

WJC 6th Anniversary Special Issues (5): Myocardial infarction**Drug-eluting stents and acute myocardial infarction: A lethal combination or friends?**

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Abstract

Primary percutaneous coronary intervention is the preferred reperfusion strategy for patients presenting with ST-segment elevation myocardial infarction (STEMI). First generation drug-eluting stents (DES), (sirolimus drug-eluting stents and paclitaxel drug-eluting stents), reduce the risk of restenosis and target vessel revascularization compared to bare metal stents. However, stent thrombosis emerged as a major safety concern with first generation DES. In response to these safety issues, second generation DES were developed with different drugs, improved stent platforms and more biocompatible durable or bioabsorbable polymeric coating. This article presents an overview of safety and efficacy of the first and second generation DES in STEMI.

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Key words: ST-segment elevation myocardial infarction; Drug-eluting stents; Stent thrombosis; Sirolimus drug-eluting; Paclitaxel drug-eluting stents; Zotarolimus-eluting stents; Zotarolimus-eluting stents; Bioresorbable vascular scaffold

Core tip: Primary percutaneous coronary intervention is the preferred reperfusion strategy for patients present-

ing with ST-segment elevation myocardial infarction (STEMI). First-generation drug-eluting stents (DES) reduce restenosis and target vessel revascularization compared to bare metal stents at the expense of an increased stent thrombosis rate. Recent improvements in second-generation DES have overcome these safety concerns. This article presents an overview of safety and efficacy of the DES in STEMI.

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INTRODUCTION

Primary percutaneous coronary intervention (PCI) has become a well-established reperfusion strategy for patients presenting with acute ST-segment elevation myocardial infarction (STEMI)^[1,2]. In this setting, bare-metal stents (BMS) reduced the risk of recurrent ischemia and restenosis compared to balloon angioplasty^[3]. First-generation drug-eluting stents (DES)-sirolimus-eluting stents (SES) and paclitaxel-eluting stents (PES)-were also able to reduce the risk of restenosis and target-vessel revascularization (TVR) compared to BMS in this context^[4,5]. However, stent thrombosis emerged as a major safety concern^[6]. In response, second-generation DES were developed with different drugs, more biocompatible durable polymers or bioabsorbable polymeric coatings, and new stent platforms, including fully bioresorbable vascular scaffolds.

PATHOPHYSIOLOGY OF STEMI

As shown in Figure 1, STEMI is an event related to ath-

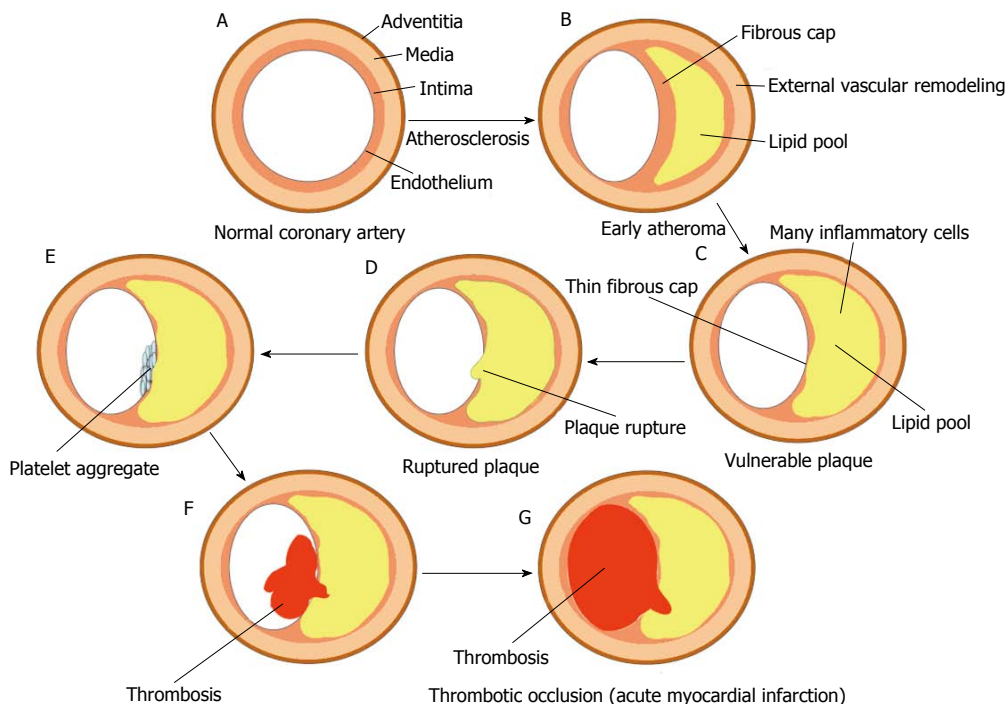


Figure 1 Pathophysiology of ST-segment elevation myocardial infarction. A: Normal coronary artery; B: Coronary artery with early atheroma; C: Vulnerable plaque with thin fibrous cap; D: Ruptured plaque; E: Platelets aggregated to heal the ruptured plaque; F: Protruding thrombus; G: Thrombotic occlusion (acute myocardial infarction).

erosclerotic plaque rupture, ulceration, fissuring, erosion, or dissection that results in intraluminal thrombus in one or more of the coronary arteries, leading to decreased myocardial blood flow or distal platelet emboli with ensuing myocyte necrosis^[7,8]. During the early years after the introduction of coronary stents, it was thought that implanting a metallic device under a thrombotic environment in the acute phase of STEMI could increase the risk of adverse outcome. However, refinement of stent implantation technique and the development of new anti-thrombotic regimen have overcome those initial concerns.

PATHOPHYSIOLOGY OF STENT THROMBOSIS

The pathophysiology of stent thrombosis includes procedure-, stent-, and patient-related factors (Figure 2). The PCI procedure for acute coronary syndrome, including STEMI, is one of the most powerful predictors for stent thrombosis in the vast majority of registries^[9-14] (Figure 3). Late stent malapposition is common in STEMI patients and may eventually provoke stent thrombosis. Late malapposition may be linked to underdeployment of stents at the time of STEMI treatment, due mainly to dissolution of thrombus behind the struts or undersized vessels due to the spastic condition of the coronary arteries in the acute phase of STEMI^[15]. Implanting DES over a necrotic core may also significantly delay healing, due to less neointimal growth and greater inflammation, fibrin deposits, and uncovered struts compared to DES implanted over coronary stable plaques^[16,17].

Currently, patients are categorized as having early or late stent thrombosis. Early stent thrombosis is defined as occurring within 30 d of implantation, and is further categorized as acute (events within 24 h) or subacute (events on day 1-30) thrombosis. Events that occur more than 30 d postimplantation are classified as late stent thrombosis, and those occurring beyond 12 mo as very late stent thrombosis^[18].

Early and late stent thrombosis differ in their pathophysiology and mechanism. Early stent thrombosis is mainly related to one or more procedural characteristics, such as stent underexpansion, incomplete stent apposition, dissection, thrombus, tissue protrusion, and persistent slow flow. It may occur after either BMS or DES implantation.

Late stent thrombosis may result when neointimal healing is delayed, as this can lead to inadequate neointimal coverage and/or to incomplete stent apposition. Evaluation of angiography, optical coherence tomography, and autopsy revealed that first-generation DES are associated with delayed arterial healing due to hypersensitive reactions to polymers that cause chronic inflammation^[9,16]. These phenomena are typically observed more than 1 year after implantation.

SAFETY AND EFFICACY OF FIRST-GENERATION DES IN STEMI

Twelve randomized controlled trials (RCTs) of first-generation DES outcomes in STEMI have been published^[14,5,19-33]. Comparisons were made as follows: BMS

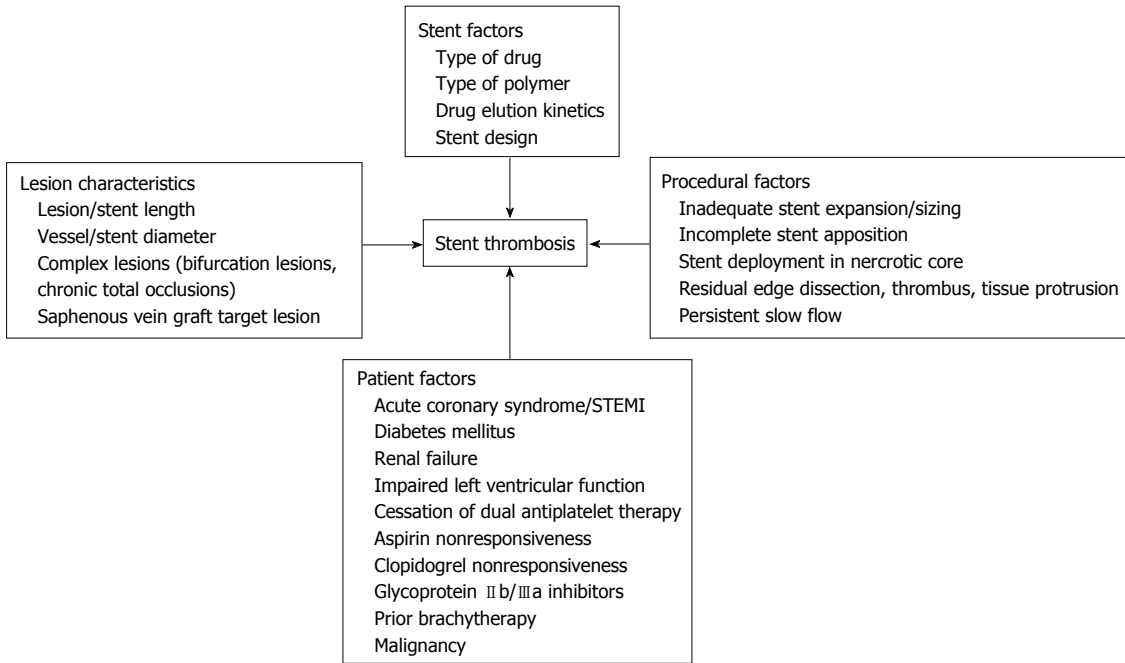


Figure 2 Potential causes of stent thrombosis. STEMI: ST-segment elevation myocardial infarction.

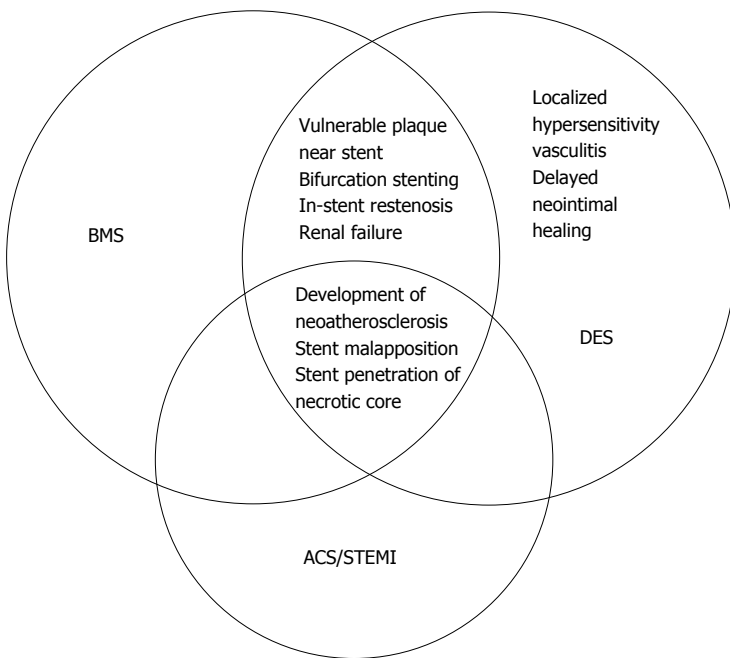


Figure 3 Multifactorial causes of late stent thrombosis. BMS: Bare metal stents; DES: Drug eluting stents; ACS: Acute coronary syndrome; STEMI: ST elevated myocardial infarction.

vs SES, 7 reports; BMS *vs* PES, 5 reports; PES *vs* SES, 2 reports; BMS *vs* SES *vs* PES, 1 report (Table 1).

The TYPHOON study^[4] was the largest RCT to consider SES, enrolling 712 patients to assess the effectiveness and safety of SES *vs* BMS at 1 year. Target-vessel failure was significantly lower in the SES (7.3%) than in the BMS (14.3%) group ($P = 0.004$), driven by a decrease in the rate of TVR (5.6% *vs* 13.4%, respectively; $P < 0.001$). There was no significant difference between the two groups in the rates of mortality (2.3% *vs* 2.2%; $P = 1.00$), repeat myocardial infarction (MI) (1.1% *vs* 1.4%; P

$= 1.00$), or stent thrombosis (3.4% *vs* 3.6%; $P = 1.00$). At 4-year follow-up^[4], freedom from target lesion revascularization was significantly better in the SES group, compared to BMS (92.4% *vs* 85.1%; $P = 0.002$). However, no differences were observed, respectively, in freedom from cardiac death (97.6% *vs* 95.9%; $P = 0.37$), freedom from repeat MI (94.8% *vs* 95.6%; $P = 0.85$), or definite/probable stent thrombosis (4.4% *vs* 4.8%, $P = 0.83$). Other studies have also reported that SES was superior or non-inferior to BMS in mortality, repeat MI, TVR, and stent thrombosis rates^[20-25,33] (Table 1).

Table 1 Randomized controlled trials of first-generation drug eluting stents in stent thrombosis elevated myocardial infarction

Study, author (Ref.)	Year	Primary endpoint	Design	Randomized ratio	Maximal length of follow-up	Stent comparators (n)	Results of the primary endpoint
Pascari <i>et al.</i> ^[19]	2003	Death, MI, recurrent ischemia at 1 yr	Single center	1:1	1 yr	BMS/SES 65 (33/32)	No significant differences between stents
TYPHOON ^[4]	2006	TVF at 1 yr	Multicenter, superiority	1:1	4 yr	BMS/SES 712 (355/357)	SES superior to BMS
STRATEGY ^[20]	2007	Death, MI, stroke, binary restenosis at 8 mo	2-center, superiority	1:1	2 yr	BMS/SES 175 (87/88)	SES superior to BMS
SFESAMI ^[21,22]	2007	Binary restenosis at 1 yr	Single-center, superiority	1:1	5 yr	BMS/SES 320 (160/160)	SES superior to BMS
Díaz de la Llera <i>et al.</i> ^[23]	2007	Death, MI, TLR at 1 yr	Single center, superiority	1:1	1 yr	BMS/SES 114 (54/60)	SES superior to BMS
MISSION ^[24]	2008	In-segment late luminal loss at 9 mo	Single center, noninferiority	1:1	5 yr	BMS/SES 310 (152/158)	SES superior to BMS
MULTISTRATEGY ^[25]	2008	Death, MI, clinically driven TVR at 8 mo	Multicenter, superiority	1:1	3 yr	BMS/SES 744 (372/372)	SES superior to BMS
HAAMU-STENT ^[26]	2006	Death, MI, late lumen loss, TVR at 1 yr	Single center, superiority	1:1	1 yr	BMS/PES 164 (82/82)	PES superior to BMS
SELECTION ^[27]	2007	Neointimal proliferation by IVUS at 7 mo	Single-center, superiority	1:1	7 mo	BMS/PES 76 (39/37)	PES superior to BMS
PASSION ^[28]	2008	Cardiac death, MI, TLR at 2 yr	2-center, superiority	1:1	5 yr	BMS/PES 619 (310/309)	Superiority not demonstrated
HORIZONS-AMI ^[5,29]	2009	TLR	Multicenter, superiority (TLR)	3:1	3 yr	BMS/PES 3006 (2257/749)	PES superior for TLR and noninferior for clinical endpoints
GRACIA-3 ^[30]	2010	In-segment binary restenosis, myocardial flow at 1 yr	Multicenter, noninferiority	1:1	1 yr	BMS/PES 419 (210/209)	BMS noninferior to PES
PROSIT ^[31]	2008	Death, MI, TVR, ST at 1 yr	Multicenter, superiority	1:1	3 yr	PES/SES 308 (154/154)	Superiority not demonstrated
Juwana <i>et al.</i> ^[32]	2009	Late lumen loss at 9 mo	Single center, superiority	1:1	1 yr	PES/SES 397 (196/201)	SES superior to PES
PASEO ^[33]	2009	TLR at 12 mo	Single-center, superiority	1:1:1	4 yr	BMS/PES/SES 270 (90/90/90)	PES and SES superior to BMS

MI: Myocardial infarction; TLR: Target lesion revascularization; ST: Stent thrombosis; PES: Paclitaxel-eluting stents; SES: Sirolimus-eluting stents; BMS: Bare metal stent stents; TVR: Target vessel revascularization; IVUS: Intra-vascular ultrasound.

With regard to PES, the HORIZONS-AMI study was the largest RCT^[5]. A total of 3006 patients were enrolled in this 12-mo trial to assess the effectiveness and safety of PES vs BMS. The PES group had significantly lower 12-mo rates of ischemia-driven target lesion revascularization (4.5% vs 7.5%; $P = 0.002$) and TVR (5.8% vs 8.7%; $P = 0.006$). There were no significant differences between the PES and BMS groups in 12-mo rates of mortality (3.5% vs 3.5%; $P = 0.98$) and stent thrombosis (3.2% vs 3.4%; $P = 0.77$). At the 3-year follow-up^[29], the PES group had lower rates of ischemia-driven target lesion revascularization (9.4% vs 15.1%; $P < 0.0001$), but did not differ from the BMS group in mortality, repeat MI, stroke, or stent thrombosis rates. Stent thrombosis was high ($\geq 4.5\%$) in both groups. Other studies have also shown that PES was superior or noninferior to BMS in mortality, repeat MI, TVR, and stent thrombosis rates^[26,27,30,33] (Table 1).

Although RCTs did not identify any safety issues with first-generation DES, this topic became a firestorm during the 2006 European Society of Cardiology Annual Meet-

Table 2 Randomized controlled trials of second-generation drug eluting stents in ST elevated myocardial infarction

Study	Year	Primary endpoint	Design	Randomized ratio	Maximal length of follow-up	Stent comparisons (n)	Results of the primary endpoint
ZEST-AMI ^[38]	2009	Death, MI, and ischemia-driven TVR at 1 yr	Multicenter, safety study	1:1:1	1 yr	PES/SES/PC-ZES 328 (110/110/108)	No significant differences between stents
KOMER ^[39]	2011	Cardiac death, MI, ischemia-driven TLR at 1 yr	Multicenter, safety study	1:1:1	18 mo	PES/SES/PC-ZES 611 (202/204/205)	PC-ZES as safe as SES and PES
EXAMINATION ^[40,41]	2011	Death, MI, any revascularization at 1 yr	Multicenter, superiority	1:1	2 yr	CoCr-EES/BMS 1504 (751/747)	CoCr-EES superior to BMS
XAMI ^[42]	2012	Cardiac death, MI, TVR at 1 yr	Multicenter, noninferiority	2:1	1 yr	EES/SES 625 (404/221)	EES noninferior to SES
COMFORTABLE AMI ^[43]	2012	cardiac death, reinfarction, and TLR at 1 yr	Multicenter, superiority	1:1	1 yr	EES/BMS 1161 (575/582)	BES superior to BMS

MI: Myocardial infarction; TLR: Target lesion revascularization; CoCr-EES: Cobalt-chromium everolimus-eluting stents; PC-ZES: Phosphorylcholine polymer based zotarolimus-eluting stent; PES: Paclitaxel-eluting stents; SES: Sirolimus-eluting stents; TVR: Target vessel revascularization; BMS: Bare metal stent stents.

ing, held in Barcelona. Meta-analysis of pooled data showed that first-generation DES increased mortality and repeat MI compared to BMS^[34]. High rates of early and late stent thrombosis after discontinuation of dual antiplatelet agents in patients treated with first-generation DES also raised safety concerns^[35,36]. Pathology studies demonstrated that the durable polymers used in first-generation DES could cause a delay in arterial healing, characterized by persistent fibrin deposits, delayed hypersensitivity reactions, and poor endothelialization of the vessel wall, all of which increased the thrombotic risk^[37].

SAFETY AND EFFICACY OF SECOND-GENERATION DES IN STEMI

Second-generation DES were developed to resolve these issues. Stent design and polymeric coating were improved by the use of biocompatible or bioabsorbable polymers. Two RCTs have been published about zotarolimus-eluting stents (ZES) implantation in STEMI patients^[38,39] (Table 2).

The multicenter, prospectively randomized, ZEST-AMI trial included 328 patients who were randomly assigned to ZES ($n = 108$), SES ($n = 110$), or PES ($n = 110$) groups^[38]. Mortality, MI, and ischemia-driven TVR rates at 12 mo were 11.3%, 8.2%, and 8.2%, respectively ($P = 0.834$); there were no differences in mortality, recurrent MI, and ischemia-driven TVR rates. The SES group had 2 acute and 2 subacute cases of stent thrombosis. In the PES group, 3 patients had subacute thrombosis.

The KOMER study was also a multicenter, prospective, single-blind RCT^[39]. The 611 participants were STEMI patients undergoing primary PCI. They were randomized to treatment with ZES ($n = 205$), SES ($n = 204$), or PES ($n = 202$). At 12-mo follow-up, the incidence of cardiac death, MI, or ischemia-driven target lesion revascularization was 5.9% in the ZES group, 3.4% in the SES group, and 5.7% in the PES group, respectively ($P = 0.457$). The rate of stent thrombosis was similar in all 3 groups (approximately 2%).

Two RCTs have studied the use of everolimus-eluting stents (EES) implantation in STEMI patients^[40,42]. The EXAMINATION study was a multicenter, prospective, randomized, all-comer, controlled trial. In this trial, 1498 patients were randomly assigned to receive EES ($n = 751$) or BMS ($n = 747$)^[40]. At 1-year follow-up, target lesion and vessel revascularization were significantly lower in the EES group (2.1% vs 5.0%; $P = 0.003$, and 3.7% vs 6.8%; $P = 0.0077$). There were no differences between the EES and BMS groups in all-cause (3.5% vs 3.5%, $P = 1.00$) or cardiac death (3.2% vs 2.8%, $P = 0.76$) or repeat-MI (1.3% vs 2.0%, $P = 0.32$). Stent thrombosis rates differed significantly between EES and BMS groups for both “definite” and “definite or probable” diagnoses (0.5% vs 1.9% and 0.9% vs 2.5%, respectively; both $P = 0.019$). At the 2-year follow-up, there were significantly fewer target lesion revascularizations in the EES group (2.9% vs 5.6% for BMS; $P = 0.009$)^[41]. Composite of all-cause death, any MI, or revascularization did not differ between groups (14.4% vs 17.3%, respectively; $P = 0.11$). Definite and probable stent thrombosis rates were significantly lower in the EES group (1.3% vs 2.8%; $P = 0.03$).

The XAMI trial randomized 625 patients with acute myocardial infarction (2:1) to receive EES or SES^[42]. Death, nonfatal MI, or any TVR at 1 year was lower at 4.0% for

Table 3 Current polymer-free stents undergoing clinical evaluation

Stent	Study	Platform	Drug	Primary endpoint	Design	Randomized ratio	Stent comparisons (n)	Result
Yukon (Translumina)	ISAR TEST ^[50]	316 L microporous surface	Sirolimus + Probuocol	MACE/ST at 1yr	RCT	2:1	Yukon/R-ZES 3002 (2002/1000)	Noninferior
Cre 8 (CID)	NEXT ^[51]	CoCr abluminal reservoirs	Amphilimus	LL at 6 mo	RCT	1:1	Cre 8/PES 323 (162/161)	Superior
BioFreedom DCS (Biosensors)	BioFreedom FIM ^[52]	316 L microstructured surface	Biolimus A9	LL at 12 mo	RCT	1:1:1	Standard dose/low dose Biofreedom/PES 182 (60/62/60)	Noninferior
Vestasync (MIV therapeutics)	VESTASYN II ^[53]	316 L microporous nanofilm Hap	Sirolimus	LL at 4 and 9 mo	RCT	2:1	VESTASync/BMS 75 (50/25)	Superior
Amazonia Pax (Minvasys)	Pax A and Pax B	CoCr nontextured	Paclitaxel	LL at 6 mo	RCT	1:1	PAXA/PES 30 (15/15), PAXB = 100	Noninferior
Yinyi (Liaoning Biomed.Mat)	FREEDOM ^[54]	316 L micropores	Paclitaxel	MACE/ST/TVR	RCT	2:1	Yinyi/SES 1626 (931/449)	Noninferior
Bicare+ (Lepu Medical)	BICARE ^[56]	316 L	Sirolimus + Probuocol	TVF at 30 d	FIM	-	<i>n</i> = 32	TVF = 9.4%, LL 0.14, ISR = 3.2%
Pronova XR (Vascular Concepts)	EURONOVA XR I ^[55]	Co-Cr	Sirolimus	LL at 6 mo	FIM	-	<i>n</i> = 50	In-stent LL 0.45
Focus NP (Envision Scientific)	Nano active FIM	316 L nontextured	Sirolimus nanoparticles	LL at 6 mo	FIM	-	<i>n</i> = 100	Ongoing
Mitsu (Meril Medical)	-	CoCr ultrathin struts	Merilimus	-	-	-	Planned	-
Hollow-core DFS (Medtronic)	-	CoCr holes and hollow tube	Sirolimus	-	-	-	Planned	-
Nano+ (Lepu medical)	Nano+	Microporous	Sirolimus	OCT evaluation	FIM	-	<i>n</i> = 45	Ongoing

MAC.E: Major adverse cardiac events; ST: Stent thrombosis; RCT: Randomized control trial; LL: Late lumen loss; R-ZES: Resolute zotarolimus-eluting stents; PES: Paclitaxel-eluting stents; BMS: Bare metal stents; SES: Sirolimus-eluting stents; TVR: Target vessel revascularization; TVF: Target vessel failure; ISR: In-stent restenosis; OCT: Optical coherence tomography; FIM: First-in-man trial.

EES vs 7.7% for SES ($P = 0.048$) and 1-year incidence of definite and/or probable stent thrombosis was 1.2% for EES vs 2.7% for SES ($P = 0.21$). The COMFORTABLE AMI is the only RCT by the use of biolimus-eluting stents (BES) in STEMI patients^[43]. A total of 1161 patients were randomized 1:1 to receive BES ($n = 575$) or BMS ($n = 582$). Major adverse cardiac events at 1 year occurred in 24 patients (4.3%) receiving BES and in 49 patients (8.7%) receiving BMS ($P = 0.004$). The difference was driven by a lower risk of target vessel-related repeat MI [β (0.5%) vs 15 (2.7%); $P = 0.01$] and ischemia-driven target-lesion revascularization [9 (1.6%) vs 32 (5.7%); $P = 0.001$] in patients receiving BES compared with those receiving BMS. Rates of cardiac death were not significantly different [16 (2.9%) vs 20 (3.5%), $P = 0.53$]. Definite stent thrombosis occurred in 5 patients (0.9%) treated with BES and 12 patients (2.1%, $P = 0.10$) treated with BMS.

Recent meta-analyses also showed that EES were associated with significantly lower rates of stent thrombosis than both BMS and PES at 1-year follow-up. In addition, EES were associated with significantly lower rates of cardiac death or MI compared with PES^[44,45].

Pathological analysis also showed that late and very late stent thrombosis occurred less often in the EES (4%) than in the SES (21%; $P = 0.029$) and PES groups (26%; $P = 0.008$). The percentage of uncovered struts was lower in the EES (media $n = 2.6\%$) than in SES (18.0%; $P < 0.0005$) or PES groups (18.7%; $P < 0.0005$). Furthermore, EES was associated with less inflammation, no hypersensitivity, and less fibrin deposit than both SES and PES^[46].

GLIMPSE INTO THE FUTURE: NEXT-GENERATION STENT PLATFORMS FOR STEMI?

A new, self-apposing stent has been developed to reduce malapposition, which may eventually provoke stent thrombosis. In the APPOSITION II study, optical coherence tomography at 3 d after implantation showed a lower rate of malapposed stent struts in the self-apposing BMS group than in the balloon-expandable group (0.58% vs 5.46%, $P = 0.001$)^[47]. In the APPOSITION IV study, patients treated with a self-apposing SES had better apposition ($P = 0.001$) and better coverage at 4-mo follow-up than the balloon-expandable ZES (31.6% vs 3.8%; $P = 0.03$)^[48].

The micronet-mesh-covered stent has been developed to prevent distal embolization. In the MASTER study, complete ST-segment resolution was significantly improved in patients treated with micronet-mesh-covered stent, compared with commercially available BMS or SES (57.8% vs 44.7%; $P = 0.008$)^[49].

NONPOLYMERIC STENTS IN STEMI

Nonpolymeric stents have been developed to avoid polymer-related delayed neointimal healing and late stent thrombosis, and several have undergone clinical investigation (Table 3). However, most of the clinical data have been gathered in low-risk patients without STEMI^[50-56]. A small study showed that polymer-free PES (PF-PES) were noninferior to polymer-based PES (PB-PES) in patients with STEMI, both in terms of target lesion failure (10.9% PB-SES vs 12.0% PF-PES; $P = 0.861$) and definite or probable stent thrombosis (1.8% PB-SES vs 2.0% PF-PES; $P = 1.000$) at one year^[57].

BIORESORBABLE SCAFFOLDS IN STEMI

Fully bioresorbable vascular scaffold (BVS) was developed to overcome problems associated with a durable polymer and metallic scaffold. Disappearance of the stent from the treated site might decrease the risk of stent thrombosis. So far, a few studies with short-term follow-up have been published about bioresorbable vascular scaffold in STEMI or acute coronary syndrome^[58-61]. Further studies in a larger number of patients and long-term follow-up are planned.

The ongoing ISAR-absorb MI trial (A Prospective, Randomized Trial of BVS vs EES in Patients Undergoing Coronary Stenting for Myocardial Infarction, www.clinicaltrials.gov, NCT01942070) tests the clinical performance of the everolimus-eluting BVS vs durable polymer EES in patients undergoing PCI in the setting of acute MI. The primary endpoint is percent diameter stenosis in angiographic follow-up at 6 to 8 mo. Subsequent clinical follow-up will be undertaken up to 5 years.

Another ongoing study is ABSORB STEMI: the TROFI II trial (www.clinicaltrials.gov, NCT01986803), a

prospective, single-blind, noninferiority, European multicenter RCT. The primary endpoint is to assess the neointimal healing score as evaluated by intracoronary optical frequency domain imaging in patients with STEMI and treated with everolimus-eluting BVS at 6 mo follow-up, compared to that of EES. Furthermore, the safety and feasibility of implanting everolimus-eluting BVS in patients with STEMI will be assessed.

CONCLUSION

The second-generation DES significantly reduced TVR compared with BMS, without an increase in mortality, MI, or stent thrombosis rates. In patients with STEMI, the use of second-generation DES appears safer and more efficacious than either BMS or first-generation DES. Results of the ongoing ISAR-absorb trial and ABSORB STEMI: the TROFI II trial will shed light on the potential benefits of the new BVS in the context of STEMI.

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