Drug-Eluting Stents during ST-Segment Elevation Acute Myocardial Infarction: A Critical Analysis

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Primary percutaneous coronary intervention is the preferred reperfusion therapy for ST-segment elevation acute myocardial infarction patients within 12 hours of symptom-onset. Routine stent implantation during the procedure significantly reduces the rate of target vessel revascularization, although restenosis still represents a current limitation of the technique. Drug-eluting stents were developed to treat and prevent coronary restenosis. Randomized trials, meta-analysis, and registries proved their efficacy and safety in different clinical situations, including acute myocardial infarction. However, the increased risk of late stent thrombosis associated with drug-eluting stents during primary percutaneous coronary interventions encourages a careful analysis to identify which patients most benefit from them, as well as those where a prolonged dual antiplatelet therapy does not represent a limiting factor.

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Introduction

Percutaneous coronary intervention (PCI) is the preferred reperfusion therapy for ST-segment elevation acute myocardial infarction (STEMI) patients during the first 12 hours of symptom-onset.1 Compared to fibrinolysis in a systematic review involving 23 randomized trials and 7,739 patients, primary PCI significantly reduced mortality, reinfarction, and stroke at 30 days.2 Routine coronary stent implantation during primary PCI significantly reduces target vessel revascularization (TVR), with similar mortality or reinfarction rates compared to balloon angioplasty, provided that it has reached an optimal result [residual stenosis <30%, absence of dissection, and Thrombolysis in Myocardial Infarction (TIMI) flow grade III].3 Recently, application of risk scores in the combined analysis of 13 studies involving 6,922 patients showed reduction in mortality among high-risk patients who underwent routine stent implantation.4 Restenosis caused by excessive neointimal proliferation with consequent lumen obstruction represents a limitation to coronary stent implantation. Randomized trials report an incidence of TVR between 10% and 13% in patients undergoing primary PCI with stents.5,6 Drug-eluting stents (DES) were developed to reduce the rate of restenosis and demonstrated efficacy and safety in a wide variety of indications and anatomic situations.7 However, concerns about their safety in the setting of STEMI, especially about increased risk of late stent thrombosis (ST),8 motivate a critical analysis of the current evidence regarding this issue. Our review is based on the results of long-term follow-up of randomized clinical trials, large controlled registries, and meta-analysis comparing DES versus bare metal stents (BMS) during primary PCI.

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Drug-Eluting Stents and Late Thrombosis

The antirestenotic effect of DES is based on the principle of antiproliferative agents delivery directly onto the lesion, by controlled release of the drug at high-local concentration, but lower systemic concentration, raising the action on the target lesion and minimizing risks of systemic adverse effects. However, the detailed report in early 2004 of 4 patients who had suffered DES thrombosis more than 11 months since implantation, after discontinuation of dual antiplatelet therapy (DAT), promoted the beginning of a debate about its safety.9 This debate had intensified after the presentation of a meta-analysis of randomized trials of first-generation DES, during the World Congress of Cardiology 2006 in Barcelona, showing an increased risk of death and myocardial infarction (MI) in patients treated with the new devices.10 These events prompted the development of expert’s consensus definitions for ST, and motivated the release of independent meta-analysis of randomized trials, based on data obtained from individual patients, a limitation found in the original study. Three major meta-analysis showed similar rates of death or MI and definite ST, with marked reduction in TVR favoring DES implantation.7,11,12 However, a slightly but statistically significant increased rate of late ST of sirolimus-eluting stents (SES) and paclitaxel-eluting stents (PES) compared to BMS was also demonstrated.12

Stent Thrombosis Pathophysiology

Recognized risk factors for DES thrombosis include early discontinuation of DAT, renal insufficiency, insulin-dependent diabetes mellitus, acute coronary syndrome, calcified lesions, poor left ventricular function, inadequate stent expansion, residual stenosis, treatment of restenosis, and bifurcation lesions.13,14 Recently, a growing interest has been shown in resistance to antiplatelet therapy, especially clopidogrel, and its clinical implications. Among patients treated with clopidogrel after PCI, the presence of reduced-function CYP2C19 genotype is associated with increased risk of ST.15 Late ST is a complication not restricted to DES.16 A human pathologic analysis suggested that delayed healing would be the primary substrate involved in the occurrence of late thrombosis. Twenty-four months after first-generation DES implantation, more than 50% of the struts were not covered by endothelium.17 In the setting of MI, different factors could result in increased risk of late ST: plaque morphology, intracoronary thrombus, and arterial response to DES. Plaque rupture is the predominant finding in acute MI, with frequent penetration of stent struts in the necrotic core during PCI. The necrotic core is characterized by rich lipid content, less vascularity, and cellularity. Because sirolimus and paclitaxel are highly lipophilic, it is likely that these agents have high affinity for lipid-rich plaques, which could be implicated with longer periods of drug exposition, cell migration and proliferation inhibition, delayed reendothelialization, inflammation, persistent fibrin deposits, and incomplete covering of the struts. These anatomopathological findings differ from fibroatheromas with thick fibrous cap that are found in stable lesions treated by PCI.18 Thrombus burden also plays an important role in the risk of adverse ischemic events. Retrospective analysis of patients undergoing primary PCI with DES showed an incidence of ST of 1.1% at 30 days and 3.2% at 2 years, with 3 additional events beyond the 2 years at 884, 1,067, and 1,074 days.19 The presence of large thrombus burden, defined by angiographic thrombus more than or equal to twice the reference vessel diameter, was the most significant predictor of ST, with cumulative rates of 8.2% at late follow-up. Thrombus compression by the stent struts in the acute phase with its subsequent abluminal resolution could be implicated with the occurrence of late stent malapposition. Furthermore, thrombus may increase drug uptake, making its concentration in the vessel wall variable and unpredictable.20 Late stent malapposition may increase the risk of thrombotic complications by intraluminal contact of uncovered struts with blood elements. The potential for complications is higher after acute MI, since stent size selection occurs in a setting characterized by vasoconstriction and thrombus presence, underestimating the real vessel diameter. Hypersensitivity reactions caused by polymer coating, coursing with necrotizing vasculitis, and positive vessel remodeling would also be responsible for the emergence of acquired late malapposition in up to 25% of patients undergoing primary PCI with SES.21

Randomized Clinical Trials Results

Several randomized trials compared the efficacy and safety of DES versus BMS during primary PCI (Table 1). In common, the studies showed reduced
Table 1. Main Characteristics of the Trials

<table>
<thead>
<tr>
<th>Study</th>
<th>Patients (n)</th>
<th>Mean Age (Years)</th>
<th>Type of DES</th>
<th>Primary End-Point</th>
<th>Length of DAT (Months)</th>
<th>Length of Follow-Up (Months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BASKET-AMI**22</td>
<td>216</td>
<td>62</td>
<td>SES / PES</td>
<td>Cardiac death, myocardial infarction, or reintervention</td>
<td>6</td>
<td>18</td>
</tr>
<tr>
<td>DEDICATION**23</td>
<td>626</td>
<td>62</td>
<td>SES / PES / ZES</td>
<td>Angiographic late lumen loss</td>
<td>12</td>
<td>8</td>
</tr>
<tr>
<td>Di Lorenzo**24</td>
<td>270</td>
<td>64</td>
<td>SES / PES</td>
<td>Death, myocardial infarction, or reintervention</td>
<td>6</td>
<td>12</td>
</tr>
<tr>
<td>Diaz de la Llera**25</td>
<td>114</td>
<td>65</td>
<td>SES</td>
<td>Death, myocardial infarction, or reintervention</td>
<td>&gt; 9</td>
<td>12</td>
</tr>
<tr>
<td>HAAMU-STENT**26</td>
<td>164</td>
<td>63</td>
<td>PES</td>
<td>Angiographic late lumen loss</td>
<td>12</td>
<td>17</td>
</tr>
<tr>
<td>HORIZONS-AMI**30</td>
<td>3,006</td>
<td>59</td>
<td>PES</td>
<td>Reintervention / death, reinfarction, stent thrombosis, or stroke</td>
<td>6–12</td>
<td>12</td>
</tr>
<tr>
<td>MISSION**27</td>
<td>310</td>
<td>59</td>
<td>SES</td>
<td>Angiographic late lumen loss</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>MULTI-STRATEGY**28</td>
<td>744</td>
<td>64</td>
<td>SES</td>
<td>Death, myocardial infarction, or reintervention</td>
<td>≥ 3</td>
<td>8</td>
</tr>
<tr>
<td>PASSION**29</td>
<td>619</td>
<td>61</td>
<td>PES</td>
<td>Cardiac death, myocardial infarction, or reintervention</td>
<td>6</td>
<td>12</td>
</tr>
<tr>
<td>SELECTION**30</td>
<td>80</td>
<td>61</td>
<td>PES</td>
<td>Obstruction of stent volume by IVUS</td>
<td>9</td>
<td>7</td>
</tr>
<tr>
<td>SESAMI**31</td>
<td>320</td>
<td>62</td>
<td>SES</td>
<td>Angiographic binary restenosis</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>STRATEGY**32</td>
<td>175</td>
<td>63</td>
<td>SES</td>
<td>Death, myocardial infarction, stroke, or angiographic binary restenosis</td>
<td>3</td>
<td>24</td>
</tr>
<tr>
<td>TITAX AMI**33</td>
<td>425</td>
<td>64</td>
<td>PES</td>
<td>Cardiac death, myocardial infarction, or reintervention</td>
<td>≥ 6</td>
<td>12</td>
</tr>
<tr>
<td>TYPHOON**34</td>
<td>712</td>
<td>59</td>
<td>SES</td>
<td>Cardiac death, myocardial infarction, or reintervention</td>
<td>6</td>
<td>12</td>
</tr>
</tbody>
</table>

n = number; DES = drug-eluting stents; SES = sirolimus-eluting stent; PES = paclitaxel-eluting stent; ZES = zotarolimus-eluting stent; IVUS = intravascular ultrasound; DAT = dual antiplatelet therapy.

number of included patients and short follow-up, limiting a judicious analysis of rare adverse ischemic events, such as late ST. First-generation SES and PES were the most common devices, while zotarolimus-eluting stents were used in only 1 study, with few cases.23 Except for the Paclitaxel-Eluting versus Uncoated Stents in Primary PCI (PASSION)29 trial, which showed no additional benefit with PES, the results were consistent demonstrating reduced need for TVR favoring DES, with no differences in mortality, reinfarction, or ST. Recently, extended follow-up of some of these series were reported. Sustained benefit of DES implantation in TVR reduction was observed after 3-year follow-up of Sirolimus Eluting Stent versus Bare Metal Stent in Acute-Myocardial Infarction (SESAMI),35 4-year follow-up of Trial Use of the Cypher Stent in Acute Myocardial Infarction Treated with Balloon Angioplasty (TYPHOON),36 and 5-year follow-up of Single High Dose Bolus Tirofiban and Sirolimus Eluting Stent versus Abciximab and Bare Metal Stent in Myocardial Infarction (STRATEGY),37, with similar incidence of late ST. However, late follow-up of Drug Elution and Distal Protection in Acute Myocardial Infarction (DEDICATION) trial showed reduced rate of TVR at 3 years favoring DES (6.1% vs. 16.3%, P < 0.001), accompanied by higher rate of cardiac mortality among this group (6.1% vs. 1.9%, P = 0.01), not attributed to the occurrence of infarction or ST.38 Besides, 5-year follow-up of PASSION trial, available in 98.7% of the 619 patients, demonstrated similar rates of the primary end-point of cardiac mortality, reinfarction, or TVR. But those undergoing PES implantation showed higher incidence of definite very late ST (3.3% vs. 0.7%, P = 0.04).39

Horizons-AMI

The large-scale, randomized, multicenter, international Harmonizing Outcomes with Revascularization and Stents in Acute Myocardial Infarction (HORIZONS-AMI) trial40 was performed to address the main limitations on previous studies, including absence of statistical power to discriminate occurrence of safety outcomes, and performance of routine coronary angiography, which could overestimate the true benefit of DES in reducing the need for repeat revascularization. Initially 3,602 patients with STEMI referred for primary PCI were randomized to an antithrombotic therapy of unfractionated heparin plus
Table 2. Meta-analysis Evaluating the Safety and Effectiveness of Drug-Eluting Stents in Primary Percutaneous Coronary Intervention

<table>
<thead>
<tr>
<th>Study, Author</th>
<th>Year</th>
<th>Number of Trials Included</th>
<th>Patients Included (n)</th>
<th>Stent Type</th>
<th>Reintervention</th>
<th>Mortality</th>
<th>Acute Myocardial Infarction</th>
<th>Thrombosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pasceri et al.5</td>
<td>2007</td>
<td>7</td>
<td>2,357 SES / PES</td>
<td>Favor DES</td>
<td>Similar</td>
<td>Similar</td>
<td>Similar</td>
<td>Similar</td>
</tr>
<tr>
<td>Kastrati et al.5</td>
<td>2007</td>
<td>8</td>
<td>2,786 SES / PES</td>
<td>Favor DES</td>
<td>Similar</td>
<td>Similar</td>
<td>Similar</td>
<td>Similar</td>
</tr>
<tr>
<td>Piscione et al.42</td>
<td>2009</td>
<td>6</td>
<td>2,381 SES</td>
<td>Favor SES</td>
<td>Similar</td>
<td>Similar</td>
<td>Similar</td>
<td>Similar</td>
</tr>
<tr>
<td>Brar et al.43</td>
<td>2009</td>
<td>13</td>
<td>7,352 SES / PES / ZES</td>
<td>Favor DES</td>
<td>Similar</td>
<td>Similar</td>
<td>Similar</td>
<td>Similar</td>
</tr>
<tr>
<td>Dibra et al.44</td>
<td>2010</td>
<td>14</td>
<td>7,781 SES / PES / ZES</td>
<td>Favor DES</td>
<td>Similar</td>
<td>Similar</td>
<td>Similar</td>
<td>Similar</td>
</tr>
<tr>
<td>Hao et al.45</td>
<td>2010</td>
<td>13</td>
<td>6,769 SES / PES / ZES</td>
<td>Favor DES</td>
<td>Similar</td>
<td>Favor DES</td>
<td>Similar</td>
<td>Similar</td>
</tr>
<tr>
<td>Piscione et al.46</td>
<td>2010</td>
<td>13</td>
<td>7,244 SES / PES / ZES</td>
<td>Favor DES</td>
<td>Similar</td>
<td>Favor DES</td>
<td>Similar</td>
<td>Similar</td>
</tr>
</tbody>
</table>

n = number; SES = sirolimus-eluting stent; PES = paclitaxel-eluting stent; ZES = zotarolimus-eluting stent; DES = drug-eluting stent.

Ilb/IIa inhibitor versus bivalirudin alone. At the end of coronary angiography and arterial patency restoration, 3,006 patients eligible for stent implantation were randomized in a 3:1 ratio for PES or its counterpart BMS. The mean age was 59.7 years, 76.7% were male and 15.9% had diabetes mellitus, with no differences in baseline characteristics between groups. DAT with aspirin and thienopyridine was recommended for at least 6 months, and encouraged for 1 year. There were no differences between procedure characteristics, except for slightly longer lesions in patients receiving DES, with consequent increase in stent length in this group. After 12 months, the primary efficacy end-point represented by ischemia-guided target lesion revascularization was 4.5% in PES group and 7.5% in BMS group (P = 0.002). There were no differences in the rates of death, reinfarction, stroke, or ST between groups (8.1% vs. 8.0%). With protocol-mandated follow-up scheduled for 5 years, the study was stopped earlier at the end of 3 years and the final results recently presented.41 Three-year follow-up involved 2,790 patients of the initially randomized sample (92.8%). A sustained benefit in TVR reduction favoring PES was demonstrated (9.4% vs. 15.1%, P < 0.001), with decreased advantage among patients who did not undergo routine coronary angiography (8.7% vs. 12.7%, P = 0.01). Rates of death (5.6% vs. 6.6%, P = 0.31), reinfarction (7.0% vs. 6.6%, P = 0.77), stroke (1.6% vs. 1.4%, P = 0.70), and ST (4.8% vs. 4.3%, P = 0.63) did not differ between groups.

**Meta-Analysis of Randomized Clinical Trials**

Randomized clinical trials stated the efficacy and safety of DES during primary PCI. However, the studies exhibited small sample size and maximum follow-up length of 24 months, making difficult the analysis of rare ischemic events, especially in selected patients, a common find in publications of this nature. Meta-analysis, adding more patients to the sample size, has the potential to increase statistical power and confirm the real value of new treatments and technologies. Table 2 summarizes the characteristics of published meta-analysis comparing DES versus BMS during primary PCI. The results exhibit a significant reduction in TVR rates favoring DES, between 53% and 67%, without increased risk of death, reinfarction, stroke, or ST.5,6,42–46 Two recently published meta-analysis, involving a larger number of studies and extended clinical follow-up (48 months), showed a significant reduction of 24%–27% in reinfarction rates favoring DES.45,46 Restenosis is considered an independent predictor of mortality, presenting as acute coronary syndrome in one-third of the cases.47–49 Besides, PCI to restenotic lesions could be associated with periprocedural MI. Promoting significant reduction in restenosis, DES would reduce MI rates, explaining the meta-analysis findings. However, these results should be interpreted with caution, since the authors had no access to patients’ individual data in all allocated studies, the mean length of follow-up would be insufficient for detection of infrequent complications, the data apply only to first-generation DES, the impossibility of extrapolation to real-world practice, given the strict inclusion criteria observed in the methodology of these studies.

**Controlled Prospective Registries**

Registries provide important contributions to clinical practice, since their results are representative of real-world patients with different clinical and...
anatomical complexity, many of them excluded from randomized studies. In a retrospective analysis of the New York state registry, Hannan et al.\textsuperscript{30} evaluated 1,926 patients undergoing primary PCI from October 2003 to December 2004, 1,154 of them with DES. The mean follow-up was 19 months. DES were associated with lower adjusted mortality rate (5.0% vs. 8.6%, \( P = 0.007 \)) and need for coronary artery bypass grafting (CABG) (3.0% vs. 6.4%, \( P = 0.004 \)), with no difference in rates of new PCI (6.7% vs. 7.6%, \( P = \text{NS} \)). Mauri et al.\textsuperscript{51} reported a prospective analysis of 7,217 patients treated for acute MI in Massachusetts, 3,379 with primary PCI. After propensity score matching, DES decreased 2-year mortality (8.5% vs. 11.6%, \( P = 0.008 \)) and TVR rates (10.7% vs. 14.9%, \( P = 0.003 \)), with no difference in recurrent MI (7.4% vs. 8.5%, \( P = \text{NS} \)) compared to BMS. Steg et al.\textsuperscript{52} performed an analysis of 5,093 primary PCI patients enrolled in the Global Registry of Acute Coronary Events (GRACE), between April 1999 and December 2007, 1,313 receiving at least 1 DES. Adjusted mortality for the first 6 months was not different between DES and BMS patients (RR: 0.65, 95% CI 0.33–1.27, \( P = 0.21 \)). Late postdischarge mortality was higher in DES patients from 6 months to 2 years (RR: 4.90, 95% CI 1.42–16.9, \( P = 0.01 \)). Brar et al.\textsuperscript{43} evaluated 18 available registry studies, comprising 26,521 patients submitted to primary PCI, 11,866 with DES. DES reduced the rate of TVR at 1 year by 46%, with sustained benefit at 2 years (RR: 0.71, 95% CI 0.61–0.83, \( P < 0.01 \)), without differences in the incidence of MI. Mortality was lower in the first year with DES (RR: 0.68, 95% CI 0.54–0.88, \( P < 0.01 \)), losing statistical significance at the end of 2 years (RR: 0.89, 95% CI 0.64–1.22, \( P = 0.45 \)). A recent study involving 1,463 patients undergoing primary PCI in a single center from 1995 to 2009 revived the controversy about DES safety.\textsuperscript{53} DES was associated with increased risk of definite or probable ST after the first year (6.9% vs. 1.7%, \( P < 0.001 \)) and was the only independent predictor of very late ST (RR: 3.79, 95% CI 1.64–8.79, \( P = 0.002 \)).

**Identifying Patients at Increased Risk of Restenosis**

Although DES substantially reduce TVR among patients undergoing PCI, this benefit is only modest in STEMI. Furthermore, questions persist about the long-term safety of these devices, motivating a class-IIa (B) indication in a recent update of ACC/AHA guidelines.\textsuperscript{54} The identification of patients exposed to higher risk of restenosis after BMS in primary PCI allows a judicious indication of DES in this setting, with potential clinical and economic impact, since health care insurance reimbursement system represents a major limitation for DES use in many countries. A recent subanalysis of HORIZONS-AMI trial identified 3 variables independently correlated to TVR at 12 months after BMS in primary PCI: lesion length \( \geq 30 \) mm, reference vessel diameter \( \leq 3.0 \) mm, and insulin-dependent diabetes mellitus.\textsuperscript{55} Among patients with 0 (low risk), 1 (intermediate risk), or \( \geq 2 \) (high risk) risk factors, rates of 12-month TVR ranged from 3.3% to 19.8%, with DES benefit more pronounced according to score severity. In addition, rates of cardiac mortality, reinfarction, and ST were higher among high-risk patients treated with BMS compared with intermediate- or low-risk ones.

**Future Directions and Final Considerations**

Compared to BMS, DES showed unequivocal superiority in reducing TVR with similar rates of adverse ischemic events. Its safety after primary PCI is not fully elucidated, with apparent conflicting results. STEMI frequently exhibits coexisting factors that are known predictors of thrombosis, such as higher thrombotic burden, late stent malapposition, delayed reendothelialization, hypotension, and left ventricular dysfunction. Acute lesions have less fibrous atheroma and may be less prone to restenosis. Recurrent angina is infrequent after primary PCI and ischemia-driven TVR is low after BMS. Therefore, questions about DES long-term safety are relevant, since they would incur an increased risk of late thrombosis and its deleterious consequences, including MI rates of 70% and mortality around 40%.\textsuperscript{56} Two important aspects should be placed in perspective. Initially, the evidence addressing DES safety after primary PCI refers only to first-generation stents and extrapolation to newer generation devices is not recommended. In fact, there is no class effect between different DES.\textsuperscript{57,58} Biocompatible and bioabsorbable polymers, abluminal release of the antiproliferative agent, DES without polymeric coating, and finally, fully bioabsorbable platforms represent new technologies, some of them already commercially available, with great potential to meet the
demand for efficiency and security necessary in primary PCI. In a randomized clinical trial involving 1,707 PCI patients, 16% with STEMI, a new biolimus-eluting stent with biodegradable polymer achieved the goal of noninferiority in primary composite end-point of cardiac death, MI, and TVR at 9 months, with similar rates of ST, compared with SES.59 In a subanalysis using optical coherence tomography, the new stent showed similar amounts of neointimal tissue covering the struts, proving its antirestenotic effectiveness, but with fewer uncovered struts. Approximately, 95% of biolimus-eluting stents exhibited complete strut coverage in 9 months, compared with two-thirds of SES.60 However, the impact and translation of these findings into clinical benefit, especially through a reduction of late ST, are uncertain making long-term follow-up of these patients necessary. The second aspect refers to DAT duration. DAT maintenance is recommended for at least 6 months after DES implantation.8 Concerns about low compliance, risk of unplanned surgery in the short term, leading to discontinuation of treatment, and a propensity to bleeding complications are relative contraindications to DES.51 STEMI is a medical emergency and the rapid restoration of antegrade flow in the occluded vessel is the main determinant of patient prognosis. Candidates to primary PCI with DES should be clarified and analyzed for adherence to antiplatelet drugs, comorbidities, risk of nonelective procedures, and socio-economic profile, without incurring a delay to the rapid conclusion of the procedure.

Conclusions

DES in primary PCI is an effective and safe therapy, reducing restenosis and TVR, with similar rates of reinfarction and mortality compared to BMS. Despite the associated increased risk of late ST, the studies suggest that DES use has no negative impact on mortality. Repeat revascularization is a less-prevalent complication in STEMI patients and is more apparent with mandated angiographic follow-up. Identification of patients at highest risk of restenosis, including diabetics, small vessels, and long lesions, enables the selection of candidates that would benefit most from DES, impacting positively when health care reimbursement policies are restrictive. The role of newer generation P2Y12 inhibitors, platelet function and genetic testing, and newer generation DES remains uncertain.

Real-world registries results providing more evidence into DES-associated ST are expected. Finally, a rigorous analysis of compliance to prolonged DAT is crucial, without delaying restoration of arterial patency.

References


