

# Percutaneous Coronary Intervention in Native Vessels With Angiographically Visible Thrombus

## Temporal Trends and Impact of Drug-Eluting Stents

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**Objectives** The aim of our study was to evaluate the temporal trends in outcomes following percutaneous coronary intervention in lesions with angiographically visible thrombus and to assess the impact of drug-eluting stents (DES) on long-term outcomes.

**Background** Percutaneous coronary intervention in the presence of angiographically visible thrombus is associated with worse clinical outcomes. Whether recent advances in devices and adjunctive pharmacotherapy have made any significant impact on clinical outcomes is unknown. Moreover, concerns have been raised about the safety of DES in thrombotic lesions.

**Methods** We conducted a retrospective analysis of 6,227 consecutive patients who had angiographically visible thrombus. Patients were grouped into 3 eras depending on the dominant interventional strategy of that time: early stent era (1990 to 1996), bare-metal stent era (1997 to 2003), and DES era (2003 to 2006).

**Results** Procedural success rates, although much improved, have remained unchanged in the last 2 cohorts (43%, 85%, 86%;  $p < 0.001$ ). Adjusted in-hospital mortality (4.7%, 3.0%, 3.6%;  $p < 0.001$ ), and major adverse cardiovascular events (7.8%, 5.0%, 5.3%;  $p < 0.001$ ) decreased modestly. During long-term follow-up, mortality and the combined end point of death or myocardial infarction were similar in the 3 cohorts; but the combined end point of death, myocardial infarction, or target lesion revascularization ( $p < 0.001$ ) was lower in the 2 most recent eras.

**Conclusions** There has been a marked improvement in procedural success accompanied by a reduction in in-hospital mortality and major adverse cardiac event rates. Importantly, the introduction of DES has not been associated with a greater risk of death or myocardial infarction among patients with angiographically visible thrombus. (J Am Coll Cardiol Intv 2010;3:937–46) © 2010 by the American College of Cardiology Foundation

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The utilization of percutaneous coronary intervention (PCI) has steadily increased over time due to greater operator experience, advances in device technology, and improved adjunctive pharmacotherapy. Percutaneous coronary intervention is now performed for a broad spectrum of indications ranging from stable disease to ST-segment elevation myocardial infarction (STEMI). However, there remain specific lesion subsets that are challenging and are associated with adverse outcomes. One such group of patients comprises those with intracoronary thrombus, which is typically present during acute coronary syndromes (ACS) (1,2). The burden of thrombus is greatest in patients with STEMI in whom it is usually occlusive, whereas non-STEMI is generally associated with nonocclusive thrombi (3,4).

See page 947

#### Abbreviations and Acronyms

**ACS** = acute coronary syndrome

**BMS** = bare-metal stent(s)

**CABG** = coronary artery bypass graft

**DES** = drug-eluting stent(s)

**MACE** = major adverse cardiac events

**MI** = myocardial infarction

**PCI** = percutaneous coronary intervention

**STEMI** = ST-segment elevation myocardial infarction

**TLR** = target lesion revascularization

Important advances over the past 15 years with respect to performing PCI in thrombus-rich lesions include: 1) the introduction of coronary stents; 2) the use of potent antiplatelet and antithrombin drugs, and, more recently; 3) thrombectomy and distal protection devices. Conversely, there have been concerns raised regarding the increased potential for early and late stent thrombosis with drug-eluting stents (DES) in ACS (5–7), because the thrombus may act as a nidus for stent thrombosis and alter arterial wall drug delivery and retention (8). Most published studies exploring outcomes with PCI in the presence

of visible thrombus have pre-dated these issues and do not reflect contemporary practice. We hypothesized that outcomes following PCI in the presence of thrombus have improved over time and that this has not been adversely influenced by the introduction of DES. Thus, the aim of our study was to evaluate the temporal trends, including the impact of DES, on in-hospital and long-term outcomes following PCI in patients with coronary lesions with angiographically visible thrombus.

#### Methods

**Study population.** The study included patients from January 1990 to August 2006. Inclusion criterion was the presence of thrombus on the diagnostic angiogram. The earliest qualifying PCI per patient was considered the index event. Patients with saphenous vein graft intervention were ex-

cluded. We identified 6,227 patients who met these criteria. The patients were divided into 3 groups according to the time of their intervention: 1) early stent era consisted of patients from a time period when stents were predominantly used as a bailout strategy (January 1990 through December 1996); 2) bare-metal stent (BMS) era included patients from a time period during which routine stenting with BMS was the preferred strategy in conjunction with dual oral antiplatelet therapy (January 1997 through March 2003); and 3) DES era consisted of patients whose PCI reflects contemporary practice, including treatment with DES (April 2003 through August 2006). The Institutional Review Board at Mayo Clinic approved this study. In accordance with a State of Minnesota statute, patients who did not grant authorization for medical records research were also excluded from the analysis (n = 441). During the same time periods, we identified 2,710, 3,812, and 2,482 patients, respectively, who presented with ACS, but without angiographic evidence of thrombus who served as a control population with respect to evaluating outcomes.

**Definitions used.** Thrombus was defined prior to PCI by visual estimation as an intraluminal filling defect with contrast on 3 sides or an area of contrast staining noted within the stenosis and not having the angiographic characteristics of dissection. The number of diseased coronary arteries was defined by visual estimation as at least 1 coronary artery with 70% stenosis and 50% stenosis in the others. Patients with  $\geq 50\%$  stenosis in the left main coronary artery were considered to have 2-vessel disease if there was right dominance and 3-vessel disease if there was left dominance. Major adverse cardiovascular events (MACE) were defined as 1 or more of the following occurring during the index hospitalization: 1) death; 2) Q-wave myocardial infarction; 3) urgent or emergent coronary artery bypass graft (CABG); and 4) cerebrovascular accident defined as transient ischemic attack or stroke. Myocardial infarction (MI) was diagnosed in the presence of 2 of the following 3 criteria: 1) typical chest pain for at least 20 min; 2) elevation of creatine kinase (or the myocardial band fraction)  $>2$  times normal; and 3) a new Q-wave on electrocardiogram. Acute coronary syndrome was defined as unstable angina or a clinical diagnosis of MI within the preceding 7 days. Data for bleeding complications were not collected systematically until 1994. Primary PCI was defined as PCI performed within 24 h of a MI without preceding administration of thrombolytic. In-hospital deaths included all deaths during the index hospital admission. Technical success was defined as a reduction of residual luminal diameter stenosis to no more than 20% in the culprit vessel. Procedural success was defined as a reduction of residual luminal diameter stenosis to no more than 20% without in-hospital death, Q-wave MI, or need for emergency CABG. For comparison with the early stent era, we also provide data for procedural success defined as a

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