Coughlan JJ, et al. Ten-year patterns of stent thrombosis after percutaneous coronary intervention with new- versus early-generation drug-eluting stents: Insights from the DECADE cooperation

SUPPLEMENTARY DATA

Table 1 of the supplementary data

Key inclusion and exclusion criteria, primary endpoints and stent thrombosis definitions for the trials included in the DECADE cooperation

| Trial name (enrollment period) | Registration number | Key inclusion criteria | Key exclusion criteria | Primary endpoint | Definition of stent thrombosis |
|--------------------------------------|------------------------|--|--|--|---|
| SIRTAX (2003-2004) | NCT00297661 | Patients aged 18 y or older with either stable angina or acute coronary syndrome were eligible to participate if they had at least 1 lesion with stenosis of ≥ 50% in a vessel with a reference diameter between 2.25 and 4.00 mm that was suitable for stent implantation. The time from symptom onset to treatment was less than 24 h in patients classified as having a myocardial infarction characterized by ST-segment elevation. There were no limitations on the number of lesions or | Allergy to antiplatelet drugs, heparin, stainless steel, contrast agents, sirolimus, or paclitaxel. Participation in another coronary-device study. End-stage disease. | Major adverse cardiac events at 9 mo (composite of cardiac death, myocardial infarction or ischemia- driven target lesion revascularization). | Acute coronary syndrome with angiographic documentation of either occlusion of the target lesion or thrombus within the previously stented segment. |

| | vessels or on the length of the lesions. | | |
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| | | • Patients older than age 18 | • Target lesion located in the | A device-oriented | According to Academic Research |
|----------------------------|-------------|---|--|--|---|
| ISAR TEST 4 (2007-2008) | NCT00598676 | Patients older than age 18 y with ischemic symptoms or evidence of myocardial ischemia (inducible or spontaneous) in the presence of ≥ 50% de novo stenosis located in native coronary vessels. Written, informed consent by the patient or her/his legally-authorized representative for participation in the study. In women with childbearing potential a negative pregnancy test was mandatory. | Target lesion located in the left main trunk. Target lesion located in the bypass graft. In-stent restenosis. Cardiogenic shock. Malignancies or other comorbid conditions (for example severe liver, renal or pancreatic disease) with life expectancy less than 12 mo or condictions that could result in protocol nonadherence. Known allergy to the study medications: clopidogrel, rapamycin, everolimus, stainless steel or cobalt chrome. Inability to take clopidogrel | A device-oriented composite endpoint of cardiac death, myocardial infarction related to the target vessel or revascularization related to the target lesion at 1 y after index intervention. | According to Academic Research Consortium criteria Definite stent thrombosis: angiographic or pathological confirmation of stent thrombosis. Probable stent thrombosis: any unexplained death within the first 30 d or any myocardial infarction (irrespective of the time after the index procedure) related to documented acute ischemia in the territory of the implanted stent without angiographic confirmation of stent thrombosis and in the absence of any other obvious cause. Possible stent thrombosis: any unexplained death from 30 d after intracoronary stenting until and of trial follow un |
| ISAR TEST 4 (2007-2008) | NCT00598676 | coronary vessels. Written, informed consent by the patient or her/his legally-authorized representative for participation in the study. In women with childbearing potential a negative pregnancy test was mandatory. | comorbid conditions (for example severe liver, renal or pancreatic disease) with life expectancy less than 12 mo or condictions that could result in protocol nonadherence. Known allergy to the study medications: clopidogrel, rapamycin, everolimus, stainless steel or cobalt chrome. Inability to take clopidogrel for at least 6 mo. Pregnancy (present, suspected or planned) or positive pregnancy text | related to the target lesion at 1 y after index intervention. | first 30 d or any myocardial infarction (irrespective of the time after the index procedure) related to documented acute ischemia in the territory of the implanted stent without angiographic confirmation of stent thrombosis and in the absence of any other obvious cause. Possible stent thrombosis: any unexplained death from 30 d after intracoronary stenting until end of trial follow-up. |
| | | | Previous enrollment in this trial. Patient inability to fully cooperate with the study protocol. | | |

| SORT OUT III (2006-2007)NCT00660478If more than 1 lesion needed treatment, the allocated study stent had to be used in all lesions.• Allergy to aspirin, clopidogrel or ticlopidine.• No upper limits were imposed for the number of treated lesions, treated vessels, or lesion length treated with 1 or more drug-eluting stents in the• Allergy to aspirin, clopidogrel or ticlopidine. | SORT OUT III (2006-2007) | NCT00660478 | All patients aged 18 y or older, had chronic stable coronary artery disease or acute coronary syndromes, and had at least 1 target lesion, defined as a lesion needing treatment with a drug-eluting stent. If more than 1 lesion needed treatment, the allocated study stent had to be used in all lesions. No upper limits were imposed for the number of treated lesions, treated vessels, or lesion length treated with 1 or more drug-eluting stents in the | The patient would not participate or could not provide informed consent. The patient participated in other randomized stent studies. Life expectancy less than 1 y. Allergy to aspirin, clopidogrel or ticlopidine. Allergy to sirolimus or zotarolimus (ABT-578). | Major adverse cardiac events within 9 mo (composite of cardiac death, myocardial infarction or ischemia- driven target lesion revascularization). | According to Academic Research Consortium criteria, definite stent thrombosis was recorded at 30-da and 12-mo follow-up to report late (30 d–1 y) and very late (>1 y) sten thrombosis. |
|---|-----------------------------|-------------|--|--|--|--|
| drug-eluting stents in the coronary arteries. | | | drug-eluting stents in the coronary arteries. | | | |

| ISAR TEST 5 (2008-2009) | NCT00598533 | Patients older than 18 y with ischemic symptoms or evidence of myocardial ischemia (inducible or spontaneous) in the presence of ≥ 50% de novo stenosis located in native coronary vessels. Written, informed consent by the patient or her/his legally-authorized representative for participation in the study. In women with childbearing potential a negative pregnancy test was mandatory. | Target lesion located in the left main trunk. Target lesion located in the bypass graft. In-stent restenosis. Cardiogenic shock. Malignancies or other comorbid conditions (for example severe liver, renal or pancreatic disease) with life expectancy less than 12 mo or condition that could result in protocol nonadherence. Known allergy to the study medications: clopidogrel, rapamycin, probucol, zotarolimus, stainless steel or cobalt chrome. Inability to take clopidogrel for at least 6 mo. Pregnancy (present, suspected or planned) or positive pregnancy test. Previous enrollment in this trial. Patient inability to fully cooperate with the study protocol. | A device-oriented composite endpoint of cardiac death, myocardial infarction related to the target vessel or target lesion revascularization at 1 y after index intervention. | According to Academic Research Consortium criteria Definite stent thrombosis: angiographic or pathological confirmation of stent thrombosis. Probable stent thrombosis: any unexplained death within the first 30 d or any myocardial infarction (irrespective of the time after the index procedure) related to documented acute ischemia in the territory of the implanted stent without angiographic confirmation of stent thrombosis and in the absence of any other obvious cause. Possible stent thrombosis: any unexplained death from 30 d after intracoronary stenting until end of trial follow-up. |
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| EXAMINATION (2008-2010) | NCT00828087 | Patients presenting with a ST-elevation myocardial infarction who had to meet at least 1 of the following criteria Patients presenting with a ST-elevation myocardial infarction < 12 h after symptom onset treated with primary angioplasty + stent implantation. Cardiogenic shock. Rescue PCI after failed thrombolysis. PCI indicated early (< 24 h) after effective thrombolysis following current ESC guidelines. Patients presenting late ("latecomers") with ST-elevation myocardial infarction (> 12 h-48 h) after symptom onset. Written informed consent. The patient or his/her family (in the event the patient could not be | Age < 18 y. Pregnancy or breastfeeding. Known intolerance to aspirin, clopidogrel, heparin, stainless steel, everolimus, contrast material. Patients with absolute indication of being chronic treated with acenocoumarol. Myocardial infarction due to a previously implanted stent thrombosis. Patients with myocardial infarction that would require elective surgical coronary revascularization within a 1 y period. | Composite endpoint of all-cause death, any myocardial infarction and any revascularization at 1 y . | According to Academic Research Consortium criteria Definite stent thrombosis: angiographic or pathological confirmation of stent thrombosis. Probable stent thrombosis: any unexplained death within the first 30 d or any myocardial infarction (irrespective of the time after the index procedure) related to documented acute ischemia in the territory of the implanted stent without angiographic confirmation of stent thrombosis and in the absence of any other obvious cause. |
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| | clinically available) accept clinical follow-up. | | |
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| | Angiographic: vessel size had to range between 2.25- | | |
| | 4.0 mm by visual | | |
| | implantation of currently | | |
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Table 2 of the supplementary data

Definite stent thrombosis through to 10 years as per individual stent type

| Group | Number of events | Number of patients | Kaplan Meier percentage |
|---|---------------------|-----------------------|----------------------------|
| Early DES | | | |
| Early-generation, permanent-polymer SES; Cypher (Cordis, Johnson & Johnson, United States) | 65 | 2325 | 3.1% |
| Early-generation, permanent-polymer PES; Taxus (Boston Scientific Corp Natick, United States) | 26 | 509 | 5.3% |
| New DES | | | |
| New-generation, biodegradable-polymer SES | 12 | 1299 | 1.0% |

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| New-generation, permanent-polymer ZES; Endeavor (Medtronic Cardiovascular, United States) | 14 | 1162 | 1.2% |
|--|----|------|------|
| New-generation, polymer-free sirolimus- and probucol-eluting stent; ISAR VIVO (Translumina Therapeutics, Germany) and Coroflex ISAR (B. Braun Melsungen, Germany) | 15 | 2002 | 0.8% |
| New-generation, permanent-polymer ZES; Resolute (Medtronic Cardiovascular, United States) | 7 | 1000 | 0.7% |
| New-generation, permanent-polymer EES; Xience V (Abbott Vascular, United States) | 21 | 1403 | 1.5% |

DES, drug-eluting stents; EES, everolimus-eluting stents; ZES, zotarolimus-eluting stent.