thrombosis and death or myocardial infarction (MI). Mohamad Ahmad Mosaad, MD, Al-Azhar University, Cairo, Egypt, presented data from a nonrandomized study that compared intermediate- and mid-term clinical outcomes between bare-metal stents (BMS) and DES that were used for either on- or off-label indications. The investigators concluded that DES, whether applied in on- or off-label situations, were safe and effective with a low incidence of stent thrombosis when compared with BMS.

The study comprised 102 patients who were admitted to two hospitals in Egypt between April 2008 and August 2010 with on- and off-label coronary artery lesions but without acute ST elevation myocardial infarction (STEMI). On-label use included treatment of lesions in native coronary arteries that were 30 mm or less in length with a reference vessel diameter of 2.5 to 3.5 mm for the Cypher stent and 28 mm or less in length with a reference vessel diameter of 2.5 to 3.75 mm for the Taxus stent. Patients who were included in the off-label group had restenotic lesions; lesions in a bypass graft; left main coronary artery disease; ostial, bifurcated, or totally occluded lesions; or a reference vessel <2.5 mm or >3.75 mm or a lesion length of >30 mm. Subjects were stratified into four groups (DES on-label, DES off-label, BMS on-label, BMS off-label), each with an approximately equal number of patients. The choice of balloon type and stent was left to the discretion of the operator. Angiograms of the coronary artery were obtained before percutaneous coronary intervention (PCI), after PCI, and at angiographic follow-up 1 year later. Major adverse cardiac events (death, MI, target lesion revascularization, and target vessel revascularization) were assessed at 12 months. Dual antiplatelet therapy with aspirin and an ADP receptor blocker were recommended for 12 months in all patients. Patients were also assessed clinically and for medication compliance at 12 months.

The incidence of in-stent restenosis (ISR) at 12 months with DES was 4% in the on-label group and 8% in the off-label group (p>0.05; compared with 29.2% and 31%, respectively, with BMS (p>0.05). In-stent thrombosis occurred in only 1 patient in each off-label group. Predictors of ISR in the BMS group were more complex lesions (p=0.046), longer mean lesion length (p=0.044), and hypertension (p=0.044). Left ventricular ejection fraction was significantly higher in the DES group (62.4%) versus the BMS group (57.7%; p<0.04). Stent diameter and length, inflation pressure, and lesion characteristics in the off-label and on-label BMS and DES groups were not significantly different.

The authors conclude that although they are not approved by the United States FDA or recommended by current guidelines, DES may be safe for some off-label indications in carefully selected patients. As these preliminary data are nonrandomized and modestly powered, the investigators recommended that this question be studied in a larger, randomized, multicenter trial of longer duration.

IC Eptifibatide Compared with IC Tirofiban In Patients With Acute Anterior STEMI Undergoing Primary PCI

Written by Phil Vinall

In patients with anterior ST segment elevation myocardial infarction (STEMI) who are treated by primary percutaneous coronary intervention (PCI), adjunct treatment with intracoronary (IC) eptifibatide did not improve the primary endpoint of post-PCI epicardial flow compared with IC tirofiban. There was, however, improvement in some secondary endpoints with IC eptifibatide including better myocardial reperfusion, reduction of in-hospital recurrent ischemia, greater ST segment resolution, and more preservation of systolic function with less TIMI minor bleeding compared with IC tirofiban.

When given systemically, platelet glycoprotein IIb/IIIa inhibitors enhance the benefits of primary PCI by improving microcirculation and tissue perfusion and reducing major adverse cardiac events (MACE) [Montalescot G et al. *N Engl J Med* 2001; Zeymer U. *Expert Opin Pharmacother* 2007; van't Hof AW & Valgimigli M. *Drugs* 2009]. Their use in selected patients is supported in the ACC/AHA 2009 STEMI/PCI Guideline Focused Update [*J Am Coll Cardiol* 2009] and the ESC/EACTS Guidelines on Myocardial Revascularization [*Eur Heart J* 2010].

IC GP IIb/IIIa inhibitors result in high local drug concentrations and may be more effective than a standard intravenous (IV) bolus in the dissolution of thrombi and micro emboli and thus may lead to improved myocardial microcirculation and reduced no reflow and infarct size with a possible decrease in adverse systemic effects (bleeding, thrombocytopenia) [Srinivasan M & Prasad A. *J Invasive Cardiol* 2009].

In the study presented by Tamer Abu Arab, MD, Ain Shams University, Cairo, Egypt, 60 patients (mean age 55 years; mostly men) with anterior STEMI undergoing primary PCI were randomized to either two IC boluses of eptifibatide (180 mcg/kg each) just after passage of the wire or first balloon inflation followed by continuous infusion of

2 µg/kg/min for 12 to 24 hours following the primary PCI or a double IC bolus dose of tirofiban (25 µg/kg) just after passage of the wire or first balloon inflation followed by continuous infusion of 0.15 µg/kg/min for 12 to 24 hours following the primary PCI. The two groups were well-matched for baseline clinical, demographic, angiographic and ECG characteristics. All patients received standard dual antiplatelet therapy and heparin (300 mg ASA, 600 mg clopidogrel, and 70 IU/kg unfractionated heparin in the cath lab). The primary end point was achievement of TIMI 3 epicardial flow and at least myocardial blush grade (MBG) 2 or 3 as a measure of successful myocardial (tissue) reperfusion.

The difference in TIMI 3 flow for the two groups was not significantly different (Figure 1). However, significantly (p=0.005) more patients in the eptifibatide group (76.6%) had MBG grade 2 or 3 versus the tirofiban group (36.6%; Figure 2). There was no significant difference in the rate of in-hospital MACE between groups with one death (3.3%) in each group. None of the patients in the eptifibatide group had recurrent ischemia versus 16.7% of patients treated with tirofiban (p.0.05). Successful ST segment resolution (70.9 % ± 11.3 vs 59.7 % ± 9) and systolic function preservation (ejection fraction of 46.6 ± 5.5 vs 39.9 ± 6) were significantly better in eptifibatide group (p<0.01). TIMI major bleeding was not different between the two groups, however TIMI minor bleeding occurred in 33.3% of tirofiban patients versus no patients in the eptifibatide group (p<0.01).

Although the primary endpoint in this trial was not met, favorable trends in secondary endpoints suggest that IC eptifibatide may be beneficial in patients with anterior STEMI. Larger randomized clinical trials examining this treatment strategy are necessary to better define the efficacy and safety of IC eptifibatide.

Figure 1. Primary Endpoint.

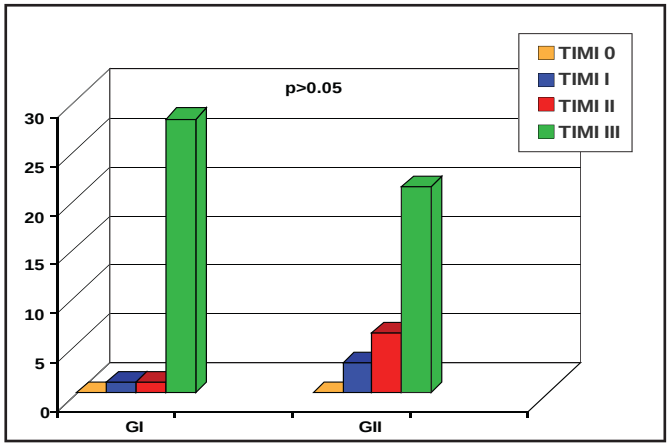

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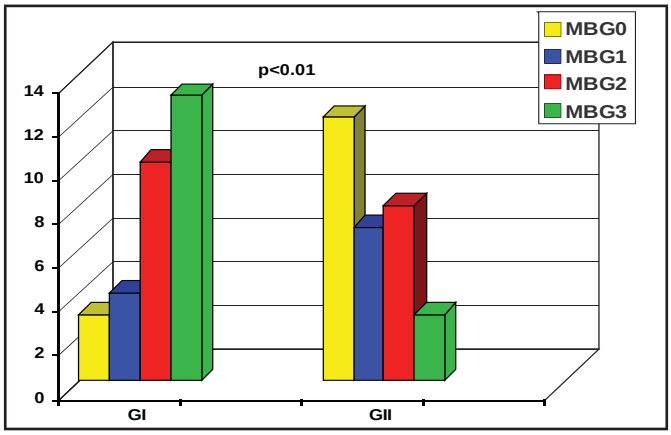
Figure 2. Post PCI MBG Among Study Groups.



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