compared to UFH group (20% vs.10%, p<0.16). In hospital MACE rate was higher in BIV patients too (12% vs. 2%, p=0.1). In UFH group, there was 1 case of urgent CABG and another 1 case of death 2 days after PCI. In univariate analysis, no one factor was found to be predictor of worse outcome. After follow up, there were no differences in end points between the groups.
Conclusions: In patients with high risk for bleeding undergoing PCI, BIV was found non-superior to UFH in categories of all bleeding complications, early and late clinical outcome.