Table. Rates of Stent Thrombosis

	Any post-PCI AC for routine prophylaxis (N=436)	No post-PCI AC for routine prophylaxis (N=1,009)	Adjusted HR [95% CI]	Adjusted p-Value
Acute (≤24 hour) stent thrombosis	3 (0.7)	10 (1.0)	0.65 [0.13, 3.18]	0.59
Thirty-day stent thrombosis	7 (1.7)	20 (2.1)	0.97 [0.37, 2.53]	0.95
	Post-PCI AC for routine prophylaxis with pre-PCI UFH (N=325)	Pre-PCI UFH with no post-PCI AC for routine prophylaxis (N=623)	Unadjusted HR [95% CI]	Unadjusted p-Value
Acute (≤24 hour) stent thrombosis	2 (0.6)	3 (0.5)	1.28 [0.21, 7.68]	0.78
Thirty-day stent thrombosis	5 (1.6)	8 (1.3)	1.20 [0.39, 3.65]	0.75
	Only post-PCI AC for routine prophylaxis with no pre-PCI UFH (N=111)	No pre-PCI UFH or post-PCI AC for routine prophylaxis (N=386)	Unadjusted HR [95% CI]	Unadjusted p-Value
Acute (≤24 hour) stent thrombosis	1 (0.9)	7 (1.9)	0.50 [0.06, 4.02]	0.50
Thirty-day stent thrombosis	2 (1.9)	12 (3.3)	0.57 [0.13, 2.55]	0.46

Values presented as n (%). Stent thrombosis was classified according to the Academic Research Consortium definition of definite or probable. AC = anticoagulation; PCI = percutaneous coronary intervention; UFH = unfractionated heparin.

TCT-464

Intracoronary Bivalirudin Bolus During Primary Angioplasty Improves Postprocedural Angiographic Flow and Myocardial Reperfusion Indexes

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Background: Bivalirudin efficacy in the very first hours after primary PCI has been questioned, due to increased acute stent thrombosis rates. Intracoronary administration of the bivalirudin bolus might furnish an extremely high local drug concentration without changing the global dose administered to the patient, with a potential favorable effect over the pro-thrombotic milieu of the infarct related artery. Thus we prospectively investigated the feasibility and safety of intracoronary bivalirudin bolus administration during primary percutaneous coronary interventions (PCI), comparing it with the standard intravenous route.
Methods: In 245 consecutive patients treated with primary PCI we administered intracoronary bivalirudin bolus followed by standard intravenous infusion. Postprocedural coronary blood flow indexes and clinical reperfusion markers of these patients were compared with a propensity score-matched cohort of primary PCI patients treated with standard intravenous bivalirudin bolus plus infusion.
Results: Our study suggests safety similar bleeding episodes were observed in the two groups. However we observed better TIMI frame count values (14.7 vs 17.9, P=0.001), higher rates of ≥ 70% ST resolution (72.7 vs 60.0%, p=0.004) and lower postprocedural peak CK-MB levels (188.3 ± 148.7 vs 242.1 ± 208.1 Ui/dL, P=0.025) in the intracoronary bolus group. Acute stent thrombosis was observed only in 3 cases, all in the intravenous bolus group (P=NS). These results were substantially confirmed when the analysis was restricted to patients with evidence of an occluded infarct related artery before PCI.
Conclusions: In the population studied intracoronary bivalirudin bolus during primary PCI is safe and might improve results obtained through the standard intravenous route over postprocedural coronary flow and clinical myocardial reperfusion.

TCT-465

Safety and efficacy of intracoronary bivalirudin administration during primary angioplasty in comparison with a standard treatment with heparin and provisional GP2b3a inhibitors

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Background: Bivalirudin efficacy in the very first hours after primary PCI has been questioned, due to increased acute stent thrombosis rates. Intracoronary administration of the bivalirudin bolus might furnish an extremely high local drug concentration without changing the global dose administered to the patient, with a potential favorable effect over the pro-thrombotic milieu of the infarct related artery. We prospectively investigated the feasibility and safety of intracoronary bivalirudin bolus administration during primary percutaneous coronary interventions (PCI), comparing this strategy with the standard treatment based upon unfractionated heparin (UFH) with provisional GP2B3A inhibitors (GPI) given through the intravenous route.
Methods: In 273 consecutive patients treated with primary PCI we administered intracoronary bivalirudin bolus followed by standard intravenous infusion. Postprocedural coronary blood flow indexes and clinical reperfusion markers of these patients were compared with a propensity score-matched cohort of primary PCI patients treated with standard treatment with intravenous UFH 70Ui/Kg (eventually with supplementary boluses to achieve an ACT>250sec) plus provisional GPI.
Results: In the intracoronary bivalirudin group we observed better TIMI frame count values (14.8±6.5 vs 16.9±9.3, P=0.002), higher rates of ≥ 70% ST resolution (72.1 vs 44.5%, p=0.001), lower incidence of no-reflow (7.0 vs 13.5%, p< 0.011) and a trend for lower postprocedural peak CK-MB levels (140.0 [53.7-235.5] vs 159.2 [64.3-269.9] Ui/dL, p=0.06). Moreover acute stent thrombosis (< 24h after PCI) was observed in 11 cases, all in the UFH/GPI group (p=0.009). Intracoronary bivalirudin administration was safe, with less internal bleedings (3.7 vs 11.2%, p=0.001) and less need for transfusion (4.6 vs 1.1, p=0.012). The results were substantially confirmed when the analysis was restricted to patients with an occluded infarct related artery before PCI.
Conclusions: In the population studied intracoronary bivalirudin during primary PCI was safe and might improve postprocedural coronary flow, clinical myocardial reperfusion and acute stent thrombosis rates, in comparison with the UFH plus provisional GPI treatment.

TCT-466

Bivalirudin Is Associated With Improved In-Hospital Outcomes After Peripheral Arterial Interventions: An Observational Analysis On 23,934 Patients From The PREMIER Hospital Database

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Background: Bivalirudin has been shown to reduce bleeding complications and improve clinical outcomes in percutaneous coronary interventions but has not been well studied in peripheral arterial interventions (PAI). We sought to evaluate the efficacy and safety of bivalirudin as compared with unfractionated heparin (UFH) in patients undergoing PAI by evaluating in-hospital outcomes from a large, real-world, US hospital database of over 600 hospitals.
Methods: We identified all patients (n=23,934) entered from 1/08-12/12 in the PREMIER hospital database following PPI of the extremities and who were treated with bivalirudin or UFH. In-hospital outcomes that were compared according to treatment included death , myocardial infarction (MI), transfusion, stroke, amputation, Major Adverse Cardiac Events (MACE: death, MI, stroke or amputation) and Net Adverse Cardiac Events (NACE: MACE and transfusion). Propensity score matching (PSM) was performed to control for selection bias.
Results: In-hospital outcomes for both the unadjusted population and the 3,649 PSM pairs are shown in the Table. After PSM, bivalirudin was still associated with significantly lower rates of death, transfusion, MACE and NACE compared with UFH. Linear regression modeling confirmed these findings. Subgroup analysis in the PSM population showed consistent treatment effect for all outcomes among subgroups.