AntiCoagulant Regimen during PCI In high risk PAtients for Bleeding - ACRIPAB Trial

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The overall bleeding complications rate during percutaneous coronary intervention (PCI) is up to 9%. By literature, bivalirudin (BIV) treated patients exhibited significantly lower rates of bleeding than patients treated with unfractionated heparin (UFH) during PCI. However, clinical outcome and bleeding complications in high risk population was not established yet. We performed randomized double blinded prospective trial to compare efficacy and safety of BIV treatment to UFH regimen on top of dual antiplatelet therapy during PCI among patients with NSTEMI or AP and with high risk for bleeding. There were 76 consecutive patients (66.7±11.6 years old, 72% males) enrolled in our study with 1:1 distribution between BIV and UFH groups. The study end points were: bleeding complications, MACE in-hospital and after 30 days follow up.

There were 88% patients with diabetes mellitus, 97% with hypertension, 22.5% with chronic renal failure, 29% older than 75 years, 18.5% with Hb plasma level < 11 mg% and 57% with systolic BP > 180 mm Hg. Radial approach was used in 80% of patients. There were more males in BIV group (84% vs. 61%, p=0.01). NSTEMI pre PCI was recognized with higher rate in UHF group (37% vs. 18%, p=0.037) without other differences between the groups.

Post PCI, there were no cases of major bleeding and 7.9% rate of minor bleeding complications similar in both categories. There was 21% rate of periprocedural MI in BIV group compared to 2.6% in UFH group (p<0.006). In hospital MACE rate was higher in BIV patients (13.2% vs. 2.6%, p=0.046). In UFH group, there was 1 case of urgent CABG and 1 case of death 2 days after PCI. After follow up there were no differences in end points.

Conclusions: In our series, among patients with high risk for bleeding underwent PCI on top of dual antiplatelet therapy, treatment with BIV was inferior to UFR in categories of immediate clinical endpoints and non-superior in prevention of bleeding complication.