Intra-Procedural Stent Thrombosis – A New Risk Factor for Adverse Outcomes in Patients Undergoing Percutaneous Coronary Intervention for Acute Coronary Syndromes

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Abstract

Background: Stent thrombosis (ST) is a rare but serious complication of percutaneous coronary intervention (PCI). The Academic Research Consortium definition of ST excludes events occurring during PCI.

Objective: To examine the incidence, correlates and consequences of intra-procedural ST (IPST) in patients with acute coronary syndromes (ACS).

Methods: Angiograms from ACUITY and HORIZONS-AMI were reviewed frame-by-frame at an independent core laboratory for the occurrence of IPST. Patients with vs. without IPST were compared in order to identify baseline characteristics associated with IPST, and to demonstrate the independent association between IPST and adjudicated events at 30 days and 1 year.

Results: IPST occurred in 47 (0.7%) of 6,591 patients. The incidence of IPST was associated with STEMI presentation, high white blood cell count, treatment of thrombotic and bifurcation lesions, bivalirudin monotherapy, bail-out lib/ilia inhibitor use, and implantation of bare metal (rather than drug-eluting) stents. Major adverse ischemic events were markedly higher in patients with vs. without IPST, including mortality at 30 days (12.9% vs. 1.4%, P<0.0001) and 1 year (12.9% vs. 3.1%, P<0.0001). Out-of-lab ARC definite or probable ST also occurred significantly more often among IPST patients at 30 days (17.4% vs. 1.8%, P<0.0001) and 1 year (19.9% vs. 2.7%, P<0.0001). IPST was a significant independent predictor of 1-year mortality (HR=3.86 [1.66, 9.00], P=0.002).

Conclusions: IPST is a relatively rare complication of PCI in ACS, but is strongly associated with out-of-lab ST and mortality. IPST should be considered as a distinct category of ST and routinely reported, particularly for ACS patients.

Methods

In HORIZONS-AMI 3,602 patients presenting with STEMI within 12 hours of symptom onset were randomized prior to angiography to bivalirudin or heparin plus a glycoprotein IIb/IIa inhibitor (GPI, 1:1 ratio). Subsequently, 3,006 patients suitable for stenting were randomized again to a padiltiapex-eluting stent or to an identical bare metal stent (3:1 ratio). In ACUITY, 13,819 patients with moderate and high-risk unstable angina and non-ST-AMI were randomized to 1 of 3 antithrombotic regimens: heparin plus GPI, bivalirudin plus GPI, or bivalirudin alone. Angiography was performed in all patients within 72 hours, followed by triage to PCI, CABG or medical therapy at the discretion of the treating physician. All patients in both trials received standard pharmacological therapy to support PCI, including routine dual antiplatelet therapy with aspirin and clopidogrel for at least 1 year. Clinical follow-up was performed through PROGRESS-AMI and through 1 year in ACUITY.

Results

PCI was performed in 6,591 patients in the combined cohort, including 3,428 patients with unstable angina or non-STEMI from ACUITY and 3,173 patients with STEMI from HORIZONS-AMI. IPST occurred in 47 patients (0.7%), in 49 lesions. These included 37 patients from HORIZONS-AMI (1.2%) and 10 patients from ACUITY (0.3%), P<0.001. Patients with IPST were more likely to have STEMI presentation, higher white blood count on admission, randomization to bivalirudin alone, subsequent bail-out use of GPI, one-vessel CABG, an occluded artery at baseline with thrombus, bifurcation lesions and bare-metal stents implanted. The peak intra-procedural activated clotting time was not significantly different between patients with vs. without IPST (342 ± 117 vs. 310 ± 114 seconds, respectively, P=0.09).

Results

Conclusion

We conclude that the occurrence of IPST is relatively rare, even in ACS patients, and is related more strongly to clinical presentation and procedural factors (e.g. anticoagulation regimen, lesion type, and presence of thrombus at baseline) than to baseline demographic characteristics. The development of IPST is strongly associated with a substantial excess of ARC defined out-of-lab ST in the first 30 days after PCI, which implies that these patients may especially benefit from more potent anti-platelet agents such as prasugrel or ticagrelor. IPST is also a powerful independent predictor of 1-year mortality. IPST should therefore be added as a separate category to the ARC definition of ST, and be recognized as a high-risk procedural complication portending a poor prognosis.