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Stent Thrombosis in New-Generation Drug-Eluting Stents in Patients With STEMI Undergoing Primary PCI

A Report From SCAAR

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ABSTRACT

BACKGROUND Some concerns still have not been resolved about the long-term safety of drug-eluting stents (DES) in patients with acute STEMI.

OBJECTIVES The aim of this study was to evaluate the stent thrombosis (ST) rate up to 3 years in patients with ST-segment elevation myocardial infarction (STEMI) treated by primary percutaneous coronary intervention (PCI) with new-generation drug-eluting stents (n-DES) compared with bare-metal stents (BMS) and old-generation drug-eluting stents (o-DES) enrolled in the SCAAR (Swedish Coronary Angiography and Angioplasty Registry).

METHODS From January 2007 to January 2013, 34,147 patients with STEMI were treated by PCI with n-DES (n = 4,811), o-DES (n = 4,271), or BMS (n = 25,065). The risks of early/late (up to 1 year) and very late definite ST (after 1 year) were estimated.

RESULTS Cox regression landmark analysis showed a significantly lower risk of early/late ST in patients treated with n-DES (hazard ratio [HR]: 0.65; 95% confidence interval [CI]: 0.43 to 0.99; p = 0.04) and o-DES (HR: 0.60; 95% CI: 0.41 to 0.89; p = 0.01) compared with the BMS group. The risk of very late ST was similar between the n-DES and BMS groups (HR: 1.52; 95% CI: 0.78 to 2.98; p = 0.21), whereas a higher risk of very late ST was observed with o-DES compared with BMS (HR: 2.88; 95% CI: 1.70 to 4.89; p < 0.01).

CONCLUSIONS Patients treated with n-DES have a lower risk of early/late ST than patients treated with BMS. The risk of very late ST is low and comparable between n-DES and BMS up to 3 years of follow-up, whereas o-DES treatment is associated with an increased risk of very late ST. The current STEMI guidelines might require an update in light of the results of this and other recent studies. (J Am Coll Cardiol 2014;64:16–24) © 2014 by the American College of Cardiology Foundation.

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Drug-eluting stents (DES) have been shown to significantly reduce the rate of restenosis and target lesion revascularization (1,2), and consequently, their use has been commonly extended to complex lesions and acute clinical settings (3–6). Concerns have been raised and still not resolved about the long-term safety of DES in patients with acute ST-segment elevation myocardial infarction (STEMI).

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Platelet activation is increased in patients with STEMI (7,8). Moreover, a delay in arterial healing has been recognized at the culprit site in patients with STEMI compared with patients treated for stable angina (9). Percutaneous coronary intervention (PCI) in STEMI patients is therefore associated with a higher risk of stent thrombosis (ST) (10–12).

Comparisons of new-generation DES (n-DES) and bare-metal stents (BMS) in the STEMI setting (13–15) are limited. The available data on the outcome of PCI in STEMI patients are mainly based on comparisons of old-generation DES (o-DES) and BMS (16–22).

The objective of this study was to evaluate the ST rate up to 3 years in patients with STEMI treated by PCI with n-DES compared with BMS and o-DES documented in a national registry with complete consecutive enrollment, the SCAAR (Swedish Coronary Angiography and Angioplasty Registry).

METHODS

All consecutive patients in Sweden with STEMI undergoing primary PCI from January 2007 to January 2013 were included. The n-DES group included the Endeavor Resolute (Medtronic Inc., Minneapolis, Minnesota); Xience V and Xience Prime (Abbott Vascular, Santa Clara, California); Promus and Promus Element (Boston Scientific, Natick, Massachusetts). The o-DES group included the Cypher and Cypher Select (Cordis Corporation, Miami, Florida), Taxus Express and Taxus Liberté (Boston Scientific), and Endeavor (Medtronic). The BMS group included the Multilink Vision, Multilink MiniVision, Multilink 8, and Multilink Flexmaster (Abbott Vascular); Driver, Micro Driver coronary, and Integrity (Medtronic); Liberté (Boston Scientific); Braun Coroflex Blue (B. Braun, Melsungen, Germany); and Chrono stent (CID, Saluggia, Italy). The choice of stent type was at the operator's discretion.

Definite ST was defined according to the Academic Research Consortium definition (23).

STATISTICAL ANALYSIS. Continuous variables are expressed as mean ± SD and discrete variables as percentages. Differences in means among groups were analyzed by a 2-sided *t* test or by 1-way analysis of variance using a Tukey-Kramer test to compare all pairs. Categorical variables are expressed as absolute numbers and percentages. Differences in categorical variables were analyzed by the chi-square test.

The predefined primary endpoint was to evaluate the ST rate after the implantation of n-DES, o-DES, and BMS in STEMI patients. The log-minus-log test was used to assess the proportional hazard assumption. Analyses were based on the first recorded procedure during the inclusion period to avoid duplicate entries. For patients receiving several stents during the same procedure, only 1 stent was randomly selected and followed over time. Patients with cardiogenic shock were excluded.

The cumulative adjusted hazard risk (HR) of ST up to 3 years was calculated using Cox proportional hazard method. The Cox analysis models were censored up to 3 years. Propensity score analysis was used to compensate for the nonrandomized nature of this study. The propensity score models were defined as the conditional probability of receiving a

ABBREVIATIONS AND ACRONYMS

BMS = bare-metal stent(s)
CI = confidence interval
DAPT = dual-antiplatelet therapy
DES = drug-eluting stent(s)
HR = hazard ratio
n-DES = new-generation drug-eluting stent(s)
o-DES = old-generation drug-eluting stent(s)
PES = paclitaxel-eluting stent(s)
SES = sirolimus-eluting stent(s)
ST = stent thrombosis
STEMI = ST-segment elevation myocardial infarction

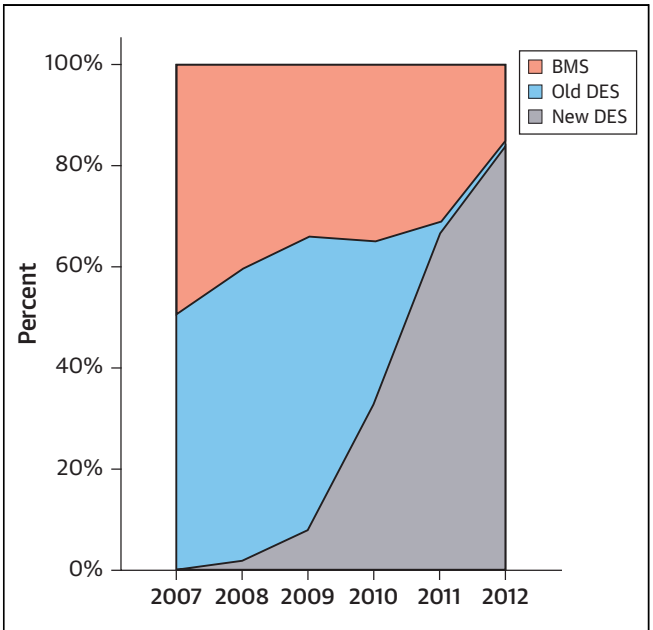

FIGURE 1 Distribution of the Use of n-DES, o-DES, and BMS During the Study Period

The use of new-generation drug-eluting stents (n-DES) increased from 10% in 2009 to 85% in 2012. The use of bare-metal stents (BMS) decreased from 50% in 2007 to 15% in 2012. The use of old-generation drug-eluting stents (o-DES) decreased from 50% in 2007 to 0.1% in 2012.